Cochlear Implants

MED EL

User Manual for

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

hearLIFE

AW31902_3.0 (English US)

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Introduction

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

Your MED-EL Cochlear Implant System consists of the Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY), Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), PULSARci^{100} (hereafter referred to as PULSAR), SONATAti^{100} (hereafter referred to as SONATA) or C40+ implants, the external SONNET audio processor (including FineTuner, DL-Coil and D Coil), the external components and accessories, and any external hardware and software used by your audiologist.

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

Important

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

The adjustment to a cochlear implant and adequate fitting of the device are gradual processes that occur over time. It is important to remember that your ability to hear with your new MED-EL system may take a little time while you become accustomed to this new method of hearing. You may choose to work with an aural rehabilitation specialist or other clinician to help you maximize your communication skills using the device. The audio processor can be activated for the first time after the surgical incision has completely healed and any remaining swelling has gone away. The implant cannot provide any sound information until the audio processor has been programmed by your audiologist, turned on, and placed on the head over the implant.

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

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

Intended use – Indications – Contraindications

Intended use

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

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic (hearing aid) and electrical stimulation to the same ear is made possible through the external SONNET EAS audio processor working in conjunction with the internal cochlear implant with either a +FLEX^{24} or +FLEX^{20} electrode variant (SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR or C40+), which together make up the MED-EL EAS System.

Indications

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

- 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.

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.

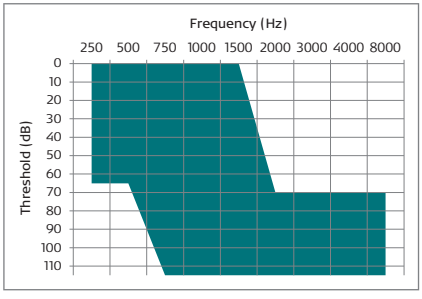

Fig. 1 EAS Indication

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

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

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

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

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

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

Contraindications

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

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

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

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

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

SONNET
audio processor

The parts of the system

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

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

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

Fig. 2 The MED-EL cochlear implants

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

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

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

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

SONNETci audio processor

1 Coil
2 Coil cable
3 SONNETci control unit
4 CI earhook
5 Microphone cover
6 Microphone openings
7 Indicator light
8 Battery pack
9 Air inlets

SONNETeas audio processor with ear mold attached

1 Coil
2 Coil cable
3 SONNETeas control unit
4 EAS earhook
5 Microphone cover
6 Microphone openings
7 Indicator light
8 Battery pack
9 Air inlets
10 Ear mold (not supplied by MED-EL)

Fig. 3 Your SONNET audio processor

The concept of EAS

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

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

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

ON/OFF switch

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

You may select the following positions:
Battery pack cover pulled back: OFF
Battery pack cover completely moved over the frame: ON

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

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

Fig. 4 The SONNET audio processor in OFF position

Fig. 5 The SONNET audio processor in ON position

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

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

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

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

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

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

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

The SONNET audio processor has an integrated telephone coil (telecoil). The telecoil picks up magnetic sound signals coming from telephone receivers or loop systems, which are installed in some public buildings, and converts them into audible signals.

To use the telecoil, proceed as follows:

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

When you switch on the audio processor, the microphone is active, even if you had the telecoil selected before you switched off the audio processor. When the telecoil is active, you may hear buzzing sounds when operating a FineTuner key. The buzzing is normal and indicates that a command is being sent. To reduce interference with various electronic and electrical equipment when the telecoil is active, we recommend you reduce audio sensitivity (see chapter 4, SONNET audio processor, FineTuner, FineTuner controls).

FineTuner

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

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

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

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

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

How to configure your FineTuner

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

For bilaterally implanted users

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

FineTuner controls

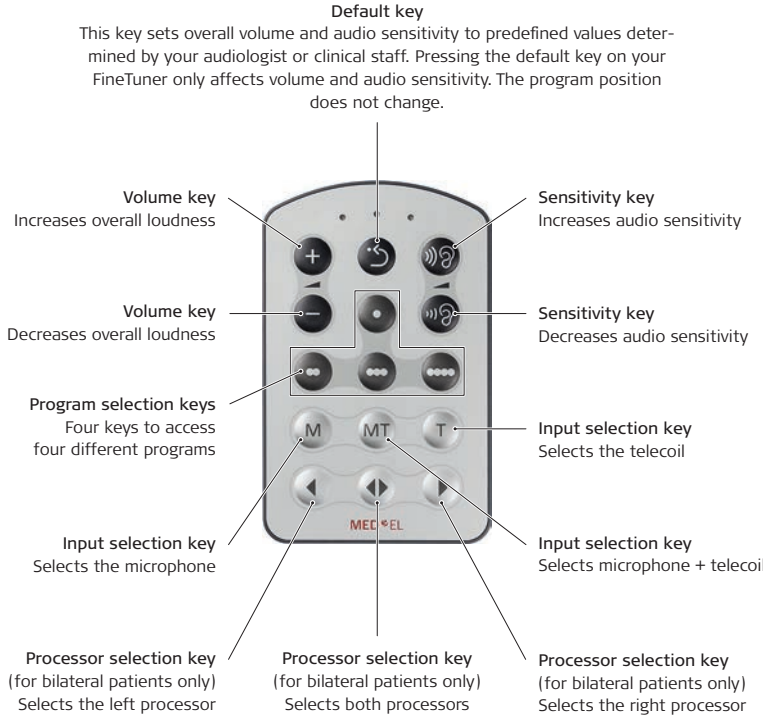

Fig. 7 FineTuner

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

FineTuner functions

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

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

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

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

Battery low warning: If you press a key and see the red indicator light on your FineTuner flashing 3 times, the voltage level of your FineTuner is critically low (see also chapter 7, Care and maintenance, Batteries, Changing the battery of your FineTuner).

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

Your FineTuner does not have an ON/OFF switch.

Three indicator lights with different colors (2 amber, 1 red) indicate various conditions of the FineTuner. For a detailed description of their function see chapter 8, Troubleshooting. The FineTuner does not affect connected assistive listening devices.

Battery pack

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

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

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

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

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

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

Fig. 8 Battery pack cover lock in unlocked position

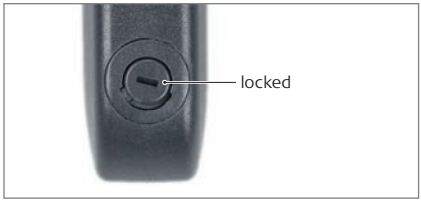

Fig. 9 Battery pack cover lock in locked position

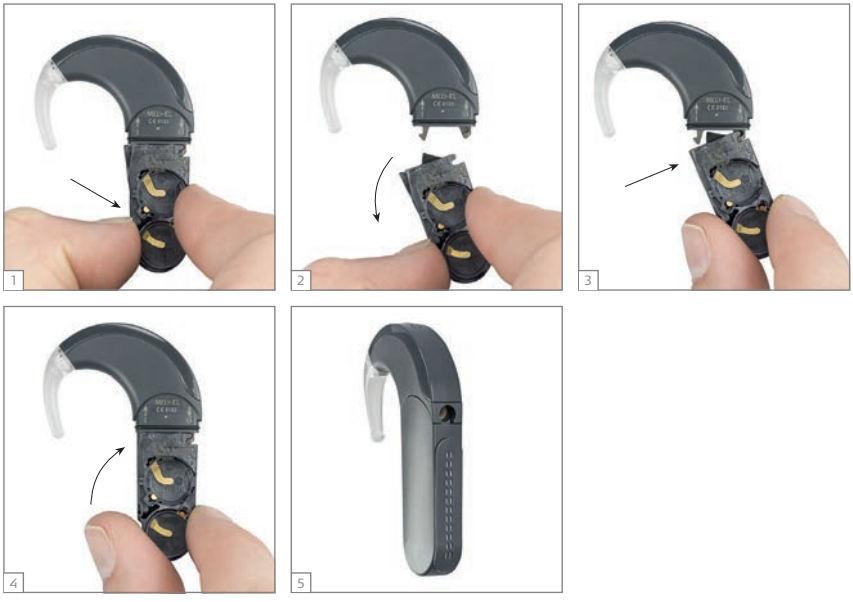

Fig. 10 How to remove/attach the battery pack from/to the control unit

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

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

Coil

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

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

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

DL-Coil

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

Fig. 11 DL-Coil

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

How to assemble your DL-Coil

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

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

Fig. 12 How to assemble your DL-Coil

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

Components of the DL-Coil

Magnet

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

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

Important

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

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

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

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

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

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

Important

The coil cover can only be attached properly when the magnet is turned towards ⊕ or ⊖. Therefore, the magnet shall not be left in the center position.
Strength 5 magnets must be turned towards ⊕, otherwise the cover cannot be attached properly.

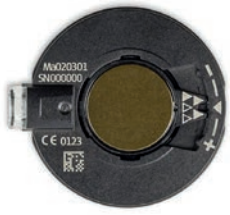

Fig. 13 Removing/inserting the magnet

Five magnet strengths are available. Magnet strength is indicated by the number of filled triangles or circles on the magnet (1=weakest, 5=strongest). The associated covers are available in two heights to accommodate magnet thickness.
In case a higher magnet strength is needed, try the ⊕ position of the current magnet first. If still too weak, insert the next magnet strength and use the ⊖ position first.

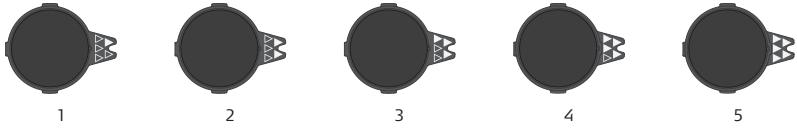

Fig. 14 Magnet strengths for SYNCHRONY implant

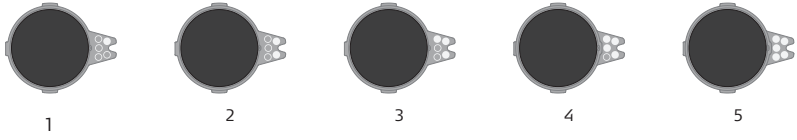

Fig. 15 Magnet strengths for all other types of implants

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

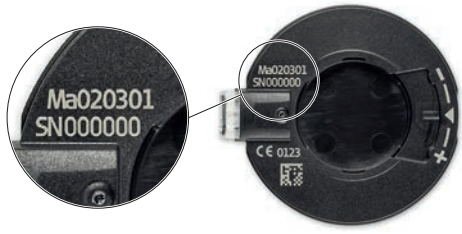

Fig. 16 Serial number and product code of DL-Coil

Important

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

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

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

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

Coil cover

How to attach the coil cover

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

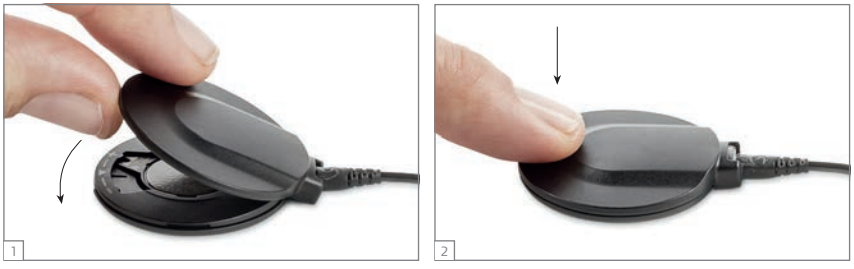

Fig. 17 Attaching the coil cover

Important

The coil cover can only be attached properly when the magnet is turned towards ⊕ or ⊖. Therefore, the magnet shall not be left in the center position.
Strength 5 magnets must be turned towards ⊕, otherwise the cover cannot be attached properly.

How to remove the coil cover

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

Fig. 18 Removing the coil cover

Cable lock

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

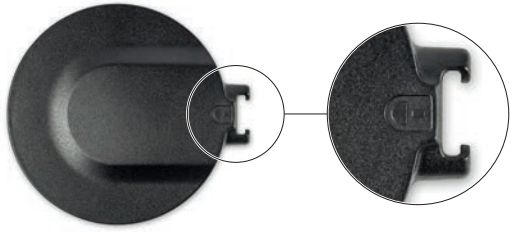

Fig. 19 Coil cover with cable lock

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

Variants

Use the coil cover L (low) for magnets number 1, 2 and 3.
Use the coil cover H (high) for magnets number 4 and 5.

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

Important

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

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

D Coil

Fig. 21 Coil (D Coil)

Important

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

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

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

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

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

To attach a new magnet insert, place it over the recess in the coil, as shown in Fig. 22. It should glide into the recess easily. Now turn the cover until it engages. You will feel a slight resistance when the cover snaps in place.

Fig. 22 Removing/inserting the magnet

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

Fig. 23 Magnet strengths for SYNCHRONY implant

Fig. 24 Magnet strengths for all other types of implants

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

Fig. 25 Serial number of D Coil

Important

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

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

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

Coil cable

The coil and audio processor control unit are connected by the coil cable. The coil cable must be disconnected for maintenance purposes or if you want to replace the cable. It is not necessary to disconnect the cable when changing the batteries.

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

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

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

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

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

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

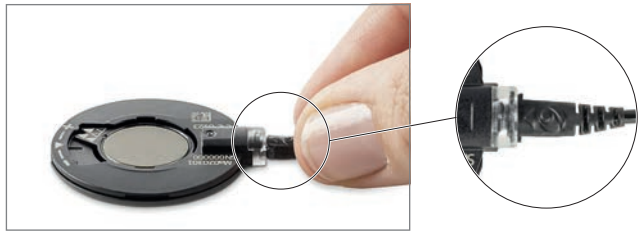

Fig. 26 Plugging the coil cable into the DL-Coil

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

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

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

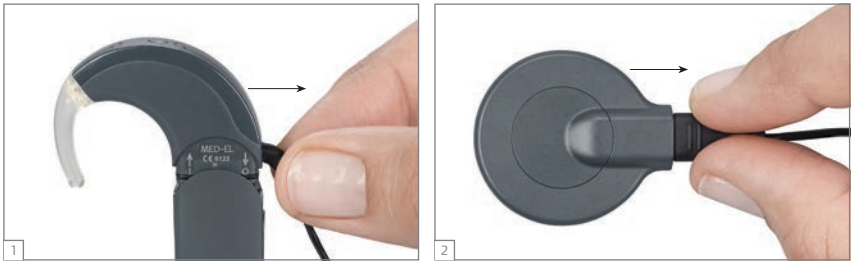

Fig. 27 Disconnecting the coil cable

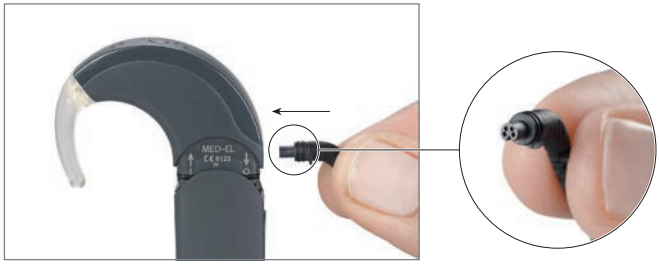

Fig. 28 Plugging the coil cable into control unit

Important

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

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

Earhook

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

Fig. 29 Earhook for SONNETci

Fig. 30 Earhook for SONNETeas

Important

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

The audiologist is also responsible to inform the patient or parents/caregiver about cleaning the ear mold to ensure optimal performance and avoid bacterial infections.

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

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

To replace the earhook, proceed as follows:

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

Fig. 31 How to remove the earhook pin

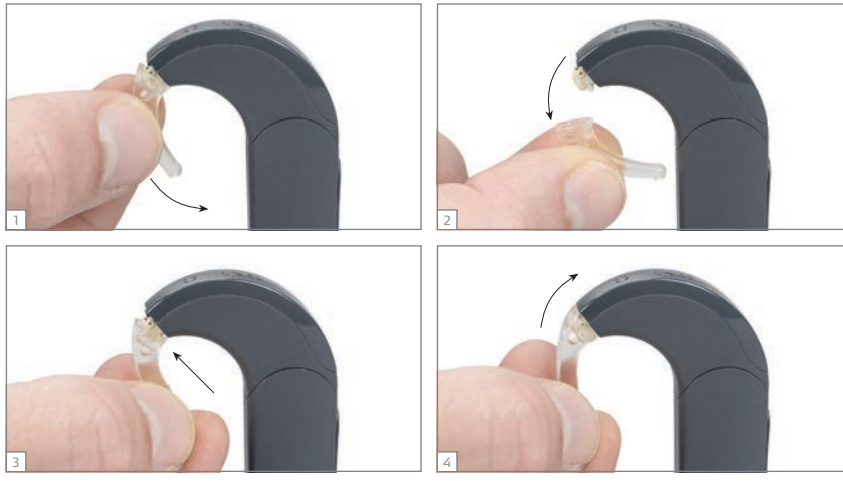

Fig. 32 Removing and attaching the earhook

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

Important

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

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

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

Fig. 33 Markings of longer earhook version

Microphone cover

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

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

To replace the microphone cover, proceed as follows:

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

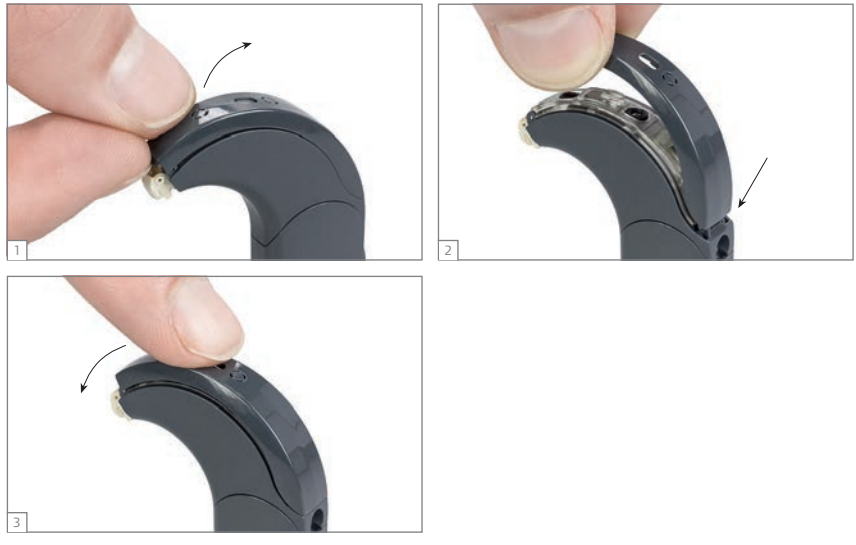

Fig. 34 Removing and attaching the microphone cover

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

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

Connecting assistive listening devices

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

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

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

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

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

An external audio device can be connected to the SONNET via an adapter cable. To do so, first insert the three-pin plug of the adapter cable (grey end) into the openings at the bottom of the FM Battery Pack Cover (mind the orientation of the three pins, and do not use excessive force when connecting the cable). Then insert the yellow or red plug of the cable into the audio output (headphone socket) of the audio device.

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

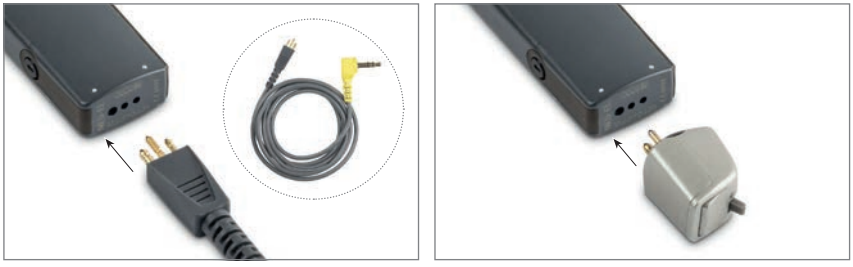

Fig. 35 Connecting the adapter cable and direct-link FM systems

Important

The provided cable is intended for the connection of external audio devices, such as portable CD players, MP3 players, AM-FM radios, etc. To connect body-worn FM or infrared systems, use the respective manufacturers' adapter cables.

Warning

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

Mix mode:

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

Ext mode:

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

Special considerations for young children

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

- Lockable earhook: The earhook is secured to the control unit with a small pin.
- Battery pack cover lock: To prevent small children from disassembling the audio processor and getting access to the batteries.
- Deactivation of certain FineTuner controls: To prevent accidental program, volume or sensitivity changes, it is possible to deactivate these FineTuner controls. Please contact your CI center for assistance.
- The DL-Coil features a coil cover with cable lock to secure the cable to the coil. When using the coil cover with cable lock, the cable cannot be detached from the coil unless the coil cover is removed. The cable lock prevents inadvertent disconnection of the coil cable from the coil.

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

Important

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

General precautions and warnings

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

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

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

Do not use the MED-EL Cochlear Implant System with any device other than those listed in this manual or approved by MED-EL. If you have problems with any component of the system, refer to chapter 8, Troubleshooting.

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

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

General precautions for your MED-EL Cochlear Implant System

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

The electronics are durable but must be treated with care.

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

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

Everyday life

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

For the external components, please observe the following:

- Your audio processor (including FineTuner and coil) does not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range is between +0 °C and +50 °C (32 °F and 122 °F) for the audio processor (including FineTuner and coil). Normally, when the audio processor is worn on the body, natural body heat helps maintain this temperature range.
- Do not leave the audio processor or FineTuner in direct sunlight (particularly inside a car).
- If you ever experience loud or uncomfortable sounds, please remove your coil and audio processor immediately: this will stop stimulation at once.
- Do not use the audio processor or FineTuner of another cochlear implant user. Your audio processor and FineTuner have been adjusted to your individual needs. Using another audio processor or FineTuner may cause painful or uncomfortable stimulation.
- Avoid getting your audio processor or FineTuner wet as this may impair its function. Always remove and switch off the external parts of your implant system and keep them in a dry place before bathing, showering or engaging in other water-related activities.
- If the external parts become wet, switch off your audio processor as quickly as possible, remove the batteries from the battery pack, unplug the battery pack from the control unit, and gently wipe all external parts dry, using a soft absorbent cloth. Then put the audio processor in the supplied drying kit to allow the audio processor to dry out (preferably overnight). If in doubt, repeat the drying process. If the FineTuner becomes wet, wipe it off with a dry tissue.
- Take care of the external components of your/your child's MED-EL Cochlear Implant System. They should not be dropped or subjected to dangerous areas (e.g. machines or high voltage), which could result in damage to the components.
- Do not use the audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.
- Do not try to shape the earhook with hot air.
- Do not use your audio processor in the vicinity of strong ionizing radiation (e.g. x-ray machines) or electromagnetic fields (e.g. MRI machines).

- Do not modify the housing, the electronics or any other parts of your audio processor in any way.
- Never place the coil or a magnet on the control unit. It is even more important to follow this guideline when you are using a SONNETeas. The SONNETeas contains elements which are sensitive to magnets and might be permanently damaged by strong magnetic fields.

Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. For young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 8), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.

Technology in everyday life

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

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

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

Air travel

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

Interference with TV reception

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

Cell phones

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

TV, radio, FM systems, etc.

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

Electrostatic discharge (ESD)

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

Following these guidelines can reduce the probability of electrostatic discharge:

- If you believe that you or your child is statically charged, discharge by touching a radiator, a water tap, or any grounded metal object.
- Do not allow another person to touch the external parts of your implant system unless both you and the other person are "discharged".
- You should always discharge before taking off or putting on the audio processor. To do this, use this two-step approach:
  (A) When removing another person's audio processor:
  Step 1: Touch the person's body
  Step 2: Touch the processor
  (B) When picking up the audio processor from a table or other surface:
  Step 1: Touch the table
  Step 2: Pick up the processor
- You or your child should always be "discharged" when leaving the car. Touching the car door is a good way to discharge. The audio processor or cables should neither touch the car door nor other parts of the car body.
- Use an antistatic spray for upholstery and TV or computer screens to reduce static build-up. These sprays are also available for carpets or clothing.
- Always remove your audio processor before dressing and undressing, especially if garments include synthetic fibers. Generally, cotton and natural fibers are less likely

to cause ESD problems. Fabric softeners might also help reduce static electricity. When getting dressed, put your audio processor on last, and remove it first when undressing.

- Always remove the audio processor and coil before touching plastic play equipment (e.g. children's slides). Switching off the audio processor may not be enough to prevent ESD damage. Completely remove the audio processor from the body. Afterwards, do not touch the site of the implant. Make sure that you or your child "discharge" before touching the audio processor. If you have any doubt about a particular material, it is best to be cautious by removing the audio processor.
- Always remove the audio processor and coil when experimenting with static electricity and "high" voltage. Van de Graaff generators, as found in school science departments or science museums should never be used by cochlear implant users, even if the processor is removed, because they produce very high levels of static electricity.
- When working at a computer, make sure the computer is grounded and use an anti-static mat under your work area to reduce static build-up. Never directly touch the screen of a computer or TV. The risk of problems from computer screens is very small but may be further reduced by attaching an anti-static screen to the computer.
- If your audio processor stops working and you suspect ESD as the cause, switch off the audio processor, wait for a few minutes and switch it on again. If it does not come on again, contact your CI center.

RFID (radio frequency identification)

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

Sports and play

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

Avoid contact sports that might result in severe blows to the head or continuous pressure on the implant, since this could damage the implant. Other physical activity is generally allowed. Make sure that you wear the audio processor securely to protect it from physical damage. Sports that require a helmet are okay as long as they do not exceed the given capabilities of the user. Use a helmet whenever necessary to protect the implant site from any blows. Your/your child's helmet should be of high quality. It may need to be modified to meet your individual needs. For specific questions about contact sports, contact your CI center.

Most water sports should not cause any problem, as long as the external parts of the implant system are removed. If headgear or face masks are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In any case, you should consult an experienced physician about the possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft.).

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

Precautions for medical procedures

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

Ear infections

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

Electrical lice combs

Cochlear implant users should not use these devices.

Meningitis vaccine and prevention

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

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

Care and maintenance

Maintenance

Your SONNET audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time. Although the coil cable is designed for maximum durability and flexibility, this part of the MED-EL Cochlear Implant System is the most likely to wear out. The battery pack and particularly its cover may wear out due to frequent opening and closing and, therefore, have to be replaced more frequently.

Do not clean the external parts in or under water. Use a damp cloth to gently clean the audio processor. Do not use aggressive cleaning agents.

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

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

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

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

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

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

Weekly maintenance of your audio processor

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

Drying your audio processor

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

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

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

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

Batteries

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

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

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

Important

- Wash your hands after handling disposable batteries.
- Do not try to recharge disposable batteries.
- Do not disassemble, deform, immerse in water or incinerate batteries.
- Avoid mix-up of old and new batteries or batteries of different types of brands.
- Do not short-circuit batteries, e.g. by allowing the terminals of batteries to touch, carrying batteries loose in your pockets, wallet or purse or touching the battery terminals with metals (coins, wires, keys, etc.).
- Store unused batteries in their original packaging, in a cool and dry place.
- Do not expose batteries to heat (e.g. never leave batteries in direct sunlight, behind a window or in a car).
- Do not use damaged, deformed batteries or leaking batteries. If any kind of substance leaks out of a battery, avoid direct skin contact with that substance. Such a substance could cause a chemical burn. In case of eye contact, rinse with copious amounts of water and seek medical attention immediately.
- If you are not going to use your audio processor for an extended period of time, you should remove the batteries and store them separately. Cover the air openings on the top with adhesive tape when storing the batteries to avoid discharge.
- Always remove used batteries immediately to avoid leaking and possibly damaging the device.
- Dispose of used batteries according to local regulations. Generally, batteries are collected separately and not discarded with the household garbage.

To prevent children from swallowing or choking on batteries, always keep new and used batteries out of the reach of children. Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. In young children, the battery pack cover lock must always be turned clockwise into the locked position (see Fig. 8), once the cover has been moved completely over the frame, to prevent the child from disassembling the audio processor.

Do not allow children to replace batteries without adult supervision.

Changing the batteries of your SONNET audio processor

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

To change the batteries, proceed as follows:

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

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

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

correct when the air inlets on the battery pack cover are on the same side as the coil cable socket in the control unit.

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

Fig. 35 Changing the batteries of your audio processor

Changing the battery of your FineTuner

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

To change the battery, proceed as follows:

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

Fig. 36 Changing the battery of your FineTuner

CHAPTER 8

Troubleshooting

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

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

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

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

Speech Processor Test Device

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

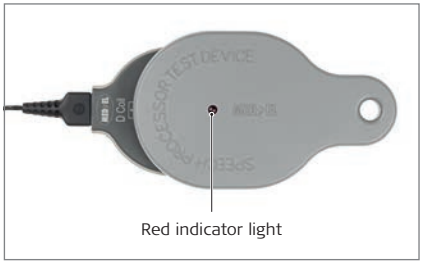

Fig. 37 Speech Processor Test Device

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

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

If you suspect a malfunction of your audio processor, contact your CI center or MED-EL or try the following procedure:
Switch on the audio processor and make sure that it is supplied with functioning batteries. Place the coil underneath the Speech Processor Test Device (see Fig. 37). The coil will position itself correctly due to magnetic attraction.

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

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

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

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

FineTuner

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

- The audio processor is out of the FineTuner's operational range. To overcome this, you should move the FineTuner closer to the audio processor.
- The FineTuner keyboard lock is active. In this case, follow the instructions for the unlocking function as described in chapter 4, SONNET audio processor, FineTuner, FineTuner functions.
- Interference from other electronic or electrical equipment is present that blocks the transmission. To eliminate this interference, you need to move the FineTuner closer to the audio processor and/or go to a different location.
- The audio processor and the FineTuner are not synchronized. In this case, you need to refer to the section described in chapter 4, SONNET audio processor, FineTuner, How to configure your FineTuner.
- In the case of a suspected malfunction of the FineTuner, you need to remove the battery and re-insert it after a few minutes, as described in chapter 7, Care and maintenance, Batteries, Changing the battery of your FineTuner.
- The FineTuner battery is low. In this case you need to replace the battery as described in chapter 7, Care and maintenance, Batteries, Changing the battery of your FineTuner.
- The desired command in the audio processor has been disabled by your audiologist during fitting. To enable this command, you will need to contact your clinic, CI center or MED-EL.
- The indicator light in the audio processor has been disabled by your audiologist during fitting. To enable the indicator light, you will need to contact your clinic, CI center or MED-EL.

Additional troubleshooting information:

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

SONNET indicator light

The multi-color indicator light on top of the audio processor flashes with different patterns and colors to indicate different conditions. If the indicator light begins flashing, use the following tables to determine the cause. Your audiologist can deactivate the blinking signals (except error patterns) if you prefer this.

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

Blinking pattern	Meaning	Required action	Remarks
Confirmation pattern			
Brief flash of indicator light	FineTuner command received and accepted	None	**Important** Pressing the Default key on your FineTuner only affects volume and audio sensitivity. The program position does not change.
Program change pattern			
	Program 1 to 4 selected	None	The indicator light will blink depending on the selected program position.
Status pattern			
	The processor is initialized and working	None	

Private alert

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

Battery low warning signal

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

End of range reached warning signal

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

Confirmation signal

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

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

DL-Coil indicator light (Link Monitoring)

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

Blinking pattern	Meaning	Required action	Remarks
Green			
●	When turning on a processor programmed for a previous generation implant (e.g. C40+, C40): Indicates functionality of coil, coil cable and audio processor	None	Applicable only to previous generation implants without I[100] serial numbers
●●●	When turning on a processor programmed for a new generation implant: Correct implant detected. Indicates functionality of coil, coil cable, audio processor and implant.	None	Applicable only to implants with a I[100] serial number saved to the audio processor memory bank
Red			
	Coil and implant are disconnected	Position the coil over the implant site	If the blinking persists, contact your clinic, audiologist or MED-EL
	Coil positioned over wrong implant (bilaterally implanted users)	Position the coil over the correct implant	
0 1 2 3s for max. 5 min.	Broken coil cable The coil will automatically power off after 5 minutes (no stimulation). Your audiologist can deactivate the automatic power off function.	Replace the coil cable. If the coil has powered off, reposition the coil over the implant site, switch the processor off and on again to resume stimulation (the processor does not switch off automatically).	

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

FineTuner indicator functions

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

Keyboard locked

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

Transmitting

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

Switch to side

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

Low battery

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

Configuration successful

If configuration of your FineTuner (see chapter 4, SONNET audio processor, FineTuner, How to configure your FineTuner) was successful, or if the automatic keyboard lock feature was successfully activated/deactivated, both amber indicator lights will illuminate for approximately one second.

Program mode

If ⏀ is pressed for more than 5 seconds (must be unlocked; see chapter 4, SONNET audio processor, FineTuner, FineTuner functions for locking/unlocking instructions), the FineTuner enters the program mode. The three indicator lights start flashing. When the red indicator light is on, the two amber indicator lights are off and vice versa. Flashing stops and the program mode is left after 5 seconds or earlier when a correct key is pressed.

Technical data

Audio processor

Dimensions of SONNET audio processor (mm/in.)[3]

Weight[3]

SONNETci: 10.6 g (0.374 oz.) (including batteries)
SONNETeas: 11.3 g (0.399 oz.) (including batteries)

Power supply

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

Hardware

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

3 typical values

Additional features in SONNETeas variant

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

Audio input

- Via FM Battery Pack Cover
- Hearing aid type three pin connection (Euro Audio) acc. to IEC 60118-12
- Sensitivity: –57.5 dBV[3] (corresponds to 70 dB SPL at 1 kHz)
- Impedance: 4.5 kΩ[3]

Controls/Indicators

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

Materials

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

Temperature and humidity range

Operating temperature range: 0 °C to 50 °C (32 °F to 122 °F)
Storage temperature range: –20 °C to 60 °C (–4 °F to 140 °F)
Relative humidity range: 10 % to 93 %

Essential performance

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

Radio frequency (RF) link (FineTuner)

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

Radio frequency link (wireless network)[4]

Frequency band of reception / transmission: 2400 MHz – 2483.5 MHz
Short Range Device (SRD) according to ERC/REC 70-03 Annex 1 (band I)
Receiver category 3
Type of modulation: Gaussian frequency shift keying (GFSK)
Maximum effective radiated power (ERP): 106 µW (–9.75 dBm)

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

Coils

DL-Coil

Dimensions in mm (in.)[3]
Diameter: 32.8 (1.29)
Height: 5.8 (0.23)
(with number 2 magnet and coil cover L)

Weight[3]
4.6 g (0.16 oz.)
(with number 2 magnet and coil cover L)

Indicators
Indicator light: 1 multi-color LED

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

D Coil

Dimensions in mm (in.)[3]
Diameter: 31.6 (1.24)
Height: 6.0 (0.24)

Weight[3]
4.4 g (0.15 oz.)
(with number 2 magnet)

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

Coil cable

Dimensions in mm (in.)[3]
65 (2.56), 90 (3.54) and 280 (11.02)

Materials
PVC and TPE Evoprene, all colors

Coil cable

Dimensions in mm (in.)[3]
85 (3.35), 110 (4.33) and 280 (11.02)

Materials
PVC and TPE Evoprene, all colors

3 typical values

FineTuner

Dimensions[3]

Length: 85.5 mm (3.366 in.)
Width: 54.0 mm (2.126 in.)
Height: 6.3 mm (0.248 in.)
Weight: 33.0 g (1.164 oz.) (incl. battery)

Controls/Indicators

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

Power supply

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

Classification

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

Materials

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

Temperature and humidity range

Operating temperature range: 0 °C to 50 °C (32 °F to 122 °F)
Storage temperature range: –20 °C to 60 °C (–4 °F to 140 °F)
Relative humidity range: 10 % to 93 %

3 typical values

Radio frequency (RF) link

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

Regulatory statements

Applicable in Canada only:
Model: SONNET (Me1310), SONNET EAS (Me1320) – IC: 11986A-ME1300
Model: FineTuner – Canada 310

The above devices comply with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
Les appareils mentionnés ci-dessus sont conformes aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Applicable in the USA only:
Model: SONNET (Me1310), SONNET EAS (Me1320) – FCC ID: VNP-ME1300
Model: FineTuner – FCC ID: VNP-FT

The above devices comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
Warning: Changes or modifications made to this equipment not expressly approved by MED-EL may void the FCC authorization to operate this equipment.
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

Symbols

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

CE mark applied in 2014

Hereby MED-EL declares that the SONNET audio processor and the FineTuner are in compliance with the essential requirements and other relevant provisions of directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment/R&TTE). The Declaration of Conformity can be obtained directly from MED-EL Worldwide Headquarters (for address see chapter 10, Appendices).

MR unsafe

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

Type BF
(IEC 60601-1)

Non-ionizing radiation

Fragile; handle with care

Relative humidity

Temperature limit

IP54 IP54
Moisture and dust protection acc. to IEC 60529

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

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

Disposal

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

Speech Processor Test Device

CE 0123

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

CE mark applied in 2005

Guidance and manufacturer's declaration

Tables according to IEC 60601-1-2 for SONNET

Electromagnetic emissions – for all equipment and systems

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

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

Electromagnetic immunity – for all equipment and systems

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendices

Warranty, guarantee and registration card

Our warranty is in agreement with statutory warranty claims.

In addition, we grant a five- year guarantee for the SONNET audio processor and coil. This warranty exclusively covers product failures; it shall not apply to any MED-EL product subjected to physical or electrical abuse or misuse, or operated in any manner inconsistent with the applicable MED-EL instructions.

Statutory warranty claims shall not be granted unless the registration card is completed and returned to MED-EL within three weeks of the initial fitting. The warranty period for the SONNET audio processor and coil begins with the date of first audio processor fitting.

The implant itself is covered by a 10-year warranty. MED-EL shall provide a new implant, free of charge, if the implant fails due to a mechanical or electrical defect caused by MED-EL. The warranty period for the implant begins with the date of implant surgery and depends on the completion and return of the registration form (CI patient card) that is delivered to the clinic with the implant.

Guarantees exceeding statutory warranty periods shall not be granted unless the registration form is completed and sent to MED-EL. Please ensure that you and your clinic complete both the registration card and registration form (CI patient card), and return them to MED-EL via registered mail.

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

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

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

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

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

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

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

Clinical trial subjects

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

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

Description of Tests

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

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

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

Clinical trial results

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

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

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

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

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

Speech Understanding with EAS

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

- The average pre-operative score on CUNY sentences was 31% (±27%), while at 12 months post-operatively 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 pre-operatively with a hearing aid.

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

- The average CUNY sentence in noise score with the cochlear implant alone was 56 % (±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 pre-operative 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 pre-operatively.
- 88 % (58/67) of subjects demonstrated similar or improved performance on CNC words in quiet with the cochlear implant alone compared to pre-operatively with a hearing aid.

Self-Assessment Questionnaires

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

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

Post-operative Residual Hearing

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

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

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

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

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

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

Degree of Low Frequency Hearing Loss After Surgery For All Subjects

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

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

Risks of receiving the MED-EL EAS System

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

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

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

*Some subjects experienced more than one adverse event.

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

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

Benefits of receiving the MED-EL EAS System

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

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

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

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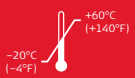

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Cochlear Implants

MED EL

MAESTRO

System Software 6.0

hearLIFE

AW32640_3.0 (English_US)

1. Table of contents

2. Introduction

This manual serves as a reference guide for trained personnel (e.g. audiologists) conducting the programming of the MED-EL audio processors and associated testing of implant users. Those performing this work will have had prior training in the use of the system from MED-EL. The MED-EL Cochlear Implant System refers to any implant type (e.g. Mi1200 SYNCHRONY, Mi1000 MED-EL CONCERT, SONATA TI100™, PULSAR CI100® and C40+) and to the processor types SONNET, SONNET EAS, RONDO, OPUS 2™, DUET 2™, OPUS 1™ and TEMPO+, the MAX Programming Interface and associated fitting software produced by MED-EL.

NOTE:
The MAESTRO 6.0 software supports the implants Mi1200 SYNCHRONY, Mi1000 MED-EL CONCERT, SONATA TI100, PULSAR CI100, and C40+ and the processors SONNET, SONNET EAS, RONDO, OPUS 2™, DUET 2™ OPUS 1™ and TEMPO+ in combination with the MAX Programming Interface.

The MED-EL Cochlear Implant System is an intracochlear, multichannel auditory prosthesis that uses the latest technology and processing strategies. Its development is based on many years of world-wide research, together with extensive experience in cochlear implant development and production by MED-EL.

This version of the manual describes the MAESTRO 6.0 software, which is used for different intraoperative and postoperative purposes for the MED-EL Cochlear Implant System. Currently, it contains the implant telemetry and fitting of the SONNET, SONNET EAS, RONDO, OPUS 2, DUET 2, OPUS 1 and TEMPO+ processor, ART™ (Auditory nerve Response Telemetry), ESRT (Electrically Evoked Stapedius Reflex Threshold), EABR (Evoked Auditory Brainstem Response), Audiogram and Acoustic Fitting functions.

The hardware and software requirements are described in section 10 (Technical Data) of this manual. The individual hardware components of the MED-EL Cochlear Implant System are described in the applicable user manuals.

CAUTION:
The software must only be used by specially trained personnel. Training can be provided by MED-EL or by clinical audiologists who have experience using the MED-EL Cochlear Implant System. Since a password is required to use the software, MAESTRO allows an administrator to limit access to trained and qualified personnel.

3. Application Information

3.1 INTENDED USE

The MED-EL Cochlear Implant (CI) System is intended to evoke auditory sensation via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal cochlear implant with either a +FLEX^{24} or +FLEX^{20} electrode variant which together make up the MED-EL EAS System.

The MAESTRO software is an external component of the MED-EL Cochlear Implant System and is intended to be used:

- in a clinical or office environment by persons adequately skilled and trained to perform all intended tasks
- with patients who received one of the intended MED-EL cochlear implants
- installed on a Personal Computer (PC) running a version of the supported Microsoft Windows operating systems listed in section 10 (Technical Data)
- in conjunction with the following MED-EL external hardware components:
    - MAX Programming Interface
    - Detectorbox C40+
    - TEMPO+ speech processor
    - OPUS 1 audio processor
    - OPUS 2 audio processor
    - DUET 2 audio processor
    - RONDO audio processor
    - SONNET audio processor
    - SONNET EAS audio processor
    - DL-Coil
- in conjunction with the following third party external hardware components:
    - HI-PRO interface box (for EAS fitting of the DUET 2)

- in conjunction with the following MED-EL implantable hardware components:
    - Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY), Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), SONATAti[100], PULSARci[100] and C40+
    - STANDARD, MEDIUM, COMPRESSED, SPLIT, FLEX[24] and FLEX[28] electrodes
- to perform the following tasks:
    - The Fitting task is intended to adjust sound processing and stimulation parameters for any intended audio processor/cochlear implant combination to specific needs of individual patients.
    - The Processor Configuration task is intended to program sound processing and stimulation parameters from the Fitting task into an intended audio processor.
    - The IFT (Impedance Field Telemetry) task is intended to ascertain the technical status of the implant's stimulator and electrodes. However, the results must not be taken as the sole basis for any decision about further medical or surgical treatment.
    - The ART (Auditory nerve Response Telemetry) task is intended to stimulate the auditory nerve and to allow the clinician to evaluate a particular electrode's evoked neural response.
    - The ESRT (Electrically Evoked Stapedius Reflex) task is intended to enable fast and simple stapedius reflex measurements to ascertain correct stimulation of the patient's auditory nerve and to indicate the relative sensitivity of the implanted cochlea for electrical stimulation.
    - The EABR (Evoked Auditory Brainstem Response) task is intended to perform stimuli for auditory evoked potential assessment. It provides user adjustable stimulation patterns and the necessary synchronization with external recording hardware.
    - The Audiogram task is intended to enter a patient's hearing data for both ears. This task also supports EAS fitting, (e.g. DUET 2, SONNET EAS) as the audiogram data are used to calculate the crossover frequency.
    - The Acoustic Fitting task is intended to adjust the acoustic unit that is a part of the DUET 2 audio processor.

3.2 INDICATIONS

The MAESTRO 6.0 application software is a component of the MED-EL Cochlear Implant System and is indicated for use with patients who have been implanted with C40+, PULSARCI^{100}, SONATATI^{100}, MED-EL CONCERT, SYNCHRONY cochlear implants. The MED-EL Cochlear Implant System is indicated for:

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

3.3 CONTRAINDICATIONS

Use of the MAESTRO software is contraindicated in combination with any hardware component not included in the intended use or any external hardware component known to be defective. The software is contraindicated to be used by patients or other unskilled, untrained persons.

There are no known contraindications for the Fitting task, Processor Configuration task and Acoustic Fitting task. The Impedance Field Telemetry (IFT) task is contraindicated for patients known to have extremely low Most Comfortable Loudness levels (MCL).

3.4 PRECAUTIONS

High Definition Continuous Interleaved Sampling (HDCIS), Fine Structure Processing (FSP, FS4 and FS4-p) are speech coding strategies offered in the MAESTRO 6.0 software. The performance of the FSP, FS4 and FS4-p speech coding strategies have been clinically studied in the post-lingually deaf adult population but not in the pediatric population. For further details on the safety and effectiveness data on the adult patients please refer to section 11 (Clinical Studies). Pediatric patients should be fit with CIS+ or HDCIS programming options. Performance of HDCIS, FSP, FS4 and FS4-p may vary between individual patients.

The correct installation of the software is a prerequisite for successful and beneficial use of the MAESTRO 6.0 software. The use of the MAESTRO 6.0 software is restricted to clinicians who are adequately skilled and have been trained to perform the required clinical tasks. In addition to the instructions for use provided by MED-EL, clinical users are strongly encouraged to follow local professional standards throughout all procedures.

3.5 INITIAL INSPECTION

Before working with the MAESTRO 6.0 software for the first time it is recommended to perform an initial inspection:

1. Make sure that the desired target platform fulfills the minimum requirements as specified in section 10.1.
2. Install the MAESTRO software as described in section 4.1 and make sure that no unexpected event or failure occurs during installation.
3. Connect the USB cable to a high power USB 2.0 compliant port on your computer and to the USB socket of the MAX Programming Interface. Make sure that no further device is connected to the MAX Programming Interface.

4. Start the MAESTRO software and log in.
    - o Verify that the MAESTRO software starts and a login is possible.
    - o Verify that a green LED on the back of the MAX Programming Interface illuminates. This means the driver is installed and the MAX Programming Interface is connected to an appropriate high power USB 2.0 port.
    - o Take a look at the Settings | Hardware dialog (see section 4.5 and Figure 1) or the status bar (see section 4.3 and Figure 2) and verify that the MAX Programming Interface is recognized by the MAESTRO software.

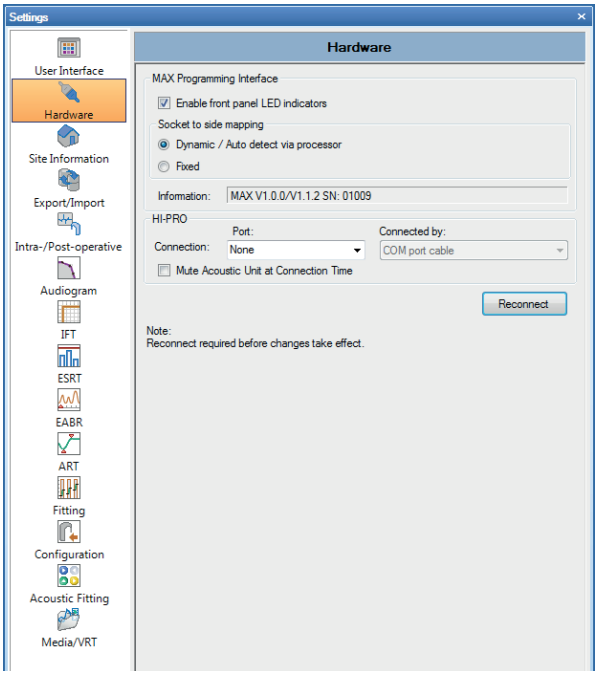


Figure 1 Hardware settings dialog

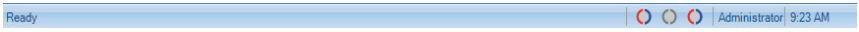


Figure 2 Status bar

See section 8 for care and maintenance of the MAESTRO software.

4. Getting Started

4.1 SOFTWARE INSTALLATION

Installation of the MAESTRO software is designed to be as easy as possible, as it is stored on a single CD-ROM, which contains all the necessary software, drivers etc. Before installing the software, carefully check all hardware and software requirements defined in section 10.

For all Windows operating systems you will need administrative rights to install the MAESTRO software.

NOTE:
Make sure that the MAX Programming Interface is not connected to the PC during installation.

To install the MAESTRO software, insert the installation CD into your CD-ROM compatible drive. The installation will begin and a dialog appears which allows you to select the language of the setup program (see Figure 3).

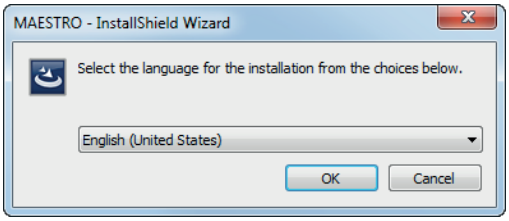


Figure 3 Language selection of the setup program

The InstallShield Wizard for MAESTRO will guide you through the installation process.

A dialog with the License Agreement will appear after launching the installation. Before you install MAESTRO you must read and confirm this License Agreement. By accepting this License Agreement, you confirm that you are informed about your rights and the conditions of use. One of the several items you agree to is to use only the Product Activation Key provided by MED-EL for your installation.

Next you will be prompted for a Product Activation Key. Enter the Product Activation Key you have received with the user manual and the installation CD (see Figure 4).

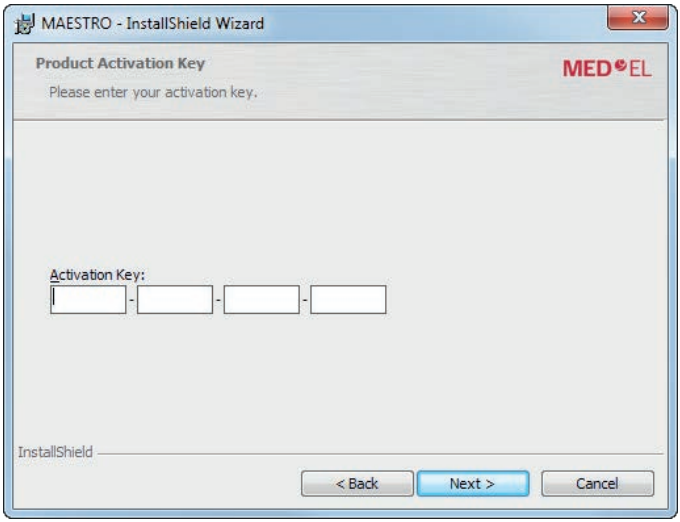


Figure 4 Dialog to enter the Product Activation Key

In the next step you will be asked to install MAESTRO and the help functions.

NOTE:
Please note that with the installation of the MAESTRO software the driver for the MAX Programming Interface is installed and this may take some time.

If a previous version of MAESTRO has already been installed on your PC, you may migrate the existing database to the current version of MAESTRO using the MAESTRO Database Management Tool (see section 4.2.2). A source database is preselected based on the previous installation of MAESTRO (see Figure 5).

If no database is migrated, MAESTRO will start with an empty MAESTRO single file database.

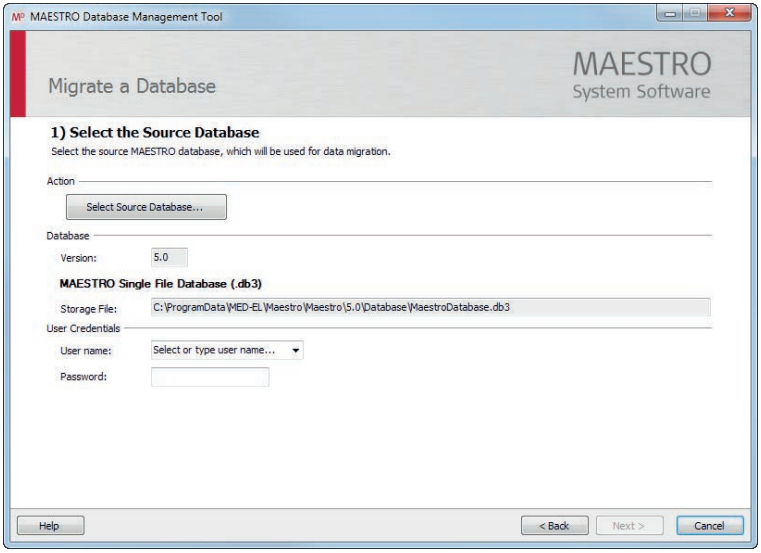


Figure 5 MAESTRO Database Management Tool – Migrate a Database

4.2 DATABASE

The MAESTRO 6.0 software needs an appropriate MAESTRO 6.0 database to work with:

- A new, and therefore empty, MAESTRO 6.0 database, e.g. the single file database routinely created during installation or a new database created by the user with the Database Management Tool (see section 4.2.2.2).
- A database of a previous MAESTRO version migrated to a MAESTRO 6.0 database (see Migrate a database).

It is not possible for MAESTRO 6.0 to connect to a database created by a previous MAESTRO version that was not migrated to MAESTRO 6.0.
Use the Database Management Tool to either create a new MAESTRO 6.0 database or to migrate a database from a previous MAESTRO version.

NOTE:
The MAESTRO 6.0 software needs an appropriate MAESTRO 6.0 database.

4.2.1 Supported database formats

All data generated with MAESTRO are saved in a database with administrative data such as user data and user-specific settings saved in the system database and patient data saved in the patient database.

MAESTRO currently supports the following database formats: SQLite, Microsoft SQL Server 2005, Microsoft SQL Server 2008, Microsoft SQL Server 2008 R2 and Microsoft SQL Server 2012.

SQLite is a single file database (.db3) used for desktop applications. Microsoft SQL Server is a complex server-based database and is particularly suitable as a central database for multiple user solutions in a network.

Installation of the software routinely installs an empty MAESTRO single file database (.db3). Installation of a Microsoft SQL Server database is not supported by MAESTRO and must be installed by a local administrator, if applicable. The delivered MAESTRO Database Management Tool allows setting up a new MAESTRO database within an existing Microsoft SQL Server and also allows to create a new single file database (see section 4.2.2.2).

NOTE:
For shared data access it is recommended to use Microsoft SQL Server. Using a single file database on a shared network drive is not as reliable and efficient as an SQL Server database.

Saved data are confidential patient data. The user or local administrator is responsible for protecting these data against unauthorized access and data loss in accordance with national laws and local clinic policy.

Backups of the MAESTRO database on a regular basis are highly recommended.

MAESTRO supports the user with three different kinds of warnings in case of database issues.

1. Failed to load data.
   To resolve this issue ensure that:
   - MAESTRO has access to the database
   - the network connection is stable and reliable when using a network drive to store the database
   - the data is not damaged (see section 4.2.2.5)

2. MAESTRO experienced an issue with the database while trying to store data.
   To resolve this issue ensure that:
   - there is enough space to save the data (disk is not full)
   - MAESTRO has access to the database
   - the network connection is stable and reliable when using a network drive to store the database
   - the data is not damaged (see section 4.2.2.5)

3. MAESTRO has detected a potential issue with the single file database.

To resolve this issue start the MAESTRO Database Management Tool and select the Repair a Database function (see section 4.2.2.5).

If none of the above mentioned suggestions resolves the issue contact your nearest MED-EL representative for further assistance.

4.2.2 MAESTRO Database Management Tool

The MAESTRO Database Management Tool is a stand-alone tool which is installed with MAESTRO. It combines the following database tools into one workflow-oriented user interface: Connect to a Different Database, Create a New Database (single file database or SQL Server database), Merge Two Databases, Migrate a Database and Repair a Database (see Figure 6).

The MAESTRO Database Management Tool can be started via the Windows program group MED-EL in the Start menu. In Windows 8 the tool is available as tile and can be found in the Apps window.

Database migration and merge functions require login to the source MAESTRO database. The user used for authentication to this database needs administrative rights to continue with the database migration or merge process.

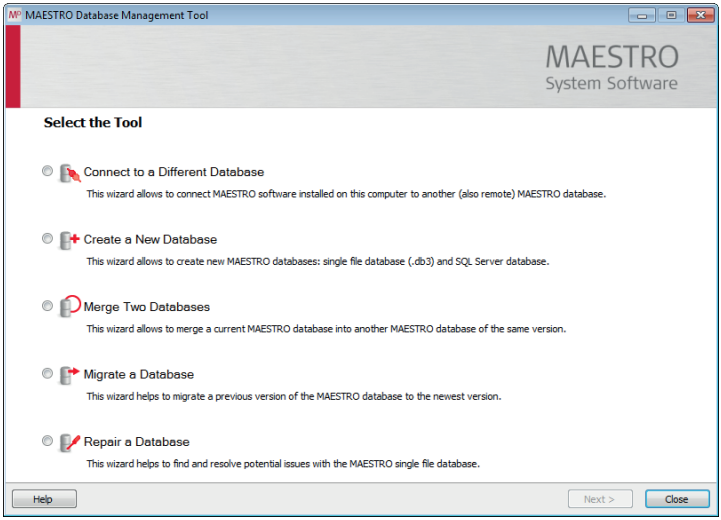


Figure 6 MAESTRO Database Management Tool

4.2.2.1 Connect to a Different Database

This tool helps the user to connect to or select a different MAESTRO database. When starting the wizard the currently connected database is displayed (see Figure 7). A click on the Select Another Database button provides the option to select a Single File Database (.db3) or an SQL Server Database.

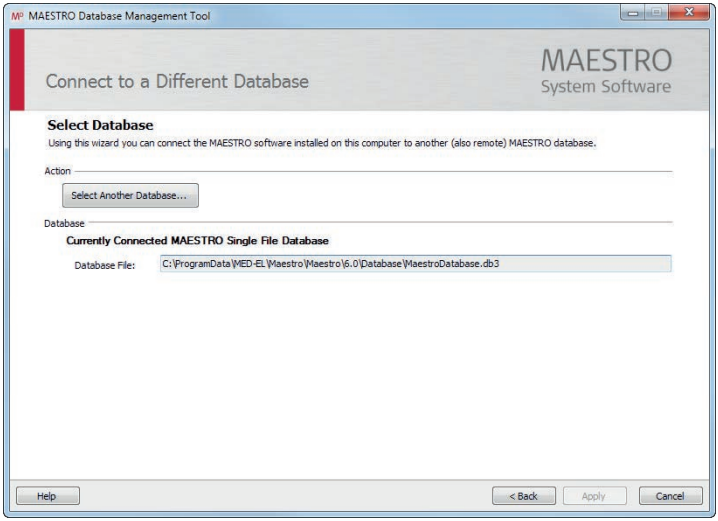


Figure 7 MAESTRO Database Management Tool – Connect to a Different Database

4.2.2.2 Create a New Database

This tool helps the user to create an empty MAESTRO single file or SQL Server database. When starting the wizard the button Create Database is displayed (see Figure 8), where the user can choose between a New Single File Database (.db3) or a New SQL Server Database. Depending on the selected option, a new window will open where the user can enter all properties of the new database.

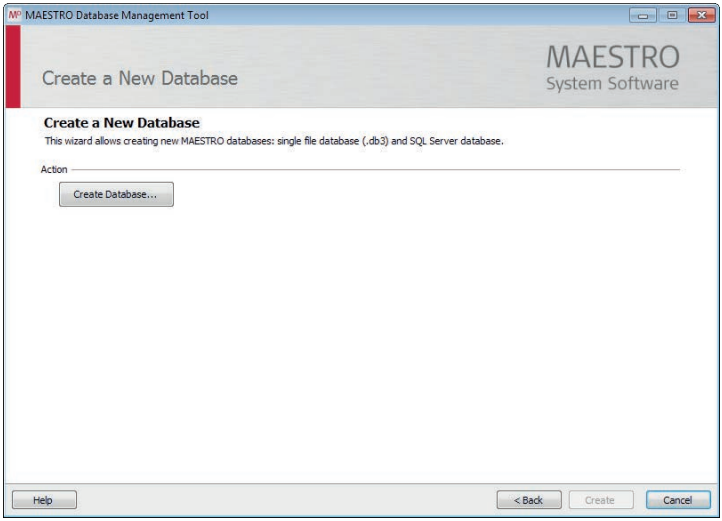


Figure 8 MAESTRO Database Management Tool – Create a New Database

To configure MAESTRO with an SQL Server Database for a network environment, click on Create Database, select New SQL Server Database and the Connection Properties dialog will open (see Figure 9). Enter a server name, the appropriate credentials and a database name, and click on OK.

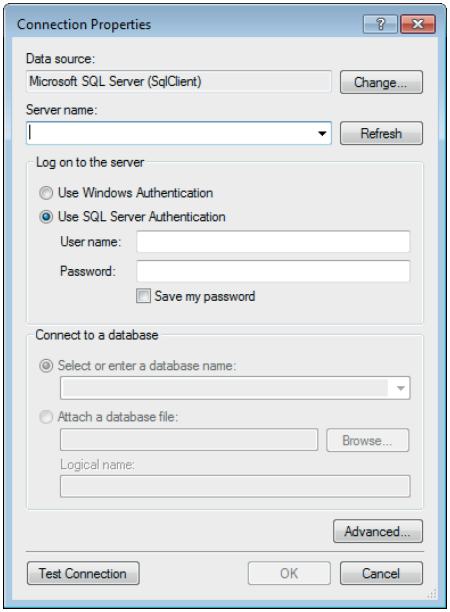


Figure 9 Setting up an SQL Server database

After confirming the new database the corresponding path appears in the main window and this database will be used as the new default MAESTRO database. Disable the checkbox at the bottom of the window to reject the usage of the new database as the default MAESTRO database.

NOTE:
When using a network-based SQL Server database, the administrator shall make sure that access is password-protected.

4.2.2.3 Merge Two Databases

This tool helps the user to merge two existing MAESTRO 6.0 databases. When starting the wizard the user has to choose the source MAESTRO database and enter the correct log in information for this database.

In the next step, the user selects the target MAESTRO database into which the source data will be loaded. After selecting the target MAESTRO database the following merge options are selected by default: Include patients and tasks, Include training data, and Include users.

Disable the checkbox at the bottom of the window to reject using the target database as the default MAESTRO database.

4.2.2.4 Migrate a Database

This tool helps the user to migrate data from a previous MAESTRO database version to the latest version. When starting the wizard, the user has to select the source MAESTRO database and enter the correct log in information for this database. In the next step, the user has to select or create the new target MAESTRO database (Single File Database or SQL Server Database). After selecting or creating the target MAESTRO database the following migrate options are selected by default: Include patients and tasks, Include training data, and Include users.

Disable the checkbox at the bottom of the window to reject using the target database as the default MAESTRO database.

NOTE:
Depending on the size of the existing database, note that the database migration process may take several minutes. Please ensure that adequate time is allotted for this process to complete.

If a previous version of MAESTRO has already been installed on your PC, you can migrate existing databases directly into the new database after installation. You may also perform database migration at any later time.

4.2.2.5 Repair a Database

Following a hardware or operating system fault the MAESTRO single file database can be corrupted. With the new Repair a Database tool the user can repair a broken database of the latest MAESTRO version as well as a broken database of the previous MAESTRO version up to a certain point. The tool distinguishes between two kinds of corruptions: those concerning the file format and those concerning the structural level.
In case of file format corruption all healthy records are extracted and put into a new database. It may happen that certain records cannot be saved and are lost.
In case of a structural corrupted database the tool restores, ignores or deletes the corrupt data depending on the kind of structural defect.

NOTE:
The Repair a Database tool can only be applied to single file databases that are not used by the MAESTRO software, i.e. to repair the currently used database the MAESTRO software has to be shut down.

To start the Repair a Database tool select Repair a Database in the Database Management Tool and click on Next.
The tool suggests to repair the currently used MAESTRO single file database, but with a click on Select Different Database other databases can be selected as well (see Figure 10).

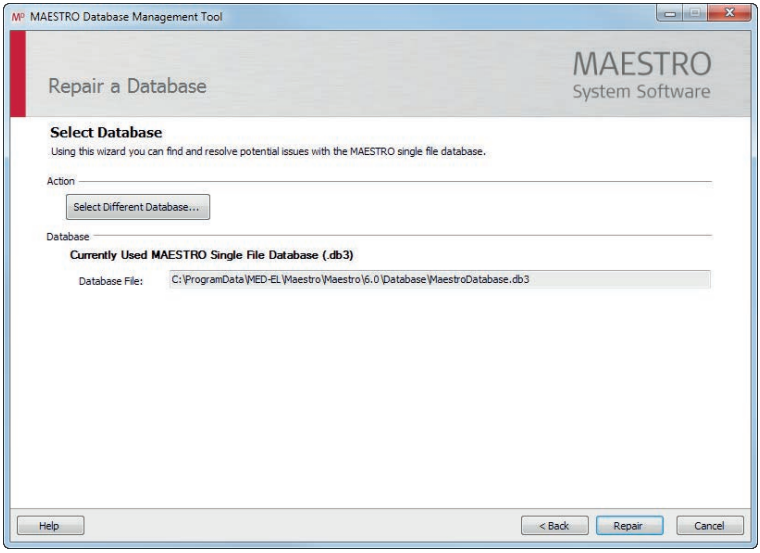


Figure 10 MAESTRO Database Management Tool – Repair a Database Tool

A click on Repair starts the repair of the selected database. A log window informs the user about the progress (see Figure 11). The repair process can be canceled at any time by a click on the button Cancel and the selected database keeps its original form.

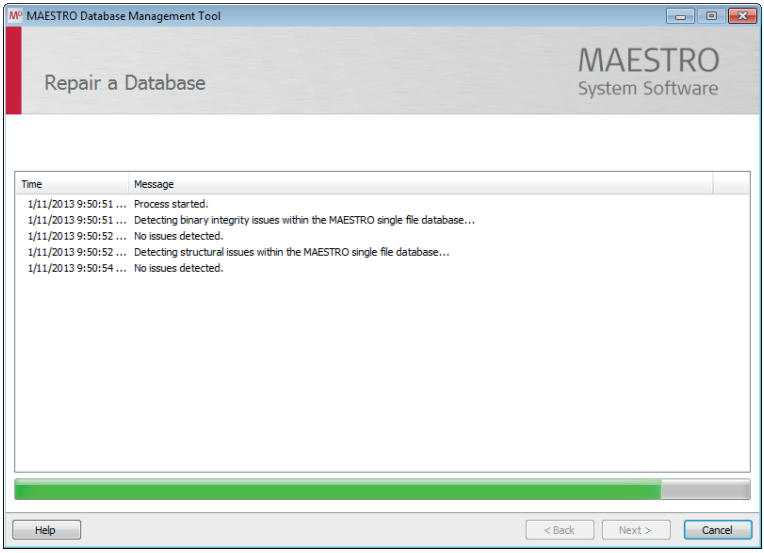


Figure 11 Repair a Database log window

NOTE:
Depending on the size of the database the repair tool may take considerable time for the repair.

After this process is completed a summary window appears.

Only one special type of defect may require further action by the user.

If the personal data of a patient is lost due to a binary corrupted database but the corresponding task data could be repaired, the repair tool restores a patient record named Patient Record, Restored and automatically adds all task data related to this patient to it. The user has to identify the restored patient with a real person, enter missing patient data, replace generic entries with real data in the patient editor and verify the restored ear data. The next time the processor of this patient is connected to the MAX Programming Interface, the software recognizes this patient and the user may decide to overwrite the personal data of the restored patient and insert the data stored on the processor.

NOTE:
In such a case data stored in the Address and Contact tab have to be added manually by the user.

In the event any repairs are performed, the tool creates a backup of the original file and saves it in the following directory:
%ProgramData%\MED-EL\MAESTRO\MAESTRO\6.0\Database\RepairBackup\YYYY-MM-DD_HH-MM-SS

If the Repair a Database tool fails to repair the corrupted database contact your nearest MED-EL representative for further assistance.

4.3 STRUCTURE OF MAESTRO

The general structure of MAESTRO is divided into five sections (see Figure 12):

1. The toolbar is displayed at the top section of the user interface. It provides various functions to customize MAESTRO, and the most important tools and symbols for quick selection.
2. The Task dialog on the left side provides buttons to work with patient data (see section 5.16), user data (see section 5.15) and the MAESTRO tasks after selecting a patient (see section 6 and sections 5.16.3, 5.16.4). Selecting the applicable tab at the bottom the user interface displays the Processor Configuration or Sessions dialog. The Processor Configurations dialog contains information about every connected processor (see section 5.6) and the Sessions dialog displays all sessions for a patient (see section 5.7).
3. The Work View in the center of the user interface displays the user editor, the patient editor and the dialogs of the tasks.
4. Selecting the applicable tab in the lower section of the user interface displays the Notifications or Log dialog. The Notifications dialog displays warnings and information to support the user while working with MAESTRO (see section 5.4). The Log dialog displays the log information which is automatically created when working with MAESTRO (see section 5.5).

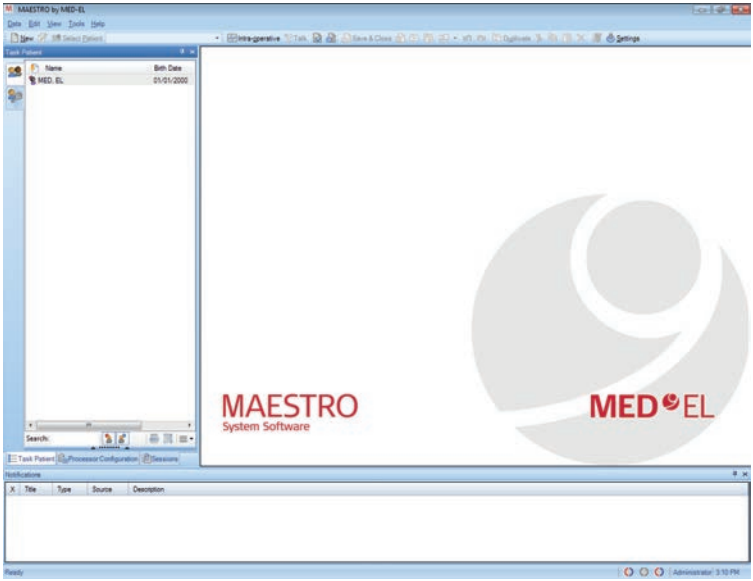


Figure 12 MAESTRO user interface

5. The status bar at the bottom of the MAESTRO window displays information such as selected patient, hardware information and the current user.

The hardware information area in the status bar represents the front panel of the MAX Programming Interface and offers information about the hardware connection. An established connection to the MAX Programming Interface is indicated by three circles which represent the three sockets on the front of the MAX Programming Interface, otherwise a message informs the user that no hardware is connected.

The left circle corresponds to the left processor socket, the right circle to the right processor socket and the circle in the middle corresponds to the telemetry socket.

Every circle symbol is divided into an outer part consisting of two half rings (see Figure 13) and an inner part, a disk (see Figure 14).

When illuminated the two half rings indicate which side the corresponding socket can work with. For the processor sockets this means that they can be either red or blue in fixed port mapping or red and blue in case of dynamic port mapping (see section 4.5).

The half rings of the telemetry socket are only enabled when the user opens a task that requires a MAX coil to be connected to the MAX Programming Interface (e.g. IFT) and therefore can be red or blue. If no such task is open they are grey. The MAESTRO software synchronizes the half rings in the status bar with the LEDs on the MAX Programming Interface. The LEDs can be disabled in the hardware settings (see section 4.5).

Figure 13 Dynamic port mapping (left) and fixed port mapping (right)

The inner part of the circles indicates if a device is plugged in:
A full red disk within a circle means that a device, e.g. MAX Programming Cable with a processor is connected to the corresponding socket and can be used for a patient's right ear. For the left ear the disk is blue-colored. On the right side of those circles additional information is displayed. If a processor is connected its type is shown and the current settings are added in brackets. Place the mouse over the processor type in the status bar to display the serial number of the processor in a tooltip. A light grey disk indicates that no external device is connected.
The disk in the middle (telemetry socket) will only be enabled when a task is opened that requires a MAX coil and a MAX coil is connected. In this case the disk has the color of the side of the task and the corresponding implant type is displayed.

An X in a circle indicates that cable and socket do not match (e.g. MAX Programming Cable with processor plugged into the telemetry socket) and can therefore not be used.

Figure 14 Left: OPUS 2 and MAX coil connected correctly; Middle: TEMPO+ connected correctly, but additional processor connected to Telemetry socket; Right: OPUS 2 connected correctly, but MAX coil connected to Processor socket

The MAESTRO user interface can be customized. The positions of individual fields can be changed. Some fields can be hidden by clicking on the symbol Auto Hide or closed by clicking on the symbol Close. The default view can be restored at any time by selecting Reset User Interface layout from Tools in the toolbar.

4.4 USER INTERFACE

Under Settings | User Interface the user interface can be customized. Figure 15 shows the User Interface Settings dialog.

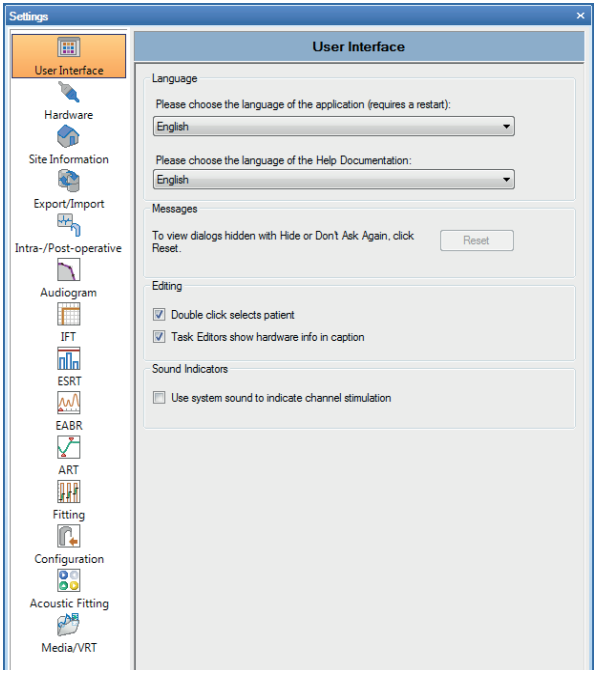


Figure 15 User Interface settings dialog

In the area Language the language of the application and the documentation can be selected.

By clicking on the Reset button in the area Messages hidden dialogs are displayed again.

The checkbox Double click selects patient defines if a patient can be activated by a double-click while Task Editors show hardware info in caption displays hardware information in the title of the task. Both checkboxes are selected by default.

Selecting the checkbox Use system sound to indicate channel stimulation activates an audible signal so that the clinician can hear a simulation of the stimulation pulses to assist with fitting.

4.5 HARDWARE CONNECTIONS

MAESTRO is used in conjunction with the MAX Programming Interface. The hardware setup is described in the MAX Programming Interface user manual. With the installation of MAESTRO the required driver for the MAX Programming Interface is installed automatically.

CAUTION:
For patients with a SYNCHRONY implant always use the MAX Coil S, for all other patients use the MAX Coil. For instructions applying to both coil types, the term MAX coil is used in this user manual.

NOTE:
In some instances the presence of metallic objects, such as metallic desks or surfaces, surgical tools, jewelry, etc. close to the MAX coil may affect measurements (e.g. Coupling Check, Telemetry, ART, etc.). In the case of unexpected results under these circumstances, reposition the metallic object further away from the MAX coil and repeat the measurement.

The MAX Programming Interface has three sockets, the left and right socket to connect processors and the middle one to connect the corresponding MAX coil. If the connected cable and socket are not compatible (e.g. MAX Programming Cable with processor plugged into the telemetry socket) an X in the status bar indicates that MAESTRO cannot communicate with this device.
The LEDs on the MAX Programming Interface as well as the half rings in the status bar indicate which side the socket can work with (see section 4.3).

MAESTRO provides two working modes for the MAX Programming Interface – a dynamic mode and a fixed mode. The dynamic mode allows the user to choose the processor socket for the right or left ear individually, while the fixed mode maps a static constellation (left socket for the right ear, right socket for the left ear) to the processor sockets.

NOTE:
In neither mode is it possible to work with two processors for the same side.

Dynamic mode:
The user can choose the processor socket to plug in a processor.
The MAESTRO software will assign the socket to the side the processor was programmed for, the other socket is then automatically assigned to the other side.
In the case of an empty processor the user has to decide which side the processor should work with.

Fixed mode:
The user can not choose the processor socket to plug in a processor.
An already programmed processor always has to be plugged into the socket mapped for the corresponding side.
An empty processor connected to a socket in fixed mode is automatically assigned to the side the socket works with.

NOTE:
MAESTRO always works with the side the MAX Programming Interface socket reflects, even if the connected processor is programmed for the other side.

In both modes it is possible to select a patient and work with a processor which is programmed for a different patient or side as long as the processor is connected to the correct socket. Nevertheless it is highly recommended to reset the processor first when not working with the same patient and side the processor is already programmed for.

NOTE:
Reset a programmed processor first before using it for a different patient or side.

Information about the connected hardware is displayed in the status bar and in the toolbar under Settings | Hardware. Figure 16 shows the Hardware dialog.

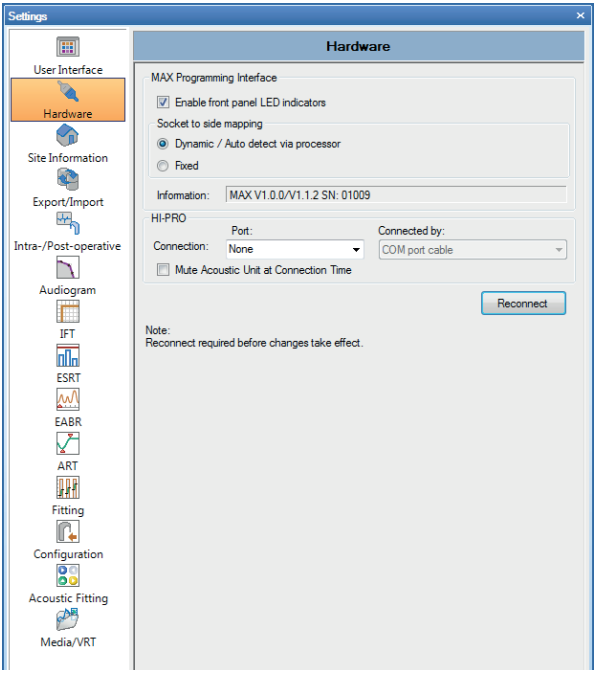


Figure 16 Hardware settings dialog

Selecting the checkbox Enable front panel LED indicators enables the LEDs on the MAX Programming Interface. In the area Socket to side mapping the user can decide to use either Dynamic/Auto detect via processor (dynamic mode) or Fixed (fixed mode). The dynamic mode allows the user to choose the processor socket for the right or left side individually when using an empty processor or to auto detect the side of an already programmed processor. The fixed mode maps a fixed configuration (left socket for the right side, right socket for the left side) to the processor sockets. When using the fixed mode the connected processor has to fit the side configuration of the socket. The line Information displays information about the connected MAX Programming Interface.

NOTE:
MAESTRO can only work with one MAX Programming Interface, therefore connect only one MAX Programming Interface to the computer.

Bilateral fitting with the MAX Programming Interface is possible by selecting a bilateral patient and connecting two processors to the two processor sockets.

In the HI-PRO field, the port for a connected HI-PRO interface box may be selected. The HI-PRO is required for software-based acoustic fitting of the DUET 2 audio processor; however, the acoustic unit can also be adjusted manually using the trimmers. Connected by determines whether the HI-PRO interface box is connected via a USB cable or a COM port cable.

Selecting the Mute Acoustic Unit at Connection Time checkbox automatically deactivates the acoustic unit of the DUET 2 audio processor when connecting with the HI-PRO interface box.

Modified settings will be effective after pressing Reconnect, otherwise the settings will be applied only after the next reboot.

After MAESTRO has identified a MAX Programming Interface, this information is also displayed in the status bar (see section 4.3) at the bottom of the MAESTRO window (see Figure 17).

Figure 17 Status bar

4.6 SITE INFORMATION

Site Information can be entered by the user under Settings | Site Information.
The entered information in the field Short Title (e.g. name of the clinic) will be printed on reports as additional information. Figure 18 shows the Site Information dialog.

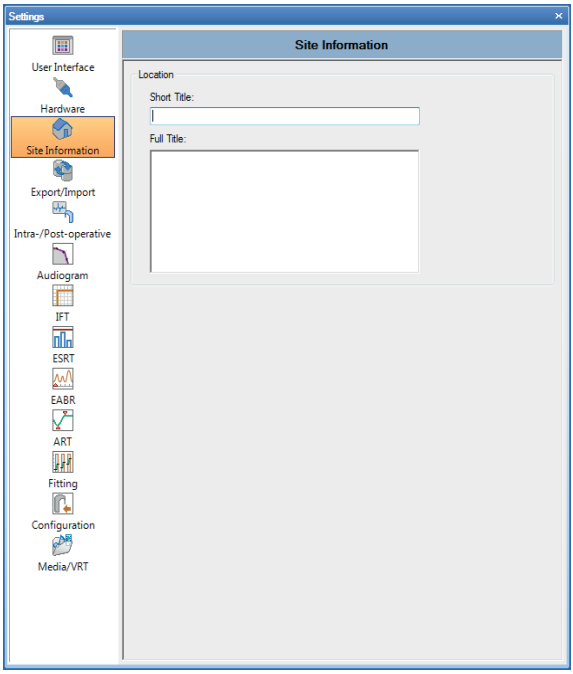


Figure 18 Site Information settings dialog

5. Working with MAESTRO

The chapters below describe the basic features necessary to work with MAESTRO. Beside the general setup of the user interface, this also includes administration of user data and patient data.

5.1 LAUNCHING MAESTRO

When launching MAESTRO, the Welcome dialog shown in Figure 19 opens.

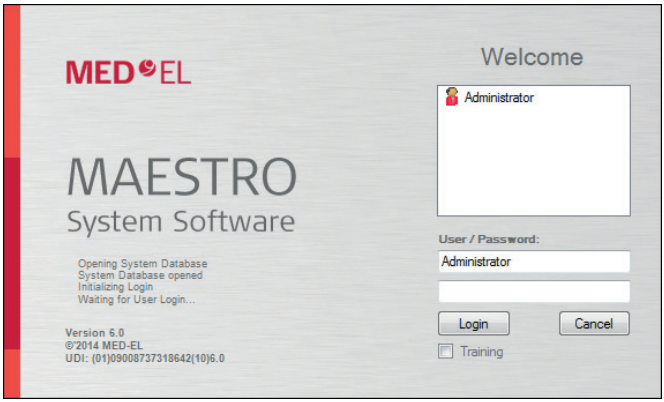


Figure 19 MAESTRO Welcome dialog

At the first launch of the application only the default user Administrator is shown in the user list. This user is automatically created during setup. Click on Administrator and then on the button Login to create a password for this user.

The default user Administrator has administrator rights and, when logged in as Administrator, can create other users (see section 5.15).
We recommend to create a separate user for every person using the application.

All created users are displayed in the Welcome screen in the user list whenever launching the software.

To log in as a certain user, click on the applicable user name or enter the user name directly in the field User. Then enter the applicable password in the field Password and click on the button Login to start the application. After successful log in, the user interface opens

5.2 LAUNCHING MAESTRO IN TRAINING MODE

For training purposes MAESTRO can be used without connected hardware. To launch MAESTRO in the Training Mode, select the checkbox Training in the Welcome dialog as shown in Figure 20. Enter the user name and password as described in section 5.1.

Figure 20 Launching MAESTRO in Training Mode

A grey title in the left upper corner of the user interface indicates that MAESTRO is used in the Training Mode. When launching MAESTRO in the Training Mode, a notification appears stating that MAESTRO is in the Training Mode. The user interface of MAESTRO in the Training Mode is shown in Figure 21.

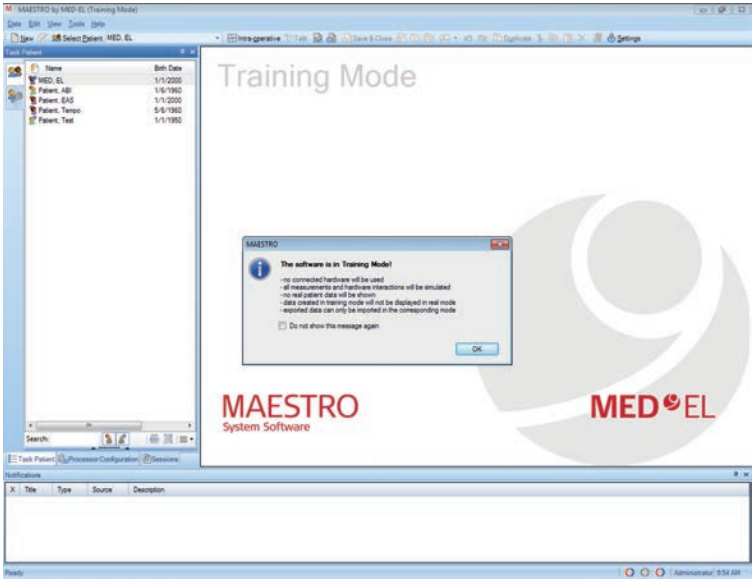


Figure 21 MAESTRO user interface in the Training Mode

The settings of the Training Mode can be changed under Settings | Training Mode in the toolbar. Figure 22 shows the Training Mode dialog.

In the General section selecting or deselecting the checkbox Simulate real-time behavior defines if the measurements performed in the Training Mode have real-time durations. This checkbox is selected by default so that all measurements in the Training Mode are performed in real-time.

In the Telemetry section selecting the applicable option defines the telemetry results. Options are Perfect measurement, Multiple short-circuits and Problematic measurements. The default is Perfect measurement.

In the ART section selecting the applicable option defines the results of the ART measurement. Options are Ideal response, Ideal response with artifacts and No response. The default is Ideal response with artifacts.

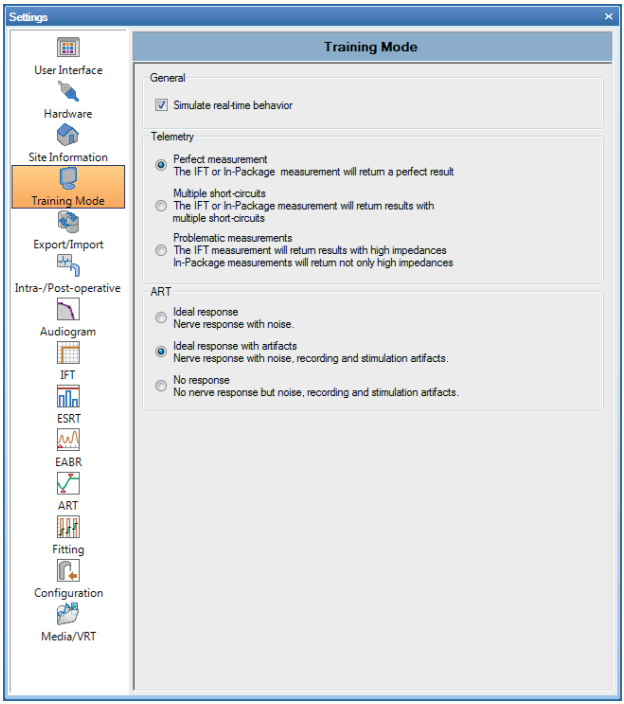


Figure 22 Training Mode settings dialog

5.3 ACTIVATING THE INTRA-OPERATIVE MODE

After launching MAESTRO the Intra-operative mode can be activated via the button Intra-operative in the toolbar. In this mode all activities are marked as Intra-operative.

The Intra-operative mode must be activated before selecting a patient (see sections 5.16.3 and 5.16.4). While a patient is selected, the Intra-operative mode cannot be activated or deactivated. Working in the Intra-operative mode is only possible when the surgical date given in the Patient Data (see section 5.16.1.3) is identical with the current date.

The tasks IFT, ART, ESRT and EABR are available in the Intra-operative mode (see section 6).

The settings of Intra and Post-operative mode can be customized under Settings | Intra/Post-operative in the toolbar. Figure 23 shows the Intra/Post-operative dialog.

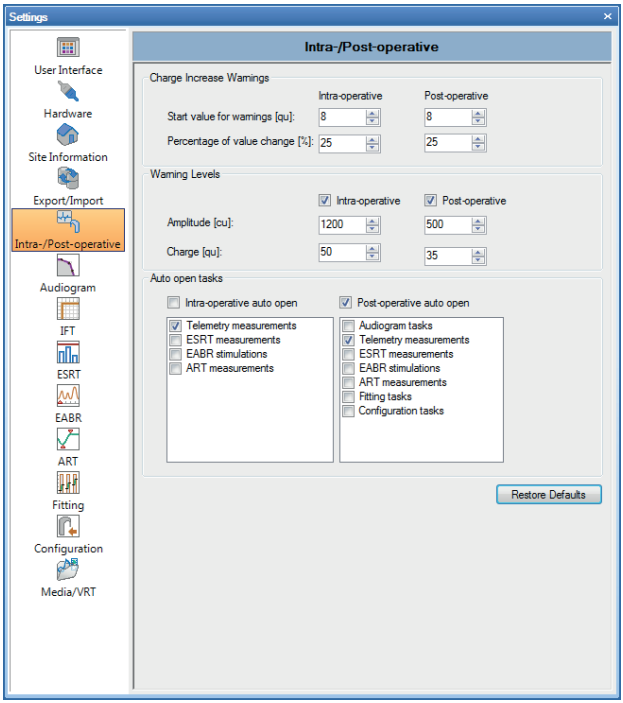


Figure 23 Intra/Post-operative settings dialog

A start value for warnings can be defined in the Charge Increase Warnings section. In addition, the percentage of value change for warnings can be defined.

An amplitude threshold in cu and a charge threshold in qu (see section 5.14) for warnings can be defined in the Warning Levels section.

Selecting the applicable checkbox in the Auto open tasks section defines if and which new tasks are automatically opened when selecting a patient. Clicking on the button Restore Defaults resets all values to their defaults.

5.4 NOTIFICATIONS

At the bottom on the left side the Notification window of the MAESTRO software provides additional information for the user, e.g. missing data the user has to add. Some of the notifications need to be confirmed before work with the software can be resumed. Notifications about problems with the connected hardware or inserted data exceeding security limits, for instance, require confirmation, while a notification about a missing implant serial number does not. Confirmation can be done by enabling the checkbox on the left side of the notification. The notification window blinks when resuming work with the software is not possible until a certain problem is solved by the user (e.g. insert missing data, confirmation of a notification).

5.5 LOG FILE

The log is automatically started every day the MAESTRO software is launched, and is saved as a separate file for each day. Therefore, a log file may contain data of several sessions, if MAESTRO has repeatedly been used during a single day. The log file is mainly used to record error messages, communication problems, etc. Only some of the log entries are visible to the user at the time.

The log is not intended to be used in a standard clinical session, but can be referred to in certain cases where it is necessary to track issues, especially if it is necessary to refer to a MED-EL Representative for troubleshooting. With the help of the log file it is much easier to identify the cause of a problem.

The log file is automatically saved to the MAESTRO standard directory for log files with its date. It can be accessed by Windows via the Windows program group MED-EL in the Start menu or via the Apps window (Windows 8). The log file can also be sent to MED-EL for troubleshooting as email using the MAESTRO tool Email log files (see section 5.12.8).

5.6 PROCESSOR CONFIGURATION

The Processor Configuration view provides information about all connected processors. This information contains processor related information, e.g. ear side, type or serial number of the processor as well as the name of the patient if the processor is already programmed. If the same patient is selected, the name of the configuration and its maps with their positions on the processor are displayed as well. For SONNET and SONNET EAS audio processors additional information about Datalogging and Link Monitoring is displayed. The Processor Configuration view may display up to two processors since the MAX Programming Interface has two processor sockets (see Figure 24). A click on the processor type enables the Reset Processor button and a further click on Reset Processor resets the processor. Selecting the patient, a specific map or configuration of a programmed processor allows opening the corresponding dialog with a click on the Edit button.

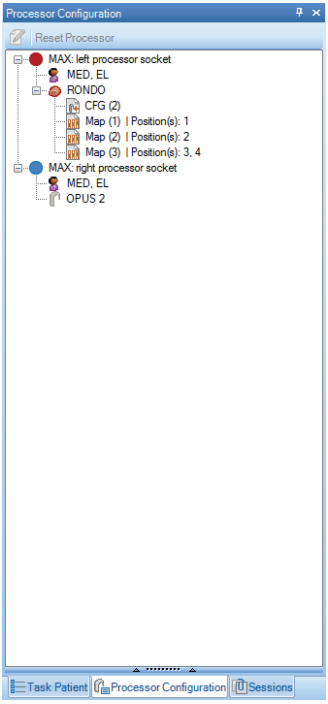


Figure 24 Processor Configuration

NOTE:
The Processor Configuration view only shows the current configuration of the processor. Changes made to configurations or maps do not affect the processor unless they are downloaded to the processor in a new configuration.

5.7 SESSIONS

The Sessions view provides information about sessions done with a patient. After selecting a patient the session view lists all sessions with their dates and MAESTRO users. A click on the session itself enables the Create Session Reports button and a session report can be created. A click on the + sign next to each session lists all tasks saved within this session. Selecting one task allows to edit or delete the task with the buttons Edit and Delete.

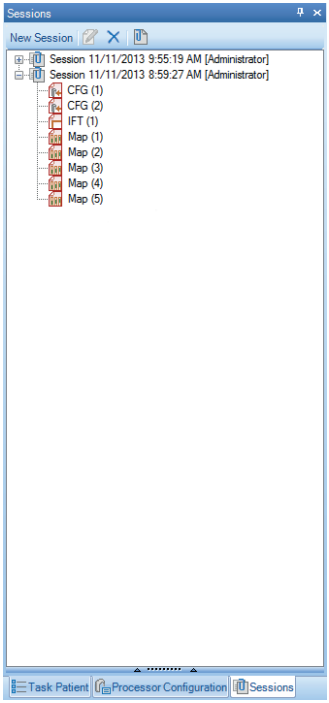


Figure 25 Sessions view

5.8 IMPORT/EXPORT

MAESTRO enables exporting and importing all patient and task data. This function can be activated by selecting the option Data | Export Data or Data | Import Data in the toolbar.

5.8.1 Export data

Selecting Data | Export Data opens the dialog shown in Figure 26.

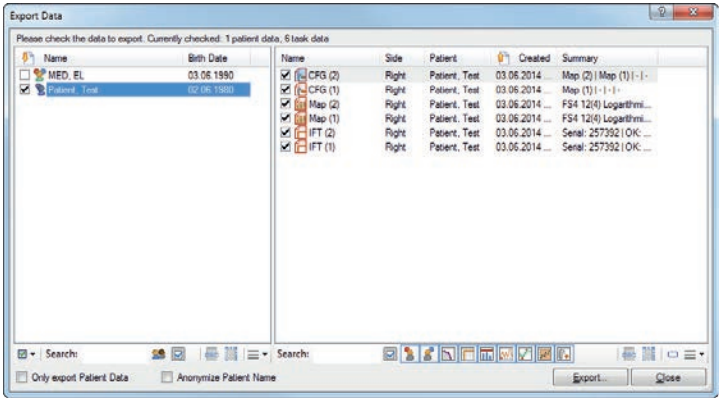


Figure 26 Export Data dialog

The left part of the dialog lists the patients in the database,the right part individual task data. Individual entries can be selected by activating the applicable checkbox. The data to be exported can be selected.

Several buttons in the lower part allow limiting the displayed datasets.

Clicking on the button Check Items ☑ in the left bottom corner opens a dialog providing various options to select or deselect individual datasets. All selects all datasets, None deselects all datasets. The option Last Task Data selects the data last saved for each task. The option Latest Configuration Data selects the configuration data last saved and the associated maps. Clicking on Advanced Selection opens the dialog shown in Figure 27.

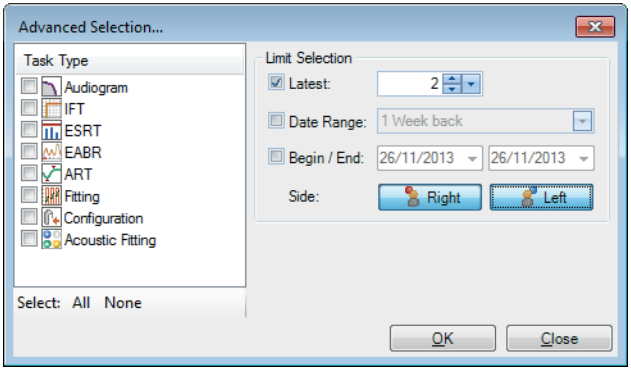


Figure 27 Advanced Selection dialog

Advanced Selection allows the user to limit the list of data to be selected for export. Task Type limits the displayed data to certain task types. Clicking on the buttons All or None selects or deselects all task types. Limit Selection limits the number of the desired data. Latest defines how many of the last saved data will be preselected. Date Range defines a period. Only data generated during the selected period will be selected. Begin/End defines an accurate date period for which data will be selected. All fields can be blocked by deselecting the associated checkbox. The applicable data will not be preselected. The buttons Right and Left define if data of one side or both sides will be selected. Clicking on OK closes the Advanced Selection dialog and applies the settings for data display. Clicking on the button Close closes the Advanced Selection dialog without applying the settings for data display.

Search allows limiting the displayed patient or task data to entries containing the character sequences entered in the field Search. After activating the field Show only Checked only the selected data are displayed. The buttons Select all and Invert Selection allow selecting all data or inverting the current selection. The button Select Columns allows the user to display further columns for the selected data. Activating the button Group Items shows a grouped display of the data.

Activating or deactivating the other symbols allows displaying the data according to current patient, side or a certain task.

Selecting the checkbox Only export Patient Data or Anonymize Patient Name limits export to patient data or personal patient data in anonymized form.

Clicking on the button Close closes the Export Data dialog and terminates export. Clicking on the button Export opens a new browser window to save the export file to the desired directory. The selected data can be exported as a MAESTRO Packed Database File (*.mpd) or a scientific XML File (*.xml). The scientific XML File is a text only XML file. Reimporting a scientific XML File into MAESTRO is not possible.

CAUTION:
Analysis of exported data must not be taken as the sole basis for any decision about further medical or surgical treatment.

5.8.2 Import data

Selecting Data | Import Data opens the dialog shown in Figure 28.

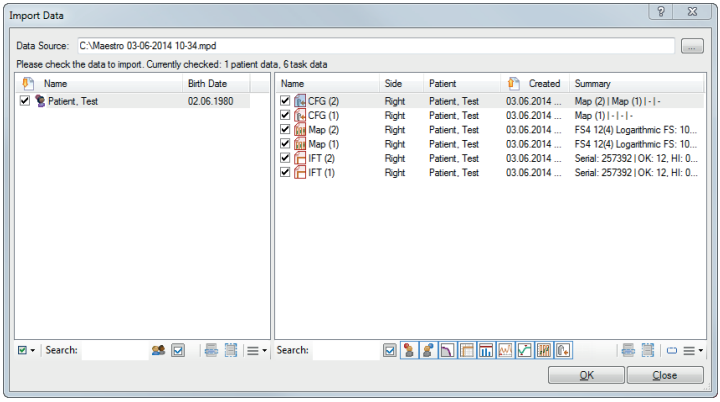


Figure 28 Import Data dialog

The basic structure and the functions of the individual buttons are similar to the Data Export dialog (see section 5.8.1). Data for import are selected by clicking on the button on the right side of the field Data Source. All *.xml (except scientific *.xml), *.xmlp and *.mpd files created by MAESTRO can be imported.

5.8.3 CI.STUDIO+ data import

MAESTRO allows importing patient and fitting data from the CI.STUDIO+ fitting software by selecting the directory where the CI.STUDIO+ data is saved in the Settings | Export/Import dialog. When creating a new patient (see section 5.16.1) the data saved to the selected directory is available in the CI.STUDIO+ Patients section.

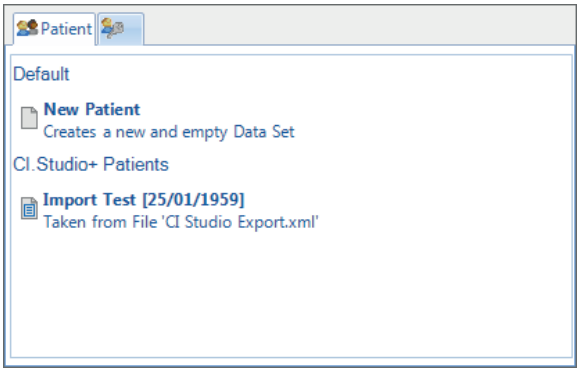


Figure 29 Dialog to create a new patient

Selecting the patient in the CI.STUDIO+ Patients section opens the Patient Data editor (see section 5.16.1). After saving the patient data an entry appears in the patient database. The patient can now be selected (see section 5.16.3 and 5.16.4).

If a TEMPO+ is connected, the dialog to open the Fitting task (see section 6.6.2) shows the maps available for this patient in the area CI.STUDIO+ based TEMPO+ maps.

If another processor type is connected, the dialog to open the Fitting task shows the maps available for this patient in the areas CI.STUDIO+ based FS4 Maps and CI.STUDIO+ based HDCIS Maps. Clicking on a map opens the fitting map (with the corresponding coding strategy) and is available for further fine tuning.

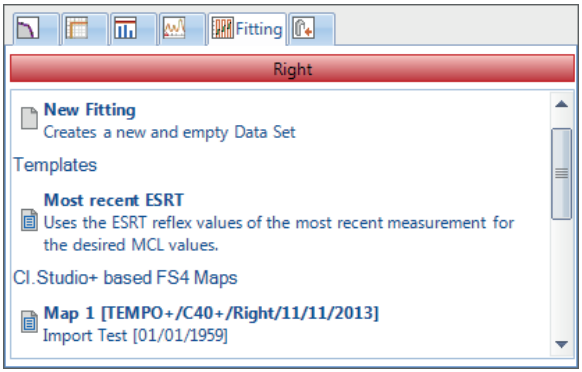


Figure 30 Dialog to open the Fitting task

Clicking on a map opens the fitting map in the legacy mode as indicated in the Notification window. If the user wants to work with the map or change any fitting parameters they have to confirm this in the Notification window and the fitting map will be converted.

If the user does not want to convert the map, the user must not check the information in the Notification window. The map will stay in read-only mode and the user can only close, save and program the map to the processor.

In both cases the map will still be compatible with the CI.STUDIO+ software.

NOTE:
To perform an upgrade from TEMPO+ to another audio processor type, it is essential that the map is converted.

5.8.4 MAESTRO Scientific Data Tool

With the MAESTRO Scientific Data Tool the data exported from the MAESTRO software into Scientific XML (eXtensible Markup Language) format can be imported into a relational database like Microsoft Access or Microsoft SQL Server. The tool allows subsequent imports of several XML files into one database. The relational database format supports easy scientific or statistical evaluations and queries.

The MAESTRO Scientific Data Tool is, like the MAESTRO Database Management Tool, an independent program which is installed with MAESTRO and accessible via the Windows program group MED-EL in the Start menu. In Windows 8 the tool is available as tile and can be found in the Apps window.

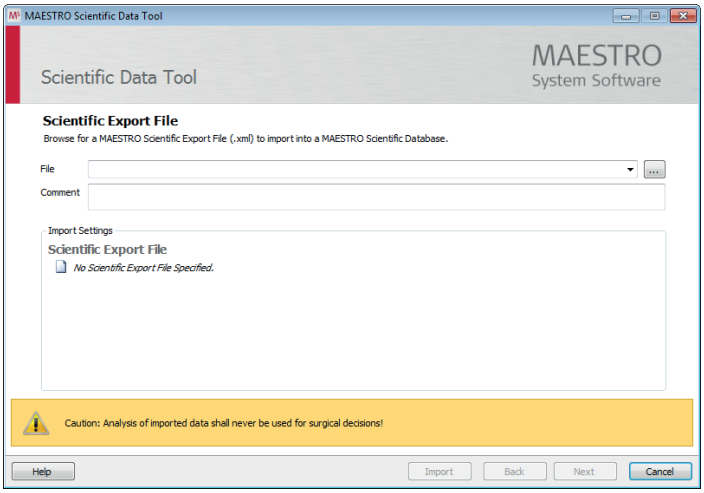


Figure 31 MAESTRO Scientific Data Tool

First select the MAESTRO export file and click on Next. Optionally, a comment can be entered. In the next step, select the type of data to be imported into the MAESTRO scientific database. In the Options section the patient data can be anonymized. The next steps require the user to select the type of the scientific database (Access or SQL Server), followed by the page dialog to select the respective file path. Additionally, the user can choose to (a) keep the existing database and preserve existing data in conflicting situations, (b) keep the existing database and overwrite existing data in conflicting situations, or (c) overwrite the existing database and/or create a new database.

Before the data is converted, a summary lists all user-selected options. A click on Import starts the import process.

CAUTION:
The output of the MAESTRO Scientific Data Tool must not be taken as the sole basis for any decision about further medical or surgical treatment.

5.9 TALK BUTTON

Select a patient and connect the patient's processor to the MAX Programming Interface. The button Talk in the taskbar activates the current processor program.

5.10 REPORTS

As support for clinicians MAESTRO also provides a report function (see Figure 32). After clicking on Data the user can choose between four different report functions: Reports, History Reports, Session Reports and User Reports. The buttons for the most used reports, Reports and History Reports, can be found in the toolbar as well. Reports can be created for user data (User Reports), session data (Session Reports), patient and task data (Reports) and period (History Reports). History Reports additionally provide an area to set a specific period so that the report only contains patient or task data created in this period.

After clicking on Data | Reports, History Reports or Session Reports the reports window opens. At the top of this window, the user can define filters to limit the data that will be contained in the report. This section is called Selector and may be shown or hidden by clicking on the Show Selector button at the bottom. On the left side of the Selector there is a filter for patients and on the right side a filter for sessions (Session Reports), tasks (Reports) and period (History Reports) corresponding to the selected patient. With the help of icons the user can choose to show only special tasks or data of the left or right side.
User Reports creates a report with information about all users. For this report no additional selection options or filters are available.

Below the Selector a preview of the report is shown with the option to zoom and switch between different pages. The user can anonymize the patient name by enabling the corresponding checkboxes at the bottom of the window.
With a click on Output Options the user can print comments, choose the file format for the report, change the page settings and decide if patient data should be printed.

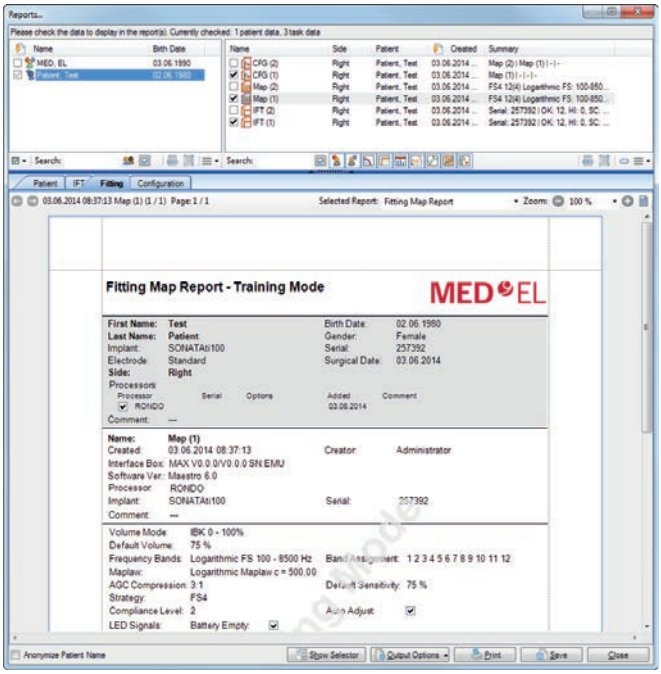


Figure 32 Reports

5.11 DUPLICATE

The function Duplicate in the toolbar allows generating new task data with settings identical to those of existing task data. A copy of the task data is labeled like the original but followed by a ~ symbol.

5.12 TOOLS

The Tools menu in the taskbar provides the options Coupling Check, Media Manager, Change Password, Combine Task Data, Tile Editors horizontally by Ear and Tile Editors vertically by Ear, Untile Editors, Reset User Interface layout, Email log files and Change Product Activation Key.

5.12.1 Coupling Check

The tool Coupling Check requires a connected MAX Programming Interface and a selected patient. Selecting Coupling Check opens the dialog shown in Figure 33.

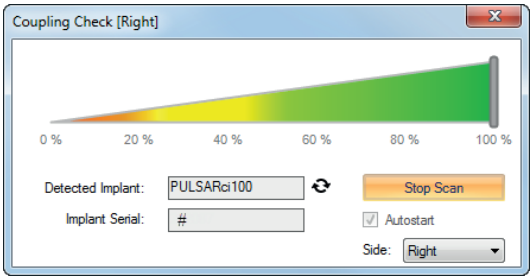


Figure 33 Coupling Check dialog

The tool allows searching for a SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} or PULSAR CI^{100} implant. Therefore place the corresponding MAX coil (see section 4.5) over the implant and click on the Start Scan button. If the implant could be found, the implant type and implant serial number are displayed.

5.12.2 Media Manager

The Media Manager tool is intended to manage media files (such as audio, video and image files) and playlists used in the Media Player tool (see section 5.13) and the Visual Reinforcement Tool (VRT) of the Fitting Editor.

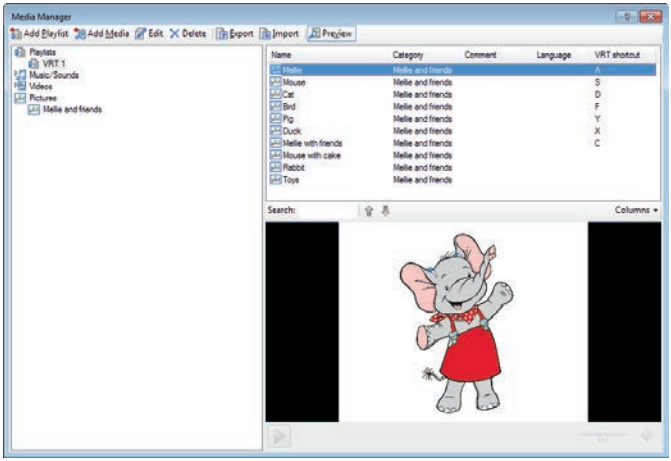


Figure 34 Media Manager

As shown in Figure 34 the user interface of the Media Manager tool consists of four parts: the toolbar on the top, the playlist and category tree view on the left side, the media list on the top right side and the preview on the bottom right side. The toolbar provides the essential functions for the Media Manager.

A new media file can be added by clicking on the Add Media button in the toolbar. New media files can also be imported by dragging them from the Windows Explorer into the Media Manager tree view. When adding a file by clicking on the Add Media button, a name and the file path have to be determined. Optionally, a category, comment or language can be entered. If no category is determined, the corresponding media file is shown in the category General. Already used entries for category and language can be selected from the drop-down menu.

A new playlist can be added by clicking on the Add Playlist button in the toolbar. To add media items to a playlist, drag and drop them from the media list to the desired playlist in the tree view. Drag and drop media files from the Windows File Explorer directly to a playlist to add them to the Media Library and to the playlist in one step. Within a playlist the first seven items

will be assigned to the VRT keys A, S, D, F, Y, X and C (for QWERTZ keyboard layout) or A, S, D, F, Z, X and C (for QWERTY keyboard layout).

With the Edit and Delete buttons, selected media files or playlists can be edited and deleted. Categories cannot be deleted but disappear when they are no longer used.

The Media Manager already contains a set of sample pictures and a sample playlist by default.

NOTE:
Opening images, videos or songs of high resolution or long play duration for display needs more time.

The whole media library can be exported to a single .pml (Packed Media Library) file with the Export button. A Packed Media Library file can be imported using the Import button or drag-and-drop from the Windows File Explorer.

The Preview button toggles the preview window on or off.

The playlist and category tree view provides a hierarchical view of the media library contents. It displays playlists and media categories grouped by media type such as music/sound, pictures or videos. The content of a media category selected in the tree view is displayed in the media list. The content of a selected media item is displayed in the preview. The volume can be adjusted using the volume slider on the right, or muted and unmuted by clicking on the speaker symbol.

To enable or disable full-screen-playback on additional monitors use the buttons with the monitor pictogram in the lower left corner of the media player. These buttons only appear when additional monitors are configured in the Media/VRT settings (see section 6.6.4). Starting playback using the Play button displays the selected media item on all enabled full-screen monitors. Stopping playback using the Stop button immediately stops display on the enabled monitors. A full-screen-monitor set to disabled will not show any images or videos until it is enabled.

Figure 35 Playback with enabled additional monitor 1 and disabled additional monitor 2

5.12.3 Change Password

The tool Change Password allows changing the password for the currently logged in user required for launching MAESTRO (see sections 5.1 and 5.2).

5.12.4 Combine Task Data

The tool Combine Task Data allows combining datasets of one patient. To combine task data and write them into one patient data set, first name, last name, date of birth and implant system (implant type and electrode) must be identical in both entries. After highlighting the datasets in the database, selecting the tool Combine Task Data opens the dialog shown in Figure 36.

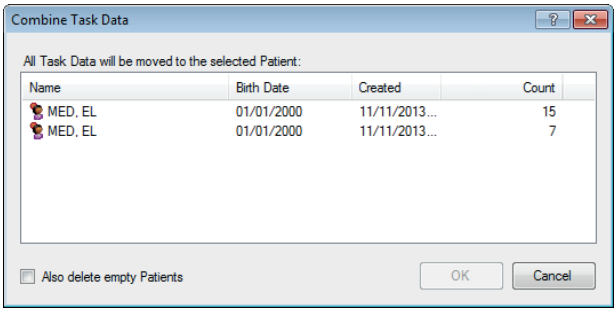


Figure 36 Combine Task Data dialog

One dataset must be highlighted in the Combine Task Data dialog. The other dataset is then added to this dataset. Selecting the checkbox Also delete empty Patients automatically deletes the not selected empty dataset.

5.12.5 Tile Editors horizontally and Tile Editors vertically by Ear

With a selected patient the tools Tile Editors horizontally by Ear and Tile Editors vertically by Ear allow dividing the user interface horizontally or vertically. All opened tasks for this patients will then be separated into two groups. Tasks for the right ear can be found on top or on the left side of the divided user interface while tasks for the left ear will be shown at the bottom or on the right side. A button in the toolbar additionally allows the user to switch between those user interface states, including Untile Editor (see section 5.12.6).

5.12.6 Untile Editors

The tool Untile Editors removes the division of the user interface and rearranges all open tasks into tabs of the work view. A button in the toolbar additionally allows the user to switch to this state, including Tile Editors (see section 5.12.5).

5.12.7 Reset User Interface layout

The tool Reset User Interface layout resets the layout of the MAESTRO user interface to the default settings.

5.12.8 Email log files

The tool Email log files allows the user to send all log files from a defined period as a password protected zip file. This is especially useful for sending log files to MED-EL.
Selecting the tool Email log files opens the dialog shown in Figure 37. The fields Start date and End date allow defining a period thus determining which log files will be sent as a password protected zip file. Clicking on the button Email opens a new e-mail notification to which the password protected zip file will be attached.

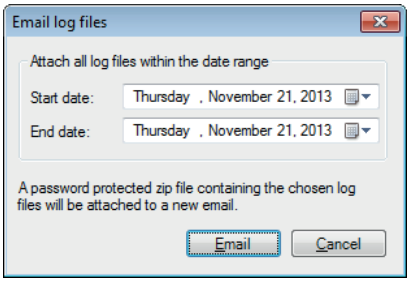


Figure 37 Email log files dialog

5.12.9 MAESTRO Product Activation Key Change Tool

The product activation key can be changed using the MAESTRO Product Activation Key Change Tool, which is installed together with MAESTRO. The user needs administrator rights within MAESTRO. The tool can be started from the Windows program group MED-EL in the Start menu. For Windows 8 the tool is available as tile and can be found in the Apps window. Additionally the tool is available by selecting Change Product Activation Key from the Tools menu in the MAESTRO toolbar.

Enter the login credentials and the new Product Activation Key. If the tool was launched within the MAESTRO application, the log in fields are already filled out and only the new Product Activation Key has to be entered. Accept the License Agreement for the Product Activation Key by selecting the checkbox (see Figure 38).

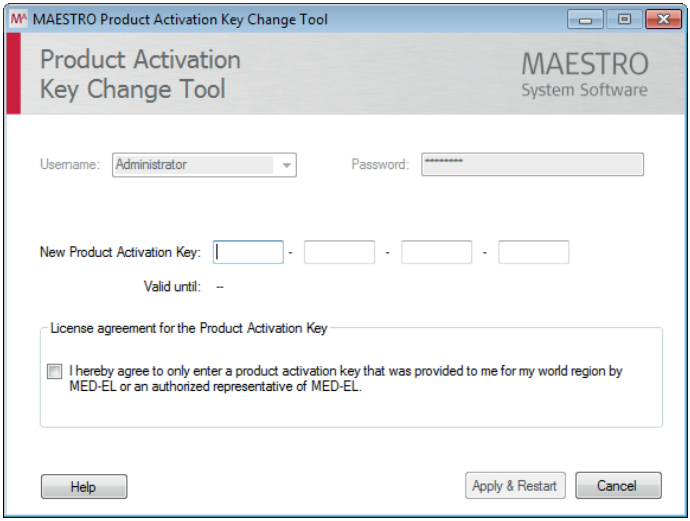


Figure 38 MAESTRO Product Activation Key Change Tool

5.13 MEDIA PLAYER

The Media Player tool can be started by selecting Media Player from the View menu in the toolbar. This tool can be used to play music and video files or to view images within MAESTRO. The Media Player also supports full-screen-playback on an additional second or third monitor oriented towards the patient. See section 6.6.4 Media/VRT settings how to configure additional monitors.

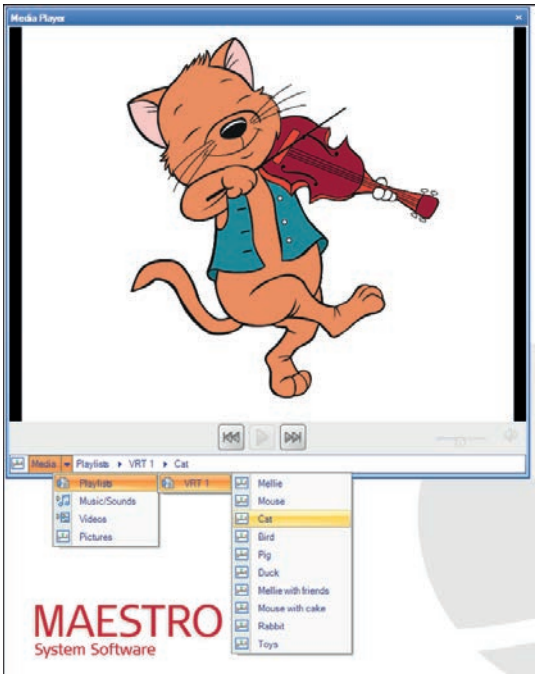


Figure 39 Media Player tool

To choose a specific media item or playlist, use the navigation at the bottom of the Media Player (see Figure 39). This navigation maps the hierarchical view in the Media Manager (see section 5.12.2) to a single line which can be navigated by clicking on the arrows between the groups, playlists, categories and media items.

Clicking on a group, category or playlist automatically selects the first media item contained in the selected item. Additionally, the Next and Previous buttons can be used to navigate within a selected playlist or category.

Start or stop playback of a selected video clip or music file by clicking on the Start/Stop toggle button at the bottom of the preview. The volume can be adjusted using the volume slider on the right, or muted and unmuted by clicking on the speaker symbol.

For a detailed description how to use additional full-screen monitors in MAESTRO please refer to the description of the VRT in section 6.6.2.2.

5.14 SPECIFIC MAESTRO UNITS

MAESTRO describes a stimulation pulse via amplitude or charge:

- The amplitude of a stimulation pulse is given in current units [cu]. One current unit is approximately 1 [µA].
- The charge of a stimulation pulse characterizes the electrical charge flowing in one direction during the stimulation pulse, i.e. the charge of one phase of a biphasic stimulation pulse. The charge of one phase is defined as the product of stimulation current in [cu] and phase duration in [ms]. One charge unit is approximately 1 [nC]. To avoid damaging the tissue, the net charge of a stimulation pulse is always zero.

5.15 USER ADMINISTRATION

Launching MAESTRO requires user identification (see section 5.1). It is recommended to set up a separate identification for each MAESTRO user to allow each user to install their own settings.

5.15.1 Create new user

The administrator can create new users. Both clicking on the button New in the toolbar and a right click on the symbol Users open the dialog shown in Figure 40. Selecting New User in the area Default opens the User Data Editor shown in Figure 41.

Alternatively a double click on the symbol Users in the taskbar opens the above mentioned User Data Editor.

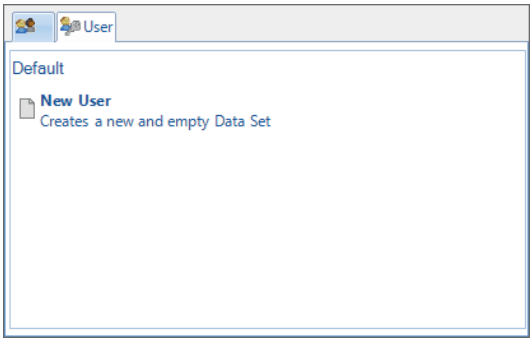


Figure 40 Dialog to create a new user

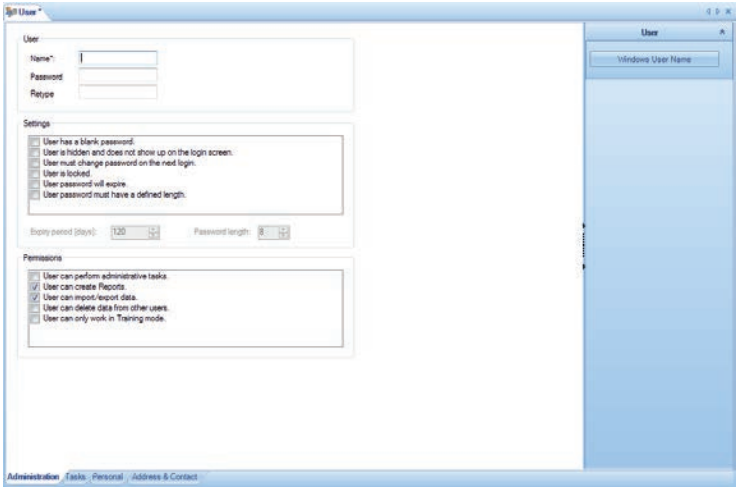


Figure 41 User Data Editor

The User Data Editor is divided into the tabs Administration, Tasks, Personal and Address & Contact.

5.15.1.1 User administration

To create a new user, name and password must be entered for the new user in the applicable input field in the area User of the tab Administration (see Figure 41). In addition, the entered password must be confirmed by retyping it in the field Retype. Clicking on the button Windows User Name enters the Windows user name as user name.

Selecting the applicable checkbox in the area Settings allows the following user settings:

- User has a blank password, automatically greys out the fields Password and Retype in the area User.
- User is hidden and does not show up on the login screen.
- User must change password on the next login.
- User is locked.
- User password will expire, allows defining the number of days until the password expires.
- User password must have a defined length, allows defining the number of characters the password shall have.

Selecting the applicable checkboxes in the area Permissions allows defining the following access rights:

- User can perform administrative tasks.
- User can create Reports (see section 5.10).
- User can import/export data (see section 5.8).
- User can delete data from other users.
- User can only work in Training mode (see section 5.2).

By default, access rights to create reports, import and export data are activated while the access rights to perform administrative tasks, delete data from other users and limitation to Training Mode are deactivated.

5.15.1.2 Tasks

Selecting the applicable checkbox under Tasks in the field User can perform the following tasks in Intra-operative mode or User can perform the following tasks in Post-operative mode allows defining which tasks the user may perform in Intra-operative or Post-operative mode.

5.15.1.3 Personal

Title, first name, middle name, last name, birth date, gender, ID and a comment can be optionally entered for the user in the area Personal. In addition, a picture of the user may be loaded by clicking on the button Browse Picture on the right side of the tab in the Picture section. Clicking on the button Remove Picture deletes the picture from the account.

5.15.1.4 Address & Contact

Address data can be entered in the area Address & Contact under Address. Phone, mobile, fax and email address of the user can be entered under Contact. The entered data can be deleted by clicking on the button Clear on the right side of the tab in the Data section.

5.16 PATIENT DATA ADMINISTRATION

All software tasks described in chapter 6 MAESTRO tasks have the same patient data administration. The patient data of MAESTRO are saved in the patient database. For safety reasons, patient data saved in the Training Mode (see section 5.2) are separated from the patient data saved in standard mode. Patient data entered in the Training Mode are not visible in the standard mode and vice versa.

5.16.1 Create a new patient

Both clicking on the button New in the toolbar and a right click on the symbol Patients open the dialog shown in Figure 42. Selecting New Patient in the area Default opens the Patient Data Editor shown in Figure 43.

Alternatively a double click on the symbol Patients in the taskbar opens the above mentioned Patient Data Editor.

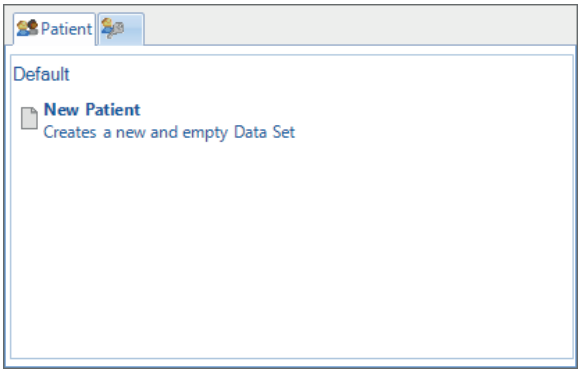


Figure 42 Dialog to create a new patient

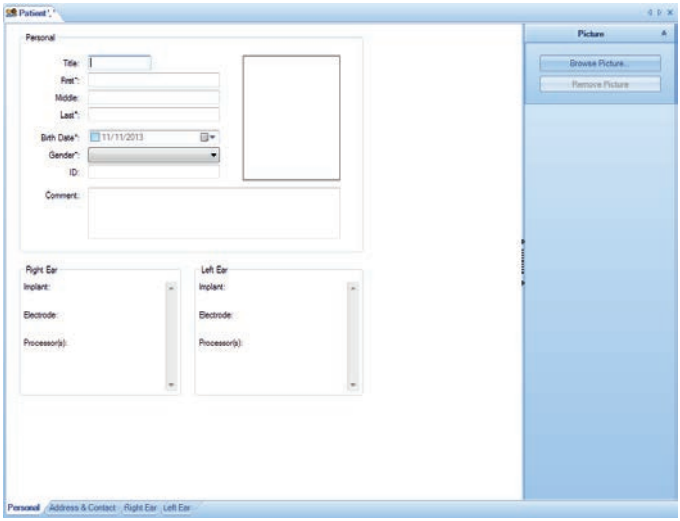


Figure 43 Patient Data Editor

The Patient Data Editor is divided into the tabs Personal, Address & Contact, Right Ear and Left Ear.

5.16.1.1 Personal

The patient's first name, last name, birth date and gender must be entered in the tab Personal (see Figure 34). Title, middle name, ID or a comment may also be entered. In addition, a picture of the patient may be loaded by clicking on the button Browse Picture on the right side of the tab in the area Picture. Clicking on the button Remove Picture deletes the picture from the account.

The areas Right Ear and Left Ear display the patient's implant, electrode, processor and medical information if available.

The patient entry may be saved after entering only the personal data. However, this patient cannot be selected. To select and work with a patient from the patient list, the device data and the surgical date must be entered in the tab Right Ear and/or Left Ear (see sections 5.16.1.3 and 5.16.1.4).

5.16.1.2 Address & Contact

The patient's address, phone, mobile phone, fax number and e-mail address can be entered in the tab Address & Contact (see Figure 44). All entries in this tab are optional and can be deleted by clicking on the button Clear in the area Data on the right side of the tab Address & Contact.

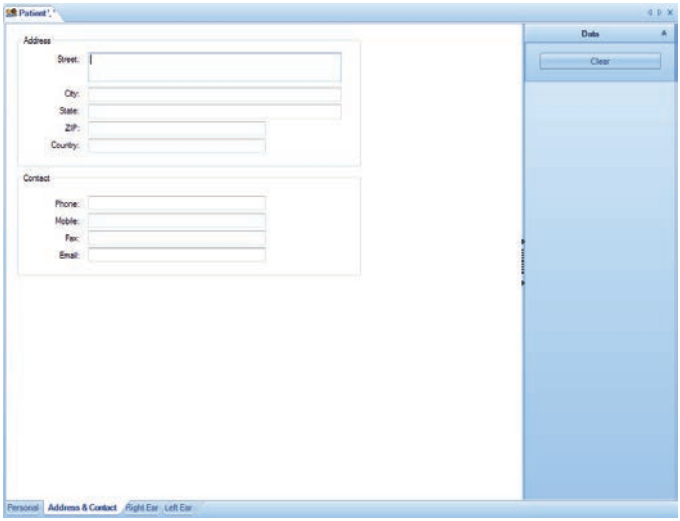


Figure 44 Address & Contact

5.16.1.3 Right Ear

Devices and medical data of the patient can be entered for the right ear in the tab Right Ear (see Figure 45). To work with a patient, implant, serial number, electrode and surgical date are required for SYNCHRONY, MED-EL CONCERT, SONATA TI100 and PULSAR CI100 implants. Electrode and surgical date are required for C40+ implants, the serial number is optional.

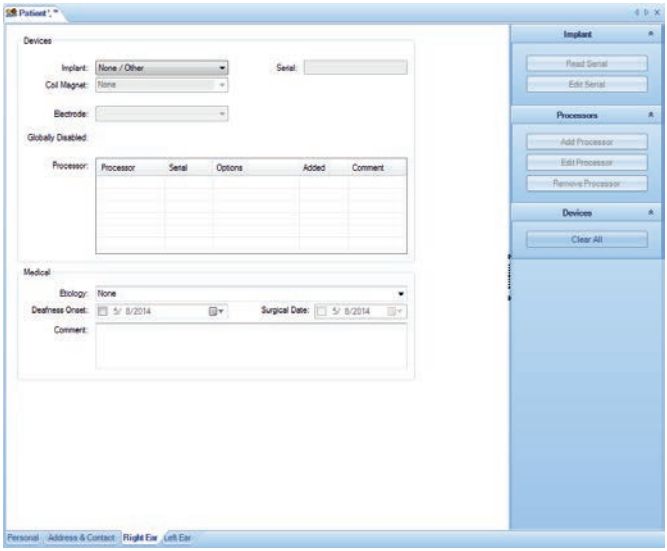


Figure 45 Right Ear Data

Implant type, serial number, coil magnet, electrode, EAS, globally disabled channels and processor can be entered in the Devices section. The implant information is necessary to activate all other input fields. A drop-down menu with the applicable input options is available to select implant, coil magnet and electrode type. The serial number required for SYNCHRONY, MED-EL CONCERT, SONATA TI100 and PULSAR CI100 implants can be entered manually into the field Serial or automatically read out from the patient's implant by clicking on the button Read Serial in the area Implant on the right side of the tab Right Ear. To automatically read out the serial number from the implant, the implant must be connected via the corresponding MAX coil (see section 4.5). After entering the serial number, the field is greyed out.

CAUTION:
Due to technical limitations, no implant type check is performed for older implants without a readable serial number (e.g. C40+) during fitting, EABR and ESRT measurements to confirm that the correct implant is connected. Please note that the implant type shall always be carefully selected.

CAUTION:
Stimulation of a SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} or PULSAR CI^{100} implant is only performed if the serial number of the implant matches the serial number stored in the patient data. Please note that the serial number shall always be carefully entered or read out with the Read Serial button.

The serial number can only be changed by clicking on the button Edit Serial under Implant on the right side of the tab Right Ear.

Selecting the electrode activates the line Globally Disabled, which allows globally disabling individual channels.

CAUTION:
The electrode type shall be carefully selected.

Selecting the checkbox EAS activates the required Frequency Distribution Settings for fitting of a patient with EAS (see section 6.6.2.4).

In the table next to Processors a list of processors assigned to a certain patient can be seen. There are different ways to add processors to the list of processors of a patient: for example by programming a processor for this patient (see section 6.7) or connecting an already programmed processor and selecting the corresponding patient. In both cases the processor will be added to the list automatically. Alternatively the data can be entered manually by clicking on the button Add Processor. This button opens the Select the Processor to add dialog where the processor type with serial number and, if applicable, the processor coil type can be entered. A comment may also be added. If a patient uses a DUET 2 audio processor, the checkbox DUET 2 battery pack can be selected after selecting an OPUS 2 processor from the menu. After clicking on OK the entry appears in the processor list.

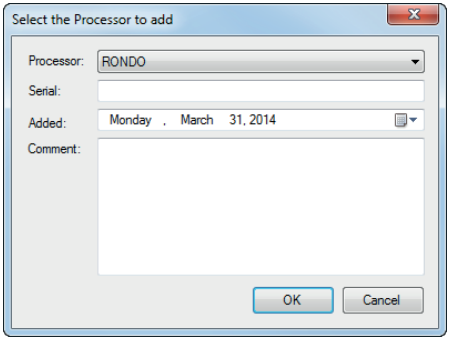


Figure 46 Select the Processor to add dialog

To edit or delete a processor in the list, the entry must be selected first. Clicking on the button Edit Processor under Processor on the right side of the tab Right Ear opens the Edit the Processor dialog and data can be edited. Clicking on Remove Processor deletes the selected entry from the processor list.

Etiology, onset of deafness, surgical date and a comment can be entered in the area Medical. The etiology can be selected from a drop-down menu. Entry of onset of deafness is optional, entry of surgical date is mandatory. A comment about the patient may be entered in the field Comment.

Clicking on Clear All in the Devices section on the right side of the tab Right Ear deletes all entries in the areas Devices and Medical.

NOTE:
A patient may also be entered without indicating implant system and processor type. This may be used, e.g, to prepare the patient data for intraoperative measurements. If the implant system is not entered, the patient cannot be selected.

5.16.1.4 Left Ear

Device and medical data of the patient can be entered for the left ear in the tab Left Ear. All entries are performed as described for the tab Right Ear in section 5.16.1.3.

5.16.2 Edit patient

A right mouse click on the patient opens a menu with the options Edit, Delete and Edit Comment. Selecting Edit opens the Patient Data Editor described in section 5.16.1. Selecting Delete opens the Delete Items dialog. Editing or deleting of patient data is only possible if the patient is not selected. The option Edit Comment allows entering a comment to the patient.

5.16.3 Auto select

MAESTRO continuously monitors the hardware connected to the MAX Programming Interface. It will upload the data from a connected audio processor and will ask automatically if the patient should be selected from the list of existing patients. If the patient does not exist in the database, this patient may be added to the database.

5.16.4 Manual selection

An existing patient in the database can be selected by double-clicking on the entry in the database. Alternatively, the patient can be selected by a single click on the name, followed by a click on the button Select Patient in the toolbar. After selecting a patient, the corresponding database entry is highlighted in bold font, the button Deselect Patient in the toolbar is highlighted in orange and the patient's name is displayed in the status bar (see section 4.3) as shown in Figure 47.

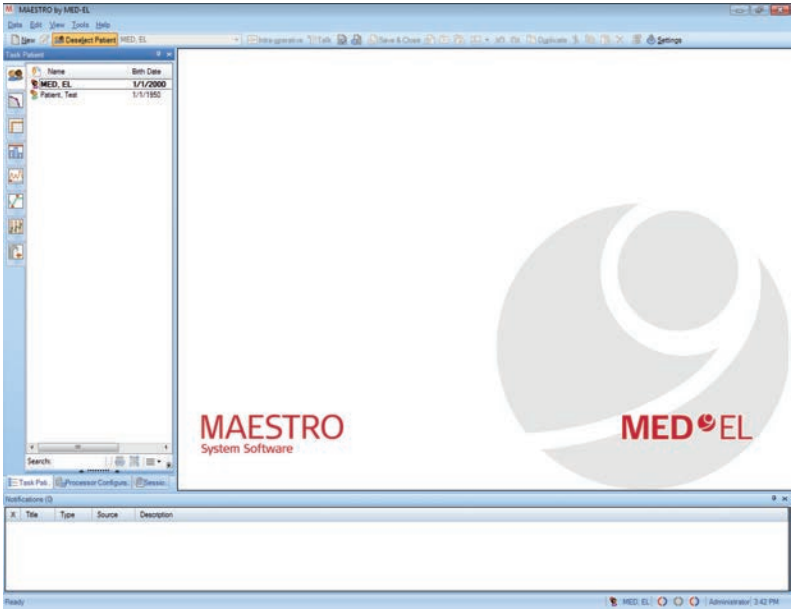


Figure 47 Selected patient

Upon selecting a patient a pop-up window appears as a reminder to check the patient's meningitis vaccination status as shown in Figure 48.

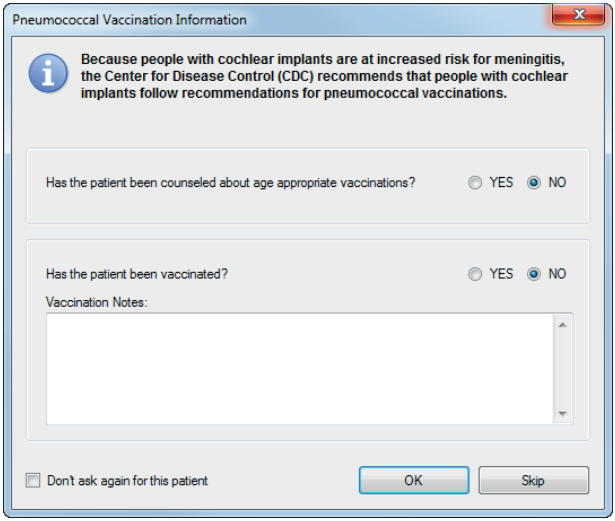


Figure 48 Pneumococcal Vaccination Information

6. MAESTRO Tasks

This section describes the tasks provided by MAESTRO. These tasks are Audiogram, IFT, ESRT, EABR, ART, Fitting, and Configuration and Acoustic Fitting. All tasks have an input field in the upper bar of the user dialog to enter a name for a specific measurement or setting. The name is then displayed in the tab and, after saving the entire dataset, also in the database view. On the right side of the input field is a short summary of the entered data and/or used parameters. Figure 49 shows an example of the input and comment field of the Audiogram task.

Figure 49 Input and comment field of the Audiogram task

The database view displays all saved entries of a task indicating side (right/left), date and time of entry and a short summary of the task. Figure 50 shows an example of the database view of the Audiogram task.

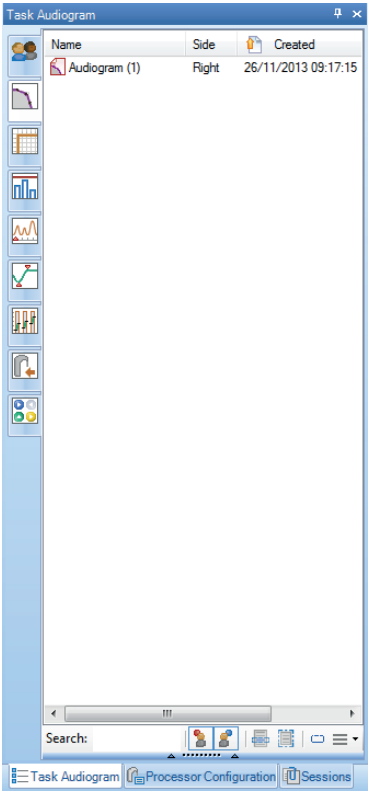


Figure 50 Database view of the Audiogram task

6.1 AUDIOGRAM TASK

The Audiogram task allows entering patient audiogram data into MAESTRO. A template as used in the hearing aid industry is available to enter auditory curves. The Audiogram task also allows the clinician to document patient audiogram data in MAESTRO. In addition, MAESTRO defines the crossover frequency necessary for Acoustic Fitting using the data points entered in the Audiogram task (see section 6.7.2).

6.1.1 Audiogram hardware

No additional hardware is required for the Audiogram task.

6.1.2 Starting the Audiogram task

To start the Audiogram task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4). After selection there are several ways to start the Audiogram task:

1. A click on the button New opens the task dialog shown in Figure 51, where the Audiogram tab can be selected and with a click on New Audiogram an Audiogram can be opened.
2. A right click on the symbol Audiogram in the taskbar opens the very same dialog with the Audiogram tab already selected. A click on New Audiogram opens a new Audiogram.
3. A double click on the symbol Audiogram in the taskbar opens a new Audiogram automatically.

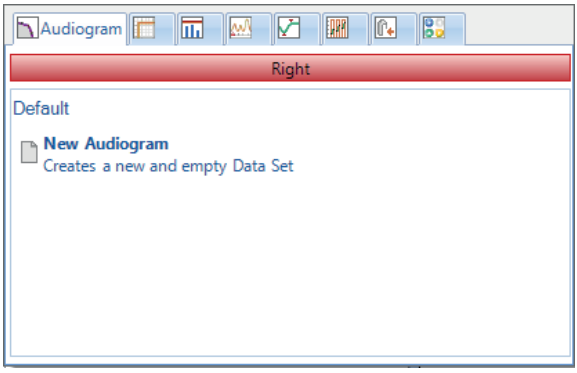


Figure 51 Audiogram task dialog

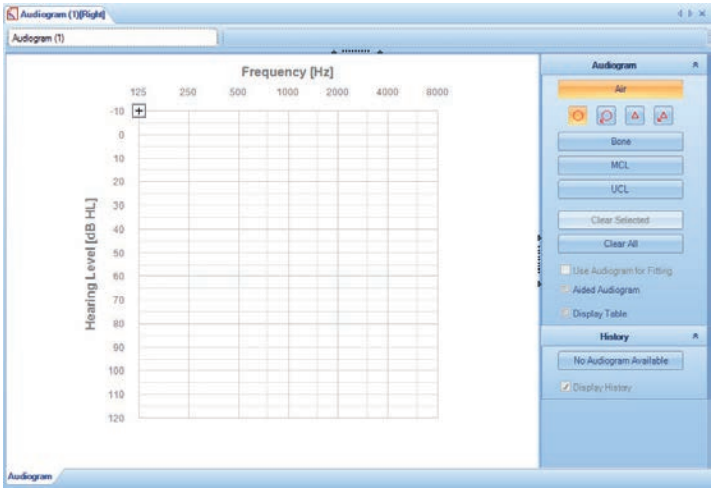


Figure 52 Dialog of the Audiogram task

Figure 52 shows the dialog of the Audiogram task. The input template graphically displays acoustic hearing thresholds in a dynamic range of −10 dB HL to 120 dB HL over a frequency range of 125 Hz to 8000 Hz. The curves can be entered by a left mouse click in the appropriate section of the input template. Alternatively, control is also possible with the arrow keys and by confirming the curve via the Enter key.

The column on the right side of the Audiogram task dialog is divided into the areas Audiogram and History. The area Audiogram (see Figure 53) contains buttons and option fields to select symbols to enter and delete audiometric data.

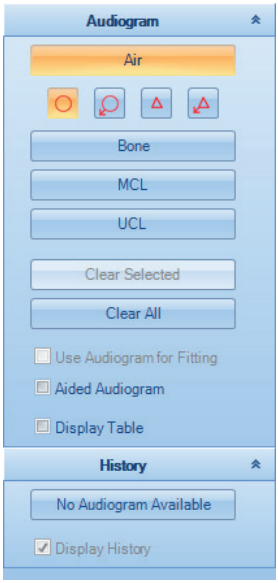


Figure 53 Area Audiogram

It offers the following buttons to select representing various data:

- Air conduction (Air)
- Bone conduction (Bone)
- Maximum comfortable loudness level (MCL)
- Uncomfortable loudness level (UCL)

Various symbols to enter audiometric data are available after selecting a button.

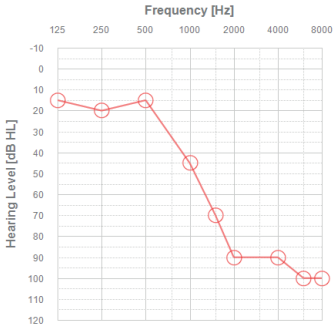
NOTE:
International symbols are used to enter audiometric data. They may be different from local symbols.

With the buttons Clear All and Clear Selected all entered auditory curves or only the selected auditory curve can be deleted from the audiogram template. Selecting or deselecting the checkbox Use Audiogram for Fitting defines if the entered audiogram may be used in the Acoustic tab of the Fitting Task for SONNET EAS or in the Acoustic Fitting task for First Fit for DUET 2. The checkbox is activated by default.

Selecting the checkbox Aided Audiogram allows the user to indicate that a hearing aid or cochlear implant was used to measure the audiogram.

NOTE:
If the checkbox Aided Audiogram is selected or the checkbox Use Audiogram for Fitting is not selected, the applicable audiogram cannot be used in the Acoustic tab of the Fitting task for SONNET EAS or in the Acoustic Fitting task for First Fit for DUET 2.

Selecting the checkbox Display Table shows all data entered in the input template as numerical values in a table below the input template as shown in Figure 54. The checkboxes Aided Audiogram and Display Table are deselected by default.



Frequency [Hz]	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
Air [dB HL]	15	20	15	-	45	70	90	-	90	100	100
Bone [dB HL]	-	-	-	-	-	-	-	-	-	-	-
MCL [dB HL]	-	-	-	-	-	-	-	-	-	-	-
UCL [dB HL]	-	-	-	-	-	-	-	-	-	-	-

Figure 54 Input template with additional display of numerical values in a table

NOTE:
Selecting the checkbox Aided Audiogram allows the user to state that a hearing aid was used to measure the audiogram.

With a click on the arrow of the drop down button in the area History an already saved Audiogram can be selected. Selecting or deselecting the checkbox Display History displays or hides the previous selected diagram as grey shaded lines next to the actual hearing curves as shown in Figure 55.

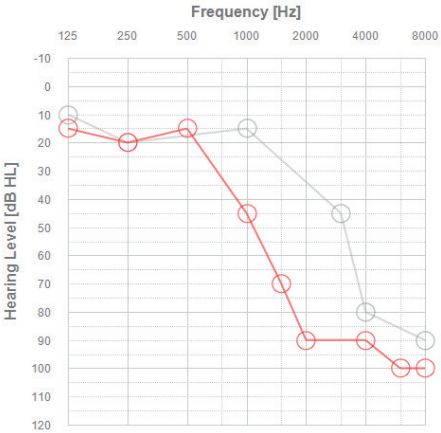


Figure 55 Display of previous audiogram data

6.1.3 Audiogram settings

Settings | Audiogram in the toolbar allows customizing Editor and Symbol settings of the Audiogram task. Figure 56 shows the Settings dialog of the Audiogram task.

Clicking on the button Restore Defaults on the right below the field Symbols restores the defaults of all settings of the Audiogram task. Changes of settings are applied when closing the Settings dialog.

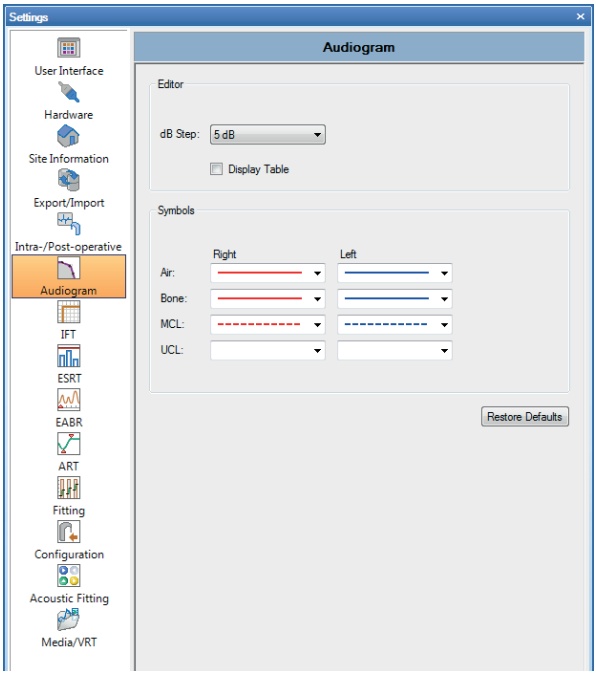


Figure 56 Settings dialog of the Audiogram task

6.1.3.1 Editor

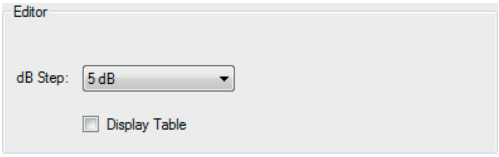


Figure 57 Editor

The Editor settings (Figure 57) of the Audiogram task allow adjusting the step size in dB HL. The step size defines the distance between two data points along the ordinate when entering data. Step sizes of 1 dB HL, 2 dB HL and 5 dB HL are available. The default step size is 5 dB HL.

Selecting the checkbox Display Table defines an additional default display of the audiogram data as numerical values (see section 6.1.2).

6.1.3.2 Symbols

The Symbols settings (Figure 58) of the Audiogram task allow setting different line types to connect data points of air or bone conduction thresholds, MCL or UCL thresholds. The default lines for air and bone conduction thresholds are solid, dashed lines are used for MCL and no lines for UCL.

Figure 58 Symbols

6.2 TELEMETRY TASK

The Telemetry task enables measurement of voltages at the intracochlear electrodes of the MED-EL implant during stimulation. The measured results show the impedances of the individual intracochlear electrodes. In addition, ground path impedance, integrity and coupling between implant and MAX coil are indicated. For SYNCHRONY, MED-EL CONCERT, SONATAti^{100} and PULSARci^{100} the implant serial number is stated. A telemetry measurement yields important information for audio processor programming and supports assessment of implant function. Therefore it is highly recommended to perform a telemetry measurement before every fitting.

6.2.1 Telemetry hardware

The Telemetry task allows stimulation with all implants supported by MAESTRO (see section 3.1). Communication with the implant is established via a MAX coil (see section 4.5), therefore the MAX coil that corresponds to the patient's implant needs to be connected to the telemetry socket of the MAX Programming Interface. It is not necessary to connect an audio processor.

CAUTION:
Make sure to use the appropriate hardware to perform the measurement.
Telemetry data generated with a pulse detector box cannot be saved into the database.

The MAX coil sends digitized data to the implant during measurement. The implant generates sequential biphasic, charge-balanced current pulses at all intracochlear electrodes. At the end of the biphasic pulse the voltage information is transmitted to the MAX Programming Interface via the MAX coil and at the end of the measurement to the computer. The result of the measurement is displayed by MAESTRO.

CAUTION:
Telemetry measurements also serve to check the integrity of the implant. Please note that decisions about further medical or surgical treatment of the patient must not be based exclusively on the results of telemetry measurements. When in doubt regarding the interpretation of telemetry data, please contact your nearest MED-EL representative.

6.2.2 Starting the Telemetry task

To start the Telemetry task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4). After selection there are several ways to start the Telemetry task:

1. A click on the button New opens the task dialog shown in Figure 59, where the IFT tab can be selected and with a click on New IFT an IFT can be opened.
2. A right click on the symbol IFT in the taskbar opens the very same dialog with the IFT tab already selected. A click on New IFT opens a new IFT.
3. A double click on the symbol IFT in the taskbar opens a new IFT automatically.

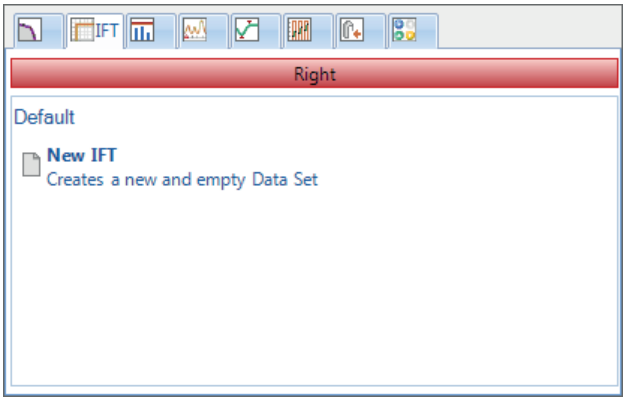


Figure 59 Dialog to open the telemetry task

Figure 60 shows the user interface of the Telemetry task. It is divided into the Telemetry and Voltage Matrix dialogs.

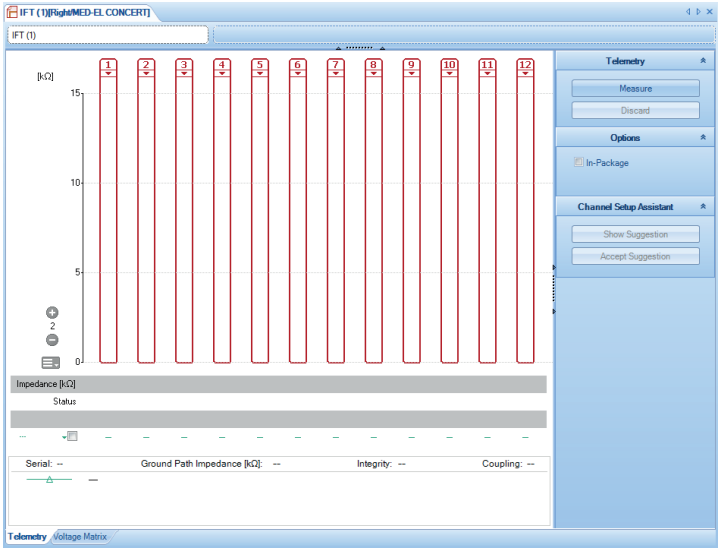


Figure 60 Telemetry dialog

6.2.2.1 Telemetry

The Telemetry dialog (see Figure 60) displays the stimulation bars of the electrodes. Click on the Measure button at the right side of the Telemetry dialog to start a measurement. During measurement the intracochlear electrodes are stimulated. The applied pulses are qualitatively identical to those used for standard stimulation of the implant. At the end of the second phase of the stimulation pulse the voltages are measured at the stimulated electrodes and the other electrodes. To calculate the electrode impedance, the voltage used is the one obtained when the same electrode is stimulated.

NOTE:
The stimulation pulses used for telemetry are in most patients' audible range.

The determined impedances of the individual intracochlear electrodes are displayed in the applicable stimulation bar after measurement. Scaling can be changed with the buttons +/- left of stimulation bar 1. The numerical impedance values in kΩ and the status of the individual electrodes are listed in a table below the stimulation bar.

The impedance values have no sign or a > sign.

- If the value is displayed without an additional sign, the current flow across the electrode was according to the desired current. The value gives the actual impedance at the electrode with the best possible accuracy.
- If the value is preceded by a > sign, the current flow across the electrode was lower than the desired current. This is caused by a partially or completely saturated current source. The actual impedance value is higher than the given value. The given value indicates the lower limit of the actual impedance.
- If the integrity test fails or indicates faint, weak, or poor coupling between MAX coil and implant, all values are displayed as --.

The electrode status is indicated with OK, HI, SC-x or HSC-x.

- If OK is displayed, the measured voltage at the electrode is within the measuring range of the system. Electrode function is technically correct.
- HI indicates that the measured voltage at the electrode exceeds the measuring range of the system. Electrode impedance is too high to allow effective current flow across the electrode during telemetry measurement.
- If electrode status is SC-x, current flow across the electrode during measurement was according to the desired current. Electrode function is technically correct but a short circuit with another electrode was detected. Each SC receives the suffix x (a letter A, B, C, D, E or F) to identify individual short circuits and indicate which electrodes short circuited.
- HSC-x indicates that the voltage measured at the electrode exceeds the measuring range of the system and an additional short circuit with another electrode was detected.
- In rare cases short circuits cannot be determined reliably. In these cases the status of the affected electrodes is indicated as SC? or HSC?. It may be useful to look at the voltage matrix dialog (see section 6.2.2.3) for additional information that may help in diagnosing a problem.

The upper area of the field below the tables displays the implant serial number (for SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} implants), the value of ground path impedance, integrity and coupling between implant and MAX coil.

- For SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} implants the implant serial number is read out in the first phase of the telemetry measurement and compared with the serial number given in the patient data (see section 5.16.1.3). No stimulation pulses are transmitted to the intracochlear electrodes in this phase. If the read-out serial number and the serial number in the patient data are identical, telemetry continues. Otherwise a warning is displayed and entry in the patient data must be corrected.
- The ground path impedance is formed by the bulk tissue impedance, the impedance of the reference electrode, and internal circuitry of the implant. The bulk tissue impedance depends highly on bulk tissue conductivity and current distribution in the extracochlear space. The impedance of the reference electrode is determined by the technical status of the electrode and the tissue properties in the close vicinity of the electrode. Thus, the ground path impedance is a complex function of various physical and technical factors. It is calculated from the voltage distribution. Determination of the ground path impedance relies on a certain minimum number of normally functioning electrodes. Thus, in very rare cases it might happen that the ground path impedance cannot be determined. Like the impedances of the intracochlear electrodes, ground path impedance is displayed without any sign or with a > sign. If it is displayed without any sign, the displayed value gives the actual ground path impedance with the highest possible accuracy. With an additional > sign the actual ground path impedance is higher than the given value. The given value indicates the lower limit of the actual ground path impedance. If the integrity test fails or indicates faint, weak, or poor coupling between MAX coil and implant, all values are displayed as --.
- Integrity is displayed either with OK or with --. OK confirms correct function of the implant electronics during telemetry. Performance of the integrity test requires good coupling between MAX Programming Interface and implant. If -- is displayed, correct function of the implant electronics could not be determined. If coupling between MAX Programming Interface and implant is faint, weak or poor, the integrity test cannot be performed and the implant electronics cannot be tested. In these cases -- is always displayed.

NOTE:
If -- is displayed despite good coupling between MAX Programming Interface and implant, please contact your nearest MED-EL representative.

- Coupling is indicated as OK, FAINT, WEAK or POOR.
    - OK indicates that the MAX Programming Interface has received all implant data necessary to identify the implant type and calculate voltages and impedances for all channels. Implant type matches the implant type saved in the patient data (see section 5.16.1.3). Communication between the implant and MAX Programming Interface is correct. This confirms that a large part of the implant electronics functioned correctly during the measurement.
    - If FAINT is displayed, the MAX Programming Interface received all implant data necessary to identify the implant type but only some data to calculate voltage and impedances. Match of actual implant type and implant type saved in the patient data could be confirmed. However, values for voltages and impedances are not available. Communication between the implant and MAX Programming Interface functioned only partly correctly.

NOTE:
Faint coupling may be caused by wrong positioning of the MAX coil above the implant. As a first step, check cable connections between MAX Programming Interface and MAX coil, then slightly adjust the position of the MAX coil and apply soft pressure on the MAX coil to try to improve coupling. If coupling remains faint after several attempts, please contact your nearest MED-EL representative.

    - If WEAK is displayed, the MAX Programming Interface received some but not all implant data. Thus, the implant type could not be identified and the implant did not query data to calculate voltages and impedances. Communication between the implant and MAX Programming Interface functioned only partly correctly.

NOTE:
Weak coupling may be caused by wrong positioning of the MAX coil above the implant. As a first step, check cable connections between MAX Programming Interface and MAX coil, then slightly adjust the position of the MAX coil and apply soft pressure on the MAX coil to try to improve coupling. If coupling remains weak after several attempts, please contact your nearest MED-EL representative.

- If POOR is displayed, the MAX Programming Interface did not receive any valid implant data. The implant type could not be identified and the implant did not query data to calculate voltages and impedances. Communication between the implant and MAX Programming Interface did not function correctly during the measurement.

NOTE:
Poor coupling may be caused by wrong positioning of the MAX coil above the implant. As a first step, check cable connections between MAX Programming Interface and MAX coil, then slightly adjust the position of the MAX coil and apply soft pressure on the MAX coil to try and improve coupling. If coupling remains poor after several attempts, please contact your nearest MED-EL representative.

In addition to the current measurement, up to three other measurements can be displayed in the Telemetry dialog. By default the impedances of the last telemetry measurement are displayed in the last line of the table as numerical values. Select the checkbox in the precolumn to graphically display the impedances in the stimulation bars. To display several telemetry measurements, select the last three telemetry measurements via the button above the precolumn. Click on the arrow symbol next to the applicable entry in the precolumn to replace the displayed measurements with any other measurement. Click on the option Open to open the currently selected telemetry measurement in a new window. In the lower area of the field below the table, the symbol used for the graphic display of the telemetry measurement is shown. Name, measurement date and implant serial number (SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} only) and the value of the ground path impedance are given for the telemetry measurement.

A measurement may be repeated if the results of the previous measurement are discarded by clicking on the button Discard on the right side of the Telemetry dialog in the area Telemetry.

Activating the In-Package checkbox before measurement, found in the Options area on the right side of the Telemetry dialog, selects measurement of the implant inside the transport packaging. Telemetry measurement results labeled In-Package are not available for other tasks.

Clicking on the arrow symbol below the electrode number in the stimulation bar allows selecting the global status of the applicable electrode. An electrode may be globally deactivated to automatically deactivate it for all other tasks. The drop-down menu offers various reasons for deactivation. If an electrode has been globally deactivated in another task, it is also indicated as globally deactivated in the Telemetry task.

NOTE:
Globally deactivated electrodes are also stimulated during telemetry measurement.

6.2.2.2 Channel Setup Assistant (CSA)

The Channel Setup Assistant in the Telemetry task is a tool to support the audiologist in deciding which channels to switch off or on according to the results of a measurement.

The user has the option to accept, ignore or hide the CSA suggestions in the area Channel Setup Assistant. To show or hide the assistant, click on Show Suggestion. The suggestions are enabled by default. The CSA suggestions (see Figure 61) are listed under the Action Summary and graphically displayed for each affected channel containing short circuit and/or high impedances with the following symbols:

- ✓ indicates that the channel is going to be enabled or that the channel stays enabled.
- ✕ indicates that the channel is going to be disabled or that the channel stays disabled.
- ? indicates that the channel stays disabled. Further investigation (e.g. review of the telemetry history or voltage matrix) might be needed in order to decide about the global state change of the channel.

Affected channels containing multiple short circuits are visually displayed as red rounded rectangles. To accept the suggestions of the CSA, click on Accept Suggestion and the suggested states of the electrodes will be globally accepted.

To ignore the CSA you can either hide or simply not accept the suggestions. As a result, global channel states remain unchanged.

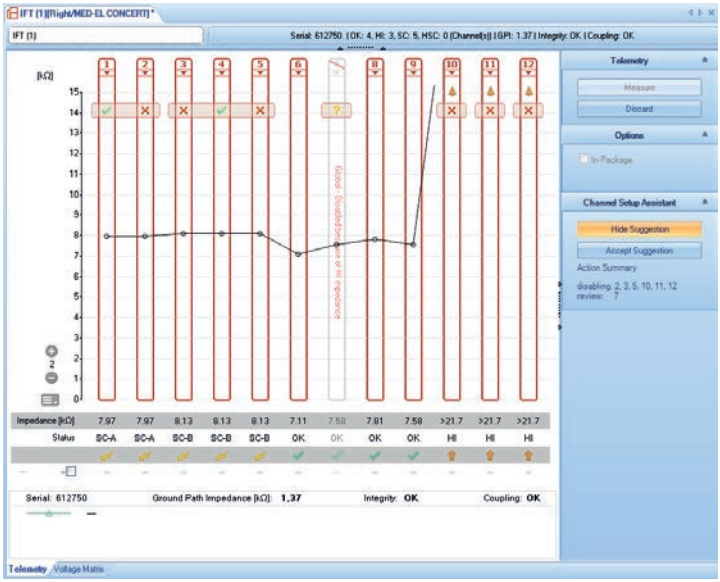


Figure 61 Suggestions of the Channel Setup Assistant

NOTE:

The CSA supports all electrode arrays supported by MAESTRO except Split electrode arrays. The Channel Setup Assistant tool is not available in the Intra-operative mode and when an In-Package or Coupling/Integrity measurement was performed.

6.2.2.3 Voltage Matrix

The Voltage Matrix dialog displays a matrix with the voltage profile determined during a single measurement. The voltages at the stimulated electrodes and the voltages at the not stimulated electrodes are measured.

The voltage matrix is displayed with bars or numbers. The display can be changed by selecting the applicable option on the right side of the Voltage Matrix dialog in the area Voltages.

Figure 62 shows the voltage matrix as bars. The length of a bar corresponds to the voltage value of the value given in the table in relation to the value in the main diagonal.

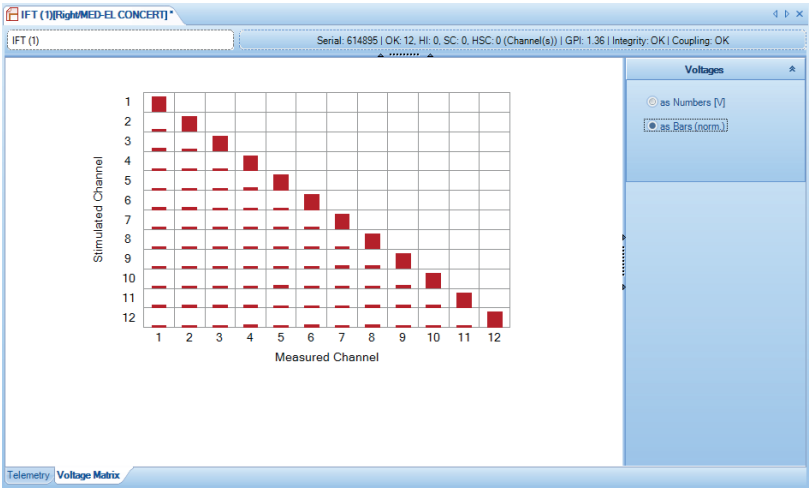


Figure 62 Voltage matrix as bars

Figure 63 shows the voltage matrix as a numerical table. The values correspond to the calculated voltages in Volts.

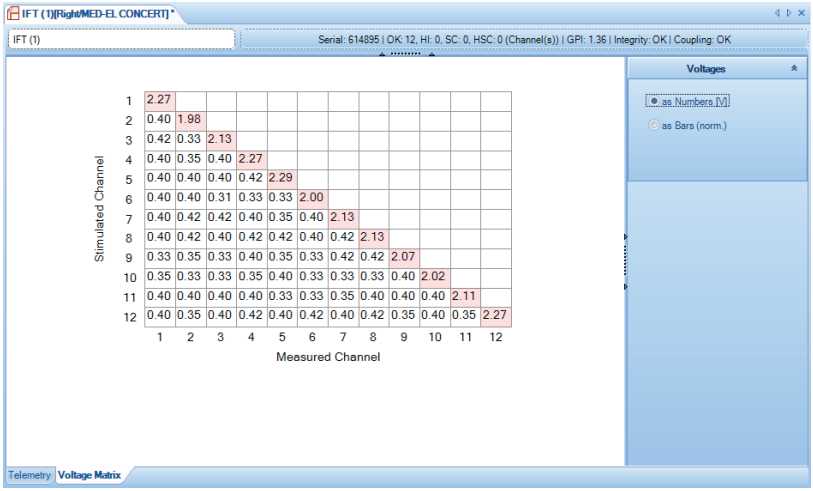


Figure 63 Voltage matrix as numbers

If the integrity test fails or indicates faint, weak, or poor coupling between MAX Programming Interface and implant, no values are entered in the Voltage Matrix dialog.

Short circuits can be identified with the voltage matrix, even if the automatic calculation in the Telemetry dialog is ambiguous. If the value outside the main diagonal is clearly increased and near the value in the main diagonal, a short circuit between the electrode of the subdiagonal and the electrode of the main diagonal is likely.

6.2.3 Telemetry settings

The Data Lines Display Status of the Telemetry task can be customized under Settings | IFT. Figure 64 shows the Settings dialog for the Telemetry task.

Clicking on the button Restore Defaults on the right side below the Channel Setup Assistant (CSA) section restores all settings of the Telemetry task to their defaults. Changed settings are applied by closing the Settings dialog.

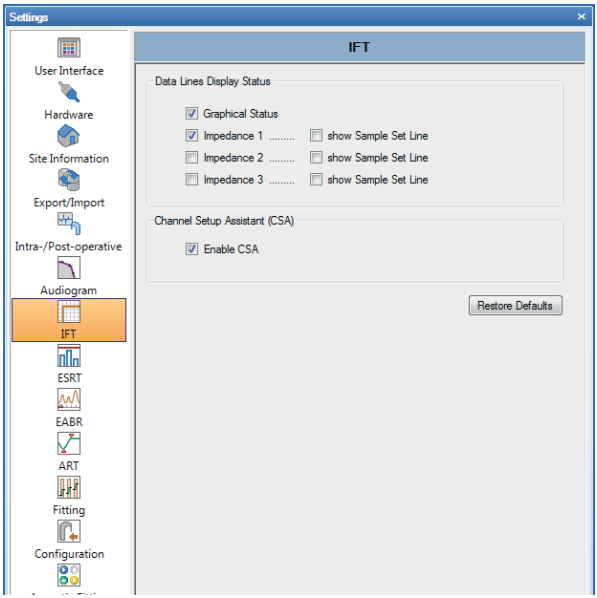


Figure 64 Telemetry settings dialog

Select the Graphical Status checkbox to graphically display the current telemetry measurements in the Telemetry dialog (see section 6.2.2.1). By default, the checkbox is selected. Select the Impedance 1, Impedance 2 and Impedance 3 checkboxes to display results of up to the last three historic telemetry measurements as numerical values in the Telemetry dialog. By default, only the Impedance 1 checkbox is selected to display the results of the last telemetry measurement. Select the show Sample Set Line checkbox to graphically display the results of the corresponding historic telemetry measurement.

In the area Channel Setup Assistant the Enable CSA checkbox is selected to display the CSA suggestions after each new telemetry measurement.

6.3 ESRT TASK

The ESRT task allows eliciting contraction of the stapedius muscle (stapedius reflex) by electrically stimulating the auditory nerve. In intraoperative ESRT measurements, the stapedius reflex can be assessed by directly observing the stapedius muscle. Postoperative measurement requires a tympanometer to record the triggered reflex. The measured ESRT thresholds can be saved in MAESTRO.

6.3.1 ESRT hardware

The ESRT task allows stimulation with all implants supported by MAESTRO (see section 3.1). Communication with the implant is established via a MAX coil (see section 4.5), therefore the MAX coil that corresponds to the patient's implant needs to be connected to the telemetry socket of the MAX Programming Interface. It is not necessary to connect an audio processor.

NOTE:
Make sure to use the appropriate hardware for measurement.
ESRT data generated with a pulse detector box cannot be saved into the database.

6.3.2 Starting the ESRT task

To start the ESRT task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4). After selection there are several ways to start the ESRT task:

1. A click on the button New opens the task dialog shown in Figure 65, where the ESRT tab can be selected and with a click on New ESRT an ESRT can be opened.
2. A right click on the symbol ESRT in the taskbar opens the very same dialog with the ESRT tab already selected. A click on New ESRT opens a new ESRT.
3. A double click on the symbol ESRT in the taskbar opens a new ESRT automatically.

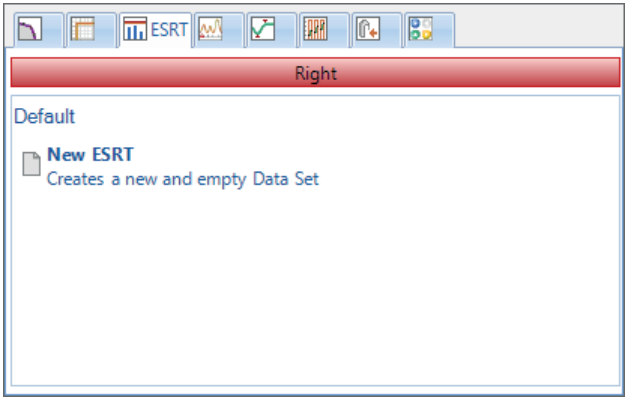


Figure 65 Dialog to open the ESRT task

Figure 66 shows the user interface of the ESRT task.

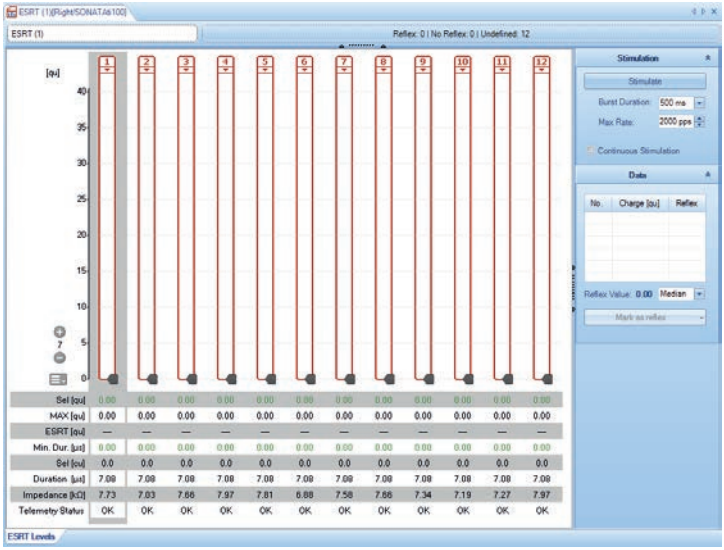


Figure 66 ESRT Levels dialog

The stimulation bars for the individual electrodes are shown. The charge per electrode applied during stimulation can be set in qu (see section 5.1). The charge value can be changed by dragging the black arrow with the mouse within the stimulation bar or by directly entering the numerical value in the field Sel (Selected) in the table below the stimulation bar. The value Sel of an electrode can be transferred to all or an individual electrode by a right mouse click and selecting the option Copy Sel to.

Scaling of the display of charge units can be changed with the buttons +/- left of stimulation bar 1.

Clicking on the arrow symbol below the electrode number in the stimulation bar allows selecting the global status of the electrode. An electrode may be globally deactivated which means it is automatically deactivated for all other tasks. Various reasons for deactivation can be selected from a drop-down menu. An electrode deactivated in another task will also be indicated as globally deactivated in the ESRT task.

Beside current charge values for stimulation, the table below the stimulation bar also shows the values MAX, ESRT, Min. Dur., Sel [cu], Duration, Impedance and Telemetry Status. The values Sel [cu], Impedance and Telemetry Status can be hidden by a mouse click on the precolumn and selecting the applicable option.

MAX is the maximum stimulation charge. It indicates the maximum value in qu (see section 5.14) at which stimulation already occurred. ESRT gives the stapedius reflex threshold in qu. It is given in the table as a numerical value after determining at least one positive reflex. In the stimulation bar it is depicted as a green line and, depending on the selection on the right side of the ESRT interface in the area Data, corresponds with the median, the mean value or the lowest value of all positively evaluated stapedius reflex thresholds. In the field Min. Dur. the minimum phase duration of the stimulation pulse at the applicable electrode can be defined. Min. Dur. covers the range between 0 and 200 µs, the default value is 0 µs. The value of Min. Dur. of an electrode can be transferred to all or an individual electrode by a right mouse click and selecting the option Copy Min. Dur. to.
Sel gives the stimulation amplitude in cu (see section 5.14).
Duration gives the actual phase duration in µs, which serves to calculate the selected stimulation charge. The fields Impedance and Telemetry Status give the impedance in kΩ determined in the last telemetry measurement (see section 6.2.2.1) and the telemetry status. If no telemetry data are available, a warning appears in the notification dialog and the user must confirm this warning. In this case, MAESTRO continues to work with the default values depending on the implant type, however the default values are not based on real patient measurements and may result in very restrictive options. It is always best to use the most recent telemetry measures for fitting and other tasks.

The right side of the ESRT user interface is divided into the areas Stimulation and Data.

In the area Stimulation a stimulation burst stimulates at the electrode highlighted in grey by clicking on the button Stimulate. In the field Burst Duration the value for the duration of the stimulation burst can be selected in the range between 50 ms and 1000 ms. The default is 500 ms. The field Max. Rate allows defining the maximum stimulation rate by clicking on the arrow keys or directly entering the numerical value in the input field. The default is 2000 pps, values between 0 and 4225 pps are available. Selection of the checkbox Continuous Stimulation leads to continuous stimulation at the selected electrodes. The checkbox is deselected by default.

When selecting the checkbox Continuous Stimulation, the settings of Burst Gap and the option Automatic value change are available. For Burst Gap a value between 200 and 1000 ms can be selected. The default is 500 ms. Selecting the checkbox Automatic value change continuously changes the stimulation amplitude during stimulation. The parameters Step

Size, Burst Count, Auto Inc Limit and Direction can be set. Step Size defines the step size between two stimulation amplitude steps. The default step size is 1 %, and can be changed between 0 and 15 % by clicking on the arrow keys or directly entering the numerical value. The Burst Count gives the number of stimulations per step size. The default is 3 times per step size. The Burst Count can be changed between 1 and 10 by clicking on the arrow keys or directly entering the numerical value. The Auto Inc Limit indicates the maximum charge of the stimulation amplitude. When reaching the defined value, the stimulation amplitude will no longer increase. The default for maximum charge is 15 qu (see section 5.14), the value can be changed between 0 and 287 qu by clicking on the arrow keys or directly entering the numerical value. The Direction field allows defining if the stimulation amplitude increases or decreases continuously. The default is continuous increase of the stimulation amplitude.

Data shows the determined stapedius reflex thresholds as a table. Individual measurement results can be highlighted and deleted by pressing the Delete key. The shown data correspond with the measurement results of the electrode highlighted in grey. The table shows the results in the sequence in which they were highlighted. Each entry indicates the charge of the stimulation pulse in qu (see section 5.14) and if the amplitude threshold was selected as reflex, as no reflex or as undefined. The selected amplitude thresholds are graphically displayed in the stimulation bars. The amplitude thresholds selected as reflex are indicated by a dashed green line, the amplitude thresholds selected as no reflex by a dashed purple line and the amplitude thresholds selected as undefined by a dashed grey line. The field Reflex Value shows the defined stapedius reflex thresholds as median, mean value or lowest value depending on the selection. This value is graphically displayed in the stimulation bar by a golden line. An amplitude threshold can be selected as reflex, as no reflex or as undefined by clicking on the selection via the button below the stapedius reflex threshold display. Alternatively, highlighting is also possible by right clicking in the stimulation bar under the option Mark as reflex.

6.3.3 ESRT settings

Click on the symbol Settings | ESRT in the toolbar to customize the standard settings of the ESRT task. Figure 67 shows the Settings dialog of the ESRT task.

Click on the button Restore Defaults below Default values for new Measurements to restore all default settings of the ESRT task. To apply the changes close the Settings dialog.

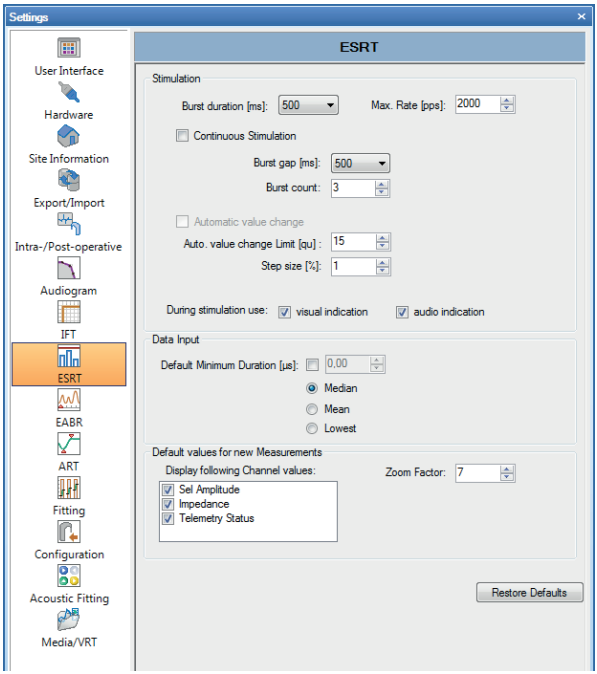


Figure 67 ESRT settings dialog

6.3.3.1 Stimulation

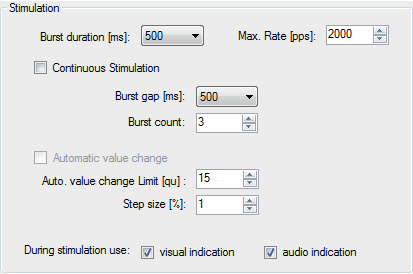


Figure 68 Stimulation

The Stimulation settings (Figure 68) allow customizing the default values of the stimulation parameters (see section 6.3.2). Table 1 lists the minimum, maximum and default values of the stimulation parameters.

Parameter	Minimum	Maximum	Default
Burst duration	50 ms	1000 ms	500 ms
Auto Increase Limit	0 qu	287 qu	15 qu
Max. Rate	0 pps	4225 pps	2000 pps
Burst gap	200 ms	1000 ms	500 ms
Burst count	1	10	3
Step size	0 %	15 %	1 %

Table 1 Minimum, maximum and default values of the stimulation settings

Select the checkbox Continuous Stimulation to use continuous stimulation as default. Selecting the checkbox Automatic value change uses continuous change of the stimulation amplitude during stimulation as default. By default, both checkboxes are deselected. In the area During stimulation use, activating the applicable checkbox allows defining whether visual indication or audio indication will be used during stimulation. By default, both visual indication and audio indication are selected.

6.3.3.2 Data Input

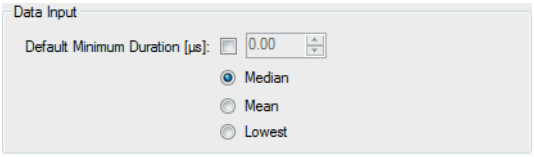


Figure 69 Data Input

The Data Input settings allow customizing default values for the Default Minimum Duration and for determining the stapedius reflex threshold (see section 6.3.2). When selecting the Default Minimum Duration checkbox, the minimum duration can be defined. This minimum duration will be used for all electrodes. The duration can be entered in the input field in steps of 1 µs between 0 and 200 µs. This option is deactivated by default. The default value in the input field is 0 µs. Select one of the options to define if the stapedius reflex threshold is determined as median, mean or lowest of the individual results. By default, the stapedius reflex threshold is determined as the median of the individual results.

6.3.3.3 Default values for new Measurements

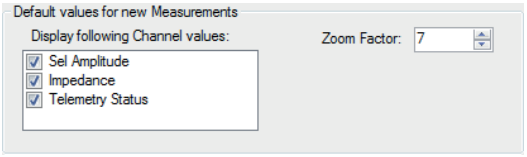


Figure 70 Default values for new Measurements

The Default values for new Measurements area allows selecting the default display of the optional parameters Sel Amplitude, Impedance and Telemetry Status in the field Display following Channel values (see section 6.3.2). By default, all three parameters are displayed. In addition, the Zoom Factor can be customized between 1 and 15. The default zoom factor is 7.

6.4 EABR TASK

The EABR task creates pulse sequences intended to elicit responses of the brainstem by stimulation of the auditory nerve or the corresponding area of the brainstem. These responses cannot be recorded and saved with MAESTRO. An additional EEG-recording device is necessary.

6.4.1 EABR hardware

The EABR task allows stimulation with all implants supported by MAESTRO (see section 3.1).

CAUTION:
Due to technical limitations, channels 2, 4, 6 and 8 cannot be stimulated in C40+ implants within the EABR task.

Communication with the implant is established via a MAX coil (see section 4.5), therefore the MAX coil that corresponds to the patient's implant needs to be connected to the telemetry socket of the MAX Programming Interface. It is not necessary to connect an audio processor.

CAUTION:
Make sure to use the appropriate hardware for measurement.
EABR data generated with a pulse detector box cannot be saved into the database.

The MAX Programming Interface sends a trigger signal with each stimulation cycle.

6.4.2 Starting the EABR task

To start the EABR task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4). After selection there are several ways to start the EABR task:

1. A click on the button New opens the task dialog shown in Figure 71, where the EABR tab can be selected and with a click on New EABR an EABR can be opened.
2. A right click on the symbol EABR in the taskbar opens the very same dialog with the EABR tab already selected. A click on New EABR opens a new EABR.
3. A double click on the symbol EABR in the taskbar opens a new EABR automatically.

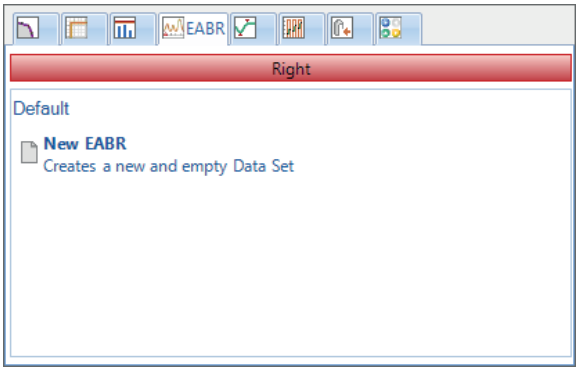


Figure 71 Dialog to open the EABR task

Figure 72 shows the user interface of the EABR task. It is divided into the tabs Stimulation, Extended Setup and Stimulation History.

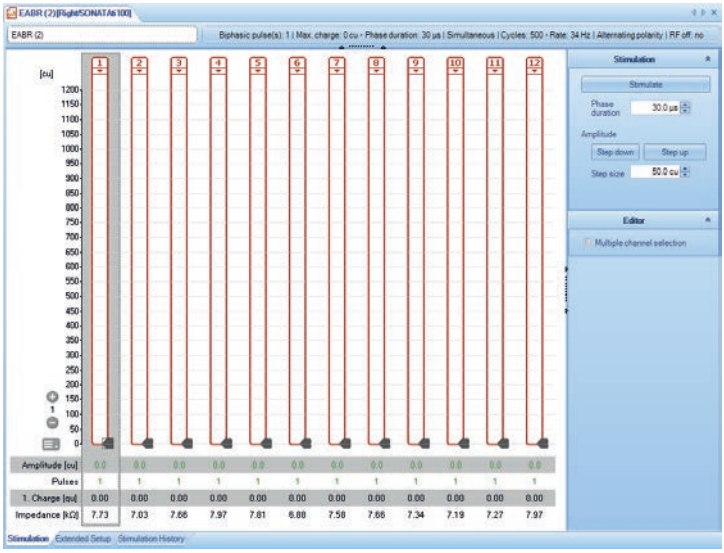


Figure 72 EABR dialog

6.4.2.1 Stimulation

In the dialog Stimulation (see Figure 72) the amplitude of the stimulation pulse in cu (see section 5.14) and the number of pulses per cycle can be set. By default, these basic stimulation parameters are shown in a table below the stimulation bars. In addition, the charge of the stimulation pulse is given in qu (see section 5.14). The length of the phase duration is the same for all channels and can be set in the field Phase Duration in the Stimulation section on the right side of the Stimulation dialog.

The buttons +/- left of stimulation bar 1 allow changing the scaling of the current units. By default, stimulation can only be elicited in one electrode. The active electrode is highlighted in grey. In the Editor section on the right side of the Stimulation dialog, selecting the checkbox Multiple channel selection allows the selection of several channels for stimulation with a single mouse click. A left mouse click on the applicable stimulation bar allows selecting as many available channels for stimulation as desired. The selected channels are highlighted in grey. In globally deactivated channels, stimulation is not possible. The global status of each electrode can be selected by clicking on the arrow symbol below the electrode number in the stimulation bar. It is possible to globally deactivate an electrode so that it is also automatically deactivated for all other tasks. The amplitude of the stimulation pulse can be set for each electrode individually.

When selecting precision triphasic pulses* (see section 6.4.2.2), it is necessary to set the amplitude for the first and the second phase. The amplitude of the third phase is the difference between the absolute value of the amplitudes of phase 1 and phase 2. To guarantee charge balance in precision triphasic pulses only sequential stimulation with one pulse per cycle and cycle-wise alternating polarity is allowed.

NOTE:
For precision triphasic pulses the amplitude of the second phase must be set higher than the amplitude of the first phase.

Table 2 lists the possible amplitude values and their default values for the various pulse types and implants. The amplitude of a stimulation pulse on an electrode can be changed graphically by shifting the black triangle in the stimulation bar with the mouse or numerically by entering the desired amplitude value in the applicable input field in the table below the stimulation bar. In addition, it is possible to control the value via the page up/down keys (+/- 15 cu), the arrow keys (+/- 3 cu) or the plus and minus keys (+/- 1 cu). The amplitude values of an electrode can be transferred to all or a specified electrode by a right mouse click and selecting the option Copy amplitude to. It is also possible to increase or decrease the stimulation amplitudes of active channels in steps by clicking on the buttons Step up or Step down in the area Stimulation on the right side of the Stimulation dialog. Individual step size can be defined in the field Step size. The default step size depends on the implant type. It is 25 cu with C40+ and 50 cu with SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100}.

If the value of the stimulation amplitude exceeds the value of the maximum possible stimulation current in one or more electrodes, a message appears in the notification window. The value of the maximum possible stimulation current is based on the data of the last telemetry measurement (see section 6.2.2.1) and states the stimulation current at which the implant reaches its cut-off voltage. If no telemetry data are available, MAESTRO uses the implant-dependent default values to display the maximum stimulation current. If the value of the stimulation amplitude exceeds the security limit defined by MAESTRO or the user in one or more electrodes (see section 5.3), a warning appears which must be confirmed to allow stimulation.

* Triphasic pulses are only FDA approved for EABR measurements and not for chronic stimulation

Pulse type	Implant type	Phase	Minimum [cu]	Maximum [cu]	Default [cu]
Biphasic	C40+	1	0	1700	0
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100			1200	
Triphasic	C40+	1	0	1700	0
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100			1200	
Precision Triphasic	C40+	1	0	1700	0
		2			
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100	1		1200	
		2			

Table 2 Minimum, maximum and default values of the adjustable amplitudes of a pulse for all supported types of pulses and implants*

The phase durations of biphasic and precision triphasic pulses are the same for all pulse phases. In triphasic pulses the given value is of the duration of the second phase, the duration of the first and third phase is half of the second phase. Table 3 shows the possible phase durations and their default settings for the various pulse types and implants.

* Triphasic pulses are only FDA approved for EABR measurements and not for chronic stimulation

Pulse type	Implant type	Minimum [µs]	Maximum [µs]	Default [µs]
Biphasic	C40+	53.3	400	53.3
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100	25		30
Triphasic	C40+	106.7	400	106.7
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100	25		30
Precision Triphasic	C40+	53.3	400	53.3
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100	25		30

Table 3 Minimum, maximum and default values of phase durations for all supported pulse and implant types*

One cycle consists of 1 to 16 pulses stimulated sequentially with short interpulse gaps (see section 6.4.2.2). The pulses can be applied to the same or to different electrodes. A cycle is followed by a stimulation gap. The default number of pulses per cycle is 1 for each electrode. The total number of pulses per cycle is the sum of pulses per cycle at all active channels. By default, all active channels are stimulated sequentially in the sequence of their electrode number. For SYNCHRONY, MED-EL CONCERT, SONATA TI100 and PULSAR CI100 implants it is also possible to stimulate on all active channels in parallel (see section 6.4.2.2).

A mouse click on the icon Hide/Show lines on the left side displays information about further stimulation parameters in the table. The additional parameters are the charge of individual pulse phases in qu (see section 5.14), the impedance values of the latest telemetry measurement in kΩ and the compliance limit of the individual channels in cu (see section 5.14), showing the value of the maximum possible stimulation current where the implant reaches its voltage limit based on the data of the last telemetry measurement (see section 6.2.2.1.) In addition to the numerical listing in the tabular view, the compliance limit is indicated by a red marker in the applicable stimulation bar. If no telemetry data is available, the default values depending on the implant type are used.

* Triphasic pulses are only FDA approved for EABR measurements and not for chronic stimulation

The stimulation starts by a left mouse click on the button Stimulate on the right side of the EABR task. Stimulation progress is displayed in a pop-up window. In addition, the current stimulation parameters are summarized. By default, MAESTRO reads out the serial numbers of SYNCHRONY, MED-EL CONCERT, SONATATI^{100} and PULSARCI^{100} implants before and regularly during stimulation. If read-out of the serial number is not possible during stimulation, stimulation stops and the user is informed that the communication link between implant and MAX coil was interrupted.

6.4.2.2 Extended Setup

The Extended Setup dialog (see Figure 73) allows setting further stimulation parameters, defining Stimulation pattern, After stimulation behavior and Trigger settings.

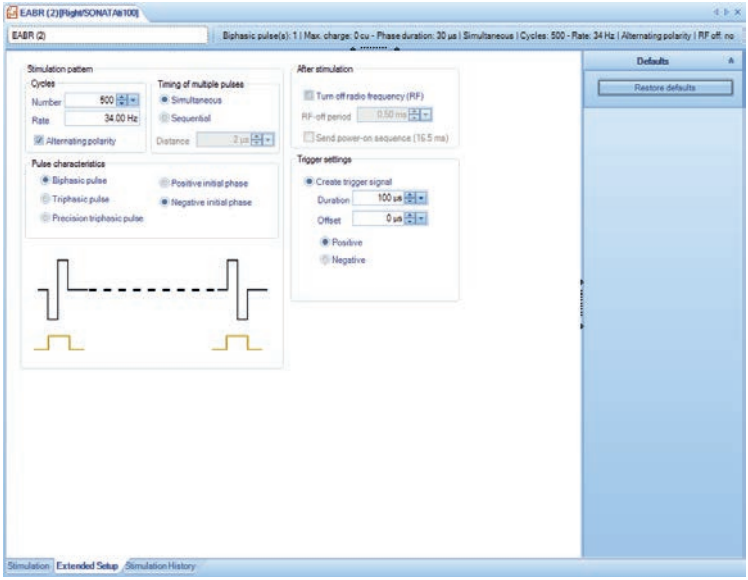


Figure 73 Extended Setup

Temporal alignment of the stimulation pulses and the trigger signal is shown in a graph (see Figure 74). The upper grey graph displays a stimulation pulse, the ochre graph below a trigger signal.

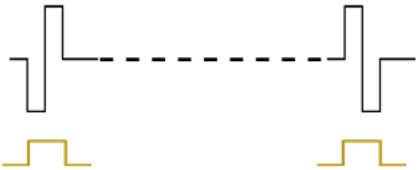


Figure 74 Graphic display of temporal alignment of stimulation pulse and trigger signal

Clicking on the button Restore defaults on the right side of the Extended Setup dialog restores all values to their default settings.

The Stimulation pattern section (see Figure 75) is divided into the subareas Cycles, Pulse characteristics and Timing of multiple pulses.

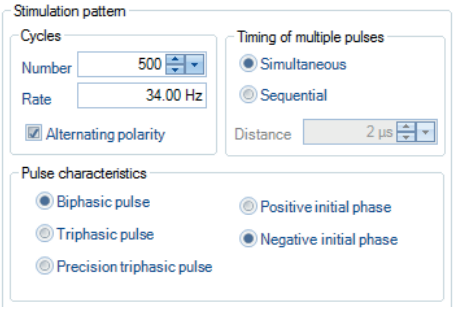


Figure 75 Stimulation pattern

The subarea Cycles allows setting the parameters Number and Rate. The parameter Number defines how often an individual cycle is repeated. The default value is 500 repetitions. The parameter Rate defines the repetition rate of the individual cycle thus determining the cycle duration. The default value is 34 Hz. In addition, selection of the checkbox Alternating polarity, allows setting an alternating stimulation pattern so that the polarity of all pulses of a cycle is always inverted when a new cycle is applied.

The subarea Pulse characteristics allows setting the pulse type and the initial phase of the pulse. The pulse type can either be biphasic, triphasic or precision triphasic. The initial phase of the pulse can be positive or negative. The default values are biphasic pulses with negative initial phase. Table 4 shows the possible input values for the parameters number of cycles, cycle rate, polarity of the first pulse and alternating polarity.

Parameter	Minimum	Maximum	Default
Number of cycles	100	5000	500
Cycle rate	0.1 Hz	150 Hz	34 Hz
Polarity of the first pulse	Negative	Positive	Negative
Alternating polarity	No	Yes	Yes

Table 4 Input values of the parameters number of cycles, cycle rate, polarity of the first pulse and alternating polarity

The subarea Timing of multiple pulses allows defining sequential or simultaneous stimulation in the selected channels for SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} implants. The default value is simultaneous stimulation. For simultaneous stimulation, only one stimulation pulse can be used per electrode and cycle. For C40+ implants simultaneous stimulation is not possible. Only sequential stimulation is available for this implant. During sequential stimulation the temporal distance between two stimulation pulses can be set in µs via the parameter Distance. The default distance is 2 µs. The possible minimum distance depends on the implant type. For SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} implants the possible minimum distance between two sequential pulses is 2 µs, for C40+ 0 µs. The possible maximum distance for all implants is 1 ms. Table 5 lists the possible input values for the parameters number of pulses per cycle, pulse distance, sequence of pulses and number of active electrodes per cycle depending on the implant type.

Parameter	Implant type	Minimum	Maximum	Default
Number of pulses per cycle	All	1	16	1
Pulse distance	C40+	0 µs	1 ms	0 µs
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100	2 µs		2 µs
Sequence of pulses	C40+	sequential	sequential	sequential
	SYNCHRONY MED-EL CONCERT SONATA TI100 PULSAR CI100		simultaneous	simultaneous
Number of active electrodes per cycle	All implants	1	8 or 12	1
			1	

Table 5 Input values for the parameters number of pulses per cycle, pulse distance, chronology and number of active electrodes per cycle

In the After stimulation section (see Figure 76) it is possible to define if RF transmission of the stimulator shall be switched off for a certain time after application of a cycle.

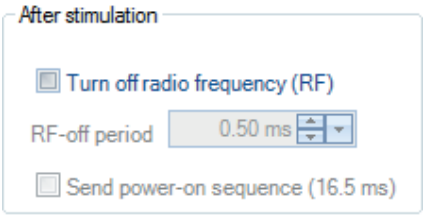


Figure 76 After stimulation

The default RF-off period is 0.50 ms. Deselection of the checkbox Turn off radio frequency (RF) prevents switching off the RF transmission of the stimulator. MAESTRO automatically adapts the maximum duration of the RF-off period to the current values of duration, cycle rate and temporal distance between two sequential pulses. If the user-selected duration of the RF-off period exceeds the upper limit determined by MAESTRO, the

duration of the RF-off period is automatically set to the limit determined by MAESTRO. If deactivation of the RF transmission of the stimulator is activated, selection of the checkbox Send power-on sequence defines that a default power-on sequence of 16.5 ms is transmitted to the stimulator after reactivating the RF transmission. By default, this function is deselected.

The Trigger settings section (see Figure 77) allows selecting different options for the trigger signal the MAX Programming Interface sends.

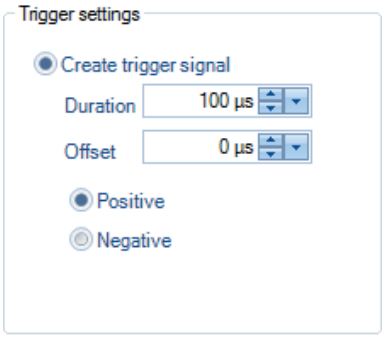


Figure 77 Trigger settings

It is possible to set the duration of the trigger in µs, the offset in relation to the stimulation pattern in µs and the polarity of the trigger signal. Table 6 shows the possible input values for the parameters of the trigger signal.

Parameter	Minimum	Maximum	Default
Trigger offset [µs]	–100	100	0
Duration of trigger signal [µs]	10	400	100
Polarity of trigger signal	Lower than in non triggered condition (negative polarity)	Higher than in non triggered condition (positive polarity)	Higher than in non triggered condition (positive polarity)

Table 6 Input values for the parameters of the trigger signal

6.4.2.3 Stimulation History

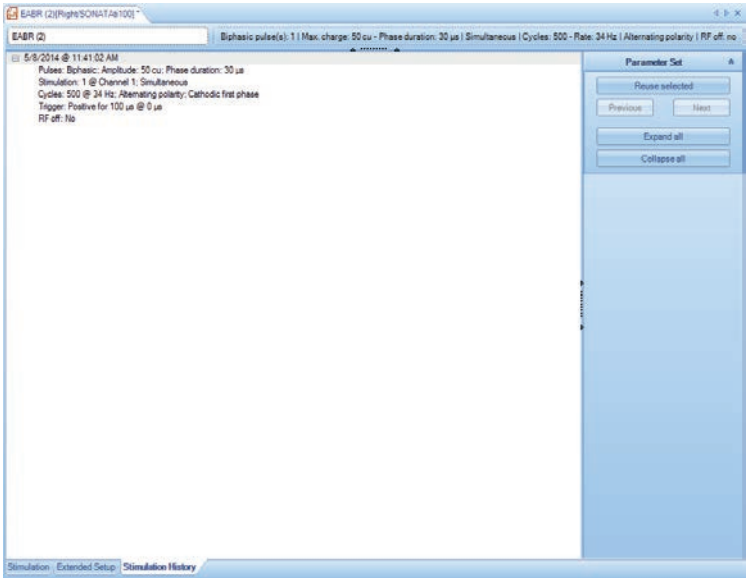


Figure 78 Stimulation History

The Stimulation History tab (see Figure 78) lists the basic and extended parameters of the individual stimulations used during measurement. The applied stimulations are listed with date and time. A left mouse click on the + sign before the applicable entry opens a list with the stimulation parameters used. Alternatively, clicking on the button Expand all on the right side of the Stimulation History editor expands the tree view of all applied sets of stimulation parameters, while clicking on the button Collapse all closes the tree view. To easily recognize differences in the parameters of two subsequent stimulations, they are colored. Double-clicking on the entry allows entering a comment to the applicable stimulation. This comment is shown in the list after the entry. Clicking on the button Reuse selected on the right side of the Stimulation History dialog allows reusing the parameters of the selected stimulation for another stimulation. The parameters need not be entered again. The buttons Next and Previous enable selecting the next or previous entry.

6.4.3 EABR settings

Clicking on the symbol Settings | EABR in the toolbar allows customizing the default settings of the EABR task. Figure 79 shows the Settings dialog of the EABR task.

Clicking on the button Restore Defaults in the right bottom corner restores all settings of the EABR task to their default values. The changed settings are applied after closing the Settings dialog.

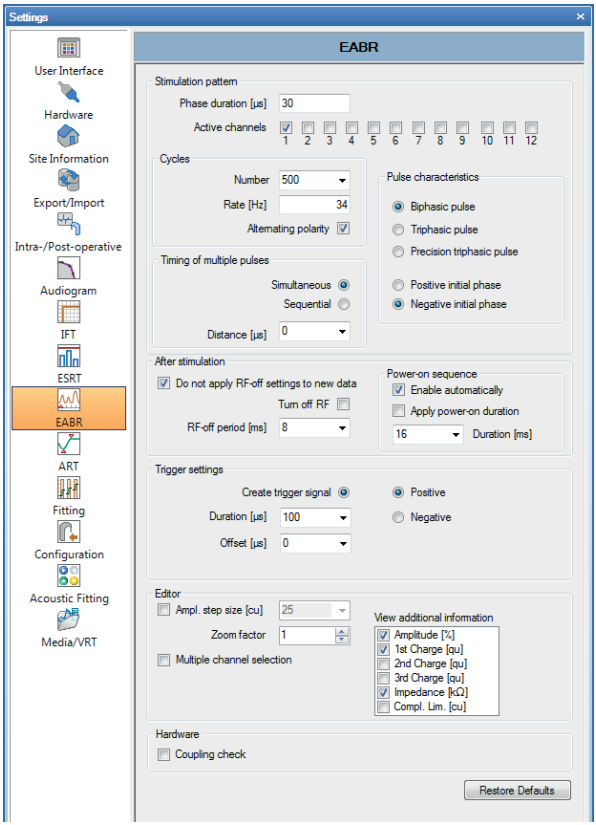


Figure 79 EABR settings dialog

6.4.3.1 Stimulation pattern

Figure 80 Stimulation pattern

When setting the Stimulation pattern (Figure 80), the phase duration which is used as default for stimulation can be defined. The phase duration can be set between 25 and 400 µs. The default is 30 µs. In addition, selection of the applicable Active channels checkbox defines which channels will be automatically active when opening the EABR task.

6.4.3.2 Cycles

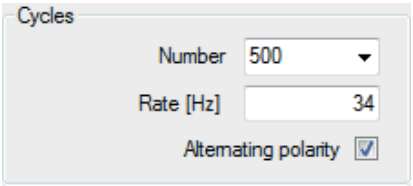


Figure 81 Cycles

Setting the cycles (Figure 81) allows changing the default number of all repetitions of a cycle via the parameter Number and the repetition rate of each cycle via the parameter Rate. The defaults are 500 repetitions and a rate of 34 Hz. The number of repetitions can be set between 100 and 5000, the rate between 0.1 and 150 Hz. The Alternating polarity checkbox defines an alternating stimulation pattern as the default. By default, this checkbox is selected.

6.4.3.3 Pulse characteristics

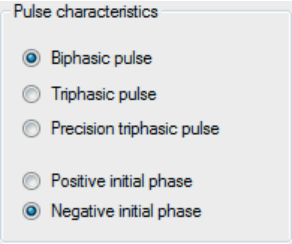


Figure 82 Pulse characteristics

Pulse characteristics (Figure 82) defines the shape of the stimulation pulses. The default value is a biphasic pulse with negative initial phase. Other options are triphasic or precision triphasic pulse and positive initial phase.

6.4.3.4 Timing of multiple pulses

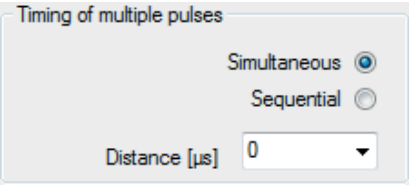


Figure 83 Timing of multiple pulses

For SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} implants, the setting Timing of multiple pulses (Figure 83) defines simultaneous or sequential stimulation patterns in the active channels. It also defines the distance for sequential stimulation which can be set between 0 and 1000 µs, with 0 as default value. The default value for Timing of multiple pulses is simultaneous stimulation.

6.4.3.5 After stimulation

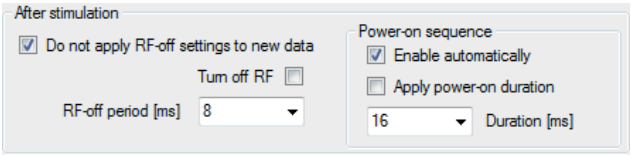


Figure 84 After stimulation

After stimulation (Figure 84) defines the use of the values of RF-off period and Turn off RF defined in the Settings dialog for new EABR measurements by activating the Do not apply RF-off settings to new data checkbox. By default, this checkbox is selected so that the default settings defined by MAESTRO are used for new EABR measurements. Deselecting the Do not apply RF-off settings to new data checkbox allows using the values defined in the Settings dialog for new EABR measurements. Selecting the Turn off RF checkbox temporarily deactivates the RF transmission of the stimulator after application of a cycle. The default of this RF-off period is 8 ms and can be set between 0.5 and 30 ms.

The RF-off period settings define if a power-on sequence is sent after reactivating the RF transmission. The Enable automatically checkbox is selected by default, i.e. sending a power-on sequence is the default mode. Selecting the Apply power-on duration checkbox allows customizing the duration of the power-on sequence. The desired duration in ms can be entered in the Duration field. By default or when deselecting the Apply power-on duration checkbox, the power-on sequence is 16 ms. The duration of the power-on sequence can be set between 0 and 54 ms.

6.4.3.6 Trigger settings

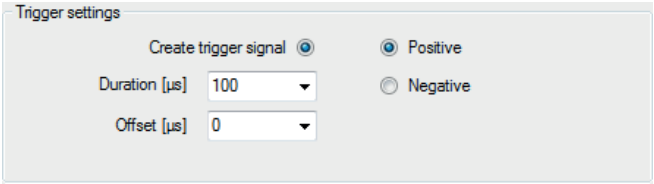


Figure 85 Trigger settings

The Trigger settings (Figure 85) allow customizing the trigger signal. By default the option Create trigger signal is active and the MAX Programming Interface sends a trigger signal. The fields Duration and Offset allow setting the duration of the trigger signal in µs and its offset in relation to the first pulse of a cycle in µs. A positive or a negative time can be selected for the offset. Selecting a negative time places the onset of the first stimulation pulse of a cycle before the onset of the trigger. The duration of the trigger signal can be set between 10 and 400 µs, the default value is 100 µs. The offset can be set between −100 and 100 µs, the default value is 0 µs. The options Positive and Negative define the polarity of the trigger signal. The default value is positive polarity.

6.4.3.7 Editor

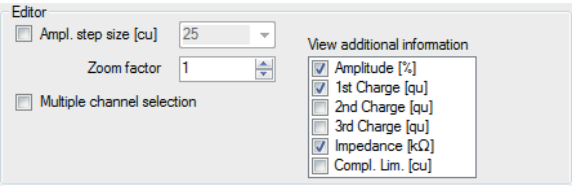


Figure 86 Editor

Editor (see Figure 86) allows defining the step size to increase or decrease the amplitude. If selected, the default value is 25 cu (see section 5.14). Step size can be set between 10 und 500. Selecting the checkbox Multiple channel selection activates the multiple channel selection option as default. Also a Zoom factor default can be defined. Selecting the checkbox Multiple channel selection allows to select more than one channel. To view additional information, select the appropriate checkboxes. By default, Amplitude, 1st Charge and Impedance are selected.

6.4.3.8 Hardware

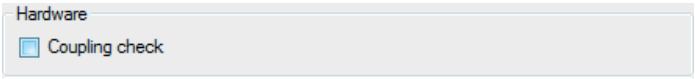


Figure 87 Hardware

Selecting the checkbox Coupling check in the Hardware settings allows defining if coupling between implant and coil should be checked during measurement. The checkbox is deselected by default, i.e. coupling is not checked.

6.5 ART TASK

The ART (Auditory nerve Response Telemetry) task allows recording the evoked compound action potential (ECAP) of the auditory nerve elicited by stimulating the intracochlear electrodes. The potential is recorded a few microseconds after the end of the stimulation pulse. The compound action potential is recorded by the intracochlear electrodes.

6.5.1 ART hardware

ART is available for SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} implants. Communication with the implant is established via a MAX coil (see section 4.5), therefore the MAX coil that corresponds to the patient's implant needs to be connected to the MAX Programming Interface. It is not necessary to connect an audio processor.

CAUTION:
Make sure to use the appropriate hardware for measurement.
ART data generated with a pulse detector box cannot be saved in the database.

6.5.2 Starting the ART task

NOTE:
ART is only possible for patients with a SYNCHRONY, MED-EL CONCERT, SONATAti[100] or PULSARci[100] implant.

To start the ART task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4). After selection there are several ways to start the ART task:

1. A click on the button New opens the task dialog shown in Figure 88, where the ART tab can be selected and with a click on New ART an ART can be opened.
2. A right click on the symbol ART in the taskbar opens the very same dialog with the ART tab already selected. A click on New ART opens a new ART.
3. A double click on the symbol ART in the taskbar opens a new ART automatically.

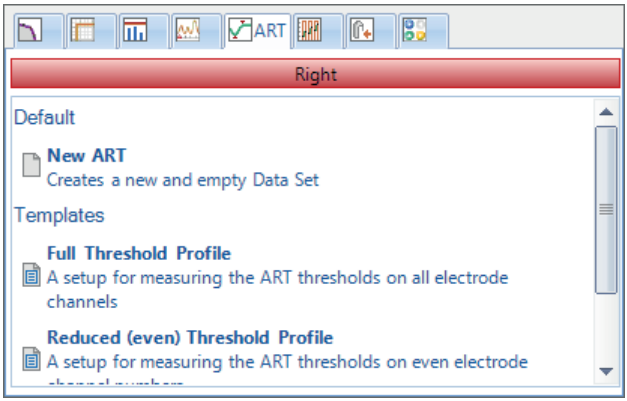


Figure 88 Dialog to open the ART task

Additionally ready-made templates are available in the area Templates of the ART tab shown in Figure 88. Full Threshold Profile, which opens the template to measure the ART thresholds on all electrodes, Reduced (even) Threshold Profile, which opens the template to measure the ART thresholds in even electrode numbers, and Reduced (odd) Threshold Profile, which opens the template to measure the ART thresholds in odd electrode numbers, can be selected.

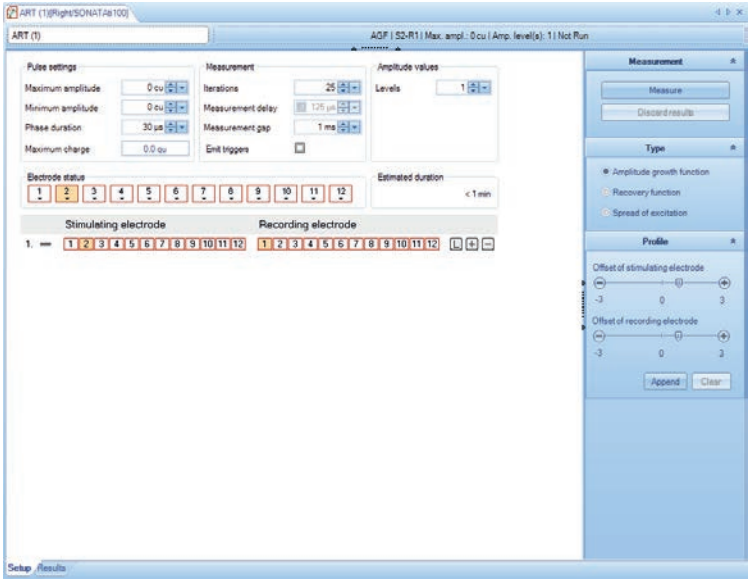


Figure 89 ART dialog

Figure 89 shows the user interface of the ART task for the selection New ART. It is divided into the tabs Setup and Results.

6.5.2.1 Setup

In the Setup editor (see Figure 89) the groups of measuring parameters Pulse Settings, Measurement and other parameters depending on the type of measurement can be defined. MAESTRO supports three types of ART measurements: Amplitude growth function, Recovery function and Spread of excitation function. The desired type can be selected on the right side of the Setup dialog in the Type section. The individual parameters for Amplitude growth function, Recovery function and Spread of excitation are described in sections 6.5.2.2, 6.5.2.3. and 6.5.2.4. Estimated duration of the ART measurement is displayed below the area for entering the parameters.

Under Electrode Status individual electrodes may be globally (de)activated so that they are automatically (de)activated for all other tasks. Various reasons for deactivation can be selected from a drop-down menu. If an electrode has already been deactivated in another task, this electrode is also indicated as globally deactivated in the ART task.

NOTE:
Stimulation and recording of compound action potentials of the auditory nerve are also possible with globally deactivated electrodes.

The stimulating electrode and recording electrode channels are displayed graphically below the Electrode status section. Additional single measurements can be inserted or deleted from the displayed profiles by clicking on the + or – button. When inserting single measurements, the stimulating electrode and recording electrode are adjusted according to the settings in the sidebar of the Setup dialog under Profile on the right side. The slider below Offset of stimulating electrode shows the value which will be added to the previous stimulating electrode number, thereby indicating the next stimulating electrode.

The slider below Offset of recording electrode indicates the value which will be added to the previous stimulating electrode number, thereby indicating the next stimulating electrode. Click on the buttons Append or Clear to add additional single measurements to the profile or delete all added single recordings from the profile.

Next to the single recordings the status of each ART measurement is graphically indicated:

- indicates that the measurement has not yet been run,
-  indicates that the measurement was successfully completed,
- indicates that the user skipped one or more objective function parameters (e.g. by clicking on the Next batch button during measurement),
-  indicates that the measurement was not performed with every iteration,
- indicates that the measurement was canceled by the user,
-  indicates that an error occurred during measurement and the measurement could not be continued (e.g. disconnected MAX Programming Interface).

Click on the button L to open the Loudness Comfort Tool dialog shown in Figure 90.

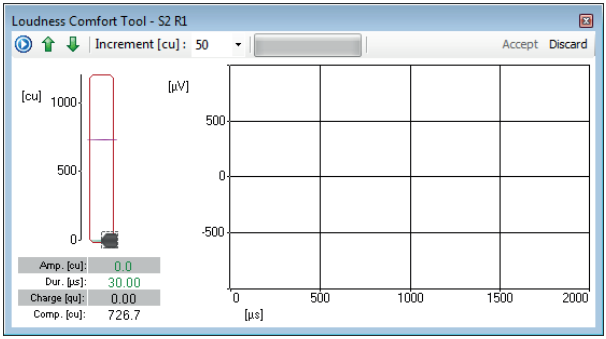


Figure 90 Loudness Comfort Tool

The Loudness Comfort Tool allows checking pulse amplitude along the dynamic range to estimate an upper limit of the stimulation whose charge elicits a compound action potential but does not cause uncomfortably loud hearing sensations. The header of the dialog displays the stimulating electrode and the recording electrode of the template for which the Loudness Comfort Tool was selected. The labeling S2 R1 in the header of Figure 90 indicates that the Loudness Comfort Tool was selected for the single measurement with Stimulating Electrode 2 and Recording Electrode 1.

The amplitude of the stimulation pulse can be set by sliding the black arrow in the stimulation bar to the desired value. Alternatively, the numerical value can be directly entered in the field Amp. [cu] (see section 5.14) in the table below the stimulation bar or the value can be set by clicking on the green arrow symbols in the header. When using the arrow symbols, the stimulation amplitude is increased or decreased according to the value given in the field Increment [cu] (see section 5.14). The set stimulation amplitude is displayed in the stimulation bar as shown in Figure 91. The green area of the bar marks the amplitude range where stimulation has already taken place, the orange area indicates the amplitude range where no stimulation has taken place.

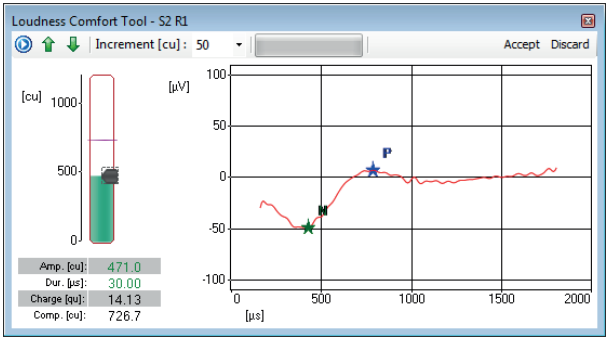


Figure 91 Loudness Comfort Tool with set stimulation amplitude

Beside the amplitude of the stimulation pulse, the table below the stimulation bar also shows the pulse phase duration in Dur. [µs], the charge in Charge [qu] (see section 5.14) and the compliance limit in Comp. [cu]. In addition, the value of the compliance limit is graphically displayed as a red line in the stimulation bar. It is based on the data of the last telemetry measurement (see section 6.2.2.1) and indicates the stimulation current at which the implant reaches its compliance limit. If no telemetry data is available, MAESTRO uses the default values depending on the implant type to display the compliance limit. The green line in the stimulation bar shows the previously selected maximum amplitude.

NOTE:
If no identifiable compound action potential can be recorded at the compliance limit, carefully increase the phase duration instead of the amplitude to ensure that the implant operates within the limits of compliance.

Click on the button Test Loudness in the header or press the space bar to start the measurement. The implant serial number is read out and compared with the serial number stated in the patient data (see section 5.16.1.3). No stimulation takes place in this phase. If the read-out serial number is identical with the serial number stated in the patient data, measurement continues. Otherwise a warning appears and the entry in the patient data must be corrected. If the selected type is the Amplitude growth function, stimulation takes place with maximum amplitude according to the parameter set in the Amplitude growth function (see section 6.5.2.2). If the selected type is the Recovery function, two pulses with the smallest interval set in the parameters area (see section 6.5.2.3) is applied. The amplitude of the first pulse corresponds with the Masker Amplitude, the amplitude of the second pulse

is the Test Pulse Amplitude. The Spread of excitation function is similar to the Recovery function but with constant masker-probe interval and change of masker electrode. During measurement, progress is displayed graphically in the header. An ongoing measurement may be aborted any time by clicking on the button Test Loudness in the header or pressing the space bar. After successful measurement the result is displayed in the diagram right of the stimulation bar. The stimulation amplitude used for the Loudness Comfort Tool can be adopted to all channels by clicking on the button Accept in the header for the measurement of the Amplitude growth function, Recovery function and Spread of excitation.

NOTE:
If the stimulation amplitude used for the Loudness Comfort Tool is applied, this value applies to all electrodes.

The Loudness Comfort Tool dialog is closed and the applicable value entered in the field Maximum Amplitude (see section 6.5.2.2) or Masker Amplitude (see section 6.5.2.3). Click on the button Discard to close the Loudness Comfort Tool without adopting the value of the stimulation amplitude.

After setting all parameters, start the measurement by clicking on the button Measure on the right side of the Setup dialog in the Measurement section. The view changes to the Results dialog (see section 6.5.2.5).

If a measurement has already been performed, the results can be deleted by clicking on the button Discard Results on the right side of the Setup dialog in the Measurement section. To repeat the measurement, click on the button Measure.

6.5.2.2 Parameters of the Amplitude growth function

The Amplitude growth function is divided into the areas Pulse Settings, Measurement and Amplitude values. Figure 92 shows the parameter view of the Amplitude growth function.

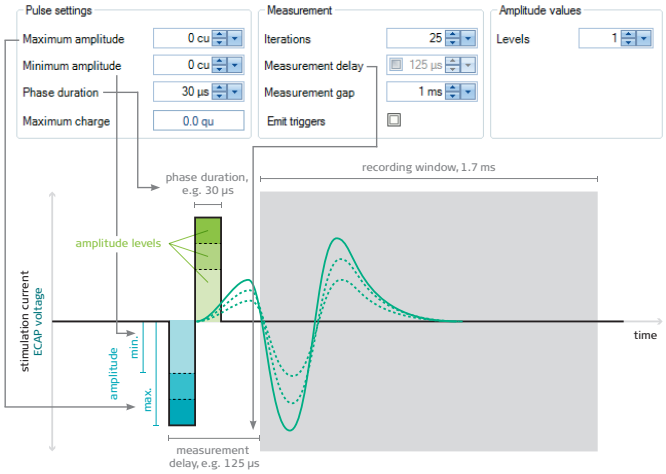


Figure 92 Parameters of the Amplitude growth function

In the area Pulse settings the parameters Maximum amplitude, Minimum amplitude and Phase duration can be set for the Amplitude growth function.

The Minimum amplitude is the stimulation amplitude where the measurement starts, the Maximum amplitude the highest stimulation amplitude applied where the measurement of the Amplitude growth function stops. Minimum amplitude and Maximum amplitude can be entered between 0 cu and 1200 cu (see section 5.14), the default is 0 cu for both parameters. Independent of the Minimum amplitude and the Maximum amplitude settings MAESTRO always performs a measurement with 0 cu amplitude which is then automatically subtracted from all other measurements (see section 6.5.2.5).

The parameter Phase duration indicates the phase duration of the stimulation pulse in µs. All stimulation pulses have the same phase duration. The phase duration can be set between 20 µs and 100 µs, the default is 30 µs.

The field Maximum charge gives the maximum stimulation charge used for measurement. This charge is derived from the settings of the parameters Maximum amplitude and Phase duration.

In the area Measurement the parameters Iterations, Measurement delay and Measurement gap can be set.

The parameter Iterations defines how often the recording will be repeated per pulse setting to obtain a single compound action potential by averaging over all recordings. This mean compound action potential represents the result for the applicable pulse setting. 1 to 99 iterations are possible, the default is 25 iterations.

NOTE:
The signal-noise ratio increases with increasing number of iterations. In addition, a higher number of iterations increases the duration of the measurement.

The parameter Measurement delay indicates the time in µs between onset of the stimulation pulse and start of the recording window. If the checkbox in the field Measurement delay is not selected, MAESTRO adapts this parameter automatically. Otherwise, the measurement delay may be set to a value between 75 µs and 400 µs.

The parameter Measurement gap defines the time in ms between the end of one iteration and the beginning of the next. The measurement gap can be set to a value between 1 ms and 1000 ms. The default is 1 ms.

With the checkbox Emit triggers selected, the MAX Programming Interface emits a trigger signal with each stimulation pulse. This option is deselected by default.

In the area Amplitude values the field Levels defines the number of equidistant amplitude levels used for stimulation. The individual amplitude levels have the same distance between the values for Minimum amplitude and Maximum amplitude and include these values. Levels can be set between 1 and 20. The default is 5 amplitude levels.

6.5.2.3 Parameters of the Recovery function

Like the parameters for the Amplitude growth function (see section 6.5.2.2), the parameters of the Recovery function are divided into Pulse Settings, Measurement and Interpulse intervals. Figure 93 shows the parameter view of the Recovery function.

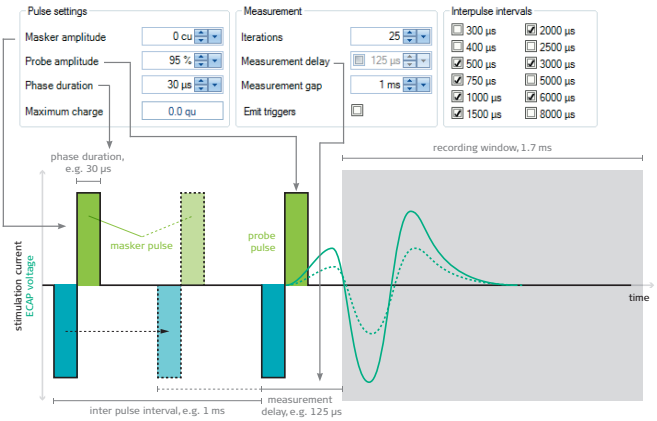


Figure 93 Parameters of the Recovery function

In Pulse settings the parameters Probe amplitude, Masker amplitude and Phase duration can be set for the Recovery function.

The parameter Masker amplitude indicates the value of the amplitude of the first stimulation pulse in cu (see section 5.14). It can be set between 0 cu and 1200 cu. The default is 0 cu.

The Probe amplitude is given as a portion relative to the Masker amplitude in %. The Probe amplitude corresponds to the first stimulation pulse and can be set between 0 % and 100 %. The default is 95 %.

The parameter Phase duration is the phase duration of the stimulation pulse in µs and applies to probe and masker. All stimulation pulses have the same phase duration. The phase duration can be set between 20 µs and 100 µs. The default is 30 µs.

The field Maximum charge gives the maximum stimulation charge used for measurement. This charge is derived from the parameter settings of Masker amplitude and Phase duration.

In the area Measurement the parameters Iterations, Measurement delay and Measurement gap can be set.

The parameters for the area Measurement are the same as for the Amplitude growth function.

In the area Interpulse intervals selection of the appropriate checkbox allows selecting the desired intervals in µs between onset of the masker and onset of the probe. By default, these intervals are 500 µs, 750 µs, 1000 µs, 1500 µs, 2000 µs, 3000 µs and 6000 µs.

6.5.2.4 Parameters of the Spread of excitation function

Like the parameters of the Recovery function (see section 6.5.2.3), the parameters of the Spread of excitation function are divided into Pulse settings, Measurement and Masker positions. The parameters for Pulse settings and Measurement are the same as for the Recovery function and are explained in section Parameters of the Recovery function. Figure 94 shows the parameter view of the Spread of excitation function.

In the Masker positions section, selection of the appropriate checkbox decides if the masker moves from the probe towards the base, the apex or in both directions. The number of masker positions can be defined in the field next to the options. They can be set between 1 and 11. The default is 6 in both directions. Activating the checkbox Skip every second skips every second masker pulse and the measurement will be faster at the cost of a lower resolution of the objective function.

The resulting masker electrodes are graphically indicated in the electrode selection control. Disabled electrodes are not used as masker electrodes and will be skipped.

Towards base	Towards apex	Skip every second	Probe electrode	Resulting masker electrodes
3	3	no	6	3, 4, 5, 6, 7, 8, 9
3	3	no	2	1, 2, 3, 4, 5
3	3	no	11	8, 9, 10, 11, 12
unchecked	4	no	6	2, 3, 4, 5, 6
unchecked	4	yes	6	2, 4, 6
6	6	yes	3	1, 3, 5, 7, 9

Table 7 Examples for resulting masker electrodes

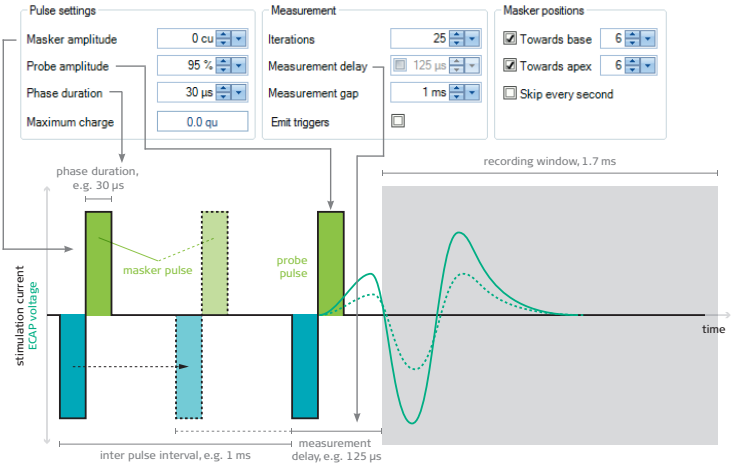


Figure 94 Parameters of the Spread of excitation function

6.5.2.5 Results

The Results dialog (see Figure 95) displays the results of the measurements of the Amplitude growth function, the Recovery function or the Spread of excitation function.

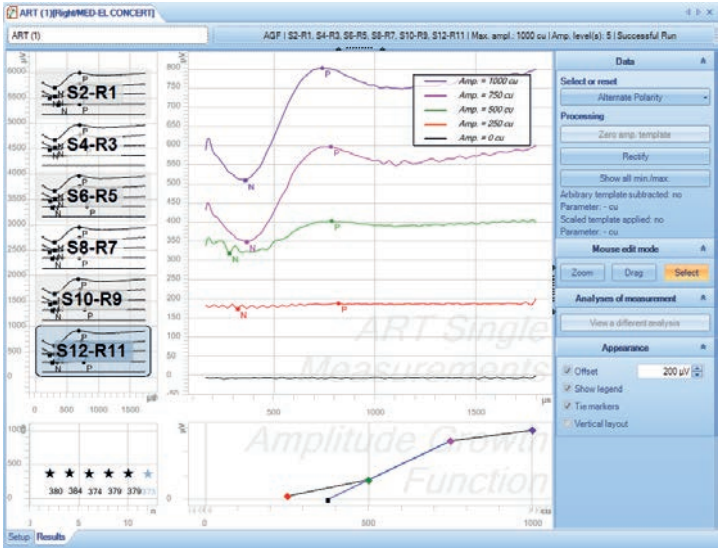


Figure 95 Results dialog

Progress is displayed during measurement in the ART Measurement dialog shown in Figure 96. This dialog shows the currently performed single measurement. Click on the buttons Pause or Cancel to pause or abort the measurement and Next batch to skip the remaining objective function parameters and advance to the next single measurement.

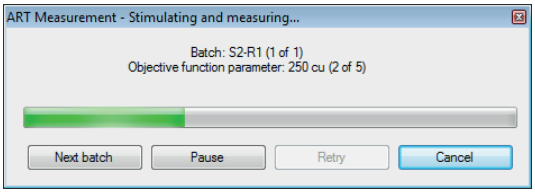


Figure 96 Performing ART measurement dialog

When pausing the measurement by clicking on the button Pause, MAESTRO stops all stimulation and recording activities in a way which allows continuation of the measurement. If a measurement was paused, the labeling of the button Pause changes to Resume. Click on the button Resume to continue the measurement.

When aborting the measurement by clicking on the button Cancel, all stimulation and recording activities are stopped. The measurement is aborted and the user informed by the message shown in Figure 97.

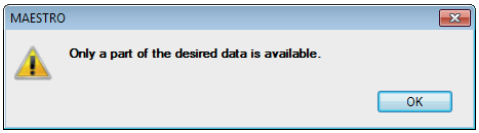


Figure 97 ART measurement canceled message

After each single measurement the implant serial number is read out to check the communication between implant and the MAX coil. If the communication with the implant is interrupted during measurement, the dialog shown in Figure 98 appears. After re-establishing communication, measurement may be retried. If the communication cannot be re-established or re-establishment is not desired, the measurement may be canceled.

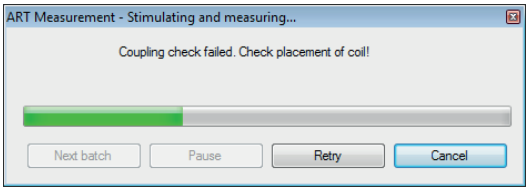


Figure 98 ART measurement interrupted message

After a measurement the results are displayed graphically. If the measurement was canceled prematurely, the so far obtained results are displayed. The Results editor (see Figure 95) is divided into 5 areas:

1. The area in Figure 99 allows selecting a certain single measurement. The signals measured for the single measurement are displayed in the area shown in Figure 100.

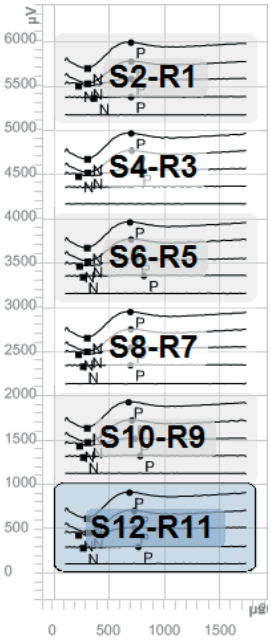


Figure 99 Selection of single measurement

2. The area in Figure 100 shows the measured signals of one single measurement as voltage over time. The signal for each objective function parameter (see sections 6.5.2.2, 6.5.2.3 and 6.5.2.4) is shown. If MAESTRO recognizes the point of the first minimum and the point of the first maximum, both points are automatically labeled N and P.

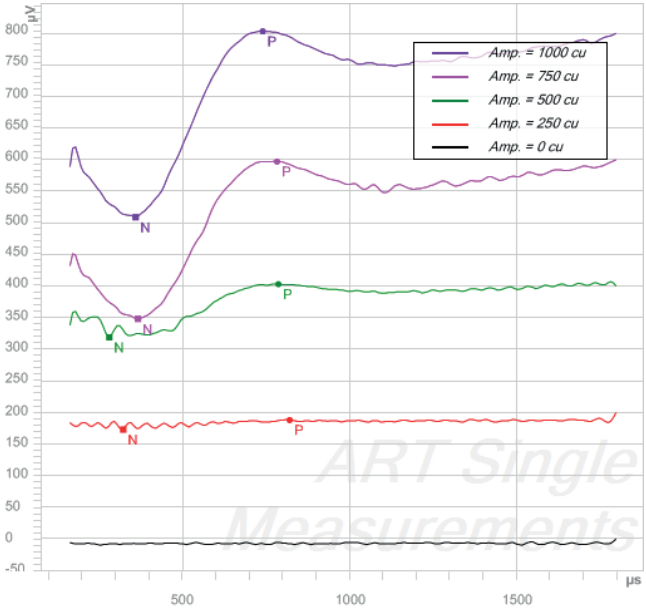


Figure 100 Signals measured for Amplitude growth function

3. The area shown in Figure 101, Figure 102 and Figure 103 provides a graphic display of the Amplitude growth function, the Recovery function and the Spread of excitation function. The Amplitude growth function gives the ECAP amplitude in µV over the stimulation amplitude levels in cu (see section 5.14), the Recovery function gives the ECAP amplitude in µV over the intervals between stimulation pulses in µs. If an ART Threshold was extrapolated for the Amplitude growth function, the corresponding cu value is marked on the x-axis. The interpolation line can be manually adjusted by shifting the markers. The graphic display for the Spread of excitation function gives the ECAP amplitude in µV over the position of the masker electrodes and therefore allows assessing the interactions between the excitation areas produced by each electrode.

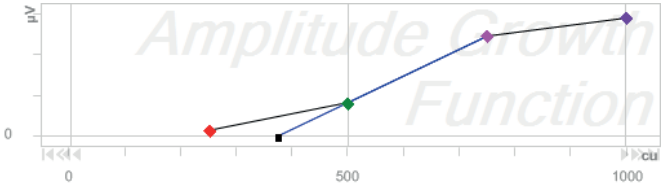


Figure 101 Amplitude growth function

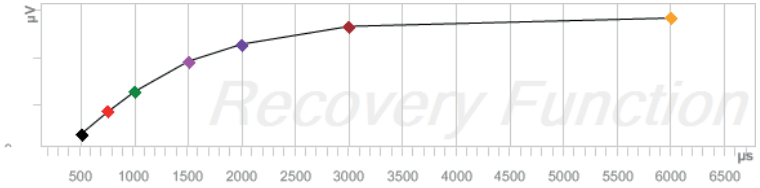


Figure 102 Recovery function

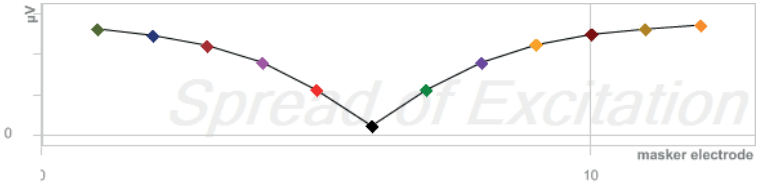


Figure 103 Spread of excitation function

4. The area in Figure 104 displays the ART thresholds for each stimulating electrode in cu (see section 5.14) if MAESTRO was able to determine an ART threshold for the applicable single measurement. This area will only appear as the result of the Amplitude growth function.

Figure 104 ART thresholds

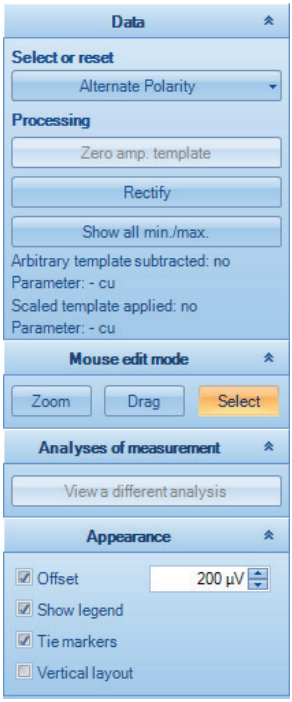


Figure 105 Sidebar with areas to edit results

5. The sidebar (Figure 105) allows editing and processing the results.

In the Data section selecting the field Select or reset allows using the measured responses of the stimulation pulses starting with a positive (anodic/cathodic) or a negative phase (cathodic/ anodic) or the responses averaged from these two sets of responses (alternate). The default is Alternate Polarity to reduce stimulation artifacts. Changes made to the initial results are undone by resetting or changing the polarity.

The area Processing provides the buttons Zero amp. template, Rectify and Show all min./max. Clicking on Zero amp. template subtracts the zero measurement automatically performed by MAESTRO from all other curves. This button cannot be selected by default since the Zero amp. template is automatically performed for the standard settings (see section 6.5.3), thus realizing artifact reduction. Clicking on the button Rectify allows subtracting a linear drift artifact. A straight line is adapted to and subtracted from each result curve in the range between 655 and 1402 µs so that each result curve ends with a 0 amplitude. A brief text information is displayed indicating whether a scaled template has been applied or not and what curve has been used as the scaled template. Also for the Arbitrary template a textual information is displayed if a template has been subtracted or not and what curve has been selected.

Mouse edit mode allows manual changes of the result curves via the buttons Zoom, Drag and Select. The various modes can also be selected with a right mouse click into the diagram of the result curves (see Figure 101).

Zoom allows enlarging individual areas of the result curves diagram (Figure 101) of the Amplitude growth function, the Recovery function diagram and the Spread of excitation function diagram. Press the left mouse key to define a corner of a new display window. Keep the mouse key pressed to open a rectangle. Click the right or center mouse key to display the complete diagram.

Drag allows moving around the zoomed area of the individual diagram windows.

Select allows manually editing individual result curves. When Select is activated, the N and P points can be moved along the corresponding result curve by dragging the mouse while pressing the left mouse key. Delete the display of the N and P points by right clicking on the result curve and selecting the option Hide Minimum/Maximum, selecting Show Minimum/ Maximum displays the N and P points again. Select Reset Minimum/Maximum to undo shifting the N and P points. Select Delete Measurement to delete the display of the corresponding result curve. For Amplitude growth functions the additional option of Do Scaled Template is available if only one curve is selected. By performing this option with a result curve with

a stimulation amplitude larger 0 with only an artifact but no compound action potential, additional artifact reduction is possible. The selected result curve will be scaled accordingly and, similar to the Zero amp. template, subtracted from all other result curves.

Similar to the scaled template, the option Subtract template is available for artifact reduction. The selected curve will be flattened and subtracted from all other curves.

NOTE:
All changes are undone by clicking in the field Select or reset in the sidebar of the Results editor.

In the Analysis of Measurement section the results of grouped ART measurements can be analyzed simultaneously. Clicking on the small arrow in View a different analysis allows choosing another measurement based on the same results.

In the Appearance section the display of the results can be changed with the checkboxes Offset, Show legend, Tie markers and Vertical layout.

Activating Offset allows changing the offset used for the individual result curves, by clicking on the arrow keys or directly entering the value between 0 and 1000 µV. This checkbox is selected by default. Deactivation of this checkbox displays the result curves without offset. This allows reading out the measured voltage ranges of a neural response. If the response is outside the measuring range of +/- 5 mV a warning message appears. Show legend hides/shows the legend in the result curves diagram. This checkbox is selected by default, meaning the legend in the result curves diagram is displayed. Tie markers defines whether or not the N and P points can be moved only along the result curve or freely. This checkbox is selected by default so that the N and P points can only be moved along the result curve. Selecting the checkbox Vertical layout changes the layout of the result curves and objective function diagrams from horizontal to vertical. This checkbox is deselected by default so that the diagrams are displayed horizontally.

With a right mouse click on the Amplitude growth function, the Recovery function and the Spread of excitation function interpolation of the curve may be adjusted. The default is linear interpolation. In addition, spline interpolation is available.

6.5.3 ART settings

Click on the symbol Settings | ART in the toolbar to customize the default settings of the ART task. Figure 107 shows the Settings dialog of the ART task.

Click on the button Restore Defaults at the bottom of the dialog to restore all settings of the ART task to their defaults. Changes of the settings are applied by closing the Settings dialog.

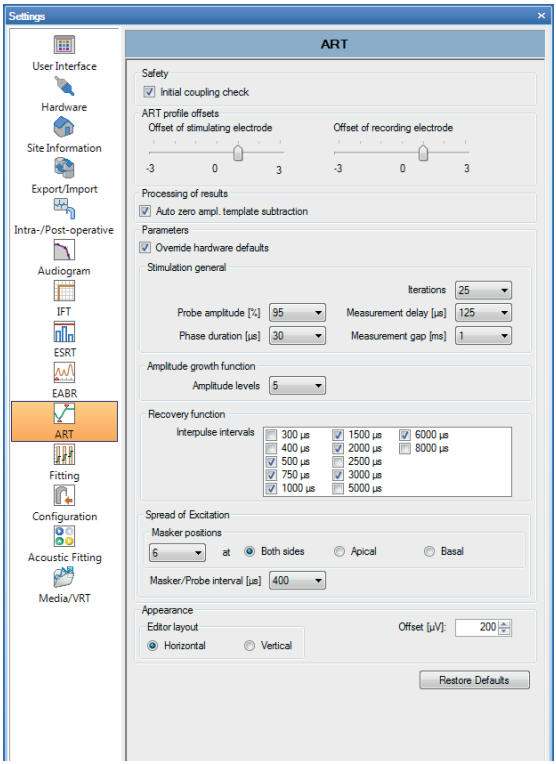


Figure 106 ART settings dialog

6.5.3.1 Safety

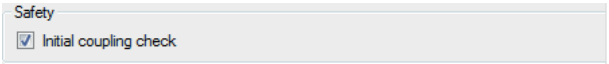


Figure 107 Safety

The checkbox Initial coupling check defines if coupling between MAX coil and implant and the implant serial number is checked before the measurement. The checkbox is selected by default so that coupling is regularly checked before commencing a new measurement. When deselecting this checkbox, special caution shall be exercised in cases of large distances between implant and coil since insufficient supply voltage may cause non-linear behavior of the measuring amplifier (e.g. drifting time signal). On the other hand, deselecting allows larger distances between implant and coil.

6.5.3.2 ART profile offsets

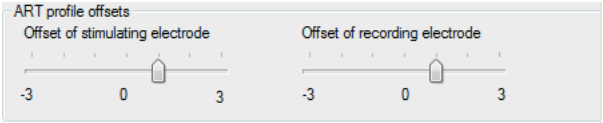


Figure 108 ART profile offsets

The ART profile offsets settings (see Figure 108) allow defining the standard offsets of stimulation and recording electrode positions of a newly added single measurement. The default settings of the sliders are +1 for the stimulating electrode and +1 for the recording electrode.

6.5.3.3 Processing of results

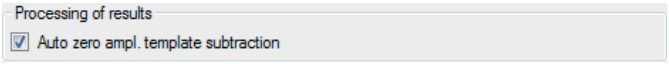


Figure 109 Processing of results

The checkbox Auto zero ampl. template subtraction is selected by default so that the Zero amplitude template (see section 6.5.2.5) is routinely performed.

6.5.3.4 Parameters

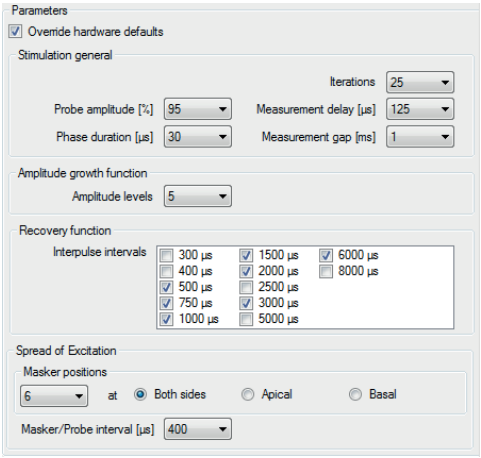


Figure 110 Parameters

The Parameters settings allow customizing the initial settings for some parameters of the Amplitude growth function, the Recovery function and the Spread of excitation function. The checkbox Override hardware defaults is selected by default so that changes to the hardware defaults are routinely applied. The hardware defaults can be changed for the following parameters: number of Iterations, Measurement delay, Measurement gap, Probe amplitude fraction, Phase duration, and Amplitude levels (see sections 6.5.2.2, 6.5.2.3 and 6.5.2.4). Table 8 lists the input area and the default settings of the individual parameters.

Parameter	Minimum	Maximum	Default
Number of Iterations	1	99	25
Measurement Gap	1 ms	1000 ms	1 ms
Phase Duration	20 µs	100 µs	30 µs
Measurement Delay	75 µs	400 µs	125 µs
Amplitude Growth Level	1	20	5
Probe Amplitude Fraction	0 %	100 %	95 %

Table 8 Minimum, maximum and standard values for adjustable Hardware Defaults

The checkboxes in the field Interpulse intervals allow selecting the desired intervals between two stimulation pulses in µs for the Recovery function (see section 6.5.2.3). The default intervals are 500 µs, 750 µs, 1000 µs, 1500 µs, 2000 µs, 3000 µs and 6000 µs. The settings for the Spread of excitation function allow adjusting the default settings for the number and direction(s) of the masker positions and the Masker/Probe interval. The number of masker positions can be set between 1 and 11 and masker pulses can be applied either on both sides, apically or basally. The default value is 3 positions on both sides. The Masker/Probe interval can be set between 200 and 600 µs in steps of 50 µs. The default value is 400 µs.

6.5.3.5 Appearance

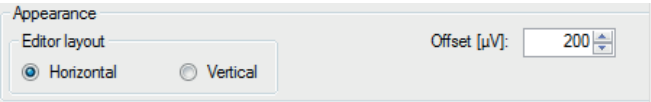


Figure 111 Appearance

The Appearance settings allow adjusting the default settings for Offset and Editor layout (see section 6.5.2.5). The offset can be set between 0 and 1000 µV, the default offset is 200 µV. The Editor layout can be set to vertical or horizontal layout, the default setting is horizontal.

6.6 FITTING TASK

The Fitting task allows processor fitting. Various strategy and processor parameters are available to optimize a map for the patient's individual needs.

6.6.1 Fitting hardware

Communication with the implant is established via the processor connected with the MAX Programming Interface, therefore the processor needs to be connected to a processor socket of the MAX Programming Interface using the MAX Programming Cable BTE, the MAX Programming Cable SONNET or the MAX Programming Cable RONDO. Depending on the hardware settings (see section 4.5) for dynamic or fixed port mapping connect the processor for a certain side to the corresponding processor socket. Use both processor sockets for bilateral fitting.

CAUTION:
Make sure to use the appropriate hardware for measurement.
If a bilateral patient uses a TEMPO+ speech processor, the right or left ear must be identified correctly prior to and during the fitting process to prevent unwanted stimulation which may go unrecognized.

6.6.2 Starting the fitting task

To start the Fitting task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4) and an empty processor or a processor programmed for the selected patient needs to be connected to the MAX Programming Interface.

After selection there are several ways to start the Fitting task:

1. A click on the button New opens the task dialog shown in Figure 112, where the Fitting tab can be selected and with a click on New Fitting a fitting map can be opened.
2. A right click on the symbol Fitting in the taskbar opens the very same dialog with the Fitting tab already selected. A click on New Fitting opens a new fitting map.
3. A double click on the symbol Fitting in the taskbar opens a new fitting map automatically.

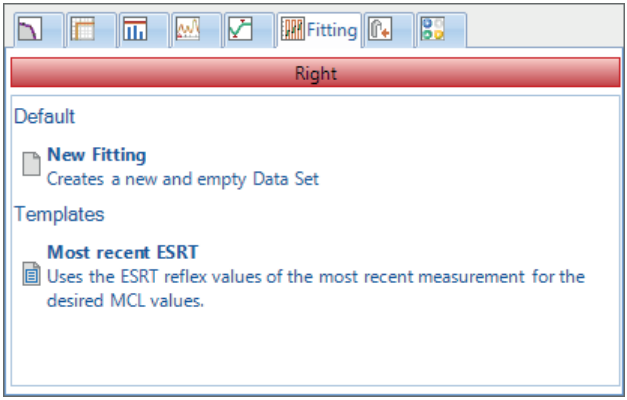


Figure 112 Dialog to open the Fitting task

In the task dialog the template Most recent ESRT may be selected in the area Default. This template sets the MCL charge of the electrodes for which ESRT values were determined during the last ESRT measurement to the determined ESRT value (see section 6.3).

CAUTION:
The appropriate coil must be correctly placed over the implant at all times during fitting.

Figure 113 shows the Fitting dialog. It is divided into the tabs Levels, Strategy, Frequency Bands, Maplaw, ASM (not available for TEMPO+ and OPUS 1) and Indicators.

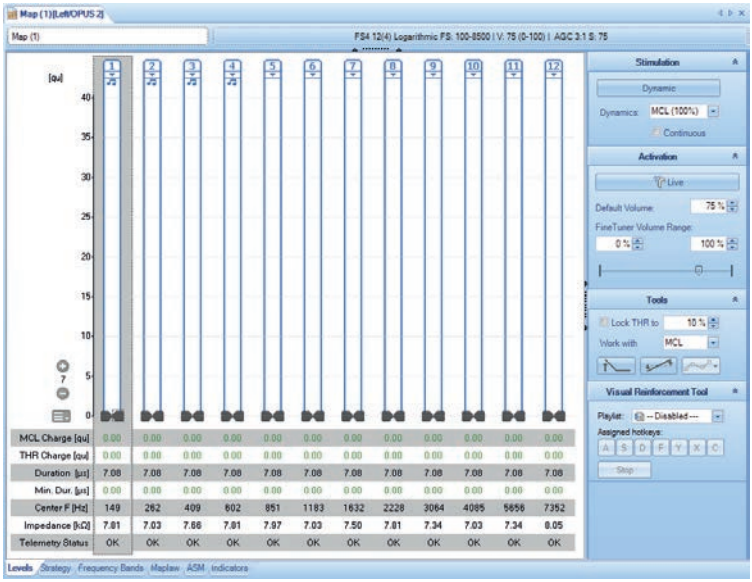


Figure 113 Fitting dialog

6.6.2.1 Levels

The Levels dialog (see Figure 114) allows setting MCL charge and THR charge in qu (see section 5.14) for the individual electrodes. The charge of the stimulation pulse of an electrode can be graphically changed with the mouse by moving the black arrow in the stimulation bar. The MCL charge is changed by moving the right arrow, the THR charge by moving the left arrow. Alternatively, the numerical value can be directly entered in the input field of the table below the stimulation bar. Control via the page up/down keys (+/- 15 %), arrow keys (+/- 3 %) or plus and minus keys (+/- 1 %) is also possible. The amplitude values of an electrode can be transferred to all or an individual electrode by a right mouse click and selecting the option Copy MCL to or Copy THR to.

Clicking on the arrow symbol below the electrode number in the stimulation bar changes the global status or local status of individual electrodes. A globally deactivated electrode is automatically deactivated for all other tasks. Locally deactivated electrodes are only deactivated for the current map.

A note symbol in the stimulation bar marks the electrode as a CSSS channel (see section 6.6.2.3).

Scaling of the charge units can be changed with the buttons +/- left of stimulation bar 1.

By default, the table below the stimulation bars gives the MCL charge and the THR charge in qu (see section 5.14), the Duration and Min. Dur. of a stimulation pulse in µs, the Center Frequency in Hz, the Impedance determined in the last telemetry measurement (see section 6.2.2.1) in kΩ and the Telemetry status. If no telemetry data is available, the user must confirm a warning appearing in the notification window. In this case, MAESTRO continues to work with the default values depending on the implant type but using default values will significantly restrict the clinician's fitting capability. Minimum phase duration of the stimulation pulse on the applicable electrode can be defined in the field Min. Dur.. Min. Dur. can be set between 0 and 200 µs, the default is 0 µs. The value of Min. Dur. of an electrode can be transferred to all or a specific electrode by a right mouse click and selecting the option Copy Min. Dur. to. Selecting Copy all values to allows transferring MCL charge, THR charge and Min. Dur. of an electrode to all or to a specific electrode.

A mouse click on the icon Hide/Show lines on the left side displays information about further stimulation parameters in the table. In addition, Stimulation Rate, MCL Amplitude and THR Amplitude in cu (see section 5.14), ESRT data (see section 6.3) and ART data (see section 6.5) in qu can also be displayed. ESRT data and ART data are displayed numerically and graphically in the stimulation bar. As shown in Figure 114, ESRT data are graphically indicated by an orange line, and ART data by a purple line. By default, the results of the last ESRT and/or ART measurement are displayed. It is, however, possible to add the results of any ESRT and/or ART measurement from the database view to the Levels dialog with drag and drop.

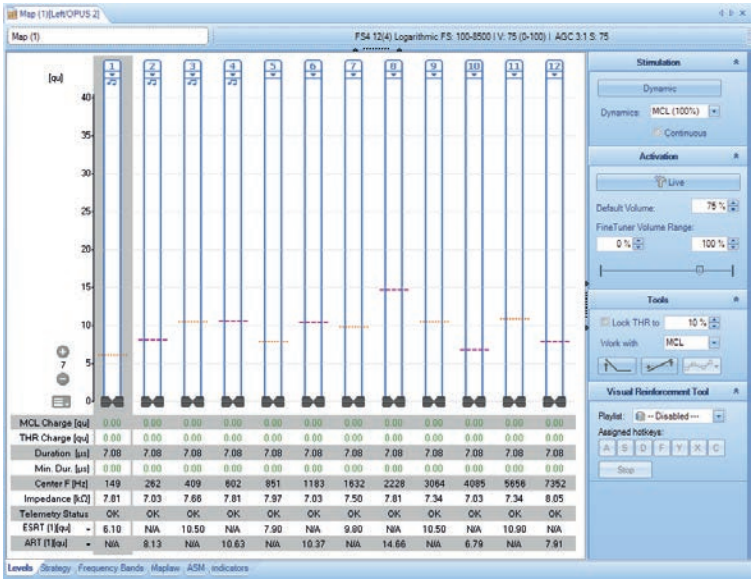


Figure 114 Display of ESRT and ART data in the Levels dialog

The right side of the Fitting dialog is divided into the areas Stimulation, Activation, Tools and Visual Reinforcement Tool. When clicking on the Dynamic button in the Stimulation section the greyed electrode is stimulated with a stimulation burst. If two electrodes are highlighted, labeling of the button changes to Balancing and both highlighted electrodes are stimulated sequentially. If more than two electrodes are highlighted, two buttons with an arrow symbol appear to enable Sweeping. All highlighted electrodes are stimulated sequentially in ascending or descending order. Alternatively, stimulation can be started by pressing the space bar.

The stimulation level can be changed in the field Dynamics. By default, stimulation is performed with 100% of the set charge. The stimulation level can be adjusted between THR charge and MCL charge in 10% steps. Activation of the Continuous checkbox allows continuous stimulation of the highlighted electrodes. By default, this checkbox is deselected for Dynamic and activated for Balancing and Sweeping.

Clicking on the button Live in the Activation section activates the processor microphone to test the map. As a visual indication a microphone symbol appears at the top in the tab, all channel numbers are highlighted and the button turns yellow. An activated map may be deactivated manually by pressing the Live button.

When using a SONNET EAS audio processor the Activation section displays three buttons for activation of the map. A click on the applicable button allows the user to select if the activation only applies to electric stimulation Electric, acoustic stimulation Acoustic or to electric and acoustic stimulation Live EAS. The related buttons are displayed in a yellow color when activated. An activated map may be deactivated manually by pressing the related button Electric, Acoustic or Live EAS. The settings in the Activate section are automatically synchronized in the Levels tab and in the Acoustic tab of a fitting map.

For all processors the map will be reactivated automatically when the user changes values in the map.
It is automatically deactivated when a notification has to be checked, e.g. when a set MCL exceeds the predefined warning limit.
The reactivation can be suppressed by disabling the live during changes checkbox in the Settings | Fitting dialog (see section 6.6.3.5). Every change made now leads to an automatic deactivation of the map and the user has to activate the map manually.

The current map is activated with the volume defined in the field Default Volume with each activation. It can be set between 0% and 100%. The default value is 75%.
For TEMPO+ and OPUS 1 processors it is labelled as Test Volume and the volume programmed into the processor has to be adjusted in the Configuration task (see section 6.7.2.1).
For all other processors the map will be saved with Default Volume as default volume.
The volume range for the TEMPO+ and OPUS 1 processors and the FineTuner Volume range for the other processors may be adjusted with the slide control or entered manually. The default values are 0% for minimum and 100% for maximum. The values can be changed between 0% and 100% in steps of 1%. The volume mode may be changed in the Strategy tab.

The area Tools allows setting the THR charge to a certain percentage of the MCL charge by activating the checkbox Lock THR to. The THR charge can be set between 0% and 20% of the MCL charge, the default is 10%. The checkbox Lock THR to is deactivated by default to allow individually setting the THR charge for each electrode.

In addition, the area Tools offers several map shaping tools. Work with allows deciding if the map shaping tools should be applied to MCL charge, THR charge or THR + MCL charge.

The buttons Shift & Tilt and Pivot allow changing the MCL charge and/or the THR charge of individual electrode groups. Clicking on the buttons displays the default groups for the stimulation bars. Electrodes 1–4, 5–8 and 9–12 may be selected as a group of four, electrodes 1–6 and 7–12 as a group of six or all electrodes may be selected. Unless using a default frequency distribution (see section 6.6.2.4), groups are selected according to their frequency band assignment.

The button Shift & Tilt allows increasing or decreasing the MCL charge and/or the THR charge of the entire selected group or of the apical or basal electrodes of the selected group. The button Pivot enables the highest increase or decrease of the MCL charge and/or the THR charge of the most apical electrode and the MCL charge and/or the THR charge of the most basal electrode. The MCL charge and/or the THR charge of the electrodes in between are changed proportionately. The MCL charge and/or the THR charge may always be changed in large or small steps.

Table 9 lists the map shaping tools.

Change	Step size (%)			
Increasing all electrodes	+15	+3	--	--
Decreasing all electrodes	--	--	–3	–15
Increasing the apical electrodes	+15	+3	--	--
Decreasing the apical electrodes	--	--	–3	–15
Increasing the basal electrodes	+15	+3	--	--
Decreasing the basal electrodes	--	--	–3	–15
Clockwise pivot	+15 relative to apex	+3 relative on to apex	--	--
Counterclockwise pivot	--	--	–3 relative to apex	–15 relative to apex

Table 9 List of map shaping tools

The button Autointerpolation allows interpolating MCL charge and/or the THR charge between selected channels. Linear or spline interpolation are available.

6.6.2.2 Visual Reinforcement Tool (VRT)

The Visual Reinforcement Tool is located in the Fitting task in the Visual Reinforcement Tool area. It is a support tool to assist audiologists during the fitting session and is designed to display media on a second or third additional monitor facing the patient (see Figure 115).

NOTE:
Prerequisite for this feature is a multi-display configuration which needs to be set up in the graphics settings of the Windows operating system.

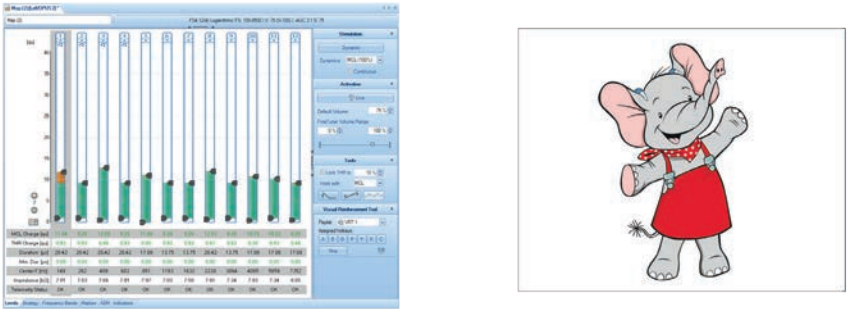


Figure 115 Visual Reinforcement Tool on two screens

The audiologist can select a playlist previously created in the Media Manager from the drop-down menu and manually control the appearance/disappearance of a visual reward (media) contained in the playlist, and condition the patient to the relationship of stimulus and visual reward. After conditioning, the patient is expected to turn toward the monitor after perceiving a stimulus – thus indicating that the stimulus was audible. The visual reward should be presented after a short delay.

The VRT keys are shown below the drop-down menu. By clicking on one of these buttons in the software or on the keyboard, the associated picture or video clip is loaded into the Media Player and displayed on the alternative display for the predefined period. This can be stopped by pressing the key again. If a second screen is configured in the Settings dialog of the Media/VRT (see section 6.6.4), the monitor icon appears below the VRT keys. By clicking on this icon the playback on the additional monitors can be toggled on or off. An additional monitor set to disabled will not show any images or videos until it is enabled.

playback enabled
playback disabled

6.6.2.3 Strategy

The Strategy dialog (see Figure 116) allows selecting the coding strategy to translate the acoustic input signal into electrical stimulation parameters.

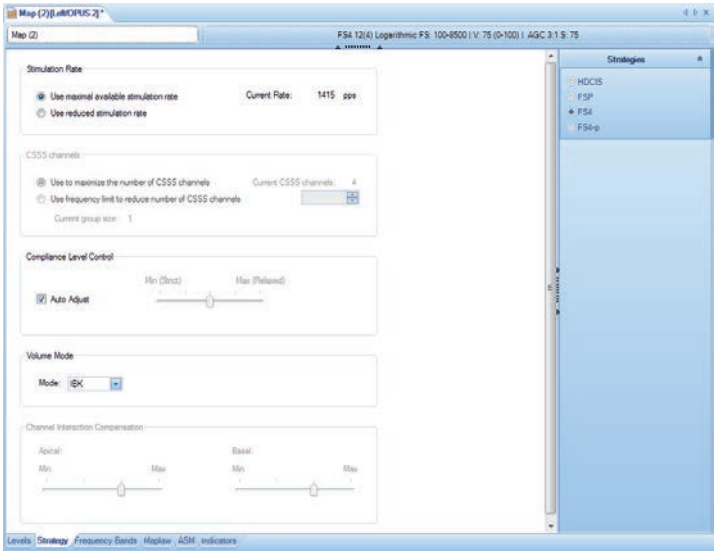


Figure 116 Strategy dialog

The right side of the Strategy dialog allows selecting the desired coding strategy. Depending on the implant type, HDCIS, FSP, FS4 and FS4-p are available to all audio processors except TEMPO+. The default is FS4 for all implant types (supported implants are listed in section 3.1), except for EAS systems which use HDCIS as the default, for the indicated adult population.

TEMPO+ speech processors exclusively use the CIS+ strategy. CIS+ is the predecessor of HDCIS, with the same functional principle but a slower sampling rate. For CIS+ (see Figure 118), only Stimulation Rate, Stimulation order and Volume Mode are available. The stimulation order determines the order of the sequential stimulation. This order can be staggered or User defined staggered. If user defined staggered is activated, the user can change the stimulation order via drag and drop.

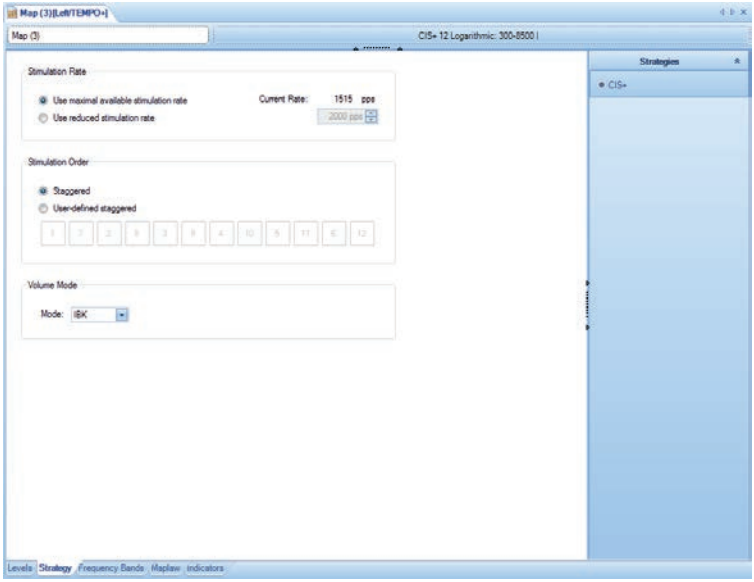


Figure 117 Strategy dialog for a TEMPO+ speech processor

HDCIS determines the envelope of the output signal of the applicable filter bank for each electrode. The envelope is the reference for the performance of each frequency band. FSP represents the fine structure of the acoustic signal on the low-frequency electrodes by coding the zero point with Channel Specific Sampling Sequences (CSSS). On all other channels the signal is processed according to HDCIS. Electrodes using the fine structure of the acoustic signal bear the note symbol in the stimulation bars in the Levels dialog (see section 6.6.2.1). The number of CSSS channels and thus the frequency range with fine structure coding depends on the patient's parameter settings. FS4 has an extended and largely constant frequency range independent of the patient's parameter settings.

For 12 active electrodes, a maximum of four electrodes are CSSS channels, the other eight electrodes process the signal according to HDCIS. In FS4 and FS4-p, temporal fine structure information is delivered to the lowest four frequency channels using CSSS, while FSP delivers temporal fine structure information via CSSS typically only to the lowest two frequency channels. The upper frequency limit for providing fine structure information is thereby increased for FS4 and FS4-p when compared to FSP. FS4 sequentially stimulates one-of-four fine structure channels, while FS4-p can additionally stimulate two-of-four fine structure channels in parallel when positive-going zero crossings on two fine structure channels

with the largest instantaneous envelope-amplitude occur simultaneously. In FS4-p, current amplitudes for parallel stimulation are calculated using a dedicated algorithm (Channel Interaction Compensation, CIC) so that the compound current amplitude matches the one for sequential stimulation.

NOTE:
The default values for volume and frequency range depend on the coding strategy. Changing the coding strategy changes the volume and frequency range settings.

The main window of the Strategy dialog is divided into Stimulation Rate, CSSS channels, Compliance Level Control, Volume Mode and Channel Interaction Compensation. Stimulation Rate reduces the stimulation rate for HDCIS, FSP, FS4 and FS4-p. The default is Use maximal available stimulation rate. For HDCIS and FSP selecting Use reduced stimulation rate allows reducing the current stimulation rate with the arrow keys or by entering the desired value in the input field. Selecting Use reduced stimulation rate for FS4 and FS4-p reduces the current stimulation rate on envelope channels to 750 pps or the previously used rate. The current rate is displayed in the upper right corner of the Stimulation Rate area.

CSSS channels defines a frequency limit for FSP to reduce the number of available CSSS channels. The default setting is Use to maximize the number of CSSS channels so that MAESTRO works with the maximum number of CSSS channels. Selecting Use frequency limit to reduce number of CSSS channels defines a frequency limit via the arrow keys or by directly entering the desired value in the input field to reduce the number of CSSS channels. The current number of CSSS channels is displayed in the upper right corner of the area CSSS channels.

Compliance Level Control defines how the compliance level of the fitting parameters is used for SYNCHRONY, MED-EL CONCERT, SONATA TI^{100} and PULSAR CI^{100} implants via a slide control. The compliance level is based on the data of the last saved telemetry measurement (see section 6.2.2.1) and states the stimulation current at which the implant reaches the cut-off voltage. By default, the checkbox Auto Adjust is selected to allow shifting the compliance limit so that at least one fine structure channel is available for FSP. For HDCIS the minimum rate of 800 pps is aspired.

Deselecting the checkbox allows setting the compliance level via the slide control between the actually measured and the theoretical maximum limit.

Volume Mode toggles the volume mode between IBK Mode and RTI Mode. The IBK Mode is the default for the strategies FSP, FS4 and FS4-p, the RTI Mode for HDCIS (see section 6.6.2.3). For TEMPO+ speech processors using the CIS+ strategy, the IBK Mode is the default volume mode. In the IBK Mode, the minimum value remains equal to the value of the THR charge when increasing or decreasing volume, while the maximum volume value increases linearly to the value of the MCL charge. In the RTI Mode at a volume setting of zero, the MCL and THR level are at zero stimulation. Both the minimum and the maximum volume value increase linearly to the value of the THR charge and/or the value of the MCL charge. Figure 118 shows the difference between IBK and RTI Mode.

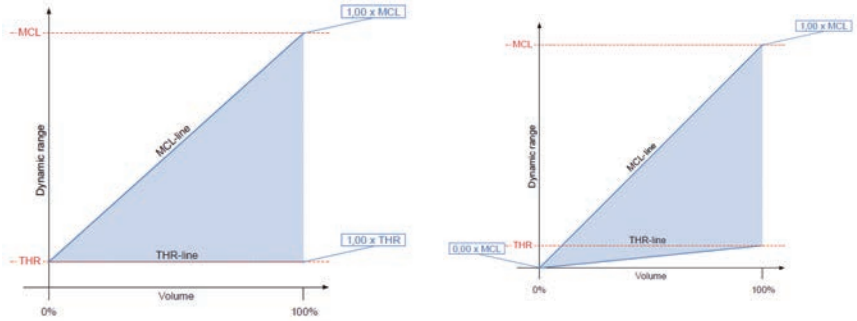
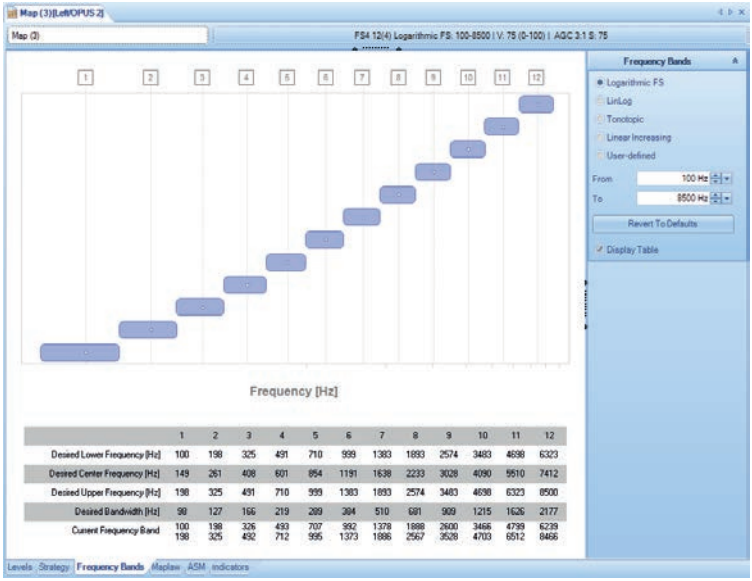


Figure 118 IBK Mode (left) and RTI Mode (right)

Channel Interaction Compensation allows adjusting the compensation level for FS4-p. Simultaneous stimulation causes increased channel interaction. The compensation level can be adjusted towards the apical or basal direction with the two slide controls. Shifting the slide control towards Max increases the compensation level, shifting it towards Min reduces the compensation level.

6.6.2.4 Frequency Bands

The Frequency Bands dialog (see Figure 119) allows adjusting the frequency range of the processor and individual frequency band assignment.



	1	2	3	4	5	6	7	8	9	10	11	12
Desired Lower Frequency [Hz]	100	198	325	491	710	999	1383	1893	2574	3483	4698	6323
Desired Center Frequency [Hz]	149	261	408	601	854	1191	1638	2233	3028	4090	5510	7412
Desired Upper Frequency [Hz]	198	325	491	710	999	1383	1893	2574	3483	4698	6323	8500
Desired Bandwidth [Hz]	98	127	166	219	289	384	510	681	909	1215	1626	2177
Current Frequency Band	100 198	198 325	326 492	493 712	707 995	992 1373	1378 1886	1888 2567	2600 3528	3466 4703	4799 6512	6239 8466

Figure 119 Frequency Bands dialog

The entire frequency range processed by the TEMPO+ speech processors with CIS+ strategy is 200 to 8500 Hz and all other processors 70 to 8500 Hz. The default frequency range for FSP, FS4 and FS4-p is 100 to 8500 Hz, for HDCIS 250 to 8500 Hz and for CIS+ 300 to 8500 Hz. The diagram is a graphic display of the frequency bands of the individual electrodes. The table below the diagram shows the numerical values of Desired Lower Frequency, Desired Center Frequency, Desired Upper Frequency, Desired Bandwidth and Current Frequency Band per electrode.

The right side of the Frequency Bands dialog in the Frequency Bands section offers five options to distribute the frequency bands. The default is Logarithmic FS (Logarithmic for CIS+ strategy). This distribution divides the frequency spectrum into approximately logarithmically equally distributed bands so that the frequency range is divided into bands with approximately equal energy content for white noise. LinLog divides the lower end of the frequency range into

linear bands of equal size, the remaining portion of the frequency range into logarithmically distributed bands so that the bands in the lower frequency range are narrower, those in the upper frequency range wider. Tonotopic groups the frequency bands in approximation to the tonotopy of the healthy ear. Linear Increasing divides the frequency range into bandwidths linearly increasing from the lower to the higher frequencies. Compared with Logarithmic FS the bandwidths are wider for the lower frequency bands and narrower for the three highest frequency bands. User Defined allows individual definition of the frequency band limits for each electrode. The frequency band limits can be graphically moved in the diagram using the mouse. Alternatively, the desired values may be entered directly into the table below the diagram. The desired values may be different from the actual values in the line Current Frequency Band due to technical limitations. Band assignment can be changed for all frequency band distributions. The default is linear assignment from apex to base. For patients with a Split electrode the individual frequency bands are assigned from apex to base by default to the electrode numbers 5 to 1 and 6 to 12. Dragging an electrode number with the mouse into the field of another electrode number changes the band assignment. The change of band assignment is displayed as shown in Figure 120.

Figure 120 Changing band assignment

The lower and upper cut-off frequency of the frequency range can be set in the two input fields below the option fields for distributing the frequency range. The default frequency range for HDCIS is 250 to 8500 Hz, for FSP, FS4 and FS4-p 100 to 8500 Hz and for CIS+ 300 to 8500 Hz. The lower cut-off frequency can be set between 70 and 350 Hz, the upper cut-off frequency between 3500 and 8500 Hz.

If the patient uses an EAS system with DUET 2, an extended frequency range from 70 to 2000 Hz is available for setting the lower cut-off frequency. If the patient uses an EAS system with SONNET EAS, an extended frequency range from 125 to 1700 Hz is available for setting the lower cut-off frequency. Clicking on the button Revert to Defaults restores all default settings. The table below the diagram is displayed when the checkbox Display Table is selected.

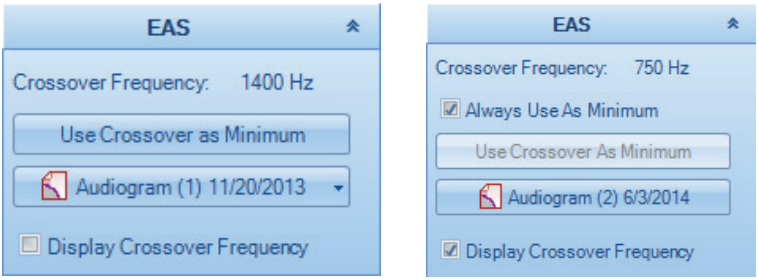


Figure 121 EAS section for DUET 2 (left) and for SONNET EAS (right)

If the patient uses an EAS system, an additional EAS section is available on the upper right side of the Frequency Bands dialog (see Figure 121).

For DUET 2 processors this area allows selecting an audiogram and displaying the applicable Crossover Frequency by MAESTRO (see section 6.1). By default, the most current patient audiogram is selected. The audiogram to be used for determining the Crossover Frequency can be selected with the drop down menu below Use Crossover as Minimum. Clicking on the arrow symbol on the right side of the button opens a list with available audiograms. The option Open Selected Audiogram in the list or directly clicking on the button labeled with the name of the audiogram opens the currently selected audiogram.
The Crossover Frequency is displayed on the upper side of the area EAS. Clicking on the button Use Crossover as Minimum automatically accepts the Crossover Frequency as the lower cut-off frequency in the area Frequency Bands.

For SONNET EAS processors, the audiogram to be used has to be selected in the Acoustic editor. Then, its name and the Crossover Frequency used are displayed. By clicking on the name of the audiogram, the desired audiogram is opened in a separate task. Clicking on the Use Crossover as Minimum button automatically accepts the Crossover Frequency as the lower cut-off frequency in Frequency Bands editor. To always accept the Crossover Frequency as the lower cut-off frequency, enable the Always Use As Minimum checkbox.

Selecting the Display Crossover Frequency checkbox displays the Crossover Frequency in a diagram as shown in Figure 122. This checkbox is deselected by default for DUET 2 and selected by default for SONNET EAS.

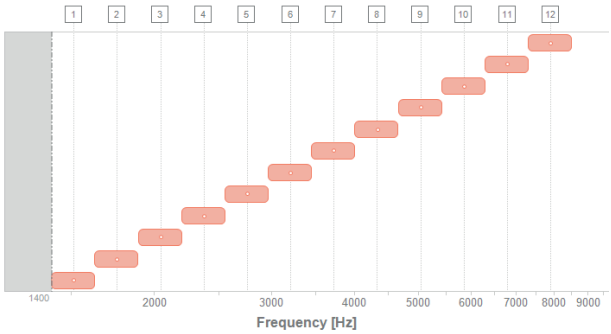


Figure 122 Graphic display of Crossover Frequency

6.6.2.5 Maplaw dialog

The Maplaw dialog (see Figure 121) allows changing the Maplaw used for the map.

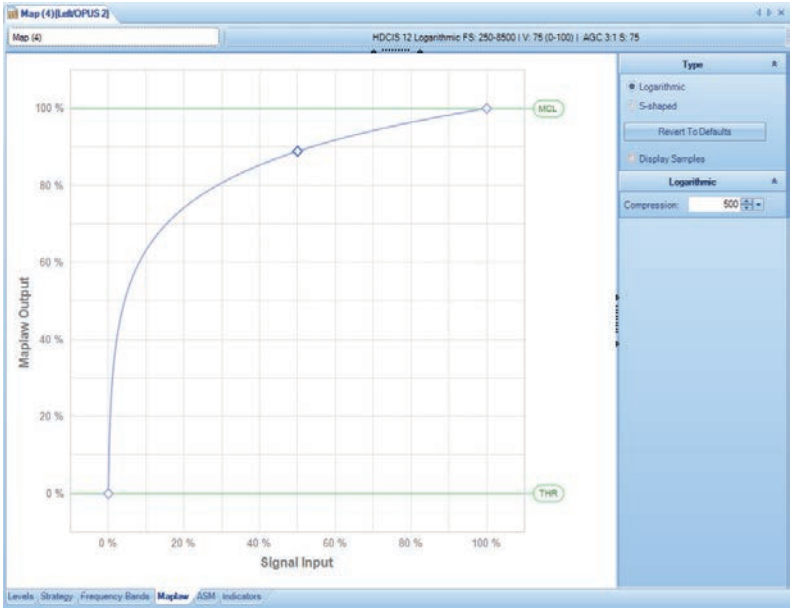


Figure 123 Maplaw dialog

The Maplaw defines the compression characteristics along the patient's dynamic range. Changing the Maplaw is a fundamental process and impacts all electrodes. The diagram shows the Maplaw output over the Signal input. Selecting the applicable option on the right side of the Maplaw dialog in the area Type defines if the Maplaw is Logarithmic or S-shaped. The default form is Logarithmic.

For a Logarithmic Maplaw the compression coefficient c can be changed between 0 and 8000 in the area Logarithmic Maplaw. If c is set to 0, the Maplaw is linear, if c is set to 8000, the lower dynamic range rises steeply. For an S-shaped Maplaw the S-shaped Maplaw area provides four coordinates to adjust the desired curve form. The two x-coordinates are the portions of the signal input in percent, the two y-coordinates the portion of the Maplaw output in percent. The default values for the x-coordinates are 4 % and 3 %, for the y-coordinates 30 % and 10 %.

The form of the Maplaw can be changed by dragging the drag points with the mouse in the diagram.

Selecting the checkbox Display Samples changes the display of the Maplaw function from a solid curve to discrete individual values. This checkbox is deselected by default.

In the Spacing section, which is only available for TEMPO+ speech processors, the distribution of the samples related to the input dynamic range of the ADC (analog-digital converter) can be switched from linear to logarithmic. Especially when using S-shaped maplaws, logarithmic spacing (which is the default) might result in a better approximation of the linear interpolation of the samples towards the intended curve shape.

6.6.2.6 ASM

The ASM (Automatic Sound Management) is available for the following processors: OPUS 2, RONDO, SONNET, SONNET EAS.

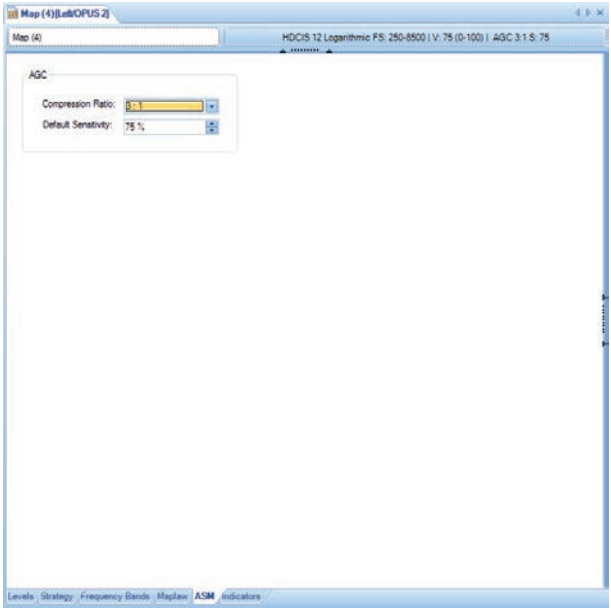


Figure 124 ASM (Automatic Sound Management) dialog

The features Compression Ratio and Default Sensitivity are available for all above mentioned audio processors.

Compression Ratio and Default Sensitivity in the AGC section allow fitting the AGC of the processor to the patient's needs. AGC Compression Ratio provides five options to select the AGC compression ratio. The default compression ratio is 3:1.

Default Sensitivity allows defining the sensitivity of the processor microphone to be used as the default setting of the processor. The value can be changed by a mouse click on the arrow symbols or by directly entering the value. The default value is 75 %, and the value can be changed between 0 % and 100 %.

All features listed on the ASM tab are map based parameters. This means that the settings are specific to each fitting map and, therefore, can be programmed differently for different fitting maps.

6.6.2.7 Indicators

Figure 123 shows the Indicators dialog for OPUS 2, RONDO and SONNET and SONNET EAS audio processors.

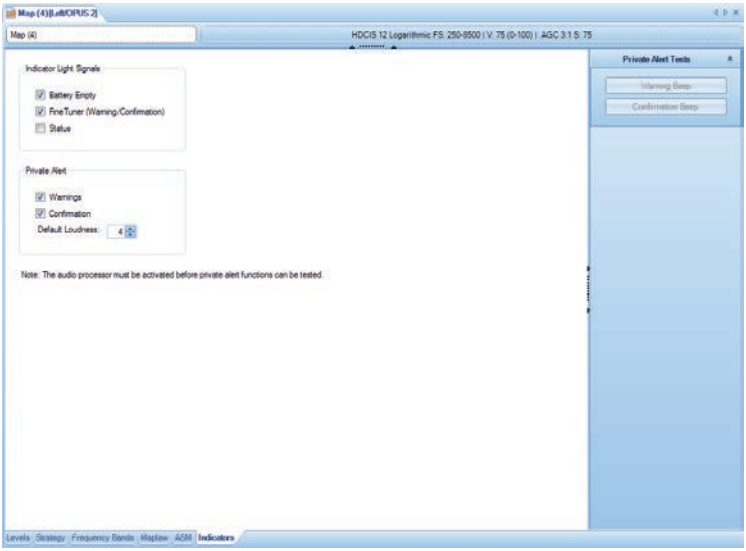


Figure 125 Indicators for OPUS 2, RONDO and SONNET audio processors

Indicator Light Signals provides three checkboxes to activate indicator light signals for Battery Empty, FineTuner (Warning/Confirmation) and Status. When selecting the Battery Empty checkbox the processor indicates low battery voltage with a blinking signal. Selecting the FineTuner (Warning/Confirmation) checkbox elicits a blinking signal whenever the processor settings are changed with the FineTuner. When selecting the Status checkbox the processor indicates operation with a continuous blinking signal. For further information see the user manual of the processors. By default, the checkboxes Battery Empty and FineTuner (Warning/Confirmation) are selected, the checkbox Status is deselected.

In Private Alert selecting the checkboxes Warnings and Confirmation allows setting an acoustic warning signal for the patient indicating low battery voltage and changing the processor settings with the FineTuner. The volume of the acoustic warning signal can be tested by selecting the applicable checkbox and the processor microphone (see section 6.6.2.1 Levels). Clicking on the button Warning Beep or Confirmation Beep on the right side of the Indicators dialog in the Private Alert Tests area makes the acoustic warning signal audible for the patient. The Default Loudness input field in the Private Alert section allows changing the volume of the acoustic signal by clicking on the buttons with the arrow symbol or directly entering the numerical value. The default level is 4, the level can be changed between 1 and 8.

Figure 124 shows the Indicators dialog for OPUS 1 and TEMPO+ processors. The Indicator Light Signal section provides a checkbox to activate an indicator light signal for an empty battery. When this checkbox is selected, the processor shows a blinking signal to indicate low battery voltage.

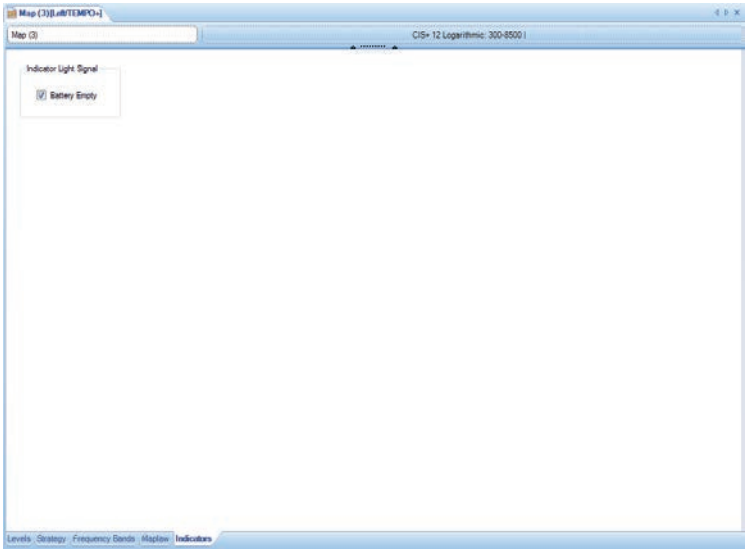


Figure 126 Indicators for TEMPO+ and OPUS 1 processors

6.6.2.8 Acoustic

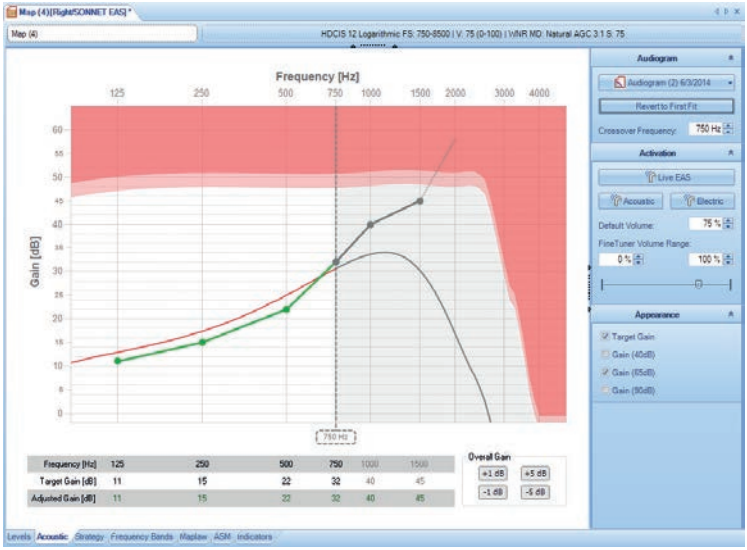


Figure 127 Acoustic for SONNET EAS processors

The Acoustic tab (see Figure 127) in the fitting task allows programming the acoustic unit of a SONNET EAS audio processor. For programming of the acoustic unit of a DUET 2 see section 6.7.

The tab shows a diagram with Crossover Frequency, Target Gain and Adjusted Gain. The sidebar of the Acoustic tab is divided into the areas Audiogram, Activation and Appearance.

The name of the audiogram used for the Acoustic tab is displayed in the area Audiogram. A drop down menu allows selection of any available audiogram (see section 6.1.2) by clicking on the name of the audiogram. The selected audiogram can be opened by clicking on the Open Selected Audiogram field in the drop down menu. When no audiogram is selected by the user, then the patient's most recent audiogram is selected by default. If no valid audiogram is available for the selected patient, the target gain curve and crossover frequency are not displayed.

A click on the button Revert to First Fit restores the amplification values shown in the table to the values initially computed by MAESTRO.

The diagram shows the acoustic amplification curves for the 40, 65 and 90 dB input levels, the target gain and the crossover frequency. Target gain and crossover frequency are computed internally according to the patient's audiogram data (see section 6.1) and displayed as a dashed green line and a gray area, respectively. The values computed from the audiogram data, the crossover frequency and the target gain, are displayed in an amplification curve. Adjustments according to the patient's hearing loss can be made by dragging the dots of the Adjusted Gain, displayed as a green, in the diagram at the main frequencies or by entering the desired value into the table beneath the diagram. The values may also be adjusted collectively with a click on one of the applicable shift buttons on the right side of the table in the Overall Gain section.
The crossover frequency may be displayed in the Acoustic tab and in the Frequency Bands tab of a fitting map, but can only be modified in the Acoustic tab.
The crossover frequency may be adjusted in the Acoustic tab by dragging the dotted line with the mouse to the desired position between 125 Hz to 1700 Hz or by entering the value into the Crossover Frequency field in the Audiogram area. It is then automatically synchronized to the Frequency Bands tab of the fitting map.

In the Activation section the processor microphone can be activated to test the map. As a visual indication, a microphone symbol appears at the top. A click on the applicable button allows the user to select if the activation only applies to electric stimulation (Electric), acoustic stimulation (Acoustic) or to electric and acoustic stimulation (Live EAS). The related buttons are displayed in a yellow color when activated. An activated map may be deactivated manually by pressing the related button Electric, Acoustic or Live EAS.
Whenever the user changes values in the map, the map will be automatically reactivated. This activation can be suppressed by disabling the live during changes checkbox in the Settings | Fitting dialog (see 6.6.3.5). Every change made now leads to an automatic deactivation of the map so that the user has to activate the map manually.
With each activation the chosen map (electric, acoustic or both) is activated with the volume defined in the field Default Volume. The volume can be set between 0% and 100%. The default value is 75%.
The settings in the Activate section are automatically synchronized in the Levels tab and in the Acoustic tab of a fitting map.

Selecting or deselecting the checkboxes Gain (40 dB), Gain (65 dB), Gain (90 dB) and Target Gain under Appearance defines if individual amplification curves and target gain curve are displayed. By default, the checkboxes Gain (65 dB) and Target Gain are activated, the checkboxes Gain (40 dB) and Gain (90 dB) are deactivated.

6.6.3 Fitting settings

Click on the symbol Settings | Fitting in the toolbar to customize Dynamic Stimulation, Balancing Stimulation, Sweeping Stimulation, Default values for new Maps and Editor Behavior of the Fitting task. Figure 125 shows the Settings dialog of the Fitting task.

Clicking on the button Restore Defaults on the right side below the field Editor Behavior resets all settings of the Fitting task to their defaults. Changed settings are applied by closing the Settings dialog.

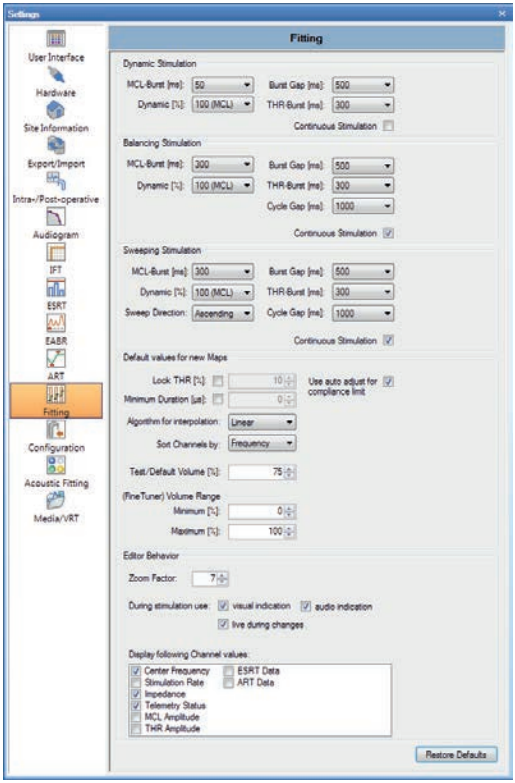


Figure 128 Fitting task settings dialog

6.6.3.1 Dynamic Stimulation

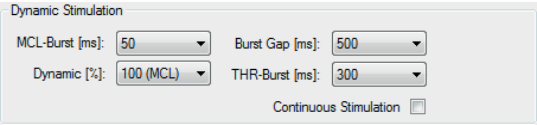


Figure 129 Dynamic Stimulation

Dynamic Stimulation (Figure 126) allows customizing the default values for MCL Burst in ms, Dynamic in %, Burst Gap in ms and THR Burst in ms. MCL Burst defines the length of a burst for stimulating the MCL (see section 6.6.2.1). The default value is 50 ms, and the MCL burst can be set between 50 and 1000 ms. Dynamic allows setting the stimulation level in %. The default value is 100 %, and the stimulation level can be set to values between THR charge and MCL charge in 10 % steps. Burst Gap defines the interval between two bursts. The default value is 500 ms, and the burst gap can be set between 200 and 1000 ms in 100 ms steps. THR Burst defines the length of a burst to stimulate the THR. The default value is 300 ms, and the THR burst can be set between 50 and 1000 ms. The checkbox Continuous Stimulation is deactivated by default.

6.6.3.2 Balancing Stimulation

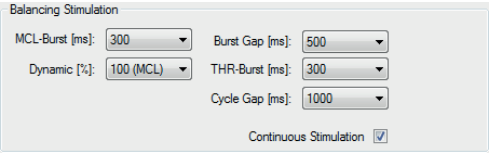


Figure 130 Balancing Stimulation

Balancing Stimulation (Figure 127) allows customizing the defaults for MCL Burst in ms, Dynamic in %, Burst Gap in ms, THR Burst in ms and Cycle Gap in ms for balancing stimulation (see section 6.6.2.1). The parameters MCL Burst, Dynamic, Burst Gap and THR Burst and their values are described in section 6.6.3.1. The defaults for Balancing Stimulation are an MCL Burst of 300 ms, a Dynamic of 100 %, a Burst Gap of 500 ms and a THR Burst of 300 ms. The parameter Cycle Gap defines the interval between two stimulation cycles. The default value is 1000 ms, and the cycle gap can be set between 200 and 1000 ms in 100 ms steps. The checkbox Continuous Stimulation is activated by default for balancing stimulation.

6.6.3.3 Sweeping Stimulation

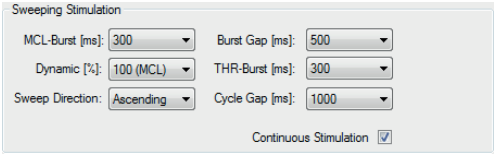


Figure 131 Sweeping Stimulation

Sweeping Stimulation (Figure 128) allows customizing the defaults for MCL Burst in ms, Dynamic in %, Sweep Direction, Burst Gap in ms, THR Burst in ms and Cycle Gap in ms for sweeping stimulation (see 6.6.2.1). The parameters MCL Burst, Dynamic, Burst Gap and THR Burst and their values are described in section 6.6.3.1. The defaults for Sweeping Stimulation are an MCL Burst of 300 ms, a Dynamic of 100 %, a Burst Gap of 500 ms and a THR Burst of 300 ms. The parameter Cycle Gap and its values are described in section 6.6.3.2. The default cycle gap for sweeping stimulation is 1000 ms. Sweep Direction defines the default direction of the sweeping stimulation. Sweep direction can be ascending or descending, the default is ascending sweep direction. The checkbox Continuous Stimulation is activated by default for sweeping stimulation.

6.6.3.4 Default values for new Maps

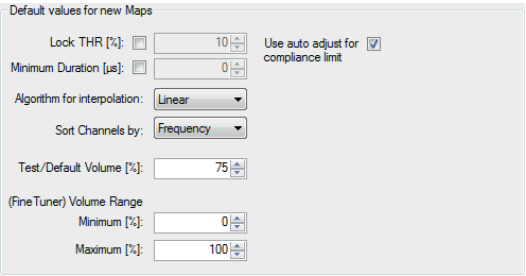


Figure 132 Default values for new Maps

Default values for new Maps (Figure 129) allows customizing the defaults for the parameters Lock THR, Minimum Duration in µs, Algorithm for interpolation, Sort Channels by, Test/Default Volume and the (FineTuner) Volume Range (see section 6.6.2.1). The parameter Lock THR allows setting the THR charge to a certain percentage of the MCL charge by activating the checkbox. The desired percentage can be entered between 0 and 20 % in 1 % steps in the input field. By default, this option is deactivated, and the default value in the input field is 10 %. The parameter Minimum Duration defines a minimum duration for all electrodes by selecting the checkbox. The desired duration can be entered between 0 und 200 µs in 1 µs steps in the input field. By default, this option is deactivated, and the default value in the input field is 0 µs. Algorithm for interpolation defines the default algorithm used for interpolation. Possible algorithms are linear interpolation and spline interpolation, the default is linear interpolation. The parameter Sort Channels by defines the default sorting of the electrodes. The electrodes can be sorted by frequency or number, the default is sorting by frequency. Selecting the Use auto adjust for compliance limit checkbox activates automatic modification of the compliance limit by MAESTRO (see section 6.6.2.3). This checkbox is activated by default.

Test/Default Volume defines the Default Volume for new fitting maps and the Test Volume for Fitting maps for OPUS 1 and TEMPO+ processors.
The default volume range may be adjusted by entering the values into the fields Minimum and Maximum.

6.6.3.5 Editor Behavior

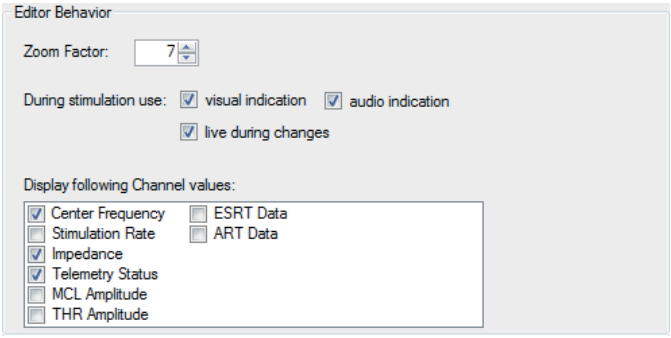


Figure 133 Editor Behavior

Editor Behavior (Figure 130) allows customizing the defaults for the parameters Zoom Factor and During stimulation use. In addition, the channel values to be displayed in the Levels dialog (see section 6.6.2.1) can be defined. Zoom Factor defines the default scaling of the unit range in the Levels dialog. The default zoom factor is 7, and the zoom factor can be changed between 1 and 15. During stimulation use defines if a visual signal or an acoustic signal is used during stimulation by selecting the appropriate checkbox. The default is visual signal and acoustic signal. The live during changes checkbox activates the live mode functionality whenever a map is activated in the fitting task. The checkbox is enabled by default. Whenever the user changes values in the map, the map will be automatically reactivated. Disabling the checkbox leads to an automatic deactivation of an activated map whenever the user makes changes. Activating the appropriate checkbox in the field Display following channel values defines which channel values are displayed in the Levels dialog. Possible channel values are Center Frequency, Stimulation Rate, Impedance, Telemetry Status, MCL Amplitude, THR Amplitude, ESRT Data and ART Data. The checkboxes Center Frequency, Impedance and Telemetry Status are activated by default.

6.6.4 Media/VRT settings

The standard settings of the VRT tool can be customized under Settings | Media/VRT in the toolbar (see Figure 131).

If the checkbox Scale videos and images to fit the screen is selected, images and videos are scaled to fit the display resolving their aspect ratio. Otherwise they are shown in their original size.

With Play duration the user can define how long the media should be played automatically in the VRT.

If the checkbox VRT always muted is checked, the Visual Reinforcement Tool will not play any sound.

The checkbox Balance audio with first and second screen allows enabling balancing audio. If the checkbox is checked, the left and right audio channel of a song or video is enabled or disabled according to the enabled/disabled state of VRT monitor 1 (left channel) and VRT monitor 2 (right channel).

Selecting Show VRT screens on application startup displays a black screen on the configured second or third computer screen already at the startup of MAESTRO. Otherwise the screen will not be occupied until playback is started the first time.

With QWERTZ keyboard layout the user can confirm that a keyboard with a QWERTZ layout is being used. Otherwise the QWERTY keyboard layout is used for VRT.

In the Playback Monitor Selection section it is possible to choose up to two additional monitors to be used for VRT playback depending on the hardware setup of the computer system. Figure 131 depicts the selection of VRT monitor 1 and VRT monitor 2 on a computer system with three configured displays. The display marked with the MAESTRO logo identifies the display where MAESTRO is currently open. This display cannot be chosen for VRT playback.

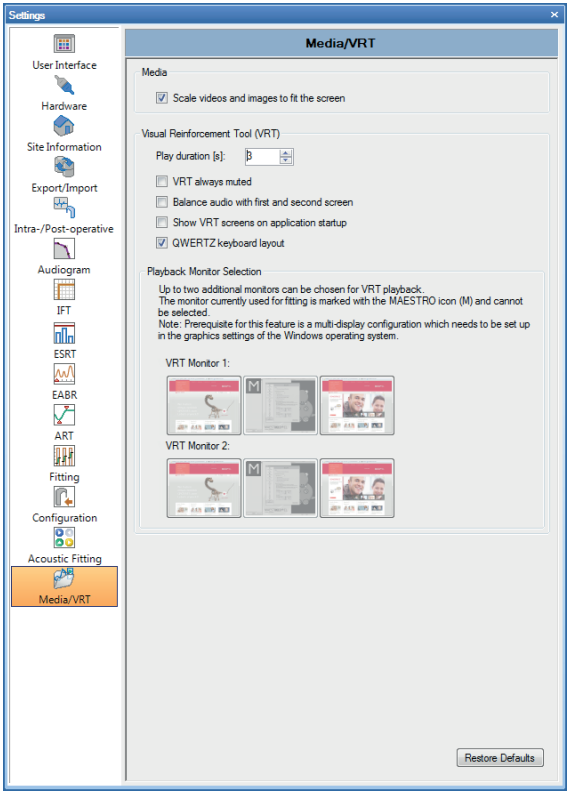


Figure 134 Media/VRT settings dialog

6.7 ACOUSTIC FITTING TASK

The Acoustic Fitting task allows programming the acoustic unit of a DUET 2 audio processor. The default determined from the audiogram data (see section 6.1) is displayed in an amplification curve and can be customized for the patient by setting the controls for Gain, Volume, AGC Ratio and Low Frequency Slope.
The acoustic unit can either be programmed manually using the trimmer or with the HI-PRO interface box via MAESTRO (see section 6.7.1).
To program the SONNET EAS processor use the Acoustic tab in the Fitting task (see section 6.6.2.8).

6.7.1 Acoustic Fitting hardware

Communication with the DUET 2 is established via the HI-PRO interface box. The DUET 2 must be connected to the HI-PRO with a DUET 2 programming cable. The DUET 2 audio processor must be switched on for fitting.

CAUTION:
Make sure to use the appropriate hardware for measurement.

6.7.2 Starting the Acoustic Fitting task

Acoustic Fitting is available for patients with a DUET 2 audio processor.

To start the Acoustic Fitting task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4) and a processor with the DUET 2 Battery pack needs to be entered in the processor list (see section 5.16.1.3).

After selection there are several ways to start the Acoustic Fitting task:

- A click on the button New opens the task dialog shown in Figure 135, where the Acoustic Fitting tab can be selected and with a click on New Acoustic Fitting an Acoustic Fitting can be opened.
- A right click on the symbol Acoustic Fitting in the taskbar opens the very same dialog with the Acoustic Fitting tab already selected. A click on New Acoustic Fitting opens a new Acoustic Fitting.
- A double click on the symbol Acoustic Fitting in the taskbar opens a new Acoustic Fitting automatically.

In the task dialog selection of Current Fitting in the area Audio Processor loads the current settings from the audio processor.

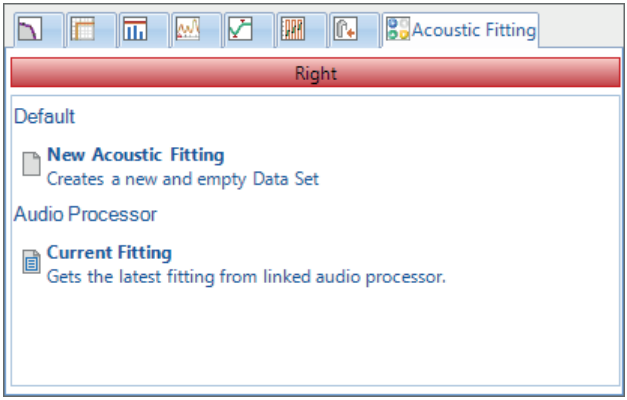


Figure 135 Dialog to open a new Acoustic Fitting task

Figure 136 shows the dialog of the Acoustic Fitting task. The parameters to be set in the Acoustic Fitting task are described in the DUET 2 Fitting Guide. The diagram shows the amplification curves for 40, 65 and 90 dB input level, the Target curve and the Crossover Frequency. Target curve and Crossover Frequency are adjusted according to the patient's audiogram data (see section 6.1). The name of the audiogram used for fitting is displayed in the field Audiogram on the right side of the diagram. A drop down menu allows the selection of any available audiogram (see section 6.1.2) by clicking on the audiogram. The selected audiogram can be opened by clicking on the field Open in the drop down menu. The patient's most current audiogram is selected by default. If no audiogram is available for the selected patient, the Target curve and Crossover Frequency are not displayed and a warning appears in the Notification window. The amplification curve settings correspond with the MAESTRO default values when starting the Acoustic Fitting task with an empty datasheet. Acoustic Amplification can be fitted to the patient's hearing loss by setting the controls Gain, Volume, AGC Ratio and Low Frequency Slope on the right side of the diagram in the area Acoustic Amplification.

Table 10 lists the minimum, maximum and default values of the control settings.

Control	Minimum	Maximum	Standard
Gain	27 dB	42 dB	27 dB
Low Frequency Slope	0 dB/Octave	18 dB/Octave	0 dB/Octave
AGC Ratio	1:1	4:1	1.33:1
Volume	0 dB	–42 dB	–20 dB

Table 10 Minimum, maximum and default values of the controls

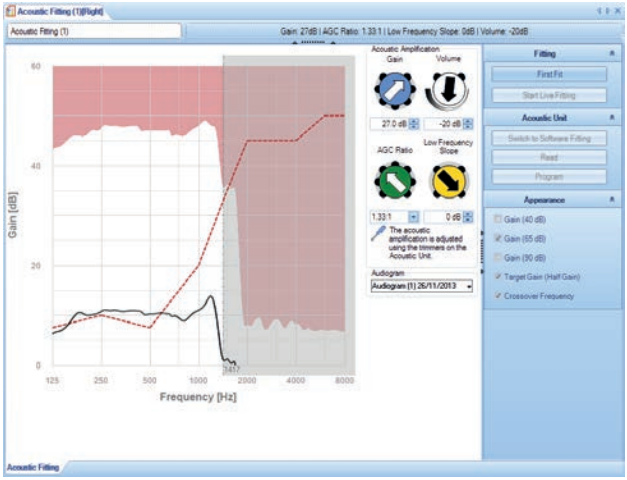


Figure 136 Acoustic Fitting task dialog

The right side of the Acoustic Fitting dialog is divided into the areas Fitting, Acoustic Unit and Appearance.

Clicking on the button First Fit under Fitting allows preliminary fitting of the Target Gain according to the patient's audiogram data. Fine fitting can be performed based on this preliminary fitting.

NOTE:
The current gain curve allows a first fitting approach and is an approximation of the target function.

To program the acoustic unit of the DUET 2 audio processor with MAESTRO, activate the option of fitting with MAESTRO by clicking on the button Switch to Software Fitting in the area Acoustic Unit. Then click on the button Start Live Fitting in the area Fitting to activate the acoustic unit of the DUET 2 audio processor and perform Live Fitting.

After activating the acoustic unit of the DUET 2 audio processor, a microphone symbol is displayed in the tab on the upper corner of the Acoustic Fitting dialog.

CAUTION:
The controls of the acoustic unit of the DUET 2 audio processor are deactivated as soon as the device is programmed with MAESTRO.

After activating the MAESTRO fitting option by clicking on the button Switch to Software Fitting, labeling of the button changes to Switch to Trimmer Fitting. Clicking on the button again deactivates the MAESTRO fitting option and activates Trimmer Fitting.

If the current settings of the acoustic unit were already programmed with MAESTRO, these settings can be read out with MAESTRO by clicking on the button Read. Read-out of manual control settings of the acoustic unit is not possible.

Clicking on the button Program downloads the settings performed in MAESTRO into the DUET 2 audio processor.

Selecting or deselecting the checkboxes Gain (40 dB), Gain (65 dB), Gain (90 dB), Target Gain (Half Gain) and Crossover Frequency under Appearance defines if individual amplification curves and, if available, Target Gain and Crossover Frequency are displayed. By default, the checkboxes Gain (65 dB), Target Gain (Half Gain) and Crossover Frequency are activated, the checkboxes Gain (40 dB) and Gain (90 dB) deselected.

CAUTION:
If a DUET 2 audio processor was programmed with MAESTRO, the controls can only be reprogrammed or reactivated with MAESTRO and a connected HI-PRO Box.

6.7.3 Acoustic Fitting settings

Click on the symbol Settings | Acoustic Fitting in the toolbar to customize Acoustic Amplification and Appearance settings of the Acoustic Fitting task. Figure 137 shows the Settings dialog of the Acoustic Fitting task.

Click on the button Restore Defaults on the right side below the field Appearance to restore all settings of the Acoustic Fitting task to their default values. Changes are applied by closing the Settings dialog.

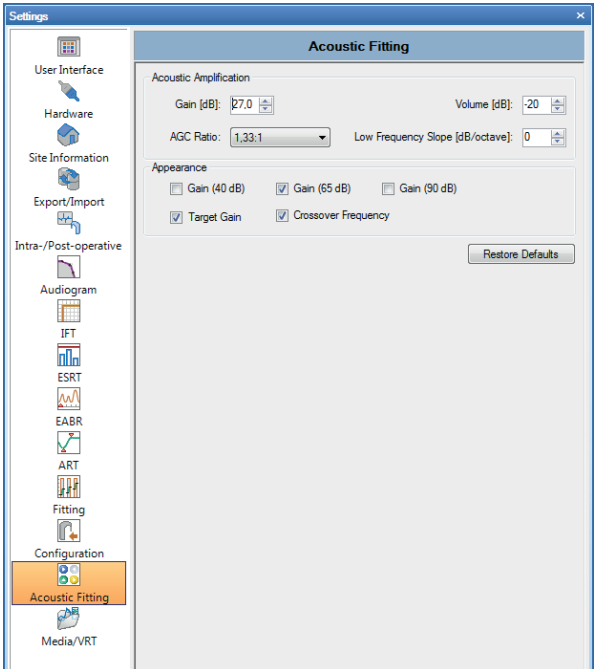


Figure 137 Acoustic Fitting settings dialog

6.7.3.1 Acoustic Amplification

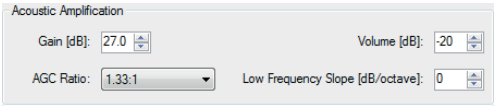


Figure 138 Acoustic Amplification

The Acoustic Amplification settings (Figure 138) allow customizing the default values for Gain in dB, Low Frequency Slope in dB, AGC Ratio and Volume in dB. The default value for Gain is 27 dB, for Low Frequency Slope 0 dB, for AGC Ratio 1.33:1 and for Volume −20 dB. The minimum and maximum values for each input range are listed in Table 10 in section 6.7.2.

6.7.3.2 Appearance

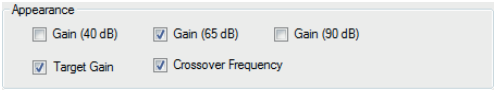


Figure 139 Appearance

The Appearance settings (Figure 139) of the Acoustic Fitting task define if the individual amplification curves or the Target Gain and Crossover Frequency are displayed in the diagram of the Acoustic Fitting task. By default, the checkboxes Gain (65 dB), Target Gain (Half Gain) and Crossover Frequency are selected and the checkboxes Gain (40 dB) and Gain (90 dB) deselected.

6.8 CONFIGURATION TASK

The Configuration task allows processor programming. Up to four maps can be saved to OPUS 2, RONDO, SONNET and SONNET EAS processors, up to nine maps to TEMPO+ and OPUS 1 processors (see section 6.6). The Processor Configuration window provides information about connected processors (see section 5.6).

6.8.1 Configuration hardware

Communication with the implant is established via the applicable processor connected to the MAX Programming Interface therefore the processor needs to be connected to a

processor socket of the MAX Programming Interface using the MAX Programming Cable BTE, MAX Programming Cable SONNET or the MAX Programming Cable RONDO. Depending on the hardware settings (see section 4.5) for dynamic or fixed port mapping connect the processor for a certain side to the corresponding processor socket.

CAUTION:
Make sure to use the appropriate hardware.

6.8.2 Starting the Configuration task

To start the Configuration task a patient needs to be selected from the patient list (see sections 5.16.3 and 5.16.4) and an empty processor or a processor programmed for the selected patient need to be connected to the MAX Programming Interface. There are several ways to start the Configuration task:

1. A click on the button New opens the task dialog shown in Figure 140, where the Configuration tab can be selected and with a click on New Configuration a Configuration can be opened.
2. A right click on the symbol Configuration in the taskbar opens the very same dialog with the Configuration tab already selected. A click on New Configuration opens a new Configuration.
3. A double click on the symbol Configuration in the taskbar opens a new Configuration automatically.

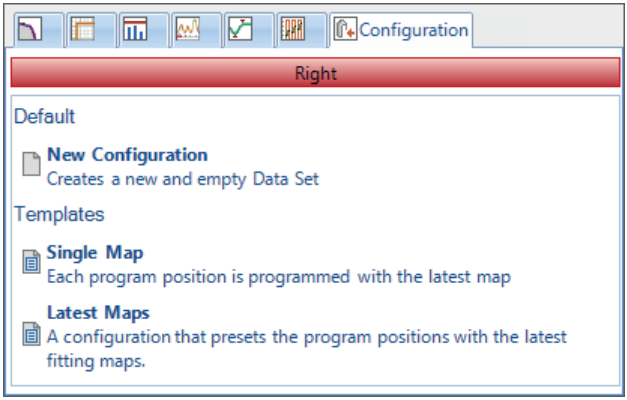


Figure 140 Dialog to open a new Configuration task

In the Configuration tab, selecting the option Single Map or Latest Maps in the area Templates opens the Configuration dialog with a default Configuration with the last map in all program positions or the last three (TEMPO+ and OPUS 1) or four (OPUS 2, RONDO and SONNET and SONNET EAS) maps.

6.8.2.1 Configuration dialog for TEMPO+ and OPUS 1 processors

Figure 141 shows the Configuration dialog for TEMPO+ and OPUS 1 processors.

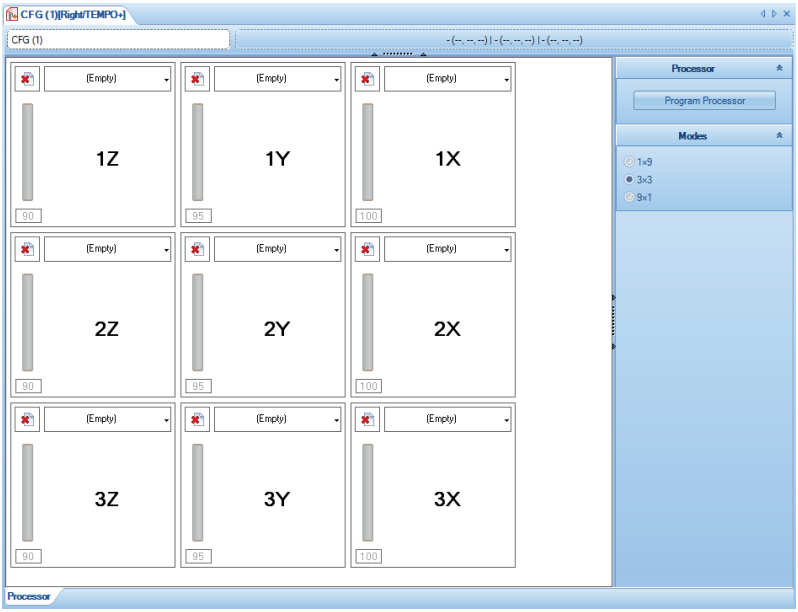


Figure 141 Configuration dialog for TEMPO+ and OPUS 1 processors

Nine program positions are available for TEMPO+ and OPUS 1 processors. After download the programs can be selected by the patient using the two switches on the processor.

On the right side of the Configuration dialog in the Modes section, a mode for the program positions can be defined by selecting the applicable option. The default mode is 3×3 so that 3 maps × 3 volumes can be set. The three maps are loaded into the positions 1, 2 and 3, the three volumes into the positions X, Y and Z. This means that each front switch position selects a different map and the rear switch provides the desired volume settings.

The mode 1×9 provides 1 map × 9 volumes. The selected map is loaded into all program positions with different volumes.

The mode 9×1 provides 9 maps × 1 volume. A different map with the same volume is loaded into each program position.

For the modes 3×3 and 1×9, volumes must be entered in ascending order.

A map can be assigned to a program position by selecting it from the drop-down list, which appears after clicking on the arrow symbol in the field in the upper area of the applicable program position or by drag and drop from the database view. After assigning a map to a program position, a preview of the map appears in the dialog of the applicable program position. The volume can be set between 0 and 100 % by shifting the black arrow in the bar left of the map preview or by directly entering the numerical value in the input field below the bar. Clicking into the field in the upper left corner of the program position reactivates the selected map with the selected volume. Activation of the map is indicated by a microphone symbol.

By clicking on a map or a group of maps with the right mouse key, various options can be selected in a separate menu. By selecting the option Interpolate, the volumes can be interpolated between the maps with the softest and the loudest setting, according to the selected mode. By selecting the option Default volumes, the volumes can be set to default values between 90 % and 100 % according to the selected mode. The option Activate/ Deactivate activates or deactivates the selected map. By selecting Download, the current configuration is downloaded into the audio processor. Processor programming with the current configuration is also possible by clicking on the button Program Processor on the right side of the Configuration dialog in the area Processor.

With each processor programming the current configuration is saved to the database. This creates a history of all configurations downloaded into the processor.

6.8.2.2 Configuration dialog for OPUS 2, RONDO, SONNET and SONNET EAS processors

Figure 142 shows the Configuration dialog for OPUS 2, RONDO and SONNET processors. The dialog is divided into Processor Configuration, Datalogging (only available for SONNET and SONNET EAS processors) and Options.

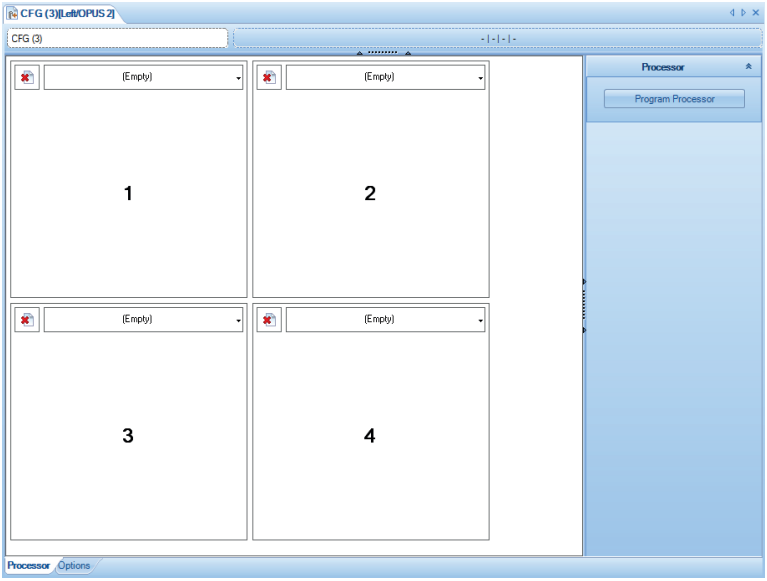


Figure 142 Configuration dialog of OPUS 2, RONDO and SONNET audio processors

Four program positions are available for OPUS 2, RONDO, SONNET and SONNET EAS processors. After programming the processor the individual programs can be selected with the FineTuner (see section 6.7.2.3). The status bar shows the program, volume and sensitivity of the current settings of the connected processor as shown in Figure 143.

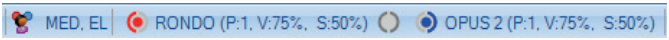


Figure 143 Display of current settings of an OPUS 2 processor in the status bar

A map can be assigned to a program position by selecting it from the drop-down list, which appears after clicking on the arrow symbol in the field in the upper area of the applicable program position or by drag and drop from the database view. After assigning a map to a program position, a preview of the map appears in the dialog of the applicable program position. Each map is downloaded with the assigned default volume (see section 6.6.2.1) and default sensitivity (see section 6.6.2.6). Changing the default volume in the Configuration task is not possible.

Clicking on the field in the upper left corner of the program positions activates the selected map with the applicable default volume and default sensitivity. Activation of the map is indicated by a microphone symbol (see Figure 144).

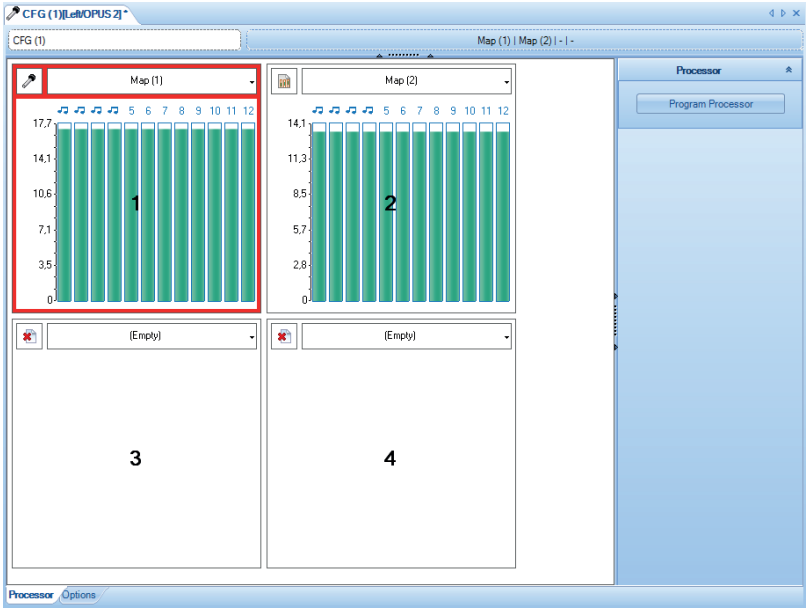


Figure 144 Activated Fitting map in configuration task

With a right mouse click on a map the options Activate/Deactivate and Download become available in a separate menu. Selecting the option Activate/Deactivate activates or deactivates the selected map. Selecting Download downloads the current configuration into the processor. Processor programming with the current configuration is also possible by clicking on the Program Processor button on the right side of the Configuration dialog in the Processor section.

With each processor programming, the current configuration is saved to the database. This creates a history of all configurations downloaded into the processor.

NOTE:
Program position 1 will be set as the default map after each download into an OPUS 2, RONDO, SONNET or SONNET EAS. Default volume and default sensitivity of this map will also be used after each download.

Program position 1 must therefore not be empty.

6.8.2.3 Options

The Options dialog (see Figure 145) allows selectively activating or deactivating individual FineTuner keys.

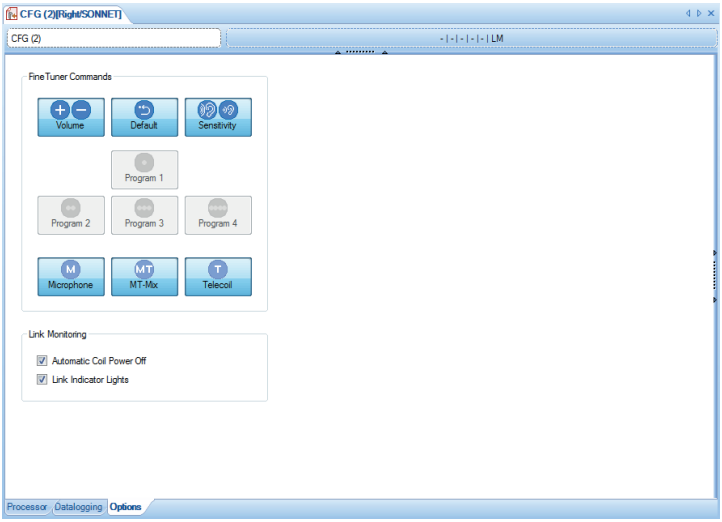


Figure 145 Options

FineTuner commands:
With a left mouse click on the symbol, a key can be activated or deactivated. Deactivated keys are greyed out. If individual program positions are not used in the configuration, the corresponding keys are automatically deactivated by MAESTRO. For additional information on the function of the individual keys, please refer to the processor user manuals.

Link Monitoring:
Only the DL-Coil, in combination with a SONNET or SONNET EAS processor, is capable of link monitoring functionality. Therefore, add the DL-Coil to a SONNET or SONNET EAS in the patient editor (see 5.16.1.3).
Link Monitoring functionality is activated if at least one of the two checkboxes Automatic Coil Power Off or Link Indicator Lights are enabled and deactivated if both checkboxes are disabled.
Both checkboxes are enabled by default for SONNET or SONNET EAS processors with DL-Coil.
Enable the Automatic Coil Power Off checkbox to activate Link Monitoring and automatically stop stimulation when the DL-Coil cannot detect the implant any more, e.g. the coil is no longer placed over the implant. This will only stop stimulation and will not turn off the processor automatically.

Please note that repositioning the coil over the implant does not start stimulation automatically. The coil has to be placed over the implant and the processor has to be switched off and on manually to start stimulation again.
Enable the Link Indicator Lights checkbox to enable the indicator lights functionality for Link Monitoring. Link Monitoring is then automatically activated and
the indicator light of the DL-Coil blinks in a certain pattern when connection to the implant could not be established. This does not only occur when the coil is not placed over the implant but also when the connected processor was not programmed for this implant.
The Link Monitoring functionality cannot be used while the processor is connected to the MAX Programming Interface.

6.8.2.4 Datalogging

With Datalogging the audio processor usage can be logged and visualized. The Datalogging dialog enables data logging for SONNET and SONNET EAS audio processors by clicking on the Enable Datalogging checkbox in the Options section (see Figure 146). Datalogging is enabled by default.

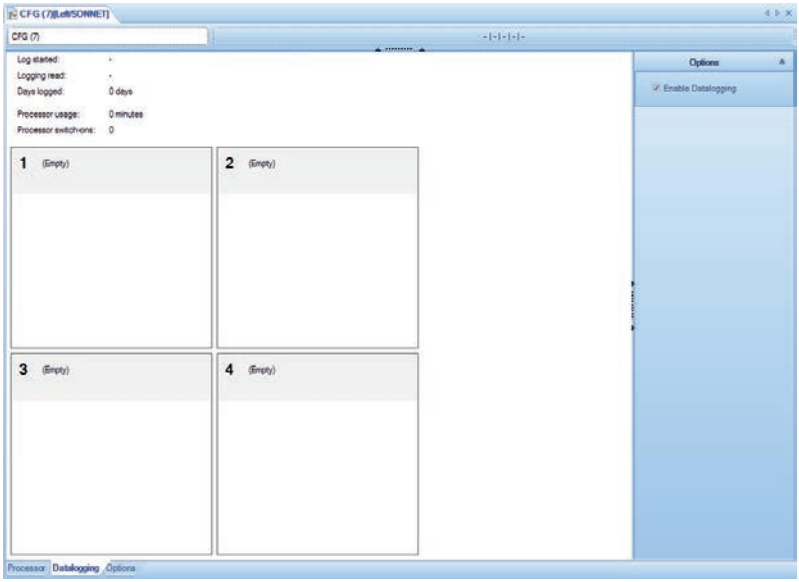


Figure 146 Datalogging dialog

A processor with enabled Datalogging logs the processor usage data. It indicates the processor usage hours, the number of processor startups, the usage time of specific programs, and also tracks volume and sensitivity used for each program (see Figure 147).
To display the current logged data on the processor, connect the processor with the appropriate programming cable to the MAX Programming Interface open the currently used configuration and switch to the Datalogging tab.
Log started gives the date the processor was programmed and the log was started. Log finished gives the date the log was read out and finished.

Days logged gives the number of logged days. Processor usage gives the average hours per day and, additionally, adds up the time the processor was switched on. Processor switch-ons gives the average number of switch-ons per day and also adds up the processor startups.

The four program positions with the name of the programmed map and logged information are displayed below. The first bar, called Map Usage, indicates how long the map was in use as a percentage of the overall processor usage time. The second bar, called Volume Usage Ranges, represents the volume used and is split into three parts. The center part is labelled Mid and ranges from default volume –10% to default volume +10%, if default volume is within the range of 10 to 90%. Otherwise, an accordingly more limited range is utilized. Low starts with the defined minimum FineTuner volume and High ends with the defined maximum FineTuner volume.

The third bar, called Sensitivity Usage Ranges, represents the sensitivity and is split again into three parts. The center is labelled Mid and defined as set default sensitivity ±10%, similar to volume.

The default volume, volume range, and default sensitivity are map based parameters and can be adjusted within the Fitting task (see section 6.6.2.1 and section 6.6.2.6).

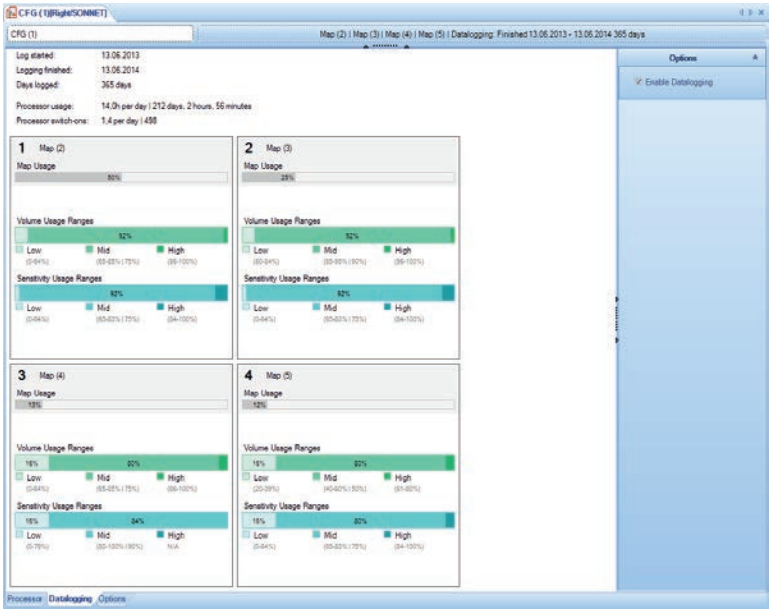


Figure 147 Datalogging

CAUTION:
Analysis of Datalogging must not be taken as the sole basis for any decision about further medical or surgical treatment.

6.8.3 Configuration settings

Click on the symbol Settings | Configuration in the toolbar to customize the parameter Datalogging and Link Monitoring of the Configuration task. Figure 148 shows the Settings dialog of the Configuration task.

Click on the button Restore Defaults on the right side to restore all settings of the Configuration task to their default values. Changes are applied by closing the Settings dialog.

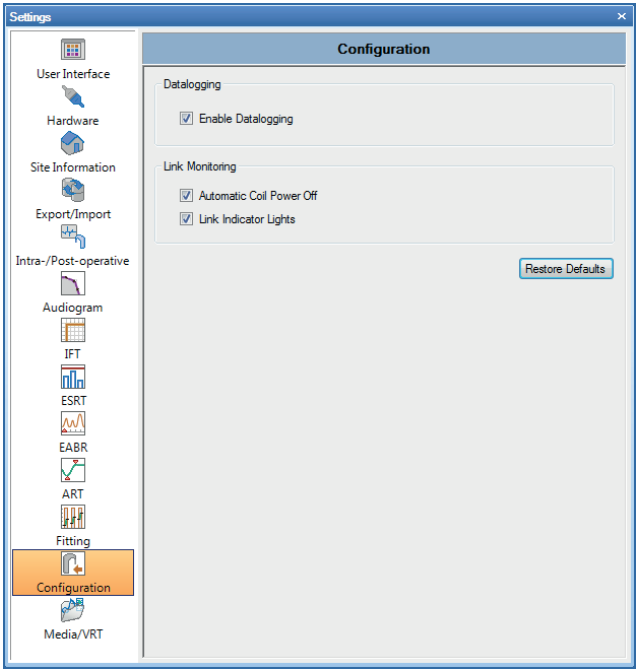


Figure 148 Configuration settings

6.8.3.1 Datalogging

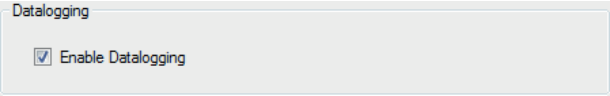


Figure 149 Datalogging

The checkbox Enable Datalogging allows customizing the default value for the Datalogging tab in the Configuration task. By default the Enable Datalogging checkbox is activated.

6.8.3.2 Link Monitoring

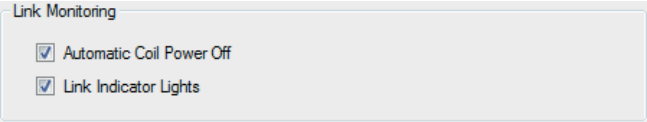


Figure 150 Link Monitoring

The section Link Monitoring allows defining the default values for Automatic Coil Power Off and Link Indicator Lights in the Options tab of the Configuration task. By default both options are enabled for processors with DL-Coil.

7. General Precautions and Warnings

7.1 GENERAL PRECAUTIONS AND WARNINGS

Please pay attention to the following precautions and warnings. Additionally, refer to the applicable user manuals.

- For safety reasons it is absolutely essential to specify the correct implant including serial number and electrode type before proceeding with any software operations.
- When you treat an unfamiliar patient for the first time or add a new patient to the database take all necessary steps to ensure correct identification of the implant and electrode type – do not make any assumptions! If the patient is already stored in the database, be sure to select the correct patient and ear (for bilaterally supplied patients) before continuing with the software.
- Channel interactions have the potential to be slightly higher with the +FLEX^{20} electrode than with the +FLEX^{24} electrode. This results from distributing a certain number of channels (12) across a very short cochlea via the +FLEX^{20} electrode, when compared to distributing the same number of channels across a longer cochlea via the +FLEX^{24} electrode. A shorter cochlea cannot accommodate a longer electrode which is linked to more favorable speech outcomes, however an audiologist can - if needed- switch off channels on the array using the fitting software, thereby increasing the average spacing of active contacts and potentially reducing channel interactions for such patients.
- Only run the MAESTRO software under the following Microsoft Operating Systems: Windows® XP Service Pack 3 (SP3) or higher or Windows Vista™ Service Pack 2 or higher, Windows® 7 Service Pack 1 or higher or Windows® 8, 8.1 or higher.
- Do not edit or alter any files generated or used by the fitting software. Do not edit and/or alter the MAESTRO software. Make sure that no attempt to alter this software is performed (e.g. by viruses).
- Install and maintain protective anti-virus software and ensure that the Windows operating system uses the latest available updates.
- Backup of patient data in the database is not automatically provided. It is the responsibility of the user to backup patient data files.
- Do not run other software applications simultaneously with the MAESTRO software to minimize the chances of interference.
- Make sure that there are no software conflicts with other programs running on your PC. If you detect a problem check to see what other programs are running in the background. Shut down all programs except for MAESTRO and see if the situation improves. Sometimes an over-aggressive virus checker program can cause strange behavior, so, if possible, disable the virus checker to see if this resolves the problem.

- If you have a problem related to printing, it may be associated with the printer driver software which comes from the printer manufacturer. Printer drivers may have software bugs or do not support all versions of Windows equally well. The best approach is to find and install the very latest driver from the manufacturer's Web page and see if the problem is resolved. Make sure you get the driver which matches the exact printer model and the version of Windows you are using.
- It is the responsibility of the user to provide adequate data privacy protection against intentional or unintentional disclosure. The User Administration features of MAESTRO can be an effective tool, but they must be maintained and used correctly.

7.2 ELECTROSTATIC DISCHARGE

Electrostatic discharge (ESD) has the potential to damage electronic components of the CI System (e.g. audio processors, MAX Programming Interface). Electrostatic charge build-up occurs most frequently on days when the air is very dry. The probability of the occurrence of electrostatic discharge can be reduced by following the list of guidelines below. Additionally, refer to the applicable sections in the appropriate user manuals.

- Whenever you think that the patient and/or you yourself have been charged with static energy, you and/or the patient should discharge yourself by touching a radiator, a water tap, or any other grounded metal.
- When you are working with a computer, make sure that the computer is grounded.
- Place an anti-static mat under your work place.
- You and/or the patient should not directly touch TV or computer screens.

8. Care and Maintenance

This software does not require calibration, service or maintenance.

9. Troubleshooting

The MAESTRO software contains several error and information messages which can be encountered at various points during operation of the software. All messages appear in a separate log window. There are three different types of messages: (i) errors, (ii) warning messages, and (iii) information messages. The messages are clear and usually self-explanatory so that the user of the MAESTRO software will find it easy to understand the problem and carry out the necessary actions. If you have difficulty understanding a message, please contact your nearest MED-EL representative.

10. Technical Data

10.1 MINIMUM HARDWARE AND SOFTWARE REQUIREMENTS

Hardware minimum requirements

- PC or Laptop/Notebook in connection with one of the supported Microsoft Windows operating systems
- Dual-core processor with a minimum clock speed of 1.6 GHz or higher
- 2 GB RAM or more
- 2 GB or more free disk space
- Color display with a minimum resolution of 1024 × 768 (1280 × 1024 recommended)
- One free high-power USB 2.0 port or higher
- One free printer port or network connection to printer
- CD ROM compatible drive for software installation

Supported Microsoft Windows operating systems

- Microsoft Windows® XP, Service Pack 3 (SP3) or higher
- Microsoft Windows Vista™, Service Pack 2 or higher
- Microsoft Windows® 7, Service Pack 1 or higher
- Microsoft Windows® 8, 8.1 or higher

10.2 DEVICES TO BE CONNECTED

The devices to be connected to the PC in order to perform all functions of the MAESTRO software is the MAX Programming Interface and the HI-PRO interface box. For setup of the system refer to the MAX Programming Interface user manual and the HI-PRO user manual.

10.3 STORAGE OF THE CD-ROM

Avoid touching the recording surface of the CD-ROM (back side) to prevent fingerprints, scratches, dust particles and smears. When not in use, store the CD-ROM in its original case with the recording surface underneath. Also be careful not to expose the disc to direct sunlight, high temperatures, humidity, dust or dirt. For cleaning, a soft dry cloth or a standard CD cleaner should be used. No other cleaning tools, solvents or abrasive cleaners should be used.

10.4 CE MARK

CE 0123 CE mark applied in 2014

11. Clinical Studies

11.1 CODING STRATEGIES

The aims and results of the MED-EL FSP Clinical Investigation of 46 post-lingually deaf adults with 6-months device experience were:

1. To investigate the effect of a fine structure speech coding strategy on auditory perception in CI users compared to the current CIS+ strategy. Results have shown that the FSP strategy is at least equal to or even better than both HDCIS and CIS+ strategies in many cases. There is a strong user preference for the FSP strategy.
2. To investigate the feasibility of deriving electrically evoked compound action potentials with the MED-EL ART system postoperatively. Results show that EAPs can be measured in almost all cases and that the system is sensitive to the difference in cochlear anatomy between the basal and apical regions of the cochlea.
3. To investigate the safety of the MED-EL CI system using MAESTRO software. During the clinical investigation, no serious adverse events were reported. One device event was report, there was a fault with the CPU which was resolved on replacing the CPU.

The aims and results of the MED-EL FSP Clinical Investigation (Inexperienced User Section only) of 22 post-lingually deaf adults who had not received a cochlear implant before and who fulfilled all subject inclusion criteria were:

1. To investigate the effect of using the OPUS 1 audio processor on performance after cochlear implantation. Results have shown that the FSP strategy provides significant benefit over and above their pre-operative scores, indicating that inexperienced users can benefit from the FSP coding strategy.
2. To investigate the feasibility of deriving electrically evoked compound action potentials with the MED-EL ART system postoperatively. 71.43 % were measured postoperatively at acute switch-on and a further 9.52 % were recorded at the 3 month post-fitting.

The aims and results of the study of Riss et al. (2013) on thirty-three post-lingually deaf adults with 1-year experience with FSP were to compare the three available fine structure strategies FS4, FS4-p and FSP with regard to speech perception, subjective sound quality and subjective preference. Objective speech tests results revealed no significant differences between the three strategies, except for a small improvement of FSP over FS4 regarding monosyllables perception.

Subjective sound quality was assessed for speech in quiet, classical, and pop music. No significant effects of strategy were found for speech in quiet and classical music, but auditory impression of pop music was rated as more natural in FSP compared to FS4. Regarding

subjective preference, a majority of the patients favored FS4 or FS4-p over their previous default FSP at the end of the study (FSP: N = 13; FS4: N = 13; FS4-p: N =7). The study found great variability in performance between patients, which demonstrates that instead of establishing a common best-performing strategy for all patients, a best performing strategy for each individual patient should be determined for optimum benefit for that patient.

11.2 EABR TASK

The EABR task has been in clinical use in MED-EL fitting software (ZEBRA 3.0) since 2001 without any reported complaints or adverse events. The EABR task is used to create the pulse sequences intended to elicit responses of the brainstem by stimulation of the auditory nerve or the corresponding area of the brainstem. The EABR task is available in MAESTRO 4.1 and subsequent versions and is equivalent to the EABR task in ZEBRA 3.0. An evaluation performed by MED-EL on the available clinical experience with the EABR task concluded that possible benefits outweigh any risks when providing the EABR task within MAESTRO to MED-EL cochlear implant patients.

The MED-EL Cochlear Implant System can thus be deemed to be both safe and effective.

12. Appendices

12.1 BACKWARD COMPATIBILITY

MAESTRO 6.0 supports the implants SYNCHRONY, MED-EL CONCERT, SONATA TI100, PULSAR CI100 and C40+ in combination with the SONNET EAS, SONNET, RONDO, OPUS 2, DUET 2, OPUS 1 and TEMPO+ processors. The software CI.STUDIO+ shall be used for all other implant/processor combinations.

12.2 WARRANTY

Our warranty is in agreement with statutory warranty claims. This warranty exclusively covers product failures; it shall not apply to any MED-EL product subjected to physical or electrical abuse or misuse, or operated in any manner inconsistent with the applicable MED-EL instructions. Statutory warranty claims shall not be granted unless the registration form, included with this user manual, is completed and returned to MED-EL within three weeks from receipt.

12.3 ADDRESS OF THE MANUFACTURER

MED-EL Elektromedizinische Geräte GmbH
Worldwide Headquarters
Fürstenweg 77a
6020 Innsbruck, Austria
Phone: +43 (0) 5 77 88
E-mail: office@medel.com

12.4 KEY COMBINATIONS

12.4.1 Main menu

Shortcut	Operation
Data	
F2	Create new task data
F3	Create a new patient
F4	Create new IFT Measurement
F5	Create new ESRT data
F6	Create new ART Measurement
F7	Create new Fitting Map
F8	Create new Configuration
F9	Create new Audiogram
F11	Create new EABR data
F12	Create new Acoustic Fitting
Ctrl + E	Edit the current item
Ctrl + S	Save the current item
Ctrl + L	Close the open editor
Ctrl + Shift + L	Close all open editors
Ctrl + P	Select/Deselect the current patient
Alt + F2	Export Data
Alt + F3	Import Data
Alt + F5	Reports
Alt + F6	History Reports
Alt + F7	Session Reports
Alt + F8	User Reports

Shortcut	Operation
Edit	
Ctrl + Z	Undo the last action
Ctrl + Y	Redo the last Undo action
Ctrl + X	Cut the current selection to the clipboard
Ctrl + C	Copy the current selection to the clipboard
Ctrl + V	Paste the current selection from the clipboard
Ctrl + R	Rename the current item
Ctrl + A	Select all items
Ctrl + I	Invert the current selection
View	
Shift + F2	View the task list
Shift + F3	View the log
Shift + F4	View the notifications generated by input
Shift + F5	View the processor configuration
Shift + F6	Display the settings dialog
Shift + F8	View the sessions
Shift + F9	View the Media Player
Shift + F11	Select the previous task editor
Shift + F12	Select the next task editor
Ctrl + Shift + F11	Select the previous task subeditor
Ctrl + Shift + F12	Select the next task subeditor
Ctrl + H	Toggles the header for editors
Ctrl + N	Acknowledge the next notification
Tools	
Ctrl + B	Launch the Coupling Check tool
Ctrl + M	Launch the Media Manager tool
Help	
Ctrl + F1	Display the Help documentation
Shift + F1	View Product Version and Copyright

12.4.2 Toolbar

Shortcut	Operation
Ctrl + T	Toggle Talk Mode
Ctrl + Shift + E	Duplicate the opened data
Ctrl + Shift + S	Save the current data set and close it

12.4.3 Task view

Shortcut	Operation
Ctrl + F3	View patient task
Ctrl + F4	View IFT task
Ctrl + F5	View ESRT task
Ctrl + F6	View ART task
Ctrl + F7	View Fitting task
Ctrl + F8	View Configuration task
Ctrl + F9	View Audiogram task
Ctrl + F11	View EABR task
Ctrl + F12	View Acoustic Fitting

12.4.4 Notification view

Shortcut	Operation
Ctrl + N	Acknowledge the next notification

12.4.5 Login

Shortcut	Operation
Alt + T	Select/Deselect Training Mode

12.4.6 Coupling Check

Shortcut	Operation
Space	Start or stop scan

12.4.7 Media Manager

Shortcut	Operation
Alt + P	Add playlist
Alt + M	Add media file
Enter	Edit selected playlist or media file
Del	Delete selected playlist or media file
Alt + E	Export Media Library
Alt + I	Import Media Library
Alt + V	Toggle preview visibility

12.4.8 Patient

12.4.8.1 Right/Left Ear Editor

Shortcut	Operation
Ctrl + Shift + R	Read Implant Serial number
Ctrl + Shift + E	Edit Implant Serial number
Alt + Arrow Down	Opens Enable/Disable Electrode menu

12.4.9 Audiogram

Shortcut	Operation
Home	Move cursor to the lowest hearing level
Ctrl + Home	Move marker to the lowest hearing level
End	Move cursor to the highest hearing level
Ctrl + End	Move marker to the highest hearing level
Page Up	Move cursor 2 x step size up
Page Down	Move cursor 2 x step size down
Ctrl + Page Up	Move marker at 2 x step size above
Ctrl + Page Down	Move marker at 2 x step size below
Up, Down, Left, Right	Move cursor up, down, left or right
Ctrl + Up, Ctrl + Down	Move marker up or down
Space or Enter	Set marker at current cursor position
Delete	Remove marker
1	Set step size to 1 dB HL
2	Set step size to 2 dB HL
5	Set step size to 5 dB HL

12.4.10 Telemetry (IFT)

Shortcut	Operation
Ctrl + Shift + M	Measure
Ctrl + Shift + X	Discard
Channel Setup Assistant	
Ctrl + Shift + C	Show CSA suggestions
Ctrl + Shift + A	Accept CSA suggestions

12.4.11 ESRT

Shortcut	Operation
Min. one channel selected	
Space	Start or stop the stimulation at the selected channel
Escape	Stop any stimulation immediately
Ctrl + Alt + Fx (x = 1...12)	Select channel x. If this channel has already been selected, it is deselected.
Ctrl + Alt + F1	Select channel 1. If this channel has already been selected, it is deselected. The key combinations Ctrl + Alt + F2 to Ctrl + Alt + F12 affect channels 2 to 12.
Tab	Change selection to the next active channel to the right. Simultaneously pressing SHIFT changes the direction.
Arrow Right	Change selection to the next active channel to the right
Arrow Left	Change selection to the next active channel to the left
Ctrl + Alt + C/D	Change between graphical and numerical entry of current desired ESRT charge, respectively move the cursor to the data field for minimum pulse duration
R	Mark as reflex
N	Mark as no reflex
M	Mark as undefined
+ key	Increase the charge value at the selected channel by the smallest increment
- key	Decrease the charge value at the selected channel by the smallest increment
Arrow up	Increase the charge value at the selected channel by the middle increment
Arrow down	Decrease the charge value at the selected channel by the middle increment
Page up	Increase the charge value at the selected channel by the biggest increment
Page down	Decrease the charge value at the selected channel by the biggest increment

12.4.12 EABR

12.4.12.1 Stimulation Editor

Shortcut	Operation
Min. one channel selected	
Space	Start or stop the stimulation at the selected channels
Escape	Stops the stimulation immediately
Home	Focus upper slider knob (if present)
Ctrl + Shift + Home	Toggle focus between upper slider knob and (related) numeric input field
End	Focus lower slider knob
Ctrl + Shift + End	Toggle focus between lower (or only) slider knob and (related) numeric input field
Ctrl + Shift + M	Toggle focus between numeric input field of number of pulses and (previously) focused slider knob, or set focus to that numeric input field if another numeric input field is already focused
+ key	Increase the current value (of the 'focused' amplitude) at the focused channel by the smallest increment
- key	Decrease the current value (of the 'focused' amplitude) at the focused channel by the smallest increment
Arrow up	Increase the current value (of the 'focused' amplitude) at the focused channel by the middle increment
Arrow down	Decrease the current value (of the 'focused' amplitude) at the focused channel by the middle increment
Page up	Increase the current value (of the 'focused' amplitude) at the focused channel by the biggest increment
Page down	Decrease the current value (of the 'focused' amplitude) at the focused channel by the biggest increment
Ctrl + C	Copy amplitude(s) of the focused channel
Ctrl + V	Paste previously copied amplitudes to the focused channel

Shortcut	Operation
Selection	
Ctrl	Select one or more channels with the mouse
Shift	Select a range of channels with the mouse
Ctrl + Alt + Fx (x = 1...12)	Select channel x. If this channel has already been selected, it is deselected
Ctrl + A	Select all channels
Ctrl + I	Invert the current selection
Tab	Change selection to the next active channel to the right. Simultaneously pressing Shift changes the direction.
Arrow right	Change selection to the next active channel to the right
Arrow left	Change selection to the next active channel to the left
Data field selected	
Arrow up	Move the cursor to the next editable data field above the currently focused data field
Arrow down	Move the cursor to the next editable data field below the currently focused data field
Enter	Open focused numerical input field

12.4.12.2 Extended Setup Editor

Shortcut	Operation
Ctrl + Shift + R	Restore default values

12.4.12.3 Stimulation History

Shortcut	Operation
Ctrl + Shift + R	Reuse selected parameter set
Tree view	
Enter	Open input box for comment related to the selected (sub) node
Arrow up	Move the cursor to the preceding node (top level or sub node, depending on expansion state of the top level node)
Arrow down	Move the cursor to the succeeding node (top level or sub node, depending on expansion state of the top level node)
Arrow right	Expand selected top level node
Arrow left	Collapse selected top level node
Comment input box	
Enter	Close the comment input box

12.4.13 ART

12.4.13.1 Setup Editor

Shortcut	Operation
Ctrl + Shift + M	Measure
Ctrl + Shift + X	Discard Results
Channel Label on Electrode Status Control focused	
Alt + Arrow Down	Opens Enable/Disable Electrode menu

12.4.13.2 Loudness Comfort Tool

Shortcut	Operation
Space	Start/Stop stimulation
Escape	Stop stimulation
Ctrl + Shift + Enter	Accept amplitude and phase duration
Ctrl + Shift + X	Discard amplitude and phase duration
Ctrl + Alt + A	Jump to edit field for amplitude
Ctrl + Alt + D	Jump to edit field for phase duration
Ctrl + N	Acknowledge charge increase warning
Slider selected	
+ key	Increase the amplitude value by the smallest increment
- key	Decrease the amplitude value by the smallest increment
Arrow up	Increase the amplitude value by the middle increment
Arrow down	Decrease the amplitude value by the middle increment
Page up	Increase the amplitude value by user defined increment
Page down	Decrease the amplitude value by user defined increment
Data field selected	
Arrow up	Move the cursor to the next higher data field at the selected channel
Arrow down	Move the cursor to the next lower data field at the selected channel
Enter	Open selected numerical input field at the selected channel

12.4.14 Fitting

12.4.14.1 Fitting Level Editor

Shortcut	Operation
Min. one channel selected	
Space	Start or stop the stimulation at the selected channels
Escape	Stop any stimulation immediately
Ctrl + Shift + A	Activate/Deactivate the processor
Ctrl + Shift + X	Activate/Deactivate the electric part of the processor (only for SONNET EAS)
Ctrl + Shift + Y	Activate/Deactivate the acoustic part of the processor (only for SONNET EAS)
M/T	Change between MCL/THR values at the selected channel
Ctrl + Shift + M/T/D	Change between graphical and numerical entry of MCL or THR, respectively move the cursor to the data field for minimum pulse duration
Ctrl + Shift + Arrow up/Arrow down	Increase/Decrease Activation Volume
+ key	Increase the charge value at the selected channel by the smallest increment
- key	Decrease the charge value at the selected channel by the smallest increment
Arrow up	Increase the charge value at the selected channel by the middle increment
Arrow down	Decrease the charge value at the selected channel by the middle increment
Page up	Increase the charge value at the selected channel by the biggest increment
Page down	Decrease the charge value at the selected channel by the biggest increment

Shortcut	Operation
Selection	
Ctrl	Select one or more channels with the mouse
Shift	Select a range of channels with the mouse
Ctrl + Alt + Fx (x = 1...12)	Select channel x. If this channel has already been selected, it is deselected
Ctrl + A	Select all channels
Ctrl + I	Invert the current selection
Tab	Change selection to the next active channel to the right. Simultaneously pressing Shift changes the direction.
Arrow right	Change selection to the next active channel to the right
Arrow left	Change selection to the next active channel to the left
Data field selected	
Arrow up	Move the cursor to the next higher data field at the selected channel
Arrow down	Move the cursor to the next lower data field at the selected channel
Enter	Open selected numerical input field at the selected channel
Interpolation	
Ctrl + Alt + M	Perform interpolation of MCL values
Ctrl + Alt + T	Perform interpolation of THR values
Ctrl + Alt + I	Perform interpolation of MCL and THR values
Visual Reinforcement Tool (VRT)	
A, S, D, F, Y/Z, X, C	Start playback of items 1–7 of the selected playlist
V	Stop playback
G	Toggle playback display on first screen
B	Toggle playback display on second screen

12.4.14.2 Frequency Bands Editor

Shortcut	Operation
Ctrl + Shift + R	Restore default values

12.4.14.3 Maplaw Editor

Shortcut	Operation
Ctrl + Shift + R	Restore default values

12.4.14.4 OPUS 2, RONDO, SONNET and SONNET Indicators Editor

Shortcut	Operation
Ctrl + Shift + W	Trigger a Warning Beep
Ctrl + Shift + C	Trigger a Confirmation Beep

12.4.14.5 Acoustic Editor (SONNET EAS)

Shortcut	Operation
General	
Ctrl + Shift + R	Restore the default values.
Ctrl + Shift + A	Activate / deactivate the processor
Ctrl + Shift + X	Activate/Deactivate the electric part of the processor
Ctrl + Shift + Y	Activate/Deactivate the acoustic part of the processor
Ctrl + Shift + Arrow Up	Increase the Activation volume.
Ctrl + Shift + Arrow Down	Decrease the Activation volume.
Graphical Display	
+, Arrow Up	Increase the target gain at the selected frequency by the small increment.
-, Arrow Down	Decrease the target gain at the selected frequency by the small increment.
Page Up	Increase the target gain at the selected frequency by the large increment.
Page Down	Decrease the target gain at the selected frequency by the large increment.
Tab	Move selection to the next input control.
Arrow Right	Move selection to the next target gain to the right.

Shortcut	Operation
Arrow Left	Move selection to the next target gain to the left.
Numerical Display	
+, Arrow Up	Increase the target gain at the selected frequency by the small increment.
-, Arrow Down	Decrease the target gain at the selected frequency by the small increment.
Page Up	Increase the target gain at the selected frequency by the large increment.
Page Down	Decrease the target gain at the selected frequency by the large increment.
Tab	Move selection to the next input control.
Arrow Right	Move selection to the next target gain to the right.
Arrow Left	Move selection to the next target gain to the left.
Enter	Open numerical input field at the selected target gain.
Esc, Enter	Close opened numerical input field at the selected target gain

12.4.15 Configuration

Shortcut	Operation
General	
Ctrl + Shift + A	Activate/Deactivate the selected map
Ctrl + Shift + P	Program processor
Ctrl + Alt + D	Default volume distribution (OPUS 1 and TEMPO+)
Ctrl + Alt + I	Interpolate volumes (OPUS 1 and TEMPO+)
Ctrl + Alt + V	Jump to volume edit field (OPUS 1 and TEMPO+)
Alt + Arrow down	Select a map for a position
Arrow up	Increase volume (OPUS 1 and TEMPO+)
Arrow down	Decrease volume (OPUS 1 and TEMPO+)
Arrow left	Jump to the previous program position
Arrow right	Jump to the next program position

12.4.16 Acoustic Fitting

Shortcut	Operation
Escape	Stops Live Fitting immediately
Ctrl + Shift + F	First Fit
Ctrl + Shift + T	Switch to Software Fitting/Switch to Trimmer Fitting
Ctrl + Shift + K	Start/Stop Live Fitting (Activate/Deactivate the acoustic unit)
Ctrl + Shift + P	Program the acoustic unit
Ctrl + Shift + R	Read the program from the acoustic unit
Ctrl + Shift + 4	Hide/Show gain curve at 40 dB input level
Ctrl + Shift + 6	Hide/Show gain curve at 65 dB input level
Ctrl + Shift + 9	Hide/Show gain curve at 90 dB input level
Ctrl + Shift + C	Hide/Show crossover frequency
Ctrl + Shift + G	Hide/Show target gain curve

12.4.17 User

12.4.17.1 Administration Editor

Shortcut	Operation
Ctrl + Shift + G	Get the user name of the logged in Windows account and set as application user name

12.4.18 Reports

Shortcut	Operation
Alt + A	Anonymize Patient Name (except User Report Dialog)
Alt + H	Show Selector (except User Report Dialog)
Alt + O	Output Options
Alt + P	Print
Alt + S	Save As
Alt + C	Close
Arrow left	Previous Report Data
Arrow right	Next Report Data
+ key	Zoom in
- key	Zoom out

13. MED-EL Contacts

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

MED-EL Elektromedizinische Geräte GmbH
Worldwide Headquarters
Fürstenweg 77a
6020 Innsbruck, Austria
office@medel.com

medel.com

Rx ONLY

USA Distributor
MED-EL Corporation, USA
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
implants.us@medel.com

CE 0123

Cochlear Implants

MED EL

Mi1200

SYNCHRONY Surgical Guideline

hearLIFE

FDA_DRAFT_AW32719_3.0 (English US)

Introduction

The MED-EL Cochlear Implant System serves to restore hearing sensations through electrical stimulation of the auditory nerve. It is the result of many years of research at leading technical institutions throughout the world.

MED-EL cochlear implants are manufactured to the highest quality standards in order to ensure long term reliability. All materials used in the implant have been rigorously tested for biocompatibility, durability and reliability. MED-EL applies a quality management system that meets all EN ISO 13485:2003 requirements and complies with US Quality System Regulations and Canadian Medical Device regulations (CAN/CSA ISO 13485-2003). Components of the MED-EL Cochlear Implant System meet the requirements for AIMD 90/385/EEC and MDD 93/42/EEC.

This Surgical Guideline describes proper techniques for implanting the M1200 SYNCHRONY Cochlear Implant (hereafter referred to as the SYNCHRONY). It serves as additional information for professionals and should not be used as an "Instructions for Use".

The information in this brochure is believed to be true and correct. However, specifications are subject to change without notice.

Not all products represented on these materials are currently approved or available in all markets. For country specific information please see the applicable "Instruction for Use" delivered with the implant system.

Table of contents

I. Patient selection and evaluation

Intended Use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways. Candidates include individuals with severe to profound hearing impairment who obtain little or no benefit from acoustic amplification in the best aided condition.

Additionally 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 18 years or older with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal cochlear implant with either a +FLEX24 or +FLEX20 electrode variant (SONATATI100, Mi1000 MED-EL CONCERT (PIN) or Mi1200 SYNCHRONY (PIN)), which together make up the MED-EL EAS System

Selection and Evaluation

Patients should fulfill the audiological criteria of their respective country for open-set sentence testing and open-set monosyllabic words when tested with hearing aids. MED-EL strongly recommends the use of optimally fitted hearing aids for a minimum of three months before deciding to pursue a cochlear implant. In cases of ossification or deafness due to infectious disease, there may be no need to try a hearing aid, and implantation should generally not be delayed.

A complete cochlear implant evaluation protocol should include an audiologic assessment, a medical/surgical evaluation, counseling sessions and, when possible, a psychological assessment. To obtain the optimal benefit from the implant, candidates should be sufficiently motivated and understand the importance of returning to the implant center for regular audio processor programming, training, and assessment sessions.

The medical evaluation prior to cochlear implant surgery serves to:

- assess the candidate's health status and ability to undergo surgery
- verify the absence of disease and infection of the outer and middle ear
- screen for cochlear obliteration and other obstacles to electrode insertion
- rule out central auditory lesions and verify a functional auditory nerve

The above evaluations usually involve an otologic/otoscopic examination and a CT scan and/or MRI. If there are concerns about the integrity of the upper auditory pathways and auditory lesions, an MRI is necessary.

It is important to realize that there are a variety of conditions that predispose a person to contracting bacterial meningitis irrespective of cochlear implantation, such as: malformations of the inner ear, history of recurrent meningitis, the presence of CSF leaks, etc. There is no evidence that implantation of a MED-EL device increases the risk for postoperative meningitis. MED-EL encourages all cochlear implant candidates and recipients, especially individuals with cochlear malformations and other risk factors, to discuss with their physician whether vaccination may be appropriate for them. The immunization status of all cochlear implant candidates should be determined prior to surgery. Vaccination may reduce the risk of infection.

II. Technical description of the implant

The SYNCHRONY is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components.

The device consists of a stimulator, a coil with a removable magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SYNCHRONY). This device is intended to be implanted by adequately trained and experienced surgeons only.

The SYNCHRONY has been designed according to the highest safety and reliability standards. All materials used in the construction of the SYNCHRONY have been extensively tested for biological compatibility and durability. The power required by the implant is transmitted from the external audio processor through the intact skin via an inductive link. The implant therefore contains no batteries or other components that require replacement.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The electronics of the SYNCHRONY contain a powerful custom-made circuit that is capable of processing large amounts of information at a very rapid rate. It can stimulate at 50,704 pulses per second. This capability makes the implant compatible with a wide range of pulsatile processing strategies and future developments in speech processing. A telemetry feature enables the clinic to verify the functional status of the implant within a matter of seconds. For added safety, each output has a capacitor to prevent any possible leakage of DC current to the auditory nerve.

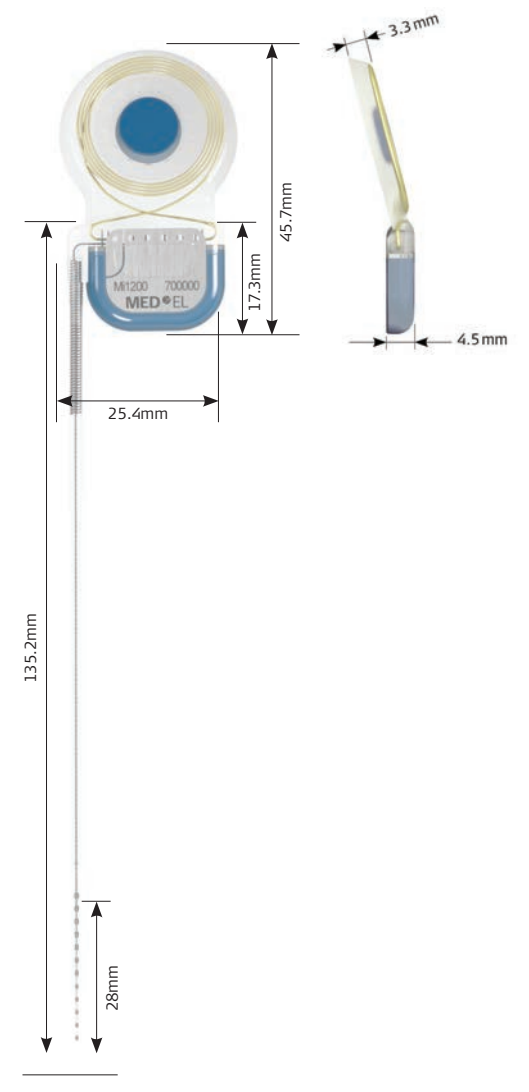


Figure 1 SYNCHRONY Cochlear Implant (~ dimensions in mm, typical values)

Performance Characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
  Maximum current amplitude:
  Median value = 1250 µA, range = 500 µA
  Maximum pulse width:
  Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to MED-EL application software user manual).
- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The implant has a mass of 7.6 g (typical value).
- The volume of the implant without electrode is 3.7 cm^3.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight and flexible design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm^2.
- Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium and parylene c.

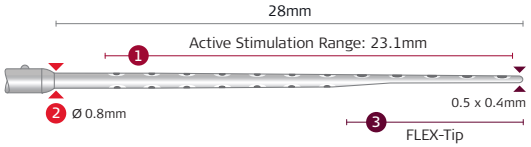
Implant Variants*

Cochleae may differ significantly in size and shape from one another as can individual cochlear duct lengths. MED-EL offers the largest selection of electrode arrays for each implant variant. Please see Section V, Step 9, "Select Appropriate Electrode Variant" for the circumstances in which each variant should be used.

FLEX28 Electrode Array

Order number: 31093

The FLEX28 Electrode Array (see Figure 2) is 28 mm long featuring FLEX tip technology suitable for 96 % of all normal cochlear duct lengths. The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 2.1 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The marker ring is located 28 mm from the electrode tip and indicates the deepest insertion. Near the marker ring, the electrode lead features an additional marker dot on the same side of the array as the single apical contacts. The marker allows the surgeon to ensure appropriate alignment of the single contacts toward the modiolus.



1. 19 platinum electrode contacts
   Optimal spacing over a 23.1 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.4 mm

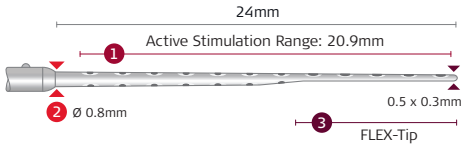
Figure 2 FLEX28 Electrode Array

* Implant variants availability is subject to regulatory approval

FLEX24 Electrode Array

Order number: 31089

The FLEX24 Electrode Array (see Figure 3) is 24 mm long featuring FLEX tip technology and designed for combined Electric Acoustic Stimulation (EAS) less than 1.5 turns. The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 1.9 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The marker ring is located 24 mm from the electrode tip and indicates the deepest insertion. Near the marker ring, the electrode lead features an additional marker dot on the same side of the array as the single apical contacts. The marker allows the surgeon to ensure appropriate alignment of the single contacts toward the modiolus.



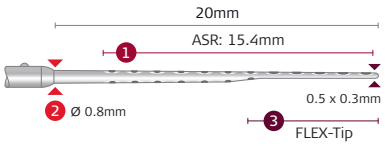
1. 19 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

Figure 3 FLEX24 Electrode Array

FLEX20 Electrode Array

Order number: 31113

The FLEX20 Electrode Array (see Figure 5) is 20 mm long featuring FLEX tip technology and designed for combined Electric Acoustic Stimulation (EAS). The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 1.4 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The marker ring is located 20 mm from the electrode tip and indicates the deepest insertion. Near the marker ring, the electrode lead features an additional marker dot on the same side of the array as the single apical contacts. The marker allows the surgeon to ensure appropriate alignment of the single contacts toward the modiolus.



1. 19 platinum electrode contacts
   Optimal spacing over a 15.4mm stimulation range
2. Diameter at basal end: 0.8mm
3. FLEX-Tip for minimal insaertion trauma
   Dimensions at apical end: 0.5 x 0.3mm

Figure 5 FLEX20 Electrode Array

EAS

EAS SURGICAL TRAINING RECOMMENDED

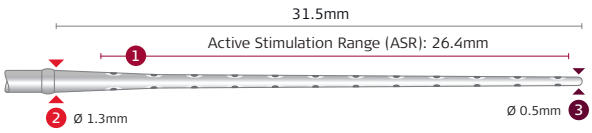
EAS

EAS SURGICAL TRAINING RECOMMENDED

Standard Electrode Array

Order number: 31084

The Standard Electrode Array (see Figure 4) is 31.5 mm long and designed for long cochlear duct lengths. Contacts are spaced over 26.4 mm with 2.4 mm spacing between each contact pair. The electrode's length allows insertion into the scala tympani and stimulation of the cochlear canal to the fullest extent possible. The array features a marker ring 31.5 mm from the apex that is used to seal and to indicate maximum electrode insertion. The diameter of the array increases to 1.3 mm at the proximal thicker part of the array just before the marker ring.



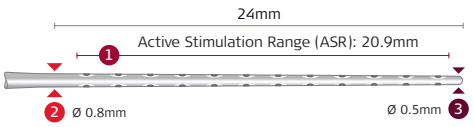
1. 24 platinum electrode contacts
   Optimal spacing over a 26.4 mm stimulation range
2. Diameter at basal end: 1.3 mm
3. Diameter at apical end: 0.5 mm

Figure 4 Standard Electrode Array

Medium Electrode Array

Order number: 31087

The Medium Electrode Array (see Figure 6) is 24 mm long and designed for cases where deep insertion is not desired or is not possible due to anatomic restrictions. It features 12 evenly spaced electrode pairs spaced over 20.9 mm, with 1.9 mm spacing between each contact pair. Note that the Medium Electrode Array is not inserted to the marker ring.



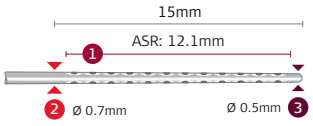
1. 24 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. Diameter at apical end: 0.5 mm

Figure 6 Medium Electrode Array

Compressed Electrode Array

Order number: 31097

The Compressed Electrode Array (see Figure 7) is 15 mm long and designed for partial ossification or malformation of the cochlea. It features 12 pairs of contacts spaced closer together in the apical end of the array. The contacts are spaced over 12.1 mm, with 1.1 mm between each contact pair. Note that the Compressed Electrode Array is not inserted to the marker ring.



1. 24 platinum electrode contacts
   Optimal spacing over a 12.1 mm stimulation range
2. Diameter at basal end: 0.7 mm
3. Diameter at apical end: 0.5 mm

Figure 7 Compressed Electrode Array

III. Surgical tools

Note that the surgical tools supplied by MED-EL should not be modified in any way. Modification of any of the tools is done at the surgeon's own risk.

Detailed instruction of the reprocessing process and the individual preparation before cleaning the tools can be found in the appropriate Instruction for Use.

Surgical Kit for the SYNCHRONY Cochlear Implant

The MED-EL Surgical Kit is a collection of tools for implantation of the SYNCHRONY Cochlear Implant.

The following tools are included in the SYNCHRONY Surgical Kit:

	Order number:
Mi1200 Implant Template	Shipped with the implant
Processor Template	01557
Skin Flap Gauge 6	03543
Surgical Claw Angled	00284
Micro Forceps Angled	05761, 05777, 05778

Mi1200 Implant Template

Shipped with the implant

This silastic template is used to assess the size and the position of the implant on the skull.

This tool is delivered in a sterile packaging and is a single-use device only.

Figure 8 Mi1200 Implant Template

Processor Template

Order number: 01557

The Processor Template (TEMPO+/OPUS template) shows the minimum spacing which must remain free behind the ear so that the external coil and the BTE Audio Processor do not interfere with each other when worn by the patient post-operatively.

This tool is a re-usable surgical instrument for transient use made from medical grade stainless steel. The device is delivered non-sterile.

Figure 9 Processor Template

Skin Flap Gauge 6

Order number: 03543

The Skin Flap Gauge 6 is used to evaluate the thickness of the skin flap in the area covering the cochlear implant. A skin flap thickness of 6 mm or less is necessary for a good magnetic hold and optimal signal transmission. Thick skin flaps should be reduced to 6 mm or less.

This tool is a re-usable surgical instrument for transient use made from medical grade stainless steel. The device is delivered non-sterile.

Figure 10 Skin Flap Gauge 6

Surgical Claw Angled

Order number: 00284

The Surgical Claw Angled can help to position and insert the electrode array into the cochlea. The tip of this instrument is slightly bent for better visualization during electrode insertion.

This tool is a re-usable surgical instrument for transient use made from medical grade stainless steel. The device is delivered non-sterile.

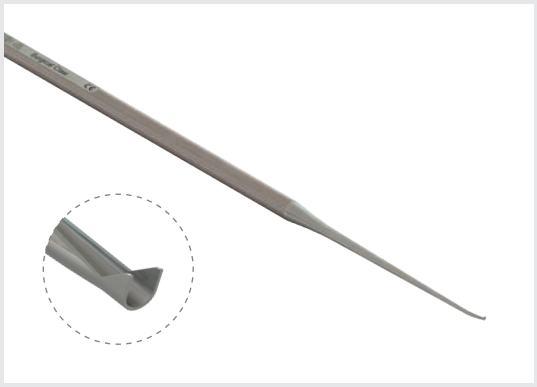


Figure 11 Surgical Claw Angled

Micro Forceps Angled

Order number: 05761 Right Angled & Left Angled
05777 Right Angled
05778 Left Angled

The Micro Forceps Left Angled and the Micro Forceps Right Angled are used to grip, hold and insert the electrode into the cochlea without damaging it. It is the surgeon's preference which angled Micro Forceps to use to insert the electrode array in either the left or the right ear. In the closed position, the tips of the forceps are parallel to each other, separated by a distance of 0.25 mm.

This tool is a re-usable surgical instrument made from medical grade stainless steel. The device is delivered non-sterile.

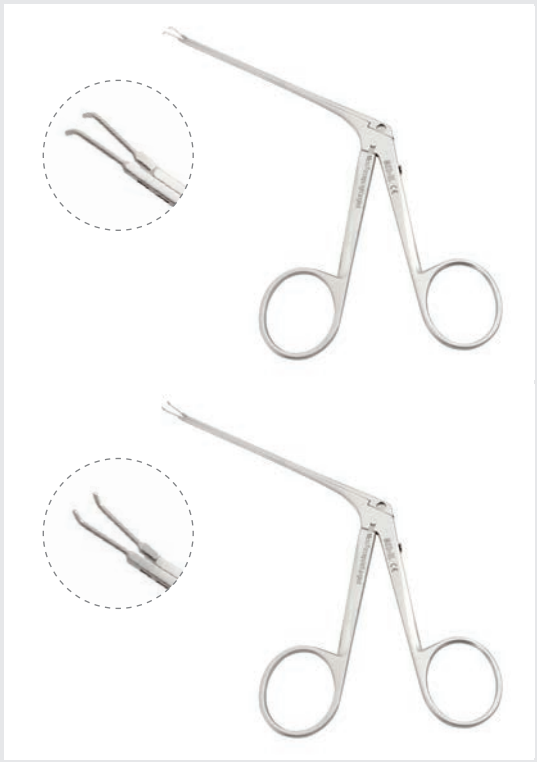


Figure 12 Micro Forceps Right Angled
Micro Forceps Left Angled

The following tools are additions to the surgical kit and may be ordered separately:

FENTEXmedical Forceps

FENTEXmedical GmbH is specialized in the development, manufacturing and marketing of surgical instruments and visualization systems for ENT, Head & Neck and Facial Surgery.

Basic description of the device:
CI Electrode Insertion Forceps L=155 mm, with longitudinal groove, for electrodes with a basal diameter in the range 0.8 – 1.3 mm

FENTEXmedical forceps have been successfully tested at headquarters with all MED-EL electrode arrays. This surgical tool is no MED-EL product and may therefore be ordered directly at your local FENTEXmedical distributor.

http://www.fentexmedical.com/

Figure 13 FENTEXmedical Forceps

Figure 14 Surgical Claw Straight

Surgical Claw Straight

Order number: 07711

The Surgical Claw can help to position and insert the electrode array into the cochlea. The tip of this instrument is straight.

This tool is a re-usable surgical instrument made from medical grade stainless steel. The device is delivered non-sterile.

Magnet Replacement Kit

Order number: 09693
Consisting of:

Non-Magnetic Spacer Ms010107
The Non-Magnetic Spacer (see Figure 15) is intended to be used as placeholder for the regular implant magnet of the Mi1200 Hearing Implant during MRI procedures, when a reduced image artifact is desirable.

Replacement Magnet Ms010108
The Replacement Magnet (see Figure 16) is intended to be used after an MRI, as replacement of the original implant magnet of the Mi1200 Hearing Implant and to restore full functionality of the Mi1200 Hearing Implant.

Magnet Tool Kit

Order number: 09734
Consisting of:

Magnet Removal Tool Ms050206
Magnet Insertion Tool Ms050205

The Magnet Removal Tool (see Figure 17) is for removal of the MED-EL removable implant magnet and the Non-Magnetic Spacer.

The Magnet Insertion Tool (see Figure 18) is for insertion of the Non-Magnetic Spacer and the Replacement Magnet.

The instruments are made of surgical grade stainless steel. The devices are delivered non-sterile

Figure 15
Non-Magnetic Spacer

Figure 16
Replacement Magnet

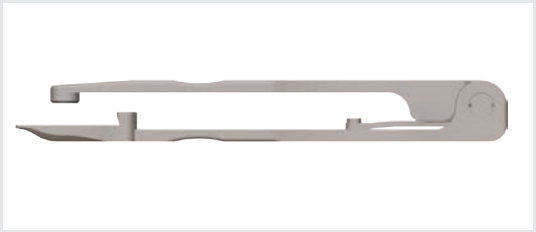


Figure 17 Magnet Removal Tool

Figure 18 Magnet Insertion Tool

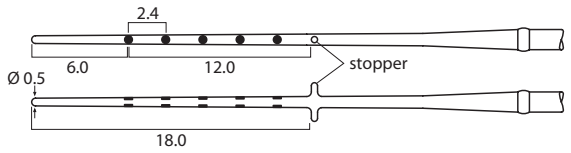
Insertion Test Tools

They are primarily used when ossification or fibrosis is suspected to aid the surgeon in determining which electrode variant to use (e.g. for detailed dimensions please see section II Implant Variants).

Insertion Test Device (ITD)

Order number: 02081

The ITD is similar to the Standard Electrode Array in dimension and shape. It has a stopper at 18.0 mm and 5 pairs of markers to help determine insertion depth up to a maximum of 18.0 mm. The Insertion Test Device is delivered in sterile packaging and is a single-use device only.



Typical dimensions in mm

Figure 19 Insertion Test Device

Contact spacing:	2.4 mm
Markers:	2×5
Max. insertion depth:	18.0 mm

Insertion Electrode (IE)

With the Insertion Electrode (IE) the surgeon can establish whether the cochlear lumen is obstructed or if it is freely accessible up to different insertion depths depending upon the considered electrode variant planned for the implantation.

The Insertion Electrodes are delivered in sterile packaging and are single-use devices only.

Order Number	Electrode Array
08348	FLEX28
08257	FLEX24
08254	Standard
08256	Medium
08258	Compressed

IV. General remarks about the surgery

- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Facial nerve monitoring is recommended. When carried out, neuromuscular blockage should be avoided.
- Evaluation of possible electrode insertion length for the individual patient should be done prior to the surgery. This can be performed by a standard X-ray or a CT scan.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface; damage to the implant or electrodes during the operation will invalidate the warranty.
- Before opening the implant box a telemetry should be done to check the function of the implant inside the box.
- In cases where the patient has a thick skin flap, the flap should be thinned to no more than 6 mm. Use the Skin Flap Gauge 6 to accurately determine skin flap thickness.
- The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.
- Do not place sutures over the active electrode lead.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Only surgical instruments approved by MED-EL should be used during the insertion process, other instruments (probes, hooks, forceps, tweezers, etc.) can damage the electrode array.
- The electrode array should be inserted as far as possible or planned, according to the individual electrode insertion length, into the cochlea without compressing the array, or using excessive force.
- After the electrode array has been inserted into the cochlea, small pieces of temporalis fascia should be placed around the electrode array at the entrance to the cochlea to secure the electrode array and to seal the cochlea opening.
- The excess electrode lead must be looped and secured with caution in the mastoid cavity. It must be secured under the cortical overhang so that the electrode array will not migrate out of the cochlea or be subject to external pressure that could cause movement and subsequent damage to the electrical connections.
- Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- A paper on pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis may be useful additional reading. (Arnold et al, ORL 2002;64:382-389).
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.

V. Surgical procedure

The SYNCHRONY Cochlear Implant can be implanted using a small incision, however, for demonstration purposes only, the following illustrations include an enlarged incision area. Additionally, some of the medical illustrations are schematic and can differ from a patient's anatomical situation.

Every CI surgery should be performed as atraumatically as possible so that residual hearing can be preserved. The following surgical procedure will ensure that. Additional important surgical steps for EAS patients can be found in the appropriate EAS Infobox. Summarized EAS information can be found in the appendix.

STEP 1: Prepare Patient

As a prophylactic measure, intravenous antibiotics should be given 1/2 to 1 hour before the incision is made.

After the patient has been anesthetized, the incision area should be shaved. Usually an area including the incision line and the area between the incision and the pinna is shaved. Some surgeons choose to shave only the area over the predetermined line of the incision, and they recommend a margin of at least 2 cm around the incision. Meticulous care should be taken to ensure that the site is well cleansed. After cleansing and draping the site, inject local anesthetics containing vasoconstrictors, e.g. adrenaline 1:200,000 up to 20 mls.

EAS

- Please ensure that corticosteroids (crystalline triamcinolone solution or dexamethasone), intravenous corticosteroids, and hyaluronic acid are all available for the surgery.
- Administer intravenous antibiotics from the Cephalosporin group approximately half an hour before the skin incision.

STEP 2: Mark Implant Position

Place the Processor Template behind the ear and position the Mi1200 Implant Template. There are various orientation options. A suggested orientation for each ear is shown in Figure 20 and Figure 21, but the orientation depends on various factors, like e.g. the curvature of the skull.

Position the implant template in such a way that the SYNCHRONY Cochlear Implant will be in the hair bearing area. The lower part of the stimulator should be under or close to the temporal line, with an angle between 30° and 60°. The electrode exits on the lateral side of the implant. Therefore the electrode lead comes out superiorly for the left ear and inferiorly for the right ear.

Particular attention should be paid to the placement of the electrode lead on the skull. The position of the reinforced part of the electrode lead should be selected to facilitate the placement of the entire length of the electrode in a recessed channel. This ensures that the reinforced part of the electrode lead does not protrude into the mastoidectomy.

Once the implant template is in place, surgical ink may be used to mark its position on the surface of the skin. Surgeons may choose to transpose the position of the implant template onto the surface of the bone by using a hypodermic needle inserted perpendicularly to the skin at points along the side of the implant template.

When implanting a patient bilaterally care should be taken of the placement of the implants. In particular the second side should be placed specifically to match the location of the first to give symmetric appearance of the external part. The skull curvature and pinna position needs to be taken into consideration when placing the second implant similar to the contralateral side.

Figure 20 Suggested orientation of the templates, left side

Figure 21 Suggested orientation of the templates, right side

STEP 3: Plan Incision

Choose the line of incision so that a well vascularized skin flap results. Make the incision 1–2 cm from the implant to ensure that the scar will not lie directly over the body of the implant. Incise the tissue with a scalpel and use bipolar electrocoagulation for hemostasis.

An example of a commonly used postaural incision is shown in Figure 22 and Figure 23. Postaural incisions start in the sulcus behind the pinna and extend posteriorly.

For greater mastoid bone exposure, each of these incisions can be extended posteriorly in the shape of an arc.

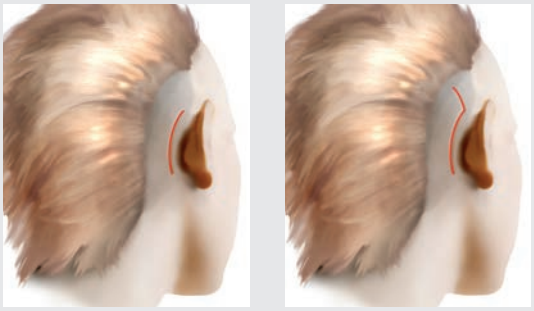


Figure 22 Minimal incision (left picture) and lazy "S" incision (right picture) – right ear

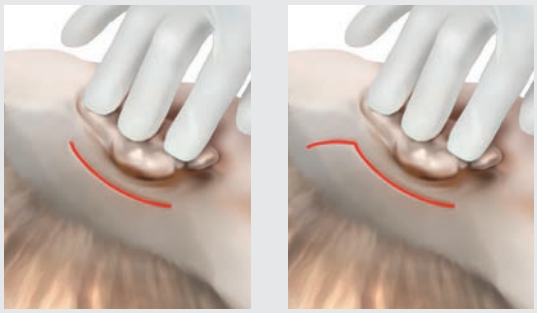


Figure 23 Minimal incision (left picture) and lazy "S" incision (right picture) – right ear – close up

STEP 4-A: Open Skin Flap

The incision is made and the wound is held open by retractors. At all times care should be taken to ensure that the flap is kept moist with damp surgical gauze.

Either a single layer skin flap – all four layers, skin, subcutis, muscle and periosteum are incised in a single cut, or a double layer skin flap can be performed.

A double layer skin flap may:

- reduce the chance of infection because the incisions are at different locations and layers, and
- allow better healing so it is often used for re-implantations and when encountering postauricular scar formation.

Double layer skin flap (see Figure 24)

The four different tissue layers skin, subcutis, muscle, and periosteum are incised with two different incisions. First, the skin, subcutis and muscle are raised and retracted. Second, the periosteum is incised, the periosteum is freed from the surface of the bone and then retracted in another location.

Various methods may be used when incising the periosteum. Care should be taken to avoid incision over the implant later on.

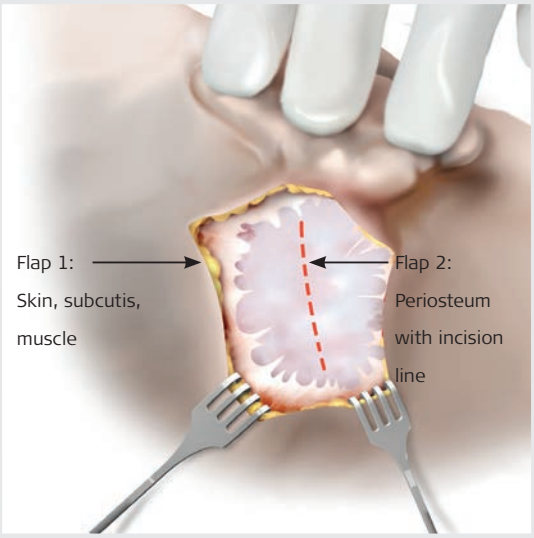


Figure 24 Double layer skin flap – right ear

STEP 4-B: Skin Flap Thickness

In order to achieve good magnetic hold and optimal signal transmission, the skin flap or the muscle may need to be thinned out so it does not exceed 6 mm.

Evaluate the portion of the flap over the magnet and receiving coil with the Skin Flap Gauge 6, as shown in Figure 25. If the flap does not fit in the gauge loosely, carefully thin the flap until it does. It is important to avoid over-thinning of the flap, which may result in wound complications. Care must be taken to avoid exposing hair follicles.

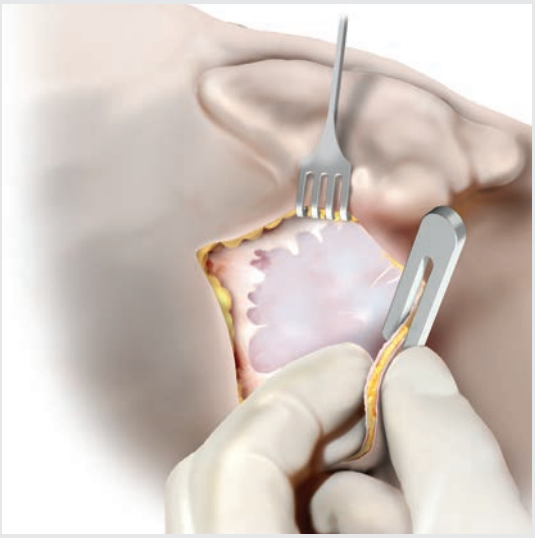


Figure 25 Using the Skin Flap Gauge 6 – right ear

STEP 5: Check Position of Implant and Electrode Lead

CAUTION

Retractors may distort the actual position of the implant in relation to the pinna as the ear is retracted.

The Mi1200 Implant Template should be placed on the skull in order to visually check its proper position. The bony ear canal should be identified and re-marking on the skull should be done if necessary (see Figure 26).

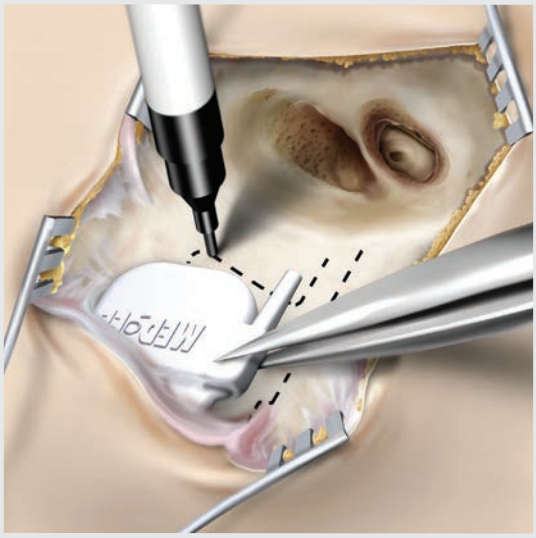


Figure 26 Marking the implant position with the Implant Template – right ear

STEP 6: Drill Mastoidectomy and Posterior Tympanotomy

CAUTION

Clear identification of the anatomical landmarks is required. When drilling, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Inadequate large exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that foudroyantly progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.

Facial nerve monitoring is recommended; when carried out, neuromuscular blockade should be avoided.

A standard cortical mastoidectomy is performed with a cutting burr, while ensuring good irrigation. A cortical overhang should be left, both superiorly and posteriorly; it can later serve as a natural support for the electrode lead as it is looped in the mastoid cavity.

The fossa incudis should be located, and the tip of the short process of the incus is identified to ensure the proper orientation of the posterior tympanotomy. This important part of the operation should be practiced many times on human cadaver temporal bones before live surgery is performed. A triangular opening is made between the mastoid and the facial nerve, which is referred to as the facial recess. The posterior limit is the vertical portion of the facial nerve, the anterior limits are the annulus and chorda tympani, and the upper aspect is a bony buttress at the level of the fossa incudis. Start drilling immediately below the fossa incudis, using a 3 mm diamond burr centered on the tip of the short process. Use high magnification and copious irrigation. Extreme care should be taken in drilling the posterior tympanotomy and the surgeon should be aware of any possible anatomical variants of the facial nerve.

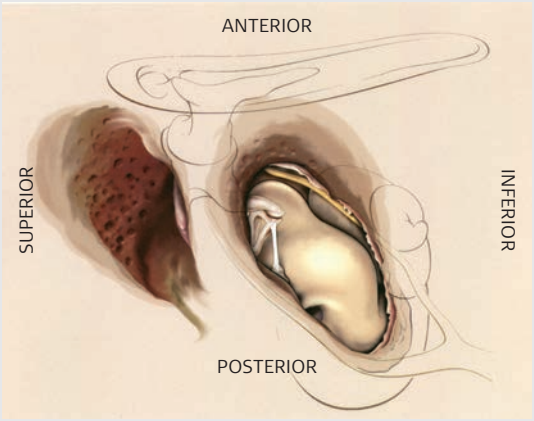


Figure 27 Anterior and posterior tympanotomy – right ear

The following should be visible after the posterior tympanotomy: the long process of the incus, the incudostapedial joint, the stapes pyramid and stapedius tendon, the promontory and the round window niche (see Figure 27 and Figure 28).

EAS

- It is recommended to create a larger posterior tympanotomy (as compared to that of a standard cochlear implantation) beside the anterior tympanotomy in order to provide a better view as well as more space to manoeuvre the electrode array.
- Elevate a mucosal flap to avoid mucosal bleeding when opening the cochlea.

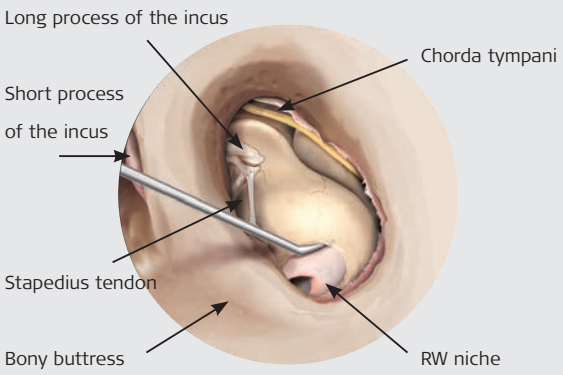


Figure 28 Posterior tympanotomy microscopic view – right ear

STEP 7: Drill Stimulator Bed and Electrode Channel

CAUTION

- The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.
- The anterior stimulator edge should not be recessed to a depth more than 2 mm.
- All sharp edges of bone must be removed in order to avoid possible damage to the electrode lead. Drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- Protect the middle ear cavity from bone dust contamination by closing it with medical gauze.

The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. In adults, it may not be necessary to expose the dura, but in small children with a thin skull, drilling to the dura may sometimes be required in order to ensure that the stimulator is well recessed in its bed. If drilling down to the dura is necessary a bony island should remain. Ideally, the stimulator is recessed approximately 2 mm.

Once again the Mi1200 Implant Template can be used to mark the flatness on the skull and the correct position for the implant bed (see Figure 29).

For protection and placement of the electrode lead, a smooth channel has to be drilled in the bone leading to the mastoid. Make sure that the channel is deep and wide enough to comfortably accommodate the electrode lead (see Figure 30).

If, for example, the implant is fixed with sutures, a diamond burr should be used to drill the holes so that the implant can be immobilized later. The suture holes should be drilled such that the sutures do not cross the electrode, but rather only cross the silicone over-mold.

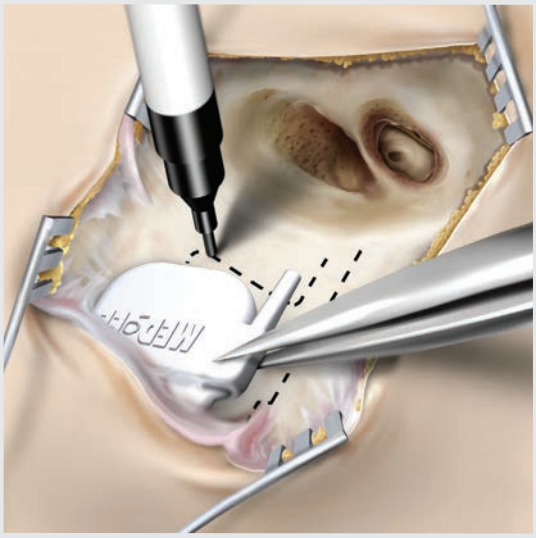


Figure 29 Marking the implant position with the Implant Template – right ear

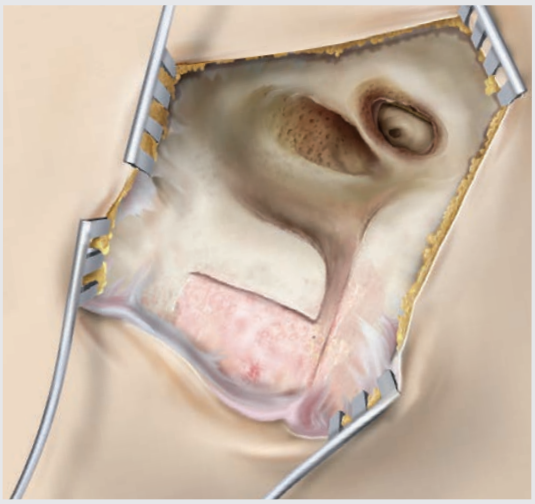


Figure 30 Flattening of the stimulator area – right ear

STEP 8 – VARIANT 1: Preparation for a Round Window opening

CAUTION

- Always use a slow turning diamond drill to avoid acoustic trauma when drilling the round window (RW) niche (approx. 1000rpm).
- Try to keep the RW membrane intact until the insertion of the electrode.

A clear view of the RW membrane is fundamental for the successful performance of a round window opening. Therefore, the posterior tympanotomy is usually slightly bigger drilled than a standard posterior tympanotomy to get a clear view onto the RW niche.

Before starting the preparation of the RW niche, a mucosal fold should be removed from the promontory. This prevents mucosal bleeding and provides better feedback from the tip of the drill (see Figure 31).

To facilitate the electrode insertion a portion of the anterior-inferior bony RW margin as well as the superior overhang of the RW niche needs to be drilled away. This increases the accessibility of the RW and prevents the electrode from being directed towards the modiolus. One potential risk associated with drilling the RW margin relates to its close proximity to the opening of the cochlear aqueduct. Care should be taken to avoid this inner ear structure.

Advantages of a RW opening:

- The amount of drilling is significantly reduced compared to a cochleostomy and no endosteal preparations in the direct vicinity of the basilar membrane are needed.
- The round window always leads into the correct scala for an electrode insertion – the scala tympani.

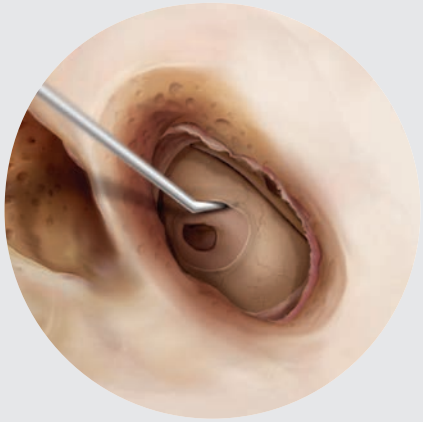


Figure 31 Elevating a mucosal flap – right ear

To enter the middle portion of the scala tympani and to get visualization of the RW membrane, the posterior-superior lip of the round window niche and the inferior margin of the round window should be drilled away. By doing this, the round window will be exposed for best insertion of the electrode array (see Figure 32).

The RW niche is drilled and exposure should be extensive enough to comfortably fit the electrode. An appropriate RW opening in relation to size, is dependent upon the type of electrode array chosen. Please refer to STEP 9, "Select Appropriate Electrode Variant".

EAS

- Begin drilling near the cochlea use a slow turning diamond drill to avoid acoustic trauma.
- To enter the middle portion of the scala tympani and to get visualization of the round window membrane, the posterior-superior lip of the round window niche and the inferior margin of the round window should be drilled away to expose the round window membrane at least 0.8 mm.
- Fill the electrode insertion site with corticosteroid.
- Protect the middle ear cavity from bone dust contamination by closing it with medical gauze.

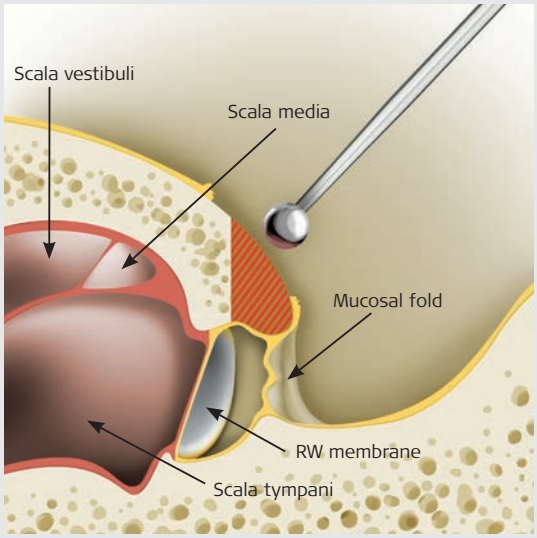


Figure 32 RW niche anatomy

STEP 8 – VARIANT 2: Preparation for a Cochleostomy

CAUTION

- For drilling the cochleostomy, always use a slowly turning diamond drill to avoid acoustic trauma (approx. 1000rpm).
- Try to keep the endosteum intact until the insertion of the electrode.

Before preparing to drill the cochleostomy, the mucosal fold should be removed over the promontory. This prevents mucosal bleeding and provides better feedback from the tip of the drill (see Figure 33).

The round window niche is identified and the cochleostomy is made inferior and slightly anterior to it. Many surgeons have a preferred technique to locate the best promontory point to begin drilling the cochleostomy. One recommendation is to use the width of the stapes as a measuring tool. The cochleostomy is made inferior to the stapedial tendon at a distance twice the width of the stapes and inferior and slightly anterior to the round window.

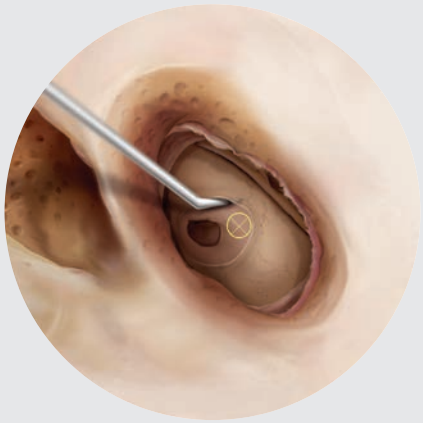


Figure 33 Removal of a mucosal fold & marking of cochleostomy – right ear

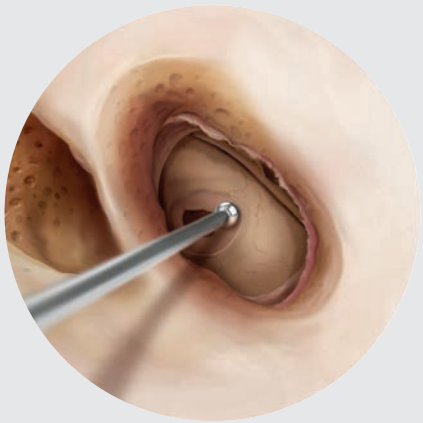


Figure 34 Drilling the cochleostomy inferior and slightly anterior to the round window – right ear

The cochleostomy is drilled and the exposure of the endosteum should be big enough to comfortable fit the electrode. An appropriate cochleostomy size is dependent upon the type of electrode array chosen. Please refer to STEP 9, "Select Appropriate Electrode Variant".

The bony lip of the cochleostomy is slightly smoothed with a small diamond drill bit.

EAS

- Begin drilling near the cochlea use a slowly turning diamond drill to avoid acoustic trauma.
- The cochleostomy should be drilled inferior and slightly anterior to the round window annulus to achieve a scala tympani insertion and to avoid damage to the osseous spiral lamina. The endosteum should be exposed to approximately 0.8 mm.
- Fill the electrode insertion site with corticosteroid.
- Protect the middle ear cavity from bone dust contamination by closing it with medical gauze.

Figure 35 Drilling the cochleostomy and leaving the endosteum intact when drilling (upper picture), smoothing the edges of the cochleostomy (lower picture)

STEP 9: Select Appropriate Electrode Variant

For programming flexibility and greater access to the entire frequency spectrum, as many electrode contacts as possible should be introduced into the cochlea. In order to optimize the number and distribution of contacts within the cochlea in even the most difficult cases of reduced cochlear duct length, cochlear ossification, obstruction or malformation, the SYNCHRONY is available with different types of electrode arrays (see Figure 36).

Reduced Cochlear Duct Length or Malformations

Depending on the cochlear duct length or the malformation of the cochlea, a FLEX24, Medium or Compressed Electrode Array may be appropriate for optimal cochlear coverage and stimulation.

Cochlear Ossifications

The surgeon must be prepared for unexpected findings during surgery. Depending on the degree of ossification, different surgical approaches and Electrode Arrays can be used.

Partial Ossification

If only the inferior section of the basal coil is ossified, drilling along the basal turn can often reveal an open lumen in the further course of the scala tympani. In such cases, a FLEX28 or Standard Electrode Array can be inserted.

If the ossification is also in the ascending section of the basal turn, and a drill-through cannot be achieved, there are various options:

- The cochleostomy can be widened in a superior direction to reach the scala vestibuli. If this scala is patent, a FLEX28 or Standard Electrode Array can be inserted.
- The bridge, the incus and the crura of the stapes can be removed and a second cochleostomy can be drilled. An implant with a Split Electrode Array can be used, inserting one electrode array into the lower cochleostomy and the other into the upper cochleostomy.
- The Compressed Electrode Array can be inserted into the tunnel which has been drilled into the lower basal coil.

Complete Ossification

In cases of complete ossification, the Split Electrode Array can be used. Two tunnels are drilled, one in the lower and one in the upper basal turn. The shorter 5-channel electrode array is inserted into the upper basal coil and the longer 7-channel electrode array into the lower basal coil.

Insertion Test Tools

Evaluation of possible electrode insertion length for the individual patient should be done prior to the surgery. This can be performed by a standard X-ray or a CT scan.

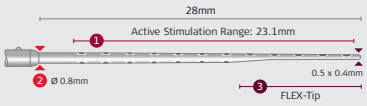
With the help of the Insertion Test Tool, the Insertion Electrode (IE), the surgeon can establish whether the cochlear lumen is obstructed or if it is freely accessible up to different insertion depths depending upon the considered electrode variant planned for the implantation.

The Insertion Electrode variants shall not be used in patients where residual hearing shall be preserved.

FLEX28

A 28 mm electrode array suitable for 96 % of all normal cochlear duct lengths featuring FLEX tip technology. Optimised for insertion into the apical region (CCC).

Order number: 31093

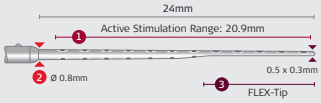


1. 19 platinum electrode contacts
   Optimal spacing over a 23.1 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.4 mm

FLEX24

A 24 mm electrode array featuring FLEX tip technology and designed for combined Electric Acoustic Stimulation (EAS) with insertion less than 1.5 turns.

Order number: 31089

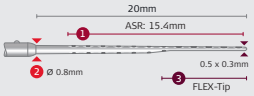


1. 19 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

FLEX20

A 20mm electrode array featuring FLEX-Tip technology and designed to be used in cases of partial deafness or for other specific needs or surgical preferences.

Order number: 31113

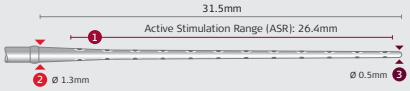


1. 19 platinum electrode contacts
   Optimal spacing over a 15.4 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insaertion trauma
   Dimensions at apical end: 0.5 x 0.3 mm

Standard

A 31.5 mm electrode array designed for long cochlear duct lengths.

Order number: 31084

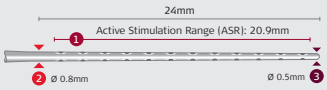


1. 24 platinum electrode contacts
   Optimal spacing over a 26.4 mm stimulation range
2. Diameter at basal end: 1.3 mm
3. Diameter at apical end: 0.5 mm

Medium

A 24 mm electrode array designed for cases where deep insertion is not desired or is not possible due to anatomic restrictions.

Order number: 31087

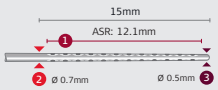


1. 24 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. Diameter at apical end: 0.5 mm

Compressed

A 15 mm electrode array designed for partial ossification or malformation of the cochlea.

Order number: 31097



1. 24 platinum electrode contacts
   Optimal spacing over a 12.1 mm stimulation range
2. Diameter at basal end: 0.7 mm
3. Diameter at apical end: 0.5 mm

Figure 36 MED-EL electrodes

STEP 10: Immobilize the Implant

CAUTION

- Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Additional immobilization of the implant needs to be performed.
- If sutures are chosen for immobilization of the implant do not place the sutures directly over the electrode lead.

Additional immobilization of the implant needs to be performed (e.g. with sutures). It should be conducted in such a way that there will be no postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.

When the implant is immobilized with sutures, the holes drilled in STEP 7 should be used to secure the implant in its bed and the electrode should be placed into the drilled channel leading into the mastoid. Make sure the electrode channel is deep enough to prevent the tie-down from exerting pressure and damaging the electrode. MED-EL recommends the use of the following techniques (details in Figure 37, Figure 38).

Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.

In the event that the placement of the implant led to the protrusion of the reinforced part of the electrode into the mastoidectomy the following measures should be undertaken:

- Gently pre-shape the reinforced part of the electrode lead; without surgical instruments, using your hands only.
- Try to coil the rest of the electrode lead into the mastoidectomy, in such a way that additional pressure is not placed on the outer ear canal or the periosteum closing the mastoid cavity.

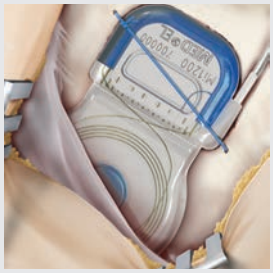


Figure 37 Implant immobilized with a single stitch – right ear

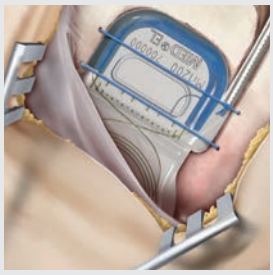


Figure 38 Implant immobilized with double stitches – right ear

STEP 11: Opening the Cochlea

Before inserting the electrode array into the cochlea, either the RW membrane for a RW insertion or the endosteum for a cochleostomy insertion, needs to be incised.

Either a micro-lancette or a micro-hook can be used to open the cochlea (see Figure 39, Figure 40 and Figure 41).

EAS

- Prior to opening the cochlea, clean the surgical field, change gloves, remove the gauze used to keep bone dust out of the middle ear cavity and administer a single dose of intravenous corticosteroids to protect the inner ear.
- Place a drop of corticosteroid on the round window membrane or endosteum to reduce fibrotic reaction and cover it with a drop of hyaluronic acid. This will keep the corticosteroid in place and protect it from bone dust.
- Using a micro-lancette or micro-hook, carefully incise the round window membrane in its inferior-anterior quadrant to approximately 0.8 mm.
- Using a micro-lancette or micro-hook, carefully incise the endosteum to approximately 0.8 mm.
- Avoid suctioning in the open region of the cochlea.

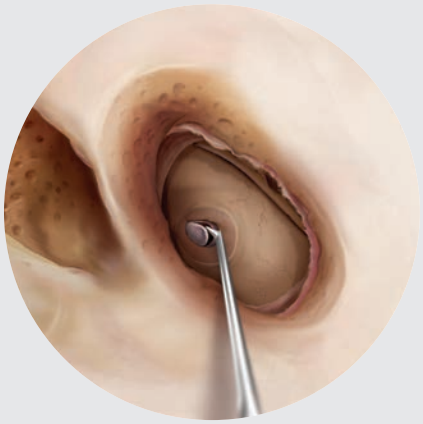


Figure 39 RW membrane incision with a 45° micro-hook

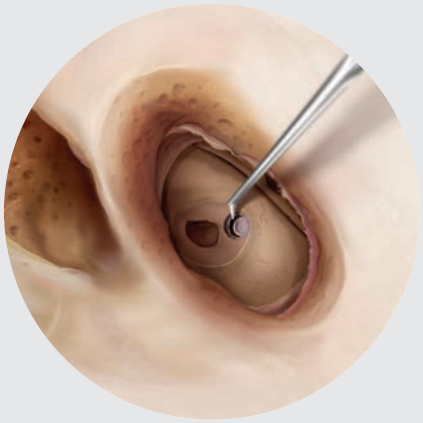


Figure 40 Endosteum incision with a 45° micro-hook

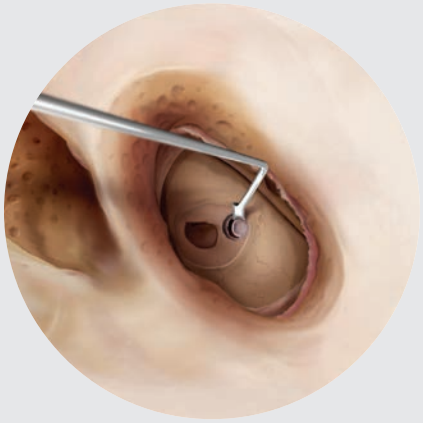


Figure 41 Endosteum incision with a micro-lancette

STEP 12: Insert the Electrode Array

CAUTION

- Only surgical tools approved by MED-EL should be used to insert the electrode array into the cochlea.
- Under no circumstances should any force be used during electrode insertion.
- Insertion of the electrode array into the cochlea will probably destroy remaining hearing that was present in that ear prior to surgery.

It is important for the electrode array to approach the anterior portion of the basal turn at an angle so that it slides along the lateral wall of the scala tympani. This procedure, known as tangential insertion, facilitates deep electrode insertion (see Figure 42).

The individual insertion angle for each case should be considered in order to reach a tangential electrode insertion (see Figure 43). Non-tangential insertion should be avoided.

Surgical tools approved by MED-EL should be used to insert the electrode array into the cochlea, please see section III. Surgical Tools. Either the Surgical Claw or the Micro Forceps Angled can be used to maneuver the electrode array. The type of Micro Forceps Angled used, to insert the electrode in a left or a right cochlea, depends on the preference of the surgeon. Use of lubrication or anti-inflammatory compounds during electrode insertion is up to the surgeon.

EAS

- Since EAS candidates show good residual hearing in the low frequencies, a tangential insertion -i.e. ideal electrode insertion vector to reach the lateral wall of the cochlear at the beginning of the basal turn in the hook region- is strongly recommended for straight electrode designs. This ensures that our highly flexible electrodes glide along the lateral wall when inserted further into the cochlear, minimizing possible damage to the delicate structures and at the same time allow a "deep insertion" (as desired by the surgeon).

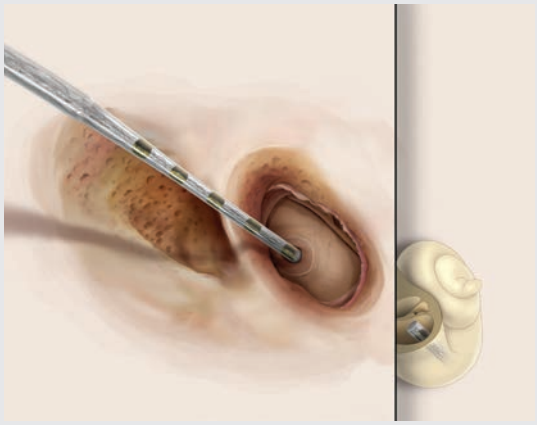


Figure 42 Direction of electrode insertion – right ear

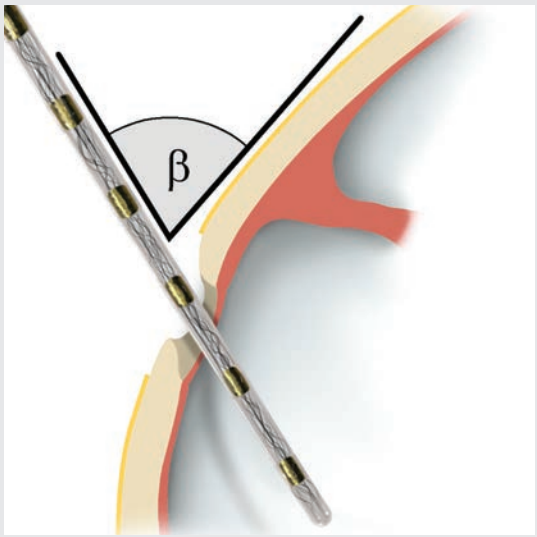


Figure 43 Insertion angle to reach a tangential electrode insertion

The electrode lead is held very carefully at the proximal thicker part, just above the marker ring. If using a FLEX-style electrode array, orient the single contacts along the apical portion of the array toward the modiolus of the cochlea during insertion so that the marker dot at the base of the array will point toward the modiolus after insertion. The tip of the electrode array is guided toward the cochlea opening. After the tip is gently maneuver further into the cochlea, griping of the electrode array between the contacts can be done (see Figure 44). During insertion it is essential that the electrode contacts are not mechanically damaged and that no excessive force should be used.

Please be aware that sealing of the cochlear opening with the marker ring should not be achieved with the Medium and Compressed Electrode Arrays.

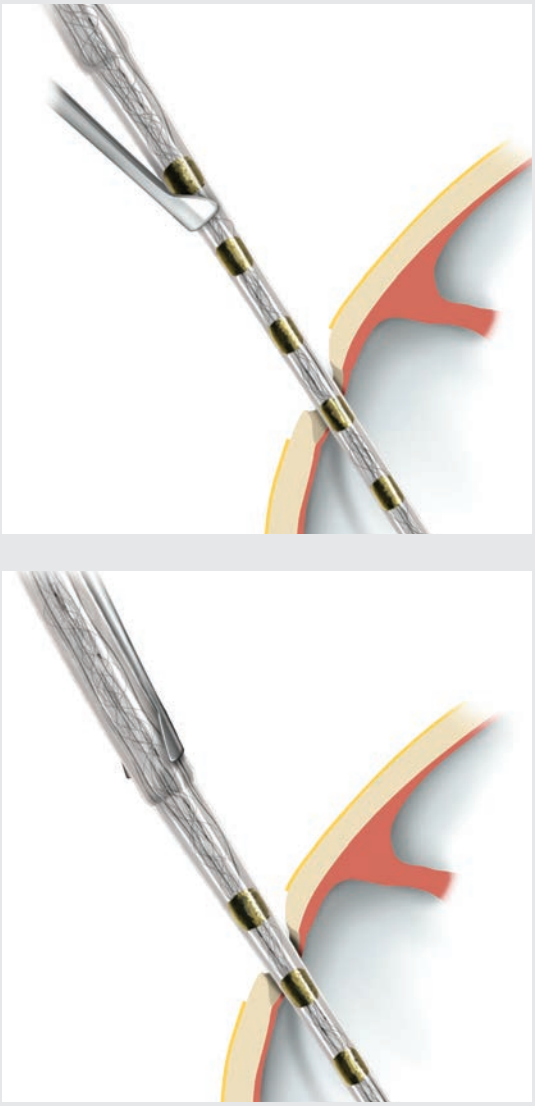


Figure 44 Detail of electrode insertion – manoeuvre the electrode array between the contacts & after the marker ring

If resistance is encountered before reaching the marker ring, the electrode array may buckle. In such cases, electrode insertion should be stopped. Excessive force should not be used, as it may result in intra-cochlear damage.

The following measures may be helpful in such situations:

- **Carefully rotate the electrode**
  Due to the unique oval design of the electrode array, the electrode can be slightly rotated to allow it to slide deeper into the cochlea.
- **Small movements close to the insertion site**
  Hold the electrode no more than 2 mm from the cochleostomy or round window opening. Gently insert the electrode with one stroke, release it and grasp it again 2 mm from the insertion side. Repeat this procedure until complete insertion is achieved.
- **Slow the rate of insertion**
  Slow the speed that the electrode is introduced into the opening. Frequent pauses during insertion can allow the electrode to gently slide along the cochlear duct.
- **Use of lubricant**
  As known from soft surgical techniques, the use of a lubricant can help smoothing the electrode insertion.

EAS

- Immediately start the electrode insertion through the drop of corticosteroid and hyaluronic acid.
- General insertion direction is from superior-posterior to anterior-inferior with the knob indicating the direction of the apical electrodes facing towards the modiolus.

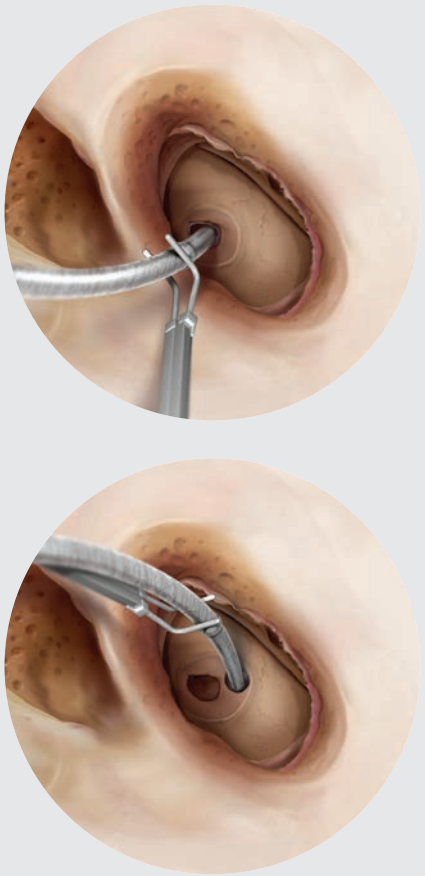


Figure 45 Full insertion of the electrode array – forceps positioned behind the marker ring – right ear

STEP 13-A: Seal Cochlear Opening

CAUTION

- To minimize the risk of postoperative infection additional sealing of the cochlear opening should be done for all MED-EL electrode arrays.
- Once the electrode array has been inserted into the cochlea, the electrode lead should be fixed so that no postoperative movement will occur.
- Please be aware that sealing of the cochlear opening with the marker ring should not be achieved with the Medium and Compressed Electrode Arrays.

When the electrode array is fully inserted, the marker ring will aid sealing the cochlear opening during surgery and providing an additional point of fixation (see Figure 46). This sealing will only take place with the FLEX28, FLEX24, and Standard Electrode Array fully inserted.
Please be aware that sealing of the cochlear opening with the marker ring should not be achieved with the Medium and Compressed Electrode Arrays since their intended insertion depths are 24 mm and 15 mm, respectively, and the marker ring is located at a distance of 31.5 mm from the tip of the electrode array.

For all MED-EL Electrode Arrays, small pieces of temporalis fascia placed around the electrode array at the entrance to the cochlea shall be used to secure the electrode array and to seal the opening. Rinse the small pieces with saline solution to prevent contamination of the electrode and to increase flexibility.

EAS

- To seal the cochlea, use a small fascial graft. To prevent contamination of the electrode and to increase flexibility, rinse the fascial graft with saline solution.

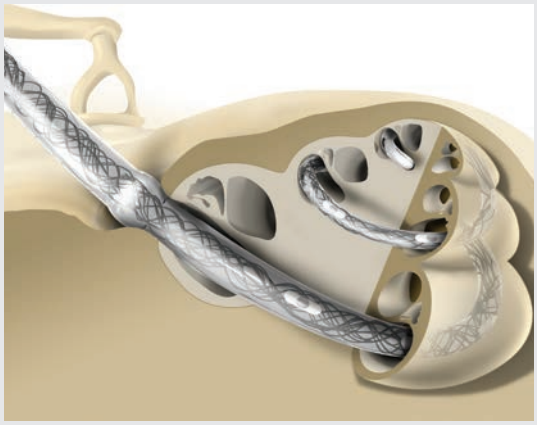


Figure 46 The marker ring of the Standard Electrode Array can seal the cochlear opening, aiding in its fixation – right ear

STEP 13-B: Secure Electrode Lead

If you choose to secure the electrode lead in the posterior tympanotomy, fibrin glue or bone paté can be used.

The electrode lead is longer than required in order to accommodate anatomical variants and to compensate for skull growth in children.

The electrode lead is looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place to avoid postoperative movements due to contractions of the temporalis muscle (see Figure 47).

Additional immobilization of the electrode lead inside the electrode channel could be done, e.g. with bone paté or bone wax.

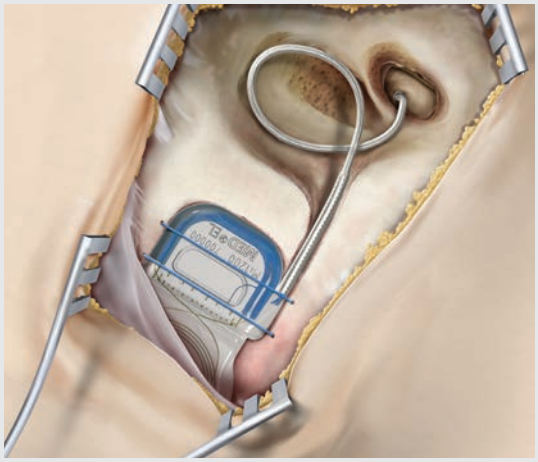


Figure 47 The electrode lead should be loosely placed unter the cortical overhang – right ear

STEP 14: Intra-operative Recordings

At this stage intra-operative recordings like Impedance Field Telemetry (IFT), Electrically Evoked Stapedius Reflex Threshold (ESRT), Electrically Evoked Brainstem Response (EABR) or Auditory Nerve Response Telemetry (ART) can be performed.

Intra-operative measurements are performed with the appropriate MED-EL application software and the MED-EL hardware interface system. For details please refer to the applicable Software User Manual. It is not possible to sterilize any component of the MED-EL hardware interface system. When used in a sterile environment, the coil and cable should be covered with sterile material (i.e. "sterile sleeve"). The appropriate coil should be used during intra-operative recordings.

Since the coil should not be placed directly on the implant, either sterile gauze drenched in saline solution or the skin flap should be placed between the coil and the implant. Moistening the underside of the skin flap with sterile saline or pooling saline over the ground electrode of the implant prior to performing intra-operative recordings may improve readings.

IFT (Impedance Field Telemetry)

After the implant is in place, a telemetry check allows:

- individual electrode impedance measurements
- verification of the absence of short and open circuits between electrodes
- determination of intra-cochlear voltage distribution

As with any telemetry system, intra-operative impedance testing may not provide an accurate representation of later electrode function. "High" values observed intra-operatively may be caused by air bubbles on the electrode contact surface. These generally dissipate within a few hours or days after surgery.

ESRT (Electrical Stapedius Reflex Threshold)

If ESRT thresholds are measured, care should be taken that no muscle relaxant is used during the last half hour before performing the measurements.

Note that observation of the reflex is not possible in some implanted patients due to various physiological and anatomical reasons. In addition, observation of the reflex may not be possible due to anesthesia. Therefore, absence of a reflex should not be taken as an indication of implant malfunction or lack of auditory response without other more direct evidence.

Intra-operatively, the presence of the reflex can be monitored either by direct observation of the ipsilateral tendon, through the microscope, or by impedance probe measurements in the contralateral ear. Direct observation is employed in most cases, as this is normally straightforward and does not require additional equipment. Probe measurements are usually restricted to research studies.

EABR (Electrically Evoked Brainstem Response)

With the addition of the EABR task, it is possible to measure and record the response of the entire auditory pathway to stimulation from the implant. EABR recordings can be used to determine the best placement of an Auditory Brainstem Implant during surgery, and they can also provide interesting information on the function of the whole auditory pathway. The MED-EL application software EABR parameters can be adjusted to facilitate recording of early, middle and late electrical potentials. To obtain measurements with the EABR task, it is necessary to also use a separate neurodiagnostic computer with a trigger input, along with scalp recording electrodes.

ART™ (Auditory Nerve Response Telemetry)

MED-EL offers implants that are capable of recording compound action potentials – small voltage changes that are created by the auditory nerve when it transmits a signal to the brainstem. The measurement is done a few microseconds after the end of a stimulation pulse. The recorded signal is called the Evoked Compound Action Potential (ECAP or EAP) of the auditory nerve. It has an amplitude of about 0.01 to 2 mV and takes place within roughly one millisecond after the stimulation pulse. Due to these very short, small response levels, special artifact reduction methods are used to enhance viewing of the nerve response.

STEP 15: Close Wound

For additional immobilization of the implant and the electrode lead, the periosteum should be separately sutured over the implant region and the mastoid cavity. Care should be taken not to damage the implant or the electrode.

The rest of the wound should be closed in layers with staples or absorbable subcutaneous sutures.

The area of the wound is covered with a compress and sterile gauze applying even pressure.

EAS

- A course of steroids and antibiotics should be given postoperatively.

Appendix

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

MRI Safety Information

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

Non-clinical testing has demonstrated that the SYNCHRONY Cochlear Implant is MR Conditional. A patient with this implant can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T or 3T
- Maximum spatial field gradient of 2,900 G/cm (29T/m)
- For 1.5T systems (See table 1):
  Sequences in Normal Operating Mode only with a maximum head specific absorption rate (SAR) of 3.2W/kg.
- For 3T systems (See table 1):
  1. For head scans and scans with a landmark location that is less than 35cm from the top of the head the MR system must be able to provide an SAR limit prediction that allows fractional SAR display.
  2. Sequences in Normal Operating Mode only with the following SAR restrictions:
     a. For head scans: Maximum average head SAR must not exceed 1.6W/kg (50% of maximum head SAR).
     b. For landmark locations less than 35cm from the top of the head: Maximum whole body SAR must not exceed 1.0W/kg.
     c. For landmark locations at least 35cm away from the top of the head: Maximum whole body SAR must not exceed 2.0W/kg.

MRI field strengths	Average head SAR	Average whole body SAR	
		Landmark location <35 cm from the top of the head	Landmark location ≥35 cm from the top of the head
1.5T	3.2 W/kg	2.0 W/kg	2.0 W/kg
3.0T	1.6 W/kg	1.0 W/kg	2.0 W/kg

Table 1: Specific Absorption Rate (SAR levels).

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

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

- Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed from the head.
- Head transmit coils or multichannel transmit coils must not be used with a 3T MR system.
- The patient should be lying on his/her back with the head aligned parallel to the long axis of the scanner. The head should not be tilted more than 30 degrees from the axis of the scanner. The patient should be advised to not tilt his/her head to the side; otherwise torque is exerted onto the implant magnet which might cause pain. For scans requiring a head coil, the head coil will maintain a proper head orientation. For scans without a head coil, appropriate padding that will prevent the head from tilting more than 30 degrees must be used.
- Testing has demonstrated that migration or magnet displacement will not occur when scanned using these conditions. For field strengths of 1.5T and 3T, an optional supportive head bandage may be placed over the implant, for instance using an elastic bandage wrapped tightly around the head at least three times (refer to Fig. A). The bandage shall fit tightly but should not cause pain.
- The implant must not be damaged mechanically, electrically or in any other way.
- In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this additional implant must be met.
- During the scan patients might perceive auditory sensations such as clicking or beeping. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.
- The magnet can be removed to reduce image artifacts. If the magnet is not removed, image artifacts are to be expected (refer to Fig. B and Fig. C). The artifacts extend approximately 10 cm (3.9") in radius around the device in a Spin Echo scan.
- The exchange of the magnets with the Non-Magnetic Spacer and vice versa has been tested for at least five repetitions.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first.

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

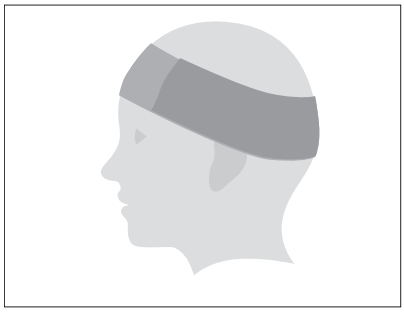


Figure A: Head bandage to support fixation of implant.implant.

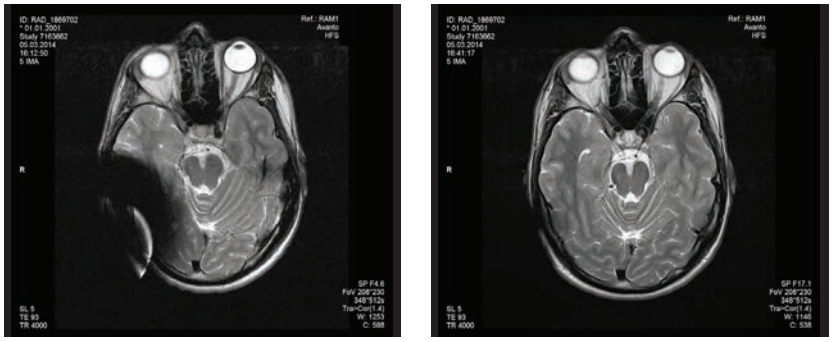


Figure B: Image artifacts of a spin echo sequence in axial view arising in a 1.5 T scanner. The left picture shows the artifacts obtained with the implant magnet in place whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

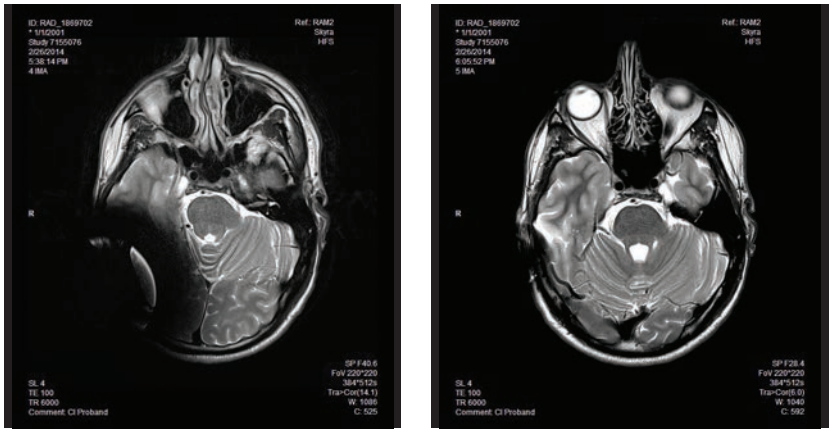


Figure C: Image artifacts of a spin echo sequence in axial view arising in a 3 T scanner. The left picture shows the artifacts obtained with the implant magnet in place whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

Magnet Removal Procedure

The following instruments are required for the Magnet Removal Procedure:

Magnet Replacement Kit

Order number: 09693
Consisting of:

Non-Magnetic Spacer Ms010107
The Non-Magnetic Spacer (see Figure 48) is intended to be used as placeholder for the regular implant magnet of the Mi1200 Hearing Implant during MRI procedures, when a reduced image artifact is desirable.

Replacement Magnet Ms010108
The Replacement Magnet (see Figure 49) is intended to be used after an MRI, as replacement of the original implant magnet of the Mi1200 Hearing Implant and to restore full functionality of the Mi1200 Hearing Implant.

Magnet Tool Kit

Order number: 09734
Consisting of:

Magnet Removal Tool Ms050206
Magnet Insertion Tool Ms050205

The Magnet Removal Tool (see Figure 50) is for removal of the MED-EL removable implant magnet and the Non-Magnetic Spacer.

The Magnet Insertion Tool (see Figure 51) is for insertion of the Non-Magnetic Spacer and the Replacement Magnet.

The instruments are made of surgical grade stainless steel. The devices are delivered non-sterile.

Figure 48
Non-Magnetic Spacer

Figure 49
Replacement Magnet

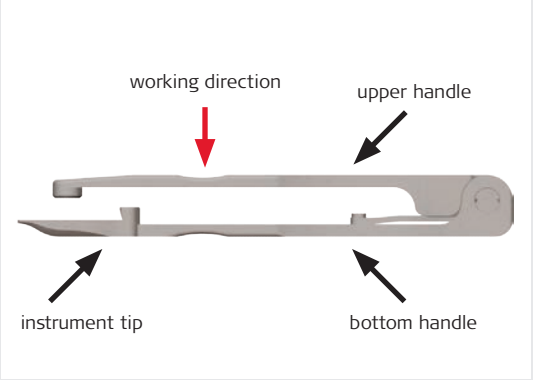


Figure 50 Magnet Removal Tool

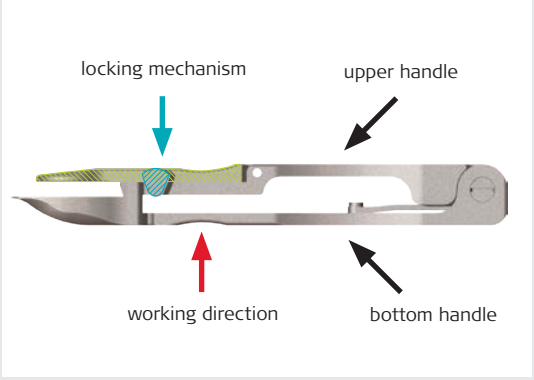


Figure 51 Magnet Insertion Tool

Surgical Procedure

STEP 1: Opening the skin flap

When opening the skin flap, keep an adequate distance between the incision and the coil. This will prevent damage to the implant under the skin. For marking the incision either the patient's audio processor coil or the MAX Coil S can be used. When used in a sterile environment, the Coil should be covered with sterile material (i.e. "sterile sleeve"). MED-EL recommends a distance of 5 to 15 mm from the coil and an opening angle between 160° and 200°. Carefully dissect the fibrous tissue to locate the coil part of the implant and expose the magnet. The wound should be opened in layers.

STEP 2: Removing the Implant Magnet or Non-Magnetic Spacer

CAUTION

To avoid movement of the implant it is recommended to fix the stimulator by pressing it against the bone with one hand.

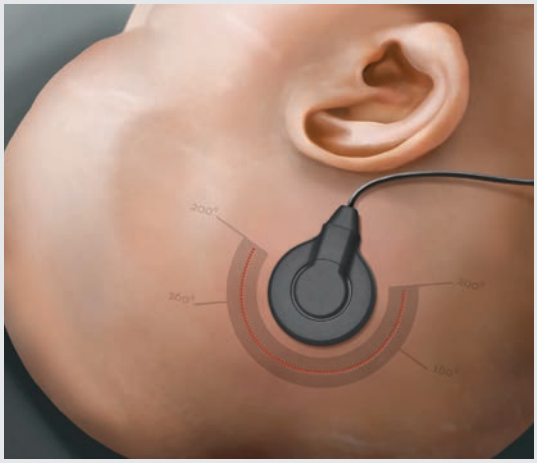


Figure 52 Showing recommended incision line with MAX Coil S in non-sterile environment

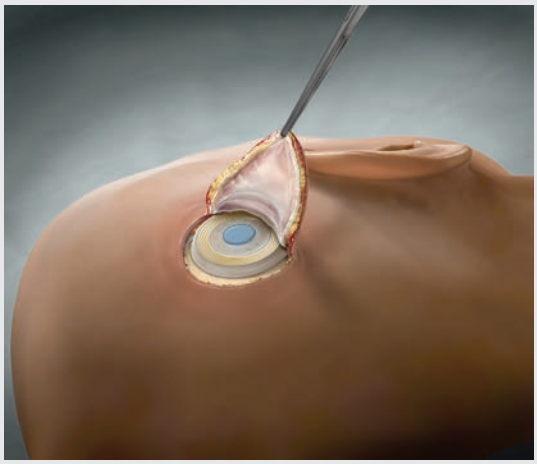


Figure 53 Implant coil with inserted magnet after opening the skin flap

1. Place the Magnet Removal Tool in front of the implant coil.

2. Lift the coil part of the implant by sliding the tip of the Magnet Removal Tool under the implant coil.

3. Center the implant coil in the tip part of the Magnet Removal Tool.

4. Push the Implant Magnet or Non- Magnetic Spacer out of the implant coil by pressing together the two handles of the Magnet Removal Tool.

5. MED-EL recommends checking that the two handles of the Magnet Removal Tool are completely re-opened before pulling out the instrument.

6. Remove the Magnet Removal Tool by slowly pulling out the instrument from the implant coil.

7. After pulling out the instrument, the Implant Magnet or Non-Magnetic Spacer can be removed from the tip of the Magnet Removal Tool by lifting the upper handle. The removed Implant Magnet or Non-Magnetic Spacer can be disposed of.

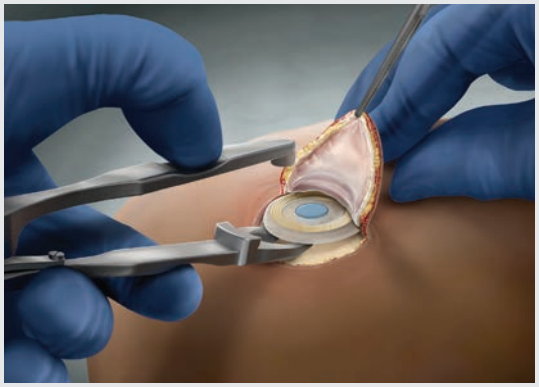


Figure 54 Lifting the implant coil with the Magnet Removal Tool

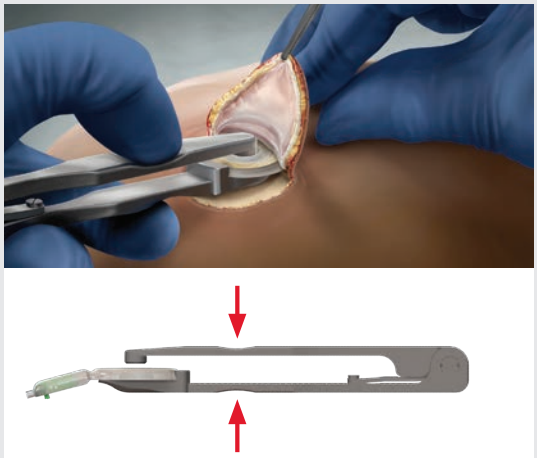


Figure 55 Centering the implant coil and pressing the two handles together for removing the magnet

Figure 56 Opening the instrument and removing the magnet from the instrument tip

STEP 3: Inserting the Non-Magnetic Spacer or Replacement Magnet

CAUTION

To avoid movement of the implant it is recommended to fix the stimulator by pressing it against the bone with one hand.

1. Open the upper handle of the Magnet Insertion Tool by unlocking the small locking mechanism and lifting the counter blade.

2. Place the Non-Magnetic Spacer or Replacement Magnet in the front part of the Magnet Insertion Tool. The Non-Magnetic Spacer or Replacement Magnet is correctly placed into the tip when the serial number labelling is not readable from the top.

3. Close the counter blade and lock the locking mechanism.

4. Place the Magnet Insertion Tool in front of the implant coil.

5. Lift the coil part of the implant by sliding the tip of the Magnet Insertion Tool under the implant coil.

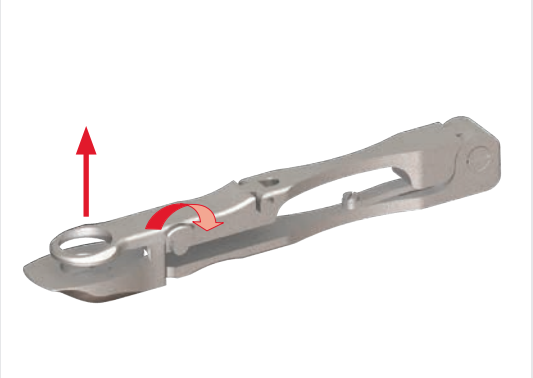


Figure 57 Unlocking the locking mechanism and lifting the upper handle

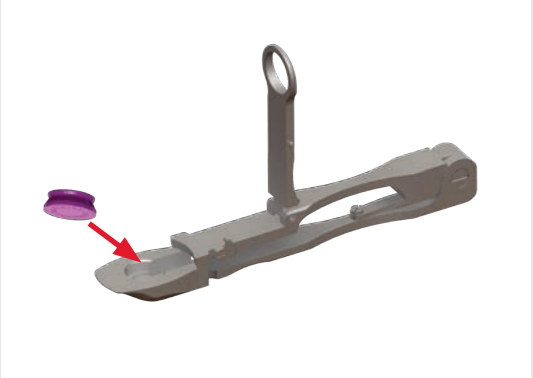


Figure 58 Placing the Non-Magnetic Spacer or the Replacement Magnet in the tip of the Magnet Insertion Tool

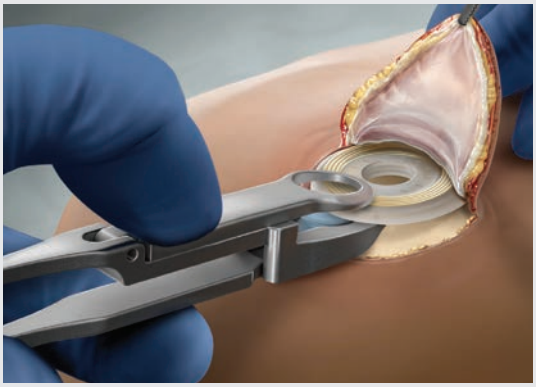


Figure 59 Lifting the implant coil with the Magnet Insertion Tool

6. Center the implant coil in the tip part of the Magnet Insertion Tool so the Non-Magnetic Spacer or Replacement Magnet is completely visible through the hole in the implant coil.

7. For complete insertion of the Non- Magnetic Spacer or Replacement Magnet into the implant coil, insert the Non- Magnetic Spacer or Replacement Magnet into the implant coil by pressing the two handles of the instrument together until the two handles are touching.

8. Re-open the two handles of the Magnet Insertion Tool.

9. MED-EL recommends checking that the two blades of the Magnet Insertion Tool are completely re-opened before pulling out the instrument.

10. Remove the Magnet Insertion Tool by slowly pulling out the instrument from the implant coil.

11. Check the correct magnet position.

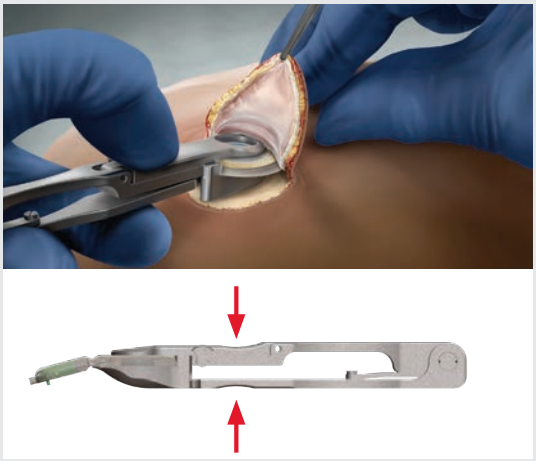


Figure 60 Centering the implant coil and pressing the two handles together for inserting the magnet

STEP 4: Close wound

Before closing the wound visually confirm that the blue Replacement Magnet (Ms010108) or the purple Non-Magnetic Spacer (Ms010107) was inserted as appropriate. When closing the wound, care should be taken not to damage the implant. The wound should be cleaned and closed in layers with staples or absorbable subcutaneous sutures. The area of the wound should then be covered with a compress and sterile gauze, and even pressure should be applied.

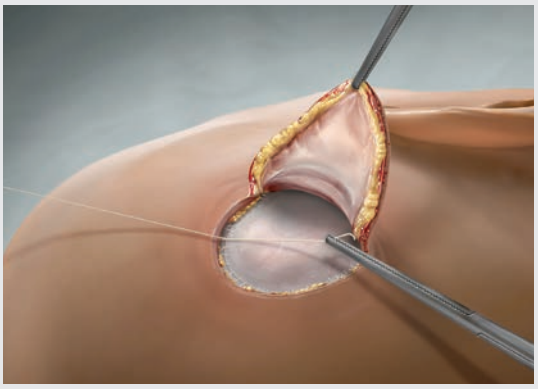


Figure 61 Suturing the wound

X-rays

The SYNCHRONY Cochlear Implant can be identified by X-ray post surgery. Right is an example for the device.

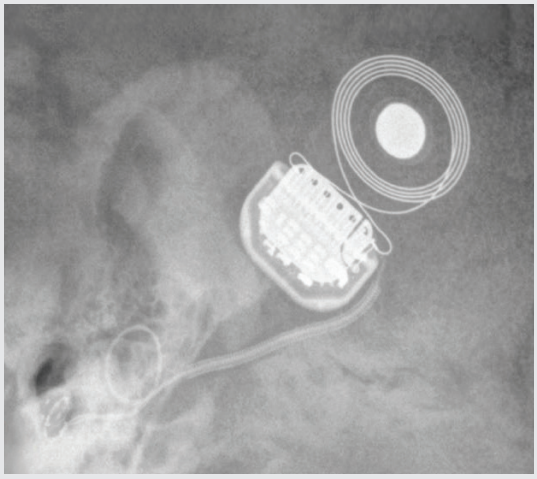


Figure 62 X-ray

Explanting the Device

- The implant may become non-functional, either by accident or due to medical or technical reasons. In this case, it is strongly recommended to replace the device.
- If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed, functional checks of the implant on a regular basis are strongly recommended.
- If possible, the device should be removed without damaging or cutting it. Damage to the device during or after explantation may prevent or reduce the manufacturer's ability to determine the root cause of failure.
- Staff should follow common universal precautions and handle the explanted device as potentially contaminated biohazardous material.
- After explantation, the implant should be appropriately cleaned and disinfected. During cleaning, extraneous tissue should be removed, but only to such an extent that damage to the implant is not risked.
- An explanted device should be placed in a leak-proof, disinfected (or sterile) container filled with saline and returned to MED-EL Headquarters. The device should be accompanied by written information including the reason for explantation.

EAS

Recommended EAS Surgical Technique

A special marked EAS paragraph can be found in each surgical step showing details which are important for facilitating a more atraumatic EAS surgery and thereby minimizing trauma to the delicate structures which are important for maintaining residual hearing sensitivity. A summary of the additional EAS related surgical steps can be found in Figure 63.

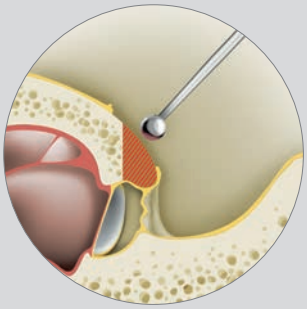
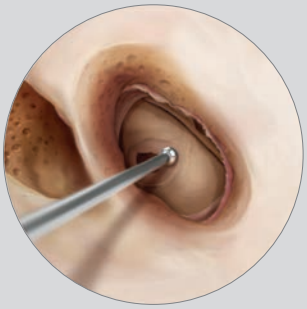
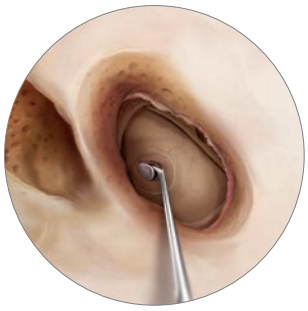
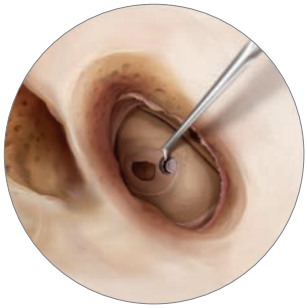
Round Window Insertion	Cochleostomy Insertion
Please ensure that corticosteroids (crystalline triamcinolone solution or dexamethasone), intravenous corticosteroids, and hyaluronic acid are all available for the surgery.	
Administer intravenous antibiotics from the Cephalosporin group and intravenous corticosteroids at least half an hour before the skin incision.	
It is recommended to create a larger posterior tympanotomy (as compared to that of a standard cochlear implantation) beside the anterior tympanotomy in order to provide a better view as well as more space to manoeuvre the electrode array.	
Elevate a mucosal flap to avoid mucosal bleeding when opening the cochlea.	
Begin drilling near the cochlea use a slowly turning diamond drill to avoid acoustic trauma.	
To enter the middle portion of the scala tympani and to get visualization of the round window membrane, the posterior-superior lip of the round window niche and the inferior margin of the round window should be drilled away to expose the round window membrane at least 0.8 mm.	The cochleostomy should be drilled inferior and slightly anterior to the round window annulus to achieve a scala tympani insertion and to avoid damage to the osseous spiral lamina. The endosteum should be exposed to approximately 0.8 mm.
	
Fill the electrode insertion site with corticosteroids.	
Protect the middle ear cavity from bone dust contamination by closing it with medical gauze.	
Drill the implant bed and immobilize the implant.	
Prior to opening the cochlea, clean the surgical field, change gloves, remove the gauze used to keep bone dust out of the middle ear cavity.	
Place a drop of corticosteroid on the round window membrane or endosteum to reduce fibrotic reaction and cover it with a drop of hyaluronic acid. This will keep the corticosteroid in place and protect it from bone dust.	

Figure 63 Recommended EAS Surgical Technique (Part 1)

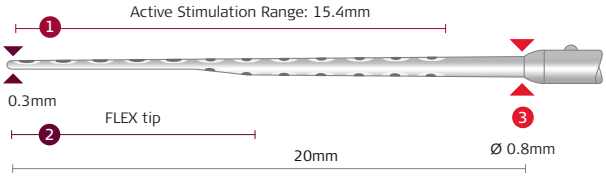
EAS

Round Window Insertion	Cochleostomy Insertion
Using a micro-lancette or micro-hook, carefully incise the round window membrane in its inferior-anterior quadrant to approximately 0.8 mm.	With a micro-lancette or micro-hook, carefully incise the endosteum to approximately 0.8 mm.
	

Avoid suctioning in the open region of the cochlea.

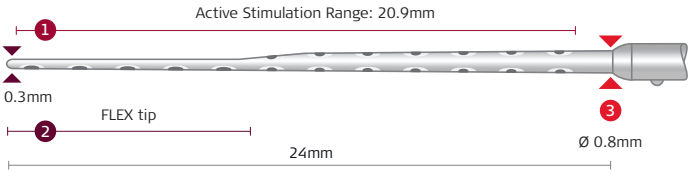
Immediately start the electrode insertion through the drop of corticosteroid and hyaluronic acid.

General insertion direction is from superior-posterior to anterior-inferior with the knob indicating the direction of the apical electrodes facing towards the modiolus.



1. 19 platinum electrode contacts
   Optimal spacing over a 15.4mm stimulation range
2. FLEX-Tip for minimal insaertion trauma
   Dimensions at apical end: 0.5 x 0.3mm
3. Diameter at basal end: 0.8mm

Insert the FLEX20 electrode so that it covers 1 turn of the cochlea
(20mm, determined by pre-operative CT scan).



1. 19 platinum electrode contacts
   Optimal spacing over a 20.9mm stimulation range
2. Flex tip for minimal insertion trauma
   Dimensions at apical end: 0.5 x 0.3mm
3. Diameter at basal end: 0.8mm

Insert the FLEX24 electrode so that it covers less than 1.5 turns of the cochlea
(22-24mm, determined by pre-operative CT scan).

To seal the cochlea, use a small fascial graft.
To prevent contamination of the electrode and to increase flexibility, rinse the fascial graft with saline solution.

A course of steroids and antibiotics should be given postoperatively.

Figure 64 Recommended EAS Surgical Technique (Part 2)

Literature

The following is a list of references on general CI surgery:

Evaluation of a minimally invasive surgical fixation technique for young children with the CONCERTO Pin cochlear implant system.
Schnabl J; Wolf-Magele A; Pok SM; Url C; Zorowka P; Sprinzl G
Eur Arch Otorhinolaryngol, 2014 Mar 23

The Effects of Insertion Speed on Inner Ear Function during Cochlear Implantation: A Comparison Study
Rajan GP; Kontorinis G; Kuthubutheen J; Audiol Neurootol, 18(1), 2012 Sep 22, p. 17–22

SYNCHRONY Pin: A Novel Concept of Cochlear Implant Fixation.
Schnabl J; Markl A; Hormann R; Wolf-Magele A; Schartinger V; Sprinzl G; Otol Neurotol, 2012.

Depth of Electrode Insertion and Postoperative Performance in Humans with Cochlear Implants: A Histopathologic Study.
Lee J; Nadol JB; Eddington DK; Audiol Neurootol, 15(5), 2010, 323-331.

Cochlear implantation in inner ear malformations
Sennaroglu L; Cochlear Implants Int, 2009.

Scala tympani cochleostomy I: results of a survey.
Adunka OF; Buchman CA; Laryngoscope 2007; 117(12):2187-2194.

Cochlear implant electrode insertion: The round window revisited.
Roland P; Wright C; Isaacson B; Laryngoscope 2007; 117(8):1397-402.

Scala tympani cochleostomy II: Topography and histology.
Adunka O; Radeloff A; Gstoettner W; Pillsbury H; Buchman C; Laryngoscope 2007; XX:1-6.

Preservation of basal inner ear structures in cochlear implantation.
Adunka O; Gstoettner W; Hambek M; Unkelbach MH; Radeloff A; Kiefer J; ORL J Otorhinolaryngol Relat Spec. 2004; 66(6):306-12.

Cochlear implantation via the round window membrane minimizes trauma to cochlear structures: A histologically controlled insertion study.
Adunka O; Unkelbach MH; Mack M; Hambek M; Gstöttner W and Kiefer J; Acta Otolaryngol 2004; 124: 807-812.

J. Müller, F. Schön, J. Helms: Safe fixation of mounts for cochlear implant electrodes initial experience with a new titanium clip.
Laryngo-Rhino-Otol 1998;77:238-240.

The length of the organ of Corti in man.
Hardy M; American Journal of Anatomy, 62(2), 1938, 179-311.

The following is a list of references on bilateral CI surgery:

Assessment of electrode placement and audiological outcomes in bilateral cochlear implantation.
Wanna GB, Noble JH, McRackan TR, Dawant BM, Dietrich MS, Watkins LD, Rivas A, Schuman TA, Labadie RF; Otol Neurotol. 2011 Apr.

Binaural cochlear implantation after bilateral temporal bone fractures.
Zanetti D, Campovecchi CB, Pasini S.; Int J Audiol. 2010 Jul 8.

Bilateral cochlear implantation in a patient with bilateral temporal bone fractures.
Chung JH, Shin MC, Min HJ, Park CW, Lee SH.; Am J Otolaryngol. 2010 May 3.

Bilateral cochlear implantation in children with anomalous cochleovestibular anatomy
Chadha NK; James AL; Gordon KA; Blaser S; Papsin BC.; Arch Otolaryngol Head Neck Surg, 135(9), 2009 Sep.

Bilateral, simultaneous cochlear implantation in children: surgical considerations.
Migirov, L. & Kronenberg, J.; J Laryngol Otol. 2009 Mar 3:1-3.

Otopathological Findings in a Patients with Bilateral Cochlear Implants.
House, W., Johnsson, L. & Linthicum, F.; USPHS Research, 74, 2006.

Cochlear implantation in a patient with bilateral temporal bone fractures.
Simons, J., Whitaker, M. & Hirsch, B.; Otolaryngol Head Neck Surg, 132, 809-811; 2005.

Bilateral cochlear implantation.
Lustig, L. & Wackym, P.; Operative Techniques in Otolaryngology, 16, 2005.

Insertion depth differences in bilateral cochlear implantees
Fielden C; Long C; Cooper H; Proops D; Donaldson I; Craddock L.; Cochlear Implants Int, 6 Suppl 1, 2005 Sep.

The following is a list of references on HP and EAS:

Hearing preservation after cochlear reimplantation
Helbig S; Rajan GP; Stover T; Lockley M; Kuthubutheen J; Green KM; Otol Neurotol, 34(1), 2013 Jan, p. 61–65

The Round Window: Is it the "Cochleostomy" of Choice? Experience in 130 Consecutive Cochlear Implants.
Gudis DA, Montes M, Bigelow DC, Ruckenstein MJ.; Otol Neurotol. 2012 Sep 11.

Evaluation of round window accessibility to cochlear implant insertion.
Leong AC, Jiang D, Agger A, Fitzgerald-O'Connor A.; Eur Arch Otorhinolaryngol. 2012 Jul 18.

Hearing preservation after cochlear implantation using deeply inserted flex atraumatic electrode arrays.
Tamir S, Ferrary E, Borel S, Sterkers O, Bozorg Grayeli A.; Audiol Neurootol. 2012;17(5):331-7.

Hearing preservation and hearing improvement after reimplantation of pediatric and adult patients with partial deafness: a retrospective case series review.
Jayawardena J, Kuthubutheen J, Rajan G.; Otol Neurotol. 2012 Jul;33(5):740-4.

Scalar localization by computed tomography of cochlear implant electrode carriers designed for deep insertion.
Helbig S, Mack M, Schell B, Bratzke H, Stöver T, Helbig M.; Otol Neurotol. 2012 Jul;33(5):745-50.

A case series of paediatric hearing preservation cochlear implantation: a new treatment modality for children with drug-induced or congenital partial deafness.
Kuthubutheen J, Hedne CN, Krishnaswamy J, Rajan GP.; Audiol Neurootol. 2012;17(5):321-30.

Cochlear implantation and hearing preservation: Results in 21 consecutively operated patients using the round window approach.
Erixon E, Köbler S, Rask-Andersen H.; Acta Otolaryngol. 2012.

Achievement of hearing preservation in the presence of an electrode covering the residual hearing region.
Usami SI; Moteki H; Suzuki N; Fukuoka H; Miyagawa M; Nishio SY; Takumi Y; Iwasaki S; Jolly C; Acta Otolaryngol, 2011.

Combined electric acoustic stimulation with the PULSARCI(100) implant system using the FLEX(EAS) electrode array.
Helbig S; Van de Heyning P; Kiefer J; Baumann U; Kleine-Punte A; Brockmeier H; Anderson I; Gstoettner W; Acta Otolaryngol, 2011.

Atraumatic round window deep insertion of cochlear electrodes.
Skarzynski H; Lorens A; Zgoda M; Piotrowska A; Skarzynski PH; Szkielkowska A.; Acta Otolaryngol, 2011.

Hearing Preservation After Complete Cochlear Coverage in Cochlear Implantation With the Free-Fitting FLEX^{SOFT} Electrode Carrier
Helbig S; Baumann U; Hey C; Helbig M; Otol Neurotol, 2011 Jul 1

Is Electric Acoustic Stimulation Better Than Conventional Cochlear Implantation for Speech Perception in Quiet?
Adunka OF; Pillsbury HC; Adunka MC; Buchman CA; Otol Neurotol, 2010.

Electric Acoustic Stimulation in Patients with Postlingual Severe High-Frequency Hearing Loss: Clinical Experience.
Arnoldner C; Helbig S; Wagenblast J; Baumgartner WD; Hamzavi JS; Riss D; Gstoettner W; Adv Otorhinolaryngol, 67, 2010.

Partial deafness cochlear implantation at the university of kansas: techniques and outcomes.
Prentiss S; Sykes K; Staecker HJ; Am Acad Audiol, 21(3), 2010.

Preliminary Results of Electric and Acoustic Stimulation Using the MED-EL Sonata Flex EAS Electrode Array.
Walker A; Mawman D; Brough J; O'Driscoll M; Ramsden R; Green K; Freeman S; Cochlear Implants Int, 11 (Suppl. 2), 2010.

Electric Acoustic Stimulation (EAS) of the Auditory System: Experience and Results of Ten Patients Using MED-EL's M and Flex^{EAS} Electrodes.
Lee A; Jiang D; McLaren S; Nunn T; Demler J; Tysome J; Connor S; Fitzgerald O'Connor A; Clinical Otolaryngology, 2010.

Results of partial deafness cochlear implantation using various electrode designs.
Skarzynski H; Lorens A; Piotrowska A; Podskarbi-Fayette R; Audiol Neurootol, 14 Suppl 1, 2009.

Preservation of low frequency hearing in partial deafness cochlear implantation (PDCI) using the round window surgical approach.
Skarzynski H; Lorens A; Piotrowska A; Anderson I; Acta Otolaryngol 2007; 127(1): 41-8.

Outcomes in adults implanted with the FLEX^{soft} electrode.
Baumgartner W; Jappel A; Morera Perez C; Gstöttner W; Müller J; Kiefer J; Van De Heyning P; Anderson I; Bryde Nielsen S.; Acta Otolaryngol, 127(579), 2007.

Method for hearing preservation in cochlear implant surgery.
Roland P; Gstoettner W; Adunka O.; Otolaryngol 2005; 16: 93-100.

Conservation of low-frequency hearing in cochlear implantation.
Kiefer J et al.; Acta Otolaryngol 2004; 124: 272-280.

The following is a list of references on young children:

Functional outcome of sequential bilateral cochlear implantation in young children: 36 months postoperative results
Scherf FW; Van DL; van WA; Wouters J; Desloovere C; Dhooge I; Offeciers E; Deggouj N; De RL; De BM; Van de Heyning PH; Int J Pediatr Otorhinolaryngol, 2009 Feb 26

Ear Surgery in Infants Under One Year of Age: Its Risks and Implications for Cochlear Implant Surgery
Johr M; Ho A; Wagner CS; Linder T; Otol Neurotol, 29(3), 2008 Apr, p. 310–313

Surgical Factors in Pediatric Cochlear Implantation and Their Early Effects on Electrode Activation and Functional Outcomes
Francis HW; Buchman CA; Visaya JM; Wang NY; Zwolan TA; Fink NE; Niparko JK; Otol Neurotol, 2008 Apr 4

Hearing benefits of second-side cochlear implantation in two groups of children
Scherf F.; van Deun L.; van Wieringen A.; Wouters J.; Desloovere C.; Dhooge I.; Offeciers E.; Deggouj N.; De Raeve L.; De Bodt M.; Van De Heyning P.; Int J Pediatr Otorhinolaryngol, 71(12), 2007 Dec, p. 1855–1863

Simultaneous versus sequential bilateral implantation in young children: Effects on central auditory system development and plasticity
Sharma A.; Gilley P.; Martin K.; Roland P.; Bauer P; Dorman M.; Audiological Medicine, 5(4), 2007, p. 218–223

Complications in children with long-term cochlear implants
Lin Y.; Lee F.; Peng S.; ORL J Otorhinolaryngol Relat Spec, 68(4), 2006, p. 237–242

Cochlear implantation in children younger than 12 months of age
Wackym P.; Firszt J.; Runge-Samuelson C; Operative Techniques in Otolaryngology, 16, 2005, p. 101–106

Cochlear implantation in deaf infants
Miyamoto R.; Houston D; Bergeson T; Laryngoscope, 115, 2005, p. 1376–1380

Cochlear implantation at under 12 months: Report on 10 patients
Colletti V; Carner M; Miorelli V; Guida M; Colletti L; Fiorino F; Laryngoscope, 115, 2005, p. 445–449

The following is a list of references on alternative approaches:

VERIA TECHNIQUE
Veria operation: Updated.
Kiratzidis T, Arnold W, Iliades T.; ORL 64:406-412, 2002.

Veria operation.
Kiratzidis T, Iliades T, Arnold W.; ORL 64:413-416, 2002.

Veria operation: Cochlear implantation without a mastoidectomy and a posterior tympanotomy.
Kiratzidis T.; Adv Otorhinolaryngol 57:127-130, 2000.

SUPRAMEATAL APPROACH
How we do it? The suprameatal approach – An alternative surgical technique for cochlear implantation.
Kronenberg J; Migirov L.; Cochlear Implants International 7:142-147, 2006.

The Suprameatal Approach: An alternative surgical approach to cochlear implantation.
Kronenberg J; Baumgartner W; Migirov L; Dagan T; Hildesheimer M.; Otol Neurotol 25:41-45, 2004.

The role of Mastoidectomy in cochlear implant surgery.
Kronenberg J; Migirov L.; Acta Otolaryngol 123:219-222, 2003.

The suprameatal approach in cochlear implant surgery: Our experience with 80 patients.
Kronenberg J; Migirov L; Baumgartner W.; ORL 64:403-405, 2002.

Suprameatal approach. New surgical approach for cochlear implantation.
Kronenberg J; Migirov L; Dagan T; J.Laryngol Otol 115:283-285, 2001.

PERI CANAL TECHNIQUE
Cochlear implantation without mastoidectomy: The pericanal electrode insertion technique.
Häusler R; Acta Oto-Laryngologica 122:715-719, 2002.

ATTICOTOMY APPROACH
Transepitympanic Approach in Cochlear Implantation.
Nahler A; Böheim K; 5th European Congress of Oto-Rhino-Laryngology Head and Neck Surgery, Rodos-Kos Hellas 2004. (Poster)

Kombinierter Epitympanaler – Transmeataler Zugang bei Cochleaimplantation.
Nahler A; Böheim K; 47. Österreichischer HNO-Kongreß 2003. (in German)

Transatical Approach Modifications.
Cózar; Fragola; Calderón; Revilla; González de Ubiéta; Poster presentation Las Palmas 2002. (Poster), Arauz: http://www.implantescocleares.com/ (in Spanish, with video).

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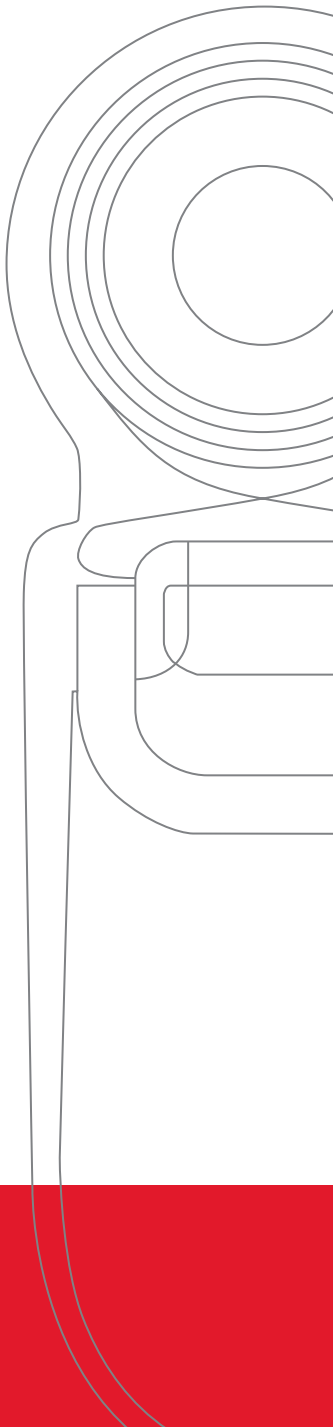
MED EL

SONATA
Cochlear Implant

+FLEX^{24} | +FLEX^{20}

English



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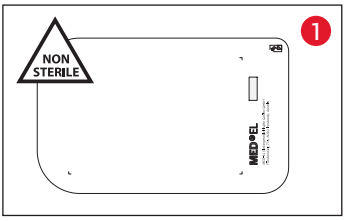
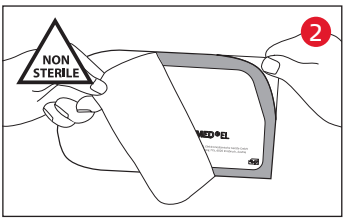
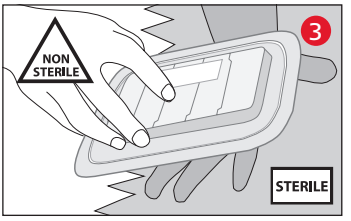
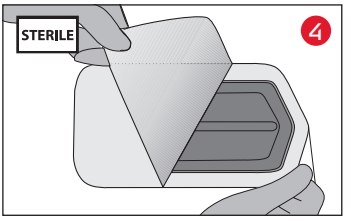
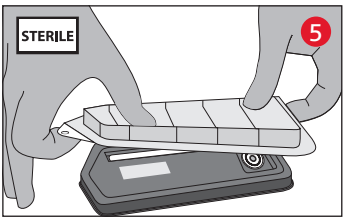
Opening instruction

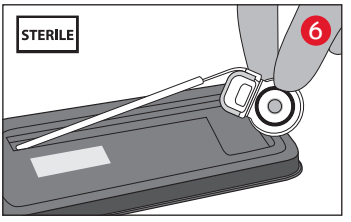


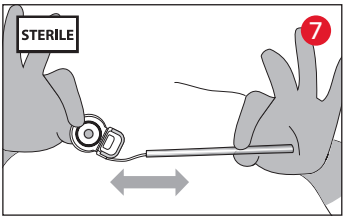




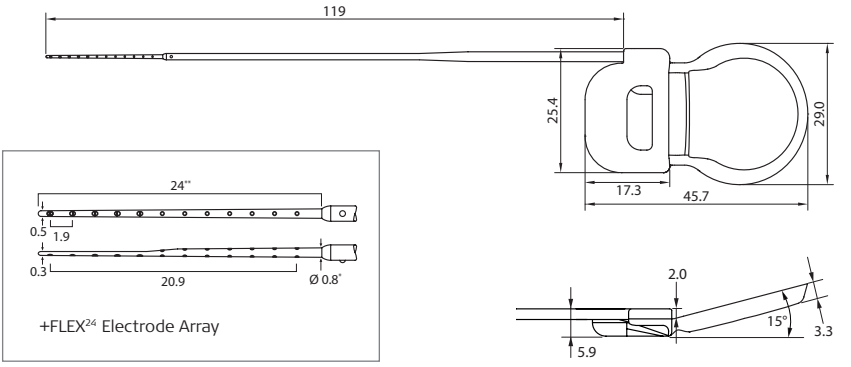






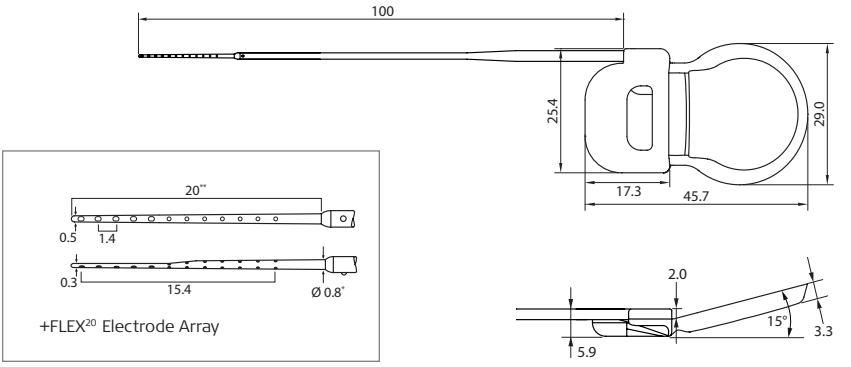


SONATA +FLEX^{24}



+FLEX^{24} Electrode Array

SONATA +FLEX^{20}



+FLEX^{20} Electrode Array

Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

Instructions for use

SONATA Cochlear Implant

Device description

The SONATA TI[100] Implant (hereafter referred to as SONATA) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SONATA)[1]. This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 8.6 g (typical weight).
For principal dimensions of the implant refer to the drawings on the first page.
The volume of the implant without electrode is 4.2 cm^3.
Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
  Maximum current amplitude: Median value = 1250 µA, range = 500 µA
  Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to MED-EL application software user manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm^2.

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+FLEX^{24}	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9
+FLEX^{20}	100 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.4	15.4

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal SONATA Cochlear Implant with either a +FLEX^{24} or +FLEX^{20} electrode variant which together make up the MED-EL EAS System.

Indications

The SONATA shares the same indications for use as the COMBI 40+ System.

- Adults, eighteen (18) years of age or older, who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences) .
- Children aged twelve (12) months to seventeen (17) years and eleven (11) months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three (3) to six (6) month period. In older children, lack of aid benefit is defined as <20 % correct on the Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills. A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.
- Cochlear implants with SONATA +FLEX^{24} and +FLEX^{20} for EAS indication are 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.

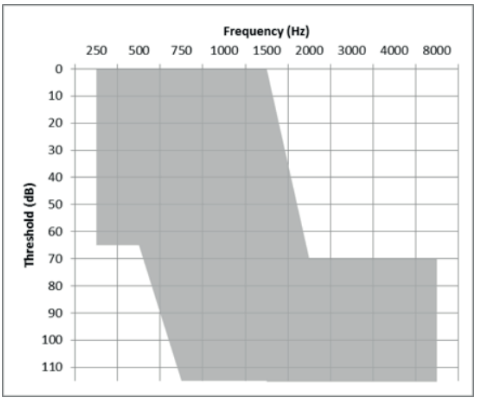


Figure 1: EAS Indication

- Implantation of Cochlear Implants SONATA +FLEX^{24} and +FLEX^{20} used for EAS is contraindicated for partially deaf individuals with unstable progressive hearing loss, who are unable to use amplification devices, and/or have cochlear malformations.
- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.
- To obtain optimal benefit from the SONATA Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training.
- A preoperative assessment according to the local professional standards must be conducted.
- Cochlear implants with SONATA +FLEX^{24} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted with the SONATA Cochlear Implant:

- If the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, platinum iridium).
- If there is an absence of cochlear development.
- If the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways.
- If external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted.
- If there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required.
- If anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery.
- If the psychological status of the patient is unstable or,
- If the patient has unrealistic expectations.

Undesirable side effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped[2] between −20 °C (−4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the "use by" date specified on the package. Packaging[3] should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.
- Most water sports should not cause any problem as long as the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In case the MED-EL implant user wants to dive, the user should consult an experienced physician about the possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis[4] can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling the mastoidectomy, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that foudroyantly progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm. The stimulator should be recessed to a depth of maximum 2 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The implant must be securely anchored in the stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.
- The bed for the implant must be flat so that the implant is stable. The transition from the implant bed to the channel for the electrode has to be smooth, ramp-like, with no sharp edges in order to avoid possible damage to the electrode lead.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

  Recommended diameter of the cochleostomy & RW opening:

Electrode type	
SONATA +FLEX[24]	0.8 mm
SONATA +FLEX[20]	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear presurgically.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.

- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.
- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- Cochlear implantation in partially deaf patients with low frequency hearing carries the risk of partial or total hearing loss which should be clearly explained to the patient by the surgeon prior to implantation. However, studies have shown benefits using electrical stimulation solely in this group of patients even if residual hearing is lost. Etiology, duration of partial deafness, and hearing aid benefit should be taken into consideration and hearing preservation surgical technique should be applied.

Interference with other equipment, robustness of the device in special environments.

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

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.
If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.
If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
  MED-EL Elektromedizinische Geräte GmbH
  Worldwide Headquarters
  Safety adviser for the transport of dangerous goods
  Fürstenweg 77a
  6020 Innsbruck
  Austria

Clinical trial description

The purpose of this prospective, multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the safety and effectiveness of MED-EL's Electric-Acoustic Stimulation (EAS) system. The MED-EL EAS System is a medical device that combines the use of a cochlear implant with an external electric-acoustic audio processor, designed to provide benefit in speech perception and sound quality to individuals who demonstrate significant residual low-frequency hearing and severe to profound high-frequency (above 1500 Hz) sensorineural hearing loss with minimal changes in residual hearing.

Four test conditions were evaluated in order to determine effectiveness of the MED-EL EAS system:

1. Preoperatively; Acoustic Alone (acoustic amplification to the ear to be implanted),
2. Postoperatively; Electric Alone (electric stimulation only to the implanted ear via the MED-EL EAS system without the use of the Acoustic Component),
3. Postoperatively; Combined (simultaneous electric and acoustic stimulation in the implanted ear via the MED-EL EAS system utilizing the Acoustic Component)
4. Postoperatively; Bimodal (electric stimulation only using the MED-EL EAS system without the Acoustic Component, with the addition of contralateral acoustic stimulation).

Of note, the Bimodal condition was only tested in one subject, when that subject lost residual hearing and had thresholds poorer than 80 dB HL at 250 Hz and above in the implanted ear. Audiometric thresholds were also assessed across test intervals in order to measure low-frequency residual hearing postoperatively.

The primary effectiveness endpoint was the improvement in CUNY sentences in noise in the combined electric and acoustic condition at 12 months. The primary safety endpoint was the evaluation of all adverse events reported. Safety data was collected on all implanted subjects.

Seventy-three subjects were implanted with either a PULSAR or a SONATA Cochlear Implant with a FLEX^{24} electrode across 14 investigational sites. Subjects were fit postoperatively with the DUET Audio Processor, combining acoustic amplification and electric stimulation in one device.

The original approval of the study was only for one arm (Arm 1). The second study arm (Arm 2) was added later for subjects with slightly better residual hearing at baseline in the ear to be implanted. Audiologic criteria for the study required subjects to have bilateral residual low-frequency hearing and severe to profound high-frequency sensorineural hearing loss. Subjects in Arm 2 could have slightly better low-frequency thresholds and a CNC word score in quiet of 60 %, as opposed to subjects in Arm 1 who had a CNC word score in quiet of 50 % or poorer. Results are presented here for all subjects, as the data for both arms has now been combined.

Inclusion/exclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

- Normal to moderate sensorineural hearing loss in the low to mid frequencies and sloping severe/profound sensorineural hearing loss in the mid to high frequencies.
- Monosyllabic word scores in quiet of ≤60 % in the best-aided condition.
- Current user of bilateral acoustic hearing aids for at least 3 months.
- Adults 18–70 years of age at time of implantation.
- English was the primary language.

Subjects were excluded from the study for any of the following reasons:

- Conductive, retrocochlear or central auditory disorders.
- Hearing loss in the ear to be implanted that demonstrated a fluctuation at two or more frequencies of 15 dB in either direction in the last 2 years.

- Any physical, psychological, or emotional disorder that interfered with surgery or the ability to perform on test and rehabilitation procedures.
- Developmental delays or organic brain dysfunction.
- Physical or geographic limitations that interfered with the completion of scheduled follow-up evaluations.
- Skin or scalp conditions that precluded magnetic attachment of the speech processor or use of the acoustic hearing aid.

Clinical trial results

Results for 73 subjects are reported. Of the 73 total subjects implanted, 67 completed follow-up at the time of submission. Five subjects withdrew from the study prior to completing the 12-month interval, and one subject was still undergoing testing at the time of submission. The table below provides details on the number of subjects implanted, as well as how many subjects completed each interval.

# of Subjects	Total
Implanted	73
3-Month Post-EAS Activation Evaluation	72
6-Month Post-EAS Activation Evaluation	70
12-Month Post-EAS Activation Evaluation	67

Demographics

The table below provides information on subject demographics, including gender, age at implantation, duration of hearing loss, and duration of hearing aid use.

Parameter/Category or Statistic	Total (n=73)
Gender	
Male	42.5 % (31/73)
Female	57.5 % (42/73)
Age (years)	53.7 (73) (17–76)
Duration of noticeable hearing loss (years)	
Left	25.7 (73) (2–60)
Right	25.7 (73) (2–60)
Duration of hearing aid use (years)	
Left	17.4 (73) (1–48)
Right	17.4 (72) (1–47)

* Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)

Description of tests

Open-set, monosyllabic words were tested using the CNC (Consonant-Nucleus-Consonant) Word Recognition test. Testing was completed in quiet at 70 dB SPL in the soundfield. One list was administered for each condition, and results are reported as a percent correct for words.

Open-set sentence testing was completed using the CUNY (City University of New York) Sentence Test. Subjects were evaluated in noise at 70 dB SPL with varying signal-to-noise ratios that were held constant for each individual subject throughout the duration of the study. One practice list and four test lists were completed for each condition. Scores are reported as the percent correct for words in the sentences.

Subjective benefit 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. Both were completed at post-operative intervals and based on the "everyday listening condition," as subjects were not instructed to ignore input from the non-implanted ear.

Speech Perception Testing

The primary endpoint was based on improvement in speech understanding at 12 months with EAS using sentence tests in noise. The CUNY Sentence Test was used as the outcome measure for this endpoint.

Additional endpoints included comparison of the EAS condition to the cochlear implant alone condition at 12 months on CUNY sentences in noise. The cochlear implant alone condition was also compared to preoperative performance with a hearing aid using CNC words in quiet.

Subjects were tested postoperatively both in the combined "EAS" condition (electric plus acoustic amplification) as well as in the "CI Alone" condition, meaning electrical stimulation only. These results were compared to the preoperative aided condition. Subjects were instructed to remove any contralateral hearing aid for speech perception testing. One subject lost residual hearing immediately following surgery early in the study. She was followed with electric stimulation only in the implanted ear and a contralateral hearing, per the protocol at the time. A second subject lost residual hearing later in the study and was followed only in the cochlear implant condition, as per the updated protocol.

Study Endpoints

Due to withdrawal of five subjects during the follow-up period, as well as one subject who was still undergoing testing at the time of submission, data is available for 67 subjects at the endpoint (12-month interval) for the effectiveness analysis.

For the primary endpoint of improvement on CUNY sentences in noise in the EAS condition, the average preoperative aided score was 31% (±27%) correct. At 12 months, in the EAS condition, subjects scored 73% (±24%) correct. This represents an improvement with EAS of 42 percentage points. This is a significant improvement in CUNY sentence scores in noise in the EAS condition, as compared to the preoperative aided condition.

Two secondary endpoints relating to speech perception were also analyzed. The improvement in CUNY sentences in noise with EAS was compared to the improvement in CUNY sentences in noise with CI Alone. At 12 months, subjects scored 56% (±30%) correct in the CI Alone condition, on average. In the EAS condition, subjects scored an average of 73% (±24%) at 12 months. The addition of acoustic amplification to electric stimulation demonstrated an average improvement of 17 percentage points. Please see the table below for detailed information on subjects' improvement in CUNY sentences scores in noise in both the EAS and CI Alone conditions.

	EAS	CI Alone
CUNY sentence test in noise	Change from baseline	Change from baseline
3 month	30.89 ± 32.41 (66)	17.99 ± 35.00 (67)
6 month	39.03 ± 27.41 (66)	25.06 ± 29.41 (67)
12 month	42.23 ± 29.96 (66)	24.62 ± 31.62 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Additionally, improvement in the CI Alone condition, compared to the preoperative aided condition, was assessed with CNC word score in quiet. Preoperatively, subjects scored 30% (±13%) correct, on average. At 12 months in the CI Alone condition, subjects scored an average of 48% (±19%) correct. This indicates an 18 percentage point improvement with electric stimulation alone. Please see the table below for detailed information on subjects' improvement in CNC word scores in quiet in both the EAS and CI Alone conditions.

	EAS	CI Alone
CNC word score in quiet	Change from baseline	Change from baseline
3 month	30.73 ± 22.36 (66)	9.25 ± 21.92 (67)
6 month	34.48 ± 23.36 (66)	13.31 ± 21.53 (67)
12 month	36.52 ± 23.58 (66)	18.03 ± 23.10 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Subjective Testing
Patients' subjective improvement was measured using the APHAB, as well as the HDSS, and differences in preoperative and postoperative performance are reported.

It should be noted that subjects were not instructed to disregard the non-implanted ear while completing these questionnaires. Thus, the data reported below is based on the everyday, bilateral condition, which may or may not include the use of a hearing aid in the non-implanted ear postoperatively.

On the APHAB questionnaire, 90% of subjects noted a decrease in listening difficulty. On the HDSS, 86% of subjects reported an increase in satisfaction, compared to their preoperative aided condition.

Global scores for the APHAB, representing the percentage of listening difficulty experienced by study subjects decreased by 30.2% (±20.4%) at 12 months, indicating a significant improvement in ease of listening. On the HDSS, the satisfaction patients experience while listening in background noise improved significantly at 12 months, as compared to the preoperative condition. The table below displays the APHAB global score at each interval from baseline through 12 months.

APHAB	Everyday Wearing Condition (Global score)
Preoperative	65.71 ± 15.23 (42)
3 month	41.62 ± 20.94 (47)
6 month	35.98 ± 16.56 (48)
12 month	35.51 ± 14.01 (48)

Benefit
In total, 65/67 subjects (97%) of subjects demonstrated benefit with the EAS device, as measured on either speech perception tests or subjective benefit questionnaires. Based on the group average, subjects in the study performed more than twice as well on both CUNY and CNC testing with EAS compared to the preoperative hearing aid alone. The table below displays the number and proportion of subjects demonstrating the same or better performance on speech perception scores in three postoperative conditions as compared to the preoperative aided condition. The results below are for the following conditions: CUNY sentences in noise with EAS, CUNY sentences in noise with the CI Alone, and CNC words in quiet with the CI Alone.

Time Point	EAS (CUNY)	CI Alone (CUNY)	CI Alone (CNC)
3 month	86% (57/66)	79% (53/67)	77% (52/67)
6 month	95% (63/66)	91% (61/67)	85% (57/67)
12 month	92% (61/66)	87% (58/67)	88% (59/67)

Hearing Sensitivity
Unaided audiologic thresholds were measured throughout the study, from preoperative to the 12-month endpoint. Although hearing preservation was not a defined endpoint in the protocol, the results of post-hoc, descriptive analyses are presented below. Mean preoperative and postoperative residual hearing thresholds are presented, as well as information on the amount of change in residual hearing and postoperative hearing threshold classification.

Hearing loss tended to occur immediately after surgery and remained stable through the follow-up period. On average, a low-frequency pure-tone average threshold (PTA=250, 500, 750, and 1000 Hz) shift of −24.07 dB HL was seen at 12 months. Changes in low-frequency residual hearing ranged between −19.26 dB HL at 250 Hz to −28.28 dB HL at 750 Hz. The figure below demonstrates the average preoperative residual hearing as well as postoperative residual hearing at 12 months for all subjects.

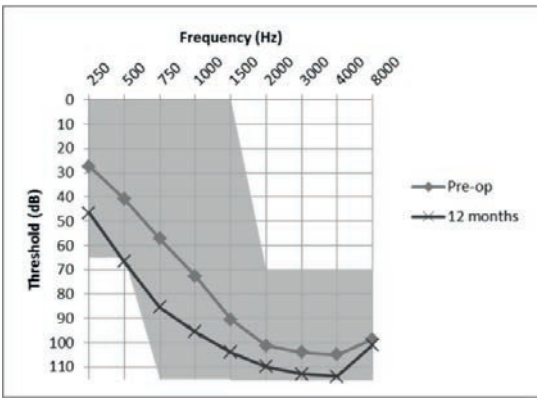


Figure 2: Average pre- and postoperative residual hearing at 12 months for all subjects

Change in residual hearing thresholds can also be described by the proportion of subjects experiencing a particular degree of shift in pure-tone average. The low-frequency threshold shift represents the change in pure-tone threshold at 250, 500, 750, and 1000 Hz. As presented below, 79% of subjects had a PTA shift of less than 30 dB at the 12-month endpoint. As noted above, the average shift in low-frequency PTA was also less than 30 dB (–24.07 dB).

Time Point	< 10 dB	10-20 dB	20–30 dB	> 30 dB
Month 3	10/71 (14.08%)	30/71 (42.25%)	18/71 (25.35%)	13/71 (18.31%)
Month 6	11/69 (15.94%)	23/69 (33.33%)	20/69 (28.99%)	15/69 (21.74%)
Month 12	8/67 (11.94%)	25/67 (37.31%)	20/67 (29.85%)	14/67 (20.90%)
Month 60				

Postoperative residual hearing can also be classified according to the degree of hearing loss as measured by a low-frequency PTA. As can be seen in the table below, 12% of EAS subjects had profound (or total) hearing loss at the 12-month endpoint. The proportion of subjects by degree of postoperative hearing loss is displayed below.

Time Point	Normal	Mild	Moderate	Moderate-Severe	Severe	Profound
Month 3	0/71 (0%)	2/71 (2.82%)	7/71 (9.86%)	30/71 (42.25%)	28/71 (39.44%)	4/71 (5.63%)
Month 6	0/69 (0%)	2/69 (2.90%)	9/69 (13.04%)	26/69 (37.68%)	26/69 (37.68%)	6/69 (8.70%)
Month 12	0/67 (0%)	2/67 (2.99%)	5/67 (7.46%)	28/67 (41.79%)	24/67 (35.82%)	8/67 (11.94%)
Month 60						

Postoperative low-frequency hearing thresholds were also used to determine whether or not subjects would be fit with the acoustic unit of the DUET Audio Processor and followed in that condition. The protocol specified that subjects would be fit with the acoustic unit if any low-frequency threshold was 80 dB or better. Based on this, 97% (65/67) of all subjects in the clinical trial were fit with the acoustic unit and followed in the EAS condition through the 12-month endpoint.

Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated.

A total of 57 adverse events were reported. Thirty-five adverse events occurring in 29 subjects were reported as related to either the device or the procedure. Of the 35 device-related adverse events, 22 were related to changes, either transient or permanent, in residual hearing or the middle ear.

Twelve adverse events were reported to be serious, occurring in 12 of the 73 subjects. Eleven of the 12 serious adverse events were reported to be related to the study device or procedure, eight of which involved changes to residual hearing. One adverse event was reported as a decrease in residual hearing and, therefore, serious). At the subsequent follow-up visit, however, the hearing thresholds in this case had improved and would no longer be considered a serious adverse event. One additional serious adverse event was reported as beeping or ringing in the ear. No unanticipated adverse events were reported.

Details on the type and number of device-related adverse events can be found below:

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects	% Resolved
Type B or Type C tympanogram	8	6	8%	100%
Profound/total loss of residual hearing	8	8	11%	0%
Conductive hearing loss	5	5	7%	0%
Pain at site	3	3	4%	67%
Electrode lead breakage after excessive micro-movements, caused by patient massaging area	1	1	1%	100%
Electrode migration	1	1	1%	100%
Occasionally off-balance	1	1	1%	100%
Ulnar nerve palsy after operation	1	1	1%	100%
Telemetry showed high status on electrode channels	1	1	1%	0%
Facial stimulation	1	1	1%	100%
Aural fullness	1	1	1%	100%
Sensation of device shifting when pushing over the implant site	1	1	1%	100%
Temporary shift in hearing threshold	1	1	1%	100%
Beeping/ringing in implanted ear	1	1	1%	0%
Bitter taste on right side of tongue	1	1	1%	100%
Total	35	29*	39,7%	574%

*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.

Symbols

CE mark. First applied in 2006

Single-use device. Do not reuse!

Catalogue number

Serial number

Caution! Consult accompanying documents

Sterilized using Ethylene Oxide

"Use by" date

Manufacturing date

Manufacturer

MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

1 This Instructions for Use refers to SONATA Implants with +FLEX^{24} or +FLEX^{20} electrodes.

2 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).

3 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.

4 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

USA Distributor
MED-EL Corporation, USA
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.

CE 0123

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a | 6020 Innsbruck, Austria
office@medel.com

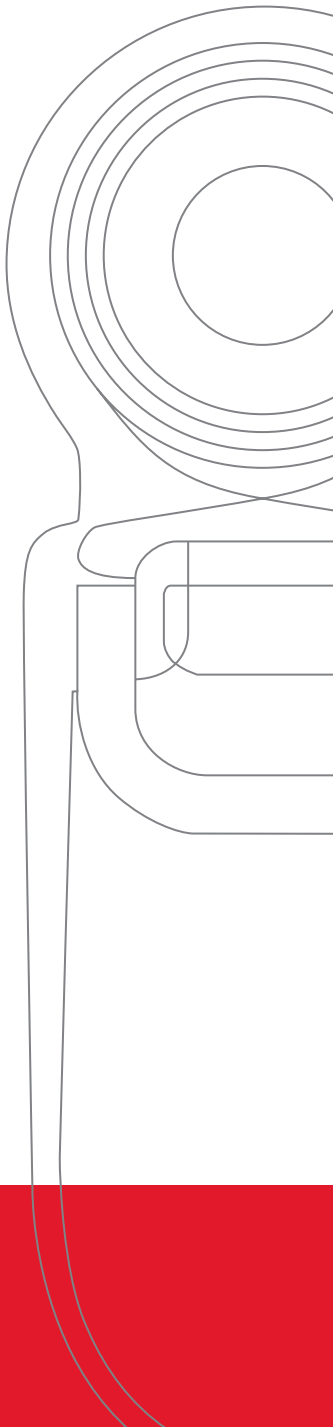
medel.com

MED-EL

Mi1000 MED-EL CONCERT Cochlear Implant

+FLEX^{24} | +FLEX^{20}

English



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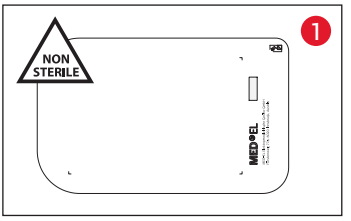
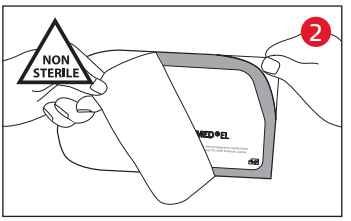
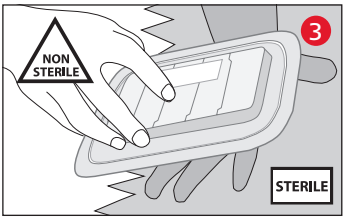
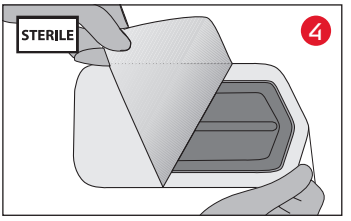
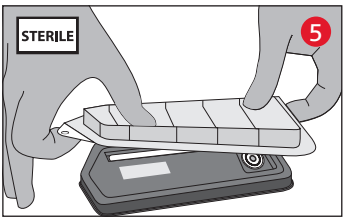
Opening instruction

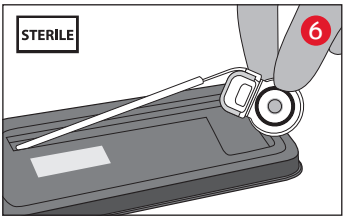


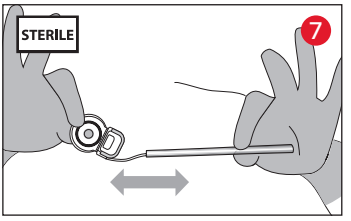




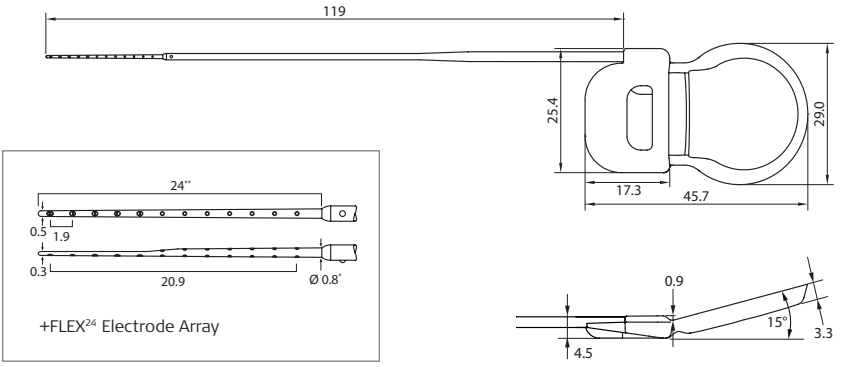




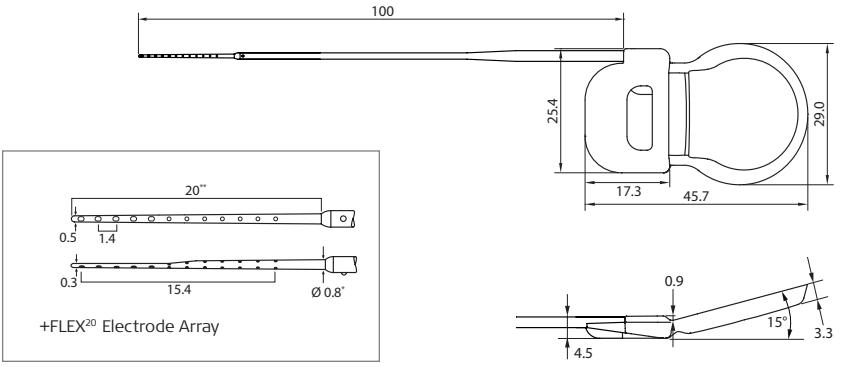




MED-EL CONCERT +FLEX^{24}



MED-EL CONCERT +FLEX^{20}



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

Instructions for use

Mi1000 MED-EL CONCERT Cochlear Implant

Device description

The Mi1000 MED-EL CONCERT Implant (hereafter referred to as MED-EL CONCERT) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family MED-EL CONCERT)[1]. This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).
For principal dimensions of the implant refer to the drawings on the previous pages.
The volume of the implant without electrode is 3.7 cm^3.
Following materials are in direct contact with human tissue: medical grade silicone, platinum and iridium.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
  Maximum current amplitude: Median value = 1250 µA, range = 500 µA
  Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to MED-EL application software user manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm^2.

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+FLEX^{24}	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9
+FLEX^{20}	100 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.4	15.4

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal MED-EL CONCERT Cochlear Implant with either a +FLEX^{24} or +FLEX^{20} electrode variant which together make up the MED-EL EAS System.

Indications

The MED-EL CONCERT shares the same indications for use as the COMBI 40+ System.

- Adults, eighteen (18) years of age or older, who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences).
- Children aged twelve (12) months to seventeen (17) years and eleven (11) months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three (3) to six (6) month period. In older children, lack of aid benefit is defined as <20 % correct on the Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills. A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.
- Cochlear implants with MED-EL CONCERT +FLEX^{24} and +FLEX^{20} for EAS indication are 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. Pro-spective candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids.

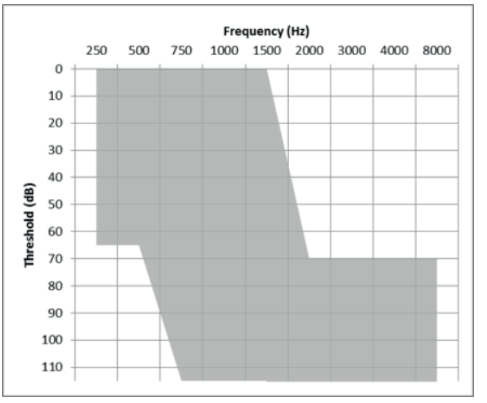


Figure 1: EAS Indication

- Implantation of Cochlear Implants MED-EL CONCERT +FLEX[24] and +FLEX[20] used for EAS is contraindicated for partially deaf individuals with unstable progressive hearing loss, who are unable to use amplification devices, and/or have cochlear malformations.
- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.
- To obtain optimal benefit from the MED-EL CONCERT Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A preoperative assessment according to the local professional standards must be conducted.
- Cochlear implants with MED-EL CONCERT +FLEX[24] are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted with the MED-EL CONCERT Cochlear Implant:

- If the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum and platinum iridium).
- If there is an absence of cochlear development.
- If the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways.
- If external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted.
- If there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required.
- If anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery.
- If the psychological status of the patient is unstable or,
- If the patient has unrealistic expectations.

Undesirable side effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use, if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped[2] between –20 °C (–4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the "use by" date specified on the package. Packaging[3] should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.
- Most water sports should not cause any problem as long as the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In case the MED-EL implant user wants to dive, the user should consult an experienced physician about the possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis[4] can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Inadequate large exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that foudroyantly progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact. The anterior stimulator edge should not be recessed to a depth more than 2 mm.
- Additional immobilization of the implant needs to be done (e.g. with sutures). It should be done in such a way that there will be no postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

  Recommended diameter of the cochleostomy & RW opening:

Electrode type	
MED-EL CONCERT +FLEX[24]	0.8 mm
MED-EL CONCERT +FLEX[20]	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear presurgically.

- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.
- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- Cochlear implantation in partially deaf patients with low frequency hearing carries the risk of partial or total hearing loss which should be clearly explained to the patient by the surgeon prior to implantation. However, studies have shown benefits using electrical stimulation solely in this group of patients even if residual hearing is lost. Etiology, duration of partial deafness, and hearing aid benefit should be taken into consideration and hearing preservation surgical technique should be applied.

Interference with other equipment, robustness of the device in special environments.

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

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.
If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.
If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
  MED-EL Elektromedizinische Geräte GmbH
  Worldwide Headquarters
  Safety adviser for the transport of dangerous goods
  Fürstenweg 77a
  6020 Innsbruck
  Austria

Clinical trial description

The purpose of this prospective, multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the safety and effectiveness of MED-EL's Electric-Acoustic Stimulation (EAS) system. The MED-EL EAS System is a medical device that combines the use of a cochlear implant with an external electric-acoustic audio processor, designed to provide benefit in speech perception and sound quality to individuals who demonstrate significant residual low-frequency hearing and severe to profound high-frequency (above 1500 Hz) sensorineural hearing loss with minimal changes in residual hearing.

Four test conditions were evaluated in order to determine effectiveness of the MED-EL EAS system:

1. Preoperatively; Acoustic Alone (acoustic amplification to the ear to be implanted),
2. Postoperatively; Electric Alone (electric stimulation only to the implanted ear via the MED-EL EAS system without the use of the Acoustic Component),
3. Postoperatively; Combined (simultaneous electric and acoustic stimulation in the implanted ear via the MED-EL EAS system utilizing the Acoustic Component)
4. Postoperatively; Bimodal (electric stimulation only using the MED-EL EAS system without the Acoustic Component, with the addition of contralateral acoustic stimulation).

Of note, the Bimodal condition was only tested in one subject, when that subject lost residual hearing and had thresholds poorer than 80 dB HL at 250 Hz and above in the implanted ear. Audiometric thresholds were also assessed across test intervals in order to measure low-frequency residual hearing postoperatively.

The primary effectiveness endpoint was the improvement in CUNY sentences in noise in the combined electric and acoustic condition at 12 months. The primary safety endpoint was the evaluation of all adverse events reported. Safety data was collected on all implanted subjects.

Seventy-three subjects were implanted with either a PULSAR or a SONATA Cochlear Implant with a FLEX^{24} electrode across 14 investigational sites. Subjects were fit postoperatively with the DUET Audio Processor, combining acoustic amplification and electric stimulation in one device.

The original approval of the study was only for one arm (Arm 1). The second study arm (Arm 2) was added later for subjects with slightly better residual hearing at baseline in the ear to be implanted. Audiologic criteria for the study required subjects to have bilateral residual low-frequency hearing and severe to profound high-frequency sensorineural hearing loss. Subjects in Arm 2 could have slightly better low-frequency thresholds and a CNC word score in quiet of 60 %, as opposed to subjects in Arm 1 who had a CNC word score in quiet of 50 % or poorer. Results are presented here for all subjects, as the data for both arms has now been combined.

Inclusion/exclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

- Normal to moderate sensorineural hearing loss in the low to mid frequencies and sloping severe/profound sensorineural hearing loss in the mid to high frequencies.
- Monosyllabic word scores in quiet of ≤60 % in the best-aided condition.
- Current user of bilateral acoustic hearing aids for at least 3 months.
- Adults 18–70 years of age at time of implantation.
- English was the primary language.

Subjects were excluded from the study for any of the following reasons:

- Conductive, retrocochlear or central auditory disorders.
- Hearing loss in the ear to be implanted that demonstrated a fluctuation at two or more frequencies of 15 dB in either direction in the last 2 years.

- Any physical, psychological, or emotional disorder that interfered with surgery or the ability to perform on test and rehabilitation procedures.
- Developmental delays or organic brain dysfunction.
- Physical or geographic limitations that interfered with the completion of scheduled follow-up evaluations.
- Skin or scalp conditions that precluded magnetic attachment of the speech processor or use of the acoustic hearing aid.

Clinical trial results

Results for 73 subjects are reported. Of the 73 total subjects implanted, 67 completed follow-up at the time of submission. Five subjects withdrew from the study prior to completing the 12-month interval, and one subject was still undergoing testing at the time of submission. The table below provides details on the number of subjects implanted, as well as how many subjects completed each interval.

# of Subjects	Total
Implanted	73
3-Month Post-EAS Activation Evaluation	72
6-Month Post-EAS Activation Evaluation	70
12-Month Post-EAS Activation Evaluation	67

Demographics

The table below provides information on subject demographics, including gender, age at implantation, duration of hearing loss, and duration of hearing aid use.

Parameter/Category or Statistic	Total (n=73)
Gender	
Male	42.5 % (31/73)
Female	57.5 % (42/73)
Age (years)	53.7 (73) (17–76)
Duration of noticeable hearing loss (years)	
Left	25.7 (73) (2–60)
Right	25.7 (73) (2–60)
Duration of hearing aid use (years)	
Left	17.4 (73) (1–48)
Right	17.4 (72) (1–47)

* Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)

Description of tests

Open-set, monosyllabic words were tested using the CNC (Consonant-Nucleus-Consonant) Word Recognition test. Testing was completed in quiet at 70 dB SPL in the soundfield. One list was administered for each condition, and results are reported as a percent correct for words.

Open-set sentence testing was completed using the CUNY (City University of New York) Sentence Test. Subjects were evaluated in noise at 70 dB SPL with varying signal-to-noise ratios that were held constant for each individual subject throughout the duration of the study. One practice list and four test lists were completed for each condition. Scores are reported as the percent correct for words in the sentences.

Subjective benefit 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. Both were completed at post-operative intervals and based on the "everyday listening condition," as subjects were not instructed to ignore input from the non-implanted ear.

Speech Perception Testing

The primary endpoint was based on improvement in speech understanding at 12 months with EAS using sentence tests in noise. The CUNY Sentence Test was used as the outcome measure for this endpoint.

Additional endpoints included comparison of the EAS condition to the cochlear implant alone condition at 12 months on CUNY sentences in noise. The cochlear implant alone condition was also compared to preoperative performance with a hearing aid using CNC words in quiet.

Subjects were tested postoperatively both in the combined "EAS" condition (electric plus acoustic amplification) as well as in the "CI Alone" condition, meaning electrical stimulation only. These results were compared to the preoperative aided condition. Subjects were instructed to remove any contralateral hearing aid for speech perception testing. One subject lost residual hearing immediately following surgery early in the study. She was followed with electric stimulation only in the implanted ear and a contralateral hearing, per the protocol at the time. A second subject lost residual hearing later in the study and was followed only in the cochlear implant condition, as per the updated protocol.

Study Endpoints

Due to withdrawal of five subjects during the follow-up period, as well as one subject who was still undergoing testing at the time of submission, data is available for 67 subjects at the endpoint (12-month interval) for the effectiveness analysis.

For the primary endpoint of improvement on CUNY sentences in noise in the EAS condition, the average preoperative aided score was 31% (±27%) correct. At 12 months, in the EAS condition, subjects scored 73% (±24%) correct. This represents an improvement with EAS of 42 percentage points. This is a significant improvement in CUNY sentence scores in noise in the EAS condition, as compared to the preoperative aided condition.

Two secondary endpoints relating to speech perception were also analyzed. The improvement in CUNY sentences in noise with EAS was compared to the improvement in CUNY sentences in noise with CI Alone. At 12 months, subjects scored 56% (±30%) correct in the CI Alone condition, on average. In the EAS condition, subjects scored an average of 73% (±24%) at 12 months. The addition of acoustic amplification to electric stimulation demonstrated an average improvement of 17 percentage points. Please see the table below for detailed information on subjects' improvement in CUNY sentences scores in noise in both the EAS and CI Alone conditions.

	EAS	CI Alone
CUNY sentence test in noise	Change from baseline	Change from baseline
3 month	30.89 ± 32.41 (66)	17.99 ± 35.00 (67)
6 month	39.03 ± 27.41 (66)	25.06 ± 29.41 (67)
12 month	42.23 ± 29.96 (66)	24.62 ± 31.62 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Additionally, improvement in the CI Alone condition, compared to the preoperative aided condition, was assessed with CNC word score in quiet. Preoperatively, subjects scored 30% (±13%) correct, on average. At 12 months in the CI Alone condition, subjects scored an average of 48% (±19%) correct. This indicates an 18 percentage point improvement with electric stimulation alone. Please see the table below for detailed information on subjects' improvement in CNC word scores in quiet in both the EAS and CI Alone conditions.

	EAS	CI Alone
CNC word score in quiet	Change from baseline	Change from baseline
3 month	30.73 ± 22.36 (66)	9.25 ± 21.92 (67)
6 month	34.48 ± 23.36 (66)	13.31 ± 21.53 (67)
12 month	36.52 ± 23.58 (66)	18.03 ± 23.10 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Subjective Testing
Patients' subjective improvement was measured using the APHAB, as well as the HDSS, and differences in preoperative and postoperative performance are reported.

It should be noted that subjects were not instructed to disregard the non-implanted ear while completing these questionnaires. Thus, the data reported below is based on the everyday, bilateral condition, which may or may not include the use of a hearing aid in the non-implanted ear postoperatively.

On the APHAB questionnaire, 90% of subjects noted a decrease in listening difficulty. On the HDSS, 86% of subjects reported an increase in satisfaction, compared to their preoperative aided condition.

Global scores for the APHAB, representing the percentage of listening difficulty experienced by study subjects decreased by 30.2% (±20.4%) at 12 months, indicating a significant improvement in ease of listening. On the HDSS, the satisfaction patients experience while listening in background noise improved significantly at 12 months, as compared to the preoperative condition. The table below displays the APHAB global score at each interval from baseline through 12 months.

APHAB	Everyday Wearing Condition (Global score)
Preoperative	65.71 ± 15.23 (42)
3 month	41.62 ± 20.94 (47)
6 month	35.98 ± 16.56 (48)
12 month	35.51 ± 14.01 (48)

Benefit
In total, 65/67 subjects (97%) of subjects demonstrated benefit with the EAS device, as measured on either speech perception tests or subjective benefit questionnaires. Based on the group average, subjects in the study performed more than twice as well on both CUNY and CNC testing with EAS compared to the preoperative hearing aid alone. The table below displays the number and proportion of subjects demonstrating the same or better performance on speech perception scores in three postoperative conditions as compared to the preoperative aided condition. The results below are for the following conditions: CUNY sentences in noise with EAS, CUNY sentences in noise with the CI Alone, and CNC words in quiet with the CI Alone.

Time Point	EAS (CUNY)	CI Alone (CUNY)	CI Alone (CNC)
3 month	86% (57/66)	79% (53/67)	77% (52/67)
6 month	95% (63/66)	91% (61/67)	85% (57/67)
12 month	92% (61/66)	87% (58/67)	88% (59/67)

Hearing Sensitivity
Unaided audiologic thresholds were measured throughout the study, from preoperative to the 12-month endpoint. Although hearing preservation was not a defined endpoint in the protocol, the results of post-hoc, descriptive analyses are presented below. Mean preoperative and postoperative residual hearing thresholds are presented, as well as information on the amount of change in residual hearing and postoperative hearing threshold classification.

Hearing loss tended to occur immediately after surgery and remained stable through the follow-up period. On average, a low-frequency pure-tone average threshold (PTA=250, 500, 750, and 1000 Hz) shift of −24.07 dB HL was seen at 12 months. Changes in low-frequency residual hearing ranged between −19.26 dB HL at 250 Hz to −28.28 dB HL at 750 Hz. The figure below demonstrates the average preoperative residual hearing as well as postoperative residual hearing at 12 months for all subjects.

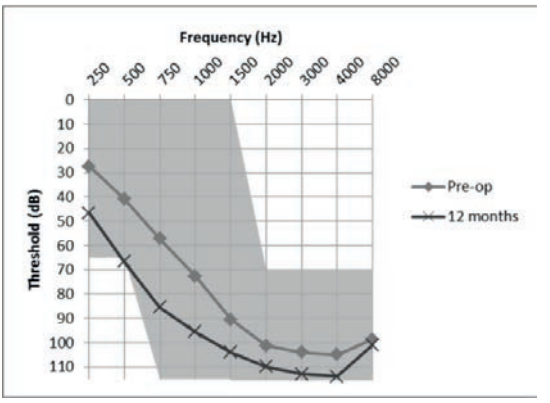


Figure 2: Average pre- and postoperative residual hearing at 12 months for all subjects

Change in residual hearing thresholds can also be described by the proportion of subjects experiencing a particular degree of shift in pure-tone average. The low-frequency threshold shift represents the change in pure-tone threshold at 250, 500, 750, and 1000 Hz. As presented below, 79% of subjects had a PTA shift of less than 30 dB at the 12-month endpoint. As noted above, the average shift in low-frequency PTA was also less than 30 dB (–24.07 dB).

Time Point	< 10 dB	10-20 dB	20–30 dB	> 30 dB
Month 3	10/71 (14.08%)	30/71 (42.25%)	18/71 (25.35%)	13/71 (18.31%)
Month 6	11/69 (15.94%)	23/69 (33.33%)	20/69 (28.99%)	15/69 (21.74%)
Month 12	8/67 (11.94%)	25/67 (37.31%)	20/67 (29.85%)	14/67 (20.90%)
Month 60				

Postoperative residual hearing can also be classified according to the degree of hearing loss as measured by a low-frequency PTA. As can be seen in the table below, 12% of EAS subjects had profound (or total) hearing loss at the 12-month endpoint. The proportion of subjects by degree of postoperative hearing loss is displayed below.

Time Point	Normal	Mild	Moderate	Moderate-Severe	Severe	Profound
Month 3	0/71 (0%)	2/71 (2.82%)	7/71 (9.86%)	30/71 (42.25%)	28/71 (39.44%)	4/71 (5.63%)
Month 6	0/69 (0%)	2/69 (2.90%)	9/69 (13.04%)	26/69 (37.68%)	26/69 (37.68%)	6/69 (8.70%)
Month 12	0/67 (0%)	2/67 (2.99%)	5/67 (7.46%)	28/67 (41.79%)	24/67 (35.82%)	8/67 (11.94%)
Month 60						

Postoperative low-frequency hearing thresholds were also used to determine whether or not subjects would be fit with the acoustic unit of the DUET Audio Processor and followed in that condition. The protocol specified that subjects would be fit with the acoustic unit if any low-frequency threshold was 80 dB or better. Based on this, 97% (65/67) of all subjects in the clinical trial were fit with the acoustic unit and followed in the EAS condition through the 12-month endpoint.

Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated.

A total of 57 adverse events were reported. Thirty-five adverse events occurring in 29 subjects were reported as related to either the device or the procedure. Of the 35 device-related adverse events, 22 were related to changes, either transient or permanent, in residual hearing or the middle ear.

Twelve adverse events were reported to be serious, occurring in 12 of the 73 subjects. Eleven of the 12 serious adverse events were reported to be related to the study device or procedure, eight of which involved changes to residual hearing. One adverse event was reported as a decrease in residual hearing and, therefore, serious). At the subsequent follow-up visit, however, the hearing thresholds in this case had improved and would no longer be considered a serious adverse event. One additional serious adverse event was reported as beeping or ringing in the ear. No unanticipated adverse events were reported.

Details on the type and number of device-related adverse events can be found below:

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects	% Resolved
Type B or Type C tympanogram	8	6	8%	100%
Profound/total loss of residual hearing	8	8	11%	0%
Conductive hearing loss	5	5	7%	0%
Pain at site	3	3	4%	67%
Electrode lead breakage after excessive micro-movements, caused by patient massaging area	1	1	1%	100%
Electrode migration	1	1	1%	100%
Occasionally off-balance	1	1	1%	100%
Ulnar nerve palsy after operation	1	1	1%	100%
Telemetry showed high status on electrode channels	1	1	1%	0%
Facial stimulation	1	1	1%	100%
Aural fullness	1	1	1%	100%
Sensation of device shifting when pushing over the implant site	1	1	1%	100%
Temporary shift in hearing threshold	1	1	1%	100%
Beeping/ringing in implanted ear	1	1	1%	0%
Bitter taste on right side of tongue	1	1	1%	100%
Total	35	29*	39,7%	574%

*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.

Symbols

CE mark. First applied in 2010

Single-use device. Do not reuse!

Catalogue number

Serial number

Caution! Consult accompanying documents

Sterilized using Ethylene Oxide

"Use by" date

Manufacturing date

Manufacturer

MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

1 This Instructions for Use refers to MED-EL CONCERT Implants with +FLEX^{24} or +FLEX^{20} electrodes.

2 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).

3 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.

4 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

USA Distributor
MED-EL Corporation, USA
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.

CE 0123

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a | 6020 Innsbruck, Austria
office@medel.com

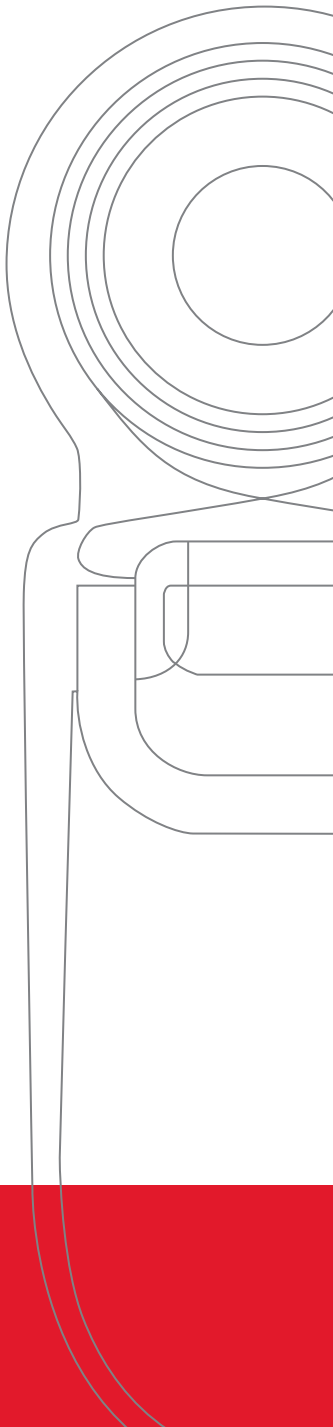
medel.com

MED-EL

Mi1000 MED-EL CONCERT PIN Cochlear Implant

+FLEX^{24} | +FLEX^{20}

English



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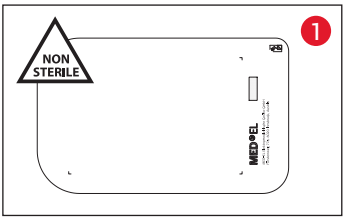
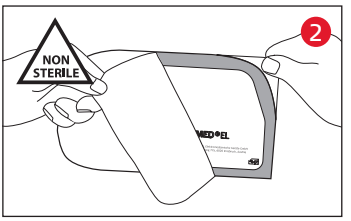
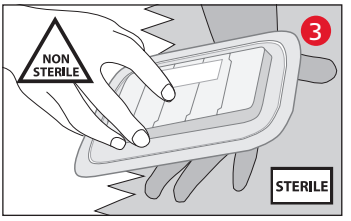
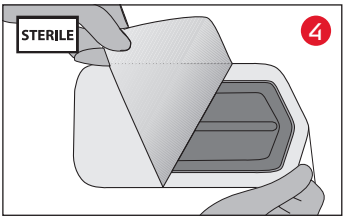
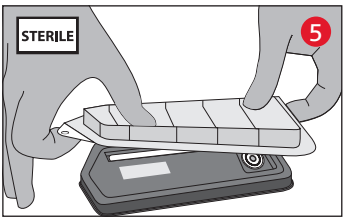
Opening instruction

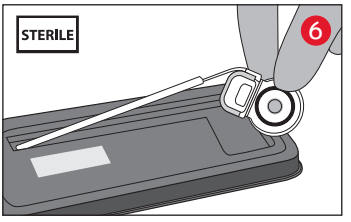


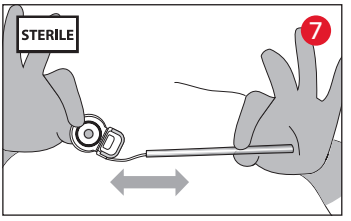




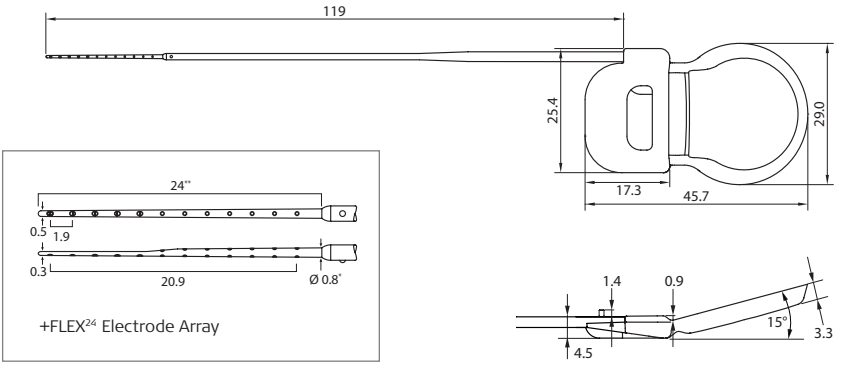








MED-EL CONCERT PIN +FLEX^{24}



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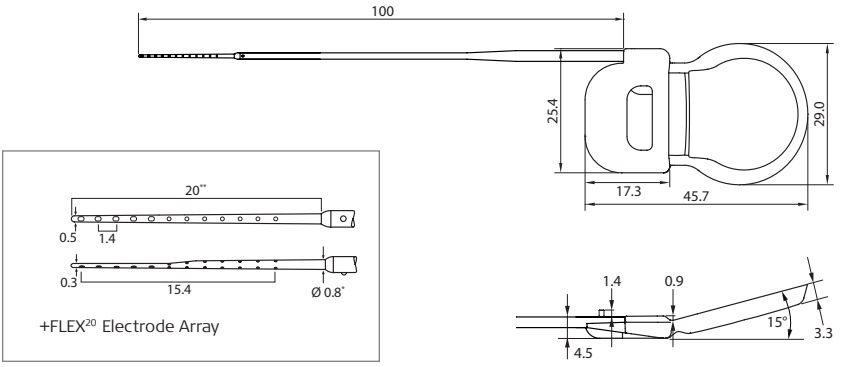


Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

Instructions for use

Mi1000 MED-EL CONCERT PIN Cochlear Implant

Device description

The Mi1000 MED-EL CONCERT PIN Implant (hereafter referred to as MED-EL CONCERT PIN) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external com-ponents. The device consists of a stimulator, a coil with a magnet within its center, a reference electrode, an EAP ref-erence electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family MED-EL CONCERT PIN)[1]. This device is intended to be implanted by ade-quately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).
For principal dimensions of the implant refer to the drawings on the previous pages.
The volume of the implant without electrode is 3.7 cm^3.
Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium and titanium.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
  Maximum current amplitude: Median value = 1250 µA, range = 500 µA
  Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to MED-EL application software user manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent elec-trode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm^2.

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+FLEX^{24}	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9
+FLEX^{20}	100 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.4	15.4

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal MED-EL CONCERT PIN Cochlear Implant with either a +FLEX^{24} or +FLEX^{20} electrode variant which together make up the MED-EL EAS System.

Indications

The MED-EL CONCERT PIN shares the same indications for use as the COMBI 40+ System.

- Adults, eighteen (18) years of age or older, who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences).
- Children aged twelve (12) months to seventeen (17) years and eleven (11) months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three (3) to six (6) month period. In older children, lack of aid benefit is defined as <20 % correct on the Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills. A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.
- Cochlear implants with MED-EL CONCERT PIN +FLEX^{24} and +FLEX^{20} for EAS indication are 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.

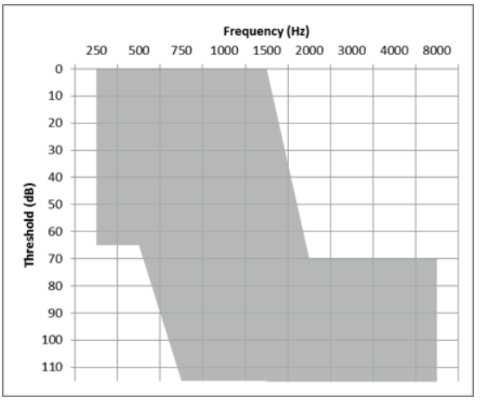


Figure 1: EAS Indication

- Implantation of Cochlear Implants MED-EL CONCERT PIN +FLEX^{24} and +FLEX^{20} used for EAS is contraindicated for partially deaf individuals with unstable progressive hearing loss, who are unable to use amplification devices, and/or have cochlear malformations.
- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.
- To obtain optimal benefit from the MED-EL CONCERT PIN Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A preoperative assessment according to the local professional standards must be conducted.
- Cochlear implants with MED-EL CONCERT PIN +FLEX^{24} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted with the MED-EL CONCERT PIN Cochlear Implant:

- If the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, platinum iridium and titanium).
- If there is an absence of cochlear development.
- If the cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways.
- If external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted.
- If there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required.
- If anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery.
- If the psychological status of the patient is unstable or,
- If the patient has unrealistic expectations.

Undesirable side effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use, if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped[2] between –20 °C (–4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the "use by" date specified on the package. Packaging[3] should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.
- Most water sports should not cause any problem as long as the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In case the MED-EL implant user wants to dive, the user should consult an experienced physician about the possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis[4] can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Inadequate large exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that foudroyantly progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The area of the stimulator on the temporal bone shall be flattened in order to secure sufficient immobilization of the implant. The two pins of the MED-EL CONCERT PIN Cochlear Implant should be recessed into the skull with the PIN Drill Guide SI to a depth of 1.5 mm. Also the electrode lead should be protected in a ramp-like bony channel drilled into the skull without sharp edges. Both should be done in such a way that there will be no postoperative movement.
- The two pins give additional stability against translational and rotational motion. Recessing the pins and efficient immobilization of the stimulator (e.g. with sutures) is important to prevent postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

  Recommended diameter of the cochleostomy & RW opening:

Electrode type	
MED-EL CONCERT PIN +FLEX[24]	0.8 mm
MED-EL CONCERT PIN +FLEX[20]	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear presurgically.

- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.
- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- Cochlear implantation in partially deaf patients with low frequency hearing carries the risk of partial or total hearing loss which should be clearly explained to the patient by the surgeon prior to implantation. However, studies have shown benefits using electrical stimulation solely in this group of patients even if residual hearing is lost. Etiology, duration of partial deafness, and hearing aid benefit should be taken into consideration and hearing preservation surgical technique should be applied.

Interference with other equipment, robustness of the device in special environments.

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

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.
If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.
If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
  MED-EL Elektromedizinische Geräte GmbH
  Worldwide Headquarters
  Safety adviser for the transport of dangerous goods
  Fürstenweg 77a
  6020 Innsbruck
  Austria

Clinical trial description

The purpose of this prospective, multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the safety and effectiveness of MED-EL's Electric-Acoustic Stimulation (EAS) system. The MED-EL EAS System is a medical device that combines the use of a cochlear implant with an external electric-acoustic audio processor, designed to provide benefit in speech perception and sound quality to individuals who demonstrate significant residual low-frequency hearing and severe to profound high-frequency (above 1500 Hz) sensorineural hearing loss with minimal changes in residual hearing.

Four test conditions were evaluated in order to determine effectiveness of the MED-EL EAS system:

1. Preoperatively; Acoustic Alone (acoustic amplification to the ear to be implanted),
2. Postoperatively; Electric Alone (electric stimulation only to the implanted ear via the MED-EL EAS system without the use of the Acoustic Component),
3. Postoperatively; Combined (simultaneous electric and acoustic stimulation in the implanted ear via the MED-EL EAS system utilizing the Acoustic Component)
4. Postoperatively; Bimodal (electric stimulation only using the MED-EL EAS system without the Acoustic Component, with the addition of contralateral acoustic stimulation).

Of note, the Bimodal condition was only tested in one subject, when that subject lost residual hearing and had thresholds poorer than 80 dB HL at 250 Hz and above in the implanted ear. Audiometric thresholds were also assessed across test intervals in order to measure low-frequency residual hearing postoperatively.

The primary effectiveness endpoint was the improvement in CUNY sentences in noise in the combined electric and acoustic condition at 12 months. The primary safety endpoint was the evaluation of all adverse events reported. Safety data was collected on all implanted subjects.

Seventy-three subjects were implanted with either a PULSAR or a SONATA Cochlear Implant with a FLEX^{24} electrode across 14 investigational sites. Subjects were fit postoperatively with the DUET Audio Processor, combining acoustic amplification and electric stimulation in one device.

The original approval of the study was only for one arm (Arm 1). The second study arm (Arm 2) was added later for subjects with slightly better residual hearing at baseline in the ear to be implanted. Audiologic criteria for the study required subjects to have bilateral residual low-frequency hearing and severe to profound high-frequency sensorineural hearing loss. Subjects in Arm 2 could have slightly better low-frequency thresholds and a CNC word score in quiet of 60 %, as opposed to subjects in Arm 1 who had a CNC word score in quiet of 50 % or poorer. Results are presented here for all subjects, as the data for both arms has now been combined.

Inclusion/exclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

- Normal to moderate sensorineural hearing loss in the low to mid frequencies and sloping severe/profound sensorineural hearing loss in the mid to high frequencies.
- Monosyllabic word scores in quiet of ≤60 % in the best-aided condition.
- Current user of bilateral acoustic hearing aids for at least 3 months.
- Adults 18–70 years of age at time of implantation.
- English was the primary language.

Subjects were excluded from the study for any of the following reasons:

- Conductive, retrocochlear or central auditory disorders.
- Hearing loss in the ear to be implanted that demonstrated a fluctuation at two or more frequencies of 15 dB in either direction in the last 2 years.

- Any physical, psychological, or emotional disorder that interfered with surgery or the ability to perform on test and rehabilitation procedures.
- Developmental delays or organic brain dysfunction.
- Physical or geographic limitations that interfered with the completion of scheduled follow-up evaluations.
- Skin or scalp conditions that precluded magnetic attachment of the speech processor or use of the acoustic hearing aid.

Clinical trial results

Results for 73 subjects are reported. Of the 73 total subjects implanted, 67 completed follow-up at the time of submission. Five subjects withdrew from the study prior to completing the 12-month interval, and one subject was still undergoing testing at the time of submission. The table below provides details on the number of subjects implanted, as well as how many subjects completed each interval.

# of Subjects	Total
Implanted	73
3-Month Post-EAS Activation Evaluation	72
6-Month Post-EAS Activation Evaluation	70
12-Month Post-EAS Activation Evaluation	67

Demographics

The table below provides information on subject demographics, including gender, age at implantation, duration of hearing loss, and duration of hearing aid use.

Parameter/Category or Statistic	Total (n=73)
Gender	
Male	42.5 % (31/73)
Female	57.5 % (42/73)
Age (years)	53.7 (73) (17–76)
Duration of noticeable hearing loss (years)	
Left	25.7 (73) (2–60)
Right	25.7 (73) (2–60)
Duration of hearing aid use (years)	
Left	17.4 (73) (1–48)
Right	17.4 (72) (1–47)

* Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)

Description of tests

Open-set, monosyllabic words were tested using the CNC (Consonant-Nucleus-Consonant) Word Recognition test. Testing was completed in quiet at 70 dB SPL in the soundfield. One list was administered for each condition, and results are reported as a percent correct for words.

Open-set sentence testing was completed using the CUNY (City University of New York) Sentence Test. Subjects were evaluated in noise at 70 dB SPL with varying signal-to-noise ratios that were held constant for each individual subject throughout the duration of the study. One practice list and four test lists were completed for each condition. Scores are reported as the percent correct for words in the sentences.

Subjective benefit 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. Both were completed at post-operative intervals and based on the "everyday listening condition," as subjects were not instructed to ignore input from the non-implanted ear.

Speech Perception Testing

The primary endpoint was based on improvement in speech understanding at 12 months with EAS using sentence tests in noise. The CUNY Sentence Test was used as the outcome measure for this endpoint.

Additional endpoints included comparison of the EAS condition to the cochlear implant alone condition at 12 months on CUNY sentences in noise. The cochlear implant alone condition was also compared to preoperative performance with a hearing aid using CNC words in quiet.

Subjects were tested postoperatively both in the combined "EAS" condition (electric plus acoustic amplification) as well as in the "CI Alone" condition, meaning electrical stimulation only. These results were compared to the preoperative aided condition. Subjects were instructed to remove any contralateral hearing aid for speech perception testing. One subject lost residual hearing immediately following surgery early in the study. She was followed with electric stimulation only in the implanted ear and a contralateral hearing, per the protocol at the time. A second subject lost residual hearing later in the study and was followed only in the cochlear implant condition, as per the updated protocol.

Study Endpoints

Due to withdrawal of five subjects during the follow-up period, as well as one subject who was still undergoing testing at the time of submission, data is available for 67 subjects at the endpoint (12-month interval) for the effectiveness analysis.

For the primary endpoint of improvement on CUNY sentences in noise in the EAS condition, the average preoperative aided score was 31% (±27%) correct. At 12 months, in the EAS condition, subjects scored 73% (±24%) correct. This represents an improvement with EAS of 42 percentage points. This is a significant improvement in CUNY sentence scores in noise in the EAS condition, as compared to the preoperative aided condition.

Two secondary endpoints relating to speech perception were also analyzed. The improvement in CUNY sentences in noise with EAS was compared to the improvement in CUNY sentences in noise with CI Alone. At 12 months, subjects scored 56% (±30%) correct in the CI Alone condition, on average. In the EAS condition, subjects scored an average of 73% (±24%) at 12 months. The addition of acoustic amplification to electric stimulation demonstrated an average improvement of 17 percentage points. Please see the table below for detailed information on subjects' improvement in CUNY sentences scores in noise in both the EAS and CI Alone conditions.

	EAS	CI Alone
CUNY sentence test in noise	Change from baseline	Change from baseline
3 month	30.89 ± 32.41 (66)	17.99 ± 35.00 (67)
6 month	39.03 ± 27.41 (66)	25.06 ± 29.41 (67)
12 month	42.23 ± 29.96 (66)	24.62 ± 31.62 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Additionally, improvement in the CI Alone condition, compared to the preoperative aided condition, was assessed with CNC word score in quiet. Preoperatively, subjects scored 30% (±13%) correct, on average. At 12 months in the CI Alone condition, subjects scored an average of 48% (±19%) correct. This indicates an 18 percentage point improvement with electric stimulation alone. Please see the table below for detailed information on subjects' improvement in CNC word scores in quiet in both the EAS and CI Alone conditions.

	EAS	CI Alone
CNC word score in quiet	Change from baseline	Change from baseline
3 month	30.73 ± 22.36 (66)	9.25 ± 21.92 (67)
6 month	34.48 ± 23.36 (66)	13.31 ± 21.53 (67)
12 month	36.52 ± 23.58 (66)	18.03 ± 23.10 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Subjective Testing
Patients' subjective improvement was measured using the APHAB, as well as the HDSS, and differences in preoperative and postoperative performance are reported.

It should be noted that subjects were not instructed to disregard the non-implanted ear while completing these questionnaires. Thus, the data reported below is based on the everyday, bilateral condition, which may or may not include the use of a hearing aid in the non-implanted ear postoperatively.

On the APHAB questionnaire, 90% of subjects noted a decrease in listening difficulty. On the HDSS, 86% of subjects reported an increase in satisfaction, compared to their preoperative aided condition.

Global scores for the APHAB, representing the percentage of listening difficulty experienced by study subjects decreased by 30.2% (±20.4%) at 12 months, indicating a significant improvement in ease of listening. On the HDSS, the satisfaction patients experience while listening in background noise improved significantly at 12 months, as compared to the preoperative condition. The table below displays the APHAB global score at each interval from baseline through 12 months.

APHAB	Everyday Wearing Condition (Global score)
Preoperative	65.71 ± 15.23 (42)
3 month	41.62 ± 20.94 (47)
6 month	35.98 ± 16.56 (48)
12 month	35.51 ± 14.01 (48)

Benefit
In total, 65/67 subjects (97%) of subjects demonstrated benefit with the EAS device, as measured on either speech perception tests or subjective benefit questionnaires. Based on the group average, subjects in the study performed more than twice as well on both CUNY and CNC testing with EAS compared to the preoperative hearing aid alone. The table below displays the number and proportion of subjects demonstrating the same or better performance on speech perception scores in three postoperative conditions as compared to the preoperative aided condition. The results below are for the following conditions: CUNY sentences in noise with EAS, CUNY sentences in noise with the CI Alone, and CNC words in quiet with the CI Alone.

Time Point	EAS (CUNY)	CI Alone (CUNY)	CI Alone (CNC)
3 month	86% (57/66)	79% (53/67)	77% (52/67)
6 month	95% (63/66)	91% (61/67)	85% (57/67)
12 month	92% (61/66)	87% (58/67)	88% (59/67)

Hearing Sensitivity
Unaided audiologic thresholds were measured throughout the study, from preoperative to the 12-month endpoint. Although hearing preservation was not a defined endpoint in the protocol, the results of post-hoc, descriptive analyses are presented below. Mean preoperative and postoperative residual hearing thresholds are presented, as well as information on the amount of change in residual hearing and postoperative hearing threshold classification.

Hearing loss tended to occur immediately after surgery and remained stable through the follow-up period. On average, a low-frequency pure-tone average threshold (PTA=250, 500, 750, and 1000 Hz) shift of −24.07 dB HL was seen at 12 months. Changes in low-frequency residual hearing ranged between −19.26 dB HL at 250 Hz to −28.28 dB HL at 750 Hz. The figure below demonstrates the average preoperative residual hearing as well as postoperative residual hearing at 12 months for all subjects.

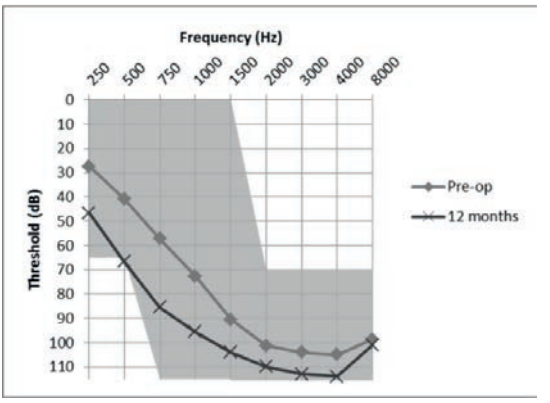


Figure 2: Average pre- and postoperative residual hearing at 12 months for all subjects

Change in residual hearing thresholds can also be described by the proportion of subjects experiencing a particular degree of shift in pure-tone average. The low-frequency threshold shift represents the change in pure-tone threshold at 250, 500, 750, and 1000 Hz. As presented below, 79% of subjects had a PTA shift of less than 30 dB at the 12-month endpoint. As noted above, the average shift in low-frequency PTA was also less than 30 dB (–24.07 dB).

Time Point	< 10 dB	10-20 dB	20–30 dB	> 30 dB
Month 3	10/71 (14.08%)	30/71 (42.25%)	18/71 (25.35%)	13/71 (18.31%)
Month 6	11/69 (15.94%)	23/69 (33.33%)	20/69 (28.99%)	15/69 (21.74%)
Month 12	8/67 (11.94%)	25/67 (37.31%)	20/67 (29.85%)	14/67 (20.90%)
Month 60				

Postoperative residual hearing can also be classified according to the degree of hearing loss as measured by a low-frequency PTA. As can be seen in the table below, 12% of EAS subjects had profound (or total) hearing loss at the 12-month endpoint. The proportion of subjects by degree of postoperative hearing loss is displayed below.

Time Point	Normal	Mild	Moderate	Moderate-Severe	Severe	Profound
Month 3	0/71 (0%)	2/71 (2.82%)	7/71 (9.86%)	30/71 (42.25%)	28/71 (39.44%)	4/71 (5.63%)
Month 6	0/69 (0%)	2/69 (2.90%)	9/69 (13.04%)	26/69 (37.68%)	26/69 (37.68%)	6/69 (8.70%)
Month 12	0/67 (0%)	2/67 (2.99%)	5/67 (7.46%)	28/67 (41.79%)	24/67 (35.82%)	8/67 (11.94%)
Month 60						

Postoperative low-frequency hearing thresholds were also used to determine whether or not subjects would be fit with the acoustic unit of the DUET Audio Processor and followed in that condition. The protocol specified that subjects would be fit with the acoustic unit if any low-frequency threshold was 80 dB or better. Based on this, 97% (65/67) of all subjects in the clinical trial were fit with the acoustic unit and followed in the EAS condition through the 12-month endpoint.

Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated.

A total of 57 adverse events were reported. Thirty-five adverse events occurring in 29 subjects were reported as related to either the device or the procedure. Of the 35 device-related adverse events, 22 were related to changes, either transient or permanent, in residual hearing or the middle ear.

Twelve adverse events were reported to be serious, occurring in 12 of the 73 subjects. Eleven of the 12 serious adverse events were reported to be related to the study device or procedure, eight of which involved changes to residual hearing. One adverse event was reported as a decrease in residual hearing and, therefore, serious). At the subsequent follow-up visit, however, the hearing thresholds in this case had improved and would no longer be considered a serious adverse event. One additional serious adverse event was reported as beeping or ringing in the ear. No unanticipated adverse events were reported.

Details on the type and number of device-related adverse events can be found below:

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects	% Resolved
Type B or Type C tympanogram	8	6	8%	100%
Profound/total loss of residual hearing	8	8	11%	0%
Conductive hearing loss	5	5	7%	0%
Pain at site	3	3	4%	67%
Electrode lead breakage after excessive micro-movements, caused by patient massaging area	1	1	1%	100%
Electrode migration	1	1	1%	100%
Occasionally off-balance	1	1	1%	100%
Ulnar nerve palsy after operation	1	1	1%	100%
Telemetry showed high status on electrode channels	1	1	1%	0%
Facial stimulation	1	1	1%	100%
Aural fullness	1	1	1%	100%
Sensation of device shifting when pushing over the implant site	1	1	1%	100%
Temporary shift in hearing threshold	1	1	1%	100%
Beeping/ringing in implanted ear	1	1	1%	0%
Bitter taste on right side of tongue	1	1	1%	100%
Total	35	29*	39,7%	574%

*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.

Symbols

CE mark. First applied in 2010

Single-use device. Do not reuse!

REF Catalogue number

SN Serial number

Caution! Consult accompanying documents

STERILE EO Sterilized using Ethylene Oxide

"Use by" date

Manufacturing date

Manufacturer

MR MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

1 This Instructions for Use refers to MED-EL CONCERT PIN Implants with +FLEX^{24} or +FLEX^{20} electrodes.

2 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).

3 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.

4 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

USA Distributor
MED-EL Corporation, USA
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.

CE 0123

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a | 6020 Innsbruck, Austria
office@medel.com

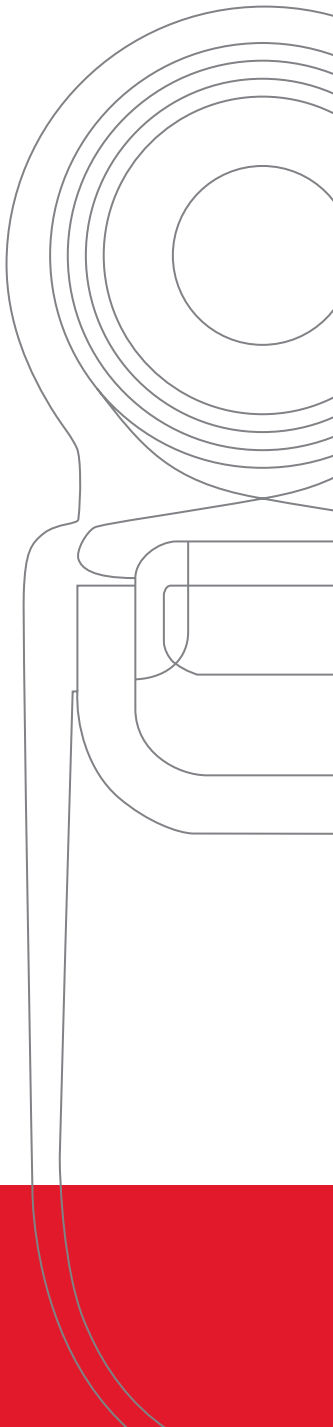
medel.com

MED EL

Mi1200 SYNCHRONY Cochlear Implant

+FLEX^{24} | +FLEX^{20}

English



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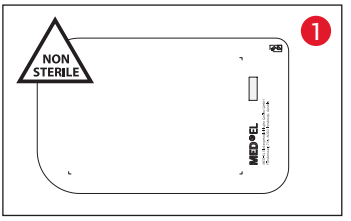
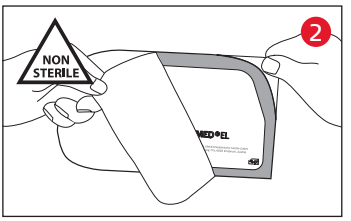
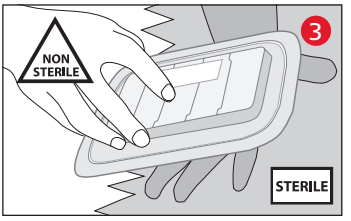
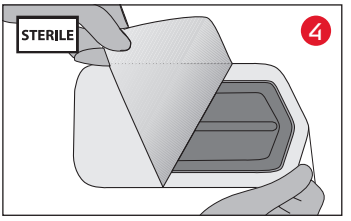
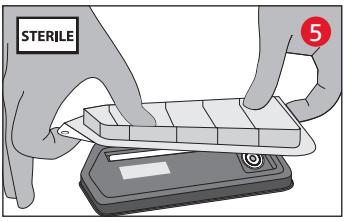
Opening instruction

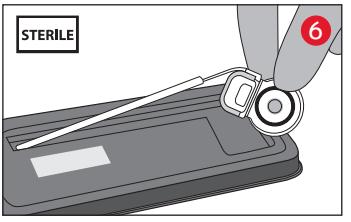


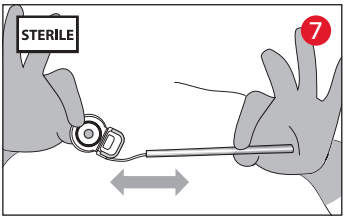




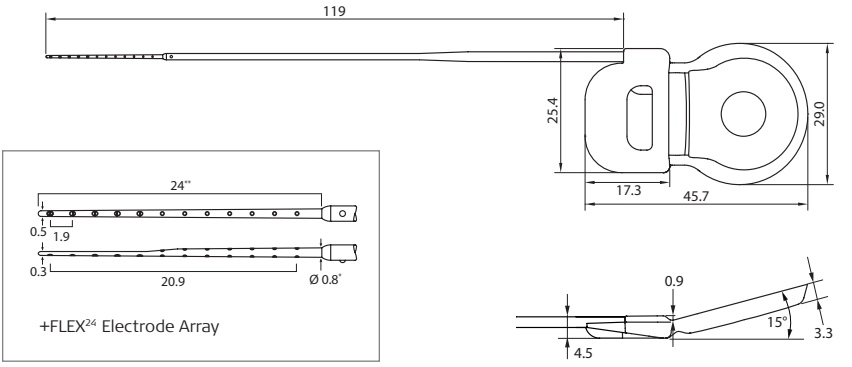




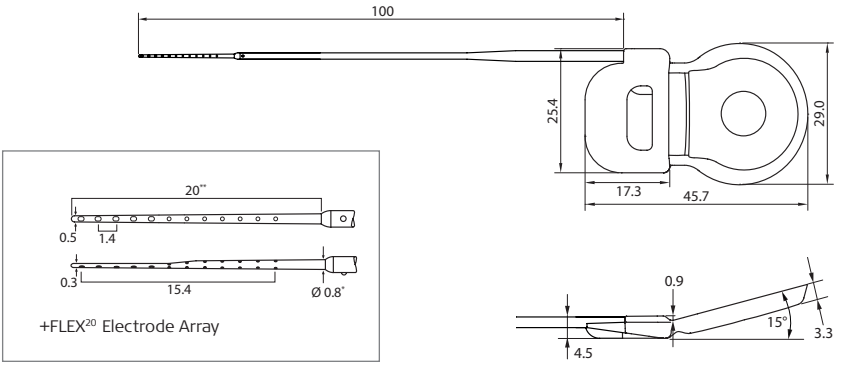




SYNCHRONY +FLEX^{24}



SYNCHRONY +FLEX^{20}



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

Instructions for use

Mi1200 SYNCHRONY Cochlear Implant

Device description

The Mi1200 SYNCHRONY Implant (hereafter referred to as SYNCHRONY) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a removable magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SYNCHRONY)[1]. This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).
For principal dimensions of the implant refer to the drawings on the previous pages.
The volume of the implant without electrode is 3.7 cm^3.
Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium and parylene c.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
  Maximum current amplitude: Median value = 1250 µA, range = 500 µA
  Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to MED-EL application software user manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm^2.

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+FLEX^{24}	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9
+FLEX^{20}	100 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.4	15.4

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal SYNCHRONY Cochlear Implant with either a +FLEX^{24} or +FLEX^{20} electrode variant which together make up the MED-EL EAS System.

Indications

- Adults, eighteen (18) years of age or older, who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences).
- Children aged twelve (12) months to seventeen (17) years and eleven (11) months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three (3) to six (6) month period. In older children, lack of aid benefit is defined as <20 % correct on the Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills. A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.
- Cochlear implants with SYNCHRONY +FLEX^{24} and +FLEX^{20} for EAS indication are 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.

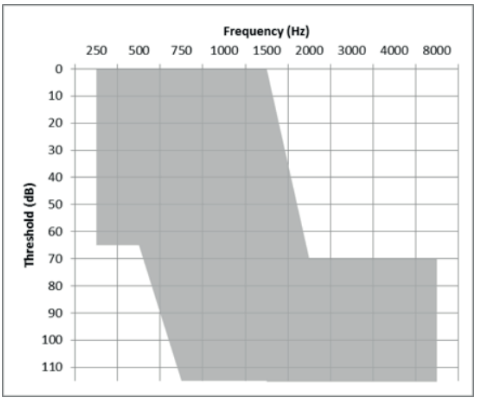


Figure 1: EAS Indication

- Implantation of Cochlear Implants SYNCHRONY +FLEX^{24} and +FLEX^{20} used for EAS is contraindicated for partially deaf individuals with unstable progressive hearing loss, who are unable to use amplification devices, and/or have cochlear malformations.
- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.
- To obtain optimal benefit from the SYNCHRONY Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A preoperative assessment according to the local professional standards must be conducted.
- Cochlear implants with SYNCHRONY +FLEX^{24} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted:

- If the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, platinum iridium and parylene c).
- If there is an absence of cochlear development.
- If the cause of deafness is non-functionality of the auditory nerve and /or the auditory pathways.
- If external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted.
- If there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required.
- If anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery.
- If the psychological status of the patient is unstable or,
- If the patient has unrealistic expectations.

Undesirable side effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use, if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped[2] between −20 °C (−4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the "use by" date specified on the package. Packaging[3] should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable Audio Processor please consult the Audio Processor User Manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.
- Most water sports should not cause any problem as long as the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In case the MED-EL implant user wants to dive, the user should consult an experienced physician about the possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, ne-

crosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis[4] can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.

- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Inadequate large exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuroradiological follow-up in cases of fractures of the anterior skull base have shown that foudroyantly progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact. The anterior stimulator edge should not be recessed to a depth more than 2 mm.
- Additional immobilization of the implant needs to be done (e.g. with sutures). It should be done in such a way that there will be no postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

  Recommended diameter of the cochleostomy & RW opening:

Electrode type	
SYNCHRONY +FLEX^{24}	0.8 mm
SYNCHRONY +FLEX^{20}	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.

- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- Cochlear implantation in partially deaf patients with low frequency hearing carries the risk of partial or total hearing loss which should be clearly explained to the patient by the surgeon prior to implantation. However, studies have shown benefits using electrical stimulation solely in this group of patients even if residual hearing is lost. Etiology, duration of partial deafness, and hearing aid benefit should be taken into consideration and hearing preservation surgical technique should be applied.
- In case of a magnet exchange surgery MED-EL recommends the use of the following tools: The Magnet Removal Tool Ms050206 or the Magnet Insertion Tool Ms050205 can be used in combination with the Non-Magnetic Spacer Ms010107 or the Replacement Magnet Ms010108. Please refer to the applicable Instructions for Use of these devices for further surgical precautions and warnings.
- After removal of the Non-Magnetic Spacer Ms010107, make sure that a fresh Replacement Magnet Ms010108 is inserted to re-establish full functionality of the implant.

Interference with other equipment, robustness of the device in special environments.

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

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.
If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.
If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
  MED-EL Elektromedizinische Geräte GmbH
  Worldwide Headquarters
  Safety adviser for the transport of dangerous goods
  Fürstenweg 77a
  6020 Innsbruck
  Austria

Clinical trial description

The purpose of this prospective, multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the safety and effectiveness of MED-EL's Electric-Acoustic Stimulation (EAS) system. The MED-EL EAS System is a medical device that combines the use of a cochlear implant with an external electric-acoustic audio processor, designed to provide benefit in speech perception and sound quality to individuals who demonstrate significant residual low-frequency hearing and severe to profound high-frequency (above 1500 Hz) sensorineural hearing loss with minimal changes in residual hearing.

Four test conditions were evaluated in order to determine effectiveness of the MED-EL EAS system:

1. Preoperatively; Acoustic Alone (acoustic amplification to the ear to be implanted),
2. Postoperatively; Electric Alone (electric stimulation only to the implanted ear via the MED-EL EAS system without the use of the Acoustic Component),
3. Postoperatively; Combined (simultaneous electric and acoustic stimulation in the implanted ear via the MED-EL EAS system utilizing the Acoustic Component)
4. Postoperatively; Bimodal (electric stimulation only using the MED-EL EAS system without the Acoustic Component, with the addition of contralateral acoustic stimulation).

Of note, the Bimodal condition was only tested in one subject, when that subject lost residual hearing and had thresholds poorer than 80 dB HL at 250 Hz and above in the implanted ear. Audiometric thresholds were also assessed across test intervals in order to measure low-frequency residual hearing postoperatively.

The primary effectiveness endpoint was the improvement in CUNY sentences in noise in the combined electric and acoustic condition at 12 months. The primary safety endpoint was the evaluation of all adverse events reported. Safety data was collected on all implanted subjects.

Seventy-three subjects were implanted with either a PULSAR or a SONATA Cochlear Implant with a FLEX^{24} electrode across 14 investigational sites. Subjects were fit postoperatively with the DUET Audio Processor, combining acoustic amplification and electric stimulation in one device.

The original approval of the study was only for one arm (Arm 1). The second study arm (Arm 2) was added later for subjects with slightly better residual hearing at baseline in the ear to be implanted. Audiologic criteria for the study required subjects to have bilateral residual low-frequency hearing and severe to profound high-frequency sensorineural hearing loss. Subjects in Arm 2 could have slightly better low-frequency thresholds and a CNC word score in quiet of 60 %, as opposed to subjects in Arm 1 who had a CNC word score in quiet of 50 % or poorer. Results are presented here for all subjects, as the data for both arms has now been combined.

Inclusion/exclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

- Normal to moderate sensorineural hearing loss in the low to mid frequencies and sloping severe/profound sensorineural hearing loss in the mid to high frequencies.
- Monosyllabic word scores in quiet of ≤60 % in the best-aided condition.
- Current user of bilateral acoustic hearing aids for at least 3 months.
- Adults 18–70 years of age at time of implantation.
- English was the primary language.

Subjects were excluded from the study for any of the following reasons:

- Conductive, retrocochlear or central auditory disorders.
- Hearing loss in the ear to be implanted that demonstrated a fluctuation at two or more frequencies of 15 dB in either direction in the last 2 years.

- Any physical, psychological, or emotional disorder that interfered with surgery or the ability to perform on test and rehabilitation procedures.
- Developmental delays or organic brain dysfunction.
- Physical or geographic limitations that interfered with the completion of scheduled follow-up evaluations.
- Skin or scalp conditions that precluded magnetic attachment of the speech processor or use of the acoustic hearing aid.

Clinical trial results

Results for 73 subjects are reported. Of the 73 total subjects implanted, 67 completed follow-up at the time of submission. Five subjects withdrew from the study prior to completing the 12-month interval, and one subject was still undergoing testing at the time of submission. The table below provides details on the number of subjects implanted, as well as how many subjects completed each interval.

# of Subjects	Total
Implanted	73
3-Month Post-EAS Activation Evaluation	72
6-Month Post-EAS Activation Evaluation	70
12-Month Post-EAS Activation Evaluation	67

Demographics

The table below provides information on subject demographics, including gender, age at implantation, duration of hearing loss, and duration of hearing aid use.

Parameter/Category or Statistic	Total (n=73)
Gender	
Male	42.5 % (31/73)
Female	57.5 % (42/73)
Age (years)	53.7 (73) (17–76)
Duration of noticeable hearing loss (years)	
Left	25.7 (73) (2–60)
Right	25.7 (73) (2–60)
Duration of hearing aid use (years)	
Left	17.4 (73) (1–48)
Right	17.4 (72) (1–47)

* Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)

Description of tests

Open-set, monosyllabic words were tested using the CNC (Consonant-Nucleus-Consonant) Word Recognition test. Testing was completed in quiet at 70 dB SPL in the soundfield. One list was administered for each condition, and results are reported as a percent correct for words.

Open-set sentence testing was completed using the CUNY (City University of New York) Sentence Test. Subjects were evaluated in noise at 70 dB SPL with varying signal-to-noise ratios that were held constant for each individual subject throughout the duration of the study. One practice list and four test lists were completed for each condition. Scores are reported as the percent correct for words in the sentences.

Subjective benefit 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. Both were completed at post-operative intervals and based on the "everyday listening condition," as subjects were not instructed to ignore input from the non-implanted ear.

Speech Perception Testing

The primary endpoint was based on improvement in speech understanding at 12 months with EAS using sentence tests in noise. The CUNY Sentence Test was used as the outcome measure for this endpoint.

Additional endpoints included comparison of the EAS condition to the cochlear implant alone condition at 12 months on CUNY sentences in noise. The cochlear implant alone condition was also compared to preoperative performance with a hearing aid using CNC words in quiet.

Subjects were tested postoperatively both in the combined "EAS" condition (electric plus acoustic amplification) as well as in the "CI Alone" condition, meaning electrical stimulation only. These results were compared to the preoperative aided condition. Subjects were instructed to remove any contralateral hearing aid for speech perception testing. One subject lost residual hearing immediately following surgery early in the study. She was followed with electric stimulation only in the implanted ear and a contralateral hearing, per the protocol at the time. A second subject lost residual hearing later in the study and was followed only in the cochlear implant condition, as per the updated protocol.

Study Endpoints

Due to withdrawal of five subjects during the follow-up period, as well as one subject who was still undergoing testing at the time of submission, data is available for 67 subjects at the endpoint (12-month interval) for the effectiveness analysis.

For the primary endpoint of improvement on CUNY sentences in noise in the EAS condition, the average preoperative aided score was 31% (±27%) correct. At 12 months, in the EAS condition, subjects scored 73% (±24%) correct. This represents an improvement with EAS of 42 percentage points. This is a significant improvement in CUNY sentence scores in noise in the EAS condition, as compared to the preoperative aided condition.

Two secondary endpoints relating to speech perception were also analyzed. The improvement in CUNY sentences in noise with EAS was compared to the improvement in CUNY sentences in noise with CI Alone. At 12 months, subjects scored 56% (±30%) correct in the CI Alone condition, on average. In the EAS condition, subjects scored an average of 73% (±24%) at 12 months. The addition of acoustic amplification to electric stimulation demonstrated an average improvement of 17 percentage points. Please see the table below for detailed information on subjects' improvement in CUNY sentences scores in noise in both the EAS and CI Alone conditions.

	EAS	CI Alone
CUNY sentence test in noise	Change from baseline	Change from baseline
3 month	30.89 ± 32.41 (66)	17.99 ± 35.00 (67)
6 month	39.03 ± 27.41 (66)	25.06 ± 29.41 (67)
12 month	42.23 ± 29.96 (66)	24.62 ± 31.62 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Additionally, improvement in the CI Alone condition, compared to the preoperative aided condition, was assessed with CNC word score in quiet. Preoperatively, subjects scored 30% (±13%) correct, on average. At 12 months in the CI Alone condition, subjects scored an average of 48% (±19%) correct. This indicates an 18 percentage point improvement with electric stimulation alone. Please see the table below for detailed information on subjects' improvement in CNC word scores in quiet in both the EAS and CI Alone conditions.

	EAS	CI Alone
CNC word score in quiet	Change from baseline	Change from baseline
3 month	30.73 ± 22.36 (66)	9.25 ± 21.92 (67)
6 month	34.48 ± 23.36 (66)	13.31 ± 21.53 (67)
12 month	36.52 ± 23.58 (66)	18.03 ± 23.10 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Subjective Testing
Patients' subjective improvement was measured using the APHAB, as well as the HDSS, and differences in preoperative and postoperative performance are reported.

It should be noted that subjects were not instructed to disregard the non-implanted ear while completing these questionnaires. Thus, the data reported below is based on the everyday, bilateral condition, which may or may not include the use of a hearing aid in the non-implanted ear postoperatively.

On the APHAB questionnaire, 90% of subjects noted a decrease in listening difficulty. On the HDSS, 86% of subjects reported an increase in satisfaction, compared to their preoperative aided condition.

Global scores for the APHAB, representing the percentage of listening difficulty experienced by study subjects decreased by 30.2% (±20.4%) at 12 months, indicating a significant improvement in ease of listening. On the HDSS, the satisfaction patients experience while listening in background noise improved significantly at 12 months, as compared to the preoperative condition. The table below displays the APHAB global score at each interval from baseline through 12 months.

APHAB	Everyday Wearing Condition (Global score)
Preoperative	65.71 ± 15.23 (42)
3 month	41.62 ± 20.94 (47)
6 month	35.98 ± 16.56 (48)
12 month	35.51 ± 14.01 (48)

Benefit
In total, 65/67 subjects (97%) of subjects demonstrated benefit with the EAS device, as measured on either speech perception tests or subjective benefit questionnaires. Based on the group average, subjects in the study performed more than twice as well on both CUNY and CNC testing with EAS compared to the preoperative hearing aid alone. The table below displays the number and proportion of subjects demonstrating the same or better performance on speech perception scores in three postoperative conditions as compared to the preoperative aided condition. The results below are for the following conditions: CUNY sentences in noise with EAS, CUNY sentences in noise with the CI Alone, and CNC words in quiet with the CI Alone.

Time Point	EAS (CUNY)	CI Alone (CUNY)	CI Alone (CNC)
3 month	86% (57/66)	79% (53/67)	77% (52/67)
6 month	95% (63/66)	91% (61/67)	85% (57/67)
12 month	92% (61/66)	87% (58/67)	88% (59/67)

Hearing Sensitivity
Unaided audiologic thresholds were measured throughout the study, from preoperative to the 12-month endpoint. Although hearing preservation was not a defined endpoint in the protocol, the results of post-hoc, descriptive analyses are presented below. Mean preoperative and postoperative residual hearing thresholds are presented, as well as information on the amount of change in residual hearing and postoperative hearing threshold classification.

Hearing loss tended to occur immediately after surgery and remained stable through the follow-up period. On average, a low-frequency pure-tone average threshold (PTA=250, 500, 750, and 1000 Hz) shift of −24.07 dB HL was seen at 12 months. Changes in low-frequency residual hearing ranged between −19.26 dB HL at 250 Hz to −28.28 dB HL at 750 Hz. The figure below demonstrates the average preoperative residual hearing as well as postoperative residual hearing at 12 months for all subjects.

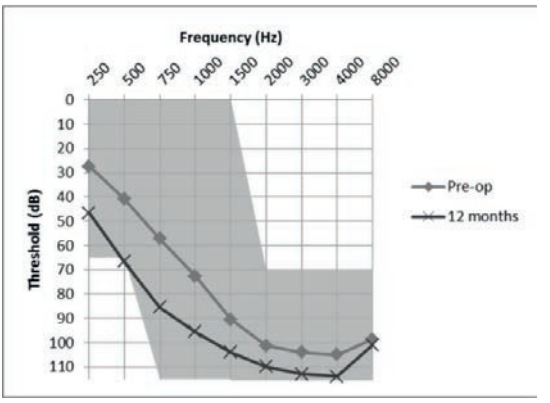


Figure 2: Average pre- and postoperative residual hearing at 12 months for all subjects

Change in residual hearing thresholds can also be described by the proportion of subjects experiencing a particular degree of shift in pure-tone average. The low-frequency threshold shift represents the change in pure-tone threshold at 250, 500, 750, and 1000 Hz. As presented below, 79% of subjects had a PTA shift of less than 30 dB at the 12-month endpoint. As noted above, the average shift in low-frequency PTA was also less than 30 dB (–24.07 dB).

Time Point	< 10 dB	10-20 dB	20–30 dB	> 30 dB
Month 3	10/71 (14.08%)	30/71 (42.25%)	18/71 (25.35%)	13/71 (18.31%)
Month 6	11/69 (15.94%)	23/69 (33.33%)	20/69 (28.99%)	15/69 (21.74%)
Month 12	8/67 (11.94%)	25/67 (37.31%)	20/67 (29.85%)	14/67 (20.90%)
Month 60				

Postoperative residual hearing can also be classified according to the degree of hearing loss as measured by a low-frequency PTA. As can be seen in the table below, 12% of EAS subjects had profound (or total) hearing loss at the 12-month endpoint. The proportion of subjects by degree of postoperative hearing loss is displayed below.

Time Point	Normal	Mild	Moderate	Moderate-Severe	Severe	Profound
Month 3	0/71 (0%)	2/71 (2.82%)	7/71 (9.86%)	30/71 (42.25%)	28/71 (39.44%)	4/71 (5.63%)
Month 6	0/69 (0%)	2/69 (2.90%)	9/69 (13.04%)	26/69 (37.68%)	26/69 (37.68%)	6/69 (8.70%)
Month 12	0/67 (0%)	2/67 (2.99%)	5/67 (7.46%)	28/67 (41.79%)	24/67 (35.82%)	8/67 (11.94%)
Month 60						

Postoperative low-frequency hearing thresholds were also used to determine whether or not subjects would be fit with the acoustic unit of the DUET Audio Processor and followed in that condition. The protocol specified that subjects would be fit with the acoustic unit if any low-frequency threshold was 80 dB or better. Based on this, 97% (65/67) of all subjects in the clinical trial were fit with the acoustic unit and followed in the EAS condition through the 12-month endpoint.

Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated.

A total of 57 adverse events were reported. Thirty-five adverse events occurring in 29 subjects were reported as related to either the device or the procedure. Of the 35 device-related adverse events, 22 were related to changes, either transient or permanent, in residual hearing or the middle ear.

Twelve adverse events were reported to be serious, occurring in 12 of the 73 subjects. Eleven of the 12 serious adverse events were reported to be related to the study device or procedure, eight of which involved changes to residual hearing. One adverse event was reported as a decrease in residual hearing and, therefore, serious). At the subsequent follow-up visit, however, the hearing thresholds in this case had improved and would no longer be considered a serious adverse event. One additional serious adverse event was reported as beeping or ringing in the ear. No unanticipated adverse events were reported.

Details on the type and number of device-related adverse events can be found below:

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects	% Resolved
Type B or Type C tympanogram	8	6	8%	100%
Profound/total loss of residual hearing	8	8	11%	0%
Conductive hearing loss	5	5	7%	0%
Pain at site	3	3	4%	67%
Electrode lead breakage after excessive micro-movements, caused by patient massaging area	1	1	1%	100%
Electrode migration	1	1	1%	100%
Occasionally off-balance	1	1	1%	100%
Ulnar nerve palsy after operation	1	1	1%	100%
Telemetry showed high status on electrode channels	1	1	1%	0%
Facial stimulation	1	1	1%	100%
Aural fullness	1	1	1%	100%
Sensation of device shifting when pushing over the implant site	1	1	1%	100%
Temporary shift in hearing threshold	1	1	1%	100%
Beeping/ringing in implanted ear	1	1	1%	0%
Bitter taste on right side of tongue	1	1	1%	100%
Total	35	29*	39,7%	574%

*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.

Symbols

CE mark. First applied in 2014

Single-use device. Do not reuse!

REF Catalogue number

SN Serial number

Caution! Consult accompanying documents

STERILE EO Sterilized using Ethylene Oxide

"Use by" date

Manufacturing date

Manufacturer

MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

1 This Instructions for Use refers to SYNCHRONY Implants with +FLEX^{24} or +FLEX^{20} electrodes.

2 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).

3 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.

4 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

USA Distributor
MED-EL Corporation, USA
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.

CE 0123

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a | 6020 Innsbruck, Austria
office@medel.com

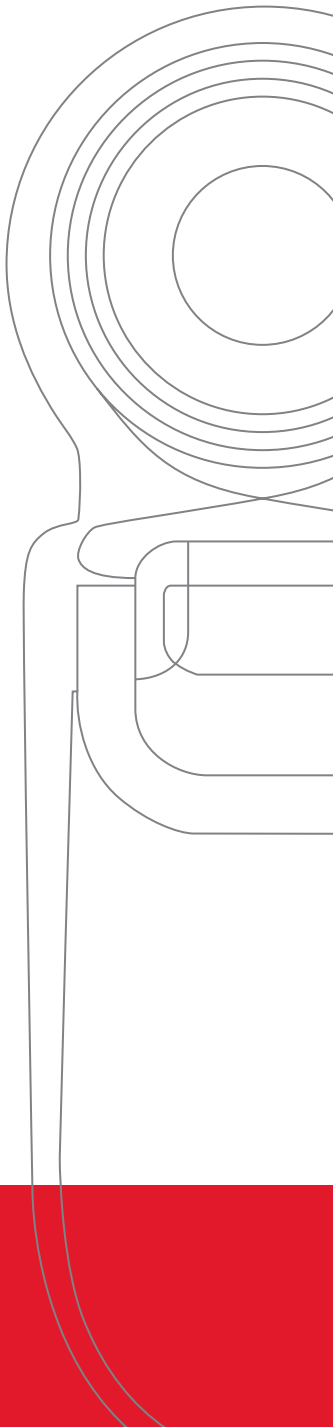
medel.com

MED EL

Mi1200 SYNCHRONY PIN Cochlear Implant

+FLEX^{24} | +FLEX^{20}

English



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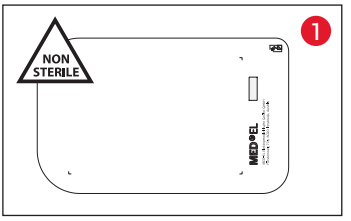
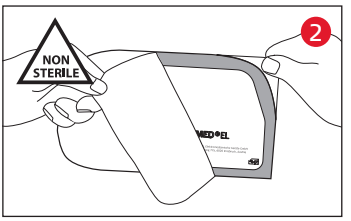
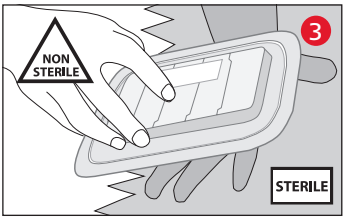
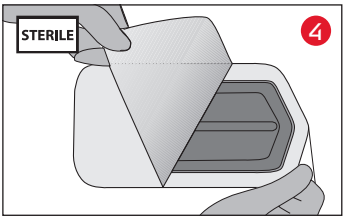
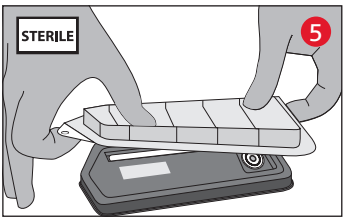
Opening instruction

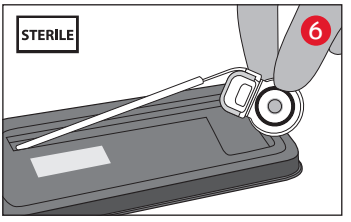


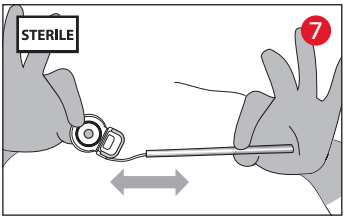




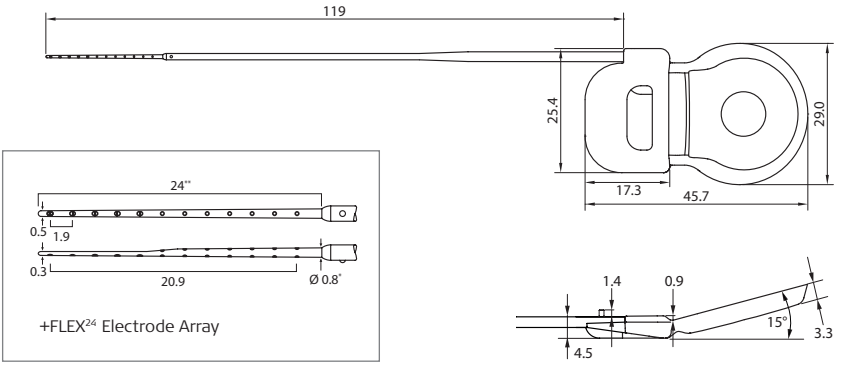




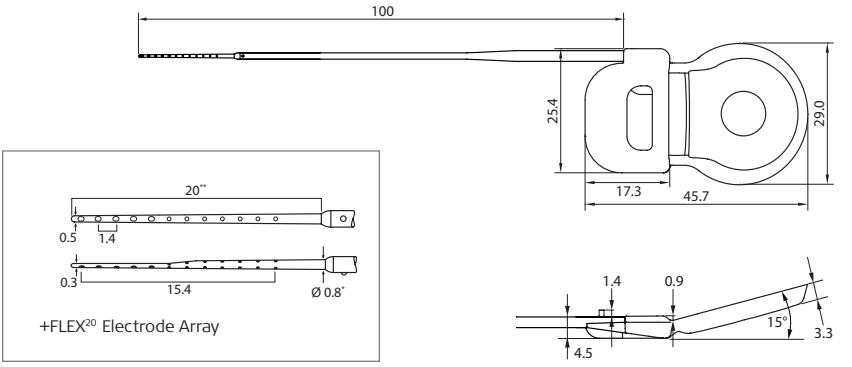




SYNCHRONY PIN +FLEX^{24}



SYNCHRONY PIN +FLEX^{20}



Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

Instructions for use

Mi1200 SYNCHRONY PIN Cochlear Implant

Device description

The Mi1200 SYNCHRONY PIN Implant (hereafter referred to as SYNCHRONY PIN) is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components. The device consists of a stimulator, a coil with a removable magnet within its center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SYNCHRONY PIN)[1]. This device is intended to be implanted by adequately trained and experienced surgeons only.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The implant has a mass of 7.6 g (typical weight).
For principal dimensions of the implant refer to the drawings on the previous pages.
The volume of the implant without electrode is 3.7 cm^3.
Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium, titanium and parylene c.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
  Maximum current amplitude: Median value = 1250 µA, range = 500 µA
  Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to MED-EL application software user manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm^2.

- Physical dimensions of the electrodes:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
+FLEX^{24}	119 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9
+FLEX^{20}	100 mm	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.4	15.4

* typical value, mm ** typical value, mm²

The implant does not have any connector.

Intended use

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The MED-EL EAS System is intended to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions, for candidates with residual low frequency hearing sensitivity. The combination of acoustic and electrical stimulation to the same ear is made possible through the external audio processor (either SONNET EAS or DUET 2) working in conjunction with the internal SYNCHRONY PIN Cochlear Implant with either a +FLEX^{24} or +FLEX^{20} electrode variant which together make up the MED-EL EAS System.

Indications

- Adults, eighteen (18) years of age or older, who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences).
- Children aged twelve (12) months to seventeen (17) years and eleven (11) months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three (3) to six (6) month period. In older children, lack of aid benefit is defined as <20 % correct on the Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills. A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.
- Cochlear implants with SYNCHRONY PIN +FLEX^{24} and +FLEX^{20} for EAS indication are 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.

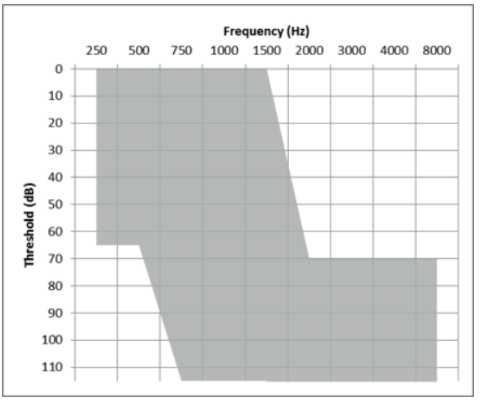


Figure 1: EAS Indication

- Implantation of Cochlear Implants SYNCHRONY PIN +FLEX[24] and +FLEX[20] used for EAS is contraindicated for partially deaf individuals with unstable progressive hearing loss, who are unable to use amplification devices, and/or have cochlear malformations.
- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferred option. However, if a patient was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not be delayed.
- To obtain optimal benefit from the SYNCHRONY PIN Cochlear Implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant. Also they shall understand the importance of returning to the implant center for regular speech processor programming, implant system testing, assessment sessions and training. A preoperative assessment according to the local professional standards must be conducted.
- Cochlear implants with SYNCHRONY PIN +FLEX[24] are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.

Contraindications

A patient must not be implanted:

- If the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, platinum iridium, titanium and parylene c).
- If there is an absence of cochlear development.
- If the cause of deafness is non-functionality of the auditory nerve and /or the auditory pathways.
- If external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted.
- If there are medical contraindications present against surgery of the middle and inner ear and anesthesia as required.
- If anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery.
- If the psychological status of the patient is unstable or,
- If the patient has unrealistic expectations.

Undesirable side effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation. Though rare, there is also a possibility of postoperative device failure or a decrease in device performance. Some postoperative complications may require revision surgery.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use, if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped[2] between −20 °C (−4 °F) and +55 °C (+131 °F) and stored inside the implant box at room temperature. Each device must be implanted before the "use by" date specified on the package. Packaging[3] should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.
- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable Audio Processor please consult the Audio Processor User Manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.
- Most water sports should not cause any problem as long as the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In case the MED-EL implant user wants to dive, the user should consult an experienced physician about the possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft).

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the

wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis[4] can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic cover, and surgical technique.

- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Clear identification of the anatomical landmarks is required. When drilling, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Inadequate large exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that foudroyantly progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.
- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The area of the temporal bone on which the stimulator will be placed, shall be flattened in order to ensure that the implant is sufficiently immobilized. The two pins of the SYNCHRONY PIN Cochlear Implant should be recessed into the skull with the PIN Drill Guide SI to a depth of 1.5 mm. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.
- The two pins give additional stability against translational and rotational motion. Recessing the pins and efficient immobilization of the stimulator (e.g. with sutures) is important to prevent postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

  Recommended diameter of the cochleostomy & RW opening:

Electrode type	
SYNCHRONY PIN +FLEX[24]	0.8 mm
SYNCHRONY PIN +FLEX[20]	0.8 mm

- To ensure proper electrical stimulation, it is important to insert the electrode array with the apical single contacts facing towards the modiolus. Using a higher magnification to focus on the electrode tip can facilitate finding the correct contact orientation. When the electrode array is inserted, the small marker on the electrode lead indicates the contact orientation at the electrode array base.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without compressing the array or touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.

- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- Cochlear implantation in partially deaf patients with low frequency hearing carries the risk of partial or total hearing loss which should be clearly explained to the patient by the surgeon prior to implantation. However, studies have shown benefits using electrical stimulation solely in this group of patients even if residual hearing is lost. Etiology, duration of partial deafness, and hearing aid benefit should be taken into consideration and hearing preservation surgical technique should be applied.
- In case of a magnet exchange surgery MED-EL recommends the use of the following tools: The Magnet Removal Tool Ms050206 or the Magnet Insertion Tool Ms050205 can be used in combination with the Non-Magnetic Spacer Ms010107 or the Replacement Magnet Ms010108. Please refer to the applicable Instructions for Use of these devices for further surgical precautions and warnings.
- After removal of the Non-Magnetic Spacer Ms010107, make sure that a fresh Replacement Magnet Ms010108 is inserted to re-establish full functionality of the implant.

Interference with other equipment, robustness of the device in special environments.

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

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.
If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed functional checks of the implant on a regular basis are strongly recommended.
If possible, the device should be removed without damaging or cutting it.

Returning explanted devices

- After the device is removed from the patient, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Follow locally established procedures for potentially bio-hazardous material at all times.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
  MED-EL Elektromedizinische Geräte GmbH
  Worldwide Headquarters
  Safety adviser for the transport of dangerous goods
  Fürstenweg 77a
  6020 Innsbruck
  Austria

Clinical trial description

The purpose of this prospective, multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the safety and effectiveness of MED-EL's Electric-Acoustic Stimulation (EAS) system. The MED-EL EAS System is a medical device that combines the use of a cochlear implant with an external electric-acoustic audio processor, designed to provide benefit in speech perception and sound quality to individuals who demonstrate significant residual low-frequency hearing and severe to profound high-frequency (above 1500 Hz) sensorineural hearing loss with minimal changes in residual hearing.

Four test conditions were evaluated in order to determine effectiveness of the MED-EL EAS system:

1. Preoperatively; Acoustic Alone (acoustic amplification to the ear to be implanted),
2. Postoperatively; Electric Alone (electric stimulation only to the implanted ear via the MED-EL EAS system without the use of the Acoustic Component),
3. Postoperatively; Combined (simultaneous electric and acoustic stimulation in the implanted ear via the MED-EL EAS system utilizing the Acoustic Component)
4. Postoperatively; Bimodal (electric stimulation only using the MED-EL EAS system without the Acoustic Component, with the addition of contralateral acoustic stimulation).

Of note, the Bimodal condition was only tested in one subject, when that subject lost residual hearing and had thresholds poorer than 80 dB HL at 250 Hz and above in the implanted ear. Audiometric thresholds were also assessed across test intervals in order to measure low-frequency residual hearing postoperatively.

The primary effectiveness endpoint was the improvement in CUNY sentences in noise in the combined electric and acoustic condition at 12 months. The primary safety endpoint was the evaluation of all adverse events reported. Safety data was collected on all implanted subjects.

Seventy-three subjects were implanted with either a PULSAR or a SONATA Cochlear Implant with a FLEX^{24} electrode across 14 investigational sites. Subjects were fit postoperatively with the DUET Audio Processor, combining acoustic amplification and electric stimulation in one device.

The original approval of the study was only for one arm (Arm 1). The second study arm (Arm 2) was added later for subjects with slightly better residual hearing at baseline in the ear to be implanted. Audiologic criteria for the study required subjects to have bilateral residual low-frequency hearing and severe to profound high-frequency sensorineural hearing loss. Subjects in Arm 2 could have slightly better low-frequency thresholds and a CNC word score in quiet of 60 %, as opposed to subjects in Arm 1 who had a CNC word score in quiet of 50 % or poorer. Results are presented here for all subjects, as the data for both arms has now been combined.

Inclusion/exclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

- Normal to moderate sensorineural hearing loss in the low to mid frequencies and sloping severe/profound sensorineural hearing loss in the mid to high frequencies.
- Monosyllabic word scores in quiet of ≤60 % in the best-aided condition.
- Current user of bilateral acoustic hearing aids for at least 3 months.
- Adults 18–70 years of age at time of implantation.
- English was the primary language.

Subjects were excluded from the study for any of the following reasons:

- Conductive, retrocochlear or central auditory disorders.
- Hearing loss in the ear to be implanted that demonstrated a fluctuation at two or more frequencies of 15 dB in either direction in the last 2 years.

- Any physical, psychological, or emotional disorder that interfered with surgery or the ability to perform on test and rehabilitation procedures.
- Developmental delays or organic brain dysfunction.
- Physical or geographic limitations that interfered with the completion of scheduled follow-up evaluations.
- Skin or scalp conditions that precluded magnetic attachment of the speech processor or use of the acoustic hearing aid.

Clinical trial results

Results for 73 subjects are reported. Of the 73 total subjects implanted, 67 completed follow-up at the time of submission. Five subjects withdrew from the study prior to completing the 12-month interval, and one subject was still undergoing testing at the time of submission. The table below provides details on the number of subjects implanted, as well as how many subjects completed each interval.

# of Subjects	Total
Implanted	73
3-Month Post-EAS Activation Evaluation	72
6-Month Post-EAS Activation Evaluation	70
12-Month Post-EAS Activation Evaluation	67

Demographics

The table below provides information on subject demographics, including gender, age at implantation, duration of hearing loss, and duration of hearing aid use.

Parameter/Category or Statistic	Total (n=73)
Gender	
Male	42.5 % (31/73)
Female	57.5 % (42/73)
Age (years)	53.7 (73) (17–76)
Duration of noticeable hearing loss (years)	
Left	25.7 (73) (2–60)
Right	25.7 (73) (2–60)
Duration of hearing aid use (years)	
Left	17.4 (73) (1–48)
Right	17.4 (72) (1–47)

* Numbers are % (Count/Sample Size) or Mean (N) (Min – Max)

Description of tests

Open-set, monosyllabic words were tested using the CNC (Consonant-Nucleus-Consonant) Word Recognition test. Testing was completed in quiet at 70 dB SPL in the soundfield. One list was administered for each condition, and results are reported as a percent correct for words.

Open-set sentence testing was completed using the CUNY (City University of New York) Sentence Test. Subjects were evaluated in noise at 70 dB SPL with varying signal-to-noise ratios that were held constant for each individual subject throughout the duration of the study. One practice list and four test lists were completed for each condition. Scores are reported as the percent correct for words in the sentences.

Subjective benefit 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. Both were completed at post-operative intervals and based on the "everyday listening condition," as subjects were not instructed to ignore input from the non-implanted ear.

Speech Perception Testing

The primary endpoint was based on improvement in speech understanding at 12 months with EAS using sentence tests in noise. The CUNY Sentence Test was used as the outcome measure for this endpoint.

Additional endpoints included comparison of the EAS condition to the cochlear implant alone condition at 12 months on CUNY sentences in noise. The cochlear implant alone condition was also compared to preoperative performance with a hearing aid using CNC words in quiet.

Subjects were tested postoperatively both in the combined "EAS" condition (electric plus acoustic amplification) as well as in the "CI Alone" condition, meaning electrical stimulation only. These results were compared to the preoperative aided condition. Subjects were instructed to remove any contralateral hearing aid for speech perception testing. One subject lost residual hearing immediately following surgery early in the study. She was followed with electric stimulation only in the implanted ear and a contralateral hearing, per the protocol at the time. A second subject lost residual hearing later in the study and was followed only in the cochlear implant condition, as per the updated protocol.

Study Endpoints

Due to withdrawal of five subjects during the follow-up period, as well as one subject who was still undergoing testing at the time of submission, data is available for 67 subjects at the endpoint (12-month interval) for the effectiveness analysis.

For the primary endpoint of improvement on CUNY sentences in noise in the EAS condition, the average preoperative aided score was 31% (±27%) correct. At 12 months, in the EAS condition, subjects scored 73% (±24%) correct. This represents an improvement with EAS of 42 percentage points. This is a significant improvement in CUNY sentence scores in noise in the EAS condition, as compared to the preoperative aided condition.

Two secondary endpoints relating to speech perception were also analyzed. The improvement in CUNY sentences in noise with EAS was compared to the improvement in CUNY sentences in noise with CI Alone. At 12 months, subjects scored 56% (±30%) correct in the CI Alone condition, on average. In the EAS condition, subjects scored an average of 73% (±24%) at 12 months. The addition of acoustic amplification to electric stimulation demonstrated an average improvement of 17 percentage points. Please see the table below for detailed information on subjects' improvement in CUNY sentences scores in noise in both the EAS and CI Alone conditions.

	EAS	CI Alone
CUNY sentence test in noise	Change from baseline	Change from baseline
3 month	30.89 ± 32.41 (66)	17.99 ± 35.00 (67)
6 month	39.03 ± 27.41 (66)	25.06 ± 29.41 (67)
12 month	42.23 ± 29.96 (66)	24.62 ± 31.62 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Additionally, improvement in the CI Alone condition, compared to the preoperative aided condition, was assessed with CNC word score in quiet. Preoperatively, subjects scored 30% (±13%) correct, on average. At 12 months in the CI Alone condition, subjects scored an average of 48% (±19%) correct. This indicates an 18 percentage point improvement with electric stimulation alone. Please see the table below for detailed information on subjects' improvement in CNC word scores in quiet in both the EAS and CI Alone conditions.

	EAS	CI Alone
CNC word score in quiet	Change from baseline	Change from baseline
3 month	30.73 ± 22.36 (66)	9.25 ± 21.92 (67)
6 month	34.48 ± 23.36 (66)	13.31 ± 21.53 (67)
12 month	36.52 ± 23.58 (66)	18.03 ± 23.10 (67)

*Numbers are Mean ± Standard Deviation (Sample Size)

Subjective Testing
Patients' subjective improvement was measured using the APHAB, as well as the HDSS, and differences in preoperative and postoperative performance are reported.

It should be noted that subjects were not instructed to disregard the non-implanted ear while completing these questionnaires. Thus, the data reported below is based on the everyday, bilateral condition, which may or may not include the use of a hearing aid in the non-implanted ear postoperatively.

On the APHAB questionnaire, 90% of subjects noted a decrease in listening difficulty. On the HDSS, 86% of subjects reported an increase in satisfaction, compared to their preoperative aided condition.

Global scores for the APHAB, representing the percentage of listening difficulty experienced by study subjects decreased by 30.2% (±20.4%) at 12 months, indicating a significant improvement in ease of listening. On the HDSS, the satisfaction patients experience while listening in background noise improved significantly at 12 months, as compared to the preoperative condition. The table below displays the APHAB global score at each interval from baseline through 12 months.

APHAB	Everyday Wearing Condition (Global score)
Preoperative	65.71 ± 15.23 (42)
3 month	41.62 ± 20.94 (47)
6 month	35.98 ± 16.56 (48)
12 month	35.51 ± 14.01 (48)

Benefit
In total, 65/67 subjects (97%) of subjects demonstrated benefit with the EAS device, as measured on either speech perception tests or subjective benefit questionnaires. Based on the group average, subjects in the study performed more than twice as well on both CUNY and CNC testing with EAS compared to the preoperative hearing aid alone. The table below displays the number and proportion of subjects demonstrating the same or better performance on speech perception scores in three postoperative conditions as compared to the preoperative aided condition. The results below are for the following conditions: CUNY sentences in noise with EAS, CUNY sentences in noise with the CI Alone, and CNC words in quiet with the CI Alone.

Time Point	EAS (CUNY)	CI Alone (CUNY)	CI Alone (CNC)
3 month	86% (57/66)	79% (53/67)	77% (52/67)
6 month	95% (63/66)	91% (61/67)	85% (57/67)
12 month	92% (61/66)	87% (58/67)	88% (59/67)

Hearing Sensitivity
Unaided audiologic thresholds were measured throughout the study, from preoperative to the 12-month endpoint. Although hearing preservation was not a defined endpoint in the protocol, the results of post-hoc, descriptive analyses are presented below. Mean preoperative and postoperative residual hearing thresholds are presented, as well as information on the amount of change in residual hearing and postoperative hearing threshold classification.

Hearing loss tended to occur immediately after surgery and remained stable through the follow-up period. On average, a low-frequency pure-tone average threshold (PTA=250, 500, 750, and 1000 Hz) shift of −24.07 dB HL was seen at 12 months. Changes in low-frequency residual hearing ranged between −19.26 dB HL at 250 Hz to −28.28 dB HL at 750 Hz. The figure below demonstrates the average preoperative residual hearing as well as postoperative residual hearing at 12 months for all subjects.

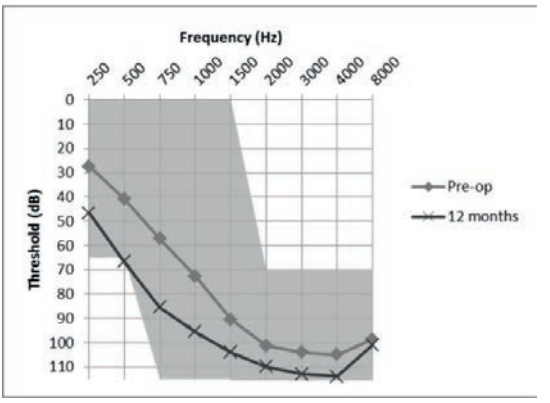


Figure 2: Average pre- and postoperative residual hearing at 12 months for all subjects

Change in residual hearing thresholds can also be described by the proportion of subjects experiencing a particular degree of shift in pure-tone average. The low-frequency threshold shift represents the change in pure-tone threshold at 250, 500, 750, and 1000 Hz. As presented below, 79% of subjects had a PTA shift of less than 30 dB at the 12-month endpoint. As noted above, the average shift in low-frequency PTA was also less than 30 dB (–24.07 dB).

Time Point	< 10 dB	10-20 dB	20–30 dB	> 30 dB
Month 3	10/71 (14.08%)	30/71 (42.25%)	18/71 (25.35%)	13/71 (18.31%)
Month 6	11/69 (15.94%)	23/69 (33.33%)	20/69 (28.99%)	15/69 (21.74%)
Month 12	8/67 (11.94%)	25/67 (37.31%)	20/67 (29.85%)	14/67 (20.90%)
Month 60				

Postoperative residual hearing can also be classified according to the degree of hearing loss as measured by a low-frequency PTA. As can be seen in the table below, 12% of EAS subjects had profound (or total) hearing loss at the 12-month endpoint. The proportion of subjects by degree of postoperative hearing loss is displayed below.

Time Point	Normal	Mild	Moderate	Moderate-Severe	Severe	Profound
Month 3	0/71 (0%)	2/71 (2.82%)	7/71 (9.86%)	30/71 (42.25%)	28/71 (39.44%)	4/71 (5.63%)
Month 6	0/69 (0%)	2/69 (2.90%)	9/69 (13.04%)	26/69 (37.68%)	26/69 (37.68%)	6/69 (8.70%)
Month 12	0/67 (0%)	2/67 (2.99%)	5/67 (7.46%)	28/67 (41.79%)	24/67 (35.82%)	8/67 (11.94%)
Month 60						

Postoperative low-frequency hearing thresholds were also used to determine whether or not subjects would be fit with the acoustic unit of the DUET Audio Processor and followed in that condition. The protocol specified that subjects would be fit with the acoustic unit if any low-frequency threshold was 80 dB or better. Based on this, 97% (65/67) of all subjects in the clinical trial were fit with the acoustic unit and followed in the EAS condition through the 12-month endpoint.

Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as anticipated/unanticipated, serious/non-serious, or device-related/unrelated.

A total of 57 adverse events were reported. Thirty-five adverse events occurring in 29 subjects were reported as related to either the device or the procedure. Of the 35 device-related adverse events, 22 were related to changes, either transient or permanent, in residual hearing or the middle ear.

Twelve adverse events were reported to be serious, occurring in 12 of the 73 subjects. Eleven of the 12 serious adverse events were reported to be related to the study device or procedure, eight of which involved changes to residual hearing. One adverse event was reported as a decrease in residual hearing and, therefore, serious). At the subsequent follow-up visit, however, the hearing thresholds in this case had improved and would no longer be considered a serious adverse event. One additional serious adverse event was reported as beeping or ringing in the ear. No unanticipated adverse events were reported.

Details on the type and number of device-related adverse events can be found below:

Events Reported as Device- or Procedure-Related	No. of Events	No. of Subjects	% of Subjects	% Resolved
Type B or Type C tympanogram	8	6	8%	100%
Profound/total loss of residual hearing	8	8	11%	0%
Conductive hearing loss	5	5	7%	0%
Pain at site	3	3	4%	67%
Electrode lead breakage after excessive micro-movements, caused by patient massaging area	1	1	1%	100%
Electrode migration	1	1	1%	100%
Occasionally off-balance	1	1	1%	100%
Ulnar nerve palsy after operation	1	1	1%	100%
Telemetry showed high status on electrode channels	1	1	1%	0%
Facial stimulation	1	1	1%	100%
Aural fullness	1	1	1%	100%
Sensation of device shifting when pushing over the implant site	1	1	1%	100%
Temporary shift in hearing threshold	1	1	1%	100%
Beeping/ringing in implanted ear	1	1	1%	0%
Bitter taste on right side of tongue	1	1	1%	100%
Total	35	29*	39,7%	574%

*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.

Symbols

CE mark. First applied in 2014

Single-use device. Do not reuse!

Catalogue number

Serial number

Caution! Consult accompanying documents

Sterilized using Ethylene Oxide

"Use by" date

Manufacturing date

Manufacturer

MR Conditional

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

1 This Instructions for Use refers to SYNCHRONY PIN Implants with +FLEX^{24} or +FLEX^{20} electrodes.

2 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).

3 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.

4 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

USA Distributor
MED-EL Corporation, USA
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.

CE 0123

MED-EL Elektromedizinische Geräte GmbH
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medel.com

Cochlear Implants

MED EL

DUET 2

Accessory in combination with OPUS 2

User Manual

AW33688_1.0 (English US)

1. Table of contents

2. Introduction

You have been provided with a MED-EL Cochlear Implant and the DUET 2 accessory to the OPUS 2 system. You will be making use of the latest technology for people with hearing loss in higher frequencies.

The DUET 2 is an accessory to the OPUS 2 audio processor that additionally features acoustic stimulation supporting an individual's capability to hear low frequencies.

This user manual is a guide to your new DUET 2 audio processor. It is an addition to the OPUS 2 user manual. If you have not received the OPUS 2 user manual, please contact your CI center or MED-EL.

Please read the OPUS 2 user manual first. It provides information about your MED-EL Cochlear Implant System and the OPUS 2 audio processor. This manual informs you about the additional acoustic stimulation and differences between the DUET 2 accessory and the standard OPUS 2 battery pack.

IMPORTANT
Please read the OPUS 2 user manual carefully before reading this manual.

3. Intended use – Indications – Contra-indications

INTENDED USE

The DUET 2 is a dispensable (i.e. not necessary for normal OPUS 2 use) accessory for the OPUS 2 audio processor (see also intended use OPUS 2) and therefore a part of the MED-EL Cochlear Implant System. When connected to the OPUS 2 audio processor, it adds the functions of digital acoustic amplification to the functionality of the OPUS 2 audio processor.

The DUET 2 audio processor is intended to:

- Provide acoustic stimulation by utilizing an analog signal provided by the OPUS 2 control unit and presenting the amplified acoustic signals to the ear canal.
- Power the OPUS 2 with battery voltage, as the DUET 2 battery pack is connected to the OPUS 2 in place of a standard battery pack.
- Provide an audio input to both the OPUS 2 and the acoustic part, when an audio device is connected to the Audio Input socket.
- 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 DUET 2 audio processor working in conjunction with the internal cochlear implant with either a +FLEX^{24} or +FLEX^{20} electrode variant (SYNCHRONY, MED-EL CONCERT, SONATA, PULSAR or C40+), which together make up the MED-EL EAS System.

INDICATIONS

The DUET 2 audio processor is intended to be used by users of the MED-EL Cochlear Implant (CI) System with functional low frequency hearing.

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.

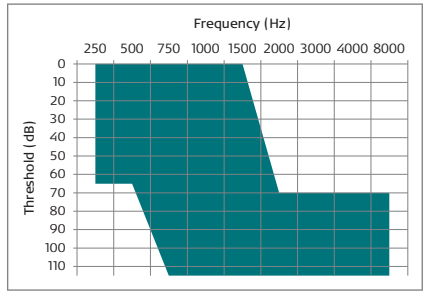


Fig. 1 EAS Indication

The DUET 2 audio processor is intended to be used by the patients as indicated above.

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

CONTRA-INDICATIONS

The DUET 2 audio processor is contra-indicated for persons not fulfilling the indication criteria.

The DUET 2 audio processor is contra-indicated for patients who are unable to use acoustic amplification devices.

Combined electric-acoustic stimulation (EAS) is contra-indicated for patients unable to use acoustic amplification. For details, please refer to chapter 8, Technical data.

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

4. The DUET 2 audio processor

This section describes the concept of EAS and the DUET 2 audio processor.

To understand this section, it is important that you are familiar with the OPUS 2 user manual. If you have not yet read the OPUS 2 user manual, please do so before continuing reading this section.

THE CONCEPT OF EAS

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

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

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

For convenience, the OPUS 2 with the DUET 2 accessory combines the cochlear implant audio processor and acoustic amplification in one device. The DUET 2 audio processor uses digital amplification technology.

THE DUET 2 ACCESSORY IN COMBINATION WITH THE OPUS 2

The DUET 2 audio processor is a variant of the OPUS 2 audio processor. Compared to the OPUS 2 audio processor, the DUET 2 audio processor additionally features acoustic stimulation.

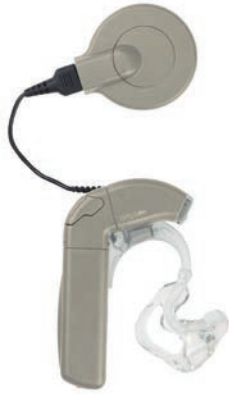
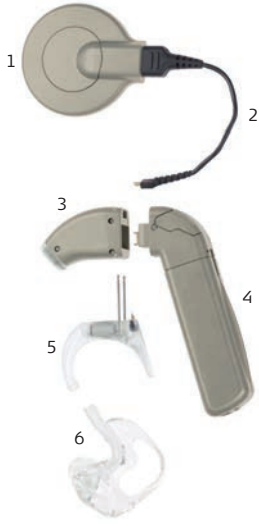


Fig. 2 DUET 2 audio processor with ear mold attached



1 Coil
2 Coil cable
3 OPUS 2 control unit
4 DUET 2 battery pack
5 AU Earhook
6 Ear mold

Fig. 3 Components of the DUET 2 audio processor as worn by the patient

The DUET 2 audio processor uses the OPUS 2 control unit. If you have questions regarding the use of the control unit, please refer to the OPUS 2 user manual.

The DUET 2 accessory consists of a special battery pack, the DUET 2 battery pack, and a special earhook, the Acoustic Unit (AU) Earhook.

Connecting the DUET 2 accessory with the OPUS 2

In order to attach the DUET 2 battery pack proceed as follows:

1) Push the DUET 2 battery pack onto the OPUS 2 control unit.
2) Fix this connection by inserting the two pins of the AU Earhook (see Fig. 4) into the two holes on the bottom of the OPUS 2 control unit. The pins should be inserted completely.

Use the same procedure whenever you connect the DUET 2 battery pack.

Fig. 4 Assembly of the DUET 2 audio processor

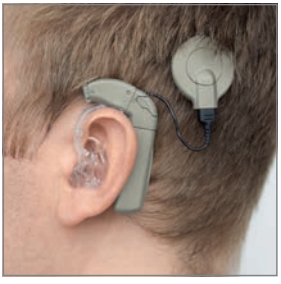


Fig. 5 DUET 2 audio processor on the ear

The acoustic output is located on the tip of the AU Earhook. Your audiologist will connect it to an ear mold with a silicone tube, just like in any standard behind-the-ear (BTE) hearing aid (see Fig. 5).

IMPORTANT

The AU Earhook contains electronics that are sensitive to magnets. Do not place your coil on the AU Earhook. Do not connect any control unit other than the OPUS 2 control unit to the DUET 2 accessory.

USE OF THE DUET 2 ACCESSORY IN COMBINATION WITH THE OPUS 2

OPUS 2 / DUET 2 controls

ON/OFF switch

The ON/OFF switch is located at the back of the battery pack. You may select the following positions:

Switch position | : ON

Switch position O : OFF

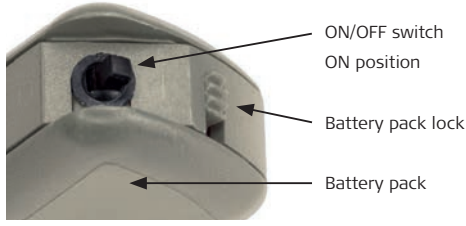


Fig. 6 DUET 2 audio processor switch position ON

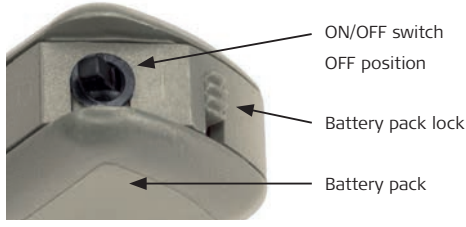


Fig. 7 DUET 2 audio processor switch position OFF

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

The DUET 2 audio processor should be switched off:

- When not in use
- While changing batteries

Controls

The controls of the DUET 2 battery pack are only required for fitting of the acoustic stimulation but are not required for daily use.

FineTuner

Please refer to the OPUS 2 user manual.

IMPORTANT

Changes in the sensitivity control and volume control of the OPUS 2 control unit with the FineTuner only affect cochlear implant stimulation. Such changes do not affect the acoustic stimulation.

The acoustic part of the DUET 2 audio processor is set to your needs using four controls located in the back of the device under the protective flap (see Fig. 8). Your audiologist will make the necessary adjustments. Never manipulate these controls yourself. Always have a skilled professional (e.g. audiologist) make the adjustments.

Fig. 8 DUET 2 audio processor controls for acoustic part

Telecoil

A telecoil function is also supported by the DUET 2 audio processor. For more information about the telecoil, please refer to the OPUS 2 user manual.

IMPORTANT

The telecoil mode may cause feedback whistling when amplification is set to maximum. If you use the telecoil mode, your audiologist has to adjust the amplification to enable telecoil mode without feedback whistling.

DIFFERENCES BETWEEN THE DUET 2 ACCESSORY AND THE STANDARD OPUS 2 BATTERY PACK

Apart from the additional acoustic stimulation, the DUET 2 audio processor functions like the OPUS 2 audio processor. Therefore, all information in the OPUS 2 user manual also applies to the DUET 2 audio processor.

This section addresses the differences between the OPUS 2 Battery Pack and the DUET 2 accessory.

IMPORTANT
The AU Earhook cannot be shaped using hot air. This would damage the DUET 2 audio processor.

Differences concerning the use of assistive listening devices that can be connected to the DUET 2 audio processor are addressed in the section Accessories.

IMPORTANT
Reprogramming of the OPUS 2 is required if it has been used without the DUET 2 accessory before.

If you decide not to take advantage of the acoustic stimulation, you can replace the DUET 2 battery pack and the AU Earhook with any other battery pack option used for the OPUS 2. The system will then function like the OPUS 2 audio processor.

ACCESSORIES

The DUET 2 audio processor features an Audio Input for assistive listening devices such as FM systems. The Audio Input is located under the protective flap on the back of the DUET 2 battery pack (see Fig. 8).

Connector for FM Systems

The DUET 2 battery pack includes a connector for assistive listening devices (ALD) like FM systems.

To connect a cable that leads to an assistive listening device proceed as follows:

1) Open the cover at the angled part of the device (see Fig. 9) by first pulling the cover straight to the back (a) and then lifting the cover by turning it as shown (b).
2) Insert the connector of the cable into the socket underneath the cover (c). Be careful not to force the connector into the socket in wrong orientation. The red dot on the cable connector must point upwards. If oriented correctly, the connector slides into the socket gently.
3) Gently push the cover back downward (d, e) until it rests on the connector (see Fig. 10). This ensures maximum protection of the connector.

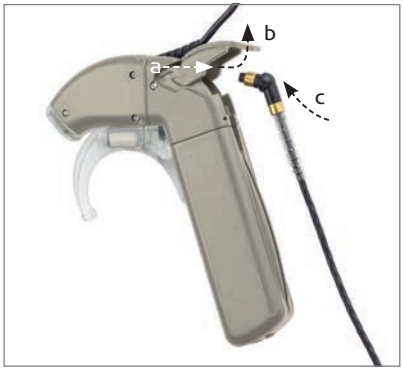


Fig. 9 Connecting the ALD cable – STEP 1

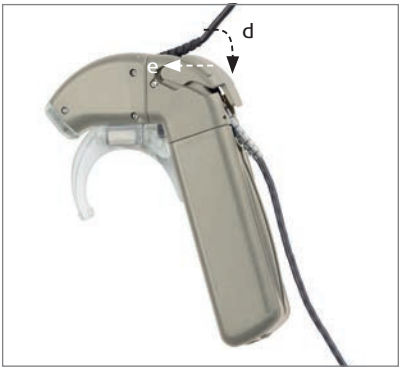


Fig. 10 Connecting the ALD cable – STEP 2

IMPORTANT

Use only recommended devices and cables provided or endorsed by MED-EL. For more information, please contact your local MED-EL representative or CI center, or visit our website (www.medel.com).

To unplug the ALD cable proceed in reverse order:

1) Open the cover at the angled part by lifting and turning it upwards.
2) Remove the connector of the cable by pulling it diagonally downward on the strain relief near the connector.
3) Close the cover completely by gently pushing it downward.

The DUET 2 audio processor only supports the "mix-mode", i.e. when you connect assistive listening devices, the microphone is still active.

The DUET 2 audio processor does not support audio devices which depend on external power supply.

IMPORTANT

Never connect any mains powered audio devices to the DUET 2 audio processor.

5. General Precautions and Warnings

This section contains information on the safe use of your DUET 2 accessory in combination with OPUS 2.

IMPORTANT

All precautions and warnings stated in the OPUS 2 user manual also apply to the DUET 2 audio processor. Please read the section "General precautions and warnings" in the OPUS 2 user manual.

- Before switching on your DUET 2 audio processor, check the external parts of the system for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the DUET 2 audio processor should not be switched on. Read the section Troubleshooting in this manual and in the OPUS 2 user manual, or contact your CI center or MED-EL.
- Handle your DUET 2 audio processor with care to avoid damage to the device.
- The defined operating temperature range for the DUET 2 audio processor is between +10 °C (50 °F) and +45 °C (113 °F). Since the DUET 2 audio processor is worn behind the ear, natural body heat helps maintain this temperature range.
- Do not expose the DUET 2 audio processor to extreme temperatures, e.g. leave it in direct sunlight, particularly inside a car.
- Do not use your DUET 2 audio processor in the vicinity of strong ionizing radiation (x-ray machines) or electromagnetic fields (MRI).
- Keep your DUET 2 audio processor away from moisture. Always remove and switch off the DUET 2 audio processor and store it in a dry place before bathing and showering.
- If you ever experience loud or uncomfortable sounds, remove your DUET 2 audio processor immediately.
- Do not manipulate the controls located under the cover in the back of the DUET 2 battery pack. These trimmers control the acoustic stimulation and should only be adjusted by professionals (e.g. audiologist).
- Never connect mains powered audio devices to the DUET 2 audio processor.
- Mobile phones may interfere with the DUET 2 audio processor if they are used in the immediate vicinity. Interference levels differ among mobile phone models. If you are considering purchasing a mobile phone, we recommend testing it beforehand for possible interference.
- The AU Earhook contains sensitive electronics. Do not place your coil onto the AU Earhook.
- Do not try to repair the electronics of your DUET 2 audio processor.
- Do not try to open the housing of your DUET 2 audio processor.

- The AU Earhook cannot be shaped using hot air. This would damage the device.
- Do not clean the AU Earhook by immersing it in water or other fluids, or by poking it with pointed objects – this will damage the device.
- Dispose of batteries according to local regulations.

IMPORTANT

It is the audiologist's responsibility to customize the ear mold according to standard hearing aid practice. The ear mold shall fulfil local hearing aid requirements, especially with regard to biocompatibility. In the EAS clinical trial, a few users reported soreness or pain from the use of the mold, which is a common issue associated with hearing aid molds. Therefore it is especially important that the audiologist ensure that the ear mold optimally fits the anatomical shape of the ear canal and the earhook of the DUET 2 Audio Processor.

The audiologist is also responsible to inform the patient or caregiver about cleaning the ear mold to ensure optimal performance and avoid bacterial infections.

In cases of otitis media (especially with effusion) it is recommended to use the DUET 2 without the ear mold, i.e. only use the CI part to leave the outer ear canal open.

6. Care and maintenance

All care and maintenance instructions stated in the OPUS 2 user manual are also valid for the DUET 2 audio processor. Please read through the respective section in the OPUS 2 user manual.

Your DUET 2 audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time. Although the coil cable is designed for maximum durability and flexibility, this part of the MED-EL Cochlear Implant System is the most likely to wear out. The battery pack and particularly its cover may wear out due to frequent opening and closing and, therefore, have to be replaced more frequently.

Do not clean the external parts in or under water. Use a damp cloth to gently clean the audio processor. Do not use aggressive cleaning agents.

Protect your DUET 2 audio processor from water.

Do not try to repair electronic parts of your DUET 2 audio processor and do not try to open the control unit or any other part of your audio processor, as this invalidates the manufacturer warranty.

If you have to remove cerumen (ear wax) from your ear mold or the AU Earhook, do so only according to the advice of your audiologist. If necessary, your audiologist can perform the cleaning. Do not clean the AU Earhook by immersing it in water or other fluids, or by poking it with pointed objects – this will damage the device.

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

To remove moisture from your device, store it regularly overnight in a drying kit. For instructions on using a drying kit, please refer to the OPUS 2 user manual or the drying kit manual.

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

WEEKLY MAINTENANCE OF YOUR AUDIO PROCESSOR

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

Drying your audio processor

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

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

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

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

BATTERIES

The DUET 2 audio processor requires three 675 zinc air batteries. These batteries supply the external and internal components of the MED-EL Cochlear Implant System with energy. If you want to get more information on batteries, please contact your local MED-EL representative or CI center.

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

NOTE:
It is recommended to only use high power zinc air batteries to power the DUET 2.

Important

- Wash your hands after handling disposable batteries.
- Do not try to recharge disposable batteries.
- Do not disassemble, deform, immerse in water or incinerate batteries.
- Avoid mix-up of old and new batteries or batteries of different types of brands.
- Do not short-circuit batteries, e.g. by allowing the terminals of batteries to touch, carrying batteries loose in your pockets, wallet or purse or touching the battery terminals with metals (coins, wires, keys, etc.).
- Store unused batteries in their original packaging, in a cool and dry place.
- Do not expose batteries to heat (e.g. never leave batteries in direct sunlight, behind a window or in a car).
- Do not use damaged, deformed batteries or leaking batteries. If any kind of substance leaks out of a battery, avoid direct skin contact with that substance. Such a substance could cause a chemical burn. In case of eye contact, rinse with copious amounts of water and seek medical attention immediately.
- If you are not going to use your audio processor for an extended period of time, you should remove the batteries and store them separately. Cover the air openings on the top with adhesive tape when storing the batteries to avoid discharge.
- Always remove used batteries immediately to avoid leaking and possibly damaging the device.
- Dispose of used batteries according to local regulations. Generally, batteries are collected separately and not discarded.

Changing the batteries of your DUET 2 audio processor

When the red indicator light in the earhook blinks continuously (|.|.|.|.|.|.|), the battery set must be replaced (see also Chapter 7, Troubleshooting).

To change the batteries, proceed as follows:

1) Remove the coil from your head and switch off the DUET 2 audio processor before replacing the batteries.
2) To open the battery pack as shown in Fig. 11, push the lever at the back of the audio processor and hold it in this position. Now push the lid on the battery pack backwards about 3 mm (a), then remove it by pushing it upwards.
3) Replace the used battery set by removing the three batteries with the coil magnet or by gently shaking them into your hand. Try not to touch the battery contacts.
4) Before inserting the new battery set, make sure that the battery contacts are clean and dry. The foil covering the zinc air batteries must be removed before use. Check for correct polarity when inserting the new batteries. The positive pole ⊕ must face outward, i.e. the ⊕ sign is still visible when the batteries are inserted.
5) To close the battery pack (see Fig. 13), put the lid on the housing so that it overhangs the back of the audio processor by about 3 mm. Gently push the lid onto the housing. When the lid is positioned correctly, it can be pushed forward (b), where it snaps in place easily. Never put the lid on the very back of the housing pushing it forward by force. This could damage the battery pack. Do not use excessive force when closing the battery pack.

Fig. 11 Opening the DUET 2 battery pack

Fig. 12 Inserting the batteries

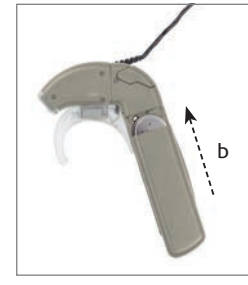


Fig. 13 Closing the DUET 2 battery pack

Changing the battery of your FineTuner

When your FineTuner generates an optical battery low warning signal (please refer to the OPUS 2 user manual), it is recommended to replace the battery of your FineTuner.

To change the battery, proceed as follows:

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

Fig. 14 Changing the battery of your FineTuner

7. Troubleshooting

Please refer to the OPUS 2 user manual.

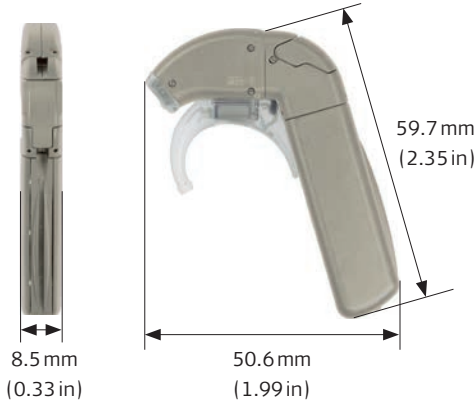
IMPORTANT

If you suspect a malfunction of your DUET 2 audio processor, contact the specialist at your CI center, your audiologist or MED-EL.

8. Technical data

Dimensions[1] (without cable)

Length: 50.6 mm (1.99 in)
Width: 8.5 mm (0.33 in)
Height: 59.7 mm (2.35 in)
Weight: 14 g (0.49 oz) (with batteries)



Temperature and humidity range

Operating temperature range[2]: 10 °C to 45 °C (50 °F to 113 °F)
Storage temperature range: –20 °C to 60 °C (–4 °F to 160 °F)
Relative humidity range: 10 % to 90 % (at or above 31 °C/87.8 °F),
10 % to 93 % (below 31 °C/87.8 °F)

Power supply

3 hearing aid batteries type 675 zinc air. The minimum battery life time for the DUET 2 audio processor is 20 hours.

Controls

OPUS 2 control unit/FineTuner controls

- Sensitivity control
- Programmable volume control
- Programme switch
- Indicator LED (red) for indicator and alarm functions

DUET 2 battery pack

- 3 controls for acoustic fitting
- Volume control
- ON/OFF switch

1 typical values
2 Since the DUET 2 audio processor is worn behind the ear, natural body heat helps maintain this temperature range.

Audio Input

Special 4-pin connector
Sensitivity: –32 dBV (typical value)
Source impedance: 40–600 Ohms

Materials

Please refer to the OPUS 2 user manual.
The housing of the AU Earhook is made of cellulose propionate.

SYMBOLS

CE 0123 — The DUET 2 audio processor is in compliance with directive 90/385/EEC (active implantable medical devices).
CE mark applied in 2008


Caution, consult accompanying documents


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


Relative humidity


Temperature limit

GUIDANCE AND MANUFACTURER'S DECLARATION

Tables according to IEC 60601-1-2 for DUET 2 audio processor

Guidance and manufacturer's declaration – electromagnetic emission

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 610004-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Mains power quality should be that of typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of typical commercial or hospital environment. If the user of the "DUET 2 in combination with OPUS 2" requires continued operation during power mains interruptions, it is recommended that the "DUET 2 in combination with OPUS 2" be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should not be used no closer to any part of the "DUET 2 in combination with OPUS 2", including cables, than the recommended separation distance caculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 * \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 * \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

Recommended separation distances between portable and mobile RF communications equipment and the "DUET 2 in combination with OPUS 2"

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 * \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 * \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

9. Appendices

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 a acoustic unit (acoustic) in the same ear. If the individual has few changes in their low pitched hearing after cochlear implant surgery, EAS can offer improved speech understanding and sound quality by taking advantage of the recipient's remaining hearing along with the cochlear implant.

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

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

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

Clinical trial subjects

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

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

Description of Tests

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

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

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

Clinical trial results

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

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

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

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

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

Speech Understanding with EAS

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

- The average pre-operative score on CUNY sentences was 31% (±27%), while at 12 months post-operatively 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 pre-operatively with a hearing aid.

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

- The average CUNY sentence in noise score with the cochlear implant alone was 56% (±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 pre-operative 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 pre-operatively.
- 88% (58/67) of subjects demonstrated similar or improved performance on CNC words in quiet with the cochlear implant alone compared to pre-operatively with a hearing aid.

Self-Assessment Questionnaires

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

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

Post-operative Residual Hearing

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

Decreases in hearing, if noted, tended to occur immediately after surgery. Hearing levels then remained stable through the follow-up period. The amount of change in the low frequencies was less than 24 dB on average at 12 months post-operatively. Change in residual hearing can be classified by the number of subjects experiencing a decrease in hearing at 12 months. In this clinical trial, 79% of subjects (53/67) experienced less than a 30 dB decrease (worsening) in residual hearing after surgery.

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

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

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

Degree of Low Frequency Hearing Loss After Surgery For All Subjects

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

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

Risks of receiving the MED-EL EAS System

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

Events Reported as Device-Related	No. of Events	No. of Subjects	% of Subjects
Type B or Type C tympanogram	8	6	8%
Profound/total loss of residual hearing	8	8	11%
Conductive hearing loss	5	5	7%
Pain at site	3	3	4%
Electrode lead breakage after excessive micro-movements, caused by patient massaging area	1	1	1%
Electrode migration	1	1	1%
Occasionally off-balance	1	1	1%
Ulnar nerve palsy after operation	1	1	1%
Telemetry showed high status on electrode channels	1	1	1%
Facial stimulation	1	1	1%
Sensation of fullness in the ear	1	1	1%
Sensation of device shifting when pushing over the implant site	1	1	1%
Temporary shift in hearing threshold	1	1	1%
Beeping/ringing in implanted ear	1	1	1%

Events Reported as Device-Related	No. of Events	No. of Subjects	% of Subjects
Bitter taste on tongue on the side of the implant	1	1	1%
Total	35	29*	39.7%

*Some subjects experienced more than one adverse event.

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

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

Benefits of receiving the MED-EL EAS System

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

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

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

WARRANTY AND GUARANTEE

Please refer to the OPUS 2 user manual.

REGISTRATION CARD

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

MANUFACTURER ADDRESS

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E-Mail: implants.us@medel.com

DUET 2 Settings

Audiologist's documentation

Last name _____

Serial number _____

First name _____

Date of birth _____

Settings

② Gain		VOL – Volume	
_____ dB			– _____ dB
③ AGC Ratio		**① Low Frequency Slope**	
_____ : 1			_____ dB/octave

Comments

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Email: implants.us@medel.com

Date _____

10. Contact MED-EL

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

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