

Instructions for use

nxtCIC R

Oticon Zeal™



oticon
life-changing technology



WARNING: People younger than 18 should go to a doctor before using this.

People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine 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 deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

**WARNING to Hearing Aid Dispenser,
Outputs over 132 dB SPL:**

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Caution: You may need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as possible. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

Note: What you can expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.



If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening –for example, noisy environments.

Note: Tell FDA about any injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit Information to FDA as soon as possible after the problem. FDA calls them “adverse events,” and they can include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Note: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nose-throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person younger than 18 years old with hearing loss should undergo medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if it is appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

Introduction to this booklet

This booklet guides you on how to use and maintain your new hearing aids. Ensure you read the booklet carefully including the **Warnings** section. This will help you get the most benefit from your new hearing aid.



Warnings

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

Your hearing care professional has adjusted the hearing aid to meet your needs. If you have additional questions, contact your hearing care professional.

A hearing care professional* (hearing aid professional, audiologist, ENT (ear, nose and throat) doctor, and hearing aid dispenser) is a person who is appropriately educated and has proven competency in professionally assessing hearing, selecting, fitting, and delivering hearing instruments and rehabilitation care to persons with hearing loss.

*The job title may vary from country to country.

The education of the hearing care professional is in accordance with national or regional regulations.

For your convenience, this booklet contains a navigation bar to help you navigate easily through the different sections.

| **About** | [Getting started](#) | [Daily use](#) | [Options](#) | [Tinnitus](#) | [Warnings](#) | [More info](#) |

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Intended use

Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	Bilateral or unilateral impaired hearing of sensorineural, conductive, or mixed type ranging from a slight (16 dB HL*) to moderately severe (65 dB HL*) degree of hearing loss, with an individual frequency configuration.
Intended users	Individuals with hearing loss who use hearing aids and their caregivers. Hearing care professionals responsible for adjusting the hearing aid.
Intended user group	Adults and children older than 36 months.
Use environment	Indoor and outdoor.
Contraindications	Not suitable for infants below 36 months. Users of active implants must pay special attention when using the hearing aid. For more information read the Warnings section.
Clinical benefits	The hearing aid is designed to provide better speech understanding to help ease communication with the aim of improving quality of life.

* As specified by the American Speech-Language-Hearing Association, [asha.org](https://www.asha.org), using pure-tone average of 0.5, 1 and 2 kHz.

IMPORTANT NOTICE

The hearing aid amplification is uniquely adjusted and optimized to your personal hearing capabilities during the hearing aid fitting performed by your hearing care professional.

Intended use DemoFlex

Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	For bilateral or unilateral sensorineural, conductive, or mixed hearing loss ranging from slight (16 dB HL*) to moderately severe (65 dB HL*), with an individual frequency configuration.
Intended users	Individuals with hearing loss who use hearing aids and their caregivers. Hearing care professionals responsible for adjusting the hearing aid. Demo hearing aids are intended to be used by multiple users.
Intended user group	Adults and children older than 36 months.
Number of allowable reuses	50 fitting cycles per hearing aid to ensure the performance and safety of a device remains equivalent to an original device.
Use environment	Indoor and outdoor.

Contraindications	Not suitable for infants below 36 months. Users of active implants must pay special attention when using the hearing aid. For more information read the Warnings section.
Clinical benefits	The hearing aid is designed to provide better speech understanding to help ease communication with the aim of improving quality of life.

* As specified by the American Speech-Language-Hearing Association, [asha.org](https://www.asha.org), using pure-tone average of 0.5, 1 and 2 kHz.

Limited market availability

The solution with demo hearing aids is only available in select markets. For further information, contact your hearing care professional.

IMPORTANT NOTICE

The hearing aid amplification is uniquely adjusted and optimized to your personal hearing capabilities during the hearing aid fitting performed by your hearing care professional.

Model overview

This booklet is valid for the following hearing aid models and styles:

Styles

- ☐ nxtCIC R

FW <<077_FW>>

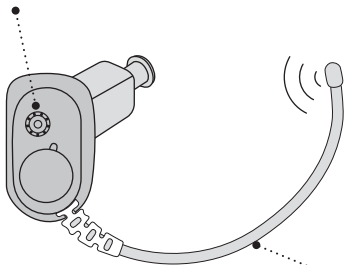
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Style>>
- ☐ <<040_HI>> <<060_PP2>> <<078_GTIN: (01) <<090_GTIN2>>
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Your hearing aid

What it is and does

Microphone inlet

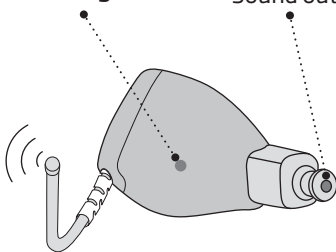
Sound in



Antenna*

Connect to external devices

LED light



Sound outlet

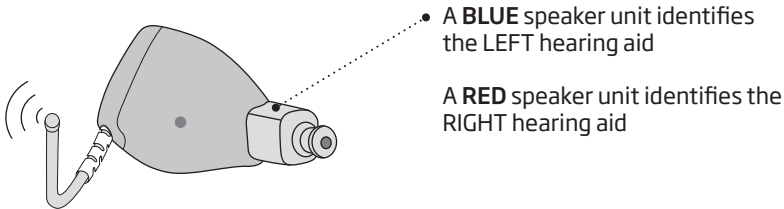
Sound out

IMPORTANT NOTICE

*Do not cut or attempt to modify the antenna. Doing so will break your hearing aid.

Identify left and right hearing aid

It is important to distinguish between the left and the right hearing aid as they might be programmed differently.



The speakers use one of the following earpieces:

Standard earpieces



☐ OpenBass dome



☐ Bass dome, double vent



☐ Bass dome, single vent



☐ Power dome

Customized earpieces



☐ Micro mold*

Dome sizes



6 mm



8 mm



10 mm



12 mm

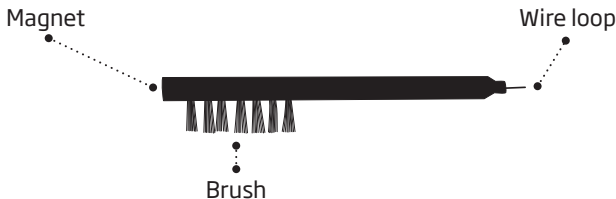
*Can be made of different materials

Note

For details on replacing the dome, see the **Replace standard earpieces** section.

Cleaning

The cleaning tool contains a brush for cleaning and removing earwax. If you need a new tool please contact your hearing care professional.

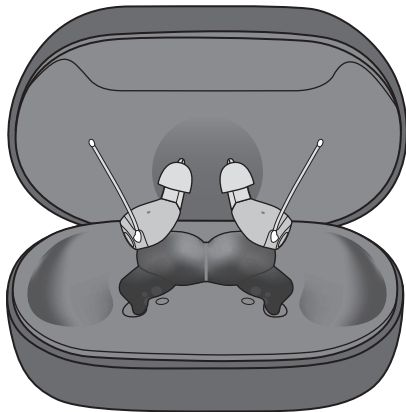


IMPORTANT NOTICE

The cleaning tool has a built-in magnet. Keep the cleaning tool at least 30 centimeters (1 foot) away from credit cards and other magnetically sensitive devices.

Turn the hearing aid ON

To turn your hearing aids ON, remove them from the charger.



Battery performance

Ensure you fully charge your hearing aids before first use and charge them every night. That ensures you start your day with fully charged hearing aids.

Battery performance varies depending on your individual use and hearing aid settings. Streaming sound from a TV, mobile phone or connectivity devices can influence this performance.

If your hearing aids do not perform for a full day, contact your hearing care professional.

For instructions on how to use your charger, see the charger's instructions for use.

IMPORTANT NOTICE

When charging in high ambient temperatures, your hearing aid may reach up to 45°C.

Low battery indication

The low battery indication is repeated periodically until the battery runs out. Your hearing care professional can set your hearing aids to match your preferences.

After the notification, you have approximately two hours before the hearing aid runs out of battery. At this point, you may continue to stream audio for approximately one hour. To extend battery performance, ensure you stop any audio streaming.

The battery is running low



Three alternate tones

The battery has run out



Four descending tones



<<084_SpoNo>>

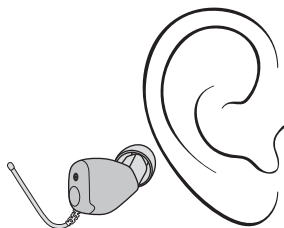
(Optional for select languages)

IMPORTANT NOTICE

Ensure that your charger is powered or that the charger's built-in battery is charged when the hearing aid is seated in the charging port. For more information, see your charger's instructions for use

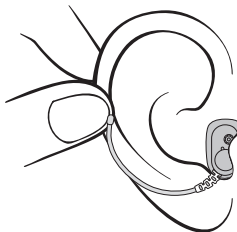
Insert the hearing aid

Step 1



Place the tip of the hearing aid in your ear canal. Ensure the antenna is oriented downwards.

Step 2



Gently pull your ear outwards and push the hearing aid into the ear canal. Follow the natural contour of the ear canal. Push the hearing aid to make sure it fits comfortably in the ear.

Step 3



Ensure the antenna is placed in the curved part of the outer ear just before the ear canal and that the hearing aid is placed upright as shown in the drawing.

Remove your hearing aid

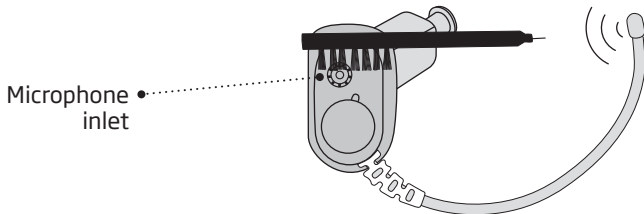
Hold the hearing aid by the antenna. Gently pull the hearing aid from the ear canal.

Caring for your hearing aid

When handling your hearing aid, hold it over a soft surface to avoid damage if you drop it.

Cleaning the hearing aid

Carefully brush away debris from the microphone inlet with a clean brush. Gently brush the surface. Make sure that the filters do not fall off.



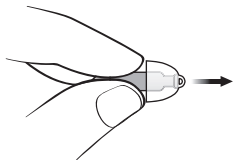
IMPORTANT NOTICE

To clean the hearing aids, use a soft, dry cloth. The hearing aids must never be washed or immersed in water or other liquids.

Replace standard earpiece

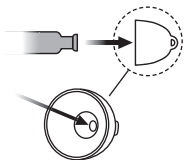
The standard earpiece (dome) should not be cleaned.
If the earpiece is filled with earwax, replace it with a new one.
Domes should be replaced at least once a month.

Step 1



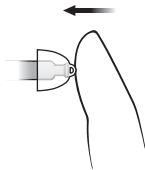
Hold on to the speaker and pull off the earpiece.

Step 2



Insert the speaker exactly into the middle of the earpiece to get a secure fit.

Step 3



Push firmly to ensure that the earpiece is securely fastened.

Clean customized earpiece

The customized earpiece should be cleaned regularly.

The earpiece has a white wax filter* that keeps earwax and debris from damaging the speaker. Ensure you replace the filter when clogged, or if the hearing aid does not sound normal.

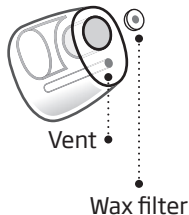
Alternatively, contact your hearing care professional.

Note

If you use a mold, your hearing care professional must replace the wax filter in the speaker.

* Not all molds have a wax filter. Filter composition can vary by mold. For more information contact your hearing care professional.

Contact your hearing care professional to get the appropriate vent cleaning tool for your earpiece.



IMPORTANT NOTICE

If the earpiece is not on the speaker when removed from the ear, the earpiece may still be in the ear canal. For further instructions, consult your hearing care professional.

Filter replacement

The filters keep wax and debris from damaging the hearing aid.

You should replace the filters at least once a month.

If the filters become clogged, replace them or contact your hearing care professional.

Refer to the following pages for instructions on how to replace the appropriate filters.

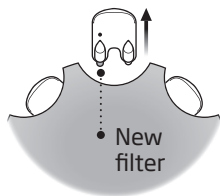
IMPORTANT NOTICE

Ensure you always use the same type of wax filter as was originally supplied with the hearing aids.

If you are in doubt about the use or replacement of filters, contact your hearing care professional.

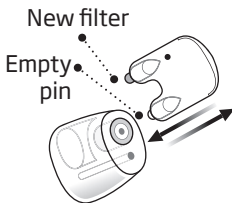
Replace ProWax filter

1. Tool



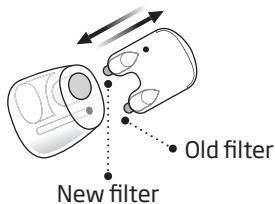
Remove the tool from the shell. The tool has two pins: one empty for removal and one with the new wax filter.

2. Remove



Insert the empty pin into the wax filter in the earpiece and pull it out.

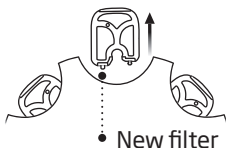
3. Insert



Insert the new wax filter using the other pin. Remove the tool and throw it out.

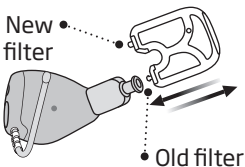
Replace ProWax miniFit filter

1. Tool



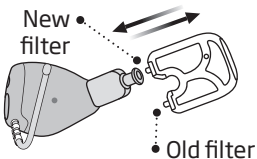
Remove the tool from the shell. The tool has two pins, one empty for removal and one with the new ProWax miniFit filter.

2. Remove



Push the empty pin into the ProWax miniFit filter in the hearing aid and pull it out.

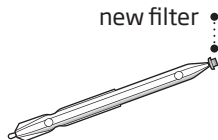
3. Insert



Insert the new ProWax miniFit filter using the other pin, remove the tool and throw it out.

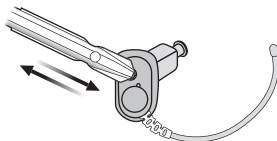
Replace O-Cap filter

1. Tool



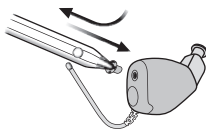
Remove the tool from the packaging. The tool has two ends, one for removal and one with the new O-Cap filter.

2. Remove



Push the pointed end of the tool into the existing O-Cap filter and pull it out.

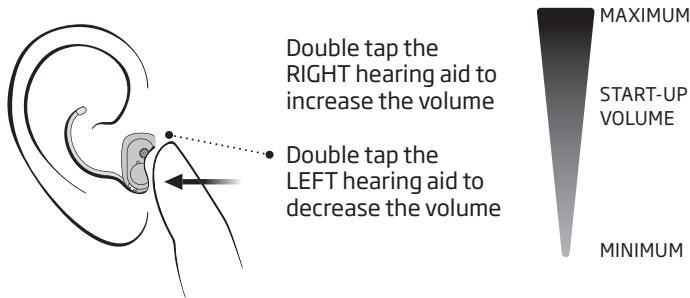
3. Insert



Insert the new O-Cap filter using the other end of the tool and remove. Throw the tool out after use.

Change volume

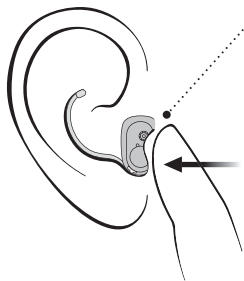
You can double tap on your ear or hearing aid to adjust the volume up or down. This is the default function in your hearing aid. You may hear a click when you turn the volume up or down.



Change programs

Your hearing aid can have up to four different programs. These are programmed by your hearing care professional. You will hear one to four tones when you change program depending on the program.

If your hearing care professional has configured your hearing aids to change programs with a double tap, you will need the app to control your hearing aid volume. If you have Tinnitus SoundSupport activated, the change program by tap feature cannot be used.



- **If you have two hearing aids:**

Double tap the RIGHT hearing aid to cycle one program forward, for example program 1 to 2.

Double tap the LEFT hearing aid to cycle one program backward for example from program 4 to 3.

If you only have one hearing aid:

Double tap your hearing aid to cycle one program forward, for example program 1 to 2 or 4 to 1.

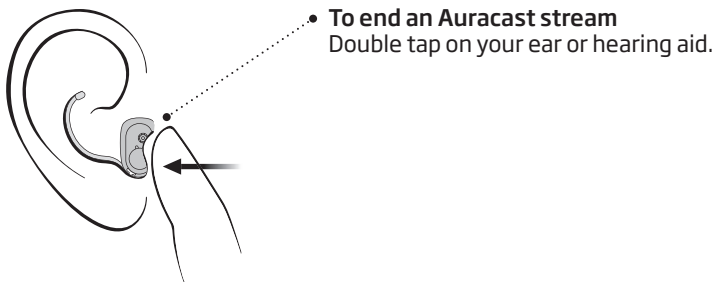


Voice Notification

(Optional for select languages)

Auracast broadcast

You can end an Auracast stream by double tapping your ear or hearing aid. To connect to an Auracast broadcast stream, see your TV or mobile device manual for availability and connection instructions.



- **To end an Auracast stream**

Double tap on your ear or hearing aid.

Call handling

You can double tap your ear or your hearing aid to answer or end calls.

To use the tap functionality, your hearing aids must be paired with a compatible mobile device.*

To accept a phone call

Double tap on your ear or hearing aid. A short tone confirms your action.

To end a phone call

Double tap on your ear or hearing aid. Short, descending tones confirm your action.

* For a list of compatible mobile devices, visit: <<170_CompatibilityURL>>.

Store your hearing aids

When you are not using your hearing aids, the charger is the best place to keep them.

To ensure the longest life of the rechargeable battery in your hearing aids, do not expose them to excessive heat. For example, do not leave your hearing aids in the sun in front of a window or in a car, even if they are in the charger.

Long-term storage

Before storing your hearing aids for more than three months, fully charge them first, then place them in the charger. This ensures the battery can be recharged later.

Note

To protect the rechargeable battery, it is necessary that you fully charge the hearing aid every six months. If a stored hearing aid is not charged within a six-month period, the battery will no longer function and your hearing aid will need to be replaced.

Use your hearing aids with digital devices

iPhone, iPad, Mac, and Vision Pro

Your hearing aids are Made for iPhone hearing aids and allow for direct streaming and hands-free communication from your iPhone®, iPad®, Mac®, or Vision Pro®.*

Android devices

Your hearing aids support Audio Streaming for Hearing Aids (ASHA) and Bluetooth® LE Audio for hands-free communication from select Android™ devices*. Your hearing aids also support Auracast™ technology. This technology allows you to connect to Auracast broadcasts and share audio with supported devices.* For more information see the **Auracast broadcast** section.

Oticon Companion can be used to control your hearing aids from your mobile device.

For assistance in using your hearing aids with any of these products, contact your hearing care professional.

* For a list of compatible devices, visit: <<170_CompatibilityURL>>

Pairing and compatibility

For instructions on how to pair your hearing aids to your smart device,
<<186_Visit>>

<<181_Pairing>>

For a list of compatible smart devices, visit:

<<170_CompatibilityURL>>

Note: Your hearing aids use Bluetooth wireless technologies. They can be used on an aircraft as hearing aids are exempt from the rules applied to portable electronic devices on an aircraft.

Optional features and accessories

The features and accessories described on the following pages are optional. Please contact your hearing care professional to find out how your hearing aid is programmed.

If you experience difficult listening situations, a special program may be helpful. These are programmed by your hearing care professional.

Write down any hearing situations in which you may need help.

Wireless accessories and other options

As an enhancement to your hearing aids, a range of wireless accessories are available. These can enable you to hear and communicate better in many everyday situations.

<<150_AudioClip>>

When paired with your mobile phone, you can use the hearing aids as a hands-free headset, or as a remote microphone.

<<180_TVAdapter>>

Wireless transmitter of sound from TV and electronic audio devices. TV Adapter streams sound directly to your hearing aids.

<<160_RemoteControl>>

Offers the ability to change program, adjust volume, or mute your hearing aids.

<<140_App>>

An application that lets you control your hearing aid from your mobile phone or tablet. For iPhone, iPad, and Android™ devices. Ensure that you only download and install the app from the official App Store or Play store.

<<175_PhoneAdapter>>

<<176_PhoneAdapterText>>

EduMic

A device that can be used as a remote microphone in classrooms, work environments, public places (using Telecoil), and other settings.

For more information, please contact your hearing care professional.

Tinnitus SoundSupport™

Intended use of Tinnitus SoundSupport

Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief for patients suffering from tinnitus as part of a tinnitus management program.

The target population is the adult population (over 18 years of age).

Tinnitus SoundSupport is targeted to licensed hearing care professionals (audiologists, hearing aid specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing loss. Fitting of Tinnitus SoundSupport must be done by a hearing care professional participating in a tinnitus management program.

Guidelines for Tinnitus SoundSupport users

Your hearing care professional will be able to offer the appropriate follow-up care. It is important to follow his/her advice and directions regarding such care.

Prescription use only

Good health practice requires that a person reporting tinnitus have a medical evaluation by a licensed ear physician before using a sound generator. The purpose of such an evaluation is to ensure that any medically treatable condition that may cause tinnitus is identified and treated prior to using a sound generator.

Limitation on use time

Daily use

The volume levels of Tinnitus SoundSupport can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Your hearing care professional will advise you of the maximum amount of time per day you should use Tinnitus SoundSupport. It should never be used at uncomfortable levels.

See the table **Tinnitus SoundSupport: Limitation on use**, in the **Your individual hearing aid settings** section at the end of this booklet to learn how many hours per day you can safely use the relief sound in your hearing aid.

Sound options and volume adjustments

Tinnitus SoundSupport is programmed by your hearing care professional to match your hearing loss and preferences for tinnitus relief.

Tinnitus SoundSupport programs

The sound generator can be activated in up to four different programs.

Volume adjustments with Tinnitus SoundSupport

Your hearing care professional can set the volume control for a hearing aid program for which Tinnitus SoundSupport is activated.

For more information about volume adjustments with Tinnitus SoundSupport, see the table **Tinnitus SoundSupport settings overview for your hearing aid** in the **Your individual hearing aid settings** section at the end of this booklet.

Warnings related to Tinnitus

If your hearing care professional has activated the sound generator Tinnitus SoundSupport, please pay attention to the following warnings.

There are some potential concerns associated with the use of any sound generated by a tinnitus management device. Among them are the potential worsening of tinnitus, and/or a possible change in hearing thresholds.

Should you experience or notice a change in hearing or tinnitus, or any dizziness, nausea, headaches, heart palpitations, or possible skin irritation at the point of contact with the device, you should immediately discontinue use of the device and consult a medical, audiology, or other hearing care professional.

As with any device, misuse of the sound generator feature may cause potentially harmful effects. Care should be taken to prevent unauthorized use and to keep the device out of reach of children and pets.

Maximum wearing time

Always follow the maximum wearing time per day of the Tinnitus SoundSupport advised by your hearing care professional. Prolonged use may lead to worsening of your tinnitus or of your hearing loss.

General warnings

For your personal safety and to ensure correct usage, you should familiarize yourself fully with the following general warnings before using your hearing aids. Consult your hearing care professional if your hearing aids exhibit unexpected behavior or you encounter serious incidents with your hearing aids. Your hearing care professional will support you with issue handling and, if relevant, reporting to the manufacturer and/or the national authorities.

Note that hearing aids do not restore normal hearing and do not prevent or improve hearing impairment resulting from natural processes such as aging or sickness.

Hearing aids are only a part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

To achieve the full benefit from your hearing aids, you should use them frequently.

Only charge the hearing aids with a designated charger. Other chargers risk destroying the hearing aids and batteries.

This hearing aid is supported by a nonremovable rechargeable lithium-ion battery cell. Please ensure to charge the hearing aid and familiarize yourself with the safety and handling information related to rechargeable hearing aids.

DemoFlex: Important information for Hearing Care Professionals

<<085_DemoFlex>> for instructions about how to handle the hearing aid between reuse.

Usage of hearing aids

Hearing aids should only be used as directed and adjusted by your hearing care professional. Misuse can result in sudden and permanent hearing loss.

Never allow others to wear your hearing aid, as incorrect usage could cause permanent damage to their hearing.

Choking hazards of swallowing small parts

Keep all small parts (for example, hearing aids, earpieces, batteries, etc.) out of reach and sight of children and others who might swallow these items. Seek emergency medical treatment immediately if someone is choking on small parts or batteries are swallowed.

If a battery, hearing aid or small part is swallowed, see a doctor immediately and contact the National Poison Center at 1-800-222-1222 or National Battery Ingestion Hotline at 1-800-498-8666.

Beware of sudden dysfunction

Your hearing aids may stop working without notice. For example, if they run out of battery. Keep this in mind especially in situations where you depend on warning sounds (for example when in traffic).

Use with active medical implants

Your hearing aid have been thoroughly tested and developed for human health according to international standards for human exposure (Specific Absorption Ratio - SAR), induced electromagnetic power and voltages into the human body.

The exposure values are well below international accepted safety limits for SAR, induced electromagnetic power and voltages into the human body defined in the standards for human health and coexistence with active medical implants, such as pacemakers and heart defibrillators.

Continues on next page

General warnings

If you have an active brain implant, contact the manufacturer of your implanted device for information about the use with a hearing aid.

Remove hearing aids before certain medical procedures

Remove your hearing aid before medical procedures such as X-ray examinations, CT/MR/PET scans, electrotherapy, surgery, etc. Your hearing aid may be damaged if exposed to strong magnetic or electromagnetic fields.

Keep away from extreme heat

Never expose your hearing aids to extreme heat. For example, do not leave your hearing aids inside a parked car in the sun. Never use an external heating device to dry your hearing aids. For example, do not dry your hearing aids using a hair dryer or in an oven such as a microwave.

Keep away from chemicals

Remove your hearing aids before applying products that contain certain chemicals that can damage your hearing aids. For example, cosmetics, hairspray, perfume, aftershave lotion, suntan lotion and insect repellent. Allow the products time to dry before putting on your hearing aids.

Potential side effects

You may produce more earwax when using hearing aids.

In rare cases, the non-allergenic materials in the product may cause skin irritation or other side effects. If you experience any such side effects, consult your doctor.

Connection to external equipment

The safety of the hearing aids, when connected to external equipment (with an auxiliary input cable and/or with USB cable and/or directly), is determined by the external signal source. When the hearing aid is connected to external equipment which is plugged into a power socket, this equipment must comply with IEC 62368-1 or equivalent safety standards.

Use of third-party accessories

Only use accessories, cables, or transducers (for example, microphones) supplied by the manufacturer. Non-original accessories may result in reduced electromagnetic compatibility (EMC) of your hearing aid.

Do not modify

Do not make any modifications to your hearing aid not expressly approved by the manufacturer. This will void the warranty.

Never attempt to replace rechargeable batteries

Do not attempt to open your hearing aid as it may damage the battery.

Never attempt to replace the battery. If battery replacement is needed, return your device to the supplier. The warranty is void if there are signs of tampering.

General warnings

Beware of battery leakage

Do not touch your hearing aid if the battery appears to be leaking as the acids may cause skin irritation. If you have been in contact with battery acids, wipe it off using a wet cloth. If you experience skin irritation, consult your doctor. In the event of battery leakage contact your hearing care professional for further instructions.

Use in fields with electromagnetic interference

Your hearing aids have been thoroughly tested for interference according to the most stringent international standards, including EN/IEC 60601-1-2 and its amendments. Electromagnetic interference may occur in the vicinity of equipment that can affect the performance of your hearing aids such as mobile phones, Wi-Fi routers or other equipment with the displayed symbol. If your hearing aids are affected by interference, move away from the source.

Keep away from environments with risk of explosions

Your hearing aid is safe to use under normal usage conditions. The hearing aid has not been tested for compliance with international standards concerning explosive environments. Do not use your hearing aid in environments with risk of explosions such as mines, oil fields, oxygen-rich environments or areas where flammable anesthetics are handled.

Use with cochlear implants

If you are using a cochlear implant (CI) on one ear and a hearing aid on the other ear, make sure to always keep your CI at least a 1 centimeter (0.4 inches) away from your hearing aid. The magnetic field from the CI may permanently damage the speaker unit in your hearing aid. Never place the devices close together on a table (for example, when cleaning or changing batteries). Do not carry the CI and the hearing aid together in the same box.

Detached earpiece in ear canal

Ensure that the earpiece is still connected to the speaker when removing the hearing aid from your ear. If the earpiece is not on the speaker, the earpiece may still be in the ear canal. Consult your hearing care professional.

Fatality hazards of swallowing batteries

Never swallow batteries. Doing so can lead to serious injury or death within hours. Swallowed batteries can cause burns that may perforate inner organs. Keep the batteries out of reach and sight of children and others who might swallow them. Batteries have occasionally been mistaken for pills. Therefore, check your medicine carefully before swallowing any pills. Seek emergency medical treatment immediately if a battery is swallowed.

Risk of placing batteries in ear or nose

Never place batteries in the ear or the nose. This can lead to permanent damage due to burns. Contact a doctor immediately if a battery is placed in the ear or nose.

Water & dust resistant (IP68)

Your hearing aid is dust-tight and protected against ingress of water which means it is designed to be worn in all daily life situations. Therefore, you do not have to worry about humidity or getting wet in the rain.

Should your hearing aid come into contact with water and stop working, gently wipe off any water and let the hearing aid dry.

IMPORTANT NOTICE

Do not wear your hearing aid while showering or participating in water activities.
Do not immerse your hearing aid in water or other liquids.

Conditions of use

Operating Conditions	Temperature: +5°C to +40°C (41°F to 104°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Transportation conditions	Temperature and humidity shall not exceed the below limits during transportation and storage: Temperature: -20°C to + 60°C (-4°F to 140°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Storage conditions	Temperature: -20°C to + 30°C (-4°F to 86°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

Your hearing aids contains a magnet. If you have an active implanted medical device, follow the guidelines from the manufacturer of your implanted medical device regarding its use with magnets. Keep the hearing aids away from credit cards and other magnetically sensitive devices.

Cell phone

Some hearing aid users have reported a buzzing sound in their hearing aid when using cell phones, indicating that the cell phone and hearing aid may not be compatible.

The ANSI C63.19 standard determines the prediction of compatibility between a specific hearing aid and a cell phone, thus hearing aid compliance is tested according to this standard. However, demonstrating compliance according to this standard cannot guarantee that all users will be satisfied.

Whereas all hearing aids have acoustic coupling, only the larger hearing aids have the physical space for telecoil (inductive) coupling.

The hearing aid is compliant with ANSI C63.19 in both microphone and telecoil mode.

IMPORTANT NOTICE

The performance of individual hearing aids may vary with individual cell phones. Therefore, ensure you try this hearing aid with your cell phone or, if you are purchasing a new phone, be sure to try it with your hearing aid prior to purchase. For additional guidance, please ask your cell phone provider for the booklet entitled "Hearing Aid Compatibility with Digital Wireless Cell Phones."

Technical information

The hearing aid contains the following two radio technologies:

The hearing aid contains a radio transceiver using short range magnetic induction technology operating at 3.84 MHz. The magnetic field strength of the transmitter is very weak and always below 15 nW (typically below $-40 \text{ dB}\mu\text{A/m}$ ($-12.20 \text{ dB}\mu\text{A/ft}$) at 10 meters (33 feet) distance).

The hearing aid also contains a radio transceiver using Bluetooth Low Energy technology and a proprietary short range radio technology, both operating at ISM band 2.4 GHz.

The radio transmitter is low power and always below 6.0 mW equal to 7.8 dBm in total radiated power.

Only use your hearing aids in areas where wireless transmission is permitted.

The hearing aids comply with international standards concerning radio transmitters, electromagnetic compatibility, and human exposure.

The hearing instrument is designed to operate in public and residential environments. It has passed the following applicable emissions and immunity tests:

Radiated emissions requirements for a CISPR 11 Group 1 Class B device as stated in table 2 of IEC 60601-1-2.

Radiated emission for communication devices operating in the ISM 2.4 GHz band as stated in 47 CFR Part 15, subpart C, RSS-247 and EN 300 328 (only for products with Bluetooth).

Radiated emission for near field magnetic induction communication operating at 3.84 MHz as stated in 47 CFR Part 15, subpart C, RSS-210 and EN 300 330 (only for products with NFMI).

RF radiated immunity at a field level of 10 V/m between 80 MHz and 2.7 GHz as stated in table 4 of IEC 60601-1-2 and, 3 V/m between 2.7 and 6.0 GHz as stated in CISPR 32.

RF radiated immunity at a field level of up to 28 V/m for selected RF wireless communication bands between 380 MHz and 5.8 GHz as stated in table 9 of IEC 60601-1-2.

RF radiated immunity at a field level of up to 65 A/m for selected proximity magnetic fields at 30 kHz, 134.2 kHz and 13.56 MHz as stated in table 11 of IEC 60601-1-2 AM1.

RF radiated immunity field levels at selected bands stated in IEC 60118-13 between 25 V/m and 60 V/m and, for proximity-fields from communication devices held to the ear, stated in ANSI C63.19.

Immunity to power frequency magnetic fields at a field level of 30 A/m as stated in table 4 of IEC 60601-1-2 (only for products with telecoil).

Immunity to ESD levels of +/- 2, 4 and 8 kV conducted discharge and +/- 2, 4, 8 and 15 kV air discharge as stated in table 4 of IEC 60601-1-2.

Due to the limited space available on the hearing aid, relevant approval markings can be found in this booklet. <<183_ TDS>>

(**<<078_Style>>** only)

This device contains a radio module (KE_AU5_NXTCIC) with the following certification ID number:

FCC ID: 2ACAH-AU5NXTCIC

Radio frequency radiation exposure information

This device complies with FCC RF exposure limits set forth for an uncontrolled environment and has been tested for portable use.

The device must not be co-located or used in conjunction with any other antenna or transmitter.

Use of other accessories not verified by the manufacturer may not ensure compliance with FCC RF exposure guidelines.

Note: This device 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 device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device 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 distance between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the manufacturer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The manufacturer declares that this hearing aid is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

This medical device complies with Medical Device Regulation (EU) 2017/745.

<<185_Trademarks>>

Declaration of Conformity is available at the <<249_Headquarters>>

<<210_HQ>>

Kongebakken 9
DK-2765 Smørum
Denmark

<<250_ConformityURL>>

Should your hearing aid require service or replacement, contact your hearing care professional for assistance. Many repair needs can be handled on-site at your local hearing care professional's office, and they will arrange for service with the manufacturer if required. You can also contact us at:
580 Howard Ave., Somerset, NJ 08873.

CE 0123

 **AURACAST**
A BLUETOOTH® TECHNOLOGY

 **Bluetooth®**



SBO Hearing A/S
Kongebakken 9
DK-2765 Smørum
Denmark



Waste from electronic
equipment must be
handled according to
local regulations.



IP68

Apple, the Apple logo, iPhone, iPad, Vision Pro and Mac and the Mac logo are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge and has been certified by the developer to meet Apple performance standards.

Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

Android, Google Play, and the Google Play logo are trademarks of Google LLC.

The Bluetooth® word mark and logo are registered trademarks owned by Bluetooth SIG, Inc. The Auracast™ word mark and logo are registered trademarks owned by Bluetooth SIG, Inc. Any use of such marks by Demant are under license. Other trademarks and trade names are those of their respective owners.

Description of symbols accompanying the product



Warnings

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



Manufacturer

The device is produced by the manufacturer whose name and address are stated next to the symbol. Indicates the medical device manufacturer, as defined in EU Regulation 2017/745.



CE mark

The device complies with all required EU regulations and directives. The four-digit number indicates the identification of the notified body.



Electronic waste (WEEE)

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



Regulatory Compliance Mark (RCM)

The device complies with electrical safety, EMC and radio spectrum requirements for devices supplied to the Australian or New Zealand markets.

IP68

IP code

Class of protections against harmful ingress of water and particulate matter according to EN 60529. IP6X indicates total dust protection. IPX8 indicates the protection against the effects of continuous immersion in water.



Bluetooth logo

Registered trademark of Bluetooth SIG, Inc. where any use of such requires a license.

Description of symbols accompanying the product



Auracast

Registered trademark of Bluetooth SIG, Inc. where any use of such requires license.



Made for Apple badges

Indicates that the device is compatible with iPhone and iPad.



Mac badge

Indicates that the device is compatible with Mac.



Apple AirPlay badge

The AirPlay button can be used to disconnect and connect hearing aids from a Mac.



Android badge

Indicates that the device is compatible with Android.



Radio Frequency (RF) transmitter

Your device contains an RF transmitter.



Global Trade Item Number

A globally unique 14-digit number used to identify medical device products including medical device software. GTIN in this booklet is related to medical device firmware (FW). GTIN on regulatory packaging label is related to medical device hardware.



Firmware

Firmware version used in the device.



Keep dry

Indicates a medical device that needs to be protected from moisture.

Description of symbols accompanying the product



Catalog number

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



Serial number

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



Medical Device

The device is a medical device.



Battery recycling symbol

Li-ion battery recycling symbol.



Temperature limit

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



Unique device identifier

Indicates a carrier that contains unique device identifier information.

International warranty

Your device is covered by an international warranty issued by the manufacturer. This international warranty covers manufacturing and material defects in the device itself, but not in accessories such as batteries, tubing, speakers, earpieces, and filters, etc. Problems arising from improper/incorrect handling or care, excessive use, accidents, repairs made by an unauthorized party, exposure to corrosive conditions, physical changes in your ear, damage due to foreign objects entering the device, or incorrect adjustments are NOT covered by the international warranty and may void it. The above international warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods in the country where you have bought your device. Your hearing care professional

may also have issued a warranty that goes beyond the clauses of this international warranty. Please consult him/her for further information.

If you need service

Take your device to your hearing care professional, who may be able to solve minor problems and adjustments immediately. Your hearing care professional may charge a fee for their services.

Warranty

Certificate

Name of owner: _____

Hearing care professional: _____

Hearing care professional's address: _____

Hearing care professional's phone: _____

Purchase date: _____

Warranty period: _____ Month: _____

Model left: _____ Serial no.: _____

Model right: _____ Serial no.: _____

Your individual hearing aid settings

To be filled out by your hearing care professional.

Tinnitus SoundSupport: Limitation on use			
☐	No limitation on use		
	Program	Start-up volume (Tinnitus)	Max volume (Tinnitus)
☐	1	Max _____ hours per day	Max _____ hours per day
☐	2	Max _____ hours per day	Max _____ hours per day
☐	3	Max _____ hours per day	Max _____ hours per day
☐	4	Max _____ hours per day	Max _____ hours per day

Tinnitus SoundSupport settings overview for your hearing aid

Left

Right

☐ Yes

☐ No

Tinnitus SoundSupport

☐ Yes

☐ No

☐ A) How to change Tinnitus SoundSupport volume in each ear separately

To **increase** or **decrease** the volume double tap on your ear or hearing aid. The volume starts at the default level set by your HCP. It then increases to the maximum level, decreases to the minimum level, and increases again in a continuous cycle.

☐ B) How to change Tinnitus SoundSupport volume in both ears simultaneously

You can use one hearing aid to **increase** the volume and the other hearing aid to **decrease** the volume.

To **increase** the volume, double tap repeatedly on your RIGHT ear or hearing aid.

To **decrease** the volume, double tap repeatedly on your LEFT ear or hearing aid.

To be filled out by your hearing care professional.

Sound indicators

Different sounds indicate the hearing aid status. The different indicators are listed below.

Your hearing care professional can set sound indicators to match your preferences.

Program	☐ Sound	Voice Notification	When to use
1	1 tone	☐ Yes ☐ No	
2	2 tones		
3	3 tones		
4	4 tones		

General settings overview for your hearing aid

Left			Right	
☐ Yes	☐ No	Change program	☐ Yes	☐ No
☐ Yes	☐ No	Change volume	☐ Yes	☐ No
Volume control indicators				
☐ On	☐ Off	Beeps at min/max volume	☐ On	☐ Off
☐ On	☐ Off	Beeps when changing volume	☐ On	☐ Off
☐ On	☐ Off	Beeps at start-up volume	☐ On	☐ Off
Battery indicators				
☐ On	☐ Off	Low battery warning	☐ On	☐ Off

To be filled out by your hearing care professional.

ON/OFF	Sound
ON	☐ Jingle
OFF	☐ 4 descending tones
Volume	Sound
Start-up volume	☐ 2 beeps
Minimum/maximum volume	☐ 3 beeps
Volume up/down	☐ 1 beep

Continues on next page

Accessories	☐ Sound
<<180_TVAdapter>>	2 different tones
EduMic	2 different tones
<<150_AudioClip>>	2 different tones

Warnings	Sound
Low battery	☐ 3 alternate tones
	☐ Voice Notification
Battery shut down	4 descending tones
Microphone cleaning or service needed	8 beeps repeated 4 times

Continues on next page

Troubleshooting guide

Symptom	Possible causes
No sound	Hearing aid is out of power
	Dead battery
	Clogged earpieces (dome, or mold)
	Clogged microphone inlet
	Clogged sound outlet
Intermittent or reduced sound	Clogged sound outlet
	Moisture
Squealing noise	Hearing aid earpiece incorrectly inserted
	Earwax accumulated in ear canal
Service alert voice notification	Issue detected by hearing aid
Beeping	If your hearing aid plays eight beeps, four times consecutively, your hearing aid may need a microphone service check.
Pairing issue with smartphone	Bluetooth connection failed
	Only one hearing aid is paired

Solutions

Charge the hearing aid

Contact your hearing care professional

Clean mold

Replace wax filter or dome

Clean microphone inlet* or replace filter (O-Cap)

Clean sound outlet* or replace the wax filter

Clean mold or replace wax filter or dome

Gently wipe the hearing aid and let it dry

Re-insert the earpiece

Have ear canal examined by your doctor

Contact your hearing care professional

First, try to clean the microphone with the cleaning tool.
If the beep persists, contact your service center.

1) Unpair your hearing aid. **2)** On your phone, turn Bluetooth OFF and ON again.
3) Turn the hearing aid OFF and then turn it back ON. **4)** Pair your hearing aid again
<<182_RePair2>>

Note

If none of the above solutions work, consult your hearing care professional.

Continues on next page

Troubleshooting guide

Symptom	Possible causes
Audio problems	Connectivity issues with Mac or Vision Pro

Solutions

- 1) Open the Control Center on Mac or Vision Pro. 2) Under Sound, click the AirPlay button OFF.
- 3) Place your hearing aids in the charger to turn them OFF, then remove them again to turn them ON.
- 4) In the Control Center under Sound, click the AirPlay button ON

If none of the above solutions work, consult your hearing care professional for assistance.

* According to guideline in this booklet

Summary of relevant studies

Clinical evaluations conducted by or for the manufacturer provide evidence to support the intended use and clinical benefits outlined in the IFU and demonstrate regulatory conformity. Clinical data is collected, assessed, and analyzed to support the performance of the hearing aids by validating that they provide sufficient audibility and hearing loss compensation based on best-practice prescriptive fitting rationales. The clinical data also demonstrate improved speech understanding and success with hearing aids using validated questionnaires and surveys.

Non-clinical data supporting the overall performance of the hearing aids includes software verification, electroacoustic verification, electrical and mechanical safety evaluation, electromagnetic compatibility (EMC) evaluation, and documentation of radio properties and performance. Additional information can be found in section Technical Information.

Technical pages to be added later

Technical pages to be added later



