### INSTRUCTIONS FOR USE

## Encanta miniRITE













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

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

A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT).

Before using this, a doctor should determine that the use of a hearing aid is appropriate.

#### WARNING to Hearing Aid Dispensers:

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

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

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

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

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

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

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

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

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

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as possible. 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 can 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 any 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 can 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 younger than 18 years old with hearing loss should undergo 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 it is 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.

### 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 trained and has proven competency in professionally assessing hearing, selecting, fitting, and delivering hearing instruments and rehabilitation care to persons with hearing loss. The hearing care professional has been trained in accordance with national or regional regulations.

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

### **Table of contents**

About		
	Model overview	10
	Intended use	12
	Your hearing aid, speaker and earpiece	14
Getting	started	
	Battery performance	18
	Low battery indication	19
	Turn hearing aids ON/OFF	20
	Identify left and right hearing aids	22
Daily us	e	
	Put on hearing aid	23
	Cleaning	24
	Clean the hearing aid	25
	Replace standard earpiece	26
	Clean customized earpiece	27
	ProWax miniFit filter	28
	Replace ProWax miniFit filter	29

Continues on next page

### **Table of contents**

	Replace ProWax filter	30
	Change volume	31
	Change program	32
	Store your hearing aids	34
Options		
	Turn Bluetooth ON/OFF	35
	Mute/unmute your hearing aids	36
	Use your hearing aids with digital devices	37
	Pairing and compatibility	38
	Call handling	40
	Wireless accessories and other options	42
Tinnitus		
	Tinnitus SoundSupport™ (optional)	44
	Guidelines for Tinnitus SoundSupport users	45
	Limitation on use time	46
	Sound options and volume adjustments	47
	Warnings related to tinnitus	49

## Warnings M

ys	
	General warnings
fo	
	Water and dust resistant (IDER)

Summary of relevant studies

Technical Data

	General warnings	50
ore info		
	Water and dust resistant (IP68)	56
	Conditions of use	57
	Technical information	58
	Cell phone	64
	t-d	70

Water and dust resistant (IP68)	56
Conditions of use	57
Technical information	58
Cell phone	64
Warranty	70
Your individual hearing aid settings	71
Sound and LED light indicators	74
Troubleshooting	80

84

86

### 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
- GTIN: (01) 05714464133208 Bernafon Encanta 200 MNR
- **Rernafon 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

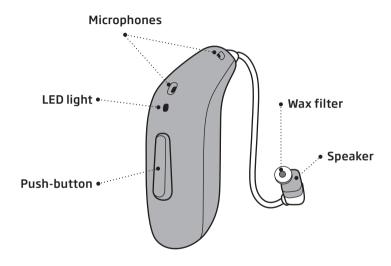
Intended use	The hearing aid is intended to amplify and transmit sound to the ear.
Indications for use	Bilateral or unilateral impaired hearing of sensorineural, conductive or mixed type ranging from a slight (16 dB HL*) to profound (95 dB HL*) degree of hearing loss, with an individual frequency configuration.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

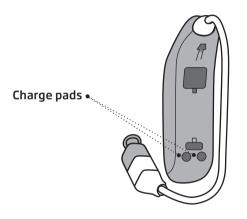
<sup>\*</sup>As specified by the American Speech-Language-Hearing Association, asha.org, using pure-tone average of 0.5, 1 and 2 kHz.

#### **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.

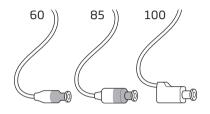
### Your hearing aid, speaker and earpiece



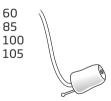


### The hearing aids use one of the following speakers:

#### miniFit Detect speakers



#### **Customized 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.

### **Customized earpieces**

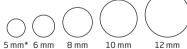


☐ LiteTip\*



☐ MicroMold\*

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. In this way, you ensure that 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  $45^{\circ}$ C ( $113^{\circ}$ F).

### 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.

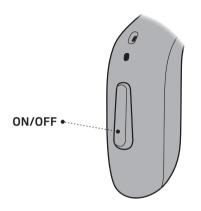
### Turn hearing aids ON/OFF

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 while 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.



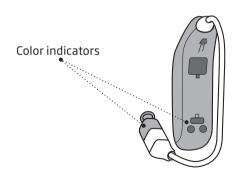
#### **IMPORTANT NOTICE**

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.

Color 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

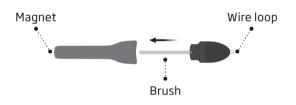


Gently push the earpiece into your ear canal until the speaker wire sits close to your head.

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 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 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.



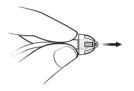
#### IMPORTANT NOTICE

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

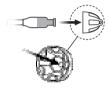
The standard earpiece (dome or Grip Tip) should not be cleaned. If the earpiece is filled with earwax, replace it with a new one. Grip Tips should be replaced at least once a month.

### Step 1



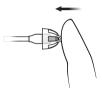
Hold on to the speaker and pull off the earpiece.

### 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 customized earpiece

The customized 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.

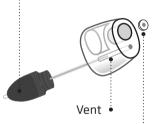
Alternatively, contact your hearing care professional.

#### Note

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

\* Not all molds have a wax filter. Filter composition can vary by mold. 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



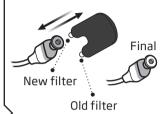
Remove the tool from the shell. The tool has two pins: one empty for removal and one with the new wax filter.

#### 2. Remove



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

#### 3. Insert



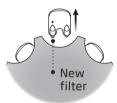
Insert the new wax filter using the other pin. Remove the tool and throw it out.

#### Note

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

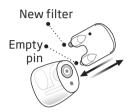
### **Replace ProWax filter**

#### 1. Tool



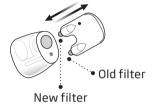
Remove the tool from the shell. The tool has two pins: one empty for removal and one with the new wax filter.

#### 2. Remove



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

#### 3. Insert

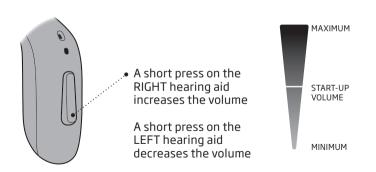


Insert the new wax filter using the other pin. Remove the tool, and throw it out.

### **Adjust 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.

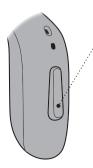
#### Note

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:

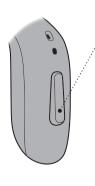
www.bernafon.com/hearing-aid-users/support/library/

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

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

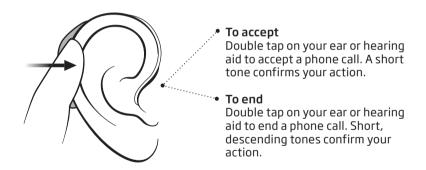
# To reject

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 handsfree 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.

### **EduMic**

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 your hearing aids to be updated 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 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.

# 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 licensed hearing care professionals (audiologists, hearing aid specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing loss. Tinnitus SoundSupport must be fitted 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.

# 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.

# 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.



# **Marnings** related to tinnitus

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

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

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

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

### Maximum wearing time

Always follow the maximum wearing time per day of the Tinnitus SoundSupport advised by your hearing care professional. Prolonged use may lead to worsening of your tinnitus or to 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 your hearing aids exhibit unexpected behavior 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 damaging the hearing aids and batteries.

This hearing aid is supported by a nonremovable rechargeable lithium-ion battery cell. Please ensure that you charge the hearing aid and familiarize 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. Unauthorized 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.

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.

# 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 anesthetics 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.

# **⚠** General warnings

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.

# 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 centimeters (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 centimeter (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.

# (((•))) 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 resistant 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.

# **Operating conditions**

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 dB $\mu$ A/m (-12.20 dB $\mu$ A/ft) at 10 meters (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

## MNR only

This device contains a radio module with the following certification ID number: FCC ID: 2ACAHAU5MNRR

# Radiofrequency radiation exposure information

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

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

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

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 distance 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.

# **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".

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

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.





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



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





Bluetooth®

# 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 logo

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

Continues on next page

## 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



#### 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.

# 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)	cus) 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 So	undSupport settings overview for yo	ur hearing aid			
Left		Rig	Right		
☐ Yes ☐ No	Tinnitus SoundSupport	☐ Yes	□No		
To increase or decre	Tinnitus SoundSupport volume in ease the volume (on one hearing aid atton repeatedly until you reach you	only), use a sh	nort		
simultaneously You can use one hea	Tinnitus SoundSupport volume in ring aid to increase the volume and		ring aid		
to <b>decrease</b> the volu To <b>increase</b> the volu the RIGHT hearing ai	me, use a short press on the push-b	utton repeate	dly on		
To <b>decrease</b> 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						
Left				Right		
☐ Yes	□No		☐ Yes	□ No		
☐ Short	press	Change program	☐ Short	☐ Short press		
☐ Long press			☐ Long	☐ Long press		
☐ Yes ☐ No Adjust volume		Adjust 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	0	Continuous or repeated three times	
Bluetooth	Sound	☐ LED light		
Bluetooth ON	4 descending tones + short jingle			
Bluetooth OFF	4 descending tones + short jingle		Only available when three-time repetition is selected	
Long GREEN blink Short GREEN blink Long ORANGE blink Short ORANGE blink				

Warnings	Sound	LED light	LED light comments
Loubatton	3 alternate tones		Continuously blinking
Low battery	☐ Voice Notification		
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.

Long GREEN blink Short GREEN blink Dong ORANGE blink Short ORANGE blink

# **Troubleshooting**

Symptom	Possible causes	
	Hearing aid is out of power	
	Dead battery	
No sound	Incompatable receiver	
	Clogged earpieces (dome, Grip Tip, or mold)	
	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 mold Replace wax filter, dome, or Grip Tip
Unmute the hearing aid microphone
Clean mold 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 charger is turned OFF
The hearing aid LED light	The hearing aid or charger's temperature is either too warm or too cold
remains turned OFF when 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 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

#### Note

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

# Summary of relevant studies

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

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



Rornafon Encanta

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

Rornafon

0 dB SPL ref. 20 μPa		Encanta 400	300, 200 & 100
OSPL90	Peak	109 dB SPL	109 dB SPL
USPL9U	HF Average	105 dB SPL	105 dB SPL
Full-on Gain	Peak	34 dB	34 dB
Full-Oll dalli	HF Average	31 dB	31 dB
Reference Test Gain		27 dB	27 dB
Frequency Range		<100-8400 Hz	<100-7500 Hz
Telecoil output	HF Average SPLITS (left/right ear)	87/87 dB SPL	87/87 dB SPL
Total Harmonic Distortion	500 Hz	<2%	<2%
	800 Hz	<2%	<2%
	1600 Hz	<2%	<2%
Equivalent Input Noise Level	(omni/dir)	18/30 dB SPL	18/30 dB SPL
Attack Time		6 ms	6 ms
Release Time		30 ms	30 ms

0 dB SPL ref. 20 μPa		Bernafon Encanta 400	Bernafon Encanta 300, 200 & 100
Expected operating time*	Hours	24 hrs	24 hrs
Latency		8.1 ms	8.1 ms
Maximum Induction Coil Sensitivity	Measured output at 1 mA/m	60 dB SPL	60 dB SPL
	Measured output at 10 mA/m	80 dB SPL	80 dB SPL
Sensitivity	Measured output at 31.6 mA/m	90 dB SPL	90 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

0 dB SPL ref. 20 μPa		Encanta 400	300, 200 & 100
050100	Peak	116 dB SPL	116 dB SPL
OSPL90	HF Average	113 dB SPL	113 dB SPL
Full-on Gain	Peak	55 dB	55 dB
Full-Oll dalli	HF Average	47 dB	47 dB
Reference Test Gain		36 dB	36 dB
Frequency Range		<100-8500 Hz	<100-7500 Hz
Telecoil output	HF Average SPLITS (left/right ear)	96/96 dB SPL	96/96 dB SPL
Total Harmonic Distortion	500 Hz	< 2 %	< 2 %
	800 Hz	< 2 %	< 2 %
	1600 Hz	< 2 %	< 2 %
Equivalent Input Noise Level	(omni/dir)	19/30 dB SPL	19/30 dB SPL
Attack Time		5 ms	5 ms
Release Time	·	26 ms	26 ms

0 dB SPL ref. 20 μPa		Bernafon Encanta 400	Bernafon Encanta 300, 200 & 100
Expected operating time*	Hours	24 hrs	24 hrs
Latency		8.1 ms	8.1 ms
Maximum Induction Coil Sensitivity	Measured output at 1 mA/m	75 dB SPL	75 dB SPL
	Measured output at 10 mA/m	95 dB SPL	95 dB SPL
Schistority	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

0 dB SPL ref. 20 μPa		Encanta 400	300, 200 & 100
OSPL90	Peak	123 dB SPL	123 dB SPL
USPL9U	HF Average	121 dB SPL	121 dB SPL
Full-on Gain	Peak	59 dB	59 dB
Full-Oll dalli	HF Average	57 dB	57 dB
Reference Test Gain		43 dB	43 dB
Frequency Range		<100-7100 Hz	<100-7100 Hz
Telecoil output	HF Average SPLITS (left/right ear)	103/103 dB SPL	103/103 dB SPL
Total Harmonic Distortion	500 Hz	< 2 %	< 2 %
	800 Hz	< 2 %	< 2 %
	1600 Hz	< 2 %	< 2 %
Equivalent Input Noise Level	(omni/dir)	16/29 dB SPL	16/29 dB SPL
Attack Time		13 ms	13 ms
Release Time		19 ms	19 ms

0 dB SPL ref. 20 μPa		Bernafon Encanta 400	Bernafon Encanta 300, 200 & 100
Expected operating time*	Hours	24 hrs	24 hrs
Latency		8.1 ms	8.1 ms
Maximum Induction Coil Sensitivity	Measured output at 1 mA/m	86 dB SPL	86 dB SPL
	Measured output at 10 mA/m	106 dB SPL	106 dB SPL
Schistority	Measured output at 31.6 mA/m	116 dB SPL	116dB 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

0 dB SPL ref. 20 μPa		Encanta 400	300, 200 & 100
OSPL90	Peak	126 dB SPL	126 dB SPL
USPL9U	HF Average	123 dB SPL	123dB SPL
Full-on Gain	Peak	63 dB	63 dB
Full-Oll dalli	HF Average	57 dB	57 dB
Reference Test Gain		45 dB	45 dB
Frequency Range		<100-8200 Hz	<100-7500 Hz
Telecoil output	HF Average SPLITS (left/right ear)	105/105 dB SPL	105/105 dB SPL
Total Harmonic Distortion	500 Hz	< 2 %	< 2 %
	800 Hz	< 2 %	< 2 %
	1600 Hz	< 2 %	< 2 %
Equivalent Input Noise Level	(omni/dir)	17/29 dB SPL	17/29 dB SPL
Attack Time		8 ms	8 ms
Release Time		19 ms	19 ms

0 dB SPL ref. 20 μPa		Bernafon Encanta 400	Bernafon Encanta 300, 200 & 100
Expected operating time*	Hours	24 hrs	24 hrs
Latency		8.1 ms	8.1 ms
Maximum Induction Coil Sensitivity	Measured output at 1 mA/m	86 dB SPL	86 dB SPL
	Measured output at 10 mA/m	106 dB SPL	106 dB SPL
Sensitivity	Measured output at 31.6 mA/m	116 dB SPL	116 dB SPL

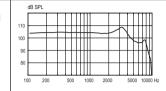
<sup>\*</sup>Expected operating time for rechargeable battery depends on use pattern, active feature set, hearing loss, sound environment, battery age and use of wireless accessories.



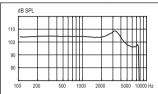


#### Bernafon Encanta 300, 200 & 100

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



dB SPI

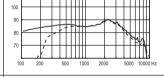


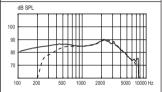
## Frequency Response

Input:

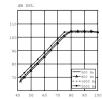
60 dB SPL (Acoustic) 31.6 mA/m (Magnetic) Technical setting: NO

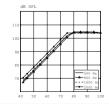




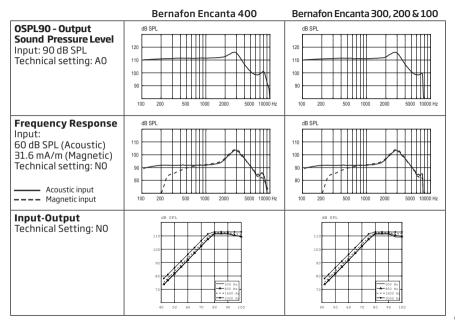


#### Input-Output Technical Setting: NO



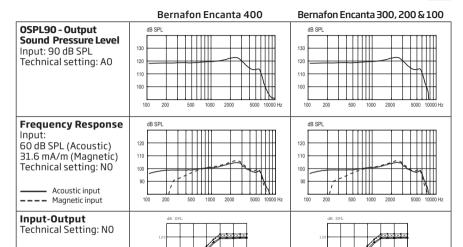








60 70



60 70

