Cochlear™ Baha® 6 Max Sound Processor

User manual part A

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Cochlear Baha 6 Max
Cochlear Baha 6 Max

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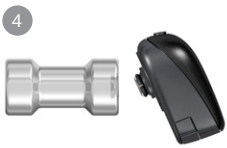

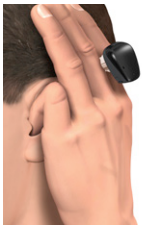

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Cochlear Baha 6 Max
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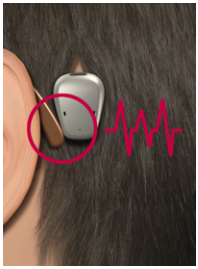


Warnings

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

People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

⚠ WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

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

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

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

⚠ WARNING

Batteries can be harmful if swallowed, put in the nose or in the ear. Be sure to keep your batteries out of reach of small children and other recipients in need of supervision. Before use, verify that the tamper-resistant battery door is properly closed. In the event a battery is accidentally swallowed, or stuck in the nose or ear, seek immediate medical attention at the nearest emergency center.

⚠ WARNING

The sound processor and removable parts of the system (batteries, battery door, safety line) can be lost or may be a choking or strangulation hazard. Keep out of reach of small children and other recipients in need of supervision.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.), to any part of your sound processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING

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

WARNING

Do not use damaged product.

Cautions

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

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

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

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

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

Notes

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

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

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

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

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

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

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

Note: Hearing loss in people younger than 18.

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

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own. Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

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

Contents

1. Introduction

Congratulations on your choice of the Cochlear™ Baha® 6 Max Sound Processor. This manual is full of tips and advice on how to best use and care for your Baha sound processor. Be sure to discuss any questions or concerns that you may have regarding your hearing or use of this system with your hearing care professional.

1.1 Overview

NOTE

Additional illustrations, figures 1-9, can be found on the inside of the cover of this user manual.

1.2 Intended use

The Cochlear Baha System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Baha 6 Max Sound Processor is intended to be used as part of the Cochlear Baha System to pick up surrounding sound and transfer it to the skull bone via a Baha Implant, Baha Softband or Baha SoundArc™ and can be used unilaterally or bilaterally.

1.3 Indications

The Cochlear Baha System is indicated for patients with conductive hearing loss, mixed hearing loss and SSD (single-sided sensorineural deafness). The Baha 6 Max Sound Processor is indicated for patients with up to 55 dB SNHL (sensorineural hearing loss).

1.4 Clinical benefit

Most recipients of a bone conduction hearing solution will experience improved hearing performance and quality of life compared to unaided listening.

1.5 Warranty

The warranty does not cover defects or damage arising from, associated with, or related to the use of this product with any non-Cochlear processing unit and/or any non-Cochlear implant. See the *"Cochlear Baha Global Limited Warranty card"* for more details.

2. Use

2.1 Turn on and off

See *figure 1*
The battery door is used to turn the sound processor on and off.

1. To turn on your sound processor, close the battery door completely.
2. To turn off your sound processor, gently open the battery door until you feel the first "click".

When your sound processor is turned off and back on again, it will return to Program 1 and default volume level. If enabled, audio and/or visual signals will let you know that the device is starting up. See *chapter 5*, *"Audio and visual indicators"*.

2.2 Sound processor indicators

See *figure 2*
Audio signals and the visual indicator will alert you of changes to your sound processor. For a complete overview see *chapter 5*, *"Audio and visual indicators"*.

2.3 Change programs

See *figure 3*
You can choose between programs to change the way your sound processor deals with sound. You and your hearing care professional will have selected up to four pre-set programs for your sound processor.

Program 1 _____
Program 2 _____
Program 3 _____
Program 4 _____

These programs are suitable for different listening situations. Ask your hearing care professional to fill in your specific programs on the lines in the previous page.

1. To change the program, press and release the control button located on the top of your sound processor once.
2. If enabled, audio and visual signals will let you know which program you have changed to. See *chapter 5, "Audio and visual indicators"*.
3. To change to any of the other programs pre-set by your clinician, repeat above steps until you get confirmation that you are in the desired program.

NOTE
If you are a bilateral recipient, program changes you make to one device will automatically apply to the second device. This function can be enabled or disabled by your hearing care professional.

2.4 Adjust volume

Your hearing care professional has set the volume level for your sound processor.

NOTE

You can change the program and adjust the volume using the optional Cochlear Baha Remote Control, Cochlear Wireless Phone Clip, Baha Smart App or from your compatible smart phone or smart device. See *section 4.4*, "*Wireless devices*".

2.5 Share the experience

See *figure 4*

Family members and friends can "share the experience" of bone conduction hearing using the Cochlear test rod, provided with the sound processor.

1. Turn on your sound processor and attach it on the test rod by tilting it into place. You will feel the snap coupling "click" into the notch on the test rod.
2. Hold the test rod against the skull bone behind an ear. (Ensure you are holding the test rod, and not the sound processor). Plug both ears and listen.

3. Power

3.1 Battery type

The Baha 6 Max Sound Processor uses a 312 size type hearing aid battery (1.45 Volt zinc air, non-rechargeable). Batteries should be replaced as needed, just as you would with many other electronic devices. Battery life will vary with e.g. daily use, volume levels, wireless streaming, sound environment, program setting, and battery strength. The average battery lifetime is typically 69-136 hours.

3.2 Low battery indication

If activated, the visual and audio signals will alert you when there is approximately one hour of battery power remaining (at this time you may experience lower amplification). If the battery runs down completely, the sound processor will stop working.

3.3 Change the battery

See *figure 5*

1. To replace the battery, remove your sound processor from the head and hold the sound processor with the front facing down.
2. Gently open the battery door until it is completely open.
3. Remove the old battery and dispose of it according to local regulations.
4. Remove the new battery from the packet and peel away the sticker on the + side.
5. Insert the battery into the battery compartment with the + side facing up.
6. Gently close the battery door.

NOTE

- To maximise battery life, switch off the sound processor when it is not in use.
- Battery life decreases as soon as the battery is exposed to air (when the plastic strip is removed), so be sure to only remove the plastic strip directly prior to use.
- If a battery leaks, replace it immediately.

3.4 Tamper-resistant battery door

See *figure 6*

To prevent the accidental opening of the battery door, an optional tamper-resistant battery door is available. This is particularly useful to prevent children, and other recipients in need of supervision, from accidentally accessing the battery. Contact your hearing care professional for a tamper-resistant battery door.

To use the tamper-resistant battery door:

1. To unlock and turn off the device, carefully insert the tamper resistant tool or the tip of a pen in the small hole on the battery door and gently open the door.
2. To lock and turn on the device, gently close the battery door until it is completely closed.

4. Wear

4.1 Safety line

See *figure 7*

The safety line is designed to reduce the risk of dropping or losing your processor. You can attach a safety line that clips onto your clothing:

1. Pinch the loop on the end of the safety line between your finger and thumb.
2. Pass the loop through the attachment hole in the sound processor from front to back.
3. Pass the clip through the loop and pull the line tight. Attach the clip to your clothing.

NOTE

Cochlear recommends connecting the safety line when engaging in physical activities. Children should use the safety line at all times.

4.2 Flight mode

See *figure 8*

Activate flight mode in situations when you need to deactivate radio signals (wireless functionality), such as when boarding a flight or other areas where radio frequency emission is prohibited.

To activate flight mode:

1. Open and close the battery door on your sound processor three times (open-close, open-close, open-close) within a 10-second period.
2. If enabled, audio and visual signals will confirm that flight mode is activated. See *chapter 5*, *"Audio and visual indicators"*.

Follow these steps to deactivate flight mode:

1. Make sure your sound processor has been running for at least 15 seconds before you attempt to turn off flight mode.
2. To turn off flight mode, open and close the battery door once on your sound processor.
3. Let the sound processor run for another 15 seconds or more before turning it off to be certain that flight mode is deactivated.

4.3 For users with two sound processors

To make identification easier, ask your hearing care professional to mark your left and right sound processor with the coloured stickers provided (red for right, blue for left).

4.4 Wireless devices

You can use Cochlear True Wireless™ devices to enhance your listening experience. To learn more about the options available, ask your hearing care professional or visit *www.cochlear.com*.

To pair your sound processor to a wireless device:

1. Press the pairing button on your wireless device.
2. Turn off your sound processor by opening the battery door.
3. Turn on your sound processor by closing the battery door.
4. You will hear an audio signal in your sound processor as a confirmation of a successful pairing.

To activate wireless audio streaming:

The following instructions are applicable for the Cochlear Wireless Mini Microphone 2/2+ and Cochlear Wireless TV Streamer.
Press and hold the control button on your sound processor until you hear an audio signal. See *chapter 5, "Audio and visual indicators"*.
If your sound processor is paired with more than one wireless device, you can toggle between the devices in the different channels by pressing the control button (long press) on your sound processor once, twice or three times, until you have selected the accessory you want.

To end wireless audio streaming:

Press and release (short press) the control button on your sound processor. The sound processor will return to the previously used program.

NOTE

For additional guidance regarding e.g. pairing, please refer to the user guide of the relevant Cochlear wireless device.

4.5 Baha Smart App

You can use the Cochlear Baha Smart App to control your Baha 6 Max Sound Processor via a compatible Bluetooth enabled smartphone. To use the Baha Smart App, please download it from App Store or Google Play and follow the on-screen instructions. For full compatibility details and more information, visit *www.cochlear.com/compatibility*.

4.6 Made for iPhone (MFi)

Your sound processor is a Made for iPhone (MFi) hearing device. This allows you to control your sound processor and stream audio directly from your Apple® devices. For full compatibility details and more information, visit *www.cochlear.com/compatibility*.

4.7 Android streaming

Your sound processor is compatible with the ASHA (Audio Streaming for Hearing Aid) protocol. This allows you to use the direct audio streaming functions of compatible Android devices. For full compatibility details and more information, visit *www.cochlear.com/compatibility*.

5. Audio and visual indicators

Your hearing care professional can set up your sound processor to show the following audio and visual signals.

5.1 General audio and visual signals

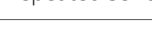
Status/action	Audio signal	Visual signal	Comment
Start up	5 beeps	4 seconds steady light	Your hearing care professional can set up the audio signal to be 1, 5 or 10 beeps.
Start up in flight mode	10x dual beeps	4 x dual flashes	
Change program	1-4 beeps	1-4 flashes	The number of flashes and beeps indicates the number of the current program.
Volume up/down	1 beep	1 short flash	
Maximum/ minimum volume	1 long beep	1 long flash	
Low battery indication	2 x 4 beeps	Repeated series of rapid flashes	

5.2 Wireless audio and visual signals

Status/action	Audio signal	Visual signal	Comment
Wireless streaming activated or change from one wireless device to another	 Ripple tone upward melody	1 long flash followed by 1 short flash	
Confirmation wireless device paring	 Ripple tone in upward melody	N/A	

5.3 Paediatric mode

This optional continuous mode is primarily intended for parents and carers who want to receive a visual feedback from their child's sound processor. It can be activated by your hearing care professional. As the child gets older the mode can also be switched off by your hearing care professional.

Status/action	Visual signal	Comment
Low battery indication	 Repeated series of rapid flashes	Continuously repeated or repeated with small pauses.
Flight mode	 4 x dual flashes	
Program 1-4	 1-4 flashes depending on the chosen program	
Streaming active	1 long flash followed by 1 short flash	

6. Care

6.1 Care and maintenance

Your sound processor is a delicate electronic device. Follow these guidelines to keep it in proper working order:

- For cleaning your sound processor and snap coupling, remove the sound processor from your head and use the Baha sound processor cleaning kit and accompanying instructions. The kit is provided by Cochlear in the sound processor box.
- After exercise, wipe your processor with a soft cloth to remove sweat or dirt.
- If the sound processor gets wet or is exposed to a very humid environment, dry it with a soft cloth, remove the battery and let the processor dry out before inserting a new one.
- Remove your sound processor before applying any hair conditioners, mosquito repellent or similar products.
- Turn off and store the sound processor away from dust and dirt.
- A storage case is provided by Cochlear in the sound processor box.
- Avoid exposing your sound processor to extreme temperatures.
- For long-term storage, remove the battery.

CAUTION

Do not use other cleaning methods than recommended by Cochlear.

6.2 IP classification

The electronics compartment in your sound processor is protected against damage by dust and by immersion in water. Without the battery, the sound processor was tested for immersion in water for 35 minutes at 1.1 meters depth and achieved an IP68 rating. This means that if you, for example, accidentally drop your sound processor in water, the electronics in the device are protected against malfunction due to water ingress. However, your sound processor has a battery that requires air to operate and malfunctions if wet. The sound processor with battery achieves an IP42 rating. This means there is a possibility that if you, for example, are out in rain or in other humid environments, water can block air supply to the battery causing a temporary malfunction. To avoid temporary malfunction, avoid exposing the sound processor to water and always remove it before swimming or bathing.

If your sound processor becomes wet and malfunctions:

1. Remove your sound processor from the head.
2. Open the battery door and remove the battery.
3. Put your sound processor in a container with drying capsules such as a Dri-Aid Kit, etc. Let your sound processor dry out before inserting a new battery. Drying kits are available from most hearing care professionals.

7. Troubleshooting

Contact your hearing care professional if you have any concerns regarding the operation or safety of your sound processor, or if the solutions below do not resolve your issue.

7.1 Processor will not turn on

1. Try turning the sound processor on again. See *section 2.1, "Turn on and off"*.
2. Replace the battery. See *section 3.3, "Change the battery"*.
3. The battery requires air to operate. Ensure that the battery air inlet and/or the battery air holes are not covered.
4. Try a different program. See *section 2.3, "Change programs"*.

7.2 Sound is too quiet or muffled

1. Try turning up the volume using a compatible smartphone or a Cochlear wireless device.
2. Check that the sound processor is not wet. If it is wet, let the sound processor dry before use. See *section 6.1, "Care and maintenance"*.

7.3 Sound is too loud or uncomfortable

1. Try turning down the volume of your sound processor. See *section 2.4, "Adjust volume"*.

7.4 You experience feedback (whistling)

1. Check to ensure that the sound processor is not in contact with items such as glasses or a hat, or in contact with your head or ear. See *figure 9*.
2. Try turning down the volume of your sound processor. See *section 2.4, "Adjust volume"*.
3. Check that there is no external damage to the sound processor.
4. Check that there is no dirt in the connection to your sound processor.

8. Other information

8.1 Sound processor and parts

- The sound processor is suited for use in a home healthcare environment. The home healthcare environment includes locations such as homes, schools, churches, restaurants, hotels, cars, and airplanes, where equipment and systems are less likely to be administered by healthcare professionals.
- A sound processor will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- Infrequent use of a sound processor may not enable a recipient to attain full benefit from it.
- The use of a sound processor is only part of hearing rehabilitation and may need to be supplemented by auditory and lip reading training.
- The sound processor is a digital, electrical, medical instrument designed for specific use. As such, due care and attention must be exercised by the recipient at all times.

A discharge of static electricity can damage the electrical components of the sound processor or corrupt the program in the sound processor. If static electricity is present (e.g. when putting on or removing clothes over the head or getting out of a vehicle), you should touch something conductive (e.g. a metal door handle) before your sound processor contacts any object or person. Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the sound processor should be removed.

- If disruptions keep occurring, please contact your clinician to resolve the issue.
- For wireless functionality, only use Cochlear Wireless devices or compatible smart devices.
- No modification of this equipment is allowed.
- Adult supervision is recommended when the recipient is a child.
- Avoid exposing your sound processor to X-ray radiation.

8.2 Serious incidents

Serious incidents are rare. Any serious incident in relation to your device should be reported to your Cochlear representative and to the medical device authority in your country, if available.

8.3 Performance characteristics

General	
Processing delay	<6 ms
Measurements according to IEC60118-9 2019 2nd Ed. (conforms to ANSI S3.22-2014 (R2020))	
Output Vibratory Force Level (re. 1µN) (90 dB SPL input, FOG)	Max 121 dB HFA 113 dB
ASML frequency response curve	Max 48 dB HFA 42 dB
RATMSL[1] level (re.1 µN/ 20 µPa) (60 dB SPL input, RTS)[1]	HFA 35 dB
Frequency range[1]	200-9850 Hz
Equivalent input noise[1]	24 dB SPL
Battery current[1] (65 dB Input SPL (rel. 20µPa) at 1kHz)	1.8 mA
Total Harmonic Distortion[1]	
70 dB SPL at 500 Hz	< 3%
70 dB SPL at 800 Hz	< 0.3%
65 dB at 1600 Hz	< 0.3%
65 dB at 3200 Hz	< 0.3%
Measurements according to IEC60118-0 2022 4th Ed. (conforms to ANSI S3.22-2014 (R2020))	
AGC characteristics[1 2]	Attack time 12 ms Release time 70 ms

[1] Performed with reference test setting of the gain control (RTS) according to IEC60118-9:2019 2nd Ed. The RTS is set to full-on-gain minus 7 dB and expansion active.

[2] Measured at 2 kHz with maximum compression ratio.

AMSL = Full-on acousto-mechanical sensitivity level re. 1 µN/20 µPa
FOG = Full On Gain
RTS = Reference Test Setting
HFA = High Frequency Average
SPL = Sound Pressure Level re. 20 µPa
RTAMSL = Reference test acousto-mechanical sensitivity level re. 1 µN/20 µPa

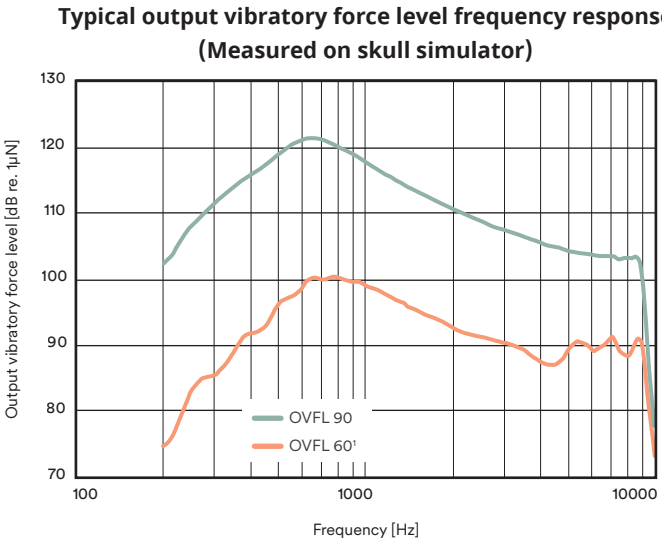


Figure 1: OVFL60 1 and OVFL90 frequency response curves for Baha 6 Max

[1] Performed with reference test setting of the gain control (RTS) according to IEC60118-9:2019 2nd Ed. The RTS is set to full-on-gain minus 7 dB and expansion active.

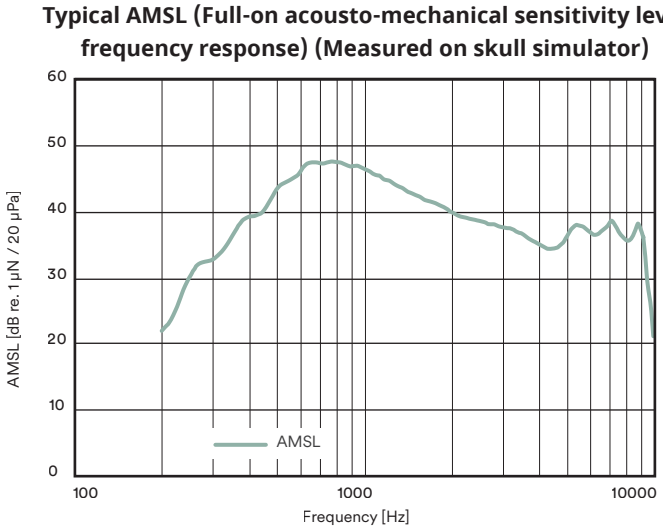


Figure 2: AMSL (Full-on acousto-mechanical sensitivity level frequency response) curve for Baha 6 Max

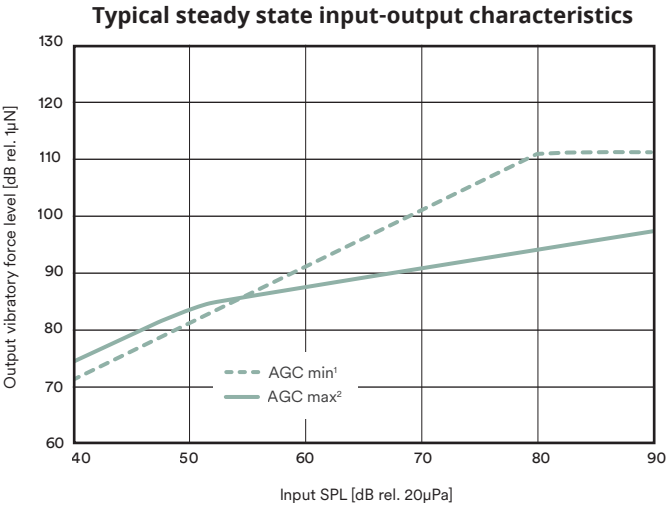


Figure 3: Input-Output characteristics for Baha 6 Max

[1] Performed with reference test setting of the gain control (RTS) according to IEC60118-9:2019 2nd Ed. The RTS is set to full-on-gain minus 7 dB and expansion active.

[2] Measured at 2 kHz with maximum compression ratio.

8.4 Environmental conditions

Condition	Minimum	Maximum
Operating temperature	+5°C (41°F)	+40°C (104°F)
Operating humidity	10% RH	90% RH
Operating pressure	700 hPa	1060 hPa
Transport temperature*	-10°C (14°F)	+55°C (131°F)
Transport humidity*	20% RH	95% RH
Storage temperature	+15°C (59°F)	+30°C (86°F)
Storage humidity	20% RH	90% RH

* Transport conditions require transport packaging used for sound processor.

NOTE

Battery performance deteriorates in temperatures below +5°C.

8.5 Environmental protection

Your sound processor contains electronic components subject to the Directive 2012/19/EU on waste electrical and electronic equipment.
Help protect the environment by not disposing of your sound processor or batteries with your unsorted household waste. Please recycle your device, batteries and electronic items in according to your local regulations.

8.6 Magnetic Resonance Imaging (MRI)

The sound processor and other external accessories should never be brought into a room with an MRI machine, as damage to the sound processor or the MRI equipment could occur. The sound processor must be removed before entering a room where an MRI scanner is located.

If you are to undergo an MRI procedure, refer to the MRI Reference Card included in the document pack.

8.7 Electromagnetic compatibility (EMC)

Interference may occur in the vicinity of equipment marked with the following symbol:

Devices such as airport metal detectors, commercial theft detection systems, and Radio Frequency ID (RFID) scanners may producve strong electromagnetic fields. Some Baha users may experience a distorted sound sensation when passing through or near one of these devices. If this occurs, you should turn off the sound processor when in the vicinity of one of these devices. The materials used in the sound processor may activate metal detection systems. For this reason, you should carry the Security Control MRI Information Card with you at all times.

9. Regulatory information

Not all products are available in all markets. Product availability is subject to regulatory approval in the respective markets.

9.1 Equipment classification and compliance

Your sound processor is internally powered equipment Type B applied part as described in the international standard IEC 60601- 1:2005/A1:2012, Medical Electrical Equipment– Part 1: General Requirements for Basic Safety and Essential Performance. This device complies with part 15 of the FCC (Federal Communications Commission) Rules and with RSS of ISED (Innovation, Science and Economic Development) Canada. Operation is subject to the following two conditions:

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

Changes or modifications made to this equipment not expressly approved by Cochlear Bone Anchored Solutions AB may void the FCC authorization to operate this equipment.
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 recipient 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 or a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC ID: QZ3BAHA6MAX
IC: 8039C-BAHA6MAX
HVIN: Baha 6 Max
FVIN: 1.0
PMN: Cochlear Baha 6 Max Sound Processor

The model is a radio transmitter and receiver. It is designed not to exceed the emission limits for exposure to radio frequency (RF) energy set by the FCC and ISED. The sound processor is designed not to exceed the emission limits according to CAN ICES-003 (B)/NMB-003(B).
The Baha 6 Max sound processor is not intended to output heat or radiation, and the Baha 6 Max sound processor does not produce unwanted outputs of electronic or magnetic field.

9.2 Certification and applied standards

The products are in compliance with the following regulatory requirements:

- In EU: the device conforms to the General Safety and Performance Requirements according to Annex I of Medical Device Regulation 2017/745 (MDR) and essential requirements and other relevant provisions of Directive 2014/53/EU (RED). The declaration of conformity may be consulted at *www. cochlear.com*
- Other identified applicable international regulatory requirements in countries outside the EU and US. Please refer to local country requirements for these areas.

10. Information

10.1 Service and repair

If your sound processor needs service repair, please contact your clinic. Contact details, including an address can be found on the back cover of this manual.

10.2 Clinical and non-clinical performance

Bench testing was conducted to compare the Baha 6 Max Sound Processor with the Baha 5 Power Sound Processor, including use with the predicate implant / abutment systems. Substantial equivalence to the predicate device was accomplished through functionality and performance testing, hardware and interface testing, reliability and environmental testing, as well as system and subsystem level testing. Software verification and validation of Baha Fitting Software 6 and Baha Smart App was also completed to establish that the software are functionally equivalent to their respective predicate and reference devices and support substantial equivalence. The results demonstrated the Baha 6 Max Sound Processor is functionally equivalent to the Baha 5 Power Sound Processor.

11. Key to symbols

The following symbols may appear on your processor, accompanying accessories and/or packaging:

Refer to instructions/booklet.
Note: Symbol is blue.

Manufacturer

REF

Catalogue number

SN

Serial number

UDI

Unique device identifier

MD

Medical device

LOT

Batch code

Date of manufacture

Temperature limitation

NOTE
Important information or advice.

MR Unsafe

Audio signal

Made for iPhone | iPad | iPod

Made for iPhone, iPad, iPod

Bluetooth®

Bluetooth®

Keep dry

CE 2797

CE mark and Notified Body number

UK CA 0086

UK Conformity mark with approved body number

Rx Only

By prescription

Recyclable material

Waste of Electrical and Electronic Equipment

Type B applied part

Interference risk

CAUTION (NO HARM)
Special care to be taken to ensure functionality. Could cause damage to equipment.

MR Conditional

Radio certification symbol for Korea

WARNING (HARMFUL)
Potential safety hazards and serious adverse reactions. Could cause harm to person.

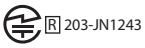
ACMA symbol (Australian Communications and Media Authority)

IP42

IP 42 Ingress Protection Rating, protected against

- ingress of solid foreign objects
- dripping water

Radio certification symbol for Brazil



Radio certification symbol for Japan

SE **Cochlear Bone Anchored Solutions AB,** Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden. Tel:+46 31 792 44 00

AU **Cochlear Ltd,** (ABN 96 002 618 073), 1 University Avenue, Macquarie University, NSW 2109 Australia. Tel:+61 2 9428 6555

US **Cochlear Americas,** 10350 Park Meadows Drive, Lone Tree, CO 80124, USA. Tel:+1 303 790 9010

CH REP CH **Cochlear AG,** Peter Merian-Weg 4, 4052 Basel, Switzerland. Tel:+41 61 205 8204

PA **Cochlear Latinoamerica, S. A.**, International Business Park Building 3835, Office 403 Panama Pacifico, Panama. Tel:+507 830 6220

GB **UK Responsible Person: Cochlear Europe Ltd,** 6 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey, KT15 2HJ, United Kingdom. Tel:+44 1932 26 3400

DE **Cochlear Deutschland GmbH & Co. KG,** Mailänder Straße 4a, 30539 Hannover, Germany. Tel:+49 511 542 770

BE **Cochlear Benelux NV,** Schaliënhoevedreef 20 I, 2800 Mechelen, Belgium. Tel:+32 15 79 55 11

FR **Cochlear France S.A.S.,** 135 route de Saint Simon, 31035 Toulouse, France. Tel:+33 5 34 63 85 85 (international), Tel: 0805 200 016 (national)

IT **Cochlear Italia s.r.l**, Via Trattati Comunitari Europei 1957 2007 n.17, 40127 Bologna (BO) Italy. Tel:+39 051 601 53 11

TR **Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Sti.,** Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3 Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye. Tel:+90 216 538 59 00

SE **Cochlear Nordic AB,** Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden. Tel:+46 31 335 14 61

CA **Cochlear Canada Inc,** 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada. Tel:+1 800 483 3123

JP **Nihon Cochlear Co Ltd,** Ochanomizu-Motomachi Bldg 2-3-7 Hongo, Bunkyo-Ku, Tokyo 113-0033, Japan. Tel:+81 3 3817 0241

SG **Cochlear Limited (Singapore Branch),** 238A Thomson Road #25-06, Novena Square Office Tower A, Singapore 307684, Singapore. Phone: +65 65533814

CN **Cochlear Medical Device (Beijing) Co Ltd,** Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road, Chaoyang District, Beijing 100022, P.R. China. Tel:+86 10 5909 7800

HK **Cochlear (HK) Ltd,** Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road, Causeway Bay, Hong Kong. Tel:+852 2530 5773

IN **Cochlear Medical Device Company India PVT Ltd,** Platina Bldg, Ground Floor, Plot No. C 59, G Block, BKC, Bandra East, Mumbai 400051 India. Tel:+91 22 6112 1111

CO **Cochlear Colombia,** Avenida Carrera 9 #115-06 Of. 1201 Edificio Tierra Firme, Bogota D.C., Colombia. Tel:+57 315 339 7169 / +57 315 332 5483

MX **Cochlear México S.A. de C.V**, Av. Tamaulipas 150 Torre A piso 9, Col. Hipódromo Condesa, 06170 Cuauhtémoc, Ciudad de México, México. Tel:+52 0155 5256 2199

www.cochlear.com

Please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always follow the directions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information. In Australia, Baha bone conduction implant systems are intended for the treatment of moderate to profound hearing loss. For the Cochlear Baha System in Australia: This product is not available for purchase by the general public. For information on funding and reimbursement please contact your healthcare professional.
For information regarding the compatibility of Cochlear's Sound Processors with Apple or Android devices, visit www.cochlear.com/compatibility.

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