# Instructions for use

IIC - CIC - ITC ITE HS - ITE FS

Oticon Own™















#### **Model overview**

E1-14 0

This booklet is valid for the Oticon Own family in the following hearing aid models, battery sizes, and styles:

FW 1.0	
□ Oticon Own 1	GTIN: (01) 05714464060986
□ Oticon Own 2	GTIN: (01) 05714464060993
□ Oticon Own 3	GTIN: (01) 05714464061006
□ Oticon Own 4	GTIN: (01) 05714464061013
□ Oticon Own 5	GTIN: (01) 05714464061020
Battery size □ 10 □ 312	
Bluetooth® ☐ Yes ☐ No	

# Styles □ IIC Invisible-In-the-Canal □ CIC Completely-In-the-Canal □ ITC In-the-Canal □ ITE HS In-the-Ear Half Shell □ ITE FS In-the-Ear Full Shell

#### Introduction to this booklet

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

Your hearing care professional has adjusted the hearing aid 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.

\*The job title may vary from country to country.

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

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

#### Intended use

Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	Bilateral or unilateral impaired hearing of sensorineural, conductive, or mixed type ranging from a slight (25 dB HL*) to severe (80 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.
Use environment	Indoor and outdoor.
Contraindications	Not suitable for infants below 36 months.** Users of active implants must pay special attention when using the hearing aid. For more information read the <b>Warnings</b> 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.

<sup>\*\*</sup> In accordance with current Pediatric Amplification guidelines, custom hearing aids are not typically considered for children of any age. However, a hearing care professional may, in special circumstance and on a case-bycase basis, select them for children older than 36 months.

# **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.

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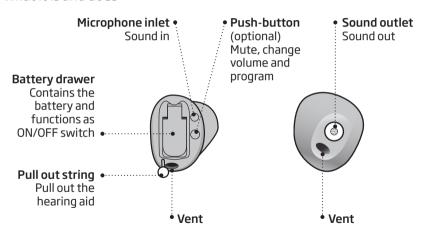
# Identify your hearing aid

For your in-the-ear hearing aid, there are several different styles available with different battery sizes. Please see the model overview for your style and battery size. This will make it easier for you to navigate through this booklet.

# Hearing aids with size 10 battery

(CIC shown)

#### What it is and does

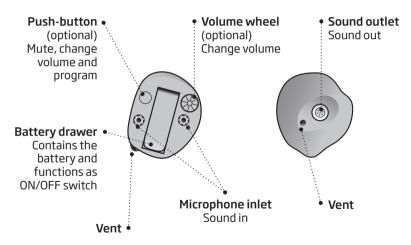


Components may be positioned differently on your hearing aid.

# Hearing aids with size 312 battery

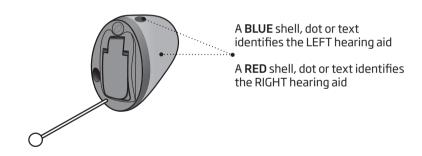
(ITC shown)

#### What it is and does



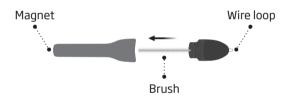
# Identify left and right hearing aid

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



# 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 a wire loop for cleaning and removing earwax. If the vent is very small, a special tool may be required. If you need a new tool 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 also used to switch the hearing aid ON and OFF. To save battery life, make sure your hearing aid is switched OFF when you are not wearing it. If you wish to return to the standard settings of the hearing aid, simply open and then close the battery drawer (quick reset).

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



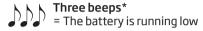
Turn OFF Open the battery drawer.

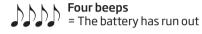


**Note:** Open the battery door fully to make sure the hearing aid does not drain the battery fully and to allow air to circulate whenever you are not using your hearing instrument, especially at night or for longer periods of time.

# Replace the battery

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





#### **Battery tip**

To make sure the hearing aid is always working, bring spare batteries with you, or replace the battery before you leave home.

<sup>\*</sup> If your hearing aid has Bluetooth® this 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 audio or music to your hearing aids.

# 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 so that the battery can draw air, to ensure optimal functioning.

#### 3. Insert



Insert the new battery into the battery drawer. Ensure that the + side of the battery and battery drawer align.

#### 4. Close



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

Hold the hearing aid close to your ear to hear the jingle.

#### Tip



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

# Insert the hearing aid

Step 1



Place the tip of the hearing aid in your ear canal.

Step 2



Gently pull your ear outwards and push the hearing aid into the ear canal, twisting slightly if necessary. Follow the natural contour of the ear canal. Push the hearing aid to make sure it fits comfortably in the ear.

# Remove your hearing aid

Hold the hearing aid by the pull-out string (if available). Gently pull the hearing aid from the ear canal.

If your hearing aid doesn't have a pull-out string, you can remove it by pulling on the edge of the hearing aid.

#### IMPORTANT NOTICE

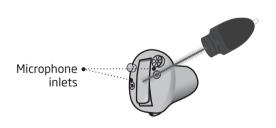
DO NOT use the battery door as a handle to insert or remove your hearing aids, as it is not designed for this purpose.

# Caring for your hearing aid

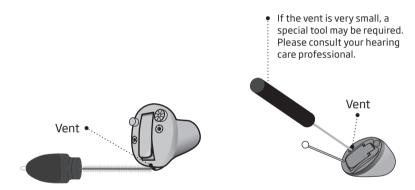
When handling your hearing aid, hold it over a soft surface to avoid damage if you drop it.

#### Cleaning the hearing aid

Carefully brush away debris from the microphone inlets with a clean brush. Gently brush the surface. Make sure that the filters do not fall off.



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



#### 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.

# Filter replacement

The filters keep wax and debris from damaging the hearing aid. If the filters becomes clogged, please replace the filters or contact your hearing care professional.

- ProWax miniFit filter protects the sound outlet.
- O-cap and T-cap protect the microphone inlet.

Please refer to the following pages for instructions on how to replace the appropriate filters.

#### 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 ProWax miniFit filters, contact your hearing care professional.

# **Replace ProWax miniFit filter**

#### 1. Tool



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

#### 2. Remove



Push the empty pin into the ProWax miniFit filter in the hearing aid and pull it out.

#### 3. Insert



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

# Replace T-Cap filter

(hearing aids with size 10 battery)

#### 1. Tool



Remove the tool from the packaging. The tool has two ends, one for removal and one with the new T-Cap filter.

#### 2. Remove



Push the tool fork under the top edge of the used T-Cap filter and lift it out.

#### 3. Insert



Insert the new T-Cap filter and remove the tool by twisting it slightly. Throw the tool out after use.

# **Replace O-Cap filter**

(hearing aids with size 312 batteries)

#### 1. Tool



Remove the tool from the packaging. The tool has two ends, one for removal and one with the new O-Cap filter.

#### 2. Remove



Push the pointed end of the tool into the existing O-Cap filter and pull it out.

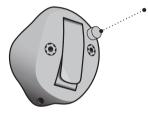
#### 3. Insert



Insert the new O-Cap filter using the other end of the tool and remove. Throw the tool out after use.

# **Change programs**

Your hearing aid can have up to 4 different programs. These are programmed by your hearing care professional.



... Press the button to change program. Use a short press if the push-button is used for program change only and a long press if it is also used for volume control.

Note that if you have two synchronized hearing aids (both hearing aids respond when either push-button is operated), the RIGHT hearing aid switches forward from e.g., program 1 to 2 and the LEFT hearing aid switches backwards from e.g., program 4 to 3.

If your hearing aids work independently, you must press the buttons on each hearing aid.

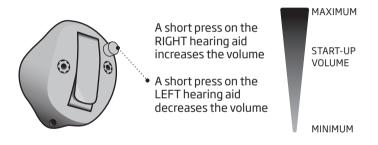
## To be filled out by the hearing care professional

Program	Sound you will hear when activated		When to use
1	<b>)</b>	"1 beep"	
2	ررر	"2 beeps"	
3	الداد	"3 beeps"	
4	תתתת	"4 beeps"	

Program change:		
□Independent	□Synchronized	
□LEFT	□RIGHT	
□Short press	□Long press	

# Change volume with push-button

The push-button allows you to adjust the volume. You may hear a click when you turn the volume up or down.

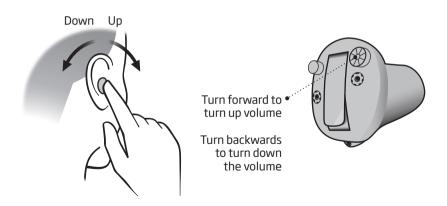


#### To be filled out by the hearing care professional

Volume change	□LEFT	□RIGHT
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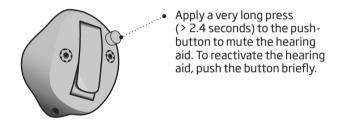
# Change volume with volume wheel

The volume wheel allows you to adjust the volume. You may hear a click when you turn the volume up or down.



# Mute the hearing aid

Use the mute function if you need to silence the hearing aid. Only available for hearing aids with push-button.



NOTE: the mute function only mutes the microphone(s) on the hearing aids.

#### IMPORTANT NOTICE

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

# Flight mode

(hearing aids with Bluetooth and push-button)

When boarding an airplane or entering an area in which it is prohibited to radiate radio signals, e.g. during flight, flight mode must be activated. The hearing aid will still be working. It is only necessary to activate flight mode on one hearing aid to turn off Bluetooth on both hearing aids. If your hearing aid does not have a push-button you need to turn off your hearing aid.

To activate and deactivate
Press the push-button for
at least 7 seconds. A jingle
confirms your action.

Opening and closing the battery drawer will also deactivate flight mode.



# Use hearing aids with iPhone, iPad, and iPod touch

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/connectivity

To see how to pair your hearing aids 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.

# Use your hearing aids with Android devices

Your hearing aids support Audio Streaming for Hearing Aids (ASHA) and allow for direct streaming from selected Android™ devices.

For assistance in using your hearing aids with Android devices, contact your hearing care professional or visit: www.oticon.com/connectivity

To see how to pair your hearing aids with your Android device visit: www.oticon.com/support

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

### **Wireless accessories**

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

### ConnectClip

When paired with your mobile phone, you can use the hearing aids as a hands-free headset, or as a remote microphone.

### TV Adapter 3.0

Wireless transmitter of sound from TV and electronic audio devices. TV Adapter streams sound directly to your hearing aids.

### Remote Control 3.0

Offers the ability to change program, adjust volume, or mute your hearing aids.

#### Oticon ON

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

### Phone Adapter 2.0

Connects wirelessly to the hearing aids via ConnectClip allowing for use of landline phones.

## For more information visit: www.oticon.com/connectivity

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# Other options

### Telecoil - optional for select styles

Telecoil helps you hear better when using a telephone with a builtin loop or when you are in buildings with teleloop systems such as theaters, churches, or lecture rooms. This symbol or a similar sign is shown wherever a teleloop has been installed.



For more information, please contact your hearing care professional.

# **Optional features and accessories**

The features and accessories described on the following pages are optional. Please contact your hearing care professional to find out how your hearing aid is programmed.

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.

# **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.

### Styles available with Tinnitus SoundSupport

Only available for CIC, ITC, ITE HS and ITE FS hearing aids with a pushbutton. Please see the Model overview section to find out which style your hearing aid is.

# **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 the hearing aid".

### Volume adjustments with Tinnitus SoundSupport

When you select a hearing aid program for which Tinnitus SoundSupport is activated, your hearing care professional can only set the push-button or volume wheel 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.

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

To be filled out by your hearing care professional.

<ul> <li>Change volume with volume wheel</li> <li>See section Change volume with volume wheel for illustration</li> </ul>		
	A) How to change Tinnitus SoundSupport volume in <u>each</u> ear separately To increase volume (on one hearing aid only), turn the volume wheel forward. To decrease volume (on one hearing aid only), turn the volume wheel backwards.	
	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, turn the volume wheel forward. To decrease volume, turn the volume wheel backwards.	

To be filled out by your hearing care professional.

Hearin	g aid with	Bluetooth
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If your hearing aid has Bluetooth connection, you will be able to adjust the environmental sounds in a program with Tinnitus SoundSupport with Remote Control 3.0 or ConnectClip.

**Oticon ON** for iPhone, iPad, iPod touch, and Android™ devices offers the possibility to adjust both the environmental sound and the Tinnitus SoundSupport in each program directly from the app.

### 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 the section **Your individual hearing aid settings** at the end of this booklet to learn how many hours per day you can safely use the relief sound in your hearing aids.

# Important information for hearing care professionals about Tinnitus SoundSupport

### **Device description**

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

# Marnings 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 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 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 aid 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 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 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.

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.

# **⚠** General warnings

#### **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 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 on use with magnets.

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

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

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

#### Heat and chemicals

The hearing aid must never be exposed to extreme heat, e.g. left inside a parked car in the sun.

The hearing aid must not be dried in microwave ovens or other ovens.

The chemicals in cosmetics, hairspray, perfume, aftershave lotion, suntan lotion, and insect repellent can damage the hearing aid. Always remove your hearing aid before applying such products and allow time to dry before use.

#### Power hearing aid

Special care should be exercised in selecting, fitting, and using a 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 aid user. For information on whether your instrument is a power hearing aid, see the Your individual hearing aids settings section in this booklet.

# **⚠** General warnings

#### Possible side effects

Hearing aids and earpieces 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

If your hearing aids have Bluetooth wireless technology, when on board an aircraft, the hearing aids must be put into flight mode to deactivate Bluetooth, unless Bluetooth is permitted by the flight personnel.

The hearing aid needs to have a pushbutton for you to be able to activate flight mode, otherwise you must turn off your hearing aids. To find out whether your hearing aids have Bluetooth wireless technology, see the model overview in your hearing aids' Instructions for use.

### 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 aid is 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 aid.

#### Modification of hearing aids is not allowed

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

(((♠))) Interference The hearing aids have been thoroughly tested for interference according to the most stringent international standards.

Electromagnetic interference may occur in the vicinity of equipment with the symbol on the left. Portable and mobile RF (radio frequency) communications equipment can affect the performance of the hearing aids. If your hearing aids are affected by electromagnetic interference, move away from the source to reduce the interference.

# \land General warnings

Warning to hearing care professional
A hearing care professional should advise
a prospective hearing aid user to consult
promptly with a licensed physician
(preferably an ear specialist) before
dispensing a hearing aid if the hearing aid
dispenser determines 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:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 dB because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 dB.)

### Important Notice for Prospective Hearing Aid Users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

# **⚠** General warnings

Federal law restricts this device to sale by or on the order of a doctor, audiologist or other hearing care practitioner licensed to dispense hearing aids in your state-in accordance with all applicable rules and regulations.

### Children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

# **Troubleshooting guide**

Symptom	Possible causes
	Worn-out battery
No sound	Clogged sound outlet
NO Souriu	Clogged microphone inlet
	Hearing aid microphone muted
	Clogged sound outlet
Intermittent or reduced sound	Moisture
	Worn-out battery
Squealing noise	Hearing aid not inserted properly
Squealing noise	Ear wax accumulated in ear canal
Pairing issue with Apple	Bluetooth connection failed
device	Only one hearing aid paired

Solutions
Replace the battery
Clean sound outlet* or replace the wax filter
Clean microphone inlet* or replace filter (T-Cap or O-Cap)
Unmute the hearing aid microphone
Clean sound outlet or replace the wax filter
Wipe battery and hearing aid with a dry cloth
Replace the battery
Re-insert the hearing aid
Have ear canal examined by your doctor
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 for assistance. \* According to guideline in this booklet

# Water & dust resistant (IP68)

Your hearing aid is dust-tight and protected against ingress of water which means it is designed to be worn in all daily life situations. Therefore you do not have to worry about sweat or getting wet in the rain. Should your hearing aid come in contact with water and stop working, please follow these guidelines:

- 1. Gently wipe off any water
- Open the battery drawer and 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:
	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

# **Cell phone**

Some hearing aid users have reported a buzzing sound in their hearing aid when they are 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 by: adding the numerical value of the rating for the hearing aid immunity to the numerical value of the rating for the cell phone emissions. A sum of 4 would indicate that the combination of wireless device and hearing aid is usable; a combined rating that equals at least 5 would provide normal use; a combined rating of 6 or greater would indicate excellent performance.

Whereas all hearing aids have acoustic coupling, only the larger hearing aids have the physical space for telecoil (inductive) coupling. These two types of coupling have different rating scales (M1-M4 for acoustic coupling and T1-T4 for telecoil coupling, respectively) and both ratings are therefore relevant when predicting the compatibility of a particular hearing aid.

For a hearing aid with both acoustic coupling and telecoil coupling with a rating of M4/T2 and with a telephone rating of M3/T3), the combined rating is 7 (M4 + M3) for the acoustic coupling and 5 (T2 + T3) for the telecoil coupling. According to the guidelines given above, both types of coupling will thereby be

acceptable, with the acoustic coupling indicating excellent performance and the telecoil coupling indicating normal use.

The above equipment performance measurements, categories and system classifications are based upon the best information available, but it cannot be guaranteed that all users will be satisfied.

The immunity of this hearing aid is at least M2/T2.

The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

#### 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."

# Warranty

### Certificate

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

# **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.

### **Technical information**

The hearing aids contain the following two radio technologies:

The hearing aids contain a radio transceiver using short range magnetic induction technology operating at 3.84 MHz. The magnetic field strength of the transmitter is very weak and always below 15 nW (typically below -40 dBµA/m at a distance of 10 meters (-12.20 dBµA/ft at a distance of 33 feet).

The hearing aids also contain a radio transceiver using Bluetooth Low Energy and a proprietary, short range radio technology both operating at ISM band 2.4 GHz. The radio transmitter is weak and always below 3 mW equal to 4.8 dBm in total radiated power.

Only use your hearing aids in areas where wireless transmission is permitted.

The hearing aids comply with international standards concerning radio transmitters, electromagnetic compatibility, and human exposure. Due to the limited space available on the hearing aid, relevant approval markings can be found in this booklet. Additional information can be found in the "Technical Data Sheet" on www.oticon.com

#### **USA** and Canada

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

# ITC, ITE HS & ITE FS:

FCC ID: 2ACAHAU5ITE IC: 11936A-AU5ITE

#### IIC & CIC:

FCC ID: 2ACAHAU5CIC IC: 11936A-AU5CIC

#### Note:

The device complies with Part 15 of the FCC Rules and with Innovation, Science and Economic Development Canada's license-exempt RSSs standards. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received,

including interference that may cause undesired operation.

# Radio frequency radiation exposure information

For body-worn operation, this device meets FCC and Innovation, Science and Economic Development Canada's RF exposure limits and has been tested while in contact with the human body. Use of other accessories not verified by the manufacturer may not ensure compliance with FCC and Innovation, Science and Economic Development Canada's RF exposure guidelines. The device must not be co-located or used in conjunction with any other antenna or transmitter.

Note: This equipment 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 equipment 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 quarantee that interference will not occur in a particular installation. If this equipment 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

**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

#### CF mark



C € n<sub>123</sub> 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\*

#### Bluetooth logo

Registered trademark of Bluetooth SIG, Inc. where any use of such requires a license.



#### 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 device contains an RF transmitter.



### 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.

# Your individual hearing aid settings

To be filled out by your hearing care professional.

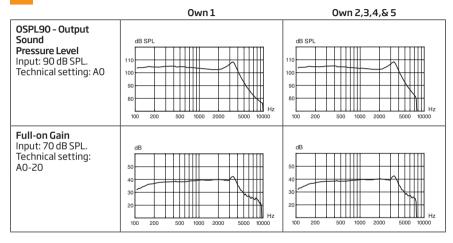
Tinnitus SoundSupport: Limitation on use					
	No limitation on use				
Program Start-up volume (Tinnitus) Max volume (Tinnit					
	1	Max hours per day	Max hours per day		
	2	Max hours per day	Max hours per day		
	3	Max hours per day	Max hours per day		
	4	Max hours per day	Max hours per day		

Power instrument ☐ Yes ☐ No					
	Settings overview for your hearing aid				
Le	Left Right				
☐ Yes	□No	Volume control	☐ Yes	□No	
☐ Yes	□No	Program shift	☐ Yes	□No	
☐Yes	□No	Mute	☐ Yes	□No	
☐ Yes	□No	Tinnitus SoundSupport	☐ Yes	□No	
Volume control indicators					
☐ 0n	☐ Off	Beeps at min/max volume	☐ On	☐ Off	
☐ 0n	☐ Off	Off Clicks when changing volume 🔲 On 🔲 Off		☐ Off	
☐ On	On Off Beeps at preferred volume On		☐ Off		
Battery indicators					
☐ On	☐ Off	Low battery warning	□ On	☐ Off	



Measured according to American National Standard ANSI \$3,22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

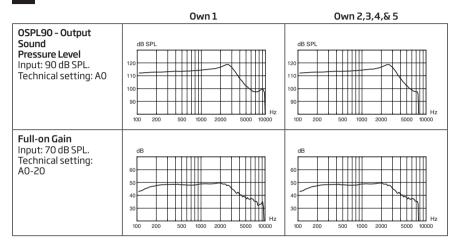
0 dB SPL ref. 20 mPa	Own 1	Own 2,3,4,& 5
Peak OSPL90	108 dB SPL	108 dB SPL
HF Average OSPL90	103 dB SPL	103 dB SPL
Peak Full-on Gain	42 dB	43 dB
HF Average Full-on Gain	39 dB	40 dB
Reference Test Gain	27 dB	27 dB
Frequency Range	100-9200 Hz	100-7500 Hz
Total Harmonic Distortion 500 Hz	<2%	<2%
Total Harmonic Distortion 800 Hz	<2%	<2%
Total Harmonic Distortion 1600 Hz	<3%	<3%
Equivalent Input Noise Level (omni)	19 dB SPL	19 dB SPL
Attack Time	5	5
Release Time	29	29



90

Measured according to American National Standard ANSI \$3,22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

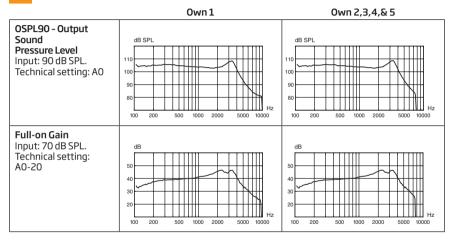
0 dB SPL ref. 20 mPa	Own 1	0wn 2,3,4,& 5
Peak OSPL90	119 dB SPL	119 dB SPL
HF Average OSPL90	116 dB SPL	116 dB SPL
Peak Full-on Gain	50 dB	50 dB
HF Average Full-on Gain	49 dB	49 dB
Reference Test Gain	39 dB	39 dB
Frequency Range	100-9400 Hz	100-7500 Hz
Total Harmonic Distortion 500 Hz	<2%	<2%
Total Harmonic Distortion 800 Hz	<2%	<2%
Total Harmonic Distortion 1600 Hz	<2%	<2%
Equivalent Input Noise Level (omni)	19 dB SPL	19 dB SPL
Attack Time	5	5
Release Time	26	26





Measured according to American National Standard ANSI \$3,22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

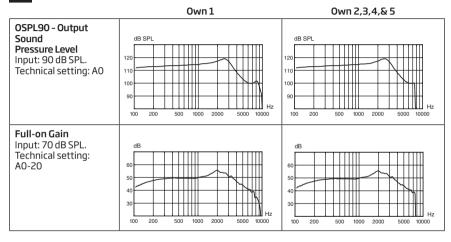
0 dB SPL ref. 20 mPa	Own 1	0wn 2,3,4,& 5
Peak OSPL90	108 dB SP	109 dB SPL
HF Average OSPL90	104 dB SPL	104 dB SPL
Peak Full-on Gain	47 dB	47 dB
HF Average Full-on Gain	43 dB	43 dB
Reference Test Gain	27 dB	27 dB
Frequency Range	100-9300 Hz	100-7500 Hz
Total Harmonic Distortion 500 Hz	<2%	<2%
Total Harmonic Distortion 800 Hz	<2%	<2%
Total Harmonic Distortion 1600 Hz	<2%	<2%
Equivalent Input Noise Level (omni)	19 dB SPL	19 dB SPL
Attack Time	5	5
Release Time	31	31



90

Measured according to American National Standard ANSI \$3,22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

0 dB SPL ref. 20 mPa	Own 1	Own 2,3,4,& 5
Peak OSPL90	119 dB SPL	119 dB SPL
HF Average OSPL90	116 dB SPL	116 dB SPL
Peak Full-on Gain	56 dB	56 dB
HF Average Full-on Gain	52 dB	52 dB
Reference Test Gain	40 dB	40 dB
Frequency Range	100-8700 Hz	100-7500 Hz
Total Harmonic Distortion 500 Hz	<2%	<2%
Total Harmonic Distortion 800 Hz	<2%	<2%
Total Harmonic Distortion 1600 Hz	<2%	<2%
Equivalent Input Noise Level (omni)	18 dB SPL	19 dB SPL
Attack Time	5	5
Release Time	32	32



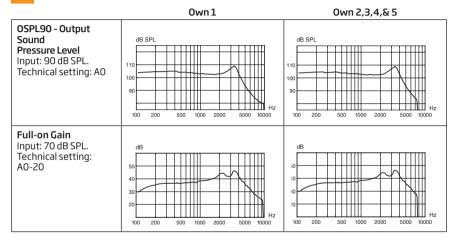
### **Technical Data**

### ITC/ITE HS/ITE FS



Measured according to American National Standard ANSI \$3,22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

0 dB SPL ref. 20 mPa	Own 1	0wn 2,3,4,& 5
Peak OSPL90	109 dB SPL	109 dB SPL
HF Average OSPL90	103 dB SPL	103 dB SPL
Peak Full-on Gain	46 dB	46 dB
HF Average Full-on Gain	40 dB	40 dB
Reference Test Gain	26 dB	26 dB
Frequency Range	100-9400 Hz	100-7500 Hz
Total Harmonic Distortion 500 Hz	<2%	<2%
Total Harmonic Distortion 800 Hz	<2%	<2%
Total Harmonic Distortion 1600 Hz	<2%	<2%
Equivalent Input Noise Level (omni/dir)	17/28 dB SPL	17/27 dB SPL
HF Average SPLITS (left/right ear)	85/85 dB SPL	85/85 dB SPL
Attack Time	5	5
Release Time	34	33



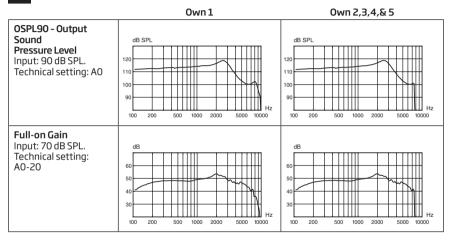
### **Technical Data**

### ITC/ITE HS/ITE FS

90

Measured according to American National Standard ANSI \$3,22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

0 dB SPL ref. 20 mPa	0wn1	Own 2,3,4,& 5
Peak OSPL90	119 dB SPL	119 dB SPL
HF Average OSPL90	116 dB SPL	116 dB SPL
Peak Full-on Gain	54 dB	54 dB
HF Average Full-on Gain	51 dB	51 dB
Reference Test Gain	39 dB	39 dB
Frequency Range	100-8500 Hz	100-7500 Hz
Total Harmonic Distortion 500 Hz	<2%	<2%
Total Harmonic Distortion 800 Hz	<2%	<2%
Total Harmonic Distortion 1600 Hz	<2%	<2%
Equivalent Input Noise Level (omni/dir)	15/27 dB SPL	15/27 dB SPL
HF Average SPLITS (left/right ear)	98/98 dB SPL	98/98 dB SPL
Attack Time	4	5
Release Time	30	30



## **Technical Data**

### ITC/ITE HS/ITE FS



Measured according to American National Standard ANSI \$3,22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

0 dB SPL ref. 20 mPa	0wn 1	0wn 2,3,4,& 5
Peak OSPL90	126 dB SPL	126 dB SPL
HF Average OSPL90	123 dB SPL	123 dB SPL
Peak Full-on Gain	64 dB	64 dB
HF Average Full-on Gain	60 dB	60 dB
Reference Test Gain	46 dB	46 dB
Frequency Range	100-5400 Hz	100-5400 Hz
Total Harmonic Distortion 500 Hz	<2%	<2%
Total Harmonic Distortion 800 Hz	<2%	<2%
Total Harmonic Distortion 1600 Hz	<2%	<2%
Equivalent Input Noise Level (omni/dir)	15/ 30 dB SPL	15/ 30 dB SPL
HF Average SPLITS (left/right ear)	105/105 dB SPL	105/105 dB SPL
Attack Time	8	7
Release Time	21	21

