Cochlear Implants

MED EL

RONDO 2 Audio Processor
User Manual

hearLIFE

Table of contents

Introduction

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

Your MED-EL Cochlear Implant System consists of the Mi1200 SYNCHRONY (hereafter referred to as SYNCHRONY), Mi1000 MED-EL CONCERT (hereafter referred to as MED-EL CONCERT), PULSARCI[100] (hereafter referred to as PULSAR), SONATATI[100] (hereafter referred to as SONATA), or C40+ implants, the external RONDO 2 audio processor (including FineTuner), the external components and accessories, and any external hardware and software used by your audiologist.

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

Important

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

The adjustment to a cochlear implant and adequate fitting of the device are gradual processes that occur over time. It is important to remember that your ability to hear with your new MED-EL Cochlear Implant System may take a little time while you become accustomed to this new method of hearing. You may choose to work with an aural rehabilitation specialist or other clinician to help you maximize your communication skills using the device.

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

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

Intended use –
Indications –
Contraindications

Intended use

The RONDO 2 is an audio processor and an external part of the MED-EL Cochlear Implant System. The MED-EL Cochlear Implant System is intended to evoke auditory sensation via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition[1].

Indications

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

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

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1 EAS users can avail of the RONDO 2 as an alternative wearing option desired and where the acoustic amplification is not needed.

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

The user of the RONDO 2 does not need any special skills or elevated level of education, however, the user (or custodian if the user is a child or a handicapped person not able to perform the actions listed below) shall at minimum be able to perform the following actions:
• Switching ON/OFF
• Charging the battery powering the device
• Placing/removing the RONDO 2 over/from implant

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

Contraindications

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

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

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

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

RONDO 2
audio processor

The parts of the system

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

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

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

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

Audio processor

Pushbutton
(ON/OFF)

Design cover

Socket seal

Socket for alternative power source (Mini Battery Pack)
or programming cable (used by your audiologist)

Magnet

Microphone opening

Attachment clip
fixtures

MED-EL

Pushbutton
(ON/OFF)

Multicolor indicator lights

Charging indicator light

Charger
(not manufactured by MED-EL)

Symbol picture

Attachment clips

Fig. 1 Your RONDO 2 audio processor and components

ON/OFF pushbutton

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

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

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

Fig. 2 Activating/deactivating your audio processor

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

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

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

Important

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

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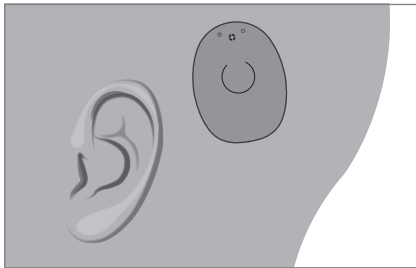

Fig. 3 Audio processor over the site of the implant. Note that the microphone is facing upwards.

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

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

If you want to store your audio processor for a longer period of time after you have already used it, proceed as follows:
• Switch off the device.
• Charge the device completely.

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

Design cover

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

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

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

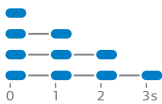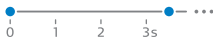Fig. 4 How to change the design cover

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

Indicator lights

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

Audio processor indicator light (blue, left side)

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

Blinking pattern	Meaning	Required action	Remarks
Confirmation pattern			
• Brief flash of blue indicator light	FineTuner command received and accepted	None	**Important** Pressing the Default key ⟳ on your FineTuner only affects volume and audio sensitivity. The program position does not change.
Program change pattern			
0 1 2 3s	Program 1 to 4 selected	None	The blue indicator light will blink depending on the selected program position. **Important** These blinking patterns may start off looking like the battery empty pattern.
Status pattern			
0 1 2 3s •••	The processor is initialized and working	None	You may perceive a clicking sound with an active telecoil whenever the indicator light blinks.

ON/OFF indicator light (amber, left side)

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

Link Monitoring (green and red, right side)

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

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

Charging indicator light

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

FineTuner

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

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

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

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

The FineTuner is configured for its designated target audio processor, i.e. only the target audio processor will execute the desired command when a certain key is pressed on the FineTuner. The typical maximum operating distance between the FineTuner and the audio processor is approximately 80 cm. This range might be less if you are close to electronic and electrical equipment even if this equipment complies with all applicable electromagnetic emission requirements.

How to configure your FineTuner

The FineTuner is configured for your individual audio processor and cannot be used by another cochlear implant user. Your audiologist or clinical staff will configure the FineTuner to suit your needs. Sometimes it may be necessary for you to synchronize your FineTuner and audio processor (e.g. if you purchase a backup FineTuner). To do so, first switch off your audio processor and place it on the keyboard of the FineTuner (approx. over key (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.

For bilaterally implanted users
One FineTuner can be configured for use with both audio processors. If you want to use your FineTuner for both audio processor systems, your audiologist or clinical engineer

has received the MAESTRO software manual with detailed programming information and will assign two audio processors to your dataset. Once your audio processors are programmed correctly, the synchronization procedure described above should be performed with both audio processors.
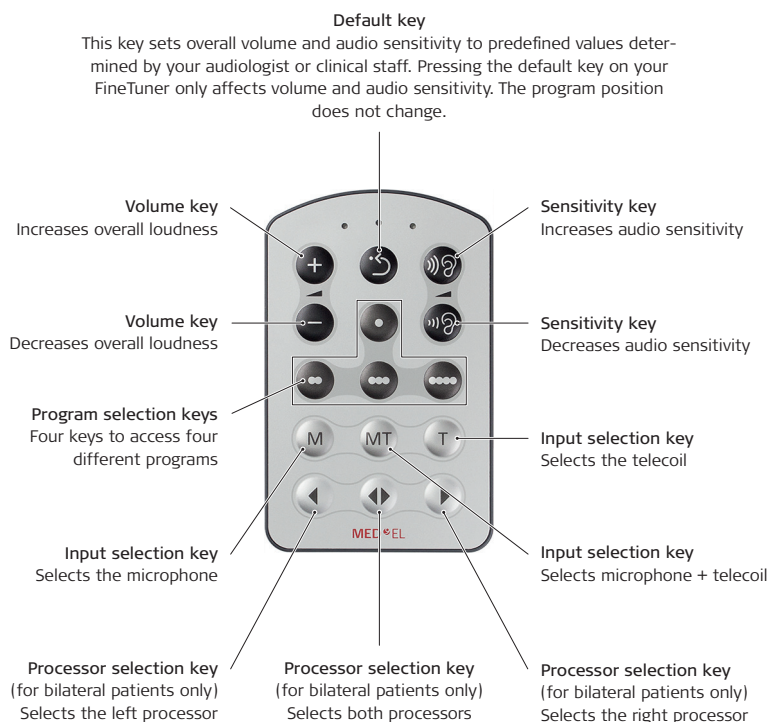
FineTuner controls

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

Volume key
Increases overall loudness

Sensitivity key
Increases audio sensitivity

Volume key
Decreases overall loudness

Sensitivity key
Decreases audio sensitivity

Program selection keys
Four keys to access four different programs

Input selection key
Selects the telecoil

Input selection key
Selects the microphone

Input selection key
Selects microphone + telecoil

Processor selection key
(for bilateral patients only)
Selects the left processor

Processor selection key
(for bilateral patients only)
Selects both processors

Processor selection key
(for bilateral patients only)
Selects the right processor

Fig. 5 FineTuner

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

FineTuner functions

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

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

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

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

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

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

Your FineTuner does not have an ON/OFF switch.

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

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

Battery

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

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

Important

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

If the date (YYYY-MM) stated next to the [⊞1°] symbol has expired before your audio processor has been charged for the first time, contact your MED-EL representative.

Charging the battery of your audio processor

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

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

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

Important

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

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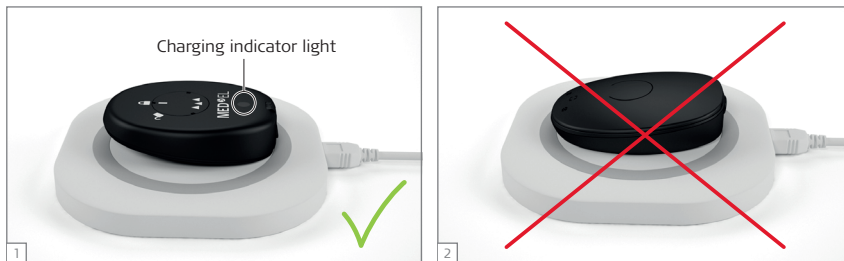

Fig. 6 Charger

Charging indicator light

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

NOTE:

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

Magnet

Important

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

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

Important

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

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

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

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

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

Fig. 8 Magnet strengths for SYNCHRONY implant

Fig. 9 Magnet strengths for all other types of implants

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

Important

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

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

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

NOTE:

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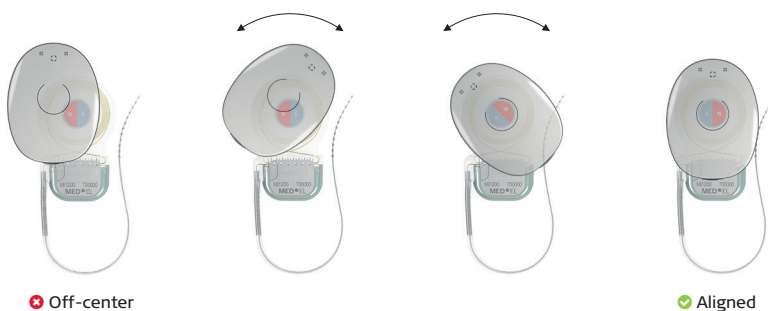

❌ Off-center   ✅ Aligned

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

How to change the magnet

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

Fig. 11 Changing the magnet

Attachment options

Attachment clip with lanyard

The attachment clip is used to attach the audio processor to your or your child's clothes or hair to reduce the risk of damaging the audio processor should it come off and drop on the floor or another hard surface.
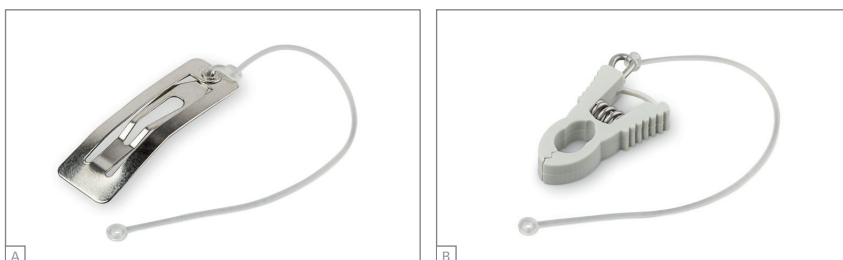
Fig. 12 Attachment clips

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

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

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

Connectivity

Direct audio input

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

Telecoil

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

To use the telecoil proceed as follows:

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

When you switch on the audio processor, the microphone is active even if you had the telecoil selected before you switched off the audio processor. When the telecoil is active, you may hear buzzing sounds when pressing a FineTuner key. The buzzing is normal and indicates that a command is being sent. To reduce interference with various electronic and electrical equipment when the telecoil is active, we recommend you reduce audio sensitivity (see chapter 4, RONDO 2 audio processor, FineTuner, FineTuner controls).

Alternative power source

Mini Battery Pack

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

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

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

Fig. 14 Mini Battery Pack connected to audio processor

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

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

Fig. 15 Reattaching the socket seal

Special considerations for young children

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

· Deactivation of certain FineTuner controls: To prevent accidental program, volume or sensitivity changes, it is possible to deactivate these FineTuner controls. Please contact your CI center for assistance.
· Attachment clips to prevent the audio processor from dropping on the floor when it comes off.
· An optional headband to keep the audio processor securely on the head. The headband may be purchased separately.
· Amber indicator light to allow parents/adults to check if the audio processor is active. The amber indicator light illuminates when briefly pressing the ON/OFF pushbutton to indicate that the audio processor is active.
· Link Monitoring functionality indicating proper connection between audio processor and implant.
· Status indicator light which blinks approx. every 3.5 seconds indicating that the audio processor is initialized and working. Your audiologist can activate this blinking pattern.

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

Important

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

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

General precautions and warnings

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

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

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

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

Important

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

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

General precautions for your MED-EL Cochlear Implant System

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

The electronics are durable but must be treated with care.
*   Never open the housing of your audio processor. Unauthorized opening invalidates the warranty.
*   Before switching on the audio processor, check the external parts of the MED-EL Cochlear Implant System for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the audio processor should not be switched on. Read chapter 8, Troubleshooting or contact your CI center or MED-EL.

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

Everyday life

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

For the external components, please observe the following:

- Your audio processor and FineTuner do not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range is between 0 °C to +50 °C (+32 °F to +122 °F) for the audio processor and the FineTuner. Normally, when the audio processor is worn on the body, natural body heat helps maintain this temperature range.
- The defined operating temperature range for charging the audio processor is between +10 °C and +30 °C (+50 °F and +86 °F).
- Do not leave the audio processor, FineTuner or charger in direct sunlight (especially inside a car). Long exposure to direct sunlight might damage the audio processor or FineTuner.
- If you ever experience loud or uncomfortable sounds, please remove your audio processor immediately: this will stop stimulation at once.
- Blowing your nose too hard might lead to (temporary) fluctuations in loudness. This is caused by air trapped over the reference electrode of the implant.
- Do not use the audio processor or FineTuner of another cochlear implant user. Your audio processor and FineTuner have been adjusted to your individual needs. Using another audio processor or FineTuner may cause painful or uncomfortable stimulation.
- Avoid getting your audio processor, FineTuner or charger wet as this may impair their function. Always remove and switch off the external parts of your implant system and keep them in a dry place before bathing, showering or engaging in other water-related activities.
- If the external parts become wet, switch off your audio processor as quickly as possible, remove the cover and gently wipe all external parts dry, using a soft, absorbent cloth. If the FineTuner becomes wet, wipe it off with a dry tissue.
- Do not use a drying kit, as this may damage the devices.
- You also have to take care of the external components of your/your child's MED-EL Cochlear Implant System. They should not be dropped or subjected to dangerous areas (e.g. machines or high voltage) which could result in damage to the components.

- Do not use the audio processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.
- Do not use your audio processor in the vicinity of strong ionizing radiation (e.g. x-ray machines) or electromagnetic fields (e.g. MRI machines). Such radiation or fields may stop your MED-EL Cochlear Implant System from working.
- Do not modify the housing, the electronics or any other parts of your audio processor, FineTuner or charger in any way.

Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury.

Warning

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

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

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

Technology in everyday life

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

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

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

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

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

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

TV, radio, FM systems, etc.

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

Electrostatic discharge (ESD)

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

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

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

Sports and play

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

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

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

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

Precautions for medical procedures

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

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

Electrical lice combs
Cochlear implant users should not use these devices.

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

Care and maintenance

Maintenance

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

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

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

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

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

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

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

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

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

Weekly maintenance of your audio processor

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

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

Battery

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

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

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

Changing the battery of your FineTuner

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

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

Fig. 16 Changing the battery of your FineTuner

Important

- Wash your hands after handling disposable batteries.
- Do not try to recharge disposable batteries.
- Do not disassemble, deform, immerse in water or incinerate batteries.
- Avoid mix-up of old and new batteries or batteries of different types 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.
- Always remove used batteries immediately to avoid leakage and possible damage to the device.
- Used batteries should be disposed of according to local regulations. If you ignore these regulations, you will contribute to pollution of the environment. Generally, batteries are collected separately and not disposed of with the household garbage.

To prevent children from swallowing or choking on batteries, always keep new and used batteries out of the reach of children. Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury.

Troubleshooting

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

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

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

Important

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

Speech Processor Test Device

Fig. 17 Speech Processor Test Device

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

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

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

If you suspect a malfunction in your audio processor, contact your CI center or MED-EL or try the following procedure:

Switch on the audio processor and make sure its battery is charged. Place the flat side of the audio processor under the Speech Processor Test Device (see Fig. 17), it will position itself correctly due to magnetic attraction.

When speaking into the microphone, the red light on the Speech Processor Test Device should flicker in the rhythm of your voice. If the red light does not light up or stays on constantly, try the following:
- Adjust the volume setting. By using the appropriate loudness setting, you should be able to recognize the flickering of the red light in the rhythm of your voice.
- Connect the Mini Battery Pack to your audio processor. Make sure that it is supplied with fresh batteries.
- Change the batteries of the Mini Battery Pack.

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

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

FineTuner

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

• The audio processor is out of the FineTuner's operational range. To overcome this you should move the FineTuner closer to the audio processor.

• The FineTuner keyboard lock is active. In this case follow the instructions for unlocking as described in chapter 4, RONDO 2 audio processor, FineTuner, FineTuner functions.

• Interference from other electronic or electrical equipment is present that blocks the transmission. To eliminate this interference you need to move the FineTuner closer to the audio processor and/or go to a different location.

• The audio processor and the FineTuner are not synchronized. In this case you need to refer to the section described in chapter 4, RONDO 2 audio processor, FineTuner, How to configure your FineTuner.

• In the case of a suspected malfunction of the FineTuner you need to remove the battery and re-insert it after a few minutes, as described in chapter 7, Care and maintenance, Batteries, Changing the battery of your FineTuner.

• The FineTuner battery is low. In this case you need to replace the battery as described in chapter 7, Care and maintenance, Batteries, Changing the battery of your FineTuner.

• The desired command in the audio processor has been disabled by your audiologist during fitting. To enable this command you will need to contact your clinic, CI center or MED-EL.

• The red indicator lights in the audio processor have been disabled by your audiologist during fitting. To enable the red indicator lights you will need to contact your clinic, CI center or MED-EL.

Additional troubleshooting information:
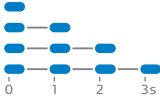
• If you or your child have used the (T) (telecoil) or (MT) (microphone and telecoil) settings and are unable to return to the (M) (microphone) signal source input with the FineTuner, you need to switch the audio processor off and on again. When the audio processor is switched on again it will automatically 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.

Blue audio processor indicator light

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

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

Blinking pattern	Meaning	Required action	Remarks
Error patterns			
0 1 2 3s	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be replaced.
0 1 2 3s	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.
0 1 2 3s	Electronic problem or program failure	Switch processor off. Switch processor back on.	If the blinking persists, the processor must be reprogrammed.
0 1 2 3s	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	
Warning patterns			
0 1 2 3s	Battery empty	Switch processor off. Charge the battery. Switch processor back on.	If the processor is not switched off, the blue indicator light will continue to blink.
0 1 2 3s	Maximum or minimum value of volume or audio sensitivity range reached	Stop pushing button(s) on FineTuner.	
Confirmation pattern			
Brief flash of blue indicator light	FineTuner command received and accepted	None	**Important** Pressing the Default key 🔄 on your FineTuner only affects volume and audio sensitivity. The program position does not change.

Blinking pattern	Meaning	Required action	Remarks
Program change pattern			
0 1 2 3s	Program 1 to 4 selected	None	The blue indicator light will blink depending on the selected program position. **Important** These blinking patterns may start off looking like the battery empty pattern.
Status pattern			
0 1 2 3s	The processor is initialized and working	None	You may perceive a clicking sound with an active telecoil whenever the indicator light blinks.

Link Monitoring

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

Blinking pattern	Meaning	Required action	Remarks
Green			
●	When turning on a processor programmed for a previous generation implant (e.g. C40+, C40): Indicates functionality of the audio processor.	None	Applicable only to previous generation implants without I^{100} serial numbers
●●●	When positioning a turned on processor programmed for a new generation implant over the implant: Correct implant detected. Indicates functionality of audio processor and implant.	None	Applicable only to implants with a I^{100} serial number saved to the audio processor memory bank
Red			
●–●–●–●–●–●●●●I 0 1 2 3s 5min 2 × per second for max. 5 minutes	Audio processor and implant are disconnected	Position the audio processor over the implant site. Make sure to use the correct magnet	If the blinking persists, contact your clinic, audiologist or MED-EL.
	Audio processor positioned over wrong implant (bilaterally implanted users)	Position the audio processor over the correct implant	
●————————●–●●● 0 10s	Audio processor has powered off	Switch the audio processor off and on again, reposition the audio processor over the implant to resume stimulation (the processor does not switch off automatically)	If the blinking persists, contact your clinic, audiologist or MED-EL

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

Private alert

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

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

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

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

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

FineTuner indicator functions

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

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

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

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

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

Configuration successful
If configuration of your FineTuner (see chapter 4, RONDO 2 audio processor, FineTuner, How to configure your FineTuner) was successful, or if the automatic keyboard lock feature was successfully activated/deactivated, both amber indicator lights will illuminate for approximately one second.

Program mode
If ◁▷ is pressed for more than 5 seconds (must be unlocked; see chapter 4, RONDO 2 audio processor, FineTuner, FineTuner functions for locking/unlocking instructions), the FineTuner enters the program mode. The three indicator lights start flashing. When the red indicator light is on, the two amber indicator lights are off and vice versa. Flashing stops and the program mode is left after 5 seconds or earlier when a correct key is pressed.

Technical data

Audio processor

Dimensions[1]

35.8 mm
(1.41 in.)

12.1 mm
(0.48 in.)

46.8 mm (1.84 in.)

Length: 46.8 mm (1.84 in.)
Width: 35.8 mm (1.41 in.)
Height: 12.1 mm (0.48 in.)

Weight[1]

14.9 g (0.53 oz.) (with cover and magnet 1)

Power supply

1 rechargeable Li-ion battery, nominal 3.7 V
Battery life expectancy is typically more than 5 years

Hardware

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

Audio input

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

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1   typical values

- Sensitivity: −61.4 dBV[1] (corresponds to 70 dB SPL at 1 kHz)
- Impedance: 2.9 kΩ[1]

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

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

Temperature and humidity range
Charging temperature range: +10 °C to +30 °C (+50 °F to +86 °F)
Operating temperature range: 0 °C to +50 °C (+32 °F to +122 °F)
Storage temperature range: −20 °C to +60 °C (−4 °F to +140 °F)
Relative humidity range: 10 % to 93 %
Atmospheric pressure range: 700 hPa (mbar) to 1060 hPa (mbar)

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

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

Radio frequency (RF) link (FineTuner)
Frequency band of reception: 9.07 kHz (±3 %)

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1 typical values

FineTuner

Dimensions[1]
Length: 85.5 mm (3.366 in.)
Width: 54.0 mm (2.126 in.)
Height: 6.3 mm (0.248 in.)
Weight: 33.0 g (1.164 oz.) (incl. battery)

Controls/Indicators
- Default key
- Volume keys
- Sensitivity keys
- Program selection keys
- Input selection keys
- Processor selection keys
- Indicator lights: 1 red LED for alarm and 2 amber LEDs for indicator functions

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

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

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

Temperature and humidity range
Operating temperature range: 0 °C to +50 °C (+32 °F to +122 °F)
Storage temperature range: −20 °C to +60 °C (−4 °F to +140 °F)
Relative humidity range: 10 % to 93 %
Atmospheric pressure range: 700 hPa (mbar) to 1060 hPa (mbar)

———

1 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: 0.65 m (2.13 ft.)

Regulatory statements

Applicable in Canada only:
Model: FineTuner – Canada 310

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

Applicable in the USA only:
Model: FineTuner – FCC ID: VNP-FT

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

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

Symbols

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

CE mark applied in 2017

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

Refer to instruction manual/booklet

Caution, consult accompanying documents (manual)

MR unsafe

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

Non-ionizing radiation (FineTuner)

Fragile; handle with care

Relative humidity

Temperature limit

Not suitable for children under 3 years

▭	Charge before first use
▭ 1st	First charge before YYYY-MM (Best before YYYY-MM)
▲	Manufacturer
SN	Serial number
REF	Catalog number

IP54 IP54
Moisture and dust protection acc. to IEC 60529

This classification means that your audio processor is protected against failure from ingressing dust and splashing water when fully assembled, i.e. when
- the design cover is snapped onto the audio processor,
- the socket seal covering the connector on the wider side of the audio processor is closed.

Speech Processor Test Device

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

CE mark applied in 2005

Disposal

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

Guidance and manufacturer's declaration

Tables according to IEC 60601-1-2 for RONDO 2

NOTE:
The RONDO 2 consists of the hermetically sealed processor containing the electronics and rechargeable battery and the separate design cover. Only the programming cable and Mini Battery Pack cable provided by MED-EL can be connected to the RONDO 2.

There are no deviations from this collateral standard and allowances.

Electromagnetic emissions for all equipment and systems
The RONDO 2 is intended for use in the home healthcare environment. The customer or the user of the RONDO 2 should assure that it is used in such an environment.

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

Electromagnetic immunity – for all equipment and systems

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±15 kV air	±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines	±1 kV	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth		
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0 % U_T for 0.5 cycle (1 phase)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	0 % U_T for 1 cycle		
	70 % U_T for 25/30 cycles (50/60 Hz)		
	0 % U_T for 250/300 cycles (50/60 Hz)		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

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

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer than 30 cm (12 in.) to any part of the RONDO 2, including cables specified by MED-EL. Otherwise degradation of the performance of this equipment could result.
	6 Vrms ISM/amateur bands	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

Electromagnetic immunity to proximity fields from RF wireless communications equipment

The RONDO 2 is intended for use in the home healthcare environment. Test as specified in IEC 61000-4-3.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Appendices

Warranty statement

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

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

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

Extensions of statutory warranties exclusively cover product failures. This does not apply to any MED-EL product subjected to physical or electrical abuse or misuse, or operated in any manner inconsistent with the applicable MED-EL instructions.

Manufacturer address

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Fax: (919) 484–9229
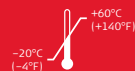Toll free: (888) MED-EL-CI (633-3524)
E-Mail: implants.us@medel.com

Contact MED-EL

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

USA Distributor:
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implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale,
distribution and use by or on the order of a physician.

+60°C
(+140°F)

−20°C
(−4°F)

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