

# HEARING AIDS

User Manual for a2o hearing aids

- lewi R Li
- risa R Li



### **Intended purpose**

audifon hearing aids are designed to enhance hearing by capturing, amplifying, and transmitting sound signals to the eardrum.

Hearing aids also prevent over-amplification of sounds that could exacerbate hearing loss.

The aim is to improve Speech Intelligibility and enhance hearing performance in both quiet and noisy environments.

- audifon hearing aids feature an integrated tinnitus module that can be activated to assist in managing chronic persistent ringing in the ear.
- Hearing aids must be individually adjusted by an audiologist or ENT doctor. Diagnosis and prescription must be performed by an ENT doctor.
- The expected useful life of an audifon hearing aid depends on the functional conditions and the care it is given. The expected service life of parts of hearing aids is 2 years from the warranty date.
- Systems are designed for a lifespan of 6 years. Additional restrictions on use are listed in Section 9 "Safety Instructions".

### **Contraindications**

audifon hearing aids are not suitable for:

- Children under 36 months of age
- Hearing loss due to central hearing disorders
- Insufficient ear or ear canal size and shape
- Deformities of the ear canal affecting insertion and removal
- Impairments such as chronic inflammation, skin irritation, or cholesteatoma
- Allergies to materials in contact with the skin

### **Indication**

The hearing aids are suitable for patients with:

- persistent conductive or sensorineural hearing loss in one or both ears
- a mild to severe hearing loss according to WHO classes 1 to 4

## **Patient clientele**

Patients with an indication from the age of 3 years.

The average hearing aid user is around 70 years old.

Patients who are not able to operate the devices independently need professional, competent assistance.

The use of hearing aids for mentally impaired persons and for children should only be used on the recommendation of a doctor. A comprehensive risk analysis should be carried out for the specific individual case.

Close supervision by a carer is recommended, to ensure the correct use of the hearing systems and to avoid accidental swallowing of hearing systems or parts thereof.

## **Declaration of conformity**

EU declaration of conformity:

audifon hereby declares that the hearing aids lewi R Li and risa R Li comply with the following directives:

- Directive on Medical Devices (EU) 2017/745 (MDR: Medical Device Regulation)
- Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment (RoHS)
- (WEEE Directive) 2012/19/EU Waste of Electrical and Electronic Equipment
- Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC
- (RED) Radio Equipment Directive 2014/53/EU

All serious incidents related to the product that occur should be reported to the manufacturer and to the responsible authorities in the member state in which the user and/or the patient are registered.

audifon GmbH & Co. KG hereby declares that the products lewi R Li and risa R Li, as radio equipment, comply with the requirements of 47 CFR Part 15.

Please refer to the notice below in accordance with these requirements:

**Notice:**

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.

Changes or modifications made to this equipment not expressly approved by audifon GmbH & Co. KG may void the FCC authorization to operate this equipment.

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.
- Consult the dealer or an experienced radio/TV technician for help.


The radiated output power of the device is below the FCC radio frequency exposure limits.


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# 1 INTRODUCTION

Congratulations on the purchase of your new audifon hearing aid. Your audiologist has carefully configured it for you. This manual will help you use your hearing aid correctly and get the most out of it.

 **Attention:**  
Text marked with a warning symbol should be read carefully before using the hearing aid.


 This section provides extra details to enhance your understanding of the hearing aid.


Please note that a hearing aid will not restore your hearing to normal or prevent physical hearing loss.


It is designed to support you in everyday situations. If your hearing aid might be affected by certain environmental conditions, your audiologist will point out these issues to you.

Effective use of your hearing aid might require additional strategies, such as auditory training and lip reading. Regular use of your hearing aid is crucial for maximum benefit.


For specific details about your hearing aid model, check the label on the packaging, refer to the warranty card and to the printing on the hearing aid itself.

 Follow these instructions closely to avoid malfunctions and ensure the optimum performance of your hearing aid. Proper care will help maintain your hearing aid as a valuable tool for effective communication.

 If you have any questions about the operation and care of your hearing aid, please contact your audiologist.

 If the hearing aid is for a child, a disabled person, or someone with cognitive impairments, involve a family member or caregiver in the process.

Refer to the instructions for use for the power case and power base. For further information please contact your audiologist.

 **Note:**  
Your audiologist has tailored the hearing aid to your specific needs and hearing capabilities.

Check the warranty card for specifications regarding consumables.

To prevent potential issue, do not interchange parts of your hearing aid.

## 2 YOUR HEARING AIDS

### 2.1 Type

Your hearing aid is a behind-the-ear hearing aid with an external receiver. The receiver is positioned directly in your ear canal.

### 2.2 Overview

This user manual is applicable to the following types of hearing aids:

Variant	Battery		Gain in dB (peak value) after the receiver unit			Indication range
	Capacity in mAh	Runtime in h	S	M	P	
lewi R Li	28	Up to 23	52	58	64	Minor to severe loss of hearing
risa R Li	28	Up to 23	52	58	64	Minor to severe loss of hearing

Transmit power: 0 dBm (1 mW)

Frequency: 2.400 – 2.485 MHz

Range: 10 metres

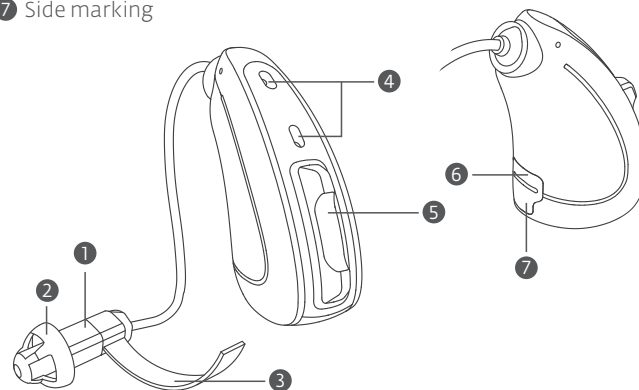
For detailed acoustic data specific to your hearing aid, please refer to the separate data specification document. This and further information are available from your audiologist or [www.audifon.com](http://www.audifon.com).

## 3 OPERATION – LEWI R LI / RISA R LI

### 3.1 Construction

Your hearing aids consist of the following elements:

- 1 Receiver module
- 2 Dome
- 3 Concha clip
- 4 Microphone inlets
- 5 Multifunctional rocker switch
- 6 Serial number plate
- 7 Side marking

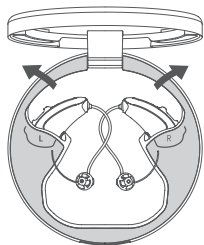


☞ The hearing aids have a side marker:  
**blue = left, red = right**

☞ Your hearing aid may differ from that shown in the picture.

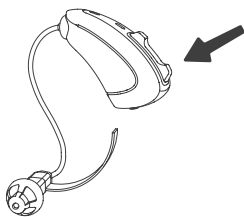
### 3.2 Switching the hearing aid on and off

Your hearing aid is switched on and off using the lower button of the multi-function rocker switch.




#### Activation

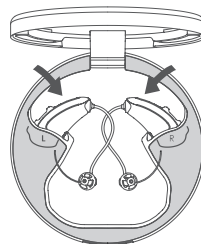
After charging, remove the hearing aid from the power case.



Briefly press the lower button of the multi-function rocker switch. Your hearing aid is now switched on.

After a preset switch-on delay and the start melody, the first hearing program activates itself. The hearing aid is ready for operation.

 The hearing aid will switch on after a 3-second delay. By arrangement with your audiologist, the switch-on delay can be set to up to 9 seconds.



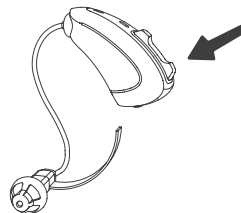
#### Switching off using the power case

Place the hearing aids into the designated recesses in the power case. The hearing aid will automatically switch off as it is magnetically positioned in the case.

The LED display on the power case will flash 5 times in white and blue for each hearing aid, indicating that charging has started.

-  Ensure the power case is EITHER
1. connected to the power supply or
  2. has a fully charged integrated lithium-ion battery.

Check the battery status on the LED display visible when you open the lid. Refer to the power case and power base user manual for more information.



#### Switching off using the multi-function rocker switch

Press and hold the lower button on the multi-function rocker switch until the deep pitch audible indicator tone stops (approximately 3-5 seconds). Once the tone ceases, release the button. The hearing aid is now switched off.



### 3.3 Lithium-ion battery within the hearing aid

Your hearing aid is powered by a modern permanently installed lithium-ion battery.

The battery life varies depending on the functions that are active, the wireless accessories being used, the degree of hearing loss and the hearing environment.

ⓘ **Note:** If you do not use your hearing aid for an extended period (more than 3 months), recharge it to prevent the battery from deep discharge, which can damage it.

### 3.4 Battery running time

An audible warning signal alerts 🎵🎵🎵 you when the battery is nearing the end of its charge, typically providing about 2 hours of remaining use. During this last 2-hour period, wireless functionality will be unavailable.

### 3.5 Charging the hearing aid battery

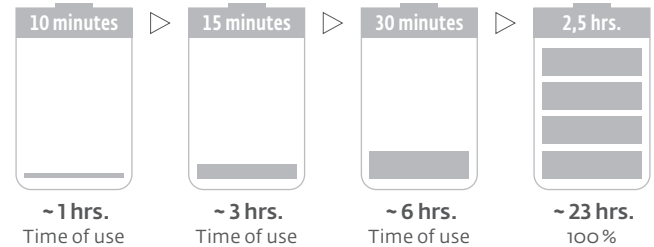
A full charge cycle takes up to 3 hours.

To ensure your hearing aids are ready for use the next day, charge them during your rest period.

For specific instructions on using the power case and power base, refer to their respective user manuals.

### 3.5.1 Charge level of the hearing aid battery

Overview of charging times:

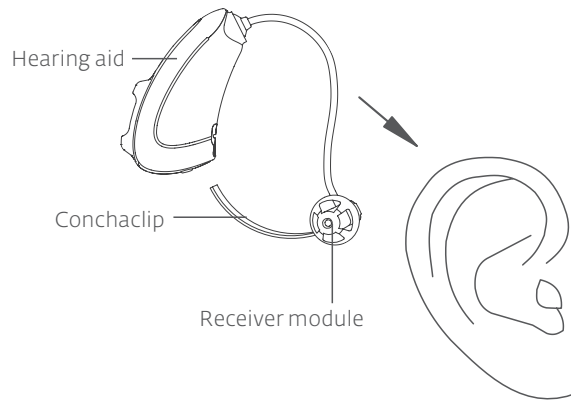


For more information refer to the power case and power base user manual.

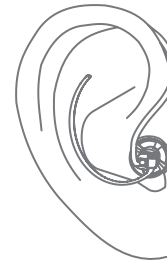
## 3.6 Inserting and removing the hearing aid

### 3.6.1 Inserting the hearing aid

Place the main body of the hearing aid behind your ear. Gently push the receiver unit into your ear canal.



 The hearing aids have markings for the sides:  
**blue = left, red = right**



The optional Concha-Clip helps improve the fit of the receiver unit in the ear.

Bend the Concha-Clip slightly and position it carefully in the outer part of your ear.

#### **Warning: Risk of injury!**

Always use the receiver unit with the appropriate dome or ear adapter. Ensure that it is fully seated on the grooves of the receiver unit.

Do not insert the Concha-Clip into the ear canal.

### 3.6.2 Removing the hearing aid

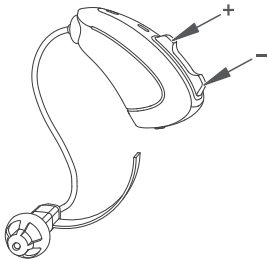
Gently lift the hearing aid and slide it over the outer part of your ear. Carefully pull the tube with the receiver unit out of the ear canal.

#### **Warning: Risk of injury!**

In rare cases, the dome may remain in the ear canal upon removal. If this occurs, contact your doctor immediately: do not attempt to remove the dome yourself.

## 3.7 Volume control and program selection


### 3.7.1 Multifunctional rocker switch



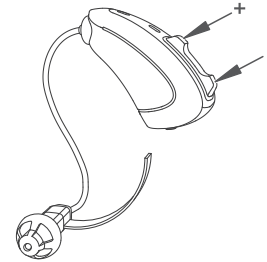
Your hearing aid has a multi-function rocker switch.

By pressing the upper (+) or lower (-) end, the following functions can be activated:

- Volume control**  
(see 3.7.2)
- Program selector switch**  
(see 3.7.3)
- Combined volume control and program selector switch**  
(see 3.7.4)

 The volume control and program selection features are optional and can be customised by your audiologist according to your needs.

### 3.7.2 Volume control



The volume can be adjusted in steps using the multi-function rocker switch:

- briefly pressing the upper (+) end increases the volume
- briefly pressing the lower (-) end reduces the volume

When you turn ON your hearing aids, they will start at the pre-programmed volume level set by your audiologist.

As you adjust the volume, each press of the button will be confirmed by a short tone, letting you know the change has been made.

When you reach the maximum or minimum volume limit, you'll hear a distinct signal indicating that you've hit the limit.

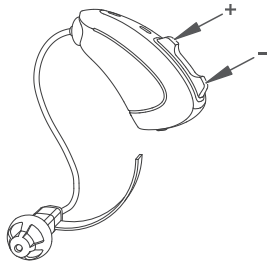
### 3.7.3 Hearing program selection

Your audiologist may have set up different hearing programs for various listening environments (e.g., noisy places, quiet rooms). When you turn your hearing aids on they will start in the base program. The multifunction rocker switch on your hearing aid allows you to switch through these different hearing programs.

If only the program selector function is stored in the hearing aid, the program is changed by briefly pressing the multi-function rocker switch:

- briefly pressing the upper (+) end >>> switch to the next hearing program
- briefly pressing the lower (-) end >>> switch to the previous hearing program

Program change sequence\*:



\* Example with 3 hearing programs

Each press of the switch is followed by audible confirmation. The number of signals indicates the number of the program selected. Your audiologist has customised the number of selectable hearing programs based on your individual needs.

Identification tones of hearing programs

#### Hearing program Identification tones

1	—————	♪
2	—————	♪♪
3	—————	♪♪♪
4	—————	♪♪♪♪

### 3.7.4 Combined volume and hearing program selection

Briefly press the upper or lower end of the rocker switch to adjust the volume. To change the hearing program, hold down the corresponding button end for about 1 second. To change the hearing program, press and hold the upper or lower end of the rocker switch for about 1 second. You will hear a high pitched indicator tone. Once you release the button, the selected program will be confirmed with an audible tone corresponding to the program number.

If you press the lower end of the switch for a longer duration (3-5 seconds), the hearing aid will turn off, as explained in section 3.2.

Holding down the upper end for a longer period (5 seconds) will put the hearing aid into Flight Mode, as described in section 5.4.

### 3.7.5 Overview of the functions of the multi-function rocker switch

Hearing aid status	Upper button	Action	Lower button
On	Increased volume	Short press	Reduced Volume
On	Next hearing program	Long press (~1 sec)	Previous hearing program
On	Flight mode	Very long press (~3 – 5 sec)	Deactivation
Off	—	Short press	Switch on (note individual switch-on delay until the switch-on melody sounds)

### 3.7.6 easyclick and binaural synchronisation

If you have two hearing aids from the same product family (such as lewi or risa), they can be paired using the easyclick function. When paired, any changes you make to the volume or hearing programs on one hearing aid will automatically be transmitted to the other.

For hearing aids in the lewi product family, there's an additional feature called binaural synchronisation. Please contact your audiologist.

## 4 TINNITUS COMBI INSTRUMENT

The audifon combined hearing aid serves as an effective tool in tinnitus therapy. Your audiologist has tailored the combination hearing aid to your specific hearing needs, helping you manage tinnitus and/or hyperacusis (noise hypersensitivity).

The device can generate sounds within a specific frequency range that are designed to mask your tinnitus. This masking effect helps divert your attention away from the tinnitus sounds. Alternatively, the device can modulate your tinnitus sounds to resemble ocean noise, which can be soothing and less distracting. For individuals with hyperacusis, the device can help you gradually acclimatise to everyday sounds by providing a more controlled auditory environment.

### **Warning: Damage to hearing!**

The maximum volume of the tinnitus combi instrument falls within a range that OSHA regulations have identified as a potential cause of hearing loss if used improperly. The tinnitus combi instrument should therefore not be used for longer than eight hours a day, at a sound pressure level (SPL) less than 90 dB SPL. At a higher sound pressure, the device should not be used for more than 2 hours daily.

Never use the device at a volume that feels uncomfortable or unpleasant to you.

## 5 WIRELESS FUNCTIONALITY / BLUETOOTH CONNECTIVITY

### Compatibility with smartphones

Your hearing aid is compatible with common smartphones that have Bluetooth version 4.0 or higher. For audio streaming, you may need the optional multistreamer pro accessory, which is available through your audiologist.

A list of smartphones, tablets etc. compatible with the hearing aids of the lewi and risa families and the audifon app is available at: **[www.audifon.com](http://www.audifon.com)**.

For more details about using the audifon app, refer to the corresponding User Manual.

### 5.1 Using hearing aids with iOS Devices

#### 5.1.1 Pairing the hearing aids with an iOS device (e.g. iPhone)

You need to pair both your hearing aids to your iOS device. Proceed as follows:

1. Touch the icon → Settings on your iPhone.
2. In the icon → Settings menu go to:  
→ Accessibility → Hearing aids under the hearing category.
3. If the function → Bluetooth is still disabled on this screen, activate Bluetooth. While your iPhone is searching for devices, restart your hearing aids.  
This action will put them into pairing mode.

4. Once your hearing aids appear in the list of devices on your iPhone, select the appropriate device name to complete the pairing process. If this does not happen within 5–7 seconds, press the upper left edge of the screen to go back to → Accessibility and open → Mfi Hearing Devices again.
5. Once your hearing aids are displayed, select them to connect the devices to the iOS device.
6. You will see two pairing requests, one for each hearing aid. Select → Pair for both requests to finalise the connection. Note that there may be a slight delay between the requests.
7. Pairing is now complete.

#### 5.1.2 Your hearing aids are now paired with your iOS device

Ensure your hearing aids are paired with your iOS device as described in chapter 5.1.1.

There are two ways for you to operate your hearing aids with your iOS device:

1. via the menu → Hearing aids (see chapter 5.1.3)
2. via the → Quick Start menu of the iOS device

In both menus you have access to the following settings:

1. Microphone volume
2. Desired hearing program
3. Enable the feature that allows audio signals from the microphone of your iOS device to be transmitted directly to your hearing aids, effectively turning your iOS device into a table microphone

### 5.1.3 Operation via the menu → MFi hearing aids

Navigieren Sie in das Untermenü → Hörhilfen.

This can be found at:

- **Settings**
- **Accessibility**
- **Hearing aids**

Select on your hearing aids under the Connected section to access their settings.

If you need assistance with pairing or using your hearing aids with your iOS device, it's recommended to contact your audiologist.

For additional operating functions and features, you can download the **free audifon smartphone app**. Your audiologist can provide more information and help you get started with the app.

### 5.2 Pairing the hearing aid with an Android device

To be able to operate your hearing aid using your Android device, pair it to them. Proceed as follows:

1. Touch the icon → Settings.
2. Select → Bluetooth and turn it on.
3. Restart your hearing aids. This puts them into pairing mode.
4. In the Paired devices section of Bluetooth settings, look for an entry with your first name followed by "hearing aid". You should see separate entries for the right and left hearing aids if you are wearing both. Select the appropriate entry based on the hearing aid you want to pair.
5. Once selected, the pairing process is complete.

### 5.3 Using hearing aids with the multistreamer pro

To connect your hearing aids to devices with an AUX output (like a TV), you can use the optional multistreamer pro accessory. Purchase the multistreamer pro from your audiologist.

For detailed instructions on using the optional multistreamer pro, refer to the product's User Manual.

## 5.4 Flight mode


When you are in areas where wireless transmissions are prohibited, such as on an aeroplane, activate Flight Mode.



In such situations, please activate Flight Mode for your hearing aids or, in case of doubt, contact trained personnel.

To activate the flight mode of your hearing aids, press the multi-function rocker on the upper button for 5 seconds. You will hear an "air mode" melody indicating that Flight Mode has been activated. Once you hear the melody, you can release the button. All wireless functions of your hearing aids will be disabled.

To deactivate Flight Mode, simply turn your hearing aids off and then turn them back on.

 Flight Mode must be activated separately on each hearing aid.

## 6 ACCESSORIES

The hearing aids of the lewi and risa families have following accessories, which you can obtain from your audiologist:

(A) Accessories/ (Oa) Optional accessories/ (Com) Components/ (Con) Consumables	Description and intended use	
(A) audifon App	Smartphone app for remote control of the hearing systems	*
(A) charging station base & case	Special charging station for lewi/risa R Li hearing aids	*
(A) UniTip Dome 5/7/10	Universal earmoulds for use with the hearing aid	***
(A) UniTip Power Domes small/medium/large	Universal earmoulds for use with the hearing aid	***
(A) UniTip Tulip Domes	Universal earmoulds for use with the hearing aid	***
(A) UniTip receiver unit S-M-P	The receiver unit is used to emit the amplified signals from the hearing aid as sound into the ear canal.	***
(Com)/ (Con) Conchadip	Supports the retention of the receiver unit in the ear canal; can be omitted when using an earmould. Suitable Conchaclips are available from your audiologists.	-
(Com)/ (Con) CeruStop filter	Filter to protect against occlusion by cerumen. Suitable CeruStop filters are available as a filter box from your audiologists.	-
(Oa) multistreamer pro	Audio streamer to expand the hearing system functions	*

CE marking: \* CE / \*\*\* CE0297



## 7 MAINTENANCE AND CARE

### 7.1 General

audifon hearing aids improve both your hearing and your quality of life. Regular cleaning and care are crucial for maintaining the performance and longevity of your hearing aids. You can obtain a personalised “pro care” cleaning and care program from your audiologist, tailored to your specific type of hearing aid.

Keep your hearing aids dry and avoid exposing them to moisture such as showers, sweat, or rain. Remove your hearing aids before using hair spray or other similar cosmetics.

### 7.2 Daily care

We recommend daily care of your hearing aids. No matter what type of hearing aid you wear: Each one is in direct contact with your skin. Since hearing aids are in direct contact with your skin and exposed to perspiration, it's important to clean and dry them daily to prevent long-term damage.

Use a charge & dry charging station to dry and care for your hearing aids daily. This accessory helps in charging, cleaning, and drying your hearing aids. For details on how to use it, consult your audiologist.

Clean your hearing aids and the receiver unit daily with cleaning wipes to remove cerumen (earwax) and other contaminants.

Your audiologist can recommend the appropriate cleaning products for your hearing aids and the receiver unit. Talk to your audiologist about the relevant products.

Regularly make sure any ear wax adhering to the hearing aid is removed. If you need a clean new dome, simply replace the old dome with a new one. You can obtain a suitable dome from your audiologist.

☞ Do not use a damp cloth to clean your hearing aids. Always use a soft dry cloth.

☞ Do not clean your hearing aids with an ultrasonic cleaning device.

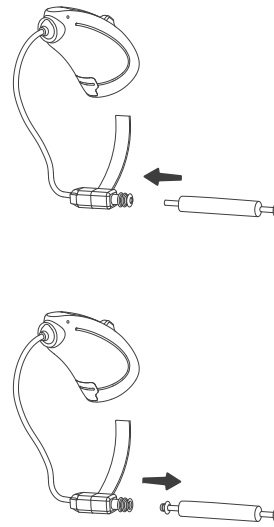
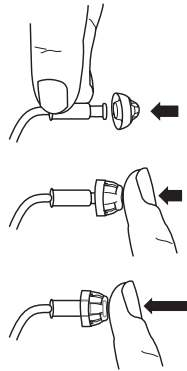
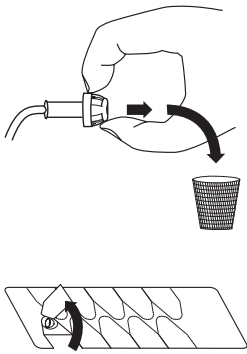
If despite regular care your hearing aid no longer functions correctly, contact your audiologist. Do not under any circumstances attempt to repair your hearing aid yourself.

### 7.3 Replacing the dome

The domes are replaceable and can be easily changed when required. To replace the dome, use your fingernail to grasp the lower end of the dome and pull it off the receiver. Attach the new dome by fitting it on to the grooves of the receiver unit. Make sure it is fully inserted. Dispose of the old dome properly.

The dome is made of soft medical-grade silicone. The recommendation is to replace the dome at least once a month, but this may vary depending on usage.

☞ We recommend that you replace it at least once a month.



#### 7.4 Changing earwax protection filter

Hearing aids with an external receiver have protective filters to prevent earwax entering the receiver and affecting its performance. Regularly changing these filters is essential for maintaining the functionality of your hearing aids. To replace the filter, proceed as follows

First remove the dome from the receiver module and clean it.

Remove the applicator pin from the filter dispenser and place its black end on the filter.

Using a twisting motion, gently pull out the old filter. Turn the applicator pin. At the other end of the applicator pin, you will find a new filter.

Push the new filter into the filter opening of the hearing aid until it clicks into place. Once the new filter is securely installed, remove the applicator pin. Dispose of the applicator pin and old filter properly.

## 8 MALFUNCTION – POSSIBLE CAUSE – SOLUTION

If you encounter issues while using your hearing aids, they may not necessarily indicate a defect.

First check the relevant hearing aid to determine whether:

- it is switched on
- its battery is sufficiently charged
- the volume setting may be in the minimum position
- the correct program is selected
- the receiver unit and CeruStop filter are clear of any obstructions

If these steps do not resolve the issue, consult your audiologist.

### ! **Note: Malfunctions**

Despite being EMC-compatible, your devices might experience interference from other electrical equipment. If this happens, try moving away from the source of interference.

Malfunction	Possible cause	Solution
<b>Nothing can be heard</b>	Hearing aid battery is drained	Charge the hearing aid
	Battery is no longer operational	Contact your audiologist
	Ear adapter pieces / domes / CeruStop filter clogged	Clean the ear fitting pieces, change the CeruStop filters or dome
	Is the hearing aid switched on?	Switch the hearing aid on
	Is the hearing aid charged?	Place the hearing aid in the charger for charging.
	Receiver unit may be defective	Ask your audiologist
	Is there excessive earwax in the ear canal?	Contact your ENT doctor
	Is the power case charged?	Connect the charging cable to the power case and insert it into a socket outlet.

<b>Dropouts, bad sound, too quiet</b>	Sound outlet from the receiver unit blocked	Clean the ear adapter or CeruStop filter, change the dome
	Moisture	Wipe the hearing aid with a dry cloth and allow it to dry, use the drying function of the power base
	Hearing aid may be defective	Contact your audiologist

Malfunction	Possible cause	Solution
Whistling	The ear adapter of the hearing aid does not sit properly in the ear or the receiver unit does not sit deeply enough in the ear canal	Reinstall the hearing aid and receiver unit.
	Earwax in the ear canal	Consult an ENT doctor

easyclick and binaural synchronisation are not working	Interconnection of hearing aids	The hearing aids reconnect themselves. Alternatively, restarting the hearing aids will help.
Problems pairing with a smartphone	Bluetooth connection failed	<ol style="list-style-type: none"> <li>1) Unpair your hearing aids.</li> <li>2) On your smartphone, switch Bluetooth OFF and ON again.</li> <li>3) Switch the hearing aid OFF and ON again.</li> <li>4) Pair the hearing aid again.</li> </ol>

## 9 SAFETY INSTRUCTIONS

### 9.1 Information about product safety

#### ⚠ **Note: Age of user!**

Behind-the-ear hearing aids are not suitable for children younger than 36 months of age. For underage patients, consult a doctor—preferably an ENT specialist—before using audifon hearing aids. Proper medical evaluation is crucial to ensure the hearing aid does not worsen the hearing impairment. The doctor should determine whether a hearing aid is appropriate.

In the case of the care of minors, due to a lack of clinical data cooperation with the doctor in charge of treatment must be ensured.

#### ⚠ **Note: Compatibility!**

Be cautious with unspecified combinations of audifon hearing aids, receiver units, or domes with products from other manufacturers. Such combinations may not have been tested or evaluated, potentially leading to unacceptable risks. Avoid using incompatible products.

#### ⚠ **Note: Damage to hearing!**

Your hearing aids are customised to your specific degree of hearing loss and should be used only by you. For the following reasons, you should not share your hearing aids with anyone else:

- they are customised products
- sharing could transmit germs
- consumables, such as domes, are matched to your needs

If you notice sudden changes in the volume of your hearing aid, contact your audiologist for assistance.

❗ **Note: Damage to hearing aid!**

Hearing aids are sensitive to impact. Avoid dropping or knocking them.

Before inserting the hearing aid, visually inspect it for any damage.

If you notice any changes, contact your audiologist immediately.

Do not wear your hearing aids:

- while swimming, showering, bathing, or using a sauna
- during hair washing or blow-drying
- when using hair spray, perfume, aftershave, or body lotion
- when receiving radio-frequency heat treatment therapy

If your hearing aid becomes damp, dry it using a drying device or container specified by the manufacturer. Do not use a microwave, oven, or similar equipment to dry it.

To prevent damage, protect your hearing aid from direct sunlight, flames, or extreme heat. Neglecting these precautions may result in damage to the hearing aid.

❗ **Note: Modifications to the hearing aid!**

Do not modify the hearing aids. Any adjustments should only be made by the manufacturer.

❗ **Note: Risk of suffocation!**

Hearing aids and small parts (like magnets) can pose a choking hazard. Such parts should be protected against unsupervised access by children under 36 months of age, mentally and physically handicapped persons or domestic animals. Keep these items away from unsupervised children under 36 months, individuals with mental or physical disabilities, and pets.

If a part is swallowed, consult a doctor immediately.

❗ **Note: Risk of injury!**

In rare cases, domes may get stuck in the ear canal when removing the hearing aid. If this occurs, contact a doctor immediately. Do not attempt to remove the dome yourself.

To avoid injury, use only original consumables and accessories specified by the manufacturer. In the worst-case scenario, unauthorised changes or modifications that have not been explicitly approved can result in injury. Ensure the ear adapter is firmly affixed to the receiver unit.

❗ **Note: Risk of explosion!**

Avoid using hearing aids in environments where there is a risk of explosion, such as mines or certain industrial settings.

❗ **Note: Risk of infection!**

Hearing aids, accessories, and components are intended for single use. If reused, the audiologist must implement measures to prevent infection.

ⓘ **Note: Electric shock!**

Ensure that audio devices connected to mains power comply with IEC 60065, IEC 60601, or similar safety standards for safe connection to your hearing aids.

ⓘ **Note: Interference with active implants!**

If you have an active implant (e.g., defibrillator, pacemaker), follow the manufacturer's instructions regarding the use of hearing aids.

ⓘ **Note: Interference with electric devices!**

In environments with restrictions on electronic or wireless devices, check whether you need to disable the wireless connection (e.g. Bluetooth) on your hearing aids.

ⓘ **Note: Damage due to deep discharging!**

If not used for an extended period, recharge your hearing aid at least once every 3 months to prevent battery damage from deep discharging.

ⓘ **Note: Reporting of serious incidents!**

Report any serious incidents involving the product to the manufacturer and to the relevant authorities in your country.

ⓘ **Note: Radio communications in rooms!**

Before connecting radio communications to your hearing aids, check if such use is restricted in the environment

ⓘ **Note: Malfunctions!**

Despite being EMC-compatible, your devices might experience interference from other electrical equipment. If this happens, try moving away from the source of interference.

ⓘ **Note: Risk of injury during CT or MRI scans!**

Remove your hearing aids before undergoing CT scans, MRI scans, or radiotherapy.

Inform the healthcare professional about your hearing aids.

ⓘ **Note: Battery!**

audifon rechargeable hearing aids use lithium-ion batteries, and the power case contains a lithium polymer battery. Check airline regulations regarding carrying these batteries when traveling.

ⓘ **Note: Charging!**

Dry your hearing aid with a dry cloth before charging. Insert it into the power case correctly and avoid applying pressure. Do not perform charging in a humid environment or if the hearing aid is mechanically damaged.

ⓘ **Note: Deactivation!**

Ensure the hearing aid is switched off properly to avoid issues with switching it on again later.

ⓘ **Note: Magnets / magnetic fields!**

Magnetic fields can cause damage and injury.

Because battery hearing aids contain a magnet:

- Strong magnetic fields can damage hearing aids. Avoid placing the hearing aid near strong magnets or directly on magnetic cards, as this can affect functionality.

ⓘ **Note: Side marking!**

Do not remove the side marking on your hearing aid. If this becomes loose or is lost, contact your audiologist.

Ensure the side markings on the hearing aid and receiver unit match. If they do not, contact your audiologist.

## 10 SIDE EFFECTS

Suchen Sie umgehend einen Arzt auf, sollten Sie folgende Nebenwirkungen bemerken:

- Sensation of a foreign body
- Build-up of earwax
- Skin irritation
- Dizziness
- Vomiting
- Headache
- Pain in or behind the ear
- a subjective deterioration in your hearing or an increase in the tinnitus level

## 11 ENVIRONMENTAL CONDITIONS

### 11.1 Operating conditions

- Relative humidity between 10% and 90%
- Operating temperature between 0 °C and 40 °C
- Air pressure between 500 and 1,100 hPa
- Battery performance may be reduced in a cold environment

### 11.2 Charging conditions

- Ambient temperature between 0 °C and 40 °C

### 11.3 Transport and storage Conditions

- Relative humidity between 10% and 95%
- Storage temperature between -20 °C and 45 °C
- Store away from magnetic fields

## 12 ENVIRONMENTALLY FRIENDLY DISPOSAL

Contact your audiologist for the environmentally responsible disposal of your hearing aids or their batteries. Your audiologist is the appropriate point of contact in the disposal chain for electronic waste.

Directive 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 04 July 2012 on waste electrical and electronic equipment.





## 13 SERVICE

Have your hearing aids checked regularly by your audiologist.

\_\_\_\_\_

Date

\_\_\_\_\_

Audiologist

\_\_\_\_\_

Date

\_\_\_\_\_

Audiologist

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Date

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Audiologist

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Date

\_\_\_\_\_

Audiologist

## 14 SYMBOLINDEX



### Comply with the instructions

Please read the following operating and maintenance instructions carefully to avoid danger to yourself and others and to prevent malfunctions or defects of the hearing system.



### Attention

This symbol is used in these instructions for use, to indicate information that requires special attention when handling or using the hearing aid, in order to avoid unwanted consequences!



### Note

Indicates possible damage to property.



### Information

Additional information for better understanding.



### Manufacturer

Indicates the medical device manufacturer in accordance with EU Medical Device Regulation (EU) 2017/745 and EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC



### Date of manufacture

Indicates the date (YYYY-MM-DD) when the medical device was manufactured.



### Electronic waste (WEEE)

Please do not dispose of hearing aids with your household waste.



### Limits of humidity

Indicates the range of humidity to which the medical device can be safely exposed.

Date

Audiologist

Date

Audiologist

Date

Audiologist

**Limits of temperature**

Indicates the temperature limits to which the medical device can be safely exposed.

**Medical device**

Indicates that the item is a medical device.

**Catalogue number**

Indicates the manufacturer's reference number so that the medical device can be identified.

**Unique product identification**

The specified number is stored in EUDAMED.

**Serial number**

Displays the manufacturer's serial number so that a specific medical device can be identified.

**Batch number**

Displays the manufacturer's batch number so that the batch or lot can be identified.

**CE mark**

The device complies with all required EU regulations and directives. The four-digit number designates the notified body.

**Keep dry**

This medical device must be protected from moisture.

**Rechargeable battery**

Indicates equipment that may be powered only by rechargeable batteries.

## 14.1 Legend

Please refer to the following terms in this manual:

- power case = charging station
- power base = base station
- charge & dry = accessory set (combination of charging station and base station)

If you have any further questions, please contact your audiologist.

For readability, the document uses a single language form and does not include all gender-specific variations (male, female, diverse - m/w/d). All personal names and references are intended to be inclusive of all genders.

# WARRANTY CARD

Name \_\_\_\_\_


No., street \_\_\_\_\_

Town, postcode \_\_\_\_\_

Telephone \_\_\_\_\_

Date of issue \_\_\_\_\_

You have chosen high-quality hearing aids from audifon. For our hearing aids, your audiologist gives a \_\_\_\_\_ month warranty from the date of purchase (invoice date). The warranty covers defects in materials and manufacture. It does not cover batteries, chemical or electrochemical effects, wear and tear or mechanical damage due to improper handling. The right to claim under warranty is voided if you or any unauthorised third persons perform modifications or improper repair. Therefore please always follow the safety and care instructions. Proof of purchase must be provided as proof of warranty. The date of purchase and the serial number must be clearly visible. Work under warranty will not result in any extension of the warranty period, nor will it give rise to a new warranty period for the hearing aid.

 The warranty period for incorporated spare parts ends at the same time as the warranty period for the entire hearing aid.

Type of hearing aid

This warranty card confirms that the combination of the hearing aid with accessories or consumables complies with the instructions/restrictions of audifon GmbH & Co. KG and that the safety and performance of the combination was tested.

**L**

Serial no. \_\_\_\_\_

Battery type \_\_\_\_\_

rechargeable

Warranty until: \_\_\_\_\_

**R**

Serial no. \_\_\_\_\_

Battery type \_\_\_\_\_

rechargeable

## Possible receiver replacement in 6 years

	Receiver unit		Date of manufacture		Batch no.	
	L	R	L	R	L	R
1						
2						
3						

## Specification of possible consumables:

Components supplied: audifon CeruStop / Conchaclip  
For further information, see table in chapter 6

UniTip Dome Art. 021955*	Power-Dome Art. 021956*	Tulip-Dome Art. 021954	Ear-mould
<input type="checkbox"/> Small -349	<input type="checkbox"/> Small -403	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medium -351	<input type="checkbox"/> Medium -284		
<input type="checkbox"/> Large -348	<input type="checkbox"/> Large -404		

\*Add the corresponding variant number. e.g.: UniTip Dome Medium Art. 021955-351

\_\_\_\_\_  
Date of sale / signature:

\_\_\_\_\_  
Your audiologist / stamp:

# audifon



## Hersteller

audifon GmbH & Co. KG  
Werner-von-Siemens-Straße 2  
D-99625 Kölleda  
Germany

Telefon +49-3635-4056-590

Fax +49-3635-4056-589

contact@audifon.com

**www.audifon.com**



\*) The products described have undergone separate conformity assessments and fulfill the required EU regulations or directives. If a notified body was involved in the fulfillment, the four-digit number 0297 identifies the notified body DQS Medizinprodukte GmbH. The applicable EU regulations can be found in the respective Declaration of Conformity (DoC).

FCC ID YU2-BT4

Made in Germany