danalogic GN

danalogic Ambio

User guide

Receiver-In-Ear hearing aids



GN Making Life Sound Better

Left Hearing Aid		Right Hearing Aid		
Serial number		Serial number		
Model		Model		
Receiver type	Medium PowerHigh PowerUltra Power	Receiver type	Medium PowerHigh PowerUltra Power	
Receiver tube length	□ 0 □ 1 □ 2 □ 3 □ 4			
Battery size	312 13			

Open/	🗆 Small	🗆 Tulip	🗆 Small	🗆 Earmould
standard	🗆 Medium		🗆 Medium	
fitting:	🗆 Large		🗆 Large	
	Open dome		Power dome	

Specific features supported by your hearing system:

Smart Start on page 11	
Telecoil on page 18	
Phone Now on page 20	
Direct Audio Input on page 22	
Tinnitus Sound Generator on page 34	

Hearing aid type designations for models included in this user guide are:

BRIE, FOC ID: X26BRIE, IC: 6941C-BRIE VE312, FCC ID: X26VE312, IC: 6941C-VE312

Please see page 52 for a list of models referring to these types.

1 Introduction

Congratulations on the purchase of your new hearing aids. The innovative sound technology and design, combined with the customized programming selected by your hearing care professional, will make hearing a more enjoyable experience.

Please read this manual carefully in order to wholly benefit from the use of your hearing aids. With proper care, maintenance, and usage, your hearing aids will aid you in better communication for many years. Ask your hearing care professional if you have any questions.

2 Intended use

Generic air-conduction hearing aids are wearable sound-amplifying devices intended to compensate for impaired hearing. The fundamental operating principle of hearing aids is to receive, amplify, and transfer sound to the eardrum of a hearing-impaired person.

3 Becoming accustomed to amplification

While purchasing hearing aids is a major step, it is only one step in a process toward more comfortable hearing. Successfully adapting to the amplification of your hearing aids takes time and consistent use. You will enjoy more benefits from your hearing aids by taking the following actions:

- Wear the hearing aids regularly in order to get comfortable with using them
- It takes time to get used to hearing aids. Ask your hearing care professional to design a schedule tailored just for you
- As you get more comfortable with your hearing aids, increase the wearing time and wear them in multiple types of listening environments

It may take as long as several months for your brain to get used to all the "new" sounds around you. Following these suggestions will give your brain time to learn how to interpret amplification and increase the benefits you get from using hearing aids.

4 I Hearing aid expectations

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Consistent use of the hearing aid is recommended. In most cases, infrequent use does not permit you to attain full benefit from it. The use of a hearing aid is only part of hearing rehabilitation and may need to be supplemented by auditory training and instructions in lip-reading.

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6 Get to know your hearing aids

6.1 Your hearing aid

6.1.1 Ambio, model 61 and model 62

- 1. Push button (model 61)
- 2. Battery door and On/Off
- 3. Receiver
- 4. Open dome
- 5. Receiver tube
- 6. Microphones
- 7. Multi button (model 62)
- 8. Manufacturer
- 9. Battery door lock (model 62)
- 10. L/R indicator
- 11. Serial number
- 12. MP receiver tube
- 13. HP receiver tube
- 14. UP receiver tube
- 15. Tulip dome
- 16. Closed dome
- 17. RIE mould

12 0



AM 61-DRW

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6.2 Recognizing left and right hearing aid

If you have two hearing aids, they may be tuned differently. One for your left ear, the other for your right. Do not swap them.

Right





Left

Ambio, model 62.

Colored side indicator: Left is blue and Right is red.

7 Getting started

The hearing aids always start in programme 1 and with the pre-set volume.

7.1 Turn off / Turn on



Turn your hearing aid off.

Turn your hearing aid on.

7.1.1 Smart Start

Smart Start delays the time before the hearing aid turns on after you close the battery door. With Smart Start, you will hear a beep (JJJJetc.) for each second of the delay period (5 or 10 seconds delay).

NOTE: If you want to turn on the hearing aids without delay, ask your hearing care professional to de-activate Smart Start.

7.2 Operation of hearing aid

7.2.1 Push button and Multi-function button

If you have a hearing aid with a push button or multi-function button, this will allow you to use up to four different listening programmes, each of them suitable for certain situations.

- 1. Tap the push button to switch between programmes
- You will then hear one or more beeps. The number of beeps indicates which programme you have selected (one beep = programme one, two beeps = programme two, etc.)
- 3. When you turn the hearing aids off and then back on, they always return to the default setting (programme one and pre-set volume).

It should not be necessary to control the volume manually. However, in addition to controlling listening programmes, the multi-function button (62-DRW only) provides you with the ability to adjust the amplification to your liking. The multi-function button is designed to change the volume or listening programmes of the hearing aid, based on different ways it is pressed.



Programme button (61 models only)



Multi-function button (62 models only)

If necessary, your hearing care practitioner can change the default settings for the multi-function button and fill in the following table to indicate the new settings:

Multi-function button action	Default setting	New setting
Short press up	Increase volume	
Short press down	Decrease volume	
Long press up (3 sec.)	Change programme	
Long press down (3 sec.)	Activate streaming	

7.3 Insert/remove hearing aid

For comfort, always turn off your hearing aids before you insert or remove them.

7.3.1 Insert earmould

- 1. Hold the earmould between your thumb and index finger and position its sound outlet in your ear canal
- 2. Slide the earmould all the way into your ear with a gentle, twisting movement
- 3. Turn the top part of the earmould gently backwards and forwards so that it tucks behind the fold of skin above your ear canal
- 4. Move the earmould up and down and gently press it to place it correctly in the ear
- 5. Make sure the hearing aid sits firmly behind the ear





Slide and twist the earmould all the way into the ear canal.

Tuck the earmould behind the fold of skin above the ear canal.

Place the hearing aid firmly behind the ear.

With proper insertion, hearing aids should fit snugly but comfortably.

CAUTION: NEVER ATTEMPT TO MODIFY THE SHAPE OF THE HEARING AID, EARMOULDS, OR TUBING YOURSELF.

NOTE: It may be helpful to pull your ear up and outward with your opposite hand during insertion.



NOTE: By experimenting, you may discover an easier method.

- 7.3.2 Remove earmould
 - 1. Lift the hearing aid from behind the ear
 - 2. Using your thumb and index finger, take hold of the earmould or the removal cord (not the hearing aid or the tubing)
 - 3. Gently, twist and pull the earmould to remove it from the ear

7.3.3 Insert receiver with dome

- 1. Hang the hearing aid over the top of the ear
- 2. Hold the thin tube where it bends and gently place/push the dome into the ear canal
- 3. Push the dome far enough into the ear canal so that the thin tube lies flush with the head (check with a mirror)



CAUTION: NEVER ATTEMPT TO BEND OR MODIFY THE SHAPE OF THE RECEIVER.

NOTE: To avoid whistling, it is important that the tube and the dome fit correctly into your ear. For other possible reasons, check with the Troubleshooting guide.

7.3.4 Remove receiver with dome

- 1. Hold the receiver with your thumb and forefinger and remove it
- 2. For receiver custom earmoulds, grasp the removal string and pull the earmould outward

7.3.5 Sport Lock

If you lead an active life, your hearing aids may come loose. To avoid that, your hearing care professional can attach and adjust a sport lock. To insert a hearing aid with sport lock:

- 1. Insert the hearing aid as usual
- 2. Tuck the sport lock in the concha
- **NOTE:** Sport locks may become stiff, brittle, or discoloured over time. Contact your hearing care professional regarding changing the sport lock.

NOTE: The sport lock comes in two different sizes: M (medium power) and H (high power). See page 2 for receiver size.

7.4 Insert/replace the battery

- 1. Prepare the new battery. Remove the protective foil to activate the battery- wait for 2 minutes before inserting the battery into the hearing aid
- 2. Open the battery door completely by using your fingernail
- Insert the new battery with the positive side (+) facing upwards. Always insert the battery in the door: never directly into the hearing aid
- 4. Gently close the battery door



WARNING: BATTERIES MAY LEAK. REMOVE THE BATTERY IF YOU LEAVE THE HEARING AIDS UNUSED FOR LONGER PERIODS.

WARNING: DO NOT RECHARGE ZINK-AIR BATTERIES- THEY MAY LEAK OR EXPLODE.

WARNING: BATTERIES CONTAIN DANGEROUS SUBSTANCES AND SHOULD BE DISPOSED OF CAREFULLY IN THE INTEREST OF YOUR SAFETY AND FOR THE ENVIRONMENT. ALSO, KEEP BATTERIES AWAY FROM CHILDREN, MENTALLY DISABLED PERSONS, AND PETS.



- Please observe the following:
- 1. Always use new Zinc-Air batteries that have a minimum remaining shelf life of 1 year.
- 2. To save battery, turn off your hearing aids when they are not in use.
- 3. At night, switch off the hearing aid and open the battery door completely to allow moisture to evaporate. This prolongs the lifespan of the hearing aid.
- 4. If the hearing aids frequently lose connection to wireless accessories, contact your hearing care professional for a list of appropriate batteries.

7.4.1 Low battery indicator

When the batteries are low on power, your hearing aids reduce the volume, and play a melody every 15 minutes until they are empty and turn off.

1 NOTE: Keep spare batteries on hand.

7.4.2 Low battery indicator when paired with wireless accessories

The batteries drain faster when you use wireless functionalities like streaming from your smartphone or from your TV with our TV Streamer 2. As the battery power goes down, the different wireless functions stop working. A short melody every five minutes indicates that battery power is too low.

The table below shows how the functionality shifts with the power level of the battery.

Battery level	Signal	Hearing aid	Remote Control	Streaming
Fully charged		\checkmark	\checkmark	\checkmark
Low	•••	\checkmark	\checkmark	×
Depleted (change battery)	••••	\checkmark	×	×

8 Telephone use

With a hearing aid you are able to use a phone in a number of ways.

8.1 Normal use

To find the best way to use a telephone or smartphone while wearing your hearing aids may require practice. One or more of the following suggestions may be helpful:

- 1. Hold the telephone towards the ear (close to the hearing aid's microphone)
- 2. If whistling occurs, it may take a few seconds of holding the telephone in the same position before the hearing aid eliminates the whistling
- 3. Whistling may also be stopped by holding the telephone slightly away from the ear

NOTE: Depending on your individual needs, your hearing care professional may activate a programme specifically for telephone use.

8.2 Telecoil (only Ambio model 62)

Your hearing aids contain a telecoil. The Telecoil programme may help to improve speech understanding with Hearing Aid Compatible (HAC) telephones and in theaters, cinemas, houses of worship etc. that have a hearing loop installed.

When you switch on the Telecoil programme, your hearing aids pick up signals from the hearing loop or HAC telephone.

Your hearing care professional can activate the Telecoil programme.

I NOTE: The telecoil cannot work without a hearing loop (aka induction-loop) or a HAC telephone.

NOTE: If you are having trouble hearing with the hearing loop, ask you hearing care professional to adjust the programme.

NOTE: If there is no sound from the hearing aids in a hearing loop system and an active Telecoil programme, the hearing loop system may not be turned on or is not operating correctly.

NOTE: The sound from the hearing loop and the hearing aids' microphones can be mixed to your preference- either during the fitting session or via your smartphone app or your Remote Control 2.

8.2.1 Hearing loop systems

To use hearing loop systems, follow these steps:

- 1. Switch your hearing aid to the Telecoil programme
- 2. Find a good spot. Reception is not clear in all locations; it depends on the hearing loop. Look for signs or find another spot to sit
- 3. If needed, adjust the volume
- 4. When you leave, switch to your preferred programme

8.2.2 HAC telephone

Some smartphones are hearing aid compatible (HAC). The HAC phone establishes a small hearing loop that your hearing aids connect to. Switch to the Telecoil programme if you want to use a HAC phone.

The telecoil picks up the HAC telephone's signal and converts it to sound. To use the HAC telephone, follow these steps:

- 1. Switch your hearing aid to the Telecoil programme
- 2. Pick up the telephone and place a call or answer a call
- 3. Hold the telephone close to the hearing aid, and tilt it slightly outwards

4. Listen to the dial tone and move the telephone to get the best reception

- 5. If needed, adjust the volume
- 6. When you hang up, switch to your preferred programme

1

NOTE: If the phone has a poor telecoil signal, use the microphone programme. To avoid whistling, do not hold the handset too tightly against your ear.

NOTE: Ask your hearing care professional to enable the Telecoil programme in your hearing aids.

NOTE: If you see a "M3", "M4", "T3", or "T4" on the box, then the smartphone is HAC compliant.

NOTE: If you find it difficult to obtain a good result while using your smartphone, your hearing care professional will be able to give you advice on available wireless accessories to enhance listening capabilities.

NOTE: Ask your smartphone dealer or hearing care professional for advice regarding HAC smartphones.

8.3 Phone Now

By placing a magnet on the telephone receiver, your hearing aids automatically switch the telephone programme on when the receiver is close to your ear.

When you remove the receiver from your ear, the hearing aids automatically return to the previous listening programme.

NOTE: Ask your hearing care professional to enable Phone Now as one of your programmes.

8.3.1 Place the Phone Now magnet

Follow these steps in order to place the Phone Now magnet properly:







Clean the telephone thoroughly.

Remove foil from magnet.

Place the magnet.

1

WARNING: IF A MAGNET IS SWALLOWED, SEEK IMMEDIATE ASSISTANCE FROM A MEDICAL PRACTITIONER.

NOTE: Ask your hearing care professional to enable Phone Now as one of your programmes.

NOTE: Do not cover the loudspeaker opening with the magnet. **NOTE:** If Phone Now does not work to your satisfaction, moving the magnet to another position may improve ease of use and comfort while speaking.

NOTE: If the hearing aids do not switch to the telephone programme every time, you can reposition the Phone Now magnet or add additional magnets.

NOTE: Use a recommended cleaning agent.

8.3.2 How to use Phone Now

- 1. Lift the telephone to your ear
- 2. When you hear a short melody, the phone programme is active



NOTE: You may need to move the telephone receiver slightly to find the best position for reliable Phone Now activation and good hearing on the telephone.

NOTE: If your hearing aids have enabled Comfort Phone functionality, the hearing aid on the non-phone ear automatically attenuates.

8.4 Direct Audio Input (only Ambio model 62)

You can connect a DAI boot accessory to the bottom of the hearing aids. Once properly clicked into place, the hearing aids automatically switch to DAI (Direct Audio Input).



Direct Audio Input adapter

The sound source is connected to the hearing instruments by a cable or a wireless FM system1 to the audio boot.

To improve spatial sense and being able to hear colleagues, fellow students etc., the DAI input can be mixed with the microphone input.



NOTE: Using the DAI functionality results in increased battery consumption.

8.4.1 Connect DAI

- 1. Align the tip of the DAI click-on adapter with the groove above the battery door
- 2. Once in place, move the click-on adapter in the direction of the battery door
- 3. Gently click the DAI click-on adapter onto the hearing aid



Attaching the DAI click-on adapter to Ambio, model 62.

8.4.2 Disconnect DAI

- 1. Slide the latch downwards with your fingernail
- 2. Gently remove the click-on adapter from the hearing aid



Remove the DAI click-on adapter from Ambio, model 62

8.5 Flight Mode (optional)

WARNING: WHEN BOARDING A FLIGH OR ENTERING AN AREA WHERE RF TRANSMITTERS ARE PROHIBITED, DEACTIVATE WIRELESS FUNCTIONALITY.

Turn on Flight Mode:

- 1. For each hearing aid, open and close the battery door three times within a 10-second period close (open-close, open-close, open-close)

Deactivate Flight Mode:

- 1. For each hearing aid, open and close the battery door once
- 2. Single dings for ten seconds (etc.) indicate that your hearing aid is in wireless mode

1

NOTE: Both hearing aids must be set in Flight Mode- even with synchronization enabled.

NOTE: It is important to wait an additional 15 seconds after wireless function resumes before opening and closing the battery door again for any reason. Flight Mode will resume if you open and close the battery door during this 15-second window.

8.6 Smartphone apps

The app must only be used with hearing aids for which they are intended, and manufacturer takes no responsibility if the app is used with other hearing aids.

Use with smartphone apps:

- Do not disable app notifications.
- Install updates to keep the app working correctly.



NOTE: For assistance with pairing and using these products with your hearing aids, please contact your hearing care professional. **NOTE:** If you have a Bluetooth enabled smartphone, you are able to answer the telephone if you use Phone Clip+.

9 How to change domes

NOTE: It is recommended that your hearing care professional shows you how to change the domes. Incorrect dome replacement could result in the dome being left in the ear when you remove the hearing aid.

9.1 Standard domes

Follow these steps to mount domes:

- 3. Push the new dome over the flanges on the receiver
- 4. Make sure that the new dome is properly and securely mounted



9.2 Tulip domes

The tulip domes are mounted in a similar manner to the ordinary domes, but a few extra steps are required. The tulip domes consist of two "petals". Follow these steps to mount tulip domes:





flanges.

Push the fitting tube over the

Then move the largest petal to

its original position.

Bend the largest petal forwards to open the tulip dome.



Check that the flanges are completely covered by the fitting tube.



Wrong!



Correct!

NOTE: Make sure that the new dome is properly and securely mounted. 10 Battery door lock

Your hearing aid can be equipped with a lock on the battery door. If you lock the battery door, you will minimize the risk of accidentally dropping the battery.

Once you lock the battery door, you can turn the hearing aid on and off. You have to unlock the battery door to replace the battery.

NOTE: Children and mentally disabled persons may benefit from a safer battery door lock system. Ask your hearing care professional for advice.

10.1 Ambio, model 61 and model 62

Use the tool to lock or unlock the battery door. To lock the battery door:





Open the battery door to the OFF position.

From the left side, push the slider to the right.

To unlock the battery door (to replace the battery):





6

Open the battery door to the OFF position.

From the right side, push the slider to the left.

Now, open the battery door completely to replace the battery.



11 Daily maintenance

It is important to keep your hearing aid clean and dry. On a daily basis, clean the hearing aids using a soft cloth or tissue.

If the microphone inlets are clogged, gently brush across the microphone inlets with a small, clean brush.



NOTE: Do not use force to press the hairs of the brush into the inlets, because the microphones may be damaged

NOTE: Do not use alcohol or other solvents to clean your hearing aids; the protective coating will be damaged.

11.1 Brush (optional)

Use the three-in-one brush for daily cleaning and battery handling.



- 1. Brush- cleaning: Use the brush on all surfaces and orifices
- 2. Wire loop- cleaning: Use the wire loop to clean the earmould
- 3. Magnet- battery handling: Use the magnet to lift and replace the battery

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NOTE: Do not use the wire loop to clean the microphone openings. If the micro-phone openings clog up, visit your hearing care professional.

NOTE: The wire loop is only intended for BTE earmoulds.

11.2 Cleaning earmoulds

- 1. Detach the earmold and tubing from the hearing aid before cleaning
- 2. Use a mild soap to clean the earmould and rinse with lukewarm water
- 3. Dry the earmould thoroughly. Use the airbulb and cleaning wire to remove residual water and debris from the tubing.
- **NOTE:** Earmould tubing may become stiff, brittle, or discoloured over time. Contact your hearing care professional regarding tube changes.

11.3 Change wax guard on RIE receiver

To replace wax filters on receivers and earmoulds, follow these steps:



- 1. Carrying box with eight wax guard tools
- 2. The wax guard tool has two functions:
- A removal tip to collect the used filter
- A replacement tip with a white filter



Insert the removal tip of the tool into the used wax guard so that the shaft touches the rim of the wax guard.



Slowly pull the wax guard straight out.

To insert the new wax filter, follow these steps:



Insert the replacement tip of the tool into the sound outlet.



Gently press the replacement tip straight into the sound outlet until the outer ring lies flush with the sound outlet.



Pull the tool straight out- the new wax guard will remain in place.



NOTE: To ease removal and insertion, it may help to twist the wax guard tool.

11.4 Cleaning thin tubes and domes

- 1. Unscrew the thin tubes from the HA counter clockwise before cleaning them.
- 2. Use a damp cloth to wipe down thin tubes, domes and hearing aid.
- 3. Push the black cleaning wire through the thin tube to clear out moisture and debris. Insert the cleaning wire opposite the dome.

NOTE: We recommend that you change the thin tube and the dome system every three months. If the parts get stiff or brittle, change them sooner.

11.5 Care and maintenance

Please follow the advices below to have the best user experience and to prolong the life of your hearing aids.

- 1. Keep your hearing aids dry and clean
- 2. Open the battery door to dry out your hearing aids when you are not wearing them
- 3. Wipe the hearing aids with a soft cloth after use to remove grease or moisture
- 4. Do not wear your hearing aids when putting on cosmetics, perfume, after-shave, hair spray, lotion etc. These might discolour the hearing aid or get into the hearing aid causing damage
- 5. Do not immerse your hearing aid in any liquid
- Keep your hearing aids away from excessive heat and direct sunlight. The heat may deform the shell, damage the electronics and deteriorate the surfaces
- 7. Do not swim, shower or steam bathe while wearing your hearing aids

12 Wireless accessories

1

Wireless eco-system features a comprehensive range of seamlessly integrated wireless accessories. This allows you to control and stream high quality stereo sound and speech directly to your hearing aids.

Please find the list of available wireless accessories below:

TV Streamer 2 allows you to stream the audio from TV sets and virtually any other audio source to your hearing aids at a volume level that suits you.

Remote Control 2 allows you to adjust the volume or mute your hearing aids, change programmes, and see all your settings at a glance on its crystal clear display.

Phone Clip+ streams phone conversations and stereo sound directly to both hearing aids, and it doubles as a simple remote control.
Micro Mic is a body worn microphone for your friend or colleague. It significantly improves speech understanding in noisy situations.
Multi Mic works like the Micro Mic but doubles as a table microphone. Connects with loop and FM systems1, and has a mini-jack input for streaming audio from a computer or music player.

NOTE: Ask your hearing care professional for more information on the range of wireless accessories.

NOTE: For use of wireless functionality only use manufacturers wireless accessories. For further guidance regarding e.g. pairing, please refer to the user guide of the relevant wireless accessory.

13 Tinnitus Sound Generator module

13.1 Intended use for TSG module

Your hearing aid includes the Tinnitus Sound Generator (TSG) module, a tool for generating sounds to be used in tinnitus management programmes to relieve suffering from tinnitus.

The TSG can generate sounds adjusted to the specific therapeutic needs and your personal preference as determined by your doctor, audiologist, or hearing care professional.

13.2 User instructions for the TSG module

13.2.1 Description of the device

The Tinnitus Sound Generator (TSG) Module is a software tool that generates sounds to be used in tinnitus management programmes to relieve suffering from tinnitus.

Depending on the selected hearing aid programme and the environment you are in, you will sometimes hear the therapeutic sound resembling a continuous or fluctuating noise.

13.2.2 Explanation of how the device functions

The TSG module is a frequency and amplitude shaped white-noise generator. Noise signal level and frequency characteristics can be adjusted to the specific therapeutic needs as determined by your doctor, audiologist or hearing care professional.

Your doctor, audiologist or hearing care professional can modulate the generated noise with the purpose of making it more pleasant. The noise can then resemble, for example, crashing waves on a shore. Modulation level and speed can also be configured to your likes and needs. An additional feature can be enabled by your hearing care professional that allows you to select predefined sounds that simulate sounds from nature, such as breaking waves or running water. If you have two wireless hearing aids that support ear-to-ear synchronization this functionality can be enabled by your hearing care professional. This will cause the Tinnitus Sound Generator to synchronize the sound in both hearing aids.

If your tinnitus troubles you only in quiet environments, your doctor, audiologist or hearing care professional can set the TSG module so that it becomes audible exclusively in such surroundings. The overall sound level can be adjusted via an optional volume control. Your doctor, audiologist or hearing care professional will review with you the need for having such a control.

For hearing aids where ear to ear synchronization is enabled, your hearing care professional can also enable environmental monitoring synchronization so that the TSG noise level is automatically adjusted simultaneously in both hearing aids dependent on the background sound level. Additionally, if the hearing aid has a volume control, then the background noise level monitored by the hearing aid and the volume control can be used simultaneously to adjust the generated noise level in both hearing aids.

13.2.3 The scientific concepts that form the basis for the device

The TSG module provides sound enrichment with the aim of surrounding the tinnitus sound with a neutral sound, which is easily ignored. Sound enrichment is an important component of most approaches to tinnitus management, such as Tinnitus Retraining Therapy (TRT).

To assist habituation to tinnitus, this needs to be audible. The ideal level of the TSG module, therefore, should be set so that it starts to blend with the tinnitus, and so that you can hear both your tinnitus as well as the sound used.

In a majority of instances, the TSG module can also be set to mask the tinnitus sound, so to provide temporary relief by introducing a more pleasant and controllable sound source.

13.2.4 TSG volume control

The sound generator is set to a specific loudness level by the hearing healthcare professional. When switching the sound generator on, the volume will have this optimal setting. Therefore, it might not be necessary to control the volume (loudness) manually.

However, the volume control provides the ability to adjust the volume, or amount of stimulus, to the liking of the user.

The volume control is an optional feature in the TSG module used for adjusting the sound generator output level. To prevent unintended usage by pediatric or physically or mentally challenged users, the volume control must, if enabled, be configured to only provide a decrease of the sound generator output level.

13.2.5 Using TSG with smartphone apps

The tinnitus sound generator control via hearing aid push buttons can be enhanced with wireless control from a TSG control app on a smartphone or mobile device. This functionality is available in supported hearing aids when a hearing healthcare professional has enabled the TSG functionality during fitting of the hearing aid.

To use smartphone apps the hearing aid must be connected with the smartphone or mobile device.



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NOTE: To use smartphone apps, the hearing aid must be connected with the smartphone or mobile device.

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13.3 Technical specifications

13.3.1 Audio signal technology Digital.

13.3.2 Available sounds

White noise signal which can be shaped with the following configurations:

The white noise signal can be modulated in amplitude with an attenuation depth of up to 14dB.

High-pass filter	Low-pass filter
500 Hz	2,000 Hz
750 Hz	3,000 Hz
1,000 Hz	4,000 Hz
1,500 Hz	5,000 Hz
2,000 Hz	6,000 Hz

13.3.3 Prescription use of a Tinnitus Sound Generator hearing aid

The TSG module should be used as prescribed by your doctor, audiologist or hearing healthcare professional. In order to avoid permanent hearing damages, the maximum daily usage depends on the level of the generated sound.

Should you develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, you should discontinue use of sound generator and seek medical evaluation.

The target population is primarily the adult population over 18 years of age. This product may also be used with children 5 years of age or older. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing healthcare professional or the guardian for the insertion and removal of the hearing instrument containing the TSG module.

13.3.4 Important notice for prospective sound generator users

A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask internal noises. It is also used as an aid in hearing external noises and speech.

Good health practice requires that a person with a tinnitus condition have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before using a sound generator. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists.

The purpose of medical evaluation is to assure that all medically treatable conditions that may affect tinnitus are identified and treated before the sound generator instrument is used.

The sound generator instrument is a tool to generate sounds to be used with appropriate counseling and/ or in a tinnitus management programme to relieve patients suffering from tinnitus.

13.4 Tinnitus Sound Generator warnings

- 1. Sound generator can be dangerous if improperly used
- 2. Sound generators should only be used as advised by your doctor, audiologist, or hearing care professional
- 3. Sound generators are not toys and should be kept out of reach of anyone who might cause themselves injury (especially children and pets)

13.4.1 A Tinnitus Sound Generator precautions

Should the user develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, the user should discontinue use of the sound generator and seek medical evaluation.

To prevent unintended usage by paediatric or physically or mentally disabled users, the volume control must, if enabled, be configured to only provide a decrease of the sound generator output level.

13.4.2 \triangle Tinnitus Sound Generator warning to hearing care professionals

A hearing care professional should advise a prospective sound generator user to consult promptly with a licensed physician (preferably an ear specialist) before getting a sound gen-erator.

If the hearing care professional determines through inquiry, actual observation, or review of any other available information concerning the prospective user that the prospective user has any of the following conditions:

- 1. Visible, congenital or traumatic deformity of the ear
- 2. History of active drainage from the ear within the previous 90 days
- 3. History of sudden or rapidly progressive hearing loss within the previous 90 days
- 4. Acute or chronic dizziness
- 5. Unilateral hearing loss of sudden or recent onset within the previous 90 days 6.
- 6. Audiometric air-bone gap equal to or greater than 15 dB at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz
- 7. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal
- 8. Pain or discomfort in the ear

CAUTION: THE MAXIMUM OUTPUT OF THE SOUND GENERATOR FALL INTO THE RANGE THAT CAN CAUSE HEARING LOSS ACCORDING TO OSHA REGULATIONS. IN ACCORDANCE WITH NIOSH RECOMMENDATIONS, THE USER SHOULD NOT USE THE SOUND GENERATOR FOR MORE THAN EIGHT (8) HOURS A DAY WHEN SET TO S LEVEL OF 85 DB SPL OR ABOVE. WHEN THE SOUND GENERATOR IS SET TO LEVELS OF 90 DB SPL OR ABOVE, THE USER SHOULD NOT USE THE SOUND GENERATOR FOR MORE THAN TWO (2) HOURS PER DAY. IN NO CASE SHOULD THE SOUND GENERATOR BE WORN AT UNCOMFORTABLE LEVELS.

14 General Warnings

- 1. If a hearing aid is broken, do not use it
- 2. Consult a hearing care professional:
- If you think there may be a foreign object in your ear canal
- If you experience skin irritation
- If excessive earwax accumulates with the use of the hearing aid
- 3. Different types of radiation, e.g. from NMR, MRI or CT scanners, may damage hearing aids. It is recommended not to wear hearing aids during these or other similar procedures. Other types of radiation, such as burglar alarms, room surveillance systems, radio equipment, mobile telephones, contain less energy and will not damage hearing aids. However, they have the potential to momentarily affect the sound quality or temporarily create undesired sounds from hearing aids
- 4. Do not wear hearing aids in mines, oil fields, or other explosive areas unless those areas are certified for hearing aid use
- 5. Do not allow others to use your hearing aids. This may cause damage to the hearing of the other individual or to the hearing aids
- 6. Hearing aid usage by children or mentally disabled persons should be supervised at all times to ensure their safety. The hearing aid contains small parts that could be swallowed by children. Please be mindful not to leave children unsupervised with this hearing aid
- 7. Hearing aids should be used only as prescribed by your hearing care professional. Incorrect use may result in sudden and permanent hearing loss
- 8. When boarding a flight or entering an area where RF transmitters are prohibited, deactivate wireless functionality. Turn off your wireless functionality by using the flight mode in areas where radio frequency emission is prohibited

15 A General precautions - Wireless hearing aids

- 1. If electronic devices in your surroundings are affected by your hearing aids with wireless function activated, move away from the affected devices.
- 2. For use of wireless functionality only use manufacturers wireless accessories. For further guidance, please refer to the User Guide of the relevant wireless accessory
- 3. Only use original consumables e.g. tubes and domes
- 4. Only connect hearing aids to manufacturers wireless accessories intended and qualified to be used with these hearing aids

16 A Phone Now warnings

- 1. Keep magnets out of reach of children, mentally disabled persons, and pets
- 2. If a magnet is swallowed, seek immediate advice from a medical practitioner
- 3. The Phone Now magnet may affect sensitive medical devices / electronic systems. Seek advice from the manufacturers regarding appropriate safety measures when using the Phone Now solution near the sensitive device / equipment (pacemakers and defibrillators) in question. If the manufacturer cannot issue a statement, we recommend keeping the magnet or a telephone equipped with the magnet 15 cm (6") away from magnetically sensitive devices (e.g. pacemakers)

16.1 A Phone Now precautions

- 1. If you experience frequent signal loss or noise during calls, move the Phone Now magnet to another place on the telephone receiver
- 2. Only use magnets supplied by manufacturer

17 A Battery warnings

Batteries contain dangerous substances and should be disposed of carefully in the interest of your safety and for the environment. Please note:

- 1. Keep batteries away from children, mentally disabled persons, and pets.
- 2. DO NOT place batteries in your mouth
- 3. Consult a physician immediately if a battery has been swallowed, as they can be harmful to your health
- 4. Do not recharge Zinc air batteries- they may leak or explode
- 5. DO NOT attempt to dispose of batteries by burning them
- 6. Used batteries are harmful to the environment. Please dispose of them according to local regulations or return them to your hearing care professional
- 7. Remove the batteries to prevent leakage when the hearing aids are not in use for an extended period
- 8. If the batteries are not inserted correctly, the device will not work and the batteries may build up heat. If this happens, please remove the batteries

18 Intended use of smartphone apps

The app must only be used with hearing aids for which they are intended, and manufacturer takes no responsibility if the app is used with other hearing aids.

19 \triangle Important points for FM

- 1. Do not use two transmitters on the same FM channel
- 2. Do not use water or fluids for cleaning the FM receiver
- 3. Do not use an FM transmitter in locations where it is forbidden to use electronic devices, for instance in airplanes
- 4. Be aware that FM signals might also be picked up and overheard by other receivers.
- 5. Before using the system in another country, contact your hearing care professional to make sure your radio channel is permitted in that country
- 6. Your FM receiver and FM transmitter may only be repaired by an authorized service centre.

20 Troubleshooting guide

SYMPTOM	CAUSE	POSSIBLE REMEDY
Feedback,	Is your earmould or dome inserted correctly?	Put it in again.
"whistling"	Is the volume very loud?	Reduce it.
	Is the plastic tube or the earmould clogged or broken?	Replace or visit your hearing care professional.
	Are you holding an object (e.g. a hat, a telephone receiver) close to a hearing aid?	Move your hand away to create more space between the hearing aid and the object.
	Is your ear full of wax?	Visit your physician.
No sound	Is the hearing aid turned on?	Switch it on.
	Is the hearing aid in telecoil mode?	Switch to the microphone program.
	Is there a battery in the hearing aid?	Insert a new battery.
	Is the battery still good?	Replace with a new one.
	Is the plastic tube or the earmould clogged or broken?	Visit your hearing care practitioner.
	Is your ear full of wax?	Visit your physician.
Sound is dis-	Is the battery dead?	Replace it with a new one.
torted, splutter- ing or weak?	Is the battery dirty?	Clean it or replace it with a new one.
Ing of weak:	Is the plastic tube or the earmould clogged or broken?	Visit your hearing care professional.
	Did your hearing aid get moist?	Use a desiccant.
Battery drains very quickly	Did you leave your hearing aid switched on for long periods of time?	Always switch off your hearing aid when you are not using them, e.g. during the night.
	Is the battery old?	Check the date on the battery packaging.

21 Technical data

RIE—MP receiver

AM561-DRW, AM562-DRW

Reference test gain (60 dB SPL input)	HFA	37	dB
Full-on gain (50 dB SPL Input)	Max	58	dB
Full-off gain (50 dB SPL liput)	HFA	51	dB
Maximum output (90 dB SPL input)	Max	116	dB SPL
Maximum output (90 dB SPL input)	HFA	114	dB SPL
	500 Hz	0.5	%
Total harmonic distortion	800 Hz	0.6	%
	1600 Hz	1.2	%
Telecoil sensitivity (SPLIV @ 31.6 mA/m)		96	dB SPL
Equivalent input noise (w/o noise reduction)		23	dB SPL
Frequency range (DIN 45605)		100–7000	Hz
Current drain (in test mode)		1.3	mA

Note: Telecoil sensitivity only applicable for 62 RIE models



FULL-ON AND REFERENCE TEST GAIN



RIE—**HP** receiver

AM561-DRW, AM562-DRW

Reference test gain (60 dB SPL input)	HFA	42	dB
Full-on gain (50 dB SPL Input)	Max	65	dB
	HFA	56	dB
Maximum output (90 dB SPL input)	Max	122	dB SPL
	HFA	118	dB SPL
Total harmonic distortion	500 Hz	0.6	%
	800 Hz	1.2	%
	1600 Hz	0.7	%
Telecoil sensitivity (SPLIV @ 31.6 mA/m)		101	dB SPL
Equivalent input noise (w/o noise reduction)		23	dB SPL
Frequency range (DIN 45605)		100–6030	Hz
Current drain (in test mode)		1.3	mA

Note: Telecoil sensitivity only applicable for 62 RIE models



FULL-ON AND REFERENCE TEST GAIN



Data in accordance with IEC60118-7 and ANSI S3.22-2009, supply Voltage 1.3V

Frequency (Hz)

RIE—UP receiver

AM561-DRW, AM562-DRW

Reference test gain (60 dB SPL input)	HFA	47	dB
Full-on gain (50 dB SPL Input)	Max	75	dB
	HFA	64	dB
Maximum output (90 dB SPL input)	Max	129	dB SPL
	HFA	124	dB SPL
Total harmonic distortion	500 Hz	1.3	%
	800 Hz	2.1	%
	1600 Hz	0.1	%
Telecoil sensitivity (SPLIV @ 31.6 mA/m)		107	dB SPL
Equivalent input noise (w/o noise reduction)		23	dB SPL
Frequency range (DIN 45605)		100-4910	Hz
Current drain (in test mode)		1.2	mA

Note: Telecoil sensitivity only applicable for 62 RIE models





Data in accordance with IEC60118-7 and ANSI S3.22-2009, supply Voltage 1.3V

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22 A Warnings for hearing care professionals

- 1. Special care should be exercised in selecting and fitting hearing aids with maximum sound pressure level that exceeds 132dB SPL with an IEC 60711:1981 occluded ear sim-ulator. The remaining hearing may risk further impairment.
- 2. External devices connected to the electrical input must be safe according to the require-ments of IEC 60601-1, IEC 60065, or IEC 60950-1, as appropriate (wired connection, for example HI-PRO, SpeedLink)

23 Statement

This device complies with part 15 of the FCC rules and ISED rules. Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference
- 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 and ISED 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 accord-ance with the instructions, may cause harmful interference to radio com-munications. 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 the one in which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Changes or modifications can void the user's authority to operate the equipment.

The products are in compliance with the following regulatory requirements:

- 1. In EU: the device conforms to the Essential Requirements according to Annex I of Council Directive 93/42/EEC for medical devices (MDD).
- 2. Hereby, GN Hearing A/S declares that the radio equipment types BRIE and VE312 are in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.declarations.resound.com
- 3. In US: FCC CFR 47 Part 15, subpart C.
- 4. Other identified applicable international regulatory requirements in countries outside the EU and US. Please refer to local country requirements for these areas.
- 5. In Canada: these hearing aids are certified under the rules of ISED.
- Japanese Radio Law and Japanese Telecommunications Business Law Compliance. This device is granted pursuant to the Japanese Radio Law (電波法) and the Japanese tele-communications Business Law (電気通信事業法) This device should not be modified (otherwise the granted designation number will become invalid.

This device operates in the frequency range of 2.4 GHz- 2.48 GHz. This device includes an RF transmitter that operates in the range of 2.4 GHz - 2.48 GHz.

Nominal RF output power transmitted is 0 dBm.

Mini Receiver In-the-Ear (RIE) hearing aids of type VE312 with FCC ID: X26VE312, IC number 6941C-VE312 and size 312 battery are available in the following variants:

AM561-DRW MP AM561-DRW HP AM561-DRW UP

Receiver-in-the-ear (RIE) hearing aids of type BRIE with FCC ID X26BRIE, IC number 6941C-BRIE and size 13 battery are available in the following variants: AM562-DRW MP AM562-DRW HP AM562-DRW UP

The identification number for the mentioned device models can be found behind the battery door as indicated in the illustrations on page 9.

24 Warranties and repairs

Manufacturer provides a warranty on hearing aids in the event of defects in workmanship or materials, as described in applicable warranty documentation. In its service policy, manufacturer pledges to secure functionality at least equivalent to the original hearing aid. As a signatory to the United Nations Global Compact initiative, Manufacturer is committed to doing this in line with environment-friendly best practices. Hearing aids therefore, at manufacturer's discretion, may be replaced by new products or products manufactured from new or serviceable used parts, or repaired using new or refurbished replacement parts. The warranty period of hearing aids is designated on your warranty card, which is provided by your hearing care professional.

For hearing aids that require service, please contact your hearing care professional for assistance. Hearing aids that malfunction must be repaired by a qualified technician. Do not attempt to open the case of hearing aids, as this will invalidate the warranty.

25 Temperature test, transport, and storage information

These hearing aids are subjected to various tests in temperature and damp heating cycling between-25°C (-13°F) and +70°C (158°F) according to internal and industry standards.

During transport or storage, the temperature should not exceed the limit values of $-20^{\circ}C(-4^{\circ}F)$ to $60^{\circ}C(140^{\circ}F)$ and relative humidity of 90% RH, non-condensing (for limited time). The air pressure between 500 hPa and 1,100 hPa is appropriate.

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26 Advisories

The Advisories contain important information which must be fully understood, shared and followed at all times.

Non-compliance may lead to severe personal injuries and/or equipment damages.

Be aware of information marked with the following symbols:



WARNING points out a situation that could lead to serious injuries.

CAUTION indicates a situation that could lead to minor and moderate injuries.



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Advice and tips on how to handle your hearing aid better.

Equipment includes RF transmitter.



Please ask your local hearing care professional concerning disposal of your hearing aid.



Please ask your local hearing care professional concerning disposal of your hearing aid



Follow instructions for use.

27 Acknowledgments

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Any issues relating to the EU Medical Device Directive 93/42/EEC or EU Radio Equipment Directive 2014/53/EU should be directed to GN Hearing A/S.

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