# Instructions for use



# miniBTE R miniBTE T

Oticon More™ Oticon Zircon Oticon Play PX









# 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 d8 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 a piece gets stuck in your ear.

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

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

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

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



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

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

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

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

# Note: Hearing loss in people younger than 18

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

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

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

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

## **Model overview**

This booklet is valid for the Oticon Oticon Play PX families in the follow	
<ul><li>□ miniBTE R</li><li>□ miniBTE T</li></ul>	
FW 1.4.0	
☐ Oticon More 1 miniBTE R	GTIN: (01) 05714464060627
☐ Oticon More 2 miniBTE R	GTIN: (01) 05714464060634
☐ Oticon More 3 miniBTE R	GTIN: (01) 05714464060641
☐ Oticon More 1 miniBTE T	GTIN: (01) 05714464060627
☐ Oticon More 2 miniBTE T	GTIN: (01) 05714464060634
☐ Oticon More 3 miniBTE T	GTIN: (01) 05714464060641

FW 1.2.0	
☐ Oticon Zircon 1 miniBTE R	GTIN: (01) 05714464060436
☐ Oticon Zircon 2 miniBTE R	GTIN: (01) 05714464060429
☐ Oticon Zircon 1 miniBTE T	GTIN: (01) 05714464060436
☐ Oticon Zircon 2 miniBTE T	GTIN: (01) 05714464060429
☐ Oticon Play PX 1 miniBTE R	GTIN: (01) 05714464060405
☐ Oticon Play PX 2 miniBTE R	GTIN: (01) 05714464060412
☐ Oticon Play PX 1 miniBTE T	GTIN: (01) 05714464060405
☐ Oticon Play PX 2 miniBTE T	GTIN: (01) 05714464060412

## **Model overview**

This booklet is valid for the Oticon More <sup>†</sup> PX families in the following hearing aid r	
□ miniBTER □ miniBTET	
FW 1.3.0	
☐ Oticon More 1 miniBTE R	GTIN: 05714464042685
☐ Oticon More 2 miniBTE R	GTIN: 05714464042678
□ Oticon More 3 miniBTE R	GTIN: 05714464042661
☐ Oticon More 1 miniBTE T	GTIN: 05714464042685
☐ Oticon More 2 miniBTE T	GTIN: 05714464042678
□ Oticon More 3 miniBTE T	GTIN: 05714464042661

FW 1.1.0  ☐ Oticon Zircon 1 miniBTE R ☐ Oticon Zircon 2 miniBTE R	GTIN: 05714464042890 GTIN: 05714464042906
<ul><li>□ Oticon Zircon 1 miniBTE T</li><li>□ Oticon Zircon 2 miniBTE T</li></ul>	GTIN: 05714464042890 GTIN: 05714464042906
<ul><li>□ Oticon Play PX 1 miniBTE R</li><li>□ Oticon Play PX 2 miniBTE R</li></ul>	GTIN: 05714464042920 GTIN: 05714464042913
<ul><li>☐ Oticon Play PX 1 miniBTE T</li><li>☐ Oticon Play PX 2 miniBTE T</li></ul>	GTIN: 05714464042920 GTIN: 05714464042913

#### Introduction to this booklet

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

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.

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

## Intended use

Oticon Play PX 1, 2 miniBTE R Oticon Play PX 1, 2 miniBTE T

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Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	Bilateral or unilateral impaired hearing of sensorineural, conductive or mixed type ranging from a slight (16 dB HL*) to severe (75 dB HL*) degree of hearing loss, with an individual frequency configuration.
Intended user	Person with hearing loss using a hearing aid and their caregivers. Hearing care professional responsible for adjusting the hearing aid.
Intended user group	Infants, children and adults.
Use environment	Indoor and outdoor
Contraindications	Users of active implants must pay special attention when using the hearing aid. For more information read the <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.

#### Intended use

Oticon More 1, 2, 3 miniBTE R / miniBTE T Oticon Zircon 1, 2 miniBTE R / miniBTE T

Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	Bilateral or unilateral impaired hearing of sensorineural, conductive or mixed type ranging from a slight (16 dB HL*) to severe (75 dB HL*) degree of hearing loss, with an individual frequency configuration.
Intended user	Person with hearing loss using a hearing aid and their caregivers. Hearing care professional responsible for adjusting the hearing aid.
Intended user group	Adults and children older than 36 months.
Use environment	Indoor and outdoor
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.

<sup>\*</sup> 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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# Warnings More info

**General Warnings** 

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Warranty

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Your individual hearing aid settings

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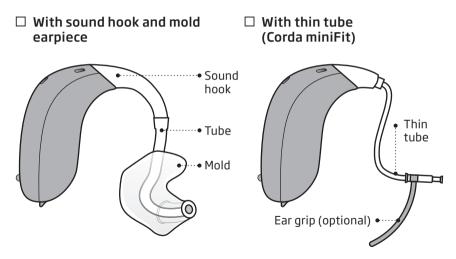
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# Your hearing aid and earpiece

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



#### The thin tube uses one of the following earpieces:

#### Standard earpieces



□ OpenBass dome



☐ Bass dome, double vent



☐ Power dome



☐ Grip Tip

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

#### **Customized earpieces**



☐ Corda miniFit Mold



☐ VarioTherm® Corda miniFit Mold

® VarioTherm is a registered trademark of Dreve









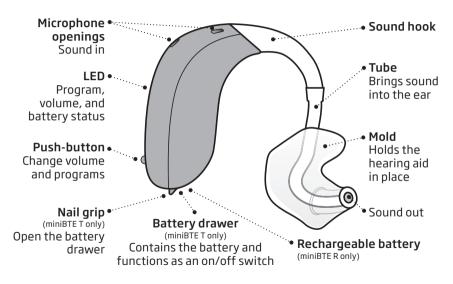




Please see details for replacing the dome in chapter "Replace standard earpieces".

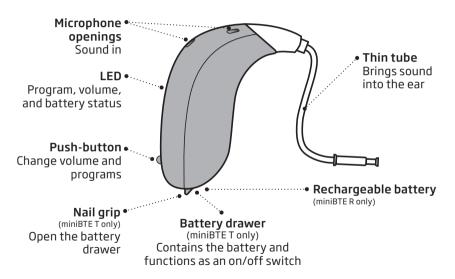
#### With sound hook and mold

#### What it is and does



#### With thin tube

#### What it is and does



# Charging time

(miniBTE R only)

Ensure you fully charge your hearing aids before first use and charge them every night. That ensures you start your day with fully charged hearing aids.

If your hearing aid's battery is completely drained, the normal charging time is:

3.5 hours	1 hour	0.5 hour
Fully charged	40% charged	20% charged

When the battery is fully charged, the charging process stops automatically.

Charging time may vary depending on the remaining capacity of the battery and between the left/right hearing aid.

For instructions on how to use your charger, see the charger's instructions for use.

# **Battery performance**

Battery performance varies depending on your individual use and hearing aid settings. Streaming sound from a TV, mobile phone or connectivity devices can influence this performance.

#### Rechargeable battery – miniBTE R only

If your rechargeable hearing aids do not perform for a full day, contact your hearing care professional.

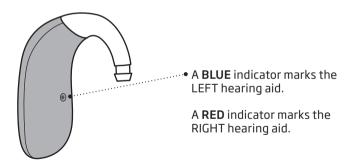
If your hearing aids run out of battery, ensure you recharge them by placing them in the charger. Be aware that restarting the hearing aids does not give you more usage time.

# Identify left and right hearing aids

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

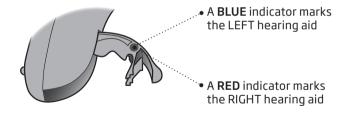
#### miniBTE R only

You can find left/right color indicators on the hearing aid itself. Indicators can also be found on Corda miniFit Mold and molds (optional).



#### miniBTE T only

You can find left/right color indicators in the battery drawer. Indicators can also be found on Corda miniFit Mold and molds (optional).



# Turn hearing aids ON/OFF

Using the charger - miniBTE R only

Your hearing aids automatically turn ON when removed from the charger.

The hearing aid LED light turns **GREEN** after a few seconds. Wait until the hearing aid LED light blinks **GREEN** twice, confirming that it is ready for use. Depending on your hearing aid settings, you may also hear a start-up jingle.

Your hearing aids automatically turn OFF and start charging when placed in the charger. The hearing aid LED light turns **ORANGE**.

#### IMPORTANT NOTICE

If applicable, ensure that your charger is powered or that the charger's built-in battery is charged when the hearing aid is seated in the charging port. For more information, see your charger's instructions for use.

#### Using the push-button - miniBTE R only

Your hearing aids can be turned ON/OFF using the push-button.



#### To turn ON

Press and hold the push-button for approximately two seconds until the hearing aid LED light turns **GREEN**. Release the push-button and wait until the hearing aid LED light blinks **GREEN** twice.

The hearing aid is now turned ON.

#### To turn OFF

Press and hold the push-button for approximately three seconds until the hearing aid LED light turns **ORANGE**. The hearing aid plays four descending tones. Release the push-button and the hearing aid is turned OFF.

For information regarding tones, see the **Sound and LED light indicators** section.

#### Using the battery drawer - miniBTE T only

The battery drawer is 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).

### LED light

Three green blinks 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



# Low battery indication

Just before the battery runs out completely, you will hear four descending tones. To extend battery performance, ensure you stop any audio streaming.

miniBTE R: When the battery is running low, you will hear three alternate beeps. This gives you approximately two hours before the hearing aid runs out of battery. At this point, you may continue to stream audio for approximately one hour.

miniBTE T: When the battery is running low, you will hear three alternate beeps. This gives you approximately 15 minutes before the hearing aid runs out of battery. At this point, Bluetooth® connectivity is turned OFF.



Four descending tones
= The battery has run out.

#### **LED light**

Continuous **ORANGE** blinks indicate low battery.

# **How to replace the battery** (size 312)

(miniBTE T only)

#### 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.

# Put on the hearing aid with sound hook

Read the following page if you have a hearing aid with a sound hook and mold.



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

#### Step 1



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

#### Step 2



Place the hearing aid behind your ear.

# Put on hearing aid with thin tube

Read the following page 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 earpiece. 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.

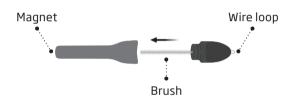
#### Step 3



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.

# Cleaning

The MultiTool contains a brush and wire loop for cleaning and removing earwax. If you need a new MultiTool, please contact your hearing care professional.



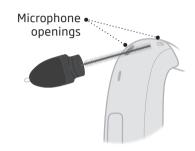
#### IMPORTANT NOTICE

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

# Clean the hearing aid

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

Clean the microphone openings
Use 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.

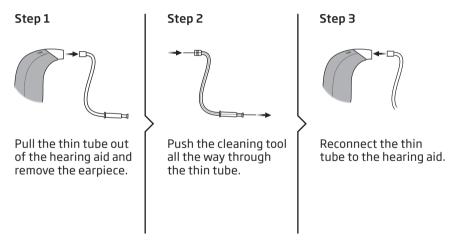


#### IMPORTANT NOTICE

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

#### Clean the thin tube

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

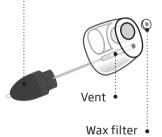


## Clean customized earpieces

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.

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



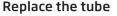
#### IMPORTANT NOTICE

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

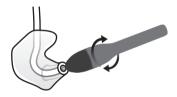
<sup>\*</sup> VarioTherm Corda miniFit Mold does not have a wax filter

## Care for the mold

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



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



#### Wash the mold

## Step 1



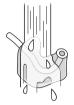
Make sure you are able to identify which mold is for which hearing aid before disconnecting them from the hearing aid.

## Step 2



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

## Step 3

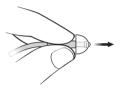


Wash the mold and tube using mild soap. Rinse and dry completely before reconnecting to the hearing aid.

## Replace standard earpieces

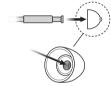
The standard earpiece (dome or Grip Tip) should not be cleaned. If the earpiece is filled with wax, replace it with a new one. Grip Tips should be replaced at least once a month.





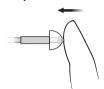
Hold on to the end of the thin tube and then pull off the earpiece.

Step 2



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

Step 3



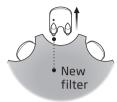
Push firmly to ensure that the earpiece is fastened securely.

#### 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.

## **Replace ProWax filter**

#### 1. Tool



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

#### 2. Remove



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

## 3. Insert



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

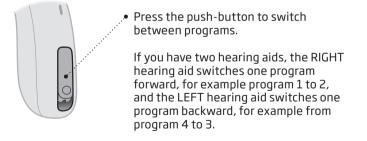
#### IMPORTANT NOTICE

Ensure you always use the same type of wax filter as originally supplied with the hearing aid. If you are in doubt about the use or replacement of wax filters, contact your hearing care professional.

## **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 indicators** section.



## Change volume

The push-button allows you to adjust the volume. When you increase or decrease the volume, you will hear a click.



## Store your hearing aids

(miniBTE R only)

When you are not using your hearing aids, the charger is the best place to keep them.

To ensure the longest life of the rechargeable battery in your hearing aids, do not expose them to excessive heat. For example, do not leave your hearing aids in the sun in front of a window or in a car, even if they are in the charger.

## Long-term storage

Before you put away or store your hearing aids for a prolonged period of time (more than 14 days), ensure you first fully charge them, and then turn them OFF. This way the battery can be charged again.

#### IMPORTANT NOTICE

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

#### Note

To protect the rechargeable battery, it is necessary that you fully charge the hearing aid every six months. If a stored hearing aid is not charged within a six month period, the rechargeable battery must be replaced.

## Flight mode

When Flight mode is activated, Bluetooth® connectivity is turned OFF. However, your hearing aids are still turned ON and functioning. Be aware that pressing the push-button on one hearing aid, activates Flight mode on both hearing aids.

For more information about sounds and lights, see the **Sound and LED light indicators** section.

## LED light

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



## . To activate and deactivate

Press the push-button for at least seven seconds. A jingle confirms your action.

Opening and closing the battery drawer will also deactivate Flight mode. (miniBTE T only)

## Mute your hearing aids

In both miniBTE T and miniBTE R you can mute your hearing aids by using one of the following optional devices/app:

- Oticon ON
- ConnectClip
- Remote Control 3.0

## How to unmute your hearing aids

You can unmute your hearing aids by using one of the optional devices/app or by applying a short press to the push-button on the hearing aids.

## miniBTE T only

You can also mute your hearing aids by pressing the push-button for four seconds.

#### IMPORTANT NOTICE

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

## Use your hearing aids with iPhone®, iPad® and iPod®

Oticon More, Zircon and Play PX are Made for iPhone® hearing aids and allow for direct streaming from your iPhone, iPad or iPod touch.\*

Oticon ON can be used to control your hearing aids from your mobile device.\*

Additionally, Oticon More, Zircon and Play PX offer hands-free communication with compatible iPhone and iPad devices.\*

For assistance in using your hearing aids with any of these products, contact your hearing care professional.

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

<sup>\*</sup>For a list of compatible iPhone, iPad, iPod touch and Android devices, visit: www.oticon.com/support/compatibility

## Use your hearing aids with Android™ devices

Oticon More, Zircon and Play PX support Audio Streaming for Hearing Aids (ASHA) and allow for direct streaming from selected Android devices.\*

Oticon ON can be used to control your hearing aids from your mobile device.\*

For assistance in using your hearing aids with Android devices, contact your hearing care professional.

## Pairing and compatibility

For instructions on how to pair your hearing aids with iPhone, iPad, iPod touch or Android devices, visit:

www.oticon.com/support

For a list of compatible iPhone, iPad, iPod touch and Android devices, visit:

www.oticon.com/support/compatibility

## **Call handling**

You can answer, reject or end phone calls with the push-button on your hearing aids. For this functionality, your hearing aids must be paired with a compatible iPhone\*.



## To accept

Use a short press on the push-button to accept a phone call. A short tone confirms your action.

## To reject

Press and hold on the push-button to reject a phone call. Short, descending tones confirm your action.

#### To end

Press and hold on the push-button to end a phone call. Short, descending tones confirm your action.

<sup>\*</sup>For a list of compatible iPhones, visit: www.oticon.com/support/compatibility

## Wireless accessories and other options

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

## ConnectClip

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

## Phone Adapter 2.0

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

## TV Adapter 3.0

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

## Remote Control 3.0

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

#### **EduMic**

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

## 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 the app from the official app stores.

#### Telecoil

Telecoil can help you hear better when using a phone with a built-in loop or when in buildings with teleloop systems such as theaters, places of worship, or lecture rooms.

This symbol is shown wherever a teleloop has been installed.

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.

## Tamper-resistant battery drawer

(miniBTE T only)

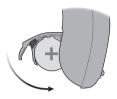
To keep the battery out of reach of infants, small children, and people with learning difficulties, a tamper-resistant battery drawer should be used.

#### IMPORTANT NOTICE

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

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

# Lock the battery drawer



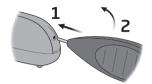
Close the battery door completely and make sure it is locked.

# Tool to unlock the battery drawer



Use this small tool provided by your hearing care professional.

# Unlock the battery drawer



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

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

## **Tinnitus SoundSupport**™ (optional)

## Intended use of Tinnitus SoundSupport

Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief for patients suffering from tinnitus as part of a tinnitus management program.

The target population is the adult population (over 18 years old).

Tinnitus SoundSupport is targeted to licensed hearing care professionals (audiologists, hearing aid specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing loss. Fitting of Tinnitus SoundSupport must be done by a hearing care professional participating in a tinnitus management program.

## **Guidelines for Tinnitus SoundSupport users**

These instructions contain information about Tinnitus SoundSupport, which may have been enabled in your hearing aids by your hearing care professional.

Tinnitus SoundSupport is a tinnitus management device intended to generate sound of sufficient intensity and bandwidth to help manage tinnitus.

Your hearing care professional will also be able to offer the appropriate follow-up care. It is important to follow his/her advice and directions regarding such care.

## Prescription use only

Good health practice requires that a person reporting tinnitus have a medical evaluation by a licensed ear physician before using a sound generator. The purpose of such an evaluation is to ensure that any medically treatable condition that may cause tinnitus is identified and treated prior to using a sound generator.

## Sound options and volume adjustment

Tinnitus SoundSupport is programmed by your hearing care professional to match your hearing loss and preferences for tinnitus relief. It offers a number of different sound options. Together with your hearing care professional, you can select your preferred sound(s).

## Tinnitus SoundSupport programs

Together with your hearing care professional you decide for which programs you may want to have Tinnitus SoundSupport activated. The sound generator can be activated in up to four different programs.

#### Mute

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

## Volume adjustments with Tinnitus SoundSupport

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

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

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

For more information about volume adjustments with Tinnitus SoundSupport, see the table **Tinnitus SoundSupport settings overview for your hearing aid** in the **Your individual hearing aid settings** section at the end of this booklet.

## 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 the hearing care professional.

## Maximum wearing time

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

#### The volume control is deactivated

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

## If the volume control is activated

A warning may be displayed if you activate the tinnitus volume control in the **Buttons & Indicators** screen. This occurs if the relief sound can be listened to at levels that may cause hearing damage.

The **Max wearing time** table in the fitting software displays the number of hours the patient can safely use Tinnitus SoundSupport.

- 1. Note the max wearing time for each program for which Tinnitus SoundSupport is activated.
- 2. Write those values in the table **Tinnitus SoundSupport: Limitation on use**, in the back of this booklet.
- 3. 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 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 aids during use or because of its use. Your hearing care professional will support you with issue handling and, if relevant, reporting to the manufacturer and/or the national authorities.

Note that hearing aids do not restore normal hearing and do not prevent or improve a hearing impairment resulting from organic conditions. Hearing aids are only a part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading. Furthermore, note that in most cases, infrequent use of hearing aids does not permit a user to attain full benefit from it.

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

## Usage of hearing aids

Hearing aids should only be used as directed and adjusted by your hearing care professional. Misuse can result in sudden and permanent hearing loss.

Never allow others to wear your hearing aid, as incorrect usage could cause permanent damage to their hearing.

# Choking hazards and risk of swallowing batteries and other small parts

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

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

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.

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

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

Talk to your hearing care professional about the availability.

## Battery use (miniBTE T only)

Always use batteries recommended by your hearing care professional. Batteries of low quality may leak and cause bodily harm.

Never attempt to recharge your batteries

and never dispose of batteries by burning them. There is a risk that the batteries will explode.

## Explosives (miniBTE R only)

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

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

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

Never swallow lithium-ion batteries nor place them in the ear or the nose, as this may lead to serious injury or death in as

## **⚠** General Warnings

little as two hours. This can be due to chemical burns, which can permanently damage the nose or ear or potentially lead to perforation of the inner organs. If a lithium-ion battery is swallowed or placed in the ear or nose, seek emergency medical treatment immediately. Keep the batteries in the original packaging until use. Dispose of used batteries immediately.

Rechargeable battery (miniBTE R only)

Do not attempt to open the hearing aid, as it may damage the battery. Never attempt to replace the battery. If battery replacement is needed, please return your device to your hearing care professional. The service guarantee is void if there are signs of tampering.

In case of battery leakage do not wear your hearing aid, as it may cause skin irritation due to acids coming from the leaking battery. If your skin has been in contact with the leaked battery acids, use

a wet cloth to wipe it off and ensure no acid is left on your skin. If you experience skin irritation, consult your doctor. For further handling instructions of your hearing instrument consult your hearing care professional. The safety of recharging batteries using a USB connector is determined by the external signal source. When connected to external equipment plugged into a power socket, this equipment must comply with IEC 62368-1 or equivalent safety standards.

#### Dysfunction

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

#### **Active implants**

The hearing aid has been thoroughly tested and 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, 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 30centimeters (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 centimeters (0.4 inches) distance from your hearing aid. The magnetic field from CI sound processors, coils and magnets may permanently damage the speaker unit in your hearing aid. Never place the devices close together on a table e.g. when cleaning or changing batteries. Do not carry the CI and the hearing aid together in the same box.

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.

#### 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 aids must be put into Flight mode to deactivate Bluetooth, unless Bluetooth is permitted by the flight personnel.

## Connection to external equipment

The safety of the hearing aids, when connected to external equipment (with an auxiliary input cable and/or USB cable and/or directly), is determined by the external signal source. When the hearing aids are connected to external equipment

which is plugged into a power socket, this equipment must comply with IEC 62368-1 or equivalent safety standards.

## Use of third-party accessories

Only use accessories, transducers, or cables supplied by the manufacturer. Nonoriginal 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.

## $(((\bullet)))$ 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 to the left. Portable and mobile RF (radio frequency) communications equipment can affect the performance of your hearing aids. If your hearing aids are affected by electromagnetic interference, move away from the source to reduce the interference.

## 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
	Hearing aid is out of power
	Dead battery
No sound	Clogged earpieces (dome, Grip Tip, mold or Corda miniFit Mold)
	Hearing aid microphone muted
Intermittent or	Clogged sound outlet
reduced sound	Moisture
	Hearing aid earpiece inserted incorrectly
Squealing noise	Earwax accumulated in ear canal
	Ear has grown
Beeping	If your hearing aid plays 8 beeps, 4 times consecutively, your hearing aid needs a microphone service check
	Bluetooth connection failed
Pairing issue with smartphone	Only one hearing aid paired

Solutions
Charge the hearing aid (miniBTE R only) / Replace the battery (miniBTE T only)
Contact your hearing care professional (miniBTE R only) / Replace the battery (miniBTE T only)
Clean mold or Corda miniFit Mold or replace wax filter
Replace dome, or GripTip
Unmute the hearing aid microphone
Clean mold or Corda miniFit Mold, replace wax filter or change dome or GripTip
Wipe battery with a dry cloth (miniBTE T only)
Re-insert the earpiece
Have ear canal examined by your doctor
Contact your hearing care professional
Contact your hearing care professional
<ol> <li>Unpair your hearing aid.</li> <li>On your phone, turn Bluetooth OFF and ON again.</li> <li>Open and close battery drawer on hearing aid (miniBTE T only) or Turn the hearing aid OFF and then turn it back ON (miniBTE R only)</li> <li>Pair your hearing aid again (For guidance, visit: www.oticon.com/support)</li> </ol>

If none of the above solutions work, consult your hearing care professional.

## **Troubleshooting**

miniBTE R only – To troubleshoot the charger, see your charger's instructions for use.

Symptom	Possible causes
	The charger is not turned ON
The hearing aid LED light remains turned OFF when	The hearing aid or charger's temperature is either too warm or too cold
the hearing aid is placed in the charger	Charging is incomplete. The charger has stopped charging to protect the battery.
	The hearing aid is incorrectly seated in the charger
The hearing aid LED light blinks GREEN when the hearing aid is placed in the charger	Hearing aid has not been in use for a prolonged period of time
The hearing aid LED light blinks ORANGE when the hearing aid is placed in the charger	System error

Solutions
Verify that the charger's power plug is correctly connected or the power bank has enough battery
Move the charger and hearing aid to a location with a temperature between +5°C and +40°C (+41°F and +104°F)
Reinsert the hearing aid into the charger. This completes the charging within approximately 15 minutes.
Check the charging ports for foreign objects
Depending on how depleted the battery in the hearing aid is, the hearing aid automatically resumes normal charging mode after a timeframe of up to 10 minutes. Ensure you leave the hearing aids in the charger during this process.
Contact your hearing care professional

#### Note

# **Find Product Information**

Information about your hearing aids, including the serial number, CE label and production date is located behind the push-button on your hearing aids. To open the push-button you need to use either the MultiTool that came with your hearing aids or another suitably pointed tool.

### Insert tool



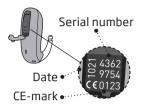
Insert tool into hole at the bottom of the push-button.

# Open push-button



Press the tool into the hole and pull back to open the button door. Ensure you hold the MultiTool as illustrated to avoid damaging it.

### Read information



Hold the instrument upside down to read the information.

# Close push-button



Push the button back into place. You will hear a click when the push-button is closed correctly.

#### IMPORTANT NOTICE

Your hearing care professional can also provide you with the serial number marked on your hearing aids. Use an appropriate tool to open the push-button to avoid damaging your hearing aids.

# **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 an individual hearing aid 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".

# Water and dust resistant (IP68)

Your hearing aid is dust tight and protected against ingress of water, which means it is designed to be worn in all daily life situations. Therefore, you do not have to worry about sweat or getting wet in the rain.

# miniBTE T only

Should your hearing aid come into contact with water and stop working, please follow these guidelines:

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

#### IMPORTANT NOTICE

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

# **Conditions of use**

(miniBTE T only)

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

# **Conditions of use**

(miniBTE R only)

Operating conditions	Temperature: +5°C to +40°C (41°F to 104°F) Humidity: 5% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Charging conditions	Temperature: +5°C to +40°C (41°F to 104°F) Humidity: 5% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Transportation and storage conditions	Temperature and humidity shall not exceed the below limits for extended periods during transportation and storage:  Transportation: Temperature: -20°C to +60°C (-4°F to 140°F) Humidity: 5% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa Storage: Temperature: -20°C to +30°C (-4°F to 86°F) Humidity: 5% to 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

#### Note

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

# **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 technology and a proprietary, short-range radio technology both operating at ISM band 2.4 GHz.

The radio transmitter is weak and always below 9 mW equal to 9.6 dBm in total radiated power.

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

The hearing aids comply with international standards concerning radio transmitters, electromagnetic compatibility, and human exposure.

Due to the limited space available on the hearing aid, relevant approval markings can be found in this booklet.

Additional information can be found in the **Technical Data Sheet** on www.oticon.com

#### miniBTE R only

This device contains a radio module with the following certification ID number: FCC ID: 2ACAHAU5MBTEMR

### miniBTE T only

This device contains a radio module with the following certification ID number:FCC ID: 2ACAHAU5MBTEM

# 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-loacated 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 quarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

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

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

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

Declaration of Conformity is available at the headquarters.

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

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

**CE** 0123





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



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



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



#### CF mark

 $\mathbf{C} \, \mathbf{C} \, \mathbf{0} \, \mathbf{1} \, \mathbf{2} \mathbf{3}$  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.





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 logo

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

### Description of symbols and abbreviations used in this booklet

### Made for Apple badges

The device is compatible with iPhone, iPad and iPod touch.

## Android badge

Indicates that the device is compatible with Android.



android 🛎

### **Hearing loop**

This logo incorporates the universal symbol for hearing assistance. The "T" signifies that a hearing loop is installed.



#### Radio Frequency (RF) transmitter

Your hearing aid contains an RF transmitter.

#### **Global Trade Item Number**

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.

### FW

FW

Firmware version used in the device

## Description of additional symbols used on labels



#### Keep dry

Indicates a medical device that needs to be protected from moisture.



#### 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.



### **Battery recycling symbol**

Li-ion battery recycling symbol.



#### **Temperature limit**

Indicates the temperature limits to which the medical device can be safely exposed.



#### **Humidity limitation**

Indicates the range of humidity to which the medical device can be safely exposed.



# Radio Frequency Identification

Indicates the presence of a passive radio-frequency identification tag incorporated into the device for manufacturing and service purposes.



#### Unique device identifier

Indicates a carrier that contains unique device identifier information.

# International warranty

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

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

#### If you need service

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

# Warranty

# Certificate

lame of owner:			
Hearing care professional:			
Hearing care professional's address:			
Hearing care professional's phone: _	earing 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					
No limitation on use					
Program	Start-up volume (Tinnitus)	Max volume (Tinnitus)			
1	Max hours per day	Max hours per day			
2	Max hours per day	Max hours per day			
☐ 3 Max hours per day		Max hours per day			
4	Max hours per day	Max hours per day			

Tinnitus SoundSupport settings overview for your hearing aid				
Left		Rig	ıht	
☐ Yes	□No	Tinnitus SoundSupport	☐ Yes	□No

☐ 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 the 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 one hearing aid only), continue to press the pushbutton repeatedly until the desired level is reached.

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

You can use one hearing aid to **increase** the volume and the other hearing aid to **decrease** the volume.

To **increase** the volume, use a short press on the push-button repeatedly on the RIGHT hearing aid.

To **decrease** the volume, use a short press on the push-button repeatedly on the LEFT hearing aid.

To be filled out by your hearing care professional.

General settings overview for your hearing aid						
Le	ft		Rig	jht		
☐ Yes	□No	Change volume	☐ Yes	□No		
☐ Yes	□No	Change program	☐ Yes	□No		
☐ Yes	□No	Mute (miniBTET only)	☐ Yes	□No		
	Volume control indicators					
□ On □ Off Beeps at min/max volume		Beeps at min/max volume	☐ On	☐ Off		
☐ On ☐ Off Beeps when changing vol		Beeps when changing volume	☐ On	☐ Off		
□ On □ Off		Beeps at start-up volume	☐ On	☐ Off		
		Battery indicators				
☐ On	□ On □ Off Low battery warning		☐ On	☐ Off		

# Sound and LED light indicators

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

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

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

Short GREEN blink

<sup>\*</sup>LED continuous or repeated three times with small pauses

ON/OFF	Sound	LED light	LED light comments	
ON	☐ Jingle			
OFF (miniBTE R only)	4 descending tones			
Volume	Sound	LED light	<b>.</b>	
Start-up volume	☐ 2 beeps		Shown once	
Minimum/maximum volume	☐ 3 beeps			
Volume up/down	☐ 1 beep			
Mute			Continuous or repeated three times	
Long CREEN blink Short CREEN blink I ong ORANGE blink Short ORANGE blink				

Accessories	Sound	LED	LED comments
Wireless programs <sup>1)</sup>	2 different tones		
Wireless programs <sup>2)</sup>	2 different tones		
Flight mode	Sound	LED	Continuous or repeated three times
Flight mode active	Short jingle	$\bigcirc \bullet \bullet$	
Flight mode inactive	Short jingle	3)	
Long GREEN blink GREEN blink ORANGE blink			

<sup>1)</sup> Hearing aid microphone, TV Adapter 2) ConnectClip remote microphone 3) Only available when three-time repetition is selected

Warnings	Sound	LED	LED comments
Low battery	□3 alternate tones		Continuously blinking
Battery shut down	4 descending tones		
Microphone service check needed	8 beeps repeated 4 times		Repeated four times
The hearing aid LED light does not turn ON when the hearing aid is placed in the charger (miniBTE R only)		Turned OFF	See the <b>Troubleshooting</b> section
The hearing aid LED light blinks ORANGE when the hearing aid is placed in the charger (miniBTE R only)			Continuously blinking. See the <b>Troubleshooting</b> section.

The hearing aid LED light blinks GREEN when the hearing aid is placed in the charger (miniBTE R only)	0	Continuously blinking. See the <b>Troubleshooting</b> section.
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Short GREEN blink Long ORANGE blink Short ORANGE blink

# **Summary of relevant studies**

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

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

Measured according to American National Standard ANSI S3.22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

Supply voltage: Lithium-ion

0 dB SPL ref. 20 μPa		Oticon More 1 & Play PX 1	Oticon More 2 & 3 Play PX 2 Oticon Zircon 1 & 2
OSPL90	Peak	123 dB SPL	123 dB SPL
USPLOU	HF Average	119 dB SPL	119 dB SPL
Full-on Gain	Peak	54 dB	54 dB
rull-oll dalli	HF Average	47 dB	47 dB
Reference Test Gain		41 dB	41 dB
Frequency Range		100-7300 Hz	100-7300 Hz
Telecoil output	HF Average SPLITS (left/right ear)	99/99 dB SPL	99/99 dB SPL
	500 Hz	< 4 %	<4%
Total Harmonic Distortion	800 Hz	<3%	<3%
Distortion	1600 Hz	<2%	<2%
Equivalent Input Noise Level	(omni/dir)	17/31 dB SPL	17/32 dB SPL
Attack Time		5 ms	5 ms
Release Time		21 ms	23 ms

0 dB SPL ref. 20 μPa		Oticon More 1 Play PX 1	Oticon More 2 & 3 Play PX 2 Oticon Zircon 1 & 2
Expected operating time*	Hours	24 hrs	24 hrs
Latency		8.4 ms	8.4 ms
Maximum Induction Coil Sensitivity	Measured output at 1 mA/m	74 dB SPL	74 dB SPL
	Measured output at 10 mA/m	94 dB SPL	94 dB SPL
	Measured output at 31.6 mA/m	105 dB SPL	105 dB SPL

<sup>\*</sup>Expected operating time for rechargeable battery depends on use pattern, active feature set, hearing loss, sound environment, battery age and use of wireless accessories.

Measured according to American National Standard ANSI S3.22-2014, IEC 60118-0:2015 and IEC 60318-5:2006

Supply voltage: Zinc-Air

0 dB SPL ref. 20 μPa		Oticon More 1 & Play PX 1	Oticon More 2 & 3 Play PX 2 Oticon Zircon 1 & 2
OSPL90	Peak	123 dB SPL	123 dB SPL
	HF Average	119 dB SPL	119 dB SPL
Full-on Gain	Peak	54 dB	54 dB
	HF Average	48 dB	48 dB
Reference Test Gain		42 dB	42 dB
Frequency Range		100-7300 Hz	100-7300 Hz
Telecoil output	HF Average SPLITS (left/right ear)	100/100 dB SPL	100/100 dB SPL
	500 Hz	< 4 %	<4%
Total Harmonic Distortion	800 Hz	<3%	<3%
Distortion	1600 Hz	Play PX 1  123 dB SPL  119 dB SPL  54 dB  48 dB  42 dB  100-7300 Hz  100/100 dB SPL	<2%
Equivalent Input Noise Level	(omni/dir)	17/29 dB SPL	17/29 dB SPL
Attack Time		5 ms	5 ms
Release Time		22 ms	23 ms

0 dB SPL ref. 20 μPa		Oticon More 1 & Play PX 1	Oticon More 2 & 3 Play PX 2 Oticon Zircon 1 & 2
Battery Consumption*	Typical	2.0 mA	2.0 mA
	Quiescent	1.9 mA	1.9 mA
Expected Battery Life (battery size 312 - IEC PR41)**	Hours	50-55 hrs	50-55 hrs
Latency		8.4 ms	8.4 ms
	Measured output at 1 mA/m	75 dB SPL	75 dB SPL
Maximum Induction Coil Sensitivity	Measured output at 10 mA/m	95 dB SPL	95 dB SPL
	Measured output at 31.6 mA/m	105 dB SPL	105 dB SPL

<sup>\*</sup>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 a minimum of 3 minutes.

<sup>\*\*</sup>Real usage of 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).

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Oticon More 2 & 3 Plav PX 2 Oticon Zircon 1 & 2

#### Oticon More 1 & Play PX 1

OSPL90 - Output Sound Pressure Level Input: 90 dB SPL Technical setting: A0

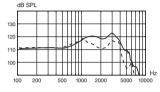
> Standard tube Thin tube (size 1.3)

Frequency response

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

Acoustic input — — Magnetic input

Input-Output Technical Setting: NO



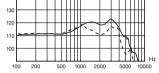
dB SPI

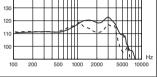
100

90

RΩ

100





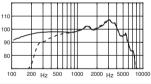


dB SPI

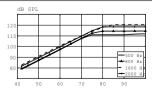
200

130

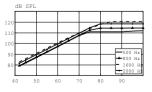




1000 2000



1000



### Oticon More 1 Play PX 1

Oticon More 2 & 3 Plav PX 2 Oticon Zircon 1 & 2

