

MED[®]EL

AudioStream Adapter

User Manual



hearLIFE

AW45075_1.0 (English US)



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1. Introduction

This user manual provides information and instructions for the MED-EL AudioStream Adapter (Ma070402), an optional adapter for the RONDO 3 audio processor. It includes assembling instructions, instructions for proper care of the device, as well as instructions on how to use the Adapter Sleeve as a wearing option.

You are the operator of the AudioStream Adapter, therefore you should read the entire manual. Do not perform any maintenance activities other than those described in this user manual.

Not all products in this document are currently approved or available in all countries. Contact your audiologist/healthcare professional or local MED-EL representative for information on current product availability in your country or with any other questions you may have.

The following symbols are used throughout this document:

-  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 minor injury or inconvenience for the user and/or property damage.
-  Information particularly relevant for parents, guardians, or caregivers of users.

2. Intended Use

The AudioStream Adapter is an optional adapter that can be used to stream audio content from compatible electronic devices to the RONDO 3 audio processor.

The Adapter Sleeve can be used as an optional fixation method for the AudioStream Adapter, the Telecoil Adapter and the RONDO 3.

2.1 Intended User

The AudioStream Adapter and the Adapter Sleeve are intended for users who have received a RONDO 3 audio processor.

2.2 Target Patient Population

The AudioStream Adapter and the Adapter Sleeve are intended for users aged 3 and older.

2.3 Indications

The AudioStream Adapter and the Adapter Sleeve are intended for users who have received a RONDO 3 audio processor.

The AudioStream Adapter and the Adapter Sleeve are intended for use in typical everyday environments (home, office, outdoor, etc.) and suitable for everyday use during a user's waking hours.

2.4 Contraindications

A user must not receive an AudioStream Adapter if the individual is known to be intolerant of the materials used in the AudioStream Adapter and the Adapter Sleeve.

The AudioStream Adapter is not intended to be used in environments where radiofrequency (RF) transmissions are prohibited.

3. Warnings and Precautions

Carefully read the following section. For additional information on the safe use of the RONDO 3 audio processor (hereafter referred to as audio processor), refer to its user manual. Contact your audiologist/healthcare professional or local MED-EL representative with any questions you may have.

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. The use of audio processors other than those specified or provided by MED-EL could result in increased electromagnetic emissions or decreases electromagnetic immunity of the AudioStream Adapter and result in improper operation. If you have problems with any component of the system, read section Troubleshooting or contact your audiologist/healthcare professional or local MED-EL representative.

3.1 Warnings



PARENTAL GUIDANCE

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

3.2 Precautions

The AudioStream Adapter contains sophisticated electronic components that require special precautions regarding electromagnetic compatibility (EMC). Always follow the guidelines outlined in this section and in section Technical Data, Guidance and Manufacturer's Declaration.

- There is a remote chance that technical failure leads to missing information or temporarily no benefit.
- The electronics are durable but must be treated with care.
- Do not modify the housing, the electronics, or any part of the AudioStream Adapter.
- Always handle the AudioStream Adapter with care to achieve maximum lifetime and to avoid any risks (e.g., damage or injury).
- Do not use the AudioStream Adapter under environmental conditions other than those described in section Technical Data as this could damage the device.
- The defined operating temperature range for the AudioStream Adapter is between 0 °C and +50 °C (+32 °F and +122 °F).
- Avoid excessive heat. Excessive heat might damage the AudioStream Adapter and make it unusable.

Warnings and Precautions

- Do not leave the AudioStream Adapter in direct sunlight (especially inside a car). Long exposure to direct sunlight could damage the AudioStream Adapter.
- Avoid getting the AudioStream Adapter wet as this may impair its function. If the AudioStream Adapter gets wet, make sure to disassemble it from the audio processor, wipe it dry and place it in a drying kit. Always remove and switch off the audio processor and keep it in a dry place before bathing, showering, or engaging in other water-related activities.
- Do not drop or subject the AudioStream Adapter to dangerous areas (e.g., machines or high voltage). This could damage the AudioStream Adapter.
- Do not use the AudioStream Adapter in the vicinity of strong ionizing radiation (x-ray machines) or electromagnetic fields (MRI machines). Such radiation or fields may stop the MED-EL Cochlear Implant System from working.
- 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 AudioStream Adapter, including cables specified by MED-EL. Otherwise, degradation of the performance of the AudioStream Adapter could result.
- Do not use the AudioStream Adapter adjacent to or stacked with other equipment because it could result in improper operation. If such use is necessary, observe the AudioStream Adapter and the other equipment to verify that they are operating normally.
- Do not use the AudioStream Adapter in environments where radio frequency (RF) transmissions are prohibited.
- Do not use accessories other than those specified or approved by MED-EL. This could result in increased electromagnetic emissions or decreased electromagnetic immunity of the AudioStream Adapter and result in improper operation.

4. Device Description

The AudioStream Adapter is an optional streaming gadget that wirelessly connects the audio processor with mobile devices (smartphone, tablet, etc.) to stream sound like a phone call or music directly to your ears without the need of intermediate accessories.



4.1 Compatibility With Other Devices

The AudioStream Adapter is compatible with the RONDO 3 audio processor. For further information on compatibility of the RONDO 3 audio processor, refer to its user manual. For compatible Apple® and Android™ ² devices, visit our webpage at medel.com.

² Android is a trademark of Google LLC

5. Basics and Handling

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

The AudioStream Adapter is activated by plugging it into the power and programming interface of the audio processor. For further information on the audio processor, refer to its user manual.

5.1 Assembling the AudioStream Adapter



WARNING

Instruct children and persons under care not to swallow or put any components of the device into their mouths or play with any components. Swallowing of components could cause suffocation or internal injury. Do not use the AudioStream Adapter with children under 3 years.

To assemble the AudioStream Adapter, proceed as follows:

- 1 Remove the audio processor from the head.
- 2 Open the socket cover.
- 3 Plug the AudioStream Adapter into the audio processor.



If you decide to use the optional Adapter Sleeve, put it onto the audio processor with the AudioStream Adapter attached to it. Start from the AudioStream Adapter and move the Adapter Sleeve over the edge of the audio processor until it snaps into place.



To remove the Adapter Sleeve, insert your fingernail on one side and lift the Adapter Sleeve off.



NOTE: The Adapter Sleeve can also provide additional fixation of the Telecoil Adapter to the audio processor, and function as a hair attachment clip. For more details, refer to the RONDO 3 user manual.

5.2 Configuring and Pairing the AudioStream Adapter

To stream sound via the AudioStream Adapter directly to your audio processor, you first have to configure and pair the AudioStream Adapter.



CAUTION

Do not pair the AudioStream Adapter with other than your own wireless devices as this could lead to undesired hearing sensations.

To configure the AudioStream Adapter on a mobile device, proceed as follows:

- 1 Download the latest AudioKey app from the app store.
- 2 Start the AudioKey app on the mobile device, tap the menu in the upper left corner and open Connectivity Options.
- 3 Select AudioStream/Configuration and follow the instructions in the app.

To pair a mobile device with the AudioStream Adapter, proceed as follows:

- 1 Remove any pairing information for the AudioStream Adapter from the mobile device if there is any (e.g., by tapping "Forget this device").
- 2 Make sure to deactivate *Bluetooth*³ on other mobile devices that the AudioStream Adapter has already been paired too.
- 3 Pair the AudioStream Adapter to the mobile device as defined by the operating system of the respective mobile device (iOS devices: use the "Accessibility" menu; Android devices: use the standard Bluetooth menu).

Once successfully configured and paired, you can use the AudioStream Adapter to enjoy sound from any paired compatible mobile device. You do not have to configure the AudioStream Adapter again.

5.3 Making Phone Calls



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 (e.g., drop-outs or audible noise), move away from this electronic and electrical equipment.

To use the AudioStream Adapter for phone calls, proceed as follows:

- 1 Switch on the audio processor.
- 2 Ensure that the AudioStream Adapter is paired with your phone and a Bluetooth connection is established.

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.

- ③ To start a phone call, proceed as you usually would on the mobile device by speaking into the phone. You will automatically hear the conversation streamed to the AudioStream Adapter.
- ④ To receive a phone call, simply pick it up on the mobile device and enjoy the conversation.

5.4 Streaming Audio

To stream music or other audio signals (e.g., an audio book) from a mobile device, proceed as follows:

- ① Switch on the audio processor.
- ② Ensure that the AudioStream Adapter is paired with your phone and a Bluetooth connection is established.
- ③ Switch on the sound source. Sound from the mobile device is now streamed directly to the AudioStream Adapter.

5.5 Care and Maintenance

The AudioStream Adapter is designed for durability and reliability. Handle the device with care.

For more information on care and maintenance of the audio processor, refer to its user manual.

If the device does not work properly, see section Troubleshooting for possible solutions.

- Do not drop the device.
- Do not try to repair the electronic parts of the AudioStream Adapter.
- Do not try to open the AudioStream Adapter, as this may damage the device.
- Protect the AudioStream Adapter from liquids, dust, and excessive temperatures.
- Do not clean the AudioStream Adapter in or under water. Use a damp cloth to gently clean the AudioStream Adapter. Never use household cleaning products.
- Dry the AudioStream Adapter overnight in a drying kit to prevent corrosion of contacts. Do not use a microwave oven or any other heating devices to dry the AudioStream Adapter.
- The AudioStream Adapter does not require regular maintenance by clinic personnel or other experts.

6. Troubleshooting

For assistance and reporting of issues associated with this MED-EL product or to report unexpected operation or events, contact your local MED-EL representative. Refer to the applicable audio processor user manual for additional troubleshooting guidelines.

Problem	Possible cause	Recommended action
Pairing process failed	Disruptions in pairing process	<ul style="list-style-type: none"> Switch on the Bluetooth functionality on the mobile device. Switch the audio processor off and on again to put the AudioStream Adapter into pairing mode. Your smartphone must be compatible with the AudioStream Adapter. Visit our website at medel.com for a list of compatible smartphones. Make sure your smartphone uses the correct operating system: Android 10 or higher for Android devices; iOS 11 or higher for Apple devices. Closely follow the pairing procedure as described in the AudioKey app. Make sure you have the correct version of the AudioKey app installed. Make sure the AudioStream Adapter is not paired to another mobile device when you want to pair it to a new device. Move the AudioStream Adapter closer to the mobile device you intend to pair it to.
Audio streaming does not start	AudioStream Adapter not yet paired	Pair the AudioStream Adapter to the mobile device (see section Basics and Handling, Configuring and Pairing the AudioStream Adapter).
No sound perceptible during active stream	AudioStream Adapter out of range	<ul style="list-style-type: none"> Ensure that the audio processor is switched on. Ensure that the audio processor is within range of the paired device.
Distortions heard during audio streaming (interruptions, noise)	Device not within range or interference from other devices	<ul style="list-style-type: none"> Clean the contacts at the bottom of the audio processor. Reduce the distance between device and audio processor. If possible, remove interfering devices (especially in the 2.4GHz band, e.g., a Wi-Fi router or computer). If possible, change the location of the Wi-Fi router and/or PC. If possible, use the 5 GHz band of the Wi-Fi system. In case of a phone call, do not place the mobile device too close to the AudioStream Adapter.
No sound perceptible or sound too low	Volume too low	<ul style="list-style-type: none"> Clean the contacts at the bottom of the audio processor. Increase the volume on the mobile device (e.g., smartphone). If the volume remains too low, increase the volume on the audio processor.
Sound too loud or cracking	Volume too high	<ul style="list-style-type: none"> Clean the contacts at the bottom of the audio processor. Decrease the volume on the mobile device (e.g., smartphone). If the volume remains too high, decrease the volume on the audio processor.

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. The AudioStream Adapter should not be used on aircrafts unless specifically permitted by the flight personnel. Remove the AudioStream Adapter unless this is the case.

8. Technical Data

For technical data of the audio processor, refer to the applicable audio processor user manual.

8.1 Device Characteristics

Model	AudioStream Adapter (Ma070402)
Dimensions ⁴	Length: 1.5 cm (5.9 in.) Width: 1.3 cm (5.1 in.) Depth: 0.5 cm (0.2 in.)
Weight ⁴	<0.8 g (<0.03 oz.)
Materials in body contact	Mixture of polycarbonate and acrylonitrile-butadiene-styrene polymer (PC/ABS)
Temperature and humidity range	<ul style="list-style-type: none"> Operating temperature range: 0°C to +50°C (+32°F to +122°F) Storage temperature range: -29°C to +60°C (-20.2°F to +140°F) Relative humidity range: 15% to 90% Atmospheric pressure range: 700 hPa (mbar) to 1060 hPa (mbar)
Essential performance	None of the performance characteristics of the AudioStream Adapter are essential performance as defined in IEC 60601-1.
Expected service life	The expected service life of AudioStream Adapter as defined in IEC 60601-1 is five years. There are no actions needed to maintain basic safety with regard to electromagnetic disturbances for the expected service life.
Radio frequency link	<ul style="list-style-type: none"> 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) Type of modulation: Gaussian frequency-shift keying (GFSK) Maximum effective radiated power (ERP): -4.8 dBm (331 µW) Channel band width: 1 MHz, 2 MHz

8.2 Regulatory Statements

Applicable in Canada only:

Model: AudioStream Adapter (Ma070402) – IC: 11986A-ASA

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.

⁴ typical values

Applicable in the USA only:

Model: AudioStream Adapter (Ma070402) – FCC ID: VNP-ASA

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

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

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

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

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

8.3 Radiofrequency/Telecommunication Information

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

8.4 Guidance and Manufacturer's Declaration

Tables according to IEC 60601-1-2 for the AudioStream Adapter

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

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

Technical Data

Electromagnetic immunity – for all equipment and systems

The AudioStream Adapter is intended for use in the home healthcare environment. The customer or the user of the AudioStream Adapter 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_r for 0.5 cycle (1 phase) 0% U_r for 1 cycle 70% U_r for 25/30 cycles (50/60Hz) 0% U_r for 250/300 cycles (50/60Hz)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) 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_r 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 AudioStream Adapter is intended for use in the home healthcare environment. The customer or the user of the AudioStream Adapter 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 AudioStream Adapter, including cables specified by MED-EL. Otherwise, degradation of the performance of the audio processor could result.
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz 3 V/m, 2.7 GHz to 6 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 IEC 61000-4-39	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

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

9.2 Storage

Store the AudioStream Adapter in a dry place and protect it from direct sunlight.

9.3 Disposal

We advise you to dispose of all components of the AudioStream Adapter 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

 CE marking, first applied in 2024

Hereby MED-EL Elektromedizinische Geräte GmbH declares that the radio equipment type AudioStream Adapter is in compliance with directive 2014/53/EU and 2011/65/EU. The full text of the EU declaration of conformity is available at the following internet address: www.medel.com/compliance

-  Caution
-  Consult instructions for use
-  Manufacturer
-  Date of manufacture
-  Catalog number
-  Serial number
-  Fragile, handle with care
-  Temperature limit
-  Humidity limitation
-  Atmospheric pressure limitation



Non-ionizing electromagnetic radiation

IP52 Moisture and dust protection acc. to IEC 60529

This classification means that the AudioStream Adapter is protected against failure from ingress of dust and dripping water when fully assembled.

RX ONLY Prescription only

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

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Durham, NC 27713, USA

Phone: 1-888-633 3524

Fax: 1-919-484-9229

Email: implants.us@medel.com

RX ONLY

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 country in which the user and/or patient is established.



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