MED EL

SONNET 3 / SONNET 3 EAS Audio Processor

User Manual

hearLIFE

AW45569_2.0D1 (English US)

Table of Contents

1. Introduction

This user manual provides information and instructions for the SONNET 3 variants: SONNET 3 (Me171x) and SONNET 3 EAS (Me172x)[1].

You are the operator of the audio processor, therefore you should read the entire manual. 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.

Contact your audiologist/healthcare professional or local MED-EL representative with any questions you may have.

The following symbols are used throughout this document:

Information indicating a hazardous situation that, if not avoided, could result in death or serious injury.

Information indicating a hazardous situation that, if not avoided, could result in minor injury or inconvenience for the user and/or property damage.

Information particularly relevant for parents, guardians, or caregivers of users.

1 x = 0, 1, 2, or 3

2. Intended Use

The SONNET 3 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 3 EAS audio processor working in conjunction with the internal cochlear implant with either a +FLEX24 or +FLEX20 electrode variant (SYNCHRONY, SYNCHRONY 2, 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.

2.1 Indications

The SONNET 3 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 a MED-EL cochlear implant with removable magnet (SYNCHRONY or SYNCHRONY 2) or with a MED-EL cochlear implant without removable magnet (MED-EL CONCERT, SONATA, PULSAR or C40+). The MED-EL Cochlear Implant System is indicated for:

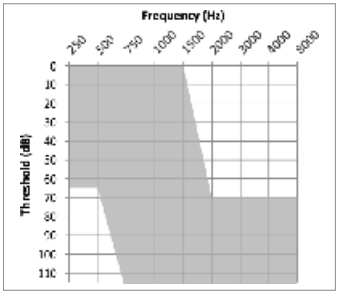
Bilateral deafness:

- 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 3 EAS audio processor is intended to be used by the patients as indicated above.

The SONNET 3 is indicated to be used in typical everyday environments (home, office, outdoor, etc.).

The SONNET 3 is intended to be used every day during a patient's waking hours.

The user of a SONNET 3 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 handicapped 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 SONNET 3 on/from the ear
- Placing/removing coil over/from the implant site

As the SONNET 3 is a component of the MED-EL Cochlear Implant System, all indications stated for the Cochlear Implant System are applicable.

2.2 Contraindication

The contraindications of the MED-EL cochlear or auditory brainstem implant apply.

A patient must not receive a SONNET 3 if the individual is known to be intolerant to the materials used in the SONNET 3.

The SONNET 3 and any external wireless device (e.g., remote control) are not intended to be used in environments where RF transmissions are prohibited (e.g., operating room).

3. Warnings and Precautions

Carefully read the following section. Contact your audiologist/healthcare professional or local MED-EL representative with any questions you may have.

The actual performance of the cochlear implant cannot be predicted accurately, but the experiences of other users of the MED-EL cochlear implant (CI) 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 CI system with any device other than those listed in this user manual or approved by MED-EL. If you have problems with any component of the system, read section Troubleshooting or contact your audiologist/healthcare professional or local MED-EL representative.

If the data logging feature has been enabled in your audio processor, data on your use of the audio processor will be collected. For more information, contact your audiologist/healthcare professional or local MED-EL representative.

3.1 Warnings

3.1.1 General

- If you connect an external audio device to the audio processor that is powered by mains power, i.e., plugged into the wall or a power strip, always make sure that this mains-powered external audio device conforms to relevant international safety standards.
- If the mains-powered device does not bear a CE marking (CE), you cannot presume that the mains-powered device meets the above safety requirements. The CE marking is usually found on the device's type label. Do not connect a mains-powered device without CE marking to the audio processor. Connecting a mains-powered device to the audio processor that does not meet the above safety requirements could cause an electric shock or even lead to death. You can safely connect battery-powered external audio devices to the audio processor. Special cables may be needed (e.g., for connection to FM systems). For more information contact MED-EL.
- If you ever experience loud or uncomfortable sounds, remove the audio processor immediately: this will stop stimulation at once. If you have an older generation implant (C40+ or C40), you should observe these instructions carefully because chronic stimulation with loud or uncomfortable sounds could damage neural tissue. If you follow the instructions, this risk is negligible.

- If a child or person under care refuses to wear the device or indicates uncomfortable hearing sensations, remove the device immediately and have it checked by your audiologist/healthcare professional.
- If you notice any signs of skin irritation around the coil or around the audio processor, contact your clinic or audiologist/healthcare professional. Skin irritation may be caused by an allergic reaction to the materials used in the external components (see section Technical Data for a list of materials).
- Be careful when handling batteries. Misuse of batteries may result in the batteries causing heat, smoke, rupture, flame, or leakage which could lead to injury. Swallowing batteries could cause suffocation, poisoning or internal injuries. If a battery has been swallowed or placed inside any part of the body, seek medical attention immediately.
- Do not use damaged, deformed, 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 fresh water. Do not rub. Seek medical attention immediately. Leaving the eyes untreated may cause eye problems. In case of contact with the mouth, gargle, and rinse thoroughly with water and seek medical attention immediately.
- Instruct children and persons under care not to swallow or put any components of the device into their mouths or play with any components. Swallowing of components could cause suffocation or internal injury.
- When the user is a child or person under care, always turn the battery pack cover lock clockwise ↻ into the locked position ⊖ once the cover has been moved completely over the frame to prevent disassembling of the audio processor.
- When the user is a child or person under care, always use the coil cover with cable lock to prevent disconnecting of the coil cable.

3.1.2 Implant-Related Warnings

For the implanted components, observe the following:

- The implant and the electrodes are located directly under the skin. Do not unnecessarily rub, stretch, or scratch the skin above the implant site. This may damage the implant. Avoid mechanical pressure on the implant site. When brushing or styling the hair at the implant site, be careful not to harm the skin (at the site of the implant there may be a slight bulge).
- Avoid blowing your nose hard as this could lead to (temporary) fluctuations in loudness, caused by air trapped over the reference electrode of the implant. If these fluctuations do not disappear contact your audiologist/healthcare professional.
- Protect the implant from sources of direct impact. Accidents like falling out of a chair or bumping into furniture with the 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, because this could damage the implant. For specific questions about contact sports, contact your audiologist/healthcare professional.
- Use a helmet whenever necessary to protect the implant site from any blows. Helmets should be of high quality. The helmet may need to be modified to meet individual needs.
- Most water sports should not cause any problem if the external parts of the MED-EL Cochlear Implant System are removed or properly protected. Use only products specifically offered or recommended by MED-EL to protect the external parts against the ingress of water. If headgear or face masks are worn, ensure that the strap is not too tight over the site of the implant. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft.).
- Before you undergo medical treatments or examinations, always inform your physician that you have a cochlear implant.
- Inform your audiologist/healthcare professional of 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.
- Bacterial meningitis is rare but has the potential to be serious. The risk of contracting meningitis after 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 any 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 the user and should check your or the user's immunization status before your implant surgery. The correct vaccinations and vaccination booster schedules are available at the cdc.gov website.

3.2 Precautions

3.2.1 General

The audio processor and other parts of the system contain sophisticated electronic components that require special precautions regarding electromagnetic compatibility (EMC). When activating the audio processor and other parts of the system, always follow the guidelines outlined in this section and in section Technical Data, Guidance and Manufacturer's Declaration.

- The electronics are durable but must be treated with care.
- Never open the housing of the audio processor. Opening the housing may damage the device.

- To change the batteries or clean the battery contacts of the audio processor, perform the steps described in these sections:
  - Basics and Handling, Changing the Batteries
  - Basics and Handling, Care and Maintenance
- Do not open or alter any audio processor components. Opening or altering components can lead to injuries and damage the device.
- Before switching on the audio processor, check the device for loose or broken parts. Loose or broken parts could lead to injury. In case of problems, do not switch on the audio processor. Read section Troubleshooting or contact your audiologist/healthcare professional or local MED-EL representative.
- Do not use cables or plugs not recommended by MED-EL because they may damage the device or cause uncomfortable stimulation.
- If you plan to enter an environment that could potentially adversely affect the operation of the audio processor (e.g., an area that is protected by a warning notice preventing entry by users fitted with a pacemaker), you should first contact your audiologist/healthcare professional or local MED-EL representative.

3.2.2 Everyday Life

- The audio processor and coil do not require regular maintenance by clinic personnel or other experts.
- Do not modify the housing, the electronics or any other parts of your audio processor or coil in any way as this could lead to injuries and damage the device.
- Do not try to shape the earhook with hot air as this could damage the device.
- You should also check if the earhook pin is properly inserted. The pin may scratch the skin when sticking out.
- Do not use the audio processor of another cochlear implant user or swap sides. The audio processor has been adjusted to your or the user's individual needs. Using another audio processor or swapping sides may cause painful or uncomfortable stimulation.
- Do not use the audio processor components under environmental conditions other than those described in section Technical Data as this could damage the device.
- The defined operating temperature range is between 0 °C and +50 °C (+32 °F and +122 °F) for the audio processor and coil. Normally, when the audio processor is worn on the body, natural body heat helps maintain this temperature range.
- Avoid excessive heat. Excessive heat might damage the audio processor or coil and make it unusable.
- Do not leave the audio processor in direct sunlight (especially inside a car). Long exposure to direct sunlight might damage the device.
- If the audio processor has been at a temperature that is outside the defined operating temperature range of 0 °C to +50 °C (+32 °F and +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]). 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.

- Avoid getting the audio processor wet as this may impair its function. Always remove and switch off the audio processor and keep it in a dry place before bathing, showering, or engaging in other water-related activities.
- If the external parts become wet
  1. Switch off the audio processor.
  2. Remove the batteries from the battery pack.
  3. Unplug the battery pack from the control unit.
  4. Gently wipe dry all external parts with a soft absorbent cloth.
  5. Put the audio processor in the supplied drying kit to allow the audio processor to dry out (preferably overnight).
     NOTE: Do not put any type of battery into the drying kit.
  6. If in doubt, repeat the drying process.
- Do not drop or subject the audio processor or coil to dangerous areas (e.g., machines or high voltage). This could damage the audio processor or coil.
- Never place the coil or a magnet on the SONNET 3 control unit. It is even more important to follow this guideline if you are using a SONNET 3 EAS. The SONNET 3 EAS contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.
- Do not use the audio processor in environments where radio frequency (RF) transmissions are prohibited.
- Do not use the audio processor in the vicinity of strong ionizing radiation (e.g., x-ray machines) or electromagnetic fields (e.g., MRI machines). Such radiation or fields may stop the MED-EL Cochlear Implant System from working.
- Do not use the audio processor adjacent to or stacked with other equipment because it could result in improper operation. If such use is necessary, observe the audio processor and the other equipment to verify that they are operating normally.
- Do not use accessories, transducers, and cables other than those specified or approved by MED-EL. This could result in increased electromagnetic emissions or decreased electromagnetic immunity of the audio processor and result in improper operation.
- Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of the audio processor, including cables specified by MED-EL. Otherwise, degradation of the performance of the audio processor could result.
- To prolong the coil 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.

3.2.3 Electrostatic Discharge

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 are damaged if the static discharge flows through the external equipment. Switching off the audio processor will not prevent damage from occurring. In rare cases, you may experience uncomfortably loud hearing sensations, but the most likely occurrence in case of an ESD event is a short interruption of stimulation or a controlled audio processor shutdown.

Following these guidelines can reduce the probability of electrostatic discharge:

- If you believe that you or the user 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 the MED-EL Cochlear Implant System unless both you and the other person are "discharged".
- "Discharge" before taking off or putting on the audio processor.
  - When removing another person's audio processor:
    1. Touch the person's body.
    2. Touch the processor.
  - When picking up the audio processor from a table or other surface:
    1. Touch the table.
    2. Pick up the processor.
- "Discharge" when leaving the car, e.g., by touching the car door. 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.
- Remove the audio processor before dressing and undressing, especially if garments include synthetic fibers. When getting dressed, put the audio processor on last, and remove it first when undressing.
- Remove the audio processor before touching plastic play equipment, such as children's slides. Simply switching off the audio processor may not prevent ESD damage. After touching plastic play equipment, do not touch the implant site. "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.
- Remove the audio processor when experimenting with static electricity and "high" voltage. Van de Graaff generators, as found in school science departments, should never be used by cochlear implant users because they produce very high levels of static electricity.
- When working at a computer, make sure the computer is grounded and use an antistatic mat under the 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 antistatic screen to the computer.

- If the 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 audiologist/healthcare professional.

3.2.4 Sports and Play

- If you have any concerns or questions, ask your physician for advice about participating in sports and any limitations of your or the user's health status.
- Make sure that you wear the audio processor securely to protect it from physical damage when doing sports.

3.2.5 Battery Information

For more information on batteries, contact your audiologist/healthcare professional or local MED-EL representative.

- Keep new and used batteries out of the reach of children.
- Wash your hands after handling disposable batteries.
- Do not use damaged, deformed, 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 fresh water. Do not rub. Seek medical attention immediately. Leaving the eyes untreated may cause eye problems. In case of contact with the mouth, gargle, and rinse thoroughly with water and seek medical attention immediately.
- Do not use or leave batteries near fire, stoves, or hot places (e.g., dashboards, inside a car or generally in areas exposed to direct sunlight) where the temperature might rise above +60 °C (+140 °F). In such cases the batteries may become dysfunctional.
- Do not burn or heat batteries. Burning or heating batteries may result in the batteries causing heat, smoke, rupture, or flame.
- Do not place batteries in microwave ovens, high-pressure containers or on induction cookware.
- Do not drive nails into batteries, strike batteries with a hammer or step on batteries. The batteries may be broken, deformed, or short-circuited causing heat, smoke, rupture, or flame.
- Do not disassemble, modify, deform, immerse in water, or incinerate a battery.
- Do not solder batteries directly. Excessive heating may cause deformation of battery components.
- Immediately discontinue using a battery if during use or storage the battery emits an unusual smell, feels hot or moist, changes color and/or shape or appears abnormal in any other way.
- Do not try to recharge disposable batteries. Charging disposable batteries may cause battery electrolyte to seethe or battery internal pressure to rise. Leakage, heating, explosion, or ignition of batteries may result.

- Do not wet batteries with water. This may cause the batteries to ignite.
- Do not short-circuit batteries, e.g., by allowing the negative and positive terminals of batteries to touch, carrying batteries loose in a pocket, wallet or purse or touching the battery terminals with metals (coins, wires, keys, etc.).
- Insert batteries correctly. Erroneous insertion of batteries may result in battery short-circuiting.
- Store unused batteries in their original packaging, in a cool and dry place. Isolate or cover the positive and negative terminals to avoid short-circuiting.
- Always remove used batteries immediately to avoid leakage and possible damage to the device.
- Avoid mix-up of old and new batteries or batteries of different types of brands.
- 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.

3.2.6 Medical Information

For safety recommendations and guidelines related to medical procedures, including MRI scanning, refer to the Medical Procedures Manual. The latest revision can be downloaded from our website (www.medel.com/us/isi).

3.3 Residual Risks and Possible Side Effects

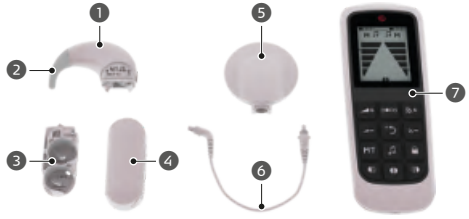
There is a remote chance that technical failure or suboptimal fitting of the audio processor leads to loud or painful sensations, missing information, suboptimal hearing or temporarily no benefit. If you ever experience uncomfortable hearing sensations, we strongly recommend that you no longer wear the external system components. Contact your audiologist/healthcare professional immediately. The probability of loud or painful sensations is higher in older generation implants (C40+ or C40) than in newer generation implants.

4. Device Description

The MED-EL CI system is an active medical device that has internal (implanted) and external parts. The internal part of the device is surgically implanted behind the ear in the skull. The external parts are worn behind the ear or on the body.

The external parts include the SONNET 3 audio processor, its components and accessories, and products that can be used with the audio processor. In its basic configuration, the SONNET 3 audio processor consists of the control unit with the earhook attached, the battery pack (consisting of frame and cover), the coil and the coil cable. A separate remote control called the FineTuner Echo facilitates access to various audio processor functions.

NOTE: For detailed information, functional descriptions, operating instructions and troubleshooting information about the MED-EL FineTuner Echo, refer to its user manual.



1. Control unit
2. Earhook
3. Battery pack frame
4. Battery pack cover
5. Coil
6. Coil cable
7. FineTuner Echo

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 3 audio processor is available in different variants:

- The SONNET 3 for CI (product code Me171x) supports electrical stimulation only.
- The SONNET 3 EAS (product code Me172x) additionally provides acoustic stimulation (amplification) and is intended to be used by recipients who have at least a certain degree of functional low frequency hearing.

Unless explicitly stated otherwise, "SONNET 3" or audio processor refers to all variants throughout this user manual.

4.1 The Concept of EAS

Cochlear implant users with low frequency hearing benefit from additional acoustic stimulation in the implanted ears 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 also report 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.

4.2 Compatibility With Other Devices

The SONNET 3 audio processor is compatible with the following MED-EL products:

- MED-EL implants with removable magnet: Mi1200 SYNCHRONY, Mi1250 SYNCHRONY 2
- MED-EL implants without removable magnet: MED-EL CONCERT, SONATA TI^{100}, PULSAR CI^{100}, C40+, C40
- D Coil
- DL-Coil
- SONNET Battery Pack
- SONNET Rechargeable Battery Kit
- SONNET Rechargeable Battery Max
- SONNET FM Battery Pack Cover
- SONNET ActiveWear Cable
- SONNET Mini Battery Pack
- MAX Programming Interface
- FineTuner Echo[3]
- AudioKey 3 (or higher)
- AudioLink XT
- Speech Processor Test Device
- SONNET Microphone Test Device (MTD)
- MAESTRO 11 (or higher)

For information on connectivity in general, see section Connectivity.

3 The FineTuner Echo must show the Bluetooth symbol ( ) on the back side, otherwise it will not work with the SONNET 3 audio processor.

4.3 Clinical Benefit

The SONNET 3 audio processor is a non-implantable medical device used with MED-EL hearing implants. Its intended clinical benefit thus corresponds to the intended clinical benefit of the hearing implants and must be seen in this context. The MED-EL hearing implant system intends to evoke auditory sensations in individuals with one of the following:

- severe to profound hearing loss,
- severe to profound hearing impairment in one ear and normal hearing or mild to moderate hearing impairment in the other ear,
- partial deafness, and who obtain benefit from acoustic amplification in the lower frequencies only,
- non-functional cochlear nerves,

all via electrical stimulation or via combined electric-acoustic stimulation (EAS) in the case of partially deaf individuals.

Specifically, the clinical benefit of the SONNET 3 audio processor as an external device of the MED-EL cochlear implant system is to (re)establish the patient's capability for the perception of environmental sound and to provide a potential for improvement of communicational abilities.

4.4 Summary of Safety and Clinical Performance

The Summary of Safety and Clinical Performance (SSCP) is available following this link: https://ec.europa.eu/tools/eudamed

5. Basics and Handling

5.1 First Steps

Read this section thoroughly to familiarize yourself with the function of the audio processor and its components. Contact your audiologist/healthcare professional or local MED-EL representative with any questions you may have.

The audio processor is shipped without batteries inserted. See section Changing the Batteries for instructions on how to insert the batteries.

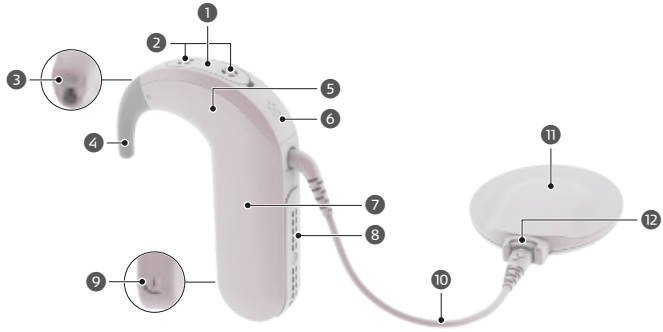
Before you can use the audio processor, your audiologist/healthcare professional must program it to your needs.

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

After initial fitting, you or the user will need to return to the clinic or healthcare 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 when becoming more and more accustomed to stimulation through the implant. As more time passes, you will likely find that you or the user may require fewer and fewer sessions. Most users continue to require occasional adjustments for as long as they use their MED-EL CI system.

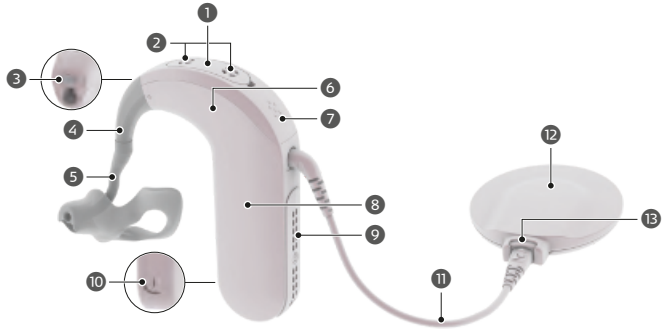
5.2 SONNET 3 Audio Processor Overview

SONNET 3 for CI Audio Processor



1 Microphone cover
2 Microphone openings
3 Indicator light
4 CI earhook
5 Control unit
6 Touch key
7 Battery pack
8 Air inlets
9 Battery pack cover lock
10 Coil cable
11 Coil
12 Coil indicator light

SONNET 3 EAS Audio Processor



1 Microphone cover
2 Microphone openings
3 Indicator light
4 EAS earhook
5 Earmold[4]
6 Control unit
7 Touch key
8 Battery pack
9 Air inlets
10 Battery pack cover lock
11 Coil cable
12 Coil
13 Coil indicator light

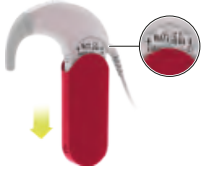
4 Not supplied by MED-EL

5.3 Switching the Audio Processor ON/OFF

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

NOTE: Before you pull back the battery pack cover, always make sure that the battery pack cover lock is in the unlocked position. When it is not in the unlocked position, use the screwdriver provided with the SONNET 3 kit to turn it counterclockwise ↺ into the unlocked position ⓘ (see section Audio Processor Components, Battery Pack for details on the battery pack cover lock).

To switch off the audio processor, proceed as follows:



1. Make sure that the battery pack cover lock is in the unlocked position ⓘ.
2. Pull the battery pack cover back so that you can see the whole labeling on the control unit. You do not have to completely remove the battery pack cover to switch off the audio processor.

In the OFF position, the audio processor is turned off and draws no power. Always pull back the battery pack cover when you do not use the audio processor to extend battery life.

WARNING
When the processor is not worn behind the ear and turned off with the battery pack cover pulled back, make sure that children or persons under care do not have access to the audio processor to prevent disassembling of the audio processor.

To switch on the audio processor, proceed as follows:

1. Make sure that the battery pack cover lock is in the unlocked position ⓘ.
2. Slide the battery pack cover completely over the battery pack frame.
3. The audio processor begins working as soon as the green indicator light comes on and blinks up to four times (if for example the green light blinks three times, then program 3 is currently active).

WARNING
When the user is a child or person under care, always turn the battery pack cover lock clockwise ↻ into the locked position ⊖ once the cover has been moved completely over the frame to prevent disassembling of the audio processor.

Switching the audio processor on or off can cause a soft sound. Remove the coil from the head before switching the audio processor on or off if this bothers you.

To activate the MED-EL CI system, proceed as follows:

1. Switch on the audio processor.
2. Place the audio processor behind the ear and the coil with the flat side to the head over the implant. The coil is automatically positioned correctly by attraction to the implant magnet.

PARENTAL GUIDANCE

An earmold can help keep the processor in position on the ear. Contact your audiologist/healthcare professional or clinic for assistance.

The audio processor has an extended implant check function that your audiologist/healthcare professional can enable. When this function is enabled, every few days the red indicator light in the earhook flashes approximately every second immediately after switching on the audio processor. The audio processor is now ready to perform an extended implant check. Place the audio processor behind the ear and the coil with the flat side to the head over the implant as usual. The extended implant check takes only a few seconds. During the check you might hear only clicks or beeps, after the check the audio processor works again normally.

5.4 Changing the Batteries

WARNING

- Misuse of batteries may result in the batteries causing heat, smoke, rupture, flame, or leakage which could lead to injury.
- Swallowing batteries could cause suffocation, poisoning or internal injuries. If a battery has been swallowed or placed inside any part of the body, seek medical attention immediately.
- Instruct children or persons under care not to swallow or put any components of the device into their mouths or to play with any components. Swallowing of components could cause suffocation or internal injury. When the user is a child or person under care, always turn the battery pack cover lock clockwise ↻ into the locked position ⊖ once the cover has been moved completely over the frame to prevent disassembling of the audio processor.

CAUTION

- Always handle batteries with care to avoid injury. Read section Warnings and Precautions, Battery Information before changing the batteries.
- It is recommended to only use high power zinc-air batteries to power the audio processor.
- Do not allow children or persons under care to replace batteries without supervision.

- To prevent children or persons under care from swallowing or choking on batteries, always keep new and used batteries out of the reach of children or persons under care.

The audio processor requires two 675 zinc-air hearing aid batteries to supply the external and internal parts of the MED-EL CI system with energy.

When the indicator light on the control unit blinks red continuously (▬–▬···), replace the battery set (see also section Indicator Lights).

To change the batteries, proceed as follows:

1. Remove the audio processor and the coil from the head.
2. Make sure that the battery pack cover lock is in 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. Move the center of the coil base over each battery separately. Try not to touch the battery contacts.

CAUTION
Do not place the coil on the control unit.

5. Before inserting the new battery set, make sure that the battery contacts are clean and dry (see section Care and Maintenance for cleaning instructions).
6. Remove the foil stickers covering the zinc-air batteries.
7. Insert the batteries with the positive pole facing outward, i.e., the **+** sign on each battery is still visible after the batteries have been inserted.

8. Make sure that the battery pack cover lock is in the unlocked position ⓘ.
9. Slide the battery pack cover completely over the battery pack frame to switch on the audio processor. 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. Do not cover the air inlets as this may shorten battery life.

WARNING
When the user is a child or person under care, always turn the battery pack cover lock clockwise ↻ into the locked position ⊖ once the cover has been moved completely over the frame to prevent disassembling of the audio processor.

5.5 Audio Processor Components

5.5.1 Control Unit

The control unit (product code Me171x or Me172x) houses the main electronics of the audio processor. The control unit also features the microphone openings, an indicator light (for a detailed description see section Indicator Lights), and a touch key.

Your audiologist/healthcare professional can deactivate the touch key or assign one of several controls to the touch key, e.g., the standby mode control (see section Standby Mode). To avoid accidental operation of the touch key when switching on and handling the audio processor, the touch key is always deactivated for approximately 10–15 seconds after switching on the audio processor.

To use the touch key, proceed as follows:

1. Put your finger on the touch key.
2. Leave your finger on the touch key for approximately 1 second.
3. Remove your finger from the touch key. The control assigned to the touch key is now triggered.

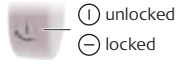
5.5.2 Battery Pack

The SONNET battery pack (product code Ma060106) consists of the battery pack frame and the battery pack cover.

The battery pack frame holds two 675 zinc-air hearing aid batteries.

The battery pack cover slides over the battery pack frame.

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



The battery pack cover has a lock. Before you pull back or reattach the battery pack cover, always make sure that the battery pack cover lock is in the unlocked position. When it is not in the unlocked position, use the screwdriver provided with the SONNET 3 kit to turn it counterclockwise ↺ into the unlocked position ⓘ.

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

1. Make sure that the battery pack cover lock is in the unlocked position ⓘ.
2. Pull back and completely remove the battery pack cover.
3. Press the release lever on the battery pack frame and separate battery pack frame and 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.
2. Push the opposite end of the battery pack frame onto the control unit until the release lever engages.
3. Make sure that the battery pack cover lock is in the unlocked position ⓘ.

4. Slide the battery pack cover completely over the battery pack frame to switch on the audio processor. 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.

WARNING
When the user is a child or person under care, always turn the battery pack cover lock clockwise ↻ into the locked position ⊖ once the cover has been moved completely over the frame to prevent disassembling of the audio processor.

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

5.5.3 Earhook

Depending on the variant of the audio processor, it is shipped with a different type of earhook.

- The earhook for the SONNET 3 for CI keeps the audio processor behind the ear.
- The earhook for the SONNET 3 EAS additionally contains a sound tube and a specially shaped tip so that the audiologist/healthcare professional can attach an acoustically

functional earmold. The earmold conducts sound from the audio processor into the ear and is necessary when using combined electric-acoustic stimulation.

Earhook for
SONNET 3 for CI

Earhook for
SONNET 3 EAS

CAUTION

- The audiologist/healthcare professional or hearing aid acoustician must customize the earmold according to standard hearing aid practice. The earmold must fulfil local hearing aid requirements, especially regarding 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. The audiologist/healthcare professional or hearing aid acoustician shall make sure that the earmold optimally fits the anatomical shape of the ear canal and the earhook of the audio processor.
- The audiologist/healthcare professional or hearing aid acoustician must also 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.
- If a child or person under care uses an earmold, regularly check to make sure the earmold still fits. The earmold must be adjusted regularly as necessary. A non-optimally fitting earmold may cause acoustic feedback (whistling).

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

To replace the earhook, proceed as follows:

1. Push the earhook pin through the holes using the pin removal tool supplied with the SONNET 3 kit. Do not pull out the earhook pin to avoid that it is lost.
2. To remove the earhook, gently pull it forwards to separate it from the control unit.
3. To attach the new earhook, gently slide it on from the front. Make sure that the new earhook is of the same type (i.e., CI earhook or EAS earhook) as the replaced earhook.
4. Push back the earhook pin or the earhook will not stay in place.

WARNING
Keep the supplied pin removal tool out of the reach of children or persons under care.

NOTE: Replacing the CI earhook in a SONNET 3 for CI audio processor with an EAS earhook does not convert the audio processor into the SONNET 3 EAS variant. Using a CI earhook with a SONNET 3 EAS audio processor will block any acoustic stimulation. Never use a CI earhook with a SONNET 3 EAS audio processor.

MED-EL provides each type of earhook also in a slightly longer version. If you and your audiologist/healthcare professional decide that the longer version is needed, order such an earhook from MED-EL. Two marks on the inside of the earhook help identify the longer version.

Additionally, MED-EL provides the CI earhook in a flexible version which allows further adaption to individual user needs.

5.5.4 Microphone Cover

The microphone cover has integrated membranes to protect the two microphones in the audio processor from moisture and dust. You should replace the microphone cover every three months, when the microphone openings appear dirty, when the microphone cover is damaged, or when you experience degraded sound quality.

Dry or replace the microphone cover when the microphone openings have become wet. Wet openings could degrade sound quality.

To replace the microphone cover, proceed as follows:

1. Insert the microphone cover removal tool into the groove at the microphone cover.
2. Gently lever the cover away from the control unit.
3. Place the new cover over the control unit. The cover is symmetrical, so the orientation does not matter.
4. Press down the cover until it has snapped into place. Ensure that the cover is completely level with the surface of the control unit housing. If this is not the case, remove the cover and try attaching it again.

NOTE: Always use the microphone cover removal tool provided by MED-EL. Do not use sharp objects (e.g., screwdrivers, nails, needles) to avoid damaging the microphones.

5.6 DL-Coil

The DL-Coil (referred to as coil in this document, product code Ma020301) connects the audio processor with the implant. It sends both energy and the coded audio signal through the intact skin to the implant.

CAUTION

- The coil contains a strong magnet. Keep clear of metallic items as they attract the magnet. Do not place the 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 3 EAS. The SONNET 3 EAS contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.

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

1. Cover
2. Magnet
3. Base
4. Cable

5.6.1 Coil Base

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

5.6.2 Coil Cover

Five variants are available:

- L (Low) for magnets number 1, 2 and 3 with cable lock.
- L (Low) for magnets number 1, 2 and 3 without cable lock.
- H (High) for magnets number 4 and 5 with cable lock.
- H (High) for magnets number 4 and 5 without cable lock.
- U (Ultra) for magnet number 6 without cable lock.

Each coil cover variant is available in several colors allowing to personalize the coil.

With the coil cover with cable lock attached the coil cable can only be connected and removed after removing the coil cover. The cable lock prevents inadvertent disconnection of the coil cable from the coil.

WARNING
When the user is a child or person under care, always use the coil cover with cable lock to prevent disconnecting of the coil cable.

NOTE: Irrespective of the type of coil cover, you should always remove the coil cover before connecting or disconnecting the coil cable. 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 the fingernail or the provided screwdriver in the small recess on the opposite side of the coil.
2. Slide the fingernail or the screwdriver from front to side until the cover comes off. A click indicates that the cover has been correctly opened.
3. Remove the cover sideways.

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

To attach the coil cover, proceed as follows:

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

NOTE: Make sure to lock the magnet in place by turning it towards the + symbol or the − symbol to avoid breaking the coil cover. Do not leave the magnet in the center position. Strength 5 and 6 magnets must be turned towards the + symbol, otherwise the cover cannot be attached properly.

5.6.3 Magnet

A small magnet in the center of the coil holds the coil in place on the head over the implant.

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

- For recipients implanted with a SYNCHRONY implant, the magnet is represented by triangles. The magnet holder is available in black.

- For recipients implanted with any other type of implant (MED-EL CONCERT, SONATA, etc.), the magnet is represented by circles. The magnet holder is available in cool gray.

- It is essential that, based on the type of implant, the correct variant of magnet is used. The wrong magnet may still hold the coil 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 magnet strength chosen should be appropriate for the individual user. Strong magnets are not recommended for users with thin skin flaps, for example young children, as excessive magnetic attraction could potentially increase the likelihood of skin irritation or cause a sensation of heat under the coil.
- If you notice any signs of skin irritation around the coil, contact your audiologist/healthcare professional.
- It is easiest to observe children or persons under care when playing or in everyday situations to determine whether the coil is properly attracted to the implant. If the coil falls off too easily, the user 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 increases, and the magnetic attraction force may have to be adjusted by increasing the magnetic strength.
- MED-EL strongly recommends that you do not change the magnet yourself, but have your audiologist/healthcare professional do it.
- The magnet design used in SYNCHRONY implants may cause misalignment of the external and internal magnets when placing the coil on the head. This misalignment may result in hearing interruptions or the coil falling off. To avoid misalignment, gently rotate the coil between a quarter and half a turn back and forth to allow the coil to position itself correctly over the implant. You will notice correct alignment by uninterrupted hearing and stronger magnetic attraction.

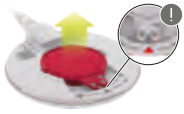
Off-center

Aligned

The magnet is available in six strengths and can be changed to adjust the magnet strength to individual needs. Magnet strength is indicated by the number of filled triangles or circles on the magnet (1=weakest, 6=strongest).

The holding force of the magnets (except magnets for number 5 and 6) can be further adjusted by engaging the magnet either in the + or − position.

To change the magnet, proceed as follows:



1. Remove the coil cover.
2. Turn the magnet to the center position and lift it off (it will fall out when you turn the coil upside down).
3. To insert a new magnet, center it in the base with the circles/ triangles facing upwards. It should glide into the recess easily.

4. After inserting the magnet, lock it in place by moving the lip to the + symbol or the − symbol indicated on the base part of the coil until it engages. Use a ballpoint pen to move the magnet in either direction. Moving the lip to the + symbol, slightly increases magnetic force. Moving the lip to the − symbol, slightly decreases magnetic force.
5. Attach the coil cover starting at the side of the socket.

NOTE: Make sure to lock the magnet in place by turning it towards the + symbol or the − symbol to avoid breaking the coil cover. Do not leave the magnet in the center position. Strength 5 and 6 magnets must be turned towards the + symbol, otherwise the cover cannot be attached properly.

5.6.4 Coil Cable

The coil cable connects the coil and the control unit of the audio processor. Disconnect the coil cable for maintenance purposes or if you want to replace the cable. You need not disconnect the cable when changing the batteries.

Although the coil cable is designed for maximum durability and flexibility, this part of the MED-EL CI system is the most likely to wear out.

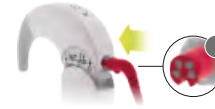
If the coil cable fails, order a new one immediately.

NOTE: Do not use the cable with devices other than a SONNET series audio processor.

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 ⓘ.
2. Pull back the battery pack cover until you can see the whole labeling of the control unit.
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. 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 ⓘ.



6. Slide the battery pack cover completely over the battery pack frame to switch on the audio processor. 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.

WARNING
When the user is a child or person under care, always turn the battery pack cover lock clockwise ↻ into the locked position ⊖ once the cover has been moved completely over the frame to prevent disassembling of the audio processor.

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

1. Remove the coil cover.
2. Grab the plug of the cable on the coil side and gently pull the plug out of its socket in the coil.

3. Plug the new coil cable into the socket in the coil. Mind the correct orientation of the plug.
4. Attach the coil cover starting at the side of the socket.

WARNING
When the user is a child or person under care, always use the coil cover with cable lock to prevent disconnecting of the coil cable.

5.6.5 Special Features of the DL-Coil

Link Indicator Light

The multicolor indicator light in the cable socket of the coil flashes with different patterns and colors to indicate different conditions. For a detailed description see section Indicator Lights.

Link Monitoring

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 to the user as 3 short beeps.

The link monitoring feature is especially useful for users who are not able to give feedback about the correct function of their MED-EL CI system (see section Indicator Lights for more details).

The link monitoring feature also regularly checks if the audio processor is sending information to the implant and if the implant receives enough energy.

Your audiologist/healthcare professional can activate or deactivate the link monitoring feature.

5.7 Standby Mode

You can put the audio processor temporarily into standby mode. In standby mode the power consumption is reduced to a minimum and you cannot hear with the audio processor. Depending on the configuration of the audio processor set by your audiologist/healthcare professional, there are several options to put the audio processor into standby mode and to switch it back on:

To put the audio processor into standby mode, use one of the following options:

- Use the touch key (see section Audio Processor Components, Control Unit).
- Remove the audio processor from the ear and the coil from the head. After approximately 5 minutes the audio processor goes into standby mode automatically.
- Use the MED-EL AudioKey mobile app[5].

To switch the audio processor back on when it is in standby mode, use one of the following options:

- Use the touch key (see section Audio Processor Components, Control Unit).
- Place the audio processor behind the ear and the coil with the flat side to the head over the implant. After approximately 5 to 10 seconds the audio processor switches on automatically.

- Switch off the audio processor (see section Switching the Audio Processor ON/OFF), wait at least 2 seconds, then switch on the audio processor.
- Use the MED-EL AudioKey mobile app[5].

NOTE: Although putting the audio processor into standby mode is similar to switching the audio processor off, MED-EL does not recommend leaving the audio processor in standby mode for a longer period of time (e.g., overnight). In standby mode the audio processor still draws a certain amount of power. The standby mode shortens the battery life.

NOTE: The automatic options are not available for previous generation implants (e.g., C40 or C40+).

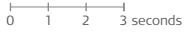
5.8 Indicator Lights

5.8.1 Audio Processor

The multicolor indicator light in the earhook of the audio processor flashes with different patterns and colors to indicate different conditions. When the indicator light begins flashing, use the following tables to determine the cause. Your audiologist/healthcare professional can deactivate the blinking signals (except error patterns and the flight mode confirmation pattern) if you prefer this.

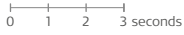
Confirmation Pattern (Green)

Blinking pattern	Meaning	Required action	Comments
	Remote control command received and accepted	None	None
	Audio processor put into standby mode	None	The indicator light fades out when the audio processor is put into standby mode.
	Direct wireless link to the audio processor of the other ear successfully activated	None	This blinking pattern is relevant for bilateral users only.



Program Change Pattern (Green)

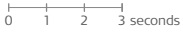
Blinking pattern	Meaning	Required action	Comments
	Program 1–4 selected	None	The indicator light blinks depending on the selected program.



5 Depending on the AudioKey app version used, this feature may not be available in the app.

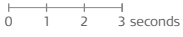
Status Pattern (Green)

Blinking pattern	Meaning	Required action	Comments
	Audio processor initialized, working, and connected to implant (connection to implant not checked in previous generation implants, e.g., C40+, C40)	None	None



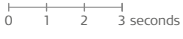
Error Patterns (Red)

Blinking pattern	Meaning	Required action	Comments
	• Electronic problem • Temporary processor disturbance	1. Switch audio processor off. 2. Switch audio processor back on.	If the blinking persists, the audio processor must be replaced.
	• Selected program not programmed • Programming failure	Select another program.	If the blinking persists, have the processor reprogrammed by your audiologist/ healthcare professional.
	• Electronic problem • Temporary processor disturbance	1. Switch audio processor off. 2. Switch audio processor back on.	If the blinking persists, have the processor reprogrammed by your audiologist/ healthcare professional. If the blinking persists after reprogramming, the audio processor must be replaced.
	• Electronic problem • Programming failure	1. Switch audio processor off. 2. Switch audio processor back on.	If the blinking persists, have the processor reprogrammed by your audiologist/ healthcare professional.
	• Electronic problem • Temporary processor disturbance	1. Switch audio processor off. 2. Switch audio processor back on.	None

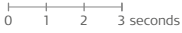


Warning Patterns (Red)

Blinking pattern	Meaning	Required action	Comments
	Batteries empty	1. Switch audio processor off. 2. Change the batteries. 3. Switch audio processor back on.	If the audio processor is not switched off, the indicator light continues to blink.
	Maximum or minimum value of volume or audio sensitivity range reached	Stop pushing buttons on the remote control.	None

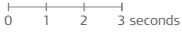


Blinking pattern	Meaning	Required action	Comments
	The audio processor is ready to perform an extended implant check	Position the coil over the implant site.	The extended implant check takes only a few seconds. During the check you might hear only clicks or beeps, after the check the audio processor works again normally.



Flight Mode Confirmation Pattern (Red)

Blinking pattern	Meaning	Required action	Comments
	Flight mode successfully activated	None	None

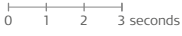


5.8.2 Coil

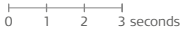
The multicolor indicator light in the cable socket of the coil flashes with different patterns and colors to indicate different conditions. When the indicator light begins flashing, use the following tables to determine the cause. Your audiologist/healthcare professional can activate or deactivate the indicator light of the coil.

Green

Blinking pattern	Meaning	Required action	Comments
	After switching on an audio processor programmed for a previous generation implant (e.g., C40+, C40) and placing the coil over the implant: 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 switching on an audio processor programmed for a new generation implant and placing the coil over the implant: Correct implant detected. Indicates functionality of coil, coil cable, audio processor and implant.	None	Applicable to PULSAR, SONATA, CONCERTO, SYNCHRONY, and later generation implants



Red

Blinking pattern	Meaning	Required action	Comments
for max. 5 min.	Coil and implant disconnected	Position the coil over the implant site.	If the blinking persists, contact your audiologist/ healthcare professional or local MED-EL representative.
	Coil positioned over the wrong implant (for bilateral users)	Position the coil over the correct implant.	
	Broken coil cable	Replace the coil cable.	
	Audio processor switched off due to empty batteries (if battery charge is still sufficient to power the coil)	Change the batteries of the audio processor.	
	Audio processor in microphone monitoring mode	1. Switch audio processor off. 2. Switch audio processor back on.	
 10 seconds	Coil powered off	1. Switch audio processor off. 2. Switch audio processor back on. 3. Reposition the coil over the implant site.	If the blinking persists, contact your audiologist/ healthcare professional or local MED-EL representative.
 0 1 2 3 seconds			

No Blinking or Arbitrary Red and Green Blinking Pattern

Blinking pattern	Meaning	Required action	Comments
No light signal when switching processor on	Audio processor not functional (e.g., batteries empty, coil cable defective, coil defective)	1. Check battery status. 2. Try spare coil cable. 3. Contact the audiologist/ healthcare professional if you suspect a coil malfunction.	If the situation persists, contact your audiologist/ healthcare professional or local MED-EL representative.
	Indicator light deactivated by audiologist/healthcare professional	None	Can be activated by your audiologist/healthcare professional.
	Fitting: Indicator light temporarily deactivated during fitting	To reactivate the indicator light after fitting: 1. Switch audio processor off. 2. Switch audio processor back on.	None
Arbitrary red and green pattern	Defective coil cable	Try spare coil cable.	If the blinking persists, contact your audiologist/ healthcare professional or local MED-EL representative.

5.9 Connectivity

5.9.1 Direct Audio Input (Cable Connection)

Use the provided SONNET FM Battery Pack Cover (product code Ma070103) to connect assistive listening devices such as FM systems, or other external audio devices (portable CD players, MP3 players, AM-FM radios, etc.) to the audio processor via an adapter cable. The FM Battery Pack Cover is slightly longer than the standard battery pack cover to accommodate the integrated EA (Euro Audio) socket.

To replace the standard battery pack 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 ⓘ.
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 ⓘ.
4. Slide the FM Battery Pack Cover completely over the battery pack frame to switch on the audio processor. 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.

WARNING
When the user is a child or person under care, always turn the battery pack cover lock clockwise ↻ into the locked position ⊖ once the cover has been moved completely over the frame to prevent disassembling of the audio processor.

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

NOTE: The FM Battery Pack Cover cannot be used with the SONNET rechargeable battery max or the SONNET rechargeable battery micro.

Use an adapter cable to connect an external audio device to the audio processor:

1. Insert the three-pin plug of the provided adapter cable (gray 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.
2. Insert the yellow plug of the cable into the audio output (headphone socket) of the audio device.

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

CAUTION

Do not use cables longer than 1m (3.28ft.). These cables may lead to increased electromagnetic emissions or decreased electromagnetic immunity of the audio processor system.

NOTE:

- Use the provided adapter cable to connect 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.
- Adapter cables from MED-EL are available for unilateral and bilateral implant use. For more information, contact your local MED-EL representative.

The direct audio input can be operated in two mixing modes, the Mix mode and the Ext mode:

Mix mode:
The audio processor microphone remains active when connected to an external audio device. You hear input from the external audio device and the audio processor. Use this mode when you want to continue hearing the external audio device and the sounds around you (for example, both music and someone talking to you).

Ext mode:
The audio processor microphone is deactivated when connected to an external audio device. You hear input from the external audio device only.

Your audiologist/healthcare professional can set the desired default mixing mode in each program.

5.9.2 General Wireless Functionality

The audio processor is equipped with 2.4GHz *Bluetooth*® [6] wireless technology. This technology allows the audio processor to be wirelessly connected to various external products like the MED-EL FineTuner Echo (remote control), the MED-EL AudioLink XT (audio streaming device), or a commercial electronic device (smartphone, tablet, etc.) with Bluetooth functionality[7] that can run the MED-EL AudioKey mobile app[8].

6 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. Other trademarks and trade names are those of their respective owners.
7 Such an electronic device must at least be compatible with the Bluetooth 4.2 specification (Bluetooth Low Energy).
8 The MED-EL AudioKey mobile app version must support the SONNET 3.

For detailed information, functional descriptions, operating instructions and troubleshooting information about the MED-EL FineTuner Echo, MED-EL AudioLink XT, and the MED-EL AudioKey mobile app, 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 2.4 GHz 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 (e.g., drop-outs or audible noise), move away from this electronic and electrical equipment.
- Do not pair the audio processor with other than your own wireless devices as this could lead to undesired hearing sensations.

NOTE: The SONNET 3 includes various security risk control measures such as encrypted communications, readback protection, authentication, encryption of personal information etc., which reduce security risks to a broadly acceptable level. You as a user can also contribute to the security of the SONNET 3 by following a few simple rules:

- Always follow the instructions in this user manual.
- Never allow anyone to tamper with your SONNET 3.
- Always keep the software of your Bluetooth/mobile device (smartphone, tablet, etc.) up to date.
- Do not use a rooted Bluetooth/mobile device.
- Do not use a Bluetooth/mobile device that has had its operating system altered.
- When pairing a Bluetooth/mobile device with your SONNET 3, always keep a distance of at least 10 feet to other people.
- Do not use any app in combination with the SONNET 3 that does not come from MED-EL.

5.9.3 Audio Streaming

The audio processor can wirelessly connect to certain mobile devices[9] (smartphone, tablet, etc.) or the MED-EL AudioLink XT to stream audio like a phone call, music, or a TV broadcast directly to the audio processor and on to the implant. For mobile devices follow the general instructions given below, for the MED-EL AudioLink XT refer to the AudioLink XT user manual.

9 Such a mobile device must support either the Android™ ASHA or the Apple® MFi LEA audio streaming protocol (Android is a trademark of Google LLC; Apple is a trademark of Apple Inc., registered in the U.S. and other countries and regions).

Pairing

To stream audio, you must first pair your mobile device with the audio processor.

To pair the audio processor and a mobile device, proceed as follows:

1. Switch off the audio processor you want to pair (see section Switching the Audio Processor ON/OFF) and wait at least 2 seconds. If you are a bilateral user and you want to pair both audio processors, switch off both audio processors[10].
2. Place the audio processor(s) close to the mobile device (closer than 3 cm).
3. Switch on the audio processor(s) (after switching on, an audio processor will be in pairing mode for 3 minutes).
4. Switch on the Bluetooth functionality on your mobile device and scan for other Bluetooth devices.

   NOTE: Refer to the user manual of the mobile device for instructions on pairing with hearing aids and hearing devices.
5. After a few seconds the mobile device should find and list one or two new Bluetooth devices with the general name "SONNET 3", or with a personalized name like "John's Hearing Device". Select the device or devices to start the pairing.

The pairing needs to be performed only once for each audio processor.

If you receive a replacement audio processor, perform the pairing for this replacement audio processor.

If you are a bilateral user and receive one or more replacement audio processors, always delete both audio processors you have used so far for audio streaming from the list of paired Bluetooth devices in the mobile device before you start pairing with the replacement audio processors.

Making Phone Calls

To use the audio processor for phone calls, proceed as follows:

1. Make sure that the audio processor is switched on.
2. Make sure that the audio processor is paired with the mobile device, that the mobile device's Bluetooth functionality is switched on, and that a Bluetooth connection between the mobile device and the audio processor is established.

10 Both audio processors must support the same audio streaming protocol and must be correctly configured as a pair of audio processors by, e.g., your audiologist/healthcare professional.

3. To start a phone call, proceed as you usually would on the mobile device by speaking into the mobile device. You automatically hear the conversation streamed to the audio processor and on to the implant.
4. To receive a phone call, simply pick it up on the mobile device and enjoy the conversation.
5. Adjust the loudness of the streamed audio as needed with the volume control buttons of the mobile device.

Streaming Audio

To stream music or other audio signals (e.g., an audio book) from a mobile device, proceed as follows:

1. Make sure that the audio processor is switched on.
2. Make sure that the audio processor is paired with the mobile device, that the mobile device's Bluetooth functionality is switched on, and that a Bluetooth connection between the mobile device and the audio processor is established.
3. Switch on the audio source (e.g., start the music player on the mobile device). You automatically hear the audio streamed to the audio processor and on to the implant.
4. Adjust the loudness of the streamed audio as needed with the volume control buttons of the mobile device.

5.9.4 Flight Mode

When boarding a flight or entering an environment where radio frequency (RF) transmissions are prohibited, you must activate the audio processor's flight mode to deactivate the 2.4 GHz wireless functionality. Wireless operations are typically not allowed on airplanes or in certain restricted environments.

NOTE: Activate the flight mode even if you do not intend to use any wireless devices at all.

To activate the flight mode, proceed as follows:

1. Switch off the audio processor (see section Switching the Audio Processor ON/OFF) and wait at least 2 seconds.
2. Switch on the audio processor and wait approximately 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 approximately 6 seconds the indicator light briefly blinks red to confirm that the flight mode has successfully been activated. If you do not see the red light, repeat steps 1 to 5.

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 2.4 GHz wireless functionality as usual.

5.10 Care and Maintenance

5.10.1 General

CAUTION

- The audio processor and coil are designed for durability and reliability but should be handled with care. Improper handling could lead to device damage or injury.
- When using an earmold, and you must remove cerumen (ear wax) from the earmold, do so only according to the advice of the audiologist/healthcare professional or hearing aid acoustician. If necessary, the audiologist/healthcare professional or hearing aid acoustician will clean the earmold.

Although the coil cable is designed for maximum durability and flexibility, it is the most likely component to wear out.

The battery pack and especially its cover may wear out due to frequent opening and closing and must be replaced more frequently.

If the audio processor or coil does not work properly, check section Troubleshooting. If you cannot solve the problem following the recommended actions, contact your audiologist/healthcare professional or local MED-EL representative for advice.

- Do not open any part of the audio processor as this may damage the device.
- Do not try to repair the electronic parts of the audio processor as this may damage the device.
- It is recommended to replace the microphone cover every three months, when the microphone openings appear dirty, when the microphone cover is damaged, or when you experience degraded sound quality (see also section Microphone Cover).
- The battery pack cover has air inlets on its outer side. Do not cover these inlets as this may shorten battery life. If the air inlets are dirty, carefully clean them with

the enclosed cleaning brush. If the dirt cannot be removed with the cleaning brush, replace the entire battery pack cover with a new one.

- 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 the audio processor from water (see also section Warnings and Precautions).
- Do not touch the battery contacts. To clean the contacts, use a cotton swab and a small amount of cleaning alcohol. Gently wipe dry after cleaning.
- Thoroughly wipe the external parts of the audio processor with a tissue at least once a week and let them dry completely.
- If you do not use the audio processor for an extended period of time, remove the batteries and dispose of or store the batteries separately.

5.10.2 Drying the Audio Processor

The SONNET 3 kit includes a drying kit (electrical drying kit or drying box with drying capsules). For detailed information, read the respective drying kit user manual.

The audio processor need not be completely disassembled for drying but the battery pack cover should be removed from the audio processor.

NOTE: Do not put any type of battery into the drying kit.

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

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

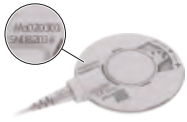
5.10.3 Component Identification

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 (Me171x or Me172x) of the control unit are indicated on the same side in the lower part of the control unit. Pull down the battery pack cover to reveal the information (see section Audio Processor Components, Battery Pack for instructions).

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 section Changing the Batteries for instructions).

The serial number and product code (Ma020301) of the DL-Coil are indicated on the base part of the coil. Remove the coil cover to reveal the information (see section DL-Coil, Coil Cover for instructions).



6. Troubleshooting

For assistance and reporting of issues associated with this MED-EL product or to report unexpected operation or events, contact your audiologist/healthcare professional or local MED-EL representative.

If troubleshooting does not eliminate the problem and you do not hear sound with the MED-EL CI system, contact your audiologist/healthcare professional immediately.

Problem	Possible cause	Recommended action
Audio processor cannot be switched on	Batteries empty	Change the batteries.
No sound	Batteries empty	Change the batteries.
	Microphone openings blocked	• Remove obstructing garments or hair. • Replace the microphone cover.
	Coil cable defective	Replace the coil cable.
	Device damaged (e.g., by moisture, shock)	Contact your audiologist/healthcare professional or local MED-EL representative.
Sound weak	Volume turned too low	Adjust the volume with the remote control.
	Microphone openings blocked	• Remove obstructing garments or hair. • Replace the microphone cover.
	Incorrect position of coil	Adjust the orientation of the coil. This is particularly important for users with a SYNCHRONY implant.
Sound too loud	Volume turned too high	Adjust the volume with the remote control.
	Internal signal processor defective	If you cannot turn down the volume with the remote control, stop using the audio processor and contact your audiologist/healthcare professional or local MED-EL representative.
Coil falls off frequently	Magnet too weak	Contact your audiologist/healthcare professional for a stronger magnet.
Skin irritation over implant	Allergic reaction	Stop wearing the audio processor and coil and contact your audiologist/healthcare professional. See section Technical Data for materials of the MED-EL CI system.
	Magnetic attraction too high	Contact your audiologist/healthcare professional.

Problem	Possible cause	Recommended action
Program selection not possible	Only one program activated	Contact your audiologist/healthcare professional.
	Remote control does not work	If program selection is not possible, refer to the solutions provided in the user manual of the FineTuner Echo.
	Electrical problems	If all other options listed in this table fail, contact your audiologist/ healthcare professional or local MED-EL representative.
Pairing process with mobile device failed	Disruptions in pairing process	• Switch on the Bluetooth functionality on the mobile device. • Switch off the audio processor, wait at least 2 seconds, then switch on the audio processor to put it into pairing mode. • The mobile device must be compatible with the audio processor. • Closely follow the instructions on pairing with hearing aids and hearing devices in the user manual of the mobile device. • Make sure the audio processor is not connected to other mobile devices when you want to pair it with a new mobile device. • Move the audio processor closer to the mobile device you intend to pair it with.
Audio streaming does not start	The audio processor is not yet paired with mobile device	Pair your mobile device with the audio processor.
No sound heard during audio streaming	The audio processor is too far away from the mobile device	• Make sure that the audio processor is switched on. • Move the mobile device closer to the audio processor.
Distortions heard during audio streaming (interruptions, noise)	The audio processor is too far away from the mobile device or interference from other devices	• Move the mobile device closer to the audio processor. • If possible, remove interfering devices (especially in the 2.4 GHz band, e.g., a Wi-Fi router or computer). • If possible, change location of Wi-Fi router and/or PC. • If possible, use the 5 GHz band of the Wi-Fi system. • In case of a phone call, do not place the mobile device too close to the audio processor.
No sound heard or sound too low during audio streaming	Volume too low	• Increase volume on mobile device. • If volume remains too low, increase volume on audio processor.

Problem	Possible cause	Recommended action
Sound too loud or cracking during audio streaming	Volume too high	• Decrease volume on mobile device. • If volume remains too high, decrease volume on audio processor.

6.1 Visual Indicators

6.1.1 Audio Processor Indicator Light

The multicolor indicator light in the earhook of the audio processor flashes with different patterns and colors to indicate different conditions. For a detailed description see section Basics and Handling, Indicator Lights.

6.1.2 Coil Indicator Light

The multicolor indicator light in the cable socket of the coil flashes with different patterns and colors to indicate different conditions. For a detailed description see section Basics and Handling, Indicator Lights.

6.2 Acoustic Indicators (Private Alert)

The private alert feature adds an acoustic warning signal to the audio signal.

Only the user of the audio processor hears this added signal. The signal can be adjusted in 8 loudness steps. Your audiologist/healthcare professional can set the loudness or deactivate these 3 signals if you prefer this.

6.2.1 Battery Low Warning Signal

If the battery voltage falls below a certain level, four short warning beeps are 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.

6.2.2 End of Range Reached Warning Signal

If a maximum or minimum value of volume or audio sensitivity has been reached, the user of the audio processor hears a continuous beeping signal as long as the key of the remote control is pressed.

6.2.3 Confirmation Signal

If a command from the remote control has been executed successfully by the audio processor, the user of the audio processor hears a confirmation beep.

6.3 Testing the Audio Processor

You can use the FineTuner Echo to test proper function of the audio processor microphones.

To test the audio processor microphones, proceed as follows:

1. Switch on the audio processor.
2. Place the coil on the FineTuner Echo.
3. When speaking into the microphone, the green light on the FineTuner Echo should flicker in the rhythm of your voice.

If the green light does not light up or stays on constantly, try the following:

1. Adjust the volume setting. When using the appropriate loudness setting, you should see the green light flicker in the rhythm of your voice.
2. Change the batteries of the audio processor.
3. Replace the existing coil cable with a substitute cable.

If these measures are not successful, immediately contact your audiologist/healthcare professional or local MED-EL representative.

7. Interference With Other Equipment

7.1 Metal Detectors and Other Radio Frequency (RF) Transmitters

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

In the unlikely event that an audio processor program becomes corrupted, it can easily be reprogrammed by your audiologist/healthcare professional. If the audio processor has more than one program, use one of the other programs in the meantime.

The implant itself may trigger a security system alarm, so make sure that you always carry the MED-EL Implant Card with you to identify yourself as a cochlear implant user, as needed.

RFID (Radio Frequency Identification) is a technology that incorporates the use of electromagnetic or electrostatic coupling in the 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 can cause interference with your device perceived as a buzzing sound. In such cases, this interference will cease when you move away from the RFID emitter. RFID emitters are becoming more prevalent and you may come in contact with these in everyday life: in shops where they are used for inventory, around animals where they are used for animal tracking, at highway tolls where they are used for payments, etc.

7.2 Interference With TV Reception

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

7.3 Cell Phones

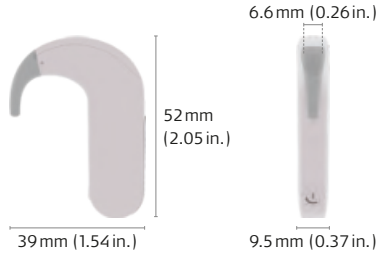
Cell phones and other portable and mobile radio frequency communications equipment may interfere (perceived as a buzzing sound) with the external parts of the MED-EL CI system if they are used within a distance of less than 3 meters (9.84 ft.).

7.4 Air Travel

During takeoff and landing, airlines request that computers, cell phones and other electronic devices be switched off to avoid interference with the airline's communication instruments. This does not apply to your audio processor. US aviation law states that medical devices such as pacemakers and hearing aid systems are exempt from this law [US Federal Aviation Regulation 91.21]. If you decide to remove or to switch off the audio processor at any time during the flight, tell the flight attendant that you are a cochlear implant user and that you may require special instructions while your audio processor is switched off. Pay special attention to section Basics and Handling, Connectivity, Flight Mode.

8. Technical Data

8.1 Audio Processor

Dimensions[11]	
Weight[11]	SONNET 3 for CI: 9.5 g (0.34 oz.) (including 2 zinc-air batteries) SONNET 3 EAS: 9.9 g (0.35 oz.) (including 2 zinc-air batteries)
Power supply	2 hearing aid batteries type 675 zinc-air (1.4 V), 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 • Audio processor self-test: checksum on programs, continuous parity check • Automatic Gain Control (AGC) configurable • Remote control commands can selectively be disabled
Additional features in the SONNET 3 EAS variant	• Acoustic stimulation up to 2000 Hz • Fully digital hearing aid signal processing • Independent compressors in up to 7 frequency bands
Audio input (cable connection)	• Via FM Battery Pack Cover • Hearing aid type three pin connection (Euro Audio) acc. to IEC 60118-12 • Sensitivity: −57.5 dBV[11] (corresponds to 70 dB SPL at 1 kHz) • Impedance: 4.7 kΩ[11]
Audio input (wireless)	• Support of Android ASHA • Support of Apple MFi LEA
Controls/Indicators	• ON/OFF switch • Indicator light: 1 multicolor LED
Materials in body contact	• Mixture of polycarbonate and acrylonitrile-butadiene-styrene polymer (PC/ABS): audio processor, all colors • Polyamide (PA): earhook • Silicone (LSR): flexible earhook

11 typical values

Temperature and humidity range	• Operating temperature range: 0 °C to +50 °C (+32 °F to +122 °F) • Storage temperature range: –29 °C to +60 °C (–20.2 °F to +140 °F) • Relative humidity range: 15 % to 90 % • Atmospheric pressure range: 700 hPa (mbar) to 1060 hPa (mbar)
Essential performance	None of the performance characteristics of the SONNET 3 (incl. all accessories) are essential performance as defined in IEC 60601-1.
Expected service life	The expected service life of the SONNET 3 (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 link (2.4 GHz wireless technology)	• Frequency band of reception/transmission: 2400 MHz to 2483.5 MHz • Short Range Device (SRD) according to ERC/REC 70-03 Annex 3 (band B) • Type of modulation: Gaussian frequency-shift keying (GFSK) • Maximum effective radiated power (ERP): <100 µW (<–10 dBm) • Channel band width: 1 MHz, 2 MHz

8.2 DL-Coil

Dimensions[12]	• Diameter: 32.8 mm (1.29 in.) • Height: 5.8 mm (0.23 in.) (with number 2 magnet and coil cover L)
Weight[12]	4.6 g (0.16 oz.) (with number 2 magnet and coil cover L)
Indicators	Indicator light: 1 multicolor LED
Materials in body contact	Mixture of polycarbonate and acrylonitrile-butadiene-styrene polymer (PC/ABS): base part and coil cover, all colors

8.3 Coil Cable

Dimensions[12]	6.5 cm (2.56 in.), 9 cm (3.54 in.), and 28 cm (11.02 in.)
Materials in body contact	PVC, TPV, TPU and TPE Evoprene, all colors

8.4 Regulatory Statements

Applicable in Canada only:

IC: 11986A-ME1700
HVIN (hardware version identification number): Me171, Me172
PMN (product marketing name): SONNET 3 (Me1710), SONNET 3 (Me1711), SONNET 3 (Me1712), SONNET 3 (Me1713), SONNET 3 EAS (Me1720), SONNET 3 EAS (Me1721), SONNET 3 EAS (Me1722), SONNET 3 EAS (Me1723)

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.

Radiofrequency radiation exposure information:
This device complies with Innovation, Science and Economic Development (ISED) Canada's RF exposure limits set forth for an uncontrolled environment and has been tested for portable use.

12 typical values

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.

Informations sur l'exposition aux radiations radiofréquences:
Cet appareil est conforme aux limites d'exposition aux radiofréquences établies par Innovation, Science et Développement économique (ISED) Canada pour un environnement non contrôlé et a été testé pour une utilisation portable.

Applicable in the USA only:

SONNET 3 (Me171x), SONNET 3 EAS (Me172x) – FCC ID: VNP-ME1700

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.

Radiofrequency radiation exposure information:
This device complies with FCC RF exposure limits set forth for an uncontrolled environment and has been tested for portable use.

8.5 Radio Frequency/Telecommunication Information

Country	Symbol/Registration Number
Canada	IC: 11986A-ME1700
USA	FCC ID: VNP-ME1700

8.6 Guidance and Manufacturer's Declaration

Tables according to IEC 60601-1-2 for SONNET 3

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

Electromagnetic emissions – for all equipment and systems

The SONNET 3 is intended for use in the home healthcare environment. The customer or the user of the SONNET 3 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SONNET 3 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.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class B	The SONNET 3 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 3 is intended for use in the home healthcare environment. The customer or the user of the SONNET 3 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 ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0 % U_T for 0.5 cycle (1 phase) 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)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
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 3 is intended for use in the home healthcare environment. The customer or the user of the SONNET 3 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the SONNET 3, including cables specified by MED-EL. Otherwise, degradation of the performance of the SONNET 3 could result.
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz	10 V/m 3 V/m, 2.7 GHz to 6 GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m, 380 MHz to 390 MHz 28 V/m, 430 MHz to 470 MHz 9 V/m, 704 MHz to 787 MHz 28 V/m, 800 MHz to 960 MHz 28 V/m, 1700 MHz to 1990 MHz 28 V/m, 2400 MHz to 2570 MHz 9 V/m, 5100 MHz to 5800 MHz	27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 28 V/m 9 V/m	
Proximity magnetic fields IEC 61000-4-39	8 A/m, 30 kHz 65 A/m, 134.2 kHz 7.5 A/m, 13.56 MHz	8 A/m 65 A/m 7.5 A/m	

9. Miscellaneous

9.1 Warranty Statement

Refer to the accompanying Warranty Statement for information about MED-EL's warranty provisions.

9.2 Storage

Store the audio processor and coil in a dry place and protect them from direct sunlight. Always remove the batteries if you do not use the audio processor for a long period of time (i.e., more than a few days) to avoid battery leakage and possible damage to the audio processor.

9.3 Disposal

We advise to dispose of all external components of the MED-EL CI system by returning them to your local MED-EL subsidiary or distributor. Isolated collection and proper recovery of electronic and electrical waste equipment at the time of disposal allow us to help conserve natural resources. Moreover, proper recycling of the electronic and electrical waste equipment ensures safety of human health and environment.

9.4 Symbols

CE 0123 The SONNET 3 audio processor is in compliance with regulation 2017/745 (Medical Device Regulation/MDR).

CE marking, first applied in 2024

Hereby MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment types SONNET 3/ SONNET 3 EAS are 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

MD Medical Device

Caution

Consult instructions for use

MR MR Unsafe

Not suitable for children under 3 years

Manufacturer

Date of manufacture

REF Catalog number

SN Serial number

 Fragile, handle with care

 Temperature limit

 Humidity limitation

 Atmospheric pressure limitation

 Type BF applied part (IEC 60601-1)

 Battery pack recommended for use with wireless devices

IP54 IP54 Moisture and dust protection acc. to IEC 60529

This classification means that the undamaged SONNET 3 EAS audio processor is protected against failure from ingressing dust and ingressing splashing water when fully assembled and in ON position, i.e., when

- the microphone cover is snapped onto the control unit,
- the earhook is attached to the control unit and secured with the earhook pin,
- an earmold is connected to the earhook,
- 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 and correctly moved over the battery pack frame (ON position).

IP68 IP68 Moisture and dust protection acc. to IEC 60529

This classification means that the undamaged SONNET 3 for CI audio processor is protected against failure from ingressing dust and ingressing water (after continuous immersion in still, clean water at 1m for 60 minutes) when fully assembled and in ON position, i.e., when

- the microphone cover is snapped onto the control unit,
- the earhook is attached to the control unit and secured with the earhook pin,
- 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 and correctly moved over the battery pack frame (ON position).

Additionally, this classification means that the undamaged DL-Coil is protected against failure from ingressing dust and ingressing water (after continuous immersion in still, clean water at 1m for 60 minutes) when fully assembled, i.e., when

- the coil cable is fully inserted into the coil,
- the coil cover is assembled.

Rx ONLY Prescription only

Made for iPhone | iPad

Use of the "Made for iPhone | iPad" badge means that an accessory has been designed to connect specifically to iPhone® or iPad®, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

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9.5 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 preoperative score on CUNY sentences was 31% (±27%), while at 12 months postoperatively the average score was 73% (±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 preoperatively 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% (±30%), while the average score with EAS was 73% (±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 preoperative score with a hearing aid was 30% (±13%); while at 12 months with the cochlear implant alone the average score was 48% (±19%).
- The average improvement on CNC words in quiet with electric stimulation only was 18% compared to preoperatively.

- 88 % (58/67) of subjects demonstrated similar or improved performance on CNC words in quiet with the cochlear implant alone compared to preoperatively 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 % (±20 %) lower than the difficulty they experienced preoperatively.

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

Postoperative 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 postoperatively. 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- or Procedure-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 %
Aural fullness	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 right side of tongue	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. 85 % of subjects (56/66) understood sentences in noise better with EAS than they did with their hearing aid preoperatively. 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.

Extended Follow-Up Study

After the clinical trial, an additional study was completed to test the long-term results of the MED-EL EAS System. Many of the same subjects from the original clinical trial participated in this long-term follow-up study. Testing was done for word understanding in quiet, understanding sentences in noise, self-reported benefit, and residual hearing through at least five years post-implantation. The same tests were used as those in the original clinical trial, and subjects were tested in either the EAS condition of the Electric Alone condition, depending on their current everyday wearing condition. Many of the subjects who participated in the long-term study received their implant more than five years before but returned to the clinic one additional time to complete the long-term testing.

Long-Term Study Results

Subjects from the original clinical trial were invited to participate in the long-term study. All of the subjects participating in this study met the original criteria for participation in

the clinical trial. Up to 68 subjects were invited to participate, with 50 subjects returning for testing in the long-term study, which is a return rate of 74%. These 50 subjects were tested across seven study sites. Forty-nine subjects were tested at least five years post-implantation, while one subject was tested at four years post-implantation. The chart below describes the gender, age, and implanted ear for the subjects participating in this study.

Parameter/Category or Statistic		All Subjects
Gender	Male	23/50 (46%)
	Female	27/50 (54%)
Age (years)		56 ± 13 (50)
Ear Implanted	Right	27/50 (54%)
	Left	23/50 (46%)

Summaries shown as mean ± std (N) or n/N(%)

The subjects in the post-approval study shared similar preoperative and audiological characteristics to the subjects in the original clinical trial. These characteristics are compared in the table below. In the original clinical trial, eight subjects had profound low-frequency hearing at the 12-month visit. Five of the eight subjects with profound hearing loss participated in this post-approval study and were tested through at least five years post-implantation.

Measure	Interval	Original Clinical Trial	Post-Approval Study
Age (years)	Baseline	53.7 (73)	55.8 (50)
CUNY	Baseline	30.9 (67)	29.1 (50)
	12 months (EAS)	73.4 (66)	75.9 (39)
	12 months (CI)	55.6 (67)	60.4 (11)
CNC	Baseline	30.4 (67)	28.2 (50)
	12 months (EAS)	66.9 (66)	72.5 (39)
	12 months (CI)	48.4 (67)	45.5 (11)
LF-PTA	Baseline	49.0 (73)	50.4 (50)
	12 months	73.6 (67)	73.7 (50)

Summaries shown as mean (N)

Speech Understanding

Speech understanding benefit was tested in quiet and in noise. In both quiet and noise, subjects continued to score better at the long-term interval compared to before surgery with a hearing aid. In quiet, no change was shown between the long-term interval and the 12-month score from the original clinical trial. In noise, scores were poorer at the long-term interval, on average, than they were at the 12-month visit of the original clinical trial. Subjects' report of benefit with the device did not change between the original clinical trial and the long-term visit.

Speech understanding in noise was tested using their sentence score in noise at the five-year (long-term) visit. The average score on sentences in noise for subjects tested in the EAS condition was 61% (±27%) at the long-term visit. The average score on sentences in noise for subjects tested in the Electric Alone condition was 43% (±33%) at the long-term visit. Subjects understood speech in noise better through five years post-implantation when using EAS compared to their own hearing aid before surgery. Compared to the 12-month score from the original clinical trial, subjects using EAS scored 15 percentage points worse and subjects using Electric Alone scored 17 percentage points worse at the long-term visit. The chart below shows the speech understanding in noise score at the preoperative, 12-month and long-term visit for all subjects in the study.

Visit	EAS	CI Alone
Preoperative	29 ± 29 (39)	29 ± 23 (11)
1-year	76 ± 23 (39)	60 ± 26 (11)
4-year		75 (1)
5-year+	61 ± 27 (39)	43 ± 33 (10)

Summaries shown as mean ± std (N)

Speech understanding in quiet was also tested using their word score at the five-year (long-term) visit. The average word score in quiet for subjects tested in the EAS condition was 74% (±14%) at the long-term visit. The average word score for subjects tested in the Electric Alone condition was 57% (±23%) at the long-term visit. Word scores in quiet did not change at the five-year post-implantation visit compared to the 12-month score from the original clinical trial. Additionally, self-reported benefit on the benefit questionnaire also did not change at the long-term visit compared to the 12-month score from the original clinical trial.

The chart below shows the speech understanding in quiet score at the 12-month and long-term visit for all subjects in the study.

Visit	EAS	CI Alone
1-year	72 ± 15 (39)	45 ± 20 (11)
4-year		58 (1)
5-year+	74 ± 14 (39)	57 ± 23 (10)

Summaries shown as mean ± std (N)

All subjects have improved scores at the long-term visit compared to before surgery on at least one test. Two subjects had worse scores on sentence understanding in noise, word understanding in quiet, and self-reported benefit at the long-term visit compared to the 12-month visit in the original clinical trial. The other 48 subjects in this study had similar scores between the 12-month visit and the five-year visit on at least one test.

Speech understanding in noise did not meet the definition of success, which was a change less than or the same as 10 percentage points between the 12-month score and the long-term score. This means subjects understood speech in noise, on average, poorer at the long-term visit than at the 12-month visit. Speech understanding in quiet showed no change from the 12-month to the long-term visit. Both speech understanding in noise and in quiet showed that subjects did better than they did before surgery with a hearing aid.

Residual Hearing

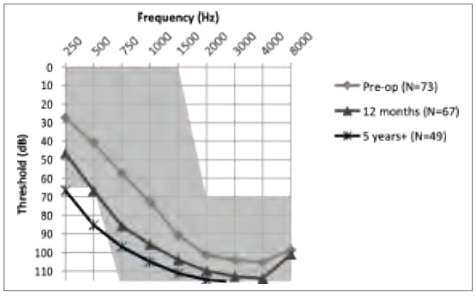
Residual hearing in the low frequencies was also tested at the long-term visit by averaging the hearing levels in the low frequencies (Low Frequency Pure Tone Average or LF-PTA). Forty-three of the 50 subjects (86 %) enrolled in this study had enough residual hearing to be able to use the acoustic unit of the audio processor. Many subjects were already past the five-year post-implantation visit and were tested anywhere from six to 10 years post-implantation.

Residual hearing was also reported through the HEARRING Scale (or S-Scale), which is a published means of analyzing residual hearing. This scale reports individuals as having complete hearing preservation, partial hearing preservation, minimal hearing preservation, or no hearing preservation. The table below reports the number of study subjects in each category for the 12-month visit in the original clinical trial and the long-term visit. At five-years post-implantation 74 % of study subjects had complete or partial hearing preservation.

Category	1-year	5-year+
Complete hearing preservation	9 (18 %)	6 (12 %)
Partial hearing preservation	37 (74 %)	31 (62 %)
Minimal hearing preservation	3 (6 %)	9 (18 %)
No hearing preservation	1 (2 %)	4 (8 %)

Summaries shown as mean ± std (N)

Residual hearing can be shown on an audiogram as average thresholds across the range of frequencies. The audiogram below shows the preoperative, 12-month, and long-term thresholds for all subjects in the study.



Change in residual hearing can be classified by the number of subjects experiencing a certain decrease in hearing. The chart below shows the number of subjects by how much low-frequency residual hearing was lost at the long-term visit.

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

Time Point	<10 dB	10–20 dB	20–30 dB	>30 dB
Long-term	5/50 (10%)	8/50 (16%)	6/50 (12%)	31/50 (62%)

Residual hearing can also be classified according to the degree of hearing loss in the low frequencies. In the chart below, subjects are listed by the degree of low-frequency hearing loss at the long-term visit, as the average of thresholds at 125, 250, 500, 750, and 1000 Hz.

Degree of Low Frequency Hearing Loss After Surgery For All Subjects

Time Point	Mild	Moderate	Moderate-Severe	Severe	Profound
Long-term	0/50 (0%)	4/50 (8%)	16/50 (32%)	13/50 (26%)	17/50 (34%)

Five subjects with profound hearing loss at the 12-month visit of the original clinical trial participated in this post-approval study. All subjects continued use of the audio processor in either the EAS or CI Alone condition. Performance was similar for these five subjects compared to the larger study population.

Adverse Events

Adverse events were also collected in the long-term study. Eight adverse events were reported in this study to be related to the device or the surgery, in eight study subjects (16%). None of these adverse events were unexpected. Seven events were reported as loss of residual hearing, while one event was reported as a device failure, with the device then being removed and a new device successfully implanted.

Study Strengths and Weaknesses

Subjects from the original clinical trial returned at a follow-up rate of 74% (50 out of 68 potential subjects). A comparison of the age, speech understandings scores, and residual hearing of the subjects from the original clinical trial and the post-approval study shows that the groups are very similar (see table below).

Measure	Interval	Original Clinical Trial	Post-Approval Study
Age (years)	Baseline	53.7 (73)	55.8 (50)
CUNY	Baseline	30.9 (67)	29.1 (50)
	12 months (EAS)	73.4 (66)	75.9 (39)
	12 months (CI)	55.6 (67)	60.4 (11)

Summaries shown as mean (N)

Measure	Interval	Original Clinical Trial	Post-Approval Study
CNC	Baseline	30.4 (67)	28.2 (50)
	12 months (EAS)	66.9 (66)	72.5 (39)
	12 months (CI)	48.4 (67)	45.5 (11)
LF-PTA	Baseline	49.0 (73)	50.4 (50)
	12 months	73.6 (67)	73.7 (50)

Summaries shown as mean (N)

Strengths of this study are the follow-up rate, similarity between groups, and word understanding scores and self-reported benefit that is unchanged from the original clinical trial. Weaknesses of the current study are the large number of subjects who were implanted at one study site (31 out of 50 subjects implanted at one site) and sentence scores that are poorer at the long-term visit compared to the 12-month visit. The test results reported here are not different when analyzed with and without the 31 subjects implanted at one site.

While sentence scores did show a decrease between the 12-month and long-term visits, average scores continued to improve compared to before surgery with hearing aids.

Additionally, word understanding in quiet and self-reported benefit did not change between the 12-month and long-term visits. Of the subjects in the study, 96 % demonstrated no change from 12 months to the long-term on at least one test.

Change in speech understanding from the 12-month visit to the long-term visit is shown in the chart below by degree of low-frequency hearing loss. Speech understanding in noise score show more change (poorer scores) for subjects with more hearing loss. Speech understanding in quiet scores do not show a difference by degree of hearing loss.

Degree of Residual Hearing	Mean Change in CUNY Score	Mean Change in CNC Score
Moderate	−9.25 ± 13.72 (4)	−1 ± 5.74 (4)
Moderately-severe	−8.13 ± 18.56 (16)	3.25 ± 15.91 (16)
Severe	−18.59 ± 21.56 (13)	1.85 ± 19.84 (13)
Profound	−18.65 ± 26.80 (17)	6.82 ± 15.31 (17)

Summaries shown as mean ± std (N)

This long-term study shows that the MED-EL EAS system is safe and effective after long-term use. Residual low-frequency hearing is maintained in two-thirds of study subjects after up to 10 years of device use. Additionally, subjects showed that speech understanding in quiet and in noise as well as self-reported benefit are improved compared to before surgery with hearing aids.

9.6 Contact

For help and assistance contact your local MED-EL office or MED-EL headquarters. Refer to the accompanying contact sheet to find your local office.

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Rx ONLY

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and, if applicable, to the competent authority of the country in which the user and/or patient is established.

9.7 Acknowledgements

Some parts of the firmware (micro-ecc) in the audio processor were written by Kenneth MacKay and licensed under the following terms and conditions:

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