

BEHIND-THE-EAR HEARING AIDS

User Manual

- sino
- kami
- rega




CONTENTS

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.

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	7
2.3.2	Low battery warning	7
2.3.3	Battery compartment lock	8
3	OPERATION – SINO, KAMI, REGA S/P	9
3.1	Construction	9
3.2	Inserting battery	10
3.3	Removing battery	11
3.4	Switching hearing aids on and off	12
3.5	Inserting and removing hearing aids	13
3.5.1	Inserting with Thin Tube	13
3.5.2	Inserting with ear mould	14
3.5.3	Removing hearing aids	15
3.6	Volume control and program selection	15
3.6.1	Multifunctional rocker switch	15
3.6.2	Volume selection	16
3.6.3	Selecting hearing programs	17
3.6.4	Direct audio input	18
4	OPERATION – SINO, KAMI, REGA XS	20
4.1	Construction	20
4.2	Inserting battery	21
4.3	Removing battery	22
4.4	Switching hearing aids on and off	22
4.5	Inserting and removing hearing aids	23
4.6	Volume control and program selection	24
4.6.1	Volume selection	24
4.6.2	Selecting hearing programs	25

Updated: 08.12.2021

5	TINNITUS FUNCTIONT.....	26
6	MAKING PHONE CALLS	26
6.1	Telephone loop (T-Coil)	27
6.2	Automatic program change	27
6.2.1	Auto T-Coil	28
6.2.2	Auto Phone	28
6.2.3	Attaching magnet.....	29
7	ACCESSORIES.....	30
8	CARE INSTRUCTIONS	31
8.1	General.....	31
8.2	Cleaning.....	32
8.3	Drying hearing aids.....	32
9	TROUBLESHOOTING	34
10	SAFETY INFORMATION	35
10.1	Important warnings.....	35
10.2	Information about product safety	38
11	SIDE EFFECTS AND CONTRAINDICATIONS	39
11.1	Side effects	39
11.2	Contraindications	40
12	OPERATING CONDITIONS.....	41
13	TRANSPORT AND STORAGE CONDITIONS	42
14	ENVIRONMENTALLY COMPATIBLE DISPOSAL	43
15	OTHER INFORMATION	44
15.1	EU declaration of conformity.....	44
15.2	FCC Statement.....	45
16	SERVICE	46
17	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 the body of the hearing aid.

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

Your hearing aids are behind-the-ear hearing aids.

2.2 Technical features

This user manual applies to the following types:

Model	Battery		Gain in dB	Indication range
	Size	Average service life (zinc air) in h		
sino S	312	100	66	Minor to moderate hearing loss
kami S	312	100	66	
rega S	312	100	66	
sino P	13	140	71	Minor to profound hearing loss verging on deafness
kami P	13	140	71	
rega P	13	140	71	
sino XS	10	60	61	Minor to severe hearing loss
kami XS	10	60	61	
rega XS	10	60	61	

Detailed acoustic data for 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.

2.3 Batteries

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


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


Always switch your hearing aids off after use. To avoid damage, remove the battery if you are not using your hearing aids for a long time.


2.3.1 Information on battery

A zinc air battery is used to supply the 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 ensures the battery remains fresh until use and 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.

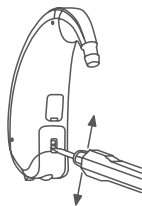
 Used batteries are considered hazardous materials and contain toxic materials, should never be disposed of in the trash. Ask about recycling programs in your area where you live or return them to your hearing care professional to dispose them appropriately.

 Further safety instructions can be found on the battery packaging.

2.3.2 Low battery warning

An audible signal indicates the end of the battery life in good time (approx. 30 minutes before the battery runs out).

2.3.3 Battery compartment lock



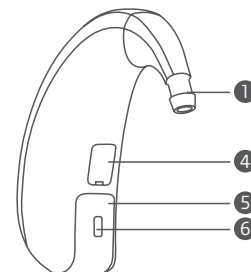
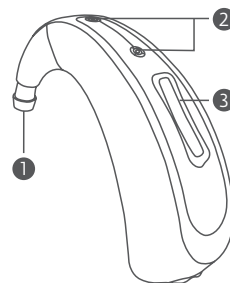
The battery compartment can be locked by sliding the lock up using a small screwdriver. In this position the hearing aid can still be switched off, but the battery cannot be removed.


3 OPERATION – SINO, KAMI, REGA S/P


3.1 Construction

The hearing aids consist of the following elements:

- ① Ear hook
- ② Microphone inlets
- ③ Multifunctional rocker switch
- ④ Audio input, optional
- ⑤ Battery compartment / ON/OFF switch
- ⑥ Battery compartment lock



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

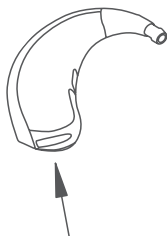
 Your hearing aids may differ from the illustrations.

3.2 Inserting battery

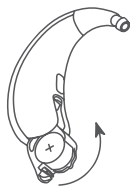


Remove a battery from its packaging.

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



First, push the battery compartment up until it clicks into the first catch position (OFF position). You should now be able to open it fully.

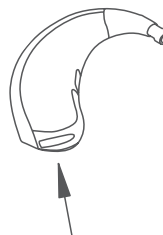


Then insert the battery in the battery compartment. Ensure that the + symbol marked on the battery is visible when you have inserted it.

⚠ 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 type of battery (see Section 2.2).

3.3 Removing battery



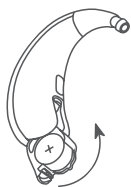
First, push the battery compartment up until it clicks into the first catch position (OFF position). You should now be able to open it fully.

Then remove the battery from the battery compartment.

⚠ Please do not open the battery compartment any wider than shown on page 9. 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 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

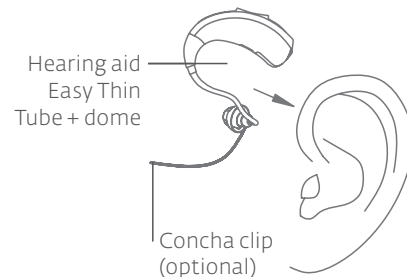
To switch the device off, press the battery compartment out to the first catch position. This is the OFF position.

If the devices are going to be out of use for a long time, open the battery compartment fully and remove the battery.

3.5 Inserting and removing hearing aids

3.5.1 Inserting with Thin Tube

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



Place the hearing aid behind your ear.

Slide the earpiece 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 support helps improve the fit of the earpiece in the ear.



To position the concha support, bend slightly and place it carefully in the outer part of your ear.

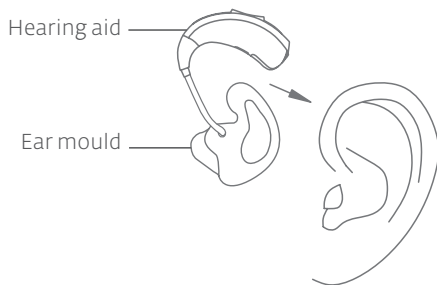


Warning: Risk of injury!

Always wear the thin sound tube with the dome and check that the dome is positioned securely on the tube.

3.5.2 Inserting with ear mould

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



Place the hearing aid behind your ear.



Insert the ear mould in your ear, rotating slightly as you do so.

Move the upper part of the ear mould backwards and forwards slightly to adjust.

3.5.3 Removing 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.



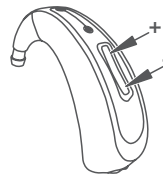
Warning: Risk of injury!

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 Multifunctional rocker switch



Your hearing aids feature a multifunctional rocker switch for controlling the volume and selecting the different programs. The rocker switch can be activated by pressing the top (+) and bottom end (-).

The rocker switch can be programmed with one of three functions. Your hearing care professional has marked here which of the functions has been set for your hearing aids:



Volume control

To control the volume, press the multi-function rocker switch briefly on the top or bottom (also see 3.6.2).



Program selector switch

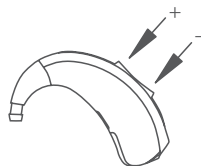
To change the program, press the multi-function rocker switch briefly on the top or bottom (also see 3.6.3).



Volume control and program selector switch combined

To control the volume, press the multi-function rocker switch briefly on the top or bottom; to change the program hold the switch down for approx. 1 second (see also 3.6.2 and 3.6.3).

3.6.2 Volume selection



The volume can be adjusted in steps using the 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 you. You can now increase or reduce the volume in steps. Each time you press the switch, you will hear audible confirmation.

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.

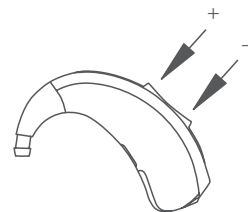
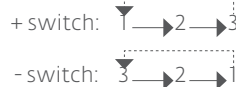
3.6.3 Selecting hearing programs

Multifunctional rocker switch

Your hearing care professional will have adjusted your hearing aids to various hearing situations with you and assigned them to specific hearing programs.

The rocker switch allows you to swap between the hearing programs. To do so, simply hold down one end of the rocker switch until you hear audible confirmation of the change in program. The number of signals indicates the number of the program selected. You can move up or down through the hearing situations.

Program change sequence*:



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

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

3.6.4 Direct audio input

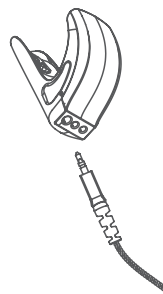
Your hearing aid is equipped with direct audio input (DAI). DAI allows you to use the audio shoe to directly connect your hearing aid to external sound sources, e.g. portable MP3 players.



Fitting the audio shoe

Unscrew the cover of the audio contacts using a small screwdriver.

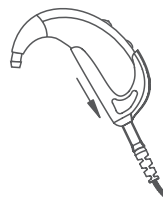
Fit the audio shoe onto the hearing aid from below as shown.



Connecting sound sources to the hearing aid

Insert the connector of the sound source you are using into the underside of the audio shoe.

✋ Please do not use force here! If the connector does not fit into your audio shoe, your hearing care professional will be pleased to assist.



Removing the audio shoe

Remove the audio shoe by pulling straight down. Protect the audio contacts of the hearing aid with its cover.

⚠ Warning: Risk of electric shock!

Audio devices supplied with mains power must comply with IEC 60065, IEC 60601 or similar safety standards to ensure that they can be connected to your hearing aids without any risk to safety.

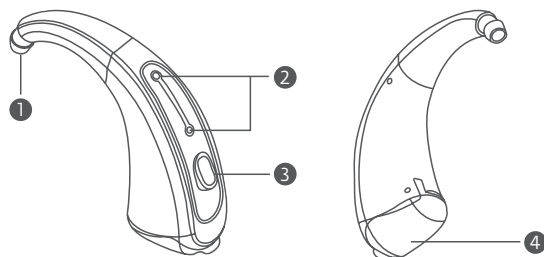
✋ The audio shoe is an optional accessory which is available from your hearing care professional.

4 OPERATION – SINO, KAMI, REGA XS

4.1 Construction

The hearing aids consist of the following elements:

- ① Ear hook
- ② Microphone inlets
- ③ Switch
- ④ Battery compartment / ON/OFF switch



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

☞ Your hearing aids may differ from the illustrations.

4.2 Inserting battery

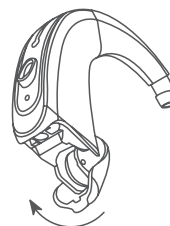


Remove a battery from its packaging.

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.

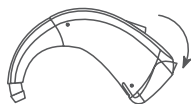


Then insert the battery in the battery compartment. Make sure the (+) symbol on the battery matches the (+) symbol on the battery compartment.

☞ 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 type of battery (see also Section 2.2).

4.3 Removing battery



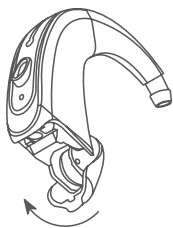
Open the battery compartment carefully with your fingernail at the edge for opening and swing it right out.

Then remove the battery from the battery compartment.

 Please do not open the battery compartment any wider than shown in Section 4.2. This might damage the device.

4.4 Switching hearing aids on and off

Your hearing aids are switched on and off via the battery compartment.

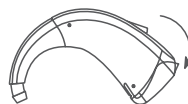


Switching on

Close the battery compartment securely 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 going to be out of use for a long time, open the battery compartment fully and remove the battery.

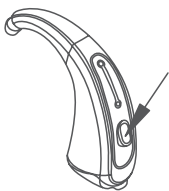
4.5 Inserting and removing hearing aids

To insert hearing aids of the type XS, please note the information in Section 3.5.

4.6 Volume control and program selection

Your hearing aid features a switch which can be used to adjust the volume or select programs.

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

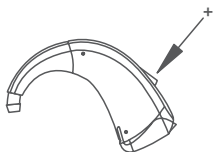


The switch can be programmed with one of two functions.

Your hearing care professional has marked here which of the functions has been set for your hearing aids:

- ☐ **Volume control**
Press briefly to adjust the volume (see also Section 4.7).
- ☐ **Program selector switch**
Press briefly to change the program (see also Section 4.8).

4.6.1 Volume selection



The volume can be adjusted in steps using the switch.

When you switch your devices on, they will be at the volume set for you. Each press of the switch is followed by audible confirmation.

4.6.2 Selecting hearing programs

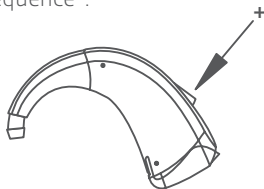
Switch

Your hearing care professional will have adjusted your hearing aids to various hearing situations with you and assigned them to specific hearing programs. The switch allows you to swap between the hearing programs. To do so, press the switch until you hear audible confirmation of the change in program. The number of signals indicates the number of the program selected.

The switch allows you to move to hearing situations in ascending order.

Program change sequence*:

1 --> 2 --> 3



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

5 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.

5.1 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.

6 MAKING PHONE CALLS

 Depending on which type of hearing aid you have, it may not feature the elements marked with an *.

6.1 Telephone loop (T-Coil)*

A telephone loop receives the magnetic signal from telephones and converts it to sound. This optional telephone program may help you to understand better what people are saying on the telephone.

When making calls with the telephone loop program, hold the handset as normal.

 To find the correct position for optimum reception, move the handset backwards and forwards slightly.

6.2 Automatic program change*

The hearing aids belonging to the kami and rega families feature automatic telephone program activation. The hearing aids can automatically switch either to telephone loop (Auto T-Coil) or to a microphone program for telephony (Auto Phone).

To prevent the hearing aids from accidentally switching programmes during a telephone call, the program switch is disabled during this time.

6.2.1 Auto T-Coil

Automatic switchover to the telephone loop program is designed for landline phones and only works with older telephones or phones which have been specially designed for use with telephone loops. Attaching the optional magnet sticker increases the reliability of the switching function. Familiarise yourself with how the automatic telephone loop switching function works before making a call.

When you move the telephone handset away from your ear again, your hearing aids will return to the program previously in use.

6.2.2 Auto Phone

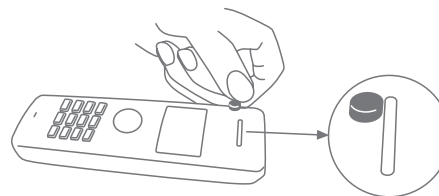
Automatic switchover to an acoustic telephone program can be used with conventional landline and mobile phones and optimises playback for telephony. Attaching the optional magnet sticker increases the reliability of the switching function. Familiarise yourself with how the automatic telephone program switching function works before making a call.

When you move the telephone handset away from your ear again, your hearing aids will return to the program previously in use.

6.2.3 Attaching magnet

To attach the magnet, proceed as follows:

1. Clean the telephone handset thoroughly.
2. Attach the magnet as shown in the illustration.
3. If necessary, you can reposition the magnet.



7 ACCESSORIES

The hearing aids from the rega, kami and sino families offer the following accessories, which are available from your hearing care professional. For further information please contact your hearing care professional.

Accessories	Description
Magnet	A little magnet that can be affixed to your telephone
Side marking	Shows the side of your hearing aids: red = right, blue = left
UniTip Soundshell	Individual ear adapter piece for your hearing aids
UniTip domes	Universal earpieces for use with your hearing aids
Easy Thin Tubes	Thin Tube for use of your hearing aids with minor to moderate hearing loss
Concha clip	Secures the Thin Tube in your ear
Open Fit adapter	Adapter for connecting Easy Thin Tubes to your hearing aid

8 CARE INSTRUCTIONS

8.1 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.

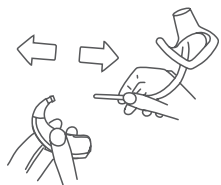
Protect your hearing aids against moisture (e.g. showers, sweat, rain), and take your hearing aids out before using hairspray or similar cosmetic products.

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 inserting 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.

8.2 Cleaning



Ear adapter piece

The ear adapter pieces and the flexible plastic tubing attached to them must be detached from the ear hook before cleaning. Only use the recommended care products for cleaning the ear adapter pieces.



Thin Tube

In the case of hearing aids with a thin sound tube, the screwed connection between the tube and hearing aid can be detached. The dome is removed for cleaning.

8.3 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 life. There are two ways of doing this. If you have an audifon drying station of the type 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. 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.



9 TROUBLESHOOTING

If you experience any malfunctions when using your hearing aids, this does not necessarily mean that they are faulty. Therefore please 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.

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 SAFETY INFORMATION

10.1 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 earpiece with the appropriate Dome or customized earmold and check that they are securely positioned on the tube.

10.2 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!**

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.

11 SIDE EFFECTS AND CONTRAINDICATIONS

11.1 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

11.2 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..

12 OPERATING CONDITIONS

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

13 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

14 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.



15 OTHER INFORMATION


15.1 EU declaration of conformity

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

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 Kölleda
and at **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.

15.2 FCC Statement

FC YU2-BT1

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.

16 SERVICE

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

Date

Hearing care professional

Date

Hearing care professional

Date

Hearing care professional

Date

Hearing care professional

Date

Hearing care professional

Date

Hearing care professional

17 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.

Hearing aid type

Date of sale

Your hearing care professional

Signature

Stamp:

Name _____

No., street _____

Town, postcode _____

Telephone _____

Date of issue _____

R

Type _____ Side _____

Serial number _____

Warranty _____ Battery type _____

L

Type _____ Side _____

Serial number _____

Warranty _____ Battery type _____

audifon



Manufacturer

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

Telephone +49-3635-4056-590

Fax +49-3635-4056-589

contact@audifon.com

www.audifon.com

CE 0297

High-tech
made in Germany