

OPUS 2

User Manual



hearLIFE



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Introduction

This user manual provides information and instructions regarding the MED-EL 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 Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY), Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), PULSARci¹⁰⁰ (hereafter referred to as PULSAR), SONATAti¹⁰⁰ (hereafter referred to as SONATA) 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.

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

Important

You are the operator of your/your child's OPUS 2 audio processor, therefore we recommend that you read this manual in its entirety. Do not perform any maintenance activities other than those described in this manual (e.g. changing batteries). When performing these maintenance activities, always remove the audio processor from the ear.

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 MED-EL 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.

Intended use – Indications – Contraindications

Intended use

The OPUS 2 audio processor is part of the MED-EL Cochlear Implant System. The MED-EL 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.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

The OPUS 2 audio processor is an external component of the MED-EL Cochlear Implant System and is indicated for use on patients who have been implanted with SYNCHRONY, MED-EL CONCERT, PULSAR, SONATA or C40+ cochlear implants. The MED-EL Cochlear Implant System is indicated for:

Bilateral deafness:

- 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 the 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 and above. 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 aided 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.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

The OPUS 2 is indicated to be used in typical everyday environments (home, office, outdoor etc.).

As the OPUS 2 is a component of the MED-EL Cochlear Implant System, all indications stated for the MED-EL 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.

Contraindications

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 MED-EL Cochlear Implant System, all contraindications stated for the MED-EL Cochlear Implant System are applicable.

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

NOTE:

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



Getting started

The parts of the system

The MED-EL 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.



Implants with titanium housing: SYNCHRONY (shown), MED-EL CONCERT and SONATA



Implants with ceramic housing: PULSAR (shown) and C40+

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 separate remote control called the 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

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

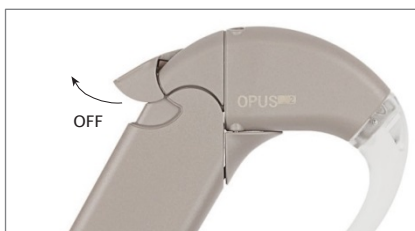


Fig. 3 The OPUS 2 audio processor in position OFF

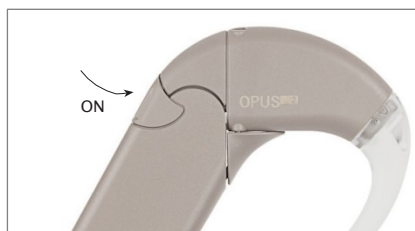


Fig. 4 The OPUS 2 audio processor in position ON

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 audio processor, i.e. only the target 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 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 audio processor and place the coil of the audio processor on the keyboard of the FineTuner (approximately over key <). Then switch on your 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 MED-EL application software manual with detailed programming information and will assign two audio processors to your dataset. Once your audio processors are programmed correctly, the synchronization procedure described above should be performed with both audio processors.

FineTuner controls

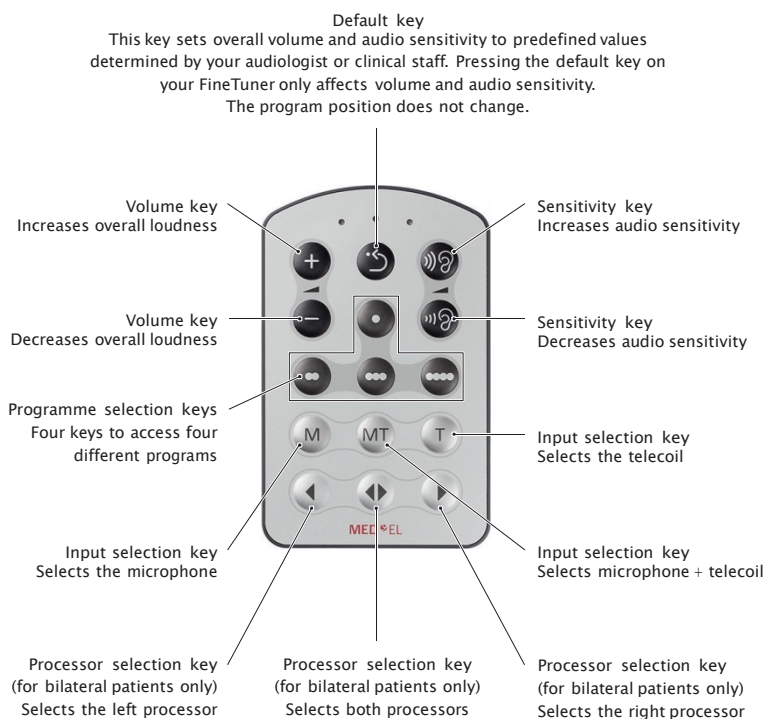


Fig. 5 FineTuner

All FineTuner functions can be selectively disabled by your audiologist or clinical staff by disabling the respective command in the control unit (via the MED-EL application software). Your FineTuner will still be able to transmit all commands, but your control unit will not execute disabled commands.

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 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.

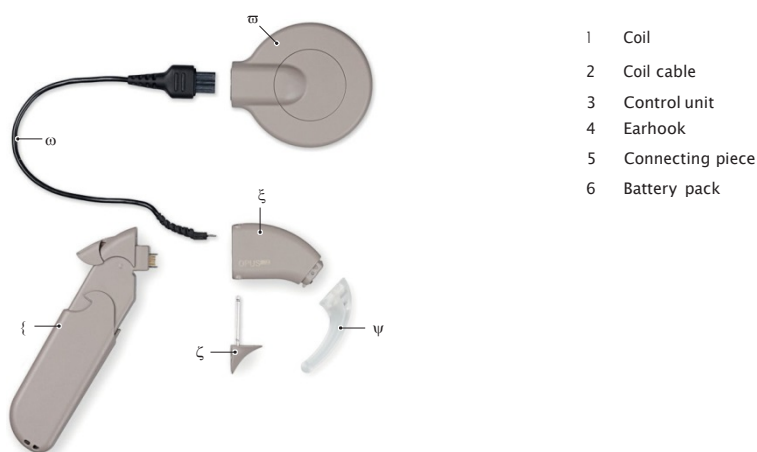


Fig. 6 How to assemble the control unit and battery pack

How to assemble your control unit and battery pack

1. Connect the coil cable to the coil. Note that the coil cable of the COMT+/COMT+ P coil has a guide pin at the coil end. 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. 15).
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. 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. The OPUS 2 audio processor can be used with the MED-EL D Coil or the COMT+/COMT+ P coils. However, for patients who received a SYNCHRONY implant, only the D Coil can be used.



Fig. 7 D Coil



Fig. 8 COMT+/COMT+ P coil

D Coil

Important

Depending on the type of implant, two variants of magnets (i.e. magnet inserts) are available for the D Coil. These two variants differ in magnet polarization. The type of implant is stated on your Patient Identification Card.



For patients implanted with a SYNCHRONY implant, the magnet insert must contain triangles as shown in Fig. 10.



For patients implanted with any other type of implant (MED-EL CONCERT, SONATA, etc.), the magnet insert must contain circles as shown in Fig. 11.

It is essential that, based on the type of implant, the correct variant of magnet is used! If the wrong variant of magnet is inserted, the coil may still be held in place over the implant. However, due to different polarization of the magnets, a slight dislocation between the implant and coil will occur which may result in improper communications between implant and coil.

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

To attach a new magnet insert, 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 filled triangles or circles on the magnet.

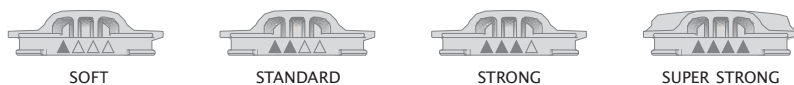


Fig. 10 Magnet strengths for SYNCHRONY implant

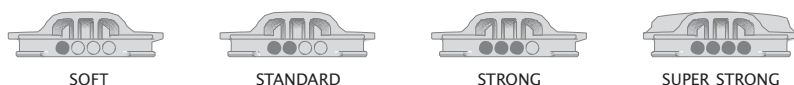


Fig. 11 Magnet strengths for all other types of implants

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



Fig. 12 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. If you notice any signs of skin irritation around the coil, contact your clinic or CI center.

Your coil contains a strong magnet. Keep clear of metallic items as they attract the magnet.

NOTE:

If you are implanted with a SYNCHRONY implant, there is a chance that the external and internal magnets may be misaligned when placing the D Coil on the head. This misalignment is due to the diametric magnet design and may result in hearing interruptions and/or the coil falling off. To avoid misalignment, gently rotate your coil between a quarter and half a turn back and forth to allow the coil to position itself correctly over the implant (Fig. 13). You will notice correct alignment by uninterrupted hearing and/or stronger magnetic attraction.

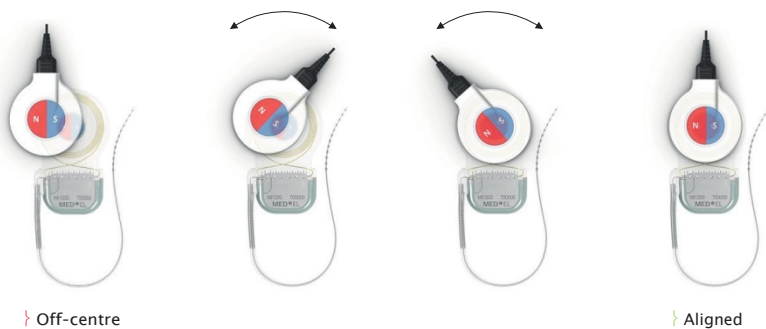


Fig. 13 Aligning D Coil and implant magnets

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.

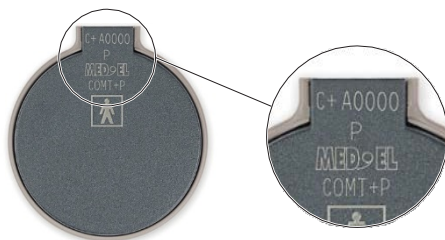


Fig. 14 Serial number of COMT+/COMT+ P coil

Important

The COMT+/COMT+ P coil must not be used for patients implanted with a SYNCHRONY implant. Using a COMT+/COMT+ P coil with a SYNCHRONY will result in a slight dislocation between the implant and coil which may result in improper communications between implant and coil.

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

When operating the cochlear implants MED-EL CONCERT, PULSAR or SONATA 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, PULSAR or SONATA 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 MED-EL 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. 15 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. The red indicator light in the earhook will blink up to four times indicating the activated program. For example, if program 3 was last selected, the light will blink 3 times to indicate program 3 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 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.

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

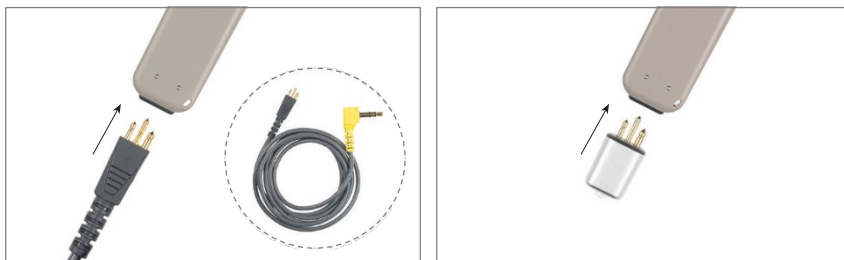


Fig. 16 Connecting the FM cable and FM receiver

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 external 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.

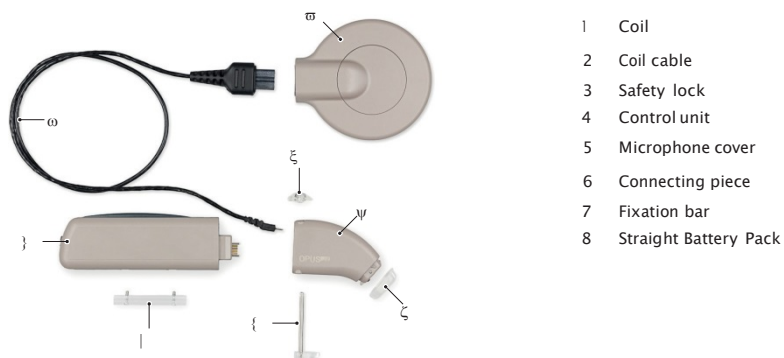


Fig. 17 How to assemble the BabyBTE™/ActiveWear

How to assemble your BabyBTE™/ActiveWear configuration

The additional components required for the BabyBTE™ assembly and the ActiveWear configuration (Straight Battery Pack, 28 cm (11 in.) coil cable, microphone cover, connecting piece, safety bar, screw-on fixation bar and fixation clip) are included in the BabyBTE™/ActiveWear Extension Kit which may be purchased separately.



Fig. 18 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. 21 + 22.
2. Attach the microphone cover to the control unit as shown in Fig. 22. 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 (11 in.) 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. 23.

< 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. 26 and hold it in this position. Now push the battery pack lid backwards about 3 mm (0.12 in.), 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 (0.12 in.). 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.

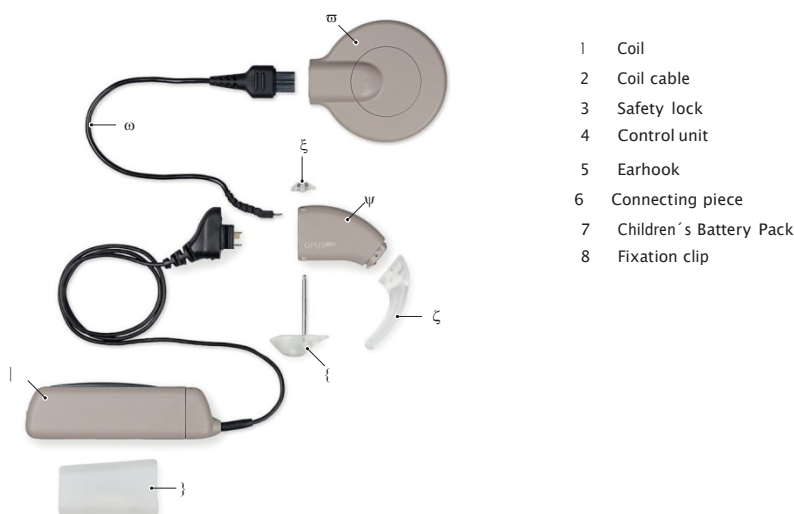


Fig. 19 How to assemble the Children's Battery Pack

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. 22. 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. 23).

< 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. 26 and hold it in this position. Now push the battery pack lid backwards about 3 mm (0.12 in.), 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 (0.12 in.). 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. 20 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. 21) using the supplied tool, then grab it and pull it out completely.



Fig. 21 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. 22). To remove the microphone cover from the control unit, push against the top rib of the cover (e,f).

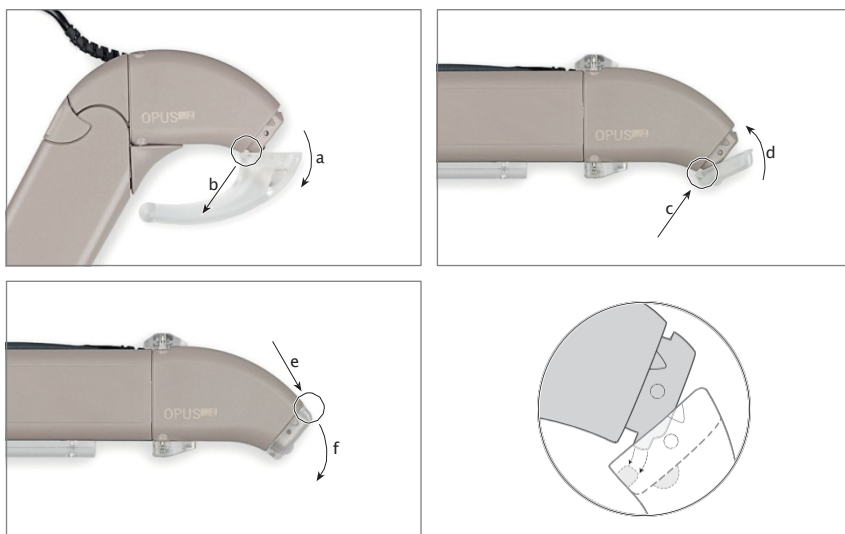


Fig. 22 How to remove the earhook or microphone cover

- < 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. 23 Safety lock

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.
- < If your child is implanted with a SYNCHRONY implant, check for correct alignment of coil and implant by gently rotating the coil a quarter or half a turn back and forth to allow the coil to position itself correctly over the implant. You will notice correct alignment by stronger magnetic attraction.

General precautions and warnings

This section contains information on the safe use of your MED-EL 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 MED-EL 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 MED-EL 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 MED-EL Cochlear Implant System

The audio processor and other parts of the system contain sophisticated electronic components, which need special precautions regarding electromagnetic compatibility (EMC). When activating your 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 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 audio processor, check the external parts of the MED-EL 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 MED-EL 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 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 audio processor and the FineTuner. Normally, when the 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). Long exposure to direct sunlight might damage the audio processor or FineTuner.
- If you ever experience loud or uncomfortable sounds, please remove your coil immediately: this will stop stimulation at once.
- Blowing your nose too hard might lead to (temporary) fluctuations in loudness. This is caused by air entrapped over the reference electrode of the implant.
- 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 put the audio processor in the supplied drying kit to allow moisture inside the audio processor to dry (preferably overnight). If in doubt, repeat the drying process. 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 MED-EL 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 audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.
 - Do not try to shape the earhook by hot air.
 - Do not use your audio processor in the vicinity of strong ionising radiation (e.g. x-ray machines) or electromagnetic fields (e.g. MRI machines).
 - Do not modify the housing, the electronics or any other parts of your audio processor in any way.
- < Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths and not to play with any components. Swallowing of system components could cause suffocation or internal injury. 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 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 audio processor. 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 MED-EL Cochlear Implant System if they are used within a distance of less than 3 meters (9.84 ft.).

TV, radio, FM systems, etc.

When intending to connect an external audio device to the audio processor that is powered by mains power, i.e. connected to an electrical outlet of any kind, including a power strip, always make sure first that this mains-powered external audio device meets the safety requirements stated in the standards EN/IEC 60065, EN/IEC 60601-1 and/or appropriate national standards. If the mains-powered device does not bear a CE mark (<), which is usually found on the device's type label, you cannot presume that the mains-powered device meets the above safety requirements and must therefore not be connected to your audio processor. You can safely connect battery-operated

external audio devices to your audio processor. Connecting a mains-powered device to your audio processor that does not meet the above safety requirements could cause an electric shock. 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 MED-EL 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 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 audio processor on last, and remove it first when undressing.
- Always remove the 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 audio processor.
- Always remove the 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 audio processor 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

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to the Medical Procedures Manual.

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 contra-indicated. 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](https://www.cdc.gov) website.

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 dispose of or store them separately.

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.

Weekly maintenance of your audio processor

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

Drying your 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.

The audio processor need not be completely disassembled. The batteries may remain in the battery pack frame but the battery pack cover should be removed from your audio processor.

We recommend that you dry your 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!

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. If any substance leaks out of a battery, avoid direct skin contact with that substance. Such a substance could cause a chemical burn. In case of eye contact, rinse with copious amounts of water and seek medical attention immediately.

Dispose of used batteries according to local regulations. If you ignore these regulations, you will contribute to pollution of the environment. 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 MED-EL Cochlear Implant System into their mouths and not to play with any components. Swallowing of system components could cause suffocation or internal injury. 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 $\rightarrow$ must face outward, i.e. the $\rightarrow$ 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.

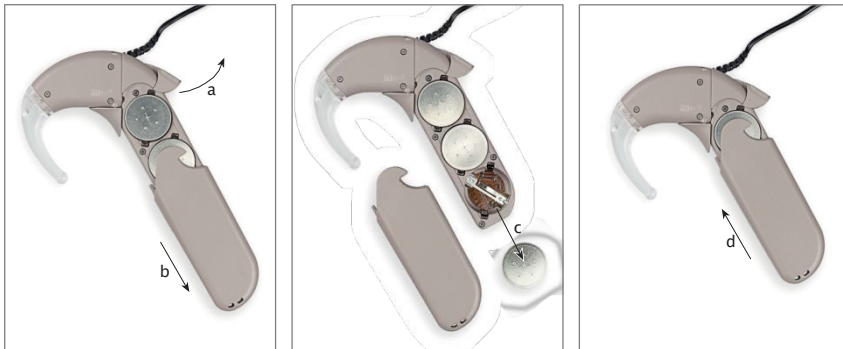


Fig. 24 Changing the batteries of your audio processor

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 $\rightarrow$ 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. 25 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 (0.12 in.) (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 (0.12 in.) (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.

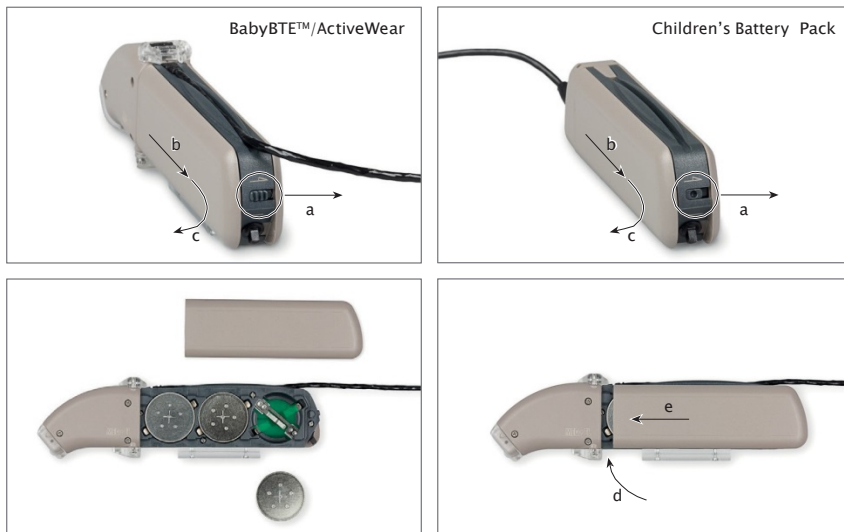


Fig. 26 Changing the batteries of your BabyBTE™/ActiveWear and Children's Battery Pack

Troubleshooting

Once you are familiar with your MED-EL 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 MED-EL 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 MED-EL Cochlear Implant System, please contact your clinic or CI center immediately.

Speech Processor Test Device

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

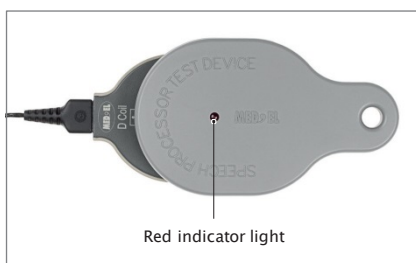


Fig. 27 Speech Processor Test Device

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 audio processor and make sure that it is supplied with batteries. Place the coil underneath the Speech Processor Test Device (see Fig. 27). 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 red light 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 audio processor (see also Chapter 7, General precautions and warnings).

FineTuner

The FineTuner transmits commands to the audio processor via a radio frequency (RF) link. If the audio processor 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 audio processor is out of the FineTuner's operating distance. To overcome this you should move the FineTuner closer to the audio processor.
- 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 audio processor and/or go to a different location.
- The audio processor 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 audio processor 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 audio processor 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

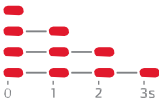
- If you or your child have used the < (telecoil) or < (microphone and telecoil) settings and are unable to return to the < (microphone) signal source input with the FineTuner, you need to switch the audio processor off and on. When the audio processor is switched on again it will automatically start with the < (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.

Blinking pattern	Meaning	Action to take	Remarks
Error patterns			
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be replaced.
	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.
	Electronic problem or program failure	Switch processor off. Switch processor back on.	If the blinking persists, the processor must be reprogrammed.
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	
Warning patterns			
	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			
	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.

Blinking pattern	Meaning	Action to take	Remarks
Program change pattern			
	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			
	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 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 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 you 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.

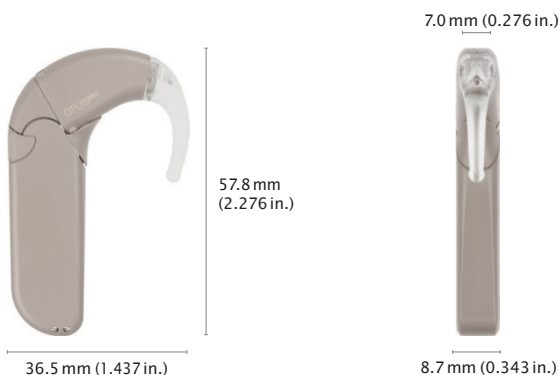
Program mode

If $\leftrightarrow$ 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.

Technical data

Audio processor

Dimensions of OPUS 2 audio processor¹



Weight¹

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 values

Audio input

- Via FM Battery Pack Cover
- Hearing aid type three pin connection (Euro-Audio) acc. to IEC 60118-12
- Sensitivity: -61.4 dBV¹ (corresponds to 70 dB SPL at 1 kHz)
- Impedance: 2.9k Ω ¹

Controls/Indicators

- ON/OFF switch
- Indicator light: 1 red LED for alarm and indicator functions

Materials

- Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS): audio processor, battery packs, all colors
- Polyamide (PA): earhook, microphone cover

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)

Atmospheric pressure range: 700 mbar (hPa) to 1060 mbar (hPa)

Essential performance

None of the performance characteristics of the OPUS 2 (incl. all accessories) are essential performance as defined in IEC 60601-1.

Expected service life

The expected service life of the OPUS 2 (incl. all accessories) as defined in IEC 60601-1 is 5 years.

Radio frequency (RF) link (FineTuner)

Frequency band of reception: 9.07 kHz ($\pm 3\%$)

1 typical values

FineTuner

Dimensions¹

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 and 2 amber LEDs

Power supply

- One lithium/manganese dioxide battery type CR2025 (3V)
- 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 A1) and Annex 12 (band A) – EU
- Equipment class 3 – EU

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS)

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)

Atmospheric pressure range: 700 mbar (hPa) to 1060 mbar (hPa)

Radio frequency (RF) link

Carrier frequency: 9.07 kHz ($\pm 0.7\%$)

Type of modulation: phase shift keying (PSK)

Maximum RF output power: 11.7 dB μ A/m @ 10 m

Maximum operating distance: ~1.15 m (3.77 ft.)

Regulatory statements

Applicable in Canada only:

Model: FineTuner – Canada 310

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:

Model: FineTuner – FCC ID: VNP-FT

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

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

0 1 2 3

CE mark applied in 2006

Hereby, MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type OPUS 2 (audio processor) and FineTuner (remote control) is in compliance with directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.medel.com/compliance



Caution, consult accompanying documents (manual)



MR unsafe



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



Non-ionizing radiation (FineTuner)



Fragile; handle with care



Relative humidity



Temperature limit

IP22 IP classification of the OPUS 2

Moisture protection and protection from solid foreign objects acc. to environmental conditions as defined in IEC 60529 for class IP22.

This classification means that the OPUS 2 remains safe when exposed to dripping water and no solid objects larger than 12.5 mm can penetrate the housing when fully assembled and ready for use.

Speech Processor Test Device



The Speech Processor Test Device is in compliance with directive 2014/30/EU (Electromagnetic Compatibility/EMC) and directive 2011/65/EU (Restriction of Hazardous Substances in Electrical and Electronic Equipment/RoHS).

CE mark applied in 2005

Disposal

We advise to dispose of all external components of your MED-EL 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.

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	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines		
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth		
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	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.
	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		
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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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 $d = 1.17 \cdot \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \cdot \sqrt{P}$ 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 $d = 1.17 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.39
100	11.70	11.70	23.30

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.

Examples for wireless (RF) communications equipment:

Equipment	Recommended separation distance in m
wireless home network device (e.g. WiFi router)	0.74
cordless telephone/base station	1.65
walkie-talkie	2.33
mobile phone	3.30

Appendices

Warranty statement

MED-EL's warranty is in agreement with mandatory local statutory warranty provisions.

Any extension of the statutory warranty is subject to agreement between MED-EL and the purchaser. Therefore these extensions may be different in various countries. Please contact your local MED-EL representative for information on your individual warranty rights.

Extension of statutory warranties shall not be granted unless the product is properly registered. You can register a product either by completing the provided registration card and sending it to MED-EL or by using MED-EL's online registration website (upon availability). Ask your local MED-EL representative for help if you need assistance in the registration process.

Extensions of statutory warranties exclusively cover product failures. This does 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.

I. SUMMARY OF PRIMARY CLINICAL STUDIES

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

MED-EL sponsored a study at the University of North Carolina at Chapel Hill to see if 40 adults with SSD and AHL who received a MED-EL cochlear implant were better able to understand speech, more likely to find the direction of a sound source and are satisfied with their implant after the first year. This group of patients had hearing loss for less than 10 years and had used a hearing aid regularly for at least some of that time. All of the people in the study had also tried some type of current hearing device to treat SSD, such as a hearing aid, bone-conduction device, or a "CROS" type of hearing aid.

Listeners' hearing history:

SSD: Fifteen people in the study experienced sudden hearing loss and five people experienced a gradual hearing loss. The cause of 16 of those peoples' hearing loss was unknown, 3 were caused by Meniere's disease, and caused by injury in one person.

AHL: Ten people had sudden hearing loss and six had a gradual hearing loss, with the remaining two having both a gradual and sudden loss. Cause of hearing loss was unknown in 14 people, due to Meniere's disease in two people, due to noise-induced hearing loss in one person and caused by viral infection in one person.

Complications:

In this study, the researchers also looked at whether the implant was a safe choice by watching for any complications or problems (also called adverse events) the recipients had during the study. Some examples of complications might include pain, dizziness, discomfort, poor sound quality, etc. For a list of major complications that are associated with cochlear implant and surgery, please visit www.medel.com/us/isi and/or talk with your doctor. A total of nine complications were reported that were related to the device or the surgery. An additional six complications were not able to be ruled out as device or surgery-related. No serious, unexpected, device-related complications were seen.

The most common problem was dizziness, which was seen a total of 11 times. In four cases, this was not related to the device or surgery. In three cases, it could not be ruled out that it was related to the device or surgery. In the remaining four cases, it was determined that it was related to the surgery only. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. All other complications occurred at a rate of 5% or less (2 or fewer people).

Results:

Speech Understanding in Quiet:

Both groups of people (SSD and AHL) improved their ability to understand speech in quiet after 1 year of implant use when tested with the implant alone. For the people with SSD, average scores when repeating single words in quiet increased from 4% before surgery to 55% after 12 months of listening with the implant. For the group of people with AHL, this same test score improved from 6% to 56% in 12 months. In the opposite ear, there was no change in their score over time. When tested with both ears, there was no change compared to the score before surgery, probably because the normal hearing ear was working as expected.

Speech Understanding in Noise:

When listening to speech in noise, both groups of people (SSD and AHL) improved over the first 12 months of listening with the cochlear implant compared to their unaided scores before surgery and compared to scores with a bone conduction hearing device. These increases were seen when both speech and noise were presented from the front of the listener. Scores also improved when speech came from the front and the noise was on the side of the normal hearing ear. This means the cochlear implant increases speech understanding, especially when the normal hearing ear is confused by noise. This improvement was seen on more than one test of speech understanding in noise.

The average improvement in the SSD group increased from 38% to 47% in 12 months on the AzBio Test, speech and noise from the front. This group also had an average increase from 17% to 53% on the AzBio Test when speech came from the front and the noise was on the side of the normal hearing ear. The AHL

group saw increases from 23% to 34% when speech and noise came from the front, and 6% to 29% when speech came from the front and noise was on the side of the better hearing ear, also on the AZ Bio Test.

Finding the Direction of a Sound Source:

People in both the SSD and AHL groups significantly improved in finding the direction of a sound after they had listened with the cochlear implant for 12 months. To take this test, listeners sat in a room with 11 speakers arranged in a half-circle in front of them, and they were asked to point to the speaker each sound came from.

Satisfaction Questionnaires:

Listeners were asked to complete two questionnaires about their experiences using the MED-EL cochlear implant. After one year of listening, both groups (SSD and AHL) reported an improvement overall when asked about their impressions of the quality of speech, ability to locate sounds around them, and overall sound quality (SSQ Test) as well as ease of communication, hearing in background noise, and hearing in environments with an echo (APHAB Test).

II. SUMMARY OF REAL-WORLD EVIDENCE AS SUPPORTING CLINICAL EVIDENCE

All relevant published medical research was reviewed on adults and children with SSD or AHL who received cochlear implants.

Published Literature on Children

There were five studies published on a total of 26 children with SSD (five used MED-EL implants) and a total of nine children with AHL. The studies reviewed were: Beck and associates (2017), Rahne and Plontke (2016), Arndt and associates (2015), Tavora-Vieira and Rajan (2015) and Gratacap and associates (2015).

The overall benefits reported were improved speech understanding in quiet and noise, improved ability to locate a sound source, and increased parent scores on questionnaires about quality of life over time. This means, independent research studies have found similar results to those we describe above. Across these independent studies, there were a few tests where some children did not show improvement during the study period, or where certain children were not able to complete the tests.

Published Literature on Adults

There were six studies on a total of 58 adults with SSD (50 used MED-EL implants) and a total of 52 adults with AHL (37 used MED-EL implants). The studies reviewed were: Lorens (2019), Doge and associates (2017), Skarzynski and associates (2017), van Loon (2017), Kitoh (2016), Rahne and Plontke (2016). Some people participated in more than one of these studies but if they did, they were not counted twice.

The overall benefits for these people include significantly better speech understanding in quiet and in noise, better ability to locate a sound source, and more satisfaction on questionnaires about quality of life, music enjoyment and ringing in the ears. The data from these independent studies show consistent benefits for CI in people with SSD or AHL. One study used a complicated setup and multi-talker noise. That study showed that 8 of 11 listeners improved on speech understanding in noise, but the remaining 3 listeners showed reduced performance with their CI in this difficult listening situation. Results on listener satisfaction questionnaires showed increased frequency and satisfaction of listening to music, as well as better music sound quality and clarity and better appreciation of different music styles. Two studies reported improvement in ringing in the ears with CI use. Results indicated a high level of patient satisfaction with the CI. This means, independent research studies have found similar results to those we describe above, supporting the value of a CI for people with SSD and AHL.

One study included six adults who lost their hearing at a young age, before they learned to talk, who didn't receive their cochlear implants until they were adults. This means, they went for a very long time without using hearing aids. While this small group of people did not show the same amount of improvement as the

people who lost their hearing later in life and wore hearing aids regularly, all of them were still using their CI more than 8 hours a day, each day, at the end of the study.

Weighing the Risks and Benefits:

A CI is the only treatment choice that can help people with SSD or AHL regain hearing in their poorer hearing ear. All the studies mentioned above show improvement in speech understanding, locating the source of a sound, listener satisfaction, and music appreciation (in adults). For people with SSD or AHL, the implanted ear has a similar hearing loss 'picture' that matches people with hearing loss in both ears who have already been receiving cochlear implants for years. This means, the risks of cochlear implantation in adults and children with SSD and AHL are considered to be the same as for people who have already been using cochlear implants for a long time. Nevertheless, a careful CI evaluation and a strong commitment to rehabilitation are important for the best possible results. Regular (yearly) hearing tests for the opposite ear are recommended, to watch for additional hearing loss that may appear over time in the good ear.

Based on this information, the benefits outweigh the risks of CI in adults and children older than 5 years with SSD and AHL, who have a profound hearing loss in the ear to be implanted. Please talk with your doctor and implant center professionals about any questions or concerns you may have.

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Contact MED-EL

Please refer to the accompanying Contact Sheet for your local office.



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medel.com

Cochlear Implants

MED[®]**EL**

RONDO

User Manual



hearLIFE



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Introduction

This user manual provides information and instructions regarding the MED-EL Cochlear Implant System with the RONDO audio processor (Me1100). It includes descriptions of available parts, wearing options, and accessories for the RONDO, as well as instructions for troubleshooting and proper care of the external cochlear implant equipment.

Your MED-EL Cochlear Implant System consists of the Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY), Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), PULSARci¹⁰⁰ (hereafter referred to as PULSAR), SONATAti¹⁰⁰ (hereafter referred to as SONATA), or C40+ implants, the external RONDO audio processor (including FineTuner), the external components and accessories, and any external hardware and software used by your audiologist.

< This symbol indicates information that is particularly relevant for parents of implanted children.

Important

You are the operator of your/your child's RONDO audio processor, therefore we recommend that you read this manual in its entirety. Do not perform any maintenance activities other than those described in this manual (e.g. changing batteries). When performing these maintenance activities, always remove the audio processor from the head.

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 MED-EL Cochlear Implant System may take a little time while you become accustomed to this new method of hearing. You may choose to work with an aural rehabilitation specialist or other clinician to help you maximize your communication skills using the device.

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 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 require 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.

Intended use – Indications – Contraindications

Intended use

The RONDO is an audio processor and an external part of the MED-EL Cochlear Implant System. The MED-EL 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.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

The RONDO audio processor is an external component of the MED-EL Cochlear Implant System and is indicated for use on patients who have been implanted with SYNCHRONY, MED-EL CONCERT, PULSAR, SONATA or C40+ cochlear implants. The MED-EL Cochlear Implant System is indicated for:

Bilateral deafness:

- 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 the 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 and above. 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 aided 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.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

The RONDO is indicated to be used in typical everyday environments (home, office, outdoor etc.).

The RONDO is intended to be used every day during a patient's waking hours.

The user of the RONDO does not need any special skills or elevated level of education, however, the user (or custodian if the user is a child or a handicapped person not able to perform the actions listed below) shall at minimum be able to perform the following actions:

- Switching ON/OFF
- Changing batteries
- Placing/removing RONDO over/from implant

As the RONDO is a component of the MED-EL Cochlear Implant System, all indications stated for the MED-EL 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 processor programming, assessment sessions and training.

Contraindications

A patient must not receive a RONDO if the individual is known to be intolerant of the materials used in the RONDO or FineTuner. For details, please refer to chapter 9, Technical data.

As the RONDO is a component of the MED-EL Cochlear Implant System, all contraindications stated for the MED-EL Cochlear Implant System are applicable.

The RONDO and the FineTuner are not intended to be used in environments where RF transmissions are prohibited.

NOTE:

Important information related to indications, contraindications, warnings and risks for your cochlear implant are shipped in a separate document (instruction for use of the implant) to your clinic together with the cochlear implant. If you want to review this information, please contact your clinic or MED-EL.

RONDO

audio processor

The parts of the system

The MED-EL Cochlear Implant (CI) 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.



Implants with titanium housing: SYNCHRONY (shown), MED-EL CONCERT and SONATA



Implants with ceramic housing: PULSAR (shown), C40+ and C40

Fig. 1 The MED-EL cochlear implants

The external parts include the RONDO audio processor and the audio processor accessories. In its basic configuration, the RONDO audio processor consists of the control unit and the battery pack. A separate remote control called the FineTuner facilitates access to various audio processor functions.

The RONDO is held in place by magnetic attraction over the implant.

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

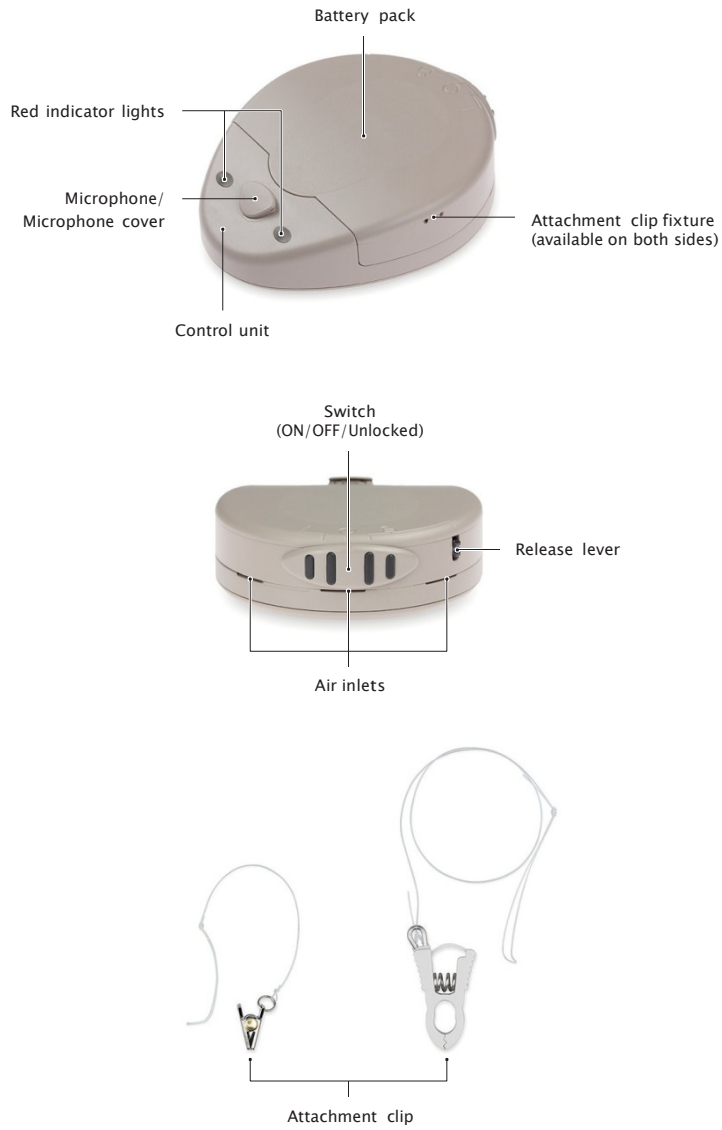


Fig. 2 Your RONDO audio processor

ON/OFF switch

The switch on the battery pack functions as an ON/OFF switch.

You may select the following positions:

RONDO OFF: <

RONDO ON: <



Fig. 3 The RONDO in OFF position



Fig. 4 The RONDO in ON position

After switching on the RONDO audio processor, the red indicator lights will blink up to four times indicating the activated programme. For example, if the lights blink three times, then programme 3 is currently active. The audio processor begins working as soon as the red lights come on and blink.

To activate your CI system, switch on the RONDO and place it with the flat side to your head and the narrow side facing up over the site of the implant (see Fig. 5). As soon as the RONDO is approximately over the implant, it is automatically positioned correctly by attraction to the implant magnet.



Fig. 5 RONDO over the site of the implant

In the OFF position, the audio processor is turned off. No current is drawn in this position. Make sure to switch off the RONDO when it is not in use, as this prolongs the lifetime of the batteries (see also chapter 7, Care and maintenance).

The RONDO 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 audible signals.

To use the telecoil proceed as follows:

- Activate the telecoil by pressing the key < (only signals picked up by the telecoil will be audible) or < (signals picked up by the microphone and the telecoil will be audible) on your FineTuner as described in chapter 4, RONDO audio processor, FineTuner, FineTuner controls.
- When you are using a telephone, position the telephone so that its earpiece is centred over the RONDO. Move the telephone slightly up or down as necessary to optimise the signal quality.
- When you are in an environment with a loop system, try to find a spot where the signal quality is best for you.
- To deactivate the telecoil when you do not need it anymore, press the key < on your FineTuner as described in chapter 4, RONDO audio processor, FineTuner, FineTuner controls.

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 4, RONDO audio processor, FineTuner, FineTuner controls).

FineTuner

Your audiologist will program your RONDO audio processor to suit your needs. The FineTuner is provided to help you optimally use your audio processor in changing daily listening situations.

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

Keeping the FineTuner out of the reach of children prevents them from inadvertently changing the settings of their audio processor.

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

The FineTuner is configured for its designated target audio processor, i.e. only the target 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 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 individual audio processor and cannot be used by another cochlear implant user. Your audiologist or clinical staff will configure the FineTuner to suit your needs. Sometimes it may be necessary for you to synchronize your FineTuner and audio processor (e.g. if you purchase a backup FineTuner). To do so, first switch off your audio processor and place it on the keyboard of the FineTuner (approx. over key <). Then switch on your audio processor. The audio processor and FineTuner will be synchronized automatically. Successful synchronization is indicated by a short blinking signal of the two amber indicator lights on your FineTuner. It is only necessary to re-synchronize the processor to the FineTuner if you replace the processor or FineTuner.

For bilaterally implanted users

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

FineTuner controls

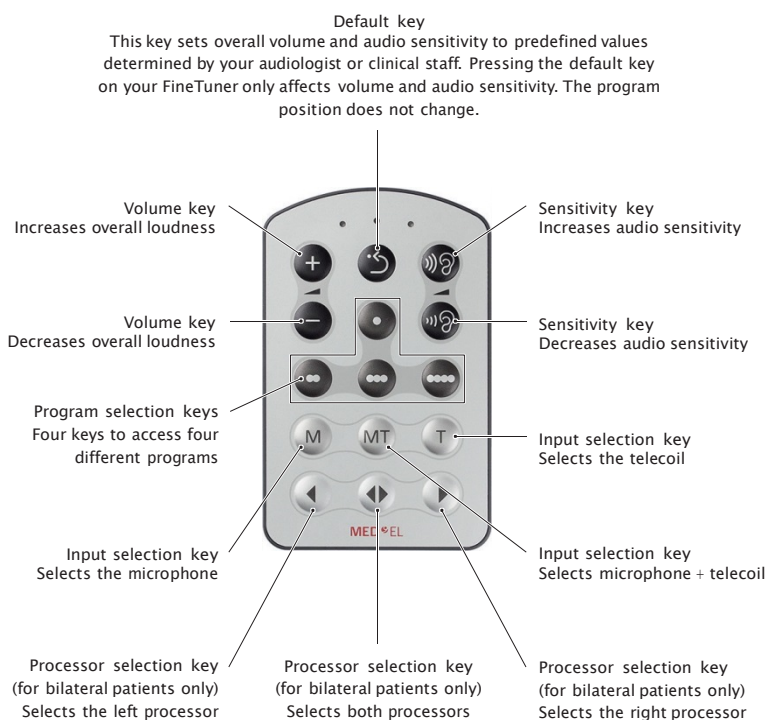


Fig. 6 FineTuner

All FineTuner functions can be selectively disabled by your audiologist or clinical staff by disabling the respective command in the control unit (via the MED-EL application software). Your FineTuner will still be able to transmit all commands, but your control unit will not execute disabled commands.

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, hold down the ↔ key for more than 5 seconds to enter the program mode (the red and both amber indicator lights on your FineTuner will 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. Just as described above, the FineTuner will confirm successful deactivation of the automatic keyboard lock with 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: If you press a key and see the red indicator light on your FineTuner flashing 3 times, then the voltage level of your FineTuner is critically low (see also chapter 7, 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 8, Troubleshooting. The FineTuner does not affect connected assistive listening devices.

Battery pack

The RONDO battery pack holds 3 hearing aid batteries. Changing the batteries is described in chapter 7, Care and maintenance, Batteries, Changing the batteries of your RONDO audio processor.

The battery pack features a tiny release lever on the right side of the ON/OFF switch. To remove the battery pack, press down the release lever and push the slide switch to the right until it engages and a shaded area becomes visible (see picture below). The arrow head on the switch faces the unlocked symbol (<). Now pull the battery pack slightly back and lift it off.

To assemble the battery pack, hold the battery pack at a slight downward angle and push it straight onto the processor. When the battery pack rests on the processor, slightly press it down and move the ON/OFF switch to the OFF position (center position). The release lever engages automatically and the battery pack is locked again.

Important

The switch must always be in the unlocked position (<) and the shaded area must be visible when removing/attaching the battery pack. Do not use excessive force. To move the switch to the unlocked position, press down the release lever (⌵) on the right side. Hold it down while pushing the switch to the right (↗).

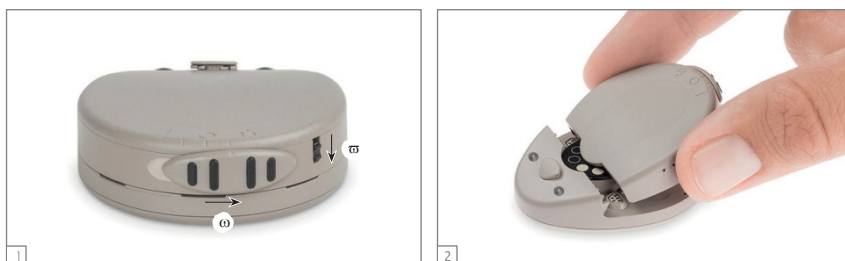


Fig. 7 How to open the battery pack of your RONDO audio processor

For more wearing options see chapter 4, RONDO audio processor, Additional wearing options.

Magnet

A small magnet is located in the centre of the RONDO to hold it in place on the head over the implant. The magnet can be changed to adjust the magnet strength to your needs.

Important

Depending on the type of implant, two variants of magnets are available for the RONDO. These two variants differ in magnet polarization. The type of implant is stated on your Patient Identification Card.



For patients implanted with a SYNCHRONY implant, the magnet must contain triangles as shown in Fig. 9.



For patients implanted with any other type of implant (MED-EL CONCERT, SONATA, etc.), the magnet must contain circles as shown in Fig. 10.

It is essential that, based on the type of implant, the correct variant of magnet is used! If the wrong variant of magnet is inserted, the RONDO may still be held in place over the implant. However, due to different polarization of the magnets, a slight dislocation between the implant and RONDO will occur which may result in improper communications between implant and RONDO.

How to change the magnet insert

1. Hold down the release lever (⌘) and push the switch (⌘) to the unlocked position (<). Remove the battery pack to access the magnet insert.
2. Grasp the magnet insert at the two serrated spots and turn it counter clockwise until the unlocked symbol (<) on the magnet faces the arrow head on the housing bottom. The magnet insert disengages and can now be lifted out.
3. Take the new magnet insert. Hold it so that the unlocked symbol (<) on the magnet faces the arrow head on the housing bottom. When positioned correctly, the magnet insert glides in easily.
4. Now turn the magnet insert clockwise until the locked symbol (<) faces straight down towards the arrow head on the housing bottom. The magnet is inserted correctly, when the circles or triangles on the magnet are symmetrically aligned with regard to the arrow head.



Fig. 8 Changing the magnet insert

Different magnet strengths are available. Magnet strength is indicated by the number of filled triangles or circles on the magnet (1 = weakest). The magnet strength chosen should be appropriate for the individual patient, that is strong magnets are not recommended for patients with thin skin flaps (e.g. young children), as excessive magnetic attraction could potentially increase the likelihood of skin irritation.



Fig. 9 Magnet strengths for SYNCHRONY implant



Fig. 10 Magnet strengths for all other types of implants

Important

MED-EL strongly recommends that you do not change the magnet yourself, but have your audiologist or clinical staff do it. If you notice any signs of skin irritation around the RONDO, contact your clinic or CI centre.

Your RONDO contains a strong magnet. Keep clear of metallic items as they attract the magnet.

- < It is easiest to observe children when playing or in everyday situations to determine whether the RONDO is properly attracted to the implant. If it falls off too easily, your child may develop an aversion to wearing the RONDO. During the first months after surgery, you should regularly check the skin under the RONDO 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.

NOTE:

If you are implanted with a SYNCHRONY implant, there is a chance that the external and internal magnets may be misaligned when placing the audio processor on the head. This misalignment is due to the diametric magnet design and may result in hearing interruptions and/or the processor falling off. To avoid misalignment, gently rotate your audio processor between a quarter and half a turn back and forth to allow the audio processor to position itself correctly over the implant (Fig. 11). You will notice correct alignment by uninterrupted hearing and/or stronger magnetic attraction.



Fig. 11 Aligning audio processor and implant magnets. Note that the microphone is facing up.

Attachment clip

The attachment clip is used to secure the RONDO to your/your child's clothes to reduce the risk of damaging the audio processor should it come off and drop on the floor or another hard surface.

MED-EL strongly recommends that you always use the attachment clip.

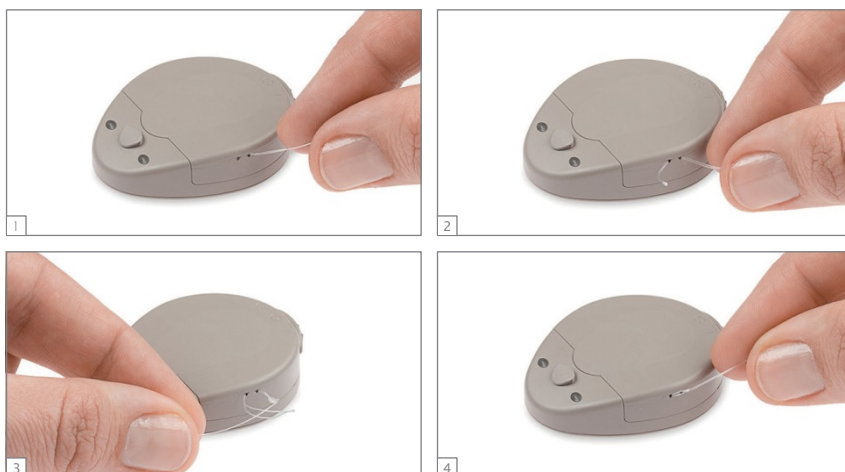


Fig. 12 Threading the attachment clip through the RONDO housing

RONDO protector

The RONDO protector is a soft silicone cover intended to absorb mechanical impacts on the housing in case the RONDO is dropped. The protector reduces the risk of damage to the audio processor. MED-EL strongly recommends that you always use the RONDO protector.

To assemble the RONDO protector, insert the narrow end of the RONDO audio processor into the protector. Next pull the protector over the opposite side so that the slide switch rests in the cutout section of the protector. The traversing section of the protector should be on the top of the processor.



Fig. 13 Assembling the RONDO protector

Microphone cover

Your RONDO audio processor is shipped with a microphone cover to protect the microphone opening from contamination. If you need to reattach the cover, proceed as shown in Fig. 14.



Fig. 14 Snapping on the microphone cover

Connecting assistive listening devices

Assistive listening devices (e.g. FM systems) or other external audio devices such as portable CD players, MP3 players, AM-FM radios, etc. can be connected to the RONDO audio processor via the MED-EL Mini Battery Pack which may be purchased separately.

Additional wearing options

Mini Battery Pack

The MED-EL Mini Battery Pack is a device enabling external power supply of your RONDO audio processor. It is connected to the RONDO control unit with a cable. The Mini Battery Pack requires one primary or one rechargeable 1.2 to 1.6 Volt size AAA battery.

Alternatively, a DaCapo PowerPack may be used. The Mini Battery Pack features an EA (Euro Audio) socket to connect external audio devices to the RONDO. The CS44 socket on the Mini Battery Pack can be used to connect the Microphone Tester to listen to the mixed signal of the external audio source connected to the EA socket and the microphone signal of the RONDO audio processor. A special cable is required for that option. For further information please contact your CI centre or MED-EL.

The Mini Battery Pack may be purchased separately.

Special considerations for young children

The RONDO audio processor has several features that are designed especially for young children. They are:

- Battery pack lock to prevent small children from disassembling the audio processor and accessing the batteries.
- Deactivation of certain FineTuner controls: To prevent accidental program, volume or sensitivity changes, it is possible to deactivate these FineTuner controls if the FineTuner may be used by the child. Please contact your CI centre for assistance.
- Attachment clip to prevent the RONDO from dropping on the floor when it comes off.
- RONDO protector: Soft silicone cover to absorb mechanical impacts on the housing in case the RONDO drops on the floor.

MED-EL strongly recommends that adult users also use the attachment clip and RONDO protector.

- < Only parents/adults are allowed to disassemble the device to change the magnet or batteries. Parents/adults should check the device frequently for damages or missing parts.
- < If your child is implanted with a SYNCHRONY implant, check for correct alignment of audio processor and implant by gently rotating the audio processor a quarter or half a turn back and forth to allow the audio processor to position itself correctly over the implant. You will notice correct alignment by stronger magnetic attraction.

General precautions and warnings

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

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 MED-EL 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 impact success with the cochlear implant, as do other factors, some of which may be unknown.

Do not use the MED-EL 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 8, 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 MED-EL Cochlear Implant System

The audio processor and other parts of the system contain sophisticated electronic components which require special precautions regarding electromagnetic compatibility (EMC). When activating your audio processor always follow the guidelines outlined in this section and chapter 9, Technical data, Guidance and manufacturer's declaration.

The electronics are durable but must be treated with care.

- Never open the housing of your audio processor. Unauthorized opening invalidates the warranty. To change the batteries or clean the battery contacts, perform the steps described in chapter 7, Care and maintenance.
- Before switching on the audio processor, check the external parts of the MED-EL Cochlear Implant System for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the audio processor should not be switched on. Read chapter 8, Troubleshooting, or contact your CI centre or MED-EL.

Important

If you plan to enter an environment that could potentially adversely affect the operation of your MED-EL 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 rub, stretch or 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 audio processor and FineTuner do not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range is between +0°C and +50°C (32°F and 122°F) for the audio processor and the FineTuner. Normally, when the 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 (especially inside a car). Long exposure to direct sunlight might damage the audio processor or FineTuner.
- If you ever experience loud or uncomfortable sounds, please remove your RONDO immediately: this will stop stimulation at once.
- Blowing your nose too hard might lead to (temporary) fluctuations in loudness. This is caused by air entrapped over the reference electrode of the implant.
- 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 and gently wipe all external parts dry, using a soft absorbent cloth. Then put the audio processor in the supplied drying kit to allow the audio processor to dry out (preferably overnight). If in doubt, repeat the drying process. 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 MED-EL Cochlear Implant System. They should not be dropped or subjected to dangerous areas (e.g. machines or high voltage) which could result in damage to the components.
- Do not use the audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.

General precautions and warnings

- Do not use your audio processor in the vicinity of strong ionising radiation (e.g. x-ray machines) or electromagnetic fields (e.g. MRI machines). Such radiation or fields may stop your MED-EL Cochlear Implant System from working.
- Do not modify the housing, the electronics or any other parts of your audio processor in any way.
- < Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury.

Technology in everyday life

Metal detectors, anti-theft systems and other radio frequency (RF) transmitters

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 field emitted by these systems. To avoid the buzzing sound, switch your audio processor off when walking through metal detectors and anti-theft systems or when you are close to RF transmitters. 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 audio processor. 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/or the antenna.

Cell phones

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

TV, radio, FM systems, etc.

When intending to connect an external audio device to the audio processor that is powered by mains power, i.e. plugged into the wall or a power strip, always make sure first that this mains-powered external audio device meets the safety requirements stated in the standards EN/IEC 60065, EN/IEC 60601-1 and/or appropriate national standards. If the mains-powered device does not bear a CE mark (<), which is usually found on the device's type label, you cannot presume that the mains-powered device meets the above safety requirements and must therefore not be connected to your

audio processor. Connecting a mains-powered device to your audio processor that does not meet the above safety requirements could cause an electric shock.

You can safely connect battery-powered external audio devices to your audio processor. Special cables may be needed (e.g. for connection to FM systems). For more information please contact MED-EL.

Electrostatic discharge (ESD)

Electronic devices are influenced by electrostatic discharge (ESD). Although the MED-EL 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 these 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 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 fibres. Generally, cotton and natural fibres are less likely to cause ESD problems. Fabric softeners might also help reduce static electricity. When getting dressed, put your audio processor on last, and remove it first when undressing.
- Always remove the audio processor 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 audio processor.

- Always remove the audio processor 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, even if the processor is removed, 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. If it does not come on again, contact your CI center.

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 audio processor securely 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 of high quality. It 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 the 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 50m (165 ft.).

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

Precautions for medical procedures

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to the Medical Procedures Manual.

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 during the surgery and immediate postoperative period 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](https://www.cdc.gov) website.

Care and maintenance

Maintenance

Your RONDO audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time. The battery pack may wear out due to frequent opening and closing and therefore must 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 RONDO audio processor from water (see also chapter 6, General precautions and warnings).

Do not try to repair electronic parts of your RONDO audio processor and do not try to open the control unit, as this invalidates the manufacturer warranty.

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 are not going to use your audio processor for an extended period of time, you should remove the batteries and dispose of or store them separately.

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.

Weekly maintenance of your audio processor

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

Drying your audio processor

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

Remove the batteries from your 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 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.

Batteries

The RONDO audio processor requires three 675 zinc air batteries. These batteries supply the external and internal components of the MED-EL Cochlear Implant System with energy. If you want to get more information on batteries, please contact your local MED-EL representative or CI center.

There are three air inlets between battery pack and control unit (see also chapter 4, RONDO audio processor, The parts of the system, Fig. 2). Do not cover these inlets as this may shorten battery life. If the air inlets become blocked, remove the battery pack and carefully clean the inlets and the air ducts leading away from the inlets.

Important

- Wash your hands after handling disposable batteries.
 - Do not try to recharge disposable batteries.
 - Do not disassemble, deform, immerse in water or incinerate batteries.
 - Avoid mix-up of old and new batteries or batteries of different types of brands.
 - Do not short-circuit batteries, e.g. by allowing the terminals of batteries to touch, carrying batteries loose in your pockets, wallet or purse or touching the battery terminals with metals (coins, wires, keys, etc.).
 - Store unused batteries in their original packaging, in a cool and dry place.
 - Do not expose batteries to heat (e.g. never leave batteries in direct sunlight, behind a window or in a car).
 - Do not use damaged, deformed batteries or leaking batteries. If any kind of substance leaks out of a battery, avoid direct skin contact with that substance. Such a substance could cause a chemical burn. In case of eye contact, rinse with copious amounts of water and seek medical attention immediately.
 - If you are not going to use your audio processor for an extended period of time, you should remove the batteries and dispose of or store them separately.
 - Always remove used batteries immediately to avoid leaking and possibly damaging the device.
 - Dispose of used batteries according to local regulations. If you ignore these regulations, you will contribute to pollution of the environment. Generally, batteries are collected separately and not disposed of 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 shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury.

Changing the batteries of your RONDO audio processor

When the red indicator lights on the control unit blink continuously (●—●—...), the battery set must be replaced (see also chapter 8, Troubleshooting).

To change the batteries, proceed as follows:

1. Remove the RONDO from your head and switch it off before replacing the batteries.
2. The battery pack features a tiny release lever on the right side of the ON/OFF switch. To remove the battery pack, press down the release lever and push the slide switch to the right towards the unlocked symbol (<) until it engages (see Fig. 15). Now pull the battery pack slightly back and lift it off.

Important

The switch must always be in the unlocked position (<) and the shaded area must be visible when removing/attaching the battery pack. Do not use excessive force. To move the switch to the unlocked position, press down the release lever (⌘) on the right side. Hold it down while pushing the switch to the right (↗).

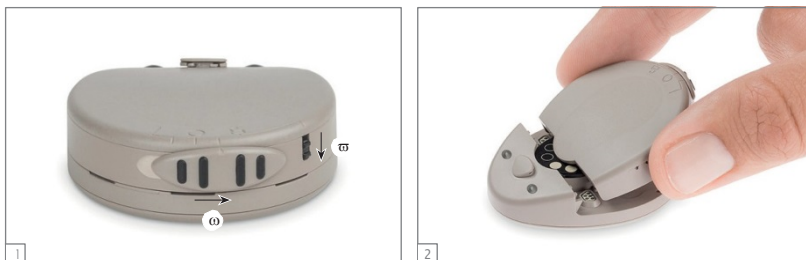


Fig. 15 How to open the battery pack of your RONDO audio processor

3. Replace the used battery set by removing the three batteries with the magnet. To do so move the centre of the bottom part of the control unit over each battery separately. Try not to touch the battery contacts (see Fig. 16).



Fig. 16 Changing the batteries of your audio processor

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 after the batteries have been inserted.
5. When assembling the battery pack, make sure that the switch is in the unlocked position ($\leftarrow$) and the shaded area is visible. Hold the battery pack at a slight downward angle and push it straight onto the processor. Be sure to center the battery pack to prevent the magnet pulling out the batteries. When the battery pack rests on the processor, slightly press it down and move the ON/OFF switch to the OFF position (center position). The release lever engages and the battery pack is locked again (see Fig. 17).



Fig. 17 Assembling the battery pack

Changing the battery of your FineTuner

When your FineTuner generates an optical low battery warning signal (see also chapter 4, RONDO audio processor, FineTuner, FineTuner functions), replacing the battery of your FineTuner is recommended.

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 RONDO 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 into place and tightening the screw.



Fig. 18 Changing the battery of your FineTuner

Troubleshooting

Once you are familiar with your MED-EL 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 supplied by MED-EL may damage your MED-EL 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 audio processor from the implant site before operating the switch if this sound bothers you.

Important

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

Speech Processor Test Device

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

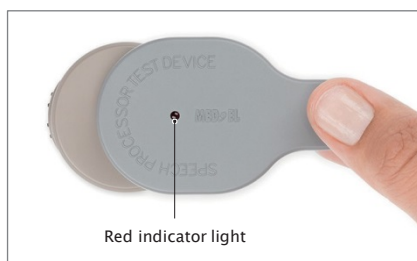


Fig. 19 Speech Processor Test Device

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

The Speech Processor Test Device is not necessary for the function of your audio processor. It is simply intended to help detect most common audio processor problems like defective 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 in your audio processor, contact your CI centre or MED-EL or try the following procedure:

Switch on the audio processor and make sure that it is supplied with functioning batteries. Place the audio processor underneath the Speech Processor Test Device (see Fig. 19), it 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 up or stays on constantly, try the following:

- Adjust the volume setting. By using the appropriate loudness setting, you should be able to recognize the flickering of the red light in the rhythm of your voice.
- Change the batteries.

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, as this will cause damage to the device and immediately void any warranty.

The Speech Processor Test Device should be handled with care to achieve maximum lifetime and to ensure proper function. Do not expose your Speech Processor Test Device to conditions other than those suitable for your audio processor (see also chapter 6, General precautions and warnings).

FineTuner

The FineTuner transmits commands to the audio processor via a radio frequency (RF) link. If the audio processor does not respond to FineTuner commands, the following may be potential reasons and solutions for this:

- The audio processor is out of the FineTuner's operational range. To overcome this you should move the FineTuner closer to the audio processor.
- The FineTuner keyboard lock is active. In this case follow the instructions for unlocking as described in chapter 4, RONDO 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 audio processor and/or go to a different location.
- The audio processor and the FineTuner are not synchronized. In this case you need to refer to the section described in chapter 4, RONDO 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 7, 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 7, Care and maintenance, Batteries, Changing the battery of your FineTuner.
- The desired command in the audio processor 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 lights in the audio processor have been disabled by your audiologist during fitting. To enable the red indicator lights you will need to contact your clinic, CI center or MED-EL.

Additional troubleshooting information:

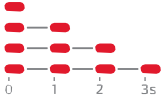
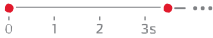
- If you or your child have used the < (telecoil) or < (microphone and telecoil) settings and are unable to return to the < (microphone) signal source input with the FineTuner, you need to switch the audio processor off and on again. When the audio processor is switched on again it will automatically start with the < (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.

RONDO red indicator lights

The red indicator lights on the control unit flash with different patterns to indicate different conditions. If the indicator lights begin flashing, use the following tables to determine the cause.

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

Blinking pattern	Meaning	Required action	Remarks
Error patterns			
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be replaced.
	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.
	Electronic problem or program failure	Switch processor off. Switch processor back on.	If the blinking persists, the processor must be reprogrammed.
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	
Warning patterns			
	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			
	Brief flash of 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.

Blinking pattern	Meaning	Required action	Remarks
Programme change pattern			
	Programme 1 to 4 selected	None	The red indicator light will blink depending on the selected program position. Important These blinking patterns may start off looking like the battery empty pattern.
Status pattern			
	The processor is initialized and working	None	You may perceive a clicking sound with an 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 you should change the batteries of the 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 audio processor, a confirmation beep is audible for the user of the audio processor.

These 3 signals may be deactivated permanently by your audiologist if you prefer this.

FineTuner indicator functions

Three indicator lights with different colors (left and right: amber; centre: 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 (for 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 4, RONDO 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.

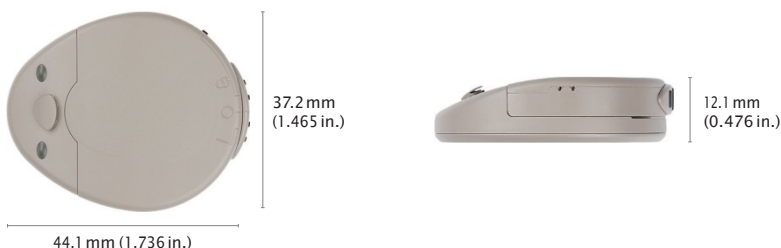
Program mode

If ↔ is pressed for more than 5 seconds (must be unlocked; see chapter 4, RONDO 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.

Technical data

Audio processor

Dimensions of RONDO audio processor³



Length (without switch): 44.1 mm (1.736 in.)

Width: 37.2 mm (1.465 in.)

Height: 12.1 mm (0.476 in.)

Weight³

Weight will vary based on selected magnet strength and battery brand:

- 17.5g (0.617 oz.) with magnets 1S and 1 including batteries

Power supply

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

Hardware

- Fully digital signal processing
- Various parameters programmable
- 4 programmes selectable
- Up to 12 band pass filters; filter characteristics programmable
- Non-linear amplification programmable
- Full frequency range: 70-10,000Hz
- Audio processor self-test: checksum on programs, continuous parity check
- Automatic Gain Control (AGC) configurable
- FineTuner commands can selectively be disabled

³ typical values

Audio input

- Via Mini Battery Pack
- Hearing aid type three pin connection (Euro-Audio) acc. to IEC 60118-12 on Mini Battery Pack
- Sensitivity: -61.4 dBV^3 (corresponds to 70 dB SPL at 1 kHz)
- Impedance: $2.9 \text{ k}\Omega^3$

Controls/Indicators

- ON/OFF switch
- Indicator lights: 2 red LEDs for alarm and indicator functions

Materials

- Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS): Control unit, battery pack, all colors
- Polyamide (PA): release lever, magnet insert cover, LED windows
- Silicone: protector

Temperature and humidity range

Operating temperature range: 0°C (32°F) to 50°C (122°F)

Storage temperature range: -20°C (-4°F) to 60°C (140°F)

Relative humidity range: 10% to 93%

Atmospheric pressure range: 700 mbar (hPa) to 1060 mbar (hPa)

Essential performance

None of the performance characteristics of the RONDO (incl. all accessories) are essential performance as defined in IEC 60601-1.

Expected service life

The expected service life of the RONDO (incl. all accessories) as defined in IEC 60601-1 is 5 years.

Radio frequency (RF) link (FineTuner)

Frequency band of reception: 9.07 kHz ($\pm 3\%$)

3 typical values

FineTuner

Dimensions³

Length: 85.5 mm (3.336 in.)

Width: 54.0 mm (2.126 in.)

Height: 6.3 mm (0.248 in.)

Weight: 33.0 g (1.164 in.) (incl. battery)

Controls/Indicators

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

Power supply

- 1 lithium/manganese dioxide battery type CR2025 (3V)
- Battery life expectancy is typically more than 6 months

Classification

- Short Range Device (SRD) according to ERC/REC 70-03 Annex 9 (band A1) and Annex 12 (band A)
- Equipment class 3
- 47 CFR Part 15 Low Power Transmitter below 1705 kHz-US

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS)

Temperature and humidity range

Operating temperature range: 0°C (32°F) to 50°C (122°F)

Storage temperature range: -20°C (-4°F) to 60°C (140°F)

Relative humidity range: 10% to 93%

Atmospheric pressure range: 700 mbar (hPa) to 1060 mbar (hPa)

Technical data

Radio frequency (RF) link

Carrier frequency: 9.07 kHz ($\pm 0.7\%$)

Type of modulation: phase shift keying (PSK)

Maximum RF output power: 11.7 dB μ A/m @ 10 m

Maximum operating distance: ~1 m

Regulatory statements

Applicable in Canada only:

Model: FineTuner – Canada 310

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:

Model: FineTuner – FCC ID: VNP-FT

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

 The RONDO audio processor and the FineTuner are in compliance with directive 90/385/EEC (Active Implantable Medical Devices/AIMD).

0 1 2 3

CE mark applied in 2012

Hereby, MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type RONDO (audio processor) and FineTuner (remote control) is in compliance with directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.medel.com/compliance



Caution, consult accompanying documents (manual)



MR unsafe



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



Non-ionizing radiation (FineTuner)



Fragile; handle with care



Relative humidity



Temperature limit

IP22 IP classification of the RONDO

Moisture protection and protection from solid foreign objects acc. to environmental conditions as defined in IEC 60529 for class IP22.

This classification means that the RONDO remains safe when exposed to dripping water and no solid objects larger than 12.5 mm can penetrate the housing when fully assembled and ready for use.

Speech Processor Test Device

 The Speech Processor Test Device is in compliance with directive 2014/30/EU (Electromagnetic Compatibility/EMC) and directive 2011/65/EU (Restriction of Hazardous Substances in Electrical and Electronic Equipment/RoHS).

CE mark applied in 2005

Disposal

We advise to dispose of all external components of your MED-EL 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.

Guidance and manufacturer's declaration

Tables according to IEC 60601-1-2 for RONDO

Electromagnetic emissions for all equipment and systems

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The RONDO 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 RONDO 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 RONDO is intended for use in the electromagnetic environment specified below. The customer or the user of the RONDO 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	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines		
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth		
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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RONDO requires continued operation during power mains interruptions, it is recommended that the RONDO be powered from an uninterrupted power supply or a battery.
	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		
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 RONDO is intended for use in the electromagnetic environment specified below. The customer or the user of the RONDO should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RONDO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 \cdot \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \cdot \sqrt{P}$ 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 metres (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 RONDO is used exceeds the applicable RF compliance level above, the RONDO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RONDO.

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 RONDO – for equipment and systems that are not life-supporting

The RONDO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RONDO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RONDO 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		
	150kHz to 80 MHz $d = 1.17 * \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 * \sqrt{P}$	800 MHz to 2.5GHz $d = 2.33 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.39
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 800MHz, 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.

Examples for wireless (RF) communications equipment:

Equipment	Recommended separation distance in m
wireless home network device (e.g. WiFi router)	0.74
cordless telephone/base station	1.65
walkie-talkie	2.33
mobile phone	3.30

Appendices

Warranty statement

MED-EL's warranty is in agreement with mandatory local statutory warranty provisions.

Any extension of the statutory warranty is subject to agreement between MED-EL and the purchaser. Therefore these extensions may be different in various countries. Please contact your local MED-EL representative for information on your individual warranty rights.

Extension of statutory warranties shall not be granted unless the product is properly registered. You can register a product either by completing the provided registration card and sending it to MED-EL or by using MED-EL's online registration website (upon availability). Ask your local MED-EL representative for help if you need assistance in the registration process.

Extensions of statutory warranties exclusively cover product failures. This does 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.

I. SUMMARY OF PRIMARY CLINICAL STUDIES

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

MED-EL sponsored a study at the University of North Carolina at Chapel Hill to see if 40 adults with SSD and AHL who received a MED-EL cochlear implant were better able to understand speech, more likely to find the direction of a sound source and are satisfied with their implant after the first year. This group of patients had hearing loss for less than 10 years and had used a hearing aid regularly for at least some of that time. All of the people in the study had also tried some type of current hearing device to treat SSD, such as a hearing aid, bone-conduction device, or a "CROS" type of hearing aid.

Listeners' hearing history:

SSD: Fifteen people in the study experienced sudden hearing loss and five people experienced a gradual hearing loss. The cause of 16 of those peoples' hearing loss was unknown, 3 were caused by Meniere's disease, and caused by injury in one person.

AHL: Ten people had sudden hearing loss and six had a gradual hearing loss, with the remaining two having both a gradual and sudden loss. Cause of hearing loss was unknown in 14 people, due to Meniere's disease in two people, due to noise-induced hearing loss in one person and caused by viral infection in one person.

Complications:

In this study, the researchers also looked at whether the implant was a safe choice by watching for any complications or problems (also called adverse events) the recipients had during the study. Some examples of

complications might include pain, dizziness, discomfort, poor sound quality, etc. For a list of major complications that are associated with cochlear implant and surgery, please visit www.medel.com/us/isi and/or talk with your doctor. A total of nine complications were reported that were related to the device or the surgery. An additional six complications were not able to be ruled out as device or surgery-related. No serious, unexpected, device-related complications were seen.

The most common problem was dizziness, which was seen a total of 11 times. In four cases, this was not related to the device or surgery. In three cases, it could not be ruled out that it was related to the device or surgery. In the remaining four cases, it was determined that the it was related to the surgery only. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. All other complications occurred at a rate of 5% or less (2 or fewer people).

Results:

Speech Understanding in Quiet:

Both groups of people (SSD and AHL) improved their ability to understand speech in quiet after 1 year of implant use when tested with the implant alone. For the people with SSD, average scores when repeating single words in quiet increased from 4% before surgery to 55% after 12 months of listening with the implant. For the group of people with AHL, this same test score improved from 6% to 56% in 12 months. In the opposite ear, there was no change in their score over time. When tested with both ears, there was no change compared to the score before surgery, probably because the normal hearing ear was working as expected.

Speech Understanding in Noise:

When listening to speech in noise, both groups of people (SSD and AHL) improved over the first 12 months of listening with the cochlear implant compared to their unaided scores before surgery and compared to scores with a bone conduction hearing device. These increases were seen when both speech and noise were presented from the front of the listener. Scores also improved when speech came from the front and the noise was on the side of the normal hearing ear. This means the cochlear implant increases speech understanding, especially when the normal hearing ear is confused by noise. This improvement was seen on more than one test of speech understanding in noise.

The average improvement in the SSD group increased from 38% to 47% in 12 months on the AzBio Test, speech and noise from the front. This group also had an average increase from 17% to 53% on the AzBio Test when speech came from the front and the noise was on the side of the normal hearing ear. The AHL group saw increases from 23% to 34% when speech and noise came from the front, and 6% to 29% when speech came from the front and noise was on the side of the better hearing ear, also on the AZ Bio Test.

Finding the Direction of a Sound Source:

People in both the SSD and AHL groups significantly improved in finding the direction of a sound after they had listened with the cochlear implant for 12 months. To take this test, listeners sat in a room with 11 speakers arranged in a half-circle in front of them, and they were asked to point to the speaker each sound came from.

Satisfaction Questionnaires:

Listeners were asked to complete two questionnaires about their experiences using the MED-EL cochlear implant. After one year of listening, both groups (SSD and AHL) reported an improvement overall when asked about their impressions of the quality of speech, ability to locate sounds around them, and overall sound quality (SSQ Test) as well as ease of communication, hearing in background noise, and hearing in environments with an echo (APHAB Test).

II. SUMMARY OF REAL-WORLD EVIDENCE AS SUPPORTING CLINICAL EVIDENCE

All relevant published medical research was reviewed on adults and children with SSD or AHL who received cochlear implants.

Published Literature on Children

There were five studies published on a total of 26 children with SSD (five used MED-EL implants) and a total of nine children with AHL. The studies reviewed were: Beck and associates (2017), Rahne and Plontke (2016), Arndt and associates (2015), Tavora-Vieira and Rajan (2015) and Gratacap and associates (2015).

The overall benefits reported were improved speech understanding in quiet and noise, improved ability to locate a sound source, and increased parent scores on questionnaires about quality of life over time. This means, independent research studies have found similar results to those we describe above. Across these independent studies, there were a few tests where some children did not show improvement during the study period, or where certain children were not able to complete the tests.

Published Literature on Adults

There were six studies on a total of 58 adults with SSD (50 used MED-EL implants) and a total of 52 adults with AHL (37 used MED-EL implants). The studies reviewed were: Lorens (2019), Doge and associates (2017), Skarzynski and associates (2017), van Loon (2017), Kitoh (2016), Rahne and Plontke (2016). Some people participated in more than one of these studies but if they did, they were not counted twice.

The overall benefits for these people include significantly better speech understanding in quiet and in noise, better ability to locate a sound source, and more satisfaction on questionnaires about quality of life, music enjoyment and ringing in the ears. The data from these independent studies show consistent benefits for CI in people with SSD or AHL. One study used a complicated setup and multi-talker noise. That study showed that 8 of 11 listeners improved on speech understanding in noise, but the remaining 3 listeners showed reduced performance with their CI in this difficult listening situation. Results on listener satisfaction questionnaires showed increased frequency and satisfaction of listening to music, as well as better music sound quality and clarity and better appreciation of different music styles. Two studies reported improvement in ringing in the ears with CI use. Results indicated a high level of patient satisfaction with the CI. This means, independent research studies have found similar results to those we describe above, supporting the value of a CI for people with SSD and AHL.

One study included six adults who lost their hearing at a young age, before they learned to talk, who didn't receive their cochlear implants until they were adults. This means, they went for a very long time without using hearing aids. While this small group of people did not show the same amount of improvement as the people who lost their hearing later in life and wore hearing aids regularly, all of them were still using their CI more than 8 hours a day, each day, at the end of the study.

Weighing the Risks and Benefits:

A CI is the only treatment choice that can help people with SSD or AHL regain hearing in their poorer hearing ear. All the studies mentioned above show improvement in speech understanding, locating the source of a sound, listener satisfaction, and music appreciation (in adults). For people with SSD or AHL, the implanted ear has a similar hearing loss 'picture' that matches people with hearing loss in both ears who have already been receiving cochlear implants for years. This means, the risks of cochlear implantation in adults and children with SSD and AHL are considered to be the same as for people who have already been using cochlear implants for a long time. Nevertheless, a careful CI evaluation and a strong commitment to rehabilitation are important for the best possible results. Regular (yearly) hearing tests for the opposite ear are recommended, to watch for additional hearing loss that may appear over time in the good ear.

Based on this information, the benefits outweigh the risks of CI in adults and children older than 5 years with SSD and AHL, who have a profound hearing loss in the ear to be implanted. Please talk with your doctor and implant center professionals about any questions or concerns you may have.

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User Manual for

**SONNET (Me1310) and SONNET EAS (Me1320)
audio processors**



hearLIFE



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Introduction

This user manual provides information and instructions regarding the MED-EL Cochlear Implant (CI) System with the two variants of the SONNET audio processor: SONNET (Me1310) and SONNET EAS (Me1320). It includes descriptions of available parts, wearing options, and accessories for the SONNET, as well as instructions for troubleshooting and proper care of the external cochlear implant equipment.

Your MED-EL Cochlear Implant System consists of the Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY), Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), PULSARci¹⁰⁰ (hereafter referred to as PULSAR), SONATAti¹⁰⁰ (hereafter referred to as SONATA) or C40+ implants, the external SONNET audio processor (including FineTuner, DL-Coil and D Coil), the external components and accessories, and any external hardware and software used by your audiologist.

< This symbol indicates information that is particularly relevant for parents of implanted children.

Important

You are the operator of your/your child's SONNET audio processor, therefore we recommend that you read this manual in its entirety. Do not perform any maintenance activities other than those described in this manual (e.g. changing batteries). When performing these maintenance activities, always remove the audio processor from the ear.

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 MED-EL system may take a little time while you become accustomed to this new method of hearing. You may choose to work with an aural rehabilitation specialist or other clinician to help you maximize your communication skills using the device. 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 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 require 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.

Intended use – Indications – Contraindications

Intended use

The SONNET audio processor is an external part of the MED-EL Cochlear Implant System. The MED-EL 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.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic (hearing aid) and electrical stimulation to the same ear is made possible through the external SONNET EAS audio processor working in conjunction with the internal cochlear implant with either a +FLEX24 or +FLEX20 electrode variant (SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR or C40+), which together make up the MED-EL EAS System.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

The SONNET audio processor is an external component of the MED-EL Cochlear Implant System and is indicated for use on patients who have been implanted with SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR or C40+ cochlear implants. The MED-EL Cochlear Implant System is indicated for:

Bilateral deafness:

- 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 the 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 and above. 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 aided benefit is defined as <20 % correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood 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.

Partial deafness:

The MED-EL EAS System is indicated for partially deaf individuals aged 18 years and older who have residual hearing sensitivity in the low frequencies sloping to a severe/ profound sensorineural hearing loss in the mid to high frequencies, and who obtain minimal benefit from conventional acoustic amplification. Typical preoperative hearing of candidates ranges from normal hearing to moderate sensorineural hearing loss in the low frequencies (thresholds no poorer than 65 dB HL up to and including 500 Hz) with severe to profound mid- to high-frequency hearing loss (no better than 70 dB HL at 2000 Hz and above) in the ear to be implanted. For the

non-implanted ear, thresholds may be worse than the criteria for the implanted ear, but may not be better. The CNC word recognition score in quiet in the best-aided condition will be 60% or less, in the ear to be implanted and in the contralateral ear. Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

The SONNET EAS audio processor is intended to be used by the patients as indicated above.

The SONNET is indicated to be used in typical everyday environments (home, office, outdoor etc.). The SONNET is intended to be used every day during a patient's waking hours.

The user of a SONNET does not need any special skills or elevated level of education; however, the user (or custodian, if the user is a child or a person with a handicap who is not able to perform the actions listed below) shall, at a minimum, be able to perform the following actions:

- Switching ON/OFF
- Changing batteries
- Placing/removing SONNET on/from the ear
- Placing/removing coil over/from the implant site

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As the SONNET is a component of the MED-EL Cochlear Implant System, all indications stated for the MED-EL 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 processor programming, assessment sessions and training.

Contraindications

A patient must not receive a SONNET if the individual is known to be intolerant of the materials used in the SONNET.

Combined electric-acoustic stimulation (EAS) is contraindicated for patients unable to use acoustic amplification. For details, please refer to chapter 9, Technical data.

The SONNET and any external wireless device (e.g. FineTuner) are not intended to be used in environments where RF transmissions are prohibited (e.g. operating room).

As the SONNET is a component of the MED-EL Cochlear Implant System, all contraindications stated for the MED-EL Cochlear Implant System are applicable.

NOTE:

Important information related to indications, contraindications, warnings and risks for your cochlear implant are shipped in a separate document (instruction for use of the implant) to your clinic, together with the cochlear implant. If you want to review this information, please contact your clinic or MED-EL.

SONNET

audio processor

The parts of the system

The MED-EL 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.



Implants with titanium housing: SYNCHRONY (shown), MED-EL CONCERT (shown) and SONATA



Implants with ceramic housing: PULSAR (shown) and C40+

Fig. 2 The MED-EL cochlear implants

The external parts include the SONNET audio processor and the audio processor accessories. In its basic configuration, the SONNET audio processor consists of the control unit with the earhook attached, the battery pack (consisting of frame and cover), the coil and the coil cable. A separate remote control called the 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.

The SONNET audio processor is available in two variants: The first variant (product code Me1310) is an audio processor that supports electrical stimulation only, while the second variant (product code Me1320) additionally features acoustic stimulation (amplification) intended to be used by patients who have at least a certain degree of functional low frequency hearing. Throughout this manual the term “SONNETci” will be used when specifically referring to the first variant, the term “SONNETeas” will be used for the second variant. “SONNET” will be used in all other cases.

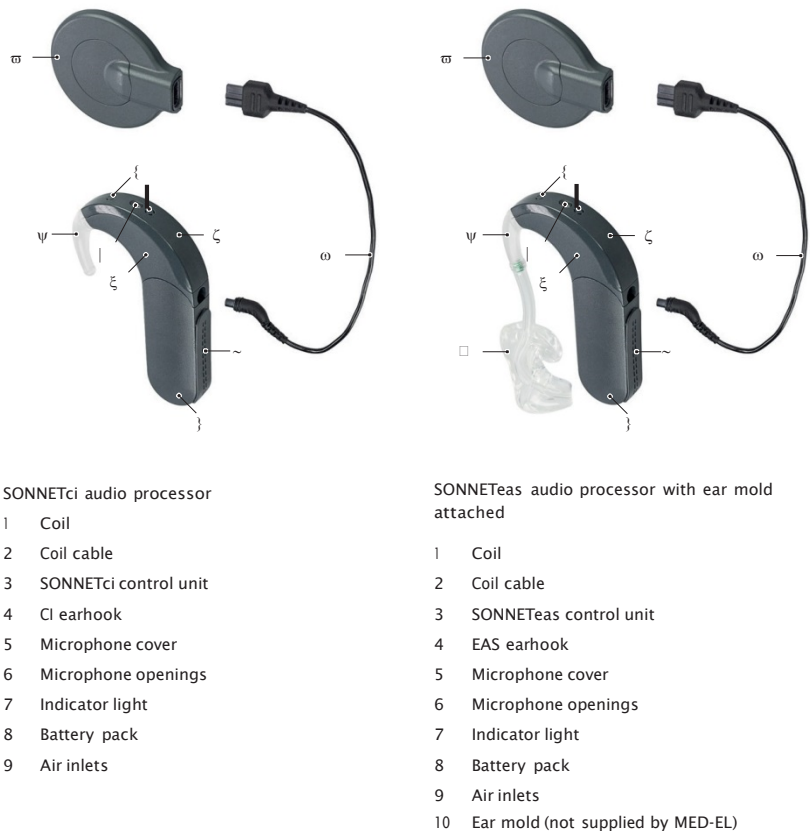


Fig. 3 Your SONNET audio processor

The concept of EAS

Cochlear implant users with low frequency hearing benefit from additional acoustic stimulation in the implanted ear as has been demonstrated in various scientific studies. This combination of cochlear implant and acoustic stimulation is known as combined electric-acoustic stimulation, or EAS. The term electric stimulation refers to the cochlear implant, while acoustic stimulation refers to the acoustic amplification unit.

Especially in listening situations with background noise (background conversations, street noise etc.), EAS can greatly improve speech understanding. Users of combined electric-acoustic stimulation have also reported that sound quality and music perception are improved compared to cochlear implant use alone.

Studies have also shown that it may take time for EAS use to show its full benefit. If you are an EAS user and do not experience an immediate benefit, do not be discouraged.

ON/OFF switch

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

You may select the following positions:

Battery pack cover pulled back: OFF

Battery pack cover completely moved over the frame: ON

Important

When trying to pull back the battery pack cover, make sure that the battery pack cover lock is in the unlocked position as shown in Fig. 8. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.

There is no need to completely remove the battery pack cover to switch off the SONNET. It is sufficient to pull it back to a position where you can see the whole labeling on the control unit (see Fig. 4).



Fig. 4 The SONNET audio processor in OFF position



Fig. 5 The SONNET audio processor in ON position

After switching on the SONNET audio processor, the indicator light will blink green up to four times indicating the activated program. For example, if the light blinks three times, then program 3 is currently active. The audio processor begins working as soon as the green light comes on and blinks.

- < In young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 9), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.

To activate your CI system, switch on the SONNET and place the control unit and battery pack, behind the ear and the coil, with the flat side to the head, over the site of the implant (see Fig. 6). As soon as the coil is approximately over the implant, it is automatically positioned correctly by attraction to the implant magnet.

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



Fig. 6 SONNET behind the ear and coil over the site of the implant

In the OFF position, the audio processor is turned off. No current is drawn in this position. Make sure to pull back the battery pack cover of your audio processor when it is not in use, as this prolongs the lifetime of the batteries (see also chapter 7, Care and maintenance).

- < If the processor is turned off (i.e., the battery pack cover pulled back), make sure that young children do not have access to the audio processor to prevent disassembling the device.

The SONNET 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 audible signals.

To use the telecoil, proceed as follows:

- Activate the telecoil by pressing the key < (only signals picked up by the telecoil will be audible) or < (signals picked up by the microphone and the telecoil will be audible) on your FineTuner, as described in chapter 4, SONNET audio processor, FineTuner, FineTuner controls.
- When you are using a telephone, position the telephone so that its earpiece is centered over the SONNET control unit. Move the telephone slightly up or down as necessary to optimize the signal quality.
- When you are in an environment with a loop system, try to find a spot where the signal quality is best for you.
- To deactivate the telecoil when you do not need it anymore, press the key < on your FineTuner, as described in chapter 4, SONNET audio processor, FineTuner, FineTuner controls.

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 4, SONNET audio processor, FineTuner, FineTuner controls).

FineTuner

Your audiologist will program your SONNET audio processor to suit your needs. The FineTuner is provided to help you optimally use your audio processor in different listening situations.

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

Keeping the FineTuner out of the reach of children prevents them from inadvertently changing the settings of their audio processor.

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

The FineTuner is configured for a specific (or target) audio processor, and only the target 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 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). To do so, first switch off your audio processor and place the coil of the audio processor on the keyboard of the FineTuner (approximately over key <). Then switch on your audio processor. The audio processor and FineTuner will be synchronized automatically. Successful synchronization is indicated by a short blinking signal of the two amber indicator lights on your FineTuner. It is only necessary to re-synchronize the processor to the FineTuner if you replace the processor or FineTuner.

For bilaterally implanted users

One FineTuner can be configured for use with one audio processor per ear. If you want to use your FineTuner for both audio processor systems, your audiologist or clinical engineer can configure one FineTuner to communicate with both the left and right audio processors. Once your audio processors are programmed correctly, the synchronization procedure described above should be performed with both audio processors.

FineTuner controls

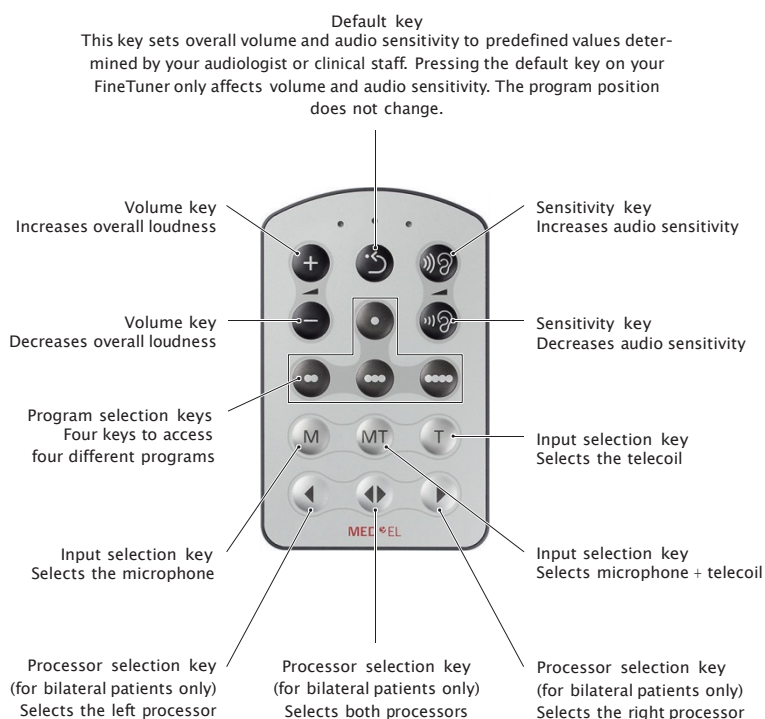


Fig. 7 FineTuner

All FineTuner functions can be selectively disabled by your audiologist or clinical staff by disabling the respective command in the control unit (via the MED-EL application software). Your FineTuner will still be able to transmit all commands, but your control unit will not execute disabled commands.

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 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 described 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: If you press a key and see the red indicator light on your FineTuner flashing 3 times, the voltage level of your FineTuner is critically low (see also chapter 7, 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 8, Troubleshooting. The FineTuner does not affect connected assistive listening devices.

Battery pack

The SONNET battery pack (product code Ma060106) consists of the battery pack frame, holding two hearing aid batteries, and the battery pack cover. The battery pack cover, which also functions as the ON/OFF switch of the SONNET (see Fig. 4 and 5) slides over the battery pack frame. This configuration allows the entire audio processor to be worn on the ear. Changing the batteries is described in chapter 7, Care and maintenance, Batteries, Changing the batteries of your SONNET audio processor.

To remove the battery pack from the control unit (e.g. to connect a MAX programming cable instead), proceed as follows:

1. Make sure that the battery pack cover lock is in the unlocked position, as shown in Fig. 8. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
2. Pull back and completely remove the battery pack cover.
3. Press the release lever (Fig. 10.1) on the battery pack frame and separate battery pack frame and control unit (Fig. 10.2).

To attach the battery pack to the control unit, proceed as follows:

1. Insert the rib on the control unit into the matching groove of the battery pack frame (Fig. 10.3).
2. Push the opposite end of the battery pack frame onto the control unit (Fig. 10.4) until the release lever engages.
3. Make sure that the battery pack cover lock is in the unlocked position as shown in Fig. 8. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
4. Slide the battery pack cover completely over the battery pack frame to switch on the SONNET (see Fig. 5). Mind the correct orientation of the battery pack cover when sliding it over the frame, and do not use excessive force. The orientation is correct when the air inlets (Fig. 10.5) on the battery pack cover are on the same side as the coil cable socket in the control unit.

< In young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 9), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.



Fig. 8 Battery pack cover lock in unlocked position



Fig. 9 Battery pack cover lock in locked position



Fig. 10 How to remove/attach the battery pack from/to the control unit

The battery pack cover is available in several colors allowing you to personalize your SONNET.

- < Only parents/adults should disassemble the device to change defective parts. Parents/adults must check the device at least once a week for damages or missing parts.

Coil

The coil connects the SONNET audio processor with the implant. It sends both energy and the coded audio 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. The magnet can be changed by your audiologist or clinical staff to adjust the magnet strength to your needs. The magnet strength chosen should be appropriate for the individual patient. Strong magnets are not recommended for patients with thin skin (e.g. young children or very slim patients), as excessive magnetic attraction could potentially increase the likelihood of skin irritation.

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

The SONNET audio processor can be used with the MED-EL DL-Coil or D Coil, it cannot be used with the previous generation COMT+/COMT+ P coils.

DL-Coil

The DL-Coil consists of the base part, the magnet, the coil cable and the coil cover. Your DL-Coil is delivered disassembled. For assembling instructions see chapter 4, SONNET audio processor, DL-Coil, How to assemble your DL-Coil.



Fig. 11 DL-Coil

The DL-Coil switches off after 5 minutes when there is no connection with the implant (e.g. when the processor is not worn). With this feature, the DL-Coil helps save power of the entire audio processor system when the audio processor is not worn and not intentionally switched off.

How to assemble your DL-Coil

Your DL-Coil is delivered disassembled. To assemble your DL-Coil, proceed as follows:

1. Insert a magnet into the base part of the DL-Coil as shown in Fig. 12.1 (mind correct orientation - The labeling on the magnet lip must face upwards).
2. After inserting the magnet, lock it in place by moving the lip to the $\rightarrow$ or $\leftarrow$ symbol indicated on the base part of the DL-Coil until it engages. Use a ballpoint pen to move the magnet in either direction as shown in Fig. 12.2. Moving the lip to the right $\rightarrow$, slightly increases magnetic force. Moving the lip to the left $\leftarrow$, slightly decreases magnetic force. Lock the magnet in place by moving it to the right or left until it engages as indicated by the red circle shown in Fig. 12.3.
3. Connect the coil cable (mind correct orientation! The logo and arrow must face upwards.) as shown in Fig. 12.3.
4. Attach the coil cover as shown in Fig. 12.4.



Fig. 12 How to assemble your DL-Coil

A detailed description of the components of the DL-Coil is provided below.

Components of the DL-Coil

Magnet

A small magnet is located in the center of the coil to hold it in place on the head over the implant. The magnet can be changed by your audiologist or clinical staff to adjust the magnet strength to your needs. The magnet strength chosen should be appropriate for the individual patient, that is strong magnets are not recommended for patients with thin skin flaps (e.g. young children or very slim patients), as excessive magnetic attraction could potentially increase the likelihood of skin irritation.

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

Important

Depending on the type of implant, two variants of magnets (i.e. magnet inserts) are available for the DL-Coil. These two variants differ in magnet polarization. The type of implant is stated on your Patient Identification Card.



For patients implanted with a SYNCHRONY implant, the magnet must contain triangles as shown in Fig. 14. The magnet holder is available in black.



For patients implanted with any other type of implant (MED-EL CONCERT, SONATA, etc.), the magnet insert must contain circles as shown in Fig. 15. The magnet holder is available in cool grey.

It is essential that, based on the type of implant, the correct variant of magnet is used! If the wrong variant of magnet is inserted, the coil may still be held in place over the implant. However, due to different polarization of the magnets, a slight dislocation between the implant and coil will occur which may result in improper communication between implant and coil.

The DL-Coil allows changing the magnet insert in the center of the coil to adjust the magnet strength to your needs. To remove the magnet, turn it to the center position and lift it off (it will fall out when the coil is turned upside down).

To insert a new magnet, center it in the base part with the circles/triangles facing upwards as shown in Fig. 13. It should glide into the recess easily. Lock the magnet in place as described above.

Important

The coil cover can only be attached properly when the magnet is turned towards $\rightarrow$ or $\leftarrow$. Therefore, the magnet shall not be left in the center position.

Strength 5 magnets must be turned towards $\rightarrow$, otherwise the cover cannot be attached properly.

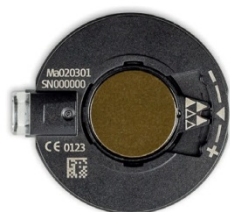


Fig. 13 Removing/inserting the magnet

Five magnet strengths are available. Magnet strength is indicated by the number of filled triangles or circles on the magnet (1=weakest, 5=strongest). The associated covers are available in two heights to accommodate magnet thickness.

In case a higher magnet strength is needed, try the $\rightarrow$ position of the current magnet first. If still too weak, insert the next magnet strength and use the $\leftarrow$ position first.



Fig. 14 Magnet strengths for SYNCHRONY implant



Fig. 15 Magnet strengths for all other types of implants

The serial number and product code (Ma020301) of the coil are indicated on the base part of the DL-Coil.

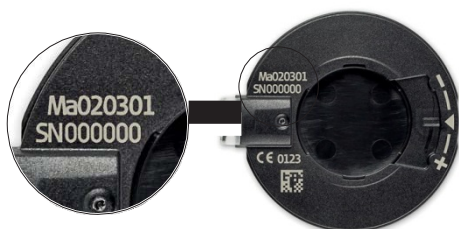


Fig. 16 Serial number and product code of DL-Coil

Important

MED-EL strongly recommends that you do not change the magnet yourself, but have your audiologist or clinical staff do it. If you notice any signs of skin irritation around the coil, contact your clinic or CI center.

Your coil contains a strong magnet. Keep clear of metallic items, as they attract the magnet. Never place the coil or a magnet on the SONNET control unit.

It is even more important to follow this guideline if you are using a SONNETeas. The SONNETeas contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.

- < 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 cover

How to attach the coil cover

Start at the socket (towards the coil cable) when attaching the coil cover as shown in Fig. 17. Snap the cover onto the coil by pressing it down firmly around the circumference.



Fig. 17 Attaching the coil cover

Important

The coil cover can only be attached properly when the magnet is turned towards $\rightarrow$ or $\leftarrow$. Therefore, the magnet shall not be left in the center position.

Strength 5 magnets must be turned towards $\rightarrow$, otherwise the cover cannot be attached properly.

How to remove the coil cover

Hold the socket between thumb and index finger and insert the fingernail in the small recess on the opposite side (see Fig. 18).



Fig. 18 Removing the coil cover

Cable lock

The coil cover is available with and without cable lock. With the coil cover with cable lock attached, the coil cable can only be removed after removing the coil cover.

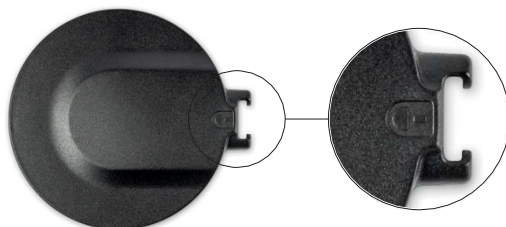


Fig. 19 Coil cover with cable lock

< In young children always use the coil cover with cable lock to prevent the child from disconnecting the coil cable.

Variants

Use the coil cover L (low) for magnets number 1, 2 and 3.

Use the coil cover H (high) for magnets number 4 and 5.



Fig. 20 Coil cover L (left) and coil cover H (right)

Important

When using a number 5 magnet, the magnet must be turned towards the $\rightarrow$ symbol, otherwise the coil cover H cannot be attached.

The coil cover is available in several colors allowing you to personalize your DL-Coil.

D Coil



Fig. 21 Coil (D Coil)

Important

Depending on the type of implant, two variants of magnets (i.e. magnet inserts) are available for the D Coil. These two variants differ in magnet polarization. The type of implant is stated on your Patient Identification Card.



For patients implanted with a SYNCHRONY implant, the magnet insert must contain triangles as shown in Fig. 22.



For patients implanted with any other type of implant (MED-EL CONCERT, SONATA, etc.), the magnet insert must contain circles as shown in Fig. 24.

It is essential that, based on the type of implant, the correct variant of magnet is used! If the wrong variant of magnet is inserted, the coil may still be held in place over the implant. However, due to different polarization of the magnets, a slight dislocation between the implant and coil will occur which may result in improper communication between implant and coil.

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

To attach a new magnet insert, place it over the recess in the coil, as shown in Fig. 22. 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. 22 Removing/inserting the magnet

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

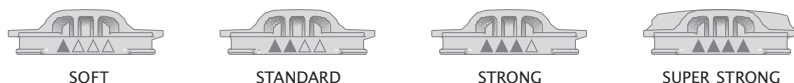


Fig. 23 Magnet strengths for SYNCHRONY implant



Fig. 24 Magnet strengths for all other types of implants

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



Fig. 25 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. If you notice any signs of skin irritation around the coil, contact your clinic or CI center.

Your coil contains a strong magnet. Keep clear of metallic items, as they attract the magnet. Never place the coil or a magnet on the SONNET control unit.

- < 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 control unit are connected by the coil cable. The coil cable must be disconnected 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 coil cable is designed for maximum durability and flexibility, this part of the MED-EL Cochlear Implant System is the most likely to wear out.

If the coil cable fails, order a new one immediately.

Important

Do not use the cable with devices other than the SONNET audio processor.

To replace the coil cable of the DL-Coil proceed as follows:

1. When using a coil cover with cable lock, remove the coil cover before disconnecting the cable (see Fig. 18).
2. Grab the plug of the cable on the coil side and gently pull the plug out of its socket in the DL-Coil.
3. Plug a new coil cable into the DL-Coil. Make sure that the cable plug is correctly positioned. The logo and the arrow on the coil cable must face upwards (see Fig. 26).
4. Attach the coil cover starting at the side of the socket (see Fig. 17).

< In young children always use the coil cover with cable lock to prevent the child from disconnecting the coil cable.

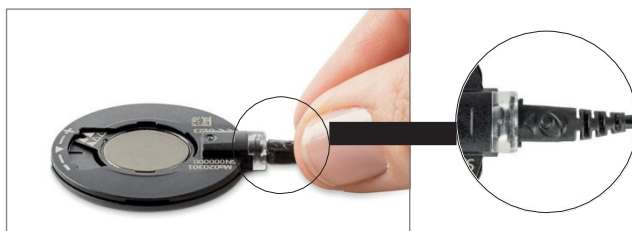


Fig. 26 Plugging the coil cable into the DL-Coil

To replace the coil cable of the D Coil proceed as follows:

1. Make sure that the battery pack cover lock is in the unlocked position as shown in Fig. 8. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
2. Pull back the battery pack cover until you can see the whole labelling of the control unit (see Fig. 4).
3. Grab the plug of the cable on the control unit side and gently pull the plug (Fig. 27.1) out of its socket in the control unit.
4. Grab the plug of the cable on the D Coil side and gently pull the plug (Fig. 27.2) out of its socket in the D Coil.
5. Plug a new coil cable into the D Coil.
6. Plug the other end of the coil cable into the control unit, as shown in Fig. 28. Make sure that the cable plug is correctly positioned. The slanting edge must face down.
7. Make sure that the battery pack cover lock is in the unlocked position, as shown in Fig. 8. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
8. Slide the battery pack cover completely over the battery pack frame to switch on the SONNET (see Fig. 5). Mind the correct orientation of the battery pack cover when sliding it over the frame, and do not use excessive force. The orientation is correct when the air inlets on the battery pack cover are on the same side as the coil cable socket in the control unit.

< In young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 9), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.

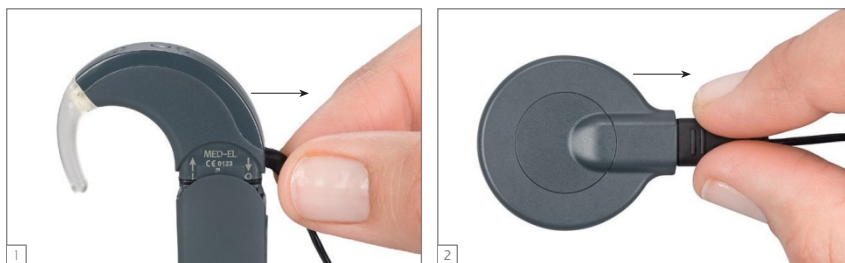


Fig. 27 Disconnecting the coil cable

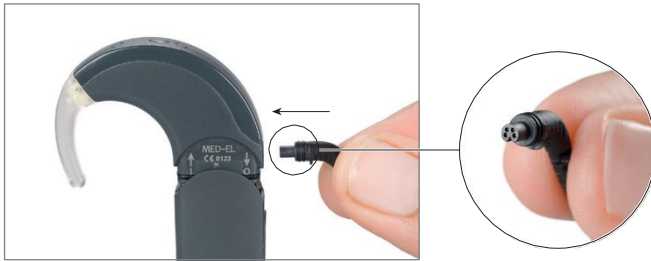


Fig. 28 Plugging the coil cable into control unit

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.
-

Earhook

Depending on the variant of your SONNET audio processor, i.e. SONNETci or SONNETeas, your SONNET is shipped with a different type of earhook. While the earhook for the SONNETci (see Fig. 29) is only intended to keep the audio processor behind the ear, the earhook for the SONNETeas (see Fig. 30) additionally contains a sound tube in its center and a specially shaped tip that allows easy attachment of an acoustically functional ear mold by an audiologist. Combined electric-acoustic stimulation always requires using an ear mold.



Fig. 29 Earhook for SONNETci



Fig. 30 Earhook for SONNETeas

Important

It is the audiologist's responsibility to customize the ear mold according to standard hearing aid practice. The ear mold shall fulfil local hearing aid requirements, especially with regard to biocompatibility. In the EAS clinical trial, a few users reported soreness or pain from the use of the mold, which is a common issue associated with hearing aid molds. Therefore it is especially important that the audiologist ensure that the ear mold optimally fits the anatomical shape of the ear canal and the earhook of the SONNET audio processor.

The audiologist is also responsible to inform the patient or parents/caregiver about cleaning the ear mold to ensure optimal performance and avoid bacterial infections. In cases of otitis media (especially with effusion) it is recommended to use the SONNET without an ear mold, i.e. only use electrical stimulation to leave the outer ear canal open.

Your SONNET audio processor is shipped with a pin securing the earhook to the control unit.

To replace the earhook, proceed as follows:

1. Remove the earhook pin by pushing it through the holes (see Fig. 31) using the tool supplied with your SONNET kit; then grab it, and pull it out completely.
2. To remove the earhook, gently push it downwards (Fig. 32.1-2), separating it from the control unit.
3. Attach the new earhook over the lip in the lower part of the control unit (Fig. 32.3), and push it gently upwards (Fig. 32.4) until it snaps into place. Make sure that the new earhook is of the same type (i.e. CI earhook or EAS earhook) as the replaced one.
4. Re-insert the earhook pin.



Fig. 31 How to remove the earhook pin

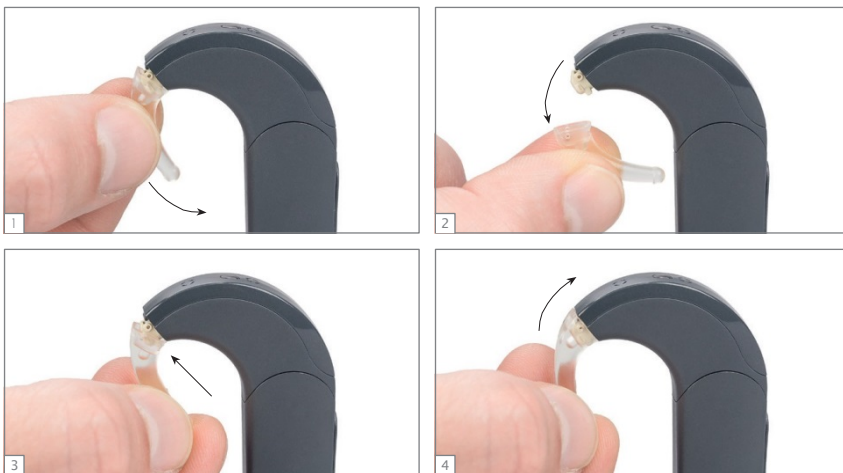


Fig. 32 Removing and attaching the earhook

- < Be sure to always insert the earhook pin when attaching the earhook. This will prevent the child from removing the earhook. Keep the supplied pin removal tool out of the reach of children.

Important

Replacing the CI earhook in a SONNETci audio processor with an EAS earhook does not convert the audio processor into the SONNETeas variant.

Using a CI earhook with a SONNETeas audio processor will block any acoustic stimulation, i.e. never use a CI earhook with a SONNETeas audio processor.

MED-EL also provides the earhook in a slightly longer version. If you and your audiologist or clinical staff decide that the longer version is needed, please order such an earhook from MED-EL. Two marks on the inside of the earhook help identify the longer version (see Fig. 33).



Fig. 33 Markings of longer earhook version

Microphone cover

The microphone cover protects the two microphones in the SONNET from moisture and dust. It is recommended to replace it every three months, when the microphone openings appear dirty or when you experience degraded sound quality.

The microphone cover should either be dried or replaced when the microphone openings have become wet as such wet openings may degrade sound quality.

To replace the microphone cover, proceed as follows:

1. Remove the earhook, as described in the previous section.
2. Snap off (Fig. 34.1) the microphone cover from the control unit.
3. Insert the two lips of the new microphone cover into the two recesses of the control unit (Fig. 34.2) and push the cover gently onto the control unit (Fig. 34.3) until it snaps completely into place.
4. Re-attach the earhook and insert the earhook pin, as described in the previous section.



Fig. 34 Removing and attaching the microphone cover

- < Be sure to always insert the earhook pin when attaching the earhook. This will prevent the child from removing the earhook. Keep the supplied pin removal tool out of the reach of children.

The microphone cover is available in several colors allowing you to personalize your SONNET.

Connecting assistive listening devices

A special battery pack cover (product code Ma070103) is provided to allow connection of assistive listening devices (e.g. FM systems) or other external audio devices such as portable CD players, MP3 players, AM-FM radios, etc. to your SONNET audio processor. This FM Battery Pack Cover is slightly longer than the standard cover to accommodate the integrated EA (Euro Audio) socket.

To replace the standard cover with the FM Battery Pack Cover, proceed as follows:

1. Make sure that the (standard) battery pack cover lock is in the unlocked position, as shown in Fig. 8. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
2. Pull back and completely remove the standard battery pack cover.
3. Make sure that the lock of the FM Battery Pack Cover is in the unlocked position, as shown in Fig. 8. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
4. Slide the FM Battery Pack Cover completely over the battery pack frame to switch on the SONNET (see Fig. 5). Mind the correct orientation of the FM Battery Pack Cover when sliding it over the frame and do not use excessive force. The orientation is correct when the air inlets on the FM Battery Pack Cover are on the same side as the coil cable socket in the control unit.

< In young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 9), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.

Proceed as described above to replace the FM Battery Pack Cover with the standard cover.

An external audio device can be connected to the SONNET via an adapter cable. To do so, first insert the three-pin plug of the adapter cable (grey end) into 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). Then insert the yellow or red plug of the cable into the audio output (headphone socket) of the audio device.

Direct-link FM systems may be connected to the FM Battery Pack Cover without an adapter cable.

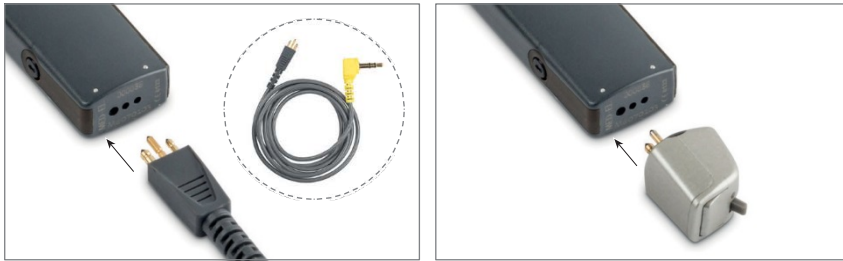


Fig. 35 Connecting the adapter cable and direct-link FM systems

Important

The provided cable is intended for the connection of external audio devices, such as portable CD players, MP3 players, AM-FM radios, etc. To connect body-worn 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 SONNET microphone remains active. This allows you to hear input 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 SONNET microphone is deactivated. You will hear input from the external device only.

Ext cables are indicated by a red 3.5 mm plug.

Special considerations for young children

The SONNET audio processor has several features that are designed especially for young children. They are:

- Lockable earhook: The earhook is secured to the control unit with a small pin.
 - Battery pack cover lock: To prevent small children from disassembling the audio processor and getting access to the batteries.
 - 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.
 - The DL-Coil features a coil cover with cable lock to secure the cable to the coil. When using the coil cover with cable lock, the cable cannot be detached from the coil unless the coil cover is removed. The cable lock prevents inadvertent disconnection of the coil cable from the coil.
- < Only parents/adults are allowed to disassemble the device to change defective parts. Parents/adults should check the device at least once a week for damage or missing parts.

Important

If the user of the SONNET is a child who also uses an ear mold, parents/caregivers should regularly check to make sure the ear mold still fits as the ear grows. The ear mold must be adjusted regularly, as necessary.

A non-optimally fitting ear mold may cause acoustic feedback (whistling).

General precautions and warnings

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

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 MED-EL 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 impact success with the cochlear implant, as do other factors, including some which may be unknown.

Do not use the MED-EL 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 8, 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 MED-EL Cochlear Implant System

The audio processor and other parts of the system contain sophisticated electronic components which require special precautions regarding electromagnetic compatibility (EMC). When activating your audio processor always follow the guidelines outlined in this section and chapter 9, Technical data, Guidance and manufacturer's declaration.

The electronics are durable but must be treated with care.

- Never open the housing of your audio processor. Unauthorized opening invalidates the warranty. To change the batteries or clean the battery contacts, perform the steps described in chapter 7, Care and maintenance.
- Before switching on the audio processor, check the external parts of the MED-EL Cochlear Implant System for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the audio processor should not be switched on. Read chapter 8, 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 MED-EL 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 rub, stretch or 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 audio processor (including FineTuner and coil) does not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range is between +0°C and +50°C (32°F and 122°F) for the audio processor (including FineTuner and coil). Normally, when the 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). Long exposure to direct sunlight might damage the audio processor or FineTuner.
- If you ever experience loud or uncomfortable sounds, please remove your coil and audio processor immediately: this will stop stimulation at once.
- Blowing your nose too hard might lead to (temporary) fluctuations in loudness. This is caused by air entrapped over the reference electrode of the implant.
- 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 put the audio processor in the supplied drying kit to allow the audio processor to dry out (preferably overnight). If in doubt, repeat the drying process. If the FineTuner becomes wet, wipe it off with a dry tissue.
- Take care of the external components of your/your child's MED-EL Cochlear Implant System. They should not be dropped or subjected to dangerous areas (e.g. machines or high voltage), which could result in damage to the components.
- Do not use the audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.

- Do not try to shape the earhook with hot air.
 - Do not use your audio processor in the vicinity of strong ionizing radiation (e.g. x-ray machines) or electromagnetic fields (e.g. MRI machines).
 - Do not modify the housing, the electronics or any other parts of your audio processor in any way.
 - Never place the coil or a magnet on the control unit. It is even more important to follow this guideline when you are using a SONNETeas. The SONNETeas contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.
- < Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury. For young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 8), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.

Technology in everyday life

Metal detectors, anti-theft systems and other radio frequency (RF) transmitters

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 field emitted by these systems. To avoid the buzzing sound, switch your audio processor off when walking through metal detectors and anti-theft systems or when you are close to RF transmitters. 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.

If an audio processor map becomes corrupted, it can easily be reprogrammed at the CI center. If your audio processor has more than one program, you can usually use one of the others in the meantime.

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 SONNET audio processor. 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 TV reception

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

Cell phones

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

TV, radio, FM systems, etc.

When intending to connect an external audio device to the audio processor that is powered by mains power, i.e. connected to an electrical outlet of any kind, including a power strip, always make sure first that this mains-powered external audio device meets the safety requirements stated in the standards EN/IEC 60065, EN/IEC 60601-1 and/or appropriate national standards. If the mains-powered device does not bear a CE mark (<), which is usually found on the device's type label, you cannot presume that the mains-powered device meets the above safety requirements and must therefore not be connected to your audio processor. Connecting a mains-powered device to your audio processor that does not meet the above safety requirements could cause an electric shock. You can safely connect battery-operated external audio devices to your 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 MED-EL 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 these 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 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 and 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 audio processor on last, and remove it first when undressing.
- Always remove the 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 audio processor.
- Always remove the 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, even if the processor is removed, 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 ESD as the cause, switch off the audio processor, wait for a few minutes and switch it on again. If it does not come on again, contact your CI center.

RFID (radio frequency identification)

RFID (radio frequency identification) is a technology that incorporates the use of electromagnetic or electrostatic coupling in the radio frequency (RF) portion of the electromagnetic spectrum and can be used to uniquely identify an object, animal, or person as an alternative to a bar code. Sometimes RFID emitters may cause interference with your device perceived as a buzzing sound. In such cases, this interference will cease when you move away from the RFID emitter. RFID emitters are becoming more prevalent and you may come in contact with these in everyday life: in shops where they are used for inventory, around animals where they are used for animal tracking, at highway tolls where they are used for payments, etc.

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 audio processor securely 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 of high quality. It 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 masks 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 the 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 50m (165 ft.).

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

Precautions for medical procedures

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to the Medical Procedures Manual.

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](https://www.cdc.gov) website.

Care and maintenance

Maintenance

Your SONNET audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time. Although the coil cable is designed for maximum durability and flexibility, this part of the MED-EL Cochlear Implant System is the most likely to wear out. 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.

Protect your SONNET audio processor from water (see also chapter 6, General precautions and warnings).

Do not try to repair electronic parts of your SONNET audio processor and do not try to open the control unit or any other part of your audio processor, as this invalidates the manufacturer warranty.

It is recommended to replace the microphone cover every three months, when the microphone openings appear dirty, or when you experience degraded sound quality (see also chapter 4, SONNET audio processor, Microphone cover).

In case an ear mold is used and you have to remove cerumen (ear wax) from the ear mold, do so only according to the advice of your audiologist. If necessary, your audiologist will clean the ear mold.

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.

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.

Weekly maintenance of your audio processor

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

Drying your 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.

The audio processor need not be completely disassembled. The batteries may remain in the battery pack frame but the battery pack cover should be removed from your audio processor.

We recommend that you dry your 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!

Batteries

The SONNET audio processor requires two 675 zinc air batteries. These batteries supply the external and internal components of the MED-EL Cochlear Implant System with energy. When following the recommendations below, the minimum battery life time for the SONNET audio processor is 18 hours. If you want to get more information on batteries, please contact your local MED-EL representative or CI center.

The battery pack cover has air inlets on its outer side. Do not cover these inlets as this may shorten battery life. If the inlets become blocked, carefully clean them with the enclosed cleaning brush. If the inlets cannot be cleaned, replace the entire battery pack cover with a new one.

NOTE:

It is recommended to only use high power zinc air batteries to power the SONNET.

Important

- Wash your hands after handling disposable batteries.
 - Do not try to recharge disposable batteries.
 - Do not disassemble, deform, immerse in water or incinerate batteries.
 - Avoid mix-up of old and new batteries or batteries of different types of brands.
 - Do not short-circuit batteries, e.g. by allowing the terminals of batteries to touch, carrying batteries loose in your pockets, wallet or purse or touching the battery terminals with metals (coins, wires, keys, etc.).
 - Store unused batteries in their original packaging, in a cool and dry place.
 - Do not expose batteries to heat (e.g. never leave batteries in direct sunlight, behind a window or in a car).
 - Do not use damaged, deformed batteries or leaking batteries. If any kind of substance leaks out of a battery, avoid direct skin contact with that substance. Such a substance could cause a chemical burn. In case of eye contact, rinse with copious amounts of water and seek medical attention immediately.
 - If you are not going to use your audio processor for an extended period of time, you should remove the batteries and dispose of or store them separately.
 - Always remove used batteries immediately to avoid leaking and possibly damaging the device.
 - Dispose of used batteries according to local regulations. If you ignore these regulations, you will contribute to pollution of the environment. 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 shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury. For young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 8), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.
- < Do not allow children to replace batteries without adult supervision.

Changing the batteries of your SONNET audio processor

When the indicator light on the control unit blinks red continuously ( —  — ...), the battery set must be replaced (see also chapter 8, Troubleshooting).

To change the batteries, proceed as follows:

1. Remove the SONNET and the coil from your head.
2. Make sure that the battery pack cover lock is in the unlocked position, as shown in Fig. 7. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
3. Pull back and completely remove the battery pack cover.
4. Replace the used battery set by removing the two batteries with the coil magnet. To do so, move the center of the bottom part of the coil over each battery separately. Try not to touch the battery contacts (see Fig. 35.2).

Important

Be careful not to place the coil on the SONNET control unit.

5. Before inserting the new battery set, make sure that the battery contacts are clean and dry. Remove the foil stickers covering the zinc air batteries before use. Check for correct polarity when inserting the new batteries. The positive pole $+$ must face outward, i.e. the $+$ sign is still visible after the batteries have been inserted.
6. Make sure that the battery pack cover lock is in the unlocked position as shown in Fig. 7. When it is not in the unlocked position, use the screwdriver provided with your SONNET kit to turn it counter-clockwise into the unlocked position.
7. Slide the battery pack cover completely over the battery pack frame to switch on the SONNET (see Fig. 4). Mind the correct orientation of the battery pack cover

when sliding it over the frame and do not use excessive force. The orientation is correct when the air inlets on the battery pack cover are on the same side as the coil cable socket in the control unit.



In young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 8), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.



Fig. 35 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 4, SONNET 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 $\rightarrow$ 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. 36 Changing the battery of your FineTuner

Troubleshooting

Once you are familiar with your MED-EL 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 supplied by MED-EL may damage your MED-EL 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 from the implant site before operating the switch if this sound bothers you.

Important

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

Speech Processor Test Device

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

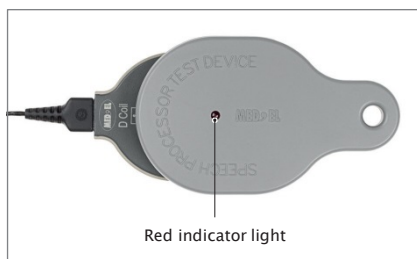


Fig. 37 Speech Processor Test Device

The Speech Processor Test Device is a simple, optional troubleshooting tool for MED-EL audio processors and is intended for use 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 simply intended to help detect most common 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 audio processor and make sure that it is supplied with functioning batteries. Place the coil underneath the Speech Processor Test Device (see Fig. 37). 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 up or stays on constantly, try the following:

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

We recommend you try these steps, even if you are not using 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 void any warranty.

The Speech Processor Test Device should be handled with care to achieve maximum lifetime and to ensure proper function. Do not expose your Speech Processor Test Device to conditions other than those suitable for your audio processor (see also chapter 6, General precautions and warnings).

FineTuner

The FineTuner transmits commands to the audio processor via a radio frequency (RF) link. If the audio processor does not respond to FineTuner commands, the following may be potential reasons and solutions for this:

- The audio processor is out of the FineTuner's operational range. To overcome this, you should move the FineTuner closer to the audio processor.
- The FineTuner keyboard lock is active. In this case, follow the instructions for the unlocking function as described in chapter 4, SONNET 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 audio processor and/or go to a different location.
- The audio processor and the FineTuner are not synchronized. In this case, you need to refer to the section described in chapter 4, SONNET 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 7, 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 7, Care and maintenance, Batteries, Changing the battery of your FineTuner.
- The desired command in the audio processor 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 indicator light in the audio processor has been disabled by your audiologist during fitting. To enable the 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 < (telecoil) or < (microphone and telecoil) settings and are unable to return to the < (microphone) signal source input with the FineTuner, you need to switch the audio processor off and on again. When the audio processor is switched on again, it will automatically start with the < (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.

SONNET indicator light

The multi-color indicator light on top of the audio processor flashes with different patterns and colors 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 (except error patterns) if you prefer this.

Blinking pattern	Meaning	Required action	Remarks
Error patterns			
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be replaced.
	Selected position is not programmed, or there has been a programming failure	Select another position.	If the blinking persists, the processor should be reprogrammed by the clinic.
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the processor should be reprogrammed by the clinic; if the blinking still persists, the audio processor must be replaced.
	Electronic problem or programming failure	Switch processor off. Switch processor back on.	If the blinking persists, the processor must be reprogrammed.
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	
Warning patterns			
	Batteries empty	Switch processor off. Change the batteries. Switch processor back on.	If the processor is not switched off, the indicator light will continue to blink.
	Maximum or minimum value of volume or audio sensitivity range reached	Stop pushing button(s) on FineTuner.	

Blinking pattern	Meaning	Required action	Remarks
Confirmation pattern			
 Brief flash of 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			
	Program 1 to 4 selected	None	The indicator light will blink depending on the selected program position.
Status pattern			
	The processor is initialized and working	None	

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 you should change the batteries of the 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 audio processor, a confirmation beep is audible for the user of the audio processor.

These 3 signals may be deactivated by your audiologist if you prefer this.

DL-Coil indicator light (Link Monitoring)

The multi-color indicator light in the cable socket of the DL-Coil flashes with different patterns and colors to indicate different conditions. If the indicator light begins flashing, use the following tables to determine the possible cause. Your audiologist can deactivate the indicator light or the automatic power off function if you prefer this.

Blinking pattern	Meaning	Required action	Remarks
Green			
	When turning on a processor programmed for a previous generation implant (e.g. C40+, C40): Indicates functionality of coil, coil cable and audio processor	None	Applicable only to previous generation implants without I ¹⁰⁰ serial numbers
	When turning on a processor programmed for a new generation implant: Correct implant detected. Indicates functionality of coil, coil cable, audio processor and implant.	None	Applicable only to implants with a I ¹⁰⁰ serial number saved to the audio processor memory bank
Red			
 for max. 5 min.	Coil and implant are disconnected	Position the coil over the implant site	If the blinking persists, contact your clinic, audiologist or MED-EL
	Coil positioned over wrong implant (bilaterally implanted users)	Position the coil over the correct implant	
	Broken coil cable The coil will automatically power off after 5 minutes (no stimulation). Your audiologist can deactivate the automatic power off function.	Replace the coil cable. If the coil has powered off, reposition the coil over the implant site, switch the processor off and on again to resume stimulation (the processor does not switch off automatically).	

Troubleshooting

Blinking pattern	Meaning	Required action	Remarks
	Coil has powered off	Reposition the coil over the implant, switch the processor off and on again to resume stimulation (the processor does not switch off automatically)	If the blinking persists, contact your clinic, audiologist or MED-EL
No signal or arbitrary red and green blinking pattern			
 No light signal when switching processor on	Processor not functional (e.g. batteries empty, cable defective, coil defective)	Check battery status	If the situation persists, contact your CI center or MED-EL.
		Try spare coil cable	
		Contact your CI center if you suspect a coil malfunction	
	Indicator light deactivated by Audiologist	None	None
	Fitting: During fitting indicator light is deactivated	After fitting, switch the processor off and on to re-activate the indicator light	
 Arbitrary red and green pattern	Defective coil cable	Try spare coil cable	If the blinking persists, contact your CI center or MED-EL.

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 mode of the FineTuner) blink synchronously to the transmitted signals. To save energy, the FineTuner stops transmitting (and the indicator light stops blinking) after 3 seconds, even if the key is still pressed.

Switch to side

If the FineTuner is programmed for two different audio processors (for 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 4, SONNET 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 $\leftrightarrow$ is pressed for more than 5 seconds (must be unlocked; see chapter 4, SONNET 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.

Technical data

Audio processor

Dimensions of SONNET audio processor³



Weight³

SONNETci: 10.6 g (0.374 oz.) (including batteries)

SONNETeas: 11.3 g (0.399 oz.) (including batteries)

Power supply

2 hearing aid batteries type 675 zinc air (1.4V), high power batteries recommended

Hardware

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

³ typical values

Additional features in SONNETas variant

- Acoustic stimulation up to 2000 Hz
- Fully digital hearing aid signal processing
- Independent compressors in up to 7 frequency bands

Audio input

- Via FM Battery Pack Cover
- Hearing aid type three pin connection (Euro Audio) acc. to IEC 60118-12
- Sensitivity: -57.5 dBV³ (corresponds to 70 dB SPL at 1 kHz)
- Impedance: 4.5 kΩ³

Controls/Indicators

- ON/OFF switch
- Indicator light: 1 multi-color LED

Materials

- Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS): audio processor, all colors
- Polyamide (PA): earhook

Temperature and humidity range

Operating temperature range: 0°C to 50°C (32°F to 122°F)

Storage temperature range: -20°C to 60°C (-4 °F to 140°F)

Relative humidity range: 10% to 93%

Atmospheric pressure range: 700 mbar (hPa) to 1060 mbar (hPa)

Essential performance

None of the performance characteristics of the SONNET (incl. all accessories) are essential performance, as defined in IEC 60601-1.

Expected service life

The expected service life of the SONNET (incl. all accessories) as defined in IEC 60601-1 is 5 years.

Radio frequency (RF) link (FineTuner)

Frequency band of reception: 9.07 kHz (±3%)

³ typical values

Radio frequency link (wireless network)⁴

Frequency band of reception / transmission: 2400 MHz – 2483.5 MHz

Short Range Device (SRD) according to ERC/REC 70-03 Annex 1 (band I)

Receiver category 3

Type of modulation: Gaussian frequency shift keying (GFSK)

Maximum effective radiated power (ERP): 106 µW (–9.75 dBm)

⁴ The 2.4GHz wireless technology is dormant and should not be used for this device

Coils

DL-Coil

Dimensions in mm (in.)³

Diameter: 32.8 (1.29)

Height: 5.8 (0.23)

(with number 2 magnet and coil cover L)

Weight³

4.6 g (0.16 oz.)

(with number 2 magnet and coil cover L)

Indicators

Indicator light: 1 multi-color LED

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS):
base part and coil cover, all colors

D Coil

Dimensions in mm (in.)³

Diameter: 31.6 (1.24)

Height: 6.0 (0.24)

Weight³

4.4 g (0.15 oz.)

(with number 2 magnet)

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS):
base part and magnet insert, all colors

Coil cable

Dimensions in mm (in.)³

65 (2.56), 90 (3.54) and 280 (11.02)

Materials

PVC and TPE Evoprene, all colors

Coil cable

Dimensions in mm (in.)³

85 (3.35), 110 (4.33) and 280 (11.02)

Materials

PVC and TPE Evoprene, all colors

³ typical values

FineTuner

Dimensions³

Length: 85.5 mm (3.366 in.)

Width: 54.0 mm (2.126 in.)

Height: 6.3 mm (0.248 in.)

Weight: 33.0 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, 2 amber LEDs

Power supply

- 1 lithium/manganese dioxide battery type CR2025 (3V)
- Battery life expectancy is typically more than 6 months

Classification

- Short Range Device (SRD) according to ERC/REC 70-03 Annex 9 (band A1) and Annex 12 (band A)
- Equipment class 3
- 47 CFR Part 15 Low Power Transmitter below 1705 kHz-US

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS)

Temperature and humidity range

Operating temperature range: 0 °C to 50 °C (32 °F to 122 °F)

Storage temperature range: -20 °C to 60 °C (-4 °F to 140 °F)

Relative humidity range: 10% to 93%

Atmospheric pressure range: 700 mbar (hPa) to 1060 mbar (hPa)

³ typical values

Radio frequency (RF) link

Carrier frequency: 9.07 kHz ($\pm 0.7\%$)

Type of modulation: phase shift keying (PSK)

Maximum RF output power: 11.7 dB μ A/m @ 10 m

Maximum operating distance: ~1.15 m (3.77 ft.)

Regulatory statements

Applicable in Canada only:

Model: SONNET (Me1310), SONNET EAS (Me1320) – IC: 11986A-ME1300

Model: FineTuner – Canada 310

The above devices comply with Industry Canada licence-exempt RSS standard(s). 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.

Les appareils mentionnés ci-dessus sont conformes aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Applicable in the USA only:

Model: SONNET (Me1310), SONNET EAS (Me1320) – FCC ID: VNP-ME1300

Model: FineTuner – FCC ID: VNP-FT

The above devices comply 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

 The SONNET audio processor and the FineTuner are in compliance with directive 90/385/EEC (Active Implantable Medical Devices/AIMD).

0 1 2 3

CE mark applied in 2014

Hereby, MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type SONNET (audio processor) and FineTuner (remote control) is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.medel.com/compliance



MR unsafe



Caution, consult the instructions for use (manual) for important cautionary information



Type BF
(IEC 60601-1)



Non-ionizing radiation



Fragile; handle with care



Relative humidity



Temperature limit

IP54

IP54

Moisture and dust protection acc. to IEC 60529

This classification means that your audio processor is protected against failure from ingress of dust and splashing water when fully assembled and in the ON position, i.e. when

- the microphone cover and the earhook are snapped onto the control unit,
- an ear mold is connected to the earhook (only relevant for SONNETeas variant),
- the coil cable and coil is connected to the control unit,
- the battery pack frame is connected to the control unit,
- the standard battery pack cover is completely moved over the battery pack frame (ON position).

Disposal

We advise to dispose of all external components of your MED-EL 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.

Speech Processor Test Device



The Speech Processor Test Device is in compliance with directive 2014/30/EU (Electromagnetic Compatibility/EMC) and directive 2011/65/EU (Restriction of Hazardous Substances in Electrical and Electronic Equipment/RoHS).

CE mark applied in 2005

Guidance and manufacturer's declaration

Tables according to IEC 60601-1-2 for SONNET

Electromagnetic emissions – for all equipment and systems

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SONNET 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 SONNET 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 SONNET is intended for use in the electromagnetic environment specified below. The customer or the user of the SONNET 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	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines		
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth		
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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SONNET requires continued operation during power mains interruptions, it is recommended that the SONNET be powered from an uninterrupt-ed power supply or a battery.
	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		
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 SONNET is intended for use in the electromagnetic environment specified below. The customer or the user of the SONNET should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SONNET, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 \cdot \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \cdot \sqrt{P}$ 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 metres (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 SONNET is used exceeds the applicable RF compliance level above, the SONNET should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SONNET.

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 SONNET – for equipment and systems that are not life-supporting

The SONNET is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SONNET 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 SONNET 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		
	150kHz to 80 MHz $d = 1.17 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \cdot \sqrt{P}$	800 MHz to 2.5GHz $d = 2.33 \cdot \sqrt{P}$
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.

Examples for wireless (RF) communications equipment:

Equipment	Recommended separation distance in m
wireless home network device (e.g. WiFi router)	0.74
cordless telephone/base station	1.65
walkie-talkie	2.33
mobile phone	3.30

Appendices

Warranty statement

MED-EL's warranty is in agreement with mandatory local statutory warranty provisions.

Any extension of the statutory warranty is subject to agreement between MED-EL and the purchaser. Therefore these extensions may be different in various countries. Please contact your local MED-EL representative for information on your individual warranty rights.

Extension of statutory warranties shall not be granted unless the product is properly registered. You can register a product either by completing the provided registration card and sending it to MED-EL or by using MED-EL's online registration website (upon availability). Ask your local MED-EL representative for help if you need assistance in the registration process.

Extensions of statutory warranties exclusively cover product failures. This does 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.

How MED-EL's Electric-Acoustic Stimulation (EAS) System was studied

A clinical trial was performed in the United States in order to test whether the MED-EL Electric-Acoustic Stimulation (EAS) system was safe and effective for use.

The MED-EL EAS System is for people with hearing loss, who have too much hearing to get a cochlear implant. A cochlear implant is for people with significant hearing loss, who do not hear well enough with a hearing aid. Cochlear implants work by sending tiny electrical pulses to the inner ear. Cochlear implants are made up of two parts: the implant (which requires surgery), and an audio processor that is worn behind the ear. EAS is for people with good low pitched hearing but very poor high pitched hearing. EAS recipients listen with a cochlear implant and amplified sound in the same ear, using a special combined CI audio processor and acoustic unit. The acoustic unit is built into the cochlear implant audio processor.

With EAS, people hear high pitched sounds through the cochlear implant, and they hear low pitched sounds through the acoustic unit at the same time. There is only one device to wear on the ear, because the acoustic unit is built into the cochlear implant audio processor. "EAS" stands for Electric-Acoustic Stimulation and means the person hears through using a combination of a cochlear implant (electric) and acoustic unit (acoustic) in the same ear. If the individual has few changes in their low pitched hearing after cochlear implant surgery, EAS can offer improved speech understanding and sound quality by taking advantage of the recipient's remaining hearing along with the cochlear implant.

People who participated in the clinical trial were able to hear low pitched sounds in the normal to moderate hearing loss range before surgery, but had severe-to-profound sensorineural hearing loss (also called "nerve hearing loss" or "nerve deafness") for high pitched sounds in both ears. Before surgery, they wore a hearing aid for testing. The tests checked how well they could understand speech in both quiet and noisy environments. Hearing was also tested both with and without the hearing aid. After surgery, they came back to repeat these tests. They were tested in two ways. First, they were tested using both the cochlear implant audio processor and its built-in acoustic unit in the same ear ("EAS condition"). Also they were tested using only the cochlear implant ("Electric Alone" condition). One person was tested with the cochlear implant in one ear and a hearing aid on the other ear, which is included in the results below as the "EAS condition." Hearing tests were completed at each follow-up visit to check for any changes in their hearing.

Although people were tested in the Electric Alone condition after receiving their implants, they did not listen to that program in daily life, with one exception explained below. In their everyday lives, they listened with the EAS condition.

The following is a summary of the clinical trial. This was a research study to test whether EAS is a safe and effective treatment for a group of people who had high frequency hearing loss. “Subjects” are the people who received EAS cochlear implants. “Residual hearing” refers to hearing levels measured after surgery.

Clinical trial subjects

Subjects could participate in the study if they met the following standards:

- Adults 18–70 years of age.
- Normal to moderate sensorineural hearing loss in the low frequencies and severe to profound sensorineural hearing loss in the high frequencies.
- Speech understanding scores in quiet of less than or equal to 60%.
- Use of hearing aids for at least 3 months prior to beginning the study.
- English was the subject’s primary language.

Description of Tests

Word understanding in quiet was tested using the CNC (Consonant-Nucleus-Consonant) Word Recognition test. This is a test made up of 10 lists of 50 words, each with one syllable. Subjects were asked to repeat the word they heard. One list was given in each of the test conditions, at a volume of 70 dB SPL. The scores below are reported as a percent correct of the words on the list.

Understanding of sentences in noise was tested using the CUNY (City University of New York) Sentence Test. The CUNY Sentence Test consists of 72 lists of 12 sentences each. Four sentence lists were presented in each condition at a volume of 70 dB SPL with competing noise in the background. Subjects were asked to repeat the sentence they heard. The scores are reported as a percent correct of the words in each sentence list.

Subjects were also asked to fill out two questionnaires about their everyday experiences. Self-reported benefit and satisfaction was measured using the APHAB (Abbreviated Profile of Hearing Aid Benefit) and HDSS (Hearing Device Satisfaction Scale). The APHAB is specifically used to measure benefit, while the HDSS measures satisfaction. When filling out these questionnaires, subjects were asked how they hear sounds in their daily life, which could include the other ear. The other ear did not receive an implant.

Clinical trial results

Seventy-three subjects were implanted at 14 cochlear implant centers as part of this clinical trial. Of the 73 total subjects implanted, 67 completed follow-up. Results are reported below for these subjects.

The chart below describes the gender, age at surgery, length of hearing loss, and length of hearing aid use of the group.

Parameter/Category or Statistic	Total (n=73)
Gender	
Male	42.5% (31/73)
Female	57.5% (42/73)
Age (years)	53.7
Length of noticeable hearing loss (years)	
Left	25.7
Right	25.7
Length of hearing aid use (years)	
Left	17.4
Right	17.4

*Numbers are % (Count/Sample Size) or Mean

All subjects were tested in the EAS condition, except for one subject who lost low frequency hearing immediately after surgery. This subject was followed in the cochlear implant alone condition. All other subjects removed their hearing aid for testing, if they used one on the other side. Results are presented for 66 subjects in the EAS condition and 67 subjects in the cochlear implant alone condition.

Speech Understanding with EAS

Subjects understood sentences in noise better when using EAS compared to their own hearing aid before surgery.

- The average pre-operative score on CUNY sentences was 31% ($\pm 27\%$), while at 12 months post-operatively the average score was 73% ($\pm 24\%$) with EAS.
- The average improvement on CUNY sentences in noise was 42%.
- 92% (61/66) of subjects performed similar or better at 12 months with EAS compared to pre-operatively with a hearing aid.

Subjects understood sentences in noise better when using EAS compared to using the cochlear implant alone.

- The average CUNY sentence in noise score with the cochlear implant alone was 56% ($\pm 30\%$), while the average score with EAS was 73% ($\pm 24\%$).
- The average improvement on CUNY sentences in noise when using EAS instead of electric stimulation only was 17%.

Speech Performance with Electric Stimulation Only

After 12 months, subjects understood words better with the cochlear implant alone compared to their own hearing aid before surgery.

- On CNC words in quiet, the average pre-operative score with a hearing aid was 30% ($\pm 13\%$); while at 12 months with the cochlear implant alone the average score was 48% ($\pm 19\%$).
- The average improvement on CNC words in quiet with electric stimulation only was 18% compared to pre-operatively.
- 88% (58/67) of subjects demonstrated similar or improved performance on CNC words in quiet with the cochlear implant alone compared to pre-operatively with a hearing aid.

Self-Assessment Questionnaires

On the APHAB questionnaire, 90% of subjects noted that listening was easier than it was before surgery (decrease in listening difficulty). Subjects reported the listening difficulty they experienced at 12 months at 30% ($\pm 20\%$) lower than the difficulty they experienced pre-operatively.

Additionally, on the HDSS, 86% of subjects reported an increase in satisfaction, compared to their pre-operative aided condition. Subjects' satisfaction while listening in background noise improved at 12 months, compared to pre-operatively.

Post-operative Residual Hearing

Although hearing was tested at each follow-up visit, change in residual hearing was not included in the clinical trial as a specific test point in the study. Residual hearing can be evaluated as the amount of change in hearing in the low frequencies or by the degree of hearing remaining after surgery. These results from all subjects through the 12 month follow-up visit are included below.

Decreases in hearing, if noted, tended to occur immediately after surgery. Hearing levels then remained stable through the follow-up period. The amount of change in the low frequencies was less than 24 dB on average at 12 months post-operatively. Change in residual hearing can be classified by the number of subjects experiencing a decrease

in hearing at 12 months. In this clinical trial, 79% of subjects (53/67) experienced less than a 30dB decrease (worsening) in residual hearing after surgery.

Amount of Hearing Lost (in dB) after Surgery For All Subjects

Time Point	< 10 dB	10-20 dB	20-30 dB	> 30 dB
Month 12	8/67 (12%)	25/67 (37%)	20/67 (30%)	14/67 (21%)

Residual hearing can also be classified according to the degree of hearing loss in the low frequencies. As can be seen in the table below, 12% of subjects had profound (or total) hearing loss at the 12-month endpoint.

Degree of Low Frequency Hearing Loss After Surgery For All Subjects

Time Point	Mild	Moderate	Moderate-Severe	Severe	Profound
Month 12	2/67 (2.99%)	5/67 (7.46%)	28/67 (41.79%)	24/67 (35.82%)	8/67 (11.94%)

Hearing levels in the low frequencies after surgery were also used to decide whether or not subjects would be fit with the acoustic portion (acoustic unit) of the EAS system. According to the study protocol, subjects used the acoustic unit built into the cochlear implant audio processor if any low-frequency hearing threshold was 80 dB or better. Based on this, 97% (65/67) of all subjects in the clinical trial had the built-in acoustic unit activated, and were followed in the EAS condition through the 12-month endpoint.

Risks of receiving the MED-EL EAS System

Certain risks are linked with receiving the MED-EL EAS system. In the clinical trial the occurrences of those risks were collected as adverse events. A total of 35 adverse events were reported to be related to the EAS device. These 35 events were reported to occur in 29 subjects in the clinical trial. The types of adverse events that were collected, along with the number of times each event occurred, and in how many subjects each event occurred are reported below. Additionally, the percent of subjects experiencing each type of event is reported.

Events Reported as Device-Related	No. of Events	No. of Subjects	% of Subjects
Type B or Type C tympanogram	8	6	8%
Profound/total loss of residual hearing	8	8	11%
Conductive hearing loss	5	5	7%
Pain at site	3	3	4%

Events Reported as Device-Related	No. of Events	No. of Subjects	% of Subjects
Electrode lead breakage after excessive micro-movements, caused by patient massaging area	1	1	1%
Electrode migration	1	1	1%
Occasionally off-balance	1	1	1%
Ulnar nerve palsy after operation	1	1	1%
Telemetry showed high status on electrode channels	1	1	1%
Facial stimulation	1	1	1%
Sensation of fullness in the ear	1	1	1%
Sensation of device shifting when pushing over the implant site	1	1	1%
Temporary shift in hearing threshold	1	1	1%
Beeping/ringing in implanted ear	1	1	1%
Bitter taste on tongue on the side of the implant	1	1	1%
Total	35	29*	39.7%

*Some subjects experienced more than one adverse event.

All of the adverse events reported resolved, except for those involving hearing loss (profound/total loss of hearing and conductive hearing loss). Additionally, one subject experienced a device/programming issue that did not resolve (telemetry showed high status), and one subject experienced beeping or ringing in the ear that did not resolve.

Changes in hearing are a risk when receiving the MED-EL EAS System. Eight subjects had a profound/total loss of hearing in the study. Two of these experienced hearing loss immediately following surgery. Six additional subjects experienced a profound loss of hearing within the 12-month follow-up period but were still able to use the acoustic unit based on at least one low-frequency threshold better than 80 dB HL. All eight of these adverse events at the 12-month follow-up visit are reported in the above adverse event table as "profound/total loss of residual hearing". 97% of subjects (65/67) had some degree of measurable hearing at the end of the study.

Benefits of receiving the MED-EL EAS System

MED-EL EAS System users may understand speech better in quiet and in noise. Additionally, they may be more satisfied with the EAS device compared to their hearing aids.

In this clinical trial, subjects understood sentences in noise better with EAS than before surgery with hearing aids only (CUNY sentences in noise). 85% of subjects (56/66) understood sentences in noise better with EAS than they did with their hearing aid pre-operatively (CUNY sentences in noise). 97% of subjects (65/67) demonstrated benefit with EAS on either speech understanding testing or self-assessment questionnaires, or both. On average, the group of EAS subjects understood speech both in quiet and in noise more than twice as well as they did compared to their own hearing aid before surgery.

Even when the acoustic unit part of the audio processor was turned off, subjects performed better with the cochlear implant alone than they did with their hearing aids before surgery. Subjects understood words in quiet better with the cochlear implant alone than with hearing aids before surgery (CNC words in quiet).

I. SUMMARY OF PRIMARY CLINICAL STUDIES

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

MED-EL sponsored a study at the University of North Carolina at Chapel Hill to see if 40 adults with SSD and AHL who received a MED-EL cochlear implant were better able to understand speech, more likely to find the direction of a sound source and are satisfied with their implant after the first year. This group of patients had hearing loss for less than 10 years and had used a hearing aid regularly for at least some of that time. All of the people in the study had also tried some type of current hearing device to treat SSD, such as a hearing aid, bone-conduction device, or a "CROS" type of hearing aid.

Listeners' hearing history:

SSD: Fifteen people in the study experienced sudden hearing loss and five people experienced a gradual hearing loss. The cause of 16 of those peoples' hearing loss was unknown, 3 were caused by Meniere's disease, and caused by injury in one person.

AHL: Ten people had sudden hearing loss and six had a gradual hearing loss, with the remaining two having both a gradual and sudden loss. Cause of hearing loss was unknown in 14 people, due to Meniere's disease in two people, due to noise-induced hearing loss in one person and caused by viral infection in one person.

Complications:

In this study, the researchers also looked at whether the implant was a safe choice by watching for any complications or problems (also called adverse events) the recipients had during the study. Some examples of complications might include pain, dizziness, discomfort, poor sound quality, etc. For a list of major complications that are associated with cochlear implant and surgery, please visit www.medel.com/us/isi and/or talk with your doctor. A total of nine complications were reported that were related to the device or the surgery. An additional six complications were not able to be ruled out as device or surgery-related. No serious, unexpected, device-related complications were seen.

The most common problem was dizziness, which was seen a total of 11 times. In four cases, this was not related to the device or surgery. In three cases, it could not be ruled out that it was related to the device or surgery. In the remaining four cases, it was determined that the it was related to the surgery only. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. All other complications occurred at a rate of 5% or less (2 or fewer people).

Results:

Speech Understanding in Quiet:

Both groups of people (SSD and AHL) improved their ability to understand speech in quiet after 1 year of implant use when tested with the implant alone. For the people with SSD, average scores when repeating single words in quiet increased from 4% before surgery to 55% after 12 months of listening with the implant. For the group of people with AHL, this same test score improved from 6% to 56% in 12 months. In the opposite ear, there was no change in their score over time. When tested with both ears, there was no change compared to the score before surgery, probably because the normal hearing ear was working as expected.

Speech Understanding in Noise:

When listening to speech in noise, both groups of people (SSD and AHL) improved over the first 12 months of listening with the cochlear implant compared to their unaided scores before surgery and compared to scores with a bone conduction hearing device. These increases were seen when both speech and noise were presented from the front of the listener. Scores also improved when speech came from the front and the noise was on the side of the normal hearing ear. This means the cochlear implant increases speech understanding, especially when the normal hearing ear is confused by noise. This improvement was seen on more than one test of speech understanding in noise.

The average improvement in the SSD group increased from 38% to 47% in 12 months on the AzBio Test, speech and noise from the front. This group also had an average increase from 17% to 53% on the AzBio Test when speech came from the front and the noise was on the side of the normal hearing ear. The AHL group

saw increases from 23% to 34% when speech and noise came from the front, and 6% to 29% when speech came from the front and noise was on the side of the better hearing ear, also on the AZ Bio Test.

Finding the Direction of a Sound Source:

People in both the SSD and AHL groups significantly improved in finding the direction of a sound after they had listened with the cochlear implant for 12 months. To take this test, listeners sat in a room with 11 speakers arranged in a half-circle in front of them, and they were asked to point to the speaker each sound came from.

Satisfaction Questionnaires:

Listeners were asked to complete two questionnaires about their experiences using the MED-EL cochlear implant. After one year of listening, both groups (SSD and AHL) reported an improvement overall when asked about their impressions of the quality of speech, ability to locate sounds around them, and overall sound quality (SSQ Test) as well as ease of communication, hearing in background noise, and hearing in environments with an echo (APHAB Test).

II. SUMMARY OF REAL-WORLD EVIDENCE AS SUPPORTING CLINICAL EVIDENCE

All relevant published medical research was reviewed on adults and children with SSD or AHL who received cochlear implants.

Published Literature on Children

There were five studies published on a total of 26 children with SSD (five used MED-EL implants) and a total of nine children with AHL. The studies reviewed were: Beck and associates (2017), Rahne and Plontke (2016), Arndt and associates (2015), Tavora-Vieira and Rajan (2015) and Gratacap and associates (2015).

The overall benefits reported were improved speech understanding in quiet and noise, improved ability to locate a sound source, and increased parent scores on questionnaires about quality of life over time. This means, independent research studies have found similar results to those we describe above. Across these independent studies, there were a few tests where some children did not show improvement during the study period, or where certain children were not able to complete the tests.

Published Literature on Adults

There were six studies on a total of 58 adults with SSD (50 used MED-EL implants) and a total of 52 adults with AHL (37 used MED-EL implants). The studies reviewed were: Lorens (2019), Doge and associates (2017), Skarzynski and associates (2017), van Loon (2017), Kitoh (2016), Rahne and Plontke (2016). Some people participated in more than one of these studies but if they did, they were not counted twice.

The overall benefits for these people include significantly better speech understanding in quiet and in noise, better ability to locate a sound source, and more satisfaction on questionnaires about quality of life, music enjoyment and ringing in the ears. The data from these independent studies show consistent benefits for CI in people with SSD or AHL. One study used a complicated setup and multi-talker noise. That study showed that 8 of 11 listeners improved on speech understanding in noise, but the remaining 3 listeners showed reduced performance with their CI in this difficult listening situation. Results on listener satisfaction questionnaires showed increased frequency and satisfaction of listening to music, as well as better music sound quality and clarity and better appreciation of different music styles. Two studies reported improvement in ringing in the ears with CI use. Results indicated a high level of patient satisfaction with the CI. This means, independent research studies have found similar results to those we describe above, supporting the value of a CI for people with SSD and AHL.

One study included six adults who lost their hearing at a young age, before they learned to talk, who didn't receive their cochlear implants until they were adults. This means, they went for a very long time without using hearing aids. While this small group of people did not show the same amount of improvement as the

people who lost their hearing later in life and wore hearing aids regularly, all of them were still using their CI more than 8 hours a day, each day, at the end of the study.

Weighing the Risks and Benefits:

A CI is the only treatment choice that can help people with SSD or AHL regain hearing in their poorer hearing ear. All the studies mentioned above show improvement in speech understanding, locating the source of a sound, listener satisfaction, and music appreciation (in adults). For people with SSD or AHL, the implanted ear has a similar hearing loss 'picture' that matches people with hearing loss in both ears who have already been receiving cochlear implants for years. This means, the risks of cochlear implantation in adults and children with SSD and AHL are considered to be the same as for people who have already been using cochlear implants for a long time. Nevertheless, a careful CI evaluation and a strong commitment to rehabilitation are important for the best possible results. Regular (yearly) hearing tests for the opposite ear are recommended, to watch for additional hearing loss that may appear over time in the good ear.

Based on this information, the benefits outweigh the risks of CI in adults and children older than 5 years with SSD and AHL, who have a profound hearing loss in the ear to be implanted. Please talk with your doctor and implant center professionals about any questions or concerns you may have.

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Contact MED-EL

Please refer to the accompanying Contact Sheet for your local office.



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RONDO 2 Audio Processor

User Manual



hearLIFE

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Introduction

This user manual provides information and instructions regarding the MED-EL Cochlear Implant System with the RONDO 2 audio processor (Me1150) (hereafter referred to as audio processor). It includes descriptions of available parts, wearing options, and accessories for the audio processor, as well as instructions for troubleshooting and proper care of the external cochlear implant equipment.

Your MED-EL Cochlear Implant System consists of the Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY), Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), PULSARci¹⁰⁰ (hereafter referred to as PULSAR), SONATAti¹⁰⁰ (hereafter referred to as SONATA), or C40+ implants, the external RONDO 2 audio processor (including FineTuner), the external components and accessories, and any external hardware and software used by your audiologist.

< This symbol indicates information that is particularly relevant for parents of implanted children.

Important

You are the operator of your/your child's audio processor, therefore we recommend that you read this manual in its entirety. Do not perform any maintenance activities other than those described in this manual (e.g. changing the design cover). When performing these maintenance activities, always remove the audio processor from the head.

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 MED-EL Cochlear Implant System may take a little time while you become accustomed to this new method of hearing. You may choose to work with an aural rehabilitation specialist or other clinician to help you maximize your communication skills using the device.

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 require occasional adjustments for as long as they use their MED-EL Cochlear Implant System.

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

Intended use – Indications – Contraindications

Intended use

The RONDO 2 is an audio processor and an external part of the MED-EL Cochlear Implant System. The MED-EL 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 condition¹.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears

Indications

The RONDO 2 is an external component of the MED-EL Cochlear Implant System and is indicated for use on patients who have been implanted with SYNCHRONY, MED-EL CONCERT, PULSAR, SONATA or C40+ cochlear implants. The MED-EL Cochlear Implant System is indicated for:

Bilateral deafness:

- 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 the 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 and above. 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 aided 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.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

The RONDO 2 is indicated to be used in typical everyday environments (home, office, outdoor etc.) and is appropriate for patients of any age.

The RONDO 2 is intended to be used every day during a patient's waking hours. The user of the RONDO 2 does not need any special skills or elevated level of education, however, the user (or custodian if the user is a child or a handicapped person not able to perform the actions listed below) shall at minimum be able to perform the following actions:

- Switching ON/OFF
- Charging the battery powering the device
- Placing/removing the RONDO 2 over/from implant

As the RONDO 2 is a component of the MED-EL Cochlear Implant System, all indications stated for the MED-EL Cochlear Implant System are applicable.

Contraindications

A patient must not receive a RONDO 2 if the individual is known to be intolerant of the materials used in the RONDO 2 or FineTuner. For details, please refer to chapter 9, Technical data.

The RONDO 2 and any external wireless device (e.g. FineTuner) are not intended to be used in environments where RF transmissions are prohibited (e.g. operating theatre).

As the RONDO 2 is a component of the MED-EL Cochlear Implant System, all contraindications stated for the MED-EL Cochlear Implant System are applicable.

NOTE:

Important information related to indications, contraindications, warnings and risks for your cochlear implant are shipped in a separate document (instruction for use of the implant) to your clinic together with the cochlear implant. If you want to review this information, please contact your clinic or MED-EL.

RONDO 2

audio processor

The parts of the system

The MED-EL Cochlear Implant (CI) 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 over the implant site.

The external parts include the audio processor and the audio processor accessories. In its basic configuration, the audio processor consists of the hermetically sealed processor containing the electronics and rechargeable battery and the separate design cover. A separate remote control called the FineTuner facilitates access to various audio processor functions.

The audio processor is held in place by magnetic attraction over the implant.

The audio processor uses a rechargeable battery that provides sufficient power for both the external and the implanted electronics. The battery is sealed into the housing and cannot be exchanged by the user. The implant does not contain batteries.



Fig. 1 Your RONDO 2 audio processor and components

ON/OFF pushbutton

Your audio processor has an integrated pushbutton to switch the processor on and off.

To switch on your audio processor, press down on the center of the processor top side (see Fig. 2) to operate the pushbutton.

To switch off your audio processor, press and hold down the pushbutton until the amber indicator light goes off. The audio processor is now turned off.



Fig. 2 Activating/deactivating your audio processor

After switching on the audio processor, the blue indicator light will blink up to four times indicating the activated program. For example, if the light blinks three times, program 3 is currently active. The audio processor begins working as soon as the blue light comes on and blinks.

Note that the red Link Monitoring indicator (see chapter 8, Troubleshooting, Link Monitoring) blinks to indicate that no link has been established between implant and audio processor, when you switch on the audio processor while it is not on the head. Your audiologist can deactivate the indicator light if you prefer this.

To activate your CI system, place the switched on audio processor with the MED-EL logo (flat side) against your head and the narrow side (microphone) facing upwards over the site of the implant (Fig. 3). As soon as the audio processor is approximately over the implant, it should be positioned correctly by attraction to the implant magnet.

Important

Please make sure to use the correct magnet (see chapter 4, RONDO 2 audio processor, Magnet).

If the audio processor should be at a temperature that is outside the defined operating temperature range of 0°C to +50°C (+32°F to +122°F), e.g. because it was stored in a cool or hot place, put the audio processor in a place with room temperature (typ. +20°C to +25°C [+68°F to +77°F]) and wait at least 30 minutes before you switch on the audio processor. This ensures that the audio processor is not operated outside its defined operating temperature range.

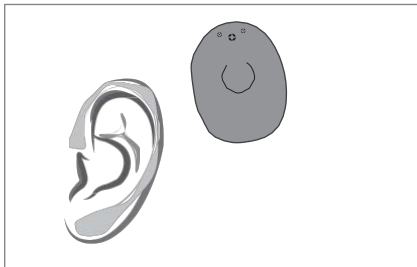


Fig. 3 Audio processor over the site of the implant. Note that the microphone is facing upwards.

When the audio processor is turned off, no current is drawn. Make sure to switch off the audio processor when it is not in use, as this prolongs battery life (see also chapter 7, Care and maintenance).

If you want to store your audio processor for a longer period of time and have not used it before, no action is required.

If you want to store your audio processor for a longer period of time after you have already used it, proceed as follows:

- Switch off the device.
- Charge the device completely.

We do not recommend storing your audio processor for more than 6 months without use.

Design cover

The design cover has an integrated membrane to protect the microphone. The design cover should be replaced if it is damaged or every 3 months. If it is not replaced, an increasingly dirty microphone cover may impair the ability of the microphone to properly pick up sound.

The design cover comes in different colors so you can customize your audio processor.

To change the design cover, proceed as follows:
Insert your finger nail into the groove between design cover and processor on the wider side of the audio processor and lift it up (see Fig. 4).



Fig. 4 How to change the design cover

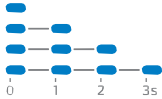
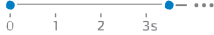
To attach the design cover, simply place it on the audio processor and push down carefully. Do not use excessive force when positioning the design cover.

Indicator lights

The indicator lights under the design cover flash with different patterns and colors to indicate different conditions.

Audio processor indicator light (blue, left side)

The blue indicator light indicates program and status changes, confirms commands received and accepted by the FineTuner and indicates errors. For a detailed description of error indications see chapter 8, Troubleshooting.

Blinking pattern	Meaning	Required action	Remarks
Confirmation pattern			
 Brief flash of blue 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			
	Program 1 to 4 selected	None	The blue indicator light will blink depending on the selected program position. Important These blinking patterns may start off looking like the battery empty pattern.
Status pattern			
	The processor is initialized and working	None	You may perceive a clicking sound with an active telecoil whenever the indicator light blinks.

ON/OFF indicator light (amber, left side)

When pressing the pushbutton in the center of the audio processor, the amber indicator light illuminates. Press and hold down the pushbutton until the amber indicator light goes off. The audio processor is now turned off.

Link Monitoring (green and red, right side)

The green indicator light illuminates when the processor is functional and the correct implant has been detected. The red indicator light indicates that no link has been established between the implant and the audio processor. For a detailed description of error indications see chapter 8, Troubleshooting.

Blinking pattern	Meaning	Required action	Remarks
Green			
	When turning on a processor programmed for a previous generation implant (e.g. C40+, C40): Indicates functionality of the audio processor.	None	Applicable only to previous generation implants without I ¹⁰⁰ serial numbers
	When positioning an activated processor programmed for a new generation implant over the implant: Correct implant detected. Indicates functionality of audio processor and implant.	None	Applicable only to implants with an I ¹⁰⁰ serial number saved to the audio processor memory bank

Charging indicator light

The charging indicator light is located on the bottom (flat) side of the audio processor. It illuminates while the audio processor is charging and goes off when the battery is fully charged. For a detailed description of the charging process see chapter 4, RONDO 2 audio processor, Battery, Charging the battery of your audio processor.

FineTuner

Your audiologist will program your audio processor to suit your needs. The FineTuner is provided to help you optimally use your audio processor in changing daily listening situations.

The audio processor itself has only an ON/OFF pushbutton. All other functions are accessed with a separate device, the FineTuner, which transmits commands to your audio processor via a radio frequency (RF) link. Its ergonomic design and larger size keys facilitate changing the settings of your audio processor, just like a remote control allows you to change channels on your television.

Keeping the FineTuner out of the reach of children prevents them from inadvertently changing the settings of their audio processor.

The FineTuner is not necessary for the function of your audio processor. When switched on, the 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 audio processor, i.e. only the target 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 audio processor is approximately 80 cm. This range might be less if you are 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 individual audio processor and cannot be used by another cochlear implant user. Your audiologist or clinical staff will configure the FineTuner to suit your needs. Sometimes it may be necessary for you to synchronize your FineTuner and audio processor (e.g. if you purchase a backup FineTuner). To do so, first switch off your audio processor and place it on the keyboard of the FineTuner (approx. over key <). Then switch on your audio processor. The audio processor and 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

One FineTuner can be configured for use with both audio processors. 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 audio processors are programmed correctly, the synchronization procedure described above should be performed with both audio processors.

FineTuner controls

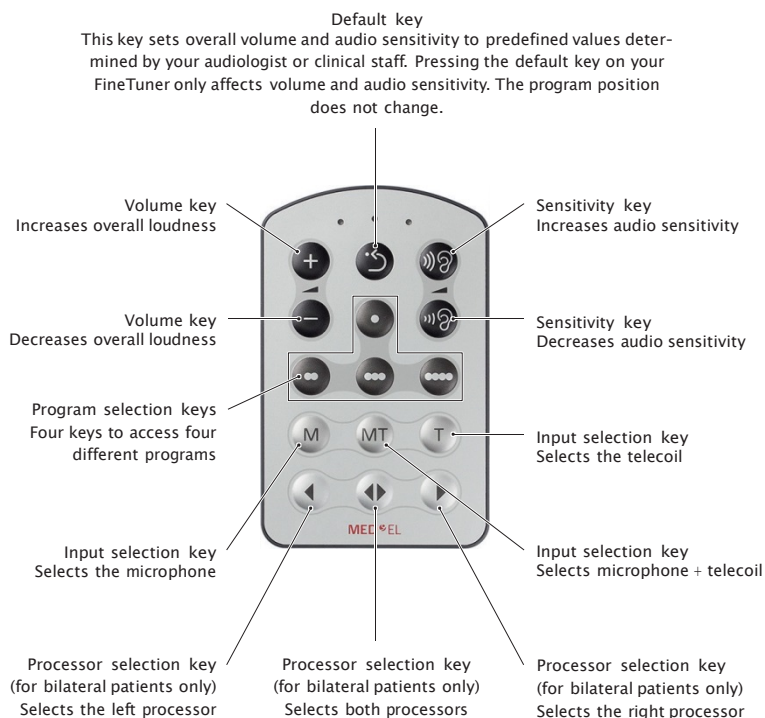


Fig. 5 FineTuner

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

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, hold down 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. Just as described above, the FineTuner will confirm successful deactivation of the automatic keyboard lock with 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 is locked again.

Battery low warning: If you press a key and see the red indicator light on your FineTuner flashing 3 times, then the voltage level of your FineTuner is critically low (see also chapter 7, 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 8, Troubleshooting. The FineTuner does not affect connected assistive listening devices.

Blinking pattern	Meaning	Required action	Remarks
Red indicator light			
○ ● ○	Keyboard locked	Unlock keyboard (see chapter 4, RONDO 2 audio processor, FineTuner, FineTuner functions for locking/unlocking instructions)	For power saving reasons the red indicator light goes off after 5 seconds even if the key is still pressed.
● ● ● — ● ● ● — ...	Low battery warning	Change battery	The FineTuner checks the battery status after each transmission to the audio processor.
Amber indicator lights			
 Synchronously with the transmitted signals	FineTuner transmits command to the audio processor	None	The blinking indicator light(s) indicate the current side mode of the FineTuner (left, right, both). To save energy, the FineTuner stops transmitting (and the indicator light stops blinking) after 3 seconds even if the key is still pressed.
 	Switch to side	None	If the FineTuner is programmed for two different audio processors (for 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).
● ● ●	FineTuner successfully programmed or automatic keyboard lock successfully activated/deactivated	None	
● ● ● ● ● ● ● — ...	Program mode	None	□ is pressed for more than 5 seconds. Flashing stops and the program mode is left after 5 seconds or earlier when a correct key is pressed.

Battery

The audio processor has one lithium-ion (Li-ion) rechargeable battery which is sealed into the processor housing and cannot be changed. This battery supplies the external and internal components of the MED-EL Cochlear Implant System with energy. The battery is integrated and no replacement is required.

The battery must be fully charged once every day. We recommend charging the battery while you are sleeping.

Important

Please make sure to charge your audio processor before using it for the first time.

If the date (YYYY-MM) stated next to the < symbol has expired before your audio processor has been charged for the first time, contact your MED-EL representative.

Charging the battery of your audio processor

The battery in your audio processor will supply energy for up to 18 hours without recharging, i.e. it provides a full day of operation. Charging the battery takes approx. 4 hours.

MED-EL recommends using only chargers provided with the RONDO 2 audio processor.

To charge the battery, proceed as follows:

1. Remove the audio processor from your head and switch it off by keeping the push-button pressed until the amber indicator light goes off.
2. Plug the USB cable into the charger. Plug the other end into a USB port or, by using an additional adapter, into a wall outlet. When the light on the charger illuminates, the charger is ready for use (see Fig. 6)
3. Place the audio processor in the center of the charger with the MED-EL logo facing upwards (see Fig. 7.1).

Important

Do not place the audio processor with the flat side on the charger as shown in Fig. 7.2. In this position the audio processor will not be charged but the process could result in heating of certain audio processor components. This could lead to skin burns when the audio processor is placed on the head directly from the charger.

4. The orange charging indicator light of the audio processor illuminates continuously while the battery is charging. When the battery is fully charged, the light goes off and no power is transferred.
5. When the charging indicator light is off, your audio processor is ready for use.



Fig. 6 Charger

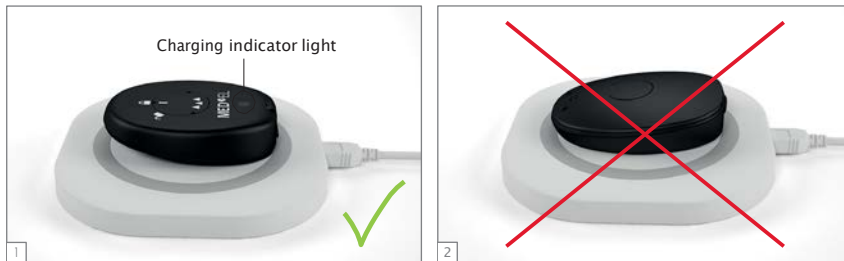


Fig. 7 Correct (1) and incorrect (2) placement of the audio processor

NOTE:

- Place the audio processor approximately in the center (± 5 mm [0.2 in.]) of the charger. If the device is not centered, the battery may not be charged or the charging process may be interrupted. This leads to an incompletely charged battery and battery life may be reduced when you use your audio processor the next time.
- The device becomes warm during charging. This is normal and does not indicate a failure.
- Do not use the charger on the head. The device becomes warm during charging and can cause skin burns.
- Always observe the specified ambient temperature for charging ($+10^{\circ}\text{C}$ to $+30^{\circ}\text{C}$ [$+50^{\circ}\text{F}$ to $+86^{\circ}\text{F}$]). High ambient temperatures may interrupt the charging process and battery life may be reduced when you use your audio processor the next time.
- Do not expose the charger with audio processor to direct sunlight. This may interrupt the charging process and battery life may be reduced when you use your audio processor the next time. Moreover, the device may become excessively hot and cause skin burns when placing the audio processor on the head directly after charging.
- Avoid interrupting the charging process as this may reduce battery life when you use your audio processor the next time.
- If the charging process needs to be interrupted, remove the audio processor from the charger and wait until the processor surface in contact with your head has cooled down to a comfortable temperature. Otherwise you may experience brief, uncomfortably warm sensations on your skin.
- Once the battery is fully charged and you place the audio processor on the charger, the battery will not be charged. The orange charging indicator light will not illuminate.
- Battery life reduces over time. This is normal for any type of rechargeable battery.
- We do not recommend storing the audio processor for more than 6 months without use. If you want to store the audio processor, refer to chapter 4, RONDO 2 audio processor, ON/OFF pushbutton.

Magnet

Important

Your audio processor contains a strong magnet. Keep clear of metallic items as they attract the magnet.

A small magnet is located in a compartment on the bottom of the audio processor (flat side) to hold it in place on the head over the implant. The magnet can be changed to adjust the magnet strength to your needs.

Important

Depending on the type of implant, two variants of magnets are available for the audio processor. These two variants differ in magnet polarization. The type of implant is stated on your Patient Identification Card.



For patients implanted with a SYNCHRONY implant, the magnet must contain triangles as shown in Fig. 8.



For patients implanted with any other type of implant (CONCERTO, SONATA, etc.), the magnet must contain circles as shown in Fig. 9.

It is essential that, based on the type of implant, the correct variant of magnet is used! If the wrong variant of magnet is inserted, the audio processor may still be held in place over the implant. However, due to different polarization of the magnets, a slight dislocation between the implant and audio processor will occur which may result in improper communications between implant and audio processor.

Different magnet strengths are available. Magnet strength is indicated by the number of filled triangles or circles on the magnet (1=weakest). The magnet strength chosen should be appropriate for the individual patient, that is, strong magnets are not recommended for patients with thin skin flaps (e.g. young children), as excessive magnetic attraction could potentially increase the likelihood of skin irritation.



Fig. 8 Magnet strengths for SYNCHRONY implant



Fig. 9 Magnet strengths for all other types of implants

- < It is easiest to observe children when playing or in everyday situations to determine whether the audio processor is properly attracted to the implant. If it falls off too easily, your child may develop an aversion to wearing the audio processor. During the first months after surgery, you should regularly check the skin under the audio processor 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.

Important

MED-EL strongly recommends that you do not change the magnet yourself, but have your audiologist or clinical staff do it. If you notice any signs of skin irritation around the audio processor, contact your clinic or CI center.

If the magnet is not correctly inserted, the device can be damaged.

If the magnet is not completely locked it can adversely affect the operation of the device and increase the likelihood of the magnet coming off the device.

NOTE:

If you are implanted with a SYNCHRONY implant, there is a chance that the external and internal magnets may be misaligned when placing the audio processor on the head. This misalignment is due to the diametric magnet design and may result in hearing interruptions and/or the processor falling off. To avoid misalignment, gently rotate your audio processor between a quarter and half a turn back and forth to allow the audio processor to position itself correctly over the implant (Fig. 10). You will notice correct alignment by uninterrupted hearing and/or stronger magnetic attraction.

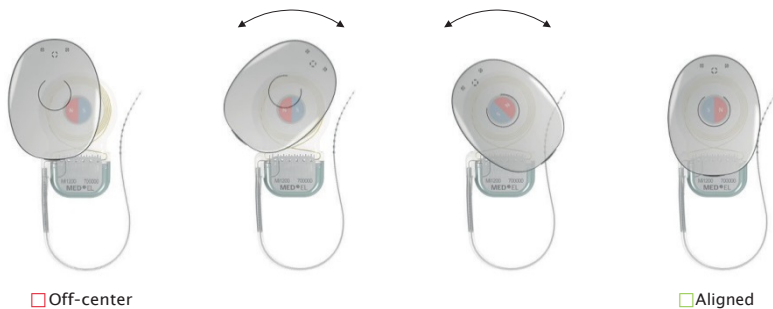


Fig. 10 Aligning audio processor and implant magnets. Note that the microphone is facing up.

How to change the magnet

1. Place the magnet exchange tool (may be purchased separately) on the magnet, aligning the arrow on the tool with the bar symbol on the magnet cover (see Fig. 11.1).
2. Turn the tool counter clockwise towards the unlocked symbol (<). The magnet disengages and can now be lifted out (Fig. 11.2 to 11.4).
3. Remove the magnet from the tool.
4. Take the new magnet. Make sure that the magnet is equipped with a white rubber ring to hold the magnet securely in the housing. Align the arrow on the magnet exchange tool with the bar symbol on the magnet cover (see Fig. 11.1).
5. Align the arrow on the magnet exchange tool with the unlocked symbol (<) on the housing (see Fig. 11.3). When positioned correctly, the magnet glides in easily.
6. Turn the magnet exchange tool clockwise until the arrow on the tool is aligned with the locked symbol (>) on the housing of the audio processor (see Fig. 11.2). The magnet is inserted correctly, when the bar symbol on the magnet cover is aligned with the locked symbol (>) on the housing. Do not use excessive force.



Fig. 11 Changing the magnet

Attachment options

Attachment clip with lanyard

The attachment clip is used to attach the audio processor to your or your child's clothes or hair to reduce the risk of damaging the audio processor should it come off and drop on the floor or another hard surface.

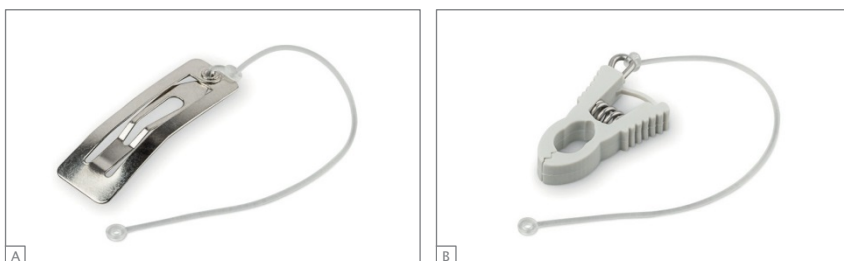


Fig. 12 Attachment clips

The audio processor patient kit includes two types of attachment clips. The smaller clip is intended as a hair clip (A), the larger clip is intended to be attached to clothing (B). These optional attachment clips allow for additional fixation of the audio processor if desired, however, MED-EL strongly recommends that you always use an attachment clip.

How to secure the attachment clip

1. Remove the cover from the audio processor.
2. Push the circular end of the leash into the matching groove at the bottom of the processor (see Fig. 13).
3. Replace the cover, securing the cable in place.
4. Clip to hair or clothes as appropriate.



Fig. 13 Securing the attachment clip to the audio processor housing

Connectivity

Direct audio input

Assistive listening devices (e.g. FM systems) or other external audio devices such as portable CD players, MP3 players, AM-FM radios, etc. can be connected to the audio processor via the MED-EL Mini Battery Pack. Please read the user manual provided with the Mini Battery Pack for further instructions.

Telecoil

The 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.

To use the telecoil proceed as follows:

- Activate the telecoil by pressing the key < (only signals picked up by the telecoil will be audible) or < (signals picked up by the microphone and the telecoil will be audible) on your FineTuner as described in chapter 4, RONDO 2 audio processor, FineTuner, FineTuner controls.
- When you are using a telephone, position the telephone so that its earpiece is centered over the audio processor. Move the telephone slightly up or down as necessary to optimize the signal quality.
- When you are in an environment with a loop system, try to find a spot where the signal quality is best for you.
- To deactivate the telecoil when you do not need it anymore, press the key < on your FineTuner as described in chapter 4, RONDO 2 audio processor, FineTuner, FineTuner controls.

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 pressing 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 4, RONDO 2 audio processor, FineTuner, FineTuner controls).

Alternative power source

Mini Battery Pack

The MED-EL Mini Battery Pack is a device enabling external power supply of your audio processor. It is connected to the audio processor with a cable. The Mini Battery Pack requires one primary or one rechargeable 1.2 to 1.6 Volt size AAA battery. Alternatively, a rechargeable DaCapo PowerPack may be used. The Mini Battery Pack features an EA (Euro Audio) socket to connect external audio devices to the audio processor. The CS44 socket on the Mini Battery Pack can be used to connect the Microphone Tester to listen to the mixed signal of the external audio source connected to the EA socket and the microphone signal of the audio processor. A special cable, which may be purchased separately, is required for that option.

Use the Mini Battery Pack when the integrated battery of your audio processor is empty and you do not want to recharge it but wish to continue using your audio processor.

Please read the user manual provided with the Mini Battery Pack before using the device or contact your CI center or MED-EL.



Fig. 14 Mini Battery Pack connected to audio processor

Important

The Mini Battery Pack has no charging function for the audio processor. It is used as an alternative power source for the audio processor.

The socket for the alternative power source is protected by a socket seal attached to the processor housing. If the socket seal should come off inadvertently, place the three small “feet” over the holes in the housing and gently push them down with a ballpoint pen.

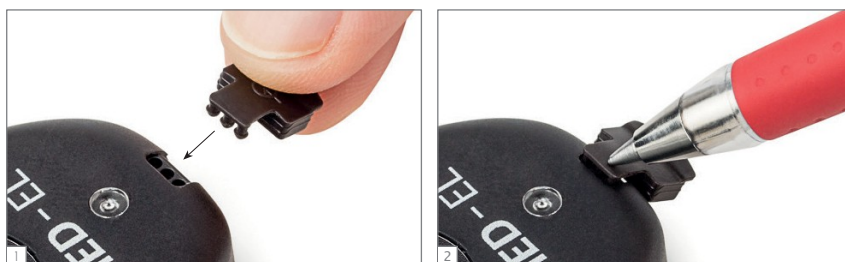


Fig. 15 Reattaching the socket seal

Special considerations for young children

The audio processor has several features and accessories that are designed especially for young children. They are:

- 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.
- Attachment clips to prevent the audio processor from dropping on the floor when it comes off.
- An optional headband to keep the audio processor securely on the head. The headband may be purchased separately.
- Amber indicator light to allow parents/adults to check if the audio processor is active. The amber indicator light illuminates when briefly pressing the ON/OFF push-button to indicate that the audio processor is active.
- Link Monitoring functionality indicating proper connection between audio processor and implant.
- Status indicator light which blinks approx. every 3.5 seconds indicating that the audio processor is initialized and working. Your audiologist can activate this blinking pattern.

MED-EL strongly recommends that adult users also use the attachment clip to secure the audio processor and the headband when engaging in sports activities.

Important

Only parents/adults shall change any parts of the audio processor (e.g. magnets, covers). Parents/adults should check the device at least once a week for damage or missing parts.

- < If your child is implanted with a SYNCHRONY implant, check for correct alignment of audio processor and implant by gently rotating the audio processor a quarter or half a turn back and forth to allow the audio processor to position itself correctly over the implant (see also chapter 4, RONDO 2 audio processor, Magnet, Fig. 10). You will notice correct alignment by stronger magnetic attraction.

General precautions and warnings

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

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 MED-EL 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 impact success with the cochlear implant, as do other factors, including some which may be unknown.

Do not use the MED-EL 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 8, 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 MED-EL Cochlear Implant System checked at your clinic or CI center.
-

General precautions for your MED-EL Cochlear Implant System

The audio processor and other parts of the system contain sophisticated electronic components which require special precautions regarding electromagnetic compatibility (EMC). When activating your audio processor always follow the guidelines outlined in this section and chapter 9, Technical data, Guidance and manufacturer's declaration.

The electronics are durable but must be treated with care.

- Never open the housing of your audio processor. Unauthorized opening invalidates the warranty.
- Before switching on the audio processor, check the external parts of the MED-EL Cochlear Implant System for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the audio processor should not be switched on. Read chapter 8, 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 MED-EL 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 rub, stretch or 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 audio processor and FineTuner do not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range is between 0°C to +50°C (+32°F to +122°F) for the audio processor and the FineTuner. Normally, when the audio processor is worn on the body, natural body heat helps maintain this temperature range.
- The defined operating temperature range for charging the audio processor is between +10°C and +30°C (+50°F and +86°F).
- Do not leave the audio processor, FineTuner or charger in direct sunlight (especially inside a car). Long exposure to direct sunlight might damage the audio processor or FineTuner.
- If you ever experience loud or uncomfortable sounds, please remove your audio processor immediately: this will stop stimulation at once.
- Blowing your nose too hard might lead to (temporary) fluctuations in loudness. This is caused by air trapped over the reference electrode of the implant.
- 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, FineTuner or charger wet as this may impair their 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 cover and gently wipe all external parts dry, using a soft, absorbent cloth. If the FineTuner becomes wet, wipe it off with a dry tissue.
- Do not use a drying kit, as this may damage the devices.
- You also have to take care of the external components of your/your child's MED-EL Cochlear Implant System. They should not be dropped or subjected to dangerous areas (e.g. machines or high voltage) which could result in damage to the components.

- Do not use the audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.
 - Do not use your audio processor in the vicinity of strong ionizing radiation (e.g. x-ray machines) or electromagnetic fields (e.g. MRI machines). Such radiation or fields may stop your MED-EL Cochlear Implant System from working.
 - Do not modify the housing, the electronics or any other parts of your audio processor, FineTuner or charger in any way.
- < Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury.
-

Warning

Use of the audio processor adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the audio processor and the other equipment should be observed to verify that they are operating normally.

Do not use accessories, transducers and cables other than those specified or approved by MED-EL as this could result in increased electromagnetic emissions or decreased electromagnetic immunity of the audio processor and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of the audio processor, including cables specified by MED-EL. Otherwise, degradation of the performance of the audio processor could result.

Technology in everyday life

Metal detectors and other radio frequency (RF) transmitters

Metal detectors, some anti-theft devices and other RF transmitters may produce sounds only heard by the implant user, if they are near to these devices. To avoid this, switch off your audio processor when walking through metal detectors or when in the vicinity of an RF transmitter.

If an audio processor map becomes corrupted, it can easily be reprogrammed at the CI center or by a clinical engineer. If your audio processor has more than one program, you can usually use one of the others in the meantime.

The implant itself may trigger a metal detector, so make sure that you carry your MED-EL ID card with you at all times to identify yourself as a cochlear implant user, as needed.

Air travel

EASA (European Aviation Safety Agency) and FAA (Federal Aviation Administration) aviation safety guidelines recommend airlines to allow the use of cochlear implants during all phases of flight, i.e. the audio processor may also remain switched on during taxi, takeoff and landing. However, we recommend to double check with your airline about possible specific regulations. If you decide to remove or to turn off your audio processor at any time during flight, tell your flight attendant that you are a cochlear implant user and that you may require special instructions while your audio processor is turned off.

Interference with TV reception

In rare cases, your audio processor may interfere with reception when using certain TV sets (with indoor antennae). Move away from the TV set and turn the antenna to reduce interference.

Mobile phones

Mobile phones and other portable and mobile RF communications equipment may interfere with the external parts of your MED-EL Cochlear Implant System. As the experiences of other MED-EL users have shown, the system is compatible with most mobile phones. Results with a certain mobile phone may vary depending on the provider or type of phone. If you are considering purchasing a mobile telephone, you should test it beforehand for possible interference.

TV, radio, FM systems, etc.

When intending to connect the audio processor to an external audio device that is powered by mains power, i.e. plugged into the wall or a power strip, always make sure first that this mains-powered external audio device meets the safety requirements stated in the standards EN/IEC 60065, EN/IEC 60601-1 and/or appropriate national standards. If the mains-powered device does not bear a CE mark (<), which is usually found on the device's type label, you cannot presume that the mains-powered device meets the above safety requirements and must therefore not be connected to your audio processor. Connecting a mains-powered device to your audio processor that does not meet the above safety requirements could cause an electric shock. You can safely connect battery-powered external audio devices to your audio processor. Special cables may be needed (e.g. for connection to FM systems). For more information please contact MED-EL.

Electrostatic discharge (ESD)

Electronic devices are influenced by electrostatic discharge (ESD). Although the MED-EL 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, but the most likely occurrence in case of an ESD event is a short interruption of stimulation or a controlled audio processor shutdown.

Following these 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 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 audio processor on last, and remove it first when undressing.
- Always remove the audio processor 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 take precautions by removing the audio processor.
- Always remove the audio processor when experimenting with static electricity and "high" voltage. Van de Graaff generators, as found in school science departments, 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. If it does not come on again, contact your CI center.

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 audio processor securely 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 of high quality. It 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 or properly protected. Use only products specifically offered and/or recommended by MED-EL to protect the external parts against the ingress of water. 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 the 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 participating in sports and any limitations of your/your child's health status.

Precautions for medical procedures

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to the Medical Procedures Manual.

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.

Care and maintenance

Maintenance

Your audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time.

The design cover should be replaced if it is damaged or every 3 months. If it is not replaced, increasing contamination may impair your hearing.

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.

Protect your audio processor from water (see also chapter 6, General precautions and warnings).

Do not use any drying kit as this may damage the external components.

Do not try to repair electronic parts of your audio processor and do not try to open the audio processor, as this invalidates the manufacturer warranty.

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

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.

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

Weekly maintenance of your audio processor

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

Important

Do not dry the audio processor or any other part of the system in a drying kit!

Battery

The audio processor has one lithium-ion (Li-ion) rechargeable battery which is sealed into the processor housing. This battery supplies the external and internal components of the MED-EL Cochlear Implant System with energy. The battery is integrated and no replacement is required.

For a detailed description of the charging process, please see chapter 4, RONDO 2 audio processor, Battery, Charging the battery of your audio processor.

Important

Battery life reduces over time. If your audio processor works less than 10 hours after fully charging the battery, contact your clinic, CI center or MED-EL.

Changing the battery of your FineTuner

When your FineTuner generates an optical low battery warning signal (see also chapter 4, RONDO 2 audio processor, FineTuner, FineTuner functions), replacing the battery of your FineTuner is recommended.

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 audio processor magnet or by gently shaking it into your hand. Try not to touch the battery contacts.
3. Insert the new battery with the $\rightarrow$ sign facing up.
4. Close the lid by carefully inserting it on the right side, then sliding it into place and tightening the screw.



Fig. 16 Changing the battery of your FineTuner

Important

- Wash your hands after handling disposable batteries.
 - Do not try to recharge disposable batteries.
 - Do not disassemble, deform, immerse in water or incinerate batteries.
 - Avoid mix-up of old and new batteries or batteries of different types or brands.
 - Do not short-circuit batteries, e.g. by allowing the terminals of batteries to touch, carrying batteries loose in your pockets, wallet or purse or touching the battery terminals with metals (coins, wires, keys, etc.).
 - Store unused batteries in their original packaging, in a cool and dry place.
 - Do not expose batteries to heat (e.g. never leave batteries in direct sunlight, behind a window or in a car).
 - Do not use damaged, deformed batteries or leaking batteries. If any kind of substance leaks out of a battery, avoid direct skin contact with that substance. Such a substance could cause a chemical burn. In case of eye contact, rinse with copious amounts of water and seek medical attention immediately.
 - Always remove used batteries immediately to avoid leakage and possible damage to the device.
 - Used batteries should be disposed of according to local regulations. If you ignore these regulations, you will contribute to pollution of the environment. Generally, batteries are collected separately and not disposed of 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 shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury.

Troubleshooting

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

Using cables or plugs not recommended or supplied by MED-EL may damage your MED-EL 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 audio processor from the implant site before operating the pushbutton if this sound bothers you.

Important

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

Speech Processor Test Device



Fig. 17 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 for use by cochlear implant users or other persons interacting with cochlear implant patients (e.g. parents, audiologists, teachers, etc.).

The Speech Processor Test Device is not necessary for the function of your audio processor. It is simply intended to help detect most common audio processor problems like defective 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 in your audio processor, contact your CI center or MED-EL or try the following procedure:

Switch on the audio processor and make sure its battery is charged. Place the flat side of the audio processor under the Speech Processor Test Device (see Fig. 17), it 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 up or stays on constantly, try the following:

- Adjust the volume setting. By using the appropriate loudness setting, you should be able to recognize the flickering of the red light in the rhythm of your voice.
- Connect the Mini Battery Pack to your audio processor. Make sure that it is supplied with fresh batteries.
- Change the batteries of the Mini Battery Pack.

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, as this will cause damage to the device and immediately void any warranty.

The Speech Processor Test Device should be handled with care to achieve maximum lifetime and to ensure proper function. Do not expose your Speech Processor Test Device to conditions other than those suitable for your audio processor (see also chapter 6, General precautions and warnings).

FineTuner

The FineTuner transmits commands to the audio processor via a radio frequency (RF) link. If the audio processor does not respond to FineTuner commands, the following may be potential reasons and solutions for this:

- The audio processor is out of the FineTuner's operational range. To overcome this you should move the FineTuner closer to the audio processor.
- The FineTuner keyboard lock is active. In this case follow the instructions for unlocking as described in chapter 4, RONDO 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 audio processor and/or go to a different location.
- The audio processor and the FineTuner are not synchronized. In this case you need to refer to the section described in chapter 4, RONDO 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 7, 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 7, Care and maintenance, Batteries, Changing the battery of your FineTuner.
- The desired command in the audio processor 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 lights in the audio processor have been disabled by your audiologist during fitting. To enable the red indicator lights you will need to contact your clinic, CI center or MED-EL.

Additional troubleshooting information:

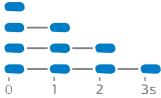
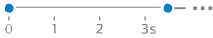
- If you or your child have used the < (telecoil) or < (microphone and telecoil) settings and are unable to return to the < (microphone) signal source input with the FineTuner, you need to switch the audio processor off and on again. When the audio processor is switched on again it will automatically start with the < (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.

Blue audio processor indicator light

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

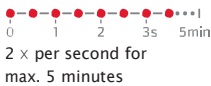
Your audiologist can deactivate the blinking signals permanently (except error and program change patterns) if you prefer this.

Blinking pattern	Meaning	Required action	Remarks
Error patterns			
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be replaced.
	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.
	Electronic problem or program failure	Switch processor off. Switch processor back on.	If the blinking persists, the processor must be reprogrammed.
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	
Warning patterns			
	Battery empty	Switch processor off. Charge the battery. Switch processor back on.	If the processor is not switched off, the blue 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			
 Brief flash of blue 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.

Blinking pattern	Meaning	Required action	Remarks
Program change pattern			
	Program 1 to 4 selected	None	The blue indicator light will blink depending on the selected program position. Important These blinking patterns may start off looking like the battery empty pattern.
Status pattern			
	The processor is initialized and working	None	You may perceive a clicking sound with an active telecoil whenever the indicator light blinks.

Link Monitoring

The multi-color indicator light on the right side under the design cover flashes with different patterns and colors to indicate different conditions. If the indicator light begins flashing, use the following tables to determine the possible cause. Your audiologist can deactivate the indicator light or the automatic power off function if you prefer this.

Blinking pattern	Meaning	Required action	Remarks
Green			
	When turning on a processor programmed for a previous generation implant (e.g. C40+, C40): Indicates functionality of the audio processor.	None	Applicable only to previous generation implants without I ¹⁰⁰ serial numbers
	When positioning a turned on processor programmed for a new generation implant over the implant: Correct implant detected. Indicates functionality of audio processor and implant.	None	Applicable only to implants with a I ¹⁰⁰ serial number saved to the audio processor memory bank
Red			
	Audio processor and implant are disconnected	Position the audio processor over the implant site. Make sure to use the correct magnet	If the blinking persists, contact your clinic, audiologist or MED-EL.
	Audio processor positioned over wrong implant (bilaterally implanted users)	Position the audio processor over the correct implant	
	Audio processor has powered off	Switch the audio processor off and on again, reposition the audio processor over the implant to resume stimulation (the processor does not switch off automatically)	If the blinking persists, contact your clinic, audiologist or MED-EL

Troubleshooting

Blinking pattern	Meaning	Required action	Remarks
No signal or arbitrary red and green blinking pattern			
○ No light signal when switching processor on	Processor not functional (e.g. batteries empty)	Charge the battery	If the situation persists, contact your CI center or MED-EL.
	Fitting: During fitting indicator light is deactivated	After fitting, switch the processor off and on to re-activate the indicator light	None

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 you should charge the battery of the 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 audio processor, a confirmation beep is audible for the user of the audio processor.

These 3 signals may be deactivated permanently by your audiologist if this is your preference.

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 mode of the FineTuner) blink synchronously to the transmitted signals. To save energy, the FineTuner stops transmitting (and the indicator light stops blinking) after 3 seconds even if the key is still pressed.

Switch to side

If the FineTuner is programmed for two different audio processors (for 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 4, RONDO 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 (must be unlocked; see chapter 4, RONDO 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.

Technical data

Audio processor

Dimensions¹



Length: 46.8 mm (1.84 in.)

Width: 35.9 mm (1.41 in.)

Height: 11.7 mm (0.46 in.)

Weight¹

14.5 g (0.51 oz.) (with cover and magnet 1)

Power supply

1 rechargeable Li-ion battery, nominal 3.7V

Battery life expectancy is typically more than 5 years

Hardware

- Fully digital signal processing
- Various parameters programmable
- 4 programs selectable
- Up to 12 band pass filters; filter characteristics programmable
- Non-linear amplification programmable
- Full frequency range: 70–10,000 Hz
- Audio processor self-test: checksum on programs, continuous parity check
- Automatic Gain Control (AGC) configurable
- FineTuner commands can selectively be disabled

Audio input

- Via Mini Battery Pack
- Hearing aid type three pin connection (Euro-Audio) acc. to IEC 60118-12 on Mini Battery Pack

¹ typical values

Technical data

- Sensitivity: -61.4 dBV^l (corresponds to 70 dB SPL at 1 kHz)
- Impedance: 2.9 kΩ^l

Controls/Indicators

- ON/OFF pushbutton
- Indicator lights: 2 multi-colored LEDs for alarm and indicator functions, 1 charging LED on the bottom side

Materials

- Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS): audio processor, cover (all colors)
- Polyamide (PA): LED windows
- Titanium grade 5: base of magnet
- Silicone: socket seal
- Tampa® Pur TPU 980 black: Tampon print color

Temperature and humidity range

Charging temperature range: +10°C to +30°C (+50°F to +86°F)

Operating temperature range: 0°C to +50°C (+32°F to +122°F)

Storage temperature range: -20°C to +60°C (-4°F to +140°F)

Relative humidity range: 10% to 93%

Atmospheric pressure range: 700 hPa (mbar) to 1060 hPa (mbar)

Essential performance

None of the performance characteristics of the RONDO 2 (incl. all accessories) are essential performance as defined in IEC 60601-1.

Expected service life

The expected service life of the RONDO 2 (incl. all accessories) as defined in IEC 60601-1 is 5 years. There are no actions needed to maintain basic safety with regard to electro-magnetic disturbances for the expected service life.

Radio frequency (RF) link (FineTuner)

Frequency band of reception: 9.07 kHz (±3%)

1 typical values

1 typical values

FineTuner

Dimensions¹

Length: 85.5 mm (3.366 in.)

Width: 54.0 mm (2.126 in.)

Height: 6.3 mm (0.248 in.)

Weight: 33.0 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

- 1 lithium/manganese dioxide battery type CR2025 (3V)
- Battery life expectancy is typically more than 6 months

Classification

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

Materials

- Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS): housing
- Polyester film: keyboard

Temperature and humidity range

Operating temperature range: 0°C to +50°C (+32°F to +122°F)

Storage temperature range: -20°C to +60°C (-4 °F to +140°F)

Relative humidity range: 10% to 93%

Atmospheric pressure range: 700 hPa (mbar) to 1060 hPa (mbar)

Radio frequency (RF) link

Carrier frequency: 9.07 kHz ($\pm 0.7\%$)

Type of modulation: phase shift keying (PSK)

Maximum RF output power: 11.7 dB μ A/m @ 10 m

Maximum operating distance: 0.65 m (2.13 ft.)

¹ typical values

Regulatory statements

Applicable in Canada only:

Model: FineTuner – Canada 310

The above devices comply with Industry Canada licence-exempt RSS standard(s). 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.

Les appareils mentionnés ci-dessus sont conformes aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Applicable in the USA only:

Model: FineTuner – FCC ID: VNP-FT

The above devices comply 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

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

0 1 2 3

CE mark applied in 2017

Hereby, MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type RONDO 2 (audio processor) and FineTuner (remote control) is in compliance with directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.medel.com/compliance



Refer to instruction manual/booklet



Caution, consult accompanying documents (manual)



MR unsafe



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



Non-ionizing radiation (FineTuner)



Fragile; handle with care



Relative humidity



Temperature limit



Not suitable for children under 3 years



Charge before first use



First charge before YYYY-MM (Best before YYYY-MM)



Manufacturer



Serial number



Catalog number

IP54

IP54

Moisture and dust protection acc. to IEC 60529

This classification means that your audio processor is protected against failure from ingressing dust and splashing water when fully assembled, i.e. when

- the design cover is snapped onto the audio processor,
- the socket seal covering the connector on the wider side of the audio processor is closed.

Speech Processor Test Device



The Speech Processor Test Device is in compliance with directive 2014/30/EU (Electromagnetic Compatibility/EMC) and directive 2011/65/EU (Restriction of Hazardous Substances in Electrical and Electronic Equipment/RoHS).

CE mark applied in 2005

Disposal

We advise to dispose of all external components of your MED-EL 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.

Guidance and manufacturer's declaration

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

NOTE:

The RONDO 2 consists of the hermetically sealed processor containing the electronics and rechargeable battery and the separate design cover. Only the programming cable and Mini Battery Pack cable provided by MED-EL can be connected to the RONDO 2.

There are no deviations from this collateral standard and allowances.

Electromagnetic emissions for all equipment and systems

The RONDO 2 is intended for use in the home healthcare environment. The customer or the user of the RONDO 2 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The RONDO 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 RONDO 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 RONDO 2 is intended for use in the home healthcare environment. The customer or the user of the RONDO 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	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±15 kV air	±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines	±1 kV	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth		
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% U_T for 0.5 cycle (1 phase)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	0% U_T for 1 cycle		
	70% U_T for 25/30 cycles (50/60 Hz)		
	0% U_T for 250/300 cycles (50/60 Hz)		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 RONDO 2 is intended for use in the home healthcare environment. The customer or the user of the RONDO 2 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer than 30 cm (12 in.) to any part of the RONDO 2, including cables specified by MED-EL. Otherwise degradation of the performance of this equipment could result.
	6 Vrms ISM/amateur bands	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

Electromagnetic immunity to proximity fields from RF wireless communications equipment

The RONDO 2 is intended for use in the home healthcare environment. Test as specified in IEC 61000-4-3.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

Appendices

Warranty statement

MED-EL's warranty is in agreement with mandatory local statutory warranty provisions.

Any extension of the statutory warranty is subject to agreement between MED-EL and the purchaser. Therefore these extensions may be different in various countries. Please contact your local MED-EL representative for information on your individual warranty rights.

Extension of statutory warranties shall not be granted unless the product is properly registered. You can register a product either by completing the provided registration card and sending it to MED-EL or by using MED-EL's online registration website (upon availability). Ask your local MED-EL representative for help if you need assistance in the registration process.

Extensions of statutory warranties exclusively cover product failures. This does 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.

I. SUMMARY OF PRIMARY CLINICAL STUDIES

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

MED-EL sponsored a study at the University of North Carolina at Chapel Hill to see if 40 adults with SSD and AHL who received a MED-EL cochlear implant were better able to understand speech, more likely to find the direction of a sound source and are satisfied with their implant after the first year. This group of patients had hearing loss for less than 10 years and had used a hearing aid regularly for at least some of that time. All of the people in the study had also tried some type of current hearing device to treat SSD, such as a hearing aid, bone-conduction device, or a "CROS" type of hearing aid.

Listeners' hearing history:

SSD: Fifteen people in the study experienced sudden hearing loss and five people experienced a gradual hearing loss. The cause of 16 of those peoples' hearing loss was unknown, 3 were caused by Meniere's disease, and caused by injury in one person.

AHL: Ten people had sudden hearing loss and six had a gradual hearing loss, with the remaining two having both a gradual and sudden loss. Cause of hearing loss was unknown in 14 people, due to Meniere's disease in two people, due to noise-induced hearing loss in one person and caused by viral infection in one person.

Complications:

In this study, the researchers also looked at whether the implant was a safe choice by watching for any complications or problems (also called adverse events) the recipients had during the study. Some examples of complications might include pain, dizziness, discomfort, poor sound quality, etc. For a list of major complications that are associated with cochlear implant and surgery, please visit www.medel.com/us/isi and/or talk with your doctor. A total of nine complications were reported that were related to the device or the surgery. An additional six complications were not able to be ruled out as device or surgery-related. No serious, unexpected, device-related complications were seen.

The most common problem was dizziness, which was seen a total of 11 times. In four cases, this was not related to the device or surgery. In three cases, it could not be ruled out that it was related to the device or surgery. In the remaining four cases, it was determined that it was related to the surgery only. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. All other complications occurred at a rate of 5% or less (2 or fewer people).

Results:

Speech Understanding in Quiet:

Both groups of people (SSD and AHL) improved their ability to understand speech in quiet after 1 year of implant use when tested with the implant alone. For the people with SSD, average scores when repeating single words in quiet increased from 4% before surgery to 55% after 12 months of listening with the implant. For the group of people with AHL, this same test score improved from 6% to 56% in 12 months. In the opposite ear, there was no change in their score over time. When tested with both ears, there was no change compared to the score before surgery, probably because the normal hearing ear was working as expected.

Speech Understanding in Noise:

When listening to speech in noise, both groups of people (SSD and AHL) improved over the first 12 months of listening with the cochlear implant compared to their unaided scores before surgery and compared to scores with a bone conduction hearing device. These increases were seen when both speech and noise were presented from the front of the listener. Scores also improved when speech came from the front and the noise was on the side of the normal hearing ear. This means the cochlear implant increases speech understanding, especially when the normal hearing ear is confused by noise. This improvement was seen on more than one test of speech understanding in noise.

The average improvement in the SSD group increased from 38% to 47% in 12 months on the AzBio Test, speech and noise from the front. This group also had an average increase from 17% to 53% on the AzBio Test when speech came from the front and the noise was on the side of the normal hearing ear. The AHL

group saw increases from 23% to 34% when speech and noise came from the front, and 6% to 29% when speech came from the front and noise was on the side of the better hearing ear, also on the AZ Bio Test.

Finding the Direction of a Sound Source:

People in both the SSD and AHL groups significantly improved in finding the direction of a sound after they had listened with the cochlear implant for 12 months. To take this test, listeners sat in a room with 11 speakers arranged in a half-circle in front of them, and they were asked to point to the speaker each sound came from.

Satisfaction Questionnaires:

Listeners were asked to complete two questionnaires about their experiences using the MED-EL cochlear implant. After one year of listening, both groups (SSD and AHL) reported an improvement overall when asked about their impressions of the quality of speech, ability to locate sounds around them, and overall sound quality (SSQ Test) as well as ease of communication, hearing in background noise, and hearing in environments with an echo (APHAB Test).

II. SUMMARY OF REAL-WORLD EVIDENCE AS SUPPORTING CLINICAL EVIDENCE

All relevant published medical research was reviewed on adults and children with SSD or AHL who received cochlear implants.

Published Literature on Children

There were five studies published on a total of 26 children with SSD (five used MED-EL implants) and a total of nine children with AHL. The studies reviewed were: Beck and associates (2017), Rahne and Plontke (2016), Arndt and associates (2015), Tavora-Vieira and Rajan (2015) and Gratacap and associates (2015).

The overall benefits reported were improved speech understanding in quiet and noise, improved ability to locate a sound source, and increased parent scores on questionnaires about quality of life over time. This means, independent research studies have found similar results to those we describe above. Across these independent studies, there were a few tests where some children did not show improvement during the study period, or where certain children were not able to complete the tests.

Published Literature on Adults

There were six studies on a total of 58 adults with SSD (50 used MED-EL implants) and a total of 52 adults with AHL (37 used MED-EL implants). The studies reviewed were: Lorens (2019), Doge and associates (2017), Skarzynski and associates (2017), van Loon (2017), Kitoh (2016), Rahne and Plontke (2016). Some people participated in more than one of these studies but if they did, they were not counted twice.

The overall benefits for these people include significantly better speech understanding in quiet and in noise, better ability to locate a sound source, and more satisfaction on questionnaires about quality of life, music enjoyment and ringing in the ears. The data from these independent studies show consistent benefits for CI in people with SSD or AHL. One study used a complicated setup and multi-talker noise. That study showed that 8 of 11 listeners improved on speech understanding in noise, but the remaining 3 listeners showed reduced performance with their CI in this difficult listening situation. Results on listener satisfaction questionnaires showed increased frequency and satisfaction of listening to music, as well as better music sound quality and clarity and better appreciation of different music styles. Two studies reported improvement in ringing in the ears with CI use. Results indicated a high level of patient satisfaction with the CI. This means, independent research studies have found similar results to those we describe above, supporting the value of a CI for people with SSD and AHL.

One study included six adults who lost their hearing at a young age, before they learned to talk, who didn't receive their cochlear implants until they were adults. This means, they went for a very long time without using hearing aids. While this small group of people did not show the same amount of improvement as the

people who lost their hearing later in life and wore hearing aids regularly, all of them were still using their CI more than 8 hours a day, each day, at the end of the study.

Weighing the Risks and Benefits:

A CI is the only treatment choice that can help people with SSD or AHL regain hearing in their poorer hearing ear. All the studies mentioned above show improvement in speech understanding, locating the source of a sound, listener satisfaction, and music appreciation (in adults). For people with SSD or AHL, the implanted ear has a similar hearing loss 'picture' that matches people with hearing loss in both ears who have already been receiving cochlear implants for years. This means, the risks of cochlear implantation in adults and children with SSD and AHL are considered to be the same as for people who have already been using cochlear implants for a long time. Nevertheless, a careful CI evaluation and a strong commitment to rehabilitation are important for the best possible results. Regular (yearly) hearing tests for the opposite ear are recommended, to watch for additional hearing loss that may appear over time in the good ear.

Based on this information, the benefits outweigh the risks of CI in adults and children older than 5 years with SSD and AHL, who have a profound hearing loss in the ear to be implanted. Please talk with your doctor and implant center professionals about any questions or concerns you may have.

Manufacturer address

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E-Mail: office@medel.com

MED-EL distributor in the U.S.:

MED-EL Corporation
2645 Meridian Parkway
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Tel.: (919) 572-2222
Fax: (919) 484-9229
Toll free: (888) MED-EL-CI (633-3524)
E-Mail: implants.us@medel.com

Contact MED-EL

Please refer to the accompanying Contact Sheet for your local office.



MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a, 6020 Innsbruck, Austria
office@medel.com

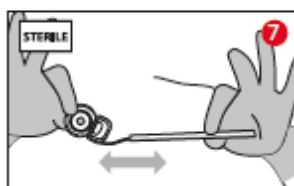
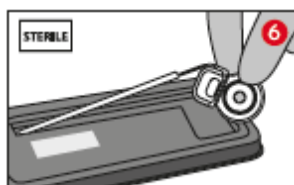
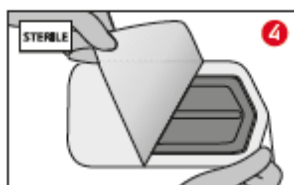
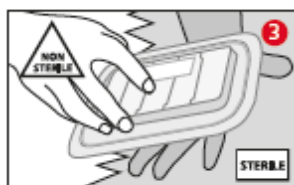
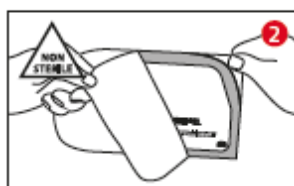
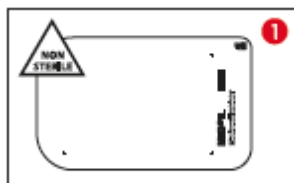
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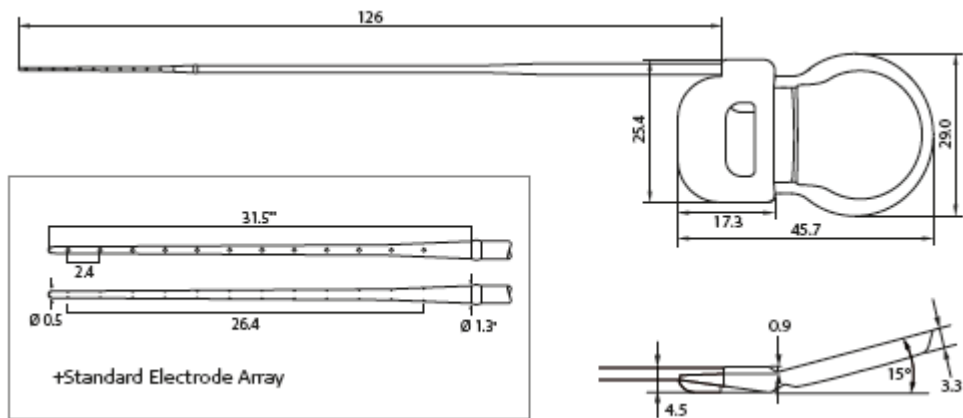
Mi1000 MED-EL CONCERT Cochlear Implant

+Standard | +Medium | +Compressed | +FLEX^{SOFT} | +FLEX28 | +FLEX24

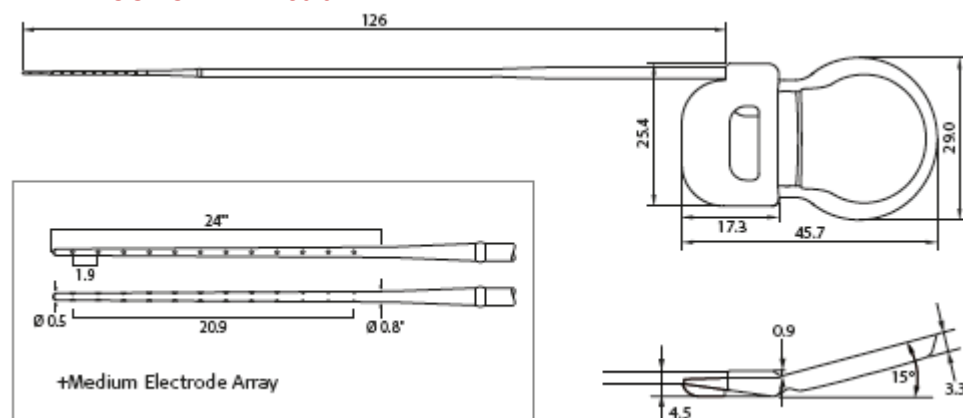
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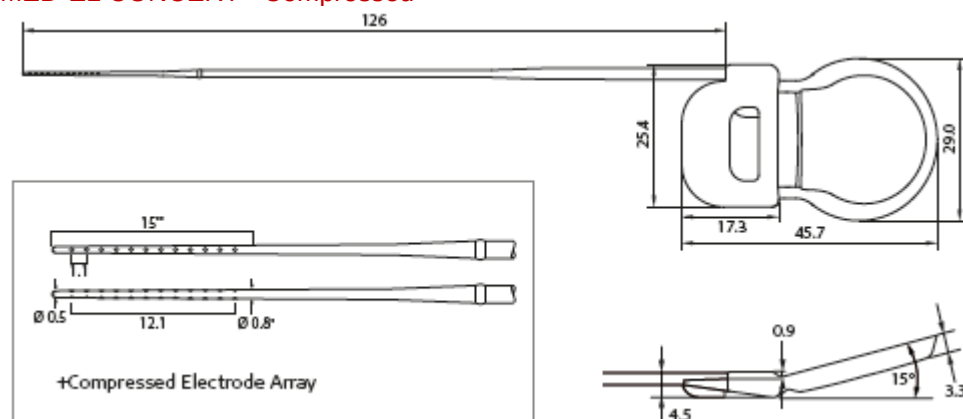
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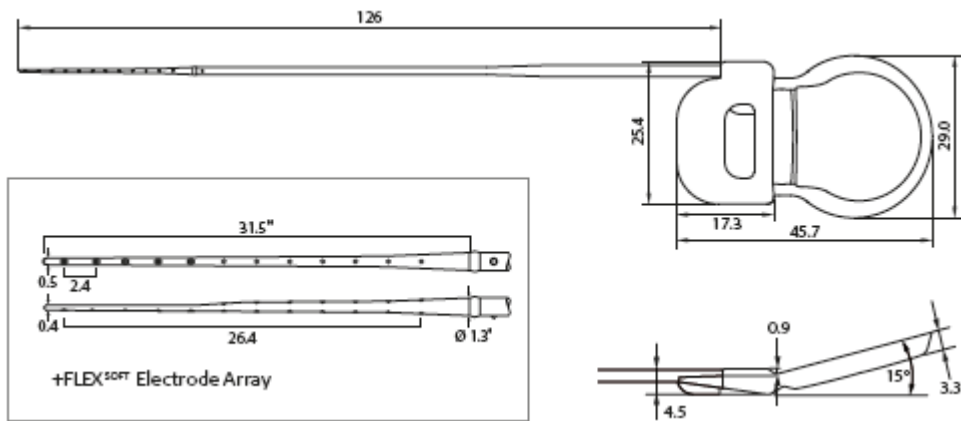
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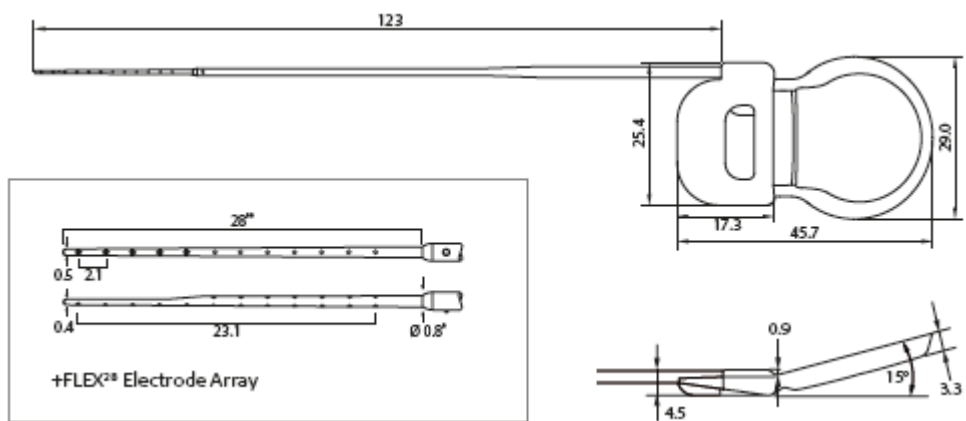
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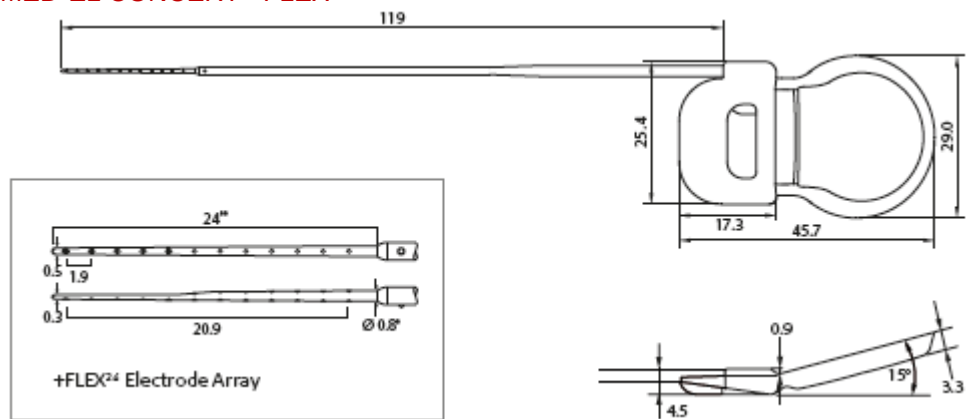
MED-EL CONCERT +FLEX^{SOFT}



MED-EL CONCERT +FLEX²⁸



MED-EL CONCERT +FLEX²⁴



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

INSTRUCTIONS FOR USE

Mi1000 MED-EL CONCERT Cochlear Implant

Device description

The Mi1000 MED-EL CONCERT Implant (hereafter referred to as MED-EL CONCERT) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family MED-EL CONCERT). This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).

For principal dimensions of the implant refer to the drawings on the previous pages.

The volume of the implant without electrode is 3.7 cm³.

Following materials are in direct contact with human tissue: medical grade silicone, platinum and iridium.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
Maximum current amplitude: Median value = 1250 µA, range = 500 µA
Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to the MED-EL Application Software User Manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm²

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+Standard	126 mm	1.3 × 1.3	0.5 × 0.5	0.14	0.14	2.4	26.4
+Medium	126 mm	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.9	20.9
+Compressed	126 mm	0.7 × 0.7	0.5 × 0.5	0.14	0.14	1.1	12.1
+FLEX ^{SOFT}	126 mm	1.3 × 1.3	0.5 × 0.4	0.13	0.14	2.4	26.4
+FLEX ²⁸	123 mm	0.8 × 0.8	0.5 × 0.4	0.13	0.14	2.1	23.1
+FLEX ²⁴	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Some implant electrode types mentioned in these Instructions for Use may not be released for distribution in all markets. Please contact your local MED-EL representative for information on current product availability in your country.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations 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.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

The MED-EL CONCERT shares the same indications for use as the COMBI 40+ System.

Bilateral deafness:

- 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 and 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 Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood 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.
- For bilateral deafness, MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- To obtain optimal benefit from the MED-EL CONCERT Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A pre-operative assessment according to the local professional standards must be conducted.
- Cochlear implants MED-EL CONCERT +Standard are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants MED-EL CONCERT +Medium are intended to be used in open cochleae (no obliteration or ossification) with mild malformation for an electrode insertion depth of about 24 mm as per request of the surgeon.
- Cochlear implants MED-EL CONCERT +Compressed are intended to be used in cochleae with moderate obliteration, ossification, or malformation for an electrode insertion depth of 15 mm as per request of the surgeon.
- Cochlear Implants MED-EL CONCERT +FLEX^{SOFT} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants MED-EL CONCERT +FLEX²⁸ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 28 mm.
- Cochlear implants MED-EL CONCERT +FLEX²⁴ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted with the MED-EL CONCERT Cochlear Implant:

- if the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, platinum iridium);
- if there is an absence of cochlear development;
- if the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways;
- if external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted;
- if there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required;
- if anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery;
- if the psychological status of the patient is unstable or
- if the patient has unrealistic expectations.

Additionally for SSD / AHL individuals should not be implanted,

- if individual has had profound hearing loss for over ten years
- if individual has an acoustic neuroma

Undesirable side-effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Clinical data supports cochlear implants as a treatment option for SSD and AHL if existing treatments do not work. Some SSD and AHL patients will benefit from Cochlear Implant (CI) implantation and the risks and benefits should be weighed by the clinician to determine if CIs are an appropriate treatment for each individual patient. All SSD and AHL patients should be offered rehabilitation. There is the potential perceptual inference of overlapping of acoustic and electric bilateral hearing which may lead to limited CI performance.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped¹ between -20 °C (-4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the “use by” date specified on the package. Packaging² should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness

which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.

- 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 case the MED-EL implant user wants to dive, the user should consult an experienced physician about the 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 50m (165ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis³ can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling the mastoidectomy, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that foudroyantly progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm. The stimulator should be recessed to a depth of maximum 2 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact. The anterior stimulator edge should not be recessed to a depth more than 2 mm.
- Additional immobilization of the implant needs to be done (e.g. with sutures). It should be done in such a way that there will be no postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

Recommended diameter of the cochleostomy & RW opening:

Electrode type	mm
MED-EL CONCERT +Standard	1.3 mm
MED-EL CONCERT +Medium	0.8 mm
MED-EL CONCERT +Compressed	0.8 mm
MED-EL CONCERT +FLEX ^{SOFT}	1.3 mm
MED-EL CONCERT +FLEX ²⁸	0.8 mm
MED-EL CONCERT +FLEX ²⁴	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.

- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear pre-surgically.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.
- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual..

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

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to Medical Procedures Manual.

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.

If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.

If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
MED-EL Elektromedizinische Geraete GmbH
Worldwide Headquarters
Safety adviser for the transport of dangerous goods
Fürstenweg 77a
6020 Innsbruck
Austria

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

UNC Feasibility Study Design

The feasibility study for the MED-EL Cochlear Implant System was conducted under IDE (G140050) to evaluate the safety and effectiveness of the MED-EL Cochlear Implant System in individuals 18 years of age and older with SSD or AHL. The primary study goal was to determine whether subjects with SSD or AHL demonstrated an improvement in speech perception, localization, and quality of life after receiving a cochlear implant. Both objective and subjective performance data were collected, as well as safety data in the form of adverse events. Forty subjects were implanted at the University of North Carolina at Chapel Hill with the MED-EL CONCERT or SYNCHRONY Cochlear Implant System in this prospective, single-site, non-randomized, non-blinded, repeated measures clinical study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in G140050 was limited to patients who met the following inclusion criteria:

- 18 years of age or older at the time of implantation
- Unilateral moderate-to-profound sensorineural hearing loss
 - o Unaided residual hearing thresholds measured from 250-8000 Hz (PTA $\geq$ 70 dB HL in the ear to be implanted)
 - o For SSD: normal to mild residual hearing thresholds from 250-8000 Hz in the contralateral ear ($\leq$ 35 dB HL at each frequency, 250-8000 Hz)
 - o For AHL: mild to moderate hearing thresholds from 250-8000 Hz in the contralateral ear (PTA $\geq$ 35 and $\leq$ 55 dB HL)
 - Aided word recognition of 80% or more as measured with CNC words (50-word list)
- Duration of moderate-to-profound sensorineural hearing loss less than or equal to 10 years
 - o Hearing loss for less than 10 years: study participants were only included if they had used a hearing aid consistently for 5 years
 - o Hearing loss for less than 5 years: study participants were only included if they had at least completed a 1-month hearing aid trial
- Previous experience (at least one month) with a current treatment option for SSD, including a conventional hearing aid, bone-conduction device, or CROS/BICROS technology
- Aided word recognition in the ear to be implanted of 60% or less as measured with CNC words (50-word list)
- Realistic expectations
- Willingness to obtain recommended meningitis vaccinations per CDC recommendations
- No reported cognitive issues: pass of the Mini Mental State Examination (MMSE) screener
- Ability and willingness to comply with study requirements, including travel to investigational site and study-related activities

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Non-native English speaker
- Conductive hearing loss in either ear
- Compromised auditory nerve, including those with a history of vestibular schwannoma
- Ossification
- Inability to participate in follow-up procedures (i.e., unwillingness, geographic location)
- History of meningitis, autoimmune disease, or any medical condition that contraindicate middle or inner ear surgery or anesthesia
- Meniere's disease with intractable vertigo
- Trauma that precludes inner ear surgery
- Case of sudden sensorineural hearing loss that has not been first evaluated by a physician
- Pregnancy
- Tinnitus as the primary purpose for seeking cochlear implantation
- Severe or catastrophic score on the Tinnitus Handicap Inventory

2. Follow-up Schedule

This study involved up to ten visits before and after implantation, for about a one-year period. Candidacy testing included medical and audiological evaluations (e.g., audiograms, speech recognition tests) to determine study eligibility. After confirming eligibility, the subject underwent baseline testing. The device was subsequently implanted based on the subject's candidacy testing. An initial follow-up visit was completed following surgery, and the cochlear implant was activated following a healing period of 2 to 4 weeks.

The baseline and postoperative measurements are summarized under 'Test Conditions' below. All patients were scheduled to return for follow-up examinations at 1, 3, 6, 9, and 12 months postoperatively. Pre-operatively and post-operatively, unaided air conduction thresholds were collected. At all intervals, speech perception in quiet and in noise and localization data was collected. Adverse events and complications were recorded at all visits.

The key timepoints (pre-op baseline and 12-months post-op) are shown below in the tables summarizing safety and effectiveness.

Test Conditions

The test battery was completed at the pre-operative interval and again at 1, 3, 6, 9, and 12 months post-operatively. For soundfield measures (speech perception and localization), a 180° arc with 11 speakers spaced 18° apart was utilized. Post-operative aided soundfield assessment was completed with the subject using the SONNET or OPUS 2 speech processor unless otherwise noted. For the AHL group, soundfield testing was completed with a hearing aid in the contralateral ear. See below for further details on testing conditions.

Subjects participated in two aural rehabilitation sessions with a board-certified speech-language pathologist. One session was completed after the initial activation of the external speech processor. The second session took place in conjunction with the 1-month post-initial activation interval.

- Unaided Diagnostic Assessment
 - o Air-conduction thresholds in both ears
 - o Assess bone-conduction thresholds if there is a PTA shift of >15 dB as compared to the previous interval
- Tympanometry for each ear
- Sound Field Measures
 - o Aided thresholds with the external speech processor on measured using pulsed, warble tones
 - Frequencies assessed: 250-8000 Hz
 - Masking presented to the contralateral ear
 - o Speech Perception Measures (recorded materials presented at 60 dB SPL)
 - Speech Perception in Quiet
 - Speech 0° azimuth
 - CNC words
 - AzBio sentences
 - Speech Perception in Noise
 - Speech and noise 0° azimuth
 - Speech 0° azimuth and noise to implanted side
 - Speech 0° azimuth and noise to contralateral ear
 - AzBio sentences
 - If >50% at SNR+10, then SNR+5; if >50% at SNR+5, then SNR0
 - BKB-SIN sentences with adaptive SNR
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
 - o Localization
 - 200-ms speech-shaped noise, presented at 70-dB SPL from one of the 11 speakers (evenly spaced -180 to 180 degrees), selected at random
 - Intensity level for each stimulus presentation randomly varied (10 dB around 70 dB SPL)
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
- Subjective questionnaires
 - o Speech, Spatial and Qualities of Hearing Scale (SSQ)
 - o Abbreviated Profile of Hearing Aid Benefit (APHAB)
 - o Tinnitus Handicap Inventory (THI)

3. Clinical Endpoints

Measures

Safety Measure: The primary safety measure was the evaluation of all adverse events reported within 12 months. The full profile of adverse events was summarized and considered, with specific attention given

to device-related adverse events. The adverse events include anticipated and unanticipated adverse events. The list of anticipated adverse device effects noted in the study protocol are as follows:

- Risks from the SYNCHRONY IFU
 - o Loss of residual hearing
 - o Increased vertigo
 - o Delay of healing of the scar
 - o Impairment of the sense of taste
 - o Potential for swallowing difficulties
 - o Numbness
 - o Increased tinnitus
 - o Stimulation of the facial nerve
 - o Temporary pain and uncomfortable sounds during stimulation
- Additional surgical risks
 - o Facial nerve injury
 - o Infection
 - o Bleeding
 - o Cerebrospinal fluid (CSF) leak
 - o Pain
 - o Scarring
- Additional post-operative risks
 - o Swelling around the incision and/or coil site
 - o Pain
 - o Reduced or loss of pinna sensitivity on the surgical side
 - o The cochlear implant may not provide any auditory stimulation
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in the perception of speech
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in localization
 - o Pain associated with the coil and/or placement of the external speech processor on the subject's ear
 - o Movement of the internal receiver
 - o Discomfort from electric stimulation
 - o Facial nerve stimulation
 - o Headache
 - o Dizziness
 - o Altered taste (i.e. reports of metallic tastes on the same side of the tongue as the surgical ear)
 - o Fatigue during follow-up assessment (completion of the test battery and/or mapping)
 - o The internal device may fail, requiring revision cochlear implantation
 - o The sound from the cochlear implant may interfere with the better hearing ear.

Effectiveness Measures: The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition. Aided speech perception performance on word and sentence materials at the post-activation intervals was evaluated to monitor trends over time. Unaided and aided (with BCHA or CI, as applicable) localization performance was also compared pre-operatively and at each of the post-activation intervals. The overall RMS error is reported for localization in each condition. Additionally, subjective report scores were compared pre-operatively and at the 12-month post-activation intervals.

Audiometric Test Methods & Effectiveness Measures

Speech perception and localization measures were recorded in a research lab that featured a 180° arc with 11 speakers spaced 18° apart. Postoperative aided sound field assessment was completed with the study participant listening with the OPUS 2 or SONNET speech processor.

Speech perception in quiet was tested at 0° azimuth, presenting CNC words (Peterson & Lehiste, 1962) or AzBio sentences (Spahr et al., 2012) at 60 dB SPL. Speech perception in noise was tested in the conditions (1) speech and noise 0° azimuth (S0N0), (2) speech 0° azimuth and noise to the affected ear/implanted side (S0NCI), and (3) speech 0° azimuth and noise to the contralateral ear (S0NContra). AzBio sentences were presented at 0 dB signal-to-noise ratio (SNR) in most cases. BKB-SIN sentences were presented with adaptive SNR.

For the localization task a 200-ms speech-shaped noise was presented at 70-dB SPL from one of the 11 speakers (selected randomly). The intensity level for each stimulus presentation was randomly varied (10 dB around 70 dB SPL). The listener was facing the center speaker during stimulus presentation and the task was to identify the source of the noise. No feedback was provided. In the condition cochlear implant speech processor OFF, study participants were only listening with the contralateral ear. In the condition cochlear implant speech processor ON, sound was perceived both via the cochlear implant and the contralateral ear.

Subjective data was collected via the SSQ and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995). The SSQ can be further divided into three subscales: speech, spatial, and quality. The APHAB consists of four subscales: Ease of Communication (EC), Background Noise (BN), Reverberation (RV), and Aversiveness (AV). The Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996) was also utilized to collect information on severity of tinnitus pre-operatively as well as at the 12-month interval.

B. Accountability of Study Cohort

In the SSD cohort, 20 subjects were enrolled and completed testing through the 12-month interval. In the AHL cohort, 20 subjects were enrolled and 18 completed testing through the 12-month interval. One subject in the AHL cohort withdrew prior to completion of all test intervals, and one subject was still undergoing follow-up testing at the time of data analysis.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a feasibility study performed in the US. Proportions enrolled are consistent with the age, sex/gender, racial and ethnic prevalence of the SSD and AHL.

1. SSD Cohort

Of the 20 implanted subjects, 12 were female and 8 were male. At the time of implantation, subjects ranged in age from 22 to 66 years of age. The duration of profound hearing loss ranged from 0.1 to 6.6 years. Fifteen subjects experienced sudden hearing loss and five subjects experienced a gradual hearing loss. Hearing loss was reported as unknown in 16 cases, due to Meniere's disease in three subjects, and caused by trauma in one case. Further information on subject demographics and hearing related variables is summarized in Table 2 below.

Table 2. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=20)
Gender	
Male	40% (8/20)
Female	60% (12/20)
Age (years)	50 (20) (22 – 66)
Duration of hearing loss (years)	
Noticeable	4.2 (20) (0.1 – 14.6)
Profound	2.6 (20) (0.1 – 6.6)
Implanted ear	
Left	55% (11/20)
Right	45% (9/20)
Tinnitus Handicap Grade Level	
Slight	35% (7/20)
Mild	40% (8/20)
Moderate	25% (5/20)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

2. AHL Cohort

Of the 18 subjects who completed follow-up, 9 were female and 9 were male. At the time of implantation, subjects ranged in age from 52 to 79 years of age. The duration of profound hearing loss ranged from 0.0

to 9.8 years. Ten subjects experienced sudden hearing loss and six subjects experienced a gradual hearing loss, with the remaining two subjects experiencing both a gradual and sudden loss. Hearing loss was reported as unknown in 14 cases, due to Meniere's disease in two subjects, due to noise-induced hearing loss in one subject, and caused by viral infection in one case. Further information on subject demographics and hearing related variables is summarized in Table 3 below.

Table 3. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=18)
Gender	
Male	50% (9/18)
Female	50% (9/18)
Age (years)	70 (18) (52 – 79)
Duration of hearing loss (years)	
Noticeable	11.5 (17) (0.0 – 51.5)
Profound	3.5 (17) (0.0 – 9.8)
Implanted ear	
Left	67% (12/18)
Right	33% (6/18)
Tinnitus Handicap Grade Level	
Slight	55% (10/18)
Mild	28% (5/18)
Moderate	17% (3/18)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on all patients implanted under G140050 (N=40) up to 12 months post implantation. Table 4 displays the adverse events reported for this study.

Adverse effects that occurred in IDE G140050:

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated. A total of nine adverse events were reported to be related to the device or procedure. An additional six adverse events were not able to be ruled out as device or procedure-related. No serious, unanticipated, device-related adverse events were reported.

Table 4. Number and percentage of adverse events observed for SSD subjects.

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects
Vertigo/dizziness/imbalance	11	9	22.5%
Unrelated infection	3	3	7.5%
Changes in sound quality/volume	3	2	5%
Depression	3	2	5%
Aural pressure	2	2	5%
Facial stimulation	2	2	5%
Headache	2	2	5%
Atrial fibrillation	1	1	2.5%
Bleeding at surgical site	1	1	2.5%
Electrode contact dislodged	1	1	2.5%
Fall involving bump to the implant	1	1	2.5%
Type C tympanogram	1	1	2.5%
Short circuit	1	1	2.5%
Total	32	21*	52.5%

*Some subjects experienced more than one device-related adverse event

The most frequently observed adverse event was vertigo, dizziness, or imbalance, which was reported a total of 11 times. In four cases, the event was deemed unrelated to the device or procedure. In three cases, it could not be ruled out that the event was related to the device or procedure. In the remaining four cases, it was determined that the event was related to the procedure. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. In all cases, the event was deemed unrelated to the device or procedure. All other events occurred at a rate of 5% or less (2 subjects or fewer), which is consistent with the rate of adverse events observed for the approved indication of bilateral, severe-to-profound, sensorineural hearing loss.

2. Effectiveness Results

The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition among 20 subjects with SSD and 17 subjects with AHL. Additionally, subjective reports from the SSQ and APHAB were also compared pre-operatively and at the 12-month post-operative interval.

Speech Perception in Quiet

SSD Cohort

Speech perception testing in quiet at the 12-month interval demonstrated an improvement in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. In the contralateral ear, no change was observed on CNC words from baseline to 12 months. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet across test intervals. The comparison of AzBio sentence score in quiet with a BCHA to scores at 12 months with the CI-ON also demonstrated no change. Table 5 displays the descriptive statistics of the speech perception in quiet scores for the SSD cohort.

Table 5. Speech perception in quiet (SSD Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	20	20	20	20	20	20	20
Mean (SD)	3.5 (6.68)	54.6 (18.15)	99.3 (2.27)	99.8 (0.62)	99.0 (1.56)	99.2 (1.15)	99.5 (1.19)
Min – Max	0 - 22	10 - 84	90- 100	98 - 100	95 - 100	95 – 100	95 - 100

AHL Cohort

For the cohort with asymmetric hearing loss, an improvement was demonstrated for speech perception testing in quiet at the 12-month interval in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. No change was observed on CNC words from baseline to 12 months in the contralateral ear. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet between the pre-operative and 12-month intervals. Additionally, no change was demonstrated in the comparison of AzBio sentence score in quiet between BCHA pre-operatively and 12 months with the CI-ON. See Table 6 below for the descriptive statistics of the speech perception in quiet scores.

Table 6. Speech perception in quiet (AHL Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	18	18	18	18	18	18	18
Mean (SD)	6.3 (7.98)	56.2 (18.41)	94.2 (7.06)	92.7 (8.68)	87.4 (13.96)	87.7 (11.01)	94.3 (8.38)
Min – Max	0 - 22	28 - 86	78 – 100	72 - 100	50 - 99	(61 – 99_	72 - 100

Speech Perception in Noise

SSD Cohort

On AzBio sentence testing in noise, subjects in the SSD cohort demonstrated an improvement between the bilateral, baseline, pre-operative, unaided testing and the bilateral, 12-month post-operative, CI + NH testing in the speech front, noise front condition. This same improvement was also noted between the bilateral, baseline, pre-operative, aided (with BCHA) condition and the bilateral, 12-month, post-operative, CI + NH condition. NO differences were found between pre-operative unaided and pre-operative, aided (with BCHA) scores. In the speech front, noise to the CI ear condition, subjects demonstrated no change in score in comparing the pre-operative interval to the CI-ON at 12 months. However, when comparing the pre-operative aided scores to the 12-month scores with CI, an improvement in performance was noted. Better scores were obtained for the pre-operative unaided condition as compared to the pre-operative aided condition.

A significant improvement was noted with the cochlear implant on at 12 months post-operative compared to the pre-operative, unaided interval for the speech front, noise to the contralateral ear condition. This same improvement was also found when comparing CI-ON at the 12-month, post-operative condition to the pre-operative, aided (with BCHA) condition. This improvement demonstrates that when noise presents as a masker to the better hearing ear, the cochlear implant provides benefit in speech understanding. Table 7 provides further details on AzBio sentence in noise scores.

Table 7. Speech perception in noise (SSD Cohort, AzBio)

SSD AzBio	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	37.5 (10.98)	31.5 (16.56)	47.2 (10.72)	83.4 (9.51)	61.25 (27.92)	85.0 (11.04)	16.5 (12.78)	18.3 (13.50)	52.6 (21.43)
Min- Max	20 - 64	0 – 59	29 - 68	59 - 94	0 – 98	60 - 97	0 - 45	0 – 59	8 - 86

A similar pattern was noted for speech in noise testing on the BKB-SIN. No significant changes were found in any comparisons for the speech front, noise front or speech front, noise to the CI ear conditions. However, in the speech front, noise to the contralateral ear condition, it was found that the CI does provide benefit in speech perception, and thus, a significant improvement was found when comparing the 12-month, post-operative CI + NH condition to the pre-operative, unaided condition or to the pre-operative, aided (with BCHA) condition. Table 8 provides the detailed descriptive statistics of the BKB-SIN scores.

Table 8. Speech perception in noise (SSD Cohort, BKB-SIN)

SSD BKB- SIN	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	0.1 (1.42)	0.8 (1.98)	-0.8 (1.74)	-4.8 (1.64)	-2.6 (2.39)	-4.8 (1.66)	1.8 (1.33)	1.8 (2.35)	-1.0 (2.20)
Min- Max	-2.5 – 3.0	-2.5 – 4.5	-3.0 – 4.0	-7.5 – -1.5	-7.0 – 1.0	-7.5 – -2.0	-0.5 – 4.0	-2.5 – 8.0	-5.0 – 5.5

AHL Cohort

For the AHL cohort, the majority of subjects were tested at 0 dB SNR. However, some subjects were tested at +5 or +10 dB SNR according to a decision tree implemented for determining SNR. Pre-operative and post-operative comparisons within subject were done at the same SNR. For this reason, only 17 subjects are included in the AzBio analysis for both the pre-operative unaided/aided (with BCHA) condition and the 12-month post-operative CI + HA condition.

In the speech front, noise front condition, a significant improvement was found on AzBio sentences for the 12-month, post-operative CI + HA condition compared to the pre-operative, unaided condition and compared to the pre-operative, aided (with BCHA) condition. Pre-operative, BCHA scores were worse than pre-operative unaided scores and worse than 12-month, post-operative CI + HA scores in the speech front, noise to the CI ear condition. In the speech front, noise to the contralateral ear condition, a signifi-

cant improvement was noted for the 12-month, post-operative CI + HA testing compared to both the pre-operative, unaided testing and the pre-operative, aided (with BCHA) testing. Table 9 below displays the descriptive statistics of the AzBio testing for the AHL Cohort.

Table 9. Speech perception in noise (AHL Cohort, AzBio)

AHL AzBio	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	17	17	17	17	17	17	17	17	17
Mean (SD)	22.7 (13.95)	20.5 (12.86)	33.5 (22.10)	44.2 (17.70)	30.5 (18.23)	44.6 (24.74)	6.3 (9.49)	11.3 (16.69)	29.4 (22.59)
Min- Max	0 – 47	0 – 47	3 – 85	9 – 78	1 – 70	5 – 94	0 – 36	0 – 66	1 – 95

For BKB-SIN testing, no changes were demonstrated in the speech front, noise to the CI ear condition. An improvement was found between the pre-operative, aided (with BCHA) condition and the 12-month, post-operative CI + HA condition in the speech front, noise front condition. Similar to the AzBio test results for the SSD cohort, there was a significant improvement for BKB-SIN in the speech front, noise to the contra-lateral ear condition when comparing the 12-month, post-operative CI + HA condition to the pre-operative, unaided condition. Table 10 below displays the analyses of BKB-SIN testing in the AHL cohort.

Table 10. Speech perception in noise (AHL Cohort, BKB-SIN)

AHL BKB- SIN	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	18	18	18	18	18	18	18	18	18
Mean (SD)	4.3 (3.62)	5.1 (3.04)	3.7 (3.28)	1.3 (3.89)	2.5 (3.77)	2.6 (3.78)	7.1 (4.14)	5.9 (4.50)	4.6 (4.44)
Min- Max	0.5 – 13.0	0 – 10	-2.0 – 9.5	-6.5 – 8.5	-3.5 – 10.0	-3.5 – 9.0	2.0 – 15.5	0 – 14.5	-1.0 – 15.5

Localization

SSD Cohort

Subjects in the SSD cohort demonstrated a significant improvement in localization performance with the CI at 12 months compared to the baseline, aided (with BCHA) condition. Additionally, results indicated an improvement in performance between the baseline, unaided condition and the 12-month, postoperative CI + NH condition. Table 11 displays localization performance in RMS error.

Table 11. Localization performance (SSD Cohort)

SSD Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	20	20	20
Mean (SD)	66.5 (20.47)	69.6 (18.71)	26.7 (6.32)
Min-Max	42.9 – 109.1	45.3 – 106.1	13.6 – 38.4

AHL Cohort

Similar to the SSD cohort, subjects in the AHL cohort demonstrated improved localization performance with the CI-ON at 12 months compared to the baseline, aided (with BCHA) condition. This improvement was also evident when comparing the 12-month, postoperative CI + HA to the pre-operative, unaided condition. Table 12 displays the analyses of the AHL Cohort's localization data.

Table 12. Localization performance (AHL Cohort)

AHL Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	18	18	18
Mean (SD)	76.5 (19.23)	77.2 (18.89)	40.1 (10.65)
Min-Max	43.8 – 105.3	45.6 – 106.5	26.6 – 73.6

Subjective Questionnaire

SSD Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the CI on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 13 below for the descriptive statistics of the SSQ.

Table 13. SSQ (SSD Cohort)

SSD SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20
Mean	3.7	7.1	2.4	6.5	5.6	7.7
Std. Deviation	1.34	0.99	1.2	1.86	2.09	1.28
Minimum	0.6	5.4	0.5	2.8	0.5	5.6
Maximum	7.2	8.9	4.5	8.9	9.8	9.8

Self-perceived benefit from the CI as reported on the APHAB demonstrated significant improvement on global score and the subscales, except for the aversiveness subscale. Table 14 below provides the detailed APHAB scores at the pre-operative and 12-month intervals.

Table 14. APHAB (SSD Cohort)

SSD APHAB	Global		EC		BN		RV		AV	
	pre	12m	Pre	12m	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20	20	20	20	20
Mean	49.8	17.9	31.6	8.7	70.1	25.2	47.5	19.7	43.1	26.7
Std. Deviation	18.65	8.91	21.06	6.15	17.32	11.95	21.96	12.43	28.64	24.83
Minimum	20.3	6.1	2.8	1.0	39.3	10.2	18.7	2.8	1.0	1.0
Maximum	86.3	36.7	81.0	24.8	95.0	56.2	87.0	41.7	93.0	91.0

AHL Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the cochlear implant on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 15 below for detailed information on the SSQ.

Table 15. SSQ (AHL Cohort)

AHL SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	18	18	18	18	18	18
Mean	3.2	5.8	2.6	6.0	4.6	6.8
Std. Deviation	1.48	1.50	1.26	1.62	1.77	1.20
Minimum	0.4	3.6	0.3	3.1	0.2	4.4
Maximum	6.0	8.9	4.7	8.5	8.3	8.7

Self-perceived benefit from the cochlear implant as reported on the APHAB demonstrated significant improvement on global score and other subscales over time except the aversiveness subscale. Table 16 below displayed the detailed APHAB scores at the pre-operative and 12-month post-operative intervals.

Table 16. APHAB (AHL Cohort)

AHL APHAB	Global		EC		BN		RV		AV	
	pre	12m	pre	12m	pre	12m	Pre	12m	pre	12m
N	18	18	18	18	18	18	18	18	18	18
Mean	54.1	28.1	42.9	16.6	63.5	39.3	56.0	28.3	43.1	42.4
Std. Deviation	16.21	10.49	24.67	13.01	16.84	17.10	18.30	11.96	35.04	29.21
Minimum	20.0	11.3	10.2	1.0	14.5	14.5	14.2	12.0	1.0	1.0
Maximum	92.3	54.1	91.0	54.0	95.0	66.3	97.0	54.2	99.0	97.0

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Literature Search Strategy

MED-EL conducted an extensive literature search to collect additional supporting clinical evidence of cochlear implants in SSD and/or AHL indications. The search terms they used are listed in Tables 17, 18, and 19, below.

Table 17. Combinations of Search Terms

Search Step	Search Terms	Review Question
1	"hearing loss" OR deaf*	P
2	single sided deafness OR SSD OR unilateral OR UHL OR asymmetric* OR AHL	P
3	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment" OR bone conduction OR BCI OR bone anchored OR BAHA OR CROS OR contralateral routing OR BiCROS OR "transcranial CROS" OR in-the-mouth device OR ITM OR soundbite OR bone-bridge OR "ad hear"	I & C
4	1 AND 2 AND 3	
5	Limit 4 to <i>Humans</i>	
6	Limit 5 to <i>Language</i> : English	
7	Limit 6 to <i>Publication date</i> : June, 2014 to May, 2017	

Search Step	Search Terms	Review Question
1	(single sided deafness) OR ((((((SSD) OR unilateral) OR UHL) OR asymmetric) OR AHL)) AND (((hearing loss) OR deaf*) OR deafness))	P
2	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment"	I & C
3	1 AND 2	
4	Limit 3 to <i>Humans</i>	
5	Limit 4 to <i>Language</i> : English	
6	Limit 5 to <i>Publication date</i> : May 1, 2017 to March 6, 2019	

Note. The different search terms are connected using Boolean logic. Activated filters are displayed in italics. P = Population, disease, or condition; I = Intervention; C = Comparator group or control.

* Wildcard symbol to broaden the search by creating a root word search.

Table 18. Inclusion and Exclusion Criteria for Retrieved Literature

Inclusion Criteria	
Population/Problem	Patients of any age who have single sided deafness
Intervention/Treatment	cochlear implant, any other treatment that makes hearing possible, or no treatment
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Inclusion Criteria	
Population/Problem	Patients of any age who have SSD or AHL
Intervention/Treatment	cochlear implant
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population e.g. different type of hearing loss
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Table 19. Literature Appraisal Criteria

Data Suitability	Description	Grading System
Appropriate Device	Where the data generated from the device in question?	D1 – Actual device D2 – Comparable device D3 – Other device
Appropriate Device Application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 – Same use A2 – Minor deviation A3 – Major deviation
Appropriate Patient Group	Were the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease including state and severity)?	P1 – Applicable P2 – Limited P3 – Different population
Acceptable Report/Data Collation	Did the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 – High quality R2 – Minor deficiencies R3 – Insufficient information
Data Contribution	Description	Grading System
Data Source Type	Was the design of the study appropriate?	T1 – Yes T2 – No
Outcome Measures	Did the outcome measures reported reflect the intended performance of the device?	O1 – Yes O2 – No
Follow-Up	Was the duration of the follow-up long enough to assess treatment effects and identify complications?	F1 – Yes F2 – No
Statistical Significance	Was a statistical analysis of the data provided and appropriate?	S1 – Yes S2 – No
Clinical Significance	Was the magnitude of the treatment effect observed clinically significant?	C1 – Yes C2 – No

Published Literature on Children

The literature search yielded five peer-reviewed papers in SSD and/or AHL children with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults and children aged 5 yrs and older. The papers comprise a total of 26 children with SSD (five of which were reported to be implanted with MED-EL devices) and a total of nine children with AHL. Tables 17, 18, and 19 above list the detailed literature search criteria and relevant information.

The overall benefits of CI in children with SSD and AHL include improved performance in speech perception in quiet and noise, sound localization and subjective measures of quality of life.

Word recognition in quiet:

Beck et al. (2017) reported diverse speech audiometry results. Some of the children showed measurable benefits on speech discrimination. The CAP scores improved for the SSD children (N = 8) with CI compared to preoperative performance. Rahne and Plontke (2016) reported that two SSD children improved with CI over time in number recognition, two SSD children showed no recognition. One child improved over time in word recognition with CI, whereas the other three children showed no recognition.

Word recognition in noise:

Arndt et al. (2015) reported on the speech perception in noise for different speech and noise configuration. Children with SSD demonstrated improved although variable performance on speech perception in spatially-separated conditions. Some children demonstrated improvement in spatially separate speech and noise. Tavora-Vieira and Rajan (2015) showed better and similar speech perception in noise with CI-on compared to CI-off for two SSD children. Gratacap et al. (2015) showed an increase in speech perception in noise in 9 children with AHL after 12 and 24 months of CI use compared to preoperative performance. Rahne and Plontke (2016) reported an improvement in speech reception thresholds in three SSD children when CI-on and CI-off are compared; in one child no measurement was possible.

Sound localization:

Arndt et al. (2015) reported a decreased localization error with CI for most of the children as compared to the preoperative unaided condition. Tavora-Vieira and Rajan (2015) reported that one child with SSD showed a de-

creased localization error after 6 and 12 months with the CI-on compared to CI-off condition, whereas the other child with SSD showed the same localization performance in both conditions. Rahne and Plontke (2016) reported an improvement in sound localization in four children with SSD when CI-on and CI-off are compared.

Subjective measures:

Beck et al. (2017) showed that the parents (N = 9) and children (N = 3) with SSD reported an increase score for the SSQ. Arndt et al. (2015) reported an increase the SSQ score in children with SSD with postlingual onset of deafness (N = 9), slight improvement in children with SSD with perilingual onset of deafness (N = 2) and minimal improvement or same performance in children with SSD who are congenitally deaf (N = 2).

Published Literature on Adults

The literature search yielded six peer-reviewed papers in SSD and/or AHL adults with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults. Although the paper by Kitoh et al. (2016) mentioned a study inclusion criterion of PTA > 70 dB HL, all five subjects included in the study had a pre-operative unaided PTA of 92 dB HL or higher. Hence, the results from this study were included in the summary below.

The six papers comprise a total of 58 adults with SSD (N = 50 of which implanted with MED-EL devices) and a total of 52 adults with AHL (N = 37 of which implanted with MED-EL devices). This subject count does not include five SSD nor 16 AHL patients from Skarzynski et al. (2017), as those subjects are part of the larger cohort from the same implant center later reported on by Lorens et al. (2019). Also note that three of the 58 adult SSD subjects might have an unaided PTA close to or below 90 dB HL in the implanted ear, as the paper by Döge et al. (2017) presents PTA data as median and interquartile range only (75%, i.e. N = 8 of 11 studied subjects have PTA > 100 dB HL).

The overall benefits of CI in SSD and AHL adult patients include improved performance regarding speech perception in quiet and in noise, sound localization and subjective measures regarding quality of life, music enjoyment and tinnitus.

Word recognition in quiet

Döge et al. (2017) showed that with a CI, the mean PTA thresholds of the deaf ear improved from the mean value of 120 dB at unaided condition to below 40 dB in the aided condition in 11 SSD subjects. In addition to the benefit of sound perception, the CI enabled better speech perception in quiet. Skarzynski et al. (2017) compared CI-on vs CI-off condition in 5 SSD and 16 AHL subjects and significantly better speech perception was observed in the CI-on condition. Results with the CI demonstrated a continuous improvement in speech recognition after 12-month of use. Rahne and Plontke (2016) reported a significant improvement in monosyllabic word and multisyllabic number recognition in quiet in comparing the 12-month and 1-month after CI activation in 17 SSD subjects. van Loon et al. (2017) reported that speech recognition scores increased from 74% pre-operatively to 88% at 12-month with bimodal stimulation in 7 AHL cases.

Speech perception in noise

Several studies found that the CI enabled better speech perception in noise. Rahne and Plontke (2016) reported a significant improved speech perception in noise at 3-month of CI activation with CI-on vs CI-off condition, and a continuous improvement occurring at 12-months in 17 SSD subjects. Skarzynski et al. (2017) reported better speech perception in noise at CI-on vs CI-off condition. van Loon et al. (2017) reported that in comparison to the CI-off or CI-only condition, bimodal stimulation resulted in significantly better speech recognition in noise and spatial speech recognition at 3-months, 6-months and 12-months post-activation. Lorens et al. (2019) reported a significant binaural benefit conveyed by CI-on in comparison to the CI-off condition, in 25 SSD and 45 AHL subjects. Kitoh et al. (2016) reported a gradually improved speech perception in noise after 12-months post-activation in comparison to the pre-operative condition. Döge et al. (2017) reported slightly improved speech reception in noise in CI-on vs CI-off condition in 8 of 11 patients. Three of 11 subjects, however, showed deteriorations at CI-on condition.

Sound localization

Döge et al. (2017) showed a significant decrease of localization error in the CI-on condition in comparison with the CI-off condition in 11 SSD subjects. Skarzynski et al. (2017) observed a significant localization benefit reflected by decrease in RMS angular error at CI-on vs CI-off condition. van Loon et al. (2017) reported a significant improved localization performance in all 7 AHL subjects with bimodal stimulation at 12-month in comparison to the pre-operative condition. Results with the CI demonstrated a continuous improvement in sound localization after 12 months of CI use. Rahne and Plontke (2016) reported that in comparison to CI-off, CI-on significantly improved

sound localization, reflected by a decrease in ADE (angular detection error) at 1-month of CI activation. A continuous improvement occurred over time. Kitoh et al. (2016) reported better sound localization in all 5 subjects, with continuous improvement through 12-month.

Subjective measures

van Loon et al. (2017) reported increased frequency and satisfaction of listening to music from 7 AHL CI users. Bimodal stimulation also resulted in better quality, clarity, and appreciation of different music styles. Skarzynski et al. (2017) reported substantial tinnitus suppression in all 15 patients with pre-operative tinnitus and Kitoh et al. (2016) reported decreased disturbance to daily life caused by tinnitus in all 5 SSD cases. Two studies addressed self-evaluation of CI performance in SSD and AHL subjects. Skarzynski et al. (2017) reported a significant improvement in the global score of APHAB, as well as sub-scales including 'Ease of communication', hearing under 'background noise' or under 'reverberation' at 14-months after CI activation in comparison to pre-operative condition. van Loon et al. (2017) reported that except for the 'speech production' subdomain, bimodal stimulation yielded a significant better outcome for all other subdomains of the NCIQ questionnaire. An average appreciation of the cochlear implant was scored 4.3/5, indicating a high satisfaction with the CI.

Conclusions from Real World Evidence

This clinical evaluation of cochlear implantation for the treatment of SSD and AHL is based on the above literature data sets relevant to the safety, performance, and effectiveness of cochlear implantation as a treatment option for individuals with AHL or SSD.

In this review of Real-World data, the latest clinical data were summarized on SSD and AHL patients from centers both in the US and around the globe that meet the proposed audiometric indication criterion of a profound hearing loss in the ear to be implanted, i.e., a PTA of 90 dB or higher. The clinical populations reported on include both adults and children older than 5 years age.

Taken together, the clinical data from this body of literature show consistent benefits of CI in individuals with SSD or AHL, in terms of improved speech perception in noise, spatial hearing, localization accuracy, and patient-reported subjective outcome measures. Consistent CI use of patients has been shown across literature reports, and notably so in the prospective study by Lorens et al. (2019) in 70 sequentially implanted SSD and AHL CI users (59 of which were implanted with MED-EL devices). These literature data provide Real World Evidence (according to the FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices") in support of the clinical benefits of CI in SSD and AHL recipients, as demonstrated in the UNC study. In this way, these literature reports do serve as supporting evidence which demonstrates a reasonable assurance of device safety and effectiveness and to characterize the benefit/risk profiles for the proposed SSD/AHL indications.

Symbols



CE mark. First applied in 2010



Single-use device. Do not reuse!



Catalogue number



Serial number



Caution! Consult accompanying documents



Sterilised using Ethylene Oxide



"Use by" date



Manufacturing date



Manufacturer



MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

- 1 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).
- 2 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.
- 3 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

USA Distributor:
MED-EL Corporation
2645 Meridian Parkway
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.



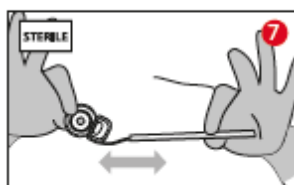
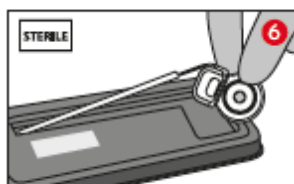
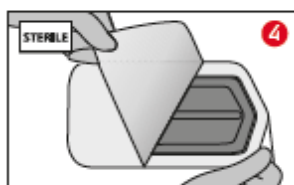
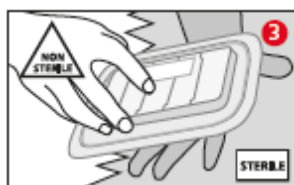
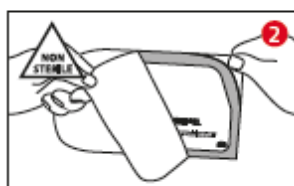
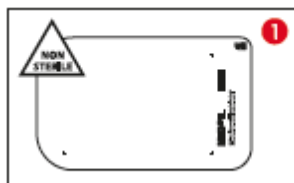
MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a | 6020 Innsbruck, Austria
office@medel.com

medel.com

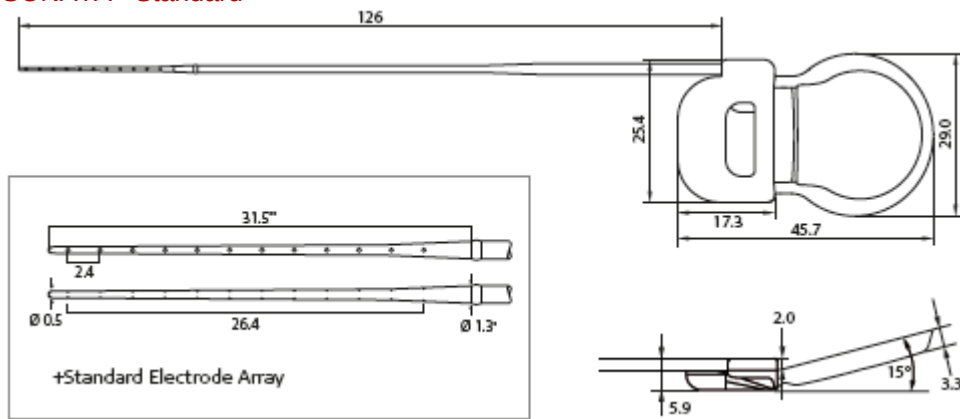
SONATA¹⁰⁰_{TI} Cochlear Implant

+Standard | +Medium | +Compressed | +FLEX^{SOFT} | +FLEX28 | +FLEX24

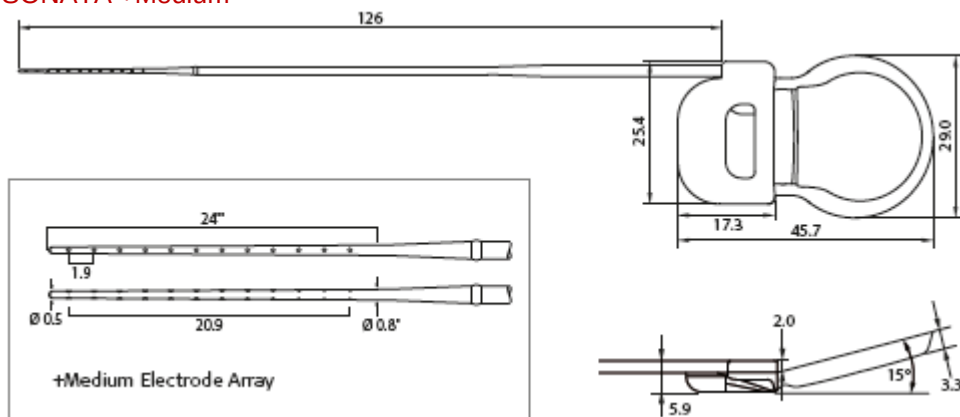
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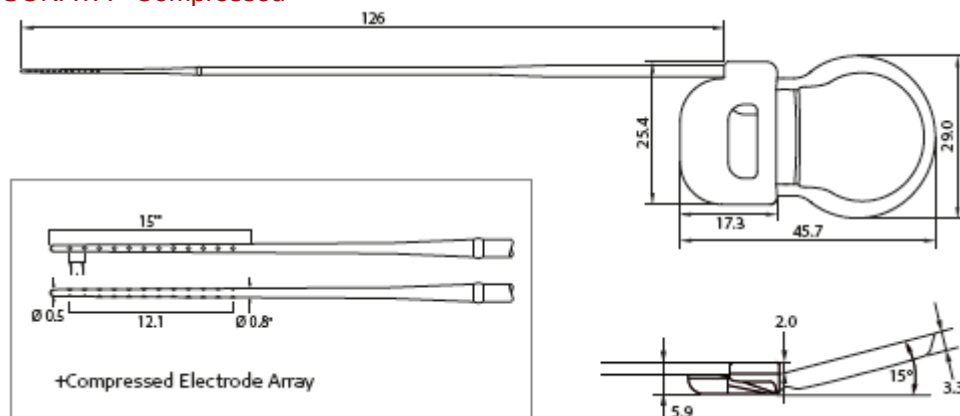
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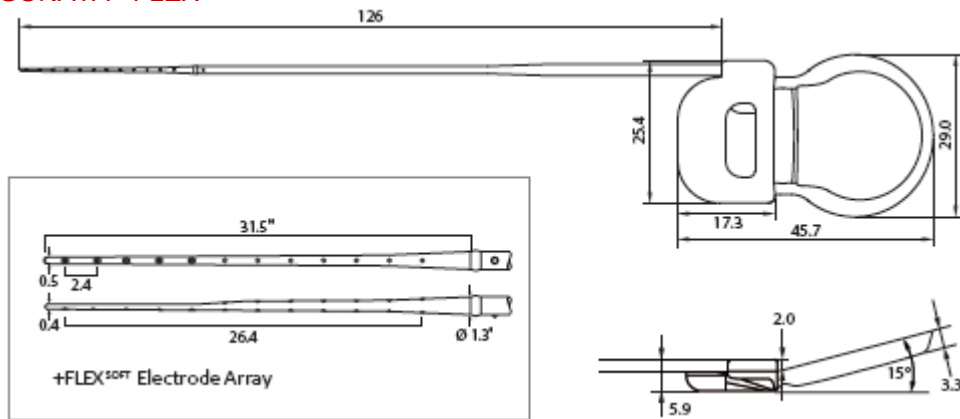
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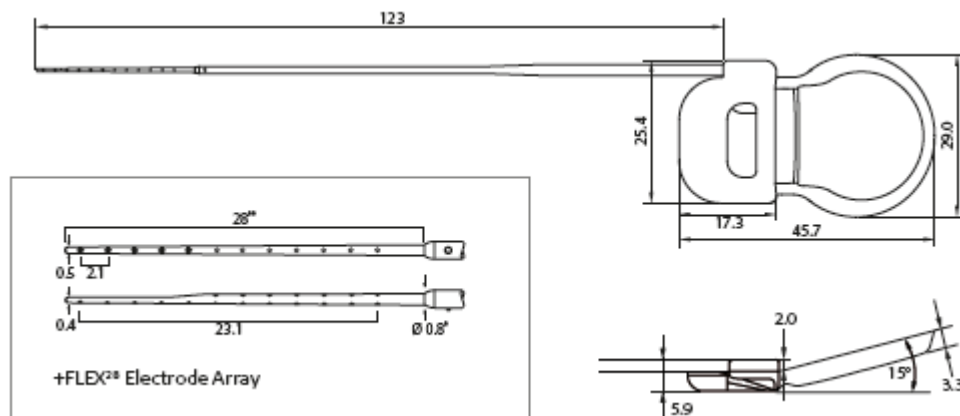
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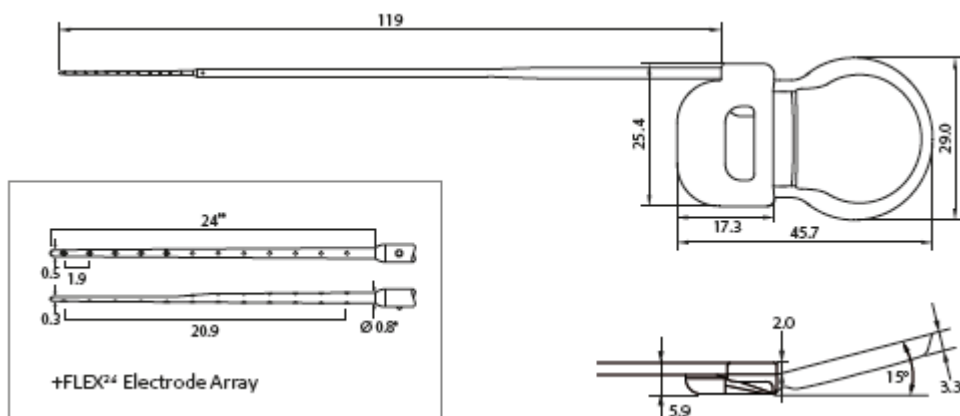
SONATA +FLEX^{SOFT}



SONATA +FLEX²⁸



SONATA +FLEX²⁴



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

INSTRUCTIONS FOR USE

SONATA Cochlear Implant

Device description

The SONATA¹⁰⁰ Implant (hereafter referred to as SONATA) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SONATA). This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 8.6 g (typical weight).

For principal dimensions of the implant refer to the drawings on the previous pages.

The volume of the implant without electrode is 4.2 cm³.

Following materials are in direct contact with human tissue: medical grade silicone, platinum and iridium.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
Maximum current amplitude: Median value = 1250 µA, range = 500 µA
Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to the MED-EL Application Software User Manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm²

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+Standard	126 mm	1.3 × 1.3	0.5 × 0.5	0.14	0.14	2.4	26.4
+Medium	126 mm	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.9	20.9
+Compressed	126 mm	0.7 × 0.7	0.5 × 0.5	0.14	0.14	1.1	12.1
+FLEX ^{SOFT}	126 mm	1.3 × 1.3	0.5 × 0.4	0.13	0.14	2.4	26.4
+FLEX ²⁸	123 mm	0.8 × 0.8	0.5 × 0.4	0.13	0.14	2.1	23.1
+FLEX ²⁴	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Some implant electrode types mentioned in these Instructions for Use may not be released for distribution in all markets. Please contact your local MED-EL representative for information on current product availability in your country.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations 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.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

The SONATA shares the same indications for use as the COMBI 40+ System.

Bilateral deafness:

- 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 and 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 Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood 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.
- For bilateral deafness, MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- To obtain optimal benefit from the SONATA Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A pre-operative assessment according to the local professional standards must be conducted.
- Cochlear implants SONATA +Standard are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants SONATA +Medium are intended to be used in open cochleae (no obliteration or ossification) with mild malformation for an electrode insertion depth of about 24 mm as per request of the surgeon.
- Cochlear implants SONATA +Compressed are intended to be used in cochleae with moderate obliteration, ossification, or malformation for an electrode insertion depth of 15 mm as per request of the surgeon.
- Cochlear Implants SONATA +FLEX^{SOFT} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants SONATA +FLEX²⁸ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 28 mm.
- Cochlear implants SONATA +FLEX²⁴ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted with the SONATA Cochlear Implant:

- if the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, platinum iridium);
- if there is an absence of cochlear development;
- if the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways;
- if external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted;
- if there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required;
- if anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery;
- if the psychological status of the patient is unstable or
- if the patient has unrealistic expectations.

Additionally for SSD / AHL individuals should not be implanted,

- if individual has had profound hearing loss for over ten years
- if individual has an acoustic neuroma

Undesirable side-effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Clinical data supports cochlear implants as a treatment option for SSD and AHL if existing treatments do not work. Some SSD and AHL patients will benefit from Cochlear Implant (CI) implantation and the risks and benefits should be weighed by the clinician to determine if CIs are an appropriate treatment for each individual patient. All SSD and AHL patients should be offered rehabilitation. There is the potential perceptual inference of overlapping of acoustic and electric bilateral hearing which may lead to limited CI performance.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped¹ between -20 °C (-4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the “use by” date specified on the package. Packaging² should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness

which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.

- 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 case the MED-EL implant user wants to dive, the user should consult an experienced physician about the 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 50m (165ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis³ can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling the mastoidectomy, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that focally progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm. The stimulator should be recessed to a depth of maximum 2 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The implant must be securely anchored in the stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.
- The bed for the implant must be flat so that the implant is stable. The transition from the implant bed to the channel for the electrode has to be smooth, ramp-like, with no sharp edges in order to avoid possible damage to the electrode lead.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

Recommended diameter of the cochleostomy & RW opening:

Electrode type	mm
SONATA +Standard	1.3 mm
SONATA +Medium	0.8 mm
SONATA +Compressed	0.8 mm
SONATA +FLEX ^{SOFT}	1.3 mm
SONATA +FLEX ²⁸	0.8 mm
SONATA +FLEX ²⁴	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear pre-surgically.

- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.
- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual..

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

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to Medical Procedures Manual.

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.

If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.

If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
MED-EL Elektromedizinische Geraete GmbH
Worldwide Headquarters
Safety adviser for the transport of dangerous goods
Fürstenweg 77a
6020 Innsbruck
Austria

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

UNC Feasibility Study Design

The feasibility study for the MED-EL Cochlear Implant System was conducted under IDE (G140050) to evaluate the safety and effectiveness of the MED-EL Cochlear Implant System in individuals 18 years of age and older with SSD or AHL. The primary study goal was to determine whether subjects with SSD or AHL demonstrated an improvement in speech perception, localization, and quality of life after receiving a cochlear implant. Both objective and subjective performance data were collected, as well as safety data in the form of adverse events. Forty subjects were implanted at the University of North Carolina at Chapel Hill with the MED-EL CONCERT or SYNCHRONY Cochlear Implant System in this prospective, single-site, non-randomized, non-blinded, repeated measures clinical study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in G140050 was limited to patients who met the following inclusion criteria:

- 18 years of age or older at the time of implantation
- Unilateral moderate-to-profound sensorineural hearing loss
 - o Unaided residual hearing thresholds measured from 250-8000 Hz (PTA $\geq$ 70 dB HL in the ear to be implanted)
 - o For SSD: normal to mild residual hearing thresholds from 250-8000 Hz in the contralateral ear ($\leq$ 35 dB HL at each frequency, 250-8000 Hz)
 - o For AHL: mild to moderate hearing thresholds from 250-8000 Hz in the contralateral ear (PTA $\geq$ 35 and $\leq$ 55 dB HL)
 - Aided word recognition of 80% or more as measured with CNC words (50-word list)
- Duration of moderate-to-profound sensorineural hearing loss less than or equal to 10 years
 - o Hearing loss for less than 10 years: study participants were only included if they had used a hearing aid consistently for 5 years
 - o Hearing loss for less than 5 years: study participants were only included if they had at least completed a 1-month hearing aid trial
- Previous experience (at least one month) with a current treatment option for SSD, including a conventional hearing aid, bone-conduction device, or CROS/BICROS technology
- Aided word recognition in the ear to be implanted of 60% or less as measured with CNC words (50-word list)
- Realistic expectations
- Willingness to obtain recommended meningitis vaccinations per CDC recommendations
- No reported cognitive issues: pass of the Mini Mental State Examination (MMSE) screener
- Ability and willingness to comply with study requirements, including travel to investigational site and study-related activities

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Non-native English speaker
- Conductive hearing loss in either ear
- Compromised auditory nerve, including those with a history of vestibular schwannoma
- Ossification
- Inability to participate in follow-up procedures (i.e., unwillingness, geographic location)
- History of meningitis, autoimmune disease, or any medical condition that contraindicate middle or inner ear surgery or anesthesia
- Meniere's disease with intractable vertigo
- Trauma that precludes inner ear surgery
- Case of sudden sensorineural hearing loss that has not been first evaluated by a physician
- Pregnancy
- Tinnitus as the primary purpose for seeking cochlear implantation
- Severe or catastrophic score on the Tinnitus Handicap Inventory

2. Follow-up Schedule

This study involved up to ten visits before and after implantation, for about a one-year period. Candidacy testing included medical and audiological evaluations (e.g., audiograms, speech recognition tests) to determine study eligibility. After confirming eligibility, the subject underwent baseline testing. The device was subsequently implanted based on the subject's candidacy testing. An initial follow-up visit was completed following surgery, and the cochlear implant was activated following a healing period of 2 to 4 weeks.

The baseline and postoperative measurements are summarized under 'Test Conditions' below. All patients were scheduled to return for follow-up examinations at 1, 3, 6, 9, and 12 months postoperatively. Pre-operatively and post-operatively, unaided air conduction thresholds were collected. At all intervals, speech perception in quiet and in noise and localization data was collected. Adverse events and complications were recorded at all visits.

The key timepoints (pre-op baseline and 12-months post-op) are shown below in the tables summarizing safety and effectiveness.

Test Conditions

The test battery was completed at the pre-operative interval and again at 1, 3, 6, 9, and 12 months post-operatively. For soundfield measures (speech perception and localization), a 180° arc with 11 speakers spaced 18° apart was utilized. Post-operative aided soundfield assessment was completed with the subject using the SONNET or OPUS 2 speech processor unless otherwise noted. For the AHL group, soundfield testing was completed with a hearing aid in the contralateral ear. See below for further details on testing conditions.

Subjects participated in two aural rehabilitation sessions with a board-certified speech-language pathologist. One session was completed after the initial activation of the external speech processor. The second session took place in conjunction with the 1-month post-initial activation interval.

- Unaided Diagnostic Assessment
 - o Air-conduction thresholds in both ears
 - o Assess bone-conduction thresholds if there is a PTA shift of >15 dB as compared to the previous interval
- Tympanometry for each ear
- Sound Field Measures
 - o Aided thresholds with the external speech processor on measured using pulsed, warble tones
 - Frequencies assessed: 250-8000 Hz
 - Masking presented to the contralateral ear
 - o Speech Perception Measures (recorded materials presented at 60 dB SPL)
 - Speech Perception in Quiet
 - Speech 0° azimuth
 - CNC words
 - AzBio sentences
 - Speech Perception in Noise
 - Speech and noise 0° azimuth
 - Speech 0° azimuth and noise to implanted side
 - Speech 0° azimuth and noise to contralateral ear
 - AzBio sentences
 - If >50% at SNR+10, then SNR+5; if >50% at SNR+5, then SNR0
 - BKB-SIN sentences with adaptive SNR
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
 - o Localization
 - 200-ms speech-shaped noise, presented at 70-dB SPL from one of the 11 speakers (evenly spaced -180 to 180 degrees), selected at random
 - Intensity level for each stimulus presentation randomly varied (10 dB around 70 dB SPL)
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
- Subjective questionnaires
 - o Speech, Spatial and Qualities of Hearing Scale (SSQ)
 - o Abbreviated Profile of Hearing Aid Benefit (APHAB)
 - o Tinnitus Handicap Inventory (THI)

3. Clinical Endpoints

Measures

Safety Measure: The primary safety measure was the evaluation of all adverse events reported within 12 months. The full profile of adverse events was summarized and considered, with specific attention given

to device-related adverse events. The adverse events include anticipated and unanticipated adverse events. The list of anticipated adverse device effects noted in the study protocol are as follows:

- Risks from the SYNCHRONY IFU
 - o Loss of residual hearing
 - o Increased vertigo
 - o Delay of healing of the scar
 - o Impairment of the sense of taste
 - o Potential for swallowing difficulties
 - o Numbness
 - o Increased tinnitus
 - o Stimulation of the facial nerve
 - o Temporary pain and uncomfortable sounds during stimulation
- Additional surgical risks
 - o Facial nerve injury
 - o Infection
 - o Bleeding
 - o Cerebrospinal fluid (CSF) leak
 - o Pain
 - o Scarring
- Additional post-operative risks
 - o Swelling around the incision and/or coil site
 - o Pain
 - o Reduced or loss of pinna sensitivity on the surgical side
 - o The cochlear implant may not provide any auditory stimulation
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in the perception of speech
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in localization
 - o Pain associated with the coil and/or placement of the external speech processor on the subject's ear
 - o Movement of the internal receiver
 - o Discomfort from electric stimulation
 - o Facial nerve stimulation
 - o Headache
 - o Dizziness
 - o Altered taste (i.e. reports of metallic tastes on the same side of the tongue as the surgical ear)
 - o Fatigue during follow-up assessment (completion of the test battery and/or mapping)
 - o The internal device may fail, requiring revision cochlear implantation
 - o The sound from the cochlear implant may interfere with the better hearing ear.

Effectiveness Measures: The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition. Aided speech perception performance on word and sentence materials at the post-activation intervals was evaluated to monitor trends over time. Unaided and aided (with BCHA or CI, as applicable) localization performance was also compared pre-operatively and at each of the post-activation intervals. The overall RMS error is reported for localization in each condition. Additionally, subjective report scores were compared pre-operatively and at the 12-month post-activation intervals.

Audiometric Test Methods & Effectiveness Measures

Speech perception and localization measures were recorded in a research lab that featured a 180° arc with 11 speakers spaced 18° apart. Postoperative aided sound field assessment was completed with the study participant listening with the OPUS 2 or SONNET speech processor.

Speech perception in quiet was tested at 0° azimuth, presenting CNC words (Peterson & Lehiste, 1962) or AzBio sentences (Spahr et al., 2012) at 60 dB SPL. Speech perception in noise was tested in the conditions (1) speech and noise 0° azimuth (S0N0), (2) speech 0° azimuth and noise to the affected ear/implanted side (S0NCI), and (3) speech 0° azimuth and noise to the contralateral ear (S0NContra). AzBio sentences were presented at 0 dB signal-to-noise ratio (SNR) in most cases. BKB-SIN sentences were presented with adaptive SNR.

For the localization task a 200-ms speech-shaped noise was presented at 70-dB SPL from one of the 11 speakers (selected randomly). The intensity level for each stimulus presentation was randomly varied (10 dB around 70 dB SPL). The listener was facing the center speaker during stimulus presentation and the task was to identify the source of the noise. No feedback was provided. In the condition cochlear implant speech processor OFF, study participants were only listening with the contralateral ear. In the condition cochlear implant speech processor ON, sound was perceived both via the cochlear implant and the contralateral ear.

Subjective data was collected via the SSQ and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995). The SSQ can be further divided into three subscales: speech, spatial, and quality. The APHAB consists of four subscales: Ease of Communication (EC), Background Noise (BN), Reverberation (RV), and Aversiveness (AV). The Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996) was also utilized to collect information on severity of tinnitus pre-operatively as well as at the 12-month interval.

B. Accountability of Study Cohort

In the SSD cohort, 20 subjects were enrolled and completed testing through the 12-month interval. In the AHL cohort, 20 subjects were enrolled and 18 completed testing through the 12-month interval. One subject in the AHL cohort withdrew prior to completion of all test intervals, and one subject was still undergoing follow-up testing at the time of data analysis.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a feasibility study performed in the US. Proportions enrolled are consistent with the age, sex/gender, racial and ethnic prevalence of the SSD and AHL.

1. SSD Cohort

Of the 20 implanted subjects, 12 were female and 8 were male. At the time of implantation, subjects ranged in age from 22 to 66 years of age. The duration of profound hearing loss ranged from 0.1 to 6.6 years. Fifteen subjects experienced sudden hearing loss and five subjects experienced a gradual hearing loss. Hearing loss was reported as unknown in 16 cases, due to Meniere's disease in three subjects, and caused by trauma in one case. Further information on subject demographics and hearing related variables is summarized in Table 2 below.

Table 2. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=20)
Gender	
Male	40% (8/20)
Female	60% (12/20)
Age (years)	50 (20) (22 – 66)
Duration of hearing loss (years)	
Noticeable	4.2 (20) (0.1 – 14.6)
Profound	2.6 (20) (0.1 – 6.6)
Implanted ear	
Left	55% (11/20)
Right	45% (9/20)
Tinnitus Handicap Grade Level	
Slight	35% (7/20)
Mild	40% (8/20)
Moderate	25% (5/20)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

2. AHL Cohort

Of the 18 subjects who completed follow-up, 9 were female and 9 were male. At the time of implantation, subjects ranged in age from 52 to 79 years of age. The duration of profound hearing loss ranged from 0.0

to 9.8 years. Ten subjects experienced sudden hearing loss and six subjects experienced a gradual hearing loss, with the remaining two subjects experiencing both a gradual and sudden loss. Hearing loss was reported as unknown in 14 cases, due to Meniere's disease in two subjects, due to noise-induced hearing loss in one subject, and caused by viral infection in one case. Further information on subject demographics and hearing related variables is summarized in Table 3 below.

Table 3. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=18)
Gender	
Male	50% (9/18)
Female	50% (9/18)
Age (years)	70 (18) (52 – 79)
Duration of hearing loss (years)	
Noticeable	11.5 (17) (0.0 – 51.5)
Profound	3.5 (17) (0.0 – 9.8)
Implanted ear	
Left	67% (12/18)
Right	33% (6/18)
Tinnitus Handicap Grade Level	
Slight	55% (10/18)
Mild	28% (5/18)
Moderate	17% (3/18)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on all patients implanted under G140050 (N=40) up to 12 months post implantation. Table 4 displays the adverse events reported for this study.

Adverse effects that occurred in IDE G140050:

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated. A total of nine adverse events were reported to be related to the device or procedure. An additional six adverse events were not able to be ruled out as device or procedure-related. No serious, unanticipated, device-related adverse events were reported.

Table 4. Number and percentage of adverse events observed for SSD subjects.

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects
Vertigo/dizziness/imbalance	11	9	22.5%
Unrelated infection	3	3	7.5%
Changes in sound quality/volume	3	2	5%
Depression	3	2	5%
Aural pressure	2	2	5%
Facial stimulation	2	2	5%
Headache	2	2	5%
Atrial fibrillation	1	1	2.5%
Bleeding at surgical site	1	1	2.5%
Electrode contact dislodged	1	1	2.5%
Fall involving bump to the implant	1	1	2.5%
Type C tympanogram	1	1	2.5%
Short circuit	1	1	2.5%
Total	32	21*	52.5%

*Some subjects experienced more than one device-related adverse event

The most frequently observed adverse event was vertigo, dizziness, or imbalance, which was reported a total of 11 times. In four cases, the event was deemed unrelated to the device or procedure. In three cases, it could not be ruled out that the event was related to the device or procedure. In the remaining four cases, it was determined that the event was related to the procedure. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. In all cases, the event was deemed unrelated to the device or procedure. All other events occurred at a rate of 5% or less (2 subjects or fewer), which is consistent with the rate of adverse events observed for the approved indication of bilateral, severe-to-profound, sensorineural hearing loss.

2. Effectiveness Results

The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition among 20 subjects with SSD and 17 subjects with AHL. Additionally, subjective reports from the SSQ and APHAB were also compared pre-operatively and at the 12-month post-operative interval.

Speech Perception in Quiet

SSD Cohort

Speech perception testing in quiet at the 12-month interval demonstrated an improvement in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. In the contralateral ear, no change was observed on CNC words from baseline to 12 months. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet across test intervals. The comparison of AzBio sentence score in quiet with a BCHA to scores at 12 months with the CI-ON also demonstrated no change. Table 5 displays the descriptive statistics of the speech perception in quiet scores for the SSD cohort.

Table 5. Speech perception in quiet (SSD Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	20	20	20	20	20	20	20
Mean (SD)	3.5 (6.68)	54.6 (18.15)	99.3 (2.27)	99.8 (0.62)	99.0 (1.56)	99.2 (1.15)	99.5 (1.19)
Min – Max	0 - 22	10 - 84	90- 100	98 - 100	95 - 100	95 – 100	95 - 100

AHL Cohort

For the cohort with asymmetric hearing loss, an improvement was demonstrated for speech perception testing in quiet at the 12-month interval in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. No change was observed on CNC words from baseline to 12 months in the contralateral ear. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet between the pre-operative and 12-month intervals. Additionally, no change was demonstrated in the comparison of AzBio sentence score in quiet between BCHA pre-operatively and 12 months with the CI-ON. See Table 6 below for the descriptive statistics of the speech perception in quiet scores.

Table 6. Speech perception in quiet (AHL Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	18	18	18	18	18	18	18
Mean (SD)	6.3 (7.98)	56.2 (18.41)	94.2 (7.06)	92.7 (8.68)	87.4 (13.96)	87.7 (11.01)	94.3 (8.38)
Min – Max	0 - 22	28 - 86	78 – 100	72 - 100	50 - 99	(61 – 99_	72 - 100

Speech Perception in Noise

SSD Cohort

On AzBio sentence testing in noise, subjects in the SSD cohort demonstrated an improvement between the bilateral, baseline, pre-operative, unaided testing and the bilateral, 12-month post-operative, CI + NH testing in the speech front, noise front condition. This same improvement was also noted between the bilateral, baseline, pre-operative, aided (with BCHA) condition and the bilateral, 12-month, post-operative, CI + NH condition. NO differences were found between pre-operative unaided and pre-operative, aided (with BCHA) scores. In the speech front, noise to the CI ear condition, subjects demonstrated no change in score in comparing the pre-operative interval to the CI-ON at 12 months. However, when comparing the pre-operative aided scores to the 12-month scores with CI, an improvement in performance was noted. Better scores were obtained for the pre-operative unaided condition as compared to the pre-operative aided condition.

A significant improvement was noted with the cochlear implant on at 12 months post-operative compared to the pre-operative, unaided interval for the speech front, noise to the contralateral ear condition. This same improvement was also found when comparing CI-ON at the 12-month, post-operative condition to the pre-operative, aided (with BCHA) condition. This improvement demonstrates that when noise presents as a masker to the better hearing ear, the cochlear implant provides benefit in speech understanding. Table 7 provides further details on AzBio sentence in noise scores.

Table 7. Speech perception in noise (SSD Cohort, AzBio)

SSD AzBio	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	37.5 (10.98)	31.5 (16.56)	47.2 (10.72)	83.4 (9.51)	61.25 (27.92)	85.0 (11.04)	16.5 (12.78)	18.3 (13.50)	52.6 (21.43)
Min- Max	20 - 64	0 – 59	29 - 68	59 - 94	0 – 98	60 - 97	0 - 45	0 – 59	8 - 86

A similar pattern was noted for speech in noise testing on the BKB-SIN. No significant changes were found in any comparisons for the speech front, noise front or speech front, noise to the CI ear conditions. However, in the speech front, noise to the contralateral ear condition, it was found that the CI does provide benefit in speech perception, and thus, a significant improvement was found when comparing the 12-month, post-operative CI + NH condition to the pre-operative, unaided condition or to the pre-operative, aided (with BCHA) condition. Table 8 provides the detailed descriptive statistics of the BKB-SIN scores.

Table 8. Speech perception in noise (SSD Cohort, BKB-SIN)

SSD BKB- SIN	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	0.1 (1.42)	0.8 (1.98)	-0.8 (1.74)	-4.8 (1.64)	-2.6 (2.39)	-4.8 (1.66)	1.8 (1.33)	1.8 (2.35)	-1.0 (2.20)
Min- Max	-2.5 – 3.0	-2.5 – 4.5	-3.0 – 4.0	-7.5 – -1.5	-7.0 – 1.0	-7.5 – -2.0	-0.5 – 4.0	-2.5 – 8.0	-5.0 – 5.5

AHL Cohort

For the AHL cohort, the majority of subjects were tested at 0 dB SNR. However, some subjects were tested at +5 or +10 dB SNR according to a decision tree implemented for determining SNR. Pre-operative and post-operative comparisons within subject were done at the same SNR. For this reason, only 17 subjects are included in the AzBio analysis for both the pre-operative unaided/aided (with BCHA) condition and the 12-month post-operative CI + HA condition.

In the speech front, noise front condition, a significant improvement was found on AzBio sentences for the 12-month, post-operative CI + HA condition compared to the pre-operative, unaided condition and compared to the pre-operative, aided (with BCHA) condition. Pre-operative, BCHA scores were worse than pre-operative unaided scores and worse than 12-month, post-operative CI + HA scores in the speech front, noise to the CI ear condition. In the speech front, noise to the contralateral ear condition, a signifi-

cant improvement was noted for the 12-month, post-operative CI + HA testing compared to both the pre-operative, unaided testing and the pre-operative, aided (with BCHA) testing. Table 9 below displays the descriptive statistics of the AzBio testing for the AHL Cohort.

Table 9. Speech perception in noise (AHL Cohort, AzBio)

AHL AzBio	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	17	17	17	17	17	17	17	17	17
Mean (SD)	22.7 (13.95)	20.5 (12.86)	33.5 (22.10)	44.2 (17.70)	30.5 (18.23)	44.6 (24.74)	6.3 (9.49)	11.3 (16.69)	29.4 (22.59)
Min- Max	0 – 47	0 – 47	3 – 85	9 – 78	1 – 70	5 – 94	0 – 36	0 – 66	1 – 95

For BKB-SIN testing, no changes were demonstrated in the speech front, noise to the CI ear condition. An improvement was found between the pre-operative, aided (with BCHA) condition and the 12-month, post-operative CI + HA condition in the speech front, noise front condition. Similar to the AzBio test results for the SSD cohort, there was a significant improvement for BKB-SIN in the speech front, noise to the contralateral ear condition when comparing the 12-month, post-operative CI + HA condition to the pre-operative, unaided condition. Table 10 below displays the analyses of BKB-SIN testing in the AHL cohort.

Table 10. Speech perception in noise (AHL Cohort, BKB-SIN)

AHL BKB- SIN	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	18	18	18	18	18	18	18	18	18
Mean (SD)	4.3 (3.62)	5.1 (3.04)	3.7 (3.28)	1.3 (3.89)	2.5 (3.77)	2.6 (3.78)	7.1 (4.14)	5.9 (4.50)	4.6 (4.44)
Min- Max	0.5 – 13.0	0 – 10	-2.0 – 9.5	-6.5 – 8.5	-3.5 – 10.0	-3.5 – 9.0	2.0 – 15.5	0 – 14.5	-1.0 – 15.5

Localization

SSD Cohort

Subjects in the SSD cohort demonstrated a significant improvement in localization performance with the CI at 12 months compared to the baseline, aided (with BCHA) condition. Additionally, results indicated an improvement in performance between the baseline, unaided condition and the 12-month, postoperative CI + NH condition. Table 11 displays localization performance in RMS error.

Table 11. Localization performance (SSD Cohort)

SSD Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	20	20	20
Mean (SD)	66.5 (20.47)	69.6 (18.71)	26.7 (6.32)
Min-Max	42.9 – 109.1	45.3 – 106.1	13.6 – 38.4

AHL Cohort

Similar to the SSD cohort, subjects in the AHL cohort demonstrated improved localization performance with the CI-ON at 12 months compared to the baseline, aided (with BCHA) condition. This improvement was also evident when comparing the 12-month, postoperative CI + HA to the pre-operative, unaided condition. Table 12 displays the analyses of the AHL Cohort's localization data.

Table 12. Localization performance (AHL Cohort)

AHL Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	18	18	18
Mean (SD)	76.5 (19.23)	77.2 (18.89)	40.1 (10.65)
Min-Max	43.8 – 105.3	45.6 – 106.5	26.6 – 73.6

Subjective Questionnaire

SSD Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the CI on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 13 below for the descriptive statistics of the SSQ.

Table 13. SSQ (SSD Cohort)

SSD SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20
Mean	3.7	7.1	2.4	6.5	5.6	7.7
Std. Deviation	1.34	0.99	1.2	1.86	2.09	1.28
Minimum	0.6	5.4	0.5	2.8	0.5	5.6
Maximum	7.2	8.9	4.5	8.9	9.8	9.8

Self-perceived benefit from the CI as reported on the APHAB demonstrated significant improvement on global score and the subscales, except for the aversiveness subscale. Table 14 below provides the detailed APHAB scores at the pre-operative and 12-month intervals.

Table 14. APHAB (SSD Cohort)

SSD APHAB	Global		EC		BN		RV		AV	
	pre	12m	Pre	12m	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20	20	20	20	20
Mean	49.8	17.9	31.6	8.7	70.1	25.2	47.5	19.7	43.1	26.7
Std. Deviation	18.65	8.91	21.06	6.15	17.32	11.95	21.96	12.43	28.64	24.83
Minimum	20.3	6.1	2.8	1.0	39.3	10.2	18.7	2.8	1.0	1.0
Maximum	86.3	36.7	81.0	24.8	95.0	56.2	87.0	41.7	93.0	91.0

AHL Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the cochlear implant on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 15 below for detailed information on the SSQ.

Table 15. SSQ (AHL Cohort)

AHL SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	18	18	18	18	18	18
Mean	3.2	5.8	2.6	6.0	4.6	6.8
Std. Deviation	1.48	1.50	1.26	1.62	1.77	1.20
Minimum	0.4	3.6	0.3	3.1	0.2	4.4
Maximum	6.0	8.9	4.7	8.5	8.3	8.7

Self-perceived benefit from the cochlear implant as reported on the APHAB demonstrated significant improvement on global score and other subscales over time except the aversiveness subscale. Table 16 below displayed the detailed APHAB scores at the pre-operative and 12-month post-operative intervals.

Table 16. APHAB (AHL Cohort)

AHL APHAB	Global		EC		BN		RV		AV	
	pre	12m	pre	12m	pre	12m	Pre	12m	pre	12m
N	18	18	18	18	18	18	18	18	18	18
Mean	54.1	28.1	42.9	16.6	63.5	39.3	56.0	28.3	43.1	42.4
Std. Deviation	16.21	10.49	24.67	13.01	16.84	17.10	18.30	11.96	35.04	29.21
Minimum	20.0	11.3	10.2	1.0	14.5	14.5	14.2	12.0	1.0	1.0
Maximum	92.3	54.1	91.0	54.0	95.0	66.3	97.0	54.2	99.0	97.0

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Literature Search Strategy

MED-EL conducted an extensive literature search to collect additional supporting clinical evidence of cochlear implants in SSD and/or AHL indications. The search terms they used are listed in Tables 17, 18, and 19, below.

Table 17. Combinations of Search Terms

Search Step	Search Terms	Review Question
1	"hearing loss" OR deaf*	P
2	single sided deafness OR SSD OR unilateral OR UHL OR asymmetric* OR AHL	P
3	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment" OR bone conduction OR BCI OR bone anchored OR BAHA OR CROS OR contralateral routing OR BiCROS OR "transcranial CROS" OR in-the-mouth device OR ITM OR soundbite OR bone-bridge OR "ad hear"	I & C
4	1 AND 2 AND 3	
5	Limit 4 to <i>Humans</i>	
6	Limit 5 to <i>Language</i> : English	
7	Limit 6 to <i>Publication date</i> : June, 2014 to May, 2017	

Search Step	Search Terms	Review Question
1	(single sided deafness) OR ((((((SSD) OR unilateral) OR UHL) OR asymmetric) OR AHL)) AND (((hearing loss) OR deaf*) OR deafness))	P
2	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment"	I & C
3	1 AND 2	
4	Limit 3 to <i>Humans</i>	
5	Limit 4 to <i>Language</i> : English	
6	Limit 5 to <i>Publication date</i> : May 1, 2017 to March 6, 2019	

Note. The different search terms are connected using Boolean logic. Activated filters are displayed in italics. P = Population, disease, or condition; I = Intervention; C = Comparator group or control.

* Wildcard symbol to broaden the search by creating a root word search.

Table 18. Inclusion and Exclusion Criteria for Retrieved Literature

Inclusion Criteria	
Population/Problem	Patients of any age who have single sided deafness
Intervention/Treatment	cochlear implant, any other treatment that makes hearing possible, or no treatment
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Inclusion Criteria	
Population/Problem	Patients of any age who have SSD or AHL
Intervention/Treatment	cochlear implant
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population e.g. different type of hearing loss
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Table 19. Literature Appraisal Criteria

Data Suitability	Description	Grading System
Appropriate Device	Where the data generated from the device in question?	D1 – Actual device D2 – Comparable device D3 – Other device
Appropriate Device Application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 – Same use A2 – Minor deviation A3 – Major deviation
Appropriate Patient Group	Were the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease including state and severity)?	P1 – Applicable P2 – Limited P3 – Different population
Acceptable Report/Data Collation	Did the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 – High quality R2 – Minor deficiencies R3 – Insufficient information
Data Contribution	Description	Grading System
Data Source Type	Was the design of the study appropriate?	T1 – Yes T2 – No
Outcome Measures	Did the outcome measures reported reflect the intended performance of the device?	O1 – Yes O2 – No
Follow-Up	Was the duration of the follow-up long enough to assess treatment effects and identify complications?	F1 – Yes F2 – No
Statistical Significance	Was a statistical analysis of the data provided and appropriate?	S1 – Yes S2 – No
Clinical Significance	Was the magnitude of the treatment effect observed clinically significant?	C1 – Yes C2 – No

Published Literature on Children

The literature search yielded five peer-reviewed papers in SSD and/or AHL children with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults and children aged 5 yrs and older. The papers comprise a total of 26 children with SSD (five of which were reported to be implanted with MED-EL devices) and a total of nine children with AHL. Tables 17, 18, and 19 above list the detailed literature search criteria and relevant information.

The overall benefits of CI in children with SSD and AHL include improved performance in speech perception in quiet and noise, sound localization and subjective measures of quality of life.

Word recognition in quiet:

Beck et al. (2017) reported diverse speech audiometry results. Some of the children showed measurable benefits on speech discrimination. The CAP scores improved for the SSD children (N = 8) with CI compared to preoperative performance. Rahne and Plontke (2016) reported that two SSD children improved with CI over time in number recognition, two SSD children showed no recognition. One child improved over time in word recognition with CI, whereas the other three children showed no recognition.

Word recognition in noise:

Arndt et al. (2015) reported on the speech perception in noise for different speech and noise configuration. Children with SSD demonstrated improved although variable performance on speech perception in spatially-separated conditions. Some children demonstrated improvement in spatially separate speech and noise. Tavora-Vieira and Rajan (2015) showed better and similar speech perception in noise with CI-on compared to CI-off for two SSD children. Gratacap et al. (2015) showed an increase in speech perception in noise in 9 children with AHL after 12 and 24 months of CI use compared to preoperative performance. Rahne and Plontke (2016) reported an improvement in speech reception thresholds in three SSD children when CI-on and CI-off are compared; in one child no measurement was possible.

Sound localization:

Arndt et al. (2015) reported a decreased localization error with CI for most of the children as compared to the preoperative unaided condition. Tavora-Vieira and Rajan (2015) reported that one child with SSD showed a de-

creased localization error after 6 and 12 months with the CI-on compared to CI-off condition, whereas the other child with SSD showed the same localization performance in both conditions. Rahne and Plontke (2016) reported an improvement in sound localization in four children with SSD when CI-on and CI-off are compared.

Subjective measures:

Beck et al. (2017) showed that the parents (N = 9) and children (N = 3) with SSD reported an increase score for the SSQ. Arndt et al. (2015) reported an increase the SSQ score in children with SSD with postlingual onset of deafness (N = 9), slight improvement in children with SSD with perilingual onset of deafness (N = 2) and minimal improvement or same performance in children with SSD who are congenitally deaf (N = 2).

Published Literature on Adults

The literature search yielded six peer-reviewed papers in SSD and/or AHL adults with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults. Although the paper by Kitoh et al. (2016) mentioned a study inclusion criterion of PTA > 70 dB HL, all five subjects included in the study had a pre-operative unaided PTA of 92 dB HL or higher. Hence, the results from this study were included in the summary below.

The six papers comprise a total of 58 adults with SSD (N = 50 of which implanted with MED-EL devices) and a total of 52 adults with AHL (N = 37 of which implanted with MED-EL devices). This subject count does not include five SSD nor 16 AHL patients from Skarzynski et al. (2017), as those subjects are part of the larger cohort from the same implant center later reported on by Lorens et al. (2019). Also note that three of the 58 adult SSD subjects might have an unaided PTA close to or below 90 dB HL in the implanted ear, as the paper by Döge et al. (2017) presents PTA data as median and interquartile range only (75%, i.e. N = 8 of 11 studied subjects have PTA > 100 dB HL).

The overall benefits of CI in SSD and AHL adult patients include improved performance regarding speech perception in quiet and in noise, sound localization and subjective measures regarding quality of life, music enjoyment and tinnitus.

Word recognition in quiet

Döge et al. (2017) showed that with a CI, the mean PTA thresholds of the deaf ear improved from the mean value of 120 dB at unaided condition to below 40 dB in the aided condition in 11 SSD subjects. In addition to the benefit of sound perception, the CI enabled better speech perception in quiet. Skarzynski et al. (2017) compared CI-on vs CI-off condition in 5 SSD and 16 AHL subjects and significantly better speech perception was observed in the CI-on condition. Results with the CI demonstrated a continuous improvement in speech recognition after 12-month of use. Rahne and Plontke (2016) reported a significant improvement in monosyllabic word and multisyllabic number recognition in quiet in comparing the 12-month and 1-month after CI activation in 17 SSD subjects. van Loon et al. (2017) reported that speech recognition scores increased from 74% pre-operatively to 88% at 12-month with bimodal stimulation in 7 AHL cases.

Speech perception in noise

Several studies found that the CI enabled better speech perception in noise. Rahne and Plontke (2016) reported a significant improved speech perception in noise at 3-month of CI activation with CI-on vs CI-off condition, and a continuous improvement occurring at 12-months in 17 SSD subjects. Skarzynski et al. (2017) reported better speech perception in noise at CI-on vs CI-off condition. van Loon et al. (2017) reported that in comparison to the CI-off or CI-only condition, bimodal stimulation resulted in significantly better speech recognition in noise and spatial speech recognition at 3-months, 6-months and 12-months post-activation. Lorens et al. (2019) reported a significant binaural benefit conveyed by CI-on in comparison to the CI-off condition, in 25 SSD and 45 AHL subjects. Kitoh et al. (2016) reported a gradually improved speech perception in noise after 12-months post-activation in comparison to the pre-operative condition. Döge et al. (2017) reported slightly improved speech reception in noise in CI-on vs CI-off condition in 8 of 11 patients. Three of 11 subjects, however, showed deteriorations at CI-on condition.

Sound localization

Döge et al. (2017) showed a significant decrease of localization error in the CI-on condition in comparison with the CI-off condition in 11 SSD subjects. Skarzynski et al. (2017) observed a significant localization benefit reflected by decrease in RMS angular error at CI-on vs CI-off condition. van Loon et al. (2017) reported a significant improved localization performance in all 7 AHL subjects with bimodal stimulation at 12-month in comparison to the pre-operative condition. Results with the CI demonstrated a continuous improvement in sound localization after 12 months of CI use. Rahne and Plontke (2016) reported that in comparison to CI-off, CI-on significantly improved

sound localization, reflected by a decrease in ADE (angular detection error) at 1-month of CI activation. A continuous improvement occurred over time. Kitoh et al. (2016) reported better sound localization in all 5 subjects, with continuous improvement through 12-month.

Subjective measures

van Loon et al. (2017) reported increased frequency and satisfaction of listening to music from 7 AHL CI users. Bimodal stimulation also resulted in better quality, clarity, and appreciation of different music styles. Skarzynski et al. (2017) reported substantial tinnitus suppression in all 15 patients with pre-operative tinnitus and Kitoh et al. (2016) reported decreased disturbance to daily life caused by tinnitus in all 5 SSD cases. Two studies addressed self-evaluation of CI performance in SSD and AHL subjects. Skarzynski et al. (2017) reported a significant improvement in the global score of APHAB, as well as sub-scales including 'Ease of communication', hearing under 'background noise' or under 'reverberation' at 14-months after CI activation in comparison to pre-operative condition. van Loon et al. (2017) reported that except for the 'speech production' subdomain, bimodal stimulation yielded a significant better outcome for all other subdomains of the NCIQ questionnaire. An average appreciation of the cochlear implant was scored 4.3/5, indicating a high satisfaction with the CI.

Conclusions from Real World Evidence

This clinical evaluation of cochlear implantation for the treatment of SSD and AHL is based on the above literature data sets relevant to the safety, performance, and effectiveness of cochlear implantation as a treatment option for individuals with AHL or SSD.

In this review of Real-World data, the latest clinical data were summarized on SSD and AHL patients from centers both in the US and around the globe that meet the proposed audiometric indication criterion of a profound hearing loss in the ear to be implanted, i.e., a PTA of 90 dB or higher. The clinical populations reported on include both adults and children older than 5 years age.

Taken together, the clinical data from this body of literature show consistent benefits of CI in individuals with SSD or AHL, in terms of improved speech perception in noise, spatial hearing, localization accuracy, and patient-reported subjective outcome measures. Consistent CI use of patients has been shown across literature reports, and notably so in the prospective study by Lorens et al. (2019) in 70 sequentially implanted SSD and AHL CI users (59 of which were implanted with MED-EL devices). These literature data provide Real World Evidence (according to the FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices") in support of the clinical benefits of CI in SSD and AHL recipients, as demonstrated in the UNC study. In this way, these literature reports do serve as supporting evidence which demonstrates a reasonable assurance of device safety and effectiveness and to characterize the benefit/risk profiles for the proposed SSD/AHL indications.

Symbols



CE mark. First applied in 2006



Single-use device. Do not reuse!



Catalogue number



Serial number



Caution! Consult accompanying documents



Sterilised using Ethylene Oxide



"Use by" date



Manufacturing date



Manufacturer



MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

- 1 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).
- 2 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.
- 3 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

USA Distributor:
MED-EL Corporation
2645 Meridian Parkway
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.



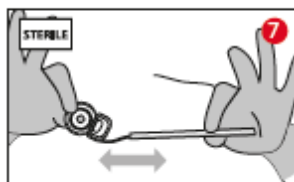
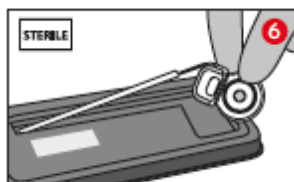
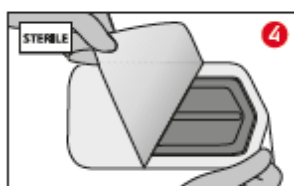
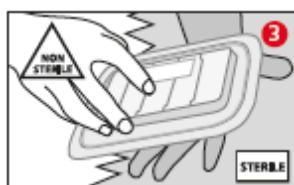
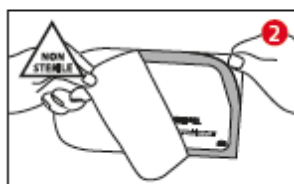
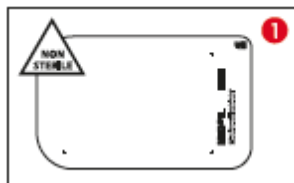
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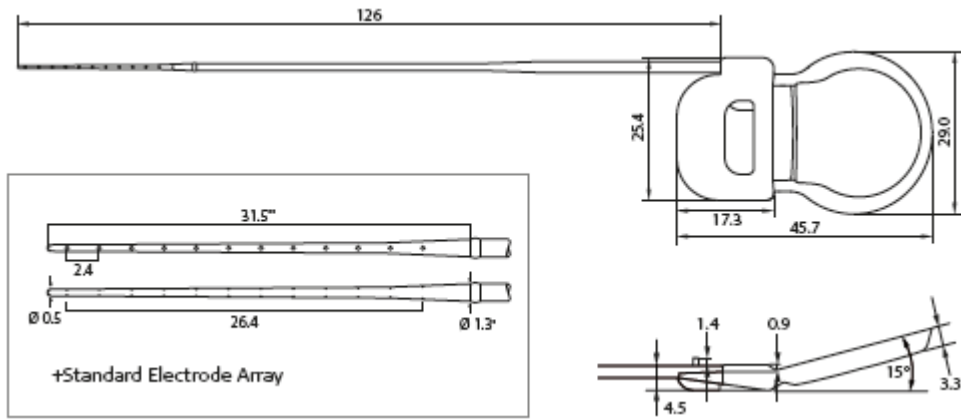
Mi1000 MED-EL CONCERT PIN Cochlear Implant

+Standard | +Medium | +Compressed | +FLEX^{SOFT} | +FLEX28 | +FLEX24

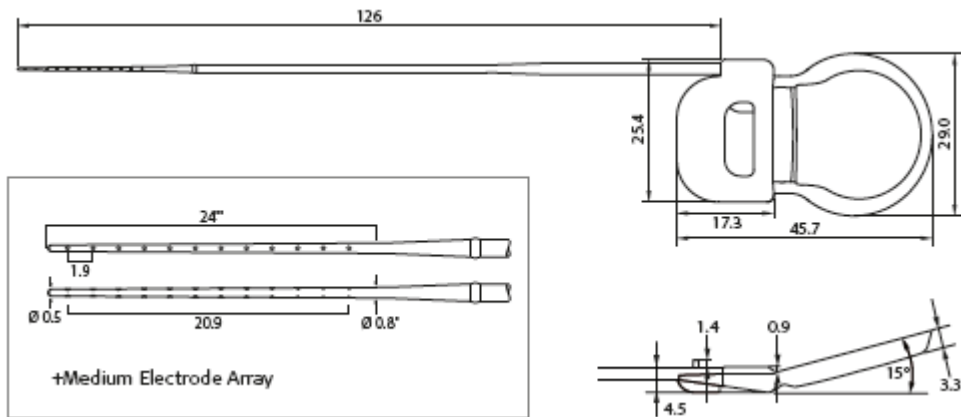
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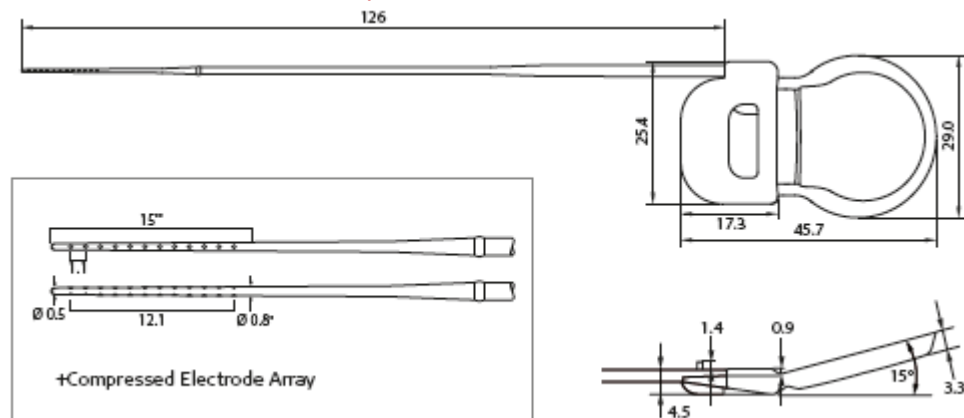
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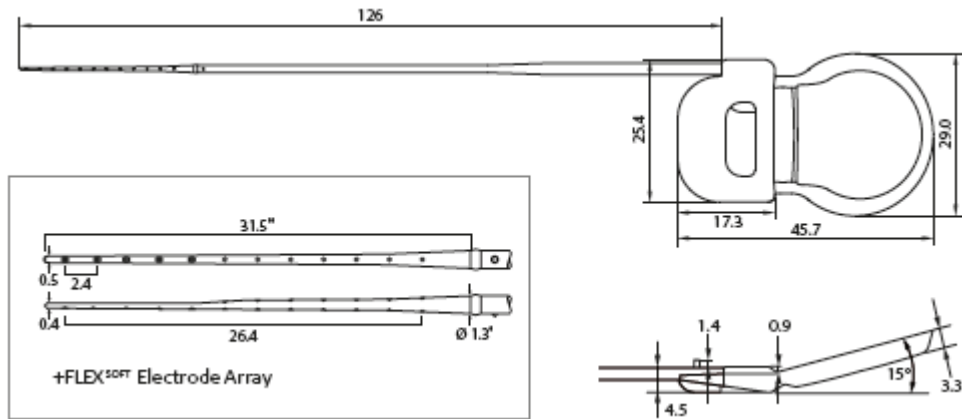
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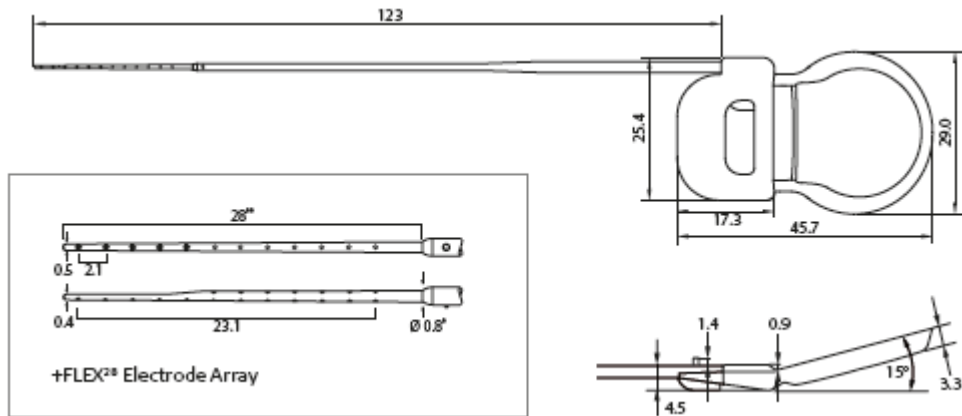
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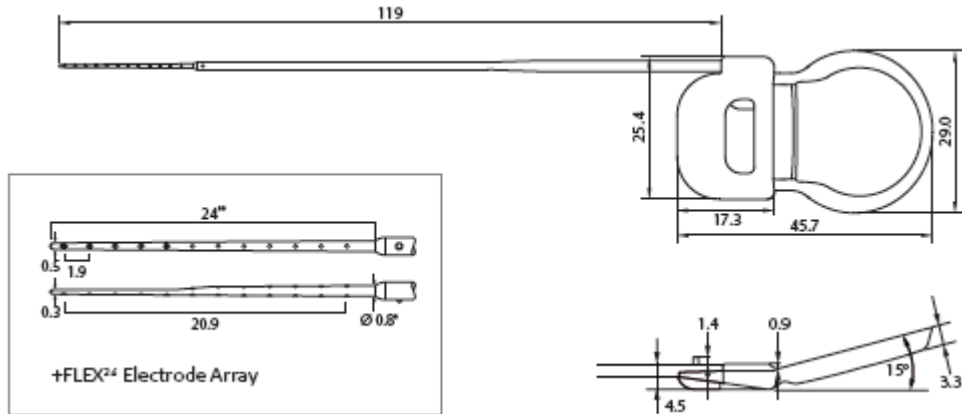
MED-EL CONCERT PIN +FLEX^{SOFT}



MED-EL CONCERT PIN +FLEX²⁸



MED-EL CONCERT PIN +FLEX²⁴



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

INSTRUCTIONS FOR USE

Mi1000 MED-EL CONCERT PIN Cochlear Implant

Device description

The Mi1000 MED-EL CONCERT PIN Implant (hereafter referred to as MED-EL CONCERT PIN) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family MED-EL CONCERT PIN). This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).

For principal dimensions of the implant refer to the drawings on the previous pages.

The volume of the implant without electrode is 3.7 cm³.

Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium and titanium.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
Maximum current amplitude: Median value = 1250 µA, range = 500 µA
Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to the MED-EL Application Software User Manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm²

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+Standard	126 mm	1.3 × 1.3	0.5 × 0.5	0.14	0.14	2.4	26.4
+Medium	126 mm	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.9	20.9
+Compressed	126 mm	0.7 × 0.7	0.5 × 0.5	0.14	0.14	1.1	12.1
+FLEX ^{SOFT}	126 mm	1.3 × 1.3	0.5 × 0.4	0.13	0.14	2.4	26.4
+FLEX ²⁸	123 mm	0.8 × 0.8	0.5 × 0.4	0.13	0.14	2.1	23.1
+FLEX ²⁴	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Some implant electrode types mentioned in these Instructions for Use may not be released for distribution in all markets. Please contact your local MED-EL representative for information on current product availability in your country.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations 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.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears..

Indications

The MED-EL CONCERT PIN shares the same indications for use as the COMBI 40+ System.

Bilateral deafness:

- 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 and 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 Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood 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.
- For bilateral deafness, MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.

Single-sided deafness and Asymmetric Hearing Loss:

- The use of the MED-EL Cochlear Implant System with CONCERT PIN +Standard, +Medium, +Compressed, +FLEX28, +FLEX24 or +FLEXSOFT is indicated for individuals aged 5 years and above with single-sided deafness (SSD) who have profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. Profound hearing loss is defined as having a pure tone average of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a pure tone average of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a pure tone average of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.
- The use of the MED-EL Cochlear Implant System with CONCERT PIN +Standard, +Medium, +Compressed, +FLEX28, +FLEX24 or +FLEXSOFT is indicated for individuals aged 5 years and above with asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears. Profound hearing loss is defined as having a pure tone average of dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a pure tone average ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.
- Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For adults, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For children, insufficient functional access to sound in the ear to be implanted must be determined by:
 - o aided speech perception test scores of five (5) percent or less on developmentally appropriate word lists when tested in the ear to be implanted alone.
- Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit.

General:

- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- To obtain optimal benefit from the MED-EL CONCERT PIN Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A pre-operative assessment according to the local professional standards must be conducted.
- Cochlear implants MED-EL CONCERT PIN +Standard are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants MED-EL CONCERT PIN +Medium are intended to be used in open cochleae (no obliteration or ossification) with mild malformation for an electrode insertion depth of about 24 mm as per request of the surgeon.
- Cochlear implants MED-EL CONCERT PIN +Compressed are intended to be used in cochleae with moderate obliteration, ossification, or malformation for an electrode insertion depth of 15 mm as per request of the surgeon.
- Cochlear Implants MED-EL CONCERT PIN +FLEX^{SOFT} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants MED-EL CONCERT PIN +FLEX²⁸ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 28 mm.
- Cochlear implants MED-EL CONCERT PIN +FLEX²⁴ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted with the MED-EL CONCERT PIN Cochlear Implant:

- if the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, platinum iridium and titanium);
- if there is an absence of cochlear development;
- if the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways;
- if external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted;
- If there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required;
- if anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery;
- if the psychological status of the patient is unstable or
- if the patient has unrealistic expectations.

Additionally for SSD / AHL individuals should not be implanted,

- if individual has had profound hearing loss for over ten years
- if individual has an acoustic neuroma

Undesirable side-effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Clinical data supports cochlear implants as a treatment option for SSD and AHL if existing treatments do not work. Some SSD and AHL patients will benefit from Cochlear Implant (CI) implantation and the risks and benefits should be weighed by the clinician to determine if CIs are an appropriate treatment for each individual patient. All SSD and AHL patients should be offered rehabilitation. There is the potential perceptual inference of overlapping of acoustic and electric bilateral hearing which may lead to limited CI performance.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped¹ between -20 °C (-4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the “use by” date specified on the package. Packaging² should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness

which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.

- 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 case the MED-EL implant user wants to dive, the user should consult an experienced physician about the 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 50m (165ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis³ can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling the mastoidectomy, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that focally progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm. The stimulator should be recessed to a depth of maximum 2 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The area of the temporal bone on which the stimulator will be placed shall be flattened in order to secure sufficient immobilization of the implant. The two pins of the MED-EL CONCERT PIN Cochlear Implant should be recessed into the skull with the PIN Drill Guide SI to a depth of 1.5 mm. Also the electrode lead should be protected in a ramp-like bony channel drilled into the skull without sharp edges. Both should be done in such a way that there will be no postoperative movement.
- The two pins give additional stability against translational and rotational motion. Recessing the pins and efficient immobilization of the stimulator (e.g. with sutures) is important to prevent postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

Recommended diameter of the cochleostomy & RW opening:

Electrode type	mm
MED-EL CONCERT PIN +Standard	1.3 mm
MED-EL CONCERT PIN +Medium	0.8 mm
MED-EL CONCERT PIN +Compressed	0.8 mm
MED-EL CONCERT PIN +FLEX ^{SOFT}	1.3 mm
MED-EL CONCERT PIN +FLEX ²⁸	0.8 mm
MED-EL CONCERT PIN +FLEX ²⁴	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear pre-surgically.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.
- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual..

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

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to Medical Procedures Manual.

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.

If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.

If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
MED-EL Elektromedizinische Geraete GmbH
Worldwide Headquarters
Safety adviser for the transport of dangerous goods
Fürstenweg 77a
6020 Innsbruck
Austria

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

UNC Feasibility Study Design

The feasibility study for the MED-EL Cochlear Implant System was conducted under IDE (G140050) to evaluate the safety and effectiveness of the MED-EL Cochlear Implant System in individuals 18 years of age and older with SSD or AHL. The primary study goal was to determine whether subjects with SSD or AHL demonstrated an improvement in speech perception, localization, and quality of life after receiving a cochlear implant. Both objective and subjective performance data were collected, as well as safety data in the form of adverse events. Forty subjects were implanted at the University of North Carolina at Chapel Hill with the MED-EL CONCERT or SYNCHRONY Cochlear Implant System in this prospective, single-site, non-randomized, non-blinded, repeated measures clinical study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in G140050 was limited to patients who met the following inclusion criteria:

- 18 years of age or older at the time of implantation
- Unilateral moderate-to-profound sensorineural hearing loss
 - o Unaided residual hearing thresholds measured from 250-8000 Hz (PTA $\geq$ 70 dB HL in the ear to be implanted)
 - o For SSD: normal to mild residual hearing thresholds from 250-8000 Hz in the contralateral ear ($\leq$ 35 dB HL at each frequency, 250-8000 Hz)
 - o For AHL: mild to moderate hearing thresholds from 250-8000 Hz in the contralateral ear (PTA $\geq$ 35 and $\leq$ 55 dB HL)
 - Aided word recognition of 80% or more as measured with CNC words (50-word list)
- Duration of moderate-to-profound sensorineural hearing loss less than or equal to 10 years
 - o Hearing loss for less than 10 years: study participants were only included if they had used a hearing aid consistently for 5 years
 - o Hearing loss for less than 5 years: study participants were only included if they had at least completed a 1-month hearing aid trial
- Previous experience (at least one month) with a current treatment option for SSD, including a conventional hearing aid, bone-conduction device, or CROS/BICROS technology
- Aided word recognition in the ear to be implanted of 60% or less as measured with CNC words (50-word list)
- Realistic expectations
- Willingness to obtain recommended meningitis vaccinations per CDC recommendations
- No reported cognitive issues: pass of the Mini Mental State Examination (MMSE) screener
- Ability and willingness to comply with study requirements, including travel to investigational site and study-related activities

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Non-native English speaker
- Conductive hearing loss in either ear
- Compromised auditory nerve, including those with a history of vestibular schwannoma
- Ossification
- Inability to participate in follow-up procedures (i.e., unwillingness, geographic location)
- History of meningitis, autoimmune disease, or any medical condition that contraindicate middle or inner ear surgery or anesthesia
- Meniere's disease with intractable vertigo
- Trauma that precludes inner ear surgery
- Case of sudden sensorineural hearing loss that has not been first evaluated by a physician
- Pregnancy
- Tinnitus as the primary purpose for seeking cochlear implantation
- Severe or catastrophic score on the Tinnitus Handicap Inventory

2. Follow-up Schedule

This study involved up to ten visits before and after implantation, for about a one-year period. Candidacy testing included medical and audiological evaluations (e.g., audiograms, speech recognition tests) to determine study eligibility. After confirming eligibility, the subject underwent baseline testing. The device was subsequently implanted based on the subject's candidacy testing. An initial follow-up visit was completed following surgery, and the cochlear implant was activated following a healing period of 2 to 4 weeks.

The baseline and postoperative measurements are summarized under 'Test Conditions' below. All patients were scheduled to return for follow-up examinations at 1, 3, 6, 9, and 12 months postoperatively. Pre-operatively and post-operatively, unaided air conduction thresholds were collected. At all intervals, speech perception in quiet and in noise and localization data was collected. Adverse events and complications were recorded at all visits.

The key timepoints (pre-op baseline and 12-months post-op) are shown below in the tables summarizing safety and effectiveness.

Test Conditions

The test battery was completed at the pre-operative interval and again at 1, 3, 6, 9, and 12 months post-operatively. For soundfield measures (speech perception and localization), a 180° arc with 11 speakers spaced 18° apart was utilized. Post-operative aided soundfield assessment was completed with the subject using the SONNET or OPUS 2 speech processor unless otherwise noted. For the AHL group, soundfield testing was completed with a hearing aid in the contralateral ear. See below for further details on testing conditions.

Subjects participated in two aural rehabilitation sessions with a board-certified speech-language pathologist. One session was completed after the initial activation of the external speech processor. The second session took place in conjunction with the 1-month post-initial activation interval.

- Unaided Diagnostic Assessment
 - o Air-conduction thresholds in both ears
 - o Assess bone-conduction thresholds if there is a PTA shift of >15 dB as compared to the previous interval
- Tympanometry for each ear
- Sound Field Measures
 - o Aided thresholds with the external speech processor on measured using pulsed, warble tones
 - Frequencies assessed: 250-8000 Hz
 - Masking presented to the contralateral ear
 - o Speech Perception Measures (recorded materials presented at 60 dB SPL)
 - Speech Perception in Quiet
 - Speech 0° azimuth
 - CNC words
 - AzBio sentences
 - Speech Perception in Noise
 - Speech and noise 0° azimuth
 - Speech 0° azimuth and noise to implanted side
 - Speech 0° azimuth and noise to contralateral ear
 - AzBio sentences
 - If >50% at SNR+10, then SNR+5; if >50% at SNR+5, then SNR0
 - BKB-SIN sentences with adaptive SNR
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
 - o Localization
 - 200-ms speech-shaped noise, presented at 70-dB SPL from one of the 11 speakers (evenly spaced -180 to 180 degrees), selected at random
 - Intensity level for each stimulus presentation randomly varied (10 dB around 70 dB SPL)
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
- Subjective questionnaires
 - o Speech, Spatial and Qualities of Hearing Scale (SSQ)
 - o Abbreviated Profile of Hearing Aid Benefit (APHAB)
 - o Tinnitus Handicap Inventory (THI)

3. Clinical Endpoints

Measures

Safety Measure: The primary safety measure was the evaluation of all adverse events reported within 12 months. The full profile of adverse events was summarized and considered, with specific attention given

to device-related adverse events. The adverse events include anticipated and unanticipated adverse events. The list of anticipated adverse device effects noted in the study protocol are as follows:

- Risks from the SYNCHRONY IFU
 - o Loss of residual hearing
 - o Increased vertigo
 - o Delay of healing of the scar
 - o Impairment of the sense of taste
 - o Potential for swallowing difficulties
 - o Numbness
 - o Increased tinnitus
 - o Stimulation of the facial nerve
 - o Temporary pain and uncomfortable sounds during stimulation
- Additional surgical risks
 - o Facial nerve injury
 - o Infection
 - o Bleeding
 - o Cerebrospinal fluid (CSF) leak
 - o Pain
 - o Scarring
- Additional post-operative risks
 - o Swelling around the incision and/or coil site
 - o Pain
 - o Reduced or loss of pinna sensitivity on the surgical side
 - o The cochlear implant may not provide any auditory stimulation
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in the perception of speech
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in localization
 - o Pain associated with the coil and/or placement of the external speech processor on the subject's ear
 - o Movement of the internal receiver
 - o Discomfort from electric stimulation
 - o Facial nerve stimulation
 - o Headache
 - o Dizziness
 - o Altered taste (i.e. reports of metallic tastes on the same side of the tongue as the surgical ear)
 - o Fatigue during follow-up assessment (completion of the test battery and/or mapping)
 - o The internal device may fail, requiring revision cochlear implantation
 - o The sound from the cochlear implant may interfere with the better hearing ear.

Effectiveness Measures: The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition. Aided speech perception performance on word and sentence materials at the post-activation intervals was evaluated to monitor trends over time. Unaided and aided (with BCHA or CI, as applicable) localization performance was also compared pre-operatively and at each of the post-activation intervals. The overall RMS error is reported for localization in each condition. Additionally, subjective report scores were compared pre-operatively and at the 12-month post-activation intervals.

Audiometric Test Methods & Effectiveness Measures

Speech perception and localization measures were recorded in a research lab that featured a 180° arc with 11 speakers spaced 18° apart. Postoperative aided sound field assessment was completed with the study participant listening with the OPUS 2 or SONNET speech processor.

Speech perception in quiet was tested at 0° azimuth, presenting CNC words (Peterson & Lehiste, 1962) or AzBio sentences (Spahr et al., 2012) at 60 dB SPL. Speech perception in noise was tested in the conditions (1) speech and noise 0° azimuth (S0N0), (2) speech 0° azimuth and noise to the affected ear/implanted side (S0NCI), and (3) speech 0° azimuth and noise to the contralateral ear (S0NContra). AzBio sentences were presented at 0 dB signal-to-noise ratio (SNR) in most cases. BKB-SIN sentences were presented with adaptive SNR.

For the localization task a 200-ms speech-shaped noise was presented at 70-dB SPL from one of the 11 speakers (selected randomly). The intensity level for each stimulus presentation was randomly varied (10 dB around 70 dB SPL). The listener was facing the center speaker during stimulus presentation and the task was to identify the source of the noise. No feedback was provided. In the condition cochlear implant speech processor OFF, study participants were only listening with the contralateral ear. In the condition cochlear implant speech processor ON, sound was perceived both via the cochlear implant and the contralateral ear.

Subjective data was collected via the SSQ and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995). The SSQ can be further divided into three subscales: speech, spatial, and quality. The APHAB consists of four subscales: Ease of Communication (EC), Background Noise (BN), Reverberation (RV), and Aversiveness (AV). The Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996) was also utilized to collect information on severity of tinnitus pre-operatively as well as at the 12-month interval.

B. Accountability of Study Cohort

In the SSD cohort, 20 subjects were enrolled and completed testing through the 12-month interval. In the AHL cohort, 20 subjects were enrolled and 18 completed testing through the 12-month interval. One subject in the AHL cohort withdrew prior to completion of all test intervals, and one subject was still undergoing follow-up testing at the time of data analysis.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a feasibility study performed in the US. Proportions enrolled are consistent with the age, sex/gender, racial and ethnic prevalence of the SSD and AHL.

1. SSD Cohort

Of the 20 implanted subjects, 12 were female and 8 were male. At the time of implantation, subjects ranged in age from 22 to 66 years of age. The duration of profound hearing loss ranged from 0.1 to 6.6 years. Fifteen subjects experienced sudden hearing loss and five subjects experienced a gradual hearing loss. Hearing loss was reported as unknown in 16 cases, due to Meniere's disease in three subjects, and caused by trauma in one case. Further information on subject demographics and hearing related variables is summarized in Table 2 below.

Table 2. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=20)
Gender	
Male	40% (8/20)
Female	60% (12/20)
Age (years)	50 (20) (22 – 66)
Duration of hearing loss (years)	
Noticeable	4.2 (20) (0.1 – 14.6)
Profound	2.6 (20) (0.1 – 6.6)
Implanted ear	
Left	55% (11/20)
Right	45% (9/20)
Tinnitus Handicap Grade Level	
Slight	35% (7/20)
Mild	40% (8/20)
Moderate	25% (5/20)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

2. AHL Cohort

Of the 18 subjects who completed follow-up, 9 were female and 9 were male. At the time of implantation, subjects ranged in age from 52 to 79 years of age. The duration of profound hearing loss ranged from 0.0

to 9.8 years. Ten subjects experienced sudden hearing loss and six subjects experienced a gradual hearing loss, with the remaining two subjects experiencing both a gradual and sudden loss. Hearing loss was reported as unknown in 14 cases, due to Meniere's disease in two subjects, due to noise-induced hearing loss in one subject, and caused by viral infection in one case. Further information on subject demographics and hearing related variables is summarized in Table 3 below.

Table 3. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=18)
Gender	
Male	50% (9/18)
Female	50% (9/18)
Age (years)	70 (18) (52 – 79)
Duration of hearing loss (years)	
Noticeable	11.5 (17) (0.0 – 51.5)
Profound	3.5 (17) (0.0 – 9.8)
Implanted ear	
Left	67% (12/18)
Right	33% (6/18)
Tinnitus Handicap Grade Level	
Slight	55% (10/18)
Mild	28% (5/18)
Moderate	17% (3/18)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on all patients implanted under G140050 (N=40) up to 12 months post implantation. Table 4 displays the adverse events reported for this study.

Adverse effects that occurred in IDE G140050:

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated. A total of nine adverse events were reported to be related to the device or procedure. An additional six adverse events were not able to be ruled out as device or procedure-related. No serious, unanticipated, device-related adverse events were reported.

Table 4. Number and percentage of adverse events observed for SSD subjects.

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects
Vertigo/dizziness/imbalance	11	9	22.5%
Unrelated infection	3	3	7.5%
Changes in sound quality/volume	3	2	5%
Depression	3	2	5%
Aural pressure	2	2	5%
Facial stimulation	2	2	5%
Headache	2	2	5%
Atrial fibrillation	1	1	2.5%
Bleeding at surgical site	1	1	2.5%
Electrode contact dislodged	1	1	2.5%
Fall involving bump to the implant	1	1	2.5%
Type C tympanogram	1	1	2.5%
Short circuit	1	1	2.5%
Total	32	21*	52.5%

*Some subjects experienced more than one device-related adverse event

The most frequently observed adverse event was vertigo, dizziness, or imbalance, which was reported a total of 11 times. In four cases, the event was deemed unrelated to the device or procedure. In three cases, it could not be ruled out that the event was related to the device or procedure. In the remaining four cases, it was determined that the event was related to the procedure. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. In all cases, the event was deemed unrelated to the device or procedure. All other events occurred at a rate of 5% or less (2 subjects or fewer), which is consistent with the rate of adverse events observed for the approved indication of bilateral, severe-to-profound, sensorineural hearing loss.

2. Effectiveness Results

The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition among 20 subjects with SSD and 17 subjects with AHL. Additionally, subjective reports from the SSQ and APHAB were also compared pre-operatively and at the 12-month post-operative interval.

Speech Perception in Quiet

SSD Cohort

Speech perception testing in quiet at the 12-month interval demonstrated an improvement in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. In the contralateral ear, no change was observed on CNC words from baseline to 12 months. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet across test intervals. The comparison of AzBio sentence score in quiet with a BCHA to scores at 12 months with the CI-ON also demonstrated no change. Table 5 displays the descriptive statistics of the speech perception in quiet scores for the SSD cohort.

Table 5. Speech perception in quiet (SSD Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	20	20	20	20	20	20	20
Mean (SD)	3.5 (6.68)	54.6 (18.15)	99.3 (2.27)	99.8 (0.62)	99.0 (1.56)	99.2 (1.15)	99.5 (1.19)
Min – Max	0 - 22	10 - 84	90- 100	98 - 100	95 - 100	95 – 100	95 - 100

AHL Cohort

For the cohort with asymmetric hearing loss, an improvement was demonstrated for speech perception testing in quiet at the 12-month interval in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. No change was observed on CNC words from baseline to 12 months in the contralateral ear. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet between the pre-operative and 12-month intervals. Additionally, no change was demonstrated in the comparison of AzBio sentence score in quiet between BCHA pre-operatively and 12 months with the CI-ON. See Table 6 below for the descriptive statistics of the speech perception in quiet scores.

Table 6. Speech perception in quiet (AHL Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	18	18	18	18	18	18	18
Mean (SD)	6.3 (7.98)	56.2 (18.41)	94.2 (7.06)	92.7 (8.68)	87.4 (13.96)	87.7 (11.01)	94.3 (8.38)
Min – Max	0 - 22	28 - 86	78 – 100	72 - 100	50 - 99	(61 – 99_	72 - 100

Speech Perception in Noise

SSD Cohort

On AzBio sentence testing in noise, subjects in the SSD cohort demonstrated an improvement between the bilateral, baseline, pre-operative, unaided testing and the bilateral, 12-month post-operative, CI + NH testing in the speech front, noise front condition. This same improvement was also noted between the bilateral, baseline, pre-operative, aided (with BCHA) condition and the bilateral, 12-month, post-operative, CI + NH condition. NO differences were found between pre-operative unaided and pre-operative, aided (with BCHA) scores. In the speech front, noise to the CI ear condition, subjects demonstrated no change in score in comparing the pre-operative interval to the CI-ON at 12 months. However, when comparing the pre-operative aided scores to the 12-month scores with CI, an improvement in performance was noted. Better scores were obtained for the pre-operative unaided condition as compared to the pre-operative aided condition.

A significant improvement was noted with the cochlear implant on at 12 months post-operative compared to the pre-operative, unaided interval for the speech front, noise to the contralateral ear condition. This same improvement was also found when comparing CI-ON at the 12-month, post-operative condition to the pre-operative, aided (with BCHA) condition. This improvement demonstrates that when noise presents as a masker to the better hearing ear, the cochlear implant provides benefit in speech understanding. Table 7 provides further details on AzBio sentence in noise scores.

Table 7. Speech perception in noise (SSD Cohort, AzBio)

SSD AzBio	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	37.5 (10.98)	31.5 (16.56)	47.2 (10.72)	83.4 (9.51)	61.25 (27.92)	85.0 (11.04)	16.5 (12.78)	18.3 (13.50)	52.6 (21.43)
Min- Max	20 - 64	0 – 59	29 - 68	59 - 94	0 – 98	60 - 97	0 - 45	0 – 59	8 - 86

A similar pattern was noted for speech in noise testing on the BKB-SIN. No significant changes were found in any comparisons for the speech front, noise front or speech front, noise to the CI ear conditions. However, in the speech front, noise to the contralateral ear condition, it was found that the CI does provide benefit in speech perception, and thus, a significant improvement was found when comparing the 12-month, post-operative CI + NH condition to the pre-operative, unaided condition or to the pre-operative, aided (with BCHA) condition. Table 8 provides the detailed descriptive statistics of the BKB-SIN scores.

Table 8. Speech perception in noise (SSD Cohort, BKB-SIN)

SSD BKB- SIN	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	0.1 (1.42)	0.8 (1.98)	-0.8 (1.74)	-4.8 (1.64)	-2.6 (2.39)	-4.8 (1.66)	1.8 (1.33)	1.8 (2.35)	-1.0 (2.20)
Min- Max	-2.5 – 3.0	-2.5 – 4.5	-3.0 – 4.0	-7.5 – -1.5	-7.0 – 1.0	-7.5 – -2.0	-0.5 – 4.0	-2.5 – 8.0	-5.0 – 5.5

AHL Cohort

For the AHL cohort, the majority of subjects were tested at 0 dB SNR. However, some subjects were tested at +5 or +10 dB SNR according to a decision tree implemented for determining SNR. Pre-operative and post-operative comparisons within subject were done at the same SNR. For this reason, only 17 subjects are included in the AzBio analysis for both the pre-operative unaided/aided (with BCHA) condition and the 12-month post-operative CI + HA condition.

In the speech front, noise front condition, a significant improvement was found on AzBio sentences for the 12-month, post-operative CI + HA condition compared to the pre-operative, unaided condition and compared to the pre-operative, aided (with BCHA) condition. Pre-operative, BCHA scores were worse than pre-operative unaided scores and worse than 12-month, post-operative CI + HA scores in the speech front, noise to the CI ear condition. In the speech front, noise to the contralateral ear condition, a signifi-

cant improvement was noted for the 12-month, post-operative CI + HA testing compared to both the pre-operative, unaided testing and the pre-operative, aided (with BCHA) testing. Table 9 below displays the descriptive statistics of the AzBio testing for the AHL Cohort.

Table 9. Speech perception in noise (AHL Cohort, AzBio)

AHL AzBio	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	17	17	17	17	17	17	17	17	17
Mean (SD)	22.7 (13.95)	20.5 (12.86)	33.5 (22.10)	44.2 (17.70)	30.5 (18.23)	44.6 (24.74)	6.3 (9.49)	11.3 (16.69)	29.4 (22.59)
Min- Max	0 – 47	0 – 47	3 – 85	9 – 78	1 – 70	5 – 94	0 – 36	0 – 66	1 – 95

For BKB-SIN testing, no changes were demonstrated in the speech front, noise to the CI ear condition. An improvement was found between the pre-operative, aided (with BCHA) condition and the 12-month, post-operative CI + HA condition in the speech front, noise front condition. Similar to the AzBio test results for the SSD cohort, there was a significant improvement for BKB-SIN in the speech front, noise to the contralateral ear condition when comparing the 12-month, post-operative CI + HA condition to the pre-operative, unaided condition. Table 10 below displays the analyses of BKB-SIN testing in the AHL cohort.

Table 10. Speech perception in noise (AHL Cohort, BKB-SIN)

AHL BKB- SIN	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	18	18	18	18	18	18	18	18	18
Mean (SD)	4.3 (3.62)	5.1 (3.04)	3.7 (3.28)	1.3 (3.89)	2.5 (3.77)	2.6 (3.78)	7.1 (4.14)	5.9 (4.50)	4.6 (4.44)
Min- Max	0.5 – 13.0	0 – 10	-2.0 – 9.5	-6.5 – 8.5	-3.5 – 10.0	-3.5 – 9.0	2.0 – 15.5	0 – 14.5	-1.0 – 15.5

Localization

SSD Cohort

Subjects in the SSD cohort demonstrated a significant improvement in localization performance with the CI at 12 months compared to the baseline, aided (with BCHA) condition. Additionally, results indicated an improvement in performance between the baseline, unaided condition and the 12-month, postoperative CI + NH condition. Table 11 displays localization performance in RMS error.

Table 11. Localization performance (SSD Cohort)

SSD Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	20	20	20
Mean (SD)	66.5 (20.47)	69.6 (18.71)	26.7 (6.32)
Min-Max	42.9 – 109.1	45.3 – 106.1	13.6 – 38.4

AHL Cohort

Similar to the SSD cohort, subjects in the AHL cohort demonstrated improved localization performance with the CI-ON at 12 months compared to the baseline, aided (with BCHA) condition. This improvement was also evident when comparing the 12-month, postoperative CI + HA to the pre-operative, unaided condition. Table 12 displays the analyses of the AHL Cohort's localization data.

Table 12. Localization performance (AHL Cohort)

AHL Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	18	18	18
Mean (SD)	76.5 (19.23)	77.2 (18.89)	40.1 (10.65)
Min-Max	43.8 – 105.3	45.6 – 106.5	26.6 – 73.6

Subjective Questionnaire

SSD Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the CI on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 13 below for the descriptive statistics of the SSQ.

Table 13. SSQ (SSD Cohort)

SSD SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20
Mean	3.7	7.1	2.4	6.5	5.6	7.7
Std. Deviation	1.34	0.99	1.2	1.86	2.09	1.28
Minimum	0.6	5.4	0.5	2.8	0.5	5.6
Maximum	7.2	8.9	4.5	8.9	9.8	9.8

Self-perceived benefit from the CI as reported on the APHAB demonstrated significant improvement on global score and the subscales, except for the aversiveness subscale. Table 14 below provides the detailed APHAB scores at the pre-operative and 12-month intervals.

Table 14. APHAB (SSD Cohort)

SSD APHAB	Global		EC		BN		RV		AV	
	pre	12m	Pre	12m	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20	20	20	20	20
Mean	49.8	17.9	31.6	8.7	70.1	25.2	47.5	19.7	43.1	26.7
Std. Deviation	18.65	8.91	21.06	6.15	17.32	11.95	21.96	12.43	28.64	24.83
Minimum	20.3	6.1	2.8	1.0	39.3	10.2	18.7	2.8	1.0	1.0
Maximum	86.3	36.7	81.0	24.8	95.0	56.2	87.0	41.7	93.0	91.0

AHL Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the cochlear implant on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 15 below for detailed information on the SSQ.

Table 15. SSQ (AHL Cohort)

AHL SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	18	18	18	18	18	18
Mean	3.2	5.8	2.6	6.0	4.6	6.8
Std. Deviation	1.48	1.50	1.26	1.62	1.77	1.20
Minimum	0.4	3.6	0.3	3.1	0.2	4.4
Maximum	6.0	8.9	4.7	8.5	8.3	8.7

Self-perceived benefit from the cochlear implant as reported on the APHAB demonstrated significant improvement on global score and other subscales over time except the aversiveness subscale. Table 16 below displayed the detailed APHAB scores at the pre-operative and 12-month post-operative intervals.

Table 16. APHAB (AHL Cohort)

AHL APHAB	Global		EC		BN		RV		AV	
	pre	12m	pre	12m	pre	12m	Pre	12m	pre	12m
N	18	18	18	18	18	18	18	18	18	18
Mean	54.1	28.1	42.9	16.6	63.5	39.3	56.0	28.3	43.1	42.4
Std. Deviation	16.21	10.49	24.67	13.01	16.84	17.10	18.30	11.96	35.04	29.21
Minimum	20.0	11.3	10.2	1.0	14.5	14.5	14.2	12.0	1.0	1.0
Maximum	92.3	54.1	91.0	54.0	95.0	66.3	97.0	54.2	99.0	97.0

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Literature Search Strategy

MED-EL conducted an extensive literature search to collect additional supporting clinical evidence of cochlear implants in SSD and/or AHL indications. The search terms they used are listed in Tables 17, 18, and 19, below.

Table 17. Combinations of Search Terms

Search Step	Search Terms	Review Question
1	"hearing loss" OR deaf*	P
2	single sided deafness OR SSD OR unilateral OR UHL OR asymmetric* OR AHL	P
3	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment" OR bone conduction OR BCI OR bone anchored OR BAHA OR CROS OR contralateral routing OR BiCROS OR "transcranial CROS" OR in-the-mouth device OR ITM OR soundbite OR bone-bridge OR "ad hear"	I & C
4	1 AND 2 AND 3	
5	Limit 4 to <i>Humans</i>	
6	Limit 5 to <i>Language</i> : English	
7	Limit 6 to <i>Publication date</i> : June, 2014 to May, 2017	

Search Step	Search Terms	Review Question
1	(single sided deafness) OR ((((((SSD) OR unilateral) OR UHL) OR asymmetric) OR AHL)) AND (((hearing loss) OR deaf*) OR deafness))	P
2	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment"	I & C
3	1 AND 2	
4	Limit 3 to <i>Humans</i>	
5	Limit 4 to <i>Language</i> : English	
6	Limit 5 to <i>Publication date</i> : May 1, 2017 to March 6, 2019	

Note. The different search terms are connected using Boolean logic. Activated filters are displayed in italics. P = Population, disease, or condition; I = Intervention; C = Comparator group or control.

* Wildcard symbol to broaden the search by creating a root word search.

Table 18. Inclusion and Exclusion Criteria for Retrieved Literature

Inclusion Criteria	
Population/Problem	Patients of any age who have single sided deafness
Intervention/Treatment	cochlear implant, any other treatment that makes hearing possible, or no treatment
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Inclusion Criteria	
Population/Problem	Patients of any age who have SSD or AHL
Intervention/Treatment	cochlear implant
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population e.g. different type of hearing loss
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Table 19. Literature Appraisal Criteria

Data Suitability	Description	Grading System
Appropriate Device	Where the data generated from the device in question?	D1 – Actual device D2 – Comparable device D3 – Other device
Appropriate Device Application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 – Same use A2 – Minor deviation A3 – Major deviation
Appropriate Patient Group	Were the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease including state and severity)?	P1 – Applicable P2 – Limited P3 – Different population
Acceptable Report/Data Collation	Did the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 – High quality R2 – Minor deficiencies R3 – Insufficient information
Data Contribution	Description	Grading System
Data Source Type	Was the design of the study appropriate?	T1 – Yes T2 – No
Outcome Measures	Did the outcome measures reported reflect the intended performance of the device?	O1 – Yes O2 – No
Follow-Up	Was the duration of the follow-up long enough to assess treatment effects and identify complications?	F1 – Yes F2 – No
Statistical Significance	Was a statistical analysis of the data provided and appropriate?	S1 – Yes S2 – No
Clinical Significance	Was the magnitude of the treatment effect observed clinically significant?	C1 – Yes C2 – No

Published Literature on Children

The literature search yielded five peer-reviewed papers in SSD and/or AHL children with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults and children aged 5 yrs and older. The papers comprise a total of 26 children with SSD (five of which were reported to be implanted with MED-EL devices) and a total of nine children with AHL. Tables 17, 18, and 19 above list the detailed literature search criteria and relevant information.

The overall benefits of CI in children with SSD and AHL include improved performance in speech perception in quiet and noise, sound localization and subjective measures of quality of life.

Word recognition in quiet:

Beck et al. (2017) reported diverse speech audiometry results. Some of the children showed measurable benefits on speech discrimination. The CAP scores improved for the SSD children (N = 8) with CI compared to preoperative performance. Rahne and Plontke (2016) reported that two SSD children improved with CI over time in number recognition, two SSD children showed no recognition. One child improved over time in word recognition with CI, whereas the other three children showed no recognition.

Word recognition in noise:

Arndt et al. (2015) reported on the speech perception in noise for different speech and noise configuration. Children with SSD demonstrated improved although variable performance on speech perception in spatially-separated conditions. Some children demonstrated improvement in spatially separate speech and noise. Tavora-Vieira and Rajan (2015) showed better and similar speech perception in noise with CI-on compared to CI-off for two SSD children. Gratacap et al. (2015) showed an increase in speech perception in noise in 9 children with AHL after 12 and 24 months of CI use compared to preoperative performance. Rahne and Plontke (2016) reported an improvement in speech reception thresholds in three SSD children when CI-on and CI-off are compared; in one child no measurement was possible.

Sound localization:

Arndt et al. (2015) reported a decreased localization error with CI for most of the children as compared to the preoperative unaided condition. Tavora-Vieira and Rajan (2015) reported that one child with SSD showed a de-

creased localization error after 6 and 12 months with the CI-on compared to CI-off condition, whereas the other child with SSD showed the same localization performance in both conditions. Rahne and Plontke (2016) reported an improvement in sound localization in four children with SSD when CI-on and CI-off are compared.

Subjective measures:

Beck et al. (2017) showed that the parents (N = 9) and children (N = 3) with SSD reported an increase score for the SSQ. Arndt et al. (2015) reported an increase the SSQ score in children with SSD with postlingual onset of deafness (N = 9), slight improvement in children with SSD with perilingual onset of deafness (N = 2) and minimal improvement or same performance in children with SSD who are congenitally deaf (N = 2).

Published Literature on Adults

The literature search yielded six peer-reviewed papers in SSD and/or AHL adults with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults. Although the paper by Kitoh et al. (2016) mentioned a study inclusion criterion of PTA > 70 dB HL, all five subjects included in the study had a pre-operative unaided PTA of 92 dB HL or higher. Hence, the results from this study were included in the summary below.

The six papers comprise a total of 58 adults with SSD (N = 50 of which implanted with MED-EL devices) and a total of 52 adults with AHL (N = 37 of which implanted with MED-EL devices). This subject count does not include five SSD nor 16 AHL patients from Skarzynski et al. (2017), as those subjects are part of the larger cohort from the same implant center later reported on by Lorens et al. (2019). Also note that three of the 58 adult SSD subjects might have an unaided PTA close to or below 90 dB HL in the implanted ear, as the paper by Döge et al. (2017) presents PTA data as median and interquartile range only (75%, i.e. N = 8 of 11 studied subjects have PTA > 100 dB HL).

The overall benefits of CI in SSD and AHL adult patients include improved performance regarding speech perception in quiet and in noise, sound localization and subjective measures regarding quality of life, music enjoyment and tinnitus.

Word recognition in quiet

Döge et al. (2017) showed that with a CI, the mean PTA thresholds of the deaf ear improved from the mean value of 120 dB at unaided condition to below 40 dB in the aided condition in 11 SSD subjects. In addition to the benefit of sound perception, the CI enabled better speech perception in quiet. Skarzynski et al. (2017) compared CI-on vs CI-off condition in 5 SSD and 16 AHL subjects and significantly better speech perception was observed in the CI-on condition. Results with the CI demonstrated a continuous improvement in speech recognition after 12-month of use. Rahne and Plontke (2016) reported a significant improvement in monosyllabic word and multisyllabic number recognition in quiet in comparing the 12-month and 1-month after CI activation in 17 SSD subjects. van Loon et al. (2017) reported that speech recognition scores increased from 74% pre-operatively to 88% at 12-month with bimodal stimulation in 7 AHL cases.

Speech perception in noise

Several studies found that the CI enabled better speech perception in noise. Rahne and Plontke (2016) reported a significant improved speech perception in noise at 3-month of CI activation with CI-on vs CI-off condition, and a continuous improvement occurring at 12-months in 17 SSD subjects. Skarzynski et al. (2017) reported better speech perception in noise at CI-on vs CI-off condition. van Loon et al. (2017) reported that in comparison to the CI-off or CI-only condition, bimodal stimulation resulted in significantly better speech recognition in noise and spatial speech recognition at 3-months, 6-months and 12-months post-activation. Lorens et al. (2019) reported a significant binaural benefit conveyed by CI-on in comparison to the CI-off condition, in 25 SSD and 45 AHL subjects. Kitoh et al. (2016) reported a gradually improved speech perception in noise after 12-months post-activation in comparison to the pre-operative condition. Döge et al. (2017) reported slightly improved speech reception in noise in CI-on vs CI-off condition in 8 of 11 patients. Three of 11 subjects, however, showed deteriorations at CI-on condition.

Sound localization

Döge et al. (2017) showed a significant decrease of localization error in the CI-on condition in comparison with the CI-off condition in 11 SSD subjects. Skarzynski et al. (2017) observed a significant localization benefit reflected by decrease in RMS angular error at CI-on vs CI-off condition. van Loon et al. (2017) reported a significant improved localization performance in all 7 AHL subjects with bimodal stimulation at 12-month in comparison to the pre-operative condition. Results with the CI demonstrated a continuous improvement in sound localization after 12 months of CI use. Rahne and Plontke (2016) reported that in comparison to CI-off, CI-on significantly improved

sound localization, reflected by a decrease in ADE (angular detection error) at 1-month of CI activation. A continuous improvement occurred over time. Kitoh et al. (2016) reported better sound localization in all 5 subjects, with continuous improvement through 12-month.

Subjective measures

van Loon et al. (2017) reported increased frequency and satisfaction of listening to music from 7 AHL CI users. Bimodal stimulation also resulted in better quality, clarity, and appreciation of different music styles. Skarzynski et al. (2017) reported substantial tinnitus suppression in all 15 patients with pre-operative tinnitus and Kitoh et al. (2016) reported decreased disturbance to daily life caused by tinnitus in all 5 SSD cases. Two studies addressed self-evaluation of CI performance in SSD and AHL subjects. Skarzynski et al. (2017) reported a significant improvement in the global score of APHAB, as well as sub-scales including 'Ease of communication', hearing under 'background noise' or under 'reverberation' at 14-months after CI activation in comparison to pre-operative condition. van Loon et al. (2017) reported that except for the 'speech production' subdomain, bimodal stimulation yielded a significant better outcome for all other subdomains of the NCIQ questionnaire. An average appreciation of the cochlear implant was scored 4.3/5, indicating a high satisfaction with the CI.

Conclusions from Real World Evidence

This clinical evaluation of cochlear implantation for the treatment of SSD and AHL is based on the above literature data sets relevant to the safety, performance, and effectiveness of cochlear implantation as a treatment option for individuals with AHL or SSD.

In this review of Real-World data, the latest clinical data were summarized on SSD and AHL patients from centers both in the US and around the globe that meet the proposed audiometric indication criterion of a profound hearing loss in the ear to be implanted, i.e., a PTA of 90 dB or higher. The clinical populations reported on include both adults and children older than 5 years age.

Taken together, the clinical data from this body of literature show consistent benefits of CI in individuals with SSD or AHL, in terms of improved speech perception in noise, spatial hearing, localization accuracy, and patient-reported subjective outcome measures. Consistent CI use of patients has been shown across literature reports, and notably so in the prospective study by Lorens et al. (2019) in 70 sequentially implanted SSD and AHL CI users (59 of which were implanted with MED-EL devices). These literature data provide Real World Evidence (according to the FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices") in support of the clinical benefits of CI in SSD and AHL recipients, as demonstrated in the UNC study. In this way, these literature reports do serve as supporting evidence which demonstrates a reasonable assurance of device safety and effectiveness and to characterize the benefit/risk profiles for the proposed SSD/AHL indications.

Symbols



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Serial number



Caution! Consult accompanying documents



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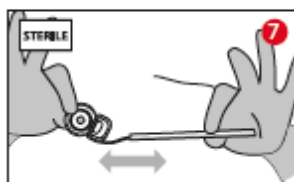
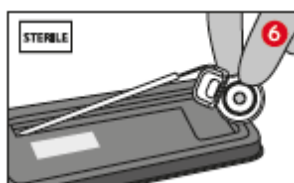
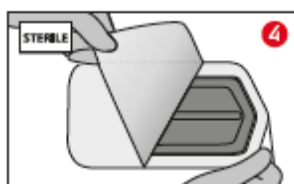
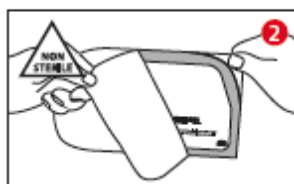
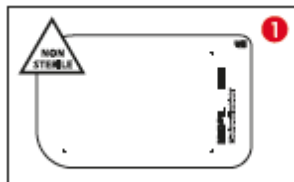
MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a | 6020 Innsbruck, Austria
office@medel.com

medel.com

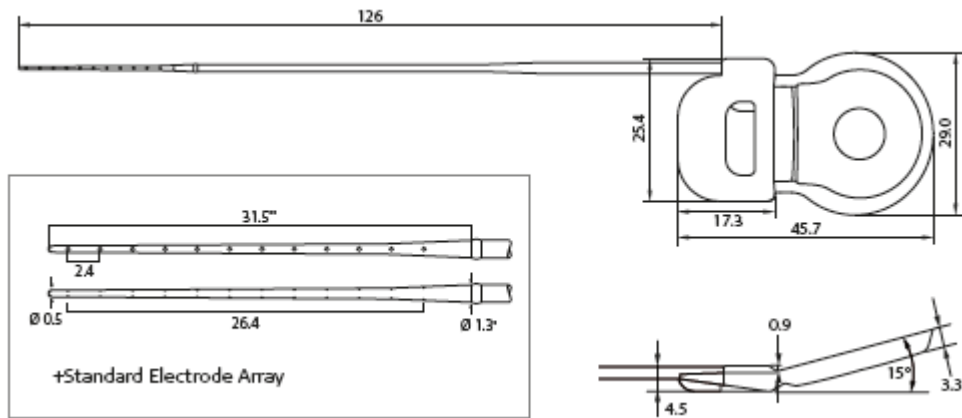
Mi1200 SYNCHRONY Cochlear Implant

+Standard | +Medium | +Compressed | +FLEX^{SOFT} | +FLEX28 | +FLEX24

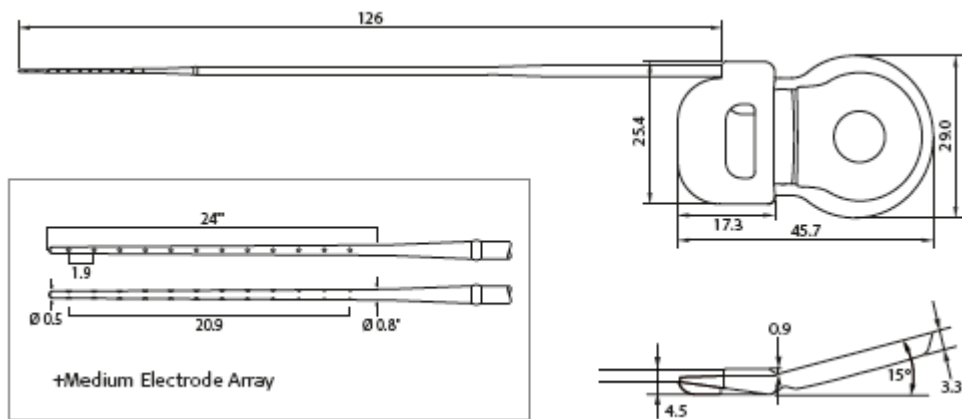
Opening instruction



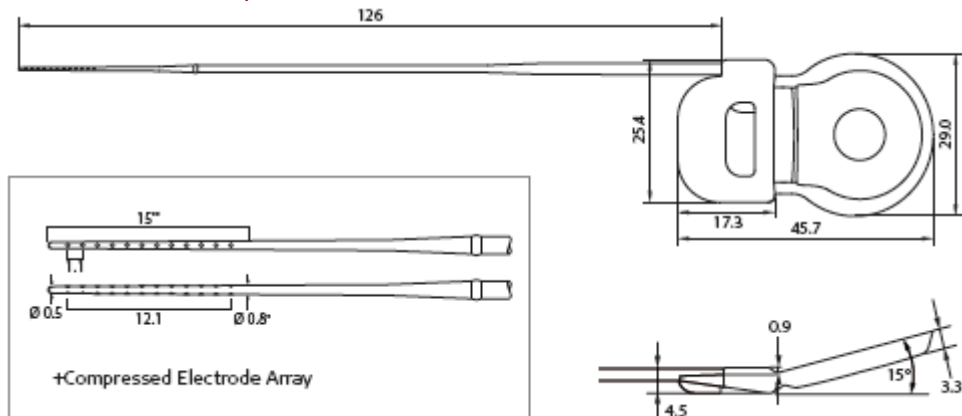
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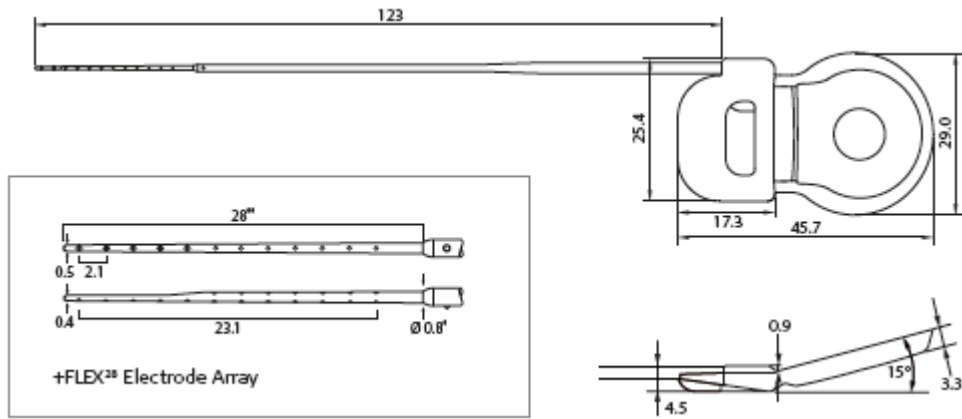
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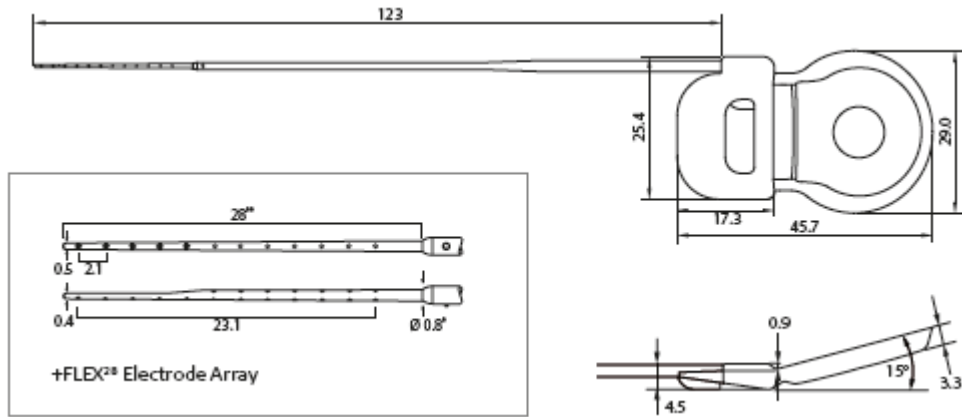
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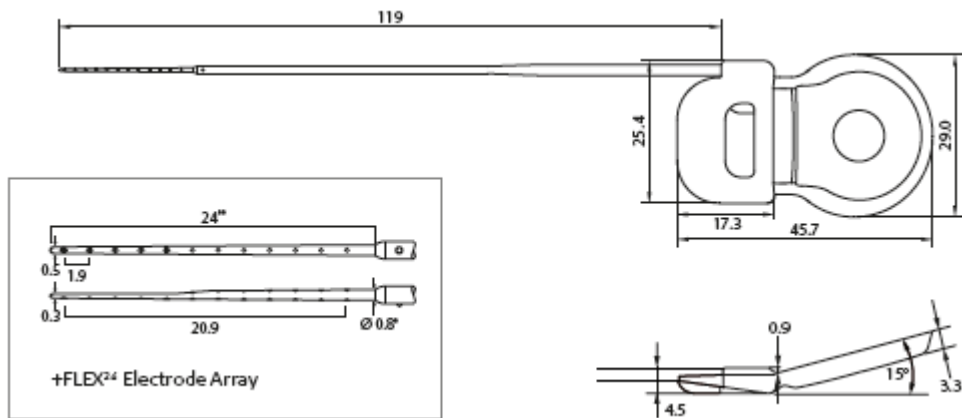
SYNCHRONY +FLEX^{SOFT}



SYNCHRONY +FLEX²⁸



SYNCHRONY +FLEX²⁴



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

INSTRUCTIONS FOR USE

Mi1200 SYNCHRONY Cochlear Implant

Device description

The Mi1200 SYNCHRONY Implant (hereafter referred to as SYNCHRONY) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a removable magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SYNCHRONY). This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).

For principal dimensions of the implant refer to the drawings on the previous pages.

The volume of the implant without electrode is 3.7 cm³.

Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium and parylene c.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
Maximum current amplitude: Median value = 1250 µA, range = 500 µA
Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to the MED-EL Application Software User Manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm²

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+Standard	126 mm	1.3 × 1.3	0.5 × 0.5	0.14	0.14	2.4	26.4
+Medium	126 mm	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.9	20.9
+Compressed	126 mm	0.7 × 0.7	0.5 × 0.5	0.14	0.14	1.1	12.1
+FLEX ^{SOFT}	126 mm	1.3 × 1.3	0.5 × 0.4	0.13	0.14	2.4	26.4
+FLEX ²⁸	123 mm	0.8 × 0.8	0.5 × 0.4	0.13	0.14	2.1	23.1
+FLEX ²⁴	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Some implant electrode types mentioned in these Instructions for Use may not be released for distribution in all markets. Please contact your local MED-EL representative for information on current product availability in your country.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations 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.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

Bilateral deafness:

- 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 and 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 Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood 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.
- For bilateral deafness, MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- To obtain optimal benefit from the SYNCHRONY Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A pre-operative assessment according to the local professional standards must be conducted.
- Cochlear implants SYNCHRONY +Standard are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants SYNCHRONY +Medium are intended to be used in open cochleae (no obliteration or ossification) with mild malformation for an electrode insertion depth of about 24 mm as per request of the surgeon.
- Cochlear implants SYNCHRONY +Compressed are intended to be used in cochleae with moderate obliteration, ossification, or malformation for an electrode insertion depth of 15 mm as per request of the surgeon.
- Cochlear Implants SYNCHRONY +FLEX^{SOFT} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants SYNCHRONY +FLEX²⁸ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 28 mm.
- Cochlear implants SYNCHRONY +FLEX²⁴ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted,

- if the individual is known to be intolerant of the materials used in the implant (including medical grade silicone, platinum, iridium and parylene c);
- if there is an absence of cochlear development;
- if the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways;
- if external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted;
- if there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required;
- if anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery;
- if the psychological status of the patient is unstable or
- if the patient has unrealistic expectations.

Additionally for SSD / AHL individuals should not be implanted,

- if individual has had profound hearing loss for over ten years
- if individual has an acoustic neuroma

Undesirable side-effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Clinical data supports cochlear implants as a treatment option for SSD and AHL if existing treatments do not work. Some SSD and AHL patients will benefit from Cochlear Implant (CI) implantation and the risks and benefits should be weighed by the clinician to determine if CIs are an appropriate treatment for each individual patient. All SSD and AHL patients should be offered rehabilitation. There is the potential perceptual inference of overlapping of acoustic and electric bilateral hearing which may lead to limited CI performance.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped¹ between -20 °C (-4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the “use by” date specified on the package. Packaging² should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness

which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.

- 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 case the MED-EL implant user wants to dive, the user should consult an experienced physician about the 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 50m (165ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis³ can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling the mastoidectomy, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that focally progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm. The stimulator should be recessed to a depth of maximum 2 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact. The anterior stimulator edge should not be recessed to a depth more than 2 mm.
- Additional immobilization of the implant needs to be done (e.g. with sutures). It should be done in such a way that there will be no postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

Recommended diameter of the cochleostomy & RW opening:

Electrode type	mm
SYNCHRONY +Standard	1.3 mm
SYNCHRONY +Medium	0.8 mm
SYNCHRONY +Compressed	0.8 mm
SYNCHRONY +FLEX ^{SOFT}	1.3 mm
SYNCHRONY +FLEX ²⁸	0.8 mm
SYNCHRONY +FLEX ²⁴	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.

- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear pre-surgically.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.
- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- In case of a magnet exchange surgery MED-EL recommends the use of the following tools: The Magnet Removal Tool Ms050206 or the Magnet Insertion Tool Ms050205 can be used in combination with the Non-Magnetic Spacer Ms010107 or the Replacement Magnet Ms010108. Please refer to the applicable Instructions for Use of these devices for further surgical precautions and warnings.
- After removal of the Non-Magnetic Spacer Ms010107, make sure that a fresh Replacement Magnet Ms010108 is inserted to re-establish full functionality of the implant.

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

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to Medical Procedures Manual.

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.

If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.

If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
MED-EL Elektromedizinische Geraete GmbH
Worldwide Headquarters
Safety adviser for the transport of dangerous goods
Fürstenweg 77a
6020 Innsbruck
Austria

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

UNC Feasibility Study Design

The feasibility study for the MED-EL Cochlear Implant System was conducted under IDE (G140050) to evaluate the safety and effectiveness of the MED-EL Cochlear Implant System in individuals 18 years of age and older with SSD or AHL. The primary study goal was to determine whether subjects with SSD or AHL demonstrated an improvement in speech perception, localization, and quality of life after receiving a cochlear implant. Both objective and subjective performance data were collected, as well as safety data in the form of adverse events. Forty subjects were implanted at the University of North Carolina at Chapel Hill with the MED-EL CONCERT or SYNCHRONY Cochlear Implant System in this prospective, single-site, non-randomized, non-blinded, repeated measures clinical study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in G140050 was limited to patients who met the following inclusion criteria:

- 18 years of age or older at the time of implantation
- Unilateral moderate-to-profound sensorineural hearing loss
 - o Unaided residual hearing thresholds measured from 250-8000 Hz (PTA $\geq$ 70 dB HL in the ear to be implanted)
 - o For SSD: normal to mild residual hearing thresholds from 250-8000 Hz in the contralateral ear ($\leq$ 35 dB HL at each frequency, 250-8000 Hz)
 - o For AHL: mild to moderate hearing thresholds from 250-8000 Hz in the contralateral ear (PTA $\geq$ 35 and $\leq$ 55 dB HL)
 - Aided word recognition of 80% or more as measured with CNC words (50-word list)
- Duration of moderate-to-profound sensorineural hearing loss less than or equal to 10 years
 - o Hearing loss for less than 10 years: study participants were only included if they had used a hearing aid consistently for 5 years
 - o Hearing loss for less than 5 years: study participants were only included if they had at least completed a 1-month hearing aid trial
- Previous experience (at least one month) with a current treatment option for SSD, including a conventional hearing aid, bone-conduction device, or CROS/BICROS technology
- Aided word recognition in the ear to be implanted of 60% or less as measured with CNC words (50-word list)
- Realistic expectations
- Willingness to obtain recommended meningitis vaccinations per CDC recommendations
- No reported cognitive issues: pass of the Mini Mental State Examination (MMSE) screener
- Ability and willingness to comply with study requirements, including travel to investigational site and study-related activities

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Non-native English speaker
- Conductive hearing loss in either ear
- Compromised auditory nerve, including those with a history of vestibular schwannoma
- Ossification
- Inability to participate in follow-up procedures (i.e., unwillingness, geographic location)
- History of meningitis, autoimmune disease, or any medical condition that contraindicate middle or inner ear surgery or anesthesia
- Meniere's disease with intractable vertigo
- Trauma that precludes inner ear surgery
- Case of sudden sensorineural hearing loss that has not been first evaluated by a physician
- Pregnancy
- Tinnitus as the primary purpose for seeking cochlear implantation
- Severe or catastrophic score on the Tinnitus Handicap Inventory

2. Follow-up Schedule

This study involved up to ten visits before and after implantation, for about a one-year period. Candidacy testing included medical and audiological evaluations (e.g., audiograms, speech recognition tests) to determine study eligibility. After confirming eligibility, the subject underwent baseline testing. The device was subsequently implanted based on the subject's candidacy testing. An initial follow-up visit was completed following surgery, and the cochlear implant was activated following a healing period of 2 to 4 weeks.

The baseline and postoperative measurements are summarized under 'Test Conditions' below. All patients were scheduled to return for follow-up examinations at 1, 3, 6, 9, and 12 months postoperatively. Pre-operatively and post-operatively, unaided air conduction thresholds were collected. At all intervals, speech perception in quiet and in noise and localization data was collected. Adverse events and complications were recorded at all visits.

The key timepoints (pre-op baseline and 12-months post-op) are shown below in the tables summarizing safety and effectiveness.

Test Conditions

The test battery was completed at the pre-operative interval and again at 1, 3, 6, 9, and 12 months post-operatively. For soundfield measures (speech perception and localization), a 180° arc with 11 speakers spaced 18° apart was utilized. Post-operative aided soundfield assessment was completed with the subject using the SONNET or OPUS 2 speech processor unless otherwise noted. For the AHL group, soundfield testing was completed with a hearing aid in the contralateral ear. See below for further details on testing conditions.

Subjects participated in two aural rehabilitation sessions with a board-certified speech-language pathologist. One session was completed after the initial activation of the external speech processor. The second session took place in conjunction with the 1-month post-initial activation interval.

- Unaided Diagnostic Assessment
 - o Air-conduction thresholds in both ears
 - o Assess bone-conduction thresholds if there is a PTA shift of >15 dB as compared to the previous interval
- Tympanometry for each ear
- Sound Field Measures
 - o Aided thresholds with the external speech processor on measured using pulsed, warble tones
 - Frequencies assessed: 250-8000 Hz
 - Masking presented to the contralateral ear
 - o Speech Perception Measures (recorded materials presented at 60 dB SPL)
 - Speech Perception in Quiet
 - Speech 0° azimuth
 - CNC words
 - AzBio sentences
 - Speech Perception in Noise
 - Speech and noise 0° azimuth
 - Speech 0° azimuth and noise to implanted side
 - Speech 0° azimuth and noise to contralateral ear
 - AzBio sentences
 - If >50% at SNR+10, then SNR+5; if >50% at SNR+5, then SNR0
 - BKB-SIN sentences with adaptive SNR
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
 - o Localization
 - 200-ms speech-shaped noise, presented at 70-dB SPL from one of the 11 speakers (evenly spaced -180 to 180 degrees), selected at random
 - Intensity level for each stimulus presentation randomly varied (10 dB around 70 dB SPL)
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
- Subjective questionnaires
 - o Speech, Spatial and Qualities of Hearing Scale (SSQ)
 - o Abbreviated Profile of Hearing Aid Benefit (APHAB)
 - o Tinnitus Handicap Inventory (THI)

3. Clinical Endpoints

Measures

Safety Measure: The primary safety measure was the evaluation of all adverse events reported within 12 months. The full profile of adverse events was summarized and considered, with specific attention given

to device-related adverse events. The adverse events include anticipated and unanticipated adverse events. The list of anticipated adverse device effects noted in the study protocol are as follows:

- Risks from the SYNCHRONY IFU
 - o Loss of residual hearing
 - o Increased vertigo
 - o Delay of healing of the scar
 - o Impairment of the sense of taste
 - o Potential for swallowing difficulties
 - o Numbness
 - o Increased tinnitus
 - o Stimulation of the facial nerve
 - o Temporary pain and uncomfortable sounds during stimulation
- Additional surgical risks
 - o Facial nerve injury
 - o Infection
 - o Bleeding
 - o Cerebrospinal fluid (CSF) leak
 - o Pain
 - o Scarring
- Additional post-operative risks
 - o Swelling around the incision and/or coil site
 - o Pain
 - o Reduced or loss of pinna sensitivity on the surgical side
 - o The cochlear implant may not provide any auditory stimulation
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in the perception of speech
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in localization
 - o Pain associated with the coil and/or placement of the external speech processor on the subject's ear
 - o Movement of the internal receiver
 - o Discomfort from electric stimulation
 - o Facial nerve stimulation
 - o Headache
 - o Dizziness
 - o Altered taste (i.e. reports of metallic tastes on the same side of the tongue as the surgical ear)
 - o Fatigue during follow-up assessment (completion of the test battery and/or mapping)
 - o The internal device may fail, requiring revision cochlear implantation
 - o The sound from the cochlear implant may interfere with the better hearing ear.

Effectiveness Measures: The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition. Aided speech perception performance on word and sentence materials at the post-activation intervals was evaluated to monitor trends over time. Unaided and aided (with BCHA or CI, as applicable) localization performance was also compared pre-operatively and at each of the post-activation intervals. The overall RMS error is reported for localization in each condition. Additionally, subjective report scores were compared pre-operatively and at the 12-month post-activation intervals.

Audiometric Test Methods & Effectiveness Measures

Speech perception and localization measures were recorded in a research lab that featured a 180° arc with 11 speakers spaced 18° apart. Postoperative aided sound field assessment was completed with the study participant listening with the OPUS 2 or SONNET speech processor.

Speech perception in quiet was tested at 0° azimuth, presenting CNC words (Peterson & Lehiste, 1962) or AzBio sentences (Spahr et al., 2012) at 60 dB SPL. Speech perception in noise was tested in the conditions (1) speech and noise 0° azimuth (S0N0), (2) speech 0° azimuth and noise to the affected ear/implanted side (S0NCI), and (3) speech 0° azimuth and noise to the contralateral ear (S0NContra). AzBio sentences were presented at 0 dB signal-to-noise ratio (SNR) in most cases. BKB-SIN sentences were presented with adaptive SNR.

For the localization task a 200-ms speech-shaped noise was presented at 70-dB SPL from one of the 11 speakers (selected randomly). The intensity level for each stimulus presentation was randomly varied (10 dB around 70 dB SPL). The listener was facing the center speaker during stimulus presentation and the task was to identify the source of the noise. No feedback was provided. In the condition cochlear implant speech processor OFF, study participants were only listening with the contralateral ear. In the condition cochlear implant speech processor ON, sound was perceived both via the cochlear implant and the contralateral ear.

Subjective data was collected via the SSQ and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995). The SSQ can be further divided into three subscales: speech, spatial, and quality. The APHAB consists of four subscales: Ease of Communication (EC), Background Noise (BN), Reverberation (RV), and Aversiveness (AV). The Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996) was also utilized to collect information on severity of tinnitus pre-operatively as well as at the 12-month interval.

B. Accountability of Study Cohort

In the SSD cohort, 20 subjects were enrolled and completed testing through the 12-month interval. In the AHL cohort, 20 subjects were enrolled and 18 completed testing through the 12-month interval. One subject in the AHL cohort withdrew prior to completion of all test intervals, and one subject was still undergoing follow-up testing at the time of data analysis.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a feasibility study performed in the US. Proportions enrolled are consistent with the age, sex/gender, racial and ethnic prevalence of the SSD and AHL.

1. SSD Cohort

Of the 20 implanted subjects, 12 were female and 8 were male. At the time of implantation, subjects ranged in age from 22 to 66 years of age. The duration of profound hearing loss ranged from 0.1 to 6.6 years. Fifteen subjects experienced sudden hearing loss and five subjects experienced a gradual hearing loss. Hearing loss was reported as unknown in 16 cases, due to Meniere's disease in three subjects, and caused by trauma in one case. Further information on subject demographics and hearing related variables is summarized in Table 2 below.

Table 2. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=20)
Gender	
Male	40% (8/20)
Female	60% (12/20)
Age (years)	50 (20) (22 – 66)
Duration of hearing loss (years)	
Noticeable	4.2 (20) (0.1 – 14.6)
Profound	2.6 (20) (0.1 – 6.6)
Implanted ear	
Left	55% (11/20)
Right	45% (9/20)
Tinnitus Handicap Grade Level	
Slight	35% (7/20)
Mild	40% (8/20)
Moderate	25% (5/20)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

2. AHL Cohort

Of the 18 subjects who completed follow-up, 9 were female and 9 were male. At the time of implantation, subjects ranged in age from 52 to 79 years of age. The duration of profound hearing loss ranged from 0.0

to 9.8 years. Ten subjects experienced sudden hearing loss and six subjects experienced a gradual hearing loss, with the remaining two subjects experiencing both a gradual and sudden loss. Hearing loss was reported as unknown in 14 cases, due to Meniere's disease in two subjects, due to noise-induced hearing loss in one subject, and caused by viral infection in one case. Further information on subject demographics and hearing related variables is summarized in Table 3 below.

Table 3. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=18)
Gender	
Male	50% (9/18)
Female	50% (9/18)
Age (years)	70 (18) (52 – 79)
Duration of hearing loss (years)	
Noticeable	11.5 (17) (0.0 – 51.5)
Profound	3.5 (17) (0.0 – 9.8)
Implanted ear	
Left	67% (12/18)
Right	33% (6/18)
Tinnitus Handicap Grade Level	
Slight	55% (10/18)
Mild	28% (5/18)
Moderate	17% (3/18)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on all patients implanted under G140050 (N=40) up to 12 months post implantation. Table 4 displays the adverse events reported for this study.

Adverse effects that occurred in IDE G140050:

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated. A total of nine adverse events were reported to be related to the device or procedure. An additional six adverse events were not able to be ruled out as device or procedure-related. No serious, unanticipated, device-related adverse events were reported.

Table 4. Number and percentage of adverse events observed for SSD subjects.

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects
Vertigo/dizziness/imbalance	11	9	22.5%
Unrelated infection	3	3	7.5%
Changes in sound quality/volume	3	2	5%
Depression	3	2	5%
Aural pressure	2	2	5%
Facial stimulation	2	2	5%
Headache	2	2	5%
Atrial fibrillation	1	1	2.5%
Bleeding at surgical site	1	1	2.5%
Electrode contact dislodged	1	1	2.5%
Fall involving bump to the implant	1	1	2.5%
Type C tympanogram	1	1	2.5%
Short circuit	1	1	2.5%
Total	32	21*	52.5%

*Some subjects experienced more than one device-related adverse event

The most frequently observed adverse event was vertigo, dizziness, or imbalance, which was reported a total of 11 times. In four cases, the event was deemed unrelated to the device or procedure. In three cases, it could not be ruled out that the event was related to the device or procedure. In the remaining four cases, it was determined that the event was related to the procedure. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. In all cases, the event was deemed unrelated to the device or procedure. All other events occurred at a rate of 5% or less (2 subjects or fewer), which is consistent with the rate of adverse events observed for the approved indication of bilateral, severe-to-profound, sensorineural hearing loss.

2. Effectiveness Results

The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition among 20 subjects with SSD and 17 subjects with AHL. Additionally, subjective reports from the SSQ and APHAB were also compared pre-operatively and at the 12-month post-operative interval.

Speech Perception in Quiet

SSD Cohort

Speech perception testing in quiet at the 12-month interval demonstrated an improvement in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. In the contralateral ear, no change was observed on CNC words from baseline to 12 months. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet across test intervals. The comparison of AzBio sentence score in quiet with a BCHA to scores at 12 months with the CI-ON also demonstrated no change. Table 5 displays the descriptive statistics of the speech perception in quiet scores for the SSD cohort.

Table 5. Speech perception in quiet (SSD Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	20	20	20	20	20	20	20
Mean (SD)	3.5 (6.68)	54.6 (18.15)	99.3 (2.27)	99.8 (0.62)	99.0 (1.56)	99.2 (1.15)	99.5 (1.19)
Min – Max	0 - 22	10 - 84	90- 100	98 - 100	95 - 100	95 – 100	95 - 100

AHL Cohort

For the cohort with asymmetric hearing loss, an improvement was demonstrated for speech perception testing in quiet at the 12-month interval in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. No change was observed on CNC words from baseline to 12 months in the contralateral ear. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet between the pre-operative and 12-month intervals. Additionally, no change was demonstrated in the comparison of AzBio sentence score in quiet between BCHA pre-operatively and 12 months with the CI-ON. See Table 6 below for the descriptive statistics of the speech perception in quiet scores.

Table 6. Speech perception in quiet (AHL Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12- month, CI-ON CNC	Baseline, unaided CNC	12- month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12- month, CI-ON AzBio
N	18	18	18	18	18	18	18
Mean (SD)	6.3 (7.98)	56.2 (18.41)	94.2 (7.06)	92.7 (8.68)	87.4 (13.96)	87.7 (11.01)	94.3 (8.38)
Min – Max	0 - 22	28 - 86	78 – 100	72 - 100	50 - 99	(61 – 99_	72 - 100

Speech Perception in Noise

SSD Cohort

On AzBio sentence testing in noise, subjects in the SSD cohort demonstrated an improvement between the bilateral, baseline, pre-operative, unaided testing and the bilateral, 12-month post-operative, CI + NH testing in the speech front, noise front condition. This same improvement was also noted between the bilateral, baseline, pre-operative, aided (with BCHA) condition and the bilateral, 12-month, post-operative, CI + NH condition. NO differences were found between pre-operative unaided and pre-operative, aided (with BCHA) scores. In the speech front, noise to the CI ear condition, subjects demonstrated no change in score in comparing the pre-operative interval to the CI-ON at 12 months. However, when comparing the pre-operative aided scores to the 12-month scores with CI, an improvement in performance was noted. Better scores were obtained for the pre-operative unaided condition as compared to the pre-operative aided condition.

A significant improvement was noted with the cochlear implant on at 12 months post-operative compared to the pre-operative, unaided interval for the speech front, noise to the contralateral ear condition. This same improvement was also found when comparing CI-ON at the 12-month, post-operative condition to the pre-operative, aided (with BCHA) condition. This improvement demonstrates that when noise presents as a masker to the better hearing ear, the cochlear implant provides benefit in speech understanding. Table 7 provides further details on AzBio sentence in noise scores.

Table 7. Speech perception in noise (SSD Cohort, AzBio)

SSD AzBio	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	37.5 (10.98)	31.5 (16.56)	47.2 (10.72)	83.4 (9.51)	61.25 (27.92)	85.0 (11.04)	16.5 (12.78)	18.3 (13.50)	52.6 (21.43)
Min- Max	20 - 64	0 – 59	29 - 68	59 - 94	0 – 98	60 - 97	0 - 45	0 – 59	8 - 86

A similar pattern was noted for speech in noise testing on the BKB-SIN. No significant changes were found in any comparisons for the speech front, noise front or speech front, noise to the CI ear conditions. However, in the speech front, noise to the contralateral ear condition, it was found that the CI does provide benefit in speech perception, and thus, a significant improvement was found when comparing the 12-month, post-operative CI + NH condition to the pre-operative, unaided condition or to the pre-operative, aided (with BCHA) condition. Table 8 provides the detailed descriptive statistics of the BKB-SIN scores.

Table 8. Speech perception in noise (SSD Cohort, BKB-SIN)

SSD BKB- SIN	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	0.1 (1.42)	0.8 (1.98)	-0.8 (1.74)	-4.8 (1.64)	-2.6 (2.39)	-4.8 (1.66)	1.8 (1.33)	1.8 (2.35)	-1.0 (2.20)
Min- Max	-2.5 – 3.0	-2.5 – 4.5	-3.0 – 4.0	-7.5 – -1.5	-7.0 – 1.0	-7.5 – -2.0	-0.5 – 4.0	-2.5 – 8.0	-5.0 – 5.5

AHL Cohort

For the AHL cohort, the majority of subjects were tested at 0 dB SNR. However, some subjects were tested at +5 or +10 dB SNR according to a decision tree implemented for determining SNR. Pre-operative and post-operative comparisons within subject were done at the same SNR. For this reason, only 17 subjects are included in the AzBio analysis for both the pre-operative unaided/aided (with BCHA) condition and the 12-month post-operative CI + HA condition.

In the speech front, noise front condition, a significant improvement was found on AzBio sentences for the 12-month, post-operative CI + HA condition compared to the pre-operative, unaided condition and compared to the pre-operative, aided (with BCHA) condition. Pre-operative, BCHA scores were worse than pre-operative unaided scores and worse than 12-month, post-operative CI + HA scores in the speech front, noise to the CI ear condition. In the speech front, noise to the contralateral ear condition, a signifi-

cant improvement was noted for the 12-month, post-operative CI + HA testing compared to both the pre-operative, unaided testing and the pre-operative, aided (with BCHA) testing. Table 9 below displays the descriptive statistics of the AzBio testing for the AHL Cohort.

Table 9. Speech perception in noise (AHL Cohort, AzBio)

AHL AzBio	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	17	17	17	17	17	17	17	17	17
Mean (SD)	22.7 (13.95)	20.5 (12.86)	33.5 (22.10)	44.2 (17.70)	30.5 (18.23)	44.6 (24.74)	6.3 (9.49)	11.3 (16.69)	29.4 (22.59)
Min- Max	0 – 47	0 – 47	3 – 85	9 – 78	1 – 70	5 – 94	0 – 36	0 – 66	1 – 95

For BKB-SIN testing, no changes were demonstrated in the speech front, noise to the CI ear condition. An improvement was found between the pre-operative, aided (with BCHA) condition and the 12-month, post-operative CI + HA condition in the speech front, noise front condition. Similar to the AzBio test results for the SSD cohort, there was a significant improvement for BKB-SIN in the speech front, noise to the contralateral ear condition when comparing the 12-month, post-operative CI + HA condition to the pre-operative, unaided condition. Table 10 below displays the analyses of BKB-SIN testing in the AHL cohort.

Table 10. Speech perception in noise (AHL Cohort, BKB-SIN)

AHL BKB- SIN	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	18	18	18	18	18	18	18	18	18
Mean (SD)	4.3 (3.62)	5.1 (3.04)	3.7 (3.28)	1.3 (3.89)	2.5 (3.77)	2.6 (3.78)	7.1 (4.14)	5.9 (4.50)	4.6 (4.44)
Min- Max	0.5 – 13.0	0 – 10	-2.0 – 9.5	-6.5 – 8.5	-3.5 – 10.0	-3.5 – 9.0	2.0 – 15.5	0 – 14.5	-1.0 – 15.5

Localization

SSD Cohort

Subjects in the SSD cohort demonstrated a significant improvement in localization performance with the CI at 12 months compared to the baseline, aided (with BCHA) condition. Additionally, results indicated an improvement in performance between the baseline, unaided condition and the 12-month, postoperative CI + NH condition. Table 11 displays localization performance in RMS error.

Table 11. Localization performance (SSD Cohort)

SSD Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	20	20	20
Mean (SD)	66.5 (20.47)	69.6 (18.71)	26.7 (6.32)
Min-Max	42.9 – 109.1	45.3 – 106.1	13.6 – 38.4

AHL Cohort

Similar to the SSD cohort, subjects in the AHL cohort demonstrated improved localization performance with the CI-ON at 12 months compared to the baseline, aided (with BCHA) condition. This improvement was also evident when comparing the 12-month, postoperative CI + HA to the pre-operative, unaided condition. Table 12 displays the analyses of the AHL Cohort's localization data.

Table 12. Localization performance (AHL Cohort)

AHL Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	18	18	18
Mean (SD)	76.5 (19.23)	77.2 (18.89)	40.1 (10.65)
Min-Max	43.8 – 105.3	45.6 – 106.5	26.6 – 73.6

Subjective Questionnaire

SSD Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the CI on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 13 below for the descriptive statistics of the SSQ.

Table 13. SSQ (SSD Cohort)

SSD SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20
Mean	3.7	7.1	2.4	6.5	5.6	7.7
Std. Deviation	1.34	0.99	1.2	1.86	2.09	1.28
Minimum	0.6	5.4	0.5	2.8	0.5	5.6
Maximum	7.2	8.9	4.5	8.9	9.8	9.8

Self-perceived benefit from the CI as reported on the APHAB demonstrated significant improvement on global score and the subscales, except for the aversiveness subscale. Table 14 below provides the detailed APHAB scores at the pre-operative and 12-month intervals.

Table 14. APHAB (SSD Cohort)

SSD APHAB	Global		EC		BN		RV		AV	
	pre	12m	Pre	12m	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20	20	20	20	20
Mean	49.8	17.9	31.6	8.7	70.1	25.2	47.5	19.7	43.1	26.7
Std. Deviation	18.65	8.91	21.06	6.15	17.32	11.95	21.96	12.43	28.64	24.83
Minimum	20.3	6.1	2.8	1.0	39.3	10.2	18.7	2.8	1.0	1.0
Maximum	86.3	36.7	81.0	24.8	95.0	56.2	87.0	41.7	93.0	91.0

AHL Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the cochlear implant on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 15 below for detailed information on the SSQ.

Table 15. SSQ (AHL Cohort)

AHL SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	18	18	18	18	18	18
Mean	3.2	5.8	2.6	6.0	4.6	6.8
Std. Deviation	1.48	1.50	1.26	1.62	1.77	1.20
Minimum	0.4	3.6	0.3	3.1	0.2	4.4
Maximum	6.0	8.9	4.7	8.5	8.3	8.7

Self-perceived benefit from the cochlear implant as reported on the APHAB demonstrated significant improvement on global score and other subscales over time except the aversiveness subscale. Table 16 below displayed the detailed APHAB scores at the pre-operative and 12-month post-operative intervals.

Table 16. APHAB (AHL Cohort)

AHL APHAB	Global		EC		BN		RV		AV	
	pre	12m	pre	12m	pre	12m	Pre	12m	pre	12m
N	18	18	18	18	18	18	18	18	18	18
Mean	54.1	28.1	42.9	16.6	63.5	39.3	56.0	28.3	43.1	42.4
Std. Deviation	16.21	10.49	24.67	13.01	16.84	17.10	18.30	11.96	35.04	29.21
Minimum	20.0	11.3	10.2	1.0	14.5	14.5	14.2	12.0	1.0	1.0
Maximum	92.3	54.1	91.0	54.0	95.0	66.3	97.0	54.2	99.0	97.0

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Literature Search Strategy

MED-EL conducted an extensive literature search to collect additional supporting clinical evidence of cochlear implants in SSD and/or AHL indications. The search terms they used are listed in Tables 17, 18, and 19, below.

Table 17. Combinations of Search Terms

Search Step	Search Terms	Review Question
1	"hearing loss" OR deaf*	P
2	single sided deafness OR SSD OR unilateral OR UHL OR asymmetric* OR AHL	P
3	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment" OR bone conduction OR BCI OR bone anchored OR BAHA OR CROS OR contralateral routing OR BiCROS OR "transcranial CROS" OR in-the-mouth device OR ITM OR soundbite OR bone-bridge OR "ad hear"	I & C
4	1 AND 2 AND 3	
5	Limit 4 to <i>Humans</i>	
6	Limit 5 to <i>Language</i> : English	
7	Limit 6 to <i>Publication date</i> : June, 2014 to May, 2017	

Search Step	Search Terms	Review Question
1	(single sided deafness) OR (((((((SSD) OR unilateral) OR UHL) OR asymmetric) OR AHL)) AND (((hearing loss) OR deaf*) OR deafness))	P
2	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment"	I & C
3	1 AND 2	
4	Limit 3 to <i>Humans</i>	
5	Limit 4 to <i>Language</i> : English	
6	Limit 5 to <i>Publication date</i> : May 1, 2017 to March 6, 2019	

Note. The different search terms are connected using Boolean logic. Activated filters are displayed in italics. P = Population, disease, or condition; I = Intervention; C = Comparator group or control.

* Wildcard symbol to broaden the search by creating a root word search.

Table 18. Inclusion and Exclusion Criteria for Retrieved Literature

Inclusion Criteria	
Population/Problem	Patients of any age who have single sided deafness
Intervention/Treatment	cochlear implant, any other treatment that makes hearing possible, or no treatment
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant
Inclusion Criteria	
Population/Problem	Patients of any age who have SSD or AHL
Intervention/Treatment	cochlear implant
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population e.g. different type of hearing loss
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Table 19. Literature Appraisal Criteria

Data Suitability	Description	Grading System
Appropriate Device	Where the data generated from the device in question?	D1 – Actual device D2 – Comparable device D3 – Other device
Appropriate Device Application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 – Same use A2 – Minor deviation A3 – Major deviation
Appropriate Patient Group	Were the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease including state and severity)?	P1 – Applicable P2 – Limited P3 – Different population
Acceptable Report/Data Collation	Did the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 – High quality R2 – Minor deficiencies R3 – Insufficient information
Data Contribution	Description	Grading System
Data Source Type	Was the design of the study appropriate?	T1 – Yes T2 – No
Outcome Measures	Did the outcome measures reported reflect the intended performance of the device?	O1 – Yes O2 – No
Follow-Up	Was the duration of the follow-up long enough to assess treatment effects and identify complications?	F1 – Yes F2 – No
Statistical Significance	Was a statistical analysis of the data provided and appropriate?	S1 – Yes S2 – No
Clinical Significance	Was the magnitude of the treatment effect observed clinically significant?	C1 – Yes C2 – No

Published Literature on Children

The literature search yielded five peer-reviewed papers in SSD and/or AHL children with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults and children aged 5 yrs and older. The papers comprise a total of 26 children with SSD (five of which were reported to be implanted with MED-EL devices) and a total of nine children with AHL. Tables 17, 18, and 19 above list the detailed literature search criteria and relevant information.

The overall benefits of CI in children with SSD and AHL include improved performance in speech perception in quiet and noise, sound localization and subjective measures of quality of life.

Word recognition in quiet:

Beck et al. (2017) reported diverse speech audiometry results. Some of the children showed measurable benefits on speech discrimination. The CAP scores improved for the SSD children (N = 8) with CI compared to preoperative performance. Rahne and Plontke (2016) reported that two SSD children improved with CI over time in number recognition, two SSD children showed no recognition. One child improved over time in word recognition with CI, whereas the other three children showed no recognition.

Word recognition in noise:

Arndt et al. (2015) reported on the speech perception in noise for different speech and noise configuration. Children with SSD demonstrated improved although variable performance on speech perception in spatially-separated conditions. Some children demonstrated improvement in spatially separate speech and noise. Tavora-Vieira and Rajan (2015) showed better and similar speech perception in noise with CI-on compared to CI-off for two SSD children. Gratacap et al. (2015) showed an increase in speech perception in noise in 9 children with AHL after 12 and 24 months of CI use compared to preoperative performance. Rahne and Plontke (2016) reported an improvement in speech reception thresholds in three SSD children when CI-on and CI-off are compared; in one child no measurement was possible.

Sound localization:

Arndt et al. (2015) reported a decreased localization error with CI for most of the children as compared to the preoperative unaided condition. Tavora-Vieira and Rajan (2015) reported that one child with SSD showed a de-

creased localization error after 6 and 12 months with the CI-on compared to CI-off condition, whereas the other child with SSD showed the same localization performance in both conditions. Rahne and Plontke (2016) reported an improvement in sound localization in four children with SSD when CI-on and CI-off are compared.

Subjective measures:

Beck et al. (2017) showed that the parents (N = 9) and children (N = 3) with SSD reported an increase score for the SSQ. Arndt et al. (2015) reported an increase the SSQ score in children with SSD with postlingual onset of deafness (N = 9), slight improvement in children with SSD with perilingual onset of deafness (N = 2) and minimal improvement or same performance in children with SSD who are congenitally deaf (N = 2).

Published Literature on Adults

The literature search yielded six peer-reviewed papers in SSD and/or AHL adults with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults. Although the paper by Kitoh et al. (2016) mentioned a study inclusion criterion of PTA > 70 dB HL, all five subjects included in the study had a pre-operative unaided PTA of 92 dB HL or higher. Hence, the results from this study were included in the summary below.

The six papers comprise a total of 58 adults with SSD (N = 50 of which implanted with MED-EL devices) and a total of 52 adults with AHL (N = 37 of which implanted with MED-EL devices). This subject count does not include five SSD nor 16 AHL patients from Skarzynski et al. (2017), as those subjects are part of the larger cohort from the same implant center later reported on by Lorens et al. (2019). Also note that three of the 58 adult SSD subjects might have an unaided PTA close to or below 90 dB HL in the implanted ear, as the paper by Döge et al. (2017) presents PTA data as median and interquartile range only (75%, i.e. N = 8 of 11 studied subjects have PTA > 100 dB HL).

The overall benefits of CI in SSD and AHL adult patients include improved performance regarding speech perception in quiet and in noise, sound localization and subjective measures regarding quality of life, music enjoyment and tinnitus.

Word recognition in quiet

Döge et al. (2017) showed that with a CI, the mean PTA thresholds of the deaf ear improved from the mean value of 120 dB at unaided condition to below 40 dB in the aided condition in 11 SSD subjects. In addition to the benefit of sound perception, the CI enabled better speech perception in quiet. Skarzynski et al. (2017) compared CI-on vs CI-off condition in 5 SSD and 16 AHL subjects and significantly better speech perception was observed in the CI-on condition. Results with the CI demonstrated a continuous improvement in speech recognition after 12-month of use. Rahne and Plontke (2016) reported a significant improvement in monosyllabic word and multisyllabic number recognition in quiet in comparing the 12-month and 1-month after CI activation in 17 SSD subjects. van Loon et al. (2017) reported that speech recognition scores increased from 74% pre-operatively to 88% at 12-month with bimodal stimulation in 7 AHL cases.

Speech perception in noise

Several studies found that the CI enabled better speech perception in noise. Rahne and Plontke (2016) reported a significant improved speech perception in noise at 3-month of CI activation with CI-on vs CI-off condition, and a continuous improvement occurring at 12-months in 17 SSD subjects. Skarzynski et al. (2017) reported better speech perception in noise at CI-on vs CI-off condition. van Loon et al. (2017) reported that in comparison to the CI-off or CI-only condition, bimodal stimulation resulted in significantly better speech recognition in noise and spatial speech recognition at 3-months, 6-months and 12-months post-activation. Lorens et al. (2019) reported a significant binaural benefit conveyed by CI-on in comparison to the CI-off condition, in 25 SSD and 45 AHL subjects. Kitoh et al. (2016) reported a gradually improved speech perception in noise after 12-months post-activation in comparison to the pre-operative condition. Döge et al. (2017) reported slightly improved speech reception in noise in CI-on vs CI-off condition in 8 of 11 patients. Three of 11 subjects, however, showed deteriorations at CI-on condition.

Sound localization

Döge et al. (2017) showed a significant decrease of localization error in the CI-on condition in comparison with the CI-off condition in 11 SSD subjects. Skarzynski et al. (2017) observed a significant localization benefit reflected by decrease in RMS angular error at CI-on vs CI-off condition. van Loon et al. (2017) reported a significant improved localization performance in all 7 AHL subjects with bimodal stimulation at 12-month in comparison to the pre-operative condition. Results with the CI demonstrated a continuous improvement in sound localization after 12 months of CI use. Rahne and Plontke (2016) reported that in comparison to CI-off, CI-on significantly improved

sound localization, reflected by a decrease in ADE (angular detection error) at 1-month of CI activation. A continuous improvement occurred over time. Kitoh et al. (2016) reported better sound localization in all 5 subjects, with continuous improvement through 12-month.

Subjective measures

van Loon et al. (2017) reported increased frequency and satisfaction of listening to music from 7 AHL CI users. Bimodal stimulation also resulted in better quality, clarity, and appreciation of different music styles. Skarzynski et al. (2017) reported substantial tinnitus suppression in all 15 patients with pre-operative tinnitus and Kitoh et al. (2016) reported decreased disturbance to daily life caused by tinnitus in all 5 SSD cases. Two studies addressed self-evaluation of CI performance in SSD and AHL subjects. Skarzynski et al. (2017) reported a significant improvement in the global score of APHAB, as well as sub-scales including 'Ease of communication', hearing under 'background noise' or under 'reverberation' at 14-months after CI activation in comparison to pre-operative condition. van Loon et al. (2017) reported that except for the 'speech production' subdomain, bimodal stimulation yielded a significant better outcome for all other subdomains of the NCIQ questionnaire. An average appreciation of the cochlear implant was scored 4.3/5, indicating a high satisfaction with the CI.

Conclusions from Real World Evidence

This clinical evaluation of cochlear implantation for the treatment of SSD and AHL is based on the above literature data sets relevant to the safety, performance, and effectiveness of cochlear implantation as a treatment option for individuals with AHL or SSD.

In this review of Real-World data, the latest clinical data were summarized on SSD and AHL patients from centers both in the US and around the globe that meet the proposed audiometric indication criterion of a profound hearing loss in the ear to be implanted, i.e., a PTA of 90 dB or higher. The clinical populations reported on include both adults and children older than 5 years age.

Taken together, the clinical data from this body of literature show consistent benefits of CI in individuals with SSD or AHL, in terms of improved speech perception in noise, spatial hearing, localization accuracy, and patient-reported subjective outcome measures. Consistent CI use of patients has been shown across literature reports, and notably so in the prospective study by Lorens et al. (2019) in 70 sequentially implanted SSD and AHL CI users (59 of which were implanted with MED-EL devices). These literature data provide Real World Evidence (according to the FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices") in support of the clinical benefits of CI in SSD and AHL recipients, as demonstrated in the UNC study. In this way, these literature reports do serve as supporting evidence which demonstrates a reasonable assurance of device safety and effectiveness and to characterize the benefit/risk profiles for the proposed SSD/AHL indications.

Symbols



CE mark. First applied in 2014



Single-use device. Do not reuse!



Catalogue number



Serial number



Caution! Consult accompanying documents



Sterilised using Ethylene Oxide



"Use by" date



Manufacturing date



Manufacturer



MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

- 1 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).
- 2 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.
- 3 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

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2645 Meridian Parkway
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.



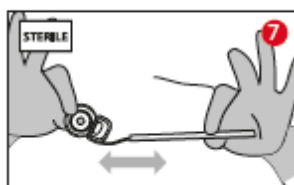
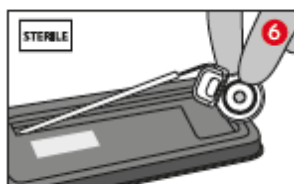
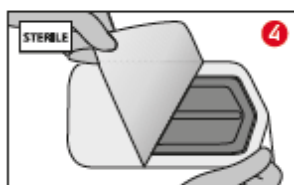
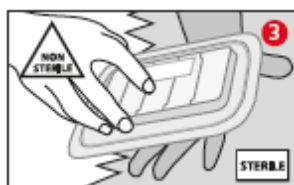
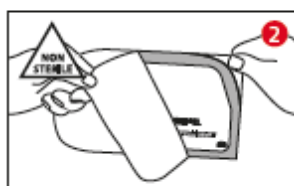
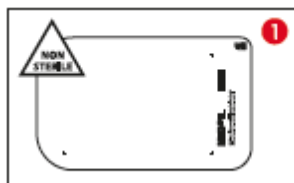
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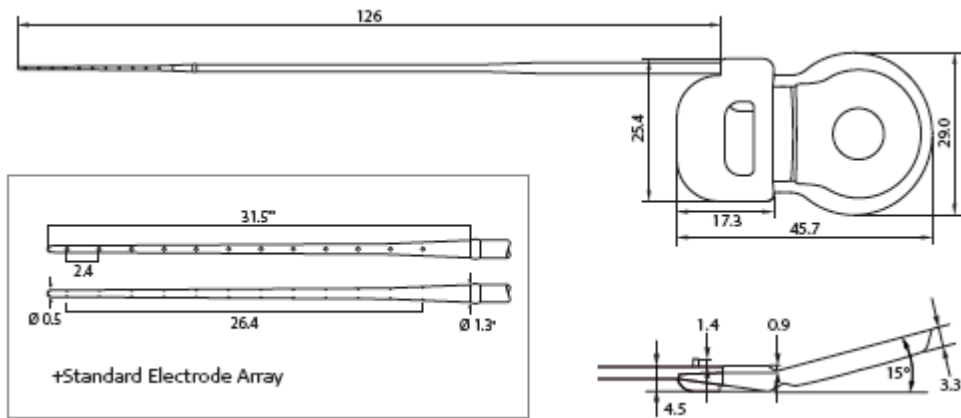
Mi1200 SYNCHRONY PIN Cochlear Implant

+Standard | +Medium | +Compressed | +FLEX^{SOFT} | +FLEX28 | +FLEX24

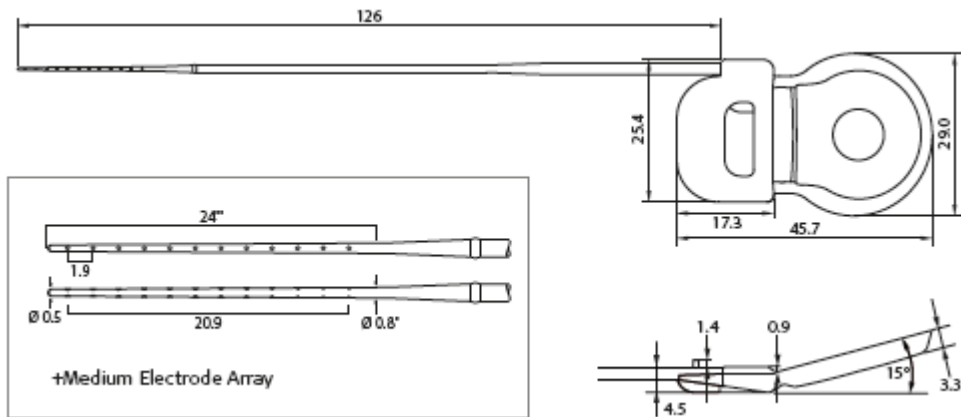
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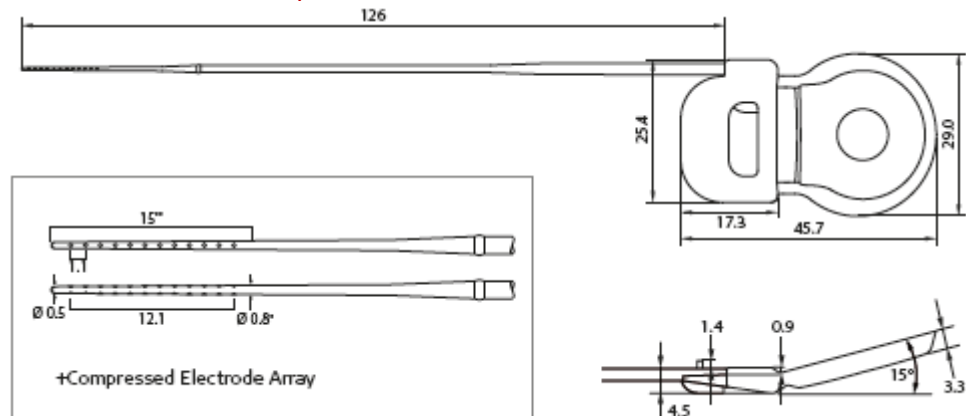
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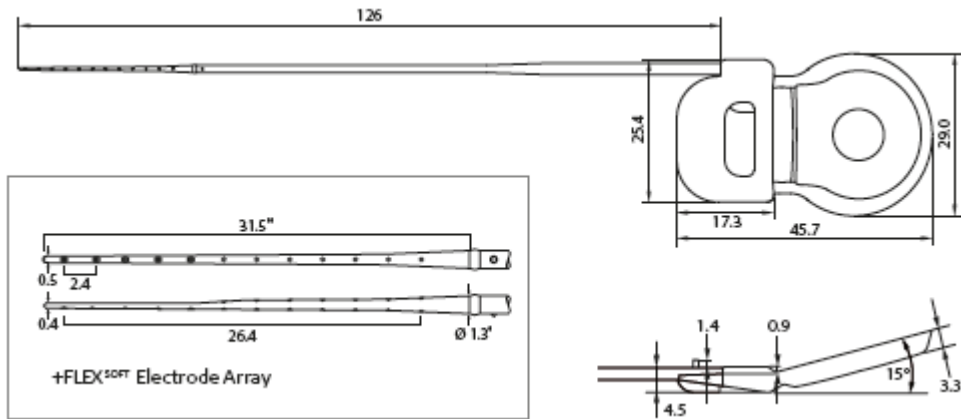
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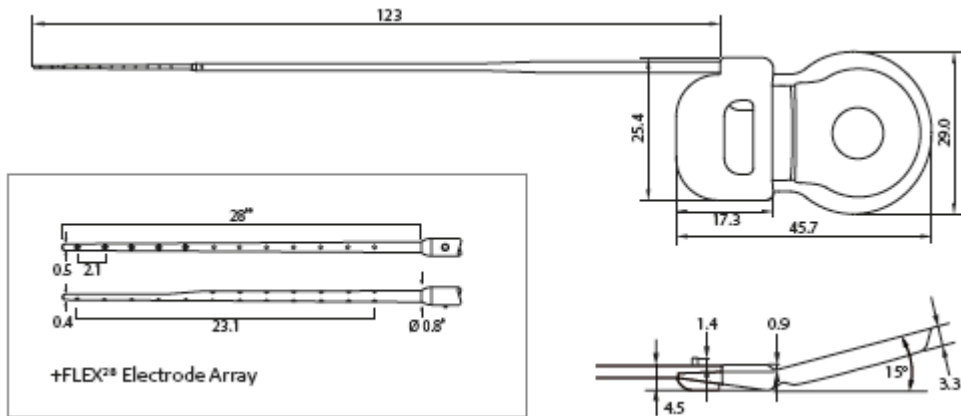
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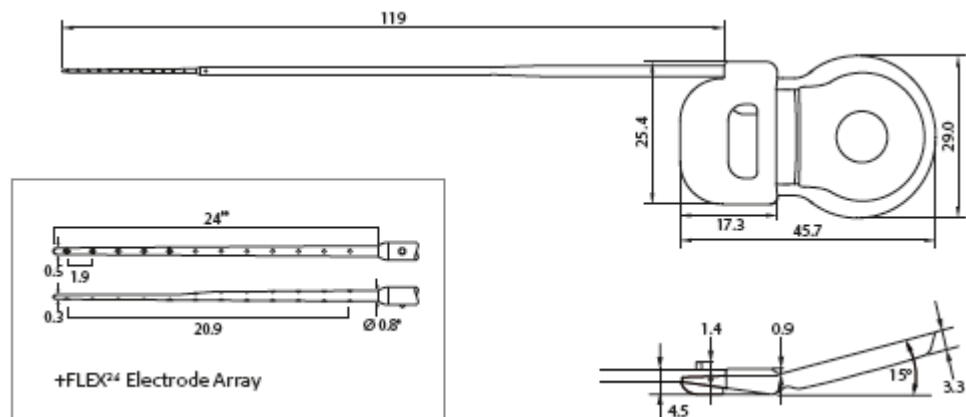
SYNCHRONY PIN +FLEX^{SOFT}



SYNCHRONY PIN +FLEX²⁸



SYNCHRONY PIN +FLEX²⁴



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

INSTRUCTIONS FOR USE

Mi1200 SYNCHRONY PIN Cochlear Implant

Device description

The Mi1200 SYNCHRONY PIN Implant (hereafter referred to as SYNCHRONY PIN) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a removable magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SYNCHRONY PIN). This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).

For principal dimensions of the implant refer to the drawings on the previous pages.

The volume of the implant without electrode is 3.7 cm³.

Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium, titanium and parylene c.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
Maximum current amplitude: Median value = 1250 µA, range = 500 µA
Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to the MED-EL Application Software User Manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm²

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+Standard	126 mm	1.3 × 1.3	0.5 × 0.5	0.14	0.14	2.4	26.4
+Medium	126 mm	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.9	20.9
+Compressed	126 mm	0.7 × 0.7	0.5 × 0.5	0.14	0.14	1.1	12.1
+FLEX ^{SOFT}	126 mm	1.3 × 1.3	0.5 × 0.4	0.13	0.14	2.4	26.4
+FLEX ²⁸	123 mm	0.8 × 0.8	0.5 × 0.4	0.13	0.14	2.1	23.1
+FLEX ²⁴	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Some implant electrode types mentioned in these Instructions for Use may not be released for distribution in all markets. Please contact your local MED-EL representative for information on current product availability in your country.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations 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.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

Bilateral deafness:

- 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 and 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 Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood 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.
- For bilateral deafness, MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General:

- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- To obtain optimal benefit from the SYNCHRONY PIN Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A pre-operative assessment according to the local professional standards must be conducted.
- Cochlear implants SYNCHRONY PIN +Standard are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants SYNCHRONY PIN +Medium are intended to be used in open cochleae (no obliteration or ossification) with mild malformation for an electrode insertion depth of about 24 mm as per request of the surgeon.
- Cochlear implants SYNCHRONY PIN +Compressed are intended to be used in cochleae with moderate obliteration, ossification, or malformation for an electrode insertion depth of 15 mm as per request of the surgeon.
- Cochlear Implants SYNCHRONY PIN +FLEX^{SOFT} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31 mm.
- Cochlear implants SYNCHRONY PIN +FLEX²⁸ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 28 mm.
- Cochlear implants SYNCHRONY PIN +FLEX²⁴ are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted,

- if the individual is known to be intolerant of the materials used in the implant (including medical grade silicone, platinum, iridium, titanium and parylene c);
- if there is an absence of cochlear development;
- if the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways;
- if external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted;
- if there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required;

- if anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery;
- if the psychological status of the patient is unstable or
- if the patient has unrealistic expectations.

Additionally for SSD / AHL individuals should not be implanted,

- if individual has had profound hearing loss for over ten years
- if individual has an acoustic neuroma

Undesirable side-effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Clinical data supports cochlear implants as a treatment option for SSD and AHL if existing treatments do not work. Some SSD and AHL patients will benefit from Cochlear Implant (CI) implantation and the risks and benefits should be weighed by the clinician to determine if CIs are an appropriate treatment for each individual patient. All SSD and AHL patients should be offered rehabilitation. There is the potential perceptual inference of overlapping of acoustic and electric bilateral hearing which may lead to limited CI performance.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped¹ between -20 °C (-4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the “use by” date specified on the package. Packaging² should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.
- 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 case the MED-EL implant user wants to dive, the user should consult an experienced physician about the 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 50m (165ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis³ can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling the mastoidectomy, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that focally progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm. The stimulator should be recessed to a depth of maximum 2 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The area of the temporal bone on which the stimulator will be placed, shall be flattened in order to ensure that the implant is sufficiently immobilized. The two pins of the SYNCHRONY PIN Cochlear Implant should be recessed into the skull with the PIN Drill Guide SI to a depth of 1.5 mm. The electrode lead should be placed in
- a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.
- The two pins give additional stability against translational and rotational motion. Recessing the pins and efficient immobilization of the stimulator (e.g. with sutures) is important to prevent postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

Recommended diameter of the cochleostomy & RW opening:

Electrode type	mm
SYNCHRONY PIN +Standard	1.3 mm
SYNCHRONY PIN +Medium	0.8 mm
SYNCHRONY PIN +Compressed	0.8 mm
SYNCHRONY PIN +FLEX ^{SOFT}	1.3 mm
SYNCHRONY PIN +FLEX ²⁸	0.8 mm
SYNCHRONY PIN +FLEX ²⁴	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear pre-surgically.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.

- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- In case of a magnet exchange surgery MED-EL recommends the use of the following tools: The Magnet Removal Tool Ms050206 or the Magnet Insertion Tool Ms050205 can be used in combination with the Non-Magnetic Spacer Ms010107 or the Replacement Magnet Ms010108. Please refer to the applicable Instructions for Use of these devices for further surgical precautions and warnings.
- After removal of the Non-Magnetic Spacer Ms010107, make sure that a fresh Replacement Magnet Ms010108 is inserted to re-establish full functionality of the implant.

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

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to Medical Procedures Manual.

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.

If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.

If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
MED-EL Elektromedizinische Geraete GmbH
Worldwide Headquarters
Safety adviser for the transport of dangerous goods
Fürstenweg 77a
6020 Innsbruck
Austria

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050)

UNC Feasibility Study Design

The feasibility study for the MED-EL Cochlear Implant System was conducted under IDE (G140050) to evaluate the safety and effectiveness of the MED-EL Cochlear Implant System in individuals 18 years of age and older with SSD or AHL. The primary study goal was to determine whether subjects with SSD or AHL demonstrated an improvement in speech perception, localization, and quality of life after receiving a cochlear implant. Both objective and subjective performance data were collected, as well as safety data in the form of adverse events. Forty subjects were implanted at the University of North Carolina at Chapel Hill with the MED-EL CONCERT or SYNCHRONY Cochlear Implant System in this prospective, single-site, non-randomized, non-blinded, repeated measures clinical study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in G140050 was limited to patients who met the following inclusion criteria:

- 18 years of age or older at the time of implantation
- Unilateral moderate-to-profound sensorineural hearing loss
 - o Unaided residual hearing thresholds measured from 250-8000 Hz (PTA $\geq$ 70 dB HL in the ear to be implanted)
 - o For SSD: normal to mild residual hearing thresholds from 250-8000 Hz in the contralateral ear ($\leq$ 35 dB HL at each frequency, 250-8000 Hz)
 - o For AHL: mild to moderate hearing thresholds from 250-8000 Hz in the contralateral ear (PTA $\geq$ 35 and $\leq$ 55 dB HL)
 - Aided word recognition of 80% or more as measured with CNC words (50-word list)
- Duration of moderate-to-profound sensorineural hearing loss less than or equal to 10 years
 - o Hearing loss for less than 10 years: study participants were only included if they had used a hearing aid consistently for 5 years
 - o Hearing loss for less than 5 years: study participants were only included if they had at least completed a 1-month hearing aid trial
- Previous experience (at least one month) with a current treatment option for SSD, including a conventional hearing aid, bone-conduction device, or CROS/BICROS technology
- Aided word recognition in the ear to be implanted of 60% or less as measured with CNC words (50-word list)
- Realistic expectations
- Willingness to obtain recommended meningitis vaccinations per CDC recommendations
- No reported cognitive issues: pass of the Mini Mental State Examination (MMSE) screener
- Ability and willingness to comply with study requirements, including travel to investigational site and study-related activities

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Non-native English speaker
- Conductive hearing loss in either ear
- Compromised auditory nerve, including those with a history of vestibular schwannoma
- Ossification
- Inability to participate in follow-up procedures (i.e., unwillingness, geographic location)
- History of meningitis, autoimmune disease, or any medical condition that contraindicate middle or inner ear surgery or anesthesia
- Meniere's disease with intractable vertigo
- Trauma that precludes inner ear surgery
- Case of sudden sensorineural hearing loss that has not been first evaluated by a physician
- Pregnancy
- Tinnitus as the primary purpose for seeking cochlear implantation
- Severe or catastrophic score on the Tinnitus Handicap Inventory

2. Follow-up Schedule

This study involved up to ten visits before and after implantation, for about a one-year period. Candidacy testing included medical and audiological evaluations (e.g., audiograms, speech recognition tests) to determine study eligibility. After confirming eligibility, the subject underwent baseline testing. The device was subsequently implanted based on the subject's candidacy testing. An initial follow-up visit was completed following surgery, and the cochlear implant was activated following a healing period of 2 to 4 weeks.

The baseline and postoperative measurements are summarized under 'Test Conditions' below. All patients were scheduled to return for follow-up examinations at 1, 3, 6, 9, and 12 months postoperatively. Pre-operatively and post-operatively, unaided air conduction thresholds were collected. At all intervals, speech perception in quiet and in noise and localization data was collected. Adverse events and complications were recorded at all visits.

The key timepoints (pre-op baseline and 12-months post-op) are shown below in the tables summarizing safety and effectiveness.

Test Conditions

The test battery was completed at the pre-operative interval and again at 1, 3, 6, 9, and 12 months post-operatively. For soundfield measures (speech perception and localization), a 180° arc with 11 speakers spaced 18° apart was utilized. Post-operative aided soundfield assessment was completed with the subject using the SONNET or OPUS 2 speech processor unless otherwise noted. For the AHL group, soundfield testing was completed with a hearing aid in the contralateral ear. See below for further details on testing conditions.

Subjects participated in two aural rehabilitation sessions with a board-certified speech-language pathologist. One session was completed after the initial activation of the external speech processor. The second session took place in conjunction with the 1-month post-initial activation interval.

- Unaided Diagnostic Assessment
 - o Air-conduction thresholds in both ears
 - o Assess bone-conduction thresholds if there is a PTA shift of >15 dB as compared to the previous interval
- Tympanometry for each ear
- Sound Field Measures
 - o Aided thresholds with the external speech processor on measured using pulsed, warble tones
 - Frequencies assessed: 250-8000 Hz
 - Masking presented to the contralateral ear
 - o Speech Perception Measures (recorded materials presented at 60 dB SPL)
 - Speech Perception in Quiet
 - Speech 0° azimuth
 - CNC words
 - AzBio sentences
 - Speech Perception in Noise
 - Speech and noise 0° azimuth
 - Speech 0° azimuth and noise to implanted side
 - Speech 0° azimuth and noise to contralateral ear
 - AzBio sentences
 - If >50% at SNR+10, then SNR+5; if >50% at SNR+5, then SNR0
 - BKB-SIN sentences with adaptive SNR
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
 - o Localization
 - 200-ms speech-shaped noise, presented at 70-dB SPL from one of the 11 speakers (evenly spaced -180 to 180 degrees), selected at random
 - Intensity level for each stimulus presentation randomly varied (10 dB around 70 dB SPL)
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
- Subjective questionnaires
 - o Speech, Spatial and Qualities of Hearing Scale (SSQ)
 - o Abbreviated Profile of Hearing Aid Benefit (APHAB)
 - o Tinnitus Handicap Inventory (THI)

3. Clinical Endpoints

Measures

Safety Measure: The primary safety measure was the evaluation of all adverse events reported within 12 months. The full profile of adverse events was summarized and considered, with specific attention given

to device-related adverse events. The adverse events include anticipated and unanticipated adverse events. The list of anticipated adverse device effects noted in the study protocol are as follows:

- Risks from the SYNCHRONY IFU
 - o Loss of residual hearing
 - o Increased vertigo
 - o Delay of healing of the scar
 - o Impairment of the sense of taste
 - o Potential for swallowing difficulties
 - o Numbness
 - o Increased tinnitus
 - o Stimulation of the facial nerve
 - o Temporary pain and uncomfortable sounds during stimulation
- Additional surgical risks
 - o Facial nerve injury
 - o Infection
 - o Bleeding
 - o Cerebrospinal fluid (CSF) leak
 - o Pain
 - o Scarring
- Additional post-operative risks
 - o Swelling around the incision and/or coil site
 - o Pain
 - o Reduced or loss of pinna sensitivity on the surgical side
 - o The cochlear implant may not provide any auditory stimulation
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in the perception of speech
 - o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in localization
 - o Pain associated with the coil and/or placement of the external speech processor on the subject's ear
 - o Movement of the internal receiver
 - o Discomfort from electric stimulation
 - o Facial nerve stimulation
 - o Headache
 - o Dizziness
 - o Altered taste (i.e. reports of metallic tastes on the same side of the tongue as the surgical ear)
 - o Fatigue during follow-up assessment (completion of the test battery and/or mapping)
 - o The internal device may fail, requiring revision cochlear implantation
 - o The sound from the cochlear implant may interfere with the better hearing ear.

Effectiveness Measures: The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition. Aided speech perception performance on word and sentence materials at the post-activation intervals was evaluated to monitor trends over time. Unaided and aided (with BCHA or CI, as applicable) localization performance was also compared pre-operatively and at each of the post-activation intervals. The overall RMS error is reported for localization in each condition. Additionally, subjective report scores were compared pre-operatively and at the 12-month post-activation intervals.

Audiometric Test Methods & Effectiveness Measures

Speech perception and localization measures were recorded in a research lab that featured a 180° arc with 11 speakers spaced 18° apart. Postoperative aided sound field assessment was completed with the study participant listening with the OPUS 2 or SONNET speech processor.

Speech perception in quiet was tested at 0° azimuth, presenting CNC words (Peterson & Lehiste, 1962) or AzBio sentences (Spahr et al., 2012) at 60 dB SPL. Speech perception in noise was tested in the conditions (1) speech and noise 0° azimuth (S0N0), (2) speech 0° azimuth and noise to the affected ear/implanted side (S0NCI), and (3) speech 0° azimuth and noise to the contralateral ear (S0NContra). AzBio sentences were presented at 0 dB signal-to-noise ratio (SNR) in most cases. BKB-SIN sentences were presented with adaptive SNR.

For the localization task a 200-ms speech-shaped noise was presented at 70-dB SPL from one of the 11 speakers (selected randomly). The intensity level for each stimulus presentation was randomly varied (10 dB around 70 dB SPL). The listener was facing the center speaker during stimulus presentation and the task was to identify the source of the noise. No feedback was provided. In the condition cochlear implant speech processor OFF, study participants were only listening with the contralateral ear. In the condition cochlear implant speech processor ON, sound was perceived both via the cochlear implant and the contralateral ear.

Subjective data was collected via the SSQ and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995). The SSQ can be further divided into three subscales: speech, spatial, and quality. The APHAB consists of four subscales: Ease of Communication (EC), Background Noise (BN), Reverberation (RV), and Aversiveness (AV). The Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996) was also utilized to collect information on severity of tinnitus pre-operatively as well as at the 12-month interval.

B. Accountability of Study Cohort

In the SSD cohort, 20 subjects were enrolled and completed testing through the 12-month interval. In the AHL cohort, 20 subjects were enrolled and 18 completed testing through the 12-month interval. One subject in the AHL cohort withdrew prior to completion of all test intervals, and one subject was still undergoing follow-up testing at the time of data analysis.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a feasibility study performed in the US. Proportions enrolled are consistent with the age, sex/gender, racial and ethnic prevalence of the SSD and AHL.

1. SSD Cohort

Of the 20 implanted subjects, 12 were female and 8 were male. At the time of implantation, subjects ranged in age from 22 to 66 years of age. The duration of profound hearing loss ranged from 0.1 to 6.6 years. Fifteen subjects experienced sudden hearing loss and five subjects experienced a gradual hearing loss. Hearing loss was reported as unknown in 16 cases, due to Meniere's disease in three subjects, and caused by trauma in one case. Further information on subject demographics and hearing related variables is summarized in Table 2 below.

Table 2. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=20)
Gender	
Male	40% (8/20)
Female	60% (12/20)
Age (years)	50 (20) (22 – 66)
Duration of hearing loss (years)	
Noticeable	4.2 (20) (0.1 – 14.6)
Profound	2.6 (20) (0.1 – 6.6)
Implanted ear	
Left	55% (11/20)
Right	45% (9/20)
Tinnitus Handicap Grade Level	
Slight	35% (7/20)
Mild	40% (8/20)
Moderate	25% (5/20)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

2. AHL Cohort

Of the 18 subjects who completed follow-up, 9 were female and 9 were male. At the time of implantation, subjects ranged in age from 52 to 79 years of age. The duration of profound hearing loss ranged from 0.0

to 9.8 years. Ten subjects experienced sudden hearing loss and six subjects experienced a gradual hearing loss, with the remaining two subjects experiencing both a gradual and sudden loss. Hearing loss was reported as unknown in 14 cases, due to Meniere's disease in two subjects, due to noise-induced hearing loss in one subject, and caused by viral infection in one case. Further information on subject demographics and hearing related variables is summarized in Table 3 below.

Table 3. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=18)
Gender	
Male	50% (9/18)
Female	50% (9/18)
Age (years)	70 (18) (52 – 79)
Duration of hearing loss (years)	
Noticeable	11.5 (17) (0.0 – 51.5)
Profound	3.5 (17) (0.0 – 9.8)
Implanted ear	
Left	67% (12/18)
Right	33% (6/18)
Tinnitus Handicap Grade Level	
Slight	55% (10/18)
Mild	28% (5/18)
Moderate	17% (3/18)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on all patients implanted under G140050 (N=40) up to 12 months post implantation. Table 4 displays the adverse events reported for this study.

Adverse effects that occurred in IDE G140050:

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated. A total of nine adverse events were reported to be related to the device or procedure. An additional six adverse events were not able to be ruled out as device or procedure-related. No serious, unanticipated, device-related adverse events were reported.

Table 4. Number and percentage of adverse events observed for SSD subjects.

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects
Vertigo/dizziness/imbalance	11	9	22.5%
Unrelated infection	3	3	7.5%
Changes in sound quality/volume	3	2	5%
Depression	3	2	5%
Aural pressure	2	2	5%
Facial stimulation	2	2	5%
Headache	2	2	5%
Atrial fibrillation	1	1	2.5%
Bleeding at surgical site	1	1	2.5%
Electrode contact dislodged	1	1	2.5%
Fall involving bump to the implant	1	1	2.5%
Type C tympanogram	1	1	2.5%
Short circuit	1	1	2.5%
Total	32	21*	52.5%

*Some subjects experienced more than one device-related adverse event

The most frequently observed adverse event was vertigo, dizziness, or imbalance, which was reported a total of 11 times. In four cases, the event was deemed unrelated to the device or procedure. In three cases, it could not be ruled out that the event was related to the device or procedure. In the remaining four cases, it was determined that the event was related to the procedure. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. In all cases, the event was deemed unrelated to the device or procedure. All other events occurred at a rate of 5% or less (2 subjects or fewer), which is consistent with the rate of adverse events observed for the approved indication of bilateral, severe-to-profound, sensorineural hearing loss.

2. Effectiveness Results

The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition among 20 subjects with SSD and 17 subjects with AHL. Additionally, subjective reports from the SSQ and APHAB were also compared pre-operatively and at the 12-month post-operative interval.

Speech Perception in Quiet

SSD Cohort

Speech perception testing in quiet at the 12-month interval demonstrated an improvement in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. In the contralateral ear, no change was observed on CNC words from baseline to 12 months. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet across test intervals. The comparison of AzBio sentence score in quiet with a BCHA to scores at 12 months with the CI-ON also demonstrated no change. Table 5 displays the descriptive statistics of the speech perception in quiet scores for the SSD cohort.

Table 5. Speech perception in quiet (SSD Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	20	20	20	20	20	20	20
Mean (SD)	3.5 (6.68)	54.6 (18.15)	99.3 (2.27)	99.8 (0.62)	99.0 (1.56)	99.2 (1.15)	99.5 (1.19)
Min – Max	0 - 22	10 - 84	90- 100	98 - 100	95 - 100	95 – 100	95 - 100

AHL Cohort

For the cohort with asymmetric hearing loss, an improvement was demonstrated for speech perception testing in quiet at the 12-month interval in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. No change was observed on CNC words from baseline to 12 months in the contralateral ear. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet between the pre-operative and 12-month intervals. Additionally, no change was demonstrated in the comparison of AzBio sentence score in quiet between BCHA pre-operatively and 12 months with the CI-ON. See Table 6 below for the descriptive statistics of the speech perception in quiet scores.

Table 6. Speech perception in quiet (AHL Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	18	18	18	18	18	18	18
Mean (SD)	6.3 (7.98)	56.2 (18.41)	94.2 (7.06)	92.7 (8.68)	87.4 (13.96)	87.7 (11.01)	94.3 (8.38)
Min – Max	0 - 22	28 - 86	78 – 100	72 - 100	50 - 99	(61 – 99_	72 - 100

Speech Perception in Noise

SSD Cohort

On AzBio sentence testing in noise, subjects in the SSD cohort demonstrated an improvement between the bilateral, baseline, pre-operative, unaided testing and the bilateral, 12-month post-operative, CI + NH testing in the speech front, noise front condition. This same improvement was also noted between the bilateral, baseline, pre-operative, aided (with BCHA) condition and the bilateral, 12-month, post-operative, CI + NH condition. NO differences were found between pre-operative unaided and pre-operative, aided (with BCHA) scores. In the speech front, noise to the CI ear condition, subjects demonstrated no change in score in comparing the pre-operative interval to the CI-ON at 12 months. However, when comparing the pre-operative aided scores to the 12-month scores with CI, an improvement in performance was noted. Better scores were obtained for the pre-operative unaided condition as compared to the pre-operative aided condition.

A significant improvement was noted with the cochlear implant on at 12 months post-operative compared to the pre-operative, unaided interval for the speech front, noise to the contralateral ear condition. This same improvement was also found when comparing CI-ON at the 12-month, post-operative condition to the pre-operative, aided (with BCHA) condition. This improvement demonstrates that when noise presents as a masker to the better hearing ear, the cochlear implant provides benefit in speech understanding. Table 7 provides further details on AzBio sentence in noise scores.

Table 7. Speech perception in noise (SSD Cohort, AzBio)

SSD AzBio	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	37.5 (10.98)	31.5 (16.56)	47.2 (10.72)	83.4 (9.51)	61.25 (27.92)	85.0 (11.04)	16.5 (12.78)	18.3 (13.50)	52.6 (21.43)
Min- Max	20 - 64	0 – 59	29 - 68	59 - 94	0 – 98	60 - 97	0 - 45	0 – 59	8 - 86

A similar pattern was noted for speech in noise testing on the BKB-SIN. No significant changes were found in any comparisons for the speech front, noise front or speech front, noise to the CI ear conditions. However, in the speech front, noise to the contralateral ear condition, it was found that the CI does provide benefit in speech perception, and thus, a significant improvement was found when comparing the 12-month, post-operative CI + NH condition to the pre-operative, unaided condition or to the pre-operative, aided (with BCHA) condition. Table 8 provides the detailed descriptive statistics of the BKB-SIN scores.

Table 8. Speech perception in noise (SSD Cohort, BKB-SIN)

SSD BKB- SIN	S0N0			S0NCI			S0NContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	0.1 (1.42)	0.8 (1.98)	-0.8 (1.74)	-4.8 (1.64)	-2.6 (2.39)	-4.8 (1.66)	1.8 (1.33)	1.8 (2.35)	-1.0 (2.20)
Min- Max	-2.5 – 3.0	-2.5 – 4.5	-3.0 – 4.0	-7.5 – -1.5	-7.0 – 1.0	-7.5 – -2.0	-0.5 – 4.0	-2.5 – 8.0	-5.0 – 5.5

AHL Cohort

For the AHL cohort, the majority of subjects were tested at 0 dB SNR. However, some subjects were tested at +5 or +10 dB SNR according to a decision tree implemented for determining SNR. Pre-operative and post-operative comparisons within subject were done at the same SNR. For this reason, only 17 subjects are included in the AzBio analysis for both the pre-operative unaided/aided (with BCHA) condition and the 12-month post-operative CI + HA condition.

In the speech front, noise front condition, a significant improvement was found on AzBio sentences for the 12-month, post-operative CI + HA condition compared to the pre-operative, unaided condition and compared to the pre-operative, aided (with BCHA) condition. Pre-operative, BCHA scores were worse than pre-operative unaided scores and worse than 12-month, post-operative CI + HA scores in the speech front, noise to the CI ear condition. In the speech front, noise to the contralateral ear condition, a signifi-

cant improvement was noted for the 12-month, post-operative CI + HA testing compared to both the pre-operative, unaided testing and the pre-operative, aided (with BCHA) testing. Table 9 below displays the descriptive statistics of the AzBio testing for the AHL Cohort.

Table 9. Speech perception in noise (AHL Cohort, AzBio)

AHL AzBio	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	17	17	17	17	17	17	17	17	17
Mean (SD)	22.7 (13.95)	20.5 (12.86)	33.5 (22.10)	44.2 (17.70)	30.5 (18.23)	44.6 (24.74)	6.3 (9.49)	11.3 (16.69)	29.4 (22.59)
Min- Max	0 – 47	0 – 47	3 – 85	9 – 78	1 – 70	5 – 94	0 – 36	0 – 66	1 – 95

For BKB-SIN testing, no changes were demonstrated in the speech front, noise to the CI ear condition. An improvement was found between the pre-operative, aided (with BCHA) condition and the 12-month, post-operative CI + HA condition in the speech front, noise front condition. Similar to the AzBio test results for the SSD cohort, there was a significant improvement for BKB-SIN in the speech front, noise to the contralateral ear condition when comparing the 12-month, post-operative CI + HA condition to the pre-operative, unaided condition. Table 10 below displays the analyses of BKB-SIN testing in the AHL cohort.

Table 10. Speech perception in noise (AHL Cohort, BKB-SIN)

AHL BKB- SIN	SON0			SONCI			SONContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	18	18	18	18	18	18	18	18	18
Mean (SD)	4.3 (3.62)	5.1 (3.04)	3.7 (3.28)	1.3 (3.89)	2.5 (3.77)	2.6 (3.78)	7.1 (4.14)	5.9 (4.50)	4.6 (4.44)
Min- Max	0.5 – 13.0	0 – 10	-2.0 – 9.5	-6.5 – 8.5	-3.5 – 10.0	-3.5 – 9.0	2.0 – 15.5	0 – 14.5	-1.0 – 15.5

Localization

SSD Cohort

Subjects in the SSD cohort demonstrated a significant improvement in localization performance with the CI at 12 months compared to the baseline, aided (with BCHA) condition. Additionally, results indicated an improvement in performance between the baseline, unaided condition and the 12-month, postoperative CI + NH condition. Table 11 displays localization performance in RMS error.

Table 11. Localization performance (SSD Cohort)

SSD Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	20	20	20
Mean (SD)	66.5 (20.47)	69.6 (18.71)	26.7 (6.32)
Min-Max	42.9 – 109.1	45.3 – 106.1	13.6 – 38.4

AHL Cohort

Similar to the SSD cohort, subjects in the AHL cohort demonstrated improved localization performance with the CI-ON at 12 months compared to the baseline, aided (with BCHA) condition. This improvement was also evident when comparing the 12-month, postoperative CI + HA to the pre-operative, unaided condition. Table 12 displays the analyses of the AHL Cohort's localization data.

Table 12. Localization performance (AHL Cohort)

AHL Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	18	18	18
Mean (SD)	76.5 (19.23)	77.2 (18.89)	40.1 (10.65)
Min-Max	43.8 – 105.3	45.6 – 106.5	26.6 – 73.6

Subjective Questionnaire

SSD Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the CI on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 13 below for the descriptive statistics of the SSQ.

Table 13. SSQ (SSD Cohort)

SSD SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20
Mean	3.7	7.1	2.4	6.5	5.6	7.7
Std. Deviation	1.34	0.99	1.2	1.86	2.09	1.28
Minimum	0.6	5.4	0.5	2.8	0.5	5.6
Maximum	7.2	8.9	4.5	8.9	9.8	9.8

Self-perceived benefit from the CI as reported on the APHAB demonstrated significant improvement on global score and the subscales, except for the aversiveness subscale. Table 14 below provides the detailed APHAB scores at the pre-operative and 12-month intervals.

Table 14. APHAB (SSD Cohort)

SSD APHAB	Global		EC		BN		RV		AV	
	pre	12m	Pre	12m	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20	20	20	20	20
Mean	49.8	17.9	31.6	8.7	70.1	25.2	47.5	19.7	43.1	26.7
Std. Deviation	18.65	8.91	21.06	6.15	17.32	11.95	21.96	12.43	28.64	24.83
Minimum	20.3	6.1	2.8	1.0	39.3	10.2	18.7	2.8	1.0	1.0
Maximum	86.3	36.7	81.0	24.8	95.0	56.2	87.0	41.7	93.0	91.0

AHL Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the cochlear implant on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 15 below for detailed information on the SSQ.

Table 15. SSQ (AHL Cohort)

AHL SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	18	18	18	18	18	18
Mean	3.2	5.8	2.6	6.0	4.6	6.8
Std. Deviation	1.48	1.50	1.26	1.62	1.77	1.20
Minimum	0.4	3.6	0.3	3.1	0.2	4.4
Maximum	6.0	8.9	4.7	8.5	8.3	8.7

Self-perceived benefit from the cochlear implant as reported on the APHAB demonstrated significant improvement on global score and other subscales over time except the aversiveness subscale. Table 16 below displayed the detailed APHAB scores at the pre-operative and 12-month post-operative intervals.

Table 16. APHAB (AHL Cohort)

AHL APHAB	Global		EC		BN		RV		AV	
	pre	12m	pre	12m	pre	12m	Pre	12m	pre	12m
N	18	18	18	18	18	18	18	18	18	18
Mean	54.1	28.1	42.9	16.6	63.5	39.3	56.0	28.3	43.1	42.4
Std. Deviation	16.21	10.49	24.67	13.01	16.84	17.10	18.30	11.96	35.04	29.21
Minimum	20.0	11.3	10.2	1.0	14.5	14.5	14.2	12.0	1.0	1.0
Maximum	92.3	54.1	91.0	54.0	95.0	66.3	97.0	54.2	99.0	97.0

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Literature Search Strategy

MED-EL conducted an extensive literature search to collect additional supporting clinical evidence of cochlear implants in SSD and/or AHL indications. The search terms they used are listed in Tables 17, 18, and 19, below.

Table 17. Combinations of Search Terms

Search Step	Search Terms	Review Question
1	"hearing loss" OR deaf*	P
2	single sided deafness OR SSD OR unilateral OR UHL OR asymmetric* OR AHL	P
3	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment" OR bone conduction OR BCI OR bone anchored OR BAHA OR CROS OR contralateral routing OR BiCROS OR "transcranial CROS" OR in-the-mouth device OR ITM OR soundbite OR bone-bridge OR "ad hear"	I & C
4	1 AND 2 AND 3	
5	Limit 4 to <i>Humans</i>	
6	Limit 5 to <i>Language</i> : English	
7	Limit 6 to <i>Publication date</i> : June, 2014 to May, 2017	

Search Step	Search Terms	Review Question
1	(single sided deafness) OR ((((((SSD) OR unilateral) OR UHL) OR asymmetric) OR AHL)) AND (((hearing loss) OR deaf*) OR deafness))	P
2	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment"	I & C
3	1 AND 2	
4	Limit 3 to <i>Humans</i>	
5	Limit 4 to <i>Language</i> : English	
6	Limit 5 to <i>Publication date</i> : May 1, 2017 to March 6, 2019	

Note. The different search terms are connected using Boolean logic. Activated filters are displayed in italics. P = Population, disease, or condition; I = Intervention; C = Comparator group or control.

* Wildcard symbol to broaden the search by creating a root word search.

Table 18. Inclusion and Exclusion Criteria for Retrieved Literature

Inclusion Criteria	
Population/Problem	Patients of any age who have single sided deafness
Intervention/Treatment	cochlear implant, any other treatment that makes hearing possible, or no treatment
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant
Inclusion Criteria	
Population/Problem	Patients of any age who have SSD or AHL
Intervention/Treatment	cochlear implant
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population e.g. different type of hearing loss
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Table 19. Literature Appraisal Criteria

Data Suitability	Description	Grading System
Appropriate Device	Where the data generated from the device in question?	D1 – Actual device D2 – Comparable device D3 – Other device
Appropriate Device Application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 – Same use A2 – Minor deviation A3 – Major deviation
Appropriate Patient Group	Were the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease including state and severity)?	P1 – Applicable P2 – Limited P3 – Different population
Acceptable Report/Data Collation	Did the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 – High quality R2 – Minor deficiencies R3 – Insufficient information
Data Contribution	Description	Grading System
Data Source Type	Was the design of the study appropriate?	T1 – Yes T2 – No
Outcome Measures	Did the outcome measures reported reflect the intended performance of the device?	O1 – Yes O2 – No
Follow-Up	Was the duration of the follow-up long enough to assess treatment effects and identify complications?	F1 – Yes F2 – No
Statistical Significance	Was a statistical analysis of the data provided and appropriate?	S1 – Yes S2 – No
Clinical Significance	Was the magnitude of the treatment effect observed clinically significant?	C1 – Yes C2 – No

Published Literature on Children

The literature search yielded five peer-reviewed papers in SSD and/or AHL children with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults and children aged 5 yrs and older. The papers comprise a total of 26 children with SSD (five of which were reported to be implanted with MED-EL devices) and a total of nine children with AHL. Tables 17, 18, and 19 above list the detailed literature search criteria and relevant information.

The overall benefits of CI in children with SSD and AHL include improved performance in speech perception in quiet and noise, sound localization and subjective measures of quality of life.

Word recognition in quiet:

Beck et al. (2017) reported diverse speech audiometry results. Some of the children showed measurable benefits on speech discrimination. The CAP scores improved for the SSD children (N = 8) with CI compared to preoperative performance. Rahne and Plontke (2016) reported that two SSD children improved with CI over time in number recognition, two SSD children showed no recognition. One child improved over time in word recognition with CI, whereas the other three children showed no recognition.

Word recognition in noise:

Arndt et al. (2015) reported on the speech perception in noise for different speech and noise configuration. Children with SSD demonstrated improved although variable performance on speech perception in spatially-separated conditions. Some children demonstrated improvement in spatially separate speech and noise. Tavora-Vieira and Rajan (2015) showed better and similar speech perception in noise with CI-on compared to CI-off for two SSD children. Gratacap et al. (2015) showed an increase in speech perception in noise in 9 children with AHL after 12 and 24 months of CI use compared to preoperative performance. Rahne and Plontke (2016) reported an improvement in speech reception thresholds in three SSD children when CI-on and CI-off are compared; in one child no measurement was possible.

Sound localization:

Arndt et al. (2015) reported a decreased localization error with CI for most of the children as compared to the preoperative unaided condition. Tavora-Vieira and Rajan (2015) reported that one child with SSD showed a de-

creased localization error after 6 and 12 months with the CI-on compared to CI-off condition, whereas the other child with SSD showed the same localization performance in both conditions. Rahne and Plontke (2016) reported an improvement in sound localization in four children with SSD when CI-on and CI-off are compared.

Subjective measures:

Beck et al. (2017) showed that the parents (N = 9) and children (N = 3) with SSD reported an increase score for the SSQ. Arndt et al. (2015) reported an increase the SSQ score in children with SSD with postlingual onset of deafness (N = 9), slight improvement in children with SSD with perilingual onset of deafness (N = 2) and minimal improvement or same performance in children with SSD who are congenitally deaf (N = 2).

Published Literature on Adults

The literature search yielded six peer-reviewed papers in SSD and/or AHL adults with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults. Although the paper by Kitoh et al. (2016) mentioned a study inclusion criterion of PTA > 70 dB HL, all five subjects included in the study had a pre-operative unaided PTA of 92 dB HL or higher. Hence, the results from this study were included in the summary below.

The six papers comprise a total of 58 adults with SSD (N = 50 of which implanted with MED-EL devices) and a total of 52 adults with AHL (N = 37 of which implanted with MED-EL devices). This subject count does not include five SSD nor 16 AHL patients from Skarzynski et al. (2017), as those subjects are part of the larger cohort from the same implant center later reported on by Lorens et al. (2019). Also note that three of the 58 adult SSD subjects might have an unaided PTA close to or below 90 dB HL in the implanted ear, as the paper by Döge et al. (2017) presents PTA data as median and interquartile range only (75%, i.e. N = 8 of 11 studied subjects have PTA > 100 dB HL).

The overall benefits of CI in SSD and AHL adult patients include improved performance regarding speech perception in quiet and in noise, sound localization and subjective measures regarding quality of life, music enjoyment and tinnitus.

Word recognition in quiet

Döge et al. (2017) showed that with a CI, the mean PTA thresholds of the deaf ear improved from the mean value of 120 dB at unaided condition to below 40 dB in the aided condition in 11 SSD subjects. In addition to the benefit of sound perception, the CI enabled better speech perception in quiet. Skarzynski et al. (2017) compared CI-on vs CI-off condition in 5 SSD and 16 AHL subjects and significantly better speech perception was observed in the CI-on condition. Results with the CI demonstrated a continuous improvement in speech recognition after 12-month of use. Rahne and Plontke (2016) reported a significant improvement in monosyllabic word and multisyllabic number recognition in quiet in comparing the 12-month and 1-month after CI activation in 17 SSD subjects. van Loon et al. (2017) reported that speech recognition scores increased from 74% pre-operatively to 88% at 12-month with bimodal stimulation in 7 AHL cases.

Speech perception in noise

Several studies found that the CI enabled better speech perception in noise. Rahne and Plontke (2016) reported a significant improved speech perception in noise at 3-month of CI activation with CI-on vs CI-off condition, and a continuous improvement occurring at 12-months in 17 SSD subjects. Skarzynski et al. (2017) reported better speech perception in noise at CI-on vs CI-off condition. van Loon et al. (2017) reported that in comparison to the CI-off or CI-only condition, bimodal stimulation resulted in significantly better speech recognition in noise and spatial speech recognition at 3-months, 6-months and 12-months post-activation. Lorens et al. (2019) reported a significant binaural benefit conveyed by CI-on in comparison to the CI-off condition, in 25 SSD and 45 AHL subjects. Kitoh et al. (2016) reported a gradually improved speech perception in noise after 12-months post-activation in comparison to the pre-operative condition. Döge et al. (2017) reported slightly improved speech reception in noise in CI-on vs CI-off condition in 8 of 11 patients. Three of 11 subjects, however, showed deteriorations at CI-on condition.

Sound localization

Döge et al. (2017) showed a significant decrease of localization error in the CI-on condition in comparison with the CI-off condition in 11 SSD subjects. Skarzynski et al. (2017) observed a significant localization benefit reflected by decrease in RMS angular error at CI-on vs CI-off condition. van Loon et al. (2017) reported a significant improved localization performance in all 7 AHL subjects with bimodal stimulation at 12-month in comparison to the pre-operative condition. Results with the CI demonstrated a continuous improvement in sound localization after 12 months of CI use. Rahne and Plontke (2016) reported that in comparison to CI-off, CI-on significantly improved

sound localization, reflected by a decrease in ADE (angular detection error) at 1-month of CI activation. A continuous improvement occurred over time. Kitoh et al. (2016) reported better sound localization in all 5 subjects, with continuous improvement through 12-month.

Subjective measures

van Loon et al. (2017) reported increased frequency and satisfaction of listening to music from 7 AHL CI users. Bimodal stimulation also resulted in better quality, clarity, and appreciation of different music styles. Skarzynski et al. (2017) reported substantial tinnitus suppression in all 15 patients with pre-operative tinnitus and Kitoh et al. (2016) reported decreased disturbance to daily life caused by tinnitus in all 5 SSD cases. Two studies addressed self-evaluation of CI performance in SSD and AHL subjects. Skarzynski et al. (2017) reported a significant improvement in the global score of APHAB, as well as sub-scales including 'Ease of communication', hearing under 'background noise' or under 'reverberation' at 14-months after CI activation in comparison to pre-operative condition. van Loon et al. (2017) reported that except for the 'speech production' subdomain, bimodal stimulation yielded a significant better outcome for all other subdomains of the NCIQ questionnaire. An average appreciation of the cochlear implant was scored 4.3/5, indicating a high satisfaction with the CI.

Conclusions from Real World Evidence

This clinical evaluation of cochlear implantation for the treatment of SSD and AHL is based on the above literature data sets relevant to the safety, performance, and effectiveness of cochlear implantation as a treatment option for individuals with AHL or SSD.

In this review of Real-World data, the latest clinical data were summarized on SSD and AHL patients from centers both in the US and around the globe that meet the proposed audiometric indication criterion of a profound hearing loss in the ear to be implanted, i.e., a PTA of 90 dB or higher. The clinical populations reported on include both adults and children older than 5 years age.

Taken together, the clinical data from this body of literature show consistent benefits of CI in individuals with SSD or AHL, in terms of improved speech perception in noise, spatial hearing, localization accuracy, and patient-reported subjective outcome measures. Consistent CI use of patients has been shown across literature reports, and notably so in the prospective study by Lorens et al. (2019) in 70 sequentially implanted SSD and AHL CI users (59 of which were implanted with MED-EL devices). These literature data provide Real World Evidence (according to the FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices") in support of the clinical benefits of CI in SSD and AHL recipients, as demonstrated in the UNC study. In this way, these literature reports do serve as supporting evidence which demonstrates a reasonable assurance of device safety and effectiveness and to characterize the benefit/risk profiles for the proposed SSD/AHL indications.

Symbols



CE mark. First applied in 2014



Single-use device. Do not reuse!



Catalogue number



Serial number



Caution! Consult accompanying documents



Sterilised using Ethylene Oxide



"Use by" date



Manufacturing date



Manufacturer



MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
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- 1 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).
- 2 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.
- 3 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

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CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.



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MAESTRO SYSTEM SOFTWARE 7.0 USER MANUAL

AW35353 rev 2.0

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1 Introduction

This manual serves as a reference guide for trained clinical personnel (e.g., clinical audiologists) conducting the programming of the MED-EL audio processors and associated testing of implant users. It describes the MAESTRO System Software 7.0 which is used for different intraoperative and postoperative purposes for the MED-EL Cochlear Implant System. Currently, it contains the implant telemetry and fitting of the supported processors and the functions: Audiogram, ESRT (Electrically Evoked Stapedius Reflex Threshold), EABR (Evoked Auditory Brainstem Response), AutoART, ART (Auditory nerve Response Telemetry), Acoustic Fitting.

CAUTION:

The software must only be used by specially trained personnel. Training can be provided by MED-EL or by other qualified clinical personnel who have experience using the MED-EL Cochlear Implant System. Since a password is required to use the software, MAESTRO allows an administrator to limit access to trained and qualified personnel.

The MED-EL Cochlear Implant System is an intracochlear, multichannel auditory prosthesis that uses the latest technology and processing strategies. Its development is based on many years of world-wide research, together with extensive experience in cochlear implant development and production by MED-EL. The MED-EL Cochlear Implant System refers to the implant types and processor types listed below, the MAX Programming Interface, and associated fitting software developed by MED-EL. The individual hardware components of the MED-EL Cochlear Implant System are described in detail in the applicable user manuals.

Implant types:

- Mi1200 SYNCHRONY
- Mi1000 MED-EL CONCERT
- SONATA_{TI}¹⁰⁰
- PULSAR_{CI}¹⁰⁰
- C40+

Processor types:

- RONDO 2
- SONNET EAS
- SONNET
- RONDO
- DUET 2
- OPUS 2
- OPUS 1
- TEMPO+

NOTE:

The MAESTRO System Software 7.0 supports the above mentioned implant types and processor types in combination with the MAX Programming Interface.

If you have questions, please contact your nearest MED-EL representative.

2 Application Information

2.1 INTENDED USE

The MAESTRO software is an external component of the MED-EL Cochlear Implant System. The MED-EL Cochlear Implant (CI) 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.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal cochlear implant with either a FLEX24 or FLEX20 electrode variant which together make up the MED-EL EAS System.

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

The MAESTRO software is intended to be used:

- in a clinical or office environment by persons adequately skilled and trained to perform all intended tasks
- with patients who received one of the intended MED-EL Cochlear Implants
- installed on a Personal Computer (PC) running a version of the supported Microsoft Windows operating systems listed in chapter **Technical Data**
- in conjunction with the following MED-EL external hardware components:
 - MAX Programming Interface
 - RONDO 2 audio processor
 - SONNET EAS audio processor
 - SONNET audio processor
 - RONDO audio processor
 - DUET 2 audio processor

- OPUS 2 audio processor
- OPUS 1 audio processor
- TEMPO+ speech processor
- All supported audio processor coils
- Detectorbox C40+
- in conjunction with the following third-party external hardware components:
 - HI-PRO interface box (for EAS fitting of the DUET 2)
- in conjunction with the following MED-EL implantable hardware components:
 - Stimulator:
 - Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY).
 - Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT)
 - SONATA_{TI} (hereafter referred to as SONATA)
 - PULSAR_{CI} (hereafter referred to as PULSAR)
 - C40+
 - Electrodes:
 - Standard
 - Medium
 - Compressed
 - Split
 - FLEX20
 - FLEX24
 - FLEX28
 - FLEXSOFT
- to perform the following tasks:
 - The Audiogram is intended to enter hearing curve data of a patient for both ears. This task also supports EAS fitting as the audiogram data are used to calculate the crossover frequency.
 - IFT (Impedance and Field Telemetry) is intended to ascertain the technical status of the implant's stimulator and electrodes. However, the results must not be taken as the sole basis for any decision about further medical or surgical treatment.
 - ESRT (Electrically Evoked Stapedius Reflex) is intended to enable fast and simple stapedius reflex measurements to ascertain correct stimulation of the patient's auditory nerve and to indicate the relative sensitivity of the implanted cochlea for electrical stimulation.
 - EABR (Evoked Auditory Brainstem Response) is intended to perform stimuli for auditory evoked potential assessment. It provides user adjustable stimulation patterns and the necessary synchronization with external recording hardware.
 - AutoART is intended to stimulate the auditory nerve and to evaluate a particular electrode's evoked neural response and automatically detect ECAP thresholds.
 - ART (Auditory nerve Response Telemetry) is intended to stimulate the auditory nerve and to evaluate a particular electrode's evoked neural response.

- Fitting is intended to adjust sound processing and stimulation parameters for any intended audio processor/cochlear implant combination to the specific needs of individual patients.
- Processor Configuration is intended to program sound processing and stimulation parameters from the Fitting task into an intended audio processor.
- Acoustic Fitting for DUET 2 is intended to adjust the hearing aid device that is part of the DUET 2 audio processor.

2.2 INDICATIONS

The MED-EL Cochlear Implant System is indicated for:

Bilateral deafness:

- 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 the 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 aided benefit is defined as <20 % correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood 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.

Partial deafness:

- The MED-EL EAS System is indicated for partially deaf individuals aged 18 years and older who have residual hearing sensitivity in the low frequencies sloping to a severe/profound sensorineural hearing loss in the mid to high frequencies, and who obtain minimal benefit from conventional acoustic amplification. Typical preoperative hearing of candidates ranges from normal hearing to moderate sensorineural hearing loss in the low frequencies (thresholds no poorer than 65 dB HL up to and including 500 Hz) with severe to profound mid- to high-frequency hearing loss (no better than

70 dB HL at 2000 Hz and above) in the ear to be implanted. For the non-implanted ear, thresholds may be worse than the criteria for the implanted ear, but may not be better. The CNC word recognition score in quiet in the best-aided condition will be 60 % or less, in the ear to be implanted and in the contralateral ear. Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids.

Single-sided deafness and Asymmetric Hearing Loss:

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

2.3 CONTRAINDICATIONS

As the MAESTRO software is an external component of the MED-EL Cochlear Implant System, all contraindications stated for the cochlear implant system are applicable.

Use of the MAESTRO software is contraindicated in combination with any hardware component not included in the intended use or any external hardware component known to be defective. The software is contraindicated for use by patients or other unskilled, untrained persons.

- The Impedance and Field Telemetry (IFT) is contraindicated for patients known to have extremely low Maximum Comfortable Loudness (MCL) levels.
- There are no known contraindications for Audiogram, ESRT, EABR, ART, AutoART, Fitting, Processor Configuration, Acoustic Fitting for DUET 2.

2.4 PRECAUTIONS

High Definition Continuous Interleaved Sampling (HDCIS), Fine Structure Processing (FSP, FS₄ and FS₄-p) are speech coding strategies offered in the MAESTRO 7.0 software. The performance of the FSP, FS₄ and FS₄-p speech coding strategies has been clinically studied in the post-lingually deaf adult population but not in the pediatric population. For further details on the safety and effectiveness data on the adult patients please refer to chapter **Clinical Studies**. Pediatric patients should be fit with CIS+ or HDCIS programming options. Performance of HDCIS, FSP, FS₄ and FS₄-p may vary between individual patients.

The correct installation of the software is a prerequisite for successful and beneficial use of the MAESTRO 7.0 software. The use of the MAESTRO 7.0 software is restricted to clinicians who are adequately skilled and have been trained to perform the required clinical tasks. In addition to the instructions for use provided by MED-EL, clinical users are strongly encouraged to follow local professional standards throughout all procedures.

2.5 INITIAL INSPECTION

Before working with the MAESTRO software for the first time it is recommended to perform an initial inspection:

1. Make sure that the desired target platform fulfills the minimum requirements as specified in chapter **Technical Data**.
2. Install the MAESTRO software as described in chapter **Software Installation** and make sure that no unexpected event or failure occurs during installation.
3. Connect the USB cable to a high-power USB 2.0 compliant port on your computer and to the USB socket of the MAX Programming Interface. Make sure that no further device is connected to the MAX Programming Interface.
4. Launch the MAESTRO software and log in.
 1. Verify that the MAESTRO software starts and login was successful.
 2. Verify that a green LED on the back of the MAX Programming Interface illuminates. This confirms that the driver is installed and the MAX Programming Interface is connected to an appropriate high-power USB 2.0 port.
 3. Take a look at the [Settings | Hardware](#) dialog (see chapter **Settings - Hardware**) or the status bar (see chapter **Status bar**) and verify that the MAX Programming Interface is recognized by the MAESTRO software.

See chapter **Technical Data** for hardware and software requirements and chapter **General Precautions and Warnings** for care and maintenance of the MAESTRO software.

3 What's New

The main new features in MAESTRO 7.0 are:

- Graphical user interface:
 - New patient list view with advanced patient search, see chapter **Patient list view**
 - New task data list, see chapter **Task Data**
 - New workflow-oriented session, see chapter **Session**
 - Improved menu and toolbar, see chapter **Menu and Toolbar**
 - New session comment functionality, see chapter **Software Tools - Comments**
- Tasks:
 - Support of objective measures using the processor coil, see chapter **Setup - Measurements with DL-Coil**
 - New task AutoART, see chapter **AutoART task**
 - New external artifact reduction method in the EABR task, see chapter **EABR task**
 - New feature to check connection to EEG recording device via trigger signals in EABR task, see chapter **EABR task**
 - New measurement type (i.e. Advanced setup) in the ART task to repeatedly measure evoked potentials based on electric and acoustic stimulations, see chapter **ART task**
- Tools:
 - New reset processor tool, see chapter **Reset Processor**
 - New progressive maps tool, see chapter **Progressive maps**
- Additional improvements:
 - Link check functionality in ESRT and Fitting task, see chapters **ESRT Levels editor** and **Levels editor**
 - Added support of Microsoft Windows 10, see chapter **Technical Data**
- Support of the RONDO 2 audio processor

MAESTRO includes several minor enhancements and improvements in addition to the features listed above.

4 MAESTRO Setup

4.1 SOFTWARE INSTALLATION

Installation of the MAESTRO System Software is designed to be as easy as possible, as all necessary files, drivers, etc. are stored on a single USB flash drive or CD-ROM.

Preconditions:

- The PC fulfills all hardware and software requirements defined in chapter **Technical Data**.
- The Windows user installing the MAESTRO has administrative rights on the PC.
- The HI-PRO and the MAX Programming Interface are not connected to the PC.

NOTE:

Be aware that installation of MAESTRO 7.0 will uninstall an already installed previous version of MAESTRO automatically.

Steps to install MAESTRO:

1. Connect the USB flash drive to a compatible port and double click on [MAESTRO_Setup.exe](#), which can be found on the USB flash drive, or insert the CD into your CD-ROM compatible drive.
2. The installation wizard starts. Choose the language of the setup program.
3. Click [Next](#) to continue.
4. Read and confirm the displayed end-user license agreement. By accepting the end-user license agreement, you confirm that you are informed about your rights and the conditions of use.
5. Click [Install](#) to start installation. After successful installation, a summary window is displayed.

NOTE:

Please note that with the installation of the MAESTRO software the driver for the MAX Programming Interface is installed automatically and this may take some time. Correct installation of the software and driver is a prerequisite for successful use.

After installation, MAESTRO will automatically create a new and empty MAESTRO single-file database, or connect to an already existing, valid MAESTRO 7.0 database.

Enable the checkbox on the summary page and use the Database Management Tool to migrate the database of a previous MAESTRO version. See chapter **Database Management Tool** for further information.

Product Activation Key

MAESTRO 7.0 and additional applications cannot be used without a valid activation key. After the installation finished or when launching MAESTRO or one of the additional applications for the first time, enter the product activation key you have received.

CAUTION:

Only use product activation keys provided by MED-EL as stated in the end-user license agreement.

The currently used activation key including expiration date is displayed in the [Help - About](#) menu.

Language of the application

Installation of the MAESTRO System Software automatically installs an English version of the software. Use of MAESTRO with other languages requires installation of the appropriate language pack after successful setup of the MAESTRO software. The USB flash drive and the CD-ROM with the MAESTRO setup provide a [Language Add-on](#) folder containing the German language pack. Additional language packs for the MAESTRO 7.0 software that can be installed are provided by MED-EL. For further information about available language packs please contact your nearest MED-EL representative.

Steps to change the language of the application:

1. Double click onto the language pack [.msi](#) file to start installation of the language pack.
2. Start MAESTRO.
3. Open the [Settings | User Interface](#) dialog.
4. Select the desired language in the drop-down menu.
5. Restart MAESTRO.

Installing and updating the help file

The MAESTRO System Software provides the option to install a region and language specific help file. Installation of the help file can be done at any time. To install a help file, double click on the single [.msi](#) file provided by MED-EL. With the next launch MAESTRO contains the help file.

In addition help files can also be updated, e.g. when new features are unlocked with the appropriate product activation key update the help file to also contain descriptions of the new features. For further information about available help files please contact your nearest MED-EL representative.

Uninstalling MAESTRO

The option to uninstall MAESTRO can be started from the Windows program group MED-EL in the Start menu. For Windows 8 and later the option is available as a tile and can be found in the Apps window.

When removing MAESTRO related language add-ons are removed automatically.

Tips, Tricks and Troubleshooting

The driver for the MAX Programming Interface is installed automatically during the MAESTRO setup and does not need to be installed separately. Nevertheless, it can be found on the USB flash drive and on the CD-ROM in the folder [MAX Driver Setup](#) as [MAX Driver Setup.exe](#).

4.2 DATABASE

The MAESTRO 7.0 software needs an appropriate MAESTRO 7.0 database to work with:

- A new and therefore empty MAESTRO 7.0 database, e.g., the single-file database routinely created during installation.

OR

- A database of a previous MAESTRO version which was migrated to a MAESTRO 7.0 database.

It is not possible for MAESTRO 7.0 to connect to a database created by a previous MAESTRO version that was not migrated to MAESTRO 7.0.

The Database Management Tool offers several options to work with the MAESTRO database, especially to create new databases or to migrate databases into a MAESTRO 7.0 database, see chapter **Database Management Tool**.

NOTE:

It is highly recommended to back up the MAESTRO database on a regular basis.

CAUTION:

Saved data are confidential patient data. The user or local administrator is responsible for protecting these data against unauthorized access and data loss in accordance with national laws and local clinic policy.

Supported database formats

All data generated with MAESTRO are saved in an encrypted database that contains patient data and administrative data.

MAESTRO currently supports the following database formats:

MAESTRO Setup

- SQLite
- Microsoft SQL Server 2008
- Microsoft SQL Server 2008 R2
- Microsoft SQL Server 2012
- Microsoft SQL Server 2014
- Microsoft SQL Server 2016

SQLite is a single-file database (.db3) used for desktop applications. Microsoft SQL Server is a complex server-based database and is particularly suitable as a central database for multiple user solutions in a network. Installation of the software routinely installs an empty MAESTRO single-file database (.db3). Installation of a Microsoft SQL Server is not supported by MAESTRO and must be done by a local administrator or the IT department. Use the Database Management Tool to set up a new MAESTRO database within an existing Microsoft SQL Server or to create a new single-file database.

NOTE:

For shared data access use a Microsoft SQL Server. Using a single-file database on a shared network drive is not as reliable as an SQL Server database and might lead to data loss.

A stable connection to the database is required to start MAESTRO. It may happen that the connection cannot be established, e.g. in an operating theater without network access when using a non-local database. In this case connect to a locally accessible database, e.g. the default SQLite database which is automatically created during installation of MAESTRO.

Tips, Tricks and Troubleshooting

MAESTRO supports the user with different kinds of warning messages in case of database issues.

In most cases the database issues can be easily resolved by ensuring that:

- MAESTRO has access to the database
- there is enough space to save the data (storage device is not full)
- the network connection is stable and reliable when using a network drive to store data
- the data is not damaged

Already damaged data in single-file databases may be repaired with the Repair a Database function, see chapter **Repair a database**.

If none of the above mentioned suggestions resolves the issue, please contact your nearest MED-EL representative for further assistance.

4.3 LAUNCHING MAESTRO

When launching MAESTRO, the Welcome dialog opens.



Welcome dialog

The welcome dialog displays a list of all MAESTRO users. Click on the applicable user name or enter the user name directly in the field **User**, then enter the password in the field **Password**. Click on the **Login** button to start the application.

For new databases, only the default user **Administrator** is displayed. Click on **Administrator**, then on the **Login** button to create a password for this user. The default user **Administrator** has administrator rights and can therefore create other users, see chapter **User Management**.

The main features in MAESTRO can be controlled with the computer mouse or key combinations. Find a list of valid key combinations for MAESTRO in chapter **Appendices**.

Working Modes

MAESTRO offers two working modes: **Normal Mode** and **Training Mode**.

Normal Mode and Training Mode share user data, but have separate patient databases which are not interchangeable. Therefore, the clinician can use the same access credentials to login to either Normal Mode or Training Mode, but patient data can only be accessed in the mode in which it was created.

Normal Mode

Normal Mode shall always be used when working with real patients.

Training Mode

Training Mode offers a playground for users new to MAESTRO and for those who want to extend their knowledge about MAESTRO. In this mode MAESTRO simulates external hardware, so there is no need to connect real hardware. To notify MAESTRO which hardware has to be simulated, it is necessary to enter patient-relevant information (e.g. implant type, processor type) in the patient data editor, see chapter [Create or edit a patient record](#).

Enable the [Training](#) checkbox in the Welcome dialog and log in to start MAESTRO in Training Mode. A grey title in the work view and a pop-up window indicate that MAESTRO is in Training Mode.

The settings of the Training Mode can be changed in [Settings - Training Mode](#).

Tips, Tricks and Troubleshooting

Hints for using the Training Mode:

- Enter the desired hardware in the patient data editor to simulate a certain hardware set, e.g. add processors and processor options to the patient data in addition to the implant type. Enable the checkbox [In Use](#) in the processor table to indicate the processor that shall be simulated.
- When MAESTRO is started in Training Mode, Training Mode settings are available. Use these settings to speed up simulated measurements or to define measurement outcomes.
- When programming a processor in the session view, the datalogging subsection is automatically filled with simulated data.

4.4 USER INTERFACE

The user interface of MAESTRO contains the **menu and toolbar**, which provide various functions and the most important tools, the **work view** as the main part of the screen together with notifications and the **status bar**, which displays information about connected hardware.

Change the settings for the user interface (e.g., the language of the application) in the settings dialog.

4.4.1 Menu and Toolbar

Menu

Data	Provides standard options such as save or close datasets and additional features such as start or close a session, create different kinds of reports or export and import data. An option to restart or exit the application is available as well.
New	Menu to create new datasets: add new patients to the database, create new task data for a patient or add a new MAESTRO user.

- Edit Provides standard functions such as undo and redo actions, edit, cut, copy, paste, rename and delete selected items or select all items and invert a selection.
- View Menu to adjust the user interface. It contains the submenu [Customize toolbar](#) to customize the quick access buttons of the toolbar. The editor header of tasks with name and summary string can also be displayed or hidden.
The option [User management](#) opens the user list and is only available for administrator users. Display the Session tab, the Task Data tab and hide or display the log view or reset the user interface layout. Switch between the tabs of different tasks in the work view and tile or untile the editors.
- Tools Provides several tools: [Session comment](#), [Talk mode](#), [Coupling Check](#), [Reset processor](#), [Duplicate task data](#), [Combine task data](#), [Acknowledge next notification](#), [Media Manager](#), [Media Player](#), [Email log files](#), [Change password](#), [Change product activation key](#). Find a detailed description of tools in chapter **Software Tools**.
- Settings Provides the option to open the settings menu.
- Help Provides the online version of the MAESTRO user manual in [Contents](#) which may also be opened by pressing the **F1** key. It additionally offers a link to the MED-EL website and information about the software.

Toolbar



Customized Toolbar

The toolbar provides the most important tools and symbols for quick selection. Customize your toolbar by enabling or disabling the quick access buttons in [View - Customize toolbar](#). The toolbar is split into two parts.

The first part contains quick access buttons for standard features such as save, save and close, undo, redo, reports and history reports. Icons for close and close all, export and import are available as well.

The second part contains functions related to patient data and is only available in an ongoing session. It contains icons to edit the session comment and to start the talk mode. Icons to tile the work view, duplicate task data, open the coupling check dialog and buttons to create new tasks are available as well.

4.4.2 Work view

The work view is the main part of the application and contains different tabs depending on data the user is currently working with. Navigate through different data sheets for users, patients, session or task data by clicking on the related tab. The positions of individual views, e.g. session comment, can be changed with drag and drop, hidden by clicking on the symbol [Auto Hide](#) or closed by clicking on the symbol [Close](#).

Notifications

Notifications related to the currently opened tab are displayed at the bottom of the work view and provide helpful information. Whenever a new notification is displayed, the notifications window blinks and an audio signal is given. Always read notifications carefully. Some notifications need to be confirmed before work with the software can be resumed. Confirm a notification by enabling the checkbox next to it or by using the [Acknowledge Next Notification](#) tool. See chapter [Settings - User Interface](#) on how to disable the audio signal for notifications.

Specific MAESTRO units

MAESTRO describes a stimulation pulse via amplitude or charge:

- [cu] current unit: gives the amplitude of a stimulation pulse. One current unit is approximately 1 [μA].
- [qu] charge unit: characterizes the electrical charge flowing in one direction during the stimulation pulse, i.e. the charge of one phase of a biphasic stimulation pulse. The charge of one phase is defined as the product of stimulation current in [cu] and phase duration in [μs]. One charge unit is approximately 1 [nC]. To avoid damaging the tissue, the net charge of a stimulation pulse is always zero.

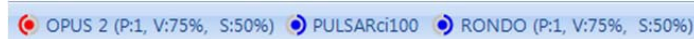
Tips, Tricks and Troubleshooting

- Restore the default view at any time by selecting [View - Reset User Interface Layout](#) in the menu.
- Click on a tab or field and press [F1](#) to open the related chapter in the help file.

4.4.3 Status bar

The status bar at the bottom of the MAESTRO window displays information such as patient name, hardware information and the currently logged in user.

The hardware information section in the status bar offers information about the connected hardware. An established connection to the MAX Programming Interface is indicated by three circles which represent the three sockets on the front of the MAX Programming Interface. The color of the circles indicates the side the socket is assigned to according to the chosen mapping, see chapter [Hardware - MAX Programming Interface](#).



Information about connected hardware

The colored half rings are synchronized with the LEDs on the MAX Programming Interface and indicate which side the socket can work with. The half rings in the middle representing the telemetry socket are only enabled when the user opens a task which can be performed with a MAX coil. If no such task is open they are grey.

A colored disk within a circle indicates that a device is connected to the corresponding socket. The text next to the circle names the connected hardware. The disk in the middle is enabled when the user opens a task which can be performed with a MAX coil and a MAX coil is connected. In this case the corresponding implant type is displayed. An X in a circle indicates that cable and socket do not match and the hardware can therefore not be used. During an ongoing measurement currently used hardware is indicated by red or blue colored background.

A connected DL-Coil is also displayed in the status bar.

Tips, Tricks and Troubleshooting

Place the mouse cursor over the processor type in the status bar to display the serial number of the processor in a tooltip.

4.5 HARDWARE

4.5.1 Setup

This chapter describes the major steps for the correct hardware setup for the MAESTRO System Software 7.0. For detailed information about the MAX Programming Interface, the MAX coils, the processors and programming cables please refer to the corresponding user manuals.

The following hardware is necessary to perform the tasks described in this manual:

- PC fulfilling the requirements in chapter **Technical Data**
- MAX Programming Interface
- USB Cable type A – B to connect the MAX Programming Interface to the PC
- MAX Coil and/or MAX Coil S (depending on the patient's implant)
- MAX Programming Cable BTE and/or MAX Programming Cable RONDO and/or MAX Programming Cable SONNET and/or MAX Programming Cable RONDO 2 (depending on the patient's processor)
- At least one of the supported processors with processor coil

Additional hardware not provided by MED-EL:

- Tympanometer for ESRT task in postoperative mode
- EEG recording device for EABR recordings
- HI-PRO for software based acoustic fitting of the DUET 2

Additionally required is a patient implanted with a supported MED-EL implant.

As a prerequisite for every fitting make sure to:

MAESTRO Setup

- Connect the MAX Programming Interface with the USB cable to the computer using a high-power USB 2.0 compliant port.
- Connect the MAX Coil to the MAX Programming Interface using the socket in the center (telemetry socket). For patients with a SYNCHRONY implant connect the MAX Coil S.
- Connect the processor with processor coil to the appropriate MAX Programming Cable and connect the cable to one of the processor sockets. Connect a second processor to the other processor socket for bilateral fitting.
- Connect the HI-PRO to the computer and the DUET 2 including batteries to the HI-PRO using the HI-PRO programming cable (for software based Acoustic Fitting of the DUET 2 only).



Example hardware setup

CAUTION:

When using the telemetry socket for measurements always use the MAX Coil S for patients with a SYNCHRONY implant, for other patients use the MAX Coil. For instructions applying to both coil types, the term MAX coil is used in this user manual.

NOTE:

In some instances the presence of metallic objects, such as metallic desks or surfaces, surgical tools, jewelry, etc. close to the coil affect measurements (e.g., Coupling Check, Telemetry, etc.). In case of unexpected results under these circumstances, position the metallic object further away from the coil and repeat the measurement.

NOTE:

Prior to fitting the RONDO 2 audio processor, the integrated battery has to be charged.

The RONDO 2 audio processor will not be charged while fitting is in process (i.e., while connected to the MAX Programming Interface).

Measurements with the DL-Coil

Communication with the implant for objective measures can be established via a processor with DL-Coil or via MAX coil.

- To use the DL-Coil for measurements, simply connect the processor with DL-Coil to the MAX Programming Interface and place the coil on the patient's head. MAESTRO automatically uses the DL-Coil to perform the measurement if a processor with DL-Coil is connected to the MAX Programming Interface.
- To use the MAX coil for measurements connect the MAX coil that corresponds to the patient's implant type to the telemetry socket of the MAX Programming Interface and place the coil on the patient's head. Ensure that no processor with DL-Coil is connected to the MAX Programming Interface.

If the MAX coil shall always be used for measurements regardless of possibly connected processors with DL-Coil, enable the corresponding checkbox in the hardware settings, see chapter **Settings - Hardware**.

NOTE:

For intraoperative measurements it is recommended to use the MAX coil. If measurements with DL-Coil cannot be performed due to poor coupling, use the MAX coil instead.

NOTE:

The RONDO 2 processor has a built-in DL-Coil. The above statements about measurements with DL-Coil therefore also apply to the RONDO 2.

Tips, Tricks and Troubleshooting

- Information about the connected hardware is displayed in the status bar. If a DL-Coil is connected, the coil is displayed in the status bar as well.
- The hardware used to perform a measurement is highlighted with red or blue background color in the status bar.

4.5.2 MAX Programming Interface

MAESTRO 7.0 is used in conjunction with the MAX Programming Interface and cannot be used with any predecessor of the MAX Programming Interface (e.g., DIB II). With the installation of MAESTRO the required driver for the MAX Programming Interface is installed automatically.

MAESTRO Setup

The MAX Programming Interface has three sockets, the left and right socket to connect processors and the center socket to connect the corresponding MAX coil. If the connected cable and socket are not compatible an X in the status bar indicates that MAESTRO cannot communicate with this device.

The LEDs on the MAX Programming Interface as well as the half rings in the status bar indicate which side the socket can work with.

NOTE:

The MAESTRO System Software only works with one MAX Programming Interface, therefore only one MAX Programming Interface shall be connected to the computer. Bilateral fitting with the MAX Programming Interface is possible by selecting a bilateral patient and connecting two processors to the two processor sockets.

MAESTRO provides two working modes for the MAX Programming Interface: a dynamic mode and a fixed mode.

The dynamic mode allows the user to choose the processor socket for the right or left ear individually, while the fixed mode maps a static constellation (left socket for the right ear, right socket for the left ear) to the processor sockets.

Dynamic mode:

The user can choose the processor socket to plug in a processor.

The MAESTRO software assigns the socket to the side the processor was programmed for, the other socket is automatically assigned to the other side. For empty processors the user has to decide which side the processor should work with.

Fixed mode:

The user cannot choose the processor socket to plug in a processor.

An already programmed processor always has to be plugged into the socket mapped for the corresponding side. An empty processor is automatically assigned to the side the socket works with.

Use the menu [Settings - Hardware](#) to switch between fixed and dynamic mode or enable and disable the LEDs on the front of the MAX Programming Interface.

NOTE:

MAESTRO always works with the side the MAX Programming Interface socket reflects, even if the connected processor is programmed for the other side. It is not possible to work with two processors for the same side simultaneously.

It is possible to work with a programmed processor for a different patient or side as long as the processor is connected to the correct socket. It is highly recommended to reset a

programmed processor before using it for a different patient or side. Open [Tools - Reset Processor](#) to reset the processor, see chapter [Reset Processor](#).

NOTE:

Reset a programmed processor before using it for a different patient or side.

Tips, Tricks and Troubleshooting

In most cases connection issues between the MAX Programming Interface and MAESTRO can be easily resolved by:

- checking the setup for loose cable connections
- exchanging the USB cable
- using a different USB port on the computer

If the LED on the back illuminates orange, the driver may not be installed correctly. Check the status of the MAX Programming Interface driver in the Device Manager of the operating system and, if necessary, install the driver manually. The driver can be found on the USB flash drive and on the CD-ROM in the folder [MAX Driver Setup](#) as [MAX Driver Setup.exe](#).

If none of the above suggestions resolves the issue, please contact your nearest MED-EL representative for further assistance.

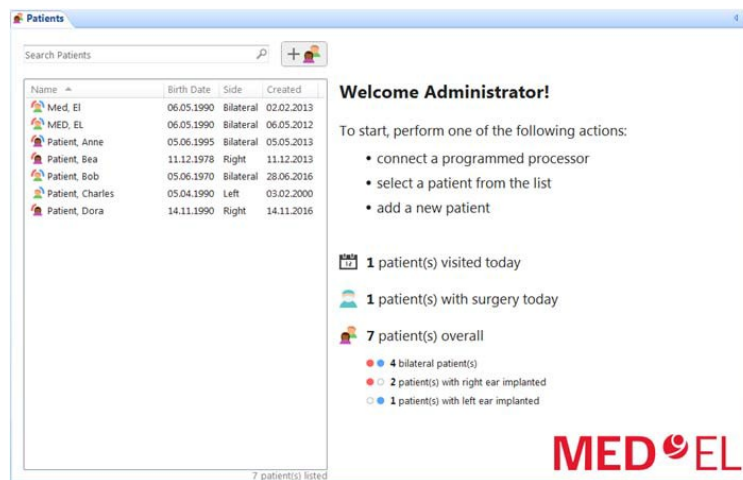
5 Working with MAESTRO

5.1 PATIENT MANAGEMENT

For safety reasons, patient data saved in the Training Mode are separated from the patient data saved in Normal Mode. Patient data entered in the Training Mode are neither visible nor accessible in Normal Mode and vice versa.

5.1.1 Patient list view

After launching MAESTRO the work view displays the tab **Patients**. It provides a list of all patients in the database, a search field to search for certain patients and a button to add new patient records. A summary is displayed on the right side.



Patients tab

Patient list

Information such as patient's name, birth date, implanted side and creation date of the record is listed. Click on the column name to sort the patient list in ascending order, click a second time to sort the list in descending order. A right click on one of the column names opens a menu to

- display additional columns such as gender, creator, ID and comments to a patient.
- hide currently displayed columns.

- automatically resize this column to fit its content.
- automatically resize all columns to fit their content.

Change the order of the columns by simply drag and drop.

Right click on the name of the patient in the list to open a menu with several options. Select [Start Session](#) to start a session for this patient, select [Edit](#) to open the patient data editor and edit the patient record. Select [Delete](#) to delete the patient. Choose [Export](#) to export the patient record and [Reports](#) to create a patient and task report for this patient. Select the option [Merge](#) to merge two selected patients, if applicable.

Search patients

Enter the text to search for into the search field above the patient list and the patient list automatically displays the search results.

MAESTRO 7.0 provides an advanced patient search. Use this feature to search for specific fields, e.g. list all patients using a certain implant type. Search for a specific entry by typing the label of the required field followed by a colon and the search text.

The advanced search supports the following labels:

Patient	Address and Contact	Ear data	Ear data side specific
name	street	implant	implant-left, implant-right
firstname	city	implantserial	implantserial-left, implantserial-right
middlename	zip	electrode	electrode-left, electrode-right
lastname	state	coilmagnet	coilmagnet-left, coilmagnet-right
title	country	processor	processor-left, processor-right
id	phone	processorserial	processorserial-left, processor-right
birthdate	mobile	coil	coil-left, coil-right
age	fax	processoradddate	processoradddate-left, processoradddate-right
side	email	processorinuse (yes, no)	processorinuse-left, processorinuse-right (yes, no)
gender		processorcomment	processorcomment-left, processorcomment-right
patientcomment		surgicaldate	surgicaldate-left, surgicaldate-right
creator		deafnessdate	deafnessdate-left, deafnessdate-right
creationdate		etiology	etiology-left, etiology-right
session		medicalcomment	medicalcomment-left, medicalcomment-right
sessioncomment		eas (yes, no)	eas-left, eas-right (yes, no)
intraoperative (yes, no)		duet (yes, no)	duet-left, duet-right (yes, no)
postoperative (yes, no)			
comment			
serial			

Example:

Type 'age:30' into the search field to search for 30 year old patients.

Working with MAESTRO

Type 'implant-right:PULSAR' into the search field to search for all patients implanted with a PULSAR on the right side.

Type 'eas:yes' into the search field to search for all EAS patients.

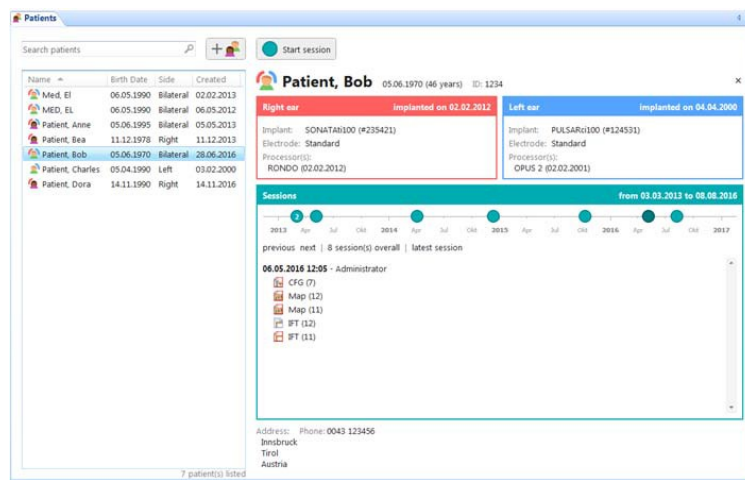
Delete the entered text or click on the close symbol next to the search field to show the complete patient list again.

Database summary

After start-up the user is welcomed and guided on how to proceed. Additionally, a database summary is displayed. This summary contains three small statistics including the number of the day's sessions, the number of patients scheduled for a surgery that day and general information about the database. The general information includes the number of overall patients, the number of bilateral patients and the number of patients implanted in a certain ear. Additionally, the number of EAS patients is displayed. Click on the corresponding text to filter the patient list accordingly.

Patient preview

Click on a patient name in the patient list to display a patient preview on the right side.



Patient preview

Main information: The top includes patient name, birth date and age, patient ID and a button to start a session for this patient. Click on the patient name to edit patient data. Click on the x to close the patient preview.

Ear data: The ear data section displays surgical date, implant type with serial number, electrode, a list of currently used processors and, if applicable, a medical comment. If the

patient is an EAS patient this is stated as well. For bilateral patients a separate table for each ear is displayed.

Click on the label of the boxes to open the patient editor and edit ear data. If the patient is unilateral, a button to add hardware information for this ear is displayed.

Session history: The session history contains a time line with all sessions presented as colored circles and a session summary. The time line gives an overview of all sessions for a patient sorted by date. Use the mouse wheel to zoom in and out and shift the time line by drag and drop with the mouse. Depending on the zoom factor some circles may be too close to each other to be displayed separately. In this case, only one circle is displayed and a number indicates the number of sessions which were combined.

Navigate through the sessions with a click on [previous](#) or [next](#). Quick access links are provided to select all sessions, intraoperative sessions, the latest session or that day's session.

Select one or more sessions with a mouse click to display the summary of these sessions below. By default the summary of the latest session is presented. The summary presents detailed information about the selected sessions, including session date, session comment and user, as well as all saved tasks with comments. Right click onto the session date in the summary to create a session report.

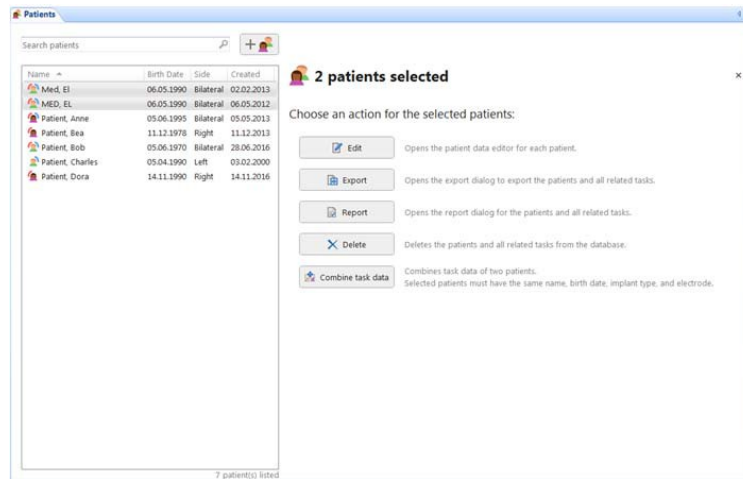
Address and Contact: If entered, address and contact data for the current patient are displayed.

Action summary for multiple patients

Use the CTRL key or SHIFT key to select more than one patient in the patient list. An overview of several possible actions is presented on the right side:

- Edit patients: Opens the patient data editors for the selected patients.
- Export patients: Opens the export dialog with the preselected patients.
- Create report: Opens the report dialog for these patients.
- Delete patients: Deletes patients from the database.
- Merge the patients to one patient: Opens the [Combine task data](#) tool for these patients. This option is only available when certain preconditions are fulfilled, see chapter **Combine Task Data**.

Click on the [x](#) to close the action summary.



Action summary

Tips, Tricks and Troubleshooting

Customize the appearance of the patient list by changing the order of first name and last name or by using uppercase letters for the last name, see chapter **Settings - User Interface**.

5.1.2 Create or edit a patient record

Click on  in the patient list view or navigate to the menu **New - Patient** to create a new patient record.

Select a patient in the patient list and click on the patient name in the preview to edit this specific patient record. Alternatively, right click on the patient name in the list and select **Edit Patient** from the displayed menu.

Enter or edit patient related information - personal information such as name or address as well as information about the implanted system - in the opened patient data editor. The patient data editor is divided into the editors **Personal editor**, **Address and Contact editor**, **Right Ear** and **Left Ear editor**.

Personal editor

The screenshot shows the 'Personal editor' window in the MAESTRO software. The window is titled 'Patients Patient (no name)'. On the right side, there is a sidebar labeled 'Picture' containing two buttons: 'Browse Picture...' and 'Remove Picture'. The main content area is divided into two main sections. The top section is labeled 'Personal' and contains the following fields: 'Title' (text box), 'First Name*' (text box), 'Middle Name' (text box), 'Last Name*' (text box), 'Birth Date*' (calendar icon showing 10.01.2017), 'Gender*' (dropdown menu), 'ID' (text box), and 'Comment' (text area). The bottom section is divided into two columns: 'Right Ear' and 'Left Ear'. Each column contains three fields: 'Implant' (text box), 'Electrode' (text box), and 'Processor(s)' (text box). At the very bottom of the window, there are four tabs: 'Personal', 'Address & Contact', 'Right Ear', and 'Left Ear', with 'Personal' currently selected.

Personal editor

Enter or edit personal information about the patient such as the patient's title, first name, middle name, last name, birth date and gender. Additionally, an ID field to enter a clinic-specific patient ID and a comment field for patient-related comments are available. Click the browse picture button in the sidebar to load a picture of the patient. Click on the remove button to delete the picture from the account.

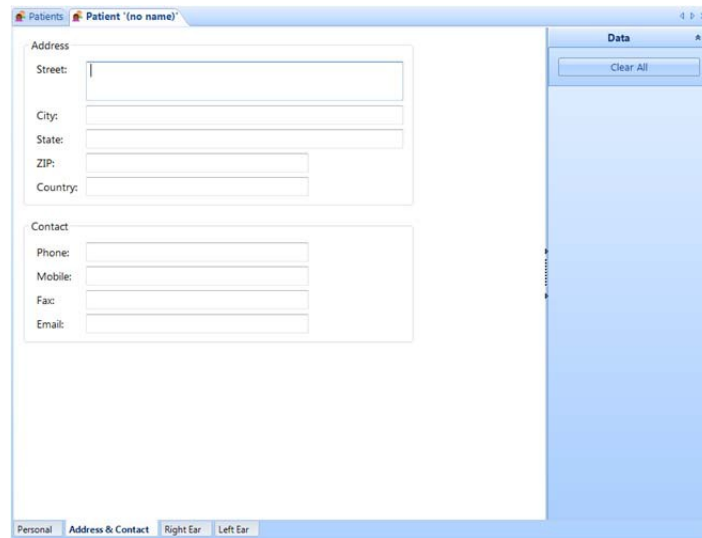
Mandatory fields are marked with an asterisk.

A summary of entered data is displayed at the bottom half.

NOTE:

Personal patient data can be saved without indicating implant system, e.g. to prepare the patient record for intraoperative measurements, but it is not possible to start a session for a patient without entered device information.

Address and Contact editor



The screenshot shows a software window titled "Patients" with a sub-tab "Patient '(no name)'". The window is divided into two main sections. The left section contains two groups of input fields: "Address" and "Contact". The "Address" group includes fields for "Street:", "City:", "State:", "ZIP:", and "Country:". The "Contact" group includes fields for "Phone:", "Mobile:", "Fax:", and "Email:". The right section is a blue sidebar titled "Data" with a "Clear All" button. At the bottom of the window, there is a tab bar with four tabs: "Personal", "Address & Contact" (which is currently selected), "Right Ear", and "Left Ear".

Address & Contact editor

Enter or edit a patient's address information as well as phone number, mobile phone, fax number and e-mail address. Click on the [Clear All](#) button in the sidebar to delete all entries. All fields are optional.

Right Ear and Left Ear editor

Right Ear editor

Enter or edit a patient's device information and medical data for a certain ear. The Right Ear and Left Ear editors are structured the same way and are divided into the two sections [Devices](#) and [Medical](#).

Devices

Select the patient's implant from the drop-down menu. The implant type is necessary to activate all other input fields.

CAUTION:

Please note that the implant type shall always be carefully selected.

Enter the serial number of the implant into the [Serial](#) field.

For implant types with readable serial number do not enter the serial number manually to avoid typing errors. We recommend reading out the serial number with the software.

Implant types with readable serial number	Implant types without readable serial number
SYNCHRONY MED-EL CONCERT SONATA PULSAR	C40+

CAUTION:

Please note that the implant type and serial number shall always be carefully entered or read out with the Read Serial button. Stimulation of implants with readable serial number is only performed if the serial number of the implant matches the serial number stored in the patient data.

Select the patient's electrode type from the drop down menu.

CAUTION:

Ensure accurate selection of the electrode type.

Select the appropriate coil magnet from the drop-down menu.

Select the EAS checkbox to indicate residual hearing in this ear. The enabled checkbox marks this side as EAS side and enables all EAS features provided by MAESTRO. It is not possible to use EAS features for a patient without enabled EAS checkbox. If a SONNET EAS is programmed, the EAS checkbox is enabled automatically.

Click on the  arrow symbol below the number to set the global status of the applicable electrode. Globally deactivate an electrode by selecting one of the various reasons for deactivation from the drop-down menu. If an electrode has been globally deactivated, it is deactivated in all tasks.

The processor table lists all processors assigned to this patient.

Click on the [Add Processor](#) button and enter a processor with serial number, date and comment. Depending on the processor type different additional options are available, such as selection of the remote control. If applicable, also enter the processor coil type. Enable the [DUET 2 battery pack](#) checkbox, if a patient uses a DUET 2 audio processor. Click on [OK](#) and the entry appears in the processor list. Programming a processor or connecting a programmed processor during a session automatically adds the processor to the list. Select a processor in the list and click on [Edit Processor](#) in the sidebar to edit processor data. Click on [Remove Processor](#) to delete the selected processor from the list.

Medical

Enter the surgical date, a date for the onset of deafness or select an aetiology from the drop-down menu and add a comment.

Click on [Clear All](#) in the sidebar to delete entered information.

Mandatory fields are marked with an asterisk after selecting the implant type.

Tips, Tricks and Troubleshooting

Steps to read out the serial number with the software:

1. Connect the corresponding MAX coil to the MAX Programming Interface and attach it to the patient's implant. If the patient has a processor with DL-Coil, connect the patient's processor to the MAX Programming Interface and attach the DL-Coil to the patient's implant.
2. Click on [Read Serial](#) in the sidebar. After reading the serial number it turns grey and can only be edited by clicking on [Edit Serial](#) in the sidebar.

5.2 SESSION

Start a session to work with a certain patient. A session contains all saved tasks for a patient per day and user.

5.2.1 Start a session

Double click on the patient's name in the list or click on the [Start session](#) button in the patient preview to start a session for this patient.

As soon as a programmed audio processor is connected, MAESTRO uploads the data from the processor and asks if a session shall be started. If the patient record does not yet exist in the database, it can be imported to the database.

If a session was started and closed for a patient on the same day, MAESTRO offers the possibility to either continue the session or start a new session. Click on [Continue session](#) to continue the session and all new tasks will be assigned to the already existing session. Choose [Start session](#) to create a new session. In this case new tasks will be assigned to the new session.

A pop-up window appears as a reminder to check the patient's meningitis vaccination status.

NOTE:

It is only possible to work with a patient (e.g., patient fitting) when all mandatory information in the patient data editor has been entered and a session has been started.

When starting or continuing a session, the patient tab disappears and the session view is displayed. The session view guides through the most important steps for intraoperative and postoperative sessions.

Click on the [Close session](#) button in the patient panel to close the session.

Tips, Tricks and Troubleshooting

After closing a session, patient fitting can be continued with a click on [Continue session](#).

5.2.2 Intraoperative Session

Start an intraoperative session by clicking on the [Intraoperative Start session](#) button. Precondition for an intraoperative session is that the patient's surgical date matches the current date.

The intraoperative session view guides through the most important measurements during surgery. All measurements done are marked as intraoperative and can therefore easily be differentiated from postoperative measurements.

The intraoperative session view consists of several panels aligned from top to bottom:

1. the patient panel, see chapter [Patient panel](#)
2. the in-package telemetry panel, see chapter [In-package telemetry panel](#)
3. the telemetry panel, see chapter [Telemetry panel](#)
4. the objective measures panel, see chapter [Objective measures panel](#)

Tips, Tricks and Troubleshooting

Click on the creation date in the related panel to open the measurement task and have a detailed look on the results.

5.2.3 Postoperative Session

The postoperative session view guides through the most important measurements during fitting. It consists of several panels aligned from top to bottom:

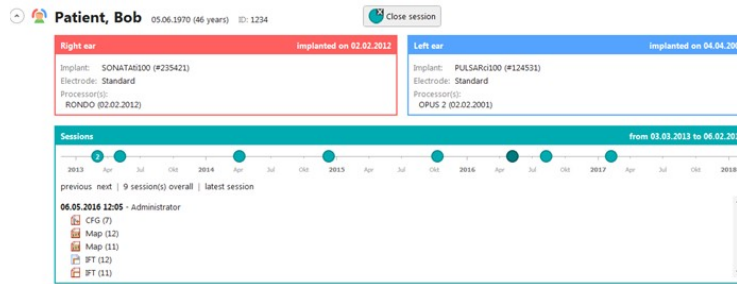
1. the patient panel, see chapter [Patient panel](#)
2. the audiogram panel for EAS patients, see chapter [Audiogram panel](#)
3. the telemetry panel, see chapter [Telemetry panel](#)
4. the configuration panel, see chapter [Configuration panel](#)
5. the acoustic fitting panel for DUET 2 fitting, see chapter [Acoustic Fitting panel](#)

Tips, Tricks and Troubleshooting

Enable the related checkbox in **Settings - Session** to display an audiogram panel in the session view for all patients.

5.2.4 Patient panel

The patient panel provides a summary of the patient. The main information about the patient is displayed in a single line and contains the patient's name, date of birth and age, the patient ID and a button to close the session.



Patient panel

Click on the arrow on the left side to open or close the detailed view.

The detailed view contains further information about ear data, the session history and address data.

Ear data: The ear data section displays surgical date, implant type with serial number, electrode, a list of currently used processors and, if applicable, a medical comment. If the patient is an EAS patient this is stated as well. For bilateral patients a separate table for each ear is displayed.

Session history: The session history contains a time line with all sessions presented as colored circles and a session summary. The time line gives an overview of all sessions for a patient sorted by date. Use the mouse wheel to zoom in and out and shift the time line by drag and drop with the mouse. Depending on the zoom factor some circles may be too close to each other to be displayed separately. In this case, only one circle is displayed and a number indicates the number of sessions which were combined.

Navigate through the sessions with a click on [previous](#) or [next](#). Quick access links are provided to select all sessions, intraoperative sessions, the latest session or that day's session.

Select one or more sessions with a mouse click to display the summary of these sessions below. By default the summary of the latest session is presented. The summary presents detailed information about the selected sessions, including session date, session comment and user, as well as all saved tasks with comments. Right click onto the session date in the summary to create a session report.

Address and Contact: If entered, address and contact data for the current patient are displayed.

Tips, Tricks and Troubleshooting

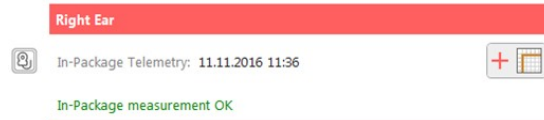
- Click on the patient name to edit the patient data, but be aware that hardware information cannot be edited while a session is ongoing.

- Click on the name of a task within the session summary of the patient panel to open it.

5.2.5 In-package telemetry panel

The In-package telemetry panel is only available in intraoperative sessions.

Click on the button to open the telemetry task and perform an in-package telemetry. After the in-package telemetry measurement was done the creation date and time and the result is displayed.



In-package telemetry panel

Tips, Tricks and Troubleshooting

Click on the creation date to open the in-package telemetry data and have a detailed look on the measurement results.

5.2.6 Objective measures panel

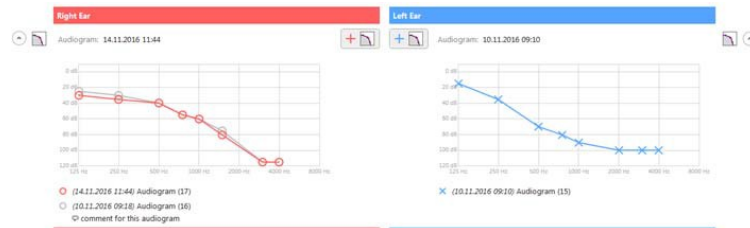
The objective measures panel is only available in intraoperative sessions and offers optionally objective measurement tasks. Click on the related button to open an objective measurement task. After the measurement was done the creation date and time is displayed.

Tips, Tricks and Troubleshooting

- Click on the creation date to open the measurement data and have a detailed look on the measurement results.
- Set which objective measures shall be offered in intraoperative sessions by enabling the related checkbox in the settings dialog, see chapter **Settings - Session**.

5.2.7 Audiogram panel

This panel provides information about the latest audiogram with creation date and a button to create a new audiogram.



Audiogram panel

Click on the arrow on the left side to open or close the detailed view.

The detailed view displays the latest two audiograms: the latest in color and the previous in grey.

The legend gives creation date, name and comment of the displayed audiograms.

Tips, Tricks and Troubleshooting

Click on the creation date to open the audiogram data and have a detailed look.

5.2.8 Telemetry panel

Click on the button to open the telemetry task and perform a new telemetry. After the telemetry measurement was done the creation date and time are displayed and the results for all electrode channels are indicated with icons.



Telemetry panel

Click on the arrow on the left side to open or close the detailed view.

The detailed view displays a graph of that day's telemetry data and also the graph of the previous telemetry for comparison.

The legend gives creation date, name and comment of the displayed telemetry measurements.

Tips, Tricks and Troubleshooting

Click on the creation date to open the telemetry data and have a detailed look on the telemetry measurement results.

5.2.9 Configuration panel

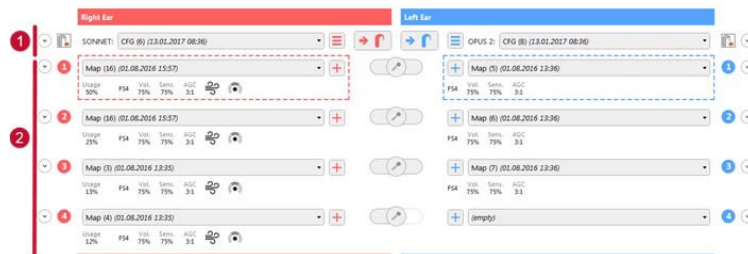
Connect the processor with processor coil to the appropriate MAX Programming Cable (MAX Programming Cable BTE, MAX Programming Cable RONDO, MAX Programming Cable SONNET, MAX Programming Cable RONDO 2).

Connect the MAX Programming Cable to the processor socket of the MAX Programming Interface depending on the hardware settings for dynamic or fixed port mapping.

CAUTION:

Make sure to use the appropriate hardware.

The configuration panel is split into two parts. The first part provides general information about the connected processors and the second part details about the maps stored on the processors.



Configuration panel

1 Processor data

The main information about the processor is displayed in a single line and contains the processor type and the configuration name with date. Click on the drop-down menu to select and load another configuration.

Programming a processor

Changes to the configuration which were not programmed so far are indicated with an * asterisk next to the configuration name in the session view. As soon as there is at least one change, the program processor button is enabled. Click on the button to program the processor. With each programming the related configuration is saved to the database. This creates a history of all configurations programmed into the processor.

NOTE:

Changes made to configurations or maps do not affect the processor unless they are programmed to the processor. After programming the processor the map in program position 1 will be set as default together with its default volume and default sensitivity. Program position 1 must therefore not be empty.

Options

The button next to the configuration name provides the different options:

- [New configuration](#) opens a new and empty configuration in the session view.
- Progressive maps create new maps out of a dedicated fitting map and places them in the other program positions:
 - [Progressive maps 3%](#) and [Progressive maps 6%](#) use the map on position 1 as base map and create progressive maps on the processor positions 2, 3 and 4 according to the mentioned percentage.
 - The option [Individual progressive maps...](#) opens the advanced progressive maps tool where further parameters for progressive maps can be set, see chapter [Software Tools - Progressive maps](#).

Click on the arrow on the left side to open or close the detailed view.

Depending on the type of the connected processors, the detailed view displays a selection of subsections with further information.

ASM

Automatic Sound Management

Click on the [ASM](#) subsection to adjust configuration based parameters for the automatic sound management.

Wind Noise Reduction: Select the option [Mild](#) or [Strong](#) for maps with enabled wind noise reduction. The [Mild](#) option is the default and does not modify the targeted audio signal, whereas, disturbing wind noise is reduced up to a certain extent. The [Strong](#) option reduces disturbing wind noise to a larger extent but may also modify the targeted audio

signal. If wind noise reduction is enabled and no wind is detected, then the microphone signal will not be modified.

Adaptive Microphone Directionality: Adjust the mode for maps with enabled adaptive microphone directionality in the **Mode** field. **Adaptive Microphone Directionality** tries to minimize disturbances originating in the back hemisphere by adjusting the sensitivity adaptively to the location and characteristic of the disturbing sound signals. A second automatic mechanism disables the adaptive directionality if the sound level falls below a defined value, turning the directionality smoothly into an omnidirectional characteristic. Possible values are **always directional**, **directional above 55 dBA** and **directional above 60 dBA**. In **always directional** mode, the adaptive microphone functionality is always enabled independent of the environmental sound level. In **directional above 55 dBA** mode, the processor will smoothly change the microphone directionality mode from adaptive directional to omnidirectional, if the sound level falls below approximately 55 dBA (corresponding to soft speech). In **directional above 60 dBA** mode, the processor will smoothly change the microphone directionality to omnidirectional, if the sound level falls below approximately 60 dBA (corresponding, more or less, to speech in normal loudness). The signal level in omnidirectional mode for **directional above 55 dBA** and **directional above 60 dBA** is further adjusted in such a way that the perceived loudness remains approximately the same in adaptive and omnidirectional mode.

Remote control

Remote control

☒ Volume

☒ Default

☒ Sensitivity

☒ Microphone

☒ MT-Mix

☒ Telecoil

FineTuner commands

Click on the **Remote control** subsection to enable or disable FineTuner commands. Disable a checkbox and the related FineTuner key is deactivated and cannot be used by the patient. FineTuner keys related to program positions with no assigned map are automatically deactivated. For additional information on the function of the individual keys, please refer to the processor user manuals.

DL-Coil

DL-Coil

☒ Automatic Coil Power Off

☒ Link Indicator Lights

DL-Coil

Click on the DL-Coil subsection to enable or disable link monitoring functionality. Precondition is a DL-Coil and an implant with readable serial number. It is essential that the DL-Coil is connected to the processor to be able to program this feature.

Enable the [Automatic Coil Power Off](#) checkbox to activate link monitoring and automatically stop stimulation when the DL-Coil cannot detect the implant any more, e.g. the coil is no longer placed over the implant. This will only stop stimulation and will not turn off the processor automatically. Please note that repositioning the coil over the implant does not restart stimulation automatically. The coil has to be placed over the implant and the processor has to be switched off and on manually to start stimulation again.

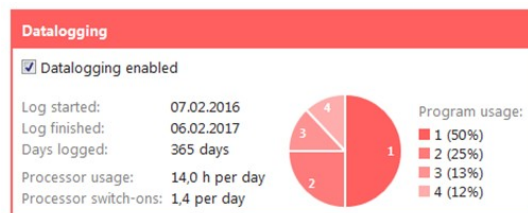
Enable the [Link Indicator Lights](#) checkbox to activate link monitoring and enable the indicator lights functionality. The indicator light of the DL-Coil blinks in a certain pattern when connection to the implant could not be established. This does not only occur when the coil is not placed over the implant but also when the connected processor was not programmed for this implant.

Link monitoring functionality is deactivated if both checkboxes are disabled. The link monitoring functionality cannot be used while the processor is connected to the MAX Programming Interface.

CAUTION:

Only the DL-Coil in combination with an implant with readable serial number is capable of link monitoring functionality.

Datalogging



Datalogging

Click on the [Datalogging](#) subsection to display currently logged data on the connected processor or to enable and disable the datalogging functionality.

Select the [Enable Datalogging](#) checkbox to enable the data logging feature.

A processor with enabled datalogging logs the processor usage data. It displays information about the dates when datalogging started and finished including the number of logged days, the average processor usage per day and the average number of switch-ons per day. A pie chart indicates the usage of the different maps. Move the mouse over the average usage to display a tooltip with total usage time.

Hover with the mouse over one piece of the pie chart and in depth information about volume and sensitivity usage for this map are presented.

Volume Usage Ranges displays a pie chart with three pieces representing the three volume ranges (**Low**, **Mid**, **High**) and their usage. **Mid** is defined as range from default volume -10% to default volume +10%. **Low** starts from the defined minimum FineTuner volume range and **High** ends with the defined maximum FineTuner volume range.

Sensitivity Usage Ranges displays a pie chart with three pieces representing the three sensitivity ranges (**Low**, **Mid**, **High**) and their usage. **Mid** is defined as range from default sensitivity $\pm 10\%$, similar to volume.

CAUTION:

Analysis of datalogging must not be taken as the sole basis for any decision regarding further medical or surgical treatment.

In Training Mode the datalogging subsection is filled with simulated data as soon as the processor is programmed.

Current status

Processor		programmed on 02.05.2017 09:38
Program:	1	
Volume:	75%	
Configuration:	CFG (2)	
	① Map (1)	
	② Map (2)	
	③ Map (3)	
	④ Map (4)	
MAX Socket:	left processor socket	

Processor

Click on the **Current status** subsection to display information about the connected hardware, such as programming date, currently used program with volume and sensitivity, configuration name and associated fitting maps, serial number of the processor and MAX Programming Interface socket.

Click on the configuration or fitting map name to open the associated task.

Depending on the processor type the firmware version is also stated.

If a DL-Coil is connected, the coil name is displayed.

See chapter **Settings - Configuration** for settings of the configuration panel.

Tips, Tricks and Troubleshooting

Depending on the processor types for bilateral patients it is possible to copy the entered information from one side to the other. Click on the arrow icon ➡ in the header of the

box to copy the values to the other side. The two boxes for right and left ear are then combined to one box.

A merged box for bilateral patients indicates that the same values are used for the right ear and left ear. Click on  to split the boxes into two independent ones again.

2 Fitting map data

The different programming slots of the connected processor are displayed as separate sections and indicated by numbers. The currently used fitting map is indicated with a dashed red or blue colored border.

Each section contains the name of the fitting map with creation date and a summary of the fitting map. The summary includes the map usage in percent, the strategy, the default volume and sensitivity and the AGC. It indicates if wind noise reduction is enabled and which microphone directionality is used. It also indicates if the map is an EAS map. It also indicates if triphasic pulses are used.

Click on the arrow on the left side to open or close the detailed view.



Detailed view for fitting map on program position 1

The detailed view displays additional information about the fitting map including frequency range, maplaw and FineTuner volume range. For EAS patients the crossover frequency is also displayed. In addition a preview of the electrodes with MCL and THR is displayed.

Activation of a map

Click on the microphone button to activate the map with default volume and sensitivity. If two processors are connected the button is split into three parts to activate the processor for the right side, for the left side and both processors together. An activated map is indicated by a red or blue shaded background.

Create a new or modify an existing map

Click on the  button next to the map name to open a new fitting map. In addition to a new and empty fitting map MAESTRO, also offers different fitting map templates.

Click on the map name to open and modify the current map.

Click on the drop-down menu to choose another fitting map from the list and assign it to this program position. The drop-down menu lists the latest 10 fitting maps. If a fitting map was created for a different processor type, the type is displayed in brackets to indicate that the map has to be converted. Click on [More](#) to open a dialog which contains a list with all fitting maps. Use the search field on the top of the dialog and a filter section at the bottom to search for the desired map.

When a map is opened from a certain program position, this position is indicated in the fitting task header .

After saving and closing the new or modified fitting map, the map is automatically assigned to this program position.

New or changed fitting maps which were not programmed so far are indicated with an  asterisk next to the map name in the session view. As soon as there is at least one new or changed fitting map, the program processor button is enabled.

Conversion of maps

Fitting maps depend on the processor type. In some cases it may be convenient to convert an already existing fitting map to a fitting map for another processor type. To convert such a map, perform the following steps:

1. Connect a new processor.
2. Click on the drop-down menu in one of the programming positions.
3. Select the map which shall be converted.
4. The fitting map opens.
5. Verify MCLs and THRs.
6. Save the map.

Additional considerations for TEMPO+ and OPUS 1 processors

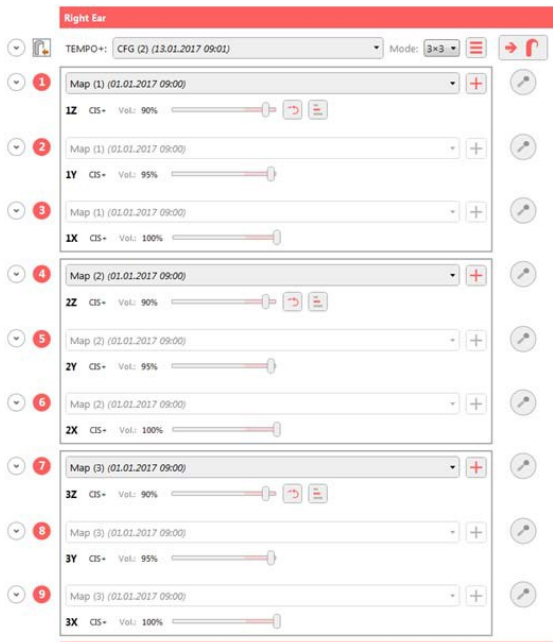
TEMPO+ and OPUS 1 processors provide nine program positions in three modes. After programming the processor the programs can be selected by the patient using the two switches on the processor. Set the desired mode by choosing it from the drop-down menu next to the configuration name.

- [1x9](#) provides 1 map × 9 volumes; The selected map is loaded into all program positions with different volumes.
- [3x3](#) provides 3 maps × 3 volumes; The three maps are loaded into the positions 1, 2 and 3, the three volumes into the positions X, Y and Z. This means that each front switch position selects a different map and the rear switch provides the desired volume settings.
- [9x1](#) provides 9 maps × 1 volume; Nine different maps with the same volume are loaded into each program position.

For the modes [3x3](#) and [1x9](#) volumes can be set between 0 and 100% by using the volume slider. The volume must be entered in ascending order for each group.

Click on  to interpolate the volume of maps in one group between the softest and the loudest setting.

Click on  to set the volume of maps in one group to the default values between 90% and 100%.



Configuration panel for TEMPO+ and OPUS 1 processors

Default settings for the configuration panel

Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

Field	Default
FineTuner keys	activated
Automatic Coil Power Off	enabled
Link Indicator Lights	enabled
Wind Noise Reduction	Mild
Adaptive Microphone Directionality	always directional
Datalogging	enabled
Mode	3x3

Default settings for configuration panel

See chapter **Settings - Configuration** for settings of the configuration panel.

Tips, Tricks and Troubleshooting

- To reset a processor use the [Reset Processor](#) tool from [Tools](#) in the menu bar.
- Copy a map to another program position simply by drag-and-drop.

5.2.10 Acoustic Fitting panel

This panel provides information about the latest acoustic fitting of DUET 2 processor with creation date and a button to create a new acoustic fitting.



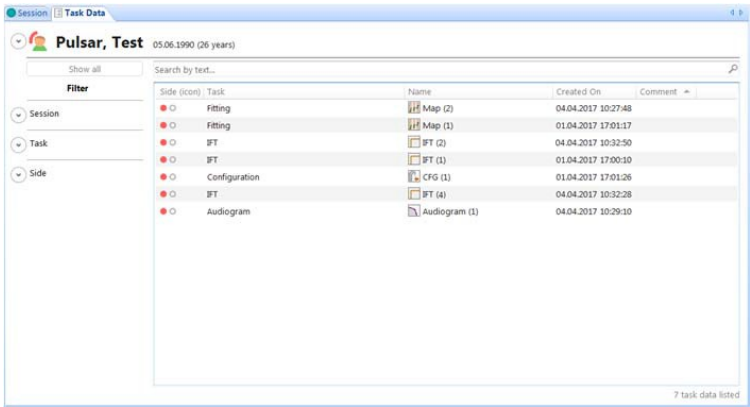
Acoustic Fitting panel

Tips, Tricks and Troubleshooting

Click on the creation date to open the acoustic fitting data and have a detailed look.

5.3 TASK DATA

All tasks for a patient saved to the database are listed in the Task Data view.
The Task Data view consists of a table displaying all task data for this patient and a system of filters to hide or display certain tasks in the table.



Task Data View

Table

The table consists of several columns indicating side, task type, task name, creation date and time, comment and other task-specific fields.

Right click on one of the column names to open a menu to

- display additional columns.
- hide currently displayed columns.
- automatically resize the column to fit its content.
- automatically resize all columns to fit their content.
- group related tasks. If maps or measurements were created by editing an already existing one, these are grouped and the name of the group is the name of the underlying data set.

Change the order of the columns simply by drag and drop.

Click on the name of the corresponding column to sort the entries according to these categories. Double click on an entry in the database to open the task in a new tab. Right click on a task or a selection of tasks to open a menu with the options to rename, open, delete or export the tasks, edit the comment or create a task report.

Search

Enter the text to search for into the search field above the table and the table automatically displays the search results. Delete the entered text, click on the close symbol next to the search field or click on [Show all](#) to show the complete table again.

Filters

On the left side filters for session, task type and side are displayed. Open the detailed view and click on the appropriate filter to hide or display tasks. An applied filter is indicated by a colored box and, if the detailed view is closed, displayed as text.

Click on [Show all](#) to remove previously used filters and show all task data.

Tips, Tricks and Troubleshooting

- Combine filters and the text search for an in-depth search.
- Click on the arrow next to the patient name to display the hardware information for this patient.

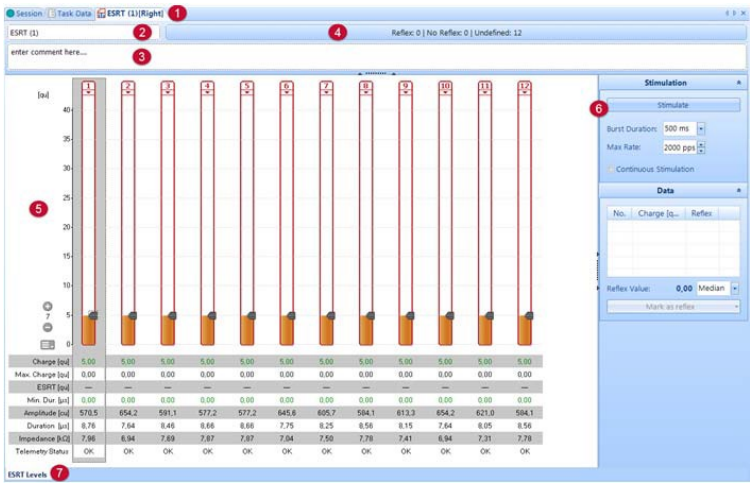
6 MAESTRO Tasks in detail

6.1 MAESTRO TASKS IN DETAIL

This chapter describes the tasks provided by MAESTRO in detail.

-  Audiogram task
-  Telemetry task
-  ESRT task
-  EABR task
-  AutoART task
-  ART task
-  Fitting task
-  Configuration task
-  Acoustic Fitting task

All tasks share the same structure:



Work view of the ESRT task

1 Tab

The tab of the currently used task contains name and, if applicable, hardware needed to perform the task. An asterisk reminds that the task has not yet been saved.

2 Name

Enter or change the name for a specific measurement or map. This name is displayed in the tab and, after saving the entire data set, also displayed in the task data view.

3 Comment

Enter comments for a specific measurement or map. Click on the line with the dots to fold or unfold the comment field.

4 Summary string

Summary string with important information about the task such as entered data and/or used parameters.

5 Work View

The work view of the task contains adjustable parameters and tables with useful information.

6 Sidebar

Depending on the task, the sidebar provides buttons to adjust parameters, start measurements or activate stimulation.

7 Task editors

Depending on the task, different editors provide the option to set parameters.

Tips, Tricks and Troubleshooting

The default parameters used in the tasks may be utilized in the settings dialog, see chapter **Settings**.

6.2 AUDIOGRAM TASK

The Audiogram task allows the user to enter and document patient audiogram data in MAESTRO. A template as used in the hearing aid industry is available to enter auditory curves. In addition, MAESTRO defines the crossover frequency necessary for acoustic fitting using the data points entered in the Audiogram task.

6.2.1 Audiogram hardware

No additional hardware is required for the Audiogram task.

6.2.2 Starting the Audiogram task

The precondition to start the task is an ongoing session for the patient.

Click on **New** in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter **Menu and Toolbar**), a new task can also be opened with a click on the related icon in the tool bar.

Choose the ear to work with for bilateral patients from the pop-up window.

It is also possible to start a new audiogram by clicking on the button in the Audiogram panel of the session view.

Editors

The Audiogram task has one editor: **Audiogram editor**

6.2.3 Audiogram editor

The input template graphically displays acoustic hearing thresholds in a dynamic range of -10 dB HL to 120 dB HL over a frequency range of 125 Hz to 8000 Hz.



Audiogram editor

Enter the curves by a left mouse click in the appropriate section of the template or use the arrow keys and confirm the curve with the Enter key.

The sidebar of the Audiogram task dialog is divided into the sections **Audiogram** and **History**.

Audiogram

Choose different symbols to represent audiometric data. Click on the appropriate button for air conduction (Air), bone conduction (Bone), maximum comfortable loudness level (MCL) or uncomfortable loudness level (UCL) and select the desired symbol. This symbol is then used when entering the auditory curve.

NOTE:
International symbols are used to enter audiometric data. They may be different from local symbols.

Click on the button **Clear Selected** to delete the selected auditory curve. Click on the button **Clear All** to delete all entered auditory curves.
Enable the **Use Audiogram for Fitting** checkbox to use the entered audiogram for acoustic fitting.
Select the **Aided Audiogram** checkbox to state that a hearing aid or cochlear implant was used to measure the audiogram.

NOTE:
Precondition to use an audiogram for acoustic fitting is an enabled **Use Audiogram for Fitting** checkbox and a disabled **Aided Audiogram** checkbox.

Enable the **Display Table** checkbox to display all data entered in the input template as numerical values in a table.

History

Select an already saved audiogram from the drop-down menu and enable the **Display History** checkbox to display the audiogram as grey shaded lines next to the actual hearing curves.

Default settings for the Audiogram editor

Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

Checkbox	Default
Use Audiogram for Fitting	enabled
Aided Audiogram	disabled
Display Table	disabled
Display History	enabled

Default settings for Audiogram editor

See chapter **Settings - Audiogram** for Audiogram settings.

6.3 TELEMETRY TASK

The Telemetry task or IFT (Impedance and Field Telemetry) task enables measurement of voltages at the intracochlear electrodes of the implant during stimulation. A telemetry measurement verifies essential functionalities of implant and electrodes. Additionally it yields important information for audio processor programming. Therefore it is highly recommended to perform a telemetry measurement before every fitting.

CAUTION:

Telemetry measurements also serve to check the integrity of the implant. Please note that decisions regarding further medical or surgical treatment of the patient must not be based exclusively on the results of telemetry measurements. When in doubt regarding the interpretation of telemetry data, please contact your nearest MED-EL representative.

6.3.1 Telemetry hardware

The Telemetry task is available for all implants supported by MAESTRO.

Connect the MAX coil that corresponds to the patient's implant type to the telemetry socket of the MAX Programming Interface and place the coil on the patient's head.

To use the DL-Coil, connect the processor with DL-Coil to the MAX Programming Interface and place the coil on the patient's head, see chapter **Setup - Measurements with DL-Coil**.

CAUTION:

Make sure to use the appropriate hardware to perform the measurement. Make sure that the coil is placed correctly over the implant during the measurement. Data generated with a pulse detector box cannot be saved into the database.

6.3.2 Starting the Telemetry task

The precondition to start the task is an ongoing session for the patient.

Click on **New** in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter **Menu and Toolbar**), a new task can also be opened with a click on the related icon in the tool bar.

Choose the ear to work with for bilateral patients from the pop-up window.

It is also possible to start a new telemetry by clicking on the button in the telemetry panel of the session view.

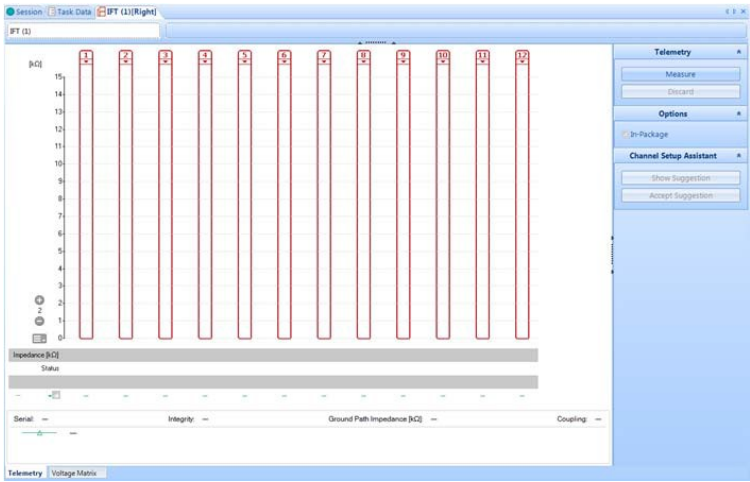
Editors

The Telemetry task provides the following editors:

- Telemetry editor
- Voltage Matrix editor

6.3.3 Telemetry editor

The Telemetry editor displays vertical bars representing the electrodes, the related table and information about additionally determined outcomes.



Telemetry editor

Click on the [Measure](#) button in the sidebar to start a measurement. During measurement the electrodes are stimulated, the applied bi-phasic pulses are qualitatively identical to those used for standard stimulation of the implant. While a stimulation pulse is applied, voltages are measured at the stimulated electrode and at the other electrodes and the electrode impedances are calculated.

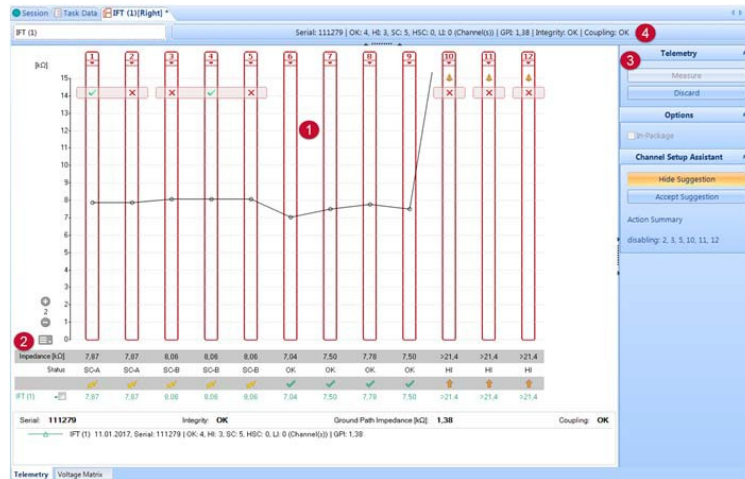
Implant type	Stimulation amplitude in cu	Phase duration in µs
SYNCHRONY	300	24.2
MED-EL CONCERT	300	24.2
SONATA	300	24.2
PULSAR	300	24.2
C40+	230	26.7

Stimulation parameters for telemetry

NOTE:

The stimulation pulses used for telemetry are in most patients' audible range. Globally deactivated electrodes are also stimulated during telemetry measurement.

After the measurement is finished, the results are displayed showing the impedances of the individual intracochlear electrodes, ground path impedance, integrity and coupling status and the implant serial number.



Telemetry measurement

1 Electrodes

The determined impedances of the individual intracochlear electrodes are displayed in the related stimulation bar.

Click on the  arrow symbol below the number to set the global status of the applicable electrode. Globally deactivate an electrode by selecting one of the various reasons for deactivation from the drop-down menu. If an electrode has been globally deactivated, it is deactivated in all tasks.

NOTE:

During telemetry stimulation pulses are also applied to globally deactivated electrodes.

Suggestions of the **Channel Setup Assistant** are also displayed in the graph.

Use the buttons +/- on the left side for scaling the axis.

2 Table

The table lists the numerical impedance values in k Ω and the status of the individual electrodes. For comparing the actual telemetry result against another measurement select the respective IFT from the drop-down menu in the last row of the table. Enable the checkbox next to it to display the impedances graphically. The summary string of the other telemetry is displayed in the legend at the bottom. Click on the name of the measurement or on the option [Open](#) in the drop-down menu to open the currently selected telemetry measurement in a new window. By default the table offers one line to compare against one other IFT.

Serial number, ground path impedance, integrity and coupling are displayed at the bottom.

Display or hide different lines of the related table by clicking on  and selecting the applicable option.

Select the applicable option for a second and third additional telemetry to display additional telemetry measurements in the table or display or hide the graphical status.

3 Sidebar

Click on [Measure](#) to start a measurement. Click on the [Discard](#) button to discard the measurement. To measure an implant inside the transport packaging, enable the [In-Package](#) checkbox in [Options](#) before clicking on [Measure](#). The telemetry measurement is then marked as in-package measurement and is not available for other tasks. The [Channel Setup Assistant](#) supports in deciding which channels to switch off or on according to the results of a measurement.

4 Summary string

The summary string contains information about the measured telemetry including read out serial number and the number of channels with its status. It also displays the ground path impedance, the integrity and the coupling status.

Detailed description:

Impedance:

- Value If a value is displayed without an additional sign, the current flow across the electrode was according to the desired current. The value gives the actual impedance at the electrode with the best possible accuracy.
- >Value If the value is preceded by a > sign, the current flow across the electrode was lower than the desired current. This is caused by a partially or completely saturated current source. The true impedance value is higher than the given value. The given value underestimates the actual impedance.
- If -- is displayed, either the integrity test failed or it indicates faint, weak or poor coupling between coil and implant.

Electrode Status:

- ✓ OK The electrode function is technically correct.

-  HI The measured voltage at the electrode exceeds the measuring range of the system. Electrode impedance is too high to allow effective current flow across the electrode during telemetry measurement.
-  SC-x Current flow across the electrode during measurement was according to the desired current. Electrode function is technically correct but a short circuit with another electrode was detected. Each SC receives the suffix x (a letter A, B, C, D, E or F) to identify individual short circuits and indicate which electrodes are short circuited.
-  LI The measured voltage at the electrode is lower than expected.
-  HSC- The measured voltage at the electrode exceeds the measuring range of the system x and an additional short circuit with another electrode was detected.
-  SC? In rare cases short circuits cannot be determined reliably. In these cases the status
-  HSC? of the affected electrodes is indicated with an additional question mark. It may be useful to look at the voltage matrix editor for additional information that may help diagnose a problem.

Serial number:

For implants with readable serial number the read-out serial number is displayed.

The implant serial number is read out and compared with the serial number stated in the patient data. During this check no stimulation pulses are transmitted. If the read-out serial number and the serial number stated in the patient data are not identical, a warning appears and the entry in the patient data needs to be corrected.

Ground Path Impedance:

The ground path impedance is formed by the bulk tissue impedance, the impedance of the reference electrode, and internal circuitry of the implant. The bulk tissue impedance depends highly on bulk tissue conductivity and current distribution in the extracochlear space. The impedance of the reference electrode is determined by the technical status of the electrode and the tissue properties in the close vicinity of the electrode. Thus, the ground path impedance is a complex function of various physical and technical factors. It is calculated from the voltage distribution. Determination of the ground path impedance relies on a certain minimum number of normally functioning electrodes. Thus, in very rare cases it might happen that the ground path impedance cannot be determined. Like the impedances of the intracochlear electrodes, the ground path impedance can have three different manifestations:

- Value If a value is displayed without any sign, the displayed value gives the actual ground path impedance with the highest possible accuracy.
- >Value If the value is preceded by a > sign, the actual ground path impedance is higher than the given value. The given value indicates the lower limit of the actual ground path impedance.
- If -- is displayed, the integrity test failed or indicates faint, weak or poor coupling between coil and implant.

Integrity:

- OK OK confirms correct function of the implant electronics during telemetry. Performance of the integrity test requires good coupling between coil and implant.
- If -- is displayed, correct function of the implant electronics could not be determined. This can also happen when coupling between coil and implant is faint, weak or poor. The integrity test cannot be performed in these cases and the implant electronics cannot be tested.

NOTE:

If -- is displayed despite good coupling between coil and implant, please contact your nearest MED-EL representative.

Coupling:

- OK MAESTRO has received all implant data necessary to calculate voltages and impedances for all channels. Communication between the implant and coil is correct. This confirms that a large part of the implant electronics functioned correctly during the measurement.
- FAINT MAESTRO received all implant data necessary to identify the implant type but not all data to calculate voltage and impedances. Match of actual implant type and implant type saved in the patient data could be confirmed. However, values for voltages and impedances are not completely available. Communication between the implant and coil functioned only partly correct.
- WEAK MAESTRO received some but not all implant data. Thus, the implant type could not be identified and the implant did not query data to calculate voltages and impedances. Communication between the implant and coil functioned only partly correct.
- POOR MAESTRO did not receive any valid implant data. The implant type could not be identified and the implant did not query data to calculate voltages and impedances. Communication between the implant and coil did not function correctly during the measurement.

NOTE:

Faint, weak or poor coupling may be caused by wrong positioning of the coil above the implant. As a first step, check cable connections between MAX Programming Interface and coil, then slightly adjust the position of the coil and apply soft pressure on the coil to try to improve coupling. If the coupling is faint, weak or poor when performing the measurement using the DL-Coil, disconnect the processor and use the MAX coil instead. If coupling remains faint, weak or poor after several measurement attempts with the MAX coil, please contact your nearest MED-EL representative.

Channel Setup Assistant (CSA)

The Channel Setup Assistant supports in deciding which channels to switch off or on according to the results of a measurement. Click on [Show Suggestion/Hide Suggestion](#) to show or hide the assistant. The suggestions of the CSA are listed under [Action Summary](#) and graphically displayed for each affected channel with short circuit and/or high impedances with the following symbols:

- ✓ indicates that the channel is going to be enabled or that the channel stays enabled.
- ✗ indicates that the channel is going to be disabled or that the channel stays disabled.
- ? indicates that the channel stays disabled. Further investigation (e.g., review of the telemetry history or voltage matrix) might be needed in order to decide about the global state change of the channel.

Affected channels containing multiple short circuits are visually displayed as red rectangles. Click on [Accept Suggestion](#) to accept the suggestions of the CSA and change the global state of the electrodes accordingly. In case of ignoring or hiding the suggestions of the CSA global channel states remain unchanged.

NOTE:

The CSA supports all electrode types supported by MAESTRO except Split electrodes. The Channel Setup Assistant tool is not available in intraoperative session or for In-Package measurements.

Default settings for the Telemetry editor

Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

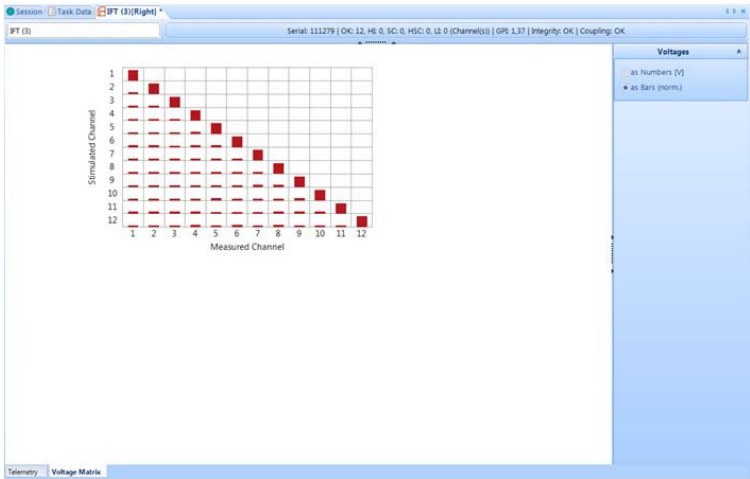
Field	Default
In-Package	disabled
Show Suggestion (CSA)	enabled

Default settings for Telemetry editor

See chapter [Settings - IFT](#) for Telemetry settings.

6.3.4 Voltage Matrix editor

The Voltage Matrix editor displays a matrix with the voltage profile determined during IFT.



Voltage Matrix editor

Switch between displaying numbers or bars by selecting the applicable option in the sidebar. The height of a bar within a row corresponds to the voltage value of the value given in the table in relation to the value in the main diagonal cell. The numbers correspond to the calculated voltages in Volts.

If the integrity test fails or indicates faint, weak, or poor coupling between MAX Programming Interface and implant, no values are entered in the Voltage Matrix editor.

Default settings for the Voltage Matrix editor

Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

Field	Default
Voltages as Numbers	disabled
Voltages as Bars	enabled

Default settings for Voltage Matrix editor

See chapter **Settings - IFT** for Telemetry settings.

Tips, Tricks and Troubleshooting

Identify short circuits from the voltage matrix, if the automatic calculation in the Telemetry editor is ambiguous. Is the value outside the main diagonal clearly increased and close to the value in the main diagonal, a short circuit between the electrode belonging to the subdiagonal and the electrode of the main diagonal is likely.

6.4 ESRT TASK

The ESRT task allows the user to elicit contraction of the stapedius muscle (stapedius reflex) by electrically stimulating the auditory nerve. The measured ESRT thresholds can be entered and saved in MAESTRO.

6.4.1 ESRT hardware

The ESRT task stimulates all implants supported by MAESTRO.

Connect the MAX coil that corresponds to the patient's implant type to the telemetry socket of the MAX Programming Interface and place the coil on the patient's head.

To use the DL-Coil, connect the processor with DL-Coil to the MAX Programming Interface and place the coil on the patient's head, see chapter **Setup - Measurements with DL-Coil**.

CAUTION:

Make sure to use the appropriate hardware to perform the measurement. Make sure that the coil is placed correctly over the implant during the measurement. Data generated with a pulse detector box cannot be saved into the database.

In intraoperative ESRT measurements, the stapedius reflex can be assessed by directly observing the stapedius muscle.

Postoperative measurement requires a tympanometer to record the triggered reflex.

Trigger

The MAX Programming Interface sends a trigger signal with each stimulation burst. The trigger signal is predefined by MAESTRO.

It is positive and has a duration of approximately 115 μ s.

6.4.2 Starting the ESRT task

The precondition to start the task is an ongoing session for the patient.

Click on **New** in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter **Menu and Toolbar**), a new task can also be opened with a click on the related icon in the tool bar.

Choose the ear to work with for bilateral patients from the pop-up window.

Editors

The ESRT task has one editor: **ESRT Levels editor**

6.4.3 ESRT Levels editor

The ESRT Levels editor displays the stimulation bars of the electrodes and the related table. Adjust several stimulation related parameters, display computed values and enter observed behavior of the stapedius muscle to a table in this editor.



ESRT measurement

1 Electrodes

Displays the stimulation bars for the individual electrodes. Set the charge per electrode applied during stimulation in qu by dragging the black arrow with the mouse in the stimulation bar or by directly entering the numerical value in the field Charge [qu] in the table.

The green bar visualizes the highest stimulation realized for this channel. The orange bar displays the difference between the highest realized stimulation and the new desired charge value. The orange bar will turn green when the stimulation is concluded.

Click on the  arrow symbol below the number to set the global status of the applicable electrode. Globally deactivate an electrode by selecting one of the various reasons for deactivation from the drop-down menu. If an electrode has been globally deactivated, it is deactivated in all tasks.

Stimulation is not possible in globally deactivated electrodes.

Use the buttons +/- on the left side for scaling the axis.

2 Table

The table displays the values [Charge \[qu\]](#), [Max. Charge \[qu\]](#), [ESRT \[qu\]](#), [Min. Dur. \[μs\]](#), [Amplitude \[cu\]](#), [Duration \[μs\]](#), [Impedance \[kΩ\]](#), [Telemetry Status](#).

Green values are adjustable, black values are computed by MAESTRO and cannot be adjusted.

[Charge](#) gives the charge value of the selected electrode in qu.

[Max. Charge](#) indicates the maximum value in qu at which stimulation already occurred and is the numerical value of the green area in the stimulation bar.

[ESRT](#) gives the stapedius reflex threshold in qu. It is given in the table as a numerical value after determining at least one positive reflex. In the stimulation bar it is depicted as an orange line and, depending on the selection in the sidebar, corresponds to the median, the mean value or the lowest value of all positively evaluated stapedius reflex thresholds.

[Min. Dur.](#) defines the minimum phase duration of the stimulation pulse at the applicable electrode.

[Amplitude](#) gives the stimulation amplitude in cu.

[Duration](#) gives the actual phase duration in μs.

[Impedance](#) gives the impedance in kΩ determined in the last telemetry measurement which is used for computation of several values of the stimulation.

[Telemetry Status](#) gives the telemetry status of the last telemetry measurement.

Display or hide different lines of the related table by clicking on  and selecting the applicable option.

3 Sidebar - Link check

The link check is available for implants with readable serial number and gives an indication if the link between coil and implant is established or not. If the connection is lost, check cable connections between MAX Programming Interface and coil, then slightly adjust the position of the coil. If the connection cannot be established when using the DL-Coil, disconnect the processor and use the MAX coil instead.

4 Sidebar - Stimulation

Hit the space bar to start the stimulation for the selected channel or click on the [Stimulate](#) button. The stimulation uses the values entered in the fields [Burst Duration](#) and [Max. Rate](#).

[Burst Duration](#) is the value for the duration of the stimulation burst.

[Max. Rate](#) defines the maximum stimulation rate by clicking on the arrow keys or directly entering the numerical value in the input field.

[Continuous Stimulation](#) leads to continuous stimulation at the selected electrodes.

5 Sidebar - Data

The [Data](#) section shows the determined stapedius reflex thresholds for the selected channel in a table.

Mark an amplitude threshold as reflex, as no reflex or as undefined by selecting the applicable option in the drop-down menu. Alternatively right click onto the channel and select the desired option in the menu.

[Reflex Value](#) shows the defined stapedius reflex thresholds as median, mean value or lowest value depending on the selection.

6 Summary string

The summary string gives the number of reflexes, no reflexes and undefined marks.

Detailed description:

Stimulation:

Change the amplitude of a stimulation pulse at an electrode graphically by shifting the black arrow in the stimulation bar with the mouse or numerically by entering the desired amplitude value in the applicable input field in the table below the stimulation bar. In addition, it is possible to control the value via the page up/down keys (+/-15 %), the arrow keys (+/-3 %) or the plus and minus keys (+/-1 %).

Right click on a value and select the option [copy value](#) to apply the value to another channel or to all channels.

The maximum possible stimulation current is based on the data of the last telemetry measurement and states the stimulation current at which the implant reaches its cut-off voltage. If no telemetry data are available, MAESTRO uses the implant-dependent default values. However, the default values are not based on real patient measurements and may result in very restrictive options. It is always good to use the most recent telemetry measures for fitting and other tasks.

If the selected stimulation charge exceeds the predefined safety limit in one or more electrodes, a warning appears which must be confirmed to allow stimulation.

Continuous Stimulation:

MAESTRO also offers the possibility to stimulate continuously and to automatically change the amplitude during stimulation according to a certain pattern. Enable the [Continuous Stimulation](#) checkbox and set [Burst Gap](#), which defines the gap between two stimulation bursts in ms, for a continuous stimulation. Enable the [Automatic value change](#) checkbox to automatically change the charge value according to the following parameters:

[Step Size](#) defines the step size between two stimulation amplitude steps.

[Burst Count](#) gives the number of stimulations per step size.

[Auto Inc Limit](#) indicates the maximum charge of the stimulation amplitude. When reaching the defined value, the stimulation amplitude will no longer increase.

[Direction](#) defines if the stimulation amplitude increases or decreases continuously.

Mark a threshold:

Marked thresholds are graphically indicated in the stimulation bars as horizontal lines (reflex - dashed green line, no reflex - dashed purple line, undefined - dashed grey line) and added to the table in the sidebar. The table corresponds to the highlighted channel and contains the charge of the stimulation pulse in qu and the type of the mark. Delete individual measurement results by selecting and pressing the [Delete](#) key. The [Reflex Value](#) is displayed in the sidebar and graphically indicated in the stimulation bar by an orange line.

Default settings for the ESRT Levels editor

Default settings to be adjusted by the user in the settings dialog are highlighted in [blue](#).

Field	Default
Charge [qu]	0
Min. Dur. [μs]	0
Burst Duration [ms]	500
Max. Rate [pps]	2000
Continuous Stimulation	disabled
Burst Gap [ms]	500
Automatic value change	disabled
Step Size [%]	1
Burst Count	3
Auto Inc. Limit [qu]	15
Direction	Up

Default settings for ESRT Levels editor

See chapter [Settings - ESRT](#) for ESRT settings.

6.5 EABR TASK

The EABR task creates pulse sequences intended to elicit responses of the brainstem by stimulation of the auditory nerve or the corresponding area of the brainstem.

6.5.1 EABR hardware

The EABR task stimulates all implants supported by MAESTRO.

Connect the MAX coil that corresponds to the patient's implant type to the telemetry socket of the MAX Programming Interface and place the coil on the patient's head.

To use the DL-Coil, connect the processor with DL-Coil to the MAX Programming Interface and place the coil on the patient's head, see chapter [Setup - Measurements with DL-Coil](#).

CAUTION:

Make sure to use the appropriate hardware to perform the measurement. Make sure that the coil is placed correctly over the implant during the measurement. Data generated with a pulse detector box cannot be saved into the database.

Due to technical limitations, channels 2, 4, 6 and 8 cannot be stimulated in C4o+ implants within the EABR task.

An additional EEG (electroencephalogram) recording device is necessary as responses cannot be recorded and saved with MAESTRO. For the successful use of the [External artifact reduction](#) option a suitable EEG recording device is required.

Trigger

The MAX Programming Interface sends a trigger signal with each stimulation cycle. The parameters of the trigger signal can be adjusted in the EABR task.

6.5.2 Starting the EABR task

The precondition to start the task is an ongoing session for the patient.

Click on [New](#) in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter [Menu and Toolbar](#)), a new task can also be opened with a click on the related icon in the tool bar.

Choose the ear to work with for bilateral patients from the pop-up window.

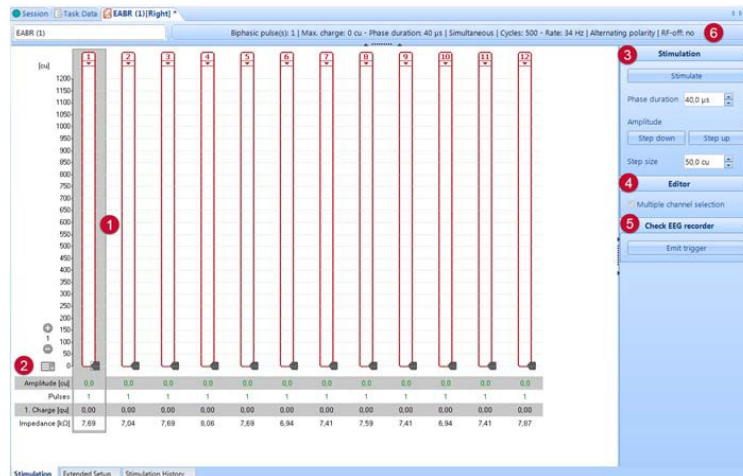
Editors

The EABR task provides the following editors:

- Stimulation editor
- Extended Setup editor
- Stimulation History editor

6.5.3 Stimulation editor

The Stimulation editor displays the stimulation bars of the electrode and the related table. Adjust the most important stimulation parameters in this editor.



Stimulation editor

1 Electrodes

Displays the stimulation bars for the individual electrodes.

Set the amplitude per electrode applied during stimulation in cu by dragging the black arrow with the mouse in the stimulation bar or by directly entering the numerical value in the field **Amplitude [cu]** in the table.

The green bar visualizes the highest stimulation realized for this channel. The orange bar displays the difference between the highest realized stimulation and the new desired charge value. The orange bar will turn green when the stimulation is concluded.

For the external artifact reduction method the maximum amplitude is displayed as dotted horizontal line.

Click on the  arrow symbol below the number to set the global status of the applicable electrode. Globally deactivate an electrode by selecting one of the various reasons for deactivation from the drop-down menu. If an electrode has been globally deactivated, it is deactivated in all tasks.

Stimulation is not possible in globally deactivated electrodes.

Use the buttons +/- on the left side for scaling the axis.

2 Table

The table displays the values: **Amplitude [cu]**, **Pulses**, **1. Charge [qu]**, **Impedance [kΩ]**. For external artifact reduction method, an additional line with **Max. Ampl. [cu]** is displayed.

Green values are adjustable, black values are computed by MAESTRO and cannot be adjusted.

[Amplitude](#) gives the amplitude of the stimulation pulse in cu.

[Pulses](#) gives the number of pulses per cycle.

[Charge](#) gives the computed charge of the stimulation pulse in qu.

[Impedance](#) gives the impedance in $k\Omega$ determined in the last telemetry measurement which is used to compute several values of the stimulation.

[Max. Ampl. \[cu\]](#) gives the maximum amplitude used with external artifact reduction method.

Display or hide different lines of the related table by clicking on  and selecting the applicable option.

Additional options are the charge of individual pulse phases in qu for triphasic pulses and the compliance limit in cu. The compliance limit gives the value of the maximum possible stimulation current and is also indicated graphically by a red marker in the stimulation bar.

3 Sidebar - Stimulation

Hit the space bar to start the stimulation for the selected electrode or click on the [Stimulate](#) button. Set the phase duration which is used for all channels in the [Phase duration](#) field. For biphasic and precision triphasic pulses all pulse phases have the same phase duration. In triphasic pulses the given value is the duration of the second phase, the duration of the first and third phase is half of the second phase.

Adjust the amplitude with a click on the buttons [Step up](#) or [Step down](#) using the value [Step Size](#).

4 Sidebar - Editor

Enable the checkbox [Multiple channel selection](#) and click on several channels to select them. Alternatively press CTRL and click on the channels. The selected channels are highlighted in grey and stimulation will be elicited in all of them.

5 Sidebar - Check EEG recorder

Click on [Emit trigger](#) to only create a trigger signal without any stimulation. The used trigger settings are displayed in the tooltip of the button. Use this option to test the connection with the EEG recording device without the need of being connected to an implant or stimulating the patient.

6 Summary string

The summary string gives an overview of used parameters such as type and number of pulses, maximum charge and phase duration. It also gives the timing of multiple pulses, the number of cycles and rate and type of polarity. Additionally information about the behavior after stimulation and the usage of external artifact reduction method is displayed.

Detailed description:

Amplitude:

Change the amplitude of a stimulation pulse at an electrode graphically by shifting the black arrow in the stimulation bar with the mouse or numerically by entering the desired amplitude value in the applicable input field in the table below the stimulation bar. In addition, it is possible to control the value via the page up/down keys (+/-15 %), the arrow keys (+/-3 %) or the plus and minus keys (+/-1 %).

It is also possible to increase or decrease the stimulation amplitudes of active channels in the sidebar.

Right click on a value and select the option [copy value](#) to apply the value to another channel or to all channels.

The maximum possible stimulation current is based on the data of the last telemetry measurement and states the stimulation current at which the implant reaches its cut-off voltage. If no telemetry data are available, MAESTRO uses the implant-dependent default values. However, the default values are not based on real patient measurements and may result in very restrictive options. It is always good to use the most recent telemetry measures for fitting and other tasks.

If the selected stimulation charge exceeds the predefined safety limit in one or more electrodes, a warning appears which must be confirmed to allow stimulation.

Set the amplitude of the stimulation pulse for each electrode individually. Set the amplitude for first and second phase of precision triphasic pulses individually to the desired values by using the two parts of the black arrow. The amplitude of the third phase is calculated as difference of the amplitudes of first and second phase. To guarantee charge balance in precision triphasic pulses only sequential stimulation with one pulse per cycle and cycle-wise alternating polarity is allowed.

NOTE:

For precision triphasic pulses the amplitude of the second phase must be set higher than the amplitude of the first phase.

Stimulation:

One cycle consists of several pulses stimulated sequentially with short interpulse gaps. The pulses can be applied to one or different electrodes. Therefore the total number of pulses per cycle is the sum of pulses per cycle at all active channels. A cycle is followed by a stimulation gap.

For implants with readable serial number MAESTRO checks the connection to the implant by default before and regularly during stimulation. If the connection is lost, stimulation

stops and the user is informed that the communication link between implant and MAX Programming Interface was interrupted.

Default settings for the Stimulation editor

Default settings to be adjusted by the user in the settings dialog are highlighted in [blue](#).

Field	Default
Step Size (SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR) [cu]	50
Step Size (C40+) [cu]	25
Multiple channel selection	disabled
Number of pulses per cycle	1

Default settings for Stimulation editor

Phase durations in μs and their default settings for the various pulse types and implants:

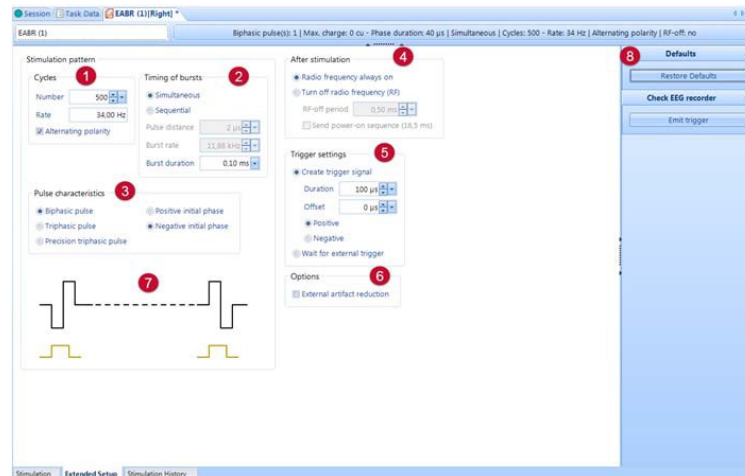
Pulse type	Implant	Default
Biphasic, Precision Triphasic	C40+	53.3
Biphasic, Triphasic, Precision Triphasic	SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR	40
Triphasic	C40+	106.7

Default settings of phase duration

See chapter **Settings - EABR** for EABR settings.

6.5.4 Extended Setup editor

Set further parameters such as stimulation pattern, behavior after stimulation, trigger settings and general options in the Extended Setup editor.



Extended Setup

1 Cycles

Number defines how often an individual cycle is repeated.

Rate defines the repetition rate of the individual cycle thus determining the cycle duration.

Alternating polarity enables an alternating stimulation pattern so that the polarity of all pulses of a cycle is always inverted when a new cycle is applied.

2 Timing of bursts

Simultaneous stimulates all active channels in parallel and only one stimulation pulse can be used per electrode and cycle. In **Sequential** all active channels are stimulated sequentially in the sequence of their electrode number using the following parameters, allowing multiple pulses for each electrode:

Pulse distance sets the temporal distance between two stimulation pulses in µs.

Burst rate defines the rate of pulses within one cycle.

Burst duration sets the burst duration, defined as time from the beginning of the first pulse up to the end of the last pulse. It takes into account other related parameters, such as phase duration, interphase gap, pulse distance, number of pulses and cycle rate.

Availability of parameters in **Timing of bursts** depends on the implant type.

3 Pulse characteristics

The pulse type can either be biphasic, triphasic or precision triphasic. The initial phase of the pulse can be positive or negative.

Triphasic pulses are only FDA approved for EABR measurements and not for chronic stimulation.

4 After stimulation

[After stimulation](#) defines if radio frequency (RF) transmission of the stimulator shall be switched off for a certain time after application of a cycle.

Select the [Turn off radio frequency \(RF\)](#) radio button to switch off the RF transmission of the stimulator after application of a cycle. If the user-selected duration of the RF-off period exceeds the upper limit determined by MAESTRO, the duration of the RF-off period is automatically set to the limit determined by MAESTRO. Select the [Send power-on sequence](#) checkbox to define that a certain power-on sequence is transmitted to the stimulator after reactivating the RF transmission. The duration of the power-on sequence is displayed in brackets and can be set in **Settings - EABR**.

5 Trigger settings

Select to either send a trigger signal or wait for an external trigger signal.

To adjust the trigger signal the MAX Programming Interface sends set the duration in μs , the polarity and a positive or negative offset in relation to the stimulation pattern in μs . A positive offset indicates the stimulation pulse is elicited after the trigger signal.

6 Options

[Options](#) offers the external artifact reduction method which provides an improved artifact reduction in combination with a suitable EEG recording device. After enabling the checkbox some parameters of the Extended Setup editor are set automatically and therefore greyed out. Be aware that this method requires a suitable EEG recording device able to support the external artifact reduction feature.

7 Preview

Temporal alignment of the stimulation pulses (black) and the trigger signal (orange) is displayed in a graph.

8 Sidebar

Click on [Restore Defaults](#) to restore all values to their default settings.

Click on [Emit trigger](#) to only create a trigger signal without any stimulation. The used trigger settings are displayed in the tooltip of the button. Use this option to test the connection with the EEG recording device without the need of being connected to an implant or stimulating the patient.

The rate and number of the trigger signals are given by the entered values in [Number](#) and [Rate](#) in the section [Cycles](#).

Default settings for the Extended Setup editor

Default settings to be adjusted by the user in the settings dialog are highlighted in [blue](#).

Field	Default
Number of cycles	500
Rate [Hz]	34
Alternating polarity	enabled
Timing of bursts	simultaneous (SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR) sequential (other implant types)
Pulse distance [μ s]	2 (SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR) 0 (C40+)
Pulse characteristics	Biphasic pulse
Polarity of the first pulse	negative
Turn off radio frequency (RF)	disabled
RF-off period [ms]	0.5 (if turn-off enabled)
Send power-on sequence (checkbox)	disabled
Power-on sequence duration [ms]	16.5 (if power-on enabled)
Trigger	create trigger signal
Trigger Duration [μ s]	100
Trigger Offset [μ s]	0
Polarity of trigger signal	positive (higher than in non triggered condition)
External artifact stimulation	disabled

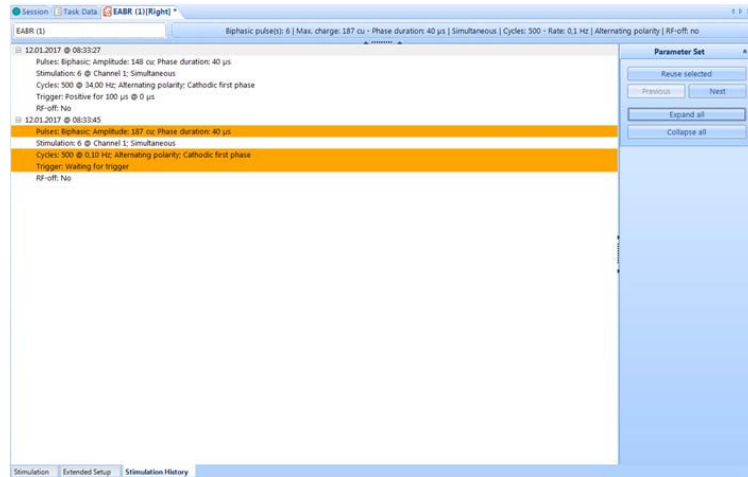
Default settings for Extended Setup editor

See chapter **Settings - EABR** for EABR settings.

6.5.5 Stimulation History editor

The Stimulation History editor lists the basic parameters of the individual stimulations used during measurement.

MAESTRO Tasks in detail



Stimulation History

The applied stimulations are listed with date and time. Unfold the list of used stimulation parameters with a left mouse click on the + sign. Differences between parameters of two subsequent stimulations are colored. Double-click on the date to enter a comment to the applicable stimulation. The comment is displayed next to date and time.

Click on the [Reuse selected](#) button in the sidebar to reuse the parameters of the selected stimulation for another stimulation. The parameters do not need to be entered again then. The buttons [Next](#) and [Previous](#) enable selecting the next or previous entry.

Click on the [Expand all](#) button to expand the tree view of all applied sets of stimulation parameters.

Click on the [Collapse all](#) button to close the tree view.

6.6 AUTOART TASK

The AutoART task allows the user to record the evoked compound action potential (ECAP) of the auditory nerve elicited by stimulating the intracochlear electrodes. The potential is recorded a few microseconds after the end of the stimulation pulse. The compound action potential is recorded by the intracochlear electrodes.

6.6.1 AutoART hardware

Supported implant types for AutoART measurement are:

- SYNCHRONY
- MED-EL CONCERT
- SONATA
- PULSAR

Connect the MAX coil that corresponds to the patient's implant type to the telemetry socket of the MAX Programming Interface and place the coil on the patient's head.

To use the DL-Coil, connect the processor with DL-Coil to the MAX Programming Interface and place the coil on the patient's head, see chapter **Setup - Measurements with DL-Coil**.

CAUTION:

Make sure to use the appropriate hardware to perform the measurement. Make sure that the coil is placed correctly over the implant during the measurement. Data generated with a pulse detector box cannot be saved into the database.

CAUTION:

Ensure that the processor on the contralateral side is turned off before starting the measurement for bilateral patients.

Trigger

The MAX Programming Interface sends a trigger signal with each stimulation burst. The trigger signal is predefined by MAESTRO.

It is positive and has a duration of approximately 50 μ s.

6.6.2 Starting the AutoART task

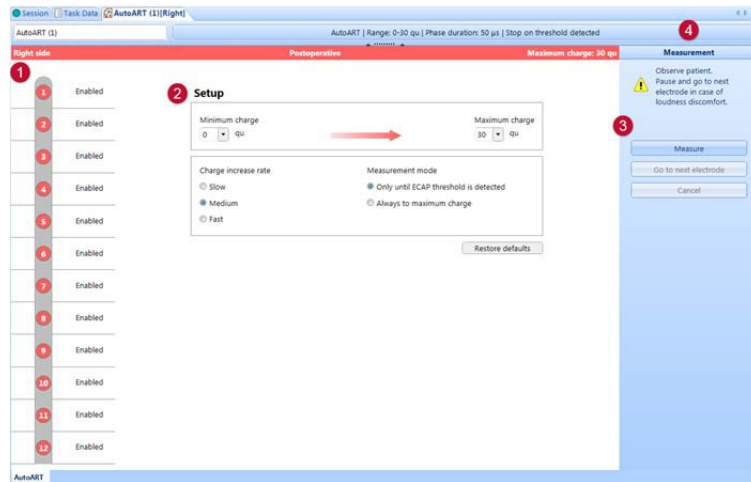
The precondition to start the task is an ongoing session for the patient.

Additionally AutoART is only available for patients with one of the supported implant types.

Click on [New](#) in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter **Menu and Toolbar**), a new task can also be opened with a click on the related icon in the tool bar.

Choose the ear to work with for bilateral patients from the pop-up window.

6.6.3 AutoART setup



AutoART setup

1 Electrodes

The electrode array on the left side displays all electrode contacts. Enabled electrodes are indicated by color and stimulated during the measurement. Click on an electrode to change the status, e.g. from **enabled** to **skipped**. Skipped electrodes are indicated by a grey color and not stimulated. Globally disabled electrodes are indicated by a grey color and cannot be enabled.

Stimulation is not possible in globally deactivated electrodes.

2 Setup

Enter a minimum and maximum charge for the AutoART measurement in qu. The measurement starts to stimulate at the minimum charge and is increased according to the **Charge increase rate**. Select in **Measurement mode** if the measurement is stopped when an ECAP threshold is detected or when the entered maximum charge is reached.

In intraoperative sessions AutoART performs an initial pre-check for ECAP presence at maximum charge before the standard AutoART measurement is started. Disable the checkbox **Initial pre-check** to not perform the pre-check.

3 Sidebar

Hit the space bar or click on **Measure** to start the measurement.

4 Summary string

The summary string contains information about the range, the phase duration and the measurement mode.

Default settings for the AutoART setup

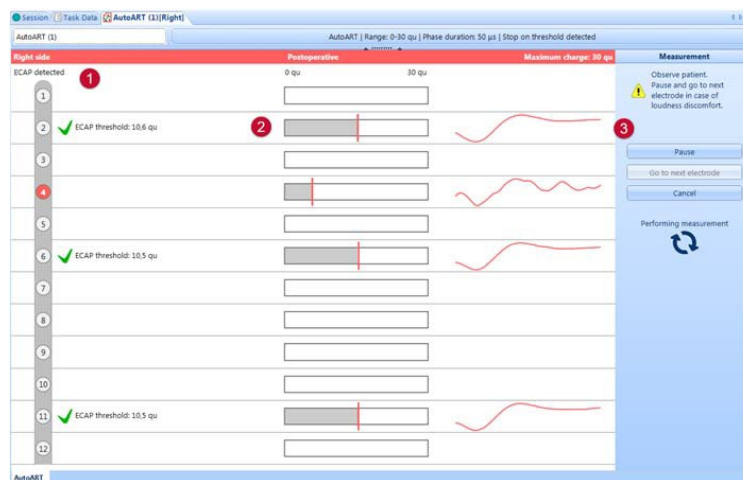
Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

Field	Default
Maximum charge [qu]	30 (postoperative) 35 (intraoperative)
Minimum charge [qu]	0
Charge increase rate	Medium (postoperative) High (intraoperative)
Measurement mode	until ECAP is detected (postoperative) always to maximum charge (intraoperative)
Initial pre-check	enabled (intraoperative)

Default settings for the postoperative AutoART setup editor

See chapter **Settings - AutoART** for AutoART settings.

6.6.4 AutoART measurement



AutoART measurement

1 Electrode

The electrode displays the state of the channel. Skipped or globally disabled channels are indicated by a grey color and are not stimulated. The currently measured channel is highlighted in color. Channels where ECAP threshold is detected show a green check mark and the threshold level. Channels where no ECAP threshold could be determined display a grey x.

2 Diagram

The diagram displays a red line indicating the current stimulation level. The horizontal bar gives the charge range for the stimulation entered during setup. Next to the bar the corresponding signal is displayed.

3 Sidebar

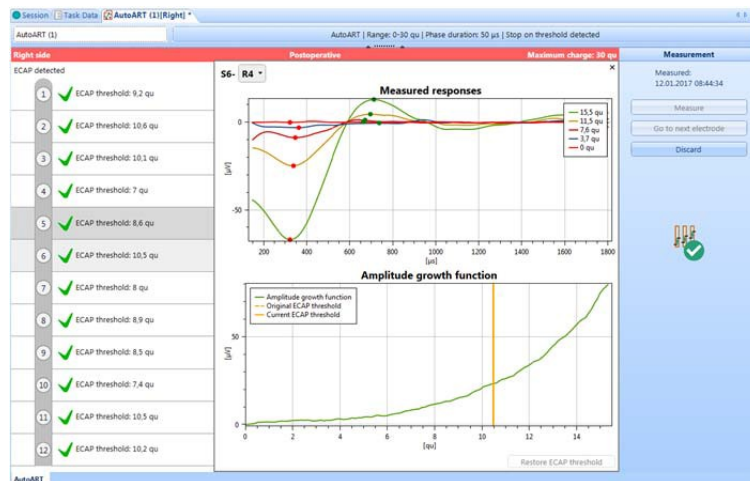
Click on [Pause](#) to pause the measurement. Click on [Resume](#) to resume a measurement that was paused. When in pause the currently measured channel can be skipped by a click on [Go to next electrode](#). The measurement then continues with the next electrode channel. An icon indicates if enough thresholds were detected to use the measurement as basis for fitting.

Click on [Cancel](#) to cancel the measurement.

NOTE:

Observe the patient during the measurement. Pause and go to next electrode in case of loudness discomfort.

6.6.5 AutoART results



AutoART detailed results

After the measurement finished all channels with their state and ECAP thresholds are displayed.

Click on one channel to open a detailed view. The detailed view contains two diagrams, a diagram showing a selection of measured responses and the amplitude growth function. Switch between the results of different recording electrodes by selecting the desired entry in the drop-down menu on top, the diagrams are then updated accordingly.

The amplitude growth function diagram displays the detected threshold as vertical line which can be shifted by drag-and-drop. The computed threshold is indicated as dashed line, a manually adjusted threshold as solid line. In case the threshold is adjusted manually an asterisk is displayed next to the value. Click on [Restore ECAP threshold](#) to discard manual adjustments and restore the originally computed threshold.

Click on **x** to close the detailed view.

Click on [Discard](#) in the sidebar to discard the measurement.

Tips, Tricks and Troubleshooting

- The number of displayed measurements in the first diagram can be adjusted in the settings dialog, see chapter **Settings - AutoART**.
- It is possible to restrict the displayed measured responses to a certain range. Define the desired range by drawing a rectangle with pressed mouse key in the AGF diagram. The selected range is highlighted as shaded area and the measured responses diagram

shows responses within this range. Left-click into the AGF diagram to show the measured responses for the overall range again.

6.7 ART TASK

The ART (Auditory nerve Response Telemetry) task allows the user to record the evoked compound action potential (ECAP) of the auditory nerve elicited by stimulating the intracochlear electrodes. The potential is recorded a few microseconds after the end of the stimulation pulse. The compound action potential is recorded by the intracochlear electrodes.

6.7.1 ART hardware

Supported implant types for ART measurement are:

- SYNCHRONY
- MED-EL CONCERT
- SONATA
- PULSAR

Connect the MAX coil that corresponds to the patient's implant type to the telemetry socket of the MAX Programming Interface and place the coil on the patient's head.

To use the DL-Coil, connect the processor with DL-Coil to the MAX Programming Interface and place the coil on the patient's head, see chapter **Setup - Measurements with DL-Coil**.

CAUTION:

Make sure to use the appropriate hardware to perform the measurement. Make sure that the coil is placed correctly over the implant during the measurement. Data generated with a pulse detector box cannot be saved into the database.

CAUTION:

Ensure that the processor on the contralateral side is turned off before starting the measurement for bilateral patients.

Auditory stimulation for the advanced setup is assumed to take place using an additional external device, while the electric stimulation is provided by the implant.

Trigger

The MAX Programming Interface sends a trigger signal with each stimulation burst. The trigger signal is predefined by MAESTRO.

It is positive and has a duration of approximately 13 μ s.

For the advanced setup the ART tasks provides a user defined trigger signal to synchronize the external auditory stimulation device.

6.7.2 Starting the ART task

The precondition to start the task is an ongoing session for the patient.

Additionally ART is only available for patients with one of the supported implant types.

Click on [New](#) in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter **Menu and Toolbar**), a new task can also be opened with a click on the related icon in the tool bar.

Choose the ear to work with for bilateral patients from the pop-up window.

Templates

When opening a new task a pop-up window is displayed. The pop-up window lists several options and templates for this task. Click on the desired option to continue:

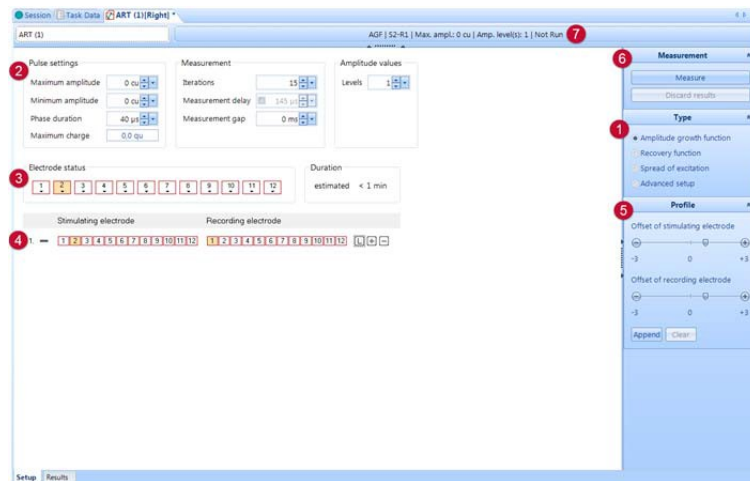
- Perform an individual new ART
- Perform a new ART on all channels
- Perform a new ART on channels with an even channel number
- Perform a new ART on channels with an odd channel number

Editors

The ART task provides the following editors:

- **Setup editor**
- **Results editor**

6.7.3 Setup editor



ART Setup editor

1 Sidebar - Type

Choose between different measurement types.

The Amplitude growth function (AGF) records the ECAP as a function of amplitude (stimulation current).

The Recovery function (RF) stimulates with two consecutive pulses (masker and probe pulse) and records the ECAP as a function of the inter-pulse-interval of both stimulation pulses.

The Spread of excitation (SoE) stimulates with a masker and a probe pulse on different channels and records the ECAP amplitude as a function of the channel distance between both stimulation pulses.

The Advanced setup records electrically evoked action potentials as well as acoustically evoked action potentials with configurable recording window length by performing a number of stimulate-record sequences.

2 Parameters

Provides fields to adjust the measuring parameters depending on the type of measurement, see [Measurement parameters of Amplitude Growth Function](#), [Measurement parameters of Recovery Function](#), [Measurement parameters of Spread of Excitation](#), [Measurement parameters of Advanced setup](#)

3 Electrode status and estimated duration

[Electrode Status](#) displays the electrode status.

Click on the  arrow symbol below the number to set the global status of the applicable electrode. Globally deactivate an electrode by selecting one of the various reasons for deactivation from the drop-down menu. If an electrode has been globally deactivated, it is deactivated in all tasks.

Additionally, electrodes selected to be stimulated are highlighted in orange.

[Estimated duration](#) gives the estimated duration of the ART measurement depending on the entered parameters.

4 Stimulating and Recording electrodes

Displays the stimulating electrode and recording electrode channels including the status of each measurement. Add or delete single measurement pairs from the profile by clicking on the **+** or **-** button. When adding a measurement pair, the stimulating electrode and recording electrode are adjusted according to the settings in the sidebar under [Profile](#).

Click on the **L** button to open the Loudness Comfort Tool dialog.

For the Advanced setup only one stimulating and recording electrode pair may be chosen and the Loudness Comfort Tool is not available.

5 Sidebar - Profile

The offset sliders indicate the electrode number offset when adding a new stimulating and recording pair. Click on the buttons [Append](#) to add additional pairs to the profile and on [Clear](#) to delete all added pairs from the profile.

6 Sidebar - Measurement

Set all parameters and click on the [Measure](#) button to start the measurement. Click on the [Discard results](#) button to delete already measured results. The Advanced setup allows the user to perform several different measurements sequentially and display them all together in the same results editor.

7 Summary string

The summary string contains information about the type of measurement, stimulating and recording electrode and amplitude. It also displays measurement type specific parameters such as number of amplitude levels and intervals. Additionally it displays the state of the measurement.

Detailed description:

Measurement parameters of Amplitude Growth Function:

[Maximum amplitude](#) sets the highest stimulation amplitude applied in every batch.

[Minimum amplitude](#) sets the lowest stimulation amplitude applied. Independent of the minimum amplitude settings MAESTRO always performs a measurement with o c u amplitude which is then automatically subtracted from all other measurements.

[Phase duration](#) indicates the phase duration of each stimulation pulse in μs .

Maximum charge displays the maximum stimulation charge used for measurement. This charge is derived from the settings of maximum amplitude and phase duration.

Iterations indicate the number of repetitions per pulse setting. By averaging, a single compound action potential curve is obtained which represents the result for the applicable pulse setting. Increasing the number of iterations improves the signal-noise ratio, but also prolongs the duration of the measurement.

Measurement delay indicates the time in μs between onset of the stimulation pulse and start of the recording window. The parameter is adjusted by MAESTRO automatically (checkbox unchecked). Enable the checkbox to set the delay manually.

Measurement gap defines the minimum time in ms between the end of one recording cycle and the beginning of the next stimulation.

Levels defines the number of equidistant amplitude levels used for stimulation. The individual amplitude levels have the same distance between the values for minimum amplitude and maximum amplitude and include these values.

Measurement parameters of Recovery Function:

Masker amplitude indicates the amplitude of the first stimulation pulse in cu.

Probe amplitude is given as a portion relative to the masker amplitude in %.

Phase duration indicates the phase duration of each stimulation pulse in μs .

Maximum charge displays the maximum stimulation charge used for measurement. This charge is derived from the settings of maximum amplitude and phase duration.

Iterations indicate the number of repetitions per pulse setting. By averaging, a single compound action potential curve is obtained which represents the result for the applicable pulse setting. Increasing the number of iterations improves the signal-noise ratio, but also prolongs the duration of the measurement.

Measurement delay indicates the time in μs between onset of the stimulation pulse and start of the recording window. The parameter is adjusted by MAESTRO automatically (checkbox unchecked). Enable the checkbox to set the delay manually.

Measurement gap defines the minimum time in ms between the end of one recording cycle and the beginning of the next stimulation.

Interpulse intervals defines the desired intervals in μs between onset of the masker and onset of the probe.

Measurement parameters of Spread of Excitation:

Masker amplitude indicates the amplitude of the first stimulation pulse in cu.

Probe amplitude is given as a portion relative to the masker amplitude in %.

Phase duration indicates the phase duration of each stimulation pulse in μs .

Maximum charge displays the maximum stimulation charge used for measurement. This charge is derived from the settings of maximum amplitude and phase duration.

Iterations indicate the number of repetitions per pulse setting. By averaging, a single compound action potential curve is obtained which represents the result for the applicable pulse setting. Increasing the number of iterations improves the signal-noise ratio, but also prolongs the duration of the measurement.

Measurement delay indicates the time in μs between onset of the stimulation pulse and start of the recording window. The parameter is adjusted by MAESTRO automatically (checkbox unchecked). Enable the checkbox to set the delay manually.

Measurement gap defines the minimum time in ms between the end of one recording cycle and the beginning of the next stimulation.

Masker positions define if the masker moves from the probe towards the base, the apex or in both directions, including the number of masker positions. It includes an option to skip every other masker pulse to speed up the measurement at the cost of a lower resolution of the objective function.

The resulting masker electrodes are graphically indicated in the electrode selection control by an orange color and the underlined channel number. Disabled electrodes are not used as masker electrodes and will be skipped.

Measurement parameters of Advanced setup:

Amplitude indicates the amplitude of the stimulation pulse in cu.

Maximum amplitude indicates the maximum amplitude applied in cu.

Phase duration indicates the phase duration of each stimulation pulse in μs .

Maximum charge displays the maximum stimulation charge used for measurement. This charge is derived from the settings of maximum amplitude and phase duration.

Iterations indicate the number of repetitions per pulse setting. By averaging, a single compound action potential curve is obtained which represents the result for the applicable pulse setting. Increasing the number of iterations improves the signal-noise ratio, but also prolongs the duration of the measurement.

Measurement delay indicates the delay of the measurement window in ms. The measurement delay must be longer than the total duration of the pulse.

Measurement window indicates the length of the measurement window in ms.

Trigger delay indicates the delay between the onset of the stimulation pulse and the trigger signal in ms. A negative value indicates that the trigger is emitted before the stimulation pulse.

External stimulus indicates the time for any external (acoustic) stimulus to complete after being triggered by the MAX Programming Interface trigger out signal.

Stimulation in the ART task:

The implant serial number is read out and compared with the serial number stated in the patient data. During this check no stimulation pulses are transmitted. If the read-out serial number and the serial number stated in the patient data are not identical, a warning appears and the entry in the patient data needs to be corrected.

The maximum possible stimulation current is based on the data of the last telemetry measurement and states the stimulation current at which the implant reaches its cut-off voltage. If no telemetry data are available, MAESTRO uses the implant-dependent default values. However, the default values are not based on real patient measurements and may result in very restrictive options. It is always good to use the most recent telemetry measures for fitting and other tasks.

If the selected stimulation charge exceeds the predefined safety limit in one or more electrodes, a warning appears which must be confirmed to allow stimulation.

NOTE:

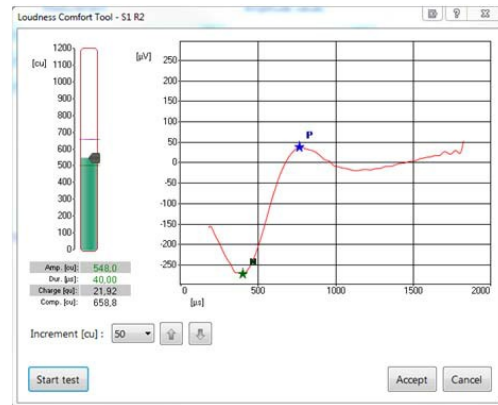
Stimulation and recording of compound action potentials of the auditory nerve are also possible with globally deactivated electrodes. If no identifiable compound action potential can be recorded, but the compliance limit is reached, carefully increase the phase duration instead of the amplitude to achieve higher charge.

Next to the single recordings the status of each measurement is graphically indicated:

-  indicates that the measurement has not yet been run,
-  indicates that the measurement was successfully completed,
-  indicates that the user skipped one or more objective function parameters (e.g., by clicking on the [Next batch](#) button during measurement),
-  indicates that the measurement was not performed with every iteration,
-  indicates that the measurement was cancelled by the user,
-  indicates that an error occurred during measurement and the measurement could not be continued (e.g., disconnected MAX Programming Interface).

Loudness Comfort Tool:

Use the Loudness Comfort Tool to estimate an upper limit of the stimulation whose charge elicits a compound action potential but does not cause uncomfortably loud hearing sensations. Open the Loudness Comfort Tool with a click on the [L](#) next to the display of stimulating and recording electrode.



Loudness Comfort Tool

The title of the dialog includes the stimulating electrode and the recording electrode, e.g. the labeling S2 R1 indicates stimulation on electrode 2 and recording on electrode 1. The stimulation bar displays the compliance limit as a purple line, the previously selected maximum amplitude as a green horizontal line.

The green bar visualizes the highest stimulation realized for this channel. The orange bar displays the difference between the highest realized stimulation and the new desired charge value. The orange bar will turn green when the stimulation is concluded.

Set the amplitude of the stimulation pulse by dragging the black arrow, increase or decrease it by entering the desired increment in **Increment [cu]** and clicking on the arrow symbols, or type it into the table in the **Amp. [uV]** field.

Besides the amplitude of the stimulation pulse, the table below the stimulation bar also shows the pulse phase duration in **Dur. [us]**, the charge in **Charge [qu]** and the compliance limit in **Comp. [uV]**.

Green values are adjustable, black values are computed by MAESTRO and cannot be adjusted.

Change parameters by entering the desired value in the applicable input field in the table below the stimulation bar or control the value via page up/down keys (+/-15 %), arrow keys (+/-3 %) or plus and minus keys (+/-1 %).

Click on **Start test** or press the space bar to start the measurement. Abort an ongoing measurement at any time by clicking on **Stop test** or pressing the space bar. For the Amplitude growth function, stimulation takes place with maximum amplitude according to the parameter set. For the Recovery function, two pulses with the smallest interval set in the parameters section are applied. The amplitude of the first pulse corresponds with the

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masker amplitude, the amplitude of the second pulse is the test pulse amplitude. The Spread of excitation is similar to the Recovery function but with constant masker-probe interval and change of masker electrode.

After successful measurement the result is displayed in the diagram. Click on [Accept](#) to transfer the used stimulation amplitude into the field with the maximum amplitude. Click on the [Discard](#) button to close the Loudness Comfort Tool without transferring the stimulation amplitude.

NOTE:

If the stimulation amplitude used for the Loudness Comfort Tool is applied, this value applies to all electrodes.

If no identifiable compound action potential can be recorded at the compliance limit, carefully increase the phase duration instead of the amplitude to ensure that the implant operates within the limits of compliance.

Default settings for the Setup editor

Default settings to be adjusted by the user in the settings dialog are highlighted in [blue](#).

Field	Default
Maximum amplitude [cu]	0
Minimum amplitude [cu]	0
Masker amplitude [cu]	0
Amplitude (Advanced setup)	0
Probe amplitude [%]	95
Phase duration [µs]	40
Iterations	15
Iterations (Advanced setup)	300
Measurement gap [ms]	0
Measurement delay [ms] (Advanced setup)	0.15
Measurement window[ms] (Advanced setup)	1.7
Levels (AGF)	10
Interpulse intervals [µs] (RF)	400, 500, 750, 1000, 1500, 2000, 3000, 6000
Towards base (SoE)	6
Towards apex (SoE)	6
Skip every second (SoE)	disabled
External stimulus duration [ms] (Advanced setup)	0
Trigger delay [ms] (Advanced setup)	0
ART measurement type	Amplitude growth function
Offset of stimulating electrode	+1
Offset of recording electrode	+1

Default settings for Setup editor

See chapter **Settings - ART** for ART settings.

6.7.4 Results editor

While an ART measurement is ongoing a progress dialog shows the currently performed single measurement. Click on the related buttons to pause (**Pause**) or resume (**Resume**) a measurement, to skip the remaining objective function parameters and advance to the next measurements (**Next batch**) or to abort the measurement and stop all stimulation and recording activities (**Cancel**). In the case a measurement is aborted only the so far obtained results are displayed.

If communication between implant and coil is interrupted during measurement check the placement of the coil. Resume measurement after re-establishing communication.

The Results editor displays the results of the measurements of the Amplitude growth function, the Recovery function, the Spread of excitation and the Advanced setup measurement.



Results editor

1 Main diagram

The measured signals are displayed as a waterfall plot. For AGF, RF and SoE measurements, MAESTRO displays the point of the first minimum (N) and the point of the first maximum (P).

2 Measurement pairs

The electrode pairs for measurements are listed on the left side. Click on the desired pair to display the measurement in detail in the main diagram. For the AGF measurements, ART thresholds in cu for each stimulating electrode are displayed, in addition, in the bottom plot.

3 Function diagram

This section shows different diagrams depending on the selected measurement type.

For AGF it displays the ECAP amplitude in μV over the stimulation amplitude levels in cu. If an ART threshold was extrapolated, the corresponding cu value is marked on the x-axis. Manually adjust the interpolation line by shifting the markers.

For RF it displays the ECAP amplitude in μV over the intervals between stimulation pulses in μs .

For SoE it displays the ECAP amplitude in μV over the position of the masker electrodes and therefore assesses the interactions between the excitation areas produced by each electrode.

With a right mouse click the interpolation of the curve may be adjusted. The default is linear interpolation. In addition, spline interpolation is available.

4 Sidebar

The sidebar gives date and time of the measurement and provides options to change the appearance of the results.

Click on the arrow keys or directly enter a value in the field [Offset](#) to change the offset used for the individual result curves. Disable this checkbox to display the result curves without offset and to read out the measured voltage ranges of a neural response. [Show legend](#) hides/shows the legend in the result curves diagram. [Tie markers](#) defines whether or not the N and P points can be moved only along the result curve or freely. Enable [Vertical layout](#) to change the layout of the result curves and objective function diagrams from horizontal to vertical.

The sidebar also offers the possibility to edit and process the results for the AGF, RF and SoE, see [Edit and process the results](#).

Detailed description:

Edit and process the results:

After an ART measurement was performed, the user can post-process the outcome of Amplitude growth function, Recovery function and Spread of excitation. Saved ART data that use the same underlying ART measurement and differ only by the done post-processing are automatically grouped. Switch between different ART analyses within a group by clicking on the [View a different analysis](#) button.

Data: Use the drop-down menu to display the measured responses of the stimulation pulses starting with a positive (Anodic/Cathodic) or a negative phase (Cathodic/Anodic) or

the responses averaged from these two sets of responses (Alternate Polarity). Undo changes made to the initial results by resetting or changing the polarity.

Processing: Zero amp. template subtracts the automatically performed zero measurement from all other curves and is done per default. Click on the **Rectify** button to remove a linear drift artifact. In this case a straight line is adapted to and subtracted from each result curve in the range between 655 and 1402 μs so that each result curve ends with a 0 cu amplitude. Click on **Show all min./max.** to show the N and P markers for all curves. A brief text information indicates whether an arbitrary template or a scaled template has been applied and at what amplitude level.

Mouse edit mode: Enlarge individual sections of the result curves diagram by clicking on **Zoom** and opening a rectangle with the mouse. Click **Drag** to move the zoomed area. Click the right or center mouse key to display the complete diagram.

Click **Select** to edit individual result curves: Move the N and P points along the corresponding result curve by dragging the mouse while pressing the left mouse key. Hide the N and P points by right-clicking on the result curve and selecting the **Hide Minimum/Maximum** option from the context menu, select **Show Minimum/Maximum** to display the points again. Select **Reset Minimum/Maximum** to undo shifting the N and P points. Select **Hide Measurement** to hide the display of the corresponding result curve.

For AGF, the additional options of **Subtract Arbitrary Template** and **Subtract Scaled Template** are available. Choose a result curve (preferably with a strong artifact but with a sub-threshold stimulation amplitude so that it contains no ECAP) to apply additional artifact reduction. By choosing **Subtract Arbitrary Template**, the selected curve will be subtracted from all curves (including the selected one), similar to the Zero amp. template. By choosing **Subtract Scaled Template**, the scaled artifact reduction will take place on all curves. For each curve, the selected curve will be first scaled to the respective amplitude and then subtracted from the corresponding result curve.

Default settings for the Results editor

Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

Field	Default
Select or reset	Alternate polarity
Zero amp. template	enabled
Rectify	disabled
Show all min./max.	disabled
Offset [μV]	enabled – 200
Show legend	enabled
Tie markers	enabled
Vertical layout	disabled

Default settings for Results editor

See chapter **Settings – ART** for ART settings.

6.8 FITTING TASK

The Fitting task allows the user to perform processor fitting. Various strategy and processor parameters are available to optimize a map according to the patient's individual needs.

6.8.1 Fitting hardware

Connect the processor with processor coil to the appropriate MAX Programming Cable (MAX Programming Cable BTE, MAX Programming Cable RONDO, MAX Programming Cable SONNET, MAX Programming Cable RONDO 2).

Connect the MAX Programming Cable to the processor socket of the MAX Programming Interface depending on the hardware settings for dynamic or fixed port mapping.

Use both processor sockets for bilateral fitting.

CAUTION:

Make sure to use the appropriate hardware.

CAUTION:

The appropriate coil must be correctly placed over the implant at all times during fitting. If a bilateral patient uses a TEMPO+ processor, the right or left ear must be identified correctly prior to and during the fitting process to prevent unwanted stimulation which may go unrecognized.

Trigger

The MAX Programming Interface sends a trigger signal with each stimulation burst. The trigger signal is predefined by MAESTRO.

It is positive and has a duration of approximately 115 μ s.

6.8.2 Starting the Fitting task

The precondition to start the task is an ongoing session for the patient and a connected processor.

Click on [New](#) in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter [Menu and Toolbar](#)), a new task can also be opened with a click on the related icon in the tool bar.

Choose the ear to work with for bilateral patients from the pop-up window.

It is also possible to start a new fitting by clicking on the + button in the configuration panel of the session view.

Templates

When opening a new task a pop-up window is displayed. The pop-up window lists several options and templates for this task. Click on the desired option to continue:

- Start a new Fitting by opening an empty map
- AutoART map: Create a new Fitting based on an existing AutoART measurement
- ESRT map: Create a new Fitting based on an existing ESRT measurement
- Cl.STUDIO+ maps: Open a map based on an existing Cl.STUDIO+ map, see chapter Cl.STUDIO+data import

Editors

The Fitting task provides the following editors:

- Levels editor
- Acoustic editor
- Strategy editor
- Frequency Bands editor
- Maplaw editor
- ASM editor
- Indicators editor

6.8.3 Levels editor



Levels editor

1 Electrodes

Displays the stimulation bars for the individual electrodes and allows the user to set MCL charge and THR charge in μC . The charge of the stimulation pulse of an electrode can be graphically changed with the mouse by moving the black arrow in the stimulation bar. The MCL charge is changed by moving the right arrow, the THR charge by moving the left arrow.

The green bar visualizes the highest stimulation realized for this channel. The orange bar displays the difference between the highest realized stimulation and the new desired charge value. The orange bar will turn green when the stimulation is concluded.

A note symbol in the stimulation bar marks the electrode as a CSSS channel.

Click on the  arrow symbol below the number to set the global status of the applicable electrode. Globally deactivate an electrode by selecting one of the various reasons for deactivation from the drop-down menu. If an electrode has been globally deactivated, it is deactivated in all tasks.

Stimulation is not possible in globally deactivated electrodes.

Locally deactivated electrodes are only deactivated for the current map.

2 Adjusting table and diagram

Use the buttons +/- on the left side for scaling the axis.

Display or hide different lines of the related table by clicking on  and selecting the applicable option.

Stimulation Rate, MCL Amplitude and THR Amplitude in cu can also be displayed.

Select [ESRT data](#) or [ECAP THR](#) to display ESRT or ECAP measurement results within a fitting map. The latest measurement is displayed numerically in the table and indicated graphically by an orange (ESRT) or purple (ECAP) line. To show a different measurement choose the desired data from the drop down menu in the table.

Display the name of measurements the fitting map relies on by clicking on [Show data sources](#).

3 Table

The table displays the values [MCL Charge](#), [THR Charge](#), [Duration](#), [Min. Dur.](#) (Minimum Duration), [Center F.](#) (Center Frequency), [Impedance](#) and [Telemetry Status](#).

Green values are adjustable, black values are computed by MAESTRO and cannot be adjusted.

Change parameters by entering the desired value in the applicable input field in the table below the stimulation bar or control the value via page up/down keys (+/-15 %), arrow keys (+/-3 %) or plus and minus keys (+/-1 %).

Right click on a value and select the option [copy value](#) to apply the value to another channel or to all channels.

[MCL Charge](#) and [THR Charge](#) give the desired stimulation charge for MCL and THR in qu.

[Duration](#) gives the calculated phase duration of the stimulation pulse in μ s.

[Min. Dur.](#) defines the minimum phase duration in μ s of the stimulation pulse on the applicable electrode.

[Center F.](#) gives the center frequency in Hz of the frequency band represented by the channel.

[Impedance](#) and [Telemetry Status](#) display the determined impedance and telemetry status of the last telemetry measurement in $k\Omega$.

The maximum possible stimulation current is based on the data of the last telemetry measurement and states the stimulation current at which the implant reaches its cut-off voltage. If no telemetry data are available, MAESTRO uses the implant-dependent default values. However, the default values are not based on real patient measurements and may result in very restrictive options. It is always good to use the most recent telemetry measures for fitting and other tasks.

If the selected stimulation charge exceeds the predefined safety limit in one or more electrodes, a warning appears which must be confirmed to allow stimulation.

4 Sidebar - Stimulation

Hit the space bar or click on the [Dynamic](#) button to perform a stimulation burst at the highlighted electrode. If two electrodes are selected, labeling of the button changes to [Balancing](#) and both selected electrodes are stimulated sequentially. If more than two electrodes are selected, two buttons with an arrow symbol appear to enable [Sweeping](#). All selected electrodes are stimulated sequentially in ascending or descending order. To select more than one electrode, press the CTRL key on the keyboard and select the desired channels with a mouse click.

The stimulation level can be changed in the field [Dynamics](#) and can be adjusted between THR charge and MCL charge in 10% steps.

Selection of the [Continuous](#) checkbox enables continuous stimulation of the selected electrodes.

5 Sidebar - Activation

Click on the [Live](#) button to activate the processor microphone and test the map. As a visual indication a microphone symbol appears next to the name of the map at the top and on the [Live](#) button, all electrode numbers are highlighted and the button turns orange. Deactivate an activated map by pressing the [Live](#) button again.

When using a SONNET EAS audio processor, the [Activation](#) section displays three buttons for activation of the map. Click on the applicable button to select if the activation only applies to electric stimulation ([Electric](#)), acoustic stimulation ([Acoustic](#)) or to electric and acoustic stimulation ([Live EAS](#)). When activated, the related buttons are displayed in an orange color and a microphone symbol appears. Deactivate an activated map by pressing the related button [Electric](#), [Acoustic](#) or [Live EAS](#). The settings in the [Activation](#) section are automatically synchronized in the Levels editor and in the Acoustic editor of a fitting map.

An activated map is automatically deactivated, when a notification has to be checked, e.g. when a set value exceeds the predefined warning limit.

When changing values the map will be reactivated automatically. The automatic reactivation can be suppressed by disabling the [live during changes](#) checkbox in the [Settings | Fitting](#) dialog. Every change made now leads to an automatic deactivation of the map and the map has to be activated manually.

The map is activated with the volume defined in the [Default Volume](#) field.

Define the default volume for a map in the field [Default Volume](#) and adjust the FineTuner Volume range with the slide control or by entering the values manually.

For OPUS 1 and TEMPO+ processors the volume for activation is labelled [Test Volume](#) and the volume programmed into the processor has to be adjusted in the configuration panel of the Session view. Adjust the volume range with the slide control or by entering the values manually.

6 Sidebar - Tools

The THR charge is set to a certain percentage of the MCL charge. Disable the [Lock THR to](#) checkbox to individually set the THR charge for each electrode.

Tools offers several map shaping tools. **Work with** defines if the map shaping tools should be applied to MCL charge, THR charge or MCL + THR charge.

The shift and tilt or pivot function can be applied to all electrodes or to a certain group of electrodes only. The different group options are displayed after selecting **Shift & Tilt** or **Pivot**. Choose the desired group and the step size (large - 15%, small - 3%). The **Shift & Tilt** button increases or decreases the charge of the entire selected group or of the apical or basal electrodes of the selected group. The **Pivot** button enables the highest increase or decrease of the charge of the most apical electrode and the charge of the most basal electrode. The charge of the electrodes in between are changed proportionately. The **Autointerpolation** button interpolates the charge of channels which are zero. Linear or spline interpolation is available.

7 Sidebar - VRT

The **Visual Reinforcement Tool** is a support tool to assist audiologists during the fitting session. It displays media in the Media Player and, if applicable on an additional monitor facing the patient.

Precondition for displaying media on an additional monitor is a multi-display configuration set up in the graphic settings of the Windows operating system and configuration of the monitor in the MAESTRO settings, see chapter **Settings - Media VRT**.

Select a playlist previously created in the Media Manager from the drop-down menu. Condition the patient to the relationship of stimulus and visual reward (media). After conditioning, the patient is expected to turn toward the monitor after perceiving a stimulus - thus indicating that the stimulus was audible.

Click on one of the VRT keys in the software or on the keyboard to display the media in the Media Player and, if applicable on the additional monitor. Stop displaying the media by pressing the key again. If an additional monitor is configured a monitor icon appears below the VRT keys. Click on this icon to enable or disable the additional monitor. A disabled monitor does not show any media.

8 Summary string

The summary string displays the fitting strategy, the number of channels and the number of fine structure channels in brackets. Additionally it shows the frequency band assignment, the default volume with FineTuner range, the AGC and the sensitivity.

9 Sidebar - Link check

The link check is available for implants with readable serial number and processors with DL-Coil. It gives an indication if the link between processor coil and implant is established or not. If the connection is lost, check cable connections, then slightly adjust the position of the coil. The link check is not available while the fitting map is activated. Deactivate the link check in the hardware settings, see chapter **Settings - Hardware**.

Default settings for the Levels editor

Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

Field	Default
Min. Dur. [μs]	0
Dynamics [%]	100
Continuous	disabled for Dynamic enabled for Balancing and Sweeping
Default Volume [%]	75
Volume Range [% -%]	70 - 100
Lock THR to	enabled
Lock THR to [%]	10

Default settings for Levels editor

See chapter **Settings - Fitting** for Fitting settings.

6.8.4 Acoustic editor

The Acoustic editor in the fitting task allows the user to program the acoustic unit of a SONNET EAS audio processor. For programming of the acoustic unit of a DUET 2 use the Acoustic Fitting task, see chapter **Acoustic Fitting task**.



Acoustic for SONNET EAS processors

1 Diagram

A diagram with Crossover Frequency, Target Gain and Adjusted Gain is shown. Target Gain and Crossover Frequency are computed internally according to the patient's audiogram data and displayed as a dashed green line or as a grey area. The values computed from the audiogram data, the Crossover Frequency and the Target Gain, are

displayed in a red amplification curve. The [Adjusted Gain](#) is displayed as solid green line in the diagram. Drag and drop the knots of the adjusted gain at the main frequencies to make adjustments according to the patient's hearing loss. Adjust the Crossover Frequency by dragging the dotted grey line with the mouse to the desired position between 125 Hz and 1700 Hz.

2 Table

Enter the desired value into the input field of the table to adjust the gain according to the patient's hearing loss.

Green values are adjustable, black values are computed by MAESTRO and cannot be adjusted.

3 Overall gain

Click on one of the applicable shift buttons in the [Overall Gain](#) section to adjust the overall gain.

CAUTION:

The gain of the acoustic unit shall be carefully adapted.

4 Sidebar - Audiogram

The name of the audiogram used for the editor is displayed. The patient's most recent audiogram is selected by default. Select a different available audiogram by choosing it from the drop-down menu. Click on the [Open selected Audiogram](#) field to open the selected audiogram.

If no valid audiogram is available for the patient, the Acoustic editor is grey and Target Gain curve and Crossover Frequency are not displayed.

The EAS feature of the SONNET EAS can be turned off by selecting the option [Disable Acoustic](#). Selection of an Audiogram from the drop-down menu switches the EAS feature on again.

Click on the [Revert to First Fit](#) button to restore the amplification values shown in the table to the values initially computed by MAESTRO.

Adjust the Crossover Frequency by entering the value into the [Crossover Frequency](#) field in the Audiogram section.

CAUTION:

The audiogram used to perform acoustic fitting of the processor shall be chosen carefully.

5 Sidebar - Activation

Click on the [Live](#) button to activate the processor microphone and test the map. As a visual indication a microphone symbol appears next to the name of the map at the top and on

the [Live](#) button, all electrode numbers are highlighted and the button turns orange. Deactivate an activated map by pressing the [Live](#) button again.

When using a SONNET EAS audio processor, the [Activation](#) section displays three buttons for activation of the map. Click on the applicable button to select if the activation only applies to electric stimulation ([Electric](#)), acoustic stimulation ([Acoustic](#)) or to electric and acoustic stimulation ([Live EAS](#)). When activated, the related buttons are displayed in an orange color and a microphone symbol appears. Deactivate an activated map by pressing the related button [Electric](#), [Acoustic](#) or [Live EAS](#). The settings in the [Activation](#) section are automatically synchronized in the Levels editor and in the Acoustic editor of a fitting map. An activated map is automatically deactivated, when a notification has to be checked, e.g. when a set value exceeds the predefined warning limit. When changing values the map will be reactivated automatically. The automatic reactivation can be suppressed by disabling the [live during changes](#) checkbox in the [Settings | Fitting](#) dialog. Every change made now leads to an automatic deactivation of the map and the map has to be activated manually.

The map is activated with the volume defined in the [Default Volume](#) field. Define the default volume for a map in the field [Default Volume](#) and adjust the FineTuner Volume range with the slide control or by entering the values manually.

6 Appearance

Select the checkboxes [Gain \(40 dB\)](#), [Gain \(65 dB\)](#), [Gain \(90 dB\)](#) and [Target Gain](#) under [Appearance](#) to display individual amplification curves and the Target Gain curve in the diagram.

NOTE:
The Crossover Frequency is displayed in the Acoustic editor and in the Frequency Bands editor of a fitting map, but can only be modified in the Acoustic editor. After modification in the Acoustic editor, it is automatically synchronized to the Frequency Bands tab of the fitting map.

Default settings for the Acoustic editor

Default settings to be adjusted by the user in the settings dialog are highlighted in [blue](#).

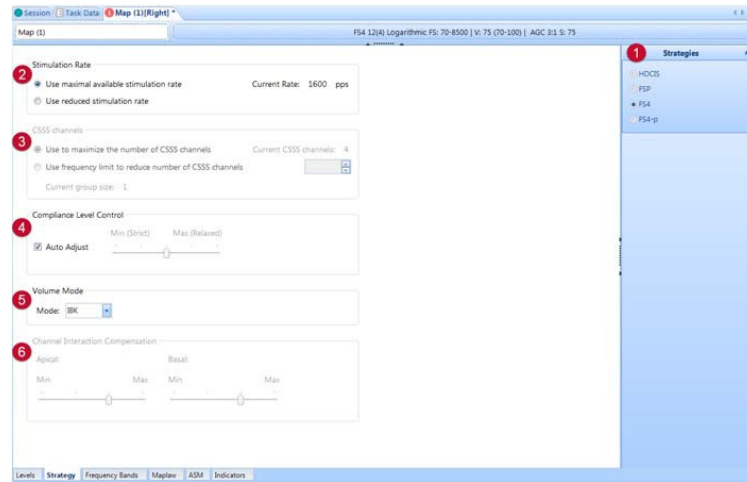
Field	Default
Default Volume [%]	75
Fine Tuner Volume Range [% - %]	70 - 100
Gain (40dB)	disabled
Gain (65dB)	enabled
Gain (90dB)	disabled
Target Gain	enabled

Default settings for Acoustic editor

See chapter **Settings - Fitting** for Fitting settings.

6.8.5 Strategy editor

The Strategy editor provides different coding strategies to translate the acoustic input signal into electrical stimulation parameters.



Strategy editor

1 Strategies

Select the desired coding strategy depending on the implant type.

- CIS+** Is the predecessor of HD-CIS, with the same functional principle but a slower sampling rate. TEMPO+ speech processors exclusively use the CIS+ strategy.
- HD-CIS** Determines the envelope of the output signal of the applicable filter bank for each electrode. The envelope is the reference for the performance of each frequency band.
- FSP** Represents the fine structure of the acoustic signal on the low-frequency electrodes by coding the zero point with Channel Specific Sampling Sequences (CSSS). On all other channels the signal is processed according to HD-CIS. Electrodes using the fine structure of the acoustic signal bear the note symbol in the stimulation bars in the Levels editor. The number of CSSS channels and thus the frequency range with fine structure coding depends on the patient's parameter settings.
- FS4,** For 12 active electrodes, a maximum of four electrodes are CSSS channels, the
- FS4-p** other eight electrodes process the signal according to HD-CIS. In **FS4** and **FS4-p**, temporal fine structure information is delivered to the lowest four frequency

channels using CSSS, while FSP delivers temporal fine structure information via CSSS typically only to the lowest two frequency channels. The upper frequency limit for providing fine structure information is thereby increased for FS4 and FS4-p when compared to FSP. FS4 sequentially stimulates one-of-four fine structure channels, while FS4-p can additionally stimulate two-of-four fine structure channels in parallel when positive-going zero crossings on two fine structure channels with the largest instantaneous envelope-amplitude occur simultaneously. In FS4-p, current amplitudes for parallel stimulation are calculated using a dedicated algorithm (Channel Interaction Compensation, CIC) so that the compound current amplitude matches the one for sequential stimulation.

Strategies using parallel stimulation are only available for the following implant types:

- SYNCHRONY
- MED-EL CONCERT
- SONATA
- PULSAR

NOTE:

The default values for volume and frequency range depend on the coding strategy. Changing the coding strategy changes the volume and frequency range settings.

Depending on the chosen strategy, the implant type and the processor type the main window displays different sections for further adjustments.

2 Stimulation Rate

Reduces the stimulation rate when enabling [Use reduced stimulation rate](#). For HDCIS and FSP use the arrow keys or enter the desired value in the input field. For FS4 and FS4-p the current stimulation rate on envelope channels is reduced to 750 pps or the previously used rate. The current rate is displayed in the upper right corner.

3 CSSS channels

Set [Use to maximize the number of CSSS channels](#) to work with the maximum number of CSSS channels. Reduce the number of available CSSS channels for FSP by selecting [Use frequency limit to reduce number of CSSS channels](#). Define a frequency limit via the arrow keys or by directly entering the desired value in the input field. The current number of CSSS channels is displayed in the upper right corner.

4 Compliance Level Control

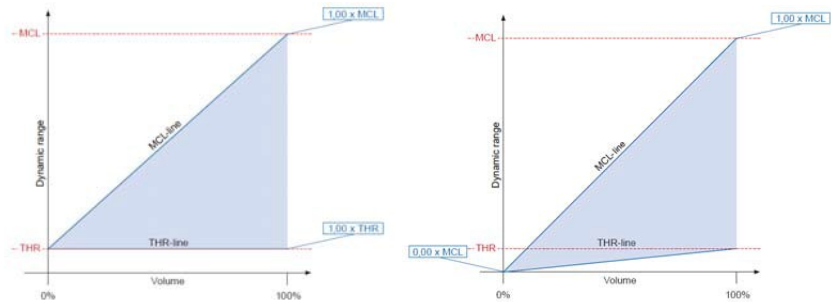
The compliance limit is based on the data of the last saved telemetry measurement and states the stimulation current the implant can deliver. With enabled [Auto Adjust](#) checkbox MAESTRO automatically shifts the compliance limit to optimize the number of fine structure channels and rate. Deselect the checkbox and use the slide control to set the compliance limit manually between actually measured and theoretical maximum limit.

5 Volume Mode

Choose the used volume mode to set the desired behavior when increasing or decreasing the volume.

IBK Mode: The minimum volume value remains equal to the value of the THR charge. The maximum volume value increases linearly to the value of the MCL charge.

RTI Mode: At a volume setting of zero, the MCL and THR level are at zero stimulation. The minimum volume value increases linearly to the value of the THR. The maximum volume value increases linearly to the value of the MCL charge.



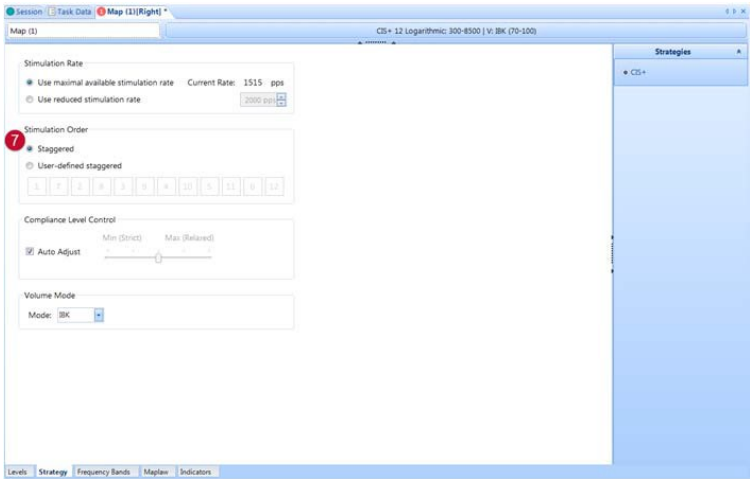
Left: IBK Mode; Right: RTI Mode

6 Channel Interaction Compensation

Simultaneous stimulation causes increased channel interaction. Adjust the compensation level for FS4-p via slide controls towards the apical or basal direction. Shift the slide control towards **Max** to increase the compensation level, shift it towards **Min** reduce the compensation level.

7 Stimulation Order

Stimulation Order is only available for CIS+ strategy and determines the order of the sequential stimulation. This order can be **staggered** or **User defined staggered**. Activate **User defined staggered** to change the stimulation order via drag and drop.



Strategy editor for a TEMPO+ speech processor

Default settings for the Strategy editor

Default settings to be adjusted by the user in the settings dialog are highlighted in blue.

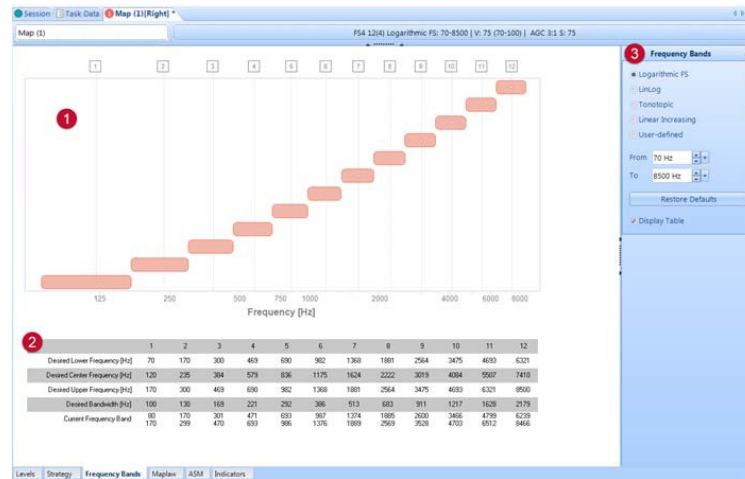
Field	Default
Strategy (TEMPO+)	CIS+
Strategy	FS4
Stimulation Rate	Use maximum available stimulation rate
CSSS Channels	Use to maximize the number of CSSS channels
Compliance Level control	Auto Adjust enabled
Volume Mode (HDCIS)	RTI
Volume Mode (other strategies)	IBK

Default settings for Strategy editor

See chapter **Settings - Fitting** for Fitting settings.

6.8.6 Frequency Bands editor

The Frequency Bands editor allows the user to adjust the frequency range of the processor and individual frequency band assignment.



Frequency Bands editor

1 Diagram

The diagram is a graphic display of the frequency bands of the individual electrodes.

The default band assignment is linear from apex to base. For patients with a Split electrode the individual frequency bands are assigned from apex to base by default to the electrode numbers 5 to 1 and 6 to 12. Drag an electrode number with the mouse into the field of another electrode number to change the band assignment.

2 Table

The table displays the numerical values of Desired Lower Frequency, Desired Center Frequency, Desired Upper Frequency, Desired Bandwidth and Current Frequency Band per electrode.

3 Sidebar

The sidebar of the Frequency Bands editor offers five options to distribute the frequency bands.

Logarithmic FS Divides the frequency spectrum into approximately logarithmically equally distributed bands so that the frequency range is divided into bands with approximately equal energy content for white noise.

LinLog Divides the lower end of the frequency range into linear bands of equal size, the remaining portion of the frequency range into logarithmically distributed bands so that the bands in the lower frequency range are narrower, those in the upper frequency range wider.

Tonotopic Groups the frequency bands in approximation to the tonotopy of the healthy

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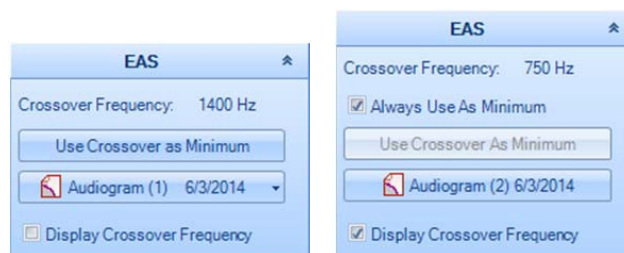
- ear.
- Linear Increasing** Divides the frequency range into bandwidths linearly increasing from the lower to the higher frequencies. Compared with Logarithmic FS, the bandwidths are wider for the lower frequency bands and narrower for the three highest frequency bands.
- User Defined** Individually define the frequency band limits for each electrode using the mouse in the diagram. Alternatively, enter the desired values directly into the table. Set the lower and upper cut-off frequency of the frequency range in the input fields **From** and **To**. The actual values (Current Frequency Band) may differ from the desired values due to technical limitations.

Click on the **Restore Defaults** button to restore all default settings.
Select the **Display Table** checkbox to display the table below the diagram.

Detailed description:

EAS:

For patients using an EAS system the sidebar additionally provides an EAS section:



Left: EAS; Right: EAS for SONNET EAS

The name of the audiogram used for the editor is displayed. The patient's most recent audiogram is selected by default. Select a different available audiogram by choosing it from the drop-down menu. Click on the **Open selected Audiogram** field to open the selected audiogram.

Click on the **Use Crossover as Minimum** button to automatically accept the Crossover Frequency as the lower cut-off frequency in the Frequency Bands editor.

For SONNET EAS processors the used audiogram has to be chosen in the **Acoustic** editor and its name and the used Crossover Frequency are displayed. A click on the name of the audiogram opens the currently selected audiogram.

Click on the **Use Crossover as Minimum** button to automatically accept the Crossover Frequency as the lower cut-off frequency in Frequency Bands editor. To always accept the

Crossover Frequency as the lower cut-off frequency, enable the [Always Use As Minimum](#) checkbox.

Select the [Display Crossover Frequency](#) checkbox to display the Crossover Frequency in the frequency diagram.

Default settings for the Frequency Bands editor

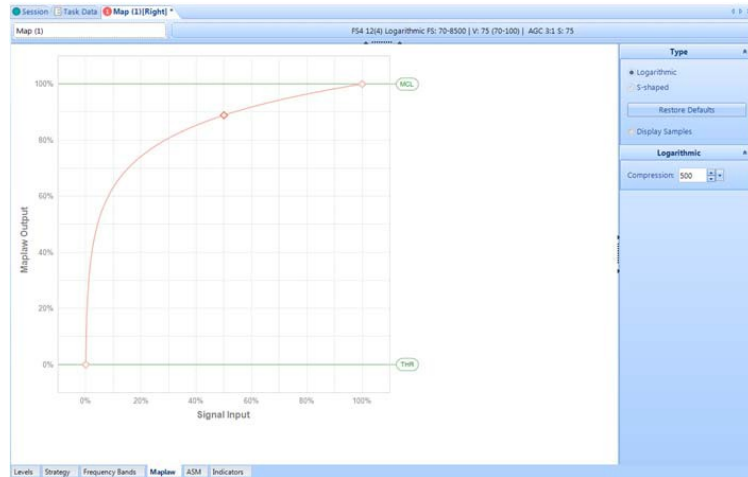
Field	Default
Frequency Bands	Logarithmic FS (Logarithmic for CIS+)
Entire Frequency range (CIS+) [Hz]	200 - 8500
Entire Frequency range (other strategies) [Hz]	70 - 8500
Default Frequency range (HDCIS) [Hz]	250 - 8500
Default Frequency range (CIS+) [Hz]	300 - 8500
Default Frequency range (FSP, FS4, FS4-p) [Hz]	70 - 8500
Lower cut-off [Hz]	70 - 350
Upper cut-off [Hz]	3500 - 8500
Lower cut-off [Hz] (EAS)	70 - 2000
Always use as Minimum (SONNET EAS)	disabled for user defined frequency bands enabled for others
Display Crossover Frequency	disabled for EAS enabled for SONNET EAS

Default settings for Frequency Bands editor

See chapter **Settings - Fitting** for Fitting settings.

6.8.7 Maplaw editor

The Maplaw defines the compression characteristics along the patient's dynamic range. Changing the Maplaw is a fundamental process and impacts all electrodes.



Maplaw editor

The diagram shows the Maplaw output over the Signal input. Select the applicable option in the [Type](#) section of the sidebar to define if the Maplaw is Logarithmic or S-shaped.

Change the compression coefficient c for a logarithmic Maplaw in the sidebar. For c equal to zero the Maplaw is linear. The higher c , the steeper rises the lower dynamic range. For an S-shaped Maplaw the sidebar provides four coordinates to adjust the desired curve form. The two x-coordinates are the portions of the signal input in percent, the two y-coordinates the portion of the Maplaw output in percent.

Change the Maplaw by dragging the drag points with the mouse in the diagram or by entering the value directly in the applicable field in the sidebar.

Select the [Display Samples](#) checkbox to change the display of the Maplaw function from a solid curve to discrete individual values.

Click on the [Restore Defaults](#) button to restore all default settings.

In the [Spacing](#) section, which is only available for TEMPO+ processors, the distribution of the samples related to the input dynamic range of the ADC (analog-digital converter) can be switched from linear to logarithmic. Especially when using S-shaped Maplaws, logarithmic spacing might result in a better approximation of the linear interpolation of the samples towards the intended curve shape.

Default settings for the Maplaw editor

Field	Default
Type	Logarithmic
Compression c (Logarithmic)	500
Compression range (Logarithmic)	0 – 8000
x-coordinate (S-shaped) [%; %]	4; 3
y-coordinate (S-shaped) [%; %]	30; 10
Display samples	disabled

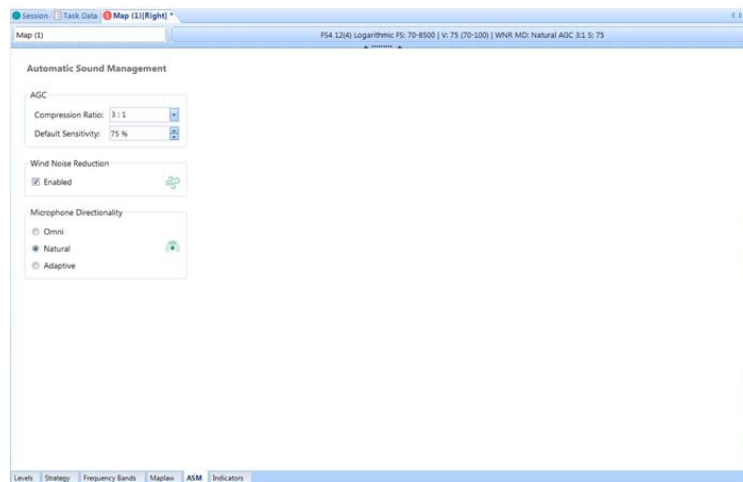
Default settings for Maplaw editor

See chapter **Settings - Fitting** for Fitting settings.

6.8.8 ASM editor

The ASM (Automatic Sound Management) editor is available for the following processors:

- RONDO 2
- SONNET EAS
- SONNET
- RONDO
- OPUS 2



ASM editor

AGC

Adapt the AGC of the processor to the patient's needs in the [AGC](#) section. Select one of the five options for the AGC compression ratio in [Compression Ratio](#). Set the default microphone sensitivity of the processor in [Default Sensitivity](#).

Wind Noise Reduction

[Wind Noise Reduction](#) is only available for SONNET and SONNET EAS processors. Enable or disable the function [Wind Noise Reduction](#) with a click on the related checkbox. The intensity of wind noise reduction has to be adjusted in the configuration panel of the session view.

Microphone Directionality

Change the microphone directionality in the [Microphone Directionality](#) section. [Microphone Directionality](#) is only available for SONNET and SONNET EAS processors.

[Omni](#) stands for omnidirectional and means that the sensitivity to incoming sounds is equally high in all directions.

[Natural](#) and [Adaptive](#) combine the signals of the two audio processor microphones in such a way that signals originating in the back hemisphere (i.e., behind the user) will be attenuated.

[Natural](#) generally attenuates the sensitivity for frequencies above approximately 500 - 1000 Hz from the back, imitating the function of the pinna to a certain extent. For frequencies below 500 - 1000 Hz the sensitivity to incoming sounds is equally high in all directions, like in [Omni](#) mode.

[Adaptive](#) tries to minimize disturbances originating in the back hemisphere by adjusting the sensitivity adaptively to the location and characteristic of the disturbing sound signals. Below a certain sound level the adaptive directionality is automatically disabled and the system goes smoothly into omnidirectional mode. This sound level threshold has to be defined in the configuration panel of the session view.

Wind noise reduction and microphone directionality were designed to work together and thus, we recommend having both features active at the same time. Wind noise reduction is also available when the omnidirectional mode is selected. The table below shows the possible combinations of microphone directionality and wind noise reduction:

Wind Noise Reduction (WNR)		Microphone Directionality		
		Omni	Natural	Adaptive
Disabled		Yes	Yes	Yes
Enabled	Mild	Yes	Yes	Yes
	Strong	Yes	Yes	Yes

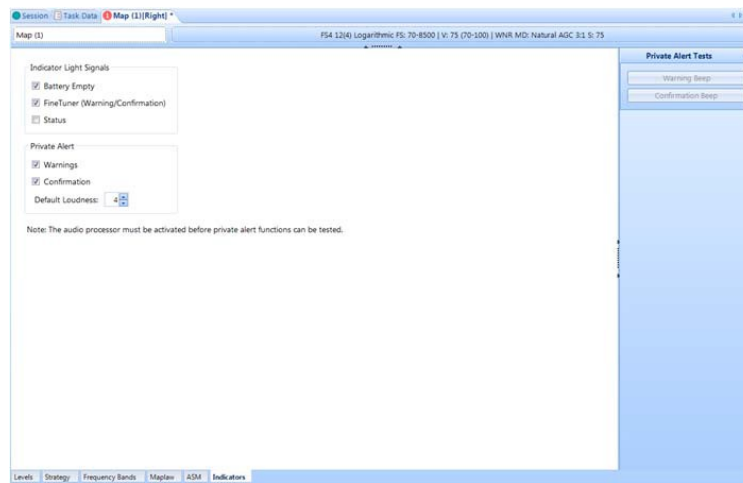
Default settings for the ASM editor

Field	Default
Compression Rate	3:1
Default Sensitivity [%]	75
Wind Noise Reduction	enabled for SONNET and SONNET EAS disabled for other processors
Microphone directionality	Natural for SONNET and SONNET EAS Omni for other processors

Default settings for ASM editor

See chapter **Settings - Fitting** for Fitting settings.

6.8.9 Indicators editor



Indicators editor

Indicator Light Signals

Indicator Light Signals provides three checkboxes to activate different indicator light signals. Select the **Battery Empty** checkbox to indicate low battery voltage of the processor

with a blinking signal. Select the [FineTuner \(Warning/Confirmation\)](#) checkbox to elicit a blinking signal whenever the processor settings are changed with the FineTuner. Select the [Status](#) checkbox and the processor indicates operation with a continuous blinking signal. For further information see the user manual of the processors.

Private Alert

Select the checkboxes [Warnings](#) and [Confirmation](#) to enable an acoustic warning signal indicating low battery voltage and changes with the FineTuner. To test the volume of the acoustic warning signal enable the applicable checkbox, activate the fitting map and click on the [Warning Beep](#) or [Confirmation Beep](#) button in the sidebar. Change the volume of the acoustic signal in the [Default Loudness](#) input field.

Battery empty

For OPUS 1 and TEMPO+ processors only the [Battery empty](#) function in the [Indicator Light Signals](#) section is available. It activates an indicator light signal for an empty battery and the processor shows a blinking signal to indicate low battery voltage.

Default settings for the Indicators editor

Field	Default
Battery empty	enabled
Fine Tuner (Warning/Confirmation)	enabled
Status	disabled
Warnings	enabled
Confirmation	enabled
Default Loudness	4
Default Loudness range	1 - 8

Default settings for Indicators editor

See chapter [Settings - Fitting](#) for Fitting settings.

6.9 CONFIGURATION TASK

The Configuration task allows the user to open saved configurations in a read-only mode. The session view allows the user to perform processor programming see chapter [Session - Configuration](#) panel.

6.9.1 Opening a Configuration

The precondition to open a configuration is an ongoing session. Switch to Task Data tab and double-click on a stored configuration.

Editors

The Configuration task provides the following editors:

- Processor editor
- Options editor
- Datalogging editor

6.9.2 Processor editor

The processor editor of the configuration task displays the available program positions. The program positions are filled with the assigned maps and a preview of the map is displayed. In case of an OPUS 1 or TEMPO+ processor the used mode is displayed in the sidebar.

6.9.3 Options editor

The Options editor is only available for the following processors:

- RONDO 2
- SONNET EAS
- SONNET
- RONDO
- OPUS 2

FineTuner Commands:

The FineTuner Commands section provides an overview of which keys were activated or deactivated.

Link Monitoring:

The [Automatic Coil Power Off](#) checkbox indicates if stimulation automatically stops when the DL-Coil cannot detect the implant any more, e.g. the coil is no longer placed over the implant.

The [Link Indicator Lights](#) checkbox indicates if the indicator lights are enable.

Link monitoring functionality is deactivated if both checkboxes are disabled.

Automatic Sound Management (ASM):

This section displays configuration-based parameters for the automatic sound management.

[Wind Noise Reduction](#) indicates which wind noise reduction option was used for maps with enabled wind noise reduction feature.

[Adaptive Microphone Directionality](#) indicates the mode for maps with enabled adaptive microphone directionality.

For a detailed description of all configuration parameters, see chapter [Session - Configuration panel](#).

6.9.4 Datalogging editor

The datalogging editor of the configuration task displays logged processor usage. This editor is only available for the following processors:

- SONNET EAS
- SONNET

The editor indicates the processor usage hours, the number of processor startups, the usage time of specific programs, and also tracks volume and sensitivity used for each program.

[Log started](#) gives the date the processor was programmed and the log was started.

[Log finished](#) gives the date the log was read out and finished.

[Days logged](#) gives the number of logged days.

[Processor usage](#) gives the average hours per day and adds up the time the processor was switched on.

[Processor switch-ons](#) gives the average number of switch-ons per day and also adds up the processor startups.

The four program positions with the name of the programmed map and logged information are displayed below.

[Map Usage](#) indicates how long the map was in use as a percentage of the overall processor usage time.

[Volume Usage Ranges](#) displays a bar with three pieces representing the three volume ranges ([Low](#), [Mid](#), [High](#)) and their usage. [Mid](#) is defined as range from default volume -10% to default volume +10%. [Low](#) starts from the defined minimum FineTuner volume range and [High](#) ends with the defined maximum FineTuner volume.

[Sensitivity Usage Ranges](#) displays a bar with three pieces representing the three sensitivity ranges ([Low](#), [Mid](#), [High](#)) and their usage. [Mid](#) is defined as range from default sensitivity $\pm$ 10%, similar to volume.

6.10 ACOUSTIC FITTING TASK

The acoustic unit of the DUET 2 can either be programmed manually using the trimmers or with the Acoustic Fitting task in MAESTRO via HI-PRO interface box.

To program the SONNET EAS processor, use the Acoustic editor in the Fitting task, see chapter [Acoustic editor](#).

6.10.1 Acoustic Fitting hardware

Communication with the DUET 2 is established via the HI-PRO interface box. Connect the DUET 2 to the HI-PRO with a DUET 2 programming cable. Turn the DUET 2 audio processor on for fitting.

CAUTION:
Make sure to use the appropriate hardware.

6.10.2 Starting the Acoustic Fitting task

The precondition to start the task is an ongoing session for the patient and a processor with the DUET 2 battery pack needs to be connected.

Click on [New](#) in the menu bar and select the task from the opened submenu. If the toolbar was customized to contain an icon for quick access (see chapter **Menu and Toolbar**), a new task can also be opened with a click on the related icon in the tool bar. Choose the ear to work with for bilateral patients from the pop-up window.

Templates

When opening a new task a pop-up window is displayed. The pop-up window lists several options and templates for this task. Click on the desired option to continue:

- Perform a new Acoustic Fitting
- Perform Acoustic Fitting based on the currently connected DUET 2 configuration

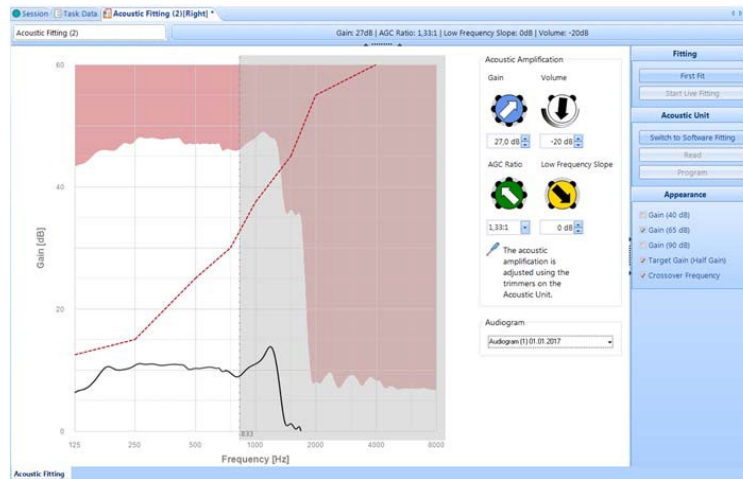
Editors

The Acoustic Fitting task has one editor: **Acoustic Fitting editor**

6.10.3 Acoustic Fitting editor

The parameters to be set in the Acoustic Fitting task are described in the DUET 2 Fitting Guide.

MAESTRO Tasks in detail



Acoustic Fitting editor

Main parameters

The diagram shows the amplification curves for 40, 65 and 90 dB input level, the target curve and the crossover frequency. Target curve and crossover frequency are adjusted according to the patient's audiogram data. Adapt the acoustic amplification to the patient's hearing loss by setting the controls **Gain**, **Volume**, **AGC Ratio** and **Low Frequency Slope**.

The name of the audiogram used for the editor is displayed. The patient's most recent audiogram is selected by default. Select a different available audiogram by choosing it from the drop-down menu. Click on the **Open selected Audiogram** field to open the selected audiogram.

If no audiogram is available for the patient, the target curve and crossover frequency are not displayed and a warning appears. When starting the task with an empty data sheet the amplification curve settings use the MAESTRO default values.

CAUTION:

The audiogram used to perform acoustic fitting of the processor shall be chosen carefully.

Sidebar

Click on the **First Fit** button to preliminarily fit the target gain according to the patient's audiogram data. Fine fitting can be performed based on this preliminary fitting.

CAUTION:

The gain of the acoustic unit shall be carefully adapted.

NOTE:

The current gain curve is a first fitting approach and is an approximation of the target function.

Click on the [Switch to Software Fitting](#) button to activate the option of fitting the acoustic unit of the DUET 2 with MAESTRO. After activating the MAESTRO fitting option, labeling of the button changes to [Switch to Trimmer Fitting](#). Click on the button again to deactivate the MAESTRO fitting option and activate trimmer fitting.

CAUTION:

As soon as the device is programmed with MAESTRO the controls of the acoustic unit of the DUET 2 audio processor are deactivated and cannot be adjusted with the trimmers. The controls can only be reprogrammed or reactivated with MAESTRO and a connected HI-PRO interface box.

Click on the [Start Live Fitting](#) button to activate the acoustic unit of the DUET 2 audio processor and perform live fitting. Activation is indicated by a microphone symbol.

If the current settings of the acoustic unit were already programmed with MAESTRO, these settings can be read out with MAESTRO by clicking on the button [Read](#). Read-out of manual control settings of the acoustic unit is not possible.

Click on the [Program](#) button to program the entered settings to the DUET 2 audio processor.

Enable or disable the checkboxes [Gain \(40 dB\)](#), [Gain \(65 dB\)](#), [Gain \(90 dB\)](#), [Target Gain \(Half Gain\)](#) and [Crossover Frequency in Appearance](#) to display or hide the individual amplification curves and, if available, target gain and crossover frequency.

Default settings for the Acoustic Fitting editor

Default settings to be adjusted by the user in the settings dialog are highlighted in [blue](#).

MAESTRO Tasks in detail

Field	Default
Gain [dB]	27
Low Frequency Slope [dB/Octave]	0
AGC Ratio	1.33:1
Volume [dB]	-20
Gain (40dB)	disabled
Gain (65dB)	enabled
Gain (90dB)	disabled
Target Gain	enabled
Crossover Frequency	enabled

Default settings for Acoustic editor

See chapter **Settings - Acoustic Fitting** for Acoustic Fitting settings.

7 Software Tools

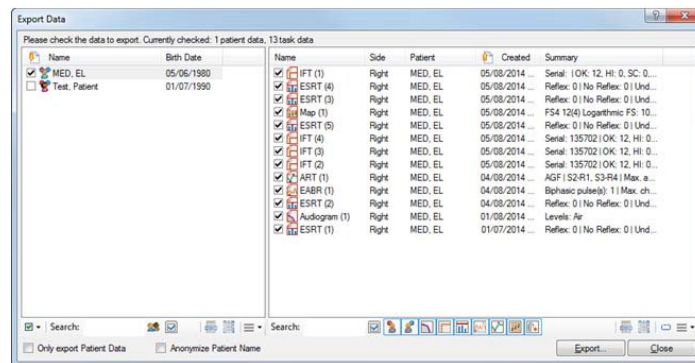
7.1 EXPORT AND IMPORT DATA

MAESTRO allows the user to export and import all patient and task data.

7.1.1 MAESTRO data export

Select **Data** in the menu bar and choose the submenu **Export data** to open the export dialog.

The tool can also be started with a click on the related icon in the tool bar, if the toolbar was customized accordingly.



Export Data dialog

The left part of the dialog lists all patients, the right part individual task data.

Filters

Filter the displayed dataset by using the options in the line below the data table.

Search limits the displayed patient or task data to entries containing the character sequences entered in the **Search** field.

Activate the option **Show only Checked** to display only the enabled patient or task data.

Activate or deactivate the patient side icon to display or hide data for the left and right ear. Activate or deactivate the task icons to display the data for certain tasks only.

The **Select all** and **Invert Selection** buttons select all data or invert the current selection. Click on **Group Items** to group maps or measurements that were created by editing an already existing one. The name of the group is the name of the underlying dataset.

The [Select Columns](#) button displays further columns for the selected data.

Export selection

Enable the checkbox next to the patient or task data to mark this dataset. Only marked datasets will be exported.

Click on the ☒ [Check Items](#) button in the left bottom corner to use predefined options for selection of datasets.

[All](#) selects all datasets, [None](#) deselects all datasets. The option [Last Task Data](#) selects the data last saved for each task. The option [Latest Configuration Data](#) selects the configuration data last saved and the associated maps.

Click on [Advanced Selection](#) to open the Advanced Selection dialog for even further refinement. [Advanced Selection](#) allows the user to limit the list of data to be selected for export by task type, number and date.

[Task Type](#) limits the selected data to certain task types. Click on the [All](#) or [None](#) buttons to select or deselect all task types. [Latest](#) defines how many of the last saved data will be preselected. [Date Range](#) defines a period. Only data generated during the selected period will be selected. [Begin / End](#) defines an accurate date period for which data will be selected. Only filters with enabled checkboxes are taken into account. The [Right](#) and [Left](#) buttons define if data of one side or both sides will be selected.

Click on [OK](#) to close the dialog and apply the settings for data display. Click on the [Close](#) button to close the Advanced Selection dialog without applying the settings.

Export options

Select the [Only export Patient Data](#) checkbox to export only patient data without any related tasks. Enable the [Anonymize Patient Name](#) checkbox to export data in anonymized form.

Click on the [Export](#) button to open a new browser window and save the export file to the desired directory. Export data as a MAESTRO Packed Database File (*.mpd) or a scientific XML File (*.xml). The scientific XML File is a text only XML file. Reimporting a scientific XML File into MAESTRO is not possible.

Click on the [Close](#) button to close the Export Data dialog and terminate export.

CAUTION:

Analysis of exported data must not be taken as the sole basis for any decision regarding further medical or surgical treatment.

Tips, Tricks and Troubleshooting

To export all tasks for a patient, select the patient in the patient list view and open the export dialog. All task data for this patient are already preselected.

7.1.2 MAESTRO data import

Select **Data** in the menu bar and choose the submenu **Import data** to open the import dialog.

The tool can also be started with a click on the related icon in the tool bar, if the toolbar was customized accordingly.

Click on the Browse button to select data for import. All *.xml (except scientific *.xml), *.xmlp and *.mpd files created by MAESTRO can be imported. The basic structure and the functions of the individual buttons are similar to the Data Export dialog.

7.1.3 CI.STUDIO+ data import

MAESTRO allows the user to import patient and fitting data from the CI.STUDIO+ fitting software.

Steps to import a CI.STUDIO+ file:

1. Open the **Settings** dialog from the menu bar and switch to the **Export/Import** submenu.
2. Use the Browse button to enter the directory where the CI.STUDIO+ files are located.
3. Open **Data** from the menu bar, navigate to **Import CI.STUDIO+ data** and choose the patient to import.
4. The patient data editor for this patient opens. Review the imported data, add missing patient information and save the data. The patient now appears in the patient list view.
5. Start a session for this patient and connect a processor.
6. Click on **New** in the menu bar and select **Fitting**.
7. The template section for new fitting maps displays a list of all available CI.STUDIO+ maps. Depending on the connected processor different strategy options are available. Choose the map with the desired coding strategy from the drop-down menu.
8. Click on the button next to the drop-down to open the fitting map for further fine tuning.

Legacy Mode

When a TEMPO+ processor is connected, the map opens first in legacy mode. In this mode the map is not converted and read-only. It can be saved and programmed to a processor, but not adjusted. Enable the related checkbox in the Notifications to convert the map and open it for further adjustments. The map will still be compatible with the CI.STUDIO+ software.

NOTE:

To perform an upgrade from TEMPO+ to another audio processor type, it is essential to convert the map.

7.2 REPORTS

MAESTRO offers the possibility to create different types of reports. Click on **Data** in the menu bar and choose the related submenu to open the Report dialog.

The tool can also be started with a click on the related icon in the tool bar, if the toolbar was customized accordingly.



Reports contains general reports for patient and tasks.



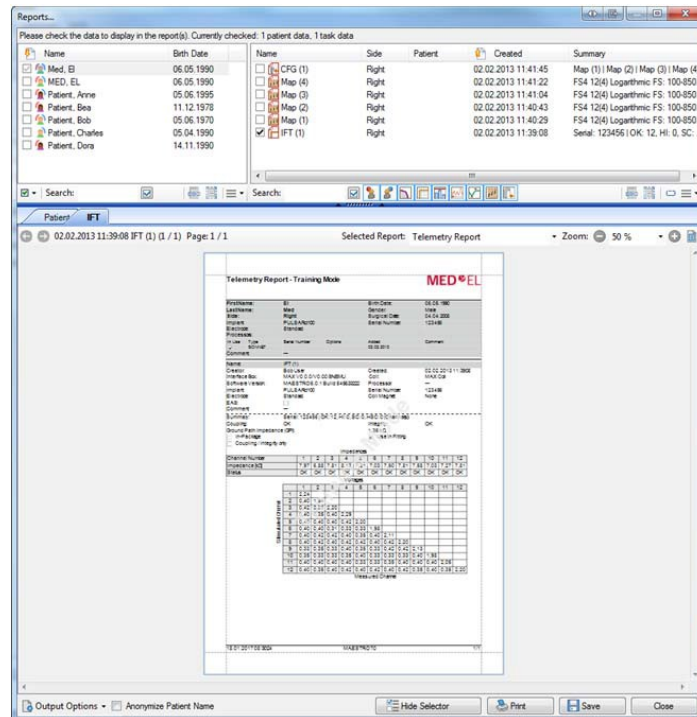
History Reports provides a section to set a specific period so that the report only contains patient or task data created in this period.



Session Reports creates a report which contains all task data related to a session.



User Reports creates a report containing information about MAESTRO users.



Reports

Filters

Define filters to limit the data for the report in the top section, called selector. Show or hide the selector by clicking on the [Show/Hide Selector](#) button at the bottom.

[User Reports](#) creates a report with information about all users and no additional selection options or filters are available.

For the other reports the left side contains a filter for the patients and the right side an additional filter for tasks, sessions or period.

For task data the following filters are available:

[Search](#) limits the displayed patient or task data to entries containing the character sequences entered in the [Search](#) field.

Activate the option [Show only Checked](#) to display only the enabled patient or task data.

Activate or deactivate the patient side icon to display or hide data for the left and right ear. Activate or deactivate the task icons to display the data for certain tasks only.

The [Select all](#) and [Invert Selection](#) buttons select all data or invert the current selection.

Click on [Group Items](#) to group maps or measurements that were created by editing an already existing one. The name of the group is the name of the underlying dataset. The [Select Columns](#) button displays further columns for the selected data.

For History Reports the following filters are available:

[Task Type](#) limits the selected data to certain task types. Click on the [All](#) or [None](#) buttons to select or deselect all task types. [Latest](#) defines how many of the last saved data will be preselected. [Date Range](#) defines a period. Only data generated during the selected period will be selected. [Begin / End](#) defines an accurate date period for which data will be selected. Only filters with enabled checkboxes are taken into account. The [Right](#) and [Left](#) buttons define if data of one side or both sides will be selected.

Report preview

Below the selector a preview of the report is shown with the option to zoom, switch between different pages and select detailed reports, where applicable. Anonymize the patient name by enabling the corresponding checkbox at the bottom of the window. Click on [Output Options](#) to choose the file format for the report, print comments, change the page settings, decide if patient data should be printed and print or save a report.

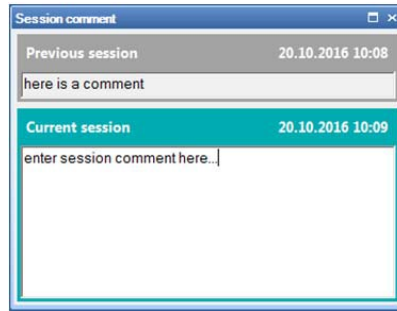
Tips, Tricks and Troubleshooting

The report for session can also be opened by a right click on the session name in the session timeline.

7.3 SESSION COMMENT

Click on [Tools - Session comment](#) or on the icon in the toolbar to open the comment dialog. Precondition for availability of this tool is a started session.

Enter session comments for the current session into the text field while working with MAESTRO. These comments are then displayed next to the session in the session timeline. If a comment was entered for the previous session, the comment dialog also displays this comment as a read-only field. Click on the icon in the toolbar again to close the comment dialog.



Session comment

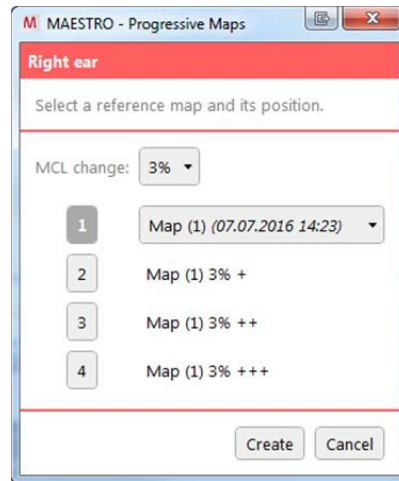
7.4 TALK MODE

This tool is available during a session and with at least one connected and programmed processor. Click on **Tools | Talk** or on the related processor icon in the toolbar to enable the talk mode. Disable it by a second click onto the icon. For bilateral patients with two processors connected the icon is split into three parts to activate the right processor, the left processor or both processors simultaneously.

The talk mode activates the current processor program of a connected processor, the MAX Programming Interface acts like a battery pack. The current processor program including volume and sensitivity which is activated by the talk mode is indicated in the status bar.

7.5 PROGRESSIVE MAPS

This tool is available during a session and with at least one connected processor. Create additional fitting maps based on a given map with adjusted MCL values according to a given percentage value. Open the Options menu in the configuration panel of the Session view and choose the option **Individual progressive maps**. The progressive maps tool opens.



Progressive maps dialog

Select the percentage which shall be used for creation of progressive maps from the drop-down menu **MCL change**. Choose the position of the base map by selecting the related program position number. Select the base map from the drop-down menu which appears next to the chosen position number. The other positions then give a preview of how the progressive maps will be created and named.

Progressive maps are created by changing the MCL value of the map according to the entered percentage. For progressive maps on a higher position number than the base map, the MCL is increased (indicated by + symbols), for maps on a lower position number the MCL is decreased (indicated by - symbols).

Tips, Tricks and Troubleshooting

See chapter **Session - Configuration panel** on how to use predefined settings for simple progressive maps.

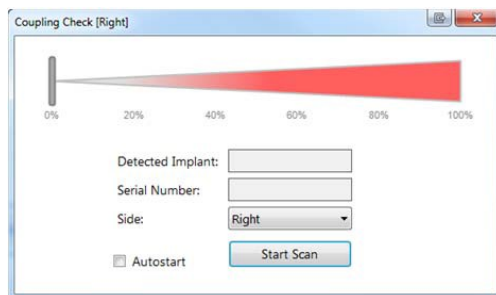
7.6 COUPLING CHECK

Select **Tools** in the menu bar and choose the submenu **Coupling Check** to open the Coupling Check dialog. Precondition for availability of this tool is a started session.

The tool can also be started with a click on the related icon in the tool bar, if the toolbar was customized accordingly.

The tool allows the user to search for implants with readable serial number.

Connect the MAX coil that corresponds to the patient's implant type to the telemetry socket of the MAX Programming Interface and place the coil on the patient's head.
To use the DL-Coil, connect the processor with DL-Coil to the MAX Programming Interface and place the coil on the patient's head, see chapter **Setup - Measurements with DL-Coil**.



Coupling Check

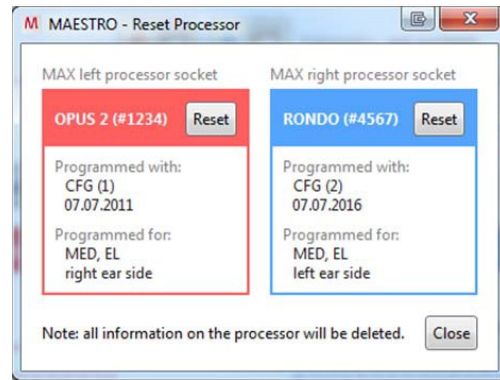
Choose the side from the drop down menu and click on **Start Scan** to start searching for the implant. If the implant could be detected, the implant type and serial number are displayed.

Tips, Tricks and Troubleshooting

Enable the **Autostart** checkbox to always start the scan automatically after the tool opened.

7.7 RESET PROCESSOR

Select **Tools** in the menu bar and choose the submenu **Reset Processor** to open the Reset Processor dialog.



Reset processor dialog

Processors connected to the sockets of the MAX Programming Interface are displayed with type and serial number. For programmed processor additional information such as patient name, side and name of the programmed configuration are indicated.

If applicable, information about the processor coil is displayed too.

If a session for a patient with DUET 2 is ongoing and a DUET 2 is connected to the computer via a HI-PRO, a separate section to reset the DUET 2 is available.

Click on the [Reset](#) button to delete all data stored on the processor and reset the processor. Be aware that a connected DL-Coil will be reset too, i.e. link monitoring parameters are set to their defaults.

Click [Cancel](#) to close the Reset Processor dialog without resetting the processor.

NOTE:

Be aware that resetting the processor will delete all patient and map specific data stored on the processor.

7.8 DUPLICATE TASK DATA

Select [Tools](#) in the menu bar and choose the submenu [Duplicate task data](#) to duplicate a task.

The tool can also be started with a click on the related icon in the tool bar, if the toolbar was customized accordingly.

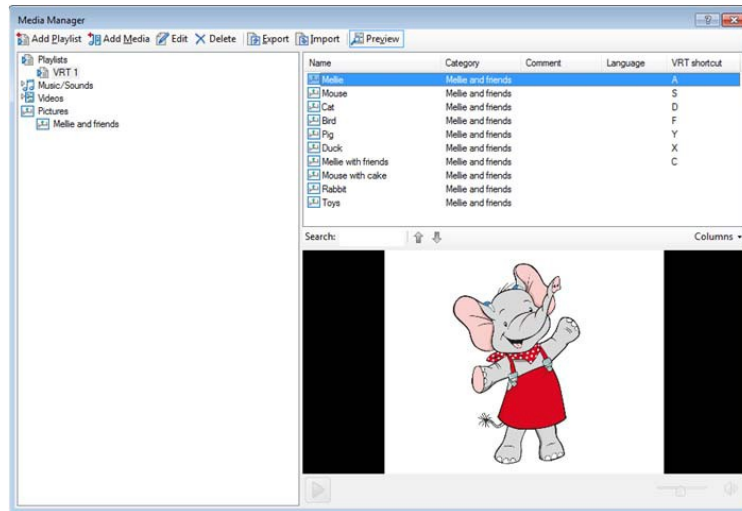
Precondition for availability of this tool is a started session and an opened task.

A duplicate of the opened task is generated and indicated by a ~ symbol in the name. The original task remains untouched.

7.9 MEDIA MANAGER

Select **Tools** in the menu bar and choose the submenu **Media Manager** to open the media manager dialog.

The Media Manager is intended to manage media files (such as audio, video and image files) and playlists used in the Media Player and the Visual Reinforcement Tool (VRT) of the fitting task.



Media Manager

The user interface of the Media Manager tool consists of four parts:

- The toolbar on the top provides the essential functions of the Media Manager.
- The playlist and category tree view on the left side provides a hierarchical view of the media library contents. It displays playlists and media categories grouped by media type such as music/sound, pictures or videos.
- The media list on the top right side displays the content of a media category selected in the tree view.
- The preview on the bottom right side displays the content of a selected media item. Adjust the volume by using the volume slider and mute or unmute by clicking on the speaker symbol.

Media files

Click on **Add Media** to open the Add Media dialog. Enter name and file path of the media, optionally also enter a category, comment or language. If no category is entered, the

media file is automatically assigned to the category [General](#). Already used entries for category and language are displayed as options in the drop-down menu.

Playlists

Click on [Add Playlist](#) to open the Add Playlist dialog and create a new playlist. Media files can be added to a playlist easily either via drag and drop from the media list or via drag and drop from the Windows File Explorer directly to a playlist. Within a playlist the first seven items are assigned to the VRT keys used in the fitting task.

Working with media

The Media Manager already contains a set of sample pictures and a sample playlist by default.

Click on the [Edit](#) and [Delete](#) buttons to edit or delete selected media files or playlists. Categories cannot be deleted but disappear automatically when they are no longer used. Click on [Export](#) to export the media library to a single .pml (Packed Media Library) file. Click on [Import](#) or drag-and-drop from the Windows File Explorer to import a Packed Media Library file. Click on [Preview](#) to switch between displaying and hiding the preview window.

NOTE:

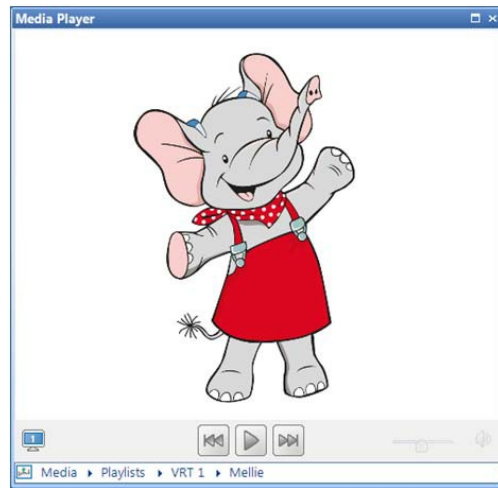
Opening images, videos or songs of high resolution or long play duration for display needs more time.

Tips, Tricks and Troubleshooting

New media files can also be imported by dragging them from the Windows Explorer into the Media Manager tree view or directly to a playlist.

7.10 MEDIA PLAYER

Select [Tools](#) in the menu bar and choose the submenu [Media Player](#) to open the media player. Use this tool to play music and video files or to view images within MAESTRO.



Media Player

Media selection

The bottom line displays the current playlist, category and media item. Click on the arrow next to a category, playlist or media item to open a drop-down menu and select a different option. Additionally, the [Next](#) and [Previous](#) buttons can be used to navigate between different media items.

Start or stop playback of a selected video clip or music file by clicking on the [Start/Stop](#) button. Adjust the volume by using the volume slider and mute or unmute by clicking on the speaker symbol.

Full-screen-playback

The Media Player also supports full-screen playback on an additional monitor. Before using additional full-screen monitors in MAESTRO, they have to be configured in [Settings | Media/VRT](#). Enable the monitor pictogram in the lower left corner to use full-screen playback. A full-screen monitor set to disabled will not show any images or videos until it is enabled.

Tips, Tricks and Troubleshooting

The monitor pictogram for full-screen playback is only displayed, when additional monitors are configured in the Media/VRT settings.

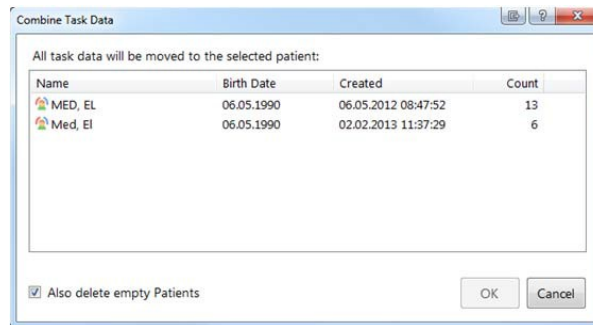
7.11 CHANGE PASSWORD

Select [Tools](#) in the menu bar and choose the submenu [Change Password](#) to open the Change Password dialog. Change the password for the currently logged-in MAESTRO user with this tool.

7.12 COMBINE TASK DATA

Merges the data of two patients into one dataset, if for example the same patient was entered twice into the patient database by mistake. Precondition to start the tool is that first name, last name, date of birth and implant system (implant type, electrode type and implanted side) are identical in both patient entries.

Select the patient entries in the patient list view and click on the [Combine task data](#) option on the right side of the screen. The dialog to combine the task data opens. Select the patient who should be kept. All tasks of the other patient is transferred to this patient. The remaining empty patient data set is deleted. Disable the checkbox if the remaining patient data set shall not be deleted automatically.



Combine Task Data

Tips, Tricks and Troubleshooting

The tool is also available in the menu [Tools](#).

7.13 TILE AND UNTILE EDITORS

Select [View](#) in the menu bar and choose the related submenu to tile and untile the user interface.

The tool can also be started with a click on the related icon in the tool bar, if the toolbar was customized accordingly.

Precondition to split the user interface is an ongoing session for a bilateral patient and opened tasks for both sides.

Click [Tile editors horizontally by ear side](#) or [Tile editors vertically by ear side](#) and all opened tasks for this patients will then be separated into two groups. Tasks for the right ear can be found on top or on the left side of the divided user interface while tasks for the left ear will be displayed at the bottom or on the right side.

Click [Untile editors](#) to arrange all open tasks into tabs of the work view.

7.14 RESET USER INTERFACE LAYOUT

Select [View](#) in the menu bar and choose the submenu [Reset user interface layout](#) to reset the layout of the MAESTRO user interface to the default settings.

7.15 ACKNOWLEDGE NEXT NOTIFICATION

Some notifications need to be confirmed before work can be continued. Confirm Notifications by clicking on the related checkbox next to the notification or by clicking on [Tool](#) and selecting the submenu [Acknowledge Next Notification](#) which automatically enables the checkbox next to the notification.

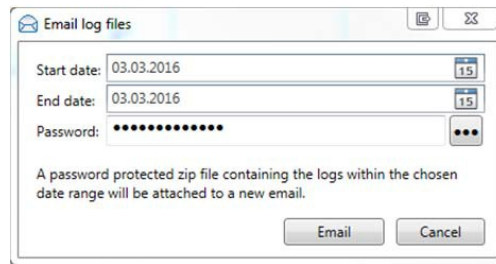
7.16 LOG FILES

Actions done by the user in the MAESTRO software and accompanying applications are tracked and saved into log files. Logging is started automatically and saved as a separate file for each day. Therefore, one log file may contain data of several sessions and users. The log file is mainly used to record error messages, communication problems, etc and is not intended to be used in a standard clinical session. It can, however, be referred to when it is necessary to track issues, especially if it is necessary to refer to a MED-EL representative for troubleshooting. With the log file it is much easier to identify the cause of a problem. The log file is saved in English and, if applicable, also in the currently used language of MAESTRO.

The log file is automatically saved to the MAESTRO standard directory for log files with the relevant date. It can be accessed by Windows via the Windows program group MED-EL in the Start menu or via the Apps window (Windows 8 and later).

The log file can also be sent to a MED-EL clinical engineer for troubleshooting as email using the MAESTRO tool [Email log files](#). Precondition is an installed email client.

1. Select [Tools](#) in the menu bar and click on [Email log files](#) to open the email log files dialog.
2. Define a period. Enter the desired dates to determine which log files will be sent.
3. Define a password for the files. The default password is 'MEDEL MAESTRO'.
4. Click on the [Email](#) button to open a new email in the installed email client. The log files are attached to the email as password-protected zip file.



Email log files dialog

It is also possible to display the most relevant log entries within MAESTRO. Select [View](#) in the menu bar and choose the submenu [Log](#) to open the Log window.

Tips, Tricks and Troubleshooting

- The Email Log Files tool only works with an email client installed on your computer, it does not work with web mail. When using web mail, the log files have to be copied from the log files folder and attached to an email manually by the user.
- Click on  to display the password as dots or in clear text.

7.17 PRODUCT ACTIVATION KEY CHANGE TOOL

Select [Tools](#) in the menu bar and choose the submenu [Change product activation key](#) to open the MAESTRO Product Activation Key Change Tool. The tool is only available if the currently logged in user has administrative rights in MAESTRO.

Enter the new product activation key and accept the end-user license agreement. Click on [Apply & Restart](#) to apply the new key and restart MAESTRO. The Product Activation Key

Change Tool is also available as accompanying application, see chapter **Additional Applications - Product Activation Key Change Tool**.

8 User Management

Launching MAESTRO requires user identification.

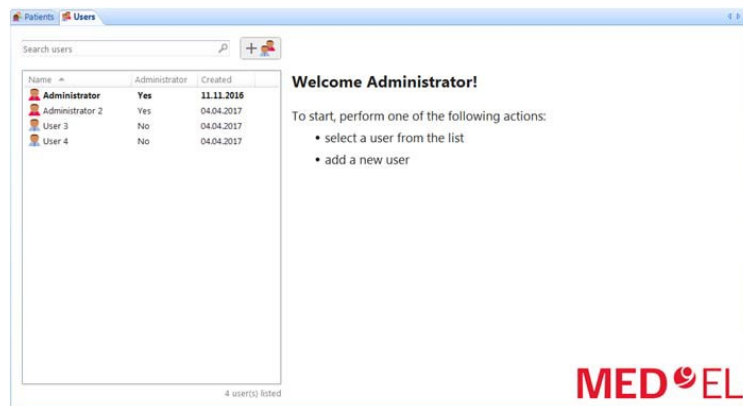
Set up a separate MAESTRO user for every person working with the application. Adjust settings and assign specific rights to the MAESTRO user accordingly.

8.1 USER LIST VIEW

The user list is only available for MAESTRO users with administrative rights.

Open the user list by clicking on [View | User management](#) in the menu. Close the user list by clicking on the close icon for the [Users](#) tab.

The [Users](#) tab provides a list of all users in the database, a search field to search for certain users and a button to add new user records. Different possible actions for the selected user are displayed on the right side.



Users tab

User list

This list displays stored users and also important information such as user name and creation date of the record. The column [Administrator](#) indicates if the user has administrative rights. The currently logged in user is highlighted in bold font.

A left mouse click on the column name sorts the user list in ascending order, a second click sorts the list in descending order. A right mouse click on one of the column names opens a menu to

- display additional columns like creator, ID and comments to a user.
- hide currently displayed columns.

- automatically resize this column to fit its content.
- automatically resize all columns to fit their content.

Change the order of the columns simply by drag and drop.

A right mouse click on the name of the user in the user list opens a menu with the options to edit or delete the user and to create a user report.

Search users

Enter the text to search for into the search field above the user list and the user list automatically displays the search results. Delete the entered text or click on the close symbol next to the search field to show the complete user list again.

Actions for selected users

Select one or more users from the list. The right side provides an overview of several possible actions:

- Edit users: Opens the user data editors for the selected users.
- Delete users: Deletes users from the database.
- Create report: Opens the report dialog for these users.

NOTE:

Be careful when deleting users. At least one user should have administrative rights.

8.2 CREATE OR EDIT A USER RECORD

Administrator rights are required to create a new user or edit an existing user record.

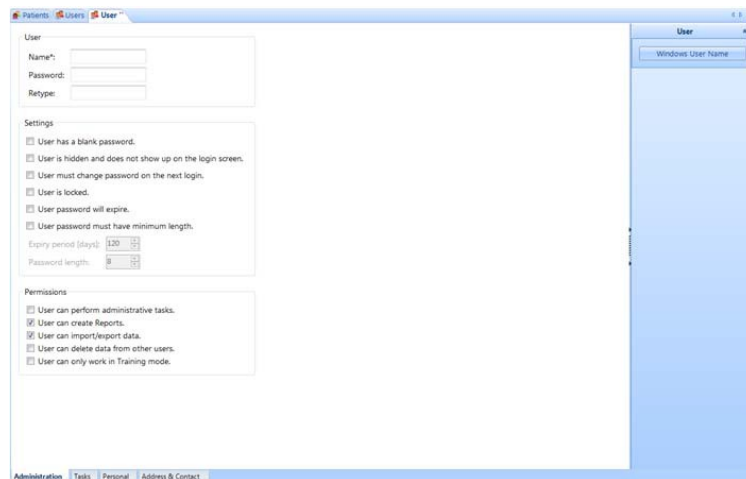
Click on the button in the user list view or navigate to the menu bar [New - User](#) to create a new user record.

Right click on the user name in the list and select [Edit User](#) from the displayed menu to edit the user record.

All relevant information for a user can be entered or edited – personal information such as name or address as well as information about the user rights – in the user data editor.

The user data editor is divided into the editors **Administration editor**, **Tasks editor**, **Personal editor**, **Address and Contact editor**.

8.2.1 Administration editor

The screenshot shows a software window titled 'Administration editor' with a tabbed interface. The 'Users' tab is active, and within it, the 'User' sub-tab is selected. The 'User' section contains three input fields: 'Name:', 'Password:', and 'Retype:'. Below these is the 'Settings' section with several checkboxes: 'User has a blank password.', 'User is hidden and does not show up on the login screen.', 'User must change password on the next login.', 'User is locked.', 'User password will expire.', and 'User password must have minimum length.'. There are also two spinners for 'Expiry period (days)' (set to 120) and 'Password length' (set to 8). The 'Permissions' section has five checkboxes: 'User can perform administrative tasks.', 'User can create Reports.', 'User can import/export data.', 'User can delete data from other users.', and 'User can only work in Training mode.'. On the right side of the window, there is a 'Windows User Name' button. At the bottom, there are tabs for 'Administration', 'Tasks', 'Personal', and 'Address & Contact'.

Administration editor

Enter name and password for a new user in the applicable input field in the [User](#) section. Confirm the password by retyping it in the [Retype](#) field. Click on the [Windows User Name](#) button to use the name of the currently logged-in Windows user as user name.

Settings

Select the applicable checkbox in the [Settings](#) section to set the following user settings:

- User has a blank password: Automatically greys out the fields [Password](#) and [Retype](#).
- User is hidden and does not show up on the login screen: The user name will not be displayed in the user list of the launch window, but a login as this user is possible.
- User must change password on the next login.
- User is locked: Login as this user is no longer possible.
- User password will expire: Defines the number of days until the password expires.
- User password must have minimum length: Defines the minimum number of characters the password shall have.

General permissions

Select the applicable checkbox in the [Permissions](#) section to set the following access rights:

- User can perform administrative tasks: The user has administrator rights.
- User can create Reports.
- User can import/export data.
- User can delete data from other users.

- User can only work in Training mode.

The default user settings provide access rights to create reports and import and export data. The other options are deactivated.

8.2.2 Tasks editor

The Tasks editor lists all task types for intraoperative and postoperative sessions. Select the applicable checkbox to enable a certain task type for the user. This task type is then available for the user during the session.

8.2.3 Personal editor

Enter or edit personal information of a user such as title, first name, middle name, last name, birth date, gender, ID and a comment. Click on [Browse Picture...](#) to load a picture of the user. Click on [Remove Picture](#) to delete the picture from the account.

8.2.4 Address and Contact editor

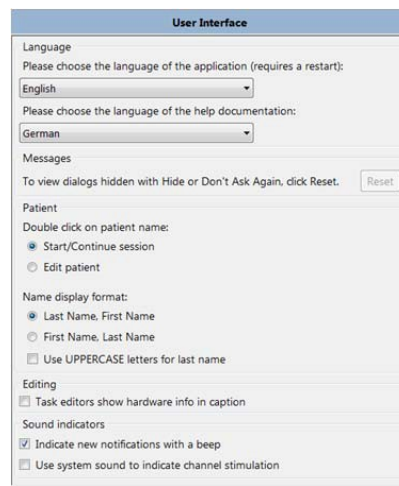
Enter or edit address and contact information of a user such as phone, mobile, fax and email address. Click on [Clear All](#) to delete the entered data.

9 Settings

Click **Settings** in the menu bar and choose the submenu **Settings management** to open the settings dialog. The settings dialog offers the possibility to modify MAESTRO to reflect the users' preferences.

It provides menus to change the user interface, to switch between different hardware modes, to import CI.STUDIO+ files and to adjust warning levels. Although MAESTRO offers well developed default values for parameters in all tasks, a user may want to change the default for certain parameters. One main feature of the settings dialog is, therefore, the possibility to set the default values for parameters used in the tasks.

9.1 USER INTERFACE



User Interface settings dialog

Open the settings dialog and choose the submenu **User Interface** to customize the user interface.

Made changes will take effect after closing the settings dialog.

Language

Select the language of the application and the help documentation after installing the corresponding language pack and help file. A restart of the application is necessary.

Messages

Press the [Reset](#) button to display hidden dialogs again.

Patient

Define if a double click on the patient name shall start/continue a session or open the patient data editor by clicking on the corresponding radio button. Switch the order of the displayed first name and surname by clicking on the applicable radio button. Enable the checkbox to display the surname of the patient in uppercase letters.

Editing

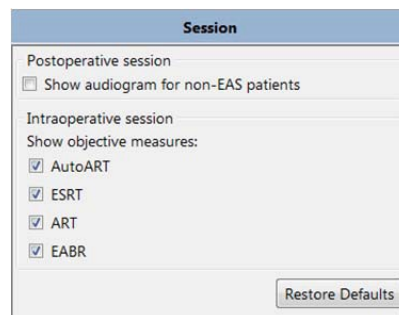
Enable the checkbox to display hardware information in the title of the task.

Sound indicators

Enable the [Indicate new notifications with a beep](#) checkbox and the system emits a beep when a new warning message is displayed.

With the [Use system sound to indicate channel stimulation](#) checkbox selected, the system sound is used to indicate a stimulation.

9.2 SESSION



Session settings dialog

Open the settings dialog and choose the submenu [Session](#) to customize the session view. Made changes will take effect after closing the settings dialog.

Postoperative session

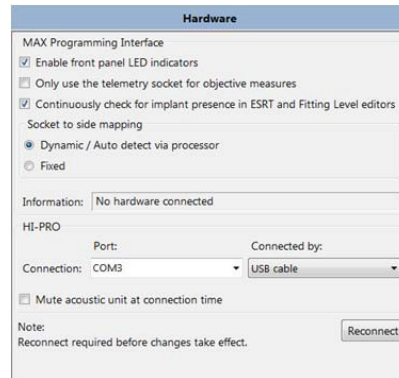
Enable the checkbox to always display an audiogram panel in the session view.

Settings

Intraoperative session

Enable the checkbox of a certain task type to display it in the objective measures panel of the intraoperative session view.

9.3 HARDWARE



Hardware settings dialog

Open the settings dialog and choose the submenu [Hardware](#) to check or adjust the hardware connections.

Modified settings will be effective after pressing [Reconnect](#), or after restarting the software.

After MAESTRO has identified connected hardware, this information is also displayed in the status bar at the bottom of the MAESTRO window.

MAX Programming Interface

Select the [Enable front panel LED indicators](#) checkbox to enable the LEDs on the MAX Programming Interface.

Enable the [Only use the telemetry socket for objective measures](#) checkbox to always use the telemetry socket in combination with a MAX coil when performing objective measurements. Disable the checkbox to use a connected DL-Coil for measurements.

Enable the checkbox [Continuously check for implant presence in ESRT and Fitting Level editors](#) to perform a link check in ESRT. The link check functionality in Fitting task is only available in combination with a DL-Coil and an implant type with readable serial number.

In the section [Socket to side mapping](#) decide to use either dynamic mode or fixed mode functionality of the MAX Programming Interface. The information line displays information about the connected MAX Programming Interface.

HI-PRO

Select the port for a connected HI-PRO interface box. [Connected by](#) determines whether the HI-PRO interface box is connected via a USB cable or a COM port cable. Enable the checkbox to automatically deactivate the acoustic unit of the DUET 2 audio processor when connected to the HI-PRO interface box.

9.4 SITE INFORMATION

The image shows a software dialog box titled "Site Information". It has a light blue header bar with the title. Below the header, there are three input fields. The first is labeled "Location" and is a text box. The second is labeled "Short title:" and is a text box. The third is labeled "Full title:" and is a larger text box. The dialog box has a standard Windows-style border with a title bar and a close button in the top right corner.

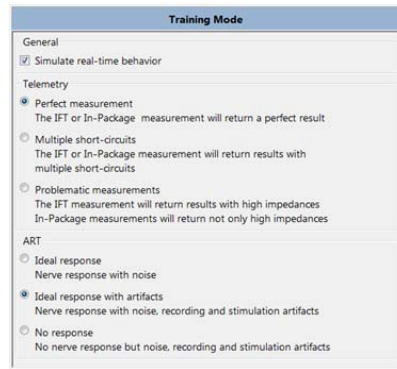
Site Information settings dialog

Open the settings dialog and choose the submenu [Site Information](#) to enter information.

Changes are applied when closing the settings dialog.

The entered information in the field [Short title](#) (e.g., name of the clinic) will be printed on reports as additional information.

9.5 TRAINING MODE



Training Mode settings dialog

Open the settings dialog and choose the submenu [Training Mode](#) to change the behavior of the application in training mode. The submenu is only available when MAESTRO was launched in training mode.

Changes are applied when closing the settings dialog.

General

Select the [Simulate real-time behavior](#) checkbox and measurements performed in the Training Mode will have real-time durations. This checkbox is selected by default so that all measurements in the Training Mode are performed in real-time.

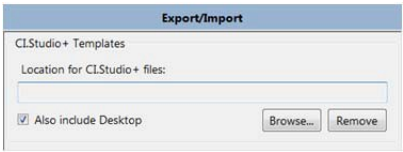
Telemetry

Select the applicable option to define the simulated telemetry results. Options are [Perfect measurement](#), [Multiple short-circuits](#) and [Problematic measurements](#). The default is [Perfect measurement](#).

ART

Select the applicable option to define the results of the simulated ART measurements. Options are [Ideal response](#), [Ideal response with artifacts](#) and [No response](#). The default is [Ideal response with artifacts](#).

9.6 EXPORT/IMPORT



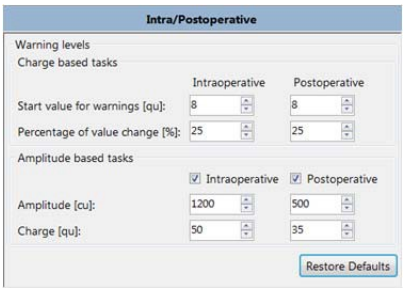
Export/Import settings dialog

Open the settings dialog and choose the submenu [Export/Import](#) to set the directory for importing CL.STUDIO+ templates.

Changes are applied when closing the settings dialog.

Click on the [Browse](#) button to set the path to the directory containing CL.STUDIO+ export files. To include all files on the desktop enable the [Also include Desktop](#) checkbox. The checkbox is enabled by default.

9.7 INTRA/POSTOPERATIVE



Intra/Postoperative settings dialog

Open the settings dialog and choose the submenu [Intra/Postoperative](#) to change warning levels for intraoperative and postoperative sessions.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Settings

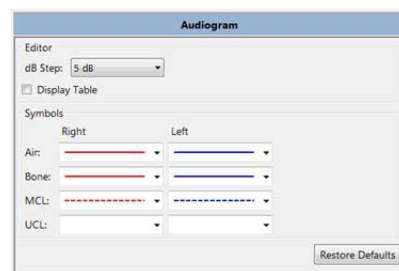
Warning levels

Before MAESTRO stimulates an entered charge, it compares the newly entered value with an already made stimulation. For safety reasons it displays a warning message that has to be accepted by the user if the desired charge was increased in too large a step or exceeds a predefined limit.

Set the start value for warnings for intraoperative and postoperative sessions in [Start value for warnings \[qu\]](#). In addition, the percentage of value change for warnings can be defined. Those warning levels take effect whenever charge is increased.

Warning levels for amplitude-based tasks can also be defined for intraoperative and postoperative sessions. A message informs the user in the amplitude based task, when the amplitude threshold in cu or the charge threshold in qu is above the entered limit.

9.8 AUDIOGRAM



Audiogram settings dialog

Open the settings dialog and choose the submenu [Audiogram](#) to change default values and parameters of the Audiogram task.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Editor

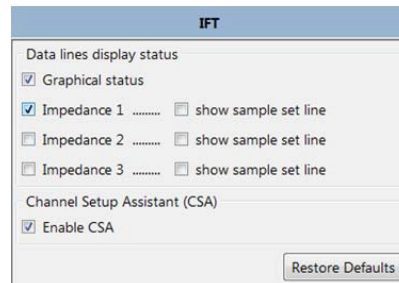
Adjust the step size in dB HL. The step size defines the distance between two data points along the ordinate when entering data. Step sizes of 1 dB HL, 2 dB HL and 5 dB HL are available. The default step size is 5 dB HL.

Enable or disable the [Display Table](#) checkbox to define if the table with numerical values is displayed for newly created Audiogram tasks. [Display Table](#) is disabled by default.

Symbols

Set different line types to connect data points of air or bone conduction thresholds and MCL or UCL thresholds. The default lines for air and bone conduction thresholds are solid, dashed lines are used for MCL and no lines for UCL.

9.9 IFT



Telemetry settings dialog

Open the settings dialog and choose the submenu **IFT** to change default values and parameters of the Telemetry task.

Changes are applied when closing the settings dialog.

Click on the **Restore Defaults** button to set all values back to the original MAESTRO defaults.

Data lines display status

Select the **Graphical status** checkbox to graphically display the current telemetry measurements in the Telemetry editor. By default the checkbox is enabled. Select the **Impedance 1**, **Impedance 2** and **Impedance 3** checkboxes to display results of up to the last three historic telemetry measurements as numerical values in the related table in the Telemetry editor. By default, only the **Impedance 1** checkbox is enabled to display the results of the last telemetry measurement. Select the **show sample set line** checkbox to graphically display the results of the corresponding historic telemetry measurement.

Channel Setup Assistant (CSA)

Enable the **Enable CSA** checkbox to display the CSA suggestions after each new telemetry measurement. The checkbox is enabled by default.

9.10 ESRT

ESRT

Stimulation

Burst duration [ms]:

500

Max. Rate [pps]:

2000

☐ Continuous Stimulation

Burst gap [ms]:

500

Burst count:

3

☐ Automatic value change

Auto. value change limit [qu] :

15

Step size [%]:

1

During stimulation use:

☒ visual indication

☒ audio indication

Data input

Default Minimum Duration [μs]:

☐ 0,00

Reflex value algorithm:

☒ Median

☐ Mean

☐ Lowest

Default values for new measurements

Zoom factor:

7

Display following channel values:

☒ Amplitude

☒ Impedance

☒ Telemetry Status

Restore Defaults

ESRT settings dialog

Open the settings dialog and choose the submenu [ESRT](#) to change default values and parameters of the ESRT task.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Stimulation

Customize the default values of the stimulation parameters of the ESRT task in this section.

Parameter	Minimum	Maximum	Default
Burst duration [ms]	50	1000	500
Max. Rate [pps]	0	4225	2000
Continuous Stimulation	disabled	enabled	disabled
Burst gap [ms]	200	1000	500
Burst count	1	10	3
Automatic value change	disabled	enabled	disabled
Auto. value change limit [qu]	0	287	15
Step size [%]	0	15	1
visual indication	disabled	enabled	enabled
audio indication	disabled	enabled	enabled

Parameters of the Stimulation section

The checkboxes [visual indication](#) and [audio indication](#) define whether visual indication or audio indication will be used during stimulation.

[Audio indication](#) will create a sound signal on the computer when stimulation occurs, [visual indication](#) will display a red horizontal line at stimulation level.

Data input

Change the minimum duration and how the stapedius reflex threshold is determined in this section.

Parameter	Minimum	Maximum	Default
Default Minimum Duration [ms]	0	200	0
Reflex value algorithm	Lowest	Mean	Median

Parameters of the Data input section

Default values for new measurements

Define the default display of optional parameters in the table. By default, [Amplitude](#), [Impedance](#) and [Telemetry Status](#) are enabled. In addition, the [Zoom Factor](#) can be customized.

Parameter	Minimum	Maximum	Default
Zoom factor	1	15	7

Parameters of the Default values for new measurements section

9.11 EABR

EABR

Stimulation pattern

Phase duration [µs] 40

Active channels ☒ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12

Cycles

Number 500

Rate [Hz] 34

☒ Alternating polarity

Timing of bursts

☒ Simultaneous

☐ Sequential

Pulse distance [µs] 0

After stimulation

Radio frequency (RF)

☒ Do not apply settings to new data

☐ Turn off RF

RF-off period [ms] 8

Power-on sequence

☒ Send power-on sequence

☐ Apply power-on duration

Duration [ms] 16

Trigger settings

☐ Wait for external trigger

☒ Create trigger signal

Duration [µs] 100

Offset [µs] 0

☒ Positive

☐ Negative

Editor

☐ Ampl. step size [cu] 25

Zoom factor 1

☐ Multiple channel selection

View additional information

☒ Amplitude [%]

☒ 1st Charge [qu]

☐ 2nd Charge [qu]

☐ 3rd Charge [qu]

☒ Impedance [kΩ]

☐ Compl. Lim. [cu]

Restore Defaults

EABR settings dialog

Open the settings dialog and choose the submenu **EABR** to change default values and parameters of the EABR task.

Changes are applied when closing the settings dialog.

Click on the **Restore Defaults** button to set all values back to the original MAESTRO defaults.

Stimulation pattern

Define the default phase duration in this section. The default phase duration depends on pulse type and implant type.

Pulse Type	Implant	Minimum	Maximum	Default
Biphasic, Precision Triphasic	C40+	53.3	400	53.3
Biphasic, Triphasic, Precision Triphasic	SYNCHRONY	25	400	40
Biphasic, Triphasic, Precision Triphasic	MED-EL CONCERT	25	400	40
Biphasic, Triphasic, Precision Triphasic	SONATA	25	400	40
Biphasic, Triphasic, Precision Triphasic	PULSAR	25	400	40
Triphasic	C40+	106.7	400	106.7

Phase duration in [μ s]

The **Active channels** checkbox defines which channels are selected and highlighted in grey when opening the EABR task.

Adjust the further default values in the subsections **Cycles**, **Pulse characteristics**, **Timing of bursts** and **Options**.

Parameter	Minimum	Maximum	Default
Number of cycles	100	5000	500
Rate [Hz]	0.1	150	34
Alternating polarity	disabled	enabled	enabled
Pulse characteristic	-	-	Biphasic pulse
Initial phase	negative	positive	negative
External artifact reduction	disabled	enabled	disabled

Parameters of the Stimulation pattern section

Implant	Minimum	Maximum	Default
C40+	sequential	sequential	sequential
SYNCHRONY	sequential	simultaneous	simultaneous
MED-EL CONCERT	sequential	simultaneous	simultaneous
SONATA	sequential	simultaneous	simultaneous
PULSAR	sequential	simultaneous	simultaneous

Timing of bursts

Implant	Minimum	Maximum	Default
C40+	0	1000	0
SYNCHRONY	2	1000	2
MED-EL CONCERT	2	1000	2
SONATA	2	1000	2
PULSAR	2	1000	2

Pulse distance in [μ s]

Settings

After stimulation

Adjust the default values for the behavior after stimulation in this section.

Parameter	Minimum	Maximum	Default
Do not apply settings to new data	disabled	enabled	enabled
Turn off RF	disabled	enabled	disabled
RF-off period [ms]	0.5	30	8
Send power-on sequence	disabled	enabled	enabled
Apply power on-duration	disabled	enabled	disabled
Duration [ms]	0	54	16

Parameters for After stimulation section

The entered parameters are not used for new EABR measurements if the [Do not apply settings to new data](#) checkbox is enabled.

Trigger settings

Choose to either create a trigger signal or wait for a trigger signal by selecting the applicable radio button.

Parameter	Minimum	Maximum	Default
Trigger offset [μ s]	-100	100	0
Duration of trigger signal [μ s]	10	400	100
Polarity of trigger signal	negative	positive	positive

Parameters for Trigger settings section

Editor

Define the step size to increase or decrease the amplitude.

Select the [Multiple channel selection](#) checkbox to activate the multiple channel selection option as default. To view additional information, select the appropriate checkboxes. By default, [Amplitude](#), [1st Charge](#) and [Impedance](#) are selected.

In addition, the [Zoom factor](#) can be customized.

Parameter	Minimum	Maximum	Default
Ampl. Step size [checkbox]	disabled	enabled	disabled
Ampl. Step size [cu]	10	500	25
Zoom factor	1	15	1
Multiple channel selection	disabled	enabled	disabled

Parameters for Editor section

9.12 AUTOART

AutoART													
Basic setup													
	<table border="1"> <thead> <tr> <th>Intraoperative</th> <th>Postoperative</th> </tr> </thead> <tbody> <tr> <td>Maximum charge [qu]: 35</td> <td>Maximum charge [qu]: 30</td> </tr> <tr> <td>Rate of charge increase: Fast</td> <td>Rate of charge increase: Medium</td> </tr> <tr> <td>Stimulation rate [Hz]: 80</td> <td>Stimulation rate [Hz]: 60</td> </tr> <tr> <td>Measure until ECAP threshold is detected: ☐</td> <td>Measure until ECAP threshold is detected: ☒</td> </tr> <tr> <td>Initial pre-check of ECAP presence at maximum charge: ☒</td> <td></td> </tr> </tbody> </table>	Intraoperative	Postoperative	Maximum charge [qu]: 35	Maximum charge [qu]: 30	Rate of charge increase: Fast	Rate of charge increase: Medium	Stimulation rate [Hz]: 80	Stimulation rate [Hz]: 60	Measure until ECAP threshold is detected: ☐	Measure until ECAP threshold is detected: ☒	Initial pre-check of ECAP presence at maximum charge: ☒	
Intraoperative	Postoperative												
Maximum charge [qu]: 35	Maximum charge [qu]: 30												
Rate of charge increase: Fast	Rate of charge increase: Medium												
Stimulation rate [Hz]: 80	Stimulation rate [Hz]: 60												
Measure until ECAP threshold is detected: ☐	Measure until ECAP threshold is detected: ☒												
Initial pre-check of ECAP presence at maximum charge: ☒													
Advanced setup													
Minimum phase duration [μs]: 40													
Interphase gap [μs]: 2.1													
Maximum recording electrodes: 4													
Results													
Number of displayed responses: 5													
Restore Defaults													

AutoART settings dialog

Open the settings dialog and choose the submenu [AutoART](#) to change default values and parameters of the AutoART task.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Basic setup

Define the stimulation parameters for intraoperative and postoperative sessions. [Maximum charge](#) gives the maximum charge applied during stimulation, [Rate of charge increase](#) gives the rate at which the charge is increased until it reaches the maximum charge. [Stimulation rate](#) can be set in Hz. A checkbox defines if the measurement will stop automatically when ECAP threshold is detected or if the measurement is performed until the maximum charge is reached. Per default the measurement stops in postoperative sessions and measures until maximum charge in intraoperative sessions. The initial pre-check checkbox is an additional feature for intraoperative sessions. Before an AutoART measurement is started, a check for ECAP is done at maximum charge. The pre-check checkbox is enabled per default.

Settings

Parameter	Minimum	Maximum	Default
Maximum charge [qu]	0	120	35 (intraoperative) 30 (postoperative)
Rate of charge increase	Slow	Fast	Fast (intraoperative) Medium (postoperative)
Stimulation rate [Hz]	10	80	80 (intraoperative) 60 (postoperative)

Stimulation parameters

Advanced setup

Customize advanced measurement parameters of the AutoART task such as the minimum phase duration used for stimulation, the interphase gap of stimulation pulses and the maximum number of recording electrodes.

Parameter	Minimum	Maximum	Default
Minimum phase duration [μs]	20	100	40
Interphase gap [μs]	2.1	30	2.1
Maximum recording electrodes	2	11	4

Advanced parameters

Results

Adjust the number of displayed responses in the detailed view of the AutoART task.

Parameter	Minimum	Maximum	Default
Number of displayed responses	3	20	5

Result parameters

9.13 ART

ART

Safety
☒ Initial coupling check

ART profile offsets

Offset of recording electrode

Offset of stimulating electrode

-3

0

+3

-3

0

+3

Processing of results
☒ Auto zero ampl. template subtraction

Parameters
Stimulation general

Probe amplitude [%]

95

Iterations

15

Phase duration [μ s]

40

Measurement gap [ms]

0

Amplitude growth function

Amplitude levels

10

Recovery function
Interpulse intervals

300 μ s

☒

400 μ s

☒

500 μ s

☒

750 μ s

☒

1000 μ s

☒

1500 μ s

☒

2000 μ s

☒

Spread of Excitation

Masker positions

6

at

☒ Both sides
☐ Apical
☐ Basal

Masker/Probe interval [μ s]

400

Advanced Setup
Default values for new measurements

Phase duration [μ s]

40

Iterations

300

Measurement delay [ms]

0.150

Measurement window [ms]

1.7 ms

External stimulus duration [ms]

0.0

Trigger delay [ms]

0.0

Trigger settings

Trigger pulse duration [μ s]

150

Trigger polarity

☒ Positive
☐ Negative

Appearance

Editor layout

☒ Horizontal
☐ Vertical

Offset [μ V]:

200

Restore Defaults

ART settings dialog

Open the settings dialog and choose the submenu **ART** to change default values and parameters of the ART task.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Settings

Safety

The [Initial coupling check](#) checkbox defines if coupling between coil and implant and the implant serial number are checked before the measurement. The checkbox is selected by default so that coupling is regularly checked before commencing a new measurement. When deselecting this checkbox, special caution shall be exercised in cases of large distances between implant and coil since insufficient supply voltage may cause non-linear behavior of the measuring amplifier (e.g., drifting time signal).

ART profile offsets

The [ART profile offsets](#) setting defines the standard offsets of stimulation and recording electrode positions of a newly added single measurement. The default settings of the sliders are +1 for the stimulating electrode and +1 for the recording electrode.

Processing of results

The [Auto zero ampl. template subtraction](#) checkbox is selected by default so that the zero amplitude template is routinely performed.

Parameters

Customize the initial settings for some parameters of the different functions in this section.

Parameter	Minimum	Maximum	Default
Probe amplitude [%]	0	100	95
Number of iterations	1	99	15
Phase duration [μ s]	20	100	40
Measurement gap [ms]	0	1000	0
Amplitude levels (AGF)	1	20	10
Interpulse intervals [μ s] (RF)	One checkbox selected	300, 400, 500, 750, 1000, 1500, 2000, 2500, 3000, 5000, 6000, 8000	400, 500, 750, 1000, 1500, 2000, 3000, 6000
Masker position (SoE)	1	11	6
Masker positions applied to (SoE)	Apical	Basal	Both sides
Masker /Probe interval [μ s] (SoE)	200	600	400

Parameters for AGF, RF and SoE

Parameter	Minimum	Maximum	Default
Phase duration [μ s]	10	200	40
Number of Iterations	1	5000	300
Measurement delay [ms]	0.15	500	0.15
Measurement window [ms]	1.7	19.4	1.7
External stimulus duration [ms]	0	30	0
Trigger delay [ms]	-5	5	0
Trigger pulse duration [μ s]	50	300	150
Trigger polarity	positive	negative	positive

Parameters for Advanced Setup

Appearance

Adjust the default settings for [Offset](#) and [Editor layout](#) in this section.

Parameter	Minimum	Maximum	Default
Editor layout	horizontal	vertical	horizontal
Offset [μ V]	0	1000	200

Parameters for Appearance section

9.14 FITTING

Fitting

Dynamic Stimulation

MCL-Burst [ms]:

50

Burst Gap [ms]:

500

Dynamics [%]:

100 (MCL)

THR-Burst [ms]:

300

☐ Continuous Stimulation

Balancing Stimulation

MCL-Burst [ms]:

300

Burst Gap [ms]:

500

Dynamics [%]:

100 (MCL)

THR-Burst [ms]:

300

Cycle Gap [ms]:

1000

☒ Continuous Stimulation

Sweeping Stimulation

MCL-Burst [ms]:

300

Burst Gap [ms]:

500

Dynamics [%]:

100 (MCL)

THR-Burst [ms]:

300

Cycle Gap [ms]:

1000

Sweep Direction:

Ascending

☒ Continuous Stimulation

Default values for new maps

☒ Use auto adjust for compliance limit

Lock THR [%]:

☒ 10

Minimum Duration [μs]:

☐ 0

Algorithm for interpolation:

Linear

Sort channels by:

Frequency

Test/Default Volume [%]:

75

(FineTuner) Volume Range

Minimum [%]:

70

Maximum [%]:

100

Editor behavior

Zoom factor:

7

During stimulation use:

☒ visual indication

☒ audio indication

☒ live during changes

Display following channel values:

☒ Center Frequency

☐ Stimulation Rate

☒ Impedance

☒ Telemetry Status

☐ MCL Amplitude

☐ THR Amplitude

☐ ESRT Data

☐ ECAP THR

Restore Defaults

Fitting task settings dialog

Open the settings dialog and choose the submenu **Fitting** to change default values and parameters of the Fitting task.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Dynamic Stimulation

Customize the default values used for dynamic stimulation in this section.

[MCL Burst](#) defines the length of a burst for stimulating the MCL. [Burst Gap](#) defines the interval between two bursts. [Dynamics](#) sets the stimulation level in %. [THR Burst](#) defines the length of a burst to stimulate the THR.

Parameter	Minimum	Maximum	Default
MCL Burst [ms]	50	1000	50
Burst Gap [ms]	200	1000	500
Dynamic [%]	THR charge (0%)	MCL charge (100%)	MCL charge (100%)
THR-Burst [ms]	50	1000	300
Continuous Stimulation	disabled	enabled	disabled

Parameters for Dynamic Stimulation section

Balancing Stimulation

Customize the default values for balancing in this section.

[MCL Burst](#) defines the length of a burst for stimulating the MCL. [Burst Gap](#) defines the interval between two bursts. [Dynamics](#) sets the stimulation level in %. [THR Burst](#) defines the length of a burst to stimulate the THR.

The parameter [Cycle Gap](#) defines the interval between two stimulation cycles.

Parameter	Minimum	Maximum	Default
MCL Burst [ms]	50	1000	300
Burst Gap [ms]	200	1000	500
Dynamic [%]	THR charge (0%)	MCL charge (100%)	MCL charge (100%)
THR-Burst [ms]	50	1000	300
Cycle Gap [ms]	200	1000	1000
Continuous Stimulation	disabled	enabled	enabled

Parameters for Balancing Stimulation section

Sweeping Stimulation

Customize the defaults for sweeping in this section.

[MCL Burst](#) defines the length of a burst for stimulating the MCL. [Burst Gap](#) defines the interval between two bursts. [Dynamics](#) sets the stimulation level in %. [THR Burst](#) defines the length of a burst to stimulate the THR.

The parameter [Cycle Gap](#) defines the interval between two stimulation cycles.

[Sweep Direction](#) defines the default direction of the sweeping stimulation.

Parameter	Minimum	Maximum	Default
MCL Burst [ms]	50	1000	300
Burst Gap [ms]	200	1000	500
Dynamic [%]	THR charge (0%)	MCL charge (100%)	MCL charge (100%)
THR-Burst [ms]	50	1000	300
Sweep Direction	Descending	Ascending	Ascending
Cycle Gap [ms]	200	1000	1000
Continuous Stimulation	disabled	enabled	enabled

Parameters for Sweeping Stimulation

Default values for new maps

Customize the main defaults for the parameters for new maps in this section.

Select the [Use auto adjust for compliance limit](#) checkbox to activate automatic modification of the compliance limit by MAESTRO. The parameter [Lock THR](#) sets the THR charge to a certain percentage of the MCL charge by selecting the checkbox. The parameter [Minimum Duration](#) defines a minimum duration for all electrodes by selecting the checkbox. [Algorithm for interpolation](#) defines the default algorithm used for interpolation. The parameter [Sort channels by](#) defines the default sorting of the electrodes.

[Test/Default Volume](#) defines the default volume for new fitting maps. For OPUS 1 and TEMPO+ processors it gives the test volume.

The default volume range may be adjusted by entering the values into the fields [Minimum](#) and [Maximum](#).

Parameter	Minimum	Maximum	Default
Lock THR (checkbox)	disabled	enabled	enabled
Lock THR [%]	20	0	10
Minimum Duration (checkbox)	disabled	enabled	disabled
Minimum Duration [µs]	0	200	0
Algorithm for interpolation	Linear	Spline	Linear
Sort Channels by	Frequency	Number	Frequency
Use auto adjust for compliance limit	disabled	enabled	enabled
Test/Default Volume [%]	0	100	75
Volume Range: Minimum [%]	0	100	70
Volume Range: Maximum [%]	0	100	100

Parameters for Default values for new maps section

Editor behavior

Customize the defaults for the editor parameters in this section.

[During stimulation use](#) defines if a visual signal or an acoustic signal is used during stimulation by selecting the appropriate checkbox.

[Audio indication](#) will create a sound signal on the computer when stimulation occurs, [visual indication](#) will display a red horizontal line at stimulation level.

The [live during changes](#) checkbox activates the live mode functionality whenever a map is activated in the fitting task. Whenever the checkbox is enabled and the user changes values in the map, the map will be automatically reactivated. Disabling the checkbox leads to an automatic deactivation of an activated map whenever the user makes changes.

Selecting the appropriate checkbox in the field [Display following channel values](#) defines which channel values are displayed in the related table in the Levels editor. The checkboxes for Center Frequency, Impedance and Telemetry Status are enabled by default.

Parameter	Minimum	Maximum	Default
Zoom factor	1	15	7
visual indication	disabled	enabled	enabled
audio indication	disabled	enabled	enabled
Live during changes	disabled	enabled	enabled

Parameters for the Editor behavior section

9.15 CONFIGURATION



Configuration settings

Open the settings dialog and choose the submenu [Configuration](#) to change default values and parameters of the configuration panel in the session view.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

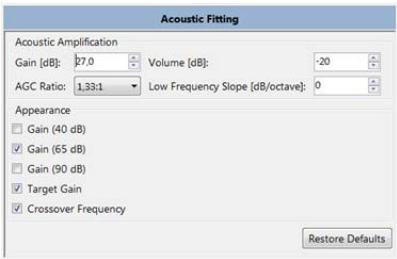
Datalogging

The [Enable Datalogging](#) checkbox customizes the default value for Datalogging and is enabled by default.

Link Monitoring

The [Link Monitoring](#) section defines the default values for [Automatic Coil Power Off](#) and [Link Indicator Lights](#). By default both options are enabled for processors with DL-Coil.

9.16 ACOUSTIC FITTING



Acoustic Fitting settings dialog

Open the settings dialog and choose the submenu [Acoustic Fitting](#) to change default values and parameters of the Acoustic Fitting task.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Acoustic Amplification

Customize the default values for [Gain](#) in dB, [Low Frequency Slope](#) in dB, [AGC Ratio](#) and [Volume](#) in dB in this section.

Parameter	Minimum	Maximum	Default
Gain [dB]	27	42	27
Low Frequency Slope [dB/Octave]	0	18	0
AGC Ratio	1:1	4:1	1.33:1
Volume [dB]	0	-42	-20

Parameters for the Acoustic Amplification section

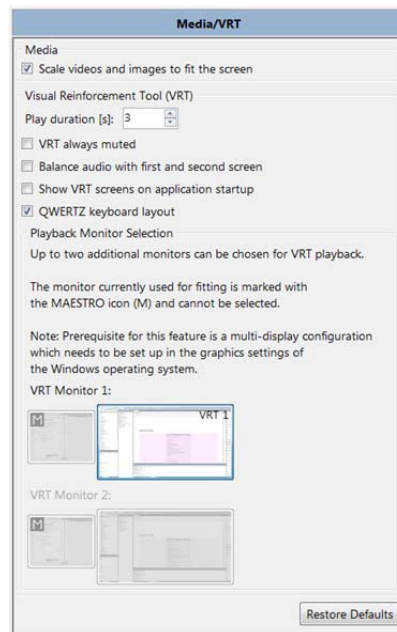
Appearance

Define if the individual amplification curves or the Target Gain and Crossover Frequency are displayed in the diagram of the Acoustic Fitting task in this section.

Parameter	Minimum	Maximum	Default
Gain (40dB)	disabled	enabled	disabled
Gain (65dB)	disabled	enabled	enabled
Gain (90dB)	disabled	enabled	disabled
Target Gain	disabled	enabled	enabled
Crossover Frequency	disabled	enabled	enabled

Parameters for the Appearance section

9.17 MEDIA/VRT



Media/VRT settings dialog

Open the settings dialog and choose the submenu [Media/VRT](#) to change default values and parameters of the media player.

Changes are applied when closing the settings dialog.

Click on the [Restore Defaults](#) button to set all values back to the original MAESTRO defaults.

Settings

Media

By default images and videos are scaled to fit the display resolving their aspect ratio. Disable the checkbox to shown them in their original size.

Visual Reinforcement Tool

Define how long the media should be played automatically in the VRT. The default are 3 seconds.

Enable the [VRT always muted](#) checkbox and the Visual Reinforcement Tool will not play any sound.

Enable [Balance audio with first and second screen](#) to enabled or disabled left and right audio channel of a song or video according to the enabled/disabled state of VRT monitor 1 (left channel) and VRT monitor 2 (right channel).

Select [Show VRT screens on application startup](#) to display a black screen on the configured second or third computer screen at the start-up of MAESTRO. Otherwise the screen will not be occupied until playback is started the first time.

Confirm that a keyboard with a QWERTZ layout is being used. Disable the checkbox to indicate that a QWERTY keyboard layout is used for VRT.

In the section [Playback Monitor Selection](#) it is possible to choose up to two additional monitors to be used for VRT playback depending on the hardware setup of the computer system. The display marked with the MAESTRO logo identifies the display where MAESTRO is currently open. This display cannot be chosen for VRT playback. A click on a display without MAESTRO logo enables this screen for the VRT. A label VRT1 or VRT2 indicates which screens are ready to be used.

NOTE:

Prerequisite for this feature is a multi-display configuration which needs to be set up in the graphic settings of the Windows operating system.

10 Additional Applications

Installation of MAESTRO installs accompanying stand-alone tools that provide additional functions.

Currently these are:

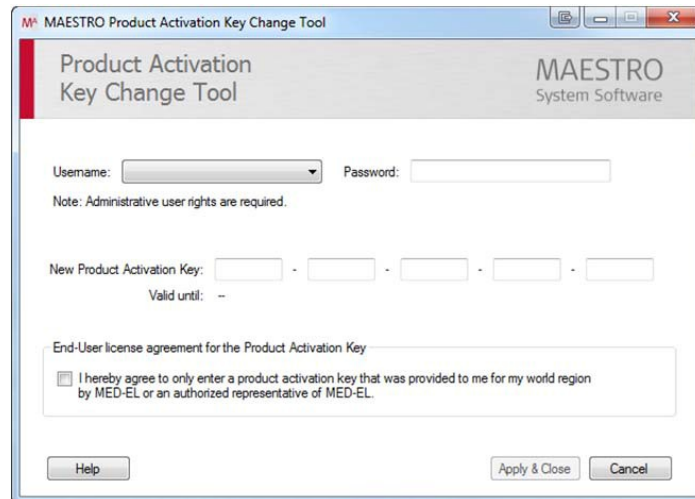
- **Product Activation Key Change Tool**, which allows the user to change the activation key MAESTRO uses.
- **Database Management Tool**, which allows the user to configure and administrate MAESTRO databases.
- **Scientific Data Tool**, which allows the user to migrate MAESTRO scientific export files into a Microsoft Access or Microsoft SQL database.

Like the MAESTRO System Software, these applications can be started from the Windows program group MED-EL in the Start menu. In Windows 8 and later they are available as tiles and can be found in the Apps window.

10.1 PRODUCT ACTIVATION KEY CHANGE TOOL

The tool can be started from the Windows program group MED-EL in the Start menu. For Windows 8 and later the tool is available as tile and can be found in the Apps window.

Additionally, the tool is available in MAESTRO by selecting [Change product activation key](#) from the menu [Tools](#) in the menu bar.



MAESTRO Product Activation Key Change Tool

Steps to change the activation key:

1. Enter login credentials of a user with administrative rights.
2. Enter the new product activation key.
3. Accept the end-user license agreement for the product activation key by enabling the checkbox.
4. Click on [Apply & Close](#) to change the activation key and close the tool.

When launching MAESTRO, the newly entered activation key is automatically used.

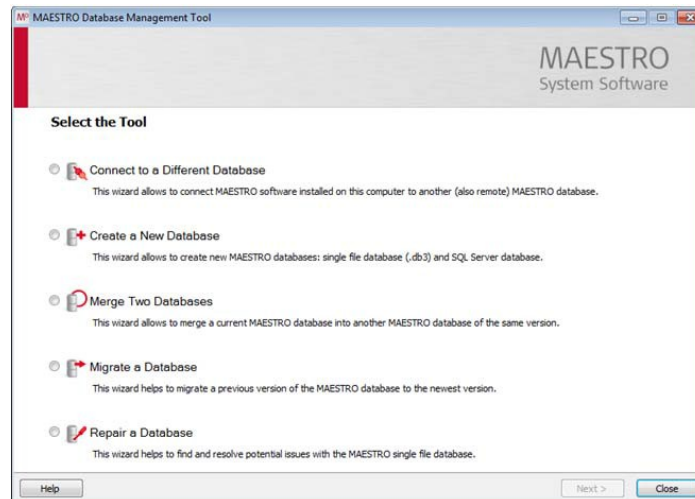
Tips, Tricks and Troubleshooting

After an activation key was entered, the dialog displays the expiration date and the related software version. If this information is not displayed, the key is not valid and should be checked for typing errors.

10.2 DATABASE MANAGEMENT TOOL

The tool can be started from the Windows program group MED-EL in the Start menu. For Windows 8 and later the tool is available as tile and can be found in the Apps window.

The MAESTRO Database Management Tool combines the following database tools into one workflow-oriented user interface: **Connect to a different database**, **Create a new database**, **Merge two databases**, **Migrate a database**, **Repair a database**

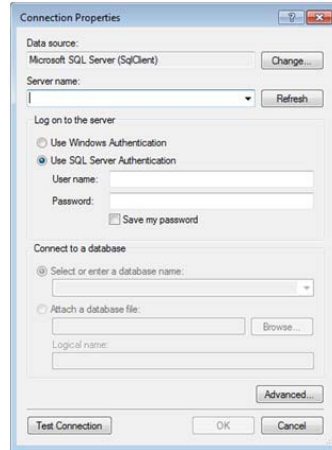


Database Management Tool

NOTE:

When using a network-based SQL Server database, the administrator shall make sure that access is password-protected.

Whenever an SQL Server is used, the server name and authentication credentials have to be entered into the Connection Properties dialog.



Connection Properties dialog

10.2.1 Connect to a Different Database

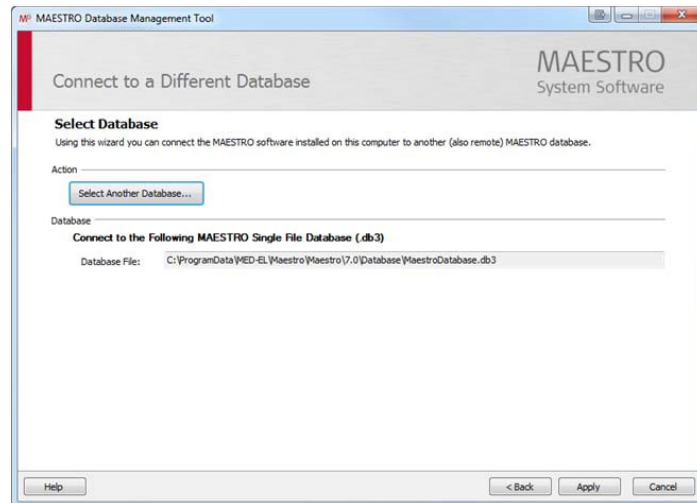
This tool connects MAESTRO to a different database so that MAESTRO works with the newly connected database. If several computers shall use the same MAESTRO database it is necessary to connect each computer to the defined database separately.

Precondition:

The database version number has to be identical to the version number of the installed MAESTRO System Software. To connect to a MAESTRO database of a previous version use the [Migrate a Database](#) function.

Steps to connect to a different database:

1. Open the Database Management Tool and click on [Connect to a Different Database](#). The currently connected database is displayed for information.



Database Management Tool – Connect to a Different Database

2. Click on [Select Another Database](#) and choose either a single-file database (.db3) or an SQL Server database:
 - Select a single-file database (.db3) to open the Windows explorer and choose the database in the appropriate folder.
 - Select a Microsoft SQL Server database to open the Connection Properties dialog and enter the server name and authentication credentials. Select the MAESTRO database from the list in the section [Connect to a database](#).
 - Click on the [Test Connection](#) button to test connection to the SQL Server.
3. Verify the displayed information about the chosen database presented in the Database Management Tool.
4. Click on [Apply](#) to connect MAESTRO to the selected database. A log window displays the progress. A click on [Cancel](#) cancels the process and MAESTRO is not connected to the selected database.

At the end a summary is shown and the Database Management Tool can be closed.

10.2.2 Create a New Database

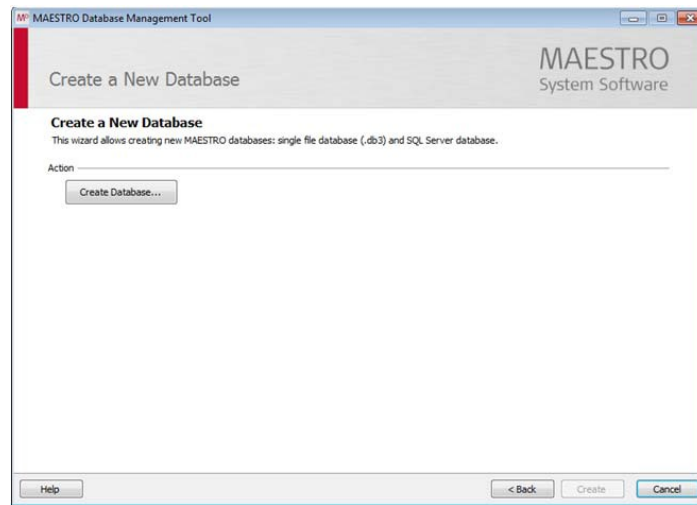
This tool creates a new and empty MAESTRO database. A new MAESTRO database always needs to be set up through the Database Management Tool. It is only possible to create a database for the installed version of MAESTRO.

Precondition:

For SQL Server: User credentials that contain the right to create a database on the server.

Steps to create a new database:

1. Open the Database Management Tool and click on [Create a New Database](#).



Database Management Tool – Create a New Database

2. Click on [Create Database](#) and choose either to create an empty MAESTRO single-file database (.db3) or an empty MAESTRO SQL Server database.
 - Select a single-file database (.db3) to open the Windows explorer automatically and enter a name for the new database in the appropriate folder.
 - Select Microsoft SQL Server database to open the Connection Properties dialog and enter the SQL Server name and authentication credentials. Ensure that those credentials contain the right to create databases on the SQL Server. Enter a name for the new MAESTRO database into the field [Select or enter a database name](#). Ensure that the name of the database is new and not already used for another database.
3. Verify the displayed information about the chosen database presented in the Database Management Tool.
4. Decide if this database shall be used as the new MAESTRO database. Disable the checkbox at the bottom of the window to reject usage of the new database as default MAESTRO database.

5. Click on [Create](#) to create the database. A log window displays the progress. A click on [Cancel](#) cancels the process and the database is not created.

At the end a summary is shown and the Database Management Tool can be closed.

If more than one computer shall use the same database (e.g. SQL Server), all of them have to be connected to the newly created database with [Connect to a Different Database](#) before work can be started.

10.2.3 Merge Two Databases

This tool merges two existing MAESTRO databases. Two databases have to be specified by the user: a source database and a target database. After the merge process is finished, the source database remains unchanged, while the target database also contains the data from the source database.

This tool may also be used to transfer data from one database format to another, e.g. when moving from an SQLite database format to an SQL Server database format.

NOTE:

Depending on the size of the database, note that the process may take several minutes. Please ensure that adequate time is allotted for this process to complete.

Precondition:

It is only possible to merge databases with version numbers identical to the version number of the installed MAESTRO System Software.

The knowledge of a user name and password for a user with administrative rights is required for the source database.

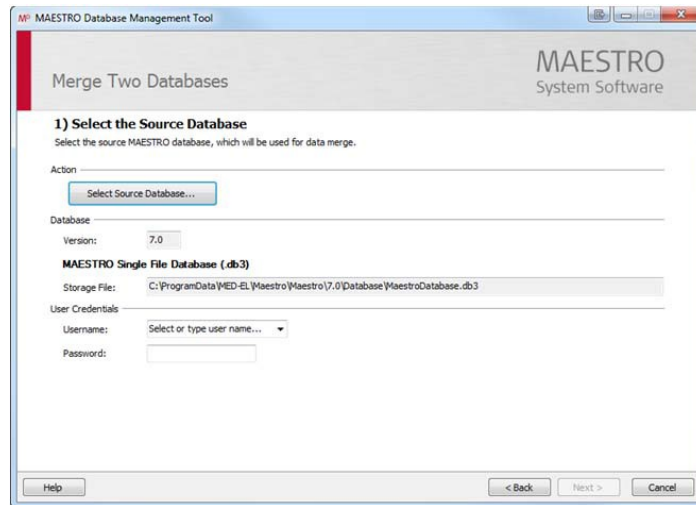
Ensure that work with the affected databases has stopped before starting the merge process.

Steps to merge two databases:

1. Open the Database Management Tool and click on [Merge Two Databases](#).
2. Click on [Select Source Database](#) to select the source MAESTRO single-file database (.db3) or MAESTRO SQL Server database.
 - Select a single-file database (.db3) to open the Windows explorer and choose the database in the appropriate folder.
 - Select a Microsoft SQL Server database to open the Connection Properties dialog and enter the server name and authentication credentials. Select the MAESTRO database from the list in the section [Connect to a database](#).
 - Click on the [Test Connection](#) button to test connection to the SQL Server.

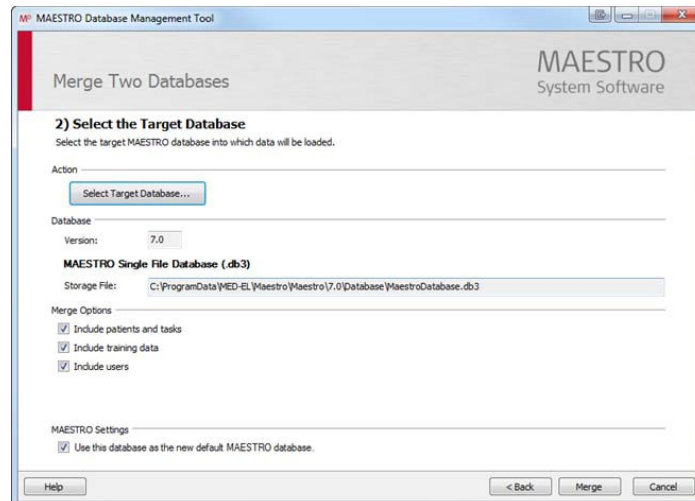
Additional Applications

3. Verify the displayed information about the source database and enter the correct login information for a MAESTRO user with administrative rights for this database.



Selected source database

4. Click on [Next](#) to continue with the target database.
5. Click on [Select Target Database](#) to select the target MAESTRO single-file database (.db3) or MAESTRO SQL Server database. Select the target database into which the source data will be loaded by performing the same steps as for selecting the source database.



Options for the target database

6. Verify the displayed information about the target database.
7. Decide on the merge options to include patients and tasks, training data and users. All three options are enabled by default, which means that patient and task data, training data and user data are merged.
8. Decide if this database shall be used as the new MAESTRO database. Disable the checkbox at the bottom of the window to reject usage of the new database as default MAESTRO database.
9. Click on **Merge** to merge the two databases. A log window displays the progress. A click on **Cancel** cancels the merge process and the selected databases keep their original form.

At the end a summary is shown and the Database Management Tool can be closed.

If more than one computer shall use the same database (e.g. SQL Server), all of them have to be connected to the newly merged database with **Connect to a Different Database** before work can be started.

Tips, Tricks and Troubleshooting

Steps to change the format of a database, e.g. to move data from an SQLite database to an SQL Server database:

1. Create a new and empty MAESTRO database on the SQL Server by using the tool **Create a new database**.

2. Ensure that work with the affected database has stopped.
3. Create a backup of the MAESTRO database.
4. In case the SQLite database showed issues before, use the **Repair a database** tool to clean up the database.
5. Start the **Merge two databases** tool to transfer data from the SQLite database (source database) to the new and empty database on SQL Server (target database).
6. Connect all computers with MAESTRO to the new SQL Server database by using the tool **Connect to a different database**.

10.2.4 Migrate a Database

This tool migrates an existing MAESTRO database from a former version to the currently installed MAESTRO version. It is not possible to migrate a database from a later version to a former version (downgrade).

During the installation process of a new MAESTRO version, the installer offers to automatically start the Database Management Tool to migrate the existing databases directly into the new database.

For migration two databases have to be specified by the user: a source database, which is migrated, and a target database into which the migrated data is loaded. After the migration process is finished, the source database remains unchanged, while the target database contains the migrated data from the source database.

NOTE:

Depending on the size of the database, note that the process may take several minutes. Please ensure that adequate time is allotted for this process to complete.

Precondition:

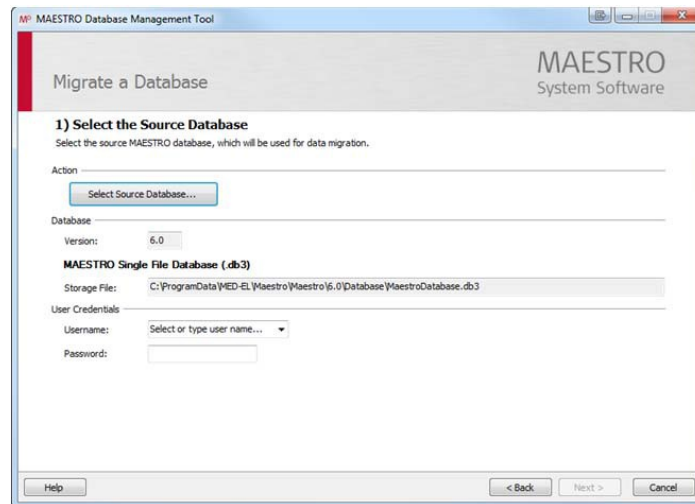
The knowledge of a user name and password for a user with administrative rights is required for the source database.

Ensure that work with the affected database has stopped before starting the migration process.

Steps to migrate a database:

1. Open the Database Management Tool and click on [Migrate a Database](#).
2. Click on [Select Source Database](#) to select either a MAESTRO MS Access database, a MAESTRO single-file database (.db3) or a MAESTRO SQL Server database as source database.
 - Select an MS Access database to open the Windows explorer and choose the database in the appropriate folder.

- Select a single-file database (.db3) to open the Windows explorer and choose the database in the appropriate folder.
 - Select a Microsoft SQL Server database to open the Connection Properties dialog and enter the server name and authentication credentials. Select the MAESTRO database from the list in the section [Connect to a database](#).
 - Click on the [Test Connection](#) button to test connection to the SQL Server.
3. Verify the displayed information about the source database and enter the correct login information for a MAESTRO user with administrative rights for this database.



Migrate a Database – Source database

4. Click on [Next](#) to continue with the target database.
5. Click on [Select or create Target Database](#) to select or create the target MAESTRO single-file database (.db3) or MAESTRO SQL Server database. Select or create the target database into which the source data will be loaded by performing the same steps as for selecting the source database. If the target database shall be a newly created database, be sure to enter a new database name in the appropriate folder for single-file databases or in the Connection Properties dialog for SQL Server databases.
6. Verify the displayed information about the target database.

7. Decide if this database shall be used as the new MAESTRO database. Disable the checkbox at the bottom of the window to reject usage of the new database as default MAESTRO database.
8. Click on [Migrate](#) to migrate the database. A log window displays the progress. A click on [Cancel](#) cancels the migration process and the selected databases keep their original form.

At the end a summary is shown and the Database Management Tool can be closed.

If more than one computer shall use the same database (e.g. SQL Server), all of them have to be connected to the newly migrated database with [Connect to a Different Database](#) before work can be started.

10.2.5 Repair a Database

This tool repairs a corrupt database of the latest MAESTRO version as well as a corrupt database of the previous MAESTRO version up to a certain point.

Following a hardware or operating system failure, the MAESTRO single-file database can be corrupted. The tool distinguishes between two kinds of corruptions: Those concerning the file format and those concerning the structural level. In case of file format corruption, all sound records are extracted and put into a new database. It may happen that certain records cannot be saved and are lost. In case of a structural corrupted database, the tool restores, ignores or deletes the corrupt data depending on the kind of structural defect.

NOTE:

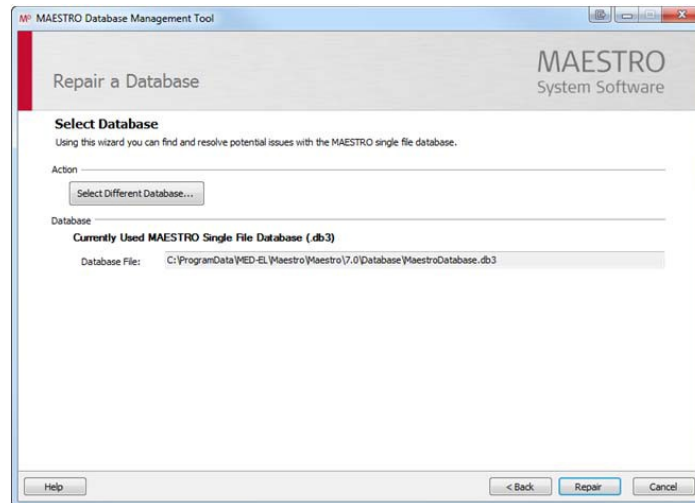
Depending on the size of the database, note that the process may take several minutes. Please ensure that adequate time is allotted for this process to complete.

Precondition:

Ensure that work with the affected database has stopped before starting the repair process.

Steps to repair a database:

1. Open the Database Management Tool and click on [Repair a Database](#).
2. The tool suggests repairing the currently used MAESTRO single-file database. Click on [Select Different Database](#) to select another database. In this case the Windows explorer is automatically opened and the database may be selected in the appropriate folder.



Database Management Tool – Repair a Database Tool

3. Click on **Repair** to start the repair of the selected database. A log window displays the progress. A click on **Cancel** cancels the repair process and the selected database keeps its original form.

At the end a summary is shown and the Database Management Tool can be closed.

In the event any repairs are performed, the tool creates a backup of the original file and saves it to the following directory:

%ProgramData%\MED-EL\MAESTRO\MAESTRO\7.0\Database\RepairBackup\YYYY-MM-DD_HH-MM-SS

If the **Repair a Database** tool fails to repair the corrupted database contact your nearest MED-EL representative for further assistance.

Manual rework:

Only one special type of defect may require further action by the user.

If the personal data of a patient are lost but task data could be repaired, the repair tool restores a patient record named **Restored, Patient Record** and automatically adds all task data related to this patient. In such a case identify the restored patient with a real person, enter missing patient data, replace generic entries with real data in the patient editor and verify the restored ear data. The next time the processor of this patient is connected to the MAX Programming Interface, the software recognizes this patient and the user may decide to overwrite the personal data of the restored patient and insert the data stored on the processor.

NOTE:

In such a case data stored in the Address & Contact editor have to be added manually by the user.

10.3 SCIENTIFIC DATA TOOL

MAESTRO exports data not only into .mpd files that can only be used within MAESTRO, but also as a Scientific XML (eXtensible Markup Language) file. It is not convenient to do further scientific or statistical evaluations and queries with the exported XML file directly. Therefore, the scientific data tool transfers data from a scientific export into a relational database such as Microsoft Access or Microsoft SQL Server, where further work with the data is easier. The tool additionally can perform subsequent imports of several XML files into one database.

CAUTION:

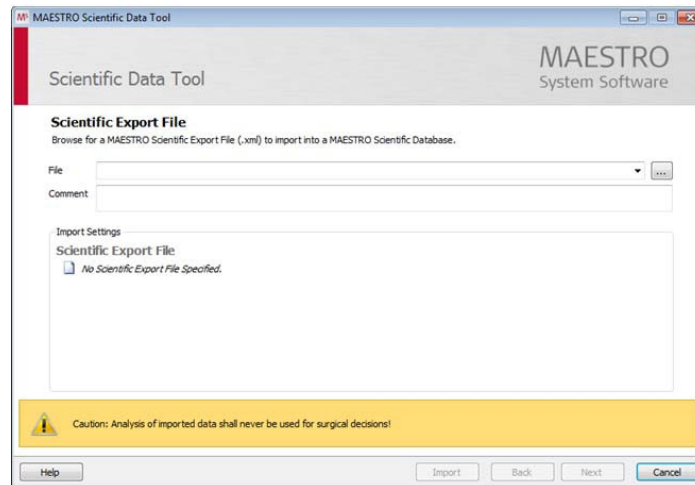
The output of the MAESTRO Scientific Data Tool must not be taken as the sole basis for any decision regarding further medical or surgical treatment.

Precondition:

The data has to be exported as scientific export from MAESTRO before the Scientific Data Tool can be used.

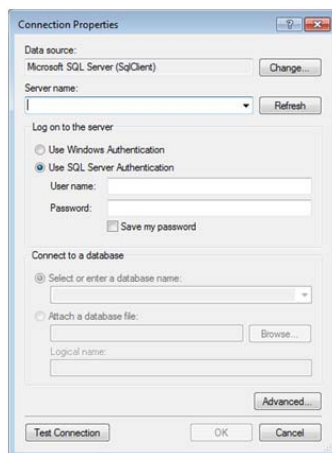
Steps to import scientific export file into a relational database:

1. Start the tool from the Windows program group MED-EL in the Start menu. For Windows 8 and later the tool is also available as tile and can be found in the Apps window.



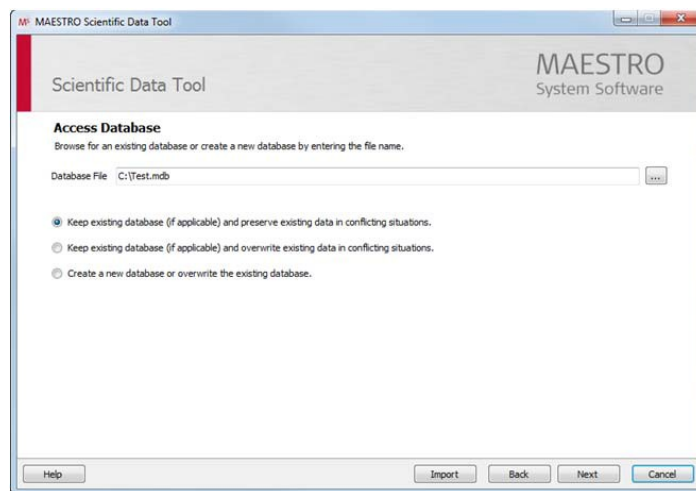
Scientific Data Tool

2. Click on the browse button to open the Windows explorer and select the previously exported MAESTRO scientific export file (.xml). Optionally enter a comment.
 3. Click on [Next](#) to open the Options dialog and select the task data to be transferred. Enable the [Anonymize Data](#) checkbox to anonymize patient data. The checkbox is enabled by default.
 4. Click on [Next](#) and select the type of the target scientific database (Access or SQL Server).
- For an MS Access database click on the browse button to open the Windows explorer. Enter or select the database in the appropriate folder.
 - For a Microsoft SQL Server database click on the browse button to open the Connection Properties dialog. Enter server name and authentication credentials. Select the desired database in the section [Connect to a database](#).
 - Click on the [Test Connection](#) button to test connection to the SQL Server.



Connection Properties dialog

5. Choose to either keep the existing database and preserve existing data in conflicting situations, or keep the existing database and overwrite existing data in conflicting situations, or overwrite the existing database and/or create a new database.



Selected MS Access database as target database

6. Click on [Next](#) to open the Summary dialog and review all entered information.
7. Click on [Import](#) to start the import process of the selected data. A log window displays the progress. A click on [Cancel](#) cancels the process and data are not transferred.
8. Click on [Close](#) to close the Scientific Data Tool.

11 General Precautions and Warnings

11.1 GENERAL PRECAUTIONS AND WARNINGS

Please pay attention to the following precautions and warnings. Additionally, refer to the applicable user manuals.

- For safety reasons it is absolutely essential to specify the correct implant including serial number and electrode type before proceeding with any software operations.
- When you treat an unfamiliar patient for the first time or add a new patient to the database take all necessary steps to ensure correct identification of the implant including serial number and electrode type – do not make any assumptions! If the patient is already stored in the database, be sure to select the correct patient and ear (for bilaterally supplied patients) before continuing with the software.
- Channel interactions have the potential to be slightly higher with the FLEX20 electrode than with the FLEX24 electrode. This results from distributing a certain number of channels (12) across a very short cochlea via the FLEX20 electrode, when compared to distributing the same number of channels across a longer cochlea via the FLEX24 electrode. A shorter cochlea cannot accommodate a longer electrode which is linked to more favorable speech outcomes, however an audiologist can - if needed- switch off channels on the array using the fitting software, thereby increasing the average spacing of active contacts and potentially reducing channel interactions for such patients.
- Only run the MAESTRO software under the supported Microsoft Operating Systems (see chapter **Technical Data**).
- Do not edit or alter any files generated or used by the fitting software. Do not edit and/or alter the MAESTRO software. Make sure that no attempt to alter this software is performed (e.g. by viruses).
- Install and maintain protective anti-virus software and ensure that the Windows operating system uses the latest available updates.
- Backup of data in the database is not automatically provided. It is the responsibility of the user to backup the database.
- Do not run other software applications simultaneously with the MAESTRO software to minimize the chances of interference.
- Make sure that there are no software conflicts with other programs running on your PC. If you detect a problem check to see what other programs are running in the background. Shut down all programs except for MAESTRO and see if the situation improves.
- If you have a problem related to printing, it may be associated with the printer driver software which comes from the printer manufacturer. Printer drivers may have software bugs or do not support all versions of Windows equally well. The best approach is to find and install the very latest driver from the manufacturer's Web page

and see if the problem is resolved. Make sure you get the driver which matches the exact printer model and the version of Windows you are using.

- It is the responsibility of the user to provide adequate data privacy protection against intentional or unintentional disclosure. The user management features of MAESTRO can be an effective tool, but they must be maintained and used correctly.
- Analysis of data obtained via MAESTRO must not be taken as the sole basis for any decision regarding further medical or surgical treatment.

11.2 ELECTROSTATIC DISCHARGE

Electrostatic discharge (ESD) has the potential to damage electronic components of the CI System (e.g., audio processors, MAX Programming Interface). Electrostatic charge build-up occurs most frequently on days when the air is very dry. The probability of the occurrence of electrostatic discharge can be reduced by following the list of guidelines below. Additionally, refer to the applicable sections in the appropriate user manuals.

Whenever you think that the patient and/or you yourself have been charged with static energy, you and/or the patient should discharge yourself by touching a radiator, a water tap, or any other grounded metal.

When you are working with a computer, make sure that the computer is grounded.

Place an anti-static mat under your work place.

You and/or the patient should not directly touch TV or computer screens.

11.3 CARE AND MAINTENANCE

This software does not require calibration, service or maintenance.

11.4 TROUBLESHOOTING

The MAESTRO software contains several error and information messages which can be encountered at various points during operation of the software. All messages appear in a separate log window. There are three different types of messages:

- errors
- warning messages
- information messages

The messages are clear and usually self-explanatory so that the user of the MAESTRO software will find it easy to understand the problem and carry out the necessary actions. If you have difficulty understanding a message, please contact your nearest MED-EL representative.

12 Technical Data

12.1 MINIMUM HARDWARE AND SOFTWARE REQUIREMENTS

Hardware minimum requirements:

- PC or Laptop/Notebook in connection with one of the supported Microsoft Windows operating systems
- Dual-core processor with a minimum clock speed of 1.6 GHz or higher
- 2 GB RAM or more
- 2 GB or more free disk space
- Color display with a minimum resolution of 1024 × 768 (1280 × 1024 recommended)
- one free high-power USB 2.0 (or higher) compliant port
- one free printer port or network connection to printer
- CD ROM compatible drive for software installation via CD ROM

Supported Microsoft Windows Operating Systems

- Microsoft Windows® 7, Service Pack 1 and later
- Microsoft Windows® 8, 8.1 and later
- Microsoft Windows® 10 and later

12.2 DEVICES TO BE CONNECTED

Devices to be connected to the PC in order to perform all functions of the MAESTRO software:

- MAX Programming Interface. For setup of the system refer to the MAX Programming Interface user manual.
- HI-PRO interface box. For setup of the system refer to the HI-PRO user manual.

12.3 STORAGE OF THE USB FLASH DRIVE OR CD-ROM

When not in use, store the USB flash drive in its original case. Also be careful not to expose the USB flash drive to high temperatures, humidity, dust or dirt.

Avoid touching the recording surface of the CD-ROM (back side) to prevent fingerprints, scratches, dust particles and smears. When not in use, store the CD-ROM in its original case with the recording surface underneath. Also be careful not to expose the disc to direct sunlight, high temperatures, humidity, dust or dirt. For cleaning, a soft dry cloth or a

standard CD cleaner should be used. No other cleaning tools, solvents or abrasive cleaners should be used.

12.4 CE MARK



CE mark applied in 2017

13 Clinical Studies

13.1 CODING STRATEGIES

The aims and results of the MED-EL FSP Clinical Investigation of 46 post-lingually deaf adults with 6-months device experience were:

1. To investigate the effect of a fine structure speech coding strategy on auditory perception in CI users compared to the current CIS+ strategy. Results have shown that the FSP strategy is at least equal to or even better than both HDCIS and CIS+ strategies in many cases. There is a strong user preference for the FSP strategy.
2. To investigate the feasibility of deriving electrically evoked compound action potentials with the MED-EL ART system postoperatively. Results show that EAPs can be measured in almost all cases and that the system is sensitive to the difference in cochlear anatomy between the basal and apical regions of the cochlea.
3. To investigate the safety of the MED-EL CI system using MAESTRO software. During the clinical investigation, no serious adverse events were reported. One device event was reported, there was a fault with the CPU which was resolved on replacing the CPU.

The aims and results of the MED-EL FSP Clinical Investigation (Inexperienced User Section only) of 22 post-lingually deaf adults who had not received a cochlear implant before and who fulfilled all subject inclusion criteria were:

1. To investigate the effect of using the OPUS 1 audio processor on performance after cochlear implantation. Results have shown that the FSP strategy provides significant benefit over and above their pre-operative scores, indicating that inexperienced users can benefit from the FSP coding strategy.
2. To investigate the feasibility of deriving electrically evoked compound action potentials with the MED-EL ART system postoperatively. 71.43% were measured postoperatively at acute switch-on and a further 9.52% were recorded at the 3 month post- fitting.

The aims and results of the study of Riss et al. (2013) on thirty-three post-lingually deaf adults with 1-year experience with FSP were to compare the three available fine structure strategies FS4, FS4-p and FSP with regard to speech perception, subjective sound quality and subjective preference. Objective speech tests results revealed no significant differences between the three strategies, except for a small improvement of FSP over FS4 regarding monosyllables perception.

Subjective sound quality was assessed for speech in quiet, classical, and pop music. No significant effects of strategy were found for speech in quiet and classical music, but

auditory impression of pop music was rated as more natural in FSP compared to FS4. Regarding subjective preference, a majority of the patients favored FS4 or FS4-p over their previous default FSP at the end of the study (FSP: N = 13; FS4: N = 13; FS4-p: N = 7). The study found great variability in performance between patients, which demonstrates that instead of establishing a common best-performing strategy for all patients, a best performing strategy for each individual patient should be determined for optimum benefit for that patient.

13.2 EABR TASK

The EABR task has been in clinical use in MED-EL fitting software (ZEBRA 3.0) since 2001 without any reported complaints or adverse events. The EABR task is used to create the pulse sequences intended to elicit responses of the brainstem by stimulation of the auditory nerve or the corresponding area of the brainstem. The EABR task is available in MAESTRO 4.1 and subsequent versions and is equivalent to the EABR task in ZEBRA 3.0. An evaluation performed by MED-EL on the available clinical experience with the EABR task concluded that possible benefits outweigh any risks when providing the EABR task within MAESTRO to MED-EL cochlear implant patients.

The MED-EL Cochlear Implant System can thus be deemed to be both safe and effective.

13.3 MICROPHONE DIRECTIONALITY AND WIND NOISE REDUCTION

An evaluation performed by MED-EL on the available clinical data on natural and adaptive microphone directionality and wind noise reduction in the SONNET and SONNET EAS audio processors and the fitting of these features with the MAESTRO software (version 6.0 and above) concluded that these features are safe and effective in improving speech understanding of CI and EAS users. This conclusion was made based on two clinical investigations sponsored by MED-EL and bench performance tests. The MED-EL-sponsored clinical investigations have not found any deleterious effect of the SONNET/SONNET EAS's microphone directionality and wind noise reduction functionalities on CI and EAS users. Furthermore, as both MED-EL sponsored clinical investigations have shown, the SONNET/SONNET EAS's default Natural directionality and wind noise reduction modes do not have a disadvantageous effect on speech intelligibility in quiet environment compared to the Omnidirectional mode of the OPUS 2 and DUET 2 audio processors. In conclusion, based on all the available data, the possible benefits from use of natural or adaptive microphone directionality and wind noise reduction outweigh any clinical risks. Addition of those features to the MED-EL cochlear implant system can be considered safe, effective, and thus compliant with the current state-of-the-art.

More details on the two clinical investigations are provided below:

13.3.1 Study title: Performance of Cochlear Implant Patients with Microphone Directionality and Wind Noise Reduction with the SONNET

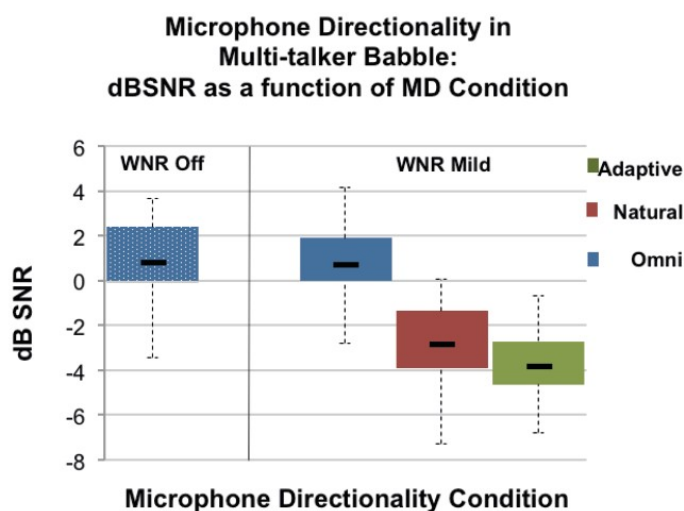
A clinical study on 31 adult cochlear implant users with a minimum of 6 months device experience was conducted to assess the Microphone Directionality (MD) and Wind Noise Reduction (WNR) features in the SONNET audio processor in quiet, noise, and windy environments. The objectives of the study were as follows:

1. To compare performance of the SONNET default settings (Natural MD and Mild WNR) with performance of the OPUS 2. Comparisons were based on evaluation of speech perception using the following tests:
 - Oldenburg Adaptive Sentence (OLSA) test (Wagener, Brand, Kollmeier, 2006) administered using either speech-shaped noise (SoN3 condition) or multi-talker babble noise (SoB3 condition). The OLSA test is an adaptive speech in noise sentence test. This test is used to identify signal-noise-ratio needed for 50% speech understanding level. The speech level is changed and the noise remains constant during testing to achieve a 50% correct score. The speech signal was presented from the front (0°) and either speech-shaped noise or multi-talker babble noise was presented from three loudspeakers located at 90°, 180° and 270°.
 - OLSA test in quiet in presence of wind: with speech presented from the front (0°) and wind from an angle of 45° towards the audio processor (SoW45 condition). In this condition, there was no additional background noise.
2. To provide additional data on performance of the SONNET using different combinations of MD and WNR modes. Comparisons were based on evaluation of speech perception using the following tests:
 - Freiburg Monosyllabic test (Alich, 1985) in quiet. The Freiburg test is an open-set monosyllabic word test. The presentation level was fixed at 65dB SPL. The percentage correct score was then calculated by the number of words correctly repeated.
 - OLSA test in quiet in presence of wind, with the speech signal presented from the front (0°) and wind blowing towards the processor from 45°. No additional background noise was used (SoW45).
 - OLSA test in the absence of wind, with a speech signal presented from the front (0°), and either speech-shaped noise (SoN3) or multi-talker babble noise (SoB3) presented from three loudspeakers located at 90°, 180°, and 270°.
 - OLSA test with a speech signal and speech-shaped noise, both presented from the front (SoNo) and no wind.
 - HISQUI19 (Hearing Implant Sound Quality Index), SSQ (Speech Spatial Questionnaire, version 12), APSQ (Audio Processor Satisfaction Questionnaire), and APSQ Product-Specific Expansion for the SONNET. These questionnaires were used to evaluate the patients' subjective impressions of new SONNET features and quality of life in real-world situations.

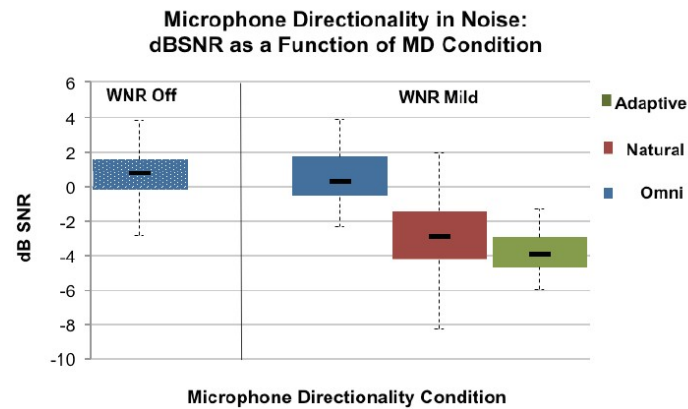
Results of the clinical study demonstrated significant improvements in speech recognition with default SONNET settings for ASM 2.0 features (mild WNR and Natural directionality) and the “Adaptive-Mild” setting compared to the OPUS 2 in a variety of noisy and reverberant environments (see graphs 1-4). Speech recognition with the SONNET improved significantly even in the most challenging listening condition: constant noise was presented from three different directions (90°, 180° and 270°) and speech was presented from the front (0°).

In quiet, word recognition with all nine combinations of MD and WNR modes of the SONNET was equal or better compared to the OPUS 2. Significant improvement in word recognition with the SONNET in quiet was seen with four different combinations of MD and WNR.

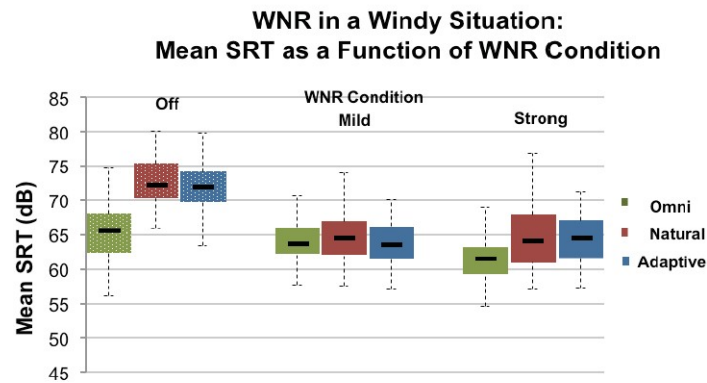
In windy conditions, research subjects showed improved speech recognition with the SONNET WNR functionality in the “Mild” and “Strong” modes compared to WNR turned off in the SONNET.



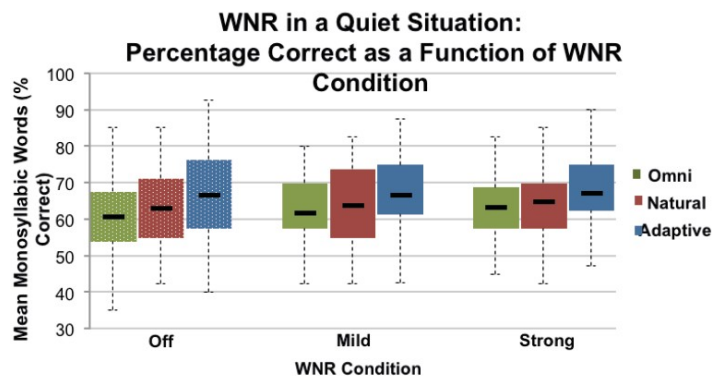
Graph 1: Mean scores of dB SNR as a function of MD mode in multi-talker babble condition. This graph shows MD providing benefit compared to omnidirectional mode. Note: For the OLSA tests, lower scores indicate better hearing ability.



Graph 2: Mean scores of dB SNR as a function of MD mode in speech weighted noise condition. This graph shows MD providing benefit compared to omnidirectional mode. Note: For the OLSA tests, lower scores indicate better hearing ability.



Graph 3: WNR in a windy situation: Mean SRT as a function of WNR condition. This graph shows lower SRT levels with WNR active in a windy environment.



Graph 4: WNR in a quiet situation: Percentage correct as a function of WNR condition. This graph shows no significant differences between WNR being disabled and enabled.

Questionnaires were used to assess subjective feedback on everyday use with the SONNET audio processor compared to the patients' impressions with their OPUS 2 audio processor. The results showed that the SONNET provided users with a significant improvement in speech perception, more device confidence, and a moderate improvement in self-perceived improvement in sound quality.

Results presented in the clinical investigation report confirm that the SONNET default settings (Natural directionality and Mild WNR) are beneficial and appropriate for everyday use in adult CI users. The results described above can also be extrapolated to the use of SONNET MD and WNR modes in children aged 6 years and above as no difference in safety and effectiveness can be found between adult and older children. Younger children below 6 years have not been specifically studied, however, there is no apparent reason that younger children should be differently impacted than older children and adults. Due to the range of post-operative performance that may be seen amongst children with a cochlear implant, it is advised to closely monitor children as they develop with a cochlear implant. Furthermore, it is strongly suggested to counsel parents on the importance of closely monitoring their child's performance with the device (please refer to MED-EL's "Clinician's Guide – ASM 2.0 for Young Children" and "Parents' Guide – ASM 2.0 for Young Children").

13.3.2 Study title: Performance of the SONNET EAS Audio Processor in experienced DUET 2 users

A clinical study on 10 adult cochlear implant users with a minimum of 9 months device experience was conducted to assess the Microphone Directionality (MD) and Wind Noise Reduction (WNR) features in the SONNET EAS audio processor in quiet, noisy and windy environments. The objectives of the study were the following:

Primary Objective

The primary objective of this study was to compare - in the unilateral EAS-only hearing condition - the performance of the SONNET EAS in the default setting (MD "Natural" and WNR "Mild") with the performance of the DUET 2 (EAS-capable audio processor). Comparisons were done through the evaluation of speech perception using the following tests:

- Freiburg Monosyllables Test in quiet
- Oldenburg Sentence Test in Multi-Source Noise Field (OLSA MSNF). As described in the final study report, the OLSA MSNF was conducted in the "closed-set" mode. The subject was placed in the center of a soundproof room. The speech signal was present from the front (0° azimuth) and the speech level was set adaptively. OL-noise (Rader et al., 2013) was constantly presented from a Multi-Source Noise Field at a fixed level a 65 dB SPL. The MSNF condition consisted of four loudspeakers set up in the corners of a soundproof room and directed towards the head of the subject.

Secondary Objectives

The secondary objectives of this study were to provide additional data on the performance of the SONNET EAS using different combinations of MD and WNR modes. Comparisons were done through the evaluation of speech perception and music discrimination using the following tests:

- Freiburg Monosyllables Test in quiet
- Oldenburg Sentence Test in Multi Source Noise Field (OLSA MSNF)
- Adaptive Melodien-Muster-Diskriminations Test (AMMDT, adaptive melody pattern discrimination test)

The following are the results and conclusions from this study:

Results and conclusions

The performance of the SONNET EAS in its default setting, namely "MD Natural – WNR Mild", was not significantly different compared to the DUET 2 for Freiburg Monosyllables test in quiet. This indicates that the SONNET EAS natural directionality and mild WNR modes do not have a disadvantageous effect on speech intelligibility in quiet environment compared to DUET 2.

When the SONNET EAS was used in its default setting (MD Natural – WNR Mild), the results were significantly better as compared to DUET 2 for speech tests in noise (OLSA MSNF test). With the MD Omni – WNR Off setting, results for the SONNET EAS were slightly better (however not significantly) as compared to DUET 2 in speech in noise test conditions (OLSA MSNF).

There was no significant difference between the SONNET EAS in the Omni-WNR Off setting and SONNET EAS in the MD Omni – WNR Strong setting for speech perception in quiet. The result was the same (i.e. no significant difference) for test in noise.

The performance of three SONNET EAS settings, namely

- MD Natural-WNR Mild,
- MD Omnidirectional-WNR Mild, and

- MD Adaptive-WNR Mild

were compared amongst each other via the evaluation of speech perception in noise test condition (OLSA MSNF). There was an improvement in SNR with both Natural or Adaptive MD compared to the Omnidirectional mode. The SONNET EAS setting that gives the best result in noise (the lowest SNR score) is Adaptive-Mild.

These results show that the front-end features of the SONNET audio processor are also suitable for EAS users, and that such users can obtain significant benefit from these features.

The AMMDT music test showed no apparent difference between devices. The results of the subjective HISQUI test showed that 6 out of 10 users performed the same or better with the SONNET EAS.

13.4 Triphasic Pulse Stimulation

The use of triphasic pulse stimulation for patients with facial nerve stimulation (FNS) is supported with the following clinical data:

1. Case series of cochlear implant recipients with severe FNS who were provided with triphasic pulse stimulation:

The seven adults (eight ears) with severe FNS included in this case series were fitted with triphasic pulses provided through the custom made device (CMD) route. All patients experienced little to no facial nerve stimulation with triphasic pulses and data collected indicates that performance is the same or better, compared to biphasic stimulation. Two patients had limited objective data available with triphasic stimulation, due to less than or equal to 3 months device experience with the CMD processor. Two patients showed limited speech understanding with triphasic stimulation, likely due to factors unrelated to the CMD. The remaining three patients showed significant progress and benefit with triphasic stimulation. One of these three patients was fitted with a combination of triphasic pulses and a longer IPG of 10 μ s and used the device for a total of 21 months. While the degree of benefit varies from case to case, none of the patients experienced unexpected problems with triphasic stimulation.

2. Published literature:

In Bahmer & Baumann [2016]¹ the objective was to assess whether triphasic pulse stimulation prevents from facial nerve stimulation (FNS) because of a different electromyographic input-output function compared with biphasic pulse stimulation. This was a study in N = 4 adult MED-EL recipients with severe FNS who were fitted with the same triphasic pulse shape as available in MAESTRO 7. Electromyographic (EMG) recordings of muscles innervated by the facial nerve (musculi orbicularis ori and oculi) were applied to quantitatively assess the effects of FNS. Triphasic and biphasic fitting maps were compared, and speech performance data obtained for both biphasic and triphasic maps. For three patients, EMG was successfully recorded depending on stimulation level up to uncomfortable and intolerable FNS stimulation as upper limit. The obtained EMG recordings demonstrated high individual variability. However, a difference between the input-output function for biphasic and triphasic pulse stimulation was visually observable.

Compared with standard biphasic stimulation, triphasic pulses required higher stimulation levels to elicit an equal amount of FNS, as reflected by EMG amplitudes. The authors concluded that triphasic pulse stimulation prevents FNS because of a smaller gradient of EMG input-output function compared with biphasic pulse stimulation. Across patients, most of the map thresholds and most-comfortable-loudness (MCL) levels were higher for triphasic compared to biphasic stimulation. While subjects experienced mild to severe FNS with biphasic stimulation at MCL levels, these side effects were substantially reduced with triphasic stimulation. Speech scores for monosyllabic words and multisyllabic numbers were equal or better in all 3 tested patients with triphasic stimulation. In some cases, biphasic maps could not be tested due to the unbearable FNS side effects.

¹ Bahmer A, Baumann U [2016]. The underlying mechanism of preventing facial nerve stimulation by triphasic pulse stimulation in cochlear implant users assessed with objective measure. *Otol Neurotol* 37, 1231-1237.

The study by Bahmer et al [2017]² continued the basic premise of Bahmer & Baumann [2016]. For this study, EMG potentials were recorded using subdermal electrodes in adult subjects during CI surgery to provide better insight into the differences between EMG input-output functions, i.e. EMG response amplitudes vs. stimulation levels, for biphasic vs. triphasic stimulation, and to investigate possible effects of the stimulus configuration (leading polarity, alternating order) on FNS reduction. EMG potentials of muscles innervated by the facial nerve (orbicularis oculi and oris muscles) were recorded to quantitatively compare the effect of biphasic and triphasic stimulation. Recordings were conducted in N = 5 anesthetized subjects during CI surgery (MED-EL Synchrony devices). While inter-subject variation remained high, intra-subject results for different electrode positions were comparable. FNS was strongly reduced for cathodic-first triphasic stimulation. In contrast, exemplary cases showed little reduction for anodic-first triphasic as well as for alternating stimulation. Concluding, FNS in CI users can be reduced using triphasic stimulation, but the ameliorative effect appeared to be dependent on the leading stimulus polarity.

Please refer to the “Guide for Using Pulse Characteristics in MAESTRO 7.0” for considerations on when to use triphasic pulses when fitting patients with FNS and the fitting procedure for triphasic pulses. Triphasic pulses are new therapeutic stimulation waveforms. Long-term safety and effectiveness data of triphasic pulses in patients with FNS is limited. The safety and effectiveness of triphasic pulses in patients without FNS have not been studied.

² Bahmer A, Adel Y, Baumann U [2017]. Preventing facial nerve stimulation by triphasic pulse stimulation in cochlear implant users: intraoperative recordings. *Otol Neurotol* 38, e438-e444.

13.5 Music Appreciation

When using MED-EL fine structure coding strategies, the majority of adult cochlear implant users can enjoy music and will find it pleasant (Müller et al., 2012).

Music sounds pleasant with MED-EL fine structure coding strategies (Müller et al., 2012).

Müller et al. (2012) found, using a non-competitive questionnaire and descriptive statistics, that experienced adult cochlear implant users (n=46) after 3 months of use of the MED-EL FSP coding strategy reported that music sounded natural and pleasant (39.1%). Overall, 91.3% reported that music sounded pleasant. MED-EL considers that when a user considers music to be pleasant then they will derive enjoyment from it.

MED-EL fine structure coding strategies are rated equal or better than MED-EL envelope only based strategies for overall hearing impression, melody recognition, the ability to distinguish between instrument and singing voice, listening to known and unknown music, melody of known music, discriminating single instruments in known music and naturalness of sound. (Müller et al., 2012).

Müller et al. (2012) found, using an acute five-step answering-scale subjective questionnaire, that adult cochlear implant users (n=46) rated the MED-EL coding strategy FSP equal or better than the MED-EL coding strategy HDCIS, with regard to overall hearing impression (68.9 – 73.3%), melody recognition (88.9 – 91.1%), and the ability to distinguish between instrument and singing voice (71.1 – 77.8%) for selected pieces of music.

Müller et al. (2012) found, using a retrospective five-step answering-scale subjective questionnaire administered after three months of FSP use, that 90.9–93.3% adult cochlear implant users (n=46) rated the MED-EL coding strategy FSP better or equal to the MED-EL coding strategy CIS+, with regard to listening to known music (93.3%), listening to unknown music (90.9%), melody of known music (91.1%), discriminating single instruments in known music (93.3%), naturalness of sound (91.1%).

MED-EL's approach of complete cochlear coverage by stimulating from the base to the apical region of the cochlear improves music sound quality compared to using basal stimulation alone (Landwehr et al., 2014).

Landwehr et al. (2014) found, using a blinded A/B comparison procedure on a 9-point analogue scale, that adult cochlear implant users (n=6) reported a significantly higher music quality rating when all eleven electrodes were activated compared to when the four most apical electrodes were deactivated. According to Landwehr et al. (2014), "Subjective music quality ratings largely relied on electrode configuration, with the deactivation of apical electrode yielding clearly worse results" and "Stimulation of shallow insertion depth by deactivating the four most apical electrodes always yielded a significantly lower quality rating than using all 11 electrodes and the spread 7 configurations". These findings support MED-EL's position that the complete coverage of the cochlear can yield better music sound quality rating.

MED-EL's fine structure coding strategies more readily provide perceivable bass frequency cues for enhanced music sound quality compared to MED-EL envelope based strategies (Boeckmann-Barthel et al., 2013).

Boeckmann-Barthel et al. (2013) found, using the M.u.S.I.C Perception Test repository, specifically the Chord discrimination task, that in 8 adult cochlear implant (CI) users in the CIS+ group, average scores were 81.9% with high pitch contrasts but only 70.8% with low pitch contrasts, whereas in 9 adult CI users in the FSP group, average scores were 80.9% with high pitch contrasts and 73.5% with low pitch contrasts. Post-hoc paired-t tests gave a significant difference of low pitch and high pitch contrasts in the CIS+ group but not in the FSP group. The results show that FSP is more balanced than CIS+ in discriminating of both low- and high-pitch chords.

Boeckmann-Barthel et al. (2013) stated that "for the FSP group, the performance for the low-pitch region was not significantly different from that for the high-pitch region, indicating that the disadvantage for the perception of low-pitch information in complex musical sounds is reduced by the use of the FSP strategy."

This means that FSP provides a more balanced perception of sound quality than CIS+. By providing this balanced perception of cues, FSP coding strategies more readily provides perceivable bass frequency cues which can allow for enhanced music sound quality.

Clinical Studies

With MED-EL's fine structure coding strategies music sounds full, resonant and complete compared to MED-EL's envelope based sound coding strategies (Müller et al., 2012 and Looi et al., 2011).

Müller et al. (2012) found, using a non-competitive questionnaire and descriptive statistics, that 64.4% of 46 experienced adult cochlear implant users reported that music sounds 'broad', 'full', 'resonant' and 'complete' with FSP. This finding by Müller is further supported by Looi et al. (2011) who concluded that "overall the results suggest that the use of FSP as the default strategy for MED-EL recipients would have a positive effect on music appreciation".

MED-EL fine structure coding strategies allows for better music perception and appreciation compared to MED-EL envelope only based strategies.

Müller et al. (2012) found, using an acute five step answering scale subjective questionnaire, that adult CI users (n=46) rated the MED-EL coding strategy FSP equal or better than the MED-EL coding strategy HDCIS, with regard to overall hearing impression (68.9 – 73.3%), melody recognition (88.9 – 91.1%), and the ability to distinguish between instrument and singing voice (71.1 – 77.8%) for selected pieces of music.

Müller et al. (2012) found, using a retrospective five step answering scale subjective questionnaire administered after three months of FSP use, that 90.9–93.3% adult CI users (n=46) rated the MED-EL coding strategy FSP better or equal to the MED-EL coding strategy CIS+, with regard to listening to known music (93.3%), listening to unknown music (90.9%), melody of known music (91.1%), discriminating single instruments in known music (93.3%), naturalness of sound (91.1%).

In these studies, music perception and music appreciation have been investigated separately from each other. When investigating music perception, the questions were: can you differentiate, discriminate, recognize, or identify two sounds (rhythms, pitches, melodies, instruments); whereas, when studying music appreciation, the questions were: how pleasant or natural is a sound. Music perception and music appreciation are two different ways to look at music. Music perception is more about identifying certain aspects of music such as melody recognition, the ability to distinguish between instrument and singing voice, listening to known and unknown music, melody of known music and discriminating single instruments in known music, etc. whereas music appreciation is more about the individual feels about the overall hearing impression.

SUMMARY OF PRIMARY CLINICAL STUDY (IDE G140050) UNC Feasibility Study Design

The feasibility study for the MED-EL Cochlear Implant System was conducted under IDE (G140050) to evaluate the safety and effectiveness of the MED-EL Cochlear Implant System in individuals 18 years of age and older with SSD or AHL. The primary study goal was to determine whether subjects with SSD or AHL demonstrated an improvement in speech perception, localization, and quality of life after receiving a cochlear implant. Both objective and subjective performance data were collected, as well as safety data in the form of adverse events. Forty subjects were implanted at the University of North Carolina at Chapel Hill with the MED-EL CONCERT or SYNCHRONY Cochlear Implant System in this prospective, single-site, non-randomized, non-blinded, repeated measures clinical study.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in G140050 was limited to patients who met the following inclusion criteria:

- 18 years of age or older at the time of implantation
- Unilateral moderate-to-profound sensorineural hearing loss
 - o Unaided residual hearing thresholds measured from 250-8000 Hz (PTA $\geq$ 70 dB HL in the ear to be implanted)
 - o For SSD: normal to mild residual hearing thresholds from 250-8000 Hz in the contralateral ear ($\leq$ 35 dB HL at each frequency, 250-8000 Hz)
 - o For AHL: mild to moderate hearing thresholds from 250-8000 Hz in the contralateral ear (PTA $\geq$ 35 and $\leq$ 55 dB HL)
 - Aided word recognition of 80% or more as measured with CNC words (50-word list)
- Duration of moderate-to-profound sensorineural hearing loss less than or equal to 10 years
 - o Hearing loss for less than 10 years: study participants were only included if they had used a hearing aid consistently for 5 years
 - o Hearing loss for less than 5 years: study participants were only included if they had at least completed a 1-month hearing aid trial
- Previous experience (at least one month) with a current treatment option for SSD, including a conventional hearing aid, bone-conduction device, or CROS/BICROS technology
- Aided word recognition in the ear to be implanted of 60% or less as measured with CNC words (50-word list)
- Realistic expectations
- Willingness to obtain recommended meningitis vaccinations per CDC recommendations
- No reported cognitive issues: pass of the Mini Mental State Examination (MMSE) screener
- Ability and willingness to comply with study requirements, including travel to investigational site and study-related activities

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Non-native English speaker
- Conductive hearing loss in either ear
- Compromised auditory nerve, including those with a history of vestibular schwannoma
- Ossification
- Inability to participate in follow-up procedures (i.e., unwillingness, geographic location)
- History of meningitis, autoimmune disease, or any medical condition that contraindicate middle or inner ear surgery or anesthesia
- Meniere's disease with intractable vertigo
- Trauma that precludes inner ear surgery
- Case of sudden sensorineural hearing loss that has not been first evaluated by a physician
- Pregnancy
- Tinnitus as the primary purpose for seeking cochlear implantation
- Severe or catastrophic score on the Tinnitus Handicap Inventory

2. Follow-up Schedule

This study involved up to ten visits before and after implantation, for about a one-year period. Candidacy testing included medical and audiological evaluations (e.g., audiograms, speech recognition tests) to determine study eligibility. After confirming eligibility, the subject underwent baseline testing. The device was subsequently implanted based on the subject's candidacy testing. An initial follow-up visit was completed following surgery, and the cochlear implant was activated following a healing period of 2 to 4 weeks.

The baseline and postoperative measurements are summarized under 'Test Conditions' below. All patients were scheduled to return for follow-up examinations at 1, 3, 6, 9, and 12 months postoperatively. Pre-operatively and post-operatively, unaided air conduction thresholds were collected. At all intervals, speech perception in quiet and in noise and localization data was collected. Adverse events and complications were recorded at all visits.

The key timepoints (pre-op baseline and 12-months post-op) are shown below in the tables summarizing safety and effectiveness.

Test Conditions

The test battery was completed at the pre-operative interval and again at 1, 3, 6, 9, and 12 months post-operatively. For soundfield measures (speech perception and localization), a 180° arc with 11 speakers spaced 18° apart was utilized. Post-operative aided soundfield assessment was completed with the subject using the SONNET or OPUS 2 speech processor unless otherwise noted. For the AHL group, soundfield testing was completed with a hearing aid in the contralateral ear. See below for further details on testing conditions.

Subjects participated in two aural rehabilitation sessions with a board-certified speech-language pathologist. One session was completed after the initial activation of the external speech processor. The second session took place in conjunction with the 1-month post-initial activation interval.

- Unaided Diagnostic Assessment
 - o Air-conduction thresholds in both ears
 - o Assess bone-conduction thresholds if there is a PTA shift of >15 dB as compared to the previous interval
- Tympanometry for each ear
- Sound Field Measures
 - o Aided thresholds with the external speech processor on measured using pulsed, warble tones
 - Frequencies assessed: 250-8000 Hz
 - Masking presented to the contralateral ear
 - o Speech Perception Measures (recorded materials presented at 60 dB SPL)
 - Speech Perception in Quiet
 - Speech 0° azimuth
 - CNC words
 - AzBio sentences
 - Speech Perception in Noise
 - Speech and noise 0° azimuth
 - Speech 0° azimuth and noise to implanted side
 - Speech 0° azimuth and noise to contralateral ear
 - AzBio sentences
 - If >50% at SNR+10, then SNR+5; if >50% at SNR+5, then SNR0
 - BKB-SIN sentences with adaptive SNR
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
 - o Localization
 - 200-ms speech-shaped noise, presented at 70-dB SPL from one of the 11 speakers (evenly spaced -180 to 180 degrees), selected at random
 - Intensity level for each stimulus presentation randomly varied (10 dB around 70 dB SPL)
 - Cochlear implant speech processor off
 - Cochlear implant speech processor on
- Subjective questionnaires
 - o Speech, Spatial and Qualities of Hearing Scale (SSQ)
 - o Abbreviated Profile of Hearing Aid Benefit (APHAB)
 - o Tinnitus Handicap Inventory (THI)

3. Clinical Endpoints

Measures

Safety Measure: The primary safety measure was the evaluation of all adverse events reported within 12 months. The full profile of adverse events was summarized and considered, with specific attention given to device-related adverse events. The adverse events include anticipated and unanticipated adverse events. The list of anticipated adverse device effects noted in the study protocol are as follows:

- Risks from the SYNCHRONY IFU
 - o Loss of residual hearing
 - o Increased vertigo
 - o Delay of healing of the scar
 - o Impairment of the sense of taste
 - o Potential for swallowing difficulties
 - o Numbness
 - o Increased tinnitus
 - o Stimulation of the facial nerve
 - o Temporary pain and uncomfortable sounds during stimulation
- Additional surgical risks
 - o Facial nerve injury
 - o Infection
 - o Bleeding
 - o Cerebrospinal fluid (CSF) leak
 - o Pain
 - o Scarring
- Additional post-operative risks

- o Swelling around the incision and/or coil site
- o Pain
- o Reduced or loss of pinna sensitivity on the surgical side
- o The cochlear implant may not provide any auditory stimulation
- o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in the perception of speech
- o The cochlear implant may provide auditory stimulation, but with a sound quality too poor to aid in localization
- o Pain associated with the coil and/or placement of the external speech processor on the subject's ear
- o Movement of the internal receiver
- o Discomfort from electric stimulation
- o Facial nerve stimulation
- o Headache
- o Dizziness
- o Altered taste (i.e. reports of metallic tastes on the same side of the tongue as the surgical ear)
- o Fatigue during follow-up assessment (completion of the test battery and/or mapping)
- o The internal device may fail, requiring revision cochlear implantation
- o The sound from the cochlear implant may interfere with the better hearing ear.

Effectiveness Measures: The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition. Aided speech perception performance on word and sentence materials at the post-activation intervals was evaluated to monitor trends over time. Unaided and aided (with BCHA or CI, as applicable) localization performance was also compared pre-operatively and at each of the post-activation intervals. The overall RMS error is reported for localization in each condition. Additionally, subjective report scores were compared pre-operatively and at the 12-month post-activation intervals.

Audiometric Test Methods & Effectiveness Measures

Speech perception and localization measures were recorded in a research lab that featured a 180° arc with 11 speakers spaced 18° apart. Postoperative aided sound field assessment was completed with the study participant listening with the OPUS 2 or SONNET speech processor.

Speech perception in quiet was tested at 0° azimuth, presenting CNC words (Peterson & Lehiste, 1962) or AzBio sentences (Spahr et al., 2012) at 60 dB SPL. Speech perception in noise was tested in the conditions (1) speech and noise 0° azimuth (SoNo), (2) speech 0° azimuth and noise to the affected ear/implanted side (SoNCI), and (3) speech 0° azimuth and noise to the contralateral ear (SoNContra). AzBio sentences were presented at 0 dB signal-to-noise ratio (SNR) in most cases. BKB-SIN sentences were presented with adaptive SNR.

For the localization task a 200-ms speech-shaped noise was presented at 70-dB SPL from one of the 11 speakers (selected randomly). The intensity level for each stimulus presentation was randomly varied (10 dB around 70 dB SPL). The listener was facing the center speaker during stimulus presentation and the task was to identify the source of the noise. No feedback was provided. In the condition cochlear implant speech processor OFF, study participants were only listening with the contralateral ear. In the condition cochlear implant speech processor ON, sound was perceived both via the cochlear implant and the contralateral ear.

Subjective data was collected via the SSQ and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995). The SSQ can be further divided into three subscales: speech, spatial, and quality. The APHAB consists of four subscales: Ease of Communication (EC), Background Noise (BN), Reverberation (RV), and Aversiveness (AV). The Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996) was also utilized to collect information on severity of tinnitus pre-operatively as well as at the 12-month interval.

B. Accountability of Study Cohort

In the SSD cohort, 20 subjects were enrolled and completed testing through the 12-month interval. In the AHL cohort, 20 subjects were enrolled and 18 completed testing through the 12-month interval. One subject in the AHL cohort withdrew prior to completion of all test intervals, and one subject was still undergoing follow-up testing at the time of data analysis.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a feasibility study performed in the US. Proportions enrolled are consistent with the age, sex/gender, racial and ethnic prevalence of the SSD and AHL.

1. SSD Cohort

Of the 20 implanted subjects, 12 were female and 8 were male. At the time of implantation, subjects ranged in age from 22 to 66 years of age. The duration of profound hearing loss ranged from 0.1 to 6.6 years. Fifteen subjects experienced sudden hearing loss and five subjects experienced a gradual hearing loss. Hearing loss was reported as unknown in 16 cases, due to Meniere's disease in three subjects, and caused

by trauma in one case. Further information on subject demographics and hearing related variables is summarized in Table 2 below.

Table 2. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=20)
Gender	
Male	40% (8/20)
Female	60% (12/20)
Age (years)	50 (20) (22 – 66)
Duration of hearing loss (years)	
Noticeable	4.2 (20) (0.1 – 14.6)
Profound	2.6 (20) (0.1 – 6.6)
Implanted ear	
Left	55% (11/20)
Right	45% (9/20)
Tinnitus Handicap Grade Level	
Slight	35% (7/20)
Mild	40% (8/20)
Moderate	25% (5/20)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

2. AHL Cohort

Of the 18 subjects who completed follow-up, 9 were female and 9 were male. At the time of implantation, subjects ranged in age from 52 to 79 years of age. The duration of profound hearing loss ranged from 0.0 to 9.8 years. Ten subjects experienced sudden hearing loss and six subjects experienced a gradual hearing loss, with the remaining two subjects experiencing both a gradual and sudden loss. Hearing loss was reported as unknown in 14 cases, due to Meniere's disease in two subjects, due to noise-induced hearing loss in one subject, and caused by viral infection in one case. Further information on subject demographics and hearing related variables is summarized in Table 3 below.

Table 3. Descriptive statistics for subject variables

Parameter/Category or Statistic	Total (n=18)
Gender	
Male	50% (9/18)
Female	50% (9/18)
Age (years)	70 (18) (52 – 79)
Duration of hearing loss (years)	
Noticeable	11.5 (17) (0.0 – 51.5)
Profound	3.5 (17) (0.0 – 9.8)
Implanted ear	
Left	67% (12/18)
Right	33% (6/18)
Tinnitus Handicap Grade Level	
Slight	55% (10/18)
Mild	28% (5/18)
Moderate	17% (3/18)
*Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)	

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on all patients implanted under G140050 (N=40) up to 12 months post implantation. Table 4 displays the adverse events reported for this study.

Adverse effects that occurred in IDE G140050:

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated. A total of nine adverse events were reported to be related to the device or procedure. An additional six adverse events were not able to be ruled out as device or procedure-related. No serious, unanticipated, device-related adverse events were reported.

Table 4. Number and percentage of adverse events observed for SSD subjects.

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects
Vertigo/dizziness/imbalance	11	9	22.5%
Unrelated infection	3	3	7.5%
Changes in sound quality/volume	3	2	5%
Depression	3	2	5%
Aural pressure	2	2	5%
Facial stimulation	2	2	5%
Headache	2	2	5%
Atrial fibrillation	1	1	2.5%
Bleeding at surgical site	1	1	2.5%
Electrode contact dislodged	1	1	2.5%
Fall involving bump to the implant	1	1	2.5%
Type C tympanogram	1	1	2.5%
Short circuit	1	1	2.5%
Total	32	21*	52.5%

*Some subjects experienced more than one device-related adverse event

The most frequently observed adverse event was vertigo, dizziness, or imbalance, which was reported a total of 11 times. In four cases, the event was deemed unrelated to the device or procedure. In three cases, it could not be ruled out that the event was related to the device or procedure. In the remaining four cases, it was determined that the event was related to the procedure. Unrelated infection was reported in three cases: two upper respiratory infections and one sinus infection. In all cases, the event was deemed unrelated to the device or procedure. All other events occurred at a rate of 5% or less (2 subjects or fewer), which is consistent with the rate of adverse events observed for the approved indication of bilateral, severe-to-profound, sensorineural hearing loss.

2. Effectiveness Results

The primary effectiveness measures were the comparisons of speech perception and localization performance between the bilateral, pre-operative, unaided/best-aided (with BCHA) condition and the bilateral, 12-month-post-operative CI + NH (or HA) condition among 20 subjects with SSD and 17 subjects with AHL. Additionally, subjective reports from the SSQ and APHAB were also compared pre-operatively and at the 12-month post-operative interval.

Speech Perception in Quiet

SSD Cohort

Speech perception testing in quiet at the 12-month interval demonstrated an improvement in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. In the contralateral ear, no change was observed on CNC words from baseline to 12 months. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet across test intervals. The comparison of AzBio sentence score in quiet with a BCHA to scores at 12 months with the CI-ON also demonstrated no change. Table 5 displays the descriptive statistics of the speech perception in quiet scores for the SSD cohort.

Table 5. Speech perception in quiet (SSD Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	20	20	20	20	20	20	20
Mean (SD)	3.5 (6.68)	54.6 (18.15)	99.3 (2.27)	99.8 (0.62)	99.0 (1.56)	99.2 (1.15)	99.5 (1.19)
Min – Max	0 – 22	10 – 84	90– 100	98 – 100	95 – 100	95 – 100	95 – 100

AHL Cohort

For the cohort with asymmetric hearing loss, an improvement was demonstrated for speech perception testing in quiet at the 12-month interval in the implant ear alone when tested with the CI-ON, compared to the pre-operative, unaided condition. No change was observed on CNC words from baseline to 12 months in the contralateral ear. When tested in soundfield with both ears (unaided v. CI-ON), no change was demonstrated on AzBio sentences in quiet between the pre-operative and 12-month intervals. Additionally, no change was demonstrated in the comparison of AzBio sentence score in quiet between BCHA pre-operatively and 12 months with the CI-ON. See Table 6 below for the descriptive statistics of the speech perception in quiet scores.

Table 6. Speech perception in quiet (AHL Cohort)

SSD speech in quiet	Implant Ear		Contralateral Ear		Soundfield, both ears		
	Baseline, unaided CNC	12-month, CI-ON CNC	Baseline, unaided CNC	12-month, unaided CNC	Baseline, unaided AzBio	Baseline, BCHA AzBio	12-month, CI-ON AzBio
N	18	18	18	18	18	18	18
Mean (SD)	6.3 (7.98)	56.2 (18.41)	94.2 (7.06)	92.7 (8.68)	87.4 (13.96)	87.7 (11.01)	94.3 (8.38)
Min – Max	0 – 22	28 – 86	78 – 100	72 – 100	50 – 99	(61 – 99)	72 – 100

Speech Perception in Noise

SSD Cohort

On AzBio sentence testing in noise, subjects in the SSD cohort demonstrated an improvement between the bilateral, baseline, pre-operative, unaided testing and the bilateral, 12-month post-operative, CI + NH testing in the speech front, noise front condition. This same improvement was also noted between the bilateral, baseline, pre-operative, aided (with BCHA) condition and the bilateral, 12-month, post-operative, CI + NH condition. NO differences were found between pre-operative unaided and pre-operative, aided (with BCHA) scores. In the speech front, noise to the CI ear condition, subjects demonstrated no change in score in comparing the pre-operative interval to the CI-ON at 12 months. However, when comparing the pre-operative aided scores to the 12-month scores with CI, an improvement in performance was noted. Better scores were obtained for the pre-operative unaided condition as compared to the pre-operative aided condition.

A significant improvement was noted with the cochlear implant on at 12 months post-operative compared to the pre-operative, unaided interval for the speech front, noise to the contralateral ear condition. This same improvement was also found when comparing CI-ON at the 12-month, post-operative condition to the pre-operative, aided (with BCHA) condition. This improvement demonstrates that when noise presents as a masker to the better hearing ear, the cochlear implant provides benefit in speech understanding. Table 7 provides further details on AzBio sentence in noise scores.

Table 7. Speech perception in noise (SSD Cohort, AzBio)

SSD AzBio	SoNo			SoNCI			SoNContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON	Baseline, unaided	Baseline, BCHA	12- month, CI-ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	37.5 (10.98)	31.5 (16.56)	47.2 (10.72)	83.4 (9.51)	61.25 (27.92)	85.0 (11.04)	16.5 (12.78)	18.3 (13.50)	52.6 (21.43)
Min-Max	20 - 64	0 - 59	29 - 68	59 - 94	0 - 98	60 - 97	0 - 45	0 - 59	8 - 86

A similar pattern was noted for speech in noise testing on the BKB-SIN. No significant changes were found in any comparisons for the speech front, noise front or speech front, noise to the CI ear conditions. However, in the speech front, noise to the contralateral ear condition, it was found that the CI does provide benefit in speech perception, and thus, a significant improvement was found when comparing the 12-month, post-operative CI + NH condition to the pre-operative, unaided condition or to the pre-operative, aided (with BCHA) condition. Table 8 provides the detailed descriptive statistics of the BKB-SIN scores.

Table 8. Speech perception in noise (SSD Cohort, BKB-SIN)

SSD BKB-SIN	SoNo			SoNCI			SoNContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI- ON	Baseline, unaided	Baseline, BCHA	12- month, CI- ON	Baseline, unaided	Baseline, BCHA	12- month, CI- ON
N	20	20	20	20	20	20	20	20	20
Mean (SD)	0.1 (1.42)	0.8 (1.98)	-0.8 (1.74)	-4.8 (1.64)	-2.6 (2.39)	-4.8 (1.66)	1.8 (1.33)	1.8 (2.35)	-1.0 (2.20)
Min-Max	-2.5 - 3.0	-2.5 - 4.5	-3.0 - 4.0	-7.5 - 1.5	-7.0 - 1.0	-7.5 - -2.0	-0.5 - 4.0	-2.5 - 8.0	-5.0 - 5.5

AHL Cohort

For the AHL cohort, the majority of subjects were tested at 0 dB SNR. However, some subjects were tested at +5 or +10 dB SNR according to a decision tree implemented for determining SNR. Pre-operative and post-operative comparisons within subject were done at the same SNR. For this reason, only 17 subjects are included in the AzBio analysis for both the pre-operative unaided/aided (with BCHA) condition and the 12-month post-operative CI + HA condition.

In the speech front, noise front condition, a significant improvement was found on AzBio sentences for the 12-month, post-operative CI + HA condition compared to the pre-operative, unaided condition and compared to the pre-operative, aided (with BCHA) condition. Pre-operative, BCHA scores were worse than pre-operative unaided scores and worse than 12-month, post-operative CI + HA scores in the speech front, noise to the CI ear condition. In the speech front, noise to the contralateral ear condition, a significant improvement was noted for the 12-month, post-operative CI + HA testing compared to both the pre-operative, unaided testing and the pre-operative, aided (with BCHA) testing. Table 9 below displays the descriptive statistics of the AzBio testing for the AHL Cohort.

Table 9. Speech perception in noise (AHL Cohort, AzBio)

AHL AzBio	SoNo			SoNCI			SoNContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI- ON	Baseline, unaided	Baseline, BCHA	12- month, CI- ON	Baseline, unaided	Baseline, BCHA	12- month, CI- ON
N	17	17	17	17	17	17	17	17	17
Mean	22.7 (13.95)	20.5 (12.86)	33.5	44.2 (17.70)	30.5 (18.23)	44.6	6.3 (9.49)	11.3 (16.69)	29.4

(SD)			(22.10)			(24.74)			(22.59)
Min-Max	0 – 47	0 – 47	3 – 85	9 – 78	1 – 70	5 – 94	0 – 36	0 – 66	1 – 95

For BKB-SIN testing, no changes were demonstrated in the speech front, noise to the CI ear condition. An improvement was found between the pre-operative, aided (with BCHA) condition and the 12-month, post-operative CI + HA condition in the speech front, noise front condition. Similar to the AzBio test results for the SSD cohort, there was a significant improvement for BKB-SIN in the speech front, noise to the contralateral ear condition when comparing the 12-month, post-operative CI + HA condition to the pre-operative, unaided condition. Table 10 below displays the analyses of BKB-SIN testing in the AHL cohort.

Table 10. Speech perception in noise (AHL Cohort, BKB-SIN)

AHL BKB-SIN	SoNo			SoNCI			SoNContra		
	Baseline, unaided	Baseline, BCHA	12- month, CI- ON	Baseline, unaided	Baseline, BCHA	12- month, CI- ON	Baseline, unaided	Baseline, BCHA	12- month, CI- ON
N	18	18	18	18	18	18	18	18	18
Mean (SD)	4.3 (3.62)	5.1 (3.04)	3.7 (3.28)	1.3 (3.89)	2.5 (3.77)	2.6 (3.78)	7.1 (4.14)	5.9 (4.50)	4.6 (4.44)
Min- Max	0.5 – 13.0	0 – 10	-2.0 – 9.5	-6.5 – 8.5	-3.5 – 10.0	-3.5 – 9.0	2.0 – 15.5	0 – 14.5	-1.0 – 15.5

Localization

SSD Cohort

Subjects in the SSD cohort demonstrated a significant improvement in localization performance with the CI at 12 months compared to the baseline, aided (with BCHA) condition. Additionally, results indicated an improvement in performance between the baseline, unaided condition and the 12-month, postoperative CI + NH condition. Table 11 displays localization performance in RMS error.

Table 11. Localization performance (SSD Cohort)

SSD Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	20	20	20
Mean (SD)	66.5 (20.47)	69.6 (18.71)	26.7 (6.32)
Min-Max	42.9 – 109.1	45.3 – 106.1	13.6 – 38.4

AHL Cohort

Similar to the SSD cohort, subjects in the AHL cohort demonstrated improved localization performance with the CI-ON at 12 months compared to the baseline, aided (with BCHA) condition. This improvement was also evident when comparing the 12-month, postoperative CI + HA to the pre-operative, unaided condition. Table 12 displays the analyses of the AHL Cohort's localization data.

Table 12. Localization performance (AHL Cohort)

AHL Localization	Baseline, unaided	Baseline, BCHA	12-month, CI-ON
N	18	18	18
Mean (SD)	76.5 (19.23)	77.2 (18.89)	40.1 (10.65)
Min-Max	43.8 – 105.3	45.6 – 106.5	26.6 – 73.6

Subjective Questionnaire

SSD Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the CI on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 13 below for the descriptive statistics of the SSQ.

Table 13. SSQ (SSD Cohort)

SSD SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20
Mean	3.7	7.1	2.4	6.5	5.6	7.7
Std. Deviation	1.34	0.99	1.2	1.86	2.09	1.28
Minimum	0.6	5.4	0.5	2.8	0.5	5.6
Maximum	7.2	8.9	4.5	8.9	9.8	9.8

Self-perceived benefit from the CI as reported on the APHAB demonstrated significant improvement on global score and the subscales, except for the aversiveness subscale. Table 14 below provides the detailed APHAB scores at the pre-operative and 12-month intervals.

Table 14. APHAB (SSD Cohort)

SSD	Global	EC	BN	RV	AV

APHAB	pre	12m	Pre	12m	pre	12m	pre	12m	pre	12m
N	20	20	20	20	20	20	20	20	20	20
Mean	49.8	17.9	31.6	8.7	70.1	25.2	47.5	19.7	43.1	26.7
Std. Deviation	18.65	8.91	21.06	6.15	17.32	11.95	21.96	12.43	28.64	24.83
Minimum	20.3	6.1	2.8	1.0	39.3	10.2	18.7	2.8	1.0	1.0
Maximum	86.3	36.7	81.0	24.8	95.0	56.2	87.0	41.7	93.0	91.0

AHL Cohort

Self-perceived quality of hearing reported on the SSQ improved significantly with the cochlear implant on all three scales (speech, spatial, and qualities). Significant changes over time were found in all three scales. See Table 15 below for detailed information on the SSQ.

Table 15. SSQ (AHL Cohort)

AHL SSQ	Speech Subscale		Spatial Subscale		Qualities Subscale	
	pre	12m	pre	12m	pre	12m
N	18	18	18	18	18	18
Mean	3.2	5.8	2.6	6.0	4.6	6.8
Std. Deviation	1.48	1.50	1.26	1.62	1.77	1.20
Minimum	0.4	3.6	0.3	3.1	0.2	4.4
Maximum	6.0	8.9	4.7	8.5	8.3	8.7

Self-perceived benefit from the cochlear implant as reported on the APHAB demonstrated significant improvement on global score and other subscales over time except the aversiveness subscale. Table 16 below displayed the detailed APHAB scores at the pre-operative and 12-month post-operative intervals.

Table 16. APHAB (AHL Cohort)

AHL APHAB	Global		EC		BN		RV		AV	
	pre	12m	pre	12m	pre	12m	Pre	12m	pre	12m
N	18	18	18	18	18	18	18	18	18	18
Mean	54.1	28.1	42.9	16.6	63.5	39.3	56.0	28.3	43.1	42.4
Std. Deviation	16.21	10.49	24.67	13.01	16.84	17.10	18.30	11.96	35.04	29.21
Minimum	20.0	11.3	10.2	1.0	14.5	14.5	14.2	12.0	1.0	1.0
Maximum	92.3	54.1	91.0	54.0	95.0	66.3	97.0	54.2	99.0	97.0

SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Literature Search Strategy

MED-EL conducted an extensive literature search to collect additional supporting clinical evidence of cochlear implants in SSD and/or AHL indications. The search terms they used are listed in Tables 17, 18, and 19, below.

Table 17. Combinations of Search Terms

Search Step	Search Terms	Review Question
1	"hearing loss" OR deaf*	P
2	single sided deafness OR SSD OR unilateral OR UHL OR asymmetric* OR AHL	P
3	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment" OR bone conduction OR BCI OR bone anchored OR BAHA OR CROS OR contralateral routing OR BiCROS OR "transcranial CROS" OR in-the-mouth device OR ITM OR soundbite OR bonebridge OR "ad hear"	I & C
4	1 AND 2 AND 3	
5	Limit 4 to Humans	
6	Limit 5 to Language: English	
7	Limit 6 to Publication date: June, 2014 to May, 2017	

Search Step	Search Terms	Review Question
1	(single sided deafness) OR ((((((SSD) OR unilateral) OR UHL) OR asymmetric) OR AHL)) AND (((hearing loss) OR deaf*) OR deafness))	P
2	cochlear implant* OR hearing aid* OR hearing system OR hearing instrument OR device* OR "no treatment"	I & C
3	1 AND 2	
4	Limit 3 to Humans	
5	Limit 4 to Language: English	
6	Limit 5 to Publication date: May 1, 2017 to March 6, 2019	

Note. The different search terms are connected using Boolean logic. Activated filters are displayed in italics. P = Population, disease, or condition; I = Intervention; C = Comparator group or control.

* Wildcard symbol to broaden the search by creating a root word search.

Table 18. Inclusion and Exclusion Criteria for Retrieved Literature

Inclusion Criteria	
Population/Problem	Patients of any age who have single sided deafness
Intervention/Treatment	cochlear implant, any other treatment that makes hearing possible, or no treatment
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant
Inclusion Criteria	
Population/Problem	Patients of any age who have SSD or AHL
Intervention/Treatment	cochlear implant
Outcomes	Safety or performance outcomes (or both) relating to the therapy
Exclusion Criteria	
E1	Not a clinical study in humans
E2	Neither safety nor performance of the therapy addressed
E3	No relevant therapy used
E4	Wrong study population e.g. different type of hearing loss
E5	Devices have been used for purposes outside their indications
E6	Publication lacking sufficient information
E7	Topic not relevant

Table 19. Literature Appraisal Criteria

Data Suitability		Description	Grading System
Appropriate Device		Where the data generated from the device in question?	D1 – Actual device D2 – Comparable device D3 – Other device
Appropriate Device Application		Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 – Same use A2 – Minor deviation A3 – Major deviation
Appropriate Patient Group		Were the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease including state and severity)?	P1 – Applicable P2 – Limited P3 – Different population
Acceptable	Report/Data	Did the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 – High quality R2 – Minor deficiencies R3 – Insufficient information
Data Contribution		Description	Grading System
Data Source Type		Was the design of the study appropriate?	T1 – Yes T2 – No
Outcome Measures		Did the outcome measures reported reflect the intended performance of the device?	O1 – Yes O2 – No
Follow-Up		Was the duration of the follow-up long enough to assess treatment effects and identify complications?	F1 – Yes F2 – No
Statistical Significance		Was a statistical analysis of the data provided and appropriate?	S1 – Yes S2 – No
Clinical Significance		Was the magnitude of the treatment effect observed clinically significant?	C1 – Yes C2 – No

Published Literature on Children

The literature search yielded five peer-reviewed papers in SSD and/or AHL children with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults and children aged 5 yrs and older. The papers comprise a total of 26 children with SSD (five of which were reported to be implanted with MED-EL devices) and a total of nine children with AHL. Tables 17, 18, and 19 above list the detailed literature search criteria and relevant information.

The overall benefits of CI in children with SSD and AHL include improved performance in speech perception in quiet and noise, sound localization and subjective measures of quality of life.

Word recognition in quiet:

Beck et al. (2017) reported diverse speech audiometry results. Some of the children showed measurable benefits on speech discrimination. The CAP scores improved for the SSD children (N = 8) with CI compared to preoperative performance. Rahne and Plontke (2016) reported that two SSD children improved with CI over time in number recognition, two SSD children showed no recognition. One child improved over time in word recognition with CI, whereas the other three children showed no recognition.

Word recognition in noise:

Arndt et al. (2015) reported on the speech perception in noise for different speech and noise configuration. Children with SSD demonstrated improved although variable performance on speech perception in spatially-separated conditions. Some children demonstrated improvement in spatially separate speech and noise. Tavora-Vieira and Rajan (2015) showed better and similar speech perception in noise with CI-on compared to CI-off for two SSD children. Gratacap et al. (2015) showed an increase in speech perception in noise in 9 children with AHL after 12 and 24 months of CI use compared to preoperative performance. Rahne and Plontke (2016) reported an improvement in speech reception thresholds in three SSD children when CI-on and CI-off are compared; in one child no measurement was possible.

Sound localization:

Arndt et al. (2015) reported a decreased localization error with CI for most of the children as compared to the pre-operative unaided condition. Tavora-Vieira and Rajan (2015) reported that one child with SSD showed a decreased localization error after 6 and 12 months with the CI-on compared to CI-off condition, whereas the other child with SSD showed the same localization performance in both conditions. Rahne and Plontke (2016) reported an improvement in sound localization in four children with SSD when CI-on and CI-off are compared.

Subjective measures:

Beck et al. (2017) showed that the parents (N = 9) and children (N = 3) with SSD reported an increase score for the SSQ. Arndt et al. (2015) reported an increase the SSQ score in children with SSD with postlingual onset of deafness (N = 9), slight improvement in children with SSD with perilingual onset of deafness (N = 2) and minimal improvement or same performance in children with SSD who are congenitally deaf (N = 2).

Published Literature on Adults

The literature search yielded six peer-reviewed papers in SSD and/or AHL adults with a candidacy criterion of PTA $\geq$ 90 dB HL in the ear to be implanted, matching the proposed candidacy criterion for CI in SSD and AHL adults. Although the paper by Kitoh et al. (2016) mentioned a study inclusion criterion of PTA $>$ 70 dB HL, all five subjects included in the study had a pre-operative unaided PTA of 92 dB HL or higher. Hence, the results from this study were included in the summary below.

The six papers comprise a total of 58 adults with SSD (N = 50 of which implanted with MED-EL devices) and a total of 52 adults with AHL (N = 37 of which implanted with MED-EL devices). This subject count does not include five SSD nor 16 AHL patients from Skarzynski et al. (2017), as those subjects are part of the larger cohort from the same implant center later reported on by Lorens et al. (2019). Also note that three of the 58 adult SSD subjects might have an unaided PTA close to or below 90 dB HL in the implanted ear, as the paper by Döge et al. (2017) presents PTA data as median and interquartile range only (75%, i.e. N = 8 of 11 studied subjects have PTA $>$ 100 dB HL).

The overall benefits of CI in SSD and AHL adult patients include improved performance regarding speech perception in quiet and in noise, sound localization and subjective measures regarding quality of life, music enjoyment and tinnitus.

Word recognition in quiet

Döge et al. (2017) showed that with a CI, the mean PTA thresholds of the deaf ear improved from the mean value of 120 dB at unaided condition to below 40 dB in the aided condition in 11 SSD subjects. In addition to the benefit of sound perception, the CI enabled better speech perception in quiet. Skarzynski et al. (2017) compared CI-on vs CI-off condition in 5 SSD and 16 AHL subjects and significantly better speech perception was observed in the CI-on condition. Results with the CI demonstrated a continuous improvement in speech recognition after 12-month of use. Rahne and Plontke (2016) reported a significant improvement in monosyllabic word and multisyllabic number recognition in quiet in comparing the 12-month and 1-month after CI activation in 17 SSD subjects. van Loon et al. (2017) reported that speech recognition scores increased from 74% pre-operatively to 88% at 12-month with bimodal stimulation in 7 AHL cases.

Speech perception in noise

Several studies found that the CI enabled better speech perception in noise. Rahne and Plontke (2016) reported a significant improved speech perception in noise at 3-month of CI activation with CI-on vs CI-off condition, and a continuous improvement occurring at 12-months in 17 SSD subjects. Skarzynski et al. (2017) reported better speech perception in noise at CI-on vs CI-off condition. van Loon et al. (2017) reported that in comparison to the CI-off or CI-only condition, bimodal stimulation resulted in significantly better speech recognition in noise and spatial speech recognition at 3-months, 6-months and 12-months post-activation. Lorens et al. (2019) reported a significant binaural benefit conveyed by CI-on in comparison to the CI-off condition, in 25 SSD and 45 AHL subjects. Kitoh et al. (2016) reported a gradually improved speech perception in noise after 12-months post-activation in comparison to the pre-operative condition. Döge et al. (2017) reported slightly improved speech reception in noise in CI-on vs CI-off condition in 8 of 11 patients. Three of 11 subjects, however, showed deteriorations at CI-on condition.

Sound localization

Döge et al. (2017) showed a significant decrease of localization error in the CI-on condition in comparison with the CI-off condition in 11 SSD subjects. Skarzynski et al. (2017) observed a significant localization benefit reflected by decrease in RMS angular error at CI-on vs CI-off condition. van Loon et al. (2017) reported a significant improved localization performance in all 7 AHL subjects with bimodal stimulation at 12-month in comparison to the pre-operative condition. Results with the CI demonstrated a continuous improvement in sound localization after 12 months of CI use. Rahne and Plontke (2016) reported that in comparison to CI-off, CI-on significantly improved sound localization,

reflected by a decrease in ADE (angular detection error) at 1-month of CI activation. A continuous improvement occurred over time. Kitoh et al. (2016) reported better sound localization in all 5 subjects, with continuous improvement through 12-month.

Subjective measures

van Loon et al. (2017) reported increased frequency and satisfaction of listening to music from 7 AHL CI users. Bimodal stimulation also resulted in better quality, clarity, and appreciation of different music styles. Skarzynski et al. (2017) reported substantial tinnitus suppression in all 15 patients with pre-operative tinnitus and Kitoh et al. (2016) reported decreased disturbance to daily life caused by tinnitus in all 5 SSD cases. Two studies addressed self-evaluation of CI performance in SSD and AHL subjects. Skarzynski et al. (2017) reported a significant improvement in the global score of APHAB, as well as sub-scales including 'Ease of communication', hearing under 'background noise' or under 'reverberation' at 14-months after CI activation in comparison to pre-operative condition. van Loon et al. (2017) reported that except for the 'speech production' subdomain, bimodal stimulation yielded a significant better outcome for all other subdomains of the NCIQ questionnaire. An average appreciation of the cochlear implant was scored 4.3/5, indicating a high satisfaction with the CI.

Conclusions from Real World Evidence

This clinical evaluation of cochlear implantation for the treatment of SSD and AHL is based on the above literature data sets relevant to the safety, performance, and effectiveness of cochlear implantation as a treatment option for individuals with AHL or SSD.

In this review of Real-World data, the latest clinical data were summarized on SSD and AHL patients from centers both in the US and around the globe that meet the proposed audiometric indication criterion of a profound hearing loss in the ear to be implanted, i.e., a PTA of 90 dB or higher. The clinical populations reported on include both adults and children older than 5 years age.

Taken together, the clinical data from this body of literature show consistent benefits of CI in individuals with SSD or AHL, in terms of improved speech perception in noise, spatial hearing, localization accuracy, and patient-reported subjective outcome measures. Consistent CI use of patients has been shown across literature reports, and notably so in the prospective study by Lorens et al. (2019) in 70 sequentially implanted SSD and AHL CI users (59 of which were implanted with MED-EL devices). These literature data provide Real World Evidence (according to the FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices") in support of the clinical benefits of CI in SSD and AHL recipients, as demonstrated in the UNC study. In this way, these literature reports do serve as supporting evidence which demonstrates a reasonable assurance of device safety and effectiveness and to characterize the benefit/risk profiles for the proposed SSD/AHL indications.

14 Appendices

14.1 BACKWARD COMPATIBILITY

MAESTRO 7.0 supports:

Implant types:

- Mi1200 SYNCHRONY
- Mi1000 MED-EL CONCERT
- SONATA_{TI}¹⁰⁰
- PULSAR_{CI}¹⁰⁰
- C40+

Processor types:

- RONDO 2
- SONNET EAS
- SONNET
- RONDO
- DUET 2
- OPUS 2
- OPUS 1
- TEMPO+

The software CI.STUDIO+ shall be used for all other implant/processor combinations.

14.2 WARRANTY

MED-EL's warranty is in agreement with mandatory local statutory warranty provisions.

Any extension of the statutory warranty is subject to agreement between MED-EL and the purchaser. Therefore these extensions may be different in various countries. Please contact your local MED-EL representative for information on your individual warranty rights.

Extension of statutory warranties shall not be granted unless the product is properly registered. You can register a product either by completing the provided registration card and sending it to MED-EL or by using MED-EL's online registration website (upon availability). Ask your local MED-EL representative for help if you need assistance in the registration process.

Extensions of statutory warranties exclusively cover product failures. This does 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.

14.3 ADDRESS OF THE MANUFACTURER

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14.4 ABBREVIATIONS

Abbreviation	Definition
ADC	Analog-Digital Converter
AGC	Automatic Gain Control
AGF	Amplitude Growth Function
ART	Auditory nerve Response Telemetry
ASM	Automatic Sound Management
CFG	Configuration
CSA	Channel Setup Assistant
CSSS	Channel Specific Sampling Sequences
DBMT	Database Management Tool
DL	Datalogging
EABR	Evoked Auditory Brainstem Response
EAS	Electric Acoustic Stimulation
ECAP	Evoked Compound Action Potential
EEG	Electroencephalography
ESRT	Evoked Stapedius Reflex Threshold
HI	High
IFT	Impedance and Field Telemetry
LM	Link Monitoring
MAESTRO	MAESTRO System Software
MAX Programming Interface	Map and Exchange Programming Interface
MCL	Maximum Comfortable Loudness
MD	Microphone Directionality
Omni	Omnidirectional
RF (EABR task)	Radio Frequency
RF (ART task)	Recovery Function
SC	Short Circuit
SoE	Spread of Excitation
VRT	Visual Reinforcement Tool
WNR	Wind Noise Reduction

14.5 HOT KEY COMBINATIONS

The main features in MAESTRO can be controlled with the computer mouse or key combinations. This chapter lists all valid key combinations for MAESTRO.

14.5.1 Login

Shortcut	Operation
ALT + T	Select/Deselect the Training Mode

14.5.2 Main menu

Data

Shortcut	Operation
CTRL + S	Save the current item
CTRL + SHIFT + S	Save and close the open editor
CTRL + L	Close the open editor
CTRL + SHIFT + L	Close all open editors
ALT + F2	Export Data
ALT + F3	Import Data
ALT + F5	Reports
ALT + F6	History Reports
ALT + F7	Session Reports
ALT + F8	User Reports

New

Shortcut	Operation
F3	Create a new patient
F9	Create a new Audiogram
F4	Create a new IFT measurement
F5	Create a new ESRT data
F11	Create a new EABR data
F6	Create a new ART measurement
F7	Create a new Fitting map
F12	Create a new Acoustic Fitting
F10	Create a new AutoART measurement

Edit

Shortcut	Operation
CTRL + Z	Undo the last action
CTRL + Y	Redo the last Undo action
CTRL + E	Edit the or open the selected data
CTRL + X	Cut the current selection to the clipboard
CTRL + C	Copy the current selection to the clipboard
CTRL + V	Paste the current selection from the clipboard
CTRL + R	Rename the current item
CTRL + A	Select all items
CTRL + I	Invert the current selection

Appendices

View

Shortcut	Operation
SHIFT + F2	View the Task Data view
SHIFT + F3	View the log
SHIFT + F7	Display the User management view
SHIFT + F8	View the Session view
SHIFT + F11	Select the previous task editor
SHIFT + F12	Select the next task editor
CTRL + SHIFT + F11	Select the previous task subeditor
CTRL + SHIFT + F12	Select the next task subeditor
CTRL + H	Toggles the header for editors

Tools

Shortcut	Operation
CTRL + B	Launch the Coupling Check tool
CTRL + M	Launch the Media Manager tool
SHIFT + F9	View the Media Player
CTRL + N	Acknowledge the next notification
CTRL + SHIFT + E	Duplicate the opened data
CTRL + D	Launch the Reset Processor Tool
ALT + F9	View the Session comment

Settings

Shortcut	Operation
SHIFT + F6	Display the settings dialog

Help

Shortcut	Operation
F1	Display the help documentation
SHIFT + F1	View Product Version and Copyright

14.5.3 Patient

Right/Left Ear editor

Shortcut	Operation
CTRL + SHIFT + R	Read Implant Serial number
CTRL + SHIFT + E	Edit Implant Serial number
ALT + Arrow Down	Opens the global electrode disable menu

14.5.4 Session

Shortcut	Operation
ALT + F10	Start or continue an intraoperative session
ALT + F11	Start or continue a postoperative session
ALT + F12	Close session
ALT + L	Program processor for left ear
ALT + R	Program processor for right ear

14.5.5 Audiogram

Shortcut	Operation
Home	Move cursor to the lowest hearing level
CTRL + Home	Move marker to the lowest hearing level
End	Move cursor to the highest hearing level
CTRL + End	Move marker to the highest hearing level
Page Up	Move cursor 2 x step size up
Page Down	Move cursor 2 x step size down
CTRL + Page Up	Move marker at 2 x step size above
CTRL + Page Down	Move marker at 2 x step size below
Up, Down, Left, Right	Move cursor up, down, left or right
CTRL + Up, CTRL + Down	Move marker up or down
Space or Enter	Set marker at current cursor position
Delete	Remove marker
1	Set step size to 1 dB HL
2	Set step size to 2 dB HL
5	Set step size to 5 dB HL

14.5.6 Telemetry (IFT)

Shortcut	Operation
Space	Measure
CTRL + SHIFT + X	Discard

Channel Setup Assistant

Shortcut	Operation
CTRL + SHIFT + C	Show CSA suggestions
CTRL + SHIFT + A	Accept CSA suggestions

Appendices

14.5.7 ESRT

Shortcut	Operation
CTRL + ALT + C/D	Change between graphical and numerical entry of current desired ESRT charge, respectively move the cursor to the data field for minimum phase duration
R	Mark as reflex
N	Mark as no reflex
M	Mark as undefined

Selection

Shortcut	Operation
CTRL + ALT + Fx (x=1...12)	Select channel x. If this channel has already been selected, it is deselected
TAB	Change selection to the next active channel to the right. Simultaneously pressing SHIFT changes the direction
Arrow Right	Change selection to the next active channel to the right
Arrow Left	Change selection to the next active channel to the left

Minimum one channel selected

Shortcut	Operation
Space	Start or stop the stimulation at the selected channel
Escape	Stop any stimulation immediately
+ key	Increase the value at the selected channel by the smallest increment
- key	Decrease the value at the selected channel by the smallest increment
Arrow Up	Increase the value at the selected channel by the middle increment
Arrow Down	Decrease the value at the selected channel by the middle increment
Page Up	Increase the value at the selected channel by the biggest increment
Page Down	Decrease the value at the selected channel by the biggest increment

14.5.8 EABR

Stimulation editor

Shortcut	Operation
CTRL + SHIFT + T	Start emitting triggers
Home	Focus upper slider knob (if present)
CTRL + SHIFT + Home	Toggle focus between upper slider knob and (related) numeric input field

End	Focus lower slider knob
CTRL + SHIFT + End	Toggle focus between lower (or only) slider knob and (related) numeric input field
CTRL + SHIFT + M	Toggle focus between numeric input field of number of pulses and (previously) focused slider knob, or set focus to that numeric input field if another numeric input field is already focused
CTRL + C	Copy amplitude(s) of the focused channel
CTRL + V	Paste previously copied amplitudes to the focused channel

Channel selection

Shortcut	Operation
CTRL	Select one or more channels with the mouse
SHIFT	Select a range of channels with the mouse
CTRL + A	Select all channels
CTRL + I	Invert the current selection

Selection

Shortcut	Operation
CTRL + ALT + Fx (x=1...12)	Select channel x. If this channel has already been selected, it is deselected
TAB	Change selection to the next active channel to the right. Simultaneously pressing SHIFT changes the direction
Arrow Right	Change selection to the next active channel to the right
Arrow Left	Change selection to the next active channel to the left

Minimum one channel selected

Shortcut	Operation
Space	Start or stop the stimulation at the selected channel
Escape	Stop any stimulation immediately
+ key	Increase the value at the selected channel by the smallest increment
- key	Decrease the value at the selected channel by the smallest increment
Arrow Up	Increase the value at the selected channel by the middle increment
Arrow Down	Decrease the value at the selected channel by the middle increment
Page Up	Increase the value at the selected channel by the biggest increment
Page Down	Decrease the value at the selected channel by the biggest increment

Extended Setup editor

Shortcut	Operation
CTRL + SHIFT + T	Start emitting triggers

Appendices

Stimulation History

Shortcut	Operation
CTRL + SHIFT + R	Reuse selected parameter set

Tree view

Shortcut	Operation
Enter	Open input box for comment related to the selected (sub) node
Arrow Up	Move the cursor to the preceding node (top level or sub node, depending on expansion state of the top level node)
Arrow Down	Move the cursor to the succeeding node (top level or sub node, depending on expansion state of the top level node)
Arrow Right	Expand selected top level node
Arrow Left	Collapse selected top level node

Comment input box

Shortcut	Operation
Enter	Close the comment input box

14.5.9 AutoART

Shortcut	Operation
Space	Start or pause the measurement
Escape	Stop the measurement
CTRL + SHIFT + X	Discard results
CTRL + SHIFT + N	Go to next electrode

14.5.10 ART

Setup editor

Shortcut	Operation
CTRL + SHIFT + M	Start the stimulation
CTRL + SHIFT + X	Discard results

Channel label on electrode status control focused

Shortcut	Operation
ALT + Arrow Down	Opens Enable/Disable electrode menu

Loudness Comfort Tool

Shortcut	Operation
CTRL + SHIFT + Enter	Accept amplitude and phase duration
CTRL + SHIFT + X	Discard amplitude and phase duration
CTRL + ALT + A	Jump to edit field for amplitude
CTRL + ALT + D	Jump to edit field for phase duration

Minimum one channel selected

Shortcut	Operation
Space	Start or stop the stimulation at the selected channel
Escape	Stop any stimulation immediately
+ key	Increase the value at the selected channel by the smallest increment
- key	Decrease the value at the selected channel by the smallest increment
Arrow Up	Increase the value at the selected channel by the middle increment
Arrow Down	Decrease the value at the selected channel by the middle increment
Page Up	Increase the value at the selected channel by the biggest increment
Page Down	Decrease the value at the selected channel by the biggest increment

14.5.11 Fitting

Fitting Level editor

Shortcut	Operation
CTRL + SHIFT + A	Activate/Deactivate the processor
CTRL + SHIFT + X	Activate/Deactivate the electric part of the processor (only for SONNET EAS)
CTRL + SHIFT + Y	Activate/Deactivate the acoustic part of the processor (only for SONNET EAS)
M/T	Change between MCL/THR values at the selected channel
CTRL + SHIFT + M/T/D	Change between graphical and numerical entry of MCL or THR, respectively move the cursor to the data field for minimum phase duration
CTRL + SHIFT + Arrow Up/Arrow Down	Increase/Decrease Activation Volume

Channel selection

Shortcut	Operation
CTRL	Select one or more channels with the mouse
SHIFT	Select a range of channels with the mouse
CTRL + A	Select all channels
CTRL + I	Invert the current selection

Appendices

Selection

Shortcut	Operation
CTRL + ALT + Fx (x=1...12)	Select channel x. If this channel has already been selected, it is deselected
TAB	Change selection to the next active channel to the right. Simultaneously pressing SHIFT changes the direction
Arrow Right	Change selection to the next active channel to the right
Arrow Left	Change selection to the next active channel to the left

Minimum one channel selected

Shortcut	Operation
Space	Start or stop the stimulation at the selected channel
Escape	Stop any stimulation immediately
+ key	Increase the value at the selected channel by the smallest increment
- key	Decrease the value at the selected channel by the smallest increment
Arrow Up	Increase the value at the selected channel by the middle increment
Arrow Down	Decrease the value at the selected channel by the middle increment
Page Up	Increase the value at the selected channel by the biggest increment
Page Down	Decrease the value at the selected channel by the biggest increment

Interpolation

Shortcut	Operation
CTRL + ALT + M	Perform interpolation of MCL values
CTRL + ALT + T	Perform interpolation of THR values
CTRL + ALT + I	Perform interpolation of MCL and THR values

Visual Reinforcement Tool (VRT)

Shortcut	Operation
A, S, D, F, Y/Z, X, C	Start playback of items 1-7 of the selected playlist
V	Stop playback
G	Toggle playback display on first screen
B	Toggle playback display on second screen

Acoustic editor

General

Shortcut	Operation
CTRL + SHIFT + A	Activate/Deactivate the processor
CTRL + SHIFT + X	Activate/Deactivate the electric part of the processor
CTRL + SHIFT + Y	Activate/Deactivate the acoustic part of the processor

CTRL + SHIFT + Arrow Up	Increase the Activation volume
CTRL + SHIFT + Arrow Down	Decrease the Activation volume

Display

Shortcut	Operation
+, Arrow Up	Increase the gain at the selected frequency by the small increment
-, Arrow Down	Decrease the gain at the selected frequency by the small increment
Page Up	Increase the gain at the selected frequency by the large increment
Page Down	Decrease the gain at the selected frequency by the large increment
Arrow Right	Move selection to the next adjusted gain to the right
Arrow Left	Move selection to the next adjusted gain to the left
Enter	Open numerical input field at the selected gain
Escape, Enter	Close opened numerical input field at the selected gain

Indicators editor

Shortcut	Operation
CTRL + SHIFT + W	Trigger a Warning Beep
CTRL + SHIFT + C	Trigger a Confirmation Beep

14.5.12 Acoustic Fitting

Shortcut	Operation
Escape	Stops Live Fitting immediately
CTRL + SHIFT + F	First Fit
CTRL + SHIFT + T	Switch to Software Fitting/Switch to Trimmer Fitting
CTRL + SHIFT + K	Start/Stop Live Fitting (Activate/Deactivate the acoustic unit)
CTRL + SHIFT + P	Program the acoustic unit
CTRL + SHIFT + R	Read the program from the acoustic unit
CTRL + SHIFT + 4	Hide/Show gain curve at 40 dB input level
CTRL + SHIFT + 6	Hide/Show gain curve at 65 dB input level
CTRL + SHIFT + 9	Hide/Show gain curve at 90 dB input level
CTRL + SHIFT + C	Hide/Show crossover frequency
CTRL + SHIFT + G	Hide/Show target gain curve

14.5.13 Software Features

Reports

Shortcut	Operation
ALT + A	Anonymize Patient Name (except User Report Dialog)
ALT + H	Show Selector (except User Report Dialog)
ALT + O	Output Options
ALT + P	Print

Appendices

ALT + S	Save As
ALT + C	Close
Arrow Left	Previous Report Data
Arrow Right	Next Report Data
+ key	Zoom in
- key	Zoom out

Coupling Check

Shortcut	Operation
Space	Start or stop scan

Media Manager

Shortcut	Operation
ALT + P	Add playlist
ALT + M	Add media file
Enter	Edit selected playlist or media file
DEL	Delete selected playlist or media file
ALT + E	Export Media Library
ALT + I	Import Media Library
ALT + V	Toggle preview visibility

14.5.14 User

Administration editor

Shortcut	Operation
CTRL + SHIFT + G	Get the user name of the logged in Windows account and set as application user name

15 MED-EL Contacts

Please refer to the accompanying Contact Sheet for your local office.

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Clinical Guidelines for Fitting Cochlear Implants on Individuals with Asymmetric Hearing Loss

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Introduction

The MED-EL Cochlear Implant System serves to restore hearing sensations through electrical stimulation of the auditory nerve. It is the result of many years of research at leading technical institutions throughout the world.

This Clinical Guideline describes proper techniques for programming and monitoring individuals with MED-EL audio processors who have asymmetric hearing loss (AHL) and who have been unilaterally implanted with a cochlear implant.

Information regarding fitting of patients with single sided deafness (SSD) who have been unilaterally implanted with a cochlear implant can be found in the “Clinical Guidelines for Fitting Single Sided Deaf Individuals with Cochlear Implants”.

This guideline serves as additional information for professionals and should not be used as an “Instructions for Use”. Please also refer to the Instructions for Use for the MED-EL audio processor, cochlear implant, MAESTRO fitting software and MAX Programming Interface which were delivered with the implant system.

The information in this Guideline is believed to be true and correct at the time of writing.

Patient Selection and Candidacy

Patient selection and candidacy for AHL is defined by indication of a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Selection and Evaluation

Patients with AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For adults, limited benefit from unilateral amplification is defined by test scores of five percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone.

For children, insufficient functional access to sound in the ear to be implanted must be determined by:

- aided speech perception test scores of five percent or less on developmentally appropriate word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, patients with AHL must have at least one month experience wearing an appropriate hearing device and not show any subjective benefit.

A complete cochlear implant evaluation protocol should include an audiologic assessment, a medical/surgical evaluation, counselling sessions and, when possible, a psychological assessment. To obtain the optimal benefit from the implant, candidates should be sufficiently motivated and understand the importance of returning to the implant center for regular audio processor programming, training, and assessment sessions.

The audiological evaluation prior to cochlear implant surgery serves to:

- assess whether the candidate is able to receive sufficient benefit from properly fitted hearing aids, health status, and the ability to undergo surgery
- verify the absence of disease and infection of the outer and middle ear
- assess hearing thresholds

Audiological Referral and Indication Criteria

Indication criteria listed below should be included as part of the standard selection criteria; however, these conditions should not be considered as exclusion criteria, instead as part of the overall evaluation of the candidate.

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

Medical evaluations usually involving an otologic/otoscopic examination and a CT scan and/or MRI are conducted.

Pre-Operative Counseling and Audiological Considerations

Prior to receiving a cochlear implant, the clinician should include the following points when counseling the CI candidate and family (if applicable):

- Realistic expectations of hearing with an implant including:
 - o When the external device will be activated
 - o The timeline of follow-up programming visits and checkups
 - o Expectations regarding rehabilitation
- Showing what the internal and external devices look like

Intra-Operative Audiological Assessment

If your clinic performs intra-operative clinical assessments, then prior to the implant surgery, it is advised to ensure that you have the proper equipment ready and working.

1. Ensure your computer which will be used for intra-operative measurements has the latest MAESTRO fitting software with a current Activation key.
2. Ensure the MAX programming interface box is connected via USB port to the computer

Prior to the surgeon placing the implant, the following procedures should be completed:

1. Open MAESTRO fitting software
2. Create new patient
 - a. Enter in patient's name, gender, date of birth
 - b. Read implant type and serial number from implant packaging
 - c. Enter in electrode type
 - d. Enter surgical date
 - e. Save and close
3. Open the intra-operative task
4. Conduct in-package measurement on implant. Ensure that the reading of OK has been achieved
 - i. Ensure that coupling and integrity are ok
 - ii. Expect all channels to be high, but no short circuits
 - iii. Save and close

Once the surgeon has placed the electrode inside the cochlea and secured the implant, the clinician is often asked to run measurements to test implant integrity. The following procedure is a step-by-step procedure for performing this process.

- a. Open MAESTRO fitting software and Select patient if not already selected
- b. Enter intra-operative mode

2. Measure Telemetry

- a. Place the according MAX coil in a sterile sleeve, on top of the skin flap, and over the implant
- b. Click on new IFT task and click on Measure to start the measurement
 - i. The channel status of each electrode, integrity and coupling should be reported as ok. If this is not what is noted, then please follow the channel setup assistant provided inside of the IFT task.
 - ii. With high channels during the surgery, air bubbles can be the issue. To combat this issue, talk with the surgeon to see if you can wait approximately 5 minutes to re-measure the IFT that has dissolved over time.

3. (Optional) Run objective measurements to test implant integrity and electrode placement.

- a. To complete AutoART measurements, please follow the described steps below:

Note: Make sure that the implant has good contact to tissue (e.g., moisten with sterile saline solution).

 - i. Open a new AutoART measurement
 - ii. Click Measure
 - iii. A complete measurement will take approximately 4 minutes. Please allow for the full measurement to run. After the measurement has finished, ecap presence/absence and ecap thresholds can be read.
- b. To complete ESRT measurements, please follow the described steps below:
 - i. Open ESRT task and select a mid-array electrode, such as channel #6
 1. telemetry status must be OK to complete measurement
 - ii. Increase stimulus amplitude and present stimulus until reflex is visible through the microscope.
 - iii. Repeat procedure on other channels to obtain data from apical and basal electrodes.

Note: Sedatives used intra-operatively may raise the reflex threshold level. For detailed information regarding post-operative ESRT measures, please refer to the ESRT Guide

NOTE: A report of all measurements can be printed for patient records if requested. This report can be found in the reports section in MAESTRO.

Post-Operative Appointments

(Optional time saving procedure) Prior to the initial stimulation programming session, it is advisable for the clinician to prepare the following steps. This initial preparation will save time when the recipient arrives for their initial stimulation.

1. Check the external components (audio processor, coil, cables, etc.). Ensure that the recipient has all of the needed equipment and accompanying Instruction for Use Manuals.
2. Enter recipient data into MAESTRO fitting software if it is not already entered.
 - o If a DL-coil is being utilized, then ensure that it is added in patient data under audio processors
3. Connect the audio processor(s) to load information and as a system check

Initial Activation

Initial Stimulation should be scheduled 4-6 weeks after the surgical date. Obviously, country regulations, clinic procedures, medical status, and individual needs should always be taken into consideration. The cochlear implant insertion site should be fully healed before proceeding with the initial activation.

The quality of the programming of a recipient's audio processor has a direct impact on the achieved and perceived benefit from a cochlear implant. The following steps are recommended for the initial activation of the audio processor:

1. Check incision site and determine if it is healing properly.
 - a. To evaluate the insertion site, ensure that there is no redness or soreness to touch around the incision site. If either of these indications is noted, please referral patient for medical attention.
 - b. If the incision site is healed, then the clinician can proceed with the initial activation
2. Ask the recipient questions about how they are feeling with regards to the incision site, have they had any difficulties? If so, what difficulties?
3. (Optional) conduct an unaided audiometric test including air conduction thresholds. Compare obtained post-operative measurements to pre surgical measurements to observe the amount of hearing preserved
4. Explain the programming procedures (the programming steps to be performed during the initial activation session).
 - a. Explain to the recipient that the programming of the audio processor is a very important first step towards effective use of the cochlear implant. There may be more programming changes that need to be made and it will take the brain time to learn how to hear with the cochlear implant.

5. Select the patient and enter post-operative mode.
6. Connect the appropriate MAX coil and open the IFT task in MAESTRO. MED-EL strongly encourages that an impedance and telemetry measurement is conducted at the beginning of every programming session
 - a. Conduct impedance and telemetry measurements by clicking measure
 - b. The telemetry status of each electrode, integrity and coupling should be reported as OK. The channel status of each electrode, integrity and coupling should be reported as ok. If this is not what is noted, then please follow the channel setup assistant provided inside of the IFT task.
7. Determine correct magnet strength.
 - a. To determine correct magnet strength, start with the number 2 magnet strength. If the coil will not stay firmly over the implant with head movements, then increase the strength of the magnet. Also please ensure that the magnet strength is not so tight as to cause irritation
8. Connect the audio processor and open a new fitting map
9. The first and most important parameter to determine per channel is the maximum comfortable level. Explain to the recipient that you will be increasing the level of sound. They should alert you when the sound is comfortably loud, but not uncomfortable.

Note: The use of ESRT measurements is encouraged when obtaining MCL levels. Research has demonstrated that there is a strong correlation between measured ESRT values and MCL values. However, in some cases, ESRT values cannot be obtained. Behavioral measures are another way of obtaining appropriate MCL levels. The following procedure outlines how MCL levels are obtained behaviorally:

 - a. Start with channel 6. Use the default pulse duration of 50mS.
 - b. Increase the amount of charge until the recipient indicates that you have reached a level that is very loud but not uncomfortable. Continually observe the recipient during this process to watch for non-verbal cues of loudness discomfort
 - c. Once the MCL has been reached, move to the next channel to be measured. It is recommended that the clinician test a basal channel and then repeat on an apical channel.
 - d. Then, the clinician should continue to measure MCL levels until all channels have been measured.
10. Once all channels have been measured, then all channels should be activated to ensure overall loudness is not uncomfortable.

Note: If a recipient has no hearing sensation on a channel, discomfort, or non-auditory side effects, then the clinician may want to consider globally deactivating this channel. The MAESTRO software will automatically realign frequency bands; thus, it is recommended to check MCL levels again for possible changes in loudness perception.

Note: if it is not possible to measure the MCL level for all channels, an interpolation may be performed to give a full map profile...

11. It is always encouraged to measure thresholds per channel similar to how MCL levels are measured. However, often times, it is difficult for a recipient to continue through this testing at the initial activation. Furthermore, it is recommended to evaluate thresholds at a later follow-up session after the recipient has gotten use to the sound. Measuring thresholds per channel at a later programming session may improve sound quality. Therefore, setting thresholds to 10% will give a good starting point.

12. Create a loud sound to ensure that recipient is feeling no discomfort

13. Set the default volume to 90-100%

- a. Other fitting parameters typically do not need to be altered during the initial activation. It will be discussed in follow-up programming sessions programming and troubleshooting considerations.

14. Save and close the measured map.

Note: please consider the use of progressive maps with initial activations. Progressive maps allow the recipient to gradually get use to the loudness perception of the electrical stimulation. To incorporate progressive maps, click Progressive maps either 3 or 6%. The four maps will automatically be created. It should be noted that MCL levels typically will stabilize by 3-6 months post activation

15. Save the maps to the processor by clicking Program processor

16. Fitting the contralateral ear.

- a. If the recipient does not wear a hearing aid on the contralateral ear, then the clinician should conduct an initial loudness balancing between the cochlear implant and the contralateral ear. A broadband sound like live speech can be used. Ensure that the loudness of the implant is similar to the loudness of the other ear. It takes time for the brain to learn to hear again in this ear. This step of loudness balancing should be repeated again as the recipient's loudness tolerance with the cochlear implant changes. Counsel the patient on using the FineTuner to adjust volume as needed.
- b. If the recipient wears a hearing aid in the contralateral ear, please follow the following steps
 - i. Either obtain a printout of how the hearing aid is programmed (e.g. is programming based on DSLi/o). If a printout cannot be obtained, then conduct real ear measurements to ensure that recipient is receiving ample amplification in the contralateral ear.
 - ii. Once amplification is verified, the conduct loudness balancing between the hearing aid and the cochlear implant. A broadband sound like live speech can be used.
 - 1. When the contralateral ear has unaided hearing that is better than 70dBHL, then it would be considered the recipient's dominant ear, thus loudness balance the cochlear implant to

the aided contralateral ear.

2. Encourage the recipient to use both devices all the time and ensure the loudness is balanced between devices at all times. Please counsel the patient that the cochlear implant will most likely not sound like the normal hearing ear in terms of sound quality. It takes time for the brain to learn to hear again in this ear. This step of loudness balancing should be repeated again as the recipient's loudness tolerance with the cochlear implant changes. Counsel the patient on using the FineTuner to adjust volume as needed.
 3. Finally, if the recipient wants audio streaming to both ears, then the optional Phonak Roger system can provide this. To find out more information about fitting the Roger system, please refer to www.phonak.com/accessories. This page will give detailed information on which receiver can be used with different hearing aids. For the SONNET audio processor, a Phonak Roger 21 battery pack cover can be used. For all other audio processors, a Phonak Roger X receiver can be used.
17. Once the different maps have been saved the in the audio processor, then it can be disconnected from the computer.
 18. Explain and demonstrate to the recipient how to handle the audio processor including how to place the coil over the implant.
 - a. Ensure that cleaning, care and maintenance of the audio processor is thoroughly explained
 19. Perform aided testing to ensure auditory detection of sound.
 - a. If the recipient cannot perform auditory detection at the initial activation, then the volume should be increased via the FineTuner until the recipient can detect sound.
 20. Prior to the recipient leaving, ensure that the next programming session is scheduled within one month of the initial activation date. Encourage the recipient to contact the clinic if they have any questions or experience any pain, discomfort, or any adverse side effect.
 21. Provide a written report about the audio processor fitting.

NOTE: It is important that the cochlear implant recipient receive rehabilitation regularly.

Follow up Sessions:

The first follow-up programming session should be within one month of the initial activation. The following step-by-step procedure is recommended for follow-up programming sessions:

1. Check incision site and magnet strength
 - a. Ensure that there is no irritation or redness surrounding the incision site. If so, please refer to medical attention
2. Ask patient about their experiences with the audio processor
3. (Optional) conduct unaided audiometric testing including air conduction thresholds to compare to previous post-operative measurements. This step can be done at the beginning of every follow-up session to monitor the amount of hearing preserved
4. Compare patient report with datalogging information (if available)
 - a. Compare recipient's report of use time to datalogging processor usage
 - b. Look at the number of days logged to see if CI user is consistently wearing their device
 - c. Look at the map usage to see which map is being used the most
 - d. Check the number of processor switch-ons per day to see if it is a high number. If so, question the recipient as to why this may be the case
5. Once the recipient returns for follow up programming sessions, these measures can then be more accurately tested if needed. To ensure that thresholds are set appropriately for an initial activation:
 - a. In the MED-EL system, threshold levels should be set just below audibility. To ensure that all thresholds are set appropriately at the initial activation, a sweep of threshold measures can be performed to ensure that the recipient does not hear any sound on any channel
6. As mentioned in the initial activation section, during follow-up sessions at 1 month and 3 month intervals, please conduct loudness balancing using a 65dBSPL broadband signal to ensure that the cochlear implant is equal to loudness of the normal hearing ear.

As mentioned in the previous section, changing of default parameters is rarely needed. However, in some cases, fine tuning is needed. The following section gives tips and tricks to commonly reported issues.

Fitting Tips and Tricks

	Report	Possible Solutions
1	Too loud	• Reduce volume • Globally reduce MCLs
2	Too soft	• Increase volume • Globally increase MCLs • Increase THRs, but keep inaudible
3	Too hollow, bassy, boomy, or low-pitched	• Reduce apical MCLs • Increase basal MCLs
4	Too sharp, tinny, squeaky, or high-pitched	• Counselling (e.g., normal effect of restoring high-frequency sounds) • Reduce basal MCLs • Increase apical MCLs
5	Echo or reverberation	• Reduce volume • Globally reduce MCLs • Reduce apical MCLs • Reduce all THRs
6	Soft sounds are too soft	• Increase THRs, but keep inaudible • Increase AGC sensitivity
7	Trouble with background noise	• Check THRs are inaudible • Decrease AGC default sensitivity • Try Natural or Adaptive microphone directionality • Decrease apical MCLs
8	Buzz or constant noise in quiet environments	• Ensure this is not just normal background noise (e.g., computer fan) • Check THRs are inaudible • Reduce AGC Sensitivity • Try omnidirectional microphone directionality
9	Facial Stimulation	• Identify channel(s) causing problem • increase duration of effected channel (use minimum duration) • try to reach MCL. If not possible, then consider deactivate channel(s). If performance decreases or patient is dissatisfied, please consider calling your local MED-EL Representative

Suggested Fitting Timeline

The following fitting schedule is recommended (Clinic procedures, medical status, and individual needs should always be taken into consideration):

- Initial activation = 4-6 weeks post cochlear implant surgery
- First follow-up programming session = within one month of initial activation
- Second follow-up session = within 3 months of initial activation
- Third follow-up session = 6 months post initial activation
- Fourth follow-up session = 1 year post initial activation
- Annual follow-up sessions should be conducted

Please remember this is a suggested timeline. A recipient may require more programming sessions depending on individual need

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Clinical Guidelines for Fitting Single Sided Deaf Individuals with Cochlear Implants

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Introduction

The MED-EL Cochlear Implant System serves to restore hearing sensations through electrical stimulation of the auditory nerve. It is the result of many years of research at leading technical institutions throughout the world.

This Clinical Guideline describes proper techniques for programming and monitoring individuals with MED-EL audio processors who have single sided deafness (SSD) and who have been unilaterally implanted with a cochlear implant.

Information regarding fitting of patients with asymmetric hearing loss (AHL) who have been unilaterally implanted with a cochlear implant, including information regarding bimodal fitting, can be found in the “Clinical Guidelines for Fitting Cochlear Implants on Individuals with Asymmetric Hearing Loss”.

This guideline serves as additional information for professionals and should not be used as an “Instructions for Use”. Please also refer to the Instructions for Use for the MED-EL audio processor, cochlear implant, MAESTRO fitting software and MAX Programming Interface which were delivered with the implant system.

The information in this brochure is believed to be true and correct at the time of writing.

Patient Selection and Candidacy

SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.

Selection and Evaluation

Patients with SSD must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For adults, limited benefit from unilateral amplification is defined by test scores of five percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone.

For children, insufficient functional access to sound in the ear to be implanted must be determined by:

-
- aided speech perception test scores of five percent or less on developmentally appropriate word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, patients with SSD must have at least one month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit.

A complete cochlear implant evaluation protocol should include an audiologic assessment, a medical/surgical evaluation, counselling sessions and, when possible, a psychological assessment. To obtain the optimal benefit from the implant, candidates should be sufficiently motivated and understand the importance of returning to the implant center for regular audio processor programming, training, and assessment sessions.

The audiological evaluation prior to cochlear implant surgery serves to:

- assess whether the candidate is able to receive sufficient benefit from properly fitted hearing aids, health status, and the ability to undergo surgery
- verify the absence of disease and infection of the outer and middle ear
- assess hearing thresholds

Audiological Referral and Indication Criteria

Indication criteria listed below should be included as part of the standard selection criteria; however, these conditions should not be considered as exclusion criteria, instead as part of the overall evaluation of the candidate.

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

Medical evaluations usually involving an otologic/otoscopic examination and a CT scan and/or MRI are conducted.

Pre-Operative Counseling and Audiological Considerations

Prior to receiving a cochlear implant, the clinician should include the following points when counseling the CI candidate and family (if applicable):

- Realistic expectations of hearing with an implant including:
 - o When the external device will be activated
 - o The timeline of follow-up programming visits and checkups
 - o Expectations regarding rehabilitation
- Showing what the internal and external devices look like

Intra-Operative Audiological Assessment

If your clinic performs intra-operative clinical assessments, then prior to the implant surgery, it is advised to ensure that you have the proper equipment ready and working.

1. Ensure your computer which will be used for intra-operative measurements has the latest MAESTRO fitting software with a current Activation key.
2. Ensure the MAX programming interface box is connected via USB port to the computer

Prior to the surgeon placing the implant, the following procedures should be completed:

1. Open MAESTRO fitting software
2. Create new patient
 - a. Enter in patient's name, gender, date of birth
 - b. Read implant type and serial number from implant packaging
 - c. Enter in electrode type
 - d. Enter surgical date
 - e. Save and close
3. Open the intra-operative task
4. Conduct in-package measurement on implant. Ensure that the reading of OK has been achieved
 - i. Ensure that coupling and integrity are ok
 - ii. Expect all channels to be high, but no short circuits
 - iii. Save and close

Once the surgeon has placed the electrode inside the cochlea and secured the implant, the clinician is often asked to run measurements to test implant integrity. The following procedure is a step-by-step procedure for performing this process.

- a. Open MAESTRO fitting software and Select patient if not already selected
 - b. Enter intra-operative mode
2. Measure Telemetry
 - a. Place the according MAX coil in a sterile sleeve, on top of the skin flap, and over the implant
 - b. Click on new IFT task and click on Measure to start the measurement

- i. The channel status of each electrode, integrity and coupling should be reported as ok. If this is not what is noted, then please follow the channel setup assistant provided inside of the IFT task.
 - ii. With high channels during the surgery, air bubbles can be the issue. To combat this issue, talk with the surgeon to see if you can wait approximately 5 minutes to re-measure the IFT that has dissolved over time.
 - 3. (Optional) Run objective measurements to test implant integrity and electrode placement.
 - a. To complete AutoART measurements, please follow the described steps below:

Note: Make sure that the implant has good contact to tissue (e.g., moisten with sterile saline solution).

 - i. Open a new AutoART measurement
 - ii. Click Measure
 - iii. A complete measurement will take approximately 4 minutes. Please allow for the full measurement to run. After the measurement has finished, ecap presence/absence and ecap thresholds can be read.
 - b. To complete ESRT measurements, please follow the described steps below:
 - i. Open ESRT task and select a mid-array electrode, such as channel #6
 - 1. telemetry status must be OK to complete measurement
 - ii. Increase stimulus amplitude and present stimulus until reflex is visible through the microscope.
 - iii. Repeat procedure on other channels to obtain data from apical and basal electrodes.

Note: Sedatives used intra-operatively may raise the reflex threshold level. For detailed information regarding post-operative ESRT measures, please refer to the ESRT Guide
- NOTE: A report of all measurements can be printed for patient records if requested. This report can be found in the reports section in MAESTRO.

Post-Operative Appointments

(Optional time saving procedure) Prior to the initial stimulation programming session, it is advisable for the clinician to prepare the following steps. This initial preparation will save time when the recipient arrives for their initial stimulation.

1. Check the external components (audio processor, coil, cables, etc.). Ensure that the recipient has all of the needed equipment and accompanying Instruction for Use Manuals.
2. Enter recipient data into MAESTRO fitting software if it is not already entered.
 - o If a DL-coil is being utilized, then ensure that it is added in patient data under audio processors

3. Connect the audio processor(s) to load information and as a system check

Initial Activation

Initial Stimulation should be scheduled 4-6 weeks after the surgical date. Obviously, country regulations, clinic procedures, medical status, and individual needs should always be taken into consideration. The cochlear implant insertion site should be fully healed before proceeding with the initial activation.

The quality of the programming of a recipient's audio processor has a direct impact on the achieved and perceived benefit from a cochlear implant. The following steps are recommended for the initial activation of the audio processor:

1. Check incision site and determine if it is healing properly.
 - a. To evaluate the insertion site, ensure that there is no redness or soreness to touch around the incision site. If either of these indications is noted, please referral patient for medical attention.
 - b. If the incision site is healed, then the clinician can proceed with the initial activation
2. Ask the recipient questions about how they are feeling with regards to the incision site, have they had any difficulties? If so, what difficulties?
3. (Optional) conduct an unaided audiometric test including air conduction thresholds. Compare obtained post-operative measurements to pre surgical measurements to observe the amount of hearing preserved
4. Explain the programming procedures (the programming steps to be performed during the initial activation session).
 - a. Explain to the recipient that the programming of the audio processor is a very important first step towards effective use of the cochlear implant. There may be more programming changes that need to be made and it will take the brain time to learn how to hear with the cochlear implant.
5. Select the patient and enter post-operative mode.
6. Connect the appropriate MAX coil and open the IFT task in MAESTRO. MED-EL strongly encourages that an impedance and telemetry measurement is conducted at the beginning of every programming session
 - a. Conduct impedance and telemetry measurements by clicking measure
 - b. The telemetry status of each electrode, integrity and coupling should be reported as OK. The channel status of each electrode, integrity and coupling should be reported as ok. If this is not what is noted, then please follow the channel setup assistant provided inside of the IFT task.
7. Determine correct magnet strength.
 - a. To determine correct magnet strength, start with the number 2 magnet

strength. If the coil will not stay firmly over the implant with head movements, then increase the strength of the magnet. Also please ensure that the magnet strength is not so tight as to cause irritation

8. Connect the audio processor and open a new fitting map
9. The first and most important parameter to determine per channel is the maximum comfortable level. Explain to the recipient that you will be increasing the level of sound. They should alert you when the sound is comfortably loud, but not uncomfortable.

Note: The use of ESRT measurements is encouraged when obtaining MCL levels. Research has demonstrated that there is a strong correlation between measured ESRT values and MCL values. However, in some cases, ESRT values cannot be obtained. Behavioral measures are another way of obtaining appropriate MCL levels. The following procedure outlines how MCL levels are obtained behaviorally:

- a. Start with channel 6. Use the default pulse duration of 50mS.
 - b. Increase the amount of charge until the recipient indicates that you have reached a level that is very loud but not uncomfortable. Continually observe the recipient during this process to watch for non-verbal cues of loudness discomfort
 - c. Once the MCL has been reached, move to the next channel to be measured. It is recommended that the clinician test a basal channel and then repeat on an apical channel.
 - d. Then, the clinician should continue to measure MCL levels until all channels have been measured.
10. Once all channels have been measured, then all channels should be activated to ensure overall loudness is not uncomfortable.

Note: If a recipient has no hearing sensation on a channel, discomfort, or non-auditory side effects, then the clinician may want to consider globally deactivating this channel. The MAESTRO software will automatically realign frequency bands; thus, it is recommended to check MCL levels again for possible changes in loudness perception.

Note: if it is not possible to measure the MCL level for all channels, an interpolation may be performed to give a full map profile...

11. It is always encouraged to measure thresholds per channel similar to how MCL levels are measured. However, often times, it is difficult for a recipient to continue through this testing at the initial activation. Furthermore, it is recommended to evaluate thresholds at a later follow-up session after the recipient has gotten use to the sound. Measuring thresholds per channel at a later programming session may improve sound quality. Therefore, setting thresholds to 10% will give a good starting point.
12. Create a loud sound to ensure that recipient is feeling no discomfort
13. Set the default volume to 90-100%
 - a. Other fitting parameters typically do not need to be altered during the initial

activation. It will be discussed in follow-up programming sessions programming and troubleshooting considerations.

14. Conduct an initial loudness balancing between the cochlear implant and the contralateral ear. A broadband sound like live speech can be used. Ensure that the loudness of the implant is similar to the loudness of the contralateral ear. Please counsel the patient that the cochlear implant will most likely not sound like normal hearing in terms of sound quality. It takes time for the brain to learn to hear again in this ear. This step of loudness balancing should be repeated again as the recipient's loudness tolerance with the cochlear implant changes. Counsel the patient on using the FineTuner to adjust volume as needed.
15. Save and close the measured map.
Note: please consider the use of progressive maps with initial activations. Progressive maps allow the recipient to gradually get use to the loudness perception of the electrical stimulation. To incorporate progressive maps, click Progressive maps either 3 or 6%. The four maps will automatically be created. It should be noted that MCL levels typically will stabilize by 3-6 months post activation
16. Save the maps to the processor by clicking Program processor
17. Once the different maps have been saved the in the audio processor, then it can be disconnected from the computer.
18. Explain and demonstrate to the recipient how to handle the audio processor including how to place the coil over the implant.
 - a. Ensure that cleaning, care and maintenance of the audio processor is thoroughly explained
19. Perform aided testing to ensure auditory detection of sound.
 - a. If the recipient cannot perform auditory detection at the initial activation, then the volume should be increased via the FineTuner until the recipient can detect sound.
20. Prior to the recipient leaving, ensure that the next programming session is scheduled within one month of the initial activation date. Encourage the recipient to contact the clinic if they have any questions or experience any pain, discomfort, or any adverse side effect.
21. Provide a written report about the audio processor fitting.

NOTE: It is important that the cochlear implant recipient receive rehabilitation regularly. In the case of single sided deafness this is extremely important to help the recipient overcome the "dominant" ear effect.

Follow up Sessions:

The first follow-up programming session should be within one month of the initial activation. The following step-by-step procedure is recommended for follow-up programming sessions:

1. Check incision site and magnet strength
 - a. Ensure that there is no irritation or redness surrounding the incision site. If so, please refer to medical attention
2. Ask patient about their experiences with the audio processor
3. (Optional) conduct unaided audiometric testing including air conduction thresholds to compare to previous post-operative measurements. This step can be done at the beginning of every follow-up session to monitor the amount of hearing preserved
4. Compare patient report with datalogging information (if available)
 - a. Compare recipient's report of use time to datalogging processor usage
 - b. Look at the number of days logged to see if CI user is consistently wearing their device
 - c. Look at the map usage to see which map is being used the most
 - d. Check the number of processor switch-ons per day to see if it is a high number. If so, question the recipient as to why this may be the case
5. Once the recipient returns for follow up programming sessions, these measures can then be more accurately tested if needed. To ensure that thresholds are set appropriately for an initial activation
 - a. In the MED-EL system, threshold levels should be set just below audibility. To ensure that all thresholds are set appropriately at the initial activation, a sweep of threshold measures can be performed to ensure that the recipient does not hear any sound on any channel
6. As mentioned in the initial activation section, during follow-up sessions at 1 month and 3 month intervals, please conduct loudness balancing using a 65dB SPL broadband signal to ensure that the cochlear implant is equal to loudness of the contralateral ear.

As mentioned in the previous section, changing of default parameters is rarely needed. However, in some cases, fine tuning is needed. The following section gives tips and tricks to commonly reported issues.

Fitting Tips and Tricks

	Report	Possible Solutions
1	Too loud	• Reduce volume • Globally reduce MCLs
2	Too soft	• Increase volume • Globally increase MCLs • Increase THR_s, but keep inaudible
3	Too hollow, bassy, boomy, or low-pitched	• Reduce apical MCLs • Increase basal MCLs
4	Too sharp, tinny, squeaky, or high-pitched	• Counselling (e.g., normal effect of restoring high-frequency sounds) • Reduce basal MCLs • Increase apical MCLs
5	Echo or reverberation	• Reduce volume • Globally reduce MCLs • Reduce apical MCLs • Reduce all THR_s
6	Soft sounds are too soft	• Increase THR_s, but keep inaudible • Increase AGC sensitivity
7	Trouble with background noise	• Check THR_s are inaudible • Decrease AGC default sensitivity • Try Natural or Adaptive microphone directionality • Decrease apical MCLs
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