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Cochlear Baha 6 Max Sound Processor User Manual

Contents

Cochlear Baha 6 Max Sound Processor

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

Overview

Control button
Microphone ports
Indicator light
Attachment hole for safety line

Snap coupling
Battery door

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

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.

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).

Clinical benefit
Most recipients of a bone conduction hearing solution will experience improved hearing performance and quality

of life compared to unaided listening.

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.

Use

Turn on and off

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".

Sound processor indicators

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".

Change programs

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.
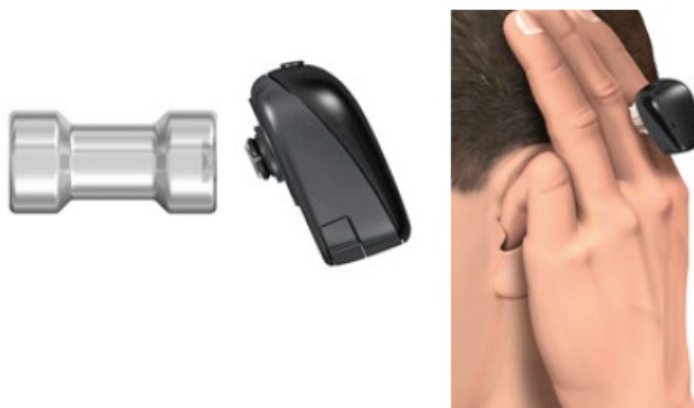
Adjust volume

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".

Share the experience

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.

Power

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.

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.

Change the battery

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.

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 in the ear, seek immediate medical attention at the nearest emergency centre.

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.

Tamper-resistant battery door

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.

Wear

Safety line

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.

Flight mode

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.

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).

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.

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**.

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**.

Audio and visual indicators

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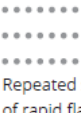
General audio and visual signals

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	

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	

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	

Care

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.

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.

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.

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

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

Sound is too loud or uncomfortable
Try turning down the volume of your sound processor. See section 2.4, "Adjust volume

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 the your sound processor.

Other information

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.
- 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.

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
Do not use damaged product.

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.

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

NOTE
Battery performance deteriorates in temperatures below +5°C.

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

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. regulations.

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 produce 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.

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 increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Regulatory information

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

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:

1. This device may not cause harmful interference.
2. 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.

- 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.
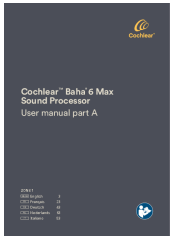- Consult the dealer or an experienced radio/TV technician for help.

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).

Certification and applied standards
The products are in compliance with the following regulatory requirements:

- In EU: the device conforms to the Essential Requirements according to Annex I of Council Directive 93/42/EEC for medical devices (MDD) and essential requirements and other relevant provisions of Directive 2014/53/EU (RED).
- Other identified applicable international regulatory requirements in countries outside the EU and US. Please refer to local country requirements for these areas.

Documents / Resources

Cochlear Baha 6 Max Sound Processor [pdf] User Manual
Baha 6 Max Sound Processor

References

- @ **Cochlear Americas | Hear Now And Always | Cochlear Implants**
- @ **Sound Processor and App Compatibility**