

RONDO 3 Audio Processor

User Manual



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1. Introduction

This user manual provides information and instructions regarding the MED-EL Cochlear Implant System with the RONDO 3 audio processor (Me155x)¹ (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.

NOTE: You are the operator of your/the user's audio processor, therefore we recommend that you read this user manual in its entirety. Do not perform any maintenance activities other than those described in this user manual. When performing these maintenance activities, always remove the audio processor from the head.

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

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

Please contact your healthcare provider or local MED-EL representative with any additional questions you may have.

Symbols used in this user manual



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



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



Information particularly relevant for parents, guardians or caregivers of children who use the system

¹ x = 0, 1, 2 or 3

2. Intended use – Indications – Contraindications

Intended use

The RONDO 3 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 condition².

Additionally, the MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL). SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages between ears.

Indications

The RONDO 3 audio processor is an external component of the MED-EL Cochlear Implant System and is indicated for use in patients who have been implanted with Mi1200 SYNCHRONY or Mi1250 SYNCHRONY 2 (hereafter referred to as SYNCHRONY), Mi1000 CONCERT (hereafter referred to as MED-EL CONCERT), SONATA¹⁰⁰ (hereafter referred to as SONATA), PULSAR¹⁰⁰ (hereafter referred to as PULSAR) or C40+ cochlear implants.

Bilateral deafness

- Adults eighteen (18) years of age or older who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40 % correct or less in the best aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences).

² Electro-acoustic stimulation (EAS) users can use the RONDO 3 audio processor as an alternative wearing option if desired, however acoustic amplification will not be available in this configuration

- 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.

Single-sided deafness and Asymmetric Hearing Loss

The MED-EL Cochlear Implant System is indicated for evoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contralateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit.

General

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

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

The user of the RONDO 3 audio processor 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 not able to perform the actions listed below) shall at minimum be able to perform the following actions:

- Switching ON/OFF
- Charging the internal battery
- Placing/removing the RONDO 3 audio processor over/from implant
- Evaluating the battery level

As the RONDO 3 audio processor 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 3 audio processor if the individual is known to be intolerant of the materials used in the RONDO 3 audio processor. For details, please refer to section Technical data.

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

As the RONDO 3 audio processor is a component of the MED-EL Cochlear Implant System, all contraindications stated for the MED-EL Cochlear Implant System are applicable.

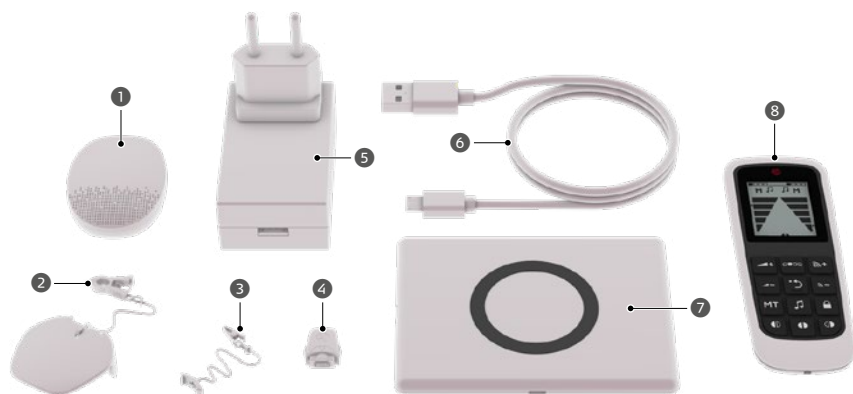
NOTE: Important information related to indications, contraindications, warnings and risks for your cochlear implant are shipped in a separate document (instruction for use of the implant) to your clinic with the cochlear implant. If you want to review this information, please contact your clinic or MED-EL.

3. RONDO 3 audio processor

The parts of the system

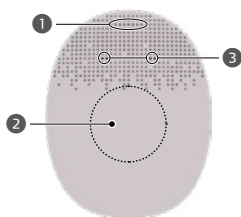
The MED-EL Cochlear Implant (CI) System is an active medical device that has internal (implanted) and external parts. The internal part of the device is surgically implanted behind the ear in the skull, while the external audio processor is worn over the implant site.

The external parts include the audio processor, the audio processor accessories and optional equipment. In its basic configuration, the audio processor consists of the main unit containing the electronics and rechargeable battery and the exchangeable cover. A separate remote control called the FineTuner Echo facilitates access to various audio processor functions.

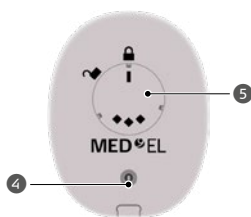


- 1 RONDO 3 audio processor
- 2 Clothing attachment clip with cap
- 3 Hair attachment clip, small, with bracket
- 4 Telecoil adapter
- 5 USB power supply
- 6 Cable for wireless charger (not manufactured by MED-EL)
- 7 Wireless charger (not manufactured by MED-EL; may not look exactly as shown)
- 8 FineTuner Echo

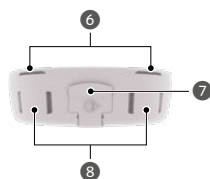
Audio processor



Top view



Bottom view



Back view

- | | |
|----------------------------|-------------------|
| ① Main indicator light | ⑤ Magnet |
| ② ON/OFF pushbutton | ⑥ Finger grooves |
| ③ Microphone openings | ⑦ Socket cover |
| ④ Charging indicator light | ⑧ Bracket grooves |

Switching the audio processor ON/OFF

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

To switch on your audio processor, proceed as follows:

- ① Press down on the center pushbutton of the processor for approx. 2 seconds.
- ② The white indicator light will fade in. The audio processor is now turned on.
- ③ 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.



NOTE: The audio processor has a Link Monitoring feature. The red indicator light will blink when implant and audio processor cannot communicate. This happens when the audio processor is not positioned over the implant or positioned over the wrong implant. Your healthcare provider can deactivate the indicator light if you prefer this.

To switch off your audio processor, proceed as follows:

- ① Press and hold down the pushbutton until the white indicator light fades out. The audio processor is now switched off.

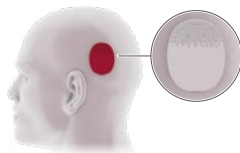


Switching the audio processor on or off can cause a soft sound. You should remove the audio processor from the implant site before operating the pushbutton if this sound bothers you.

The audio processor has an automatic power-off function and switches off after approx. 5 minutes when there is no connection with the implant (e.g. when the audio processor is not worn). This feature helps maintain battery life when the audio processor is not worn and not intentionally switched off. Your healthcare provider can deactivate this function if you prefer this.

Placing the audio processor over the implant

- 1 Switch on the audio processor.
- 2 Place the audio processor over the site of the implant. The bottom of the audio processor holding the magnet should be against your head and the microphones face upwards.
- 3 As soon as the audio processor is near the implant, it should be positioned correctly by attraction to the implant magnet. The audio processor is held in place by magnetic attraction over the implant.



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



❌ Off-center



✅ Aligned

Charging the audio processor

The audio processor has one lithium-ion (Li-ion) rechargeable battery which is integrated in the processor housing and cannot be changed. This battery supplies the external and internal components of the MED-EL Cochlear Implant System with power.

The integrated battery in your audio processor will supply power for up to 24 hours without recharging, i.e. it provides a full day of operation. Charging the battery takes approx. 2.5 to 4 hours depending on ambient temperature. We recommend charging the battery once a day while you are sleeping.

MED-EL recommends using only the wireless charger provided with the audio processor. The wireless charger is an off-the-shelf product and may vary from country to country depending on availability.

To charge the audio processor, proceed as follows:

- 1 Connect the wireless charger to a power supply.
- 2 Remove the audio processor from the head. You do not have to switch off the audio processor for charging. The audio processor will automatically switch off when placed on the wireless charger.
- 3 Place the audio processor in the center of the wireless charger with the round charging indicator light on the bottom of the audio processor facing upwards. If any clips are attached, make sure to position them off the wireless charger, so that the metallic parts are not attracted by the magnet.
- 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.
- 5 When the charging indicator light of the audio processor is off, the audio processor is ready for use.



CAUTION


- Do not place the audio processor on the wireless charger as shown below. In this position the audio processor will not be charged.



- Do not use the wireless charger on the head. The audio processor becomes warm during wireless charging and can cause skin burns.

When charging the audio processor wirelessly, you should observe the following:

- The audio processor becomes warm during wireless charging. This is normal and does not indicate a failure.
- Always observe the specified ambient temperature for wireless charging (0°C to +30°C [+32°F to +86°F]). High ambient temperatures may slow down the charging process.
- Do not expose the wireless charger with audio processor to direct sunlight. This may interrupt the charging process and battery run-time may be reduced when you use your audio processor the next time. Moreover, the audio processor may become excessively hot and cause skin burns when placing it on the head directly after charging.

- Please note that the battery run-time will be reduced if the audio processor was not fully charged. If you interrupt the charging process and remove the audio processor from the wireless charger, make sure that the audio processor is not too hot before putting it on the head.
- If the battery is fully charged and you place the audio processor on the wireless charger, the battery will not be charged. The orange charging indicator light will not illuminate.
- If the wireless charger indicates an error, remove the audio processor from the wireless charger. Should the error occur repeatedly, exchange the wireless charger.
- The audio processor is delivered only partially charged, so the initial battery lifetime may be reduced. Please make sure to fully charge your audio processor before using it for the first time.
- If the date (YYYY-MM) stated next to the  symbol has expired before your audio processor has been charged for the first time, contact your local MED-EL representative.






Battery life reduces over time. This is normal for any type of rechargeable battery. If your audio processor works less than 10 hours after fully charging the battery, contact your healthcare provider or local MED-EL representative.

Checking the battery status

To check the battery status, proceed as follows:

- 1 Make sure that the audio processor is switched on.
- 2 Briefly push the pushbutton again. The main indicator light will blink in different patterns and colors according to remaining battery charge.

Battery status (green, orange, red)

Blinking pattern	Meaning	Required action
	Battery fully charged (75 % to 100 %)	None
	Battery charge 50 % to 75 %	None
	Battery charge 25 % to 50 %	None
	Battery charge low to 25 %	Consider charging the audio processor.
	Battery charge low	Charge the audio processor.

0

1

2

3 seconds

Cover

The cover has integrated membranes to protect the microphones from dust, deterioration and water. The cover should be replaced every 3 months or if it is damaged. If it is not replaced, increasing contamination may impair your hearing.

To change the cover, proceed as follows:

- 1 Insert your fingernail into one of the finger grooves between cover and processor and lift the cover up.
- 2 Place the new cover on the audio processor and gently push down. Do not use excessive force when positioning the cover.
- 3 Ensure that the cover completely snaps into place. You should see no gaps between the audio processor and the cover.



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

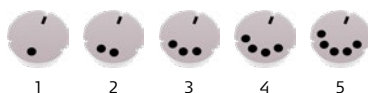
Magnet

A magnet is located in a compartment on the bottom of the audio processor to hold the audio processor in place on the head over the implant. Keep clear of metallic items as they attract the magnet.

Different magnet strengths are available. Magnet strength is indicated by the number of diamonds or circles on the magnet (1=weakest). Your healthcare provider can change the magnet to adjust the magnet strength to your needs.



Magnet strengths for SYNCHRONY implant



Magnet strengths for all other types of implants



CAUTION

- Depending on the type of implant, two variants of magnets are available for the audio processor. The type of implant is stated on your Patient Identification Card.
- For recipients implanted with a SYNCHRONY implant, the magnet strength is represented by diamonds.
- For recipients implanted with any other type of implant (MED-EL CONCERT, SONATA, etc.), the magnet strength is represented by circles.
- 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 communication between implant and audio processor.
- The magnet strength chosen should be appropriate for the individual user. Strong magnets are not recommended for users with thin skin flaps (e.g. young children), as excessive magnetic attraction could potentially increase the likelihood of skin irritation.

- If you notice any signs of skin irritation around the audio processor, contact your healthcare provider.



PARENTAL GUIDANCE

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. Please contact your healthcare provider for assistance.

How to change the magnet

NOTE: MED-EL strongly recommends that you do not change the magnet yourself, but have your healthcare provider do it.

- 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.
- 2 Turn the tool counter clockwise towards the unlocked symbol (🔓). The magnet disengages and can now be lifted out.
- 3 Remove the magnet from the tool.
- 4 Make sure that the new 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.
- 5 Align the arrow on the magnet exchange tool with the unlocked symbol (🔓) on the housing. 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. 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.



Attachment options

Attachment clip

The audio processor user kit includes various types of clips to attach to the audio processor with the bracket or cap. These optional attachment clips provide additional fixation of the audio processor to hair or clothing if desired.



Hair attachment clip
with bracket



Clothing attachment clip
with bracket



Clothing attachment clip
with cap

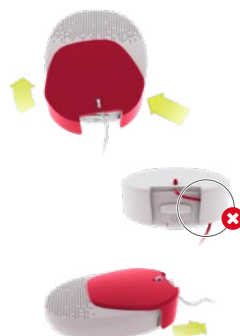
To use the bracket, proceed as follows:

- 1 To snap the bracket into the bracket grooves on the side of the audio processor next to the socket cover, push first one lip, then the other into the bracket grooves. You can attach the bracket on either side of the audio processor.
- 2 To remove the bracket, insert your fingernail on the side closer to the socket cover and lift the bracket off.



To use the cap, proceed as follows:

- 1 To snap on the cap, hold the audio processor with the top facing up in one hand and the cap between thumb and forefinger of your other hand. Now slide the cap onto the audio processor so that first one lip, then the other glides into the outermost bracket grooves on the side of the audio processor. The socket cover rests between the side wings of the cap. Make sure that the leash does not get caught under the cap.
- 2 To remove the cap, insert your fingernail on one side and lift the cap off.



MED-EL strongly recommends that you always use an attachment clip to reduce the risk of damaging the audio processor should it come off and drop on the floor or another hard surface.



PARENTAL GUIDANCE

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.

Indicator lights

The audio processor has two indicator lights which illuminate and/or blink with different patterns and colors to indicate different conditions. Your healthcare provider can deactivate the blinking signals (except error patterns, ON/OFF indication, flight mode confirmation pattern, battery status and charging indicator light) if you prefer this.



Main indicator light
(top view)



Charging indicator light
(bottom view)

Main indicator light

Audio processor status (white, blue)

Blinking pattern	Meaning	Required action	Remarks
	ON indicator light	None	The white light fades in or out when pressing the pushbutton in the center of the audio processor.
	OFF indicator light	None	
	Program 1 to 4 selected	None	The blue indicator light will blink depending on the selected program (i.e. after switching on the processor or changing the program).
	FineTuner Echo command received and accepted	None	

0

1

2

3 seconds

Battery status (green, orange, red)

Blinking pattern	Meaning	Required action
	Battery fully charged (75 % to 100 %)	None
	Battery charge 50 % to 75 %	None
	Battery charge 25 % to 50 %	None
	Battery charge low to 25 %	Consider charging the audio processor.
	Battery charge low	Charge the audio processor.





0

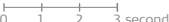
1

2




3 seconds


Link Monitoring (red, green)

Blinking pattern	Meaning	Required action	Remarks
	After placing an audio processor programmed for a previous generation implant (e.g. C40+, C40) over the implant: Indicates functionality of the audio processor.	None	Applicable only to previous generation implants (e.g. C40, C40+)
	After placing an audio processor programmed for a new generation implant over the implant: Correct implant detected. Indicates functionality of audio processor and implant.	None	Applicable only to PULSAR, SONATA, MED-EL CONCERT, SYNCHRONY and later generation implants
	Optional visual indication of activated link monitoring. This check is repeated whenever the audio processor is moved relative to the implant.	None	Can be activated by your audiologist.
	Audio processor and implant disconnected	Position the audio processor over the implant site.	If the blinking persists, contact your clinic, audiologist or MED-EL. The audio processor will automatically power off after 5 minutes (no stimulation). Your audiologist can deactivate the automatic power off function.
	Audio processor positioned over wrong implant (bilaterally implanted users)	Position the audio processor over the correct implant.	
	Audio processor has switched off due to empty batteries (if battery charge is still sufficient to power the audio processor).		
	Audio processor is in microphone monitoring mode.	Switch the audio processor off and on again.	






Error indication (red)

Blinking pattern	Meaning	Required action	Remarks
	Maximum or minimum value of volume or audio sensitivity range reached	Stop pushing button(s) on FineTuner Echo.	
	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 not programmed or programming failure	Select another position.	If the blinking persists, the audio processor should be reprogrammed by the healthcare provider.



0 1 2 3 seconds

Blinking pattern	Meaning	Required action	Remarks
	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be replaced.
	Electronic problem or programming failure	Switch processor off. Switch processor back on.	If the blinking persists, the audio processor must be reprogrammed by the audiologist.
	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 3 seconds

Flight mode confirmation pattern (red)

Blinking pattern	Meaning	Required action
	Flight mode successfully activated	None

0 1 2 3 seconds

Charging indicator light (bottom, orange)

Blinking pattern	Meaning	Required action	Remarks
	Audio processor battery is charging	None	The light goes off when the battery is fully charged.

0 1 2 3 seconds

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 healthcare provider will set the loudness accordingly. Your healthcare provider can also deactivate these 3 signals if you prefer this.

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 Echo is pressed.

Confirmation signal

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

Link Monitoring

The audio processor has a Link Monitoring function. When activated, the main indicator light blinks with different patterns and colors to indicate different conditions. The indicator light blinks green when the audio processor is functional and the correct implant has been detected. The indicator light blinks red when no link has been established between the implant and the audio processor. Please consult the table Link Monitoring (red, green) in section Indicator lights for more information about the blinking patterns.

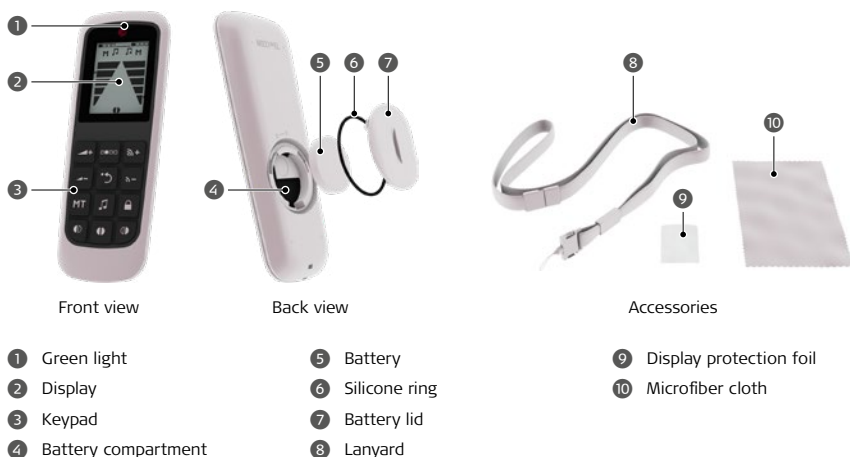
FineTuner Echo

NOTE: The previous generation FineTuner cannot be used with this audio processor.



The FineTuner Echo is a small and light-weight remote control provided to help you optimally use your audio processor in changing daily listening situations. Its ergonomic design and display facilitate changing the settings of your audio processor.

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

FineTuner Echo system components



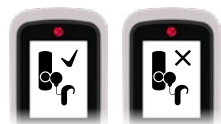
Using the FineTuner Echo for the first time

- 1 Clean the FineTuner Echo screen with the microfiber cloth.
- 2 To apply the display protection foil, pull off a small section of the backing and attach the adhesive side to the top part of the display. Slowly pull off the backing from the foil while carefully pressing out any trapped air bubbles with the microfiber cloth.
- 3 Insert a coin cell battery (type CR2032) with the **+** sign facing up. Hold the battery at a slight angle and insert it under the lip in the battery compartment, then gently push it down.
- 4 To close the lid, align the arrow on the lid with the  symbol on the housing and push down gently. Use a coin to turn the lid until the arrow on the lid meets the  symbol on the housing. You will feel a slight resistance when the lid locks in place.
- 5 After inserting the battery, a pairing notification appears automatically, prompting you to pair your FineTuner Echo. The pairing screen shows a symbolic audio processor, not the actual model.



To pair the FineTuner Echo, proceed as follows:












- 1 Switch off the audio processor.
- 2 Place the audio processor on the battery lid of the FineTuner Echo.
- 3 Switch on the audio processor.
- 4 If the pairing process was successful, a **✓** appears next to the pairing screen. If the pairing process was not successful, a **✗** is displayed.
- 5 For bilateral users, repeat the steps above for the other side.



NOTE: Your audio processor has to be configured for use with the FineTuner Echo. If the audio processor is not programmed correctly, the pairing process will not be successful. For bilaterally implanted users it is particularly important that the audio processors are correctly programmed for the right and left side. Otherwise only one processor can be paired to the right or left side.

If you experience problems when trying to pair the FineTuner Echo and the audio processor, please contact your healthcare provider.

FineTuner Echo keys

Key	Name	Function
	Volume key	Increases overall loudness
	Volume key	Decreases overall loudness
	Sensitivity key	Increases audio sensitivity
	Sensitivity key	Decreases audio sensitivity
	Program selection key	Toggles between different programs
	Default key	Sets overall volume and audio sensitivity of the selected program to predefined values
MT	Input selection key	Monitoring mode function only
	Audio streaming key	Blocks/unblocks active external audio stream
	Keypad lock	Locks/unlocks the keypad
	Processor selection key	Selects left audio processor
	Processor selection key	Selects left and right audio processor
	Processor selection key	Selects right audio processor

Your FineTuner Echo does not have an ON/OFF switch. If you want to switch off the device completely, you must remove the battery. Please note that the FineTuner Echo may still show the last screen even after removing the battery.







With the volume and sensitivity keys you can change volume and sensitivity in fast mode. Keep the desired key pressed to change the setting continuously instead of stepwise.






Your healthcare provider can selectively disable all FineTuner Echo functions by disabling the respective command in the audio processor.

FineTuner Echo display










The FineTuner Echo has a display to provide direct feedback. The display reflects the last action executed with the keys of the FineTuner Echo. It does not update automatically.

Status symbols

Symbol	Meaning	Required action
	Bilateral mode: right side selected	
	Bilateral mode: left side selected	
	Bilateral mode: both sides selected	
	FineTuner (streaming via accessory) enabled	
	FineTuner (streaming via accessory) disabled	
	The filled square indicates the selected program	
M	Microphone: Sound is perceived via the audio processor microphones.	

Symbol	Meaning	Required action
	Monitoring mode enabled	Press MT button for 3 seconds to leave the monitoring mode
	Sensitivity (for bilateral users only: a transparent symbol indicates that the respective side is currently disabled)	
	Loudness (for bilateral users only: a transparent symbol indicates that the respective side is currently disabled)	
MED-EL 	Lock Screen: The keypad of the FineTuner Echo is locked	Press  for approx. 3 seconds to lock/unlock keypad

Notification symbols

Symbol	Meaning	Required action	Remarks
	Audio processor battery low	Charge battery of audio processor	
	Audio processor battery empty	Charge battery of audio processor	
	FineTuner Echo battery low	Change battery of FineTuner Echo	
	Pairing Screen: The FineTuner Echo must be paired with an audio processor	Pair your FineTuner Echo	See section Using the FineTuner Echo for the first time for instructions
	Screen indicating successful pairing	None	
	Screen indicating unsuccessful pairing	Repeat the pairing process.	If repeated pairing is not successful, contact your healthcare provider or local MED-EL representative.
	Function deactivated	None	Contact your healthcare provider for further information.
	Connection Error: <ul style="list-style-type: none"> Indicates that an error occurred during communication with the audio processor (e.g. the FineTuner Echo may be too far away from the audio processor) The audio processor did not respond to the last command The audio processor is switched off Empty battery of audio processor Interference from other electronic or electrical equipment is blocking the transmission 	Move the FineTuner Echo closer to your ear and try to switch settings again.	If you only move the FineTuner Echo closer to your ear, the out of range indication will still be displayed. When you try to switch settings again, the FineTuner Echo will indicate if it is within range.
	An unexpected event prevented the command being executed by the audio processor.	Try again.	If the command still cannot be executed, contact your healthcare provider or local MED-EL representative.

FineTuner Echo battery

The FineTuner Echo requires one coin cell battery type CR2032. If you want to get more information on batteries, please contact your healthcare provider or local MED-EL representative.



CAUTION

- Wash your hands after handling disposable batteries.
- Do not try to recharge disposable batteries. Charging disposable batteries may cause battery electrolyte to seethe or battery internal pressure to rise. Leakage, heating, explosion or ignition of batteries may result.
- Do not disassemble, deform, immerse in water or incinerate batteries.
- Do not wet batteries with water. This may cause ignition of batteries.
- Do not short-circuit batteries, e.g. by allowing the negative and positive 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.).
- Do not solder batteries directly. Excessive heating may cause deformation of battery components.
- Insert batteries correctly. Erroneous insertion of batteries may result in battery short-circuiting.
- Store unused batteries in their original packaging, in a cool and dry place. Isolate or cover the positive and negative terminals to avoid short-circuiting.
- Do not store or use batteries in high temperature and high humidity locations and where batteries are exposed to direct sunlight (e.g. behind a window or in a car).
- Immediately discontinue using the battery if during use or storage, the battery emits an unusual smell, feels hot, changes color and/or shape or appears abnormal in any way.
- 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. In case of contact with the mouth, gargle and rinse thoroughly with water and seek medical attention immediately.
- If you are not going to use your FineTuner Echo for an extended period of time, you should remove the battery and dispose of or store it separately.
- Always remove used batteries immediately to avoid leakage and possible damage to the device.
- Used batteries should be disposed of according to local regulations. Generally, batteries are collected separately and not disposed of with the household garbage.



WARNING


- Misuse may result in the battery causing heat, smoke, rupture, flame or leakage which could lead to injury.
- Swallowing batteries could cause suffocation or internal injuries. If a battery is swallowed, contact your physician or local poison control center immediately.






PARENTAL GUIDANCE

- 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.
- Do not allow children to replace batteries without adult supervision.
- If the battery compartment does not close securely, stop using the FineTuner Echo and keep it out of the reach of children.

Changing the battery of your FineTuner Echo

When your FineTuner Echo displays this symbol  in the status line (see also section FineTuner Echo display), replacing the battery of your FineTuner Echo is recommended.

To change the battery, proceed as follows:

- 1 Open the lid on the back of the FineTuner Echo. Use a coin to turn it until the arrow on the lid meets the  symbol on the housing.
- 2 Lift the lid carefully with our fingernail and make sure that the black silicone ring does not fall out. If you lose the black silicone ring, please order a replacement from MED-EL.
- 3 Replace the used coin cell battery by gently shaking it into your hand. Try not to touch the battery contacts.
- 4 Insert the new battery with the **+** sign facing up. Hold the battery at a slight angle and insert it under the lip in the battery compartment, then gently push it down.
- 5 To close the lid, align the arrow on the lid with the  symbol on the housing and push down gently. Use a coin to turn the lid until the arrow on the lid meets the  symbol on the housing. You will feel a slight resistance when the lid locks in place.




Additional functions of your FineTuner Echo

Testing your audio processor

You can use your FineTuner Echo to test proper function of the audio processor microphones (see section Troubleshooting, Testing your audio processor for details).

Monitoring mode

When pressing the **MT** button for 3 seconds, the FineTuner Echo changes into the monitoring mode. The symbol  appears on the bottom of the display. The monitoring mode is used with the Microphone Test Device. For further information about this optional service tool for the MED-EL Cochlear Implant System, please read the applicable user manual or ask your healthcare provider for assistance.

In addition, you can switch your audio processor to silent mode if required.

Wearing options for your FineTuner Echo

You can wear your FineTuner Echo on the upper body using the optional lanyard. The FineTuner Echo features a lanyard fixation on the lower end below the battery compartment. To attach a lanyard, thread it through the small openings.



PARENTAL GUIDANCE

- Do not use the lanyard with children under 3 years to avoid the risk of strangulation.
- Keep the lanyard out of the reach of children under 3 years.

Due to its smaller size, the FineTuner Echo can also be worn comfortably in a pocket.

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.

Wireless functionality

The audio processor is equipped with 2.4GHz MED-EL proprietary as well as *Bluetooth*®³ wireless technology. This technology allows the audio processor to be wirelessly connected to various external devices like the MED-EL FineTuner Echo (remote control), the MED-EL AudioLink (audio streaming device), or a commercial electronic device (smartphone, tablet, etc.) with Bluetooth functionality⁴ that is capable of running the MED-EL AudioKey mobile app.

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



CAUTION

- Use of Bluetooth wireless technology or any changes to the Bluetooth wireless technology (e.g. firmware updates, hardware changes, connection/disconnection of additional devices, etc.) could introduce previously unidentified risks. If such risks are identified, they shall be analyzed, evaluated and controlled.
- The 2.4GHz wireless functionality may be affected by electromagnetic interference from other close electronic and electrical equipment even if this equipment complies with all applicable electromagnetic emission requirements. If such interference is experienced, move away from this electronic and electrical equipment.

Flight mode

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

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

To activate the flight mode, proceed as follows:

- 1 Switch off the audio processor (see chapter 3, RONDO 3 audio processor, Switching the audio processor ON/OFF) and wait at least 2 seconds.
- 2 Switch on the audio processor and wait until the main indicator light blinks blue for the first time.
- 3 Repeat steps 1 and 2.

³ The Bluetooth word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by MED-EL is under license.

⁴ Such an electronic device must at least be compatible with the Bluetooth 4.2 specification (Bluetooth Low Energy).

- 4 Repeat steps 1 and 2 again.
- 5 Repeat steps 1 and 2 one more time.
- 6 After approx. 3.5 seconds the main indicator light will briefly blink red to confirm that the flight mode has successfully been activated. If you do not see the red light, repeat steps 1 to 5.

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

To deactivate the flight mode, proceed as follows:

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

Telecoil adapter

When connecting the telecoil adapter to the direct audio input of the audio processor, telecoil signals are automatically added to the microphone signal of the audio processor. 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 adapter, proceed as follows:

- 1 Remove the audio processor from your head.
- 2 Open the socket cover.
- 3 Plug the telecoil adapter into the audio processor.
- 4 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.
- 5 When you are in an environment with a loop system, try to find a spot where the signal quality is best for you.
- 6 To deactivate the telecoil function, disconnect the telecoil adapter from the audio processor.



When the telecoil is active, you may hear buzzing sounds when operating a FineTuner Echo 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 section RONDO 3 audio processor, FineTuner Echo, FineTuner Echo keys).

NOTE: The input selection key (**MT**) of the FineTuner Echo has no effect on the telecoil adapter. Your healthcare provider can adjust the loudness of the adapter for each audio processor program.



PARENTAL GUIDANCE

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. Do not use the telecoil adapter with children under 3 years.

Alternative power source

When the battery level is very low (e.g. after the audio processor was stored for a long time), the audio processor will not power up immediately when an alternative power source is connected. In such a case you should charge the audio processor for at least 10 minutes before using it.

When the battery is low and you connect an alternative power source, you may perceive a brief period of silence while the battery low status of the system is reset. Remove the audio processor from your head before connecting an alternative power source if this bothers you.

The audio processor switches on automatically when an alternative power source is connected.



PARENTAL GUIDANCE

Ensure that the cable is not around your/your child's neck to avoid the risk of strangulation.

To connect an alternative power source, proceed as follows:

- 1 Remove the audio processor from the head.
- 2 Open the socket cover.
- 3 Connect the power source to the audio processor.



Charging cable

You can use the MED-EL charging cable with an appropriate power source to charge your audio processor and supply it with power during operation.



CAUTION

- Use the charging cable only in combination with a battery powered supply (e.g. USB power bank). Do not connect the charging cable directly to a mains adapter as this may lead to increased emissions and might not offer adequate protection to radio frequency communication services. This could disturb electronic devices close to the audio processor.
- Do not charge the power supply and the audio processor at the same time as this may lead to increased emissions and might not offer adequate protection to radio frequency communication services.
- In case of increased emissions it might be necessary to relocate or re-orientate the equipment for proper function.

To connect the charging cable, proceed as follows:

- 1 Plug the small plug of the charging cable into the audio processor. Plug the other end into a USB port or a USB power bank.
- 2 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.



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.



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.

Make sure that the Mini Battery Pack is switched on when used as an alternative power source for the 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.

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

4. 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 Echo controls: To prevent accidental program, volume or sensitivity changes, it is possible to deactivate these FineTuner Echo controls. Please contact your healthcare provider 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.
- Link Monitoring functionality indicating proper connection between audio processor and implant.
- Status indicator light which blinks approx. every 5 seconds indicating that the audio processor is initialized and working. Your healthcare provider can activate this blinking pattern.

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



PARENTAL GUIDANCE

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 section RONDO 3 audio processor, Magnet). You will notice correct alignment by stronger magnetic attraction.

5. 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 healthcare provider or local MED-EL representative will assist you with any additional questions you may have.

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

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



CAUTION

If you ever experience uncomfortable hearing sensations, we strongly recommend that you no longer wear your external system components. Please contact your healthcare provider immediately.



PARENTAL GUIDANCE

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 by your healthcare provider.

General precautions

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 in section 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 or FineTuner Echo. To change the battery or clean the battery contacts of the FineTuner Echo, perform the steps described in section Changing the battery of the FineTuner Echo or in section Maintenance, Cleaning, FineTuner Echo.
- Do not open or alter any system component as this may damage the system. Opening or altering system components can lead to serious injuries.
- 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 section Troubleshooting or contact your healthcare provider or local MED-EL representative.

- 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 users fitted with a pacemaker), it is advisable to first contact your healthcare provider or local MED-EL representative.

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 or impact at 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 Echo 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 to +122°F) for the audio processor and between +5°C and +40°C (+41°F and +104°F) for the FineTuner Echo. Normally, when the audio processor is worn on the body, natural body heat helps maintain this temperature range.
- Avoid excessive heat. Excessive heat might damage the audio processor or FineTuner Echo and make it unusable.
- If the audio processor has been at a temperature that is outside the defined operating temperature range of 0°C to +50°C (+32°F 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 [+32°F to +122°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. The same applies to the FineTuner Echo. The respective operating range for the FineTuner Echo is +5°C to +40°C (+41°F and +104°F).
- The defined operating temperature range for wirelessly charging the audio processor is between 0°C and +30°C (+32°F and +86°F).
- Do not leave the audio processor, FineTuner Echo or wireless charger in direct sunlight (especially inside a car). Long exposure to direct sunlight might damage the device.
- 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 Echo of another cochlear implant user. Your audio processor and FineTuner Echo have been adjusted to your individual needs. Using another audio processor may cause painful or uncomfortable stimulation. Using another FineTuner will not allow you to change the settings (volume etc.) of your audio processor.

- Avoid getting your audio processor, FineTuner Echo or wireless charger wet as this may impair their function. Always remove and switch off the external parts of your MED-EL Cochlear Implant System and keep them in a dry place before bathing, showering or engaging in other water-related activities.
- 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 Echo 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.
- Use of the audio processor and FineTuner Echo 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 or FineTuner Echo 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 or FineTuner Echo and result in improper operation.
- Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of the audio processor or FineTuner Echo, including cables specified by MED-EL. Otherwise, degradation of the performance of the audio processor or FineTuner Echo could result.
- Do not operate the FineTuner Echo while in control of a vehicle. Doing so will detract from your control and operation of that vehicle. In some countries, operating such devices while in control of a vehicle is an offense.



PARENTAL GUIDANCE

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.

Keeping your audio processor water- and dust-resistant

The audio processor has been tested in a controlled environment and is certified to be water and dust resistant in specific situations. It meets the requirements of Ingress Protection level 68 (IP68) as described in the international standard IEC 60529 – Degrees of Protection provided by Enclosures (IP code) at 1m for 60 minutes in still clean water when the cover is applied correctly, and the socket cover is closed. To keep the audio processor

water and dust resistant, please observe the following instructions. Ingressing water and dust may damage the audio processor.

- Do not immerse the audio processor in water deeper than 1 meter (3.28ft.) for more than 60 minutes.
- Do not expose the audio processor to moving water.
- If the audio processor was exposed to water, switch off the audio processor and dry it thoroughly with a soft, absorbent cloth. Then remove the cover and gently wipe all parts dry, using a soft, absorbent cloth.
- If the audio processor was immersed in water and the microphone openings are wet, sound may not be heard clearly due to water in front of the microphones. Remove the cover after drying the audio processor as described above and gently shake out the water from the microphone openings. You may also consider leaving the cover to dry for several hours before reusing it. If sound is still distorted, please exchange the cover.

NOTE: You should use the appropriate water protection measures provided by MED-EL if you want to use your audio processor during activities in water.

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 clinic 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. Please pay special attention to section RONDO 3 audio processor, Flight mode.

In addition to EASA (European Aviation Safety Agency) and FAA (Federal Aviation Administration) requirements, airline regulations require suspending wireless operations before boarding an airplane. The FineTuner Echo should not be used on aircrafts unless specifically permitted by the flight personnel. Please secure your FineTuner Echo by placing it, for instance, in a garment pocket.

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 an external audio device to the audio processor that is powered by mains power, i.e. plugged into the wall or a power strip, always make sure 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 MED-EL Cochlear 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 healthcare provider.

Battery information

- If battery electrolyte should be leaking from the audio processor, do not touch the fluids directly. If electrolyte gets into your eyes, rinse with copious amounts of fresh water as soon as possible. Do not rub. Seek medical care immediately. Leaving the eyes untreated may cause eye problems.
- Do not use or leave the audio processor near fire, stoves or hot places (e.g. dashboards, inside a car or generally in areas exposed to direct sunlight) where the temperature might rise above +60°C (+140°F). In such cases the battery may become dysfunctional.
- Do not burn or heat the audio processor. Burning or heating the integrated battery may result in the integrated battery causing heat, smoke, rupture or flame.
- Do not drive nails into the audio processor, strike it with a hammer or step on it. The integrated battery may be broken, deformed or short-circuited causing heat, smoke, rupture or flame.
- Do not disassemble or modify the integrated battery. The battery features safety protection devices which, if damaged, may cause the battery to generate heat, to rupture or to ignite.
- Do not place the audio processor in microwave ovens, high-pressure containers or on induction cookware.
- Immediately discontinue using the audio processor if during use, charging or storage the audio processor emits an unusual smell, feels hot or moist, changes color and/or shape or appears abnormal in any other way.

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 healthcare provider.

Most water sports should not cause any problem as long as the external parts of the MED-EL Cochlear 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 50m (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

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

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 healthcare provider 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.

6. Care and maintenance

Maintenance

Your audio processor and FineTuner Echo are designed for durability and reliability. When handled with sufficient care, they will function for a long time.

If the device does not work properly, check section Troubleshooting. If you cannot solve the problem following the recommended actions in the troubleshooting section, please contact your healthcare provider or local MED-EL representative for advice.

Audio processor

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

FineTuner Echo

- Other than replacing the battery, there are no serviceable features in the FineTuner Echo.
- Do not try to repair electronic parts of your FineTuner Echo and do not try to open the device as this invalidates the warranty.
- Store the FineTuner Echo in a safe place when not in use.
- Protect the FineTuner Echo from liquids, dust and excessive temperatures.
- Do not stick adhesive labels to the FineTuner Echo.

Cleaning

Audio processor

- Do not clean the audio processor 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.
- Do not clean the protective membranes of the cover to avoid damaging them.
- 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.
- Thoroughly wipe the external parts of your audio processor with a damp cloth at least once a week and let them dry completely.

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

FineTuner Echo

- Do not clean the FineTuner Echo in or under water. Use a damp cloth to gently clean the FineTuner Echo. Do not use household cleaning products or alcohol.
- 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.
- Do not use a microwave or any other heating devices to dry the FineTuner Echo. If necessary, wipe it off with a dry tissue.

Socket cover

The socket cover protects the audio processor socket (see sections Connectivity and Alternative power source for details) from dirt and moisture. To ensure proper protection, correctly close the socket cover. The socket cover is attached to the processor housing. If the socket cover should come off inadvertently, place the three small “feet” over the holes in the housing and gently push them down with a ballpoint pen.



Storage

If you want to store the audio processor for a longer period of time, please observe the following:

- If the audio processor has not yet been activated, no further action is required. If the date indicating the “First charge before MM/YY” has expired, please contact your local MED-EL representative.
- After you have already used the audio processor, proceed as follows:
 - Charge the audio processor completely.
 - Ensure that the audio processor is switched off and store it in a dry place.

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

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.

7. Troubleshooting

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

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 healthcare provider or local MED-EL representative.

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

Audio processor

Problem	Possible cause	Recommended action
Audio processor cannot be switched on	Battery empty	Charge the battery
	Storage mode	Charge the battery
No sound	Batteries empty	Charge the battery
	Microphone openings blocked	<ul style="list-style-type: none"> • Replace the cover • Remove obstructing garments or hair
	Device damaged (e.g. by moisture, shock)	Contact your healthcare provider or MED-EL
Sound weak	Volume turned too low	Adjust the volume with the FineTuner Echo
	Microphone openings blocked	<ul style="list-style-type: none"> • Replace the microphone cover • Remove obstructing garments or hair
	Incorrect position of audio processor	Adjust the orientation of the audio processor. This is particularly important for users with a SYNCHRONY implant
Sound too loud	Volume turned too high	Adjust the volume with the FineTuner Echo
	Internal signal processor defective	If you cannot turn down the volume with the FineTuner Echo, stop using the audio processor and contact your healthcare provider or local MED-EL representative
Audio processor falls off frequently	Magnet too weak	Contact your healthcare provider for a stronger magnet
Skin irritation over implant	Allergic reaction	Stop wearing the audio processor and contact our healthcare provider. Refer to section Technical data for materials of the MED-EL Cochlear Implant System
	Magnetic attraction too high	Contact your healthcare provider

Problem	Possible cause	Recommended action
Program selection not possible	Only one program activated	Contact your healthcare provider
	FineTuner Echo does not work	If program selection is not possible, refer to the solutions provided in section FineTuner Echo
	Electrical problems	If all other options listed in this table fail, contact your healthcare provider or local MED-EL representative
FineTuner Echo does not work		Refer to section FineTuner Echo

Audio processor main indicator light

The multi-color main indicator light flashes with different patterns and colors to indicate different conditions. When the main indicator light begins flashing, use the tables in section Indicator lights to determine the possible cause.

Testing your audio processor

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

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

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




- 1 Adjust the volume setting. By using the appropriate loudness setting, you should be able to recognize the flickering of the green light in the rhythm of your voice.
- 2 Charge the battery of your audio processor.

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








FineTuner Echo

If the audio processor does not respond to FineTuner Echo commands, consult the following table for potential reasons and solutions.

Display	Possible cause	Recommended action
	<ul style="list-style-type: none"> The audio processor is out of the FineTuner Echo's operational range, i.e. too far away from the audio processor or the audio processor is switched off, and no commands will be executed. The audio processor did not respond to the last command. The audio processor is switched off. The battery of the audio processor is empty. Interference from other electronic or electrical equipment is blocking the transmission. 	Move the FineTuner Echo closer to your ear and try to switch settings again.
	<p>The pairing process was unsuccessful:</p> <ul style="list-style-type: none"> The detected audio processor is not compatible with the FineTuner Echo. The detected audio processor is configured for the previous generation FineTuner. 	Proceed as described in section Using the FineTuner Echo for the first time. If pairing is unsuccessful again, contact your healthcare provider or local MED-EL representative.
	An unexpected event prevented the command being executed by the audio processor.	Try again. If the command still cannot be executed, contact your healthcare provider or local MED-EL representative.

Additional troubleshooting information:

- Reset your FineTuner Echo when you suspect a malfunction of the device. To reset the FineTuner Echo, proceed as follows:
 - Remove the battery.
 - Press 3 keys simultaneously, i.e. 1 key in row 1, 1 key in row 2 and 1 key in row 4, for example ,  and . Keep the keys pressed until the indicator light of the FineTuner Echo goes on and off again.
 - Reinsert the battery.
- If you press  or  for more than 3 seconds, your FineTuner Echo and the respective audio processor will be unpaired. Repeat the pairing process described in section FineTuner Echo, Using your FineTuner Echo for the first time.
- If the screen of your FineTuner Echo appears "cluttered", e.g., due to remaining display fragments, lock and unlock the FineTuner Echo to clear the display. Weak batteries or cold temperatures, i.e., when the FineTuner Echo is below its operating temperature range, can also lead to slow reaction of the screen and the display may appear "cluttered".

8. Technical data


Audio processor

Dimensions ⁵	Length: 44.9 mm (1.77 in.) Width: 35.7 mm (1.41 in.) Height: 11.9 mm (0.47 in.)
Weight ⁵	14.2 g (0.50 oz.) (without Magnet) 15.9 g (0.56 oz.) (with Magnet M1)
Power Supply	1 rechargeable Li-ion battery, nominal 3.8 V Battery life expectancy is typically more than 5 years.
Hardware	<ul style="list-style-type: none"> Fully digital signal processing Various parameters programmable 4 programs selectable Up to 12 band pass filters; filter characteristics programmable Non-linear amplification programmable 2 omnidirectional microphones Audio processor self-test: checksum on programs, continuous parity check Automatic Gain Control (AGC) configurable FineTuner Echo commands can selectively be disabled
Audio Input	<ul style="list-style-type: none"> Via Mini Battery Pack Hearing aid type three pin connection (Euro Audio) acc. to IEC 60118-12 Sensitivity: -57.5 dBV⁵ (corresponds to 70 dB SPL at 1 kHz) Impedance: 4.5 kΩ
Controls/Indicators	<ul style="list-style-type: none"> Pushbutton for ON/OFF, Request of battery level Main indicator light: multi-color LED Charging Indicator light (bottom): single-color LED
Materials	<ul style="list-style-type: none"> Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS): audio processor (all colors), cover (all colors) Polyamide (PA): Charging Indicator window, attachment clips Titanium grade 5 (anodized): base of magnet Silicone: socket cover
Temperature and humidity range	<p>Operating temperature range: 0 °C to +50 °C (+32 °F to +122 °F)</p> <p>Charging temperature range: 0 °C to +30 °C (+32 °F to +86 °F)</p> <p>Storage temperature range: -29 °C to +60 °C (-20.2 °F to +140 °F)</p> <p>Relative humidity range: 15 % to 90 %</p> <p>Atmospheric pressure range: 700 hPa (mbar) to 1060 hPa (mbar)</p>
Essential performance	None of the performance characteristics of the RONDO 3 (incl. all accessories) are essential performance as defined in IEC 60601-1.
Expected service life	The expected service life of the RONDO 3 (incl. all accessories) as defined in IEC 60601-1 is 5 years. There are no actions needed to maintain basic safety with regard to electromagnetic disturbances for the expected service life.
Radio frequency (RF) link (wireless network)	<p>Frequency band of reception/transmission: 2400 MHz – 2483.5 MHz</p> <p>Short Range Device (SRD) according to ERC/REC 70-03 Annex 1 (band I)</p> <p>Type of modulation: Gaussian frequency shift keying (GFSK)</p> <p>Maximum effective radiated power (ERP): -6.3 dBm (235 µW)</p> <p>Channel band width: 2 MHz (MED-EL proprietary wireless technology)</p> <p>Channel band width: 1 MHz (Bluetooth® wireless technology)</p>

⁵ typical values

Radio frequency (RF) link (wireless charging)	Frequency band of reception/transmission: 87 Hz – 205 kHz Resonant inductive coupling Type of modulation of receiver: Amplitude shift keying (ASK) Type of modulation of transmitter: Frequency shift keying (FSK)
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FineTuner Echo

Model	FineTuner Echo (Ma010201)
Dimensions⁶	Length: 104 mm (4.1 in.) Width: 38 mm (1.5 in.) Height: 11 mm (0.43 in.)
Weight⁶	32 g (1.13 oz.) (incl. battery)
Mode of operation	Continuous
Controls/Indicators	<ul style="list-style-type: none"> Keypad with 12 keys Display 1 green LED
Power supply	<ul style="list-style-type: none"> 1 lithium/manganese dioxide battery type CR2032 (3 V, ) Internally powered Battery life expectancy is typically more than 6 months
Materials	Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS)
Temperature and humidity range	Operating temperature range: +5 °C to +40 °C (+41 °F to +104 °F) Storage temperature range: –20 °C to +60 °C (–4 °F to +140 °F) Relative humidity range: 10 % to 93 % Atmospheric pressure: Ambient to 700 hPa (mbar) (0 to 3,000 meters [0 to 9,843 ft.])
Essential performance	None of the performance characteristics of the FineTuner Echo are essential performance as defined in IEC 60601-1.
Expected service life	The expected service life of the FineTuner Echo as defined in IEC 60601-1 is 5 years. There are no actions needed to maintain basic safety with regard to electromagnetic disturbances for the expected service life.
Applied parts	The surface of the FineTuner Echo, which is in contact with the user, is a Type BF Applied Part.
Degree of protection	IP52: Dust-protected. Protected against vertically falling water drops when enclosure tilted up to 15°.
Radio frequency link	Frequency band of reception/transmission: 2400 MHz to 2483.5 MHz Short Range Device (SRD) according to ERC/REC 70-03 Annex 3 (band B) Receiver category 3 Type of modulation: Gaussian frequency shift keying (GFSK) Equivalent isotropic radiated power (EIRP): 3.3 dBm Channel band width: 2 MHz
Typical operating distance	40 cm (15.75 in.)

⁶ typical values

Regulatory statements

Applicable in Canada only:

Model: RONDO 3 (Me155) – IC: 11986A-ME1550

Model: FineTuner Echo (Ma010201) – IC: 11986A-FTE

The above devices contain licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence exempt RSS(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans les appareils mentionnés ci-dessus est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Applicable in the USA only:

Model: RONDO 3 (Me155x) – FCC ID: VNP-ME1550

Model: FineTuner Echo (Ma010201) – FCC ID: VNP-FTE

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

CE marking, first applied in 2020

Hereby, MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type RONDO 3 incl. FineTuner Echo is in compliance with directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.medel.com/compliance




Caution, consult the instructions for use for important cautionary information




Refer to instructions for use





MR Unsafe


 Not suitable for children under 3 years

 Manufacturer


 Catalogue number


 Serial number


 Fragile; handle with care

 Temperature limit

 Humidity limitation

 Atmospheric pressure limitation

 Type BF applied part (IEC 60601-1/EN 60601-1): The surface of the FineTuner Echo, which is in contact with the user, is a Type BF applied part

 Non-ionizing electromagnetic radiation

 Direct current

IP52 Moisture and dust protection acc. to IEC 60529


This classification means that the FineTuner Echo remains safe when exposed to dripping water. Ingress of dust is not entirely prevented, but it must not enter in sufficient quantity to interfere with the satisfactory operation of the equipment when fully assembled, i.e. when the battery lid is fully closed.


IP68 Moisture and dust protection acc. to IEC 60529


This classification means that your audio processor is protected against failure from ingressing dust and the effects of continuous immersion in still, clean water (at 1m for 60 minutes) when fully assembled, i.e. when

- the cover is snapped onto the audio processor,
- the socket cover covering the audio processor socket is closed.

 First charge before YYYY-MM (Best before YYYY-MM)

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

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

 Information relevant for parents, guardians or caregivers of children who use the system

Radio frequency/Telecommunication information

Country	Symbol/Registration Number
Canada	IC: 11986A-Me1550
USA	FCC ID: VNP-Me1550

Guidance and manufacturer's declaration

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

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

Electromagnetic emissions – for all equipment and systems

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

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

Electromagnetic immunity – for all equipment and systems

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

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

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Not applicable	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the RONDO 3, including cables, specified by MED-EL. Otherwise degradation of the performance of the RONDO 3 could result.
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz	10 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m, 380 MHz to 390 MHz	27 V/m	
	28 V/m, 430 MHz to 470 MHz	28 V/m	
	9 V/m, 704 MHz to 787 MHz	9 V/m	
	28 V/m, 800 MHz to 960 MHz	28 V/m	
	28 V/m, 1700 MHz to 1990 MHz	28 V/m	
	28 V/m, 2400 MHz to 2570 MHz	28 V/m	
	9 V/m, 5100 MHz to 5800 MHz	9 V/m	

9. Appendices

Supplies and accessories

- RONDO 3 Cover
- Mini Battery Pack cable for RONDO 3 (21cm [8.27in.], 100cm [39.37in.])
- Charging cable (100cm [39.37in.])
- Telecoil adapter
- Clothing attachment clip
- Clothing attachment clip with cap
- Hair attachment clip, large
- Hair attachment clip, small
- Wireless charger (not manufactured by MED-EL)
- USB power supply (not manufactured by MED-EL)
- Magnet 12.5 mm (4.92 in.) 1(S)–5(S)

Warranty

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

Manufacturer address

MED-EL Elektromedizinische Geräte GmbH
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E-Mail: office@medel.com

MED-EL distributor in the U.S.:

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Durham, NC 27713, USA
Tel.: (919) 572-2222
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.



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