

IMPORTANT INFORMATION FOR AUDIOLOGISTS

Service Instruction



*) You can find the current version here:
<https://audifon.com>

General purpose

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

Hearing aids will 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.

The specific purpose of the hearing system in question can be found in the applicable instructions for use.

Hearing aids must be individually adjusted by an audiologist or ENT doctor. Diagnosis and prescription of hearing aids must be performed by an ENT doctor.

The expected useful life of the hearing aids is 6 years, but depends on functional conditions and care.

For receiver units, the expected useful life is 2 years.

Additional restrictions on use are listed in Section 15 "Safety Instructions".

For reasons of better readability, the simultaneous use of the language forms male, female and diverse (m/w/d) is dispensed with.

All personal names apply equally to all genders.

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 of the outer ear and/or ear canal, such as: chronic inflammation, skin irritation or cholesteatoma
- The patient has allergies to materials in contact with the skin

Technical features

The performance characteristics of audifon hearing systems can be found in the respective data sheets. These are available at www.audifon.com and in the fitting software.

Declaration of conformity

For this and more information, please visit

www.audifon.com

and in the respective instructions for use.

These service instructions have been optimised for printing on standard printers.

A printed version of 'IMPORTANT INFORMATION FOR HEARING ACOUSTICIAN' is available free of charge on request from your audifon sales representative.

CONTENTS

1	INTRODUCTION.....	8	3.3	Operation and structure of the product variants rega, kami, sino P/S/ XS	30
2	BTE HEARING SYSTEM (a10)	10	3.3.1	Construction	30
	2.1 Type	10	3.3.2	Start-up	31
	2.2 RITE technical features	10	3.3.3	Inserting battery	32
	2.3 Operation and design of the product variant lewi R, risa R, rega R, kami R and sino R.....	12	3.3.4	Removing battery.....	33
	2.3.1 Construction	12	3.3.5	Switching on & off.....	34
	2.3.2 Start-up.....	13	3.4	Operation & design of the product type lewi S/ risa S.....	35
	2.3.3 Information on the battery	13	3.4.1	Construction	35
	2.3.4 Battery warning signal	14	3.4.2	Start-up	35
	2.3.5 Inserting battery	14	3.4.3	Battery warning signal	36
	2.3.6 Removing battery.....	15	3.4.4	Inserting battery	36
	2.3.7 Switching hearing aids ON and OFF	16	3.4.5	Removing battery.....	37
	2.4 Operation and design of the product variant lewi R Li and risa R Li	17	3.4.6	Switching on and off.....	37
	2.4.1 Construction	17	3.5	Compatibility of the product variants.....	38
	2.4.2 Energy supply	18	3.6	UniTip ThinTube and Easy ThinTube/ Easy ThinTube 2.....	38
	2.4.3 Switching the hearing aid ON and OFF.....	18	3.6.1	Intended purpose	38
	2.4.4 Battery warning tone	20	3.6.2	ThinTubes selection and length.....	38
	2.4.5 Charging the battery	21	3.6.3	Connecting the ThinTube	39
	2.4.6 Battery charge status	21	3.6.4	Using the ear hook tool.....	41
	2.5 Compatibility of the product variants.....	22	3.6.5	Replacing the dome	42
	2.6 Selecting the length of the receiver unit	22	4	SIDE MARKER/BATTERY COMPARTMENT LOCK	43
	2.6.1 Fitting and adjusting the Conchaclip	23	4.1	Side marker for Wings R Li hearing aids	43
	2.6.2 Assembling the receiver unit.....	24	4.2	Side marker for Wings S device	44
	2.6.3 Removing the receiver unit	24	4.3	Side marker, battery compartment lock and microphone filter replacement for Cosma S & P BTE devices	44
	2.7 Replacing the CeruStop filter.....	25	4.4	Side marker and battery compartment lock for Cosma Family XS.....	45
	2.8 Replacing the dome	26	5	ITE HEARING AIDS (a30).....	47
	2.9 Ear moulds for receiver units	27	5.1	Type	47
	2.9.1 Suitable ear moulds	27	5.2	ITE Technical Features.....	47
3	BTE HEARING SYSTEM (a10)	29	5.3	Operation and design of product variants sino, kami, rega.....	48
	3.1 Type	29			
	3.2 Technical features	29			

5.4 Start-up.....	49	12 ACCESSORIES/ OPTIONAL ACCESSORIES/ COMPONENTS/ CONSUMABLES.....	67
5.5 Inserting battery.....	49	13 TROUBLESHOOTING.....	68
5.6 Battery end of life signal.....	50	14 SAFETY INSTRUCTIONS.....	69
5.7 Removing battery.....	50	14.1 Important warnings.....	69
5.8 Switching on and off.....	50	15 SIDE EFFECTS AND CONTRAINDICATIONS.....	75
5.9 Replacing the CeruStop filter.....	51	15.1 Side effects.....	75
6 APPLICATION OF THE FITTING-SOFTWARE AND PROGRAMMING.....	52	15.2 Contraindications.....	75
6.1 Selecting the Programming Cable.....	52	16 OPERATING CONDITIONS.....	77
6.2 Connecting the Programming Adapter and using the Programming Aid.....	52	17 CHARGING CONDITIONS.....	77
6.3 Wings platform firmware update.....	54	18 TRANSPORT AND STORAGE CONDITIONS.....	77
7 INFORMATION ON WINGS.....	55	19 ENVIRONMENTALLY FRIENDLY DISPOSAL.....	78
7.1 Features.....	55	20 OTHER INFORMATION.....	78
7.2 Binaural synchronisation.....	55	21 KEY TO SYMBOLS.....	79
7.3 easyclick.....	56		
7.4 Volume control and program selection.....	56		
7.4.1 Automatic side adjustment of hearing aids.....	56		
7.4.2 Multifunctional rocker switch.....	57		
7.4.3 Volume selection.....	58		
7.4.4 Selecting hearing programs.....	59		
8 NOISE GENERATOR MODULE.....	60		
8.1 Intended purpose.....	60		
8.2 Duration of use.....	60		
9 WIRELESS FUNCTIONALITY / BLUETOOTH CONNECTIVITY.....	62		
9.1 Using hearing aids with the multistreamer pro.....	62		
9.1.1 Pairing the hearing systems with the multistreamer pro.....	63		
9.1.2 Pairing the smartphone with the multistreamer pro.....	63		
9.2 Unpairing hearing aids.....	64		
10 COMPATIBILITY.....	65		
11 FLIGHT MODE WINGS HEARING SYSTEMS.....	66		

1 INTRODUCTION



Follow these instructions closely to avoid malfunctions and ensure the optimal performance of your hearing aid.



Attention:

Text marked with a warning symbol must be read before using the hearing aid.



Additional information for better understanding.

Hearing aids are designed to accompany and support patients in their everyday lives. If there are environmental conditions where the selected hearing aid could pose a risk, these will be highlighted separately.

The specific model of your hearing aids can be found on the sticker on the packaging, on the warranty card, or printed directly on the hearing aids.



Ensure that the patient is aware of and has access to the appropriate current Instructions for Use for the hearing aid or accessories and that the warranty card is fully filled in.



Make sure the patient understands and can follow your instructions. For children, individuals with disabilities, or patients with cognitive impairments, a family member or caregiver should be involved in the process to ensure proper use and care.

The following devices are supported by the chip platforms:

Wings chip platform	Cosma chip platform
lewi risa	rega kami sino sueno pro

2 RITE HEARING AIDS (incl. a40 receiver units and a50 dome)

2.1 Type

These hearing aids are behind-the-ear hearing aids.
The receiver unit is located directly in the ear canal.

2.2 RITE technical features

These instructions for use apply to the following variants:

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

Transmission power: 0 dBm (1 mW)
Frequency: 2,400 – 2,485 MHz
Range: 10 metres

Model	Battery			Gain in dB (peak value)			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	minor to severe loss of hearing
risa R	312	70	65	60	45	56	67	minor to severe loss of hearing

Transmission power: 0 dBm (1 mW) Class 2
Frequency: 2,402 – 2,450 MHz

Model	Battery			Gain in dB (peak value)		Indication range
	Size	Average service life (zinc air) in h		HE S	HE M	
		HE S	HE M			
sino R	312	110	90	45	55	mild to severe hearing loss
kami R	312	110	90	45	55	mild to severe hearing loss
rega R	312	110	90	45	55	mild to severe hearing loss

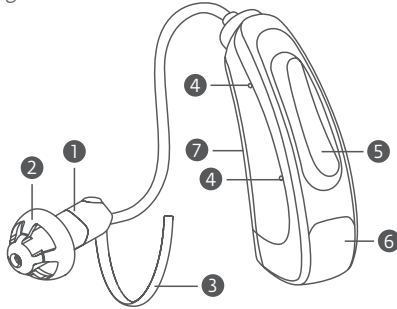
For detailed acoustic data specific to your hearing aids, please refer to the separate data specification document. This and other information can be found at www.audifon.com.

2.3 Operation and design of the product variant lewi R, risa R, rega R, kami R and sino R

2.3.1 Construction

The hearing system consists of the following elements:

- ① Receiver module
- ② Domes or ear moulds
- ③ Conchaclip (optional)
- ④ Microphone inlets
- ⑤ Multifunctional rocker switch
- ⑥ Battery compartment/on/off
- ⑦ Type designation



☞ The hearing aids have side markings on the receiver unit:
blue = left, red = right

⚠ **Attention:**
Ensure the patient knows how to insert their hearing aids correctly. Paying special attention to the fit of the Conchaclip.

2.3.2 Start-up

2.3.3 Information on battery

Use a zinc-air battery, activated when air enters through holes in the battery to start a chemical reaction. During manufacture, the air holes are therefore closed with a sealing tab. This means that the battery remains fresh until use, and it lasts longer when it is sealed.

☞ Reattaching the tab when the battery is not in use will not increase its service life.

☞ Store batteries at room temperature; avoid hot, humid places. There is no need to store the batteries in any special area.

☞ (Spent) Used batteries must not be disposed together in household waste! This is because they may contain harmful substances or heavy metals that can harm the environment and health.
Recycle batteries at designated collection points to prevent environmental harm and recover valuable materials.
Consumers are obliged to dispose of batteries at a collection point provided by the local authority or a sales outlet.

☞ Refer to the battery pack for additional safety information.

2.3.4 Battery warning signal

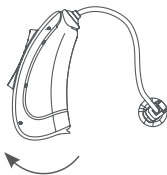
An audible warning signal gives an early indication that the battery is near depletion. This will disable the wireless functions, including smartphone connectivity, with about 2 hours remaining. This means that the hearing systems are no longer connected to the smartphone and that no audio signal can be streamed.

If desired, this can be deactivated via audifit.
If this is disabled, please inform your patient about any risks associated with this.

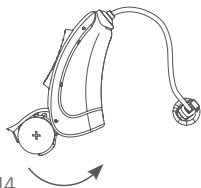
2.3.5 Inserting battery



Remove a battery from its packaging. Remove the seal tab and wait a few minutes before placing the battery into the compartment.




Open the compartment carefully with your fingernail at the edge, and swing it fully open.

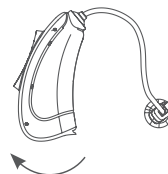


Then insert the battery into the battery compartment. Make sure the (+) symbol on the battery is aligned with the (+) on the battery compartment.

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


 **Attention:**
Avoid applying pressure when inserting the battery into the battery compartment. If it does not fit, check that the battery is correctly placed into the battery compartment and that it is the correct type of battery (see chapter 2.2).

2.3.6 Removing battery



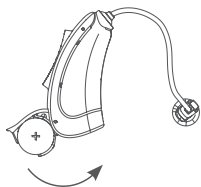
Carefully open the compartment with a fingernail, and remove the battery. Swing it to fully open.

Remove the battery from the battery compartment.

 Please do not open the battery compartment any further than shown in chapter 2.3.5. The hearing aid may be damaged.

2.3.7 Switching hearing aids ON and OFF

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

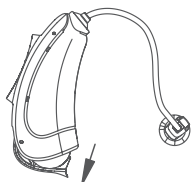


Switching on

When switching ON, close the battery compartment fully and partially open the battery compartment to the first latch to switch it OFF.

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

After a preset delay time and start melody, the first hearing programme is activated. The hearing system is ready for operation.



Switching off

To turn the hearing aid off, press the battery compartment out to the first latch position.

This is the OFF position.

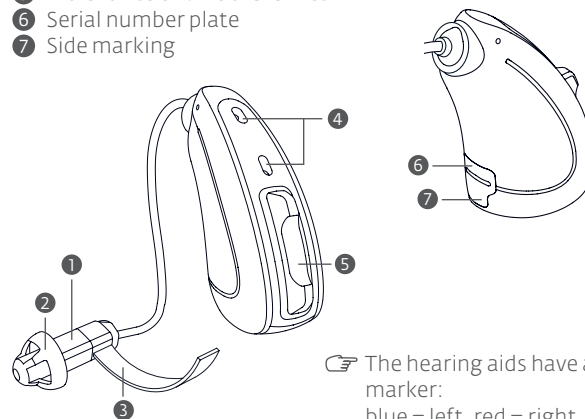
If your hearing aids are going to be out of use for an extended period of time, fully open the battery compartment and remove the battery.

2.4 Operation and design of the product variant lewi R Li and risa R Li

2.4.1 Construction

The hearing system consists of the following elements:

- 1 Receiver module
- 2 Dome / Ear mould
- 3 Conchaclip (optional)
- 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

☞ The dome may differ from that shown in the picture.

⚠ Attention:

Ensure the patient knows how to insert their hearing aids correctly. Paying special attention to the fit of the Conchaclip.

2.4.2 Energy supply

These hearing aids use a modern, permanently installed lithium-ion battery.

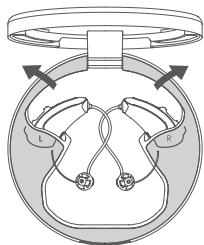
The battery operating time depends on active functions, wireless accessories in use, hearing loss degree, and the environment.

Always switch your hearing aid OFF after use.

If the hearing aids won't be used for an extended period, recharge them within a 3-month interval to avoid deep discharging, which could damage the battery.

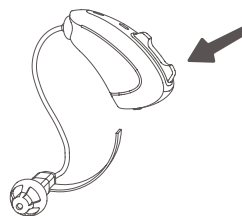
2.4.3 Switching the hearing aid ON and OFF

lewi R Li and risa R Li are switched ON and OFF using the lower button of the multifunction rocker switch.




Switching on

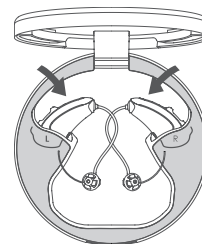
After charging, remove the hearing aid from the power case.



Briefly press the lower button of the multifunction rocker switch. Your hearing aid is now switched ON.

After a preset delay time and start melody, the first hearing programme is activated. The hearing system is ready for operation.

 The hearing aid will switch on after a 3-second delay (can be extended up to 9 seconds).



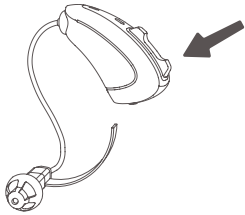
Switching OFF using the power case

Place the hearing aids in the designated recesses in the power case. When the hearing aid is inserted into the power case, it is magnetically drawn into position. At the same time, the hearing aid switches off automatically.

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

 Please note that the power case must either be connected to the power supply or the lithium-ion battery is charged.

☞ The power case's LED display will show the battery status when the lid is opened. For more information about the LED display, refer to the power case and power base user manual.



Switching off using the multi-function rocker switch

Press and hold the lower button until the high pitch audible tone ceases (approximately 3-5 seconds).

The hearing aid will switch OFF.

☞ If the hearing aids won't be used for an extended period, recharge them within a 3-month interval to avoid deep discharging, which could damage the battery.

2.4.4 Battery warning tone

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

This means that the hearing systems are no longer connected to the smartphone and that no audio signal can be streamed.

2.4.5 Charging the battery

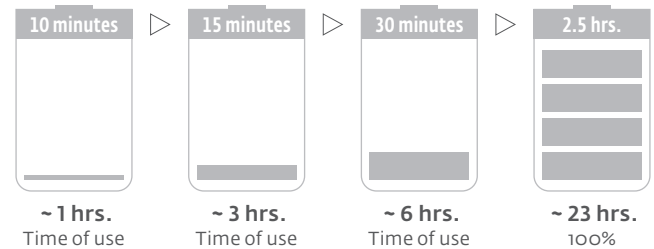
lewi R Li and risa R Li automatically switch OFF when inserted into the power case. A complete charging cycle takes up to 3 hours.

To ensure reliable use the next day, charge the hearing aids during your rest period.

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

2.4.6 Battery charge status

Overview of charging times:



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

2.5 Compatibility of the product variants

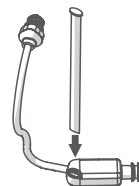
	sino R kami R rega R	risa R lewi R	risa R Li lewi R Li	sueno pro R
HE-S	X	X	X	X
HE-M	X	X	X	—
HE-P	X	X	X	—
Domes	X	X	X	X
Conchaclip	X	X	X	X
Cerustop filter	X	X	X	X
easyfit R	X	X	X	X

2.6 Selecting the length of the receiver unit



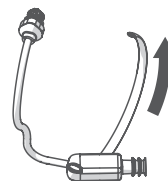
- Place the ear measuring template on the ear as indicated.
- To determine the correct length, place the template on the ear and read the highest point of the ear canal opening. If the measurement falls between two numbers, choose the shorter length to prevent the tube protruding.
- Lengths 0 to 3 refer to the lengths of the receiver units.

2.6.1 Fitting and adjusting the Conchaclip

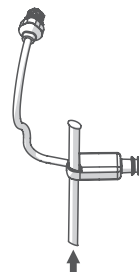


If the receiver unit is used with a dome instead of an earmould, we recommend using the Conchaclip.

This optimises the hold of the receiver unit in the ear.



The decision to use it is dependent on the shape of the patient's ear.



Insertion:

Insert and slightly bend the Conchaclip into the designated area.

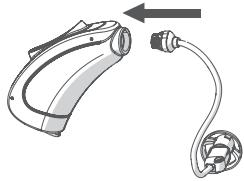
Removal:

Remove the Conchaclip from the receiver unit.

The receiver unit must always be affixed with a matching dome or an ear mould into the patient's ear. Make sure that they are securely connected to the receiver unit.

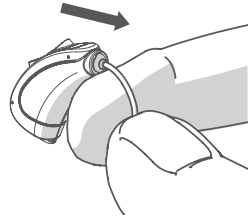
2.6.2 Assembling the receiver unit

Since in some product variants the colour side marking is only on the receiver units, there is a risk of confusion. The mounting or changing of a receiver unit should be performed by audiologists to avoid any risk of confusion or improper handling.



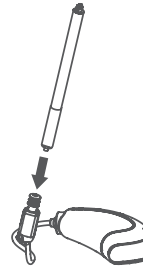
Select a receiver unit suitable for the ear size and click it into place in the RITE housing.

2.6.3 Removing the receiver module

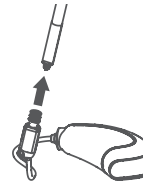


Hold the receiver unit cable between your fingers and carefully pull it out of the housing.

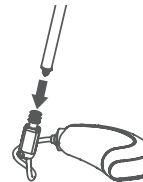
2.7 Replacing the CeruStop filter



The receiver units have a CeruStop filter, which protects the receiver becoming blocked. The CeruStop filter should be changed at regular intervals.



For this, use the application pin, which contains a new filter. Insert the side with the hook into the old filter. Using a twisting motion, gently pull the old filter out.

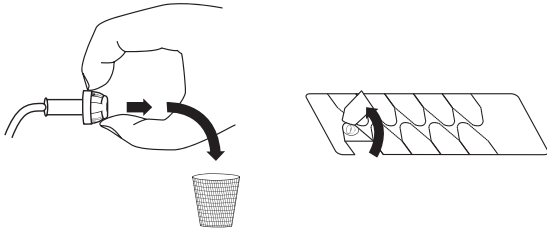


Using the end of the applicator pin with the new filter, insert it into the receiver unit.

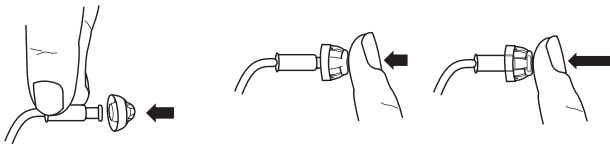
2.8 Replacing the dome

The domes are replaceable and can be easily changed when required.

- Hold the lower end of the dome with your fingernail. Remove the dome.
- Place a new dome on the receiver, ensuring it is securely attached.
- Dispose of the old dome.



The dome is made of soft, medically tested silicone material and must be replaced regularly depending on the frequency of use. We recommend that you replace it at least once a month.



☞ Use the receiver unit only with the securely attached dome / ear mould!

2.9 Ear moulds for receiver units

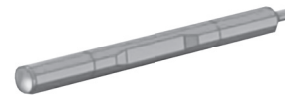
2.9.1 Suitable ear moulds

An ear mould is an individually made ear adapter. On a receiver unit this can be used instead of a dome.

The following table shows which materials can be used for the ear mould, depending on the choice of receiver unit:

Receiver module	Material for suitable ear mould
S	Silicone Shore A hardness 60 or Dreve FotoTec SL E
M	Silicone Shore A hardness 60 or Dreve FotoTec SL E
P	Silicone Shore A hardness 60

The contour of the ear mould contour must be specified by audifon to ensure a secure connection with the receiver unit. It's crucial to consult with your contact person at audifon Sales for detailed information on the manufacturing process.



To release the receiver unit from the ear mould or easyfit R, we recommend the use of an audifon universal tool.

This tool allows you to slide the thin end against the CeruStop filter to push the receiver out of the ear mould.

The ear mould must be arranged to allow the CeruStop filter to be changed without removing the ear mould. The ear mould should not be unplugged and plugged in again more frequently than once every two months to maintain the stability of the connector.

Only an audiologist should disconnect the ear mould or easyfit R from the receiver unit.

⚠ Warning: Risk of injury!

The receiver unit should be used only with a UniTip dome or a custom-made ear mould.

3 BTE HEARING SYSTEM (a10)

3.1 Type

These hearing aids mentioned are behind-the-ear (BTE) types. The connection between the hearing aid and the ear can be made using either an ear mould or a ThinTube variant.

3.2 Technical features

These instructions for use apply to the following variants:

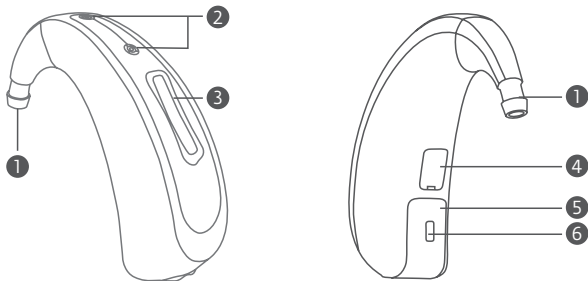
Model	Battery		Gain in dB	Indication range
	Size	Average service life (zinc air) in h		
sino S	312	100	66	minor to moderate loss of hearing
kami S	10	100	66	
rega S	10	100	66	
sino P	13	140	71	minor to profound loss of hearing verging on deafness
kami P	13	140	71	
rega P	13	140	71	
sino XS	10	60	61	minor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

Model	Battery		Gain in dB (peak value)	Indication range
	Size	Average service life (zinc air) in h		
lewi S	13	100	67	minor to severe loss of hearing
risa S	13	100	67	mild to severe hearing loss

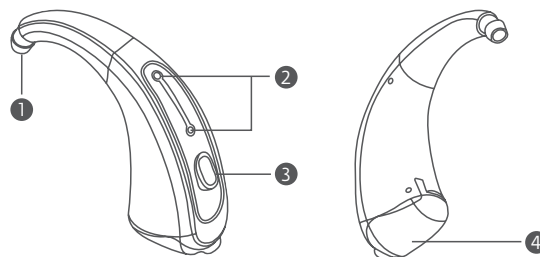
3.3 Operation and structure of the product variants rega, kami, sino P/S/XS

3.3.1 Construction

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



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



All models are available universally with ear mould or optionally with ThinTube.

3.3.2 Start-up

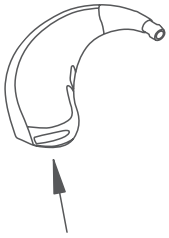
To start these hearing aids, please first insert a battery into the battery compartment. Use only zinc-air batteries specifically recommended for these hearing aids.

Follow the instructions on the battery packaging. The exact battery type is listed in the overview table in chapter 3.2 of the manual.

These hearing aids should always be switched off after use.

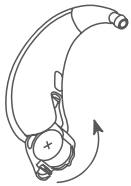
To avoid damage, remove the battery if the hearing aid will not be used for an extended period.

3.3.3 Inserting battery



Push the battery compartment up until it clicks into the first latch position (OFF position).

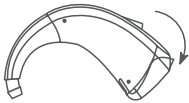
This should allow you to open it fully.



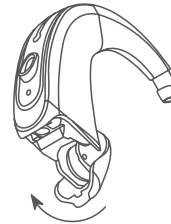
Then insert the battery into the battery compartment.

Ensure that the (+) symbol on the battery is aligned with the (+) symbol on the compartment.

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



Open the compartment carefully with your fingernail at the edge, and swing it fully open.



Then insert the battery into the battery compartment.

Make sure the (+) symbol on the battery is aligned with the (+) on the battery compartment.

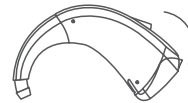
Please do not open the battery compartment any wider than shown here. This might damage the device.

3.3.4 Removing battery



Push the battery compartment up until it clicks into the first latch position (OFF position). This should allow you to open it fully.

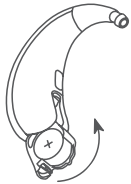
Then remove the battery from the battery compartment.



Open the compartment carefully with your fingernail at the edge, and swing it fully open.

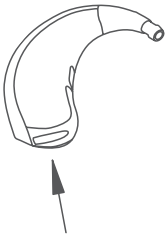
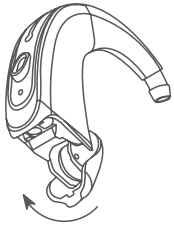
Then remove the battery from the battery compartment.

3.3.5 Switching on & off



Switching on

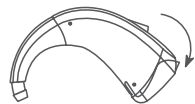
Fully close the battery compartment, allowing it to click into place. This action switches the hearing aids on, and after a brief delay and start-up melody, the first program will activate.



Switching off

To turn the hearing aid off, press the battery compartment out to the first latch position.

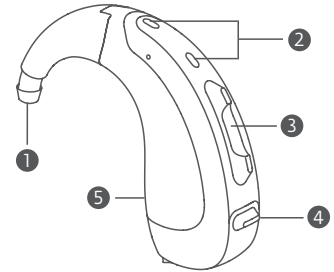
This is the OFF position.



3.4 Operation & design of the product type lewi S/ risa S

3.4.1 Construction

- 1 Ear hook
- 2 Microphone inlets
- 3 Multifunction rocker switch
- 4 Battery compartment
- 5 Model identification



3.4.2 Start-up

To start these hearing aids, please first insert a battery into the battery compartment. Make sure you use only zinc air batteries.

Follow the instructions on the battery packaging. The specific battery type for these hearing systems can be found in the overview table in chapter 3.2.

These hearing aids should always be switched off after use. To avoid damage, remove the battery if the hearing aid will not be used for an extended period.

3.4.3 Battery warning signal

An audible tone will indicate the end of the battery life approximately 30 minutes before the battery is completely depleted.

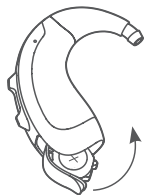
At the end of battery life, the hearing aid's wireless function will turn off.

If desired, the audible tone can be deactivated via audifit, but patients should be informed of the potential risks if this is disabled.

3.4.4 Inserting battery



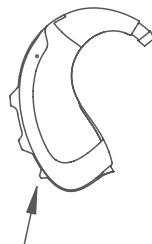
Open the battery compartment carefully with your fingernail at the opening edge or press the ON/OFF switch on the battery compartment until it springs up, then swing it right out.



Then insert the battery into the battery compartment.

Make sure the (+) symbol on the battery is aligned with the (+) on the battery compartment.

3.4.5 Removing battery



Open the battery compartment carefully with your fingernail at the opening edge or press the ON/OFF switch on the battery compartment until it springs up, then swing it right out.

Then remove the battery from the battery compartment.

3.4.6 Switching on and off

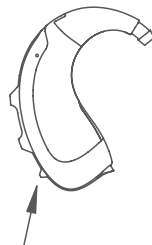


Switching on

With the battery inserted, close the compartment by moving it past the latch from the OFF position into the casing.

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

The hearing aids will switch on, and after a short delay and a start-up jingle, they will be ready to use.



Switching off

To turn off the hearing aid, press the battery compartment out to the first latching position.

This is the OFF position.

3.5 Compatibility of the product variants

- rega/ kami/ sino (S/P/XS) = Easy ThinTube
- lewi/ risa S = UniTip ThinTube

3.6 UniTip ThinTube and Easy ThinTube/ Easy ThinTube 2

3.6.1 Intended use

ThinTubes are accessories for audifon BTE hearing aids and tinnitus instruments. They are used for sound transmission and come with preassembled couplings for hearing aids and domes.

3.6.2 ThinTubes selection and length



- Place the ear measuring template on the ear as indicated.
- To determine the correct length, place the template on the ear and read the highest point of the ear canal opening. If the measurement falls between two numbers, choose the shorter length to prevent the tube protruding.
- Lengths -1 to 3 refer to the lengths of the UniTip ThinTubes.

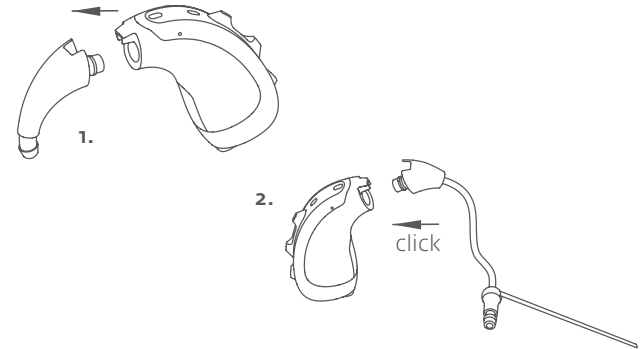
UniTip ThinTube = 0 - 3

**Easy ThinTube/
Easy ThinTube 2 = -1 - 3**

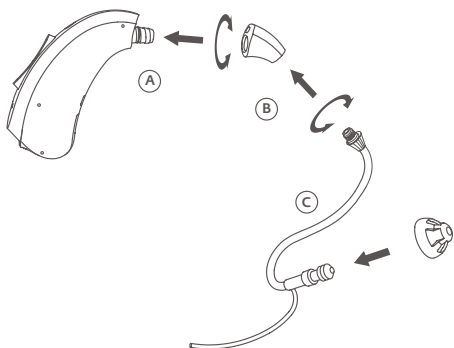
3.6.3 Connecting the ThinTube

UniTip ThinTube

A = Remove the ear hook by pulling it
B = Install the UniTip ThinTube



Easy ThinTube / Easy ThinTube 2



A = Rotate

B = Rotate

C = Attaching the dome

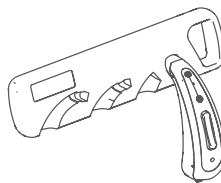
 Use the ThinTube only with properly attached domes!

Attention:

Ensure the patient knows how to insert their hearing aids correctly. Paying special attention to the fit of the Conchaclip.

3.6.4 Using the ear hook tool

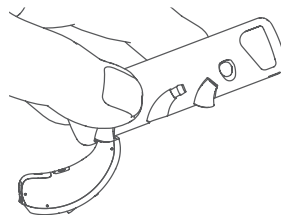
The ear hook tool is used to mount or remove the OpenFit adapter or ear hook on Cosma BTE devices.



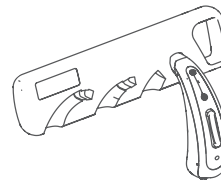
1. Insert the hearing aid with the ear hook into the appropriately sized opening of the tool.



2. Turn the hearing aid 180° within the tool.



3. Insert the hearing aid into the appropriate recess in the tool to remove the ear hook.



4. To attach a new ear hook or OpenFit adapter, use the corresponding recess in the tool and ensure it fits securely.

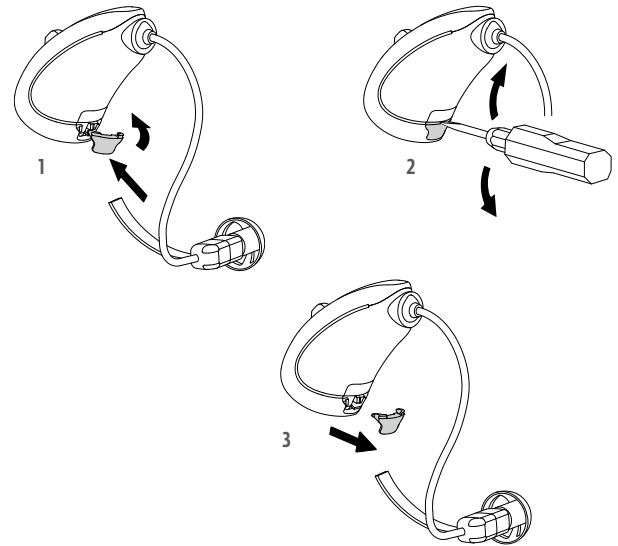
3.6.5 Replacing the dome

The domes are replaceable and can be easily changed when required.

- Hold the lower end of the dome with your fingernail, and pull the dome off.
- Then place the new dome onto the receiver. Ensure it is pushed far enough on to the ThinTube to be securely attached.
- Savelly dispose of the old dome.

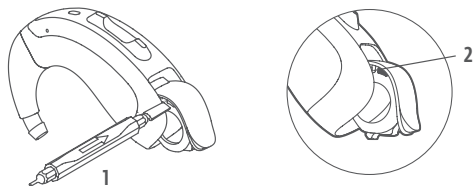
4 SIDE MARKER/BATTERY COMPARTMENT LOCK

4.1 Side marker for Wings R Li hearing aids



1. Insert the side marker slightly obliquely and press until it snaps into place.
2. Insert a small screwdriver below the serial number plate to gently remove the side marker.
3. The side marker can now be removed.

4.2 Side marker for Wings S device

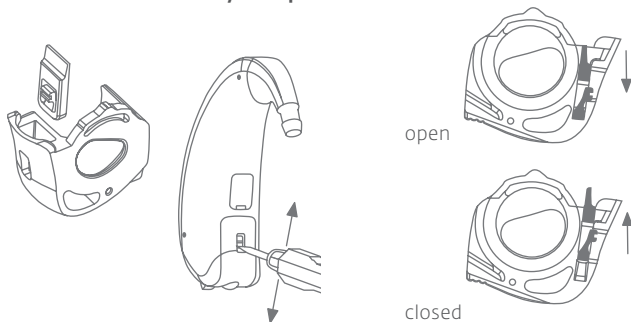


1. Inserting the side marker.
2. Insert the side marker and then close the battery door.

4.3 Side marker, battery compartment lock and microphone filter replacement for Cosma S & P BTE devices

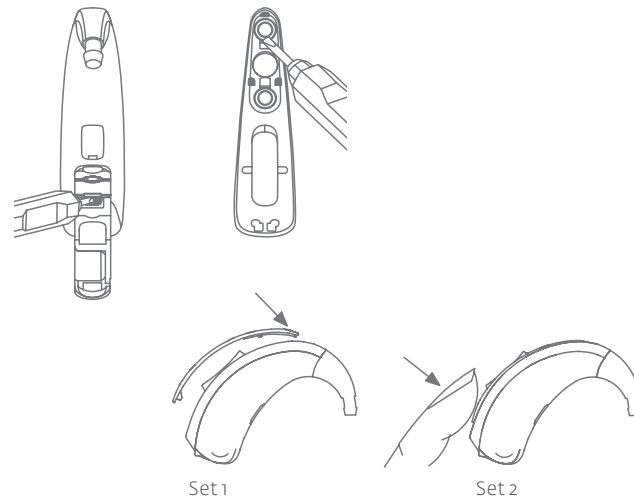
Apply appropriate side markers (blue/red) if using two Cosma family hearing aids with different settings to avoid confusion.

Side marker / battery compartment lock



Changing the microphone filter

 Recommended to change every 3-6 months.

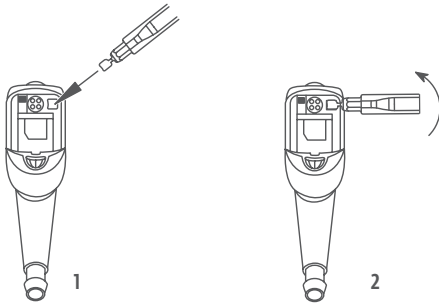


4.4 Side marker and battery compartment lock for Cosma Family XS

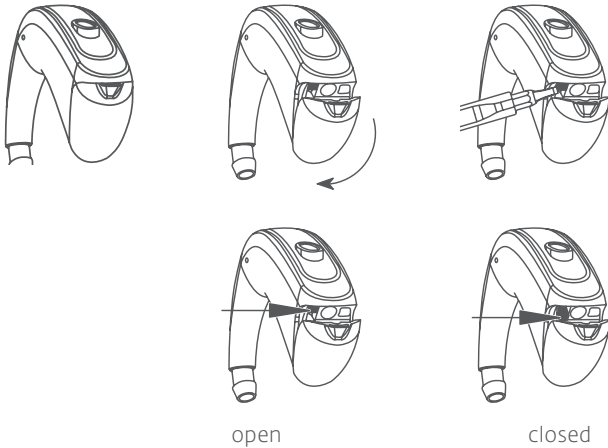
Side marking

1. Inserting the side marker.
2. Insert the side marker and then close the battery door.

Side marking



Battery compartment lock



5 ITE HEARING SYSTEMS (a30)

5.1 Type

These hearing aids are in-ear hearing aids.

5.2 ITE Technical Features

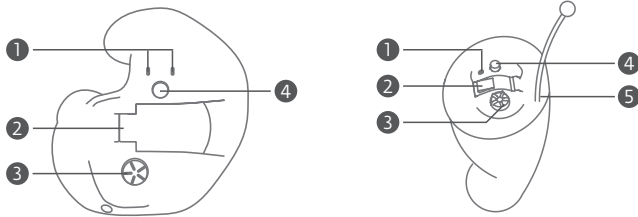
These instructions for use apply to the following variants:

Model	Battery		Gain in dB	Indication range
	Size	Average service life (zinc air) in h		
rega pico	10	60	41	minor to moderate loss of hearing
rega CIC	10	60	50	
kami CIC	10	60	50	
sino CIC	10	60	50	
rega ITE V50	312/13	110/180	50	minor to moderate loss of hearing
kami ITE V50	312/13	110/180	50	
sino ITE V50	312/13	110/180	50	
rega ITE V60	312/13	110/170	61	minor to severe loss of hearing
kami ITE V60	312/13	110/170	61	
sino ITE V60	312/13	110/170	61	
rega ITE V70	312/13	90/160	70	moderate to severe loss of hearing
kami ITE V70	312/13	90/160	70	
sino ITE V70	312/13	90/160	70	

5.3 Operation and design of product variants sino, kami, rega

The hearing aid consists of the following elements:

- 1 Microphone inlets
- 2 Battery compartment
- 3 Volume controller*
- 4 Program switch*
- 5 Drawstring*



The hearing aid components may differ from the illustrations due to customisation to suit customer-specific ear impressions. Depending on the type, the elements marked with asterisks* may be absent from that hearing aid.

Depending on the model, the hearing aids have side markings:

blue = left
red = right

5.4 Start-up

First, insert a battery into the battery compartment. Use zinc-air batteries only.

Follow the instructions on the battery packaging. The specific battery type can be found in the overview table in chapter 5.2.

These hearing aids should always be switched off after use.

To avoid damage, remove the battery if the hearing aid will not be used for an extended period.

5.5 Inserting battery



Open the compartment carefully with your fingernail at the edge, and swing it fully open.



Then remove the battery from the battery compartment.

5.6 Battery end of life signal

An audible tone will signal the end of battery life approximately 30 minutes in advance.

This can be deactivated via audifit.

Please inform your patient about any risks associated with this.

5.7 Removing battery

Open the compartment carefully with your fingernail at the edge, and swing it fully open. Then remove the battery from the battery compartment.

5.8 Switching on and off

These hearing aids are switched on and off via the battery compartment. They are switched on as soon as the battery compartment is closed. After a preset delay and a start-up jingle, the first program will activate and the hearing aids are ready for use.

The hearing aids are switched off as soon as the battery compartment is opened.

Fully open the battery compartment and remove the battery if the hearing aids will be unused for a long period.

5.9 Replacing the CeruStop filter

The receiver units have a CeruStop filter, which protects the receiver against becoming blocked. The CeruStop filter should be changed at regular intervals.



For this, use the application pin, which contains a new filter. Insert the side with the hook into the old filter. Using a twisting motion, gently pull the old filter out.

Rotate the pin so the new filter is at the bottom.

Press it into the opening until it clicks in place, then remove and discard the pin.

6 APPLICATION OF THE FITTING-SOFTWARE AND PROGRAMMING

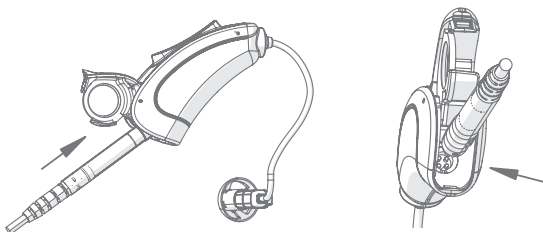
audifon fitting software is used to configure and set audifon hearing aids and noisers.

In the fitting software you will find step-by-step guidance on how to configure and program audifon hearing aids. Information on selecting the correct programming cable for your specific hearing aid model. Detailed specifications and information relevant to the particular hearing aid model you're working with.

6.1 Selecting the Programming Cable

Use the audifon Cable Guide to select the right cables. Select the corresponding cable set from the options listed.

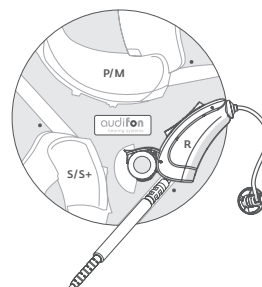
6.2 Connecting the Programming Adapter and using the Programming Aid



When connecting the programming adapter, make sure to hold the adapter slightly obliquely.

Align the red dot on the adapter with the red mark on the hearing aid.

The audifon programming tool offers an alternative method for connecting the audifon programming cable to audifon hearing aids. Note the design: S/S+, M/P and R. (not applicable to the WINGS family).



Open battery door and place the hearing aid in the recess that matches the shape of the housing. Hold it by hand if needed.

Insert the audifon programming cable and align the red mark on the programming tool with the red mark on the hearing aid.

Ensure both marks face outwards. Take out the hearing aid along with the inserted programming cable from the programming aid.

6.3 Wings platform firmware update

The Wings chip platform supports firmware updates. Within the fitting software, these hearing aids can be checked and if necessary updated with a firmware update.

The Wings platform supports firmware updates, which can be done using the fitting software and a HIPRO 2 connected to a programming cable (see 6.2) For this purpose, the "Firmware Update" function can be started from the menu bar → Setting → WINGS Device Update within the fitting software. This update function should not be used during a fitting session!

☞ If you are already in a fitting session, please exit it. Restart the software if necessary.

Avoid any interruption to the update! Otherwise, the device may not be initialised correctly and thus not recognised correctly in the fitting software.

Attention:

Do not perform the update whilst the hearing aid is in the patient's ear. Once the firmware is successfully updated, close the update screen. Continue with hearing aid fitting.

7 INFORMATION ON WINGS

The Wings chip supports Bluetooth and 2.4 GHz radio frequencies, allowing for advanced wireless capabilities.

7.1 Features

The Wings hearing system can connect to MFi (Made for iPhone) devices for wireless streaming, media playback, and phone calls directly to the hearing aids.

The audifon App allows users to adjust the microphone input settings to reduce background noise and optimise sound quality from media sources.

7.2 Binaural synchronisation

The Scene Detect Function automatically detects different sound environments and synchronises settings between both hearing aids to ensure optimal hearing comfort. to achieve optimum hearing comfort: Adaptive and automatic.

Binaural synchronisation can be used for the following settings:

- Synchronisation of hearing device settings
- Directionality of microphones
- TRT module with different sound wave settings

7.3 easyclick

Facilitates wireless control of settings such as volume and memory programs between both hearing aids. easyclick automatically transmits settings made using the switch rocker of one hearing aid to the other.

Ensuring both hearing aids retain the same settings.

7.4 Volume control and program selection

7.4.1 Automatic side adjustment of hearing aids

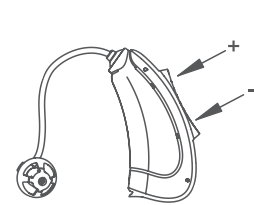
If a patient is using two hearing aids of the same type, they synchronise automatically as a pair.

After pairing, any setting adjustments on one hearing aid are automatically applied to the other. Recognition tones and melodies play with a slight delay in both hearing aids to indicate changes.

If the connection between the devices is lost, they will automatically attempt to reconnect.

If unsuccessful, both hearing aids should be restarted.

7.4.2 Multifunctional rocker switch



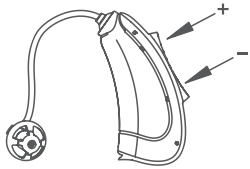
Wings hearing systems feature a multifunction rocker for volume control and the choice between the various programs.

The multifunction rocker switch can be pressed and activated on the upper (+) and lower (-) ends.

- Volume control**
To adjust the volume, briefly press the upper or lower end of the rocker switch.
- Program selector switch**
To change the program, briefly press the upper or lower end of the rocker switch.
- Volume control and program selector switch combined**
To adjust the volume, briefly press the upper or lower end of the switch; to change the program, press and hold the switch for about 1 second.


7.4.3 Volume selection

The volume can be adjusted step by step using the multifunction rocker switch. Brief pressure at the upper end increases the volume, while brief pressure at the lower end decreases the volume.



When switched on, the Wings hearing aids resumes at the pre-programmed volume setting. You can now increase or decrease the volume in steps. Each time the volume is adjusted, you will hear an audible confirmation.

When the maximum or minimum volume is reached, a clear signal sounds.

 Volume control and program selection are optional functions. You can customise the settings for your patients.

7.4.4 Selecting hearing programs

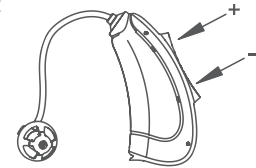
Multifunction rocker switch


Allows you to switch between the hearing programs set via the audifit software.

Hold down one end of the multifunction rocker switch until you hear a confirmation tone. Release the switch; the recognition jingle of the selected program will play. The number of tones corresponds to the number of the selected program.

You can move up or down through different hearing situations by pressing the switch in either direction.

Program change sequence*:



 Volume control and program selection are optional functions.


8 NOISE GENERATOR MODULE

The integrated noise generator module can be optionally activated to support tinnitus therapy.

8.1 Intended use

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

It is designed to help reduce the perception of tinnitus when used alongside other therapeutic measures.

 Activation of the noise generator module as part of tinnitus therapy is suitable for adults aged 18 years and older.

8.2 Wearing period

The maximum volume of the noise module is within a range that, according to occupational safety regulations, could lead to hearing loss if used improperly. For patients without hearing loss, a maximum sound pressure level of 70 dB SPL (on a 2 cm³ coupler) should not be exceeded.

For patients with hearing loss, the adjustment of the noise module should take into account the respective hearing loss.

The noise generator module should never be used at a volume that is uncomfortable for the patient.

At sound pressure levels up to 80 dB SPL (on the 2 cm³ coupler), the noise generator module can be used up to 8 hours a day.

At higher sound pressure levels, the safe wearing duration is reduced accordingly. The noise generator module should then not be used more than 2 hours a day.

Warning: Damage to hearing!

According to OSHA regulations, exposure to sound pressure levels (SPL) above certain thresholds for extended periods can cause hearing damage.

The tinnitus instrument should not be used for more than eight (8) hours at a sound pressure level (SPL) of less than 90 dB SPL.

At a higher sound pressure limit usage to two (2) hours daily or less.

Never use the tinnitus device at a volume that feels uncomfortable or painful.

9 WIRELESS FUNCTIONALITY / BLUETOOTH CONNECTIVITY

The Wings family hearing aids are compatible with most smartphones that have Bluetooth 4.0 capability or higher. For some devices you may need the multistreamer pro accessory for audio transmission.

Hearing aids from the lewi and risa families, as well as the audifon app, are compatible with a range of smartphones and tablets. A full list of compatible devices can be found at www.audifon.com.

The audifon app is available for free download on the relevant platforms.

For specific steps on pairing the hearing aids with iOS or Android devices, refer to the Instructions for Use.

 To reconnect your hearing aids to the fitting software, you must first disconnect the Bluetooth connection with your smartphone.

9.1 Using hearing aids with the multistreamer pro

The multistreamer pro enhances the functionality of the Wings hearing aids by allowing seamless streaming of external audio sources.

Thanks to Bluetooth technology, the multistreamer pro enables convenient streaming of external audio sources directly into the Wings hearing aids:

- Clearer TV audio for an enhanced viewing experience

- Improved enjoyment with relaxed and clear music and audiobook
- Easier communication at conferences or similar settings
- Hands-free so you can answer calls directly through your hearing aids

9.1.1 Pairing the hearing systems with the multistreamer pro

Switch on the multistreamer pro. Turn the hearing aids on within 180 seconds. The multistreamer pro should connect to the hearing aids automatically.

9.1.2 Pairing the smartphone with the multistreamer pro

Switch on the multistreamer pro. Press the multifunction button for 5 seconds until the LED turns red and then flashes blue. Update the → Bluetooth menu of the smartphone. Select the multistreamer pro from the list and confirm pairing.

For further details on operating functions, consult the multistreamer pro User Manual.

9.2 Unpairing hearing aids

You can also delete the pairing of the Wings hearing aids with the smartphone and the multistreamer pro.

This may be necessary if the hearing aids are paired to a new accessory.

To do this, proceed as follows:

1. Turn on the hearing aids.
2. Press the multifunction rocker switch down for 5 seconds. A jingle will play, confirming that the pairing has been deleted.
3. Now also delete the pairing in the smartphone menu.
4. By switching the hearing aids off once and then on again, the pairing can be re-established within 180 seconds.

10 COMPATIBILITY

The multistreamer pro is compatible with all popular smartphones and MP3 players with Bluetooth Classic version 4.0 or higher.

A list of smartphones, tablets, etc. compatible with the hearing aids of the lewi and risa families and the audifon app can be found at: **www.audifon.com**

In rare cases, electromagnetic fields or electrostatic discharges may affect the function. The multistreamer pro then interrupts the transmission and goes into a safety sleep state.

In this case, switch on the multistreamer pro again and restart the transfer, e.g. by pressing the "Play" function again.

11 FLIGHT MODE WINGS HEARING SYSTEMS

When entering areas where radio signals are prohibited, such as on an aeroplane, you should turn off the wireless functions of the hearing aids.



To activate Flight Mode, press the multifunction rocker upwards for 5 seconds. All wireless functions of the hearing aids will be turned off.

To deactivate Flight Mode, turn the hearing aids off and then back on.

Flight Mode must be activated separately on each hearing aid.

12 ACCESSORIES / OPTIONAL ACCESSORIES / COMPONENTS / CONSUMABLES

(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)	multistreamer pro	Audio streamer to expand the hearing system functions	*
(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.	**
(A)	UniTip Thin Tube	Thin tube for Wings BTE hearing aids	**
(A)	Thin Tube SF2C	Thin tube for Cosma BTE hearing aids	*
(A)	Dome SF3	Universal earmoulds for use with the Thin Tube SF2C	**
(Com)/ (Con)	Conchaclip	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)	Universal tool	Universal tool for audifon hearing aids	-

CE marking: * CE / ** CE0297

13 TROUBLESHOOTING

If malfunctions occur, perform these checks before assuming the hearing aids are faulty.

- Ensure the hearing aid is switched on.
- Verify that the batteries are not weak or dead.
- Check if the volume control is set too low >>> increase it if necessary.
- Make sure the correct program is set; change the program if needed.
- Inspect the receiver unit or earwax protection system for blockage.

For additional troubleshooting, refer to the specific instructions provided with your hearing aid.

14 SAFETY INFORMATION

14.1 Important warnings

- ⓘ **Note: Patient Age**
Behind-the-ear hearing aids are not suitable for children under 36 months. A physician, preferably an ear, nose, and throat (ENT) specialist, should be consulted before minors start to use hearing aids. This ensures proper care and prevents potential worsening of hearing impairment. The doctor should decide if it is appropriate to wear a hearing aid.

Cooperation with the treating doctor is essential due to the lack of clinical data on minors.

- ⓘ **Note: Compatibility**
Avoid using unspecified combinations of audifon hearing aids, receiver units, or domes with products from other manufacturers, as these combinations have not been tested or evaluated and may pose unacceptable risks.

- ⓘ **Note: Damage to hearing**
Hearing aids are programmed to each patient's specific hearing loss and should be worn only by that patient.

If the hearing aids suddenly becomes quieter or louder, the patient should consult their audiologist immediately. Hearing aids must not be shared with others due to:

- Customisation to the individual user
- Risk of infection from germs
- Consumables, e.g. domes, are individually matched

ⓘ **Note: Damage to the hearing system**

Hearing aids are sensitive to impact. Avoid dropping them or exposing them to hard knocks.

Before inserting the hearing aid, perform a visual inspection for any signs of damage.

If damage is detected, consult an audiologist immediately.

Do not wear hearing aids during:

- Swimming, showering, or bathing and sauna sessions
- Washing or blow-drying the hair
- When using hair spray, perfume, aftershave or body lotion
- Treatment using radiofrequency heat therapy.

If the hearing aid becomes damp: Remove the battery immediately. Dry it using a drying device or container specified by the manufacturer.

Do not dry hearing aids in a microwave, oven, or similar equipment.

Avoid leaving hearing aids in direct sunlight, near an open flame, or in a hot vehicle, as this may cause damage.

Taking these precautions will help maintain the functionality and longevity of your hearing aids.

ⓘ **Note: Modifications to the hearing aid**

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

ⓘ **Note: Asphyxia hazard**

Batteries, hearing systems, and small parts (like magnets) can be swallowed, and pose a choking hazard. These items should be kept out of reach of children under 36 months, individuals with mental or physical disabilities, and pets. If such items are swallowed, consult a doctor immediately.

ⓘ **Note: Risk of injury**

Domes may occasionally remain in the ear canal when removing the hearing aid. If this happens, contact a physician immediately; do not attempt to remove the dome yourself.

Use only original consumables specified by the manufacturer (e.g., domes, filters) and authorised accessories (e.g., receiver units). Unauthorised changes or modifications to hearing aids that have not been explicitly approved by the manufacturer can lead to serious consequences, including potential injury.

Ear adapters (domes, ear moulds) should always be used with sound tubes, ThinTubes, or receiver units, ensuring they are firmly attached to avoid injury or device malfunction.

ⓘ **Note: Risk of explosion**

Hearing aids should not be used in environments where there is a risk of explosion, such as mining sites or industrial areas with explosive materials.

ⓘ **Note: Risk of infection**

Hearing aids and accessories are single-use products. If reused, the audiologist is responsible for implementing measures to prevent transmission of infection.

- ⓘ **Note: Electric shock**
Audio devices connected to mains power should comply with IEC 60065, IEC 60601, or similar safety standards to ensure safe use with hearing aids.
- ⓘ **Note: Interference with active implants**
Wearers of active implants (like pacemakers or defibrillators) should follow the implant manufacturer's instructions to prevent interference.
- ⓘ **Note: Interference with electronic devices**
In areas where electronic or wireless devices are restricted, check whether the wireless connection (e.g., Bluetooth) on the hearing aid has to be turned off.
- ⓘ **Note: Damage due to deep discharge**
Recharge your hearing aids at least every 3 months if they are not in use to prevent battery damage from deep discharging.
- ⓘ **Note: Reporting of serious incidents**
Any serious incidents involving the hearing aid should be reported to the manufacturer and relevant authorities in the user's country.
- ⓘ **Note: Radio communications in rooms**
Before connecting hearing aids to any radio communication device, check if the use of radio communications is restricted.

- ⓘ **Note: Malfunctions**
Despite being designed for EMC compatibility, hearing aids may experience interference from other electrical devices; if so, move away from the source of interference.
- ⓘ **Note: Risk of injury during CT & MRI scans**
Advise patients to remove hearing aids during CT or MRI scans, other magnetic field-based scans, or radiotherapy, and to inform healthcare professionals about the device.
- ⓘ **Note: About the battery**
audifon rechargeable hearing aids use a lithium-ion battery. The power case contains a lithium polymer battery. Check with airlines before air travel to confirm if these batteries can be brought on board.
- ⓘ **Note: About charging**
Dry the hearing aid with a dry cloth before charging. Insert the hearing aid correctly into the power charging case. Avoid the application of pressure.

Avoid charging the hearing aid in humid environments such as in the bath or where there is condensation. Do not charge the hearing aid if it is damaged.
- ⓘ **Note: Switching off**
Improper switching off of the hearing aid may make it difficult to turn it on again.

- ⓘ **Note: Interaction with magnetic fields**
Magnetic fields can cause damage and injury.

Since battery hearing aids contain a magnet:

- Avoid placing strong magnets near hearing aids or placing hearing aids directly on bank cards or similar items to prevent damage.

- ⓘ **Note: Side marking**
Always use side markers on the hearing aid to distinguish between the left and right devices.

15 SAFETY INFORMATION

15.1 Side effects

Advise patients to see a doctor immediately if they experience any of the following side effects:

- Sensation of a foreign body in the ear
- Build-up of cerumen (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

15.2 Contraindications

Hearing aids should not be used if:

- Hearing loss due to central hearing disorders
- The size and shape of the ear canal are insufficient

- Deformity of the ear canal that prevents easy insertion and removal of the hearing aids
- There are impairments to the outer ear and/or ear canal, such as chronic inflammation or skin irritation; cholesteatoma
- The patient has allergies to materials in contact with the skin

Make your patients aware of the following:

- Patients unable to operate their hearing aids independently need competent assistance.
- The use of hearing aids by mentally impaired persons and children should be recommended only by a physician.

Conduct a comprehensive risk analysis for each individual case.

Close supervision by a caregiver is recommended to ensure correct use and to prevent accidental ingestion of hearing aids or parts.

16 OPERATING CONDITIONS

- Relative humidity between 10% and 90%
- Operating and charging temperature between 0 °C and 40 °C
- Air pressure between 500 hPa and 1100 hPa
- Battery performance can be reduced in a cold environment

17 CHARGING CONDITIONS

- Ambient temperature between 0 °C and 40 °C

18 TRANSPORT AND STORAGE CONDITIONS

- Relative humidity between 10% and 95%
- Storage temperature of battery-powered devices: between -20 °C and +60 °C
- Storage temperature of battery devices: between -20 °C and +45 °C
- Store devices away from magnetic fields
- Shelf life of the products at least 2 years from the date of manufacture

19 ENVIRONMENTALLY COMPATIBLE DISPOSAL

Follow local regulations for the disposal of devices, batteries, and rechargeable batteries.

- Comply with Directive 2012/19/EU on waste electrical and electronic equipment.



20 OTHER INFORMATION

Tell your patient:

- Regular care and maintenance of the hearing system are essential for optimal performance.
- Ensure there is no risk of confusion between different hearing systems, accessories, components, and consumables in the household.
- Check patients' hearing aids quarterly
- Provide appropriate instructions for use, a completed warranty card, and any necessary information.



*) The products mentioned have undergone separate Conformity assessments to ensure that they comply with the required European Union (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).

21 KEY TO SYMBOLS



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 DD-MM-YYYY 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.



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 item number so that the medical device can be identified.



Unique product identification

The specified number is stored in EUDAMED.



Serial number

Indicates 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 indicates the identification of 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.

audifon



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Made in Germany