Instructions for use



BTE SP BTE UP

Oticon Xceed
Oticon Xceed Play







WARNING: People younger than 18 should go to a doctor before using this.

People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability.

A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other

available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- · Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

Caution: This is not hearing protection. You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.



If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening – for example, noisy environments.

Note: Tell FDA about Injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit Information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Note: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nosethroat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify

the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to

assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

Model overview

	is booklet is valid for Oticon > llowing hearing aid models:	Kceed and Oticon Xceed Play in the
	BTE SP (Battery size 13) BTE UP (Battery size 675)	
- W	V 8.0	
	Oticon Xceed 1	GTIN: (01) 05714464061075
	Oticon Xceed 2	GTIN: (01) 05714464061082
	Oticon Xceed 3	GTIN: (01) 05714464061099
- W	V 8.0	
	Oticon Xceed Play 1	GTIN: (01) 05714464061105
	Oticon Xceed Play 2	GTIN: (01) 05714464061112
		lelps caregivers, parents, and teachers to give instructions on relevant functions and notices the booklet).

Introduction to this booklet

This booklet guides you on how to use and maintain your new hearing aid. Ensure you read this booklet carefully, including the Warnings section. This will help you get the most benefit from your hearing aid.

Your hearing care professional has adjusted the hearing aids to meet your needs. If you have additional questions, contact your hearing care professional. A hearing care professional* (hearing aid professional, audiologist, ENT (ear, nose and throat) doctor, and hearing aid dispenser) is a person who is appropriately educated and has proven competency in professionally assessing hearing, selecting, fitting, and delivering hearing instruments and rehabilitation care to persons with hearing loss. The education of the hearing care professional is in accordance with national or regional regulations.

| About | Getting started | Daily use | Options | Tinnitus | Warnings | More info |

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

^{*}The job title may vary from country to country.

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.
Contraindications	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.

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

Table of contents

About		
	Hearing aid parts and functions	
	Identify left and right hearing aid	
	MultiTool for handling batteries and cleaning	17
Getting st	arted	
	Turn the hearing aid ON and OFF	18
	When to replace the battery	19
	How to replace the battery	20
Daily use		
	Put on the hearing aid	22
	Caring for the hearing aid	23
	Flight mode	26
Options		
	Optional features and accessories	27
	Change program	28
	Change volume	29
	Mute your hearing aids	30

	Wireless accessories	
	Other options	
	Tamper-resistant battery drawer	
Tinnitus		
	Tinnitus SoundSupport™ (optional)	38
	Guidelines for Tinnitus SoundSupport users	39
	Sound options and volume adjustment	40
	Limitation on use time	43
	Warnings related to Tinnitus	46
Warnings		

31

48

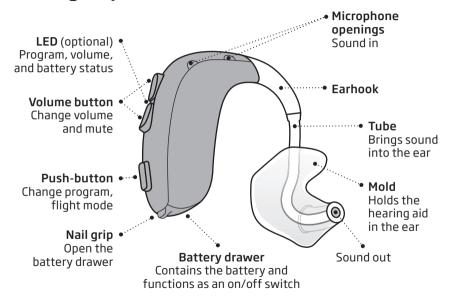
Use the hearing aid with iPhone and iPad

General warnings

More info

Troubleshooting	5.
Water and dust resistant (IP68)	5
Conditions of use	5
Cell phone	5
Technical information	6
Warranty	6
Your individual hearing aid settings	7
Sound and LED indicators	7
Summary of relevant studies	7
Technical Data	78

Hearing aid parts and functions

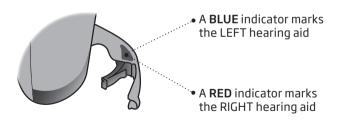


The handling of BTE SP and BTE UP is the same. Therefore the illustrations in this booklet only show the BTE SP.

Identify left and right hearing aid

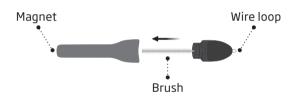
It is important to distinguish between the left and the right hearing aid as they may be programmed differently.

You can find left/right color indicators in the battery drawer. Indicators can also be found on the molds.



MultiTool for handling batteries and cleaning

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



IMPORTANT NOTICE

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

Turn the hearing aid ON and OFF

The battery drawer is used to turn the hearing aid ON and OFF. To save battery life, make sure your hearing aid is turned OFF when you are not wearing it. When you turn ON the hearing aid, it will play a jingle. When you turn it OFF, it will play four descending tones.

If you wish to return to the standard settings of the hearing aid, simply open and close the battery drawer.

Optional LED

Two long green flashes indicate that the hearing aid is turned on.

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



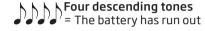
Turn OFF Open the battery drawer.



When to replace the battery

When it is time to replace the battery, you will hear three alternate tones repeated in moderate intervals until the battery runs out.





Battery tip

Keep a spare battery with you at all times to ensure your hearing aid always works.

Optional LED

Continuous orange flashes indicate low battery.

^{*} Bluetooth® will be turned off and it will not be possible to use wireless accessories. Note: Batteries need to be replaced more often if you are streaming to your hearing aid.

How to replace the battery

1. Remove



Fully open the battery drawer. Remove the battery.

2. Uncover



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

Tip: Wait 2 minutes for the battery to draw air to ensure optimal functioning.

3. Insert



Insert the new battery into the battery drawer. Make sure the + side is facing up.

Insert it from above. NOT from the side.

4. Close



Close the battery drawer. The hearing aid will play a jingle through the earpiece.

Hold the earpiece close to your ear to hear the jingle.

Tip



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

The MultiTool is provided by your hearing care professional.

Put on the hearing aid



The mold is customized for you and fits your ear shape. The molds are unique for the left or the right ear.

Step 1



Gently pull your ear outwards and press the mold in the direction of the ear canal, twisting it slightly.

Step 2



Place the hearing aid behind your ear.

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

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



IMPORTANT NOTICE

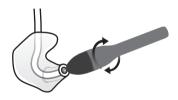
To clean the hearing aids, use a soft, dry cloth. The hearing aids must never be washed or immersed in water or other liquids.

Clean the mold

The mold should be cleaned regularly. Use a soft cloth to clean its surface. Use the MultiTool wire loop to clean the opening.

Replace the tube

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



Wash the mold

Step 1



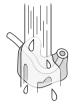
Make sure you are able to identify which mold is for which hearing aid before disconnecting them from the hearing aid.

Step 2



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

Step 3



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

Flight mode

When flight mode is activated, Bluetooth® is turned OFF. The hearing aid will still be working. Pressing the push-button on one hearing aid will activate flight mode on both hearing aids.

Optional LED

When flight mode is activated, the LED continuously flashes green, orange and orange.



• To activate and deactivate Press button for at least seven seconds. A short jingle confirms your action.

Opening and closing the battery drawer will also deactivate flight mode. A short jingle confirms your action.

Optional features and accessories

The features and accessories described in the following pages are optional. Please contact your hearing care professional for more information about features and accessories.

If you experience difficult listening situations, a special program may be helpful. These are programmed by your hearing care professional.

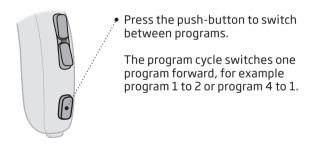
Write down any hearing situations in which you may need help.		

Change program

Your hearing aid can have up to four different programs. You will hear one to four tones when you change program depending on the program.

Optional LED

The number of green flashes indicates the selected program.

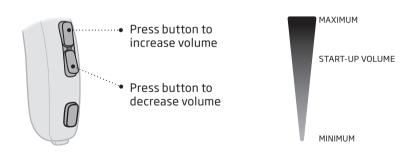


Change volume

The volume button allows you to adjust the volume. You will hear a beep when you increase or decrease the volume.

Optional LED

A green flash confirms a change of volume. A long green flash indicates that start-up volume has been reached. An orange flash will appear when you reach the minimum or maximum level.

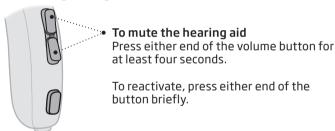


Mute your hearing aids

Use the mute function if you need to turn off the sounds temporarily, while wearing the hearing aid. The mute function only mutes the microphones on the hearing aid.

Optional LED

Continues orange and green flashes indicate mute.



IMPORTANT NOTICE

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

Use the hearing aid with iPhone and iPad

Your hearing aids are Made for iPhone® and allow for direct communication and control with iPhone, iPad® or iPod touch®.

For assistance in using these products with your hearing aids, contact your hearing care professional or visit: www.oticon.com/support

To see how to pair your hearing aid with your iPhone, visit: www.oticon.com/support

For information on compatibility, visit: www.oticon.com/support/compatibility

Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple products 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.

Note that use of this accessory with iPod, iPhone, or iPad may affect wireless performance.

Wireless accessories

As an enhancement to your wireless hearing aids, a range of accessories is available. These can enable you to hear and communicate better in many everyday situations.

ConnectClip

A device that can be used as remote microphone and hands-free headset when paired to your cell phone.

TV Adapter 3.0

A device that streams sound from a TV or electronic audio device, to your hearing aids.

Phone Adapter 2.0

A device that when used together with hearing aids and ConnectClip, lets you communicate hands-free via a landline phone.

Remote Control 3.0

A device that lets you change program, adjust volume, or mute your hearing aids.

Oticon ON

An application that lets you control your hearing aid from your cell phone or tablet. For iPhone, iPad, iPod touch, and Android devices. Ensure that you only download and install Oticon ON app from the official app stores.

EduMic

A device that can be used as a remote microphone in classrooms, work environments, public places (using Telecoil), and other settings.

For more information visit www.oticon.com or contact your hearing care professional.

Apple, the Apple logo, iPhone, iPad, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc. Android, Google Play, and the Google Play logo are trademarks of Google LLC.

Other options

Telecoil

Telecoil can help you hear better when using a phone with a built-in loop or when in buildings with teleloop systems such as theaters, places of worship, or lecture rooms. This symbol is shown wherever a teleloop has been installed.

Direct Audio Input (DAI)

Allows your hearing aid to receive signals directly from external sources such as TV, radio, music players, etc. The DAI adaptor is mounted to your hearing aid and via a cable connected to an external sound source.

IMPORTANT NOTICE

When the DAI adapter is connected to an audio source plugged into a wall outlet, the audio source must comply with IEC 62368-1 or equivalent safety standards.

FΜ

Allows you to receive speech or audio signals directly to your hearing aid from a dedicated transmitter.

CROS

Solution for people with an unaidable hearing loss in one ear. A transmitter on the poorer ear transmits sound to a hearing aid on the better ear.

For more information, please contact your hearing care professional.

Tamper-resistant battery drawer

To keep the battery out of reach of infants, small children, and people with learning difficulties, a tamper-resistant battery drawer should be used.

IMPORTANT NOTICE

Avoid excessive force when opening the battery drawer in the locked position. Do not force the battery drawer beyond its fully opened position. Make sure to insert the battery correctly.

Contact your hearing care professional if you suspect the tamper-resistant battery drawer's effectiveness and locking ability is reduced.

Lock the battery drawer



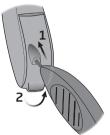
Close the battery door completely and make sure it is locked.

Tool to unlock the battery drawer



Use this small tool provided by your hearing care professional.

Unlock the battery drawer



Insert the tip of the tool into the small hole at the back of the battery drawer.

- 1. Push in the tool fully and hold
- 2. Lift to open the drawer

	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 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 pushbutton repeatedly. To decrease volume, use a short press on the lower part of the pushbutton 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 the 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", in the back of this booklet.
- Instruct your patient accordingly.

If your hearing care professional has activated the sound generator Tinnitus SoundSupport, please pay attention to the following warnings.

There are some potential concerns associated with the use of any sound generated by a tinnitus management device. Among them are the potential worsening of tinnitus, and/or a possible change in hearing thresholds.

Should you experience or notice a change in hearing or tinnitus, or any dizziness, nausea, headaches, heart palpitations, or possible skin irritation at the point of contact with the device, you should immediately discontinue use of the device and consult a medical, audiology, or other hearing care professional.

As with any device, misuse of the sound generator feature may cause potentially harmful effects. Care should be taken to prevent unauthorized use and to keep the device out of 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.

⚠ General warnings

For your personal safety and to ensure correct usage, you should familiarize yourself fully with the following general warnings before using your hearing aids. Consult your hearing care professional if 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 under 36 months must always use a hearing aids 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 and contact the National Poison Center at 1-800-222-1222 or National Battery Ingestion Hotline at 1-800-498-8666.

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.

Use in explosive environments - only applies to BTE UP hearing aid

The hearing aid is safe to use under normal usage conditions. The BTE UP hearing aid with size 675 battery has not been tested for compliance with international standards concerning explosive environments.

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

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 ear wax.

⚠ General warnings

Active implants

The hearing aid has been thoroughly tested and characterized 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 centimeters (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 centimeter (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 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.

For information on whether your instrument is a power hearing aid, see the model overview section in this booklet.

Possible side effects

Hearing aids, molds 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.

⚠ General warnings

(((•))) 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.

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.

Troubleshooting

Symptom	Possible causes	
	Dead battery	
No sound	Clogged mold	
	Microphones muted	
	Clogged sound outlet	
Intermittent or reduced sound	Moisture	
	Dead battery	
	Mold inserted incorrectly	
Squealing noise	Earwax accumulated in ear canal	
	Ear has grown	
Beeping/orange flashes (optional)	If your hearing aid plays 8 beeps, 4 times consecutively, and/or repeatedly flashes orange 4 times with small pauses, your hearing aid needs a microphone service check	
Pairing issue with	Bluetooth connection failed	
Apple device	Only one hearing aid paired	

Solutions
Replace the battery
Clean mold
Unmute microphones
Clean mold
Wipe battery with a dry cloth
Replace the battery
Re-insert the mold
Have ear canal examined by your doctor
Contact your hearing care professional
Contact your hearing care professional
1) Unpair your hearing aid. 2) Turn Bluetooth off and on again. 3) Open and close battery drawer on hearing aid. 4) Re-pair hearing aid (visit www.oticon.com/support).

If none of the above solutions work, 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. Should your hearing aid come into contact with water and stop working, please follow these guidelines:

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

IMPORTANT NOTICE

Do not wear your hearing aid while showering or participating in water activities. Do not immerse your hearing aid in water or other liquids.

Conditions of use

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

Cell phone

Some hearing aid users have reported a buzzing sound in their hearing aid when using cell phones, indicating that the cell phone and hearing aid may not be compatible.

The ANSI C63.19 standard determines the prediction of compatibility between a specific hearing aid and a cell phone, thus hearing aid compliance is tested according to this standard. However, demonstrating compliance according to this standard cannot guarantee that all users will be satisfied.

Whereas all hearing aids have acoustic coupling, only the larger hearing aids have the physical space for telecoil (inductive) coupling.

The hearing aid is compliant with ANSI C63.19 in both microphone and telecoil mode.

IMPORTANT NOTICE

The performance of individual hearing aids may vary with individual cell phones. Therefore, ensure you try this hearing aid with your cell phone or, if you are purchasing a new phone, be sure to try it with your hearing aid prior to purchase. For additional guidance, please ask your cell phone provider for the booklet entitled "Hearing Aid Compatibility with Digital Wireless Cell Phones."

Technical information

The hearing aids contain 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 dB μ A/m at a distance of 10 meters (-12.20 dB μ A/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.com

BTE SP only

This device contains a radio module with the following certification ID numbers: FCC ID: 2ACAHSBOBTESP

BTE UP only

This device contains a radio module with the following certification ID numbers: FCC ID: 2ACAHSBOBTEUP

Radiofrequency radiation exposure information

This device complies with FCC RF exposure limits set forth for an uncontrolled environment and has been tested for portable use.

The device must not be co-located or used in conjunction with any other antenna or transmitter.

Use of other accessories not verified by the manufacturer may not ensure compliance with FCC RF exposure guidelines.

Note: This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the manufacturer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The manufacturer declares that this hearing aid is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

This medical device complies with Medical Device Regulation (EU) 2017/745.

Declaration of Conformity is available at the headquarters.

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

Should your hearing aid require service or replacement, contact your hearing care professional for assistance. Many repair needs can be handled on-site at your local hearing care professional's office, and they will arrange for service with the manufacturer if required. You can also contact us at: 580 Howard Ave., Somerset, NJ 08873.

CE 0123











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





C € 0123 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 FN 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.



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

GTIN

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.



Catalog number

Indicates the manufacturer's catalog 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.

International warranty

Your device is covered by an international warranty issued by the manufacturer. This international warranty covers manufacturing and material defects in the device itself, but not in accessories such as batteries, tubing, speakers, earpieces and filters, etc. Problems arising from improper/incorrect handling or care, excessive use, accidents, repairs made by an unauthorized party, exposure to corrosive conditions, physical changes in your ear, damage due to foreign objects entering the device, or incorrect adjustments are NOT covered by the international warranty and may void it. The above international warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods in the country where

you have bought your device. Your hearing care professional may also have issued a warranty that goes beyond the clauses of this international warranty. Please consult him/her for further information.

If you need service

Take your device to your hearing care professional, who may be able to sort out minor problems and adjustments immediately. Your hearing care professional may charge a fee for their services.

Warranty

Certificate

Name of owner:				
Hearing care professional:				
Hearing care professional's address:				
Hearing care professional's phone: _	learing care professional's phone:			
Purchase date:				
Warranty period:	Month:			
Model left:	Serial no.:			
Model right:	Serial no.:			

Your individual hearing aid settings

To be filled out by your hearing care professional.

Settings overview for your hearing aid					
Left Right					
☐ Yes	□No	Change volume	☐ Yes	□No	
☐ Yes	□No	Change program	☐ Yes	□No	
☐ Yes	□ No	Mute	☐ Yes	□No	
☐ Yes	□No	Tinnitus SoundSupport	☐ Yes	□No	
Volume control indicators					
☐ On	☐ Off	Beeps at min/max volume	☐ On	☐ Off	
☐ On	☐ Off	Beeps when changing volume	☐ On	☐ Off	
☐ On	☐ Off	Beeps at start-up volume	☐ On	☐ Off	
Battery indicators					
☐ On	☐ Off	Low battery warning	☐ On	☐ Off	

Tinnitus SoundSupport: Limitation on use						
No limitation on use						
Program	Start-up volume (Tinnitus)	Max volume (Tinnitus)				
1	Max hours per day	Max hours per day				
2	Max hours per day	Max hours per day				
3	Max hours per day	Max hours per day				
4	Max hours per day	Max hours per day				

Sound and LED indicators

Different sounds and LED lights indicate the hearing aid status. The different indicators are listed on the following pages.

Your hearing care professional can set sound and LED indicators to match your preferences.

Program	Sound	LED ¹⁾	When to use
1	1 tone	0	
2	2 tones	00	
3	3 tones	000	
4	4 tones	0000	

Green flash

1) LED continuous or repeated three times with small pauses

ON/OFF	Sound	LED	LED comments
On	☐ Jingle		Shown one time
Volume	Sound	LED	
Start-up volume	☐ 2 beeps		
Minimum/maximum volume	☐ 3 beeps		Shown one time
Volume up/down	☐ 1 beep		
Mute	☐ Descending tone		Continuous or repeated three times
Unmute	☐ Ascending tone		

Long green flash Green flash Orange flash

Accessories	Sound	LED	LED comments
FM and wireless programs ¹⁾	2 different tones		Continuous or
FM and wireless programs ²⁾	2 different tones		repeated three times
Flight mode	Sound	LED	LED comments
Flight mode active	Short jingle	$\circ \bullet \bullet$	Continuous or
Flight mode inactive	Short jingle	3)	repeated three times

Long green flash Green flash Orange flash

¹⁾ DAI/FM + hearing aid microphone, TV Adapter 3.0

²⁾ DAI/FM signal only, ConnectClip remote microphone

³⁾ Only available when three-time repetition is selected

Warnings	Sound	LED	LED comments
Low battery	3 alternate tones		Continuously flashing
Battery shut down	4 descending tones		
Microphone service check needed	8 beeps repeated 4 times		Repeated four times

Orange flash Long orange flash

Summary of relevant studies

Clinical evaluations conducted by or for the manufacturer provide evidence to support the intended use and clinical benefits outlined in the IFU and demonstrate regulatory conformity. Clinical data is collected, assessed, and analyzed to support the performance of the hearing aids by validating that they provide sufficient audibility and hearing loss compensation based on bestpractice prescriptive fitting rationales. The clinical data also demonstrate improved speech understanding and success with hearing aids using validated questionnaires and surveys.

Non-clinical data supporting the overall performance of the hearing aids includes software verification, electroacoustic verification, electrical and mechanical safety evaluation, electromagnetic compatibility (EMC) evaluation, and documentation of radio properties and performance. Additional information can be found in section Technical Information.



Measured according to American National Standard ANSI S3.22-2014 and ANSI S3.55-2014/Part 5 $\,$

Supply voltage: Zinc Air

0 dB SPL ref. 20 µPa

OSPL90	Peak	139 dB SPL
	HF Average	130 dB SPL
Full-on Gain	Peak	79 dB
rull-oli dalli	HF Average	70 dB
Reference Test Gain		53 dB
Frequency Range		100-6100 Hz
Total Harmonic Distortion	500 Hz	4 %
	800 Hz	<2%
	1600 Hz	<2%
Equivalent Input Noise Level	(omni/dir)	19/34 dB SPL
HF Average SPLITS	(left/right ear)	115/115 dB SPL
Attack Time		< 5 ms
Release Time		<90 ms

Battery Consumption	Typical	2.5 mA
	Quiescent	1.4 mA
Expected battery life (bat. size 13) Hours		75-115 hrs
Latency		8.4 ms
	Measured output at 1 mA/m	110 dB SPL
Maximum Induction Coil Sensitivity	Measured output at 10 mA/m	129 dB SPL
	Measured output at 31.6 mA/m	137 dB SPL



Measured according to American National Standard ANSI S3.22-2014 and ANSI \$3.55-2014/Part 5

Supply voltage: Zinc Air

0 dB SPL ref. 20 μPa

		-
OSPL90	Peak	142 dB SPL
	HF Average	130 dB SPL
Full-on Gain	Peak	83 dB
ruii-oii uaiii	HF Average	69 dB
Reference Test Gain		53 dB
Frequency Range		100-5300 Hz
Total Harmonic Distortion	500 Hz	9%
	800 Hz	<2%
	1600 Hz	<2%
Equivalent Input Noise Level	(omni/dir)	23/38 dB SPL
HF Average SPLITS	(left/right ear)	112/112 dB SPL
Attack Time		<5 ms
Release Time		<90 ms

Battery Consumption	Typical	4.1 mA
	Quiescent	1.5 mA
Expected battery life (bat. size 675)	Hours	80-250 hrs
Latency		8.4 ms
	Measured output at 1 mA/m	110 dB SPL
Maximum Induction Coil Sensitivity	Measured output at 10 mA/m	127 dB SPL
	Measured output at 31.6 mA/m	135 dB SPL



Measured according to American National Standard ANSI S3.22-2014 and ANSI \$3.55-2014/Part 5

Supply voltage: Zinc Air

0 dB SPL ref. 20 μPa

OSPL90	Peak	139 dB SPL
	HF Average	130 dB SPL
Full-on Gain	Peak	79 dB
ruii-oii uaiii	HF Average	70 dB
Reference Test Gain		53 dB
Frequency Range		100-6100 Hz
Total Harmonic Distortion	500 Hz	4 %
	800 Hz	<2%
	1600 Hz	<2%
Equivalent Input Noise Level	(omni/dir)	19/34 dB SPL
HF Average SPLITS	(left/right ear)	115/115 dB SPL
Attack Time		<5 ms
Release Time		<90 ms

Battery Consumption	Typical	2.5 mA
	Quiescent	1.4 mA
Expected battery life (bat. size 13)	Hours	75-115 hrs
Latency		8.4 ms
	Measured output at 1 mA/m	110 dB SPL
Maximum Induction Coil Sensitivity	Measured output at 10 mA/m	129 dB SPL
	Measured output at 31.6 mA/m	137 dB SPL



Measured according to American National Standard ANSI S3.22-2014 and ANSI \$3.55-2014/Part 5

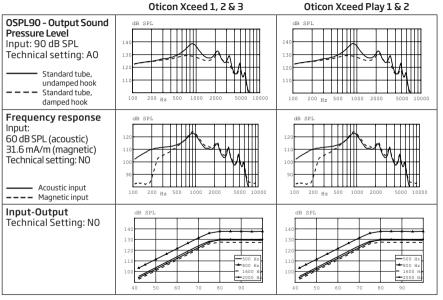
Supply voltage: Zinc Air

0 dB SPL ref. 20 μPa

OSPL90	Peak	142 dB SPL
	HF Average	130 dB SPL
Full-on Gain	Peak	83 dB
Full-Oll Galli	HF Average	69 dB
Reference Test Gain		53 dB
Frequency Range		100-5300 Hz
Total Harmonic Distortion	500 Hz	9%
	800 Hz	<2%
	1600 Hz	<2%
Equivalent Input Noise Level	(omni/dir)	23/38 dB SPL
HF Average SPLITS	(left/right ear)	112/112 dB SPL
Attack Time		<5 ms
Release Time		<90 ms

Battery Consumption	Typical	4.1 mA
	Quiescent	1.5 mA
Expected battery life (bat. size 675)	Hours	80-250 hrs
Latency		8.4 ms
	Measured output at 1 mA/m	110 dB SPL
Maximum Induction Coil Sensitivity	Measured output at 10 mA/m	127 dB SPL
	Measured output at 31.6 mA/m	135 dB SPL

BTESP 110



Oticon Xceed 1, 2 & 3

