

Instructions for use

Part 2

Oticon Xceed, Oticon Xceed Play
BTE SP, BTE UP



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oticon

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 mild (30 dB HL*) to profound (107 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	Infants, children, and adults.
Use environment	Indoor and outdoor.

Contra-indications	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.

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 a hearing aids does not permit a user to attain full benefit from it.

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 and risk of swallowing batteries or 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 younger than 36 months must always use 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

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. 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.

If you have an active brain implant, contact the manufacturer of your implantable device for information about the risk of disturbance.

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

Heat and chemicals

The hearing aids must never be exposed to extreme heat, e.g. left inside a parked car in the sun. The hearing aids 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 aids. Always remove your hearing aids before applying such products and allow time to dry before use.

Power hearing aids

Special care should be exercised in selecting, fitting and using hearing aids where maximum sound pressure capability exceeds 132 dB SPL (IEC 60138-4 / IEC 711) as there may be 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 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 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 with 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. Nonoriginal 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, 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.

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 the person reporting tinnitus has 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 your hearing aids.

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 upper part of the push button repeatedly until desired level is reached. To decrease volume (on one hearing aid only), use a short press on the lower part of 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/decrease the sound in both hearing aids. When changing the volume in one hearing aid, the volume on the other hearing aid will follow. To increase volume, use a short press on the upper part of the push button repeatedly. To decrease volume, use a short press on the lower part of the push button repeatedly.

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 "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.

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 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 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 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, 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.

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.

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

IMPORTANT NOTICE
Be aware when the ambient temperature is 40 °C (104 °F), the surface of your hearing aid could reach a permissible temperature just below 43 °C (109 °F).

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

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.
	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 protections against harmful ingress of water and particulate matter according to EN 60529. IP6X indicates total dust protection. IPX8 indicates the protection against the effects of continuous immersion in water.
	Bluetooth logo Registered trademark of Bluetooth SIG, Inc. where any use of such requires a license.
	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
	Firmware 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.
	Unique device identifier Indicates a carrier that contains unique device identifier information

Caring for 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 openings.

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

Clean the mould
The mould should be cleaned regularly. Use a soft cloth to clean its surface. Use a tool with a wire loop 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.

