

Instructions for use Part 2

Oticon Sage
miniBTE T
miniBTE R



Made for
iPhone | **iPad** | **iPod**

Works with
android

266829GB / 2024.01.23 / 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.

Intended use

Oticon Sage miniBTE R and miniBTE T

Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	Bilateral or unilateral impaired hearing of sensorineural, conductive or mixed type ranging from a slight (16 dB HL*) to moderately severe (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 and children older than 36 months.
Use environment	Indoor and outdoor

Contra-indications	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*

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 of age. Tinnitus SoundSupport is targeted to licenced 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 also 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.

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

Tinnitus SoundSupport can be activated in up to four different programs.

Mute

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 Tinnius 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.



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.



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

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 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 intellectual and developmental disabilities. Children under 36 months must always use a hearing aid with a tamper-resistant battery drawer.

Talk to your hearing care professional about the availability.

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

Battery use (miniBTE T only)

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.

Explosives (miniBTE R only)

The hearing aid is safe to use under normal usage conditions. The hearing aid has not been tested for compliance with international standards concerning explosive environments.

Therefore, do not use the hearing aid in environments with danger of explosions e.g. mines, oxygen rich environments or areas where flammable anaesthetics are handled.

Fatality hazards and risk of swallowing lithium-ion batteries or placing them in the ear or nose (miniBTE R only)

Never swallow lithium-ion batteries nor place them in the ear or the nose, as this may lead to serious injury or death in as little as two hours. This can be due to chemical burns, which can permanently damage the nose or ear or potentially lead to perforation of the inner organs. If a lithium-ion battery is swallowed or placed in the ear or nose, seek emergency medical treatment immediately. Keep the batteries in the original packaging until use. Dispose of used batteries immediately.

Rechargeable battery (miniRITE R only)

Do not attempt to open the hearing aid, as it may damage the battery. Never attempt to replace the battery. If battery replacement is needed, return your device to your hearing care professional. The service guarantee is void if there are signs of tampering. In case of battery leakage do not wear your hearing aid, as it may cause skin irritation due to acids coming from the leaking battery. If your skin has been in contact with the leaked battery acids, use a wet cloth to wipe it off and ensure no acid is left on your skin. If you experience skin irritation, consult your doctor. For further handling instructions of your hearing instrument consult your hearing care professional. The safety of recharging batteries using a USB connector 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.

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, contact the manufacturer of your implantable device for information about the risk of disturbance. The Autophone magnet and MultiTool (which has a built-in magnet) should be kept at least 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 (0.4 inches) 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 closely 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, 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.

Possible side effects

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

If these conditions occur, seek consultation with a physician.

⦿ Interference

The hearing aid has been thoroughly tested for interference, in accordance with 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.

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.

Use on aircraft

Your hearing aids have Bluetooth wireless technology. On board an aircraft, the hearing aids must be put into Flight mode to deactivate 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 the hearing aids are 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, transducers, or cables supplied by the manufacturer. Non-original accessories may result in reduced electromagnetic compatibility (EMC) of your device.

Modification of hearing aids is not allowed

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

Detached earpiece in ear canal

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

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.

miniBTE T only

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 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 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 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 sort out minor problems and adjustments immediately. 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 metres (-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 9 mW equal to 9.6 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 Sheet on www.oticon.global

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.

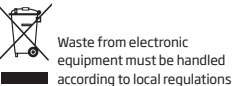
Declaration of Conformity is available from the manufacturer.



SBO Hearing A/S
Kongebakken 9
DK-2765 Smørum
Denmark
www.sbohearing.com/declarations-of-conformity



IP68



Conditions of use

Operating conditions	Temperature: +5°C to +40°C (41°F to 104°F) Humidity: 5% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Charging conditions	Temperature: +5°C to +40°C (41°F to 104°F) Humidity: 5% to 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: -20°C to +60°C (-4°F to 140°F) Humidity: 5% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa Storage: Temperature: -20°C to +30°C (-4°F to 86°F) Humidity: 5% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

Note
For more information about the charger's conditions of use, see your charger's instructions for use.

Operating conditions	Temperature: +1°C to +40°C (34°F to 104°F) Humidity: 5 to 93% relative humidity, noncondensing 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 to 93% relative humidity, noncondensing Atmospheric pressure: 700 hPa to 1060 hPa Storage: Temperature: -25°C to + 60°C (-13°F to 140°F) Humidity: 5 to 93% relative humidity, noncondensing Atmospheric pressure: 700 hPa to 1060 hPa

Description of symbols and abbreviations 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.
	Bluetooth logo Registered trademark of Bluetooth SIG, Inc. where any use of such requires a license.

	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.
	Made for Apple badges Indicates that the device is compatible with iPhone, iPad and iPod touch.
	Android badge Indicates that the device is compatible with Android.
	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.
	FW Firmware version used in the device.

Description of additional symbols used on labels	
	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.
	Battery recycling symbol Li-ion battery recycling symbol.
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.
	Radio Frequency Identification Indicates the presence of a passive radio-frequency identification tag incorporated into the device for manufacturing and service purposes.
	Unique device identifier Indicates a carrier that contains unique device identifier information.

Apple, the Apple logo, iPhone, iPad, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

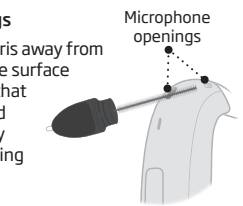
Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

Clean the hearing aid

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

Clean the microphone openings

Use a tool to carefully brush debris away from the openings. Carefully brush the surface around the opening. Make sure that no parts of the tool are squeezed into the microphone openings by force. This may destroy the hearing aid.



Care for the mould

The mould should be cleaned regularly. Use a soft cloth to clean the surface of the mould. Use a tool to clean the opening.

Replace the tube

The tubing between the mould and the hearing aid should be replaced if it becomes yellow or stiff. Consult your hearing care professional about this.



Wash the mould

Step 1

Make sure you are able to identify which mould is for which hearing aid before disconnecting them from the hearing aid.



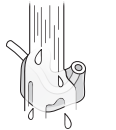
Step 2

Disconnect the tube and mould from the hook. Hold the hook firmly when pulling it off the tube. Otherwise the hearing aid may be damaged.



Step 3

Wash the mould and tube using mild soap. Rinse and dry completely before reconnecting to the hearing aid.



IMPORTANT NOTICE

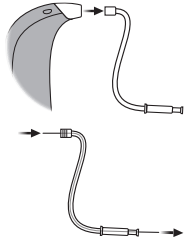
To clean the hearing aids, use a soft, dry cloth. The hearing aids must never be washed or immersed in water or other liquids.

Clean the thin tube

The thin tube should be cleaned to keep it clear of moisture and wax. If not cleaned, it may become blocked with wax, which stops sound from coming out.

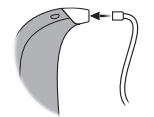
Step 1

Pull the thin tube out of the hearing aid and remove the earpiece.



Step 2

Push the cleaning tool all the way through the thin tube.



Step 3

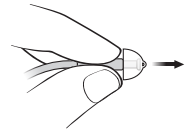
Reconnect the thin tube to the hearing aid.

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.

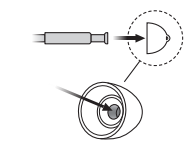
Step 1

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



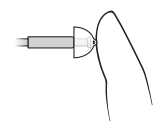
Step 2

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.



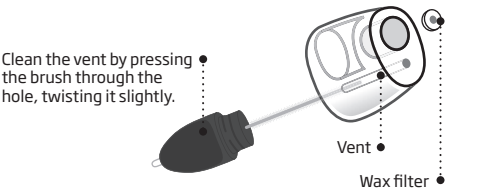
IMPORTANT NOTICE

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

Clean customised earpieces

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

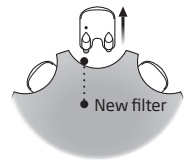
Replace the filter when clogged, or if the sound is not normal, or contact your hearing care professional.



Replace ProWax filter

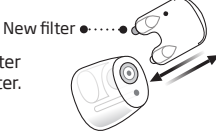
1. Tool

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



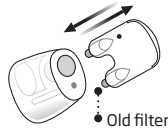
2. Remove

Push the empty pin into the wax filter in the earpiece. Pull out the wax filter.



3. Insert

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



* VarioTherm Micro mould does not have a wax filter

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.