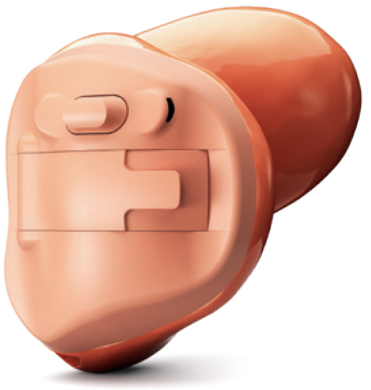
Brio 5 I

User Guide





Phonak Brio™ 5 I-312/10 NW 0

This user guide is valid for:

Wireless model
Phonak Brio 5 I-312

Non wireless model
Phonak Brio 5 I-10 NW 0

CE 0459

Your hearing aids have been developed by Phonak – the world leader in hearing solutions based in Zurich, Switzerland.

These premium products are the result of decades of research and expertise and are designed with your well-being in mind. We thank you for making such a great choice and wish you many years of listening pleasure.

Please read the user guide carefully to make sure that you understand and get the best out of your device. Training is not required for handling of this device. A hearing care professional will help set up this device according to your individual preferences during the fitting consultation.

For more information regarding features, benefits, set up, use, maintenance or repairs of your hearing aid and accessories, please contact your hearing care professional or the manufacturer representative. Additional information can be found in the data sheet of your product.

Your hearing aid details

ⓘ If no box is checked and you do not know the model of your hearing aid, please ask your hearing care professional.

ⓘ Your Brio 5 I-312 hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 14.

Model	Battery size
☐ Phonak Brio 5 I-312	312
☐ Phonak Brio 5 I-10 NW 0	10

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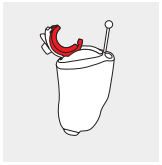
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1. Quick guide

Left and right hearing aid markings



Left

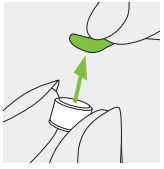


Right

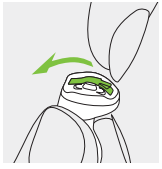
Blue marking for **left hearing aid.**

Red marking for **right hearing aid.**

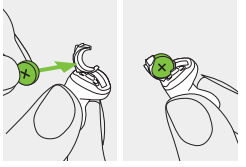
Changing batteries



1.
Remove the sticker from the new battery and wait two minutes.

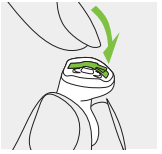


2.
Open the battery door.

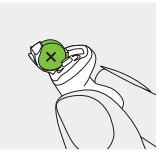


3.
Place battery in the battery door with the "+" symbol facing upwards.

On/Off

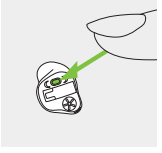


On



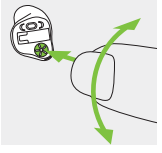
Off

Push button



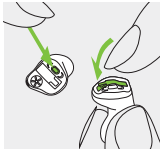
Models with this option only:
The push button on your hearing aid can have various functions.

Volume control



Models with this option only:
To increase the volume, turn the volume control forwards. To decrease the volume, turn the volume control backwards.

Flight mode Brio 5 I-312



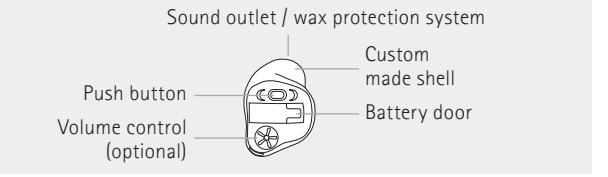
To enter flight mode press the push button for 7 seconds while closing the battery door. To exit flight mode, simply open and close the battery door again.

2. Parts of the hearing aid

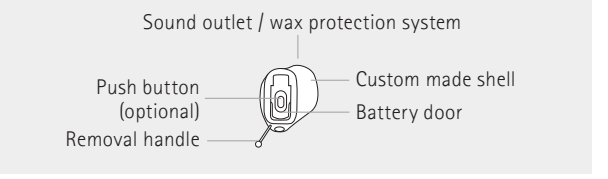
The following pictures show the models described in this user guide. You can identify your personal model by:

- Checking "Your hearing aid details" on page 5.
- Or comparing your hearing aid with the following shown models. Pay attention to the shape of the hearing aid and if a volume control is present.

Brio 5 I-312



Brio 5 I-10 NW O



3. Left and right hearing aid markings

There is a red or blue marking to tell you if it is a left or a right hearing aid. The color mark is located on the battery door, on the shell (text printed in red or blue) or shell is colored red or blue.

Blue marking for **left hearing aid.**



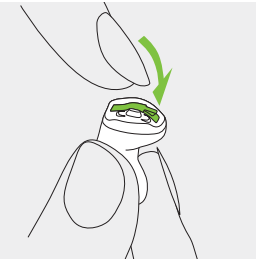
Red marking for **right hearing aid.**



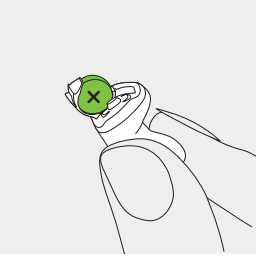
4. On/Off

The battery door is also the on/off switch.

1.
Closed battery door = hearing aid is **on**

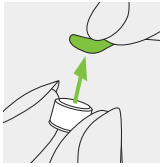


2.
Opened battery door = hearing aid is **off**

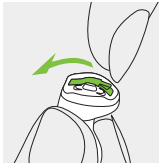


ⓘ When you switch on the hearing aid you may hear a start-up melody.

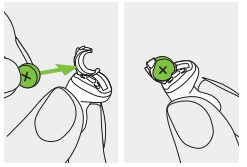
5. Batteries



1.
Remove the sticker from the new battery and wait two minutes.



2.
Open the battery door.



3.
Place battery in the battery door with the "+" symbol facing upwards.

ⓘ If it is difficult to close the battery door: Check that the battery is inserted correctly and the "+" symbol is facing upwards. If the battery is not inserted correctly, the hearing aid will not work and the battery door can be damaged.

Low power: You will hear two beeps when the battery is low. You will have approximately 30 minutes to change the battery (this can vary, depending on the hearing aid settings and battery). We recommend that you always have a new battery on hand.

Replacement battery
This hearing aid requires zinc-air batteries. Identify the correct battery size (312 or 10) by:

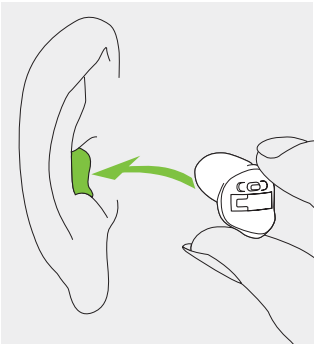
- Checking "Your hearing aid details" on page 5.
- Checking the marking on the inner side of the battery door.
- Checking the following table.

Model	Zinc air battery size	Color marking on package	IEC code	ANSI code
Phonak Brio 5				
I-312	312	brown	PR41	7002ZD
I-10 NW 0	10	yellow	PR70	7005ZD

ⓘ Please ensure you use the correct type of battery in your hearing aids (zinc-air). Please also read chapter 21.2 for further information on product safety.

6. Putting on the hearing aid (all models)

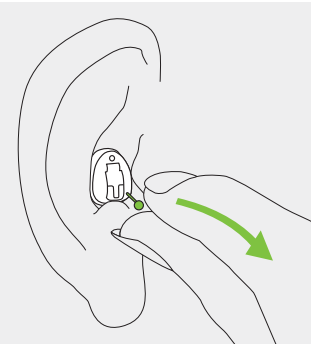
1.
Take your hearing aid up to your ear and place the ear canal part into your ear canal.



7. Removing the hearing aid

7.1 Removing the hearing aid with a removal handle

1.
Hold the removal handle and carefully pull the hearing aid up and out of the ear.

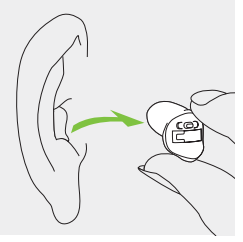


7.2 Removing the hearing aid without a removal handle

1.
Put your thumb behind your lobe and gently press your ear upward to push the hearing aid out of the canal. In order to help it along, make chewing movements with your jaw.

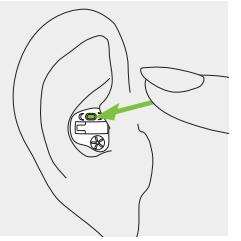


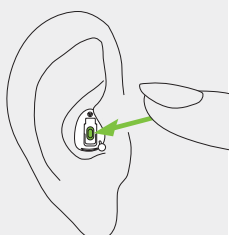
2.
Grasp the protruding hearing aid and remove it.



8. Push button

Models with this option only:
The push button on your hearing aid can have various functions or is not active. This depends on the programming of the hearing aid, which is indicated in your individual "Hearing aid instructions." Please ask your hearing care professional for this printout.

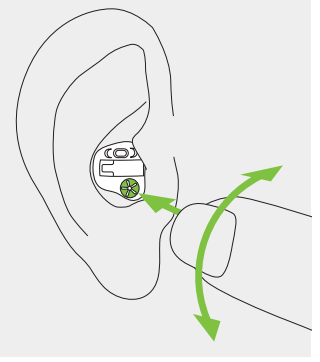




Brio 5 I-312:
If your hearing aid is paired with a Bluetooth® enabled phone, a short press on the push button will accept an incoming call and a long press will reject an incoming call – refer to chapter 13.

9. Volume control

Models with this option only:
To increase the volume, turn the volume control forwards (towards nose). To decrease the volume, turn the volume control backwards (towards back of head). The volume control can be disabled by the hearing care professional.

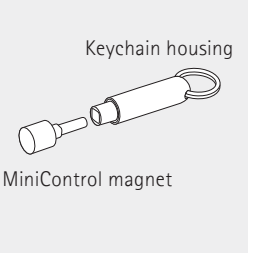


10. Adjusting Brio 5 I-10 NW 0 with MiniControl

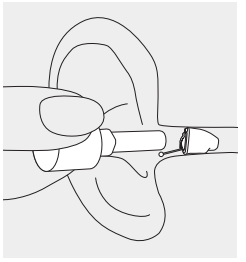
The MiniControl contains a magnet that functions like a remote control to change the settings of your Brio 5 I-10 NW 0.

Your Brio 5 I-10 NW 0 in combination with MiniControl can have various functions or can remain inactive. This depends on your individual settings, which are indicated in your individual "Hearing aid instructions." Please ask your hearing care professional for this print out.

To use the MiniControl, unscrew the magnet from the keychain housing and hold it inside the ear canal without touching the hearing aid.



While the hearing aid is on, hold the magnet inside the ear canal without touching the hearing aid. Promtly remove the magnet as soon as your Brio 5 I-10 NW 0 is in the desired program or the volume is ideal for you.

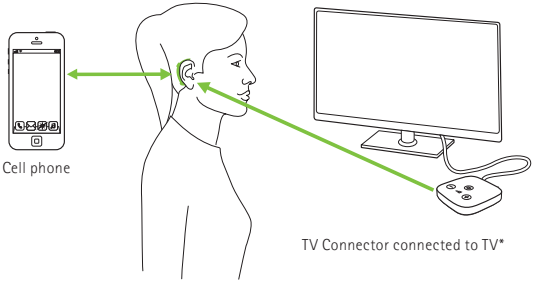


ⓘ If you use a medical device like a pacemaker or ICD device (implantable cardioverter defibrillator), please read the specific user guide to clarify possible impact of magnetic fields to your medical device.

ⓘ Do not place the MiniControl (neither open nor closed) in your breast pocket. Keep a distance of at least 15 cm (6 inches) between the MiniControl and any medical device.

11. Connectivity overview Brio 5 I-312

The illustration below shows the connectivity options available for your hearing aid.



* The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.

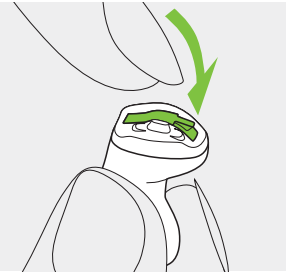
12. Initial pairing Brio 5 I-312

12.1 Initial pairing to Bluetooth® enabled device

ⓘ It is only necessary to perform the pairing procedure once with each device featuring Bluetooth wireless technology. After the initial pairing, your hearing aids will connect automatically to the device. This can take up to 2 minutes.

1.
On your device (e.g. a phone), ensure that Bluetooth wireless technology is enabled and search for Bluetooth enabled devices in the connectivity setting menu.

2.
Switch on both hearing aids. You now have 3 minutes to pair your hearing aids with your device.



3.
Select the hearing aid in the list of Bluetooth enabled devices. This will pair both hearing aids simultaneously. A beep confirms successful pairing.

ⓘ For more information about pairing instructions for Bluetooth wireless technology, specific to some of the most popular phone manufacturers, contact your hearing care professional.

12.2 Connecting to the device

After your hearing aids have been paired to your device, they will automatically connect again when switched on.

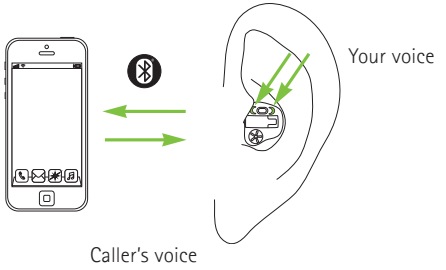
ⓘ The connection will be maintained as long as the device remains ON and within range.

ⓘ Your hearing aids can be paired to up to two devices.

ⓘ Your hearing aids can be connected to one device at a time.

13. Phone calls Brio 5 l-312

Your hearing aids connect directly with Bluetooth® enabled phones. When paired and connected to your phone, you will hear the caller's voice directly in your hearing aids. Your hearing aids pick up your voice through their own microphones.



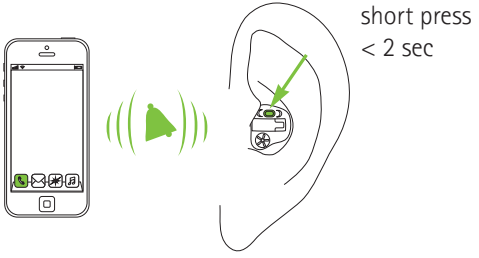
Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc.

13.1 Making a call

Enter the phone number and press the dial button.
You will hear the ring tone through your hearing aids.
Your hearing aids pick up your voice through their own microphones.

13.2 Accepting a call

When receiving a call, a calling notification will be heard in the hearing aids. The call can be accepted by a short press on the push button on the hearing aid (less than 2 seconds) or directly on your phone.



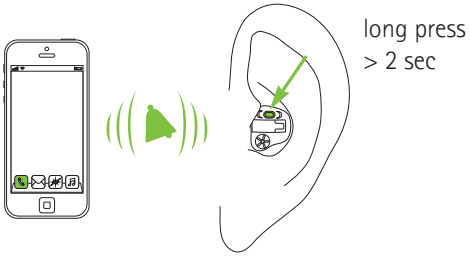
13.3 Ending a call

A call can be ended by a long press on the push button on the hearing aid (more than 2 seconds) or directly on your phone.



13.4 Rejecting a call

An incoming call can be rejected by a long press on the push button on the hearing aid (more than 2 seconds) or directly on your phone.



14. Flight mode Brio 5 I-312

Your hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying some operators require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

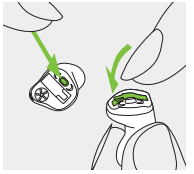
14.1 Enter flight mode

To disable the wireless function and enter flight mode in each hearing aid:



1.
Open battery door.

2.
Hold down the push button on the hearing aid for 7 seconds while closing the battery door.



In flight mode, your hearing aid cannot connect directly to your phone.

14.2 Exit flight mode

To enable the wireless function and exit flight mode in each hearing aid:

1.
Open battery door.



2.
Close the battery door again.



15. Care and maintenance

Diligent and routine care of your hearing aid contributes to outstanding performance and a long service life. To ensure a long service life, Sonova AG provides a minimum of a five year service period after phase out of the respective hearing aid.

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 21.2.

General information
Before using hair spray or applying cosmetics, you should remove your hearing aid from your ear, because these products may damage it.

Daily

Daily cleaning and the use of a drying system is highly recommended. C&C line from Phonak is a complete set of cleaning products. Your hearing care professional will be glad to advise you. Never use household cleaning products (washing powder, soap, etc.) to clean your hearing aids.

If your hearing aid is performing weakly or fails to operate, clean or replace the wax guard system. If your hearing aid fails to operate after you have correctly cleaned or replaced your wax protection system and inserted new batteries, contact your hearing care professional for advice.

Weekly

For more in depth maintenance instructions or for more than basic cleaning, please see your hearing care professional.

16. Operating, transport and storage conditions

The product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in this user guide.

Please ensure to use, transport and store the hearing aids according to the following conditions:

	Use	Transport	Storage
Temperature	0° to +40°C (32° to 104°F)	-20° to +60°C (-4° to 140°F)	-20° to +60°C (-4° to 140°F)
Humidity	0% to 85% (non condensing)	0% to 70% (non condensing)	0% to 70% (non condensing)
Atmospheric pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

Phonak Brio 5 I-10 NW 0 hearing aids are classified as IP68. This means that they are water and dust resistant and designed to withstand daily life situations. It can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities. The hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

17. Service and warranty

Local warranty
Please ask the hearing care professional where you purchased your hearing aid about the terms of the local warranty.

International warranty
Sonova AG offers a one year limited international warranty, valid starting from the date of purchase. This limited warranty covers manufacturing and material defects in the hearing aid itself, but not accessories such as batteries, tubes, earmolds and external receivers. The warranty only comes into force if a proof of purchase is shown.

The international warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods.

Warranty limitation
This warranty does not cover damage from improper handling or care, exposure to chemicals or undue stress. Damage caused by third parties or non-authorized service centers renders the warranty null and void. This warranty does not include any services performed by a hearing care professional in their office.

Serial number (left side):

Authorized hearing care professional (stamp/signature):

Serial number (right side):

Date of purchase:

18. Compliance information

Europe:

Declaration of Conformity
Hereby Sonova AG declares that this product meets the requirements of the the Medical Devices Regulation(EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The full text of the EU Declaration of Conformity can be obtained from the manufacturer or the local Phonak representative whose address can be taken from the list on www.phonak.com/us/en/certificates (Phonak worldwide locations).

Australia/New Zealand:



R-NZ

Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia.

The compliance label R-NZ is for radio products supplied in the New Zealand market under conformity level A1.

The wireless models listed on page 2 are certified under:

Phonak Brio 5 I-312, models M / P / SP / UP

USA	**FCC ID:** KWC-VTP
Canada	**IC:** 2262A-VTP

Notice 1:
This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:
1) this device may not cause harmful interference, and
2) this device must accept any interference received, including interference that may cause undesired operation.

Notice 2:
Changes or modifications made to this device not expressly approved by Sonova AG may void the FCC authorization to operate this device.

Notice 3:
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 and ICES-003 of Industry Canada. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in

accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and 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 device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Radio information of your hearing aid

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DPSK, GMSK
Radiated power	< 1 mW
Bluetooth®	
Range	~1m
Bluetooth	4.2 Dual-Mode
Profiles supported	HFP (Hands-free profile), A2DP

Compliance with emission and immunity standards

Emission standards	EN 60601-1-2
	IEC 60601-1-2
	EN 55011
	CISPR11
	CISPR32

Immunity standards	EN 60601-1-2
	IEC 60601-1-2
	EN 61000-4-2
	IEC 61000-4-2
	EN IEC 61000-4-3
	IEC 61000-4-3
	EN 61000-4-4
	IEC 61000-4-4
	EN 61000-4-5
	IEC 61000-4-5
	EN 61000-4-6
	IEC 61000-4-6
	EN 61000-4-8
	IEC 61000-4-8
	EN 61000-4-11
	IEC 61000-4-11
	IEC 60601-1

19. Information and description of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation and directive.



This symbol indicates that the products described in these user instructions adhere to the requirements for an applied part of Type B of EN 60601-1. The surface of the hearing aid is specified as an applied part of Type B.



Indicates the medical device manufacturer, as defined in the Medical Devices Regulation 2017/745.

	Indicates the date when the medical device was manufactured.
EC REP	Indicates the Authorized representative in the European Community. The EC REP is also the importer to the European Union.
	This symbol indicates that it is important for the user to read and take into account the relevant information in these user guides.
	This symbol indicates that it is important for the user to pay attention to the relevant warning notices in these user guides.
	This symbol indicates that it is important for the user to pay attention to the relevant warning notices related to batteries in these user guides.

	Important information for handling and product safety.
	This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.
	Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia.
Bluetooth®	The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Sonova AG is under license. Other trademarks and trade names are those of their respective owners.

	The Compliance Identification Mark indicates that the device is in accordance with Brazilian conformity assessment requirements for equipment under health surveillance system. OCP indicates the certification body.
	Japanese mark for certified radio equipment.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF	Indicates the manufacturer's serial number so that a specific medical device can be identified.
MD	Indicates that the device is a medical device.

	This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide.
IP68	Ingress Protection Rating. IP68 rating indicates that the hearing aid is water and dust resistant. It survived continuous immersion in 1 meter of water for 60 minutes and 8 hours in a dust chamber as per the IEC60529 standard.
	Temperature during transportation and storage: –20° to +60° Celsius (–4° to +140° Fahrenheit).
	Humidity during transportation and storage: 0% to 70%, if not in use. See instruction in chapter 21.2 regarding drying the hearing aid after use.

	Atmospheric pressure during transportation and storage: 500 hPa to 1060 hPa
	During transportation keep dry.
	The symbol with the crossed-out garbage bin is to make you aware that this hearing aid may not be thrown away as normal household waste. Please dispose of old or unused hearing aids, at waste disposal sites intended for electronic waste, or give your hearing aid to your hearing care professional for disposal. Proper disposal protects the environment and health.

20. Troubleshooting

Problem	Causes	What to do
Hearing aid not functioning	Dead battery	Change battery (chapter 5)
	Blocked sound outlet	Clean sound outlet
	Battery not inserted correctly	Insert battery correctly (chapter 5)
	Hearing aid switched off	Switch hearing aid on by completely closing the battery door (chapter 4)
Hearing aid whistles	Hearing aid not inserted correctly	Insert hearing aid correctly (chapter 6)
	Earwax in ear canal	Contact your ENT/GP or hearing care professional
Hearing aid too loud	Volume too loud	Decrease volume if volume control available (chapter 8 + 9)
Hearing aid not loud enough or distorted	Low battery	Change battery (chapter 5)
	Blocked sound outlet	Clean sound outlet
	Volume too low	Turn volume up if volume control available (chapter 8 + 9)
	Physical hearing condition has changed	Contact your hearing care professional
Hearing aid plays two beeps	Indication for low battery	Change battery within the next 30 minutes (chapter 5)
Hearing aid switches on and off (intermittent)	Moisture on battery or hearing aid	Wipe battery and hearing aid with dry cloth
Phone call function does not work (Brio 5 I-312 only)	Hearing aid is in flight mode	Open and close battery door (chapter 14.2)
	Hearing aid not paired to the phone	Pair it to the phone (chapter 12)

ⓘ If the problem persists, contact your hearing care professional for assistance.

21. Important safety information

Please read the information and limitations-of-use information on the following pages before using your hearing aid.

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Infrequent use of a hearing aid does not permit a user to attain full benefit from it. The use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

Hearing aids are suitable for the home healthcare environment and due to their portability it may happen that they are used in professional healthcare facility environments like physician offices, dental offices, etc.

Feedback, poor sound quality, too loud or too soft sounds, inadequate fitting or problems when chewing or swallowing, can be resolved or improved during the fine-tuning process at the fitting procedure by your hearing care professional.

Any serious incident that has occurred in relation to the hearing aid, should be reported to the manufacturer representative and the competent authority of the state of residence. The serious incident is described as any incident that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat

To report an unexpected operation or event, please contact the manufacturer or a representative.

Intended use:
The hearing aid is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

The Tinnitus Balance software feature is intended for use by people with tinnitus who also desire amplification. It provides supplementary noise stimulation which can help defocus the user's attention from their tinnitus.

Intended patient population:
This device is intended for patients with unilateral and bilateral, mild to profound hearing loss from 18 years of age. The Tinnitus feature is intended for patients with chronic tinnitus from 18 years of age.

Intended user:
Intended for people with hearing loss using a hearing aid and their caregivers. A hearing care professional is responsible for adjusting the hearing aid.

Indications:
General clinical indications for the use of hearing aids and Tinnitus software feature are:

- Presence of hearing loss
- Uni- or bilateral
- Conductive, sensorineural or mixed
- Mild to profound
- Presence of a chronic tinnitus (only applicable for devices which provide the Tinnitus software feature)

Contraindications:
General clinical contra-indications for the use of hearing aids and Tinnitus software feature are:

- Hearing loss is not in the fitting range of the hearing aid (i.e. gain, frequency response)
- Acute tinnitus
- Deformity of the ear (i.e. closed ear canal)
- Neural hearing loss

The primary criteria for the referral of a patient for a medical or other specialist opinion and / or treatment are as follows:

- Visible congenital or traumatic deformity of the ear;
- History of active drainage from the ear in the previous 90 days;
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days;
- Acute or chronic dizziness;
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz;
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;
- Pain or discomfort in the ear;
- Abnormal appearance of the eardrum and ear canal such as:
  - Inflammation of the external auditory canal
  - Perforated eardrum
  - Other abnormalities which the hearing care professional believes are of medical concern

The hearing care professional may decide that referral is not appropriate or in the best interest of the patient when the following applies:

- When there is sufficient evidence that the condition has been fully investigated by a medical specialist and any possible treatment has been provided;
- The condition has not worsened or changed significantly since the previous investigation and / or treatment.
- If the patient has given their informed and competent decision not to accept advice to seek a medical opinion, it is permissible to proceed to recommend appropriate hearing aid systems subject to the following considerations:
  - The recommendation will not have any adverse effects on the patients health or general well being;
  - The records confirm that all necessary considerations about the patient's best interest have been made. If legally required, the patient has signed a disclaimer to confirm that the referral advice has not been accepted and that it is an informed decision.

Clinical benefit:
Hearing aid: Improvement of speech understanding.
Tinnitus feature: Tinnitus feature provides supplementary noise stimulation which can help defocus the user's attention from their tinnitus.

Side effects:
Physiological side-effects of hearing aids like tinnitus, dizziness, wax build up, too much pressure, sweating or moisture, blisters, itching and/or rashes, plugged or fullness and their consequences like headache and/ or ear pain, may be resolved or reduced by your hearing care professional.

Conventional hearing aids have the potential to expose patients to higher levels of sound exposure, which might result in threshold shifts in the frequency range affected by acoustic trauma.

21.1 Hazard warnings

⚠ Your Brio 5 I-312 hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 14.

⚠ Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.

⚠ Do not use the hearing aids in explosive areas (mines or industrial areas with danger of explosions, oxygen-rich environments or areas where flammable anesthetics are handled). This device is not ATEX certified.

⚠ WARNING: Device batteries are hazardous and can cause serious injuries if they are swallowed or placed inside any part of the body, whether the battery is used or new! Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!

⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.

⚠ In very rare cases if not securely attached, a cerumen stop can remain in your ear canal when removing the hearing aid from the ear. In the unlikely case that such part gets stuck in your ear canal, it is strongly recommended to see a physician for safe removal.

⚠ Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.

⚠ This hearing aid is not for children below 36 months. The hearing aid is a small device and contains small parts. Do not leave children, individuals with cognitive impairment or pets unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can be choking or poisonous hazard.

⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):

- Keep the wireless device at least 15 cm (6 inches) away from the active implant. If you experience any interference do not use the wireless hearing aids and contact the manufacturer of the active implant. Please, note that the interference can also be caused by powerlines, electrostatic discharge, airport metal detectors etc.
- Keep magnets (i.e. battery handling tool, EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Brio 5 I-312 only: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ Avoid strong physical impacts to the ear when wearing in-the-ear hearing aids. The stability of in-the-ear shells is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the in-the-ear shell to break. This may lead to perforation of the ear canal or ear drum.

⚠ After mechanical stress or shock to the hearing aid, please ensure that the hearing aid shell is intact before placing it in the ear.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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⚠ The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.

⚠ Patients implanted with magnetic externally programmable CSF shunt valves may have a risk of experiencing an unintended change in their valve setting when exposed to strong magnetic fields. The receiver (loudspeaker) of hearing aids, the Lyric SoundLync, the Lyric programming wand and the MiniControl contain static magnets. Keep a distance of 2 inches (approx. 5 cm) or more between the magnets and the site of the implanted shunt valve.

⚠ The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.

21.2 Information on product safety

ⓘ Phonak hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! These hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aid before these activities, as the hearing aid contains sensitive electronic parts. Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.

ⓘ Protect your hearing aid from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.

ⓘ When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.

ⓘ Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.

ⓘ Always use new batteries for your hearing aid. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.

ⓘ The batteries used in these hearing aids should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your hearing aids.

ⓘ Remove the battery if you are not using your hearing aid for a long period of time.

ⓘ Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your hearing aids. Remove and keep them outside the examination room/area before undergoing:

- Medical or dental examination with X-ray (also CT scan).
- Medical examinations with MRI/NMRI scans, generating magnetic fields.
- Hearing aids don't need to be removed when passing security gates (airports etc.). If X-ray is used at all, it will be in very low doses, and will not affect the hearing aids.

ⓘ Do not use your hearing aid in areas where electronic equipment is prohibited.

ⓘ Do not kink or buckle the removal handle. Repeated stress to the removal handle may cause it to break. In case of a broken removal handle the battery door may exceptionally be used to carefully pull the hearing aid out of the ear canal.

22. For the US market only, complies with the FDA regulations

Important information: Cell phones

Some hearing aid users have reported a buzzing sound in their hearing aids when they are using cell phones. According to the ANSI 63.19 (American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Instruments) standard, the compatibility of a particular hearing aid and cell phone can be predicted by adding the rating for the hearing aid immunity to the rating for the cell phone emissions. The sum of the hearing aid rating (e.g. M2/T2=2) and the telephone rating (e.g. M3/T3=3) is 5, and any combination that equals 5 will provide "normal use"; a sum of 6 or greater would indicate "excellent performance". The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied. The immunity of this hearing aid is at least M2/T2.

Note: the performance of individual hearing aids may vary with individual cell phones. Therefore, please try the 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 hearing care professional for the booklet entitled "hearing aid compatibility with digital wireless cell phones."

Important information in case of battery ingestion

If a battery is swallowed, call the 24-hour National Battery Ingestion Hotline at 202-625-3333 or consult your physician immediately.

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 the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

Children with hearing loss

In addition to seeing a physician for a 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 the 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.

Your hearing care professional:

EC REP

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Document Detail

Type: PDL
Document No.: PDL-8821
Rev.: 2
Title: 029-1172-03 User guide Brio 5 I (ITE)
Process: Innovation Management
Owner: 53TMARINIC Tiia Marinic

Status: CURRENT
Effective Date: 07-Feb-2022

Attributes

Attribute Type	Value	Description
Affected Site	1100	Stafa (CH)
Affected Site		
Product Family	Virto P	
Project	Mozart ITE Product	
Project		
Project Phase	Finished Product	
Project Phase		

Approvals

Level	Actor	Job Title	Sign-off Date	Sign-off By
1	Lora Braun	Quality Assurance Manager Marketing	07-Feb-2022	11LBRAUN
2	Isabelle Mattmann	Product Manager	07-Feb-2022	11IMATTMANN

Revision Notes

Access Activity	Note	Accessed By	Accessed Date
Remark	fixed emissions and immunity standards to match WI-112 [4]	53TMARINIC	02-Feb-2022