

Instructions for use
Part 2

Oticon Engage
miniRITE



241623GB / 2023.01.04 / v2



oticon

Please read both Instructions for use Part 1 and Part 2 carefully.

IMPORTANT NOTICE

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

⚠ Warnings

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 (16dB HL*) to profound (95dB 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 and children older than 36 months.
User 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.
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* As specified by the American Speech-Language-Hearing Association, asha-org, using pure-tone average of 0.5, 1 and 2 kHz.

General Warnings

For your personal safety and to ensure correct usage, you should familiarise yourself fully with the following general warnings before using your hearing aids.

Consult your hearing care professional if you experience unexpected operations or serious incidents with your hearing aids during use or because of its use. 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 a hearing impairment resulting from organic conditions. Hearing aids are only a part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading. Furthermore, note that in most cases, infrequent use of hearing aids does not permit a user to attain full benefit from it. This hearing aid is supported by a non-removable rechargeable lithiumion battery cell. Please ensure to charge the hearing aid and familiarise yourself with the safety and handling information related to rechargeable hearing aids.

Do not try to get access to the battery inserted in the hearing instrument. The battery must only be replaced by your hearing care professional. Only charge the hearing aids with a designated charger. Other chargers risk destroying the hearing aids and batteries. *If a battery or hearing aid is swallowed, see a doctor immediately.*

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 and risk of swallowing small parts

Choking hazards & risk of swallowing batteries and other small parts Hearing aids, their parts, and batteries should be kept out of reach of children and anyone who might swallow these items or otherwise cause injury to themselves. Batteries have occasionally been mistaken for pills. Therefore, check your medicine carefully before swallowing any pills.

If a battery, hearing aid or small part is swallowed, see a doctor immediately.

Battery use

Always use batteries recommended by your hearing care professional. Batteries of low quality may leak and cause bodily harm. Never attempt to recharge your batteries, and never dispose of batteries by burning them. There is a risk that the batteries will explode.

Dysfunction

Be aware of the possibility that your hearing aids may stop working without notice. Keep this in mind when you depend on warning sounds (e.g. when you are in traffic). The hearing aids may stop functioning for instance if the batteries have expired or if the tubing is blocked by moisture or earwax.

Active implants

The hearing aid has been thoroughly tested and characterised 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. If you have an active brain implant, please contact the manufacturer of your implantable device for information about the risk of disturbance. The Autophone magnet or MultiTool (which has a built-in magnet) should be kept more than 30 centimetres (1 foot) away from the implant, e.g. do not carry it in your breast pocket. Follow the guidelines recommended by the manufacturers of implantable defibrillators and pacemakers regarding their use with magnets.

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 at a 1 centimetre distance from your hearing aid. The magnetic field from CI sound processors, coils, and magnets may permanently damage the speaker unit in your hearing aid. Never place the devices close together on a table e.g. when cleaning or changing batteries. Do not carry the CI and the hearing aid together in the same box.

X-ray/CT/MR/PET scanning, electrotherapy and surgery

Remove your hearing aid before X-ray examinations and CT/ MR/PET scans, electrotherapy, surgery, etc. as your hearing aid may be damaged when exposed to strong electromagnetic fields.

Heat and chemicals

The hearing aid must never be exposed to extreme heat, e.g. left inside a parked car in the sun. The hearing aid must not be dried in microwave ovens or other ovens. The chemicals in cosmetics, hairspray, perfume, aftershave lotion, suntan lotion, and insect repellent can damage the hearing aid. Always remove your hearing aid before applying such products and allow time to dry before use.

Detached earpiece in ear canal

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.

Power hearing aid

Special care should be exercised in selecting, fitting, and using hearing aids where the maximum sound pressure capability exceeds 132 dB SPL (IEC 60318-4/IEC 711) as there may be a risk of impairing the remaining hearing of the hearing aids user.

Possible side effects

Hearing aids, moulds or domes may cause an accelerated accumulation of earwax. The non-allergenic materials used in your hearing aids may, in rare cases cause a skin irritation or other side effects.

If these conditions occur, seek consultation with a physician

Use on aircraft

Your hearing aids have Bluetooth wireless technology. On board an aircraft, the hearing aids must be put into flight mode to deactivated Bluetooth, unless Bluetooth is permitted by the flight personnel.

Connection to external equipment

The safety of the hearing aids, when connected to external equipment (with an auxiliary input cable and/or USB cable and/or directly), is determined by the external signal source. When connected to external equipment 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, transducers or cables supplied by the manufacturer. Non-original accessories may result in reduced electromagnetic compatibility (EMC) of your hearing aids.

Modification of hearing aids is not allowed

Changes or modifications not expressly approved by the manufacturer will void the warranty of the equipment.

⦿ Interference

The hearing aids have been thoroughly tested for interference according to the most stringent international standards. Electromagnetic interference may occur in the vicinity of equipment with the symbol to the left. Portable and mobile RF (radio frequency) communications equipment can affect the performance of your hearing aids. If your hearing aids are affected by electromagnetic interference, move away from the source to reduce the interference.

Tinnitus SoundSupport™ (optional)
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 old). 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

These instructions contain information about Tinnitus SoundSupport, which may have been enabled in your hearing aids by your hearing care professional. Tinnitus SoundSupport is a tinnitus management device intended to generate sound of sufficient intensity and bandwidth to help manage tinnitus. Your hearing care professional will also 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.

Sound options and volume adjustment

Tinnitus SoundSupport is programmed by your hearing care professional to match your hearing loss and preferences for tinnitus relief. It offers a number of different sound options. Together with your hearing care professional, you can select your preferred sound(s).

Tinnitus SoundSupport programs

Together with your hearing care professional you decide for which programs you may want to have Tinnitus SoundSupport activated. 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 will mute only the environmental sounds, and not the sound from Tinnitus SoundSupport. See chapter: "Mute".

Volume adjustments with Tinnitus SoundSupport

When you select a hearing aid program for which Tinnitus SoundSupport is activated, your hearing care professional can only set the push button on your hearing aid to work as a volume control for the tinnitus relief sound.

Your hearing care professional will set the volume control for the sound generator in one of two ways:

- A) Change volume in each ear separately, or
- B) Change volume in both ears simultaneously.

☐	A) How to change Tinnitus SoundSupport volume in each ear separately To increase volume (on one hearing aid only), use a short press on the push button repeatedly until desired level is reached. The sound will always be louder with the first press(es) until two beeps are heard. Hereafter the volume will decrease. To decrease volume (on only one hearing aid), continue to press the push button repeatedly until desired level is reached.
☐	B) How to change Tinnitus SoundSupport volume in both ears simultaneously You can use one hearing aid to increase the sound and the other hearing aid to decrease the sound: To increase volume, use a short press on the push button repeatedly on the RIGHT hearing aid. To decrease volume, use a short press on the push button repeatedly on the LEFT hearing aid.

To be filled out by your hearing care professional.

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

Important information for hearing care professionals about Tinnitus SoundSupport
Device description

Tinnitus SoundSupport is a module function that can be enabled in the hearing aids by a hearing care professional.

Maximum wearing time

The wearing time of Tinnitus SoundSupport will decrease as you increase the level above 80 dB(A) SPL. The fitting software will automatically display a warning when the hearing aid exceeds 80 dB(A) SPL. See "Max wearing time indicator" next to the tinnitus fitting graph in the fitting software.

The volume control is deactivated

By default, the volume control for the sound generator is deactivated in the hearing aid. Risk of noise exposure increases when the volume control is activated.

If the volume control is activated

A warning may be displayed if you activate the tinnitus volume control in the "Buttons & Indicators" screen. This occurs if the relief sound can be listened to at levels that may cause hearing damage. The "Max wearing time" table in the fitting software displays the number of hours the patient can safely use Tinnitus SoundSupport.

- Note the max wearing time for each program for which Tinnitus SoundSupport is activated.
- Write those values in the table "Tinnitus SoundSupport: Limitation on use", found in the back of this booklet.
- Instruct your patient accordingly.

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 from the manufacturer.

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



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



IP68

CE0123

Tinnitus SoundSupport Warnings

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 unauthorised 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.

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 sweat or getting wet in the rain. Should your hearing aid come into contact with water and stop working, please follow these guidelines:

1. Gently wipe off any water.
2. Open the battery drawer and remove the battery and gently wipe off any water in the battery drawer.
3. Let the hearing aid dry with the battery drawer left open for approximately 30 minutes.
4. Insert a new battery.

International warranty

Your hearing aid is covered by an international limited warranty issued by the manufacturer for a period of 12 months from the date of delivery to you. This limited warranty covers manufacturing and material defects in the hearing aid itself, but not in accessories such as batteries, tubing, speakers, earpieces, filters, etc. Problems arising from improper/incorrect handling or care, excessive use, accidents, repairs made by an unauthorised 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 limited warranty and may void it. Under this warranty, the manufacturer will choose, at its sole discretion, whether to repair the hearing aid, or replace it with an equivalent model. The above warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods. Your hearing care professional may have issued a warranty that goes beyond the clauses of this limited warranty. Consult him/her for further information.

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.

If you need service

Take your hearing aid to your hearing care professional, who may be able to solve minor problems and make adjustments immediately. Your hearing care professional can assist you in obtaining warranty service from the manufacturer. Your hearing care professional may charge a fee for their services

Technical information

The hearing aids contain the following two radio technologies:

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 -40 dBµA/m at a distance of 10 meters (-12.20 dBµA/ ft) at a distance of 33 feet]. The hearing aids also contain 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 weak and always below 3 mW equal to 4.8 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. 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 sheets" on www.oticon.global

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: Transportation: 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 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

Information about Charger: Condition of use, see Charger Instruction for use

Description of symbols used in this booklet	
	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.
	IP code Class of protection 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.
	Made for Apple badges The device is compatible with iPhone, iPad and iPod touch.
	Hearing loop This logo incorporates the universal symbol for hearing assistance. The "T" signifies that a hearing loop is installed.
	Radio Frequency (RF) transmitter Your hearing aid 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.

Description of symbols used on the regulatory packaging label	
	Keep dry Indicates a medical device that needs to be protected from moisture.
	Catalogue number Indicates the manufacturer's catalogue 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.
	Unique device identifier Indicates a carrier that contains unique device identifier information

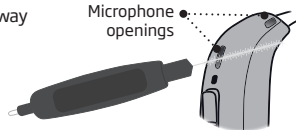
Caring for your hearing aid

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

Clean the microphone openings

Use the brush of the MultiTool to carefully brush debris away from the openings. Carefully brush the surface around the opening.

Make sure that no parts of the MultiTool are squeezed into the microphone openings by force. This may damage the hearing aid.



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 earpieces

The standard earpiece (dome and Grip Tip) should not be cleaned. If the earpiece is filled with wax, replace it with a new one. Grip Tip needs to be replaced at least once a month.

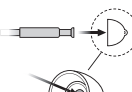
Step 1

Hold on to the speaker and pull off the earpiece.



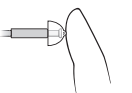
Step 2

Insert the speaker exactly into the middle of the earpiece to obtain a secure attachment.



Step 3

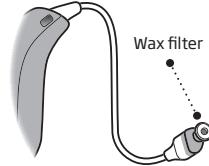
Push firmly to ensure that the earpiece is fastened securely.



ProWax miniFit filter

The speaker has a white wax filter attached to the end where the earpiece is attached. The wax filter keeps wax and debris from damaging the speaker. Replace the filter when clogged, or if the hearing aid does not sound normal. Alternatively, contact your hearing care professional.

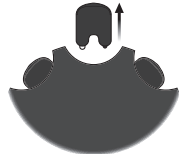
Remove the earpiece from the speaker before replacing the wax filter.



Replace ProWax miniFit filter

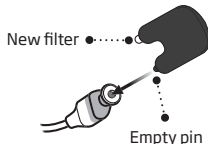
1. Tool

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



2. Remove

Push the empty pin into the wax filter in the speaker and pull it out.

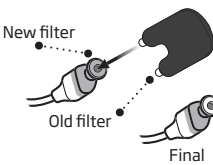


IMPORTANT NOTICE

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.

3. Insert

Insert the new wax filter using the other pin, remove the tool, and throw it out

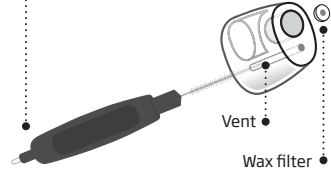


Clean customised earpieces

The earpiece should be cleaned regularly. The earpiece has a white wax filter*. The filter keeps wax and debris from damaging the speaker.

Replace the filter when clogged, or if the hearing aid does not sound normal. Alternatively, contact your hearing care professional.

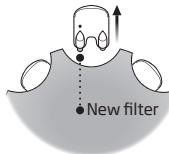
- Clean the vent by pressing the brush through the hole, twisting it slightly.



Replace ProWax filter

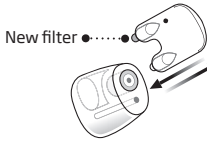
1. Tool

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



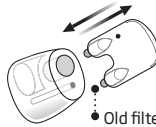
2. Remove

Push 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.



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 wax filters, contact your hearing care professional.

* VarioTherm Micro mould and LiteTip do not have a wax filter