Cochlear Implants

MED EL

RONDO

User Manual

AW9389_3.0 (English US)

1. Table of contents

2. Introduction

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

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

We recommend that you read this manual in its entirety.

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

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

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

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

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

3. Intended use – Indications – Contra-Indications

INTENDED USE

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

INDICATIONS

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

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

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

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

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

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

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

CONTRA-INDICATIONS

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

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

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

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

4. RONDO audio processor

THE PARTS OF THE SYSTEM

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

Implants with titanium housing: SYNCHRONY (shown), MED-EL CONCERT and SONATA TI[100]

Implants with ceramic housing: PULSAR CI[100] (shown) and C40+

Fig. 1 The MED-EL cochlear implants

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

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

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

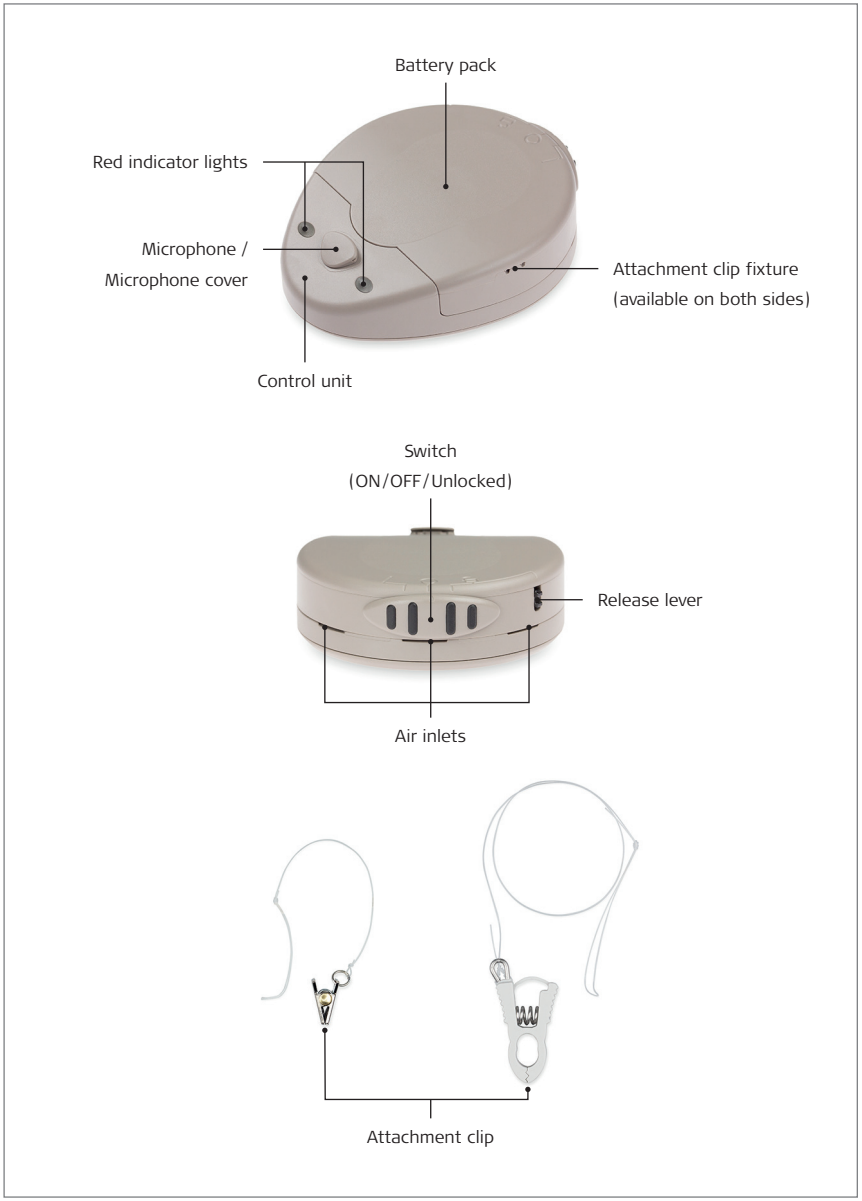


Fig. 2 Your RONDO audio processor

ON/OFF SWITCH

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

You may select the following positions:
RONDO OFF: O
RONDO ON: I

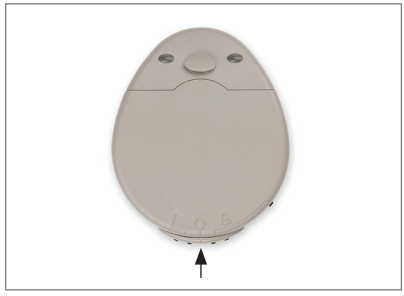


Fig. 3 The RONDO in OFF position

Fig. 4 The RONDO in ON position

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

Fig. 5 RONDO over the site of the implant

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

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

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

To use the telecoil proceed as follows:

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

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

FINETUNER

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

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

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

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

The FineTuner is configured for its designated target RONDO audio processor, i.e. only the target RONDO 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 RONDO 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 RONDO audio processor and place it on the keyboard of the FineTuner (approximately over key **MT**). Then switch on your RONDO audio processor. The audio processor and the FineTuner will be synchronized automatically. Successful synchronization is indicated by a short blinking signal of the two amber indicator lights on your FineTuner. It is only necessary to re-synchronize the processor to the FineTuner if you replace the processor or FineTuner.

For bilaterally implanted users

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

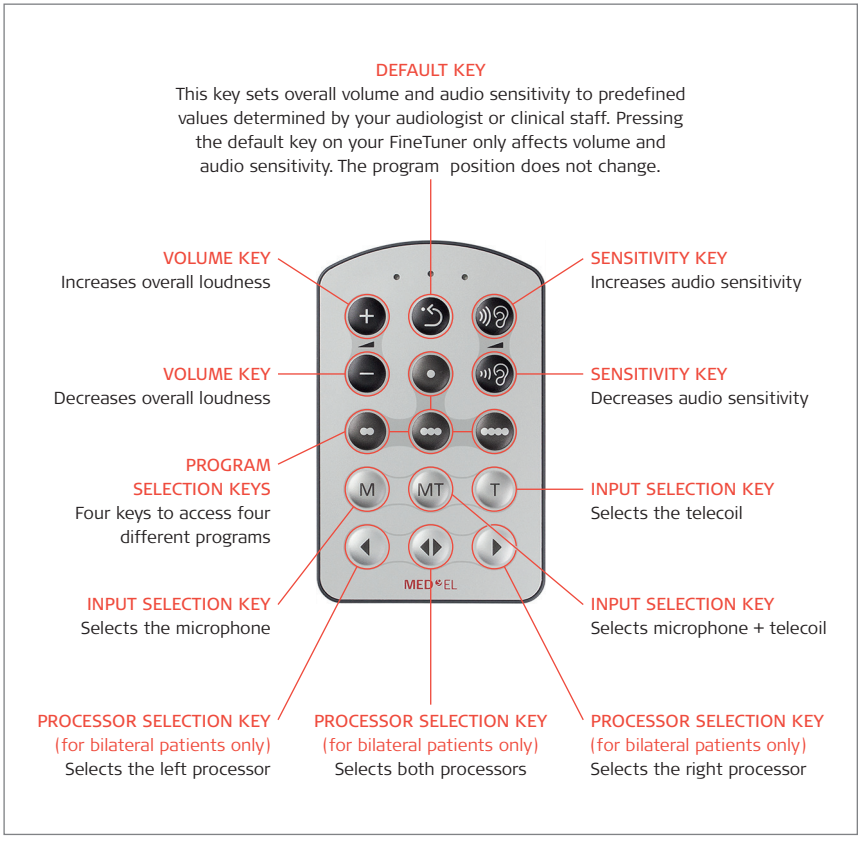


Fig. 6 FineTuner

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

FineTuner functions

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

To activate the 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, holding down on the second press for more than 5 seconds to enter the program mode. Press the ◄ key to deactivate the keyboard lock. As above, the FineTuner will confirm successful deactivation of the automatic keyboard lock by a short blinking signal of the two amber indicator lights.

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

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

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

Your FineTuner does not have an ON/OFF switch.

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

BATTERY PACK

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

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

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

IMPORTANT

The switch must always be in the unlocked position ( ) when removing/attaching the battery pack. Do not use excessive force. To move the switch to the unlocked position, press down the release lever (1) on the right side. Hold it down while pushing the switch to the right (2).

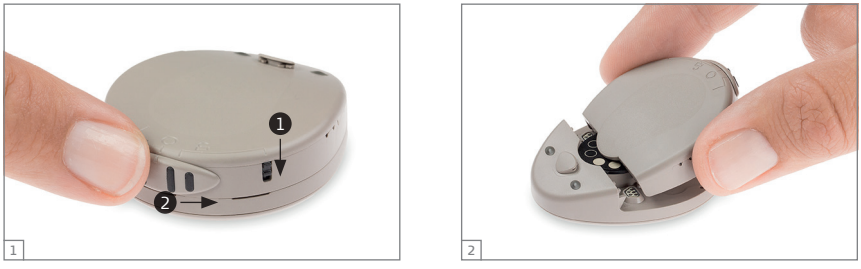


Fig. 7 How to open the battery pack of your RONDO audio processor

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

MAGNET

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

IMPORTANT

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

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

For patients implanted with any other type of implant (MED-EL CONCERT, SONATA TI[100], etc.), the magnet must contain circles as shown in Fig. 10.

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

How to change the magnet insert

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

Fig. 8 Changing the magnet insert

Four magnet strengths are available. Magnet strength is indicated by the number of filled triangles or circles on the magnet. The magnet strength chosen should be appropriate for the individual patient, that is 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.

Fig. 9 Magnet strengths for SYNCHRONY implant

Fig. 10 Magnet strengths for all other types of implants

IMPORTANT

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

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

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

ATTACHMENT CLIP

The attachment clip is used to secure the RONDO to your / your child's clothes to reduce the risk of damaging the audio processor should it come off and drop on the floor or another hard surface. MED-EL strongly recommends that you always use the attachment clip.

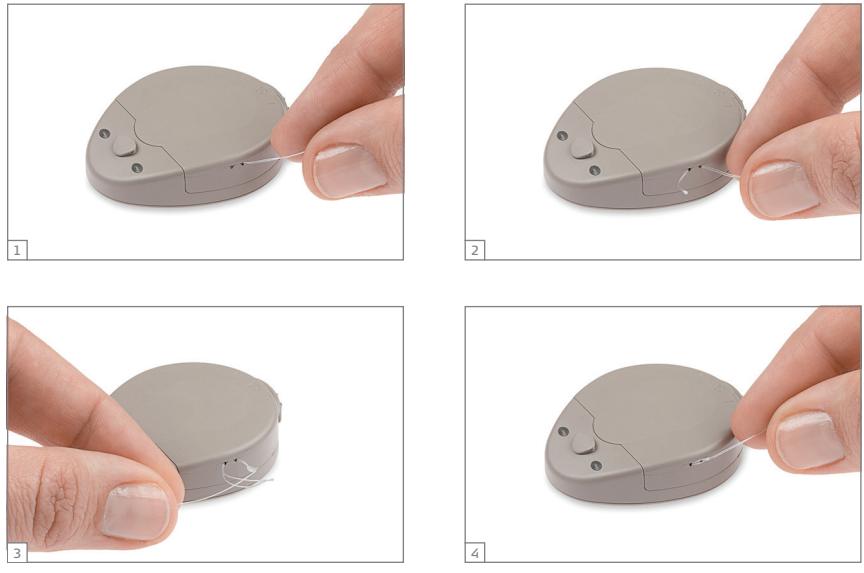


Fig. 11 Threading the attachment clip through the RONDO housing

RONDO PROTECTOR

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

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

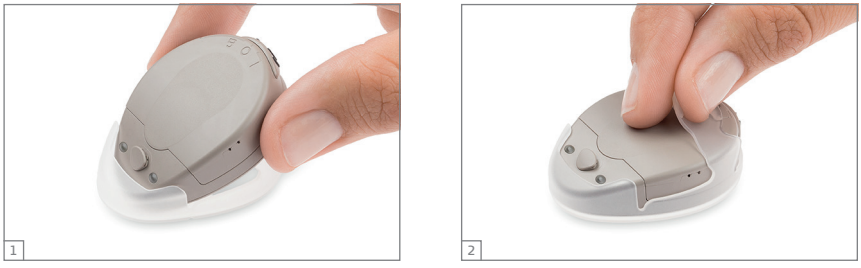


Fig. 12 Assembling the RONDO protector

MICROPHONE COVER

Your RONDO audio processor is shipped with a microphone cover to protect the microphone opening from contamination. If you need to reattach the cover, proceed as shown in Fig. 13.

Fig. 13 Snapping on the microphone cover

CONNECTING ASSISTIVE LISTENING DEVICES

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

ADDITIONAL WEARING OPTIONS

Mini Battery Pack

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

The Mini Battery Pack may be purchased separately.

5. Special considerations for young children

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

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

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

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

6. General precautions and warnings

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

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

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

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

The RONDO audio processor and other parts of the system contain sophisticated electronic components which need special precautions regarding electromagnetic compatibility (EMC). When activating your RONDO 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 RONDO 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 RONDO 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 Cochlear Implant System (e.g. an area that is protected by a warning notice preventing entry by patients fitted with a pacemaker) it is advisable to first contact your clinic or MED-EL.

Everyday life

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

For the external components, please observe the following:

- Your RONDO audio processor and FineTuner do not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range is between +0 °C and +50 °C (32 °F and 122 °F) for the RONDO audio processor and the FineTuner. Normally, when the RONDO 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 RONDO 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, and gently wipe all external parts dry, using a soft, absorbent cloth. Then put the audio processor in the supplied drying kit to allow moisture inside the audio processor to dry (preferably overnight). If in doubt, repeat the drying process. If the FineTuner becomes wet, wipe it off with a dry tissue.
- You also have to take care of the external components of your / your child's 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 RONDO audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.

Children shall be instructed not to swallow or put any components of their Cochlear Implant System into their mouths and not to play with any components.

Technology in everyday life

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

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

Air travel

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

Interference with reception of TV

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

Cell phones

Cell phones and other portable and mobile RF communications equipment may interfere (perceived as a buzzing sound) with the external parts of your 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 MAESTRO Cochlear Implant System has several internal safety features designed to reduce ESD, there is a small risk that the external or internal equipment can be damaged if the static discharge flows through the external equipment. Switching off your audio processor will not prevent damage from occurring. In rare cases, the user may experience uncomfortably loud hearing sensations, however the most likely occurrence in case of an ESD event is a short interruption of stimulation or a controlled audio processor shutdown.

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

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

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

Sports and play

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

Avoid contact sports that might result in severe blows to the head or continuous pressure on the implant, since this could damage the implant. Other physical activity is generally allowed. Make sure that you wear the RONDO securely (see Chapter 4, RONDO audio processor, Additional wearing options) to protect it from physical damage. Sports that require a helmet are okay as long as they do not exceed the given capabilities of the user. Use a helmet whenever necessary to protect the implant site from any blows. Your / your child's helmet should be high quality and may need to be modified to meet your individual needs. For specific questions about contact sports, contact your CI center. Most water sports should not cause any problem as long as the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In any case you should consult an experienced physician about possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m (165 ft).

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

PRECAUTIONS FOR MEDICAL PROCEDURES

Neurostimulation or diathermy

Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue.

Electrosurgery and other treatment with electrical current

Monopolar electrosurgical instruments must not be used in the head and neck area. Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of the cochlear implant. Such currents may damage the implant and/or the surrounding tissue.

In general remove your RONDO audio processor from your head any time a medical treatment is given in which an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire Cochlear Implant System during the initial stages of the treatment.

Ultrasound

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

Electroconvulsive therapy

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

Therapy using ionizing radiation

The SYNCHRONY, MED-EL CONCERT, SONATA and PULSAR Cochlear Implants are robust against 240 Gray ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your Cochlear Implant System and such damage may not be immediately detected. In order to minimize the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radio-therapeutic beam.

Magnetic Resonance Imaging (MRI) Safety Information

	The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL Cochlear Implant System are MR Conditional.	

SYNCHRONY & SYNCHRONY PIN

Patients implanted with a SYNCHRONY or SYNCHRONY PIN 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 and SYNCHRONY PIN 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
1.5 T	3.2 W/kg	2.0 W/kg	2.0 W/kg
3.0 T	1.6 W/kg	1.0 W/kg	2.0 W/kg

Table 1: Specific Absorption Rate (SAR levels).

For 1.5 T 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 3 T 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 3 T 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 1.5 T and 3 T, 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.

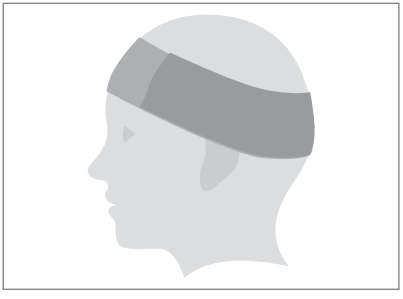


Figure A: Head bandage to support fixation of the implant.

- 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.

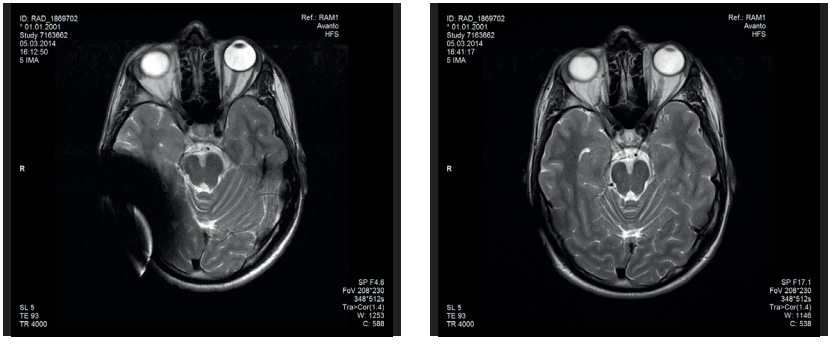


Figure B: Image artifacts of a spin echo sequence in axial view arising in a 1.5 T scanner. The left picture shows the artifacts obtained with the implant magnet in place whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

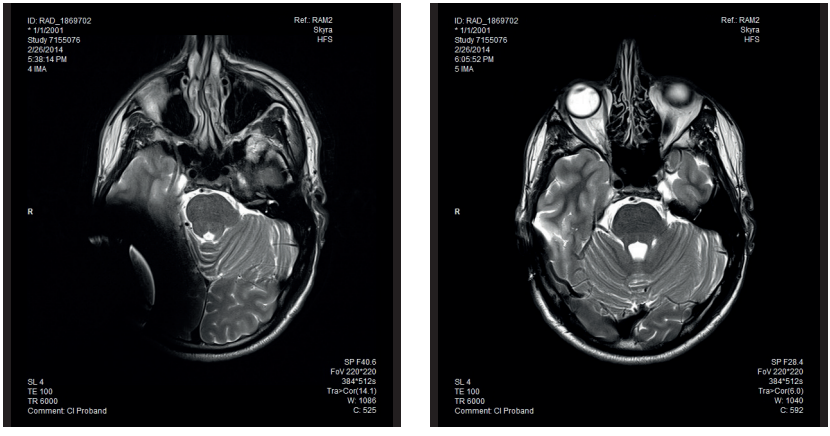


Figure C: Image artifacts of a spin echo sequence in axial view arising in a 3 T scanner. The left picture shows the artifacts obtained with the implant magnet in place whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

- 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!

MED-EL CONCERT, MED-EL CONCERT PIN, SONATA & PULSAR

Non-clinical testing has demonstrated that the MED-EL CONCERT, MED-EL CONCERT PIN, SONATA & PULSAR cochlear implants are MR Conditional. They can be safely scanned under the following conditions:

0.2 or 1.5 Tesla

Conditions:

- **Bone thickness underneath the implant magnet of at least 0.4 mm. Bone thickness must be determined using CT images.**
- Static magnetic field of 0.2 T or 1.5 T.
- Spatial gradient field of up to 8 T/m (800 G/cm).
- Sequences in Normal Operating Mode only with a maximum whole-body averaged specific absorption rate (SAR) of 2 W/kg and a maximum head averaged SAR of 3.2 W/kg.
- Implantation performed at least 6 months ago.
- **Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed.**
- The implant is not damaged mechanically, electrically or in any other way.

Additional MRI safety information for 0.2 or 1.5 T scanning:

- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Fig. B).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Fig. A). The bandage needs to fit tightly but should not cause pain.
- Head orientation: In case of 1.5 T systems, the longitudinal axis of the head must be parallel to the main magnetic field of the scanner. For example this is the case when the patient is in a supine position with the head kept straight. The patient should not turn or bend his/her head to the side; otherwise partial demagnetization of the implant magnet is possible.
- During the scan, patients might perceive auditory sensations such as clicking or beeping. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.
- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first to minimize any risk of weakening the implant magnet.

- In non-clinical testing and electromagnetic in-vivo computer simulations, the implant produced a maximum temperature rise < 2 °C during 15 minutes of continuous MR scanning in the Normal Operating Mode at a maximum whole-body averaged SAR of 2.0 W/kg and a maximum head averaged SAR of 3.2 W/kg.

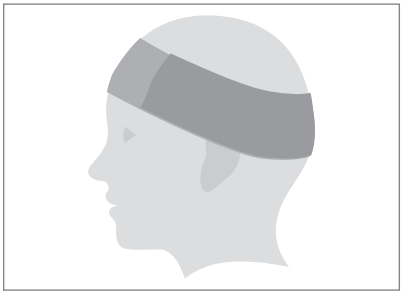


Fig. A Head bandage to support fixation of the implant

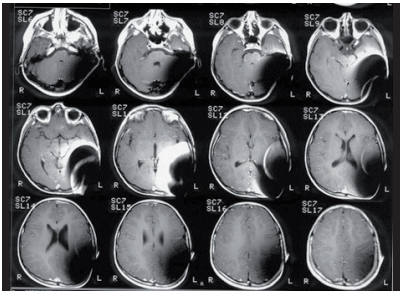


Fig. B MR images obtained with a 1.5 T scanner (8 year old child)

C40+

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

0.2 Tesla

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

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

CAUTION:

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

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

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

Other treatments

The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.

Ear infections

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

Electrical lice combs

Cochlear implant users should not use these devices.

Meningitis vaccine and prevention

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

7. Care and maintenance

MAINTENANCE

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

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

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

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

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

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

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

WEEKLY MAINTENANCE OF YOUR RONDO AUDIO PROCESSOR

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

Drying your RONDO audio processor

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

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

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

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

BATTERIES

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

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

IMPORTANT

Always remove used batteries immediately to avoid leaking and possibly damaging the device. If any kind of substance leaks out of a battery, avoid direct skin contact with that substance.

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 Cochlear Implant System into their mouths and not to play with any components.

Changing the batteries of your RONDO audio processor

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

To change the batteries, proceed as follows:

1. Remove the RONDO from your head and switch it off before replacing the batteries.
2. The battery pack features a tiny release lever on the right side of the ON/OFF switch. To remove the battery pack, press down the release lever and push the slide switch to the right towards the unlocked symbol (🔓) until it engages (see Fig. 16). Now pull the battery pack slightly back and lift it off.

IMPORTANT

The switch must always be in the unlocked position (🔓) when removing/attaching the battery pack. Do not use excessive force. To move the switch to the unlocked position, press down the release lever (❶) on the right side. Hold it down while pushing the switch to the right (❷).

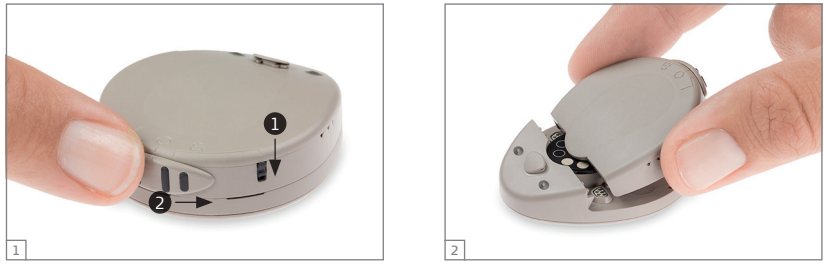


Fig. 16 How to open the battery pack of your RONDO audio processor

3. Replace the used battery set by removing the three batteries with the magnet. To do so move the center of the bottom part of the control unit over each battery separately. Try not to touch the battery contacts (see Fig. 17).

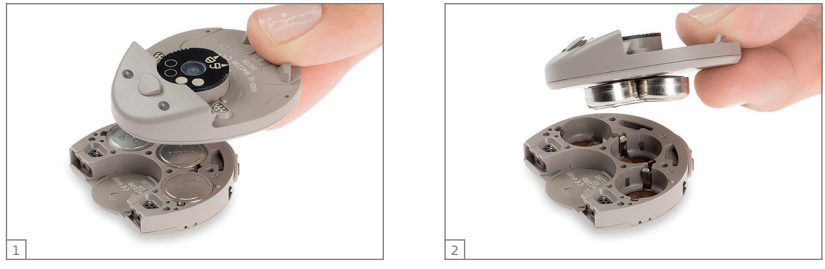


Fig. 17 Changing the batteries of your audio processor

4. Before inserting the new battery set, make sure that the battery contacts are clean and dry. The foil covering the zinc air batteries must be removed before use. Check for correct polarity when inserting the new batteries. The positive pole ⊕ must face outward, i.e. the ⊕ sign is still visible when the batteries are inserted.

5. When assembling the battery pack, make sure that the switch is in the unlocked position (🔓). Hold the battery pack at a slight downward angle and push it straight onto the processor. Be sure to center the battery pack to prevent the magnet pulling out the batteries. When the battery pack rests on the processor, slightly press it down and move the ON/OFF switch to the OFF position (center position). The release lever engages and the battery pack is locked again (see Fig. 18).

Fig. 18 Assembling the battery pack

Changing the battery of your FineTuner

When your FineTuner generates an optical battery low warning signal (see also chapter 4, RONDO 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 RONDO magnet or by gently shaking it into your hand. Try not to touch the battery contacts.
3. Insert the new battery with the ⊕ sign facing up.
4. Close the lid by carefully inserting it on the right side, then sliding it in place and tightening the screw.

Fig. 19 Changing the battery of your FineTuner

8. Troubleshooting

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

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

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

IMPORTANT

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

SPEECH PROCESSOR TEST DEVICE

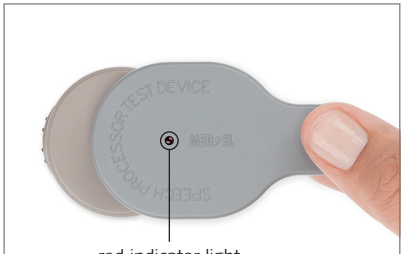


Fig. 20 Speech Processor Test Device

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

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

The Speech Processor Test Device is not necessary for the function of your audio processor, it is just intended to help detect most common functional audio processor problems like defective 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 RONDO audio processor and make sure that it is supplied with batteries. Place the RONDO underneath the Speech Processor Test Device (see Fig. 20), it will position itself correctly due to magnetic attraction.

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

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

We recommend you try these steps 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, as this will cause damage to the device and immediately voids any warranty.

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

FINETUNER

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

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

Additional troubleshooting information:

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

RONDO RED INDICATOR LIGHTS

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

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

Error patterns

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

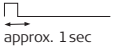
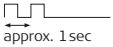
Warning patterns

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

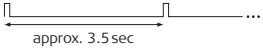
Confirmation pattern

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

Program change pattern

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

Status pattern

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

PRIVATE ALERT

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

Battery low warning signal

If the battery voltage falls below a certain level, four short warning beeps will be generated approximately every 14 seconds. You are still able to hear, but should change the batteries of the RONDO 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 RONDO audio processor, a confirmation beep is audible for the user of the audio processor.

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

FINETUNER INDICATOR FUNCTIONS

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

Keyboard locked

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

Transmitting

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

Switch to side

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

Low battery

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

Configuration successful

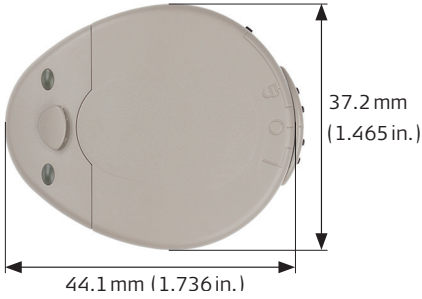
If configuration of your FineTuner (see chapter 4, RONDO audio processor, FineTuner, How to configure your FineTuner) was successful, or if the automatic keyboard lock feature was successfully activated/deactivated, both amber indicator lights will illuminate for approximately one second.

Program mode

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

9. Technical data

AUDIO PROCESSOR



Dimensions of RONDO audio processor[1]

Length (without switch): 44.1 mm (1.736 in.)
Width: 37.2 mm (1.465 in.)
Height: 12.1 mm (0.476 in.)

Weight[1]

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

- 17.5 g (0.617 oz.) with SOFT Magnet (1)
- 18.5 g (0.653 oz.) with STANDARD Magnet (2)
- 20.2 g (0.713 oz.) with STRONG Magnet (3)
- 21.5 g (0.758 oz.) with SUPER STRONG Magnet (4)

including batteries

Power supply

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

Hardware

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

Audio input

- Via Mini Battery Pack
- Hearing aid type three pin connection (Euro-Audio) acc. to IEC 60118-12 on Mini Battery Pack
- Sensitivity: –61.4 dBV[1] (corresponds to 70 dB SPL at 1 kHz)
- Impedance: 2.9 kΩ[1]

Controls / Indicators

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

Materials

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

Temperature and humidity range

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

Radio frequency (RF) link (FineTuner)

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

1 typical values

FINETUNER

Dimensions[1]

Length: 85.5 mm (3.336 in.)
Width: 54.0 mm (2.126 in.)
Height: 6.3 mm (0.248 in.)
Weight: 33.0 g (1.164 oz.) (incl. battery)

Controls / Indicators

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

Power supply

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

Classification

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

Materials

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

Temperature and humidity range

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

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 m

1 typical values

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

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

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

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

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

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

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

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

1 typical values

SYMBOLS

CE 0123

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

CE mark applied in 2012

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

MR unsafe

Caution, consult accompanying documents (manual)

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

Non-ionizing radiation (FineTuner)

Fragile; handle with care

Relative humidity

Temperature limit

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

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

SPEECH PROCESSOR TEST DEVICE

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

CE mark applied in 2005

GUIDANCE AND MANUFACTURER'S DECLARATION

Tables according to IEC 60601-1-2 for RONDO

Electromagnetic emissions for all equipment and systems

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

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

Electromagnetic immunity – for all equipment and systems

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

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

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

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

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

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

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

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

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

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	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.

10. Appendices

WARRANTY, GUARANTEE AND REGISTRATION CARD

Our warranty is in agreement with statutory warranty claims.

MED-EL grants a three-year guarantee for the RONDO audio processor.

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

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

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

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

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

MANUFACTURER ADDRESS

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Durham, NC 27713, USA
Tel.: (919) 572–2222
Fax: (919) 484–9229
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E-Mail: implants.us@medel.com

11. Contact MED-EL

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

Contact MED-EL

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CE
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