

AudioLink

User Manual



hearLIFE



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1. Introduction

This user manual provides information and instructions for the MED-EL AudioLink (Ma070301). It contains important information on handling and operation of the device. Please read these instructions carefully and completely so that you are familiar with the operation and maintenance of AudioLink.

AudioLink is an optional component of the MED-EL Cochlear Implant System to be used with compatible MED-EL audio processors. Please read the user manual of your audio processor carefully before reading this manual.

NOTE: You are the operator of your/the recipient's AudioLink, 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 the battery).

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.

Intended use – Indications –Contraindications

Intended use

AudioLink is an optional, external part of the MED-EL Cochlear Implant System.

AudioLink is intended to be used as a wireless connection between compatible MED-EL audio processors and electronic devices (mobile phones, smartphones, tablets, etc.) equipped with Bluetooth^{®1} wireless technology.

In combination with a mobile or smartphone, AudioLink provides the functionality of a Bluetooth® headset where the incoming audio signal is wirelessly streamed to the audio processor(s).

AudioLink is intended to be used to wirelessly stream audio signals from an audio source featuring Bluetooth® wireless technology or an analog audio source to the audio processor(s).

AudioLink is intended to be used as a wireless remote microphone.

AudioLink provides a general communication and data pathway between an electronic device featuring Bluetooth® wireless technology running a specific MED-EL software and the audio processor(s).

Indications

AudioLink is an optional component of the MED-EL Cochlear Implant System and is indicated for use by recipients who have received a compatible MED-EL audio processor. Additionally, persons interacting with a MED-EL Cochlear Implant user (e.g. parents of implanted children, audiologists, teachers of implanted children, etc.) can use AudioLink.

AudioLink is indicated to be used in typical everyday environments (home, office, outdoor, etc.) and also in clinical environments (audiologist's office, etc.).

¹ 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.

AudioLink is indicated to be used every day during a recipient's waking hours. There are no restrictions in the frequency of use.

The user of AudioLink does not need any special skills or elevated level of education, however, for children under the age of five years 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.

Contraindications

A recipient must not receive an AudioLink if the individual is known to be intolerant of the materials used in AudioLink.

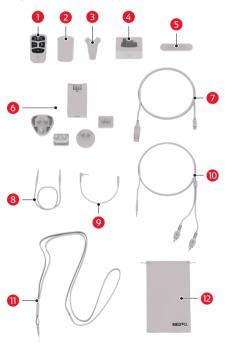
AudioLink is not intended to be used in environments where RF transmissions are prohibited.

3. AudioLink

AudioLink wirelessly connects your audio processor(s) with electronic devices (smart-phones, tablets, etc.). AudioLink can be used to watch TV, listen to music via the phone or a connected device, take phone calls and as a remote microphone. Information from the AudioLink is transmitted to the audio processor(s) via a 2.4 GHz radio frequency (RF) link.

AudioLink is not necessary for the function of your audio processor.

System components²



- AudioLink main unit
- 2 AudioLink battery
- 3 AudioLink clip
- Ocking station
- 6 AudioLink opening tool
- 6 USB power adapter with country-specific input plugs
- Micro USB cable
- 8 Stereo cable with two 3.5 mm audio jacks
- 9 Adapter cable with a 2.5 mm audio jack and 3.5 mm socket
- 10 Stereo cable with a 3.5 mm audio jack and RCA connectors
- Lanyard
- 12 Pouch

² Not all products in this document are currently approved or available in all countries. Please contact your local MED-EL representative for information on current product availability in your country.

AudioLink overview

In its basic configuration AudioLink consists of the AudioLink main unit (hereafter referred to as main unit) and the AudioLink battery (hereafter referred to as battery).



- Microphone
- 2 Groove
- Status light
- 4 Main button & Connection symbols: Shows connection between devices, indicates successful pairing and switches AudioLink ON/OFF
- (5) Mix button: Switches between audio input from the AudioLink microphone only or mixed input from AudioLink and the audio processor microphone(s)

- 6 Mic button: Activates the remote microphone functionality
- 7 Volume button: Increases (+) and decreases (-) the volume
- 8 Lanyard opening
- Attachment clip
- Rubber socket cover
- Audio socket (2.5 mm stereo)
- Micro USB socket

Using AudioLink for the first time

Assembling AudioLink

To assemble AudioLink, proceed as follows:

1 Your AudioLink is delivered disassembled.



2 Attach the battery to the main unit, starting at the bottom at a 45° angle.



3 Starting at the bottom, press the two parts together until the battery fully snaps into the main unit. AudioLink is now switched on. This is indicated by the status light slowly pulsing green.



Optional: Connect the AudioLink clip to AudioLink by aligning the clip with the back of AudioLink and applying pressure until the designated holes in the clip snap into place.



Optional: To attach the lanyard, remove the AudioLink clip from AudioLink by slightly lifting one side of the clip with your fingernail or with the AudioLink opening tool. Insert the thin string of the lanyard into the hole of the AudioLink clip and thread the other end of the lanyard through the resulting loop. Tighten the loop and reattach the AudioLink clip to AudioLink.





CAUTION

Do not touch the battery contacts with your hands or metal objects.



PARENTAL GUIDANCE

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

NOTE: Your AudioLink is delivered with the battery not fully charged. We recommend that you fully charge the device before using AudioLink.

Charging AudioLink

To charge AudioLink, proceed as follows:

- Choose the appropriate input plug for the USB power supply. Connect the input plug with the USB power supply by pushing down the plug until it clicks into place. Then connect the micro USB cable.
- 2 Pull aside the rubber socket cover.
- 3 Plug the micro USB cable into the charging socket of AudioLink.
- 4 Connect the USB power supply to a power outlet (100-240V AC, 50-60 Hz).









5 The status light will be orange while charging.



When the status light turns green, AudioLink is fully charged. Optional: Disconnect the micro USB cable from the charging socket and the USB power supply from the power outlet.



You can also use the AudioLink docking station to charge the battery (see chapter Streaming audio from TV on how to use the AudioLink docking station).

You can still use all functions of AudioLink while it is charging or connected to a charger as long as AudioLink is switched on. When switched off, AudioLink automatically changes to standby mode while being charged. It will take approximately three hours to charge a fully depleted battery.



CAUTION

Only use the provided USB power supply and cable to prevent any damage to the device and to avoid any injuries.

Switching AudioLink ON/OFF

To switch ON AudioLink, proceed as follows:

1 Press the main button for approximately 2 seconds.



Release the main button. When AudioLink is successfully switched ON, the status light illuminates in green or orange.



AudioLink is automatically switched ON and in standby mode during charging.

To switch OFF AudioLink, proceed as follows:

1 Press the main button for approximately 2 seconds.



Release the main button. When AudioLink is switched OFF, the status light does not illuminate.



AudioLink switches off automatically when not used for approximately 5 minutes and not powered via USB.

Pairing your audio processor with AudioLink

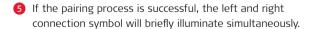
If you want to use AudioLink with your audio processor, you need to pair your audio processor with AudioLink.

To pair your audio processor with AudioLink, proceed as follows:

- 1 Switch off the audio processor.
- Press the main button for approximately 2 seconds to switch on AudioLink and make sure it is in standby mode (only the status light is active, i.e. orange or green).



- 3 Place the coil on the top side of AudioLink, approximately over the Volume button.
- 4 Switch on the audio processor.





6 Optional for bilateral users: Repeat pairing for the second processor. If AudioLink is paired with two audio processors, i.e. for the left and the right ear, it automatically tries to synchronise and stream to both audio processors. However, synchronisation might not be simultaneous and if an audio stream is active during that time, audio quality might be degraded (for up to 25 seconds). You can only pair one audio processor for each side.

AudioLink will automatically try to resynchronise to the audio processor(s) if it loses connection. If it is not possible to resynchronise to the audio processor(s) within 25 seconds, AudioLink returns to standby mode (unless streaming audio via a stereo cable connection).

NOTE: The audio processor(s) must be paired with AudioLink before any other connection to an external device can be established.

Pairing AudioLink with a Bluetooth® device

To pair AudioLink to an electronic device with Bluetooth® functionality, proceed as follows:

Ensure that AudioLink is switched on and in standby mode (only the status light is active, i.e. orange or green).



2 Simultaneously press the Mix button and Mic button for approximately 2 seconds. AudioLink is now in Bluetooth® pairing mode (indicated by a fast blinking Bluetooth® connection symbol). The Bluetooth® pairing mode is active for 60 seconds. AudioLink must be in pairing mode to be visible to other electronic devices.



3 Turn on Bluetooth® on your mobile device and scan for other Bluetooth® devices.



NOTE: Refer to the user manual of the Bluetooth® device for instructions on Bluetooth® connections.



4 After a few seconds the device should find a new Bluetooth® device called MED-EL AudioLink. Select this device and start pairing.

NOTE: Further interaction might be required. If asked for a code, enter '0000'. Otherwise just confirm the pairing.

- After successful pairing, the Bluetooth® device will automatically connect to AudioLink. This is indicated by a slowly pulsing Bluetooth® connection symbol on your AudioLink.
- You can manually connect or disconnect AudioLink on the device. Bluetooth® functionality is only provided if AudioLink is connected.







NOTE: AudioLink can only be connected to one Bluetooth® device at the same time.

If necessary, you can delete the stored Bluetooth® pairings as follows:

Ensure that AudioLink is switched on and in standby mode (only the status light is active, i.e. orange or green).



Simultaneously press the Mix button and Mic button for approximately 2 seconds. AudioLink is now in Bluetooth® pairing mode (indicated by a fast blinking Bluetooth® connection symbol).



Press Volume + and Volume - simultaneously for approximately 1.5 seconds. The Bluetooth® connection symbol will stop blinking, indicating that all stored Bluetooth® pairings have been successfully deleted from your AudioLink.



AudioLink functions

AudioLink offers the following input modes:

- Answer phone calls
- Stream TV audio via cable connection between AudioLink and TV
- Stream music via a connected device
- Use the AudioLink as a remote microphone

If one audio streaming mode is currently active and another mode is activated, AudioLink will change to the mode with the higher priority. Phone calls have the highest priority, followed by the remote microphone and, finally, the streaming options requiring a cable connection. For example: If you receive a phone call while streaming via a cable connection, streaming (lower priority) will be interrupted until you terminate the phone call (higher priority).

There is a delay when terminating streaming and returning to standby mode (only the status light is active, i.e. orange or green). It will take approximately 5 seconds between switching off streaming (e.g. pressing the Microphone button in active remote microphone mode) and returning to standby mode.

While audio streaming is active, you have several options to adjust the volume level of the streamed audio signal:

- Via the source device (mobile phone, TV, etc.), if possible. This option is recommended.
- Via AudioLink (Volume button).
- Directly on the audio processor(s) (FineTuner Echo, AudioKey, etc.). This option is not recommended. If you decide to change the volume on your audio processor(s), make sure to readjust the volume setting before terminating streaming to avoid uncomfortably loud sensations.



PARENTAL GUIDANCE

To prevent accidental volume changes, keep AudioLink out of reach of young children.

Making phone calls via Bluetooth®

With AudioLink you can stream phone calls directly to your audio processor(s) (including calls via WhatsApp, Skype, Hangouts, Facetime, etc.). The voice of your conversation partner is streamed from the phone to AudioLink via Bluetooth® and forwarded to the audio processor(s). Your voice is picked up by the integrated microphone of AudioLink and returned to the mobile phone via Bluetooth®.

To use AudioLink for phone calls, proceed as follows:

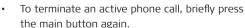
- Switch on AudioLink.
- Ensure that a Bluetooth® connection between AudioLink and your phone is established (see chapter Pairing AudioLink with a Bluetooth® device). This is indicated by a slowly pulsing Bluetooth® connection symbol.



3 During a phone call the integrated AudioLink microphone will be used instead of the microphone of the phone. You should wear AudioLink in a way that the microphone can pick up your voice. It is recommended to wear AudioLink close to your mouth, e.g. on the upper body, attached to a collar, shirt pocket, etc. with the AudioLink clip or the lanyard. Do not cover the microphone. For best sound reception of the integrated microphone, make sure that the front of AudioLink always faces away from your body and that the top of AudioLink faces upwards.



- 4 To start a phone call, proceed as you usually would on your mobile phone.
- When you receive a phone call, the ring tone will be streamed to the audio processor(s), even if your phone is in silent mode:
 - To answer the phone call, briefly press the main button of AudioLink.
 - In case you want to reject the phone call, press the main button of AudioLink a little longer (approx. 2 seconds).





You can also answer, reject and terminate phone calls directly on the mobile phone.

NOTE: By default, your audio input is a mix of the AudioLink signal and the audio processor microphones. You can change this setting with the Mix button.

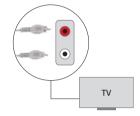
Streaming audio from TV

With AudioLink you can stream from your TV (or other consoles and devices) directly to your audio processor(s). The signal is transmitted over a cable connection to AudioLink and then streamed to your device(s).

To connect AudioLink to a TV, proceed as follows:

1 Connect the stereo cable with RCA (or cinch) connectors with the TV. To do so, insert the red and white audio plug into the appropriate RCA sockets on the TV (typically located on the side or the back of the TV).

NOTE: If your TV does not have RCA input sockets, use commercially available RCA adapters.



2 Connect the 3.5 mm audio jack of the stereo cable with the AudioLink docking station.



3 Pull the rubber socket cover aside and turn it to the back to access the connectors.



Place AudioLink in the AudioLink docking station. Make sure that the rubber socket cover is positioned in the designated groove of the AudioLink docking station.



Switch on the TV and set the output volume to a medium level. If necessary, change the TV settings so that the RCA connectors are set as an output signal instead of input. If your TV does not support such settings, we recommend using the 3.5 mm jack stereo cable in combination with the provided adapter as described in chapter Streaming audio via stereo cable.

Once an audio signal is received from the TV, AudioLink automatically synchronises to the audio processor(s). Once synchronised, AudioLink starts streaming to the audio processor(s). The corresponding left/right connection symbol starts pulsing slowly.



7 To stop the streaming mode, unplug the cable from AudioLink. Audio streaming stops automatically when no audio signal is received from the source device for approx. 3.5 minutes. If you have the Fine Tuner Echo remote control, you may use the Fine Tuner Echo to deactivate the stream by pressing the music symbol. Please refer to the FineTuner Echo and/or audio processor user manual for further information.

It is recommended to use the stereo cable with RCA connectors and the AudioLink docking station for TV streaming as signal quality improves.

NOTE: Do not forget to put the rubber socket cover back over the connectors after removing AudioLink from the AudioLink docking station.

NOTE: By default, your audio input is a mix of TV signal and the audio processor microphone signal. You can change this setting with the Mix button.

Streaming audio via stereo cable

You can stream the signal of any compatible audio source (e.g. tablet, PC, laptop) to your audio processor by establishing a wired connection to AudioLink. Use the provided stereo cables with the 2.5 mm to 3.5 mm audio adapter cable and proceed as follows:

1 Connect the stereo cable with two 3.5 mm audio jacks to the target audio source (or the AudioLink docking station).



2 Connect the 3.5 mm audio socket of the audio adapter cable to the 3.5 mm audio jack of the stereo cable.



3 Connect the 2.5 mm audio jack of the audio adapter cable to the audio socket of AudioLink.



- Start audio playback on your device. We recommend setting the output volume of the source device to a medium level.
- If an audio signal is received from your device, AudioLink automatically synchronises to the audio processor(s). Once synchronised, AudioLink starts streaming to the audio processor(s). The corresponding left/right connection symbol starts pulsing slowly.



6 To stop streaming, unplug the cable from AudioLink. Audio streaming stops automatically when no audio signal is received from the source device for approx. 3.5 minutes.

You can also use the AudioLink docking station for streaming via cable connection. Please refer to chapter Streaming audio from TV for information on how to establish the connection to the audio source (use the stereo cable with two 3.5 mm audio jacks instead of the stereo cable with RCA connectors).

NOTE: By default, your audio input is a mix of the audio source signal and the audio processor microphone signal. You can change this setting with the Mix button.

Using the remote microphone

In remote microphone mode, AudioLink picks up surrounding acoustic signals with its integrated microphone and streams them to the audio processor(s).

The remote microphone feature of AudioLink can be used in several situations:

Meeting room situation:

Place AudioLink in a stationary position (e.g. in the middle of a table) to pick up the voices of all participants. The AudioLink docking station can be used to position the AudioLink properly.



Conversation/school situation:

The conversation partner wears AudioLink so that the microphone can pick up the partner's voice which is then streamed to your audio processor(s). Your conversation partner can wear AudioLink on the upper body, attached to a collar, shirt pocket, etc. with the AudioLink clip or use the lanyard.





To use the remote microphone function, proceed as follows:

- Switch on AudioLink.
- Press the Mic button of AudioLink.



3 AudioLink synchronises to the audio processor(s) and starts streaming (indicated by slow pulsing of the corresponding left/right connection symbol). The microphone symbol will also illuminate.



To terminate the remote microphone mode, press the Mic button of AudioLink again.

NOTE: By default, the audio input will be the AudioLink microphone only and the microphones of the audio processor(s) will be deactivated. You can change this setting with the Mix button.

Using AudioLink with AudioKey

AudioKey is an optional mobile phone app that works in conjunction with AudioLink to allow your smartphone to remotely control certain functions of your audio processor(s), e.g. volume or sensitivity. AudioKey can be downloaded from the respective App Store. For a detailed description of the app, please follow the instructions in the applicable user manual.

NOTE: A Bluetooth® connection between AudioLink and your phone is necessary in order to use certain functions of the AudioKey mobile app (see chapter Pairing AudioLink with a Bluetooth® device).

With AudioKey you can further customize your default audio streaming configuration for the different audio streaming functions. Please refer to your AudioKey user manual for more information.

To use AudioLink via app, proceed as follows:

Ensure that a Bluetooth® connection between AudioLink and your phone is established (see chapter Pairing AudioLink with a Bluetooth® device).



2 Open the AudioKey mobile app.



AudioLink indicator lights

The AudioLink indicator lights will illuminate in different patterns to indicate different conditions of the system.



Status light

Blinking pattern	Meaning	Required action
Slowly pulsing green	AudioLink active and battery level sufficiently charged	None
Permanently green	Charger connected and charging process finished	Remove AudioLink from the power outlet. AudioLink can remain connected to the AudioLink docking station (e.g. when watching TV).
Slowly pulsing orange	AudioLink active and battery level low (less than 5%)	Charge AudioLink
Permanently orange	Charger connected and battery charging	None



Left/right connection symbol

Blinking pattern	Meaning	Required action
Fast blinking	AudioLink is synchronising to the audio processor(s)	None
Slowly pulsing	AudioLink is streaming to the audio processor(s)	None
Single pulse approx. 1 second (both sides)	Audio processor pairing successful	None
oo—oo—oo Double flashing (together with Bluetooth connection symbol)	Incoming phone call	Answer or reject call

Bluetooth® connection symbol



Blinking pattern	Meaning	Required action
Fast blinking	AudioLink is in Bluetooth® pairing mode	None
Slowly pulsing blue	Active Bluetooth® connection	None
Double flashing (together with both connection symbols)	Incoming phone call	Answer or reject call



Mix button

Blinking pattern	Meaning	Required action
Permanently illuminated	The audio signal from the audio processor(s) and the signal from AudioLink are provided	None



Mic button

Blinking pattern	Meaning	Required action
Permanently illuminated	Remote microphone is active	None

When changing from one state to another, the indicator lights will illuminate in full brightness. To save energy and reduce distraction, illumination of the indicator lights will be dimmed after approximately 30 seconds.

4. Care and maintenance

Maintenance

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

- Do not drop the device.
- Do not try to repair electronic parts of your AudioLink and do not try to open the device, except to detach the battery, as this invalidates the warranty.
- Protect AudioLink from liquids, dust and excessive temperatures.
- Do not clean AudioLink in or under water. Use a damp cloth to gently clean AudioLink. Never use household cleaning products or alcohol.
- Do not use a microwave or any other heating devices to dry AudioLink.
 If necessary, wipe AudioLink dry with a tissue.
- Your AudioLink 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.



CAUTION

Do not perform any maintenance activities other than those described in this manual (e.g. changing the battery). When performing these maintenance activities, always switch off AudioLink.

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.

Cables

To prolong your cable's life, we recommend the following:

- Do not bend the cable.
- When unplugging the cable, pull on the plug and not on the cable itself.
- Do not lift AudioLink or any other device by the cable.
- Do not use excessive force when unplugging the cable.



CAUTION

The provided cables are intended for the connection of external audio devices, such as mobile phones, tablet PCs, MP3 players, AM-FM radios, etc. to AudioLink. We recommend to only use the cables which were provided with AudioLink. Do not use cables longer than 1.7 m as these cables may result in increased electromagnetic emissions or decreased electromagnetic immunity of AudioLink. For more information, please contact your local MED-EL representative.

Battery

AudioLink has an integrated rechargeable LiPo (lithium polymer) battery. If you want to get more information on batteries, please contact your healthcare provider or local MED-EL representative.

Replacing the battery of your AudioLink

Battery performance will deteriorate over time. When the battery of your AudioLink lasts less than 2 hours although fully charged, the battery should be replaced. Contact your healthcare provider or local MED-EL representative to receive a replacement battery.

To replace the battery, proceed as follows:

1 Remove the AudioLink clip.



2 Disassemble AudioLink by inserting the AudioLink opening tool into the groove. Carefully press the tool into the slot until a gap opens.





CAUTION

Do not use tools with sharp edges (screwdriver, knife, etc.) to open AudioLink when changing the battery. Only use the provided AudioLink opening tool.

Slide the tool around the housing until the main unit and the battery come apart. Do not twist the tool while opening AudioLink to avoid damaging the housing.



1 Take the new battery and assemble the device as described in chapter Assembling AudioLink.



CAUTION

Do not touch the battery contacts with your hands or metal objects.

- **5** Make sure that battery and main unit are properly connected with no open recesses.
- 6 Reattach the AudioLink clip.





WARNING

Misuse may result in the battery causing heat, smoke, rupture, flame or leakage which could lead to injury.



PARENTAL GUIDANCE

Do not allow children to replace batteries without adult supervision.



CAUTION

- Do not dispose of the old/depleted battery with common household waste but at a hazardous waste collection site.
- In case the battery shows signs of internal or external damage or chemical modification (battery swollen, leakage) store the battery in a safe container (e.g. a jar) until disposal.

5. 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.

Problem	Possible cause	Recommended action
Not possible to pair both audio processors	Processors are not correctly programmed.	If you are a bilateral user and only one processor at one time but not both audio processors can be successfully paired, contact your audiologist and ensure that your processors are correctly programmed. NOTE: You can only pair one audio processor for each side.
Audio streaming does not start. Connection symbols do not illuminate.	Audio processor(s) are not yet paired.	Pair your audio processor(s) as described above.
Bluetooth® connection does not work. The Bluetooth® connection symbol does not illuminate.	AudioLink is not yet paired with Bluetooth® device.	Pair AudioLink to the device as described in chapter Pairing AudioLink with a Bluetooth® device.
No sound perceptible during audio streaming and the indi- cator lights continue flashing	Audio processors are out of range (not present).	Ensure that your audio processor is turned on. Replace audio processor battery if empty. Ensure that the audio processor(s) is within range.
Distortions during audio streaming (interruptions, noise)	Device is not within range or interference from other devices.	Reduce distance between AudioLink and audio processor(s). If possible, remove interfering device (especially in the 2.4 GHz band). If possible, change location of Wi-Fi router and/or PC. If possible, use the 5 GHz band of your Wi-Fi system When using AudioLink for phone calls, do not place the phone too close to AudioLink.
No sound perceptible or sound too low	Volume too low	Increase volume on audio source device If volume remains too low, increase volume on AudioLink
Sound too loud or cracking	Volume too high	Decrease volume on audio source device If volume remains too high, decrease volume on AudioLink
Audio streaming via cable connection does not work properly (no sound at all, noisy, single-sided, low) although streaming is indicated.	Audio jack has loose contact.	Check if the stereo cable is attached properly or if AudioLink sits completely in the AudioLink docking station
AudioLink frozen, i.e. does not respond at all	AudioLink crashed due to unexpected input.	Switch AudioLink off and on again. Remove and reattach the battery.

General precautions and warnings

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

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

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

- Always handle your AudioLink with care to achieve maximum lifetime and to avoid any risks.
- The electronics are durable but must be treated with care.
- Do not use the system components under environmental conditions other than those described in chapter Technical data.
- The defined operating temperature range is between 0°C and +45°C for AudioLink.
 Avoid excessive heat. Excessive heat might damage AudioLink and make it unusable.
- If AudioLink should be at a temperature that is outside the defined operating
 temperature range of 0°C to +45°C, e.g. because it was stored in a cool or hot
 place, put AudioLink in a place with room temperature (typ. +20°C to +25°C) and
 wait at least 30 minutes before you use AudioLink. This ensures that AudioLink is
 not operated outside its defined operating temperature range.
- Do not leave AudioLink in direct sunlight (especially inside a car). Long exposure to direct sunlight might damage AudioLink.
- Do not open, except to detach the battery, 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 AudioLink wet as this may impair its function. Keep AudioLink in a dry place while bathing, showering or engaging in other water-related activities.
- Do not use AudioLink in the vicinity of strong ionizing radiation (e.g. x-ray machines) or electromagnetic fields (e.g. MRI machines).
- Use of AudioLink adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, AudioLink and the other equipment should be observed to verify that they are operating normally.
- Do not use accessories, transducers and cables other than those specified or approved by MED-EL as this could result in increased electromagnetic emissions or decreased electromagnetic immunity of AudioLink and result in improper operation.

- 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 AudioLink, including cables specified by MED-EL. Otherwise, degradation of the performance of AudioLink could result.
- Do not use AudioLink in environments where radio frequency (RF) transmissions are prohibited.



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 analysed, 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.

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. AudioLink should not be used on aircrafts unless specifically permitted by the flight personnel. Please secure your AudioLink by placing it, for instance, in a garment pocket.

TV. radio. etc.

When intending to connect an external audio device to AudioLink that is powered by mains power, i.e. plugged into the wall or a power strip, always make sure that this mains-powered external audio device meets the safety requirements stated in the standards EN/IEC 60065, EN/IEC 60601-1 and/or appropriate national standards. If the mains-powered device does not bear a CE mark (CC), which is usually found on the device's type label, you cannot presume that the mains-powered device meets the above safety requirements and must therefore not be connected to your AudioLink. Connecting a mains-powered device to your AudioLink that does not meet the above safety requirements could cause an electric shock. You can safely connect battery-powered external audio devices to your AudioLink. For more information please contact MED-FL.

7. Technical data

AudioLink

Model

AudioLink (Ma070301)

Dimensions³

Length: 68.0 mm Width: 38.0 mm Height: 17.5 mm Weight: 35.0 g (with clip attached)

Mode of operation

Continuous

Controls/Indicators

Main button (on/off) Mix button Mic button Volume buttons

Power supply

1 LiPo Battery (3.7V, 550 mA)

Internally powered

Battery operating time: approx. 6 hours for audio streaming

approx. 5 days in standby

Battery aging: >80% of minimum capacity after 500 charging cycles

Classification

Short Range Device (SRD) according to ERC/REC 70-03 Annex 1 (band I) and Annex 3 (band B)

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS)

³ typical values

Temperature and humidity range

Operating temperature range: 0 °C to +45 °C

Storage/transport temperature range: -20°C to +45°C Recommended storage temperature range: 0°C to +30°C

Relative humidity range: 10 % to 93 %

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

Essential performance

None of the performance characteristics of AudioLink are essential performance as defined in IFC 60601-1.

Expected service life

The expected service life of AudioLink 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

Frequency band of reception/transmission: 2400 MHz to 2483.5 MHz Short Range Device (SRD) according to ERC/REC 70-03 Annex 1 (band I) and Annex 3 (band B)

Type of modulation: Gaussian frequency shift keying (GFSK)

Equivalent isotropic radiated power (EIRP): 6.2 dBm

Channel band width: 2 MHz

Typical operating distance

30 cm to 3 m

AudioLink docking station

Model

AudioLink docking station (Ma070302)

Dimensions⁴

Length: 60.5 mm Width: 37.5 mm Height: 42.0 mm Weight: 50 g

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PC/ABS)

Temperature and humidity range

Operating temperature range: 0°C to +45°C

Storage/transport temperature range: -20°C to +45°C Recommended storage temperature range: 0°C to +30°C

Relative humidity range: 10 % to 93 %

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

Essential performance

None of the performance characteristics of the AudioLink docking station are essential performance as defined in IEC 60601-1.

Expected service life

The expected service life of the AudioLink docking station 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.

⁴ typical values

Symbols



AudioLink 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 AudioLink 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



Manufacturer



Direct current



Atmospheric pressure limitation



Humidity limitation



Temperature limit

IP52 Moisture and dust protection acc. to IEC 60529

This classification means that AudioLink and the AudioLink docking station are protected against failure from ingress of dust and dripping water when fully assembled, i.e. when the battery is fully snapped into the main unit and the silicone flap covers the connectors.



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 $\,$

Regulatory statements

Applicable in Canada only:

Model: MED-EL AudioLink IC: 11986A-AL Contains IC: 5123A-BGTWT32I

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: AudioLink FCC ID: VNP-AL Contains FCC ID: OOOWT32I

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.

Guidance and manufacturer's declaration

Tables according to IEC 60601-1-2 for AudioLink

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

Electromagnetic emissions – for all equipment and systems

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	AudioLink 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	AudioLink is suitable for use in all establishments, incluing domestic establishments and those directly connect
Harmonic emissions IEC 61000-3-2	Not applicable	to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity – for all equipment and systems

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

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic	± 8kV contact	± 8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
discharge (ESD) IEC 61000-4-2	± 15 kV air	± 15 kV air	
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	±1kV for input/output lines	±1kV for input/output lines	
Surge IEC 61000-4-5	±1kV line(s) to line(s)	±1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on	$0\% \ U_{\scriptscriptstyle T}$ for 0.5 cycle (1 phase)	$0\% \ U_{\scriptscriptstyle T}$ for 0.5 cycle (1 phase)	Mains power quality should be that of a typical commercial or hospital environment.
power supply lines IEC 61000-4-11	0 % U _T for 1 cycle	0 % U _T for 1 cycle	
	70% U _T for 25/30 cycles (50/60 Hz)	70% U _T for 25/30 cycles (50/60 Hz)	
	0% U _T for 250/300 cycles (50/60 Hz)	0% U _T for 250/300 cycles (50/60 Hz)	
Power frequency (50/60 Hz) 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_{τ} is the a.c. mains voltage prior to application of the test level.

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

AudioLink is intended for use in the home healthcare environment. The customer or the user of AudioLink 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	3Vrms	Portable and mobile RF communications equipment should be used
	6Vrms in ISM and amateur 6Vrms in ISM and amateur 150 kHz and 80 MHz	6Vrms	no closer than 30 cm to any part of AudioLink, including cables, specified by MED-EL. Otherwise degradation of the per- formance of AudioLink could result.
Radiated RF	10V/m	10 V/m	
IEC 61000-4-3	80 MHz to 2.7 GHz	3V/m 2.7 GHz to 6 GHz	
Proximity fields from RF wireless	27V/m 380 MHz to 390 MHz	27V/m	
communications equipment IEC 61000-4-3	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 accessories⁵

- AudioLink clip
- · AudioLink opening tool
- Docking station
- Lanyard
- Pouch⁶
- USB power supply⁶
- Cable kit:
 - Micro USB cable⁶
 - Stereo cable with a 3.5 mm audio jack and RCA connectors⁶
 - Stereo cable with two 3.5 mm audio jacks6
 - Adapter cable with a 2.5 mm audio jack and 3.5 mm socket⁶

For ordering replacement parts please contact your 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

⁵ Not all products in this document are currently approved or available in all countries. Please contact your local MED-EL representative for information on current product availability in your country.

⁶ Not manufactured by MED-EL

9. Contact MED-EL

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

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