

Cochlear Implants

MED⁹**EL**

AudioStream

User Manual



hearLIFE

AW40784_1.0 (English US)



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1. Introduction

This user manual provides information and instructions for the MED-EL AudioStream (Ma070401), an optional battery pack cover for the SONNET and SONNET EAS series¹, referred as SONNET series in this user manual. It includes descriptions of assembling instructions and instructions for proper care of the device.

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

NOTE: Please read the user manual of your audio processor carefully before reading this manual.

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

¹ This covers SONNET/SONNET EAS and SONNET 2/SONNET 2 EAS audio processors.

2. Intended use – Indications – Contraindications

Intended use

AudioStream is an optional battery pack cover that can be used with the SONNET series audio processor to stream audio content from mobile devices (e.g. smartphone) to the SONNET series audio processor.

Indications

AudioStream is intended for users of any age, who have received a SONNET series audio processor.

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

Contraindications

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

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

3. AudioStream

AudioStream wirelessly connects your 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. For compatible Apple® and Android™² devices please visit our webpage at medel.com.


AudioStream is an optional streaming gadget that is activated by slipping the cover over your battery pack option.

Please refer to the applicable audio processor user manual for further information about how to lock the cover into place.

Using AudioStream for the first time

Assembling AudioStream

To assemble AudioStream, proceed as follows:

- 1 Switch off the audio processor by sliding off the battery pack cover you have been using (make sure that the lock on the cover is in the unlocked position).
- 2 Assemble a compatible battery pack frame or rechargeable battery adapter to your audio processor if not already in use. A compatible battery pack frame or rechargeable battery adapter is indicated by this symbol .
- 3 Make sure that the lock of the AudioStream cover is in the unlocked position.
- 4 Slide AudioStream completely over the battery pack frame or rechargeable battery adapter to switch on the audio processor.



PARENTAL GUIDANCE

When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position once the cover has been moved completely over the frame or rechargeable battery adapter to prevent the child from disassembling the audio processor. The micro rechargeable battery is NOT suitable for young children under 3 years with the SONNET series audio processors as the battery cannot be locked in place.

² Android is a trademark of Google LLC

Pairing and configuring AudioStream

To stream sound via AudioStream directly to your processor, you first have to pair AudioStream.

To pair your mobile device with AudioStream and configure AudioStream, proceed as follows:

- 1 Download the latest AudioKey app from your app store.
- 2 Start the AudioKey app on your mobile device and enter the connectivity options menu.
- 3 Select AudioStream/Configuration and follow the instructions in the app.

Once successfully configured, you can use AudioStream to enjoy sound from any paired compatible mobile device. You need not configure AudioStream again.

How to use AudioStream

Making phone calls

To use AudioStream for phone calls, proceed as follows:

- 1 Switch on the audio processor.
- 2 Ensure that your AudioStream is paired with your phone and a *Bluetooth*^{®3} wireless technology connection is established.
- 3 To start a phone call, proceed as you usually would on your mobile phone by speaking into your phone. You will automatically hear the conversation streamed to your implant.
- 4 To receive a phone call, simply pick it up on your phone and enjoy your conversation.

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 your AudioStream is paired with your phone and a Bluetooth connection is established.
- 3 Switch on your sound source and sound from your mobile device is now streamed directly to AudioStream.

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

4. General precautions and warnings

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

AudioStream contains electronic components which require special precautions regarding electromagnetic compatibility (EMC).

Always follow the guidelines outlined in this section and chapter Technical data, Guidance and manufacturer's declaration.

- Always use AudioStream with the compatible battery pack frame or rechargeable battery adapter.
- Always handle AudioStream with care to achieve maximum lifetime and to avoid any risks.
- The electronics are durable but must be treated with care.
- Do not use AudioStream under environmental conditions other than those described in chapter Technical data.
- The defined operating temperature range for AudioStream is between 0°C and +50°C (+32°F and +122°F). Avoid excessive heat. Excessive heat might damage AudioStream and make it unusable.
- Do not leave AudioStream in direct sunlight (especially inside a car). Long exposure to direct sunlight could damage AudioStream.
- Avoid getting AudioStream wet as this may impair its function. If AudioStream gets wet, make sure to disassemble it from your audio processor, wipe it dry and place it in your drying kit. Always remove and switch off the external parts of your MED-EL Cochlear Implant System and keep them in a dry place before bathing, showering or engaging in other water-related activities.
- Do not use AudioStream in the vicinity of strong ionizing radiation (x-ray machines) or electromagnetic fields (MRI). Such radiation or fields may stop your MED-EL Cochlear Implant System from working.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of AudioStream, including cables specified by MED-EL. Otherwise, degradation of the performance of AudioStream could result.
- Do not use AudioStream in environments where radio frequency (RF) transmissions are prohibited.
- Use of audio processors other than those specified or provided by MED-EL could result in increased electromagnetic emissions or decreased electromagnetic immunity of AudioStream and result in improper operation.

- Do not modify the housing, the electronics or any part of AudioStream.
- Do not use AudioStream with any device other than those listed in this manual or approved by MED-EL to ensure proper operation of AudioStream.



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.



PARENTAL GUIDANCE

Children shall be instructed not to swallow or put any components of their MED-EL Cochlear Implant System into their mouths or to play with any components. Swallowing of system components could cause suffocation or internal injury. When the user is a young child, the battery pack cover lock must always be turned clockwise into the locked position once the cover has been moved completely over the frame or rechargeable battery adapter to prevent the child from disassembling the audio processor. The micro rechargeable battery is therefore not suitable for young children.

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. AudioStream should not be used on aircrafts unless specifically permitted by the flight personnel. Please replace your AudioStream with another battery pack cover.

5. Care and maintenance

Maintenance

AudioStream is designed for durability and reliability. Handle your AudioStream with care.

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

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

If you still cannot solve the problem, please contact your healthcare provider or local MED-EL representative for advice.

Disposal

We advise to dispose 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.

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.

Please also refer to the applicable audio processor user manual for 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 processor off and on to put AudioStream in pairing mode. • Your smartphone must be compatible with AudioStream. 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 AudioStream is not paired to another mobile device when you want to pair it to a new device. • Move AudioStream device(s) closer to the mobile device you intend to pair to.
Audio streaming does not start	AudioStream is not yet paired	<ul style="list-style-type: none"> • Pair AudioStream to the mobile device (see chapter 3, AudioStream, Pairing and configuring AudioStream).
No sound perceptible during an active stream	AudioStream is out of range	<ul style="list-style-type: none"> • Ensure that your audio processor is turned on. • Replace audio processor battery if empty. • Ensure that the audio processor is within range.
Distortions during audio streaming (interruptions, noise)	Device is not within range or interference from other devices	<ul style="list-style-type: none"> • Clean the FM contacts on the side of the audio processor. • Reduce distance between device and audio processor. • If possible, remove interfering device (especially in the 2.4GHz band, e.g. a Wi-Fi router or computer). • If possible, change location of Wi-Fi router and/or PC. • If possible, use the 5GHz band of your Wi-Fi system. • In case of a phone call, do not place the phone too close to AudioStream.
No sound perceptible or sound too low	Volume too low	<ul style="list-style-type: none"> • Clean the FM contacts on the side of the audio processor. • Increase volume on mobile device (e.g. smartphone). • If volume remains too low, increase volume on audio processor.
Sound too loud or cracking	Volume too high	<ul style="list-style-type: none"> • Clean the FM contacts on the side of the audio processor. • Decrease volume on mobile device (e.g. smartphone). • If volume remains too high, decrease volume on audio processor.

7. Technical data

Model	AudioStream (Ma070401)
Dimensions⁴	<p>5.9 mm (0.232 in.)</p> <p>63.7 mm (2.51 in.)</p> <p>37.4 mm (1.472 in.)</p> <p>9.3 mm (0.366 in.)</p>
Weight³	<ul style="list-style-type: none"> • SONNET series for CI with AudioStream (including batteries): 11.5 g (0.41 oz.) • SONNET series for EAS with AudioStream (including batteries): 12.2 g (0.43 oz.)
Materials	Mixture of polycarbonate and acrylonitrile-butadiene-styrol 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 AudioStream are essential performance as defined in IEC 60601-1.
Expected service life	The expected service life of AudioStream as defined in IEC 60601-1 is 5 years. There are no actions needed to maintain basic safety with regard to electromagnetic disturbances for the expected service life.
Radio frequency link	<ul style="list-style-type: none"> • Frequency band of reception/transmission: 2400 MHz – 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): 702 μW (-1.54 dBm) • Channel band width: 2 MHz

⁴ typical values

Regulatory statements

Applicable in Canada only:

Model: AudioStream (Ma070401) – IC: 11986A-AS

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: AudioStream (Ma070401) – FCC ID: VNP-AS

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.

Symbols



0123

AudioStream is in compliance with directive 90/385/EEC (Active Implantable Medical Devices/AIMD).

CE marking, first applied in 2020

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



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



Refer to instructions for use





Manufacturer




Catalog number


Technical data


 Serial number

 Fragile; handle with care


 Temperature limit

 Humidity limitation

 Atmospheric pressure limitation

 Type BF (IEC 60601-1/EN 60601-1): The surface of AudioStream, which is in contact with the user, is a Type BF Applied Part


 Non-ionizing electromagnetic radiation

 Battery pack recommended for use with wireless accessories

IP54 Moisture and dust protection acc. to IEC 60529

This classification means that your audio processor is protected against failure from ingressing dust and splashing water when fully assembled, i.e. when

- the microphone cover and the earhook are snapped onto the control unit,
- an earmold is connected to the earhook (only relevant for SONNET series EAS)
- the coil cable and coil are connected to the control unit,
- the battery pack frame or rechargeable battery adapter is connected to the control unit,
- AudioStream is completely moved over the battery pack frame or rechargeable battery adapter.

 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

Tables according to IEC 60601-1-2 for AudioStream

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

Electromagnetic emissions – for all equipment and systems

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	AudioStream 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	AudioStream 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			
AudioStream is intended for use in the home healthcare environment. The customer or the user of AudioStream 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			
AudioStream is intended for use in the home healthcare environment. The customer or the user of AudioStream 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	Not applicable	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the audio processor, 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	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	

8. Appendices

Warranty

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

Manufacturer address

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E-Mail: implants.us@medel.com

9. Contact MED-EL

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



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