Instructions for use

IIC - CIC

Oticon Own SI™

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.

Model overview

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

Styles

☐ IIC	Invisible-In-the-Canal
☐ CIC	Completely-In-the-Canal

Battery
Size 10

1.0

☐ Oticon Own SI 1	GTIN: (01) 05714464139934
☐ Oticon Own SI 2	GTIN: (01) 05714464139927
☐ Oticon Own SI 3	GTIN: (01) 05714464139910
☐ Oticon Own SI 4	GTIN: (01) 05714464140039

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

*The job title may vary from country to country.

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

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 severe (75 dB HL*) degree of hearing loss, with an individual frequency configuration.
Intended user	Person with hearing loss using a hearing aid and their caregivers. Hearing care professional responsible for adjusting the hearing aid.
Intended user group	Adults.
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, using pure-tone average of 0.5, 1 and 2 kHz.*

** *In accordance with current Pediatric Amplification guidelines, custom hearing aids are not typically considered for children of any age. However, a hearing care professional may, in special circumstance and on a case-by-case basis, select them for children older than 36 months.*

IMPORTANT NOTICE

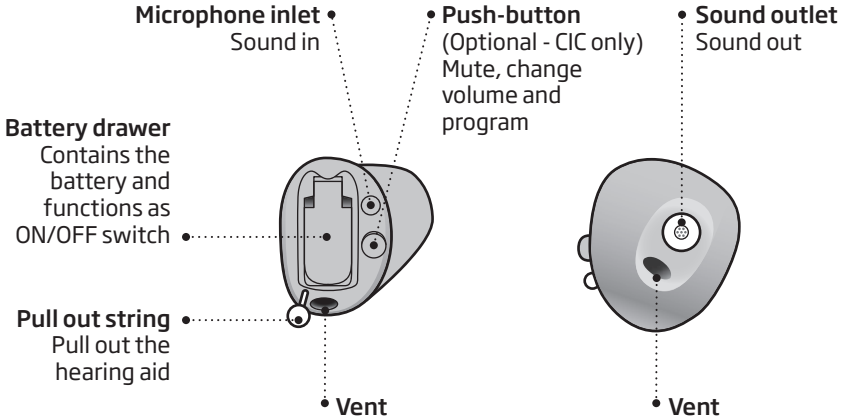
The hearing aid amplification is uniquely adjusted and optimized to your personal hearing capabilities during the hearing aid fitting performed by your hearing care professional.

Table of contents

Your hearing aid

(CIC shown)

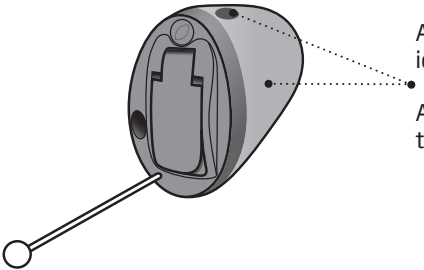
What it is and does



Components may be positioned differently on 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 shaped and programmed differently.

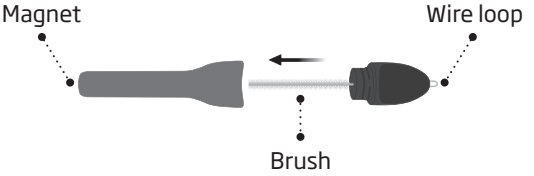


A **BLUE** shell, dot or text identifies the LEFT hearing aid

A **RED** shell, dot or text identifies the RIGHT hearing aid

MultiTool for handling batteries and cleaning

The MultiTool contains a magnet that makes it easier to replace the battery in the hearing aid. It also contains a brush and a wire loop for cleaning and removing earwax. If the vent is very small, a special tool may be required. If you need a new tool please contact your hearing care professional.



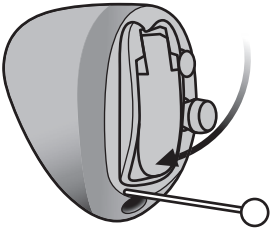
IMPORTANT NOTICE

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

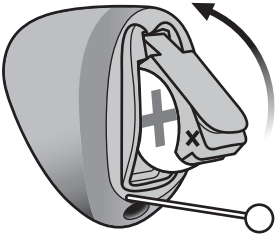
Turn the hearing aid ON and OFF

The battery drawer is also used to switch the hearing aid ON and OFF. To save battery life, make sure your hearing aid is switched OFF when you are not wearing it. If you wish to return to the standard settings of the hearing aid, simply open and then close the battery drawer (quick reset).

Turn ON
Close the battery drawer with the battery in place.



Turn OFF
Open the battery drawer.



Note: Open the battery door fully to make sure the hearing aid does not drain the battery fully and to allow air to circulate whenever you are not using your hearing instrument, especially at night or for longer periods of time.

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.

The battery is running low

 Three alternate tones

The battery has run out

 Four descending tones

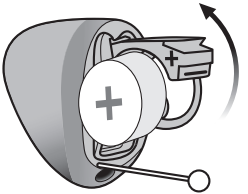
 Voice Notification
(Optional for select languages)

Battery tip

To make sure the hearing aid is always working, bring spare batteries with you, or replace the battery before you leave home.

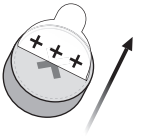
How to replace the battery

1. Remove



Fully open the battery drawer. Remove the battery.

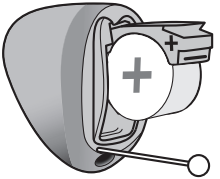
2. Uncover



Remove the sticky label from the + side of the new battery.

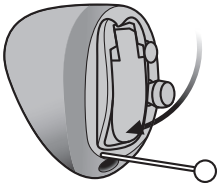
Tip:
Wait 2 minutes so that the battery can draw air, to ensure optimal functioning.

3. Insert



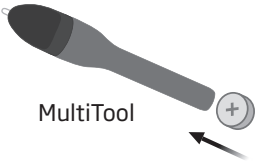
Insert the new battery into the battery drawer. Ensure that the + side of the battery and battery drawer align.

4. Close



Close the battery drawer. The hearing aid will play a jingle.
Hold the hearing aid close to your ear to hear the jingle.

Tip



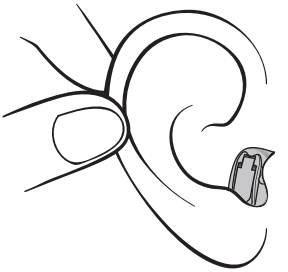
The MultiTool can be used for battery change. Use the magnetic end to remove and insert batteries.

Insert the hearing aid

Step 1

Place the tip of the hearing aid in your ear canal.

Step 2



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

Remove your hearing aid

Hold the hearing aid by the pull-out string (if available). Gently pull the hearing aid from the ear canal.

If your hearing aid doesn't have a pull-out string, you can remove it by pulling on the edge of the hearing aid.

IMPORTANT NOTICE

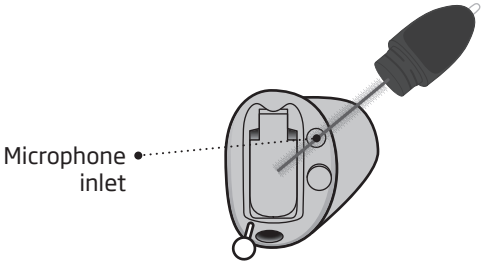
DO NOT use the battery door as a handle to insert or remove your hearing aids, as it is not designed for this purpose.

Caring for your hearing aid

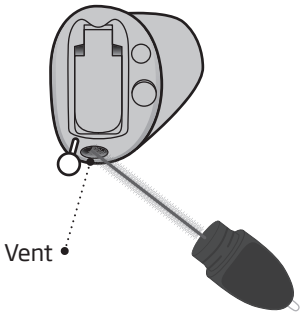
When handling your hearing aid, hold it over a soft surface to avoid damage if you drop it.

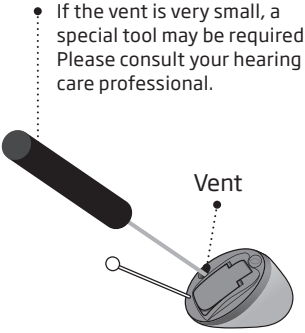
Cleaning the hearing aid

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



Clean the vent by pressing the brush through the hole while twisting it slightly.





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.

Filter replacement

The filters keep wax and debris from damaging the hearing aid.
If the filters become clogged, please replace the filters or contact your hearing care professional.

- ProWax miniFit filters protect the sound outlet.
- T-cap filters protect the microphone inlet.

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

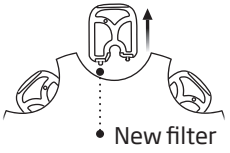
IMPORTANT NOTICE

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 ProWax miniFit filters, contact your hearing care professional.

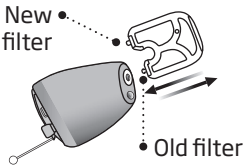
Replace ProWax miniFit filter

1. Tool



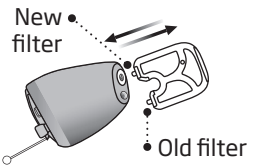
Remove the tool from the shell. The tool has two pins, one empty for removal and one with the new ProWax miniFit filter.

2. Remove



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

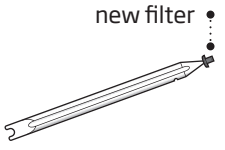
3. Insert



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

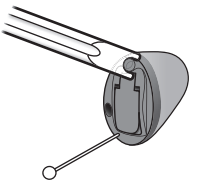
Replace T-Cap filter

1. Tool



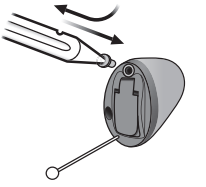
Remove the tool from the packaging. The tool has two ends, one for removal and one with the new T-Cap filter.

2. Remove



Push the tool fork under the top edge of the used T-Cap filter and lift it out.

3. Insert

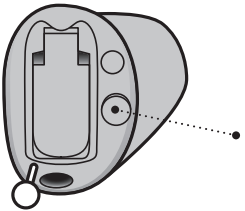


Insert the new T-Cap filter and remove the tool by twisting it slightly. Throw the tool out after use.

Change volume with push-button

(Optional - CIC only)

The push-button allows you to adjust the volume.
You may hear a click when you turn the volume up or down.



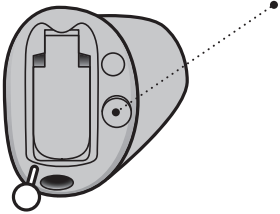
A short press on the RIGHT hearing aid increases the volume

A short press on the LEFT hearing aid decreases the volume

Change programs

(Optional - CIC only)

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.



- Use a short press to switch between programs. If Volume control is enabled, use a long press to switch programs.

If you have two synchronized hearing aids:

The RIGHT hearing aid switches one program forward, for example program 1 to 2.

The LEFT hearing aid switches one program backward, for example from program 4 to 3.

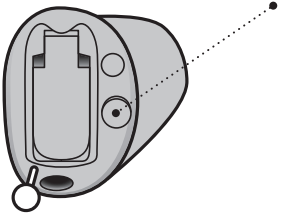
If your hearing aids work independently, you must press the buttons on each hearing aid.

For information regarding tones, see the **Sound indicators** section.

For information regarding button press times see the table **General settings overview for your hearing aid**, in the **Your individual hearing aid settings** section at the end of this booklet.

Mute the hearing aid

Use the mute function if you need to silence the hearing aid. Only available for hearing aids with push-button.



Press and hold the push-button for two seconds to mute the hearing aid.

To unmute, press the push-button.

NOTE: the mute function only mutes the microphone(s) on the hearing aids.

IMPORTANT NOTICE

Do not use the mute function as an off switch, as the hearing aids are still using battery power in this mode.

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.

Tinnitus SoundSupport™

(Optional - CIC only)

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.

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.

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.

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.

Mute
If you are in a program for which Tinnitus SoundSupport is activated, the mute functionality only mutes the environmental sounds, and not the sound from Tinnitus SoundSupport. For information on how to mute your hearing aids, see the **Mute your hearing aids** section.

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.

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.

Continues on next page

⚠ General warnings

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.

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.

Use of replaceable batteries
Only use batteries recommended by your hearing care professional.

Batteries of low quality may leak and cause bodily harm.

Never attempt to recharge your replaceable batteries.

Never dispose of batteries by burning them. There is a risk that the batteries will explode. Follow local guidelines for proper and safe disposal of batteries.

Beware of sudden dysfunction
Your hearing aids may stop working without notice. For example, if they run out of battery or if the tubing is blocked. 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 aids 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.

Accessories with built-in magnets (for example the Autophone magnet and the MultiTool) should be kept at least 30 centimeters (12 inches) away from any implanted medical device. Follow the guidelines from the manufacturer of your implanted medical device regarding their use with magnets.

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.

Continues on next page

⚠ General warnings

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.

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.

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: +1°C to +40°C (34°F to 104°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Transportation and storage conditions	Temperature and humidity shall not exceed the below limits for extended periods during transportation and storage: Temperature: -25°C to + 60°C (-13°F to 140°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

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 aids contain 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 –15 dBμA/m at a distance of 10 meters (–4.6 dBμA/ft at a distance of 33 feet).

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.

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. Additional information can be found in the Technical data document on www.oticon.com

CIC
This device contains a radio module (AM_AU5_KIT10) with the following certification ID number:

FCC ID: 2ACAHAU5CIC

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.

Declaration of Conformity is available at the headquarters.

Oticon A/S
Kongebakken 9
DK-2765 Smørum
Denmark
www.oticon.global/doc

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

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

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

IP68

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 0123	**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.

Description of symbols accompanying the product	
	**Radio Frequency (RF) transmitter** Your device contains an RF transmitter.
GTIN	**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.
FW	**Firmware** Firmware version used in the device.
	**Keep dry** Indicates a medical device that needs to be protected from moisture.
REF	**Catalog number** Indicates the manufacturer's catalog number so that the medical device can be identified.
SN	**Serial number** Indicates the manufacturer's serial number so that a specific medical device can be identified.
MD	**Medical Device** The device is a medical device.
UDI	**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.

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 (on one hearing aid only), use a short press on the push-button repeatedly until you reach your desired level.

☐ **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, use a short press on the push-button repeatedly on the RIGHT hearing aid.
To **decrease** the volume, use a short press on the push-button repeatedly on the LEFT 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
☐ Short press			☐ Short press	
☐ Long press			☐ Long press	
☐ 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.

Troubleshooting guide

Symptom	Possible causes
No sound	Worn-out battery
	Clogged sound outlet
	Clogged microphone inlet
	Hearing aid microphone muted
Intermittent or reduced sound	Clogged sound outlet
	Moisture
	Worn-out battery
Squealing noise	Hearing aid not inserted properly
	Ear wax accumulated in ear canal
Service alert voice notification	Issue detected by hearing aid

Solutions
Replace the battery
Clean sound outlet* or replace the wax filter
Clean microphone inlet* or replace filter (T-Cap)
Unmute the hearing aid microphone
Clean sound outlet or replace the wax filter
Wipe battery and hearing aid with a dry cloth
Replace the battery
Re-insert the hearing aid
Have ear canal examined by your doctor
Contact your hearing care professional

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 Data

Measured according to American National Standard ANSI S3.22-2014, IEC 60118-0:2015 and IEC 60318-5:2006
Supply voltage: Zinc-Air

0 dB SPL ref. 20 µPa		**Oticon Own SI 1**	**Oticon Own SI 2,3,4**
OSPL90	Peak	109 dB SPL	109 dB SPL
	HF Average	104 dB SPL	104 dB SPL
Full-on Gain	Peak	42 dB	42 dB
	HF Average	38 dB	38 dB
Reference Test Gain		26 dB	26 dB
Frequency Range		<100-8300 Hz	<100-7500 Hz
Total Harmonic Distortion	500 Hz	<2 %	<2 %
	800 Hz	<2 %	<2 %
	1600 Hz	<2 %	<2 %
Equivalent Input Noise Level	(omni)	20 dB SPL	20 dB SPL
Attack Time		5 ms	5 ms
Release Time		26 ms	26 ms

0 dB SPL ref. 20 µPa		Oticon Own SI 1	Oticon Own SI 2,3,4
Battery Consumption	Typical	1.8 mA	1.8 mA
	Quiescent	1.7 mA	1.7 mA
Expected battery life (bat. size 10)	Hours	45-55	45-55
Latency		8,2 ms	8,2 ms

Technical Data

Measured according to American National Standard ANSI S3.22-2014, IEC 60118-0:2015 and IEC 60318-5:2006
Supply voltage: Zinc-Air

0 dB SPL ref. 20 µPa		**Oticon Own SI 1**	**Oticon Own SI 2,3,4**
OSPL90	Peak	119 dB SPL	119 dB SPL
	HF Average	116 dB SPL	116 dB SPL
Full-on Gain	Peak	49 dB	49 dB
	HF Average	48 dB	48 dB
Reference Test Gain		38 dB	38 dB
Frequency Range		<100-7700 Hz	<100-7500 Hz
Total Harmonic Distortion	500 Hz	<2 %	<2 %
	800 Hz	<2 %	<2 %
	1600 Hz	<2 %	<2 %
Equivalent Input Noise Level	(omni)	20 dB SPL	20 dB SPL
Attack Time		5 ms	5 ms
Release Time		20 ms	20 ms

0 dB SPL ref. 20 µPa		Oticon Own SI 1	Oticon Own SI 2,3,4
Battery Consumption	Typical	2.4 mA	2.4 mA
	Quiescent	1.8 mA	1.8mA
Expected battery life (bat. size 10)	Hours	40-55	40-55
Latency		8,2 ms	8,2 ms

Technical Data

Measured according to American National Standard ANSI S3.22-2014, IEC 60118-0:2015 and IEC 60318-5:2006
Supply voltage: Zinc-Air

0 dB SPL ref. 20 µPa		**Oticon Own SI 1**	**Oticon Own SI 2,3,4**
OSPL90	Peak	109 dB SPL	109 dB SPL
	HF Average	104 dB SPL	104 dB SPL
Full-on Gain	Peak	47 dB	47 dB
	HF Average	42 dB	42 dB
Reference Test Gain		26 dB	26 dB
Frequency Range		<100-6900 Hz	<100-6900 Hz
Total Harmonic Distortion	500 Hz	<2 %	<2 %
	800 Hz	<2 %	<2 %
	1600 Hz	<2 %	<2 %
Equivalent Input Noise Level	(omni)	19 dB SPL	19 dB SPL
Attack Time		5 ms	5 ms
Release Time		32 ms	32 ms

0 dB SPL ref. 20 µPa		Oticon Own SI 1	Oticon Own SI 2,3,4
Battery Consumption	Typical	1.7 mA	1.7 mA
	Quiescent	1.6 mA	1.6 mA
Expected battery life (bat. size 10)	Hours	50-55	50-55
Latency		8,2 ms	8,2 ms

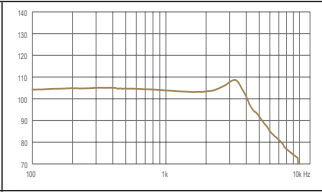
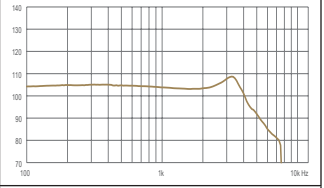
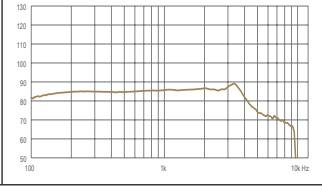
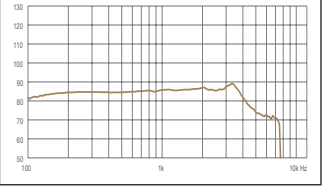
Technical Data

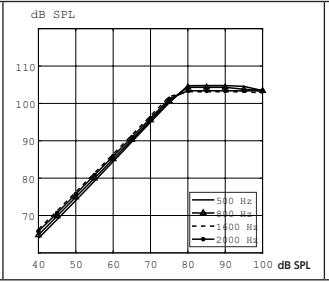
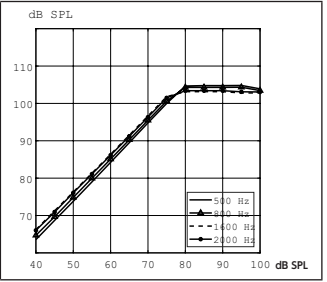
Measured according to American National Standard ANSI S3.22-2014, IEC 60118-0:2015 and IEC 60318-5:2006
Supply voltage: Zinc-Air

0 dB SPL ref. 20 µPa		**Oticon Own SI 1**	**Oticon Own SI 2,3,4**
OSPL90	Peak	119 dB SPL	119 dB SPL
	HF Average	116 dB SPL	116 dB SPL
Full-on Gain	Peak	55 dB	55 dB
	HF Average	52 dB	52 dB
Reference Test Gain		38 dB	38 dB
Frequency Range		<100-7500 Hz	<100-7500 Hz
Total Harmonic Distortion	500 Hz	<2 %	<2 %
	800 Hz	<2 %	<2 %
	1600 Hz	<2 %	<2 %
Equivalent Input Noise Level	(omni)	19 dB SPL	19 dB SPL
Attack Time		4 ms	4 ms
Release Time		29 ms	29 ms

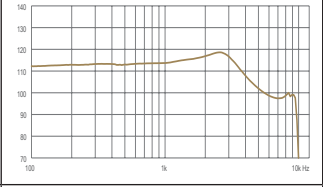
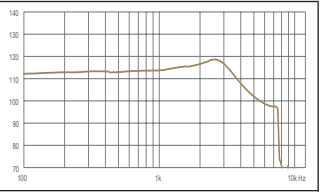
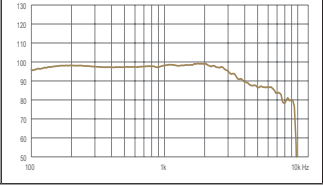
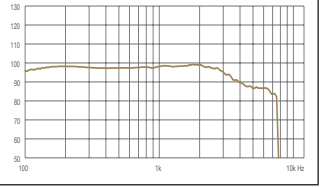
0 dB SPL ref. 20 µPa		Oticon Own SI 1	Oticon Own SI 2,3,4
Battery Consumption	Typical	1.9 mA	1.9 mA
	Quiescent	1.6 mA	1.6 mA
Expected battery life (bat. size 10)	Hours	30-55	30-55
Latency		8,2 ms	8,2 ms

Technical Data

	Oticon Own SI 1	Oticon Own SI 2,3,4
OSPL90 - Output Sound Pressure Level (dB SPL) Input: 90 dB SPL Technical setting: A0		
Frequency response (dB SPL) Input: 60 dB SPL Technical setting: N0		

	Oticon Own SI 1	Oticon Own SI 2,3,4
Input-Output Technical Setting: N0		

Technical Data

	Oticon Own SI 1	Oticon Own SI 2,3,4
OSPL90 - Output Sound Pressure Level (dB SPL) Input: 90 dB SPL Technical setting: A0		
Frequency response (dB SPL) Input: 60 dB SPL Technical setting: N0		

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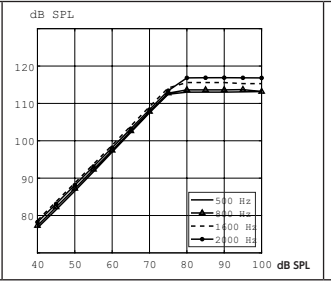
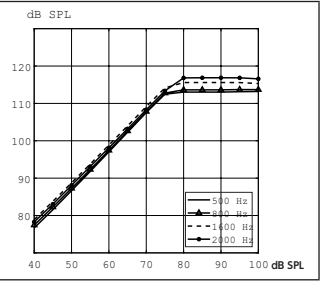
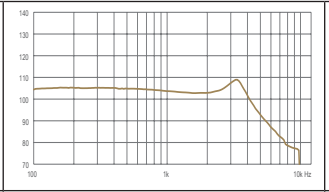
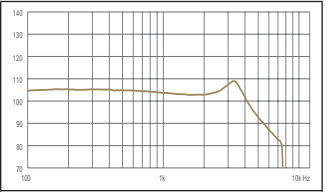
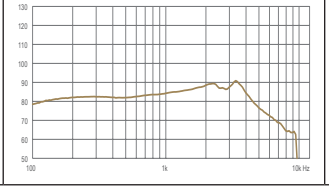
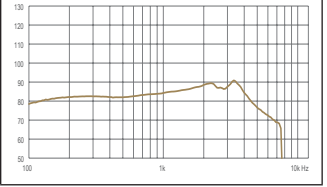
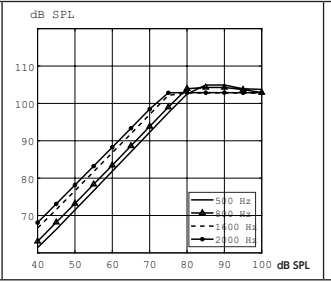
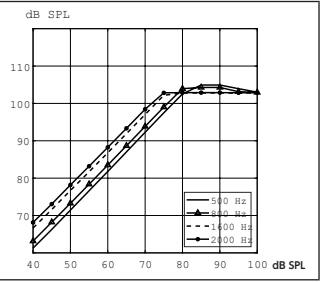
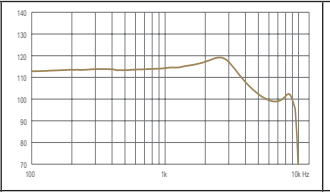
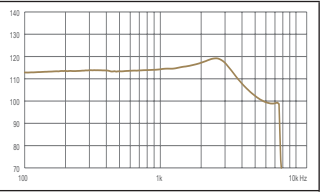
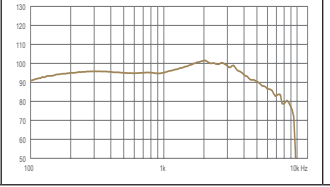
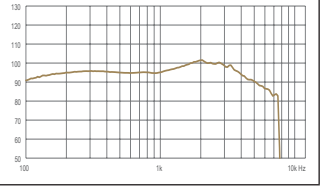
Input-Output Technical Setting: NO		

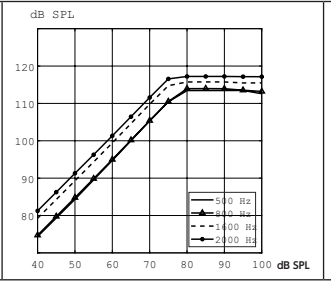
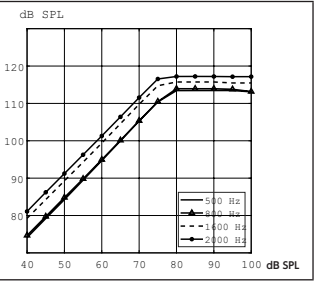
Technical Data

	Oticon Own SI 1	Oticon Own SI 2,3,4
OSPL90 - Output Sound Pressure Level (dB SPL) Input: 90 dB SPL Technical setting: A0		
Frequency response (dB SPL) Input: 60 dB SPL Technical setting: N0		

	Oticon Own SI 1	Oticon Own SI 2,3,4
Input-Output Technical Setting: N0		

Technical Data

	Oticon Own SI 1	Oticon Own SI 2,3,4
OSPL90 - Output Sound Pressure Level (dB SPL) Input: 90 dB SPL Technical setting: A0		
Frequency response (dB SPL) Input: 60 dB SPL Technical setting: N0		

	Oticon Own SI 1	Oticon Own SI 2,3,4
Input-Output Technical Setting: N0		

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