

# BEHIND-THE-EAR HEARING AIDS

User Manual

- lewi R
- risa R



## **Intended purpose**

Hearing aids reduce the effects of hearing loss as much as possible. Personal discomfort thresholds in loud noises are also taken into account.

In quiet environments as well as in situations with background noise, speech intelligibility should be improved and hearing effort reduced.

 The hearing aids are designed to last 6 years. Further restrictions on use are listed in section 9 Safety instructions.

 Hearing aids and the noiser module must be individually fitted by a hearing care professional or an ENT doctor.

# CONTENTS

1	INTRODUCTION .....	5
2	YOUR HEARING AID .....	6
2.1	Type .....	6
2.2	Technical features .....	6
2.3	Batteries.....	7
2.3.1	Information on battery .....	8
2.3.2	Low battery warning .....	9
3	OPERATION – LEWI R, RISA R .....	10
3.1	Construction .....	10
3.2	Inserting battery .....	11
3.3	Removing battery .....	12
3.4	Switching hearing aids ON and OFF .....	13
3.5	Inserting and removing hearing aids .....	14
3.5.1	Inserting the hearing aids .....	14
3.5.2	Removing hearing aids .....	15
3.6	Volume control and program selection .....	16
3.6.1	Automatic side balancing of hearing aids .....	16
3.6.2	Multifunctional rocker switch.....	17
3.6.3	Volume selection .....	18
3.6.4	Selecting hearing programs .....	19
4	TINNITUS FUNCTION.....	21
4.1	Intended purpose .....	21
5	WIRELESS FUNCTIONALITY / BLUETOOTH CONNECTIVITY .....	22
5.1	Using hearing aids with iOS devices .....	22
5.1.1	Pairing hearing aids with an iOS device / iPhone .....	22
5.1.2	Operating hearing aids with an iOS device / iPhone .....	23
5.1.3	Operation via the Hearing Devices menu .....	24
5.1.4	Operation via the quick start menu .....	24

5.2	Pairing hearing aids with an Android device .....	25
5.3	Unpairing hearing aids .....	26
5.4	Using hearing aids with the MULTISTREAMER PRO .....	26
5.4.1	Pairing hearing aids with the MULTISTREAMER PRO .....	27
5.4.2	Pairing your smartphone with the MULTISTREAMER PRO .....	27
5.5	Flight mode .....	28
6	ACCESSORIES .....	29
7	CARE INSTRUCTIONS .....	31
7.1	General .....	31
7.2	Cleaning .....	32
7.3	Changing the earwax protection filter .....	33
7.4	Drying hearing aids .....	34
8	TROUBLESHOOTING .....	36
9	SAFETY INFORMATION .....	37
9.1	Important warnings .....	37
9.2	Information about product safety .....	39
10	SIDE EFFECTS AND CONTRAINDICATIONS .....	41
10.1	Side effects .....	41
10.2	Contraindications .....	42
11	OPERATING CONDITIONS .....	43
12	TRANSPORT AND STORAGE CONDITIONS .....	43
13	ENVIRONMENTALLY COMPATIBLE DISPOSAL .....	44
14	OTHER INFORMATION .....	45
14.1	EU declaration of conformity .....	45
14.2	FCC Statement .....	46
15	SERVICE .....	47
16	KEY TO SYMBOLS .....	48

## WARRANTY CARD

# 1 INTRODUCTION

Congratulations on the purchase of your new audifon hearing aids. Your hearing care professional has set this for your individual requirements. These instructions are therefore intended to help you use your audifon hearing aids properly.

Please read through the following operating and care instructions carefully to avoid malfunctions and damage. If you follow the instructions, your hearing aids will prove an invaluable help in day-to-day communication in your surroundings and with other people.

The specific model of your hearing aids is shown on the sticker on the packaging, on the warranty card or printed on the hearing aids themselves.

A hearing aid cannot restore your hearing to normal or cure your hearing loss and neither will it make your hearing worse. However, a hearing aid will go a long way to restoring normal hearing levels for many of those activities you may have been missing out on. Hearing aids are the treatment of choice for most types of hearing loss.

If you have any further questions, please contact your hearing care professional.

## 2 YOUR HEARING AID

### 2.1 Type

Behind-the-ear hearing aid with an external receiver worn inside your ear canal.

### 2.2 Technical features

Model	Battery				Gain in dB			Indication range
	Size	Average service life (zinc air) in h						
		HE S	HE M	HE P	HE S	HE M	HE P	
lewi R	312	70	65	60	45	56	67	Moderate to severe hearingloss
risa R	312	70	65	60	45	56	67	Moderate to severe hearingloss

#### Transmission power

Leistung: 0dBm (1mW) Class 2

Frequenz: 2.402 – 2.450MHz

The detailed acoustic data of your hearing aid can be found in a separate data specification. This and further information are available from your hearing care professional or [www.audifon.com](http://www.audifon.com).

## 2.3 Batteries





To start your hearing aids, first insert a battery in the battery compartment.

Make sure you only use zinc air battery. Please follow the instructions on the battery packaging. For the exact size of battery to use in your hearing aids please see the overview table.

Always switch your hearing aids OFF after use. To avoid damage, remove the battery if you do not intend to use the hearing aids for a long time.

### 2.3.1 Information on battery

A zinc air battery is used to supply power for your hearing aids. This type of battery is only activated when oxygen comes through the air holes into the button cell and a chemical reaction is initiated. During production, the air holes are sealed with a protective strip. This means that the battery remains fresh until use, and it lasts longer when it is sealed. Removing the protective strip allows oxygen to enter and the chemical reaction is initiated.

-  Refitting the strip when the battery is not in use will not extend its service life.
-  Battery should be stored at room temperature. Avoid keeping them in hot places or rooms with high humidity (e.g. bathroom). Storage in a cooled location is not necessary.
-  Used batteries are considered hazardous materials and contain toxic materials, should never be disposed of in the trash. Ask about recycling programs in your area where you live or return them to your hearing care professional to dispose them appropriately.
-  Further safety instructions can be found on the battery packaging.

### **2.3.2 Low battery warning**

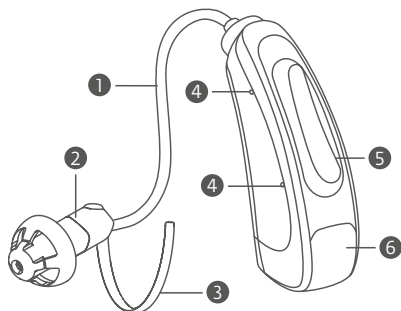
audifon hearing aids are equipped with a low battery signal which can be heard as a series of beeps approximately 30 minutes before the end of the battery life. The wireless function will be switched off, when the battery becomes empty.

## 3 OPERATION – LEWI R, RISA R

### 3.1 Construction

Hearing aid consists of the following elements:

- ❶ Receiver module
- ❷ Domes or ear molds
- ❸ Concha clip (optional)
- ❹ Microphone inlets
- ❺ Multifunctional rocker switch
- ❻ Battery compartment / ON/OFF switch



✎ The hearing aids have markings for the sides on the receiver module: blue = left, red = right

✎ Hearing aids may differ from the illustrations.

### 3.2 Inserting battery



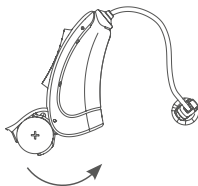
Remove a battery from its packaging.

If the battery has a protective film, remove and wait a few minutes before inserting the battery.



Open the battery compartment carefully with your fingernail at the edge for opening and swing it right out.

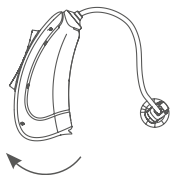
Then insert the battery in the battery compartment. Make sure the (+) symbol on the battery matches the (+) symbol on the battery compartment.



⚠ Please do not open the battery compartment any wider than shown here. This might damage the device.


❗ **NOTE:** Do not force the battery into the battery compartment. If it does not fit, check, whether you are inserting it correctly and that it is the correct size of battery (see Section 2.2).

### 3.3 Removing battery



Open the battery compartment carefully with your fingernail at the edge for opening and swing it right out.

Then remove the battery from the battery compartment.

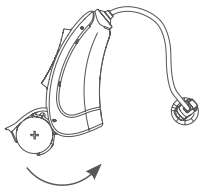
 Please do not open the battery compartment any wider than shown in Section 3.2. This might damage the device.

### 3.4 Switching hearing aids ON and OFF

Your hearing aids are switched ON and OFF via the battery compartment.

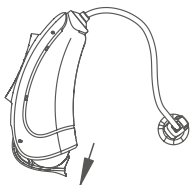
#### Switching ON

Close the battery compartment securely with a battery inserted by moving it past the catch of the OFF position into the casing.



You will feel the battery compartment clicking into place as you close it.

The hearing aids are now switched ON. After a preset delay and a start-up jingle, the first program will activate and the hearing aids are ready for use.



#### Switching OFF

To switch the device OFF, press the battery compartment out to the first catch position.

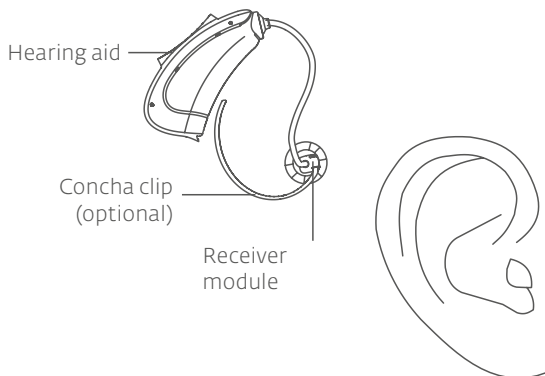
This is the OFF position.


If the devices are not intended to be used over a long period, open the battery compartment fully and remove the battery.

## 3.5 Inserting and removing hearing aids

### 3.5.1 Inserting the hearing aids

Place the hearing aid behind your ear.



 The hearing aids are marked left and right:  
blue = left, red = right

Slide the receiver unit carefully into your ear canal. Rotate slightly until it is positioned properly.

Open and close your mouth to avoid air being trapped in the ear canal.



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

To position the Concha-Clip, bend slightly and place the Concha-Clip carefully in the outer part of your ear.

Switch the hearing aid on by closing the battery compartment securely.

**⚠ Warning: Risk of injury!**

Always wear the receiver module with its dome or PowerSleeve and check that they are positioned securely on the tube.

### 3.5.2 Removing the hearing aids

Lift your hearing aid and slide it carefully over the outer part of your ear. Carefully pull the tube with the earpiece out of the ear canal. Switch the hearing aid off by moving the battery compartment to the OFF position.

**⚠ Warning: Risk of injury!**

In some very rare cases the dome may remain in the ear canal on removal. Should this happen, please contact your doctor or hearing care professional at once. Please do not try to remove the dome yourself.

## **3.6 Volume control and program selection**

### **3.6.1 Automatic side balancing of hearing aids**

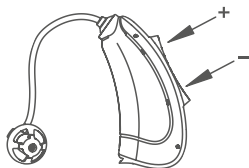
If you have two hearing aids of the same type adjusted by your hearing care professional, they are synchronised as a pair. You can tell this because after your devices have been switched ON, the pairing melody plays in both hearing aids.

After the hearing aids have been paired, all settings made in one device are also activated to the second device. The tones and melodies are played in both hearing aids with a slight delay.

If the connection is broken, you do not need to take action. The devices renew the connection quickly by themselves. You can tell this, because after your devices have been switched ON, the pairing melody plays in both hearing aids.

If this does not work once, please restart both hearing aids.

### 3.6.2 Multifunctional rocker switch

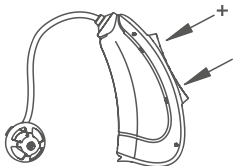


Your hearing aids feature a multifunctional rocker switch for controlling the volume and selecting the different programs.

The multifunctional rocker switch can be activated by pressing the top (+) and bottom end (-).

- **Volume control**  
To control the volume, press the multifunctional rocker switch briefly on the top or bottom (also see 3.6.3).
- **Program selector switch**  
To change the program, press and hold the multifunctional rocker switch briefly on the top or bottom (also see 3.6.4).
- **Volume control and program selector switch combined**  
To control the volume, press the multifunctional rocker switch briefly on the top or bottom. To change the program, hold the switch down for approx. 1 second (see also 3.6.3 and 3.6.4).


### 3.6.3 Volume selection



The volume can be adjusted in steps using the multifunctional rocker switch. Briefly pressing the top end of the switch increases the volume, while briefly pressing the bottom end reduces the volume.

When you switch your devices ON, they will be at the volume set for by your hearing care professional.. You can now increase or reduce the volume in steps. Each time you press the switch, you will hear audible tone.

Once you have reached the upper or lower volume limit, you will hear a clear signal.

 Volume control and program selection are optional functions. Your hearing care professional will adjust your devices to your individual requirements.

### 3.6.4 Selecting hearing programs

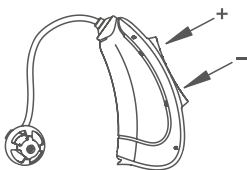
#### Multifunctional rocker switch


Your hearing care professional would have adjusted your hearing aids to various hearing situations with you and assigned them to specific hearing programs. The multifunction rocker switch allows you to swap between the hearing programs.

To do so, simply hold down one end of the multifunctional rocker switch until you hear audible confirmation of the change in program with a tone. After you have released the multifunctional rocker switch, the melody for the selected program is played. The number of signals indicates the number of the program selected.

You can move through the hearing situations up or down. Your hearing care professional has set the number of selectable programs for your individual requirements.

Program change sequence\*:



 Volume control and program selection are optional functions. Your hearing care professional will adjust your devices to your individual requirements.

\* Example with 3 hearing programs.

Hearing program	Description of setting
1	_____
2	_____
3	_____
4	_____

## 4 TINNITUS FUNCTION

Combi hearing aids from audifon play an effective part in tinnitus therapy.


Your hearing care professional would have adjusted the combi hearing aids to your individual hearing situation with you.

Information on operating devices with active tinnitus modules can be found in Section 3 on this user manual.

### 4.1 Intended purpose

The integrated noiser module can be optionally activated and can be used to support tinnitus therapy.

In combination with other therapeutic measures, the noise is intended to help reduce the perception of tinnitus.

 Activation of the noiser module as part of a tinnitus therapy is suitable for adults aged 18 and over.

## 5 WIRELESS FUNCTIONALITY / BLUETOOTH CONNECTIVITY

### 5.1 Using hearing aids with iOS devices

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

To use your hearing aids via your iOS device, you have to pair them with the iOS device. This is how the hearing aids and the iOS device communicate with each other. Please follow the instructions to successfully pair the hearing aids.

1. Press the Settings icon on your iOS device.
2. In the Settings menu go to: Accessibility → Hearing Devices under the Hearing category
3. If the Bluetooth function is still deactivated on this screen, activate Bluetooth. While the iOS device is looking for hearing aids, open and close the battery compartments of your hearing aids (this puts the hearing aids into pairing mode).
4. The device name of your hearing aids, generated based on your first name, appears among the devices now displayed. If this does not happen within 5–7 seconds, press the upper left edge of the screen to go back to <Accessibility and open Hearing Devices again.
5. After your hearing aids are displayed, select them from the list to connect them with the iOS device.

6. If you wear two hearing aids, two pairing requests will appear - one for each hearing aid. Select Pair to make a final connection. Both requests can be delayed by a couple of seconds.
7. Pairing is now complete.

### **5.1.2 Operating hearing aids with an iOS device (e.g. iPhone)**

Your made-for-iPhone hearing aid is equipped for operation with an iPhone, iPad or iPod Touch.

To use your hearing aid with an iOS device, pair the hearing aid as described in Section 5.1.

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

1. via the Hearing Devices menu
2. via the quick start menu of the iOS device

In both menus you have access to set

1. the microphone volume
2. the desired hearing program
3. the listening function via your iOS device, with which the audio signals from the microphone of the iOS device are transmitted directly to your hearing aids.

### 5.1.3 Operation via the Hearing Devices menu

Navigate to the Hearing Devices sub-menu.

You can find this under:

**Settings**

→ **Accessibility**

→ **Hearing Devices**

Your connected hearing aids are displayed here. Select the connected hearing aids via Connected to access the hearing aid settings.

### 5.1.4 Operation via the quick start menu

Press the home button three times.

The Hearing Devices menu opens.

If you require support with pairing or using your iOS device with your hearing aid, please contact your hearing care professional.

For further operating functions, let your hearing care professional explain to you about the related free app.

## **5.2 Pairing hearing aids with an Android device**

To use your hearing aids via your Android device, you have to pair them with your Android device. This is how the hearing aids and the Android device communicate with each other. Please follow the instructions to successfully pair the hearing aids.

- 1.** Press the Settings icon.
- 2.** Select Bluetooth.
- 3.** Change the settings to ON if Bluetooth is switched OFF. Open and close the battery compartment of the hearing aids. This puts the hearing aids into pairing mode.
- 4.** Under Paired devices you can see your first name, followed by Hearing Aid, if the hearing systems were detected. If the name does not appear on the list of paired devices within 5–7 seconds, press the Accessibility icon in the top left corner, then on hearing aids.
- 5.** The right hearing system appears on the list once, as does the left hearing system. Both list entries must be clicked for pairing.
- 6.** Pairing is complete.

### **5.3 Unpairing hearing aids**

You can delete pairing of your hearing aids with your smartphone and MULTISTREAMER PRO from the hearing aids. This may be necessary if you wish to pair your hearing aids with a new accessory. To do so, proceed as follows:

- 1.** Switch your hearing aids ON.
- 2.** Press the multifunctional rocker switch down for 5 seconds. A melody will confirm deletion of the pairing.
- 3.** Now also delete pairing in the menu of your smartphone.
- 4.** You can pair your hearing aids once again within 180 seconds by switching them OFF once and then back ON.

### **5.4 Using hearing aids with the MULTISTREAMER PRO**

To use your hearing systems hands-free, with your TV set or other devices with an AUX output, you can purchase the MULTISTREAMER PRO accessory from your hearing care professional.

### **5.4.1 Pairing hearing aids with the MULTISTREAMER PRO**

When you purchased your MULTISTREAMER PRO from your hearing care professional, you would have connected your hearing aids to the MULTISTREAMER PRO during the first consultation. This means that the initialisation of the connection is completed.

From now on you can connect your hearing aids automatically to your MULTISTREAMER PRO. To do so, just switch ON the MULTISTREAMER PRO and then (within 180 seconds) your hearing aid(s).

### **5.4.2 Pairing your smartphone with the MULTISTREAMER PRO**

Switch ON the MULTISTREAMER PRO. Then press the multi-function button for 5 seconds. The LED changes to red then flashing blue. Refresh the Bluetooth menu in your smartphone. The MULTISTREAMER PRO is displayed for selection. Select the device, then Pair. The MULTISTREAMER PRO is paired with your smartphone.

For further operating functions, see the operating instructions of the MULTISTREAMER PRO included with your MULTISTREAMER PRO.

## 5.5 Flight mode

Whenever you enter an aeroplane or areas where transmission of wireless signals is forbidden, you must switch off the wireless functions on your electronic devices.



For this reason, please put your hearing aids in flight mode in these situations, or if in doubt speak to trained personnel.

To switch your hearing aid to flight mode, please press the multifunctional rocker switch up for 5 seconds. All wireless functions of your hearing aids are now switched OFF.

If you switch the hearing aids OFF and ON again, all functions are reactivated.

## 6 ACCESSORIES

The hearing aids from the lewi and risa families offer the following accessories, which are available from your hearing care professional. You can download the audifon App free of charge on the relevant platforms. For further information please contact your hearing care professional.

Accessories	Description
audifon App	Smartphone App for remote control of your hearing aids
MULTISTREAMER PRO	Audio streamer for extending the functions of your hearing aids
UniTip Soundshell	Individual ear adapter piece for your hearing aids
UniTip domes	Universal earpieces for use with your hearing aids
UniTip receiver module S-M-P	The receiver module is used to emit amplified sound to the ear canal
Concha clip	Fastens the UniTip receiver module in the ear canal
CeruStop filter	Small filter that protects the receiver module from blockages and should be replaced regularly

The hearing aids belonging to the lewi and risa families are compatible with standard smartphones equipped with Bluetooth version 4.0 or higher. The MULTISTREAMER PRO accessory may be required for audio transmission (e.g. for smartphones with an Android operating system).

For a list of smartphones, tablets etc. that are compatible with the hearing aids in the lewi and risa ranges and the audifon App, please visit:

**[www.audifon.com](http://www.audifon.com)**

## 7 CARE INSTRUCTIONS

### 7.1 General

audifon hearing aids will improve your hearing ability as well as your quality of life. To ensure your hearing aids function perfectly and so make hearing a pleasant experience for years to come, audifon offers special care products designed to enable optimum cleaning of your devices.

Protect your hearing aids against moisture (e.g. showers, sweat, rain), and take your hearing aids out before using hairspray or similar cosmetic products.

No matter what type of hearing aid you use, we also recommend carrying out daily care on them as these devices are exposed to moisture and dust through intended use, even when handled with care: Each one is in direct contact with the skin. Resulting perspiration may damage your hearing aid in the long term unless dried on a daily basis. audifon's behind-the-ear hearing aids are coated with a water-repellent finish to prevent any damage from moisture.

Wearing a hearing aid or insertion of the ear adapter piece in the ear canal will always involve soiling with earwax. For this reason we recommend regular cleaning. Do not use a damp cloth to clean your hearing aids. Always use a soft, dry cloth.

Should your hearing aid still not function correctly despite regular care, call on your hearing care professional. Do not try under any circumstances to repair your hearing aid yourself.

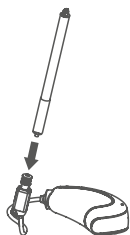
## **7.2 Cleaning and care of behind-the-ear hearing aids with an external receiver**

Hearing aids with an external receiver have special requirements in terms of cleaning and care. Please proceed as follows:

To clean your hearing aids on the outside, either use an audifon Pro Care Cleaning-Tissue or a soft, dry, lint-free cloth which you have moistened with audifon Pro Care Cleaning-Spray. Rub your hearing aid carefully with a tissue or cloth. This will remove soiling and residues of earwax quickly and easily. When handling the external receiver, please take special care. Make sure that moisture does not get into the microphone inlets of the hearing aid.

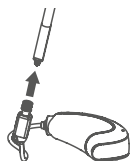
## 7.3 Changing the earwax protection filter

Hearing aids with an external receiver feature protection filters to prevent earwax being deposited inside the receiver. It is necessary to regularly change the filter to ensure your hearing aids function perfectly. To replace the filter, proceed as follows:



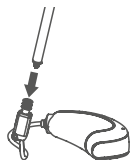
First remove the dome from the receiver module and clean it.

Remove the replacement tool from the filter dispenser and slide it into the filter.



Pull out the filter with a gentle turning motion.

Turn the changing tool. At the other end of the changing tool is a new filter.



Press the new filter with the changing tool into the filter opening of the hearing aid until it clicks into place. Then simply pull out the replacement tool and dispose of it.

## 7.4 Drying hearing aids

Your hearing aids should be dried after use at the end of the day and above all after cleaning. If you take care of your hearing aids by drying them carefully, this will significantly increase their service lifespan. There are two ways of doing this. If you have an audifon electric dehumidifier; Dry Star UV 2 or Dry Go, use this for drying. Take note of the individual product instructions for further details. Alternatively, you can dry your hearing aids in the audifon Pro Care Drying-Tub with an audifon Drying-Capsule.

### Dry Star UV 2

The audifon Dry Star UV 2 will dry your hearing aids gently yet thoroughly through the constant circulation of uniformly warm air inside the It utilises a ultraviolet light to disinfect and prevent fungal, bacterial, and viral growth.

The audifon Dry Star UV 2 is not only has an auto-power cut off function but also consumes very little power, switching itself off at the end of the drying program. The drying station is simple to operate using a single sensor button.



## Dry Go

The audifon Dry Go is the perfect solution for drying your devices when on trips or when out and about. Once connected, for example to the USB port on your laptop, the drying program can be conveniently started at the touch of a single button. A flow of warm air inside the audifon Dry Go will then dry your devices reliably. The drying station switches off automatically at the end of the drying program.



## 8 TROUBLESHOOTING

If you experience any malfunctions when using your hearing aids, this does not necessarily mean that they are faulty. Therefore first check your hearing aid to make sure that:

- the hearing aid is switched ON (see "Switching ON and OFF" Section 3.4),
- the batteries are not weak or dead,
- the volume control is not at the lowest setting (increase the volume slightly if necessary),
- the right program has been set (change program if necessary),
- the receiver unit / earwax protection system is not blocked.

If this does not eliminate the fault, consult your hearing care professional, who will be pleased to help you.

### **Note: Malfunctions!**

Your devices may be subject to interference from other electrical equipment despite their EMC-compatible design. In this case move away from the source of interference.

## 9 SAFETY INFORMATION

### 9.1 Important warnings

 **Warning: Risk of suffocation!**

Batteries, hearing aids and other small parts can be swallowed. For this reason, these hearing aids are not intended for use by children under 36 months of age. Never leave children unattended with your hearing aids! Should a battery, hearing aid or other small parts be accidentally swallowed, please consult a doctor immediately.

 **Warning: Risk of injury!**

In some very rare cases the dome may remain in the ear canal on removal. Should this happen, please contact your doctor or hearing care professional at once. Please do not try to remove the dome yourself.

 **Warning: Damage to hearing!**

The maximum volume of the noiser modul is in a range that may lead to hearing loss according to OSHA regulations. For users without hearing loss, the noiser modul should not exceed sound pressure levels above 70 dB SPL (as measured at a 2cc coupler). For users with hearing loss, the hearing loss needs to be taken into consideration when adjusting the noise levels. Under no circumstances should the noiser module be used at a volume that is uncomfortable to the user.

For sound pressure levels up to 80 db SPL (as measured at the 2cc coupler) the noiser module can be used for up to 8 hours daily. For higher sound pressure levels, the uncritical duration of applications is reduced. The noiser modul should not be used for more than 2 hours daily at higher sound pressure levels.

Higher sound levels and/or longer times of application might harm the hearing ability over time.

 **Warning: Risk of explosion!**

Do not use hearing aids in environments where there is a risk of explosion (e.g. in mines or industrial plants subject to such risk).

 **Warning: Risk of injury!**

Hearing aids are adjusted to the individual hearing loss of each wearer and should therefore only be used by this person.

If the hearing aid is worn by other persons, this may harm their hearing.

 **Warning: Risk of injury!**

Please only use genuine consumables specified by the manufacturer (dome, tubing, etc.) and accessories.

Unauthorised changes or modifications that have not been explicitly approved may in the worst-case scenario result in injury.

 **Warning: Interference with active and inactive implants!**

If you have an active or inactive implant (e.g. defibrillator, pacemaker), follow the implant manufacturer's instructions regarding the use of mobile devices. In the event of malfunctions, stop using your hearing aid and contact your doctor or the implant manufacturer.

If you have an active brain implant, ask your doctor or the implant manufacturer for a risk analysis.

**Warning: Risk of injury!**

Always wear your receiver unit with the appropriate Dome or customized earmold and check that they are securely positioned on receiver unit.

## 9.2 Information about product safety

**Note: Interference with electronic devices!**

If you are in an environment where use of electronic or wireless devices is restricted, check whether your hearing aids must be turned off.

**Note: Damage to hearing aid!**

Hearing aids are susceptible to impact, so avoid any hard knocks (e.g. by dropping them).

**Note: Damage to hearing aid!**

To avoid damage to your hearing aids, please do not wear them in the following situations:

- when swimming, in the shower or bath
- when washing or blow-drying your hair
- when using hair spray, perfume, aftershave or body lotion
- during high-frequency heat therapy treatment
- when it is very hot or raining heavily

Should your hearing aid become damp, remove the battery and dry the hearing aid in one of the drying containers specified by the manufacturer. Do not dry your hearing aid in the microwave under any circumstances.

**Note: Damage to hearing aid!**

No modifications should be made to the hearing aids unless performed directly by the manufacturer.

- ❗ **Note: Damage to hearing aid!**  
Do not force the battery into the battery compartment. If it does not fit, check whether you are inserting it correctly and that it is the correct size of battery.
- ❗ **Note: Leaking batteries can damage your hearing aid hearing aid!**  
If you do not intend to use your hearing aids for a long time, remove the battery to increase its service lifespan, to avoid leakage and to prevent corrosion to the battery contacts.
- ❗ **Note: Strong radiation can damage hearing aids!**  
Make sure you take out your hearing aids if you are undergoing a CT or MRI scan, other magnetic field-based examinations or radiotherapy.
- ❗ **Note: Damage to hearing aid!**  
Never leave your hearing aid in the sun, near a naked flame or in a hot vehicle. Otherwise your hearing aids might become damaged.
- ❗ **Note: Damage to hearing aid!**  
Never try to change the shape of your hearing aid, ear mould or tubing yourself. Otherwise your hearing aids might become damaged.
- ❗ **Note: Malfunctions!**  
Your devices may be subject to interference from other electrical equipment despite their EMC-compatible design. In this case move away from the source of interference.

## 10 SIDE EFFECTS AND CONTRAINDICATIONS

### 10.1 Side Effects

Please consult a doctor at once if you notice the following side effects:

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

## 10.2 Contraindications

Hearing aids should not be used under the following circumstances:

- Hearing loss due to mainly neural deficits
- Insufficient size/shape of the ear canal or malformations at the ear that do not allow for easy insertion and retrieval of the respective device.
- Adverse medical conditions of the outer ear and the ear canal e.g., chronic inflammations, chronic skin irritations, cholesteatoma
- Known allergies to any materials that have skin contact

Patients who are unable to operate the devices independently require competent assistance. The use of hearing aids for mentally impaired persons and for children should only be done on the recommendation of a doctor. A comprehensive risk assessment should be performed for the specific individual case. Close supervision by a caregiver is recommended to ensure proper use of the hearing instruments and to avoid accidental swallowing of hearing instruments or parts thereof.

## 11 OPERATING CONDITIONS

- Relative humidity between 10% and 90%
- Operating temperature between 0 °C and 40 °C
- Air pressure between 500 and 1060 hPa

## 12 TRANSPORT AND STORAGE CONDITIONS

- Relative humidity between 10% and 60%
- Storage temperature between -20 °C and 60 °C
- Remove battery for prolonged storage periods
- Store away from magnetic fields

## 13 ENVIRONMENTALLY COMPATIBLE DISPOSAL

In accordance with European defaults used electrical and electronics devices may no more be given to the unsorted waste. The symbol of the waste bin on wheels refers to the necessity of separate collection. Please help with environmental protection and see to it that this device is given to the for this purpose designated systems of waste sorting if you do not use it any longer.

GUIDELINE 2012/19/EU of the EUROPEAN PARLIAMENT AND THE COUNCIL of July 04th 2012 about electrical and electronics old devices.

Alternatively, you can return your worn-out hearing aids and batteries to your hearing aid specialist for environmentally friendly disposal. He is your contact in the disposal chain for electronic waste.



## 14 OTHER INFORMATION


### 14.1 EU declaration of conformity

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

EU-Medical Device Regulation MDR 2017/745  
93/42/EEC for medical devices  
2011/65/EU RoHs for the reduction of hazardous substances.  
RED directive 2014/53/EU on radio and telecommunications  
terminal equipment

The declaration of conformity can be viewed at

audifon GmbH & Co. KG  
Werner-von-Siemens-Straße 2  
D-99625 Köllda  
and at **[www.audifon.com](http://www.audifon.com)**

 All serious incidents involving 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.

### Federal Communications Commission Statement

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.

#### 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.

## 15 SERVICE

Arrange for your hearing aids to be checked preferably quarterly by a hearing care professional.

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Date

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Hearing care professional

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Date

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Hearing care professional

---

Date

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Hearing care professional

## 16 KEY TO SYMBOLS



### **Caution**

Indicates a situation that may result in serious, moderate or minor injury.

Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



### **Notice**

Indicates possible damage to property.



### **Information**

Additional information for better understanding of the device.



### **Manufacturer**

Indicates the medical device manufacturer, as defined in the EU Medical Devices Regulation (EU) 2017/745 and in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.



### **Date of manufacture**

Indicates the date when the medical device was manufactured.



### **Electronic waste (WEEE)**

Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal. Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).

**Consult instructions for use**

Indicates the need for the user to consult the instructions for use.

**Humidity limitation**

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

**Temperature limit**

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

**Medical device**

Indicates the item is a medical device

**Catalogue number**

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

**Serial number**

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

**Lot number, batch code**

Indicates the manufacturer's batch code 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 indicates the identification of the notified body.

# WARRANTY CARD

You have chosen high-quality hearing aids from audifon.

Your hearing care professional offers a \_\_\_\_\_ month warranty on our hearing aids from the date of purchase (date of invoice). 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. Warranty obligations will not result in any extension of the warranty period, nor will they give rise to a new warranty period for the hearing aid. The warranty period for built-in spare parts ends at the same time as the warranty period for the entire hearing aid.

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

Hearing aid type

\_\_\_\_\_  
Date of sale

\_\_\_\_\_  
Your hearing care professional

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Stamp:

Name \_\_\_\_\_

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

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

Telephone \_\_\_\_\_

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



Type \_\_\_\_\_ Side \_\_\_\_\_

Serial number \_\_\_\_\_

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



Type \_\_\_\_\_ Side \_\_\_\_\_

Serial number \_\_\_\_\_

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

# audifon



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CE 0297

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made in Germany