DANAVOX GN



Custom hearing aids

Danavox Brisa

User guide

Hearing aid information

Left hearing aid		Right hearing aid	
Serial number		Serial number	
Model number		Model number	
Battery type	☐ 10A		

Program	Beep	Description
1	One beep	
2	Two beeps	
3	Three beeps	
4	Four beeps	

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Introduction

We recommend that you use your hearing aids every day to fully benefit from them.

NOTE: Read this booklet carefully before using your hearing aids.

Intended purpose

The hearing aid is intended to compensate for hearing impairment by amplifying and transmitting sound to the ear.

User profile

- The hearing aid is intended to be used by adults and children 12 years of age or older.
- The hearing aid is intended to be used by lay persons.
- The hearing aid is intended to be fitted by qualified hearing care professionals.

Therapeutic indications

Sensorineural, conductive or mixed hearing loss.

Contra-indications

A hearing care professional should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid, if the hearing aid dispenser 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:

- Visible, congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.

- History of sudden or rapidly progressive hearing loss within the previous 90 days.
- Acute or chronic dizziness.
- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- Pain or discomfort in the ear.

Side effects

If you experience side effects, contact a hearing care professional or a physician. Possible side effects from wearing a hearing aid may be:

- Dizziness
- Tinnitus
- Perceived worsening of hearing loss
- Nausea
- Headache
- Skin reaction
- Ear wax accumulation

Symbols

The symbols below are used in this user guide, on the device, or on the packaging.



WARNING: Points out a situation that could lead to serious injuries.



Legal manufacturer.



Follow instructions for use. (Logo in blue)



Medical device.



REF Catalogue number.



Product is a Type B applied part.



IMDA label for Singapore.



Follow local regulations when disposing of electronic devices.



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



Date of manufacture.



Regulatory compliance mark for EU with notified body number.



Unique Device Identification.



Serial number.



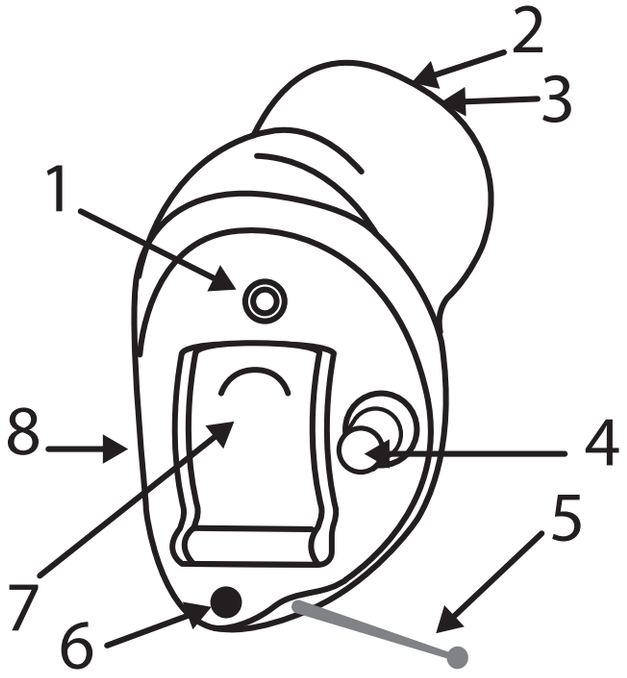
Regulatory compliance mark for Australia and New Zealand.

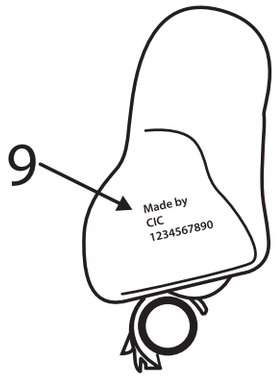


Equipment includes an RF transmitter.

Your hearing aid – Completely-In-the-Canal (CIC)

1. Microphone inlet
2. Sound outlet with wax guard
3. Vent (optional)
4. Push button (optional)
5. Removal cord
6. Vent (optional)
7. Battery door and On/Off switch
8. Manufacturer, model and serial number.
9. Manufacturer, model and serial number. Side view.

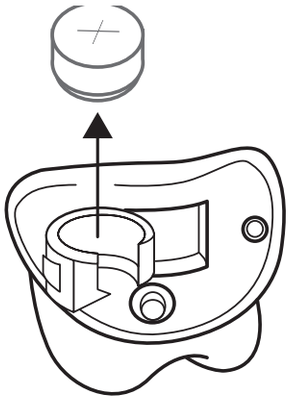




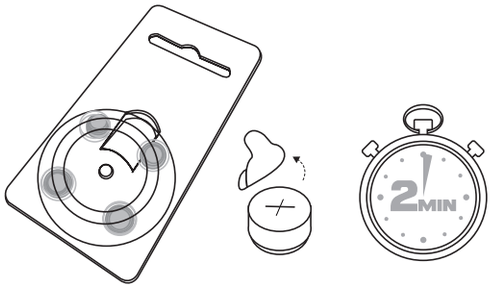
How to get your hearing aid ready for use

Replacing the battery

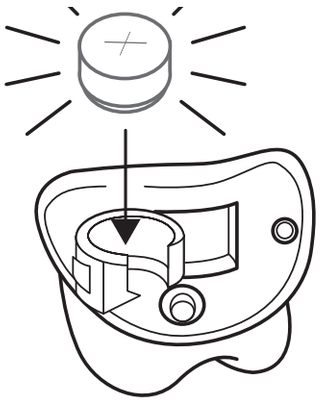
1. Open the battery door completely by using your fingernail. Remove the used battery, if present.



2. Prepare the new battery. Remove the protective foil to activate the battery. Wait for 2 minutes before inserting the battery into the hearing aid.



3. Insert the new battery in the battery door with the + side facing upwards. Gently close the battery door.



When the hearing aid is not in use, open the battery door to turn it off.Open the battery door completely to allow moisture to evaporate and prolong the hearing aids' life span.

Battery warnings



WARNING:

- Batteries may leak. If you are not going to use your hearing aids for a few days, you must remove the batteries.
- Battery leakage can cause chemical burns. If you get exposed to battery leakage material, rinse immediately with warm water. If you get chemical burns, redness, or skin irritation from battery leakage, seek medical attention.
- Never try to charge hearing aids with zinc-air batteries as this can cause leakage or a small explosion.
- Never swallow batteries nor place them inside any part of the body, as the battery can cause serious injuries. If a hearing aid or battery has been swallowed or placed inside any part of the body, seek immediate medical attention.
- Batteries are harmful to the environment. Therefore, never try to burn them. Dispose of your used batteries according to your country's regulations or return them to a hearing care professional.

NOTE:

- Always use zinc-air batteries with at least one year left before they expire.
- Keep spare batteries on hand.
- To save battery power, turn off your hearing aids when they are not in use.

Low battery alert

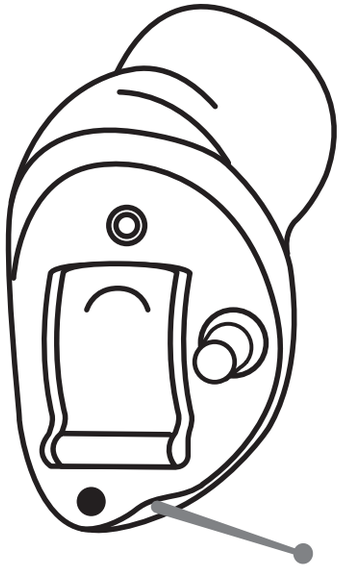
When the batteries are low on power, your hearing aids reduce the volume, and play a melody every 15 minutes until they are completely drained and turn off.

Placing your hearing aids in your ears

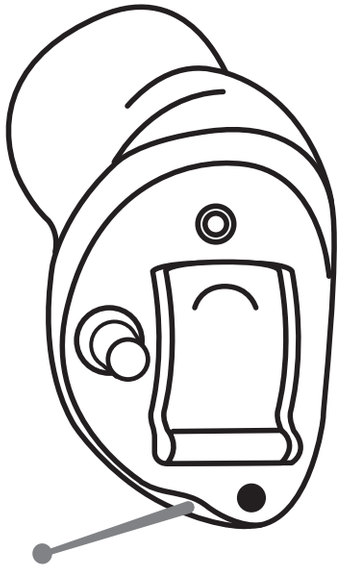
How to tell left from right

CAUTION: If you have two hearing aids, they may be programmed differently. Do not swap them as this could damage your hearing.
Your hearing aids are colour coded.

Left hearing aid
(blue marking)



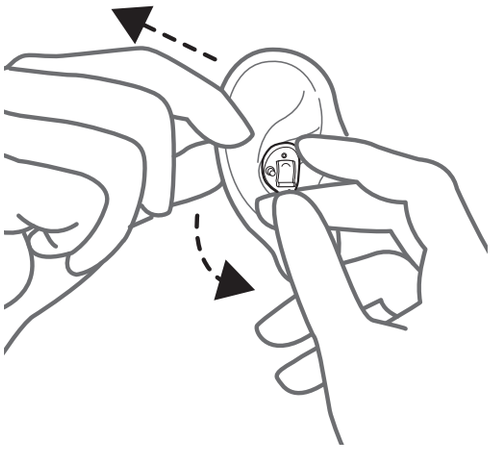
Right hearing aid
(red marking)



NOTE: Your hearing aids are made to fit exactly into your left and your right ear respectively. So each of them will only fit correctly to the ear it is made for.

Inserting the hearing aids

1. Hold the hearing aid between your thumb and index finger.
2. Insert the hearing aid into your ear canal:
   Place the sound outlet portion into your ear canal. Turn the top part of the hearing aid gently backwards and forwards so that it tucks behind the fold of skin above your ear canal.



3. Check that the vent opening is in the notch just above your earlobe.

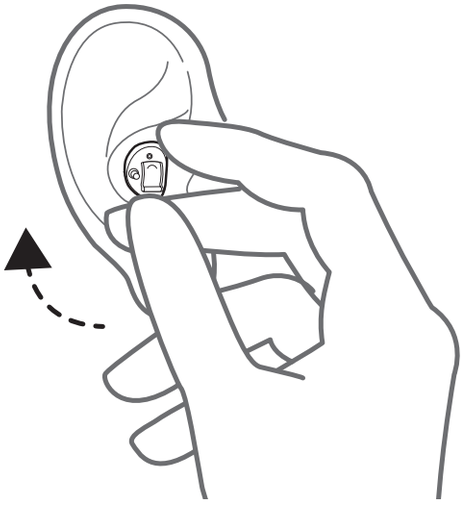


By experimenting, you may discover an easier method. With proper insertion, hearing aids should fit snugly but comfortably.

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

Removing your hearing aids from your ears

1. Hold the edges of the hearing aid with your thumb and index finger. Pull out and slightly upward, while slightly rotating your hand forward.
2. If your hearing aid has a pull-out wire, pull at the wire to remove the hearing aid.



3. Wipe your hearing aids to remove any debris.
4. If you are not going to use the hearing aids now, turn them off. See "Turning your hearing aids on and off", page 15.

Using your hearing aids

Turning your hearing aids on and off

To turn your hearing aid ON:
Close the battery door (with a battery correctly placed in the door).
Your hearing aids always start in program 1 at the pre-set volume.

To turn your hearing aid OFF:
Use a fingernail to open the battery door.

Volume control

If your hearing aids have a push button, they can be set up with different programs to support a variety of listening situations. See Push button (optional) below.

To control the volume, shift to the program that has the best match to your current listening situation.

Push button (optional)

Your hearing aid may have a push button allowing you to use up to four different listening programs. See "Listening programs (optional)", page 16.

1. Push the program button to switch between programs.
2. You will then hear one or more beeps. The number of beeps indicates which program you have selected (one beep = program one, two beeps = program two, etc.).

3. When you turn the hearing aids off and then back on, they always return to the default setting (program 1 and preset volume).

NOTE: If you have two hearing aids with the Synchronised Push Button enabled, program changes to one hearing aid automatically repeats in the second hearing aid. The same number of confirmation beeps will follow in the second hearing aid. This Synchronised Push Button can also be configured to allow one side to control volume increase and the other to control volume decrease. The volume changes to one hearing aid are repeated on the other side to keep levels the same.

Listening programs (optional)

Your hearing care professional can activate one or more listening programs in your hearing aids. These programs can help you in specific situations. Ask your hearing care professional about which programs could be useful for you.

Programs	Use
All-Around	The best option if you want only one program.
Hear in Noise	Dedicated program for hearing speech in very noisy places such as restaurants or social gatherings.
Music	For listening to music.
Acoustic phone	A special program for phone conversations.
Outdoor	For outdoor use (to reduce wind noise).

Using a telephone

Your hearing aid allows you to use your telephone as you normally do. Finding the optimal position for holding the phone may require practice.

The following suggestions may be helpful:

- Hold the telephone up to your ear canal as usual.
- If you hear whistling, try holding the telephone in the same position for a few seconds. The hearing aid may be able to cancel the whistling.
- You can also try holding the telephone slightly away from the ear.

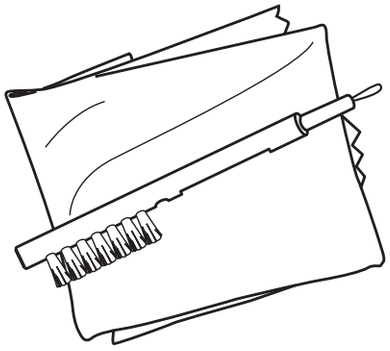
Mobile phones

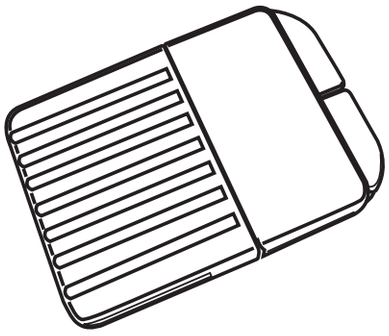
Your hearing aids comply with the most stringent Standards of International Electromagnetic Compatibility. Any degree of disturbance can be due to the nature of your particular mobile phone or of your wireless telephone service provider.

Cleaning and caring for your hearing aids

Cleaning tools

These cleaning tools come with your hearing aids:





- Soft cloth.
- A brush with a battery magnet.

Your hearing care professional may give you a set of wax filters.

General instructions for care and maintenance

To ensure you get the highest quality experience and longest useful lifetime out of your hearing aids, it is important to clean and care for them.

To maintain your hearing aids, clean and disassemble them one at a time to prevent mixing them up.

Follow these steps:

1. When you remove your hearing aids, turn them off by opening the battery doors completely. This helps to dry them out.
2. After removing your hearing aids, wipe them with a soft cloth to keep them clean and dry.
3. If you use a drying agent, only use recommended products.
4. Apply cosmetics, perfume, after-shave, hairspray, lotions etc. before putting on your hearing aids. These products can damage or discolour your hearing aids.

NOTE:

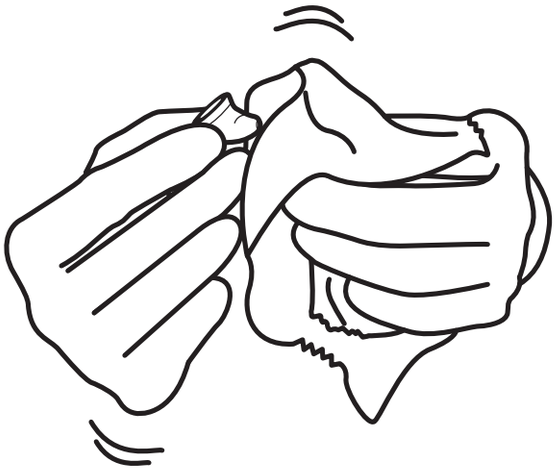
- Never immerse your hearing aids in liquid.
- Keep your hearing aids away from excessive heat and direct sunlight.
- The hearing aid is dust, splash, and water resistant:
  - The hearing aid has IP6X dust resistance. Avoid exposure to extensive dust.
  - The hearing aid has IPX8 water resistance. Avoid exposure to liquids, and do not swim, shower or sauna while wearing the hearing aid.

CAUTION:

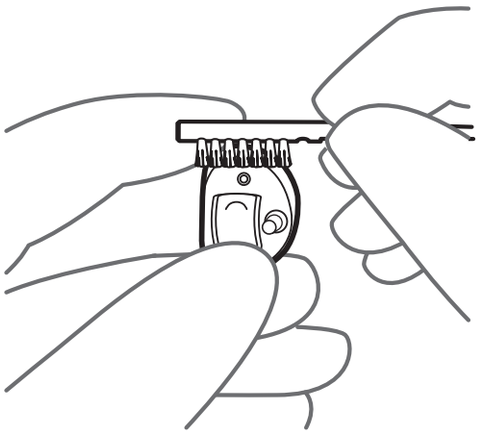
- Never use alcohol or other cleaning solutions to clean your hearing aids. This can damage your hearing aids and may cause a skin reaction.
- Ear wax or other residue on your hearing aids can cause an infection. To avoid this, clean your hearing aids as instructed.

Daily care and maintenance

It is important to keep your hearing aids clean and dry on a daily basis. Use a cloth and brush to clean the hearing aids.



1. Wipe your hearing aids with a cloth.



2. Swipe the small brush across the microphone.

3. Use the supplied cleaning wire to cleans the vent that goes through the hearing aid. Insert the wire from the outside of the hearing aid to push out any debris.

NOTE:

- Never try to put the brush bristles or the cleaning wire into the microphone inlets. This can damage your hearing aids.

Replacing the wax filters

Custom hearing aids may have wax filters that protect against wax and moisture. It is recommended that these are changed as needed. Consult your hearing care professional for advice on how often you need to change. This will depend on how much wax your ears produce.

The wax filter is located at the inward end of the hearing aid.

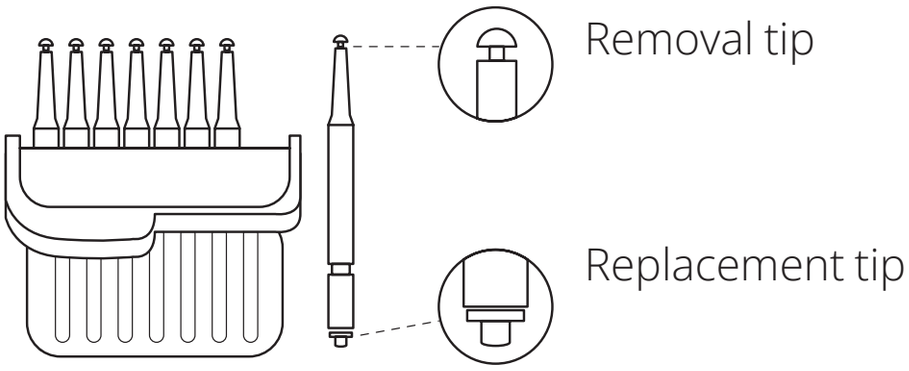
For information on obtaining more wax filters contact your hearing care professional.

If you don't feel comfortable replacing the wax filter, ask your hearing care professional to do it for you.

Changing the wax filter using the wax guard tool

To change a wax filter, you will need your case of wax filter tools.

The wax filter tool has two functions: A removal tip to collect the used filter, and a replacement tip with the new filter.

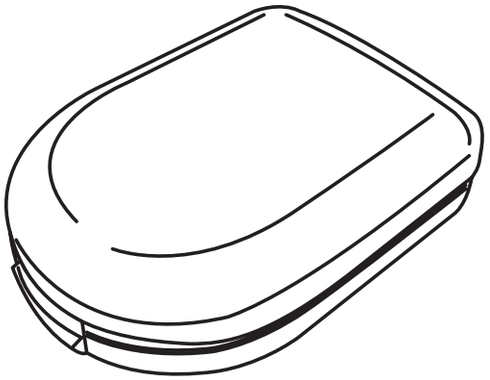


Box of 8 wax filter tools.

1. To remove the old wax filter, insert the removal tip into the used wax filter. Slowly pull the wax filter straight out.
2. To insert the new wax filter, gently press the replacement end of the wax filter tool straight into the hole of the sound outlet until the outer ring lies flush with the outside of the hearing aid.
3. Pull the filter tool straight out. Your new filter will remain in place.

NOTE: Your hearing aid may have a vent hole next to the wax filter outlet. Make sure not to put the wax filter tool into the vent. Pressing on the new wax filter with the flat side of the tool can ensure that the wax filter is correctly in place.

Storing your hearing aids



The best storage for your hearing aids is the case they came in.

Tinnitus management

Tinnitus Sound Generator module

Your hearing aid includes the Tinnitus Sound Generator (TSG) module, a tool for generating sounds to be used in tinnitus management programs to temporarily 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. Depending on the selected hearing aid program and the environment you are in, you will sometimes hear the therapeutic sound resembling a continuous or fluctuating noise.

Indications for use of the TSG module

The Tinnitus Sound Generator module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus. The target population is primarily the adult population over 18 years of age. This product may also be used with children 12 years of age or older. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing care professional or the guardian for the insertion and removal of the hearing aid containing the TSG module.

For healthcare professionals

The Tinnitus Sound Generator module is targeted for healthcare professionals who are treating patients suffering from Tinnitus, as well as conventional hearing disorders. The

initial fitting of the Tinnitus Sound Generator module must be done during an in-office visit by a hearing professional participating in a Tinnitus Management Program.

User instructions for the TSG module

Description of the device

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

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 to make it more pleasant. The noise can then resemble, for example, breaking 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 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 a volume control. Your doctor, audiologist or hearing care professional will review with you the need for having such a control.

The scientific concepts that form the basis for the device

The TSG module provides sound enrichment intending to surround 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 most instances, the TSG module can also be set to mask the tinnitus sound, to provide temporary relief by introducing a more pleasant and controllable sound source.

TSG volume control

The sound generator is set to a specific loudness level by the hearing care 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 tinnitus sound generator volume can only be adjusted within the range set by the hearing care professional.

The volume control is an optional feature in the TSG module used for adjusting the sound generator output level.

TSG - Technical specifications

Audio signal technology: Digital

Available sounds

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

High-pass filter	Low-pass filter
500 Hz	2000 Hz
750 Hz	3000 Hz
1000 Hz	4000 Hz
1500 Hz	5000 Hz
2000 Hz	6000 Hz
-	8000 Hz

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

⚠ WARNING

Prescription use of this device

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

To adjust TSG, please consult your hearing healthcare professional.

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 the use of the sound generator and seek medical evaluation.

Target population

The target population is primarily the adult population over 18 years of age. This product may also be used with children 12 years of age or older. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing care professional or the guardian for the insertion and removal of the hearing aid containing the TSG module.

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 ensure 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 counselling and/or in a tinnitus management program to relieve patients suffering from tinnitus.

Warning information



WARNING:

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



CAUTION:

- 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.
- Discontinue use of the sound generator and consult promptly with a licensed physician if you experience any of the following conditions:
    a. Visible, congenital or traumatic deformity of the ear.
    b. History of active drainage from the ear within the previous 90 days.
    c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
    d. Acute or chronic dizziness.
    e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
    f. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
    g. Pain or discomfort in the ear.

- Discontinue use of the sound generator and consult promptly with your hearing care professional if you experience changes in the tinnitus perception, discomfort or interrupted speech perception, while using the tinnitus sound generator.
- The volume control is a feature in the TSG module used for adjusting the sound generator output level. To prevent unintended usage by paediatric or physically or mentally disabled users, the volume control must be configured to only provide a decrease of the sound generator output level.
- Children and physically or mentally disabled users will require guardian supervision while wearing the TSG hearing aid.

⚠ 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 generator. 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:

a. Visible, congenital or traumatic deformity of the ear.
b. History of active drainage from the ear within the previous 90 days.
c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
d. Acute or chronic dizziness.
e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.

f. Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.

g. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

h. Pain or discomfort in the ear.



CAUTION: The maximum output of the sound generator falls 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 this is set to a 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.

General warnings and cautions

WARNING:

- Consult a hearing care professional or a physician:
  - If you think there may be a foreign object in your ear canal
  - If you experience skin irritation
  - If excessive ear wax accumulates with the use of the hearing aid

See also "Contra-indications", page 5

- Seek immediate medical help if a hearing aid, any of its parts, a battery, or a magnet is swallowed, as it can cause choking and harm your health.
- Keep hearing aids, their parts, batteries, and magnets away from pets, children, and people with cognitive, intellectual, or mental health challenges.
- Always supervise children or individuals with cognitive, intellectual, or mental health challenges when they are using their hearing aids. Hearing aids contain small pieces that can be dangerous if swallowed.
- Do not wear your hearing aids while being exposed to radiation. Some types of radiation, e.g. from MRI or CT scanners, can affect the settings in your hearing aids, causing malfunction and potentially damage to your hearing.
- Other types of radiation, such as burglar alarms, room surveillance systems, mobile phones, metal detectors, and radio equipment will not damage your hearing aids. However, they may briefly affect the sound quality in your hearing aids and may create undesired sounds.

- Never use your hearing aids in places with explosive gases such as mines, oil fields, or similar unless these areas are certified for hearing aid use. Using your hearing aids in places that are not certified for hearing aid use can be dangerous.
- Do not dry your hearing aids in an oven, microwave oven, or other heating equipment. This will cause them to melt and may cause burns to your skin.
- In general, exposure to loud sounds can damage your hearing. This could be loud music or loud environments. You can best protect your hearing by reducing exposure to loud sounds and environments or by using hearing protection.
- External devices connected to the electrical input must be safe according to the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60065, or IEC 60950-1, IEC 62368-1 as appropriate.
- Your hearing aids have been fitted to amplify soft and loud sounds according to your needs. If the amplification seems too loud or you suspect the hearing aid is malfunctioning (e.g. you hear distorted or unusual sound), contact your hearing care professional. A malfunctioning hearing aid can damage your hearing.
- Only use original consumables with your hearing aids (e.g. wax filters). Consult your hearing aid professional for more information.
- No modification of this hearing aid is allowed.

Warning related to power hearing aids

- A power hearing aid can produce very loud sound to compensate for severe or profound hearing loss. There is a risk that the loud sound can further impair the user's hearing.



CAUTION:

- Use your hearing aids as your hearing care professional recommends. Incorrect use may damage your hearing.
- Do not use a broken or modified hearing aid. It may not work properly and may be harmful to your hearing. It may also cause scratches or sores due to sharp edges.
- Do not modify the shape of your hearing aid or its accessories. This can cause skin reactions or sharp edges leading to scratches or sores.
- If you suspect that you have a detached wax filter or another object in your ear canal, consult your hearing care professional. These objects can be harmful and can cause an infection in your ear.
- If you have a sore or injury where your hearing aid touches your ear or head, continued use of the hearing aid may cause it to worsen or prevent it from healing. Consult a hearing care professional for assistance.
- Your hearing aids are tuned to your hearing. Do not allow others to use your hearing aids as this can damage their hearing.

For hearing care professionals

 WARNING:

- The developed sound pressure level in the ears of children can be substantially higher than in average adults. It is recommended to perform an RECD measurement to ensure the correct target for the fitted OSPL90.
- Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level that exceeds 132 dB SPL or higher maximum OSPL 90 measured with an IEC 60711:1981 occluded ear simulator. The remaining hearing may risk further impairment.

 CAUTION: Do not change the outer casing or any parts of a hearing aid unless appropriately protected against ESD.

Troubleshooting

Issue	Potential cause	Potential solution
No sound	Is the hearing aid turned on?	Turn it on.See "Turning your hearing aids on and off", page 15.
	Is there a battery in the hearing aid?	Insert a new battery.
	Is the battery still good?	Replace with a new one.
	Is your ear full of wax?	Visit your physician.
Sound is distorted or weak?	Did your hearing aid get moist?	Use a desiccant (drying kit).
	Is the battery dirty?	Clean it or replace it with a new one.
	The battery is dead	Replace it with a new one.
Battery drains very quickly	Did you leave your hearing aid turned on for long periods of time?	Always switch off your hearing aids when you are not using them, e.g. during the night.
	Is the battery old?	Check the date on the battery pack.
Still having an unresolved issue?		Consult your hearing care professional.

Regulatory information

Warranties and repairs

The 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, the manufacturer pledges to secure functionality at least equivalent to the original hearing aid. As a signatory to the United Nations Global Compact initiative, the manufacturer is committed to doing this in line with environment-friendly best practices. Hearing aids therefore, at the 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.

Ambient conditions

Temperature test

Our 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 use

During normal operation the temperature should not exceed the limit values of 5 °C (41 °F) to 40 °C (104 °F), at a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa. An atmospheric pressure between 700 hPa and 1060 hPa is appropriate.



CAUTION: During use, your hearing aids may reach temperatures up to 43 °C (109 °F).

During transport or storage

During transport or storage, the temperature should not exceed the limit values of:

- -25 °C (-13 °F) to 5 °C (41 °F)
- 5 °C (41 °F) to 35 °C (95 °F) at a relative humidity up to 90 %, non-condensing
- 35 °C (95 °F) to 70 °C (158 °F) at a water vapour pressure up to 50 hPa.

Warm-up time: 5 minutes.
Cool-down time: 5 minutes.

Expected service lifetime

The expected service lifetime for the product when used as intended is:

Product	Lifetime
Hearing aid	5 years

Statement

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

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used following the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment to an outlet or a circuit that is different from the one to 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

- In the EU: The device conforms to the General Safety and Performance Requirements according to Annex I of the EU Medical Device Regulation 2017/745 (MDR).
- The full text of the EU declaration of conformity is available at the following internet address:
  www.declarations.resound.com/en.
- In the US: FCC CFR 47 Part 15, subpart B.
- In Canada: these hearing aids are certified under the rules of ISED.
- For other international regulatory requirements, please refer to the regulatory requirements of the specific country.

Type designations

The hearing aid type designation for modelsthe model included in this user guide is:

CAI10.

Hearing aid variants

Availability of models may vary by country.

Completely-In-the-canal (CIC) hearing aid type **CAI10** , using a zinc-air battery, is available in the following variants:

XF9CIC-LP, XF7CIC-LP, XF5CIC-LP, XF4CIC-LP.
XF9CIC-MP, XF7CIC-MP, XF5CIC-MP, XF4CIC-MP.
XF9CIC-HP, XF7CIC-HP, XF5CIC-HP, XF4CIC-HP.

Technical specifications

Hearing aid model	Maximum output
Low Power (LP) models	114 dB SPL (typical)
All Medium Power (MP) models	116 dB SPL (typical)
All High Power (HP) models	121 dB SPL (typical)

	LP	MP	HP
Current Drain (Quiescent/Operating)	0.53/0.73 mA	0.52/0.87 mA	0.54/0.75 mA

Data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7:2005 and ANSI S3.22-2014.

For further technical data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7:2005 and ANSI S3.22-2014, please see the data sheet for your hearing aids.

Additional information

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Notes

DANAVOX GN

Manufacturer according to EU
Medical Device Regulation
2017/745:

GN Hearing A/S
Lautrupbjerg 7
DK-2750 Ballerup
Denmark

402743000GB- 24.10 - Rev. C (Date of issuance: 2024.10.01)

CE
0297

Any serious incident that has occurred in relation to the device should be reported to the Legal manufacturer GN Hearing A/S and the competent authority of the EU Member State in which the user and/or patient is established.