

Cochlear Implants

MED<sup>9</sup>EL

# FineTuner Echo

User Manual



AW4381\_2.0 (English)

hearLIFE



# Table of Contents

1. Introduction .....	2
2. Intended use – Indications – Contraindications .....	3
Intended use .....	3
Indications.....	3
Contraindications .....	3
3. FineTuner Echo.....	4
System components.....	4
Using the FineTuner Echo for the first time .....	6
FineTuner Echo keys .....	8
FineTuner Echo display .....	9
Additional functions of your FineTuner Echo .....	12
Wearing options for your FineTuner Echo .....	13
4. General precautions and warnings.....	14
5. Care and maintenance .....	16
Maintenance .....	16
Disposal.....	16
Battery .....	17
6. Troubleshooting .....	20
7. Technical data .....	22
FineTuner Echo.....	22
Regulatory statements.....	24
Symbols.....	25
Guidance and manufacturer's declaration .....	27
8. Appendices .....	30
Supplies and accessories .....	30
Warranty .....	30
Manufacturer address.....	30
9. Contact MED-EL .....	31

# 1. Introduction

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

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

You are the operator of your/the recipient's FineTuner Echo, therefore we recommend that you read this manual in its entirety. Do not perform any maintenance activities other than those described in this manual (e.g. changing batteries).

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 carer shall operate the device.

Please do not hesitate to 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 relevant for parents, guardians or carers of children who use the system.

## 2. Intended use – Indications – Contraindications

### Intended use

The FineTuner Echo is an external part of the MED-EL Cochlear Implant System. The FineTuner Echo is intended to be used as a remote control for recipients having received a compatible MED-EL audio processor. The FineTuner Echo is intended to be used as an audio processor test device (formerly known as Speech Processor Test Device) 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 by a patient 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).

### Indications

Any user having received a MED-EL Cochlear Implant is a potential user of the FineTuner Echo. Additionally, any person that interacts with a MED-EL Cochlear Implant user (e.g. parents of implanted children, audiologists, teachers of implanted children, etc.) might use the FineTuner Echo.

As the FineTuner Echo 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 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. Patients who are not able to use the FineTuner Echo are not intended to use the device. Parents/carers shall operate the FineTuner Echo for them.

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

## 3. FineTuner Echo

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.

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 programme, volume and sensitivity setting it had when it was switched off.

### System components

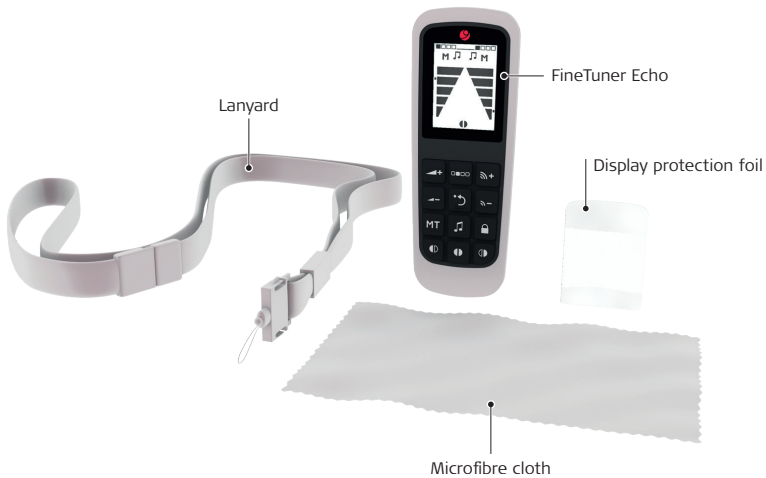
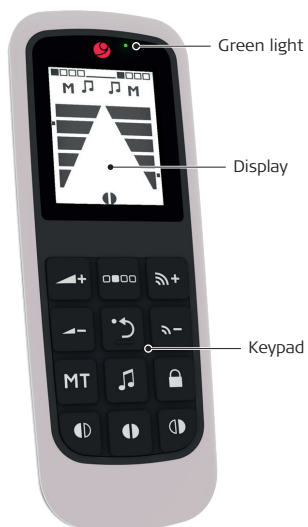


Fig. 1 System components

Front view





Back view



Fig. 2 FineTuner Echo overview

## Using the FineTuner Echo for the first time

1. Clean the FineTuner Echo screen with the microfibre 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 microfibre cloth (Fig. 3.1).
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 (Fig. 3.2), 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 (Fig. 3.3). You will feel a slight resistance when the lid locks in place.
5. After inserting the battery, a pairing notification appears automatically (Fig. 3.4), prompting you to pair your FineTuner Echo.

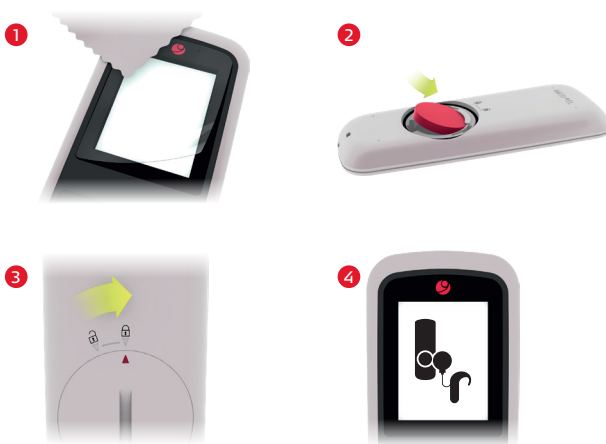


Fig. 3 Preparing the FineTuner Echo



To pair the FineTuner Echo, proceed as follows:

1. Switch off the audio processor.
2. Place the coil on the battery lid of the FineTuner Echo (Fig. 4).
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.














Fig. 4 Pairing the FineTuner Echo and the audio processor

**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 audiologist.

## 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
	Programme selection key	Toggles between different programmes
	Default key	Sets overall volume and audio sensitivity of the selected programme to predefined values
<b>MT</b>	Input selection key	Toggles between microphone, telecoil or microphone and telecoil
	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 audiologist or clinical staff can selectively disable all FineTuner Echo functions by disabling the respective command in the audio processor (via the MED-EL application software).








## 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	
	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 programme	
<b>M</b>	Microphone: Sound is perceived via the audio processor microphones only.	
<b>MT</b>	Microphone and telecoil: Sound is perceived via the audio processor microphones and telecoil input equally.	
<b>T</b>	Telecoil: Sound is perceived via the audio processor telecoil input.	
	Monitoring mode enabled	
	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)	
<b>MED</b>  <b>EL</b> 	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	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 your FineTuner Echo	See chapter 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 audiologist for further information.

### Error symbols

Symbol	Meaning	Required action	Remarks
	<p>Connection Error:</p> <ul style="list-style-type: none"> <li>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)</li> <li>The audio processor did not respond to the last command</li> <li>The audio processor is switched off</li> <li>Empty battery of audio processor</li> <li>Interference from other electronic or electrical equipment is blocking the transmission</li> </ul>	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.

## 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:

1. Switch on the audio processor.
2. Place the coil over the battery compartment of FineTuner Echo (see Fig. 5).
3. When speaking into the microphone, the green light on the FineTuner Echo should flicker in the rhythm of your voice.




Fig. 5 Testing your audio processor

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 healthcare provider or local MED-EL representative.

### 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 the MED-EL Cochlear Implant System, please read the applicable user manual or ask your audiologist 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 as shown in Fig. 6.

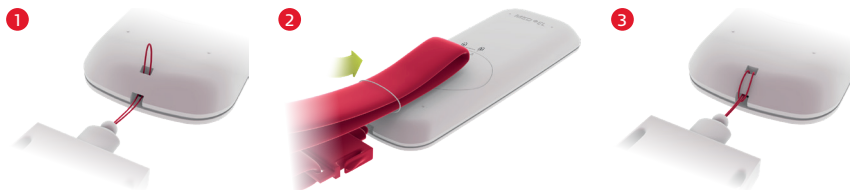


Fig. 6 Attaching the lanyard to the FineTuner Echo



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.

## 4. General precautions and warnings

This section contains information on the safe use of your FineTuner Echo. Please read this information carefully. Your healthcare provider or local MED-EL representative will assist you with any additional questions you may have.

The FineTuner Echo contains sophisticated electronic components which require special precautions regarding electromagnetic compatibility (EMC).

When activating your FineTuner Echo always follow the guidelines outlined in this section and chapter Technical data, Guidance and manufacturer's declaration.

- Always handle your FineTuner Echo with care to achieve maximum lifetime and to avoid any risks (e.g. injury).
- The electronics are durable but must be treated with care.
- Your 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.
- The defined operating temperature range is between +5 °C and +40 °C for FineTuner Echo. Avoid excessive heat. Excessive heat might damage the FineTuner Echo and make it unusable.
- If the FineTuner Echo should be at a temperature that is outside the defined operating 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) and 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.
- Never open the housing of your FineTuner Echo. Unauthorized opening invalidates the warranty. To change the battery or clean the battery contacts, perform the steps described in chapter Care and maintenance.
- Do not open or alter any system component as this may damage the system and voids warranty claims. Opening or altering system components can lead to serious injuries.
- Avoid getting your 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 becomes wet, wipe it off with a dry tissue.
- Do not use the FineTuner Echo in environments where radio frequency (RF) transmissions are prohibited.
- Do not use the FineTuner Echo in the vicinity of strong ionising 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 that 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 30cm to any part of the FineTuner Echo, including cables specified by MED-EL. Otherwise, degradation of the performance of the FineTuner Echo could result.



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.

## 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. 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.

## Precautions for medical procedures

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

## 5. Care and maintenance

### Maintenance

The FineTuner Echo is designed for durability and reliability. When handled with sufficient care, it will function for a long time:

- Do not drop the device.
- 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.
- You should always remove the battery if you do not use the FineTuner Echo for a longer period of time to avoid battery leakage.
- 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.
- Protect the FineTuner Echo from liquids, dust and excessive temperatures.
- Do not clean the FineTuner Echo in or under water. Use a damp cloth to gently clean the FineTuner Echo. Never use household cleaning products or alcohol.
- Do not use a microwave or any other heating devices to dry the FineTuner Echo. If necessary, wipe it off with a dry tissue.
- Do not stick adhesive labels to the FineTuner Echo.

Other than replacing the battery, there are no serviceable features in the FineTuner Echo.

If the device does not work properly, check chapter 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.

### 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.

## 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.

- 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 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 or storage, the battery emits an unusual smell, feels hot, changes colour 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.

---




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 chapter FineTuner Echo, 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 the lid until the arrow on the lid meets the  symbol on the housing (Fig. 7.1).
2. Lift the lid carefully with your 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 (Fig. 7.2), 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 (Fig. 7.3). You will feel a slight resistance when the lid locks in place.

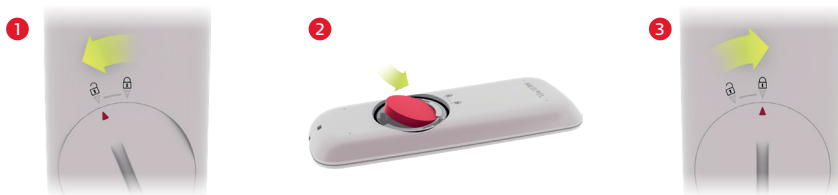





Fig. 7 Changing the battery of your FineTuner Echo






## 6. 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.

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"> <li>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.</li> <li>The audio processor did not respond to the last command.</li> <li>The audio processor is switched off.</li> <li>The battery of the audio processor is empty.</li> <li>Interference from other electronic or electrical equipment is blocking the transmission.</li> </ul>	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"> <li>The detected audio processor is not compatible with the FineTuner Echo.</li> <li>The detected audio processor is configured for the previous generation FineTuner</li> </ul>	<p>Proceed as described in chapter FineTuner Echo, Using the FineTuner Echo for the first time.</p> <p>If pairing is unsuccessful again, contact your healthcare provider or local MED-EL representative.</p>
	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:
  1. Remove the battery.
  2. 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.
  3. 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, you need to switch the audio processor off and on again. When the audio processor is switched on again it will automatically start with the **M** (microphone) setting activated.
- If you press  or  for more than 3 seconds, your FineTuner Echo and the respective audio processor will be unpaired. Repeat the pairing process described in chapter FineTuner Echo, Using the 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”.

## 7. Technical data

### FineTuner Echo

#### Model

FineTuner Echo (Ma010201)

#### Dimensions<sup>1</sup>

Length: 104 mm

Width: 38 mm

Height: 11 mm

#### Weight<sup>1</sup>

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 (3V, )
- 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

Storage temperature range: -20 °C to +60 °C

Relative humidity range: 10% to 93%

Atmospheric pressure: Ambient to 700 hPa (mbar) (0 to 3,000 metres)

---

<sup>1</sup> typical values



### 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

## Regulatory statements

### Applicable in Canada only:

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

This 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 le présent appareil 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 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 FineTuner Echo is in compliance with directive 90/385/EEC (Active Implantable Medical Devices/AIMD).

CE mark applied in 2019

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



Type BF

(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



Manufacturer



Direct current



Atmospheric pressure limitation



Humidity limitation



Temperature limit

**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.

Technical data



Serial number



Catalogue number



Refer to instructions for use



Not suitable for children under 3 years



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



Non-ionizing radiation



Fragile; handle with care



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



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



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

## Guidance and manufacturer's declaration

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

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

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

The 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	3Vrms 150kHz to 80 MHz	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.
	6Vrms in ISM and amateur radio bands between 150kHz and 80 MHz		
	80% AM at 1kHz		
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27V/m 380 MHz to 390 MHz	27V/m	
	28V/m 430 MHz to 470 MHz	28V/m	
	9V/m 704 MHz to 787 MHz	9V/m	
	28V/m 800 MHz to 960 MHz	28V/m	
	28V/m 1700 MHz to 1990 MHz	28V/m	
	28V/m 2400 MHz to 2570 MHz	28V/m	
	9V/m 5100 MHz to 5800 MHz	9V/m	

## 8. Appendices

### Supplies and accessories

Description	Model number <sup>1</sup>
Battery CR2032 <sup>2</sup>	34307

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

### Warranty

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

### Manufacturer address

MED-EL Elektromedizinische Geräte GmbH  
Worldwide Headquarters  
Fürstenweg 77a  
6020 Innsbruck, Austria  
Tel: +43 (0) 5 77 88  
E-Mail: office@medel.com

---

<sup>1</sup> Subject to change without notice

<sup>2</sup> Not manufactured by MED-EL



## 9. Contact MED-EL

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







MED-EL Elektromedizinische Geräte GmbH  
Fürstenweg 77a, 6020 Innsbruck, Austria  
office@medel.com

[medel.com](http://medel.com)

