

Instructions for use Part 2

Oticon Engage
miniRITE



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oticon
PEOPLE FIRST

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 Oticon Engage

The hearing aid is intended to amplify and transmit sound to the ear, and thereby compensate for impaired hearing within mild to severe-to-profound hearing loss. This hearing aid is intended for use by adults and children older than 36 months.

General warnings

You should familiarise yourself fully with the following general warnings before using your hearing aid for your personal safety and to ensure correct usage. Please note that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Furthermore, note that in most cases, infrequent use of a hearing aid does not permit a user to attain its full benefits. Consult your hearing care professional if you experience unexpected operations or events with your hearing aid.

Usage of hearing aids

Hearing aids should be used only 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 & 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. Most hearing aids can be supplied with a tamper-resistant battery drawer upon request. This is strongly recommended for infants, small children, and people with learning difficulties. Please talk to your hearing care professional about the availability of this option.

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

Battery use

Always use batteries recommended by your hearing care professional. Low quality batteries 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 aid 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 should be kept at least 30 cm away from the implant, e.g. do not carry it in a breast pocket.

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

Remove your hearing aid before X-ray, CT/MR/PET scanning, 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, sunscreen 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.

Power instrument

Special care should be exercised when selecting, fitting and using a hearing aid when the maximum sound pressure capability exceeds 132 dB SPL (IEC 711), as there may be risk of impairing the remaining hearing of the hearing aid user.

For information of whether your hearing aid is a power instrument, see the model overview in the front of the Instructions for use part 1

Possible side effects

Hearing aids and earpieces may cause an accelerated accumulation of earwax.

The otherwise non-allergenic materials used in hearing aids may in rare cases cause skin irritation or other side effects.

Please consult a physician if these conditions occur.

Interference

The hearing aid has been thoroughly tested for interference, in accordance with the most stringent international standards. However, interference between the hearing aid and other devices (e.g. some mobile telephones, citizens band systems, shop alarm systems and other devices) may occur. If this occurs, increase the distance between the hearing aid and the interfering device.

Use on aircraft

Your hearing aid have Bluetooth. On board an aircraft, flight mode must be activated, unless Bluetooth is permitted by the flight personnel.

Connection to external equipment

The safety of the hearing aid when connected to external equipment with an auxiliary input cable, is determined by the external signal source. When connected to external equipment plugged into a wall outlet, this equipment must comply with IEC-62368 (or IEC-60065, IEC-60950 until June 20, 2019) or equivalent safety standards.

Incompatible non-supplied accessories

Only use accessories, transducers or cables supplied by the manufacturer of this device. Incompatible accessories may result in increased emission or decreased immunity.

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 sound generator 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 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 can 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 the hearing aid".

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.

<input type="checkbox"/>	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.
<input type="checkbox"/>	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" in section "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.

If you need service


Take your hearing aid to your hearing care professional, who may be able to sort out minor problems and adjustments immediately.

The manufacturer declares that this hearing aid is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (R&TTE).

Declaration of Conformity is available from the manufacturer.

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CE 0543

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

IP68

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 for 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 seek a consultation with a medical, audiology, or other hearing care professional. As with any device, misuse of the sound generator feature could present some potentially harmful effects. Care should be taken to prevent the unauthorised use and to keep the device out of the 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 and 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, 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. This limited warranty covers manufacturing and material defects in the hearing aid itself, but not in accessories such as batteries, tubing, speakers, earpieces and filters, etc. Problems resulting from improper or 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. The above warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods. Your hearing care professional may have issued a warranty that goes beyond the clauses of this limited warranty. Please 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 sort out minor problems and adjustments immediately.

Technical information

The hearing aid contains two radio technologies, which are described below:

The hearing aid contains a radio transceiver using short-range magnetic induction technology working at 3.84 MHz. The magnetic field strength of the transmitter is very weak and is always below 15 nW (typically below -40 dBµA/m at a 10 metre distance).

The hearing aid also contains a radio transceiver using Bluetooth Low Energy (BLE) and a proprietary short-range radio technology both working 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.

The hearing aid complies with international standards concerning electromagnetic compatibility and human exposure.

Due to the limited space available on the hearing aid, relevant approval markings can be found in this document.

Additional information can be found in the "Technical Data sheet" on www.oticon.global

Conditions of use

Operating conditions	Temperature: +1°C to +40°C Relative humidity: 5% to 93%, non-condensing
Storage and transport conditions	Temperature and humidity shall not exceed the below limits for extended periods during transport and storage: Temperature: -25°C to +60°C Relative humidity: 5% to 93%, non-condensing

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 Directives 90/385/EEC, 93/42/EEC and 98/79/EC.



CE mark

The device complies with Medical Device Directive 93/42/EEC. 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 market.

IP68	IP code Indicates the 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	Bluetooth logo Registered trademark of Bluetooth SIG, Inc. where any use of such requires a license.
iPhone iPad iPod	Made for Apple badges Indicates that the device is compatible with iPhone, iPad and iPod touch.

Description of symbols used on the regulatory packaging label



Keep dry

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



Caution symbol

Consult instructions for use for warnings and cautions.



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.

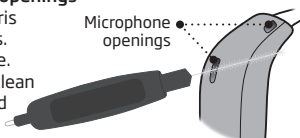
Caring for your hearing aid

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

Clean the microphone openings

Carefully brush any debris away from the openings. Gently brush the surface.

Make sure the brush is clean and that it is not pressed into the openings.



Replace standard earpieces

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

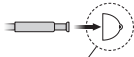
Step 1

Hold on to the end of the thin tube and then pull off the earpiece.



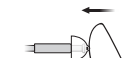
Step 2

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



Step 3

Push firmly to ensure that the earpiece is fastened securely.



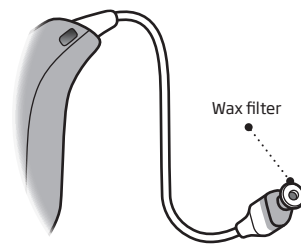
IMPORTANT NOTICE

Use a soft, dry cloth to clean the hearing aid. The hearing aid must never be washed or immersed in water or other liquids.

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 or contact your hearing care professional.

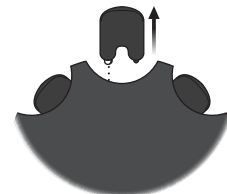
Remove the earpiece from the speaker before replacing the wax filter.



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.



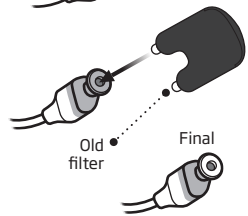
2. Remove

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



3. Insert

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



IMPORTANT NOTICE

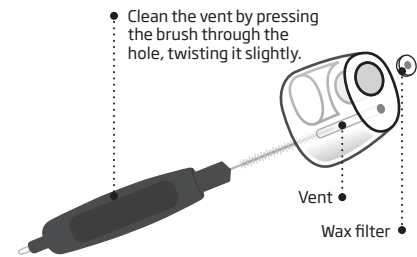
Always use the same type of wax filter as was originally supplied with the hearing aid. If you are in any doubt about the use or replacement of wax filters, contact your hearing care professional.

Clean customised earpieces

Micro mould/LiteTip

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

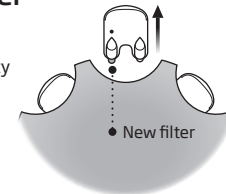
Replace the filter when clogged, or if the hearing aid does not sound normal. Alternatively, contact your hearing care professional.



Replace ProWax filter

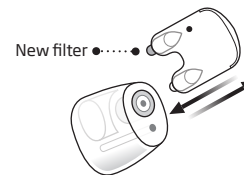
1. Tool

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



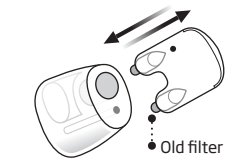
2. Remove

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

Always use the same type of wax filter as was originally supplied with the hearing aid. If you are in any 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