

User Manual for

SONNET 2 and SONNET 2 EAS audio processors



hearLIFE



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2. Introduction

This user manual provides information and instructions regarding the MED-EL Cochlear Implant (CI) System with the two variants of the SONNET 2 audio processor: SONNET 2 (Me151x)¹ and SONNET 2 EAS (Me152x)¹. 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), SONATAci¹⁰⁰ (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 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. 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 users 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.

¹ x = 0, 1, 2 or 3

3. Intended use – Indications – Contraindications

Intended use

The SONNET 2 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 2 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 2 audio processor is an external component of the MED-EL Cochlear Implant System and is indicated for use with 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 2 EAS audio processor is intended to be used by the patients as indicated above.

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

The SONNET 2 is intended to be used every day during a patient's waking hours.

The user of an SONNET 2 does not need to have any special skills or a certain elevated level of education, however, the user (or custodian if the user is a child or a handi-capped person not being able to perform the actions listed below) shall at minimum be able to perform the following actions:

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

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

Contraindications

A patient must not receive a SONNET 2 if the individual is known to be intolerant of the materials used in the SONNET 2. 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 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 theater).

As the SONNET 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 with the cochlear implant. If you want to review this information, please contact your clinic or MED-EL.

4. SONNET 2 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.

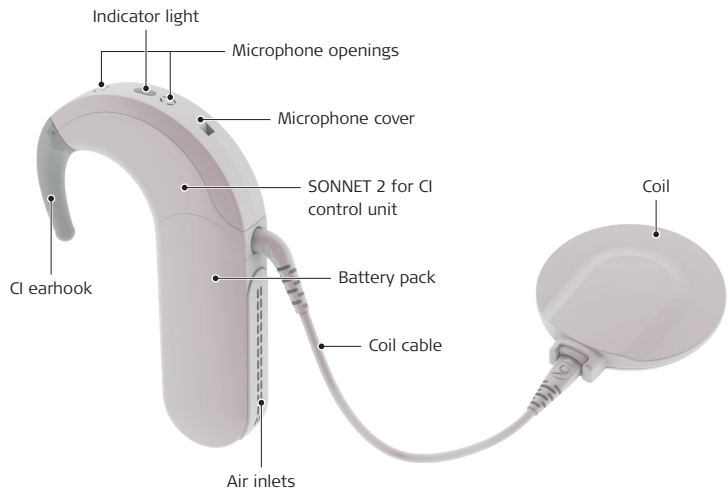
The external parts include the SONNET 2 audio processor and the audio processor accessories. In its basic configuration, the SONNET 2 audio processor consists of the control unit with the earhook attached, the battery pack (consisting of frame and cover), the coil and the coil cable. A separate device called 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 2 audio processor is available in two variants: The SONNET 2 (product code Me151x) is an audio processor that supports electrical stimulation only, while the SONNET 2 EAS (product code Me152x) additionally features acoustic stimulation (amplification) intended to be used by recipients who have at least a certain degree of functional low frequency hearing. Unless explicitly stated otherwise, "SONNET 2" refers to both variants throughout this user manual.

SONNET 2 for CI audio processor



SONNET 2 EAS audio processor

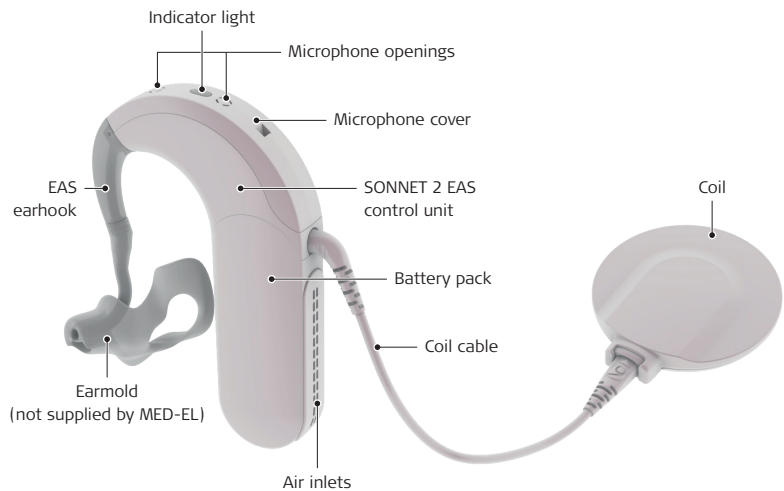


Fig. 1 Your SONNET 2 audio processor

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.

Switching the audio processor ON/OFF

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. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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 audio processor. It is sufficient to pull it back to a position where you can see the labelling on the control unit (see Fig. 2).

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.

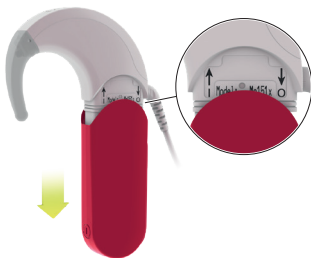


Fig. 2 The SONNET 2 audio processor in OFF position



Fig. 3 The SONNET 2 audio processor in ON position

After switching on the 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.



When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 6) 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 audio processor, 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. 4). As soon as the coil is approximately over the implant, it is automatically positioned correctly by attraction to the implant magnet.



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



Fig. 4 Audio processor 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 not worn behind the ear and 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.

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 audible signals.

To use the telecoil, proceed as follows:

- Activate the telecoil by pressing the key **(T)** (only signals picked up by the telecoil will be audible) or **(MT)** (signals picked up by the microphone and the telecoil will be audible) on your FineTuner as described in chapter 4, SONNET 2 audio processor, FineTuner, FineTuner controls.
- When you are using a telephone, position the telephone so that its earpiece is centered over the 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 **(M)** on your FineTuner as described in chapter 4, SONNET 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 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 2 audio processor, FineTuner, FineTuner controls).

FineTuner

The FineTuner is a small remote control for the audio processor. The FineTuner is provided to help you optimally use your audio processor in changing daily listening situations.

If you are using the FineTuner Echo, please refer to the user manual of the FineTuner Echo.

The audio processor itself has only an ON/OFF switch. All other functions are accessed with 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.

Keep the FineTuner out of the reach of children to prevent 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 (31.5 in.). 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 synchronize your FineTuner, proceed as follows:

1. Switch off the audio processor.
2. Place the coil on the keypad of the FineTuner (approx. over key .
3. Switch on the 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 audio processor to the FineTuner if you replace the audio processor or FineTuner.

For bilaterally implanted users

One FineTuner can be configured for use with one audio processor per ear. If you are a bilateral user, your audiologist will configure the left and right audio processors. The synchronization procedure described above should be performed with both audio processors.

FineTuner controls

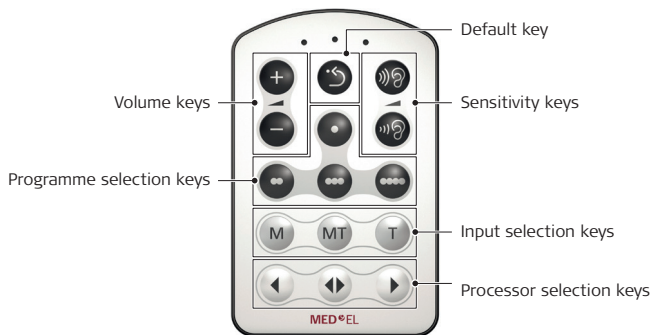


Fig. 5 FineTuner

Volume keys

⊕ increases overall loudness, ⊖ decreases overall loudness



Program selection keys

Four keys to access four different programs

Default key

This key sets overall volume and audio sensitivity to predefined values determined by your audiologist or clinical staff. Pressing the default key on your FineTuner only affects volume and audio sensitivity. The program position does not change.




Sensitivity keys

 increases audio sensitivity,  decreases audio sensitivity

Input selection keys

 selects the microphone,  selects microphone + telecoil,  selects the telecoil

Processor selection keys (for bilateral users only)

 selects the left processor,  selects both processors,  selects the right processor



All FineTuner controls 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 automatic keyboard lock, proceed as follows:

1. Press the  key for more than 5 seconds. The FineTuner goes into the programming mode (the red and both amber indicator lights on your FineTuner will start blinking alternately).
2. Press the  key to activate the automatic keyboard lock (a short blinking signal of the two amber indicator lights indicates that the automatic keyboard lock is active).

To deactivate the automatic keyboard lock, proceed as follows:

1. Press the  key twice. The keyboard is now unlocked for 10 seconds.
2. Hold down the  key for more than 5 seconds to enter the programming mode.
3. Press the  key to deactivate the keyboard lock. The FineTuner will confirm successful deactivation of the automatic keyboard lock with a short blinking signal of the two amber indicator lights.

To operate a certain control while the keyboard lock is active, press the desired 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, 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 audio processor (see Fig. 2 and 3) 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 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. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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. 7.1) on the battery pack frame and separate battery pack frame and control unit (Fig. 7.2).

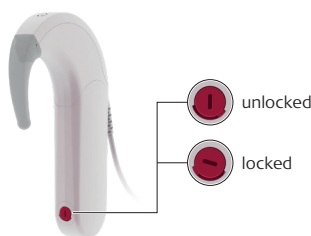


Fig. 6 Battery pack cover lock in unlocked/locked position

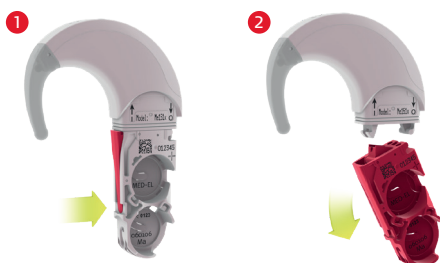


Fig. 7 How to remove the battery pack from the control unit

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. 8.1).
2. Push the opposite end of the battery pack frame onto the control unit (Fig. 8.2) until the release lever engages.
3. Make sure that the battery pack cover lock is in the unlocked position as shown in Fig. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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 audio processor (see Fig. 3). 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. 8.3) on the battery pack cover are on the same side as the coil cable socket in the control unit.

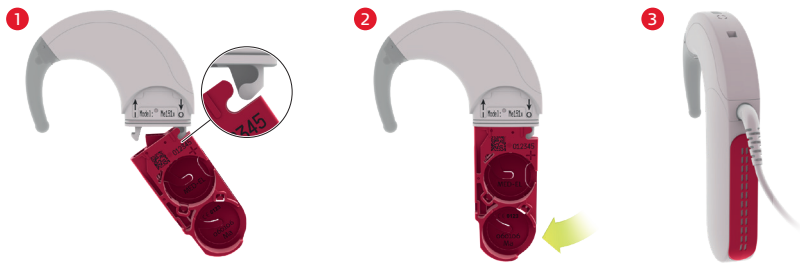


Fig. 8 How to attach the battery pack to the control unit



When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 6) once the cover has been moved completely over the frame to prevent the child from disassembling the audio processor.

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



Only parents/caregivers should disassemble the device to change defective parts. Parents/caregivers must check the device at least once a week for damage or missing parts.

Coil

The coil connects the audio processor with the implant. It sends both power 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 to adjust the magnet strength to your needs. The magnet strength chosen should be appropriate for the individual user. Strong magnets are not recommended for users with thin skin flaps (e.g. young children), as excessive magnetic attraction could potentially increase the likelihood of skin irritation or cause a sensation of heat under the 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.

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 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. 9). You will notice correct alignment by uninterrupted hearing and/or stronger magnetic attraction.

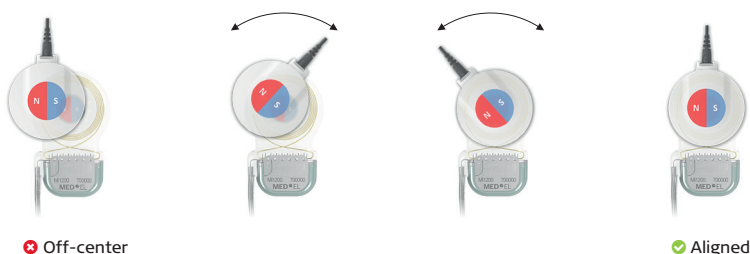


Fig. 9 Aligning coil and implant magnets

The 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



Fig. 10 DL-Coil

The DL-Coil provides several features:

Link indicator light

The multi-color indicator light in the cable socket of the DL-Coil flashes with different patterns and colors to indicate different conditions. The green indicator light indicates functionality of the audio processor and implant. For a detailed description of error indications see chapter Troubleshooting.

Blinking pattern	Meaning	Required action	Remarks
●	After placing the coil over the implant and turning on a processor programmed for a previous generation implant (e.g. C40+, C40): Indicates functionality of coil, coil cable and audio processor. Implant functionality is not checked.	None	Applicable only to previous generation implants (e.g. C40, C40+)
●●●	After placing the coil over the implant and 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 to PULSAR, SONATA, MED-EL CONCERT, SYNCHRONY and later generation implants
● — 1 — 2 — 3s — ...	Optional visual indication of activated link monitoring	None	Can be activated by your audiologist.

Link monitoring

The link monitoring feature is active after switching on the audio processor and monitors proper communication between the audio processor and the implant. It regularly checks if the audio processor is sending information to the implant. It also checks if the implant receives sufficient energy and correct stimulation information. This check is only repeated when the DL-Coil is moved relative to the implant. This feature is especially useful for users who are not able to give feedback about the correct function of their MED-EL Cochlear Implant System.


After switching on the audio processor or when the coil is moved above the implant, the link between coil and implant is checked. This check can be audible as 3 short beeps.

Automatic coil power off

With the automatic coil power off feature the DL-Coil switches off after 5 minutes when there is no connection with the implant (e.g. when the DL-Coil 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.

Important

Only the DL-Coil switches off, the audio processor does not switch off. If only the indicator light of the audio processor blinks, you cannot assume that the user hears acoustic signals.

Blinking pattern	Meaning	Required action	Remarks
	Coil has powered off	Switch the processor off and on again to resume stimulation (the processor does not switch off automatically) and reposition the coil over the implant	If the blinking persists, contact your clinic, audiologist or MED-EL.

To re-activate the DL-Coil, switch the audio processor on and off.

The automatic coil power off function is not available for previous generation implants (e.g. C40 or C40+).

Your audiologist can activate or deactivate the link indicator light and the automatic coil power off function of your DL-Coil if you prefer this.

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 connected and removed after removing the coil cover.



Fig. 11 Coil cover with cable lock



When the user is a young child, always use the coil cover with cable lock to prevent the child from disconnecting the coil cable.

Exchangeable design covers

The coil cover is available in several colors and designs allowing you to personalize your DL-Coil. Please contact your CI center or MED-EL for further information.

Adjustable magnet

Several magnet options are available and with all magnets (except number 5) a fine adjustment of the holding force is possible by engaging the magnet either in the \oplus or \ominus position.

Components of the DL-Coil

The DL-Coil consists of a base, a magnet, a cover and a cable.

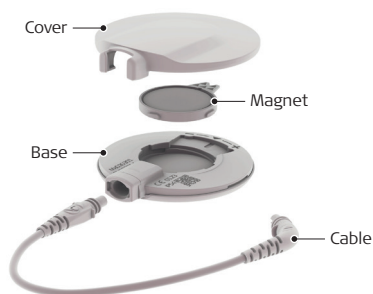


Fig. 12 Components of the DL-Coil

Coil cover

Four variants are available in different colors and designs.

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. 13 Coil cover L (left) and coil cover H (right)

Both, the coil cover L and the coil cover H are available with and without cable lock (Fig. 11). With the coil cover with cable lock attached, the coil cable can only be connected and removed after removing the coil cover.



When the user is a young child, always use the coil cover with cable lock to prevent the child from disconnecting the coil cable.

Important

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

NOTE: Irrespective of the type of coil cover, you should always disassemble the coil cover before connecting or disconnecting the coil cable from the coil. Removing the coil cover helps protect the coil cable against damage.

To remove the coil cover, proceed as follows:

1. Hold the socket between thumb and index finger and insert a fingernail or the provided plastic screwdriver in the small recess on the opposite side of the coil (Fig. 14.1).
2. Slide your fingernail or the plastic screwdriver in from front to side (Fig. 14.2) until the cover comes off. A clicking sound indicates that the coil cover has been correctly opened.
3. Remove the cover sideways (Fig. 14.3).

Always open the coil cover this way to avoid breaking the cover.



Fig. 14 Removing the coil cover

To attach the coil cover, proceed as follows:

1. Attach the coil cover starting at the side of the socket (Fig. 15.1)
2. Gently press down along the edge of the cover (Fig. 15.2). Make sure to completely close the cover to prevent dust or moisture from entering and possibly damaging the coil.

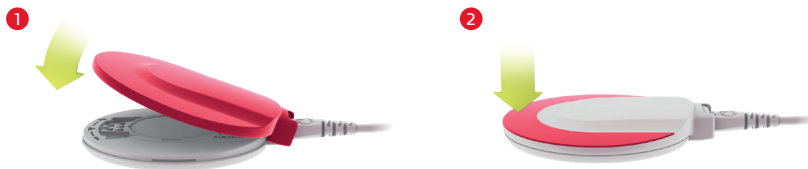


Fig. 15 How to assemble the coil cover

Important

Make sure to lock the magnet in place by turning it towards the \oplus or \ominus symbol to avoid breaking the coil cover. Leaving the magnet in center position is not allowed. Strength 5 magnets must be turned towards \oplus , otherwise the cover cannot be attached properly.

DL-Coil base

The DL-Coil base houses the electronics. All other components are attached to the base. The base is available in different colors.

Magnet

Important

Depending on the type of implant, two variants of magnets 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 recipients implanted with a SYNCHRONY implant, the magnet must contain triangles as shown in Fig. 18. The magnet holder is available in black.



For recipients implanted with any other type of implant (MED-EL CONCERT, SONATA¹⁰⁰, etc.), the magnet must contain circles as shown in Fig. 19. 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 to adjust the magnet strength to your needs.

To change the magnet, proceed as follows:

1. Open the cover as described in section Coil cover in this chapter.
2. Turn the magnet to the center position and lift it off (it will fall out when the coil is turned upside down).
3. To insert a new magnet, center it in the base with the circles/triangles facing upwards as shown Fig. 17.1. It should glide into the recess easily.
4. After inserting the magnet, lock it in place by moving the lip to the \oplus or \ominus symbol indicated on the base part of the DL-Coil until it engages as shown in Fig. 17.2. Use a ballpoint pen to move the magnet in either direction. Moving the lip to the right \oplus , slightly increases magnetic force. Moving the lip to the left \ominus , slightly decreases magnetic force.

Important

Make sure to lock the magnet in place by turning it towards the \oplus or \ominus symbol to avoid breaking the coil cover. Leaving the magnet in center position is not allowed as this might damage the assembled coil cover.

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

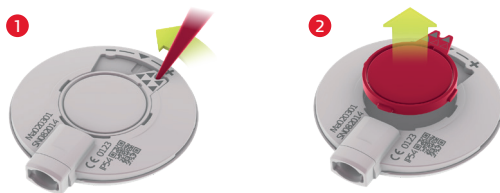


Fig. 16 Removing the magnet



Fig. 17 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.

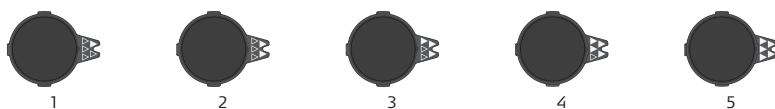


Fig. 18 Magnet strengths for SYNCHRONY implant

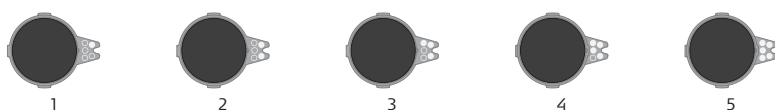


Fig. 19 Magnet strengths for all other types of implants

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 coil, contact your clinic or CI center.

Your coil contains a strong magnet. Keep clear of metallic items as they attract the magnet. Do not place your DL-Coil on metallic surfaces. As the magnet is made of metal, do not place two coils on one another while the audio processor (or audio processors if you are a bilateral user) is switched on. Contact with metallic surfaces might lead to excessive battery drain and blinking lights indicating error conditions.

Never place the coil or a magnet on the control unit. It is even more important to follow this guideline if you are using a SONNET EAS. The SONNET EAS contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.

D Coil



Fig. 20 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 recipients implanted with a SYNCHRONY implant, the magnet insert must contain triangles as shown in Fig. 23.



For recipients 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 change the magnet, proceed as follows:

1. To remove the magnet insert, turn it to either side until it disengages and lift it off (Fig. 21).
2. To attach a new magnet insert, place it over the recess in the coil (Fig. 22.1). It should glide into the recess easily.
3. Turn the cover until it engages (Fig. 22.2). You will feel a slight resistance when the cover snaps in place.

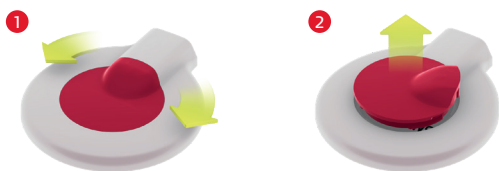


Fig. 21 Removing the magnet



Fig. 22 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

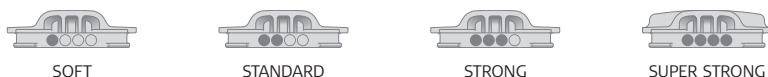


Fig. 24 Magnet strengths for all other types of implants

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 control unit. It is even more important to follow this guideline if you are using a SONNET 2 EAS. The SONNET 2 EAS contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.

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 or SONNET 2 audio processor.

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.
-

To replace the coil cable on the control unit side, proceed as follows:

1. Make sure that the battery pack cover lock is in the unlocked position as shown in Fig. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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. 2).
3. Grab the plug of the cable on the control unit side and gently pull the plug out of its socket in the control unit.
4. Plug the new coil cable into the control unit as shown in Fig. 27. Make sure that the cable plug is correctly positioned. The slanting edge must face down.
5. Make sure that the battery pack cover lock is in the unlocked position, as shown in Fig. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 kit to turn it counter-clockwise into the unlocked position.
6. Slide the battery pack cover completely over the battery pack frame to switch on the audio processor (see Fig. 3). 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.



Fig. 27 Plugging the coil cable into control unit



When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 6) once the cover has been moved completely over the frame to prevent the child from disassembling the audio processor.

To replace the coil cable on the DL-Coil side (if your coil is a DL-Coil), proceed as follows:

1. Remove the coil cover (see Fig. 14).
2. Grab the plug of the cable on the DL-Coil side and gently pull the plug out of its socket in the DL-Coil.
3. Plug the new coil cable into the DL-Coil. Mind correct orientation of the plug (see Fig. 28).
4. Attach the coil cover starting at the side of the socket (see Fig. 15).



When the user is a young child, always use the coil cover with cable lock to prevent the child from disconnecting the coil cable.



Fig. 28 Plugging the coil cable into the DL-Coil

To replace the coil cable on the D Coil side (if your coil is a D Coil), proceed as follows:

1. Grab the plug of the cable on the D Coil side and gently pull the plug out of its socket in the D Coil.
2. Plug the new coil cable into the D Coil (Fig. 29).



Fig. 29 Plugging the coil cable into the D Coil

Earhook

Depending on the variant of your audio processor, i.e. SONNET 2 for CI or SONNET 2 EAS, your audio processor is shipped with a different type of earhook. While the earhook for the SONNET 2 for CI (see Fig. 30) is only intended to keep the audio processor behind the ear, the earhook for the SONNET 2 EAS (see Fig. 31) additionally contains a sound tube in its center and a specially shaped tip that allows easy attachment of an acoustically functional earmold by a hearing aid acoustician. Combined electric-acoustic stimulation always requires using an ear mold.



Fig. 30 Earhook for SONNET 2 for CI



Fig. 31 Earhook for SONNET 2 EAS

Important

It is the audiologist's responsibility to customize the earmold according to standard hearing aid practice. The earmold 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 earmold, which is a common issue associated with hearing aid molds. Therefore it is especially important that the audiologist ensure that the earmold optimally fits the anatomical shape of the ear canal and the earhook of the audio processor.

The audiologist is also responsible to inform the user or parents/caregivers about cleaning the earmold to ensure optimal performance and avoid bacterial infections.

In cases of otitis media (especially with effusion) it is recommended to use the audio processor without an earmold i.e. only use electrical stimulation to leave the outer ear canal open.

Your 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. 32.1) using the tool supplied with your SONNET 2 kit, then grab it and pull it out completely.
2. To remove the earhook gently push it downwards (Fig. 32.2), separating it from the control unit.
3. Attach the new earhook over the lip in the lower part of the control unit (Fig. 33.1) and push it gently upwards (Fig. 33.2) 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.

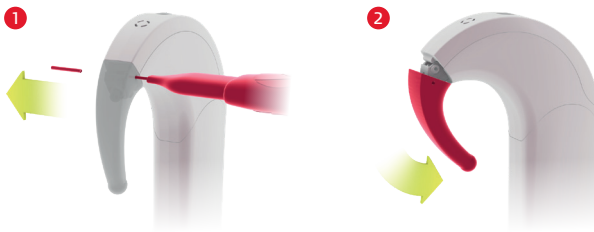


Fig. 32 Removing the earhook



Fig. 33 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 SONNET 2 for CI audio processor with an EAS earhook does not convert the audio processor into the SONNET 2 EAS variant.

Using a CI earhook with a SONNET 2 EAS audio processor will block any acoustic stimulation, i.e. never use a CI earhook with a SONNET 2 EAS audio processor.

MED-EL also provides the earhook in a slightly longer version which can be ordered separately. Two marks on the inside of the earhook help identify the longer version (see Fig. 34).

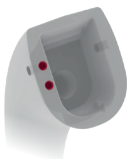


Fig. 34 Markings of longer earhook version

Microphone cover

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

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

There are two types of microphone covers.



Fig. 35 Microphone cover with groove



Fig. 36 Microphone cover without groove

To replace the microphone cover with groove, proceed as follows:

1. Insert the screwdriver into the groove at the bottom of the microphone cover.
2. Gently lever the cover away from the control unit.
3. Place the new cover over the control unit.
4. Starting at the earhook end, press down until the cover snaps into place.



Fig. 37 Removing the microphone cover



Fig. 38 Attaching the microphone cover

To replace the microphone cover without groove, proceed as follows:

1. Remove the earhook as described in the previous section.
2. Snap off (Fig. 39) 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 and push the cover gently onto the control unit (Fig. 40) until it snaps completely into place.
4. Re-attach the earhook and insert the earhook pin as described in the previous section.



Fig. 39 Removing the microphone cover

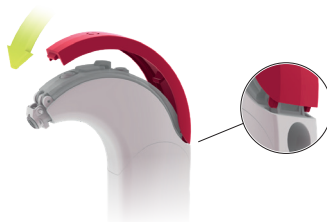


Fig. 40 Attaching the microphone cover



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 audio processor.

Connecting assistive listening devices

A special battery pack cover (product code Ma070103) is available as an option 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 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. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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 audio processor (see Fig. 3). 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.



When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 6) 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 audio processor 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. 37 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 1m (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 audio processor 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 audio processor microphone is deactivated. You will hear input from the external device only.

Ext cables are indicated by a red 3.5 mm plug.

Wireless functionality

The audio processor is equipped with 2.4GHz MED-EL proprietary as well as Bluetooth®² wireless technology. This technology allows the audio processor to be wirelessly connected to various external devices like the MED-EL FineTuner Echo (remote control), the MED-EL AudioLink (audio streaming device), or a commercial electronic device (smartphone, tablet, etc.) with Bluetooth® functionality³ that is capable of running the MED-EL AudioKey mobile app.

For detailed information, functional descriptions, operating instructions and troubleshooting information of the MED-EL FineTuner Echo, the MED-EL AudioLink, and the MED-EL AudioKey mobile app, please see their respective user manuals.

Caution

Use of Bluetooth® wireless technology or any changes to the Bluetooth® wireless technology (e.g. firmware updates, hardware changes, connection/disconnection of additional devices, etc.) could introduce previously unidentified risks. If such risks are identified, they shall be analyzed, evaluated and controlled.

The 2.4GHz wireless functionality may be affected by electromagnetic interference from other close electronic and electrical equipment even if this equipment complies with all applicable electromagnetic emission requirements. If such interference is experienced, move away from this electronic and electrical equipment.

2 The Bluetooth® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by MED-EL is under license.

3 Such an electronic device must at least be compatible with the Bluetooth 4.2 specification (Bluetooth Low Energy).

Flight mode

When boarding a flight or entering an environment where RF transmissions are prohibited, the 2.4GHz wireless functionality must be deactivated, i.e. the audio processor's flight mode must be activated, as wireless operations are typically not allowed on airplanes or in certain restricted environments.

NOTE: The flight mode must be activated even if you do not intend to use the MED-EL FineTuner Echo, the MED-EL AudioLink, or the MED-EL AudioKey mobile app at all.

To activate the flight mode, proceed as follows:

1. Switch off the audio processor (see chapter 4, SONNET 2 audio processor, Switching the audio processor ON/OFF) and wait at least 2 seconds.
2. Switch on the audio processor and wait approx. 2 seconds or until the indicator light blinks green for the first time.
3. Repeat steps 1 and 2.
4. Repeat steps 1 and 2 again.
5. Repeat steps 1 and 2 one more time.
6. After approx. 3.5 seconds the indicator light will briefly blink red to confirm that the flight mode has successfully been activated. If you do not see the red light, repeat steps 1 to 5.

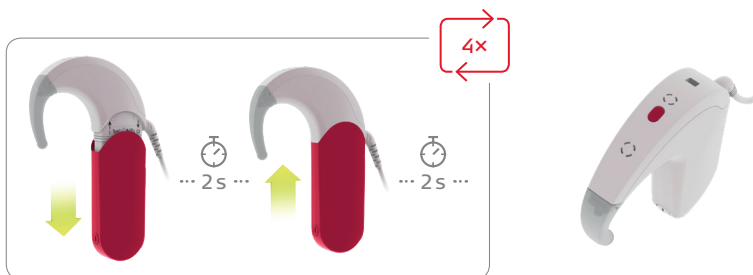


Fig. 38 Activating the flight mode

When leaving the airplane or the restricted environment, you may deactivate the flight mode.

To deactivate the flight mode, proceed as follows:

1. Switch off the audio processor and wait at least 2 seconds.
2. Switch on the audio processor. You can now use the audio processor and the 2.4GHz wireless functionality as usual.

5. Special considerations for young children

The 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/caregivers are allowed to disassemble the device to change defective parts. Parents/caregivers should check the device at least once a week for damage or missing parts.

Important

If the user of the audio processor is a child who also uses an earmold for retention, parents/caregivers should regularly check to make sure the earmold still fits as the ear grows. The earmold must be adjusted regularly as necessary. A non-optimally fitting earmold may cause acoustic feedback (whistling).



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.

6. 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 user'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.

If the data logging feature has been enabled in your audio processor, data on your use of your audio processor will be collected. For more information please speak to your audiologist.

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 (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 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 may cause painful or uncomfortable stimulation. Using another FineTuner will not allow you to change the settings (volume etc.) of your audio processor.
- 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). Disposable batteries may remain in the battery pack frame. If in doubt, repeat the drying process. If the FineTuner becomes wet, wipe it off with a dry tissue.

Important

Do not put rechargeable batteries into the drying kit.

- 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 SONNET 2 control unit. It is even more important to follow this guideline when you are using a SONNET 2 EAS. The SONNET 2 EAS contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.
- 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 30cm to any part of the audio processor, including cables specified by MED-EL. Otherwise, degradation of the performance of the audio processor could result.



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. When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 6) once the cover has been moved completely over the frame to prevent the child from disassembling the audio processor.

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 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 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.

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 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. Please pay special attention to chapter 4, SONNET 2 audio processor, Flight mode.

Interference with TV reception

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. 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 (CE), 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 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 take precautions 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 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.

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 interfer-

ence 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.

Precautions for medical procedures

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to the Medical Procedures Manual, available at www.medel.com/us/isi.

Ear infections

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

Electrical lice combs

Cochlear implant users should not use these devices.

Meningitis vaccine and prevention

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

The correct vaccinations and vaccination booster schedules are available at the cdc.gov website.

7. 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. 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 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.

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

Do not try to repair electronic parts of your 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, sooner if the microphone openings appear dirty, or you experience degraded sound quality (see also chapter 4, SONNET 2 audio processor, Microphone cover).

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

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.

Thoroughly wipe the external parts of your audio processor with a tissue at least once a week 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. Disposable batteries may remain in the battery pack frame but the battery pack cover should be removed from your audio processor.

Important

Do not put rechargeable batteries into the drying kit.

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!

Component identification

Should it be necessary to identify the serial numbers and/or product codes of the audio processor components (e.g. for service requests), the information can be found in these positions:

The serial number and product code (Me151x or Me512x) of the control unit are indicated on opposite sides in the lower part of the control unit. Pull down the battery pack cover to reveal the information (see chapter 4 SONNET 2 audio processor, Battery Pack for instructions).



Fig. 39 Serial number and product code of control unit

The serial number of the battery pack frame is indicated on the side of the battery insertion slots. The product code (Ma060106) is indicated in the lower battery insertion slot. Pull off the battery pack cover and remove the batteries to reveal the information (see chapter 7 Care and maintenance, Batteries, Changing the batteries of your audio processor for instructions).



Fig. 40 Serial number and product code of battery pack frame

The serial number and product code (Ma020301) of the DL-Coil are indicated on the base part of the DL-Coil. Remove the coil cover to reveal the information (see chapter 4 SONNET 2 audio processor, DL-Coil, Magnet for instructions).



Fig. 41 Serial number and product code of DL-Coil

The serial number of the D Coil is indicated in the magnet compartment. Remove the magnet insert to reveal the information (see chapter 4 SONNET 2 audio processor, D Coil for instructions).



Fig. 42 Serial number of D Coil

Batteries

The audio processor requires two 675 zinc air batteries. These batteries supply the external and internal components of the MED-EL Cochlear Implant System with power. 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 audio processor.

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 metal (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 leakage and possible damage to 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. When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 6) 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 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 audio processor and the coil from your head.
2. Make sure that the battery pack cover lock is in the unlocked position as shown in Fig. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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. 43).

Important

Be careful not to place the coil on the 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. 6. When it is not in the unlocked position, use the screwdriver provided with your SONNET 2 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 audio processor (see Fig. 3). 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.



When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 6) once the cover has been moved completely over the frame to prevent the child from disassembling the audio processor.

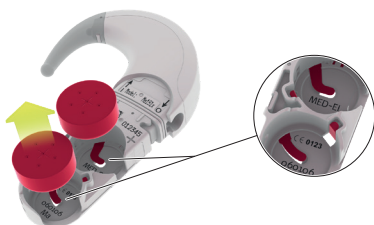


Fig. 43 Changing the batteries of your audio processor

Changing the battery of your FineTuner

When your FineTuner generates an optical low battery warning signal (see also chapter 4, SONNET 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 coil magnet or by gently shaking it into your hand. Try not to touch the battery contacts.
3. Insert the new battery with the \oplus 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. 44 Changing the battery of your FineTuner

8. 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 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. 45 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 users (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. 45). 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 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 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 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, SONNET 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 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.



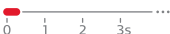
Additional troubleshooting information:

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

Audio processor 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 and the flight mode confirmation pattern) if you prefer this.

Blinking pattern	Meaning	Required action	Remarks
Confirmation pattern			
<ul style="list-style-type: none"> 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.
Programme 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	
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.	

Blinking pattern	Meaning	Required action	Remarks
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.	
Flight mode confirmation pattern			
	Flight mode successfully activated	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.



Your audiologist can deactivate these 3 signals 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			
	After placing the coil over the implant and turning on a processor programmed for a previous generation implant (e.g. C40+, C40): Indicates functionality of coil, coil cable and audio processor. Implant functionality is not checked.	None	Applicable only to previous generation implants (e.g. C40, C40+)
	After placing the coil over the implant and 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 to PULSAR, SONATA, MED-EL CONCERT, SYNCHRONY and later generation implants
	Optional visual indication of activated link monitoring. This check is repeated whenever the coil is moved relative to the implant.	None	Can be activated by your audiologist.
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. The coil will automatically power off after 5 minutes (no stimulation). Your audiologist can deactivate the automatic power off function.
	Coil positioned over wrong implant (bilaterally implanted users)	Position the coil over the correct implant	
	Broken coil cable	Replace the coil cable.	
	Processor has switched off due to empty batteries (if battery charge is still sufficient to power the coil)		
	Processor is in microphone monitoring mode.	Switch the processor off and on again	

Troubleshooting

Blinking pattern	Meaning	Required action	Remarks
	Coil has powered off	Switch the processor off and on again to resume stimulation (the processor does not switch off automatically) and reposition the coil over the implant	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 lights

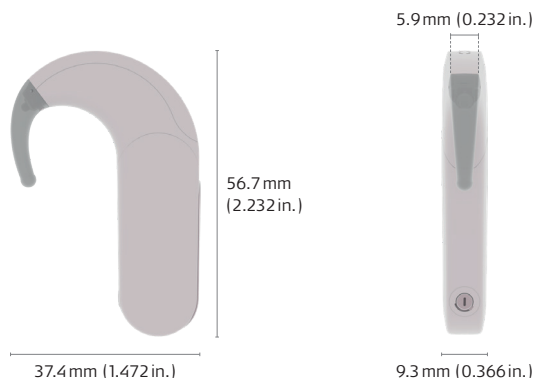
Three indicator lights with different colors (left and right: amber; center: red [warnings]) indicate various conditions of the FineTuner.

Blinking pattern	Meaning	Remarks
○ ● ○	Keyboard locked	If you press any key while the keyboard is locked, the red indicator light comes on. To save power, the red indicator light goes off after 5 seconds even if the key is still pressed.
● ○ ○ ○ ○ ● ● ○ ○	Transmitting	The amber indicator lights blink synchronously to the signals transmitted by the FineTuner to the audio processor. The left light blinks if the left processor is selected. The right light blinks if the right processor is selected. Both lights blink if both processors (for bilateral users) are selected. To save energy, the FineTuner stops transmitting (and the indicator lights stop blinking) after 3 seconds even if the key is still pressed.
⬅ → ● ○ ○ ➡ → ○ ○ ● ⬅ ➡ → ● ○ ○	Select processor	Press ⬅ to select the left processor. Press ➡ to select the right processor. The corresponding amber light will come on. Press ⬅ ➡ to select both processors. Both amber lights will come on. To save energy, any indicator light goes off after 5 seconds even if the key is still pressed. NOTE: A processor can only be selected when the FineTuner is configured for use with two different audio processors (for bilateral users).
● ○ ● ○ ● ○ ○ ○ ○ ⋮	Programming mode	Press ⬅ ➡ for more than 5 seconds to activate the programming mode. The three indicator lights start flashing alternately. Flashing stops and the programming mode is left after 5 seconds or earlier when a correct key is pressed. NOTE: The keyboard must be unlocked to enter the programming mode.
○ ● ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ● ○ ⋮	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 in the center blinks 3 times in a regular pattern.
● ○ ●	Configuration successful	If configuration of your FineTuner was successful or if the automatic keyboard lock feature was activated/deactivated, both amber indicator lights will illuminate for approximately one second.

9. Technical data

Audio processor

Dimensions⁴



Weight⁴

SONNET 2 for CI: 10.6 g (0.374 oz.) (including batteries)

SONNET 2 EAS: 11.0 g (0.388 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

⁴ typical values

Additional features in SONNET 2 EAS 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 dBV^4 (corresponds to 70 dB SPL at 1 kHz)
- Impedance: $4.5 \text{ k}\Omega^4$

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 $+50^\circ\text{C}$ ($+32^\circ\text{F}$ to $+122^\circ\text{F}$)

Storage temperature range: -25°C to $+60^\circ\text{C}$ (-4°F to $+140^\circ\text{F}$)

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 SONNET 2 (incl. all accessories) are essential performance as defined in IEC 60601-1.

Expected service life

The expected service life of the SONNET 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 electromagnetic disturbances for the expected service life.

Radio frequency (RF) link (FineTuner)

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

⁴ typical values

Radio frequency link (2.4 GHz wireless technology)

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

Short Range Device (SRD) according to ERC/REC 70-03 Annex 1 (band I) and Annex 3 (band B)

Type of modulation: Gaussian frequency shift keying (GFSK)

Maximum effective radiated power (ERP): 610 μ W (-2.15 dBm)

Channel band width: 2 MHz (MED-EL proprietary protocol)

Channel band width: 1 MHz (Bluetooth®)

Coils

DL-Coil

Dimensions in mm (in.)⁴

Diameter: 32.8 (1.29)

Height: 5.8 (0.23)

(with number 2 magnet and coil cover L)

Weight⁴

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.)⁴

Diameter: 31.6 (1.24)

Height: 6.0 (0.24)

Weight⁴

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 cm (in.)⁴

6.5 (2.56), 90 (3.54) and 280 (11.02)

Materials

PVC and TPE Evoprene, all colors

Coil cable

Dimensions in cm (in.)⁴

8.5 (3.35), 110 (4.33) and 280 (11.02)

Materials

PVC and TPE Evoprene, all colors

⁴ typical values

FineTuner

Dimensions⁴

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)
- 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: -25 °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)

⁴ typical values

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: ~1.15 m (3.77 ft.)

Regulatory statements

Applicable in Canada only:

Model: SONNET 2 (Me151x), SONNET 2 EAS (Me152x) – IC: 11986A-ME1500

Model: FineTuner – Canada 310

The above devices contain licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(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.

L'émetteur/récepteur exempt de licence contenu dans les appareils mentionnés ci-dessus est conforme aux CNR d'Innovation, Sciences et Développement économique 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 2 (Me151x), SONNET 2 EAS (Me152x) – FCC ID: VNP-ME1500

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

CE marking, first applied in 2017

Hereby MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type SONNET 2/SONNET 2 EAS incl. FineTuner 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 the instructions for use (manual) for important cautionary information



Refer to instruction manual/booklet



MR unsafe



Type BF
(IEC 60601-1)



Non-ionizing radiation



Fragile; handle with care



Relative humidity



Temperature limit

SN

Serial number

REF

Catalogue 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 and in ON position, i.e. when

- the microphone cover and the earhook are snapped onto the control unit,
- an earmold is connected to the earhook (only relevant for SONNET 2 EAS),
- the coil cable and coil are 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).

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 SONNET 2

There are no deviations from this collateral standard and no allowances are used.

Electromagnetic emissions – for all equipment and systems

The SONNET 2 is intended for use in the home healthcare environment. The customer or the user of the SONNET 2 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SONNET 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 SONNET 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 SONNET 2 is intended for use in the home healthcare environment. The customer or the user of the SONNET 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 SONNET 2 is intended for use in the home healthcare environment. The customer or the user of the SONNET 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	3Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the SONNET 2, including cables, specified by MED-EL. Otherwise degradation of the performance of the SONNET 2 could result.
	6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	6Vrms	
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	
		3V/m 2.7 GHz to 6 GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27V/m 380 MHz to 390 MHz	27V/m	
	28V/m 430 MHz to 470 MHz	28V/m	
	9V/m 704 MHz to 787 MHz	9V/m	
	28V/m 800 MHz to 960 MHz	28V/m	
	28V/m 1700 MHz to 1990 MHz	28V/m	
	28V/m 2400 MHz to 2570 MHz	28V/m	
	9V/m 5100 MHz to 5800 MHz	9V/m	

10. Appendices

Warranty

Please refer to the accompanying Warranty Statement for information on our warranty provisions.

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 30 dB 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%
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 question-

naires 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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