

# Instructions for use



**BTE PP**  
**BTE**

Oticon Opn™  
Oticon Opn S™  
Oticon Opn Play™  
Oticon Siya  
Oticon Ruby

Made for  
iPhone | iPad | iPod

**oticon**  
life-changing technology



**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-nose-throat 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

This booklet is valid for Oticon Opn™, Oticon Opn S™, Oticon Opn Play™, Oticon Siya and Oticon Ruby families, in the following hearing aid models:

- ☐ BTE
- ☐ BTE PP

### Oticon Opn FW 6.1

- |                                       |                           |
|---------------------------------------|---------------------------|
| <input type="checkbox"/> Oticon Opn 1 | GTIN: (01) 05714464013111 |
| <input type="checkbox"/> Oticon Opn 2 | GTIN: (01) 05714464013128 |
| <input type="checkbox"/> Oticon Opn 3 | GTIN: (01) 05714464013135 |

### Oticon Opn S FW 8.0

- |                                         |                           |
|-----------------------------------------|---------------------------|
| <input type="checkbox"/> Oticon Opn S 1 | GTIN: (01) 05714464013166 |
| <input type="checkbox"/> Oticon Opn S 2 | GTIN: (01) 05714464013173 |
| <input type="checkbox"/> Oticon Opn S 3 | GTIN: (01) 05714464013180 |

### **Oticon Opn Play FW 8.0**

- ☐ Oticon Opn Play 1
- ☐ Oticon Opn Play 2

GTIN: (01) 05714464013197

GTIN: (01) 05714464013203

### **Oticon Siya FW 1.1**

- ☐ Oticon Siya 1
- ☐ Oticon Siya 2

GTIN: (01) 05714464013142

GTIN: (01) 05714464013159

### **Oticon Ruby FW 1.0**

- ☐ Oticon Ruby 1
- ☐ Oticon Ruby 2

GTIN: (01) 05714464013210

GTIN: (01) 05714464013227

- ☐ LED light for visual indication. Not available for Oticon Siya and Oticon Ruby.

The LED light helps caregivers, parents, and teachers to operate the hearing aid and to give instructions on relevant functions and modes (see relevant information throughout 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** | [Start-up](#) | [Handling](#) | [Options](#) | [Tinnitus](#) | [Warnings](#) | [More info](#) |

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

## Intended use

|                                                    |                                                                                                                                                                                                                  |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Intended use</b>                                | The hearing aid is intended to amplify and transmit sound to the ear.                                                                                                                                            |
| <b>Indications for use</b>                         | Bilateral or unilateral impaired hearing of sensorineural, conductive, or mixed type ranging from a slight (16 dB HL*) to severe (85 dB HL*) degree of hearing loss, with an individual frequency configuration. |
| <b>Intended user</b>                               | Person with hearing loss using a hearing aid and their caregivers. Hearing care professional responsible for adjusting the hearing aid.                                                                          |
| <b>Oticon Opn Play<br/>Intended user<br/>group</b> | Infants, children, and adults                                                                                                                                                                                    |
| <b>Intended user<br/>group</b>                     | Adults and children older than 36 months.                                                                                                                                                                        |
| <b>User environment</b>                            | Indoor and outdoor.                                                                                                                                                                                              |

|                                          |                                                                                                                                                                           |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Oticon Opn Play Contraindications</b> | Users of active implants must pay special attention when using the hearing aid. For more information read the Warnings section.                                           |
| <b>Contraindications</b>                 | Not suitable for infants below 36 months. Users of active implants must pay special attention when using the hearing aid. For more information read the Warnings section. |
| <b>Clinical benefits</b>                 | 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.

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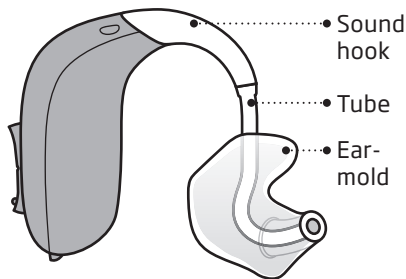
## More info

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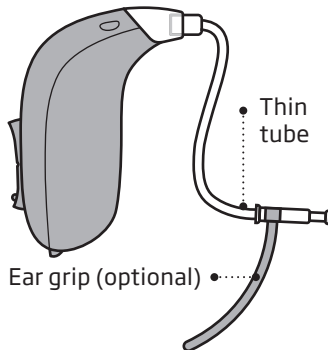
## Your hearing aid and earpiece

There are two different attachments and several different earpieces available for the hearing aid.

- ☐ **With sound hook and earmold earpiece**



- ☐ **With thin tube (Corda miniFit)**



The thin tube uses one of the following earpieces:

### Standard earpieces:



☐ Open dome



☐ Bass dome, single vent



☐ Bass dome, double vent



☐ Power dome



☐ Grip Tip

Available in small and large, left and right, with or without vent.

### Customized earpieces



☐ MicroMold\*



☐ LiteTip\*

### Dome sizes



5 mm\*\*

6 mm

8 mm

10 mm

12 mm\*\*\*

Please see details for replacing the dome in chapter "Replace standard earpieces".

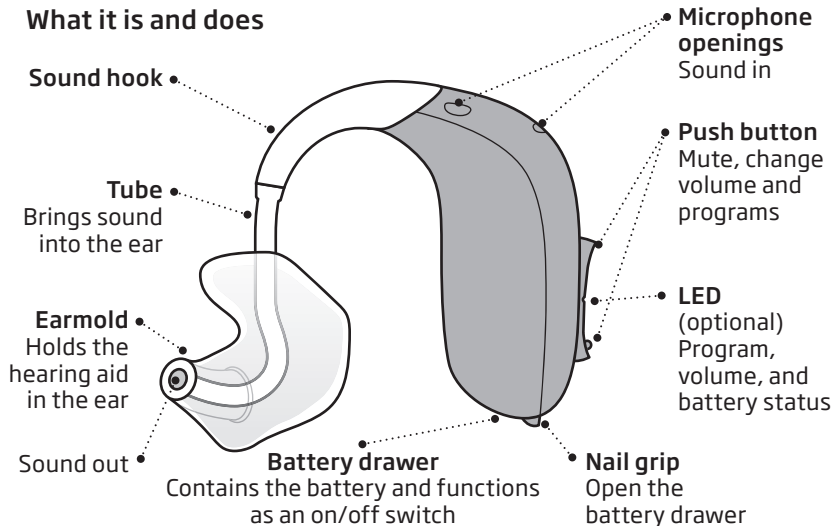
\* Can be made of different materials

\*\* only for Corda miniFit 0.9mm

\*\*\* not for open dome

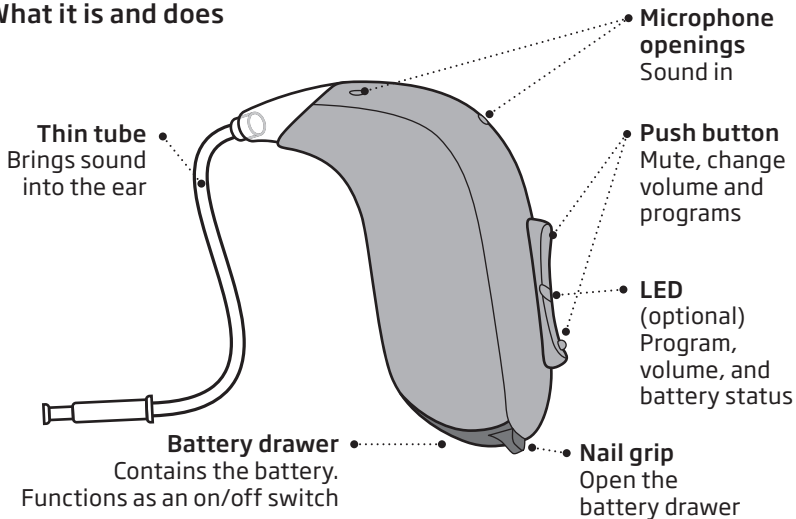
## With sound hook and earmold

### What it is and does



## With thin tube

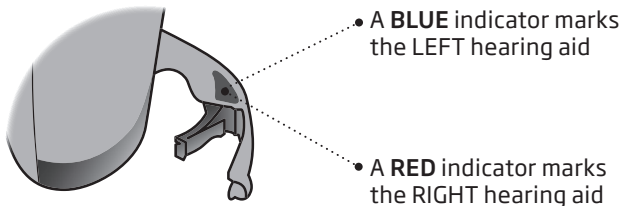
What it is and does



## Identify left and right hearing aid

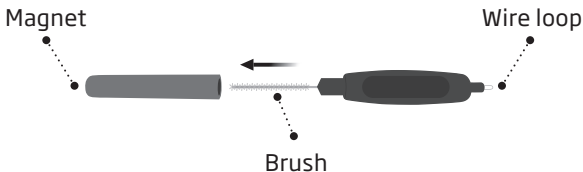
It is important to distinguish between the left and the right hearing aid as they may be programmed differently.

You can find left/right color indicators in the battery drawer. Indicators can also be found on MicroMolds and earmolds (optional).



## 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 at least 30 centimeters (1 foot) away from credit cards and other magnetically sensitive devices.

## Turn the hearing aid ON and OFF

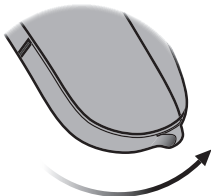
The battery drawer is also used to switch the hearing aid on and off. To save battery life, make sure your hearing aid is switched off when you are not wearing it. If you wish to return to the standard settings of the hearing aid, simply open and close the battery drawer (quick reset).

### Optional LED

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

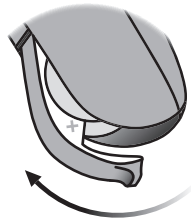
#### Turn ON

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 tones repeated in moderate intervals until the battery runs out.

 **Three alternate tones\***  
= The battery is running low

 **Four descending tones**  
= The battery has run 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.

### Optional LED

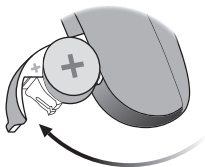
Continuous red flashes indicate low battery.

\* 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 (size 13)

## 1. Remove



Fully open the battery drawer. Remove the battery.

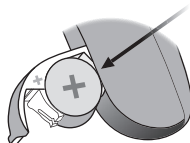
## 2. Uncover



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.

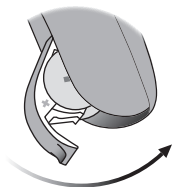
## 3. Insert



Insert the new battery into the battery drawer. Insert it from above, NOT from the side.

Make sure the + side is facing up.

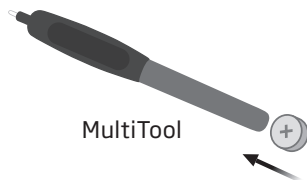
#### 4. Close



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

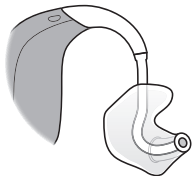


The MultiTool can be used to change the battery. Use the magnetic end to remove and insert batteries.

The MultiTool is provided by your hearing care professional.

## Put on the hearing aid with sound hook

Read the following pages if you have a hearing aid with a sound hook and earmold.



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

### Step 1



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

### Step 2



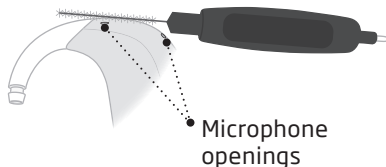
Place the hearing aid behind your ear.

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



### IMPORTANT NOTICE

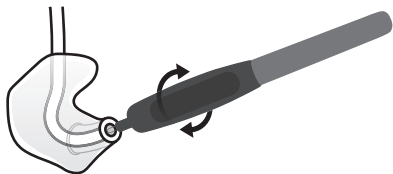
Use a soft, dry cloth to clean the hearing aid. The hearing aids must never be washed or immersed in water or other liquids.

### **Clean the earmold**

The earmold should be cleaned regularly. Use a soft cloth to clean it's surface. Use the MultiTool wire loop to clean the opening.

### **Replace the tube**

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



## Wash the earmold

### Step 1



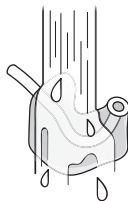
Make sure you are able to identify which earmold is for which hearing aid before disconnecting them from the hearing aid.

### Step 2



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

### Step 3



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

## Put on hearing aid with thin tube

Read the following pages if your hearing aid has a thin tube.

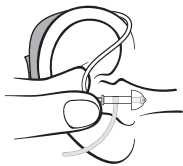
### Step 1



Place the hearing aid behind your ear.

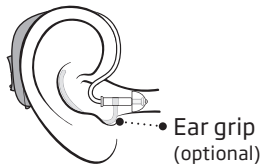
The thin tube should only be used with an attached ear-piece. Use only parts designed for your hearing aid.

### Step 2



Hold the bend of the tube between your thumb and index finger. The earpiece should point towards the ear canal opening.

### Step 3

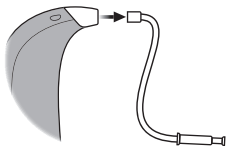


Gently push the earpiece into your ear canal until the thin tube sits close to your head. If the thin tube has an ear grip, place it in the ear so it follows the contour of the ear.

## Clean the thin tube

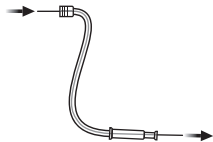
The thin tube should be cleaned to keep it clear of moisture and wax. If not cleaned, it may become blocked with wax, which stops sound from coming out.

### Step 1



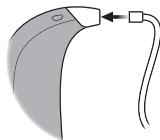
Pull the thin tube out of the hearing aid.

### Step 2



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

### Step 3

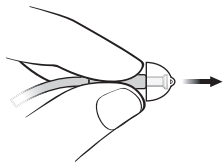


Reconnect the thin tube to the hearing aid.

## Replace standard earpieces

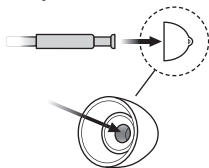
The standard earpiece (dome or Grip Tip) should not be cleaned. If the earpiece is filled with wax, replace it with a new one. Grip Tips should be replaced at least once a month.

### Step 1



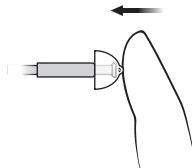
Hold on to the end of the thin tube and then pull off the earpiece.

### Step 2



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

### Step 3



Push firmly to ensure that the earpiece is fastened securely.

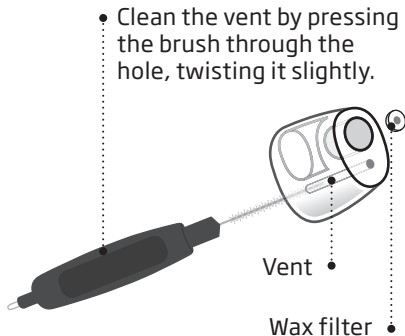
**IMPORTANT NOTICE**

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

## Clean customized earpieces

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

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



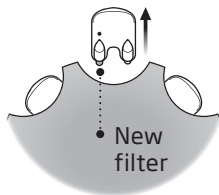
### IMPORTANT NOTICE

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

\* Not all molds have a wax filter. Filter composition can vary by mold.  
For more information contact your hearing care professional.

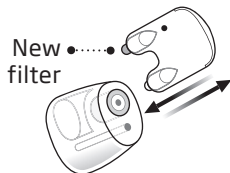
# Replace ProWax filter

## 1. Tool



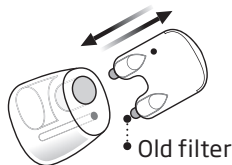
Remove the tool from the shell. The tool has two pins: One empty for removal and one with the new wax filter.

## 2. Remove



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

## 3. Insert



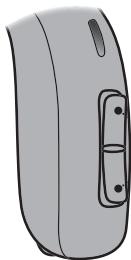
Insert the new wax filter using the other pin. Remove the tool, and throw it out.

## 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

The LED will flash green, red, red a few times. This confirms that flight mode is activated.



**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.

## 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.*

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## **Change program**

Your hearing aid can have up to four different programs. These are programmed by your hearing care professional. You will hear one to four tones when you change program depending on the program.

See the Sound and LED indicator section.

### **Optional LED**

The number of green flashes indicate the selected program.

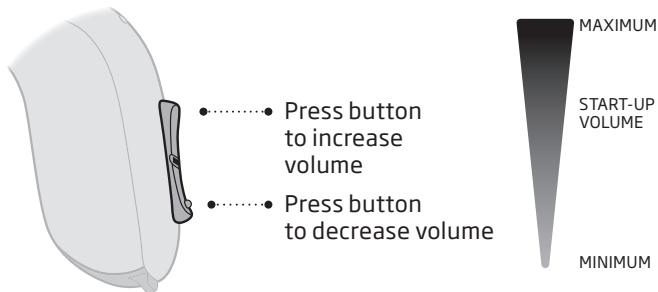


Press the push button to switch between programs.

The program cycle switches one program forward, for example program 1 to 2 or program 4 to 1.

## Change volume

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



### **Optional LED**

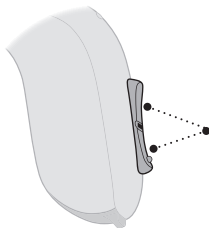
The LED will flash green to confirm changes in volume, and a long green flash at start-up level. The LED will show a red flash when the volume reaches the minimum or maximum level.

## Mute

Use the mute function if you need to silence the hearing aid. The mute function only mutes the microphone(s) on the hearing aid.

### Optional LED

Green and red flashes, continuously repeated, to indicate mute.



Apply a long press (4 seconds) to either end of the button to mute the hearing aid.

To reactivate the hearing aid, push the button briefly.

### 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 hearing aid with iPhone and iPad

Your hearing aid is Made for iPhone® and allows for direct communication and control with iPhone, iPad® or iPod touch®. For assistance in using these products with your hearing aid, please contact your hearing care professional.



To see how to pair your hearing aid with your iPhone please visit [www.oticon.com/support](http://www.oticon.com/support)

For information on compatibility, please visit [www.oticon.com/support/compatibility](http://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 product(s) identified in the badge, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

Please note that use of this Accessory with iPod, iPhone, or iPad may affect wireless performance.

## Wireless accessories

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

### ConnectClip

When ConnectClip is paired with your mobile phone, you can use the hearing aid as a hands-free headset. ConnectClip can also be used as a remote microphone

### TV Adapter 3.0

Streams sound directly from TV and electronic audio devices to your hearing aid.

### FM

Your hearing aid supports the option of attaching an FM system. The FM system allows you to receive speech or audio signals directly to your hearing aid from a dedicated transmitter. When in an FM program the hearing aid switches to flight mode.

### **Remote Control 3.0**

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

### **Phone Adapter 2.0**

Phone Adapter 2.0 connects wirelessly to the ConnectClip allowing for hassle-free daily use of traditional phones.

### **Oticon ON App**

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 Oticon ON app from the official app stores.

For more information visit [www.oticon.com/support](http://www.oticon.com/support) 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 program**

Helps you hear better when using a telephone with a built-in 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.



### **AutoPhone - optional for Oticon Opn and Oticon Siya**

Activates a phone program in the hearing aid, if you place a dedicated magnet on your phone.

## **CROS - optional for Oticon Opn S 1, Opn S 2, Oticon Opn Play 1, Oticon Ruby 1 and Ruby 2**

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

## **Direct Audio Input (DAI)**

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

For more information, please contact your hearing care professional.

### **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.

## 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.

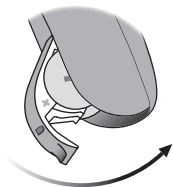
If needed your hearing care professional can help you change the drawer.

### 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.

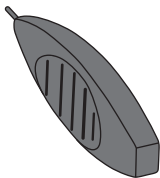
Contact your hearing care professional if you suspect the tamper-resistant battery drawer's effectiveness and locking ability is reduced.

### To lock the battery drawer



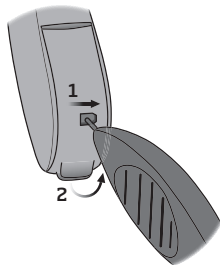
Close the battery door completely and make sure it is locked.

### 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. Move it to the right and hold it
2. Open the battery 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 can decide for which programs you may want to have Tinnitus SoundSupport activated. The sound generator can be activated in up to four different programs.

## **Mute**

If you are in a program for which Tinnitus SoundSupport is activated, the mute functionality will mute only the environmental sounds, and not the sound from Tinnitus SoundSupport. See earlier chapter: “Mute”.

## **Volume adjustments with Tinnitus SoundSupport**

When you select a hearing aid program for which Tinnitus SoundSupport is activated, your hearing care professional can only set the push button on your hearing aid to work as a volume control for the tinnitus relief sound.

Your hearing care professional will set the volume control for the sound generator in one of two ways:

- A) Change volume in each ear separately or
- B) Change volume in both ears simultaneously.

**A) How to change Tinnitus SoundSupport volume in each ear separately**

To **increase** volume (on one hearing aid only), use a short press on the upper part of the push button repeatedly until desired level is reached. To **decrease** volume (on one hearing aid only), use a short press on the lower part of the push button repeatedly until desired level is reached.

**B) How to change Tinnitus SoundSupport volume in both ears simultaneously**

You can use one hearing aid to increase/decrease the sound in both hearing aids. When changing the volume in one hearing aid, the volume on the other hearing aid will follow.

To **increase** volume, use a short press on the upper part of the push button repeatedly.

To **decrease** volume, use a short press on the lower part of the push button repeatedly.

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

# **Important information for hearing care professionals about Tinnitus SoundSupport**

## **Device description**

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

## **Maximum wearing time**

The wearing time of Tinnitus SoundSupport will decrease as you increase the level above 80 dB(A) SPL. The fitting software will automatically display a warning when the hearing aid exceeds 80 dB(A) SPL. See “Max wearing time indicator” next to the tinnitus fitting graph in the fitting software.

## **The volume control is deactivated**

By default, the volume control for the sound generator is deactivated in the hearing aid. Risk of noise exposure increases when the volume control is activated.

### **If the volume control is activated**

A warning may be displayed if you activate the tinnitus volume control in the “Buttons & Indicators” screen. This occurs if the relief sound can be listened to at levels that may cause hearing damage. The “Max wearing time” table in the fitting software displays the number of hours the patient can safely use Tinnitus SoundSupport.

- Note the max wearing time for each program for which Tinnitus SoundSupport is activated.
- Write those values in the table “Tinnitus SoundSupport: Limitation on use”, found in the back of this booklet.
- Instruct your patient accordingly.



## Warnings related to Tinnitus

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

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

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

As with any device, misuse of the sound generator feature could present some potentially harmful effects. Care should be taken to prevent the 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 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.

Please note that a hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Hearing aids is 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 and other small parts**

Hearing aids, their parts, and batteries should be kept out of reach of children and anyone who might swallow these items or otherwise cause injury to themselves.

Continues on next page

## **General warnings**

Batteries have occasionally been mistaken for pills. Therefore, check your medicine carefully before swallowing any pills.

Most hearing aids can be supplied with a tamper-resistant battery drawer upon request. This is strongly recommended for infants, small children, and people with intellectual and developmental disabilities.

Children younger than 36 months must always use a tamper-resistant battery drawer. Talk to your hearing care professional about the availability..

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

### **Dysfunction**

Be aware of the possibility that your hearing aid may stop working without notice. Keep this in mind when you depend on warning sounds (e.g. when you are in traffic). The hearing aids may stop functioning, for instance if the batteries have expired or if the tubing is blocked by moisture or earwax.

### **Active implants**

The hearing aid has been thoroughly tested and 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.

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

The Autophone magnet and 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.

### **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 the 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.

Continues on next page

## **General warnings**

### **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 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.*

### **Use on aircraft**

Your hearing aids have Bluetooth wireless technology. On board an aircraft, the hearing aid 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 use of hearing aids when connected to external equipment (with an auxiliary input cable and/or USB cable and/or directly), is determined by the external signal source. When the hearing aids are connected to external equipment which is plugged into a power socket, this equipment must comply with IEC 62368-1 or equivalent safety standards.

### **Use of third-party accessories**

Only use accessories, transducers or cables supplied by the manufacturer. Non-original accessories may result in reduced electromagnetic compatibility (EMC) of your device.

### **Modification of hearing aids is not allowed**

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

Continues on next page

## **General Warnings**



### **Interference**

The hearing aid has been thoroughly tested for interference according to 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 aid. If your hearing aid is affected by electromagnetic interference, move away from the source to reduce the interference.

### **Detached earpiece in ear canal**

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



# Troubleshooting

| Symptom                         | Possible causes                                                                                                                                                      |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No sound                        | Dead battery                                                                                                                                                         |
|                                 | Clogged earpieces (dome, Grip Tip, earmold or MicroMold)                                                                                                             |
|                                 | Hearing aid microphone muted                                                                                                                                         |
| Intermittent or reduced sound   | Clogged sound outlet                                                                                                                                                 |
|                                 | Moisture                                                                                                                                                             |
| Squealing noise                 | Hearing aid earpiece inserted incorrectly                                                                                                                            |
|                                 | Earwax accumulated in ear canal                                                                                                                                      |
|                                 | Ear has grown                                                                                                                                                        |
| Beeping/LED flashing (optional) | If your hearing aid plays 8 beeps, 4 times consecutively, and/or repeatedly flashes red 4 times with small pauses, your hearing aid needs a microphone service check |
| Pairing issue with Apple device | Bluetooth connection failed                                                                                                                                          |
|                                 | Only one hearing aid paired                                                                                                                                          |

## Solutions

Replace the battery

Clean earmold or MicroMold or replace wax filter

Consider to replace dome, or GripTip

Unmute the hearing aid microphone

Clean earmold or MicroMold, replace wax filter or change dome or GripTip

Wipe battery with a dry cloth

Re-insert the earpiece

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 (please visit [www.oticon.com/support](http://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
2. Open the battery drawer, remove the battery, and gently wipe off any water in the battery drawer
3. Let the hearing aid dry with the battery drawer left open for approximately 30 minutes
4. Insert a new battery

### 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

|                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Operating conditions</b>                  | Temperature: +1°C to +40°C (34°F to 104°F)<br>Humidity: 5 to 93% relative humidity, noncondensing<br>Atmospheric pressure: 700 hPa to 1060 hPa                                                                                                                                                                                                                                                                                                                                    |
| <b>Transportation and storage conditions</b> | Temperature and humidity shall not exceed the below limits for extended periods during transportation and storage:<br><br><b>Transportation:</b><br>Temperature: -25°C to + 60°C (-13°F to 140°F)<br>Humidity: 5 to 93% relative humidity, noncondensing<br>Atmospheric pressure: 700 hPa to 1060 hPa<br><br><b>Storage:</b><br>Temperature: -25°C to + 60°C (-13°F to 140°F)<br>Humidity: 5 to 93% relative humidity, noncondensing<br>Atmospheric pressure: 700 hPa to 1060 hPa |

## 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 contains a radio transceiver using short-range magnetic induction technology working at 3.84 MHz. The magnetic field strength of the transmitter is very weak and always below 15 nW [typically below  $-40 \text{ dB}\mu\text{A/m}$  at a distance of 10 meters ( $-12.20 \text{ dB}\mu\text{A/ft}$ ) at a distance of 33 feet].

The hearing aid also contains a radio transceiver using Bluetooth Low Energy technology and a proprietary short-range radio technology both working at ISM band 2.4 GHz.

The radio transmitter is weak and always below 3 mW equal to 4.8 dBm in total radiated power.

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 sheets" on [www.oticon.com](http://www.oticon.com)

This device contains a radio module with the following certification ID numbers: FCC ID: 2ACAH-AUBTEP

### **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

Continues on next page

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 company headquarters.

Oticon A/S  
Kongebakken 9  
DK-2765 Smørum  
Denmark  
[www.oticon.global/doc](http://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



SBO Hearing A/S  
Kongebakken 9  
DK-2765 Smørum  
Denmark



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

 **Bluetooth®**



**IP68**

## Description of symbols and abbreviations used in this booklet



### Warnings

Text marked with a warning symbol must be read before using the device.



### Manufacturer

The device is produced by the manufacturer whose name and address are stated next to the symbol. Indicates the medical device manufacturer, as defined in EU Regulation 2017/745.



### CE mark

The device complies with all required EU regulations and directives. The four digit number indicates the identification of the notified body.



### Electronic waste (WEEE)

Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal. Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).



### Regulatory Compliance Mark (RCM)

The device complies with electrical safety, EMC and radio spectrum requirements for devices supplied to the Australian or New Zealand market.

IP68

### IP code

Class of protection against harmful ingress of water and particulate matter according to EN 60529. IP6X indicates total dust protection. IPX8 indicates the protection against the effects of continuous immersion in water.



**Bluetooth**

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.

**GTIN**

### **Global Trade Item Number**

A globally unique 14-digit number used to identify medical device products including medical device software. GTIN in this booklet is related to medical device firmware. GTIN on regulatory packaging label is related to medical device hardware

## 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 hearing aid is covered by an international limited warranty issued by the manufacturer for a period of 12 months from the date of delivery to you. This limited warranty covers manufacturing and material defects in the hearing aid itself, but not in accessories such as batteries, tubing, speakers, earpieces and filters, etc. Problems 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 limited warranty and may void it.

Under this warranty, the manufacturer will choose, at its sole discretion, whether to repair the hearing aid, or replace it with an equivalent model. The above warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods. Your hearing care professional may have issued a warranty that goes beyond the clauses of this limited warranty. Consult him/her for further information.

**If you need service**

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

Your hearing care professional can assist you to obtain warranty service from the manufacturer. 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: \_\_\_\_\_

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.*

| Tinnitus SoundSupport: Limitation on use |                      |                            |                         |
|------------------------------------------|----------------------|----------------------------|-------------------------|
| <input type="checkbox"/>                 | No limitation on use |                            |                         |
|                                          | Program              | Start-up volume (Tinnitus) | Max volume (Tinnitus)   |
| <input type="checkbox"/>                 | 1                    | Max _____ hours per day    | Max _____ hours per day |
| <input type="checkbox"/>                 | 2                    | Max _____ hours per day    | Max _____ hours per day |
| <input type="checkbox"/>                 | 3                    | Max _____ hours per day    | Max _____ hours per day |
| <input type="checkbox"/>                 | 4                    | Max _____ hours per day    | Max _____ hours per day |

| Settings overview for your hearing aid |                              |                            |                              |                              |  |
|----------------------------------------|------------------------------|----------------------------|------------------------------|------------------------------|--|
| Left                                   |                              |                            | Right                        |                              |  |
| <input type="checkbox"/> Yes           | <input type="checkbox"/> No  | Change volume              | <input type="checkbox"/> Yes | <input type="checkbox"/> No  |  |
| <input type="checkbox"/> Yes           | <input type="checkbox"/> No  | Change program             | <input type="checkbox"/> Yes | <input type="checkbox"/> No  |  |
| <input type="checkbox"/> Yes           | <input type="checkbox"/> No  | Mute                       | <input type="checkbox"/> Yes | <input type="checkbox"/> No  |  |
| <input type="checkbox"/> Yes           | <input type="checkbox"/> No  | Tinnitus SoundSupport      | <input type="checkbox"/> Yes | <input type="checkbox"/> No  |  |
| Volume control indicators              |                              |                            |                              |                              |  |
| <input type="checkbox"/> On            | <input type="checkbox"/> Off | Beeps at min/max volume    | <input type="checkbox"/> On  | <input type="checkbox"/> Off |  |
| <input type="checkbox"/> On            | <input type="checkbox"/> Off | Beeps when changing volume | <input type="checkbox"/> On  | <input type="checkbox"/> Off |  |
| <input type="checkbox"/> On            | <input type="checkbox"/> Off | Beeps at start-up volume   | <input type="checkbox"/> On  | <input type="checkbox"/> Off |  |
| Battery indicators                     |                              |                            |                              |                              |  |
| <input type="checkbox"/> On            | <input type="checkbox"/> Off | Low battery warning        | <input type="checkbox"/> On  | <input type="checkbox"/> Off |  |

## 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 | <input type="checkbox"/> Sound | <input type="checkbox"/> LED <sup>1)</sup>                                        | When to use |
|---------|--------------------------------|-----------------------------------------------------------------------------------|-------------|
| 1       | 1 tone                         |  |             |
| 2       | 2 tones                        |  |             |
| 3       | 3 tones                        |  |             |
| 4       | 4 tones                        |  |             |

 Green flash

1) LED continuous or repeated three times with small pauses

| ON                     | Sound                            | LED                                                                                                                                                                                          | LED comments                       |
|------------------------|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| On                     | <input type="checkbox"/> Jingle  | <input type="checkbox"/>   | Shown one time                     |
| Volume                 | Sound                            | LED                                                                                                                                                                                          |                                    |
| Start-up volume        | <input type="checkbox"/> 2 beeps | <input type="checkbox"/>                                                                                    | Shown one time                     |
| Minimum/maximum volume | <input type="checkbox"/> 3 beeps | <input type="checkbox"/>                                                                                    |                                    |
| Volume up/down         | <input type="checkbox"/> 1 beep  | <input type="checkbox"/>                                                                                    |                                    |
| Mute                   |                                  | <input type="checkbox"/>   | Continuous or repeated three times |

 Long green flash
  Green flash
  Red flash

Continues on next page

| Accessories                            |  Sound |  LED                                                                                                                                                                 | LED comments                       |
|----------------------------------------|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| FM and wireless programs <sup>1)</sup> | 2 different tones                                                                       |                                                                                     | Continuous or repeated three times |
| FM and wireless programs <sup>2)</sup> | 2 different tones                                                                       |                                                                                     |                                    |
| <b>Flight mode</b>                     | <b>Sound</b>                                                                            |  LED                                                                                                                                                                 |                                    |
| Flight mode active                     | Short jingle                                                                            |    |                                    |
| Flight mode inactive                   | Short jingle                                                                            |   <sup>3)</sup>                                                                     |                                    |

 Long green flash    Green flash    Red flash

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

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   |

● Red flash    ■ Long red 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 best-practice 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.



# Technical Data

**BTE****85**

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

Supply voltage: Zinc Air 1.4 Volt

| 0 dB SPL ref. 20 $\mu$ Pa    |                  | Siya 1, Siya 2, Ruby 1, Ruby 2 |
|------------------------------|------------------|--------------------------------|
| OSPL90                       | Peak             | 120 (121*) dB SPL              |
|                              | HF Average       | 115 (105*) dB SPL              |
| Full-on Gain                 | Peak             | 57 (54*) dB                    |
|                              | HF Average       | 50 (41*) dB                    |
| Reference Test Gain          |                  | 39 dB                          |
| Frequency Range              |                  | 100-7000 Hz                    |
| Total Harmonic Distortion    | 500 Hz           | < 2 %                          |
|                              | 800 Hz           | < 2 %                          |
|                              | 1600 Hz          | < 2 %                          |
| Equivalent Input Noise Level | (omni/dir)       | 18/28 dB SPL                   |
| HF Average SPLITS            | (left/right ear) | 97/97 dB SPL                   |
| Attack Time                  |                  | < 5 ms                         |
| Release Time                 |                  | < 30 ms                        |

\*For instruments fitted with thin tube

**0 dB SPL ref. 20  $\mu$ Pa**

**Siya 1, Siya 2, Ruby 1, Ruby 2**

|                                        |                              |               |
|----------------------------------------|------------------------------|---------------|
| Battery Consumption*                   | Typical                      | 1.7 mA        |
|                                        | Quiescent                    | 1.7 mA        |
| Expected battery life (bat. size 13)** | Hours                        | 105 - 115 hrs |
| Latency                                |                              | 8.2 ms        |
| Maximum Induction Coil Sensitivity     | Measured output at 1 mA/m    | 77 dB SPL     |
|                                        | Measured output at 10 mA/m   | 97 dB SPL     |
|                                        | Measured output at 31.6 mA/m | 107 dB SPL    |

\*Battery current is measured according to IEC 60118-0:1983/AMD1:1994 §7.11, IEC 60118-0:2015 §7.7 and ANSI S3.22:2014 §6.13 after a settling time of minimum 3 minutes.

\*\*Real usage battery life is shown as an estimated interval based on mixed use cases with variable amplification settings and variable input levels, incl. direct stereo streaming from a TV (25% of the time) and streaming from a mobile phone (6% of the time).

# Technical Data

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

Supply voltage: Battery Zinc Air 1.4 Volt

| 0 dB SPL ref.<br>20 µPa         |                  | Oticon<br>Opn 1, Opn S 1,<br>Opn Play 1 | Oticon<br>Opn 2, Opn S 2,<br>Siya 1, Ruby 1 | Oticon<br>Opn 3, Opn S 3,<br>Opn Play 2, Siya<br>2, Ruby 2 |
|---------------------------------|------------------|-----------------------------------------|---------------------------------------------|------------------------------------------------------------|
| OSPL90                          | Peak             | 131 (129*) dB SPL                       | 131 (129*) dB SPL                           | 131 (129*) dB SPL                                          |
|                                 | HF Average       | 126 (118*) dB SPL                       | 126 (118*) dB SPL                           | 126 (118*) dB SPL                                          |
| Full-on Gain                    | Peak             | 66 (66*) dB                             | 66 (66*) dB                                 | 66 (66*) dB                                                |
|                                 | HF Average       | 61 (54*) dB                             | 61 (54*) dB                                 | 61 (54*) dB                                                |
| Reference Test Gain             |                  | 50 dB                                   | 50 dB                                       | 50 dB                                                      |
| Frequency Range                 |                  | 120-7000 Hz                             | 120-7000 Hz                                 | 120-7000 Hz                                                |
| Total Harmonic<br>Distortion    | 500 Hz           | 3 %                                     | 3 %                                         | 3 %                                                        |
|                                 | 800 Hz           | < 2 %                                   | < 2 %                                       | < 2 %                                                      |
|                                 | 1600 Hz          | < 2 %                                   | < 2 %                                       | < 2 %                                                      |
| Equivalent Input Noise<br>Level | (omni/dir)       | 14/27 dB SPL                            | 14/27 dB SPL                                | 14/27 dB SPL                                               |
| HF Average SPLITS               | (left/right ear) | 109/109 dB SPL                          | 109/109 dB SPL                              | 109/109 dB SPL                                             |
| Attack Time                     |                  | < 5 ms                                  | < 5 ms                                      | < 5 ms                                                     |
| Release Time                    |                  | < 50 ms                                 | < 50 ms                                     | < 50 ms                                                    |

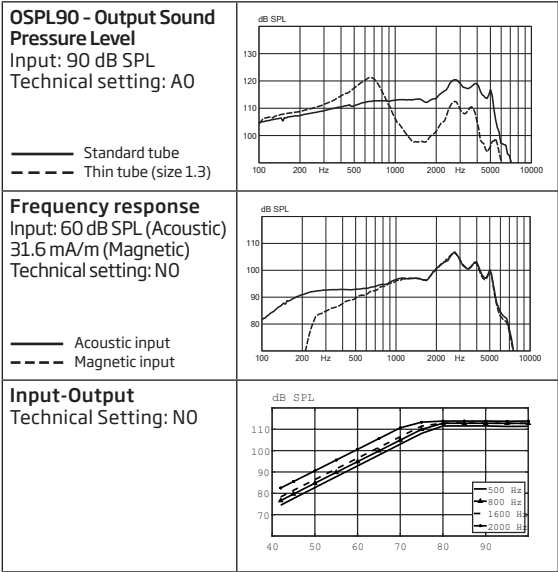
\*For instruments fitted with thin tube

| 0 dB SPL ref. 20 µPa                   |                              | <b>Oticon</b><br><b>Opn 1, 2, 3, Opn S 1, 2, 3</b><br><b>Opn Play 1, 2, Siya 1, 2, Ruby 1, 2</b> |
|----------------------------------------|------------------------------|--------------------------------------------------------------------------------------------------|
| Battery Consumption*                   | Typical                      | 1.9 mA                                                                                           |
|                                        | Quiescent                    | 1.6 mA                                                                                           |
| Expected battery life (bat. size 13)** | Hours                        | 80-105 hrs                                                                                       |
| Latency                                |                              | 8.3 ms                                                                                           |
| Maximum Induction Coil Sensitivity     | Measured output at 1 mA/m    | 91 dB SPL                                                                                        |
|                                        | Measured output at 10 mA/m   | 111 dB SPL                                                                                       |
|                                        | Measured output at 31.6 mA/m | 121 dB SPL                                                                                       |

\*Battery current is measured according to IEC 60118-0:1983/AMD1:1994 §7.11, IEC 60118-0:2015 §7.7 and ANSI S3.22:2014 §6.13 after a settling time of minimum 3 minutes.

\*\*Real usage battery life is shown as an estimated interval based on mixed use cases with variable amplification settings and variable input levels, incl. direct stereo streaming from a TV (25% of the time) and streaming from a mobile phone (6% of the time).

Oticon  
Siya 1, Siya 2, Ruby 1, Ruby 2



# Technical Data

**BTE PP** 105

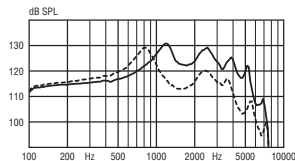
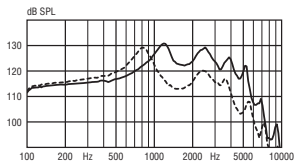
## Oticon Opn 1, Opn S 1 & Opn Play 1

## Oticon Opn 2, Opn 3, Opn S 2, Opn S 3, Opn Play 2, Siya 1, Siya 2, Ruby 1, Ruby 2

### OSPL90 - Output Sound Pressure Level

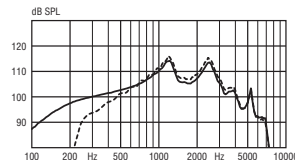
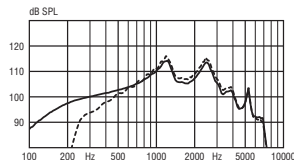
Input: 90 dB SPL  
Technical setting: A0

— Standard tube  
- - - Thin tube (size 1.3)

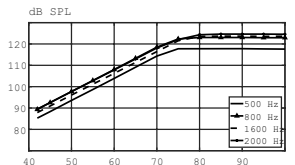
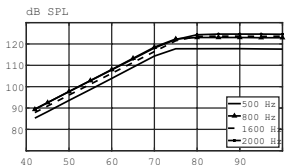


### Frequency response Input: 60 dB SPL (Acoustic) 31.6 mA/m (Magnetic) Technical setting: NO

— Acoustic input  
- - - Magnetic input



### Input-Output Technical Setting: NO





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