### INSTRUCTIONS FOR USE

# Encanta miniRITE









### 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.



#### Warnings

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

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.

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### **Model overview**

This booklet is valid for the following hearing aid models:

□ MNR

### FW 1.0

- ☐ Bernafon Encanta 400 MNR GTIN: (01) 05714464133185
  ☐ Bernafon Encanta 300 MNR GTIN: (01) 05714464133192
- ☐ Bernafon Encanta 300 MNR GTIN: (01) 05714464133192
- ☐ Bernafon Encanta 200 MNR GTIN: (01) 05714464133208
- ☐ Bernafon Encanta 100 MNR GTIN: (01) 05714464133215

The following speakers are available for the above models:

- □ miniFit Detect speaker 60
- □ miniFit Detect speaker 85
- □ miniFit Detect speaker 100 (Power Instrument)
- ☐ MicroShell Detect 60
- ☐ MicroShell Detect 85
- ☐ MicroShell Detect 100 (Power Instrument)
- ☐ MicroShell Detect 105 (Power Instrument)

The packaging box contains the following elements:

- Hearing aids
- Multitool
- Soft cloth

### Intended use

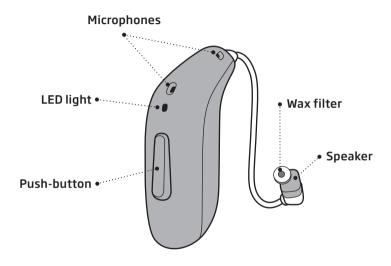
Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	Bilateral or unilateral impaired hearing of sensorineural, conductive or mixed type ranging from a slight (16 dB HL*) to profound (95 dB HL*) degree of hearing loss, with an individual frequency configuration.
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.

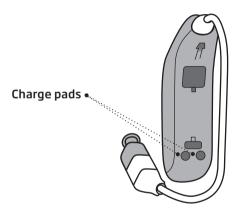
As specified by the American Speech-Language-Hearing Association, asha.org, using pure-tone average of 0.5, 1 and 2 kHz.

#### IMPORTANT NOTICE

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

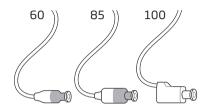
## Your hearing aid, speaker and earpiece



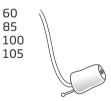


### The hearing aids use one of the following speakers:

#### miniFit Detect speakers



### **Customised speakers**



MicroShell Detect

### The speakers use 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.

### **Customised earpieces**

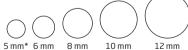


☐ LiteTip\*



☐ Micro mould\*

### Dome sizes



<sup>\*</sup>Only as OpenBass dome for miniFit Detect speaker 60

#### Note

For details on replacing the dome, see the **Replace standard earpieces** section.

<sup>\*</sup>Can be made of different materials

## **Battery performance**

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.

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.

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

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

#### IMPORTANT NOTICE

When charging in high ambient temperatures, your hearing aid may reach up to  $45^{\circ}\text{C}$ .

## Low battery indication

The low battery indication is repeated periodically until the battery runs out. Your hearing care professional can set your hearing aids to match your preferences.

After the notification, you have approximately two hours before the hearing aid runs out of battery. At this point, you may continue to stream audio for approximately one hour. To extend battery performance, ensure you stop any audio streaming.

The battery is running low

Three alternate tones

The battery has run out

Sour descending tones



Spoken indicators

**Hearing aid LED light**Continuous fast **ORANGE** blinks indicate low battery.

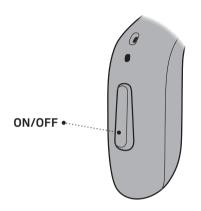
## Turn hearing aids ON/OFF

Your hearing aids can be turned ON or OFF using either the charger or the push-button.

	Charger	Push-button	Indicator
ON	Remove hearing aids from charger*	Press and hold the push-button for two seconds	Hearing aid LED light turns GREEN. Depending on your hearing aid settings, you may also hear a start-up jingle when they are removed from the charger
OFF		Press and hold the push-button for approximately three seconds	Hearing aid LED light turns ORANGE. Four descending tones are played

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

<sup>\*</sup> If the charger is disconnected from power or runs out of battery whilst charging your hearing aids, your hearing aids may turn OFF to save power. If your hearing aids do not automatically turn ON when removed from the charger, turn them on manually using the push-button.



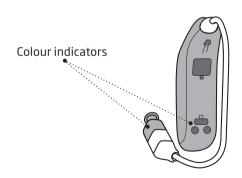
#### IMPORTANT NOTICE

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.

## 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.

Colour indicators mark the left and right hearing aids. A **RED** indicator marks the RIGHT hearing aid. A **BLUE** indicator marks the LEFT hearing aid.



## Put on hearing aid

#### Step 1



Place the hearing aid behind your ear.

You should always use the speaker with an earpiece attached.

Use only parts designed for your hearing aid.

#### Step 2



Hold the bend of the speaker wire between your thumb and index finger.

The earpiece should point towards the opening of the ear canal.

#### Step 3

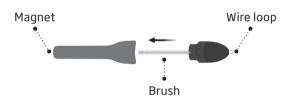


Gently push the earpiece into your ear canal until the speaker wire sits close to your head.

If the speaker 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, contact your hearing care professional.



#### IMPORTANT NOTICE

The MultiTool has a built-in magnet. Keep the MultiTool at least 30 centimetres (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 and the surface around the openings.

Ensure that you do not forcefully squeeze parts of the MultiTool into the microphone openings. This may damage the hearing aid.

Keep the charge pads clean to ensure optimal charging. Clean the charge pads using a dry cloth.



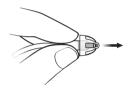
#### IMPORTANT NOTICE

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

## Replace standard earpiece

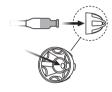
The standard earpiece (dome or Grip Tip) should not be cleaned. If the earpiece is filled with earwax, replace it with a new one. Grip Tips should be replaced at least once a month.

### Step 1



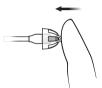
Hold on to the speaker and pull off the earpiece.

### Step 2



Insert the speaker exactly into the middle of the earpiece to get a secure fit.

#### Step 3



Push firmly to ensure that the earpiece is securely fastened.

## Clean customised earpiece

The customised earpiece should be cleaned regularly.

The earpiece has a white wax filter\* that keeps earwax and debris from damaging the speaker. Ensure you replace the filter when clogged, or if the hearing aid does not sound normal.

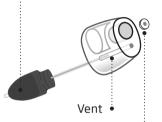
Alternatively, contact your hearing care professional.

#### Note

If you use a mould or LiteTip, your hearing care professional must replace the wax filter in the speaker.

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

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



ProWax filter •

#### IMPORTANT NOTICE

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

### ProWax miniFit filter

The speaker has a white wax filter attached to the end where the earpiece is attached. The wax filter keeps earwax and debris from damaging the speaker.

Ensure you replace the filter when clogged, or if the hearing aid does not sound normal. Alternatively, contact your hearing care professional. Ensure you remove the earpiece from the speaker before replacing the wax filter. To do this, see the **Replace standard earpiece** section.



#### IMPORTANT NOTICE

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

## **Replace ProWax miniFit filter**

#### 1. Tool



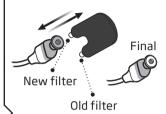
Remove the tool from the shell. The tool has two pins: one empty for removal and one with the new wax filter.

#### 2. Remove



Insert the empty pin into the wax filter in the speaker and pull it out.

#### 3. Insert



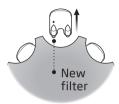
Insert the new wax filter using the other pin. Remove the tool and throw it out.

#### Note

If you use a mould or LiteTip, your hearing care professional must replace the wax filter in the speaker.

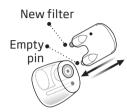
## **Replace ProWax filter**

#### 1. Tool



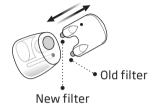
Remove the tool from the shell. The tool has two pins: one empty for removal and one with the new wax filter.

#### 2. Remove



Insert the empty pin into the wax filter in the earpiece and pull it out.

#### 3. Insert

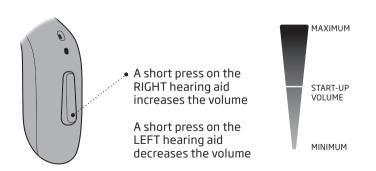


Insert the new wax filter using the other pin. Remove the tool, and throw it out.

## **Change volume**

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

For information regarding button press times, see the table **General** settings overview for your hearing aid, in the Your individual hearing aid settings section at the end of this booklet.



## **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.



Press the push-button to switch between programs.

If you have two hearing aids:

The RIGHT hearing aid switches one program forward, for example program 1 to 2.

The LEFT hearing aid switches one program backward, for example from program 4 to 3.

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

For information regarding button press times see the table **General** settings overview for your hearing aid, in the Your individual hearing aid settings section at the end of this booklet.

## Store your hearing aids

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 three months), ensure you first fully charge them, and then turn them OFF. This way the battery can be charged again.

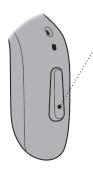
#### Note

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 may need to be replaced.

### Turn Bluetooth ON/OFF

Bluetooth connectivity can be turned ON/OFF on your hearing aids. When Bluetooth is turned OFF the hearing aids are still turned ON and functioning. Be aware that pressing the push-button on one hearing aid, turns OFF bluetooth for both hearing aids. For information about sounds and lights, see the **Sound and LED light indicators** section.

Your hearing aids use Bluetooth wireless technology. They can be used on an aircraft as hearing aids are exempt from the rules applied to portable electronic devices on an aircraft.



#### • To activate and deactivate

Press and hold the push-button for approximately seven seconds.

Four descending tones, a jingle and an LED light pattern confirm your action.

## Mute/unmute your hearing aids

You can mute and unmute your hearing aids by using the optional app or select devices. Additionally you can unmute by applying a short press to the push-button on your hearing aids. For more information, contact your hearing care professional.

#### IMPORTANT NOTICE

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

## Use your hearing aids with digital devices

### iPhone, iPad, iPod touch and Mac

Your hearing aids are Made for iPhone hearing aids and allow for direct streaming from your iPhone, iPad, iPod touch or Mac.\*

#### **Android devices**

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

Bernafon App can be used to control your hearing aids from your mobile device.\*

Additionally, your hearing aids offer hands-free communication with compatible Apple iOS and select Android 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 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.

<sup>\*</sup>For a list of compatible iPhone, iPad, iPod touch, Mac and Android devices, visit: www.bernafon.com/hearing-aid-users/hearing-aids/connectivity/compatibility.

## Pairing and compatibility

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

www.bernafon.com/hearing-aid-users/support/library/

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

www.bernafon.com/hearing-aid-users/hearing-aids/connectivity/compatibility

## **Call handling**

You can accept, reject or end phone calls with the push-buttons on your hearing aids. You can also use the tap control to answer or end phone calls.



#### To accept

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

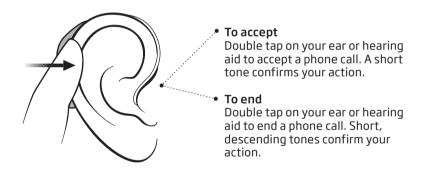
### To reject

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

#### To end

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

To use the call handling functionality, your hearing aids must be paired with a compatible mobile device.\*



<sup>\*</sup> For a list of compatible mobile devices, visit: www.bernafon.com/hearing-aid-users/hearing-aids/connectivity/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.

# SoundClip-A

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

## TV-A

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

## RC-A

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

### **FduMic**

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

## **Bernafon App**

An application that gives you wireless access to your hearing aids through a mobile device for control of functionality, and that allows an update of your hearing aids remotely. For iPhone, iPad, iPod touch and Android devices. Ensure that you only download Bernafon 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 theatres, places of worship, or lecture rooms. This symbol is shown wherever a teleloop has been installed.

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# **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 of age.

Tinnitus SoundSupport is targeted to licenced 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**

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

## 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 the table **Tinnitus SoundSupport: Limitation on use**, in the **Your individual hearing aid settings** section at the end of this booklet to learn how many hours per day you can safely use the relief sound in your hearing aid.

# Sound options and volume adjustments

Tinnitus SoundSupport is programmed by your hearing care professional to match your hearing loss and preferences for tinnitus relief.

# Tinnitus SoundSupport programs

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 only mutes the environmental sounds, and not the sound from Tinnitus SoundSupport. For information on how to mute your hearing aids, see the **Mute your hearing aids** section.

## Volume adjustments with Tinnitus SoundSupport

Your hearing care professional can set the volume control for a hearing aid program for which Tinnitus SoundSupport is activated.

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.

# 

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 unauthorised use and to keep the device out of reach of children and pets.

## Maximum wearing time

Always follow the maximum wearing time per day of the Tinnitus SoundSupport advised by your hearing care professional. Prolonged use may lead to worsening of your tinnitus or of your hearing loss.

# **⚠** General warnings

For your personal safety and to ensure correct usage, you should familiarise yourself fully with the following general warnings before using your hearing aids. Consult your hearing care professional if your hearing aids exhibit unexpected behaviour or you encounter serious incidents with your hearing aids. 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 hearing impairment resulting from natural processes such as aging or sickness.

Hearing aids are only a part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

To achieve the full benefit from your hearing aids, you should use them frequently.

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

This hearing aid is supported by a nonremovable rechargeable lithium-ion battery cell. Please ensure to charge the hearing aid and familiarise yourself with the safety and handling information related to rechargeable hearing aids.

### Usage of hearing aids

Hearing aids should only be used as directed by your hearing care professional. Misuse can result in sudden and permanent hearing loss. Never allow others to wear your hearing aids. Unauthorised use could cause permanent damage to their hearing.

# Choking hazards of swallowing small parts

Keep all small parts (for example, hearing aids, earpieces, batteries, etc.) out of reach and sight of children and others who might swallow these items. Seek emergency medical treatment immediately if someone is choking on small parts or batteries are swallowed

# Keep away from environments with risk of explosions

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

Do not use the hearing aid in environments with danger of explosions such as mines, oil fields, oxygen rich environments or areas where flammable anaesthetics are handled

Fatality hazards of swallowing batteries
Never swallow batteries. Doing so can lead
to serious injury or death within hours.
Swallowed batteries can cause burns that
may perforate inner organs. Keep the
batteries out of reach and sight of children
and others who might swallow them.
Batteries have occasionally been mistaken
for pills. Therefore, check your medicine
carefully before swallowing any pills. Seek
emergency medical treatment immediately
if a battery is swallowed.

Risk of placing batteries in ear or nose Never place batteries in the ear or the nose. This can lead to permanent damage due to burns. Contact a doctor immediately if a battery is placed in the ear or nose.

# **⚠** General warnings

# Never attempt to replace rechargeable batteries

Do not attempt to open your hearing aids as it may damage the battery.

Never attempt to replace the battery. If battery replacement is needed, return your device to the supplier. The warranty is void if there are signs of tampering.

## Beware of battery leakage

Do not touch your hearing aids if the battery appears to be leaking as the acids may cause skin irritation. If you have been in contact with battery acids, wipe it off using a wet cloth. If you experience skin irritation, consult your doctor. In the event of battery leakage contact your hearing care professional for further instructions.

## Beware of sudden dysfunction

Your hearing aids may stop working without notice. For example, if they run out of battery or if the tubing is blocked. Keep this in mind especially in situations where you depend on warning sounds (for example when in traffic).

### Use with active medical implants

Your hearing aids have been thoroughly tested and developed 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 implanted device for information about the use with a hearing aid.

Accessories with built-in magnets (for example the Autophone magnet and the MultiTool) should be kept at least 30 centimetres (12 inches) away from any implanted medical device. Follow the guidelines from the manufacturer of your implanted medical device regarding their use with magnets.

## Use with 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 a 1 centimetre (0.4 inches) away from your hearing aid. The magnetic field from the CI may permanently damage the speaker unit in your hearing aid. Never place the devices close together on a table (for example, when cleaning or changing batteries).

Do not carry the CI and the hearing aid together in the same box.

## Detached earpiece in ear canal

Ensure that the earpiece is still connected to the speaker when removing the hearing aid from your ear. If the earpiece is not on the speaker, the earpiece may still be in the ear canal. Consult your hearing care professional.

# Remove hearing aids before certain medical procedures

Remove your hearing aids before medical procedures such as X-ray examinations, CT/MR/PET scans, electrotherapy, surgery, etc. Your hearing aids may be damaged if exposed to strong magnetic or electromagnetic fields.

# **⚠** General warnings

### Keep away from extreme heat

Never expose your hearing aids to extreme heat. For example, do not leave your hearing aids inside a parked car in the sun.

Never use an external heating device to dry your hearing aids. For example, do not dry your hearing aids using a hair dryer or in an oven such as a microwave.

## Keep away from chemicals

The Remove your hearing aids before applying products that contain certain chemicals that can damage your hearing aids. For example, cosmetics, hairspray, perfume, aftershave lotion, suntan lotion and insect repellent. Allow the products time to dry before putting on your hearing aids.

# Connecting the charger to external equipment

If you connect your hearing aid charger using a USB connector other than the one originally supplied with your charger, the USB connector must comply with IEC 62368-1 or equivalent safety standards.

#### Potential side effects

You may produce more earwax when using hearing aids. In rare cases, the non-allergenic materials in the product may cause skin irritation or other side effects. If you experience any such side effects, consult your doctor.

## Use of third-party accessories

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

## Do not modify hearing aids

Do not make any modifications to your hearing aids not expressly approved by the manufacturer. This will void the warranty.

# $((\bullet))$ Use in fields with electromagnetic interference

Your hearing aids have been thoroughly tested for interference according to the most stringent international standards, including EN/IEC 60601-1-2 and its amendments. Electromagnetic interference may occur in the vicinity of equipment that can affect the performance of your hearing aids such as mobile phones, Wi-Fi routers or other equipment with the displayed symbol. If your hearing aids are affected by interference, move away from the source.

# 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 humidity or getting wet in the rain. Should your hearing aid come into contact with water and stop working, please follow these quidelines.

Before charging the hearing aid, make sure to wipe off any moisture.

### IMPORTANT NOTICE

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

# **Conditions of use**

Operating conditions	Temperature: +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 aid contains the following two radio technologies:

The hearing aid contains 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 (-12.20 dBµA/ft) at 10 metres (33 feet) distance).

The hearing aid also contains 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 4.5 mW equal to 6.5 dBm in total radiated power.

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

The hearing aid complies with international standards concerning radio transmitters, electromagnetic compatibility, and human exposure.

The hearing instrument is designed to operate in public and residential environments. It has passed the following applicable emissions and immunity tests:

Radiated emissions requirements for a CISPR 11 Group 1 Class B device as stated in table 2 of IEC 60601-1-2.

Radiated emission for communication devices operating in the ISM 2.4 GHz band as stated in 47 CFR Part 15, subpart C, RSS-247 and EN 300 328 (only for products with Bluetooth).

Radiated emission for near field magnetic induction communication operating at 3.84 MHz as stated in 47 CFR Part 15, subpart C, RSS-210 and EN 300 330.

RF radiated immunity at a field level of 10 V/m between 80 MHz and 2.7 GHz as stated in table 4 of IEC 60601-1-2 and, 3 V/m between 2.7 and 6.0 GHz as stated in CISPR 32.

RF radiated immunity at a field level of up to 28 V/m for selected RF wireless communication bands between 380 MHz and 5.8 GHz as stated in table 9 of IEC 60601-1-2.

RF radiated immunity at a field level of up to 65 A/m for selected proximity magnetic fields at 30 kHz, 134.2 kHz and 13.56 MHz as stated in table 11 of IEC 60601-1-2 AM1.

RF radiated immunity field levels at selected bands stated in IEC 60118-13 between 25 V/m and 60 V/m and, for proximity-fields from communication devices held to the ear, stated in ANSI C63.19.

Immunity to power frequency magnetic fields at a field level of 30 A/m as stated in table 4 of IEC 60601-1-2 (only for products with telecoil).

Immunity to ESD levels of +/- 2, 4 and 8 kV conducted discharge and +/- 2, 4, 8 and 15 kV air discharge as stated in table 4 of IEC 60601-1-2.

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 document on www. hernafon.com

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

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

Declaration of Conformity is available from the headquarters.

Bernafon Kongebakken 9 DK-2765 Smørum Denmark www.bernafon.com/doc

**CE** 0123











## Description of symbols accompanying the product



### 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 Regulations 2017/745





C € 0123 The device complies with all required EU regulations and directives. The four digit number indicates the identification of the notified body.

### Electronic waste (WEEE)



Recycle hearing aids, accessories or batteries according to local regulations.

Hearing aid users can also return electronic waste to their hearing care professional for disposal. Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).



## Regulatory Compliance Mark (RCM)

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

#### IP code



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

## Bluetooth

### Bluetooth logo

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

## Description of symbols accompanying the product



### Made for Apple badges

Indicates that the device is compatible with iPhone and iPad.



#### Mac badge

Indicates that the device is compatible with Mac.



### Apple AirPlay badge

The AirPlay button can be used to disconnect and connect hearing aids from a Mac.



### Android badge

Indicates that the device is compatible with Android.



#### Hearing loop

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



### Radio Frequency (RF) transmitter

Your 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

Firmware version used in the device.



## Keep dry

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

## Description of symbols accompanying the product



### Catalogue number

Indicates the manufacturer's catalogue number so that the medical device can be identified.



#### Serial number

Indicates the manufacturer's serial number so that a specific medical device can be identified.



#### **Medical Device**

The device is a medical device



### 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 unauthorised party, exposure to corrosive conditions, physical changes in your ear, damage due to foreign objects entering the device, or incorrect adjustments are NOT covered by the international warranty and may void it. The above international warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods in the country where

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

## If you need service

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

# 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 y	our hearing aid
Left		Right
☐ Yes ☐ No	Tinnitus SoundSupport	☐ Yes ☐ No
To increase or de	nge Tinnitus SoundSupport volume crease the volume (on one hearing aid n-button repeatedly until you reach you	d only), use a short
simultaneously	nge Tinnitus SoundSupport volume nearing aid to increase the volume and volume.	
To <b>increase</b> the v	olume, use a short press on the push-l g aid.	outton repeatedly on
To <b>decrease</b> the the LEFT hearing	volume, use a short press on the pushaid.	button repeatedly on

To be filled out by your hearing care professional.

	Ge	neral settings overview for your hearing	aid	
Le	ft		Rig	jht
☐ Yes	□ No		☐ Yes	□No
☐ Short press		Change program	☐ Short	press
☐ Long press			☐ Long	press
☐ Yes	□ No	Change volume	☐ Yes	□No
		Volume control indicators		
□ On	☐ Off	Beeps at min/max volume	☐ On	☐ Off
□ On	☐ Off	Beeps when changing volume	☐ On	☐ Off
☐ On	☐ Off	Beeps at start-up volume	☐ On	☐ Off
		Battery indicators		
☐ On	☐ Off	Low battery warning	☐ On	☐ Off

To be filled out by your hearing care professional.

# Sound and LED light indicators

Different sounds and light patterns indicate the hearing aid status. The different indicators are listed on the following pages. For light indicators on your charger, see the charger's instructions for use.

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

Program	Sound	☐ LED light*	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 light blinks continuously or is repeated three times with short pauses.

ON/OFF	Sound	LED light	LED light comments
ON	☐ Jingle		
OFF	4 descending tones		
Volume	Sound	LED light	
Start-up volume	☐ 2 beeps		Shown once
Minimum/maximum volume	☐ 3 beeps		
Volume up/down	☐ 1 beep		
Mute			Continuous or repeated three times
Long GREEN blink Short GREEN blink Long ORANGE blink Short ORANGE blink			

Accessories	☐ Sound	☐ LED light	LED light comments
TV-A	2 different tones		
EduMic	2 different tones		
SoundClip-A	2 different tones		Continuous or repeated three times
Bluetooth	Sound	☐ LED light	
Bluetooth ON	4 descending tones + short jingle		
Bluetooth ON Bluetooth OFF			Only available when three-time repetition is selected

Warnings	Sound	LED light	LED light comments
Lowbatton	3 alternate tones		Continuously
Low battery	☐ Voice Notification		blinking
Battery shut down	4 descending tones		
Microphone cleaning or service needed	8 beeps repeated 4 times		Repeated four times. See the <b>Trouble</b> - <b>shooting</b> section
The hearing aid LED light does not turn ON when the hearing aid is placed in the charger		Turned OFF	See the <b>Trouble-</b> <b>shooting</b> section

Warnings	Sound	LED light	LED light comments
The hearing aid LED light blinks ORANGE when the hearing aid is placed in the charger			Continuously blinking. See the <b>Troubleshooting</b> section.

# **Troubleshooting**

Symptom	Possible causes	
	Hearing aid is out of power	
	Dead battery	
No sound	Incompatable receiver	
	Clogged earpieces (dome, Grip Tip, or mould)	
	Hearing aid microphone muted	
Intermittent or reduced	Clogged sound outlet	
sound	Moisture	
Squealing noise	Hearing aid earpiece incorrectly inserted	
Squealing noise	Earwax accumulated in ear canal	
Beeping	If your hearing aid plays eight beeps, four times consecutively, your hearing aid may need a microphone service check.	
Pairing issue with	Bluetooth connection failed	
smartphone	Only one hearing aid is paired	
Connectivity issues with Mac	Audio problems	

Solutions
Charge the hearing aid
Contact your hearing care professional
Contact your hearing care professional
Clean mould Replace wax filter, dome, or Grip Tip
Unmute the hearing aid microphone
Clean mould or replace wax filter, dome, or Grip Tip
Gently wipe the hearing aid and let it dry
Re-insert the earpiece
Have ear canal examined by your doctor
First, try to clean the microphone with the cleaning tool. If the beep persists, contact your service center.
1) Unpair your hearing aid. 2) On your phone, turn Bluetooth OFF and ON again. 3) Turn the hearing aid OFF and then turn it back ON. 4) Pair your hearing aid again (for guidance, visit: www.bernafon.com/hearing-aid-users/support/library/)
1) Open the Control Center on Mac. 2) Under Sound, click the AirPlay button OFF. 3) Turn your hearing aids OFF, then ON again. 4) In the Control Center under Sound, click the AirPlay button ON

# **Troubleshooting**

To troubleshoot the charger, see your charger's instructions for use.

Symptom	Possible causes
The hearing aid LED light remains turned OFF when the hearing aid is placed in the charger	The charger is turned OFF
	The hearing aid or charger's temperature is either too warm or too cold
	Charging is incomplete. The charger has stopped charging to protect the battery.
in the charger	The hearing aid is incorrectly seated in the charger
	The hearing aid charge pins are dirty
The hearing aid LED light pulses ORANGE when the hearing aid is placed in the charger but does not power ON when removed from the charger	Battery is very low and insufficient to power ON hearing aids
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
Clean the contacts using a dry cloth
The hearing aids are charging. Ensure you leave the hearing aids in the charger during this process
Contact your hearing care professional
 <u> </u>

