ITE

In-the-Ear Hearing Aids
IIC, CIC, ITC, ITE HS, ITE FS

ZERENA











Made for **≰** iPhone | iPad | iPod

* only for 2.4 GHz models

Instructions for Use



Model overview

EWS Madala

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

| | vo ividucio | | |
|-----|------------------------------|--|--|
| | Zerena 9 – ZR9 | | |
| | GTIN:(01)05711584090473 | | |
| | Zerena 7 – ZR7 | | |
| | GTIN:(01)05711584090466 | | |
| | Zerena 5 – ZR5 | | |
| | GTIN:(01)05711584090459 | | |
| | Zerena 3 – ZR3 | | |
| | GTIN:(01)05711584094006 | | |
| | Zerena 1 – ZR1 | | |
| | GTIN:(01)05711584094013 | | |
| | | | |
| Ba | ttery size | | |
| | 10 🗆 312 🗆 13 | | |
| 2.4 | l GHz | | |
| | Yes □ No | | |
| | | | |
| NF | MI | | |
| | Yes □ No | | |
| St | yles | | |
| | IIC Invisible-In-the-Canal | | |
| П | CIC Completely-In-the-Canal | | |
| | ITC In-the-Canal | | |
| | ITE HS In-the-Ear Half Shell | | |
| _ | ITE FS In-the-Far Full Shell | | |

Introduction to this booklet

This booklet shows you how to use and maintain your new hearing aid. Please read the booklet carefully including the warning sections. This will help you to achieve the full benefit of your new hearing aid.

Your hearing care professional has adjusted the hearing aid to meet your needs. If you have further questions, please contact your hearing care professional.

Intended use

The hearing aid is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing within mild to severe hearing loss. This hearing aid is intended for use by adults and children older than 36 months.

IMPORTANT NOTICE

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

Identify your hearing aid

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

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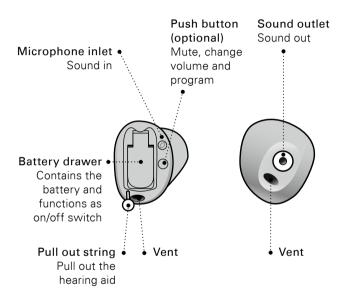
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Size 10 battery (CIC shown)

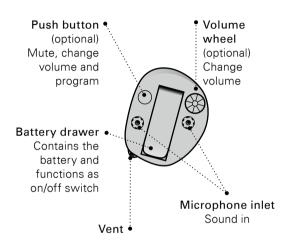
What it is and does

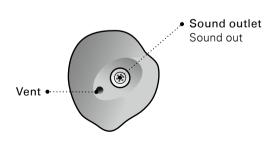


Components may be positioned differently on your hearing aid.

Size 312 battery (ITC shown)

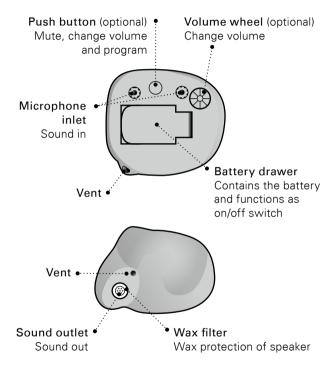
What it is and does





Size 13 battery (ITE HS shown)

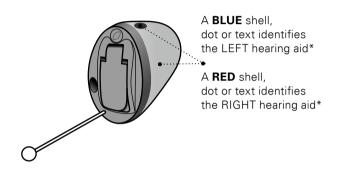
What it is and does



Components may be positioned differently on your hearing aid.

Identify left and right hearing aid

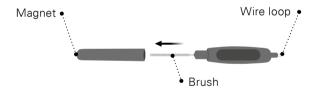
It is important to distinguish between the left and the right hearing aid as they might be shaped and programmed differently.



* Shell and dot is only available for IIC

MultiTool for handling batteries and cleaning

The MultiTool contains a magnet that makes it easier to replace the battery in the hearing aid. It also contains a brush and a wire loop for cleaning and removing ear wax from your earpiece. If you need a new MultiTool, please contact your hearing care professional.



IMPORTANT NOTICE

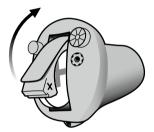
The MultiTool has a built-in magnet. Keep the MultiTool at least 30 cm away from credit cards and other magnetically sensitive devices.

Turn the hearing aid ON and OFF

The battery drawer is also used to switch the hearing aid on and off. To preserve the battery, make sure your hearing aid is switched off when you are not wearing it. If you wish to return to the standard settings of the hearing aid programmed by your hearing care professional, simply open and then close the battery drawer.



Turn ONClose the battery drawer with the battery in place



Turn OFFOpen the battery drawer

*

Whenever the hearing instrument is not in use for longer periods of time (e.g., at night), fully open the battery door to allow air to circulate and to make sure the hearing aid does not drain the battery.

When to replace a battery

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



Three beeps*
The battery is running low



Four beepsThe battery has run out

Battery tip

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

* If your hearing aid has Bluetooth® this will be turned off and it will not be possible to use wireless accessories.

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Batteries need to be replaced more often if you are streaming audio or music to your hearing aids.

Replace the battery

1. Remove

Fully open the battery drawer. Remove the battery.



2. Uncover

Remove the sticky label from the + side of the new battery.



Tip:

Wait 2 minutes so that the battery can draw air, to ensure optimal functioning.

3. Insert

Insert the new battery into the battery drawer.

Make sure the + side faces the + on the battery drawer.



4. Close

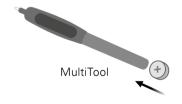
Close the battery drawer. The hearing aid will play a jingle through the earpiece. Hold the earpiece close to your ear to hear the jingle.



Tip

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

The MultiTool is provided by your hearing care professional.



Insert the hearing aid

Step 1

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



Step 2

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



Remove your hearing aid

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

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

IMPORTANT NOTICE

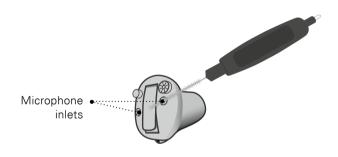
DO NOT use the battery door as a handle to insert or remove your hearing aid. It is not designed for this purpose.

Caring for your hearing aid

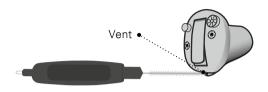
When handling your hearing aid, hold it over a soft surface to avoid damage if you drop it.

Cleaning the hearing aid

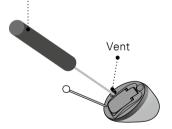
Carefully brush away debris from the microphone inlets with a clean brush. Gently brush the surface. Make sure that the filters do not fall off.



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



 If the vent is very small, a special tool may be required. Please consult your hearing care professional.



IMPORTANT NOTICE

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

Filter replacement

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

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

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

IMPORTANT NOTICE

Always use the same type of wax filter as was originally supplied with the hearing aid. If you are in any 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 ProWax miniFit filter.



2. Remove

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



3. Insert

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

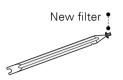


☐ Replace T-Cap filter

(hearing aids with size 10 batteries)

1. Tool

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



2. Remove

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



3. Insert

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



☐ Replace O-Cap filter

(hearing aids with size 312 and size 13 batteries)

1. Tool

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



2. Remove

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



3. Insert

Insert the new O-Cap filter using the other end of the tool. Discard the tool after use.



☐ Flight mode

(hearing aids with Bluetooth® and push button)

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

To activate and deactivate

Press the push button for at least 7 seconds. A jingle confirms your action.

Opening and closing the battery drawer for each hearing aid will also deactivate the flight mode.



Optional features and accessories

The features and accessories described on the following pages are optional. Please contact your hearing care professional to find out how your hearing aid is programmed. If you experience difficult listening situations, a special program may be helpful. These are programmed by your hearing care professional.

Write down any hearing situations in which you may

| need help. | | |
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☐ Change programs

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



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

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

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

To be filled out by the hearing care professional

Program change:

| ☐ Independer | nt 🗆 | Synchronized* |
|---------------|------|---------------|
| □ LEFT | | RIGHT |
| ☐ Short press | ; | Long press |

^{*} Only available for models with NFMI

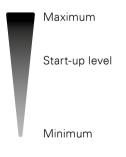
☐ Change volume with push button

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



A short press on the RIGHT hearing aid increases the volume

A short press on the LEFT hearing aid decreases the volume



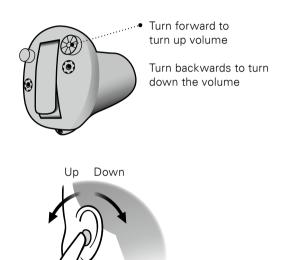
You will hear 2 beeps at the start-up level. You will hear 3 beeps at Maximum and Minimum.

To be filled out by the hearing care professional

Volume change ☐ LEFT ☐ RIGHT

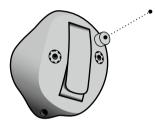
☐ Change volume with volume wheel

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



☐ Mute the hearing aid

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



Apply a very long press (4 seconds) to the push button to mute the hearing aid.

To reactivate the hearing aid, push the button briefly.

IMPORTANT NOTICE

Do not use the mute function as an off switch, as the hearing aid still draws current from the battery in this mode.

Using hearing aids with iPhone, iPad, and iPod touch

Your hearing aids are Made for iPhone® and allow for direct communication and control with an iPhone®, iPad® or iPod® touch.

For assistance in pairing and using these products with your hearing aid, please contact your hearing care professional or visit our support site at: www.bernafon.com/library.

Zerena is compatible with iPhone X, iPhone 8 Plus, iPhone 8, iPhone 7 Plus, iPhone 7, iPhone SE, iPhone 6s Plus, iPhone 6s, iPhone 6 Plus, iPhone 6, iPhone 5s, iPhone 5c, iPhone 5, 9.7-inch iPad Pro, 12.9-inch iPad Pro, iPad Air 2, iPad Air, iPad (4th generation), iPad mini 4, iPad mini 3, iPad mini 2, iPad mini, and iPod touch (5th and 6th generation). Devices must be running iOS 9.3 or later.

"Made for iPod", "Made for iPhone", and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod, iPhone, or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod, iPhone, or iPad may affect wireless performance.

Pairing hearing aid with iPhone

1. Settings



Open your iPhone and go to "Settings". Make sure Bluetooth® is on. Then choose "General".

2. General



On the "General" screen, choose "Accessibility".

3. Accessibility



On the "Accessibility" screen, choose "MFi Hearing Devices".

4. Prepare



Open and close the battery drawer on both hearing aids, and place them close to your iPhone. The hearing aids remain in pairing mode for 3 minutes.

5. Select



Your iPhone will detect the hearing aids for pairing. Detected devices will appear in your iPhone list. Choose your hearing aids.

6. Confirm pairing



Confirm pairing. If you have two hearing aids, pairing confirmation is needed for each hearing aid.

Re-connect your hearing aids to your iPhone, iPad, or iPod touch

When you turn off your hearing aids or Apple device, these will no longer be connected. To connect them again, turn on your hearing aids by opening and closing the battery door. The hearing aids will then automatically re-connect to your Apple device.

Bernafon EasyControl-A app

Bernafon EasyControl-A app for iPhone, iPad, iPod touch, and Android™ devices offers an intuitive and discreet way to control your hearing aid. Bernafon EasyControl-A app also enables you to connect and control an endless range of other devices by linking to IFTTT via the internet.

Go to www.bernafon.com/products/accessories for more details and information on compatibility. Bernafon EasyControl-A app is available on App Store® and on Google Play™. When downloading Bernafon EasyControl-A app on iPad, search for iPhone apps on App Store.

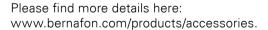
*

Direct audio streaming is currently not supported by Android.









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Wireless accessories (optional)

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

☐ SoundClip-A

When this device is paired with your mobile phone, you can use the hearing aids like stereo headphones. SoundClip-A can also function as a remote microphone and remote control.

□ TV-A

TV-A adapter is a wireless transmitter of sound from TV and electronic audio devices. The TV-A streams sound directly to your hearing aid.

☐ RC-A

RC-A remote control offers the ability to change programs, adjust volume or mute your hearing aid.

☐ Bernafon EasyControl-A app

Offers an intuitive and discreet way to control your hearing aids. For iPhone, iPad, iPod touch, and Android devices.

For more information, please contact your hearing care professional or visit: www.bernafon.com/products/accessories.

Other options

□ Telecoil – only optional for some styles*

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



☐ Auto Telephone – only optional for some styles

The Auto Telephone can automatically activate a phone program in the hearing aid, if your telephone has a dedicated magnet. The magnet needs to be placed on your telephone next to the sound outlet.



* Be aware that when you activate 2.4 GHz and Telecoil at the same time, an artifact sound can occur

For more information, please contact your hearing care professional.

| ☐ Tinnitus SoundSupport | (optional) |
|-------------------------|------------|
|-------------------------|------------|

Intended use of Tinnitus SoundSupport

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

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

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

Styles available with Tinnitus SoundSupport CIC, ITC, ITE HS & ITE FS for hearing aids with push button. Please see the model overview to find out which style your hearing aid is.

Guidelines for tinnitus sound generator users

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

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

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

Prescription use only

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

Sound options and volume adjustment

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

Tinnitus SoundSupport programs

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

Mute

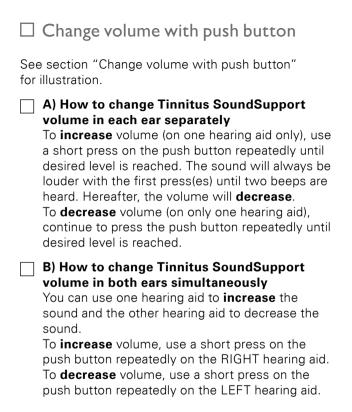
If you are in a program for which Tinnitus SoundSupport is activated, the mute functionality will mute only the environmental sounds, and not the sound from Tinnitus SoundSupport. See chapter: "Mute the hearing aid".

Volume adjustments with Tinnitus SoundSupport

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

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

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



To be filled out by your hearing care professional.

| Change volume with volume wheel |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| e section "Change volume with volume wheel" illustration. |
| A) How to change Tinnitus SoundSupport volume in each ear separately To increase volume (on one hearing aid only), turn the volume wheel forward. To decrease volume (on one hearing aid only), turn the volume wheel backwards. |
| B) How to change Tinnitus SoundSupport volume in both ears simultaneously You can use one hearing aid to increase/decrease the sound in both hearing aids. When changing the volume in one hearing aid, the volume on the other hearing aid will follow. To increase volume, turn the volume wheel forward. To decrease volume, turn the volume wheel |

To be filled out by your hearing care professional.

backwards.

☐ Hearing aid with Bluetooth®

If your hearing aid has Bluetooth® connection, you will be able to adjust the environmental sounds in a program with Tinnitus SoundSupport with EasyControl-A or SoundClip-A.

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

Limitation on use time

Daily use

The volume levels of Tinnitus SoundSupport can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Your hearing care professional will advise you of the maximum amount of time per day you should use Tinnitus SoundSupport. It should never be used at uncomfortable levels.

See table "Tinnitus SoundSupport: Limitation on use" at the end of this booklet to learn how many hours per day you can safely use the relief sound in your hearing aids.

Important information for hearing care professionals about Tinnitus SoundSupport

Device description

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

Maximum wearing time

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

The volume control is deactivated

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

If the volume control is activated

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

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

The Tinnitus SoundSupport is manufactured for Bernafon AG

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

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

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

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

Maximum wearing time

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

You should familiarize yourself fully with the following general warnings before using your hearing aid for your personal safety and to ensure correct use.

Please note that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Furthermore, note that in most cases, infrequent use of a hearing aid does not permit a user to attain full benefit from it.

Consult your hearing care professional if you experience unexpected operations or events with your hearing aid.

Usage of hearing aids

- Hearing aids should be used only as directed and adjusted by your hearing care professional. Misuse can result in sudden and permanent hearing loss.
- Never allow others to wear your hearing aid, as incorrect usage could cause permanent damage to their hearing.

Choking hazards & risk of swallowing batteries and other small parts

- Hearing aids, their parts, and batteries should be kept out of reach of children and anyone who might swallow these items or otherwise cause injury to themselves.
- Batteries have occasionally been mistaken for pills.
 Therefore, check your medicine carefully before swallowing any pills.
- Most hearing aids can be supplied with a tamperresistant battery drawer upon request. This is strongly recommended for infants, small children, and people with learning difficulties.
- Children younger than 36 months must always use a tamper-resistant battery drawer. Please talk to your hearing care professional about the availability of this option.

If a battery or hearing aid is swallowed, see a doctor immediately. Contact the National Poison Center at 1-800-222-1222 or National Battery Ingestion Hotline at 202-625-3333.

Battery use

- Always use batteries recommended by your hearing care professional. Batteries of low quality may leak and cause bodily harm.
- Never attempt to recharge your batteries, and never dispose of batteries by burning them.
 There is a risk that the batteries will explode.

Dysfunction

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

Active implants

- Caution must be taken with active implants.
 In general, follow the guidelines recommended by manufacturers of implantable defibrillators and pacemakers regarding use with mobile phones and magnets.
- The Auto Telephone magnet and MultiTool (which has a built-in magnet) should be kept more than 30 cm away from the implant, for example, do not carry it in a breast pocket.
- If you have an active brain implant, please contact the manufacturer of your implantable device for information about the risk of disturbance.

X-ray, CT, MR, PET scanning and electrotherapy

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

Heat and chemicals

- The hearing aid must never be exposed to extreme heat, for example, left inside a parked car in the sun.
- The hearing aid must not be dried in microwave ovens or other ovens.
- The chemicals in cosmetics, hairspray, perfume, aftershave lotion, suntan lotion and insect repellent can damage the hearing aid. Always remove your hearing aid before applying such products and allow time to dry before use.

Power instrument

 Special care should be exercised in selecting, fitting and using a hearing aid where maximum sound pressure capability exceeds 132 dB SPL (IEC 711), as there may be risk of impairing the remaining hearing of the hearing aid user.

For information on whether your hearing aid is a power instrument, see the "Model overview" section in the front of this booklet.

Possible side effects

- Hearing aids and earpieces may cause an accelerated accumulation of ear wax.
- The otherwise non-allergenic materials used in hearing aids may in rare cases cause a skin irritation or other side effects.

Please seek consultation with a physician if these conditions occur.

Interference

 The hearing aid has been thoroughly tested for interference, according to the most stringent international standards. However, interference between the hearing aid and other devices (e.g. some mobile telephones, citizens band systems and shop alarm systems and other devices) may occur. If this occurs, increase the distance between the hearing aid and the interfering device.

Use on aircraft

 Your hearing aid contains Bluetooth®. On board an aircraft, flight mode must be activated, unless Bluetooth® is permitted by the flight personnel.

Please see the model overview to see if your hearing aid has Bluetooth®.

Connection to external equipment

 The safety of the hearing aid when connected to external equipment with an auxiliary input cable and/or with a USB cable and/or directly, is determined by the external signal source. When connected to external equipment plugged into a wall outlet, this equipment must comply with IEC-62368 (or IEC-60065, IEC-60950 until June 20, 2019) or equivalent safety standards.

Warning to Hearing Aid Dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

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

Important Notice for Prospective Hearing Aid Users

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

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

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

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

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

Children with Hearing Loss

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

Troubleshooting guide

| Symptom | Possible causes |
|---------------------------------------|-----------------------------------|
| | Dead battery |
| No sound | Clogged sound outlet |
| NO Sound | Clogged microphone inlet |
| | Hearing aid microphone muted |
| | Clogged sound outlet |
| Intermittent or reduced sound | Moisture |
| | Dead battery |
| 0 | Hearing aid not inserted properly |
| Squealing noise | Ear wax accumulated in ear canal |
| Pairing issue with Apple device | Bluetooth® connection failed |
| | Only one hearing aid paired |

Solutions

Replace the battery

Clean sound outlet* or replace the wax filter

Clean microphone inlet* or replace filter (T-Cap or O-Cap)

Un-mute the hearing aid microphone

Clean sound outlet or replace the wax filter

Wipe battery and hearing aid with a dry cloth

Replace the battery

Re-insert the hearing aid

Have ear canal examined by your doctor

- Unpair your hearing aids
 (Settings → General → Accessibility → Hearing Devices → Devices → Forget this device).
- 2. Turn Bluetooth® off and on again.
- 3. Open and close battery drawer on hearing aids.
- Re-pair hearing aids (see section "Pair Hearing Aids with iPhone").

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

^{*} According to guideline in this booklet

Water & dust resistance (IP68)

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

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

IMPORTANT NOTICE

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

Conditions of use

| Operating conditions | Temperature: +34°F to +104°F Relative humidity: 5% to 93%, non-condensing |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Storage and transportation | Temperature and humidity should not exceed the following limits for extended periods during transportation and storage: |
| conditions | Temperature: -13°F to +140°F Relative humidity: 5 % to 93 %, non-condensing |

Warranty certificate

| Hearing care professional: | | |
|------------------------------------|--------------------|--|
| Hearing care professional | address: | |
| | | |
| Hearing care professional | ohone: | |
| | | |
| Purchase date: | | |
| Purchase date: Warranty period: | Month: | |
| | Month: Serial no.: | |

International warranty

Your hearing aid is covered by an international limited warranty issued by the manufacturer for a period of 12 months from the date of delivery. This limited warranty covers manufacturing and material defects in the hearing aid itself, but not in accessories such as batteries, tubing, speakers, earpieces and filters. etc. Problems arising from improper/incorrect handling or care, excessive use, accidents, repairs made by an unauthorized party, exposure to corrosive conditions, physical changes in your ear, damage due to foreign objects entering the device or incorrect adjustments are NOT covered by the limited warranty and may void it. The above warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods. Your hearing care professional may have issued a warranty that goes beyond the clauses of this limited warranty. Please consult him/her for further information

If you need service

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

Mobile Phone

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

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

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

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

The immunity of this hearing aid is at least M2/T2. The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

IMPORTANT NOTICE

The performance of individual hearing aids may vary with individual mobile phones. Therefore, please try this hearing instrument with your mobile 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 mobile phone provider for the booklet entitled "Hearing Aid Compatibility with Digital Wireless Cell Phones".

Technical information

The hearing aid contains two radio technologies, which are described below:

The hearing aid contains a radio transceiver using short range magnetic induction technology working at 3.84 MHz. The magnetic field strength of the transmitter is very weak and is always below –40 dBµA/m at a 10 meter distance.

The hearing aid also contains a radio transceiver using Bluetooth® Low Energy (BLE) and a proprietary short range radio technology both working at ISM band 2.4 GHz. The radio transmitter is weak and is always below 4.8 dBm e.i.r.p. in total radiated power.

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

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

Additional information can be found in the "Product Information" on www.bernafon.com.

USA and Canada

The hearing aid contains a radio module with the following certification ID numbers:

CIC NFMI instruments contain a module with:

FCC ID: U6XAUCIC IC: 7031A-AUCIC

ITC, ITE HS & ITE FS 2.4 GHz instruments contain a module with:

Battery size 13:

FCC ID: U6XAUITE13 IC: 7031A-AUITE13

Battery size 312:

FCC ID: U6XAUITE312 IC: 7031A-AUITE312

The device complies with Part 15 of the FCC Rules and with Industry Canada's licence-exempt RSSs.

Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This Class B digital apparatus complies with Canadian ICES-003.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

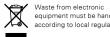
To comply with FCC RF exposure requirements, the device and the antenna for this device must be installed to ensure a minimum separation distance of 20 cm or more from a person's body. Other operating configurations should be avoided.

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

Declaration of Conformity is available from the manufacturer.

Bernafon AG Morgenstrasse 131 CH-3018 Bern Switzerland









IP68

Your individual hearing aid settings

To be filled out by your hearing care professional.

Settings overview for your hearing aid

| L | .eft | | Righ | nt |
|------|-------|-----------------------------|------|-------|
| Yes | □No | Volume control | Yes | □No |
| Yes | □No | Program shift | Yes | □No |
| Yes | □No | Mute | Yes | □No |
| Yes | □No | Tinnitus SoundSupport | Yes | □No |
| | V | olume control indicato | rs | |
| ☐ On | Off | Beeps at min/max volume | On | Off |
| On | ☐ Off | Clicks when changing volume | ☐ On | ☐ Off |
| On | Off | Beeps at preferred volume | ☐ On | ☐ Off |
| | | Battery indicators | | |
| On | Off | Low battery warning | ☐ On | Off |

Description of symbols used in this booklet or on the packaging label



Warnings

Text marked with a marking symbol must be read before using the product.



Manufacturer

The product is produced by the manufacturer whose name and address are stated next to the symbol. Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.



CE mark

The product complies with Medical Device Directive 93/42/EEC. The four digits number indicates the identification of the notified body.



Electronic waste (WEEE)

Recycle your hearing aids, accessories or batteries according to local regulations or return them to your hearing care professional for disposal.

Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).



Regulatory Compliance Mark (RCM)

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





This symbol indicates the class of protections against harmful ingress of water and particulate matter according to EN 60529:1991/A1:2002. IP6X indicates total dust protection. IPX8 indicates the protection against the effects of continuous immersion in water.

| ₿ Bluetooth [°] | Bluetooth® logo Registered trademark of Bluetooth® SIG, Inc. where any use of such requires a license. |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Made for & iPhone iPad iPod | Made for iPod, iPhone, and iPad Indicates that the device is compatible with iPod, iPhone and iPad. Description of symbols used on the packaging label. |
| * | Keep dry Indicates a medical device that needs to be protected from moisture. |
| | Caution symbol Consult instructions for use for warnings and cautions. |
| REF | Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified. |
| SN | Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified. |

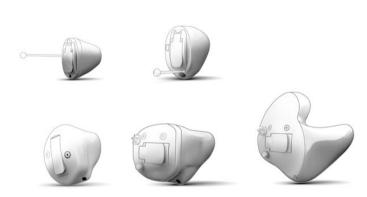
Tinnitus SoundSupport: Limitation on use

| □ No lim | nitation 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 |

Ref. OSHA (Occupational Safety & Health Administration, U.S. department of Labour) / DIRECTIVE 2003/10/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) / Occupational exposure to noise: evaluation, prevention and control – Special Report S 64, WHO.

Technical Data

In-the-Ear Hearing Aids (ITE) IIC, CIC, ITC, ITE HS, ITE FS



Additional Information

"2cc" refers to a coupler according to IEC 60318-5:2006. Applied standard: ANSI S3.22:2014.

Full-on gain is measured with the gain control of the hearing aid set to its full-on position minus 20 dB and with an input SPL of 70 dB. This is to obtain a gain response equal to the full-on gain response from e.g. IEC 60118-0+A1:1994 but without influence of feedback.

2CC COUPLER¹⁾

| Zerena 9 | IIC | | CIC | |
|--------------------------------|------------|------------|------------|------------|
| | 75-Speaker | 85-Speaker | 75-Speaker | 85-Speaker |
| OSPL90, HFA (dB SPL) | 102 | 113 | 104 | 115 |
| Full-on Gain, HFA (dB) | 38 | 46 | 42 | 49 |
| Reference Test Gain (dB) | 26 | 37 | 27 | 38 |
| Operating Current (mA) | 1.1 | 1.4 | 1 | 1.3 |
| Distortion 500/800/1600 Hz (%) | 2 2 2 | <2 2 <2 | 1 1 2 | <2 <2 2 |
| Frequency Range (Hz) | 100–9200 | 100–9200 | 100–7000 | 100–9000 |
| Equivalent Input Noise1) dB(A) | 18 | 18 | 19 | 17 |
| Release Time (ms) | <30 | <45 | <25 | <35 |
| Attack Time (ms) | < 5 | <5 | <5 | <5 |

| Zerena 7 5 3 1 | IIC | | CIC | |
|--------------------------------------------|------------|------------|------------|------------|
| | 75-Speaker | 85-Speaker | 75-Speaker | 85-Speaker |
| OSPL90, HFA (dB SPL) | 102 | 113 | 104 | 115 |
| Full-on Gain, HFA (dB) | 38 | 46 | 42 | 49 |
| Reference Test Gain (dB) | 26 | 37 | 27 | 38 |
| Operating Current (mA) | 1.1 | 1.4 | 1 | 1.3 |
| Distortion 500/800/1600 Hz (%) | 2 2 2 | <2 2 <2 | 1 1 2 | <2 <2 2 |
| Frequency Range (Hz) | 100-7500 | 100–7500 | 100–7000 | 100–7500 |
| Equivalent Input Noise ¹⁾ dB(A) | 18 | 18 | 19 | 17 |
| Release Time (ms) | <30 | < 45 | <25 | <35 |
| Attack Time (ms) | <5 | <5 | <5 | <5 |

 $^{^{\}rm II}$ Technical data measured with expansion, corresponding to the test box measurement settings.

2CC COUPLER¹⁾

Zerena 9 - ITC, ITE HS, ITE FS

| | 75-Speaker | 85-Speaker | 90-Speaker | 100-Speaker |
|--------------------------------|------------|------------|------------|-------------|
| OSPL90, HFA (dB SPL) | 103 | 112 | 116 | 122 |
| Full-on Gain, HFA (dB) | 41 | 47 | 50 | 58 |
| Reference Test Gain (dB) | 27 | 35 | 39 | 45 |
| Operating Current (mA) | 1.8 | 1.9 | 1.8 | 1.8 |
| Distortion 500/800/1600 Hz (%) | <2 <2 <2 | <2 <2 <2 | <2 <2 <2 | <2 <2 <2 |
| Frequency Range (Hz) | 100-7500 | 100–8800 | 100–7900 | 100–7100 |
| Equivalent Input Noise1) dB(A) | 16 | 15 | 15 | 15 |
| Telecoil HFA SPLITS (dB SPL) | 83 | 92 | 96 | 103 |
| Release Time (ms) | <25 | <35 | <25 | < 15 |
| Attack Time (ms) | <5 | <5 | <5 | <5 |

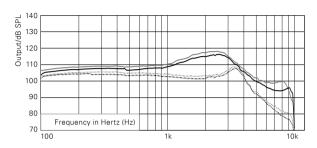
Zerena 7|5|3|1 - ITC, ITE HS, ITE FS

| | 75-Speaker | 85-Speaker | 90-Speaker | 100-Speaker |
|--------------------------------|------------|------------|------------|-------------|
| OSPL90, HFA (dB SPL) | 103 | 112 | 116 | 122 |
| Full-on Gain, HFA (dB) | 41 | 47 | 50 | 58 |
| Reference Test Gain (dB) | 27 | 35 | 39 | 45 |
| Operating Current (mA) | 1.8 | 1.9 | 1.8 | 1.8 |
| Distortion 500/800/1600 Hz (%) | <2 <2 <2 | <2 <2 <2 | <2 <2 <2 | <2 <2 <2 |
| Frequency Range (Hz) | 100–7500 | 100–7500 | 100–7500 | 100–7100 |
| Equivalent Input Noise1) dB(A) | 16 | 15 | 15 | 15 |
| Telecoil HFA SPLITS (dB SPL) | 83 | 92 | 96 | 103 |
| Release Time (ms) | <25 | <35 | <25 | <15 |
| Attack Time (ms) | <5 | <5 | <5 | < 5 |

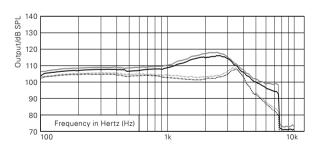
 $^{^{\}rm II}$ Technical data measured with expansion, corresponding to the test box measurement settings.

2CC COUPLER - OSPL 90

Zerena 9 - IIC/CIC



Zerena 7|5|3|1 - IIC/CIC

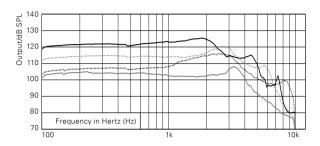


Legend:

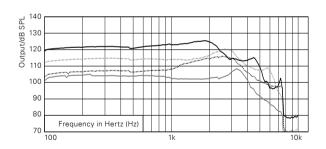
85-Speaker CIC 85-Speaker IIC 75-Speaker CIC 75-Speaker IIC

2CC COUPLER - OSPL 90

Zerena 9 - ITC, ITE HS, ITE FS



Zerena 7|5|3|1 - ITC, ITE HS, ITE FS

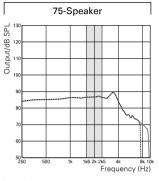


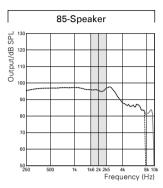
Legend:

- 100-Speaker ITC, ITE HS, ITE FS
 90-Speaker ITC, ITE HS, ITE FS
 85-Speaker ITC, ITE HS, ITE FS
- _____ 75-Speaker ITC, ITE HS, ITE FS

2CC COUPLER - FREQUENCY RESPONSE CURVE

Zerena 9|7|5|3|1 - IIC

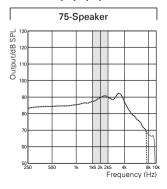


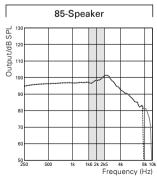


Legend:

ZR 9 ZR 7|5|3|1

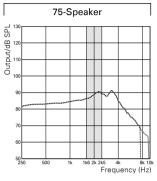
Zerena 9|7|5|3|1 - CIC

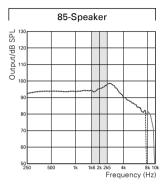




2CC COUPLER - FREQUENCY RESPONSE CURVE

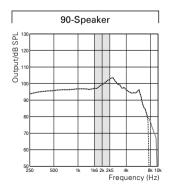
Zerena 9|7|5|3|1 - ITC, ITE HS, ITE FS

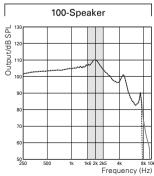




Legend:

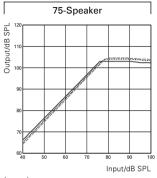
ZR 9 ZR 7|5|3|1

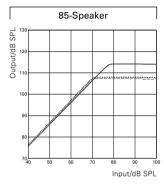




2CC COUPLER - INPUT-OUTPUT CURVE

Zerena 9|7|5|3|1 - IIC

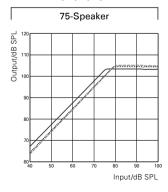


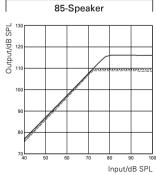


Legend: _____ 1600 Hz 800 Hz

500 Hz

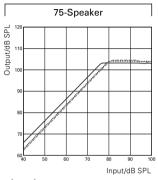
Zerena 9|7|5|3|1 - CIC

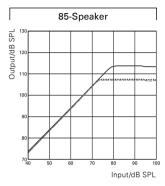


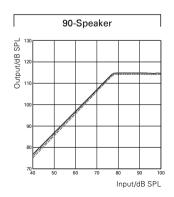


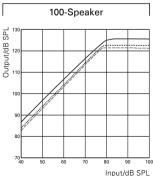
2CC COUPLER - INPUT-OUTPUT CURVE

Zerena 9|7|5|3|1 - ITC, ITE HS, ITE FS









| Notes |
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United States of America

Bernafon, LLC 2501 Cottontail Lane Somerset, NJ 08873 Phone +1 888-941-4203 info@bernafon-us.com



Bernafon AG Morgenstrasse 131 3018 Bern Switzerland Phone +41 31 998 15 15 info@bernafon.com www.bernafon.com



