

FineTuner Echo

User Manual



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1. Introduction

This user manual provides information and instructions for the MED-EL FineTuner Echo (Ma010201). It contains important information on handling and operating the device.

The FineTuner Echo can only be used with compatible MED-EL audio processors. Read the user manual of your audio processor carefully before reading this manual.

You are the operator of the FineTuner Echo, therefore you should read the entire manual. Do not perform any maintenance activities other than those described in this manual (e.g., changing the battery).

The user of the FineTuner Echo does not need any special skills or elevated level of education, however, for young children and those who, for a variety of reasons, lack the ability to appropriately handle and manipulate small parts, the parents and/or caregiver shall operate the device.

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

The following symbols are used throughout this document:



Information indicating a hazardous situation that, if not avoided, could result in 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 users.

2. Intended Use

The FineTuner Echo is intended to be used as a remote control for compatible MED-EL audio processors.

The FineTuner Echo is additionally intended to be used as an audio processor test device which has no medical purpose for easy recognition of the working status and the most common functional problems such as defective coil cables, defective microphones or weak batteries of MED-EL audio processors.

The FineTuner Echo is intended to be used all day long during waking hours, there are no restrictions in the frequency of use. The FineTuner Echo is intended to be used in typical everyday environments (e.g., home, office, outdoor, etc.) and also in a clinical environment (e.g., audiologist's office).

2.1 Intended Purpose

Remote control for changing the settings of compatible MED-EL audio processors within predefined limits.

2.2 Intended User

The FineTuner Echo is intended to be used by recipients of compatible MED-EL audio processors and the caregivers (e.g., parents, teachers, audiologists) of these recipients.

2.3 Target Patient Population

The FineTuner Echo is intended to be used by recipients of compatible MED-EL audio processors.

2.4 Indications

The FineTuner Echo is indicated for recipients of compatible MED-EL audio processors.

2.5 Contraindications

A user must not receive a FineTuner Echo if the individual is known to be intolerant of the materials used in the FineTuner Echo. The FineTuner Echo is not intended to be used in environments where RF transmissions are prohibited. Recipients who are not able to use the FineTuner Echo are not intended to use the device. Caregivers shall operate the FineTuner Echo for them.

3. Warnings and Precautions

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

If you have problems with the FineTuner Echo, read section Troubleshooting or contact your audiologist/healthcare professional or local MED-EL representative.

3.1 Warnings

If you notice any signs of skin irritation after or while touching the FineTuner Echo, contact your clinic or audiologist/healthcare professional. Skin irritation may be caused by an allergic reaction to the materials used in the external components (see section Technical Data for a list of materials).



PARENTAL GUIDANCE

Instruct children and persons under care not to swallow or put any components of their FineTuner Echo into their mouths or play with any components. Swallowing of components could cause suffocation or internal injury.

3.2 Precautions

3.2.1 General

The FineTuner Echo contains sophisticated electronic components which require special precautions regarding electromagnetic compatibility (EMC). When activating the FineTuner Echo, always follow the guidelines outlined in this section and chapter Technical Data, Guidance and Manufacturer's Declaration.

- The electronics are durable but must be treated with care.
- Always handle the FineTuner Echo with care to achieve maximum lifetime and to avoid any risks (e.g., damage or injury).
- Never open the housing of the FineTuner Echo. Unauthorized opening may damage the device. To change the battery or clean the battery contacts, perform the steps described in chapter Care and Maintenance.
- Do not open or alter any FineTuner Echo component as this may damage the system. Opening or altering FineTuner Echo components can lead to serious injuries.
- The FineTuner Echo does not require regular maintenance by clinic personnel or other experts.
- Do not use the system components under environmental conditions other than those described in chapter Technical Data.

- Immediately discontinue using the device if during use or storage, it emits an unusual smell, feels hot, changes color and/or shape or appears abnormal in any way.
- The defined operating temperature range is between +5 °C and +40 °C for the FineTuner Echo. Avoid excessive heat. Excessive heat might damage the FineTuner Echo and make it unusable.
- If the FineTuner Echo has been at a temperature that is outside the defined operating temperature range of +5 °C to +40 °C, e.g., because it was stored in a cool or hot place, put the FineTuner Echo in a place with room temperature (typ. +20 °C to +25 °C). Wait at least 30 minutes before you use the FineTuner Echo. This ensures that the FineTuner Echo is not operated outside its defined operating temperature range.
- Do not leave the FineTuner Echo in direct sunlight (especially inside a car). Long exposure to direct sunlight might damage the FineTuner Echo.
- Avoid getting the FineTuner Echo wet as this may impair its function. Keep the FineTuner Echo in a dry place before bathing, showering, or engaging in other water-related activities.
- If the FineTuner Echo gets wet, wipe it off with a dry tissue.
- Do not use the FineTuner Echo in environments where radio frequency (RF) transmissions are prohibited. This equipment generates, uses, and can radiate RF energy. The FineTuner Echo 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.
- Do not use the FineTuner Echo in the vicinity of strong ionizing radiation (e.g., x-ray machines) or electromagnetic fields (e.g., MRI machines).
- Do not operate the FineTuner Echo while in control of a vehicle. Doing so will detract from your control and operation of the vehicle. In some countries, operating such devices while in control of a vehicle is an offense.
- Use of the 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 FineTuner Echo and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the FineTuner Echo, including cables specified by MED-EL. Otherwise, degradation of the performance of the FineTuner Echo could result.
- 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.

3.2.2 Electrostatic Discharge

Electronic devices are influenced by electrostatic discharge (ESD). Although the FineTuner Echo has several internal safety features designed to reduce ESD, there is a small risk that the device is damaged if the static discharge flows through it.

Following these guidelines can reduce the probability of electrostatic discharge:

- If you believe that you or the user is statically charged, “discharge” by touching a radiator, a water tap, or any grounded metal object.
- Do not allow another person to touch the external parts of the MED-EL Cochlear Implant System unless both you and the other person are “discharged”.
- “Discharge” before using the FineTuner Echo.
 - When taking the FineTuner Echo from another person:
 1. Touch the person's body
 2. Touch the FineTuner Echo
 - When picking up FineTuner Echo from a table or other surface:
 1. Touch the table
 2. Pick up the FineTuner Echo
- “Discharge” when leaving the car, e.g., by touching the car door. The FineTuner Echo 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.
- Put away the FineTuner Echo before dressing and undressing, especially if garments include synthetic fibers.
- Put away the FineTuner Echo before touching plastic play equipment, such as children's slides. After touching plastic play equipment, do not touch the implant site. “Discharge” before touching the FineTuner Echo.
- Put away the FineTuner Echo when experimenting with static electricity and “high” voltage. Van de Graaff generators, which are found in school science departments, should never be used by FineTuner Echo users because they produce very high levels of static electricity.
- When working at a computer, make sure the computer is grounded and use an antistatic mat under the work area to reduce static build-up. Never directly touch the screen of a computer or TV. The risk of problems from computer screens is very small but may be further reduced by attaching an antistatic screen to the computer.
- If the FineTuner Echo stops working and you suspect an ESD is the cause, switch off the FineTuner Echo by removing the battery, wait for a few minutes and switch it on again. If it does not come on again, contact your audiologist/healthcare professional.

3.2.3 Battery Information

- 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 a pocket, 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 nor 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, charging 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, 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.
- 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.

3.2.4 Medical Information

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

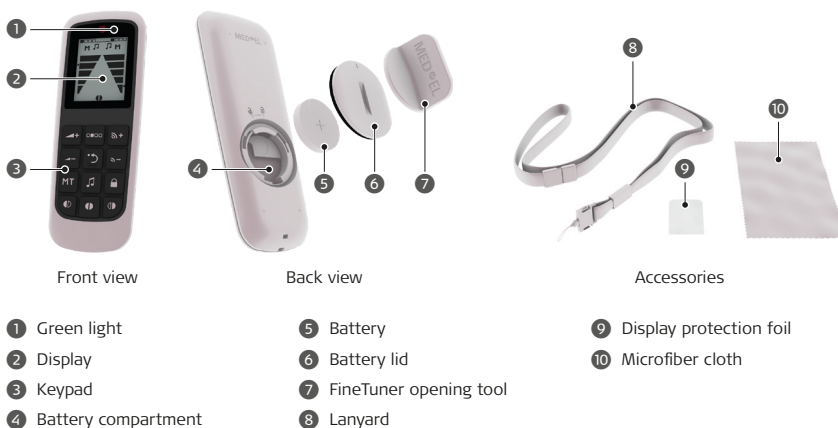
4. Device Description

The FineTuner Echo is a small and light-weight remote control for compatible MED-EL audio processors. The FineTuner Echo is provided to help you optimally use your audio processor in changing daily listening situations.

The FineTuner Echo transmits commands to the audio processor via a radio frequency (RF) link. Its ergonomic design and display facilitate changing the settings of the audio processor.

Keep the FineTuner Echo out of the reach of children or persons under care to prevent them from inadvertently changing the settings of the audio processor.

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



4.1 Compatibility With Other Devices

The FineTuner Echo can only be used with compatible MED-EL audio processors. Read the user manual of your audio processor for further information on compatibility and to familiarize yourself with using the FineTuner Echo with the audio processor.

4.1.1 Supplies and Accessories

Description	Model number ¹
Battery CR2032 ²	34307
FineTuner opening tool	40794

For ordering replacement parts, contact your local MED-EL representative.

4.2 Clinical Benefit

The FineTuner Echo does not provide any direct clinical benefit to the recipient of the compatible audio processor or their caregiver. However, the FineTuner Echo functionalities i.e., possibility to modify predefined audio processor settings (e.g., volume, sensitivity, input, and programs) provides indirect clinical benefits that will positively impact the users' everyday life.

¹ Subject to change without notice

² Not manufactured by MED-EL

5. Basics and Handling

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

5.1 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 the FineTuner opening tool 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.



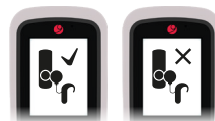
NOTE: Previous versions of the FineTuner Echo featured a black sealing ring that had to be inserted in the groove of the battery compartment. This sealing ring must not be used with the current version of the FineTuner Echo because the new lid has an integrated ring. Adding another sealing ring prevents the lid from closing properly.

- 5 After inserting the battery, a pairing notification appears automatically, prompting you to pair the 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 coil (if you are using a behind-the-ear [BTE] audio processor) or the audio processor (if you are using a single-unit 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: The audio processor must 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, contact your audiologist/healthcare professional.

5.2 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	- BTE audio processors: Toggles between microphone, telecoil or microphone and telecoil - No function for single-unit audio processors
	Audio streaming key	Blocks/unblocks audio streaming
	Keypad lock	Locks/unlocks keypad
	Processor selection key	For bilateral users only: Selects left audio processor
	Processor selection key	For bilateral users only: Selects left and right audio processor
	Processor selection key	For bilateral users only: Selects right audio processor

The FineTuner Echo does not have an ON/OFF switch. If you want to switch off the FineTuner Echo completely, you must remove the battery. The FineTuner Echo may still show the last screen even after removing the battery. This is caused by the display design and does not indicate a device failure.

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 audiologist/healthcare professional can selectively disable all FineTuner Echo functions by disabling the respective command in the audio processor (via the MED-EL application software).

5.3 FineTuner Echo Display

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

Status Symbols

Symbol	Meaning	Required action
	Bilateral mode: right side selected	None
	Bilateral mode: left side selected	None
	Bilateral mode: both sides selected	None
	Audio streaming unblocked	None
	Audio streaming blocked	None
	The filled square indicates the selected program	None
M	Microphone: Sound perceived via the audio processor microphones only	None
MT	- BTE audio processors: Microphone and telecoil: Sound is perceived via the audio processor microphones and telecoil input equally. - No function for single-unit audio processors	None
T	- BTE audio processors: Telecoil: Sound is perceived via the audio processor telecoil input. - No function for single-unit audio processors	None
	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)	None
	Loudness (for bilateral users only: a transparent symbol indicates that the respective side is currently disabled)	None
MED-EL 	Lock Screen: The keypad of the FineTuner Echo is locked	Press  for approx. 3 seconds to lock/unlock the keypad.

Notification Symbols

Symbol	Meaning	Required action	Remarks
	Audio processor battery low	Change battery of audio processor.	
	Audio processor battery empty	Change 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 the 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 audiologist/healthcare professional or local MED-EL representative.
	Function deactivated	None	Contact your audiologist/healthcare professional for further information.

Error Symbols

Symbol	Meaning	Required action	Remarks
	Connection Error: - Indicates that an error occurred during communication with the audio processor (e.g., 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 the audio processor and try to switch settings again.	If you only move the FineTuner Echo closer to the audio processor, 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 audiologist/healthcare professional or local MED-EL representative.

5.4 Additional Functions

5.4.1 Testing the Audio Processor

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

- 1 Switch on the audio processor.
- 2 Place the coil (if you are using a BTE audio processor) or the audio processor (if you are using a single-unit audio processor) over the battery compartment of 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 Change the batteries of your audio processor.
- 3 Replace the existing coil cable with a substitute cable.

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

5.4.2 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 SONNET MTD. For further information about this optional service tool for MED-EL audio processors, read the applicable user manual or ask your audiologist/healthcare professional for assistance.

5.5 Changing the Battery



WARNING

- Misuse of batteries may result in the batteries causing heat, smoke, rupture, flame, or leakage which could lead to injury.
- Swallowing batteries could cause suffocation, poisoning or internal injuries. If a battery has been swallowed or placed inside any part of the body, seek medical attention immediately.
- To prevent children or persons under care from swallowing or choking on batteries, always keep new and used batteries out of the reach of children or persons under care.

- Instruct children or persons under care not to swallow or put any components of their FineTuner Echo into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury.
- Do not allow children or persons under care to replace batteries without supervision.
- If the battery compartment of the FineTuner Echo does not close securely, stop using the FineTuner Echo and keep it out of the reach of children or persons under care.



CAUTION

Always handle batteries with care to avoid injury. Read section Warnings and Precautions, Battery Information before changing the battery.

The FineTuner Echo requires one coin cell battery type CR2032.

When the FineTuner Echo displays this symbol  in the status line (see also chapter Basics and Handling, FineTuner Echo Display), replacing the battery of the FineTuner Echo is recommended.

To change the battery, proceed as follows:

- 1 Open the lid on the back of the FineTuner Echo. Stick the FineTuner opening tool into the battery lid groove and use it to turn the lid until the arrow on the lid meets the  symbol on the housing.
- 2 Lift the lid carefully. When you pick up the lid with your fingers, be careful to only touch the edge of the lid.
- 3 Replace the used coin cell battery by gently shaking it into your hand. Do not touch the battery contacts.
- 4 Insert the new 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.
- 5 To close the lid, align the arrow on the lid with the  symbol on the housing and push down gently. Use the FineTuner opening tool 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.



NOTE: Previous versions of the FineTuner Echo featured a black sealing ring that had to be inserted in the groove of the battery compartment. This sealing ring must not be used with the current version of the FineTuner Echo because the new lid has an integrated ring. Adding another sealing ring prevents the lid from closing properly.

5.6 Wearing Options

You can wear the 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 the lanyard, thread it through the small openings.



WARNING

- 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 small size, the FineTuner Echo can also be worn comfortably in a pocket.

5.7 Care and Maintenance



CAUTION

- Do not drop the FineTuner Echo.
- Protect the FineTuner Echo from liquids, dust, and excessive temperatures.
- Keep the FineTuner Echo away from pets and other potential sources of contamination.
- Do not clean the FineTuner Echo in or under water. Use a damp cloth to gently clean the FineTuner Echo. Do not use aggressive cleaning agents.
- Do not use a microwave or any other heating devices to dry the FineTuner Echo. If necessary, wipe the FineTuner Echo off with a dry tissue.

The FineTuner Echo is designed for durability and reliability but should be handled with care. Improper handling could lead to device damage or injury.

Other than replacing the battery, the FineTuner Echo has no serviceable features.

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

- Do not open the FineTuner Echo.
- Do not try to repair the electronic parts of the FineTuner Echo.
- Store the FineTuner Echo in a safe place when not in use.
- Do not stick adhesive labels to the FineTuner Echo.
- Do not touch the battery contacts. To clean the contacts, use a cotton swab and a small amount of cleaning alcohol. Gently wipe dry after cleaning.
- If you do not use the FineTuner Echo for an extended period of time, remove the battery and dispose of or store the battery separately.

6. Troubleshooting

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

The FineTuner Echo transmits commands to the audio processor via a radio frequency (RF) link. If the audio processor does not respond to FineTuner Echo commands, consult the following table for potential reasons and solutions. If troubleshooting does not eliminate the problem, contact your audiologist/healthcare professional or local MED-EL representative immediately.

Display	Possible cause	Recommended action
	- The audio processor is too far away from the FineTuner Echo. - The audio processor did not respond to the last command. - The audio processor is switched off. - The batteries of the audio processor are empty. - Interference from other electronic or electrical equipment is blocking the transmission.	- Move the FineTuner Echo closer to the audio processor and try to switch settings again. - Switch on the audio processor. - Replace the batteries of the audio processor. - Retry the last command.
	The pairing process was unsuccessful: - 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 Basics and Handling, Using the FineTuner Echo for the First Time. If pairing is unsuccessful again, contact your audiologist/healthcare professional 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 audiologist/healthcare professional or local MED-EL representative.

Additional troubleshooting information:

- Reset the FineTuner Echo if 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/the recipient have used the **T** (telecoil) or **MT** (microphone and telecoil) settings and are unable to return to the **M** (microphone) signal source input with the FineTuner Echo, switch the audio processor off and on again. When the audio processor is switched on again, it will automatically start with the **M** (microphone) setting activated.

- If you press  or  for more than 3 seconds, the FineTuner Echo and the respective audio processor will be unpaired. Repeat the pairing process described in section Basics and Handling, Using the FineTuner Echo for the First Time.
- If the screen of the 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”.

7. Interference With Other Equipment

7.1 Air Travel

In addition to EASA (European Aviation Safety Agency) and FAA (Federal Aviation Administration) requirements, airline regulations require suspending wireless operations before boarding an airplane. Do not use the FineTuner Echo on aircrafts unless specifically permitted by the flight personnel. Secure the FineTuner Echo by placing it, for example, in a garment pocket.

8. Technical Data

8.1 Device Characteristics

Model	FineTuner Echo (Ma010201)
Dimensions ³	- Length: 104 mm - Width: 38 mm - Height: 11 mm
Weight ³	32 g (incl. battery)
Mode of operation	Continuous
Controls/Indicators	- Keypad with 12 keys - Display 1 green LED
Power supply	1 lithium/manganese dioxide battery type CR2032 (3 V, ) - Internally powered - Battery life expectancy is typically 6 months
Materials in body contact	Mixture of polycarbonate and acrylonitrile-butadiene-styrene polymer (PC/ABS)
Temperature and humidity range	- Operating temperature range: +5 °C to +40 °C - Storage temperature range: -20 °C to +60 °C - Relative humidity range: 10 % to 93 % - Atmospheric pressure range: Ambient to 700 hPa (mbar) (0 to 3,000 meters)
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

³ typical values

8.2 Regulatory Statements

Applicable in Canada only:

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

The above device contains 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: FineTuner Echo (Ma010201) – FCC ID: VNP-FTE

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

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

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

8.3 Radiofrequency/Telecommunication Information

Country	Symbol/Registration Number
Argentina	 C-24557
Australia/New Zealand	
Brazil	 08087-19-02433
Canada	IC: 11986A-FTE
Japan	 204-A00006
Mexico	 NOM-208-SCFI-2016
South Africa	 TA-2019-1543 APPROVED

Country	Symbol/Registration Number
Taiwan	 CCAK19LP2520T6
USA	FCC ID: VNP-FTE

8.4 Guidance and Manufacturer's Declaration

Tables according to IEC 60601-1-2 for FineTuner Echo

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

Electromagnetic emissions – for all equipment and systems

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The FineTuner Echo 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 FineTuner Echo 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 FineTuner Echo is intended for use in the home healthcare environment. The customer or the user of the FineTuner Echo should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0 % U_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 FineTuner Echo is intended for use in the home healthcare environment. The customer or the user of the FineTuner Echo 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 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 FineTuner Echo, including cables specified by MED-EL. Otherwise degradation of the performance of the FineTuner Echo could result.
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz	10 V/m 3 V/m, 2.7 GHz to 6 GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m, 380 MHz to 390 MHz 28 V/m, 430 MHz to 470 MHz 9 V/m, 704 MHz to 787 MHz 28 V/m, 800 MHz to 960 MHz 28 V/m, 1700 MHz to 1990 MHz 28 V/m, 2400 MHz to 2570 MHz 9 V/m, 5100 MHz to 5800 MHz	27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 28 V/m 9 V/m	
Proximity magnetic fields	8 A/m, 30 kHz 65 A/m, 134.2 kHz 7.5 A/m, 13.56 MHz	8 A/m 65 A/m 7.5 A/m	

9. Miscellaneous

9.1 Warranty Statement

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

9.2 Storage

Store the FineTuner Echo in a dry place and protect it from direct sunlight. Always remove the battery if you do not use the FineTuner Echo for a long period of time to avoid battery leakage and possible damage to the device.

9.3 Disposal

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

9.4 Symbols



The FineTuner Echo is in compliance with regulation 2017/745 (Medical Device Regulation/MDR).
CE marking, first applied in 2019

Hereby MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type 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



Medical device



Caution



Refer to instructions for use



Consult instructions for use



Not suitable for children under 3 years



Manufacturer



Date of manufacture



Catalog number

-  Serial number
-  Fragile, handle with care
-  Temperature limit
-  Humidity limitation
-  Atmospheric pressure limitation
-  Type BF applied part (IEC 60601-1)
-  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 does 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.

9.5 Contact

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

MED-EL Elektromedizinische Geräte GmbH
Worldwide Headquarters
Fürstenweg 77a
6020 Innsbruck
Austria
<https://www.medel.com>
Phone: +43 5 77 88
Email: office@medel.com

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



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