

Cochlear™ Baha® 5 System

# Candidate Selection Guide



*Hear now. And always*



This Candidate Selection Guide provides information to help you identify, evaluate and counsel candidates who may benefit from a Cochlear™ Baha® System.

<b>Introduction</b>	<b>3</b>
<b>Identifying candidates</b>	<b>4</b>
<b>Medical indications</b>	<b>6</b>
<b>Evaluation of Adult candidates</b>	<b>9</b>
<b>Evaluation of Pediatric candidates</b>	<b>12</b>
<b>Selecting the sound processor</b>	<b>15</b>
<b>Listening through the Baha System</b>	<b>18</b>
<b>Fitting the Baha SoundArc</b>	<b>20</b>
<b>Fitting the Baha Softband</b>	<b>21</b>
<b>Choosing the right Baha System</b>	<b>23</b>
<b>Counseling candidates</b>	<b>27</b>

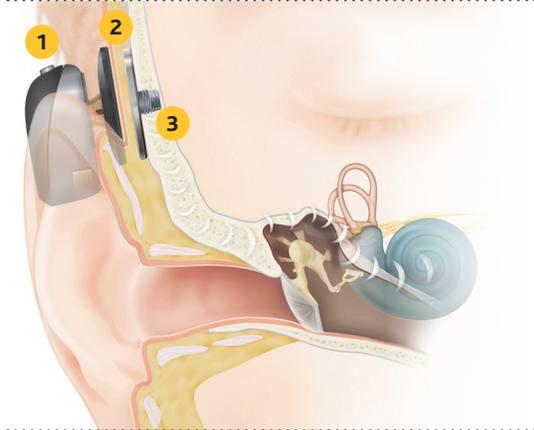
# Introduction

Through bone conduction, sound is conducted naturally through the bone directly to the cochlea, independent of the outer and middle ear. The Cochlear™ Baha® System uses this natural process by amplifying sound signals, converting them into vibrations and transmitting them to an implant in the bone.

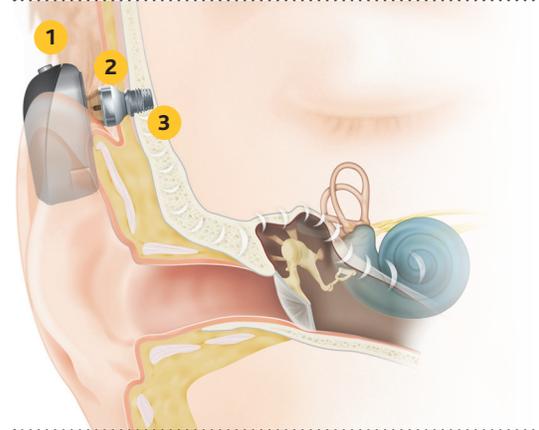
Implantable bone conduction is, therefore, an effective hearing solution for people with conductive or mixed hearing loss because it bypasses any problems associated with the outer or middle ear. The system can also help those who suffer from Single-Sided sensorineural Deafness (SSD) by transmitting sound received on the deaf side directly to the hearing ear.

Today, there are two types of connections between the implant and the sound processor – the Baha Attract System (*magnetic*) and the Baha Connect System (*abutment*).

## Baha Attract System



## Baha Connect System



- [1] The sound processor captures sounds in the air.
- [2] The sound processor turns the sound into vibrations and sends the vibrations through the magnetic or abutment connection to the tiny implant.
- [3] The implant transmits the vibrations through the bone directly to the inner ear.

### INVISIBLE CONNECTION

The major benefit is that there is no skin- penetrating abutment, providing a good aesthetic outcome with no need for daily care.

### MAXIMUM PERFORMANCE

The major benefit is the efficient transmission of vibrations which provides maximum hearing performance should the candidate need it.

*Once you have identified, evaluated and counseled potential candidates for a Baha System, they must be referred to an ENT specialist for a consultation.*

# Identifying candidates

An audiological evaluation is the first step in determining those who will benefit from a Baha System.

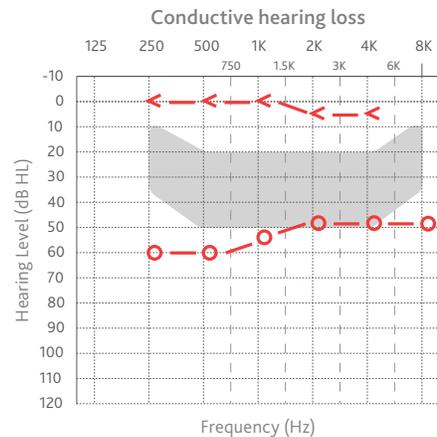
## CONDUCTIVE HEARING LOSS

### Selection criteria:

Studies suggest that the degree of conductive hearing loss on candidates with an air-bone gap of more than 30 dB (PTA) will experience significant advantages from the Baha System, compared to using an air conduction (AC) hearing aid.<sup>1-3</sup>

### Conductive hearing loss can be caused by:

- Chronic Suppurative Otitis Media (*ear infection or fluid in the middle ear*)
- Eustachian tube dysfunction
- Otosclerosis, malformation or dislocation of the middle ear bones
- A benign tumor or cholesteatoma causing damage to the middle ear
- Atresia/Microtia (*a malformation of the outer ear or ear canal*)
- Syndromic Hearing Loss (*Down Syndrome, Treacher Collins, etc.*)

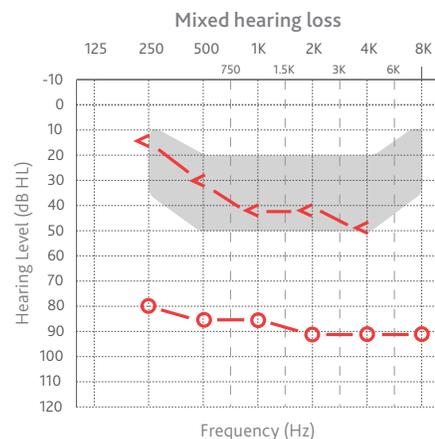


## MIXED HEARING LOSS

Many individuals with mixed hearing loss are suitable candidates for a Baha System. Bypassing the conductive element of the hearing loss means that less amplification is required because the Baha System only needs to compensate for the sensorineural loss.

### Selection criteria:

- Degree of conductive hearing loss - the air-bone gap is a good indicator of suitability for a Baha System. The greater the air-bone gap, the more the candidate will benefit from an implantable bone conduction system. Studies suggest that candidates with an air-bone gap of more than 30-35 dB (PTA4) derive greater benefit from a Baha System than an AC hearing aid.<sup>4</sup>
- Extent of the sensorineural hearing loss – those with a mild-to-moderate sensorineural component in their hearing loss are suitable candidates. The sound processor can compensate for some of the sensorineural loss. However, as the conductive part of the loss is bypassed, less amplification is needed compared to an AC hearing aid. The most powerful Baha sound processor can compensate for a sensorineural element of up to 65 dB HL (*measured at 0.5, 1, 2 and 3 kHz*).



## SINGLE-SIDED DEAFNESS (SSD)

Candidates with SSD and normal hearing in their good ear could benefit from a Baha System. The sound processor picks up sound on the deaf side and it is sent via bone conduction to the contralateral cochlea, overcoming the head shadow effect. This gives improved speech understanding and 360° sound awareness.<sup>5-7</sup>

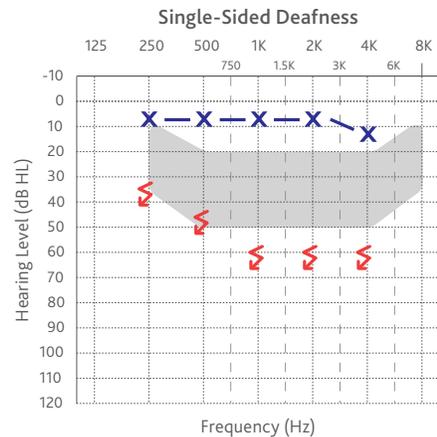
### Selection criteria:

The level of hearing in the good ear should be assessed. Candidates with normal hearing in their good ear may benefit from a Baha System.<sup>8</sup> In cases where there is a sensorineural hearing loss in the good ear, a bone conduction implant may not be the best solution.

Candidate motivation - as SSD patients may have specific expectations due to their type of hearing loss, it is important to ensure such expectations are realistic and that they perceive the prospect of hearing from their deaf side as a need.

### SSD can be caused by:

- Sudden deafness (*exposure to very loud noise*)
- Genetics Factors (*family-related or genetic*)
- Ménière's disease (*a rare disorder affecting the inner ear*)
- Acoustic neuroma (*a benign tumor on the hearing nerve*)
- Head injury or trauma
- Virus, infection or disease (*e.g. measles, mumps, or labyrinthitis*)
- Ototoxicity (*certain medications being toxic to the ear*)
- Autoimmune inner ear disease



## TREATMENT BENEFITS



### Compared To a CROS Aid:<sup>9</sup>

- No occlusion in the hearing ear
- No need to wear hearing devices on both ears
- No hardware in the hearing ear

# Medical indications

When evaluating candidates with conductive, mixed, or SSD hearing loss one should also take into account the type of medical condition that has caused the hearing loss. For some indications, such as chronic otitis media and allergies, implantable bone conduction may be the only feasible solution,<sup>2-4</sup> regardless of the size of the air-bone gap.

## ACOUSTIC NEUROMA

An acoustic neuroma is a growth that develops on the auditory nerve. It can cause problems with hearing and balance. A patient might find it difficult to localize sounds. A Baha System may improve speech understanding for patients with an acoustic neuroma.<sup>10</sup>

## CHRONIC SUPPURATIVE OTITIS MEDIA (CSOM)

CSOM is a chronic inflammation of the middle ear. It involves perforation in the ear drum and a bacterial infection in the middle ear that lasts for several weeks. This infection can be an eternal cycle of suffering with wet ears and can lead to constant difficulties. This may result in conductive hearing loss. Wearing AC hearing aids exacerbates the problem by aggravating the condition and preventing ear canals from drying out. With a Baha System, the ear canal remains open at all times, allowing the ear to dry.<sup>1</sup> It also helps provide a higher quality of hearing outcome for patients while resulting in significant economic savings both for the clinic and patient by reducing recurring visits.<sup>11</sup>

## EAR CANAL STENOSIS

A stenotic ear canal occurs when the canal leading from the middle ear is abnormally narrow. Patients with stenosis of the ear canal are not suitable for a surgical intervention, and the use of AC hearing aids with an ear mold can also be difficult. A Baha system is recommended in this case to bypass the non-functioning ear canal for improved hearing performance.

## TREATMENT BENEFITS



### CONDUCTIVE/MIXED HEARING LOSS

#### Compared To a Middle Ear Surgery:<sup>1</sup>

- Safe and reliable means of restoring hearing
- A reversible intervention
- No risk of additional hearing impairment by placing the implant
- Opportunity to evaluate benefit prior to surgery

#### Compared To Air Conduction Hearing Aids:<sup>2-4</sup>

- Less need for amplification - because the conductive element of the hearing loss is bypassed
- No occlusion of the ear canal
- Reduced risk of sound feedback due to less amplification

## **MÉNIÈRE'S DISEASE**

Ménière's disease is a rare disorder that affects the inner ear. It can cause vertigo, tinnitus, hearing loss and a feeling of pressure deep inside the ear. Symptoms can happen suddenly, and may happen daily or infrequently. This results in difficulty hearing in adverse listening situations such as in noise, group conversations, listening at a distance or in a reverberant environment.

## **OTOSCLEROSIS**

Otosclerosis is a form of bone overgrowth in the middle ear which affects the movement of the tiny bones in the middle ear. This can lead to conductive or mixed hearing loss. A Baha System is recommended as the ear canal may be effectively bypassed.

## **MICROTIA AND ATRESIA**

Microtia refers to the spectrum of deformities of the external ear. A common cause of conductive or mixed hearing loss is atresia, where there is an absence or closure of the external auditory canal. The Baha System provides access to sound helping to promote speech development in children.<sup>12</sup>

## **PREVIOUS EAR SURGERY**

Candidates who have had previous surgeries using, for example, a canal wall down procedure, may find it difficult to wear an ear mold without feedback problems. The Baha System is a good solution because an ear mold is not required.

## **RADICAL CAVITY**

Individuals treated for chronic mastoiditis with a radical cavity may be unable to use conventional hearing aids because the ear canal could become occluded, thus aggravating their condition. With a Baha System, the ear canal remains open.

## **SKIN ALLERGIES**

Allergies in the outer ear and/or the ear canal may be aggravated by the placement of an ear mold. In contrast, a Baha System maintains an open ear canal.

## **SYNDROMIC HEARING LOSSES**

Individuals with syndromes such as Downs,<sup>13</sup> Goldenhar and Treacher Collins,<sup>9,14-16</sup> can be suitable candidates for a Baha System. Treatment of these individuals often requires special consideration and counseling. A personal counseling plan which takes into account the type of syndrome, the severity of the condition and the individual's general abilities is recommended. For such candidates, parents or carers will often play an active role in the maintenance of the system, so they will need to be involved early on in the candidate and system selection process.<sup>13,14,17</sup>



*Debra — Baha Connect user*

# Evaluation of Adult candidates

Candidacy evaluation for an implantable bone conduction system includes audiological testing as well as a personal trial with the Baha System.

## CONDUCTIVE/MIXED HEARING LOSS

### Audiological evaluation

Use the candidate's air-bone gap as a guide to the benefits that can be expected from choosing a Baha System. Comparing the results of speech testing in their sound field, with and without the sound processor, will also be useful. For a realistic experience, allow the candidate to test a sound processor in different sound environments for example by taking a walk around the hospital/clinic or preferably a home trial. Field testing of a sound processor fitted on a demo device allows the candidate to hear through a Baha device before surgery.

### Recommended tests:

- Pure tone audiometry, average bone thresholds at 500, 1000, 2000, and 3000 Hz.<sup>18</sup>
  - Listening test – evaluation on a SoundArc or a Softband (*Please refer to the section Listening through the Baha System for a detailed description about how to perform listening test*).
  - Speech audiometry – use words or speech in noise tests.
- 

## BILATERAL OR UNILATERAL FITTING

### Bilateral fitting

For candidates with binaural hearing loss, a bilateral fitting of Baha sound processors is recommended as this helps improve speech understanding, sound localization and general candidate satisfaction.<sup>19</sup> To optimize the benefit from a bilateral fitting, bone conduction thresholds should be symmetrical, with an average difference of less than 10 dB (PTA4) or less than 15 dB at individual frequencies. However, candidates with asymmetric thresholds may still perceive benefits from a bilateral fitting in terms of a reduction in the head shadow effect.<sup>19</sup>

### Unilateral fitting

The general recommendation is to choose the side with the best cochlea function, i.e. with the best bone conduction thresholds. However, the side from which the candidate perceives the greatest handicap should also be taken into account.

### Practical points to consider:

- Candidate's manual dexterity.
- Cosmetic aspects.
- Driving needs – if the candidate is a taxi driver, for example, the passenger-facing side may be a good alternative.
- Telephone use – if the candidate uses a telephone frequently, the side which leaves the 'writing hand' free may be best.

## SINGLE-SIDED DEAFNESS

### Audiological evaluation

For SSD, the main benefits of the Baha System will be a reduction in the head shadow effect and improved hearing in noisy situations. It is therefore important for candidates to compare their hearing when it is both aided and unaided. An extended trial, if possible, allowing testing of a sound processor at home and/or work, may also be effective in indicating the potential benefit.

### Recommended test

Hearing-in-noise tests, such as QuickSIN or HINT, are recommended to evaluate the benefit of a Baha System. The recommended set-up is to place the candidate between two loudspeakers (see Image A). Noise should come from the speaker facing the hearing ear, while speech comes from the speaker nearest the deaf ear. The test should first be performed in an unaided condition to establish the signal-to-noise ratio under which the candidate will achieve 50 per cent correct answers. The same test should then be carried out with the candidate aided by a sound processor fitted on a test band, SoundArc or a Softband. The difference in the signal-to-noise ratio between the two situations has been shown to be a good predictor of individual benefit. The bigger the difference between the two scenarios, the more benefit can be expected from the Baha System.<sup>20</sup>

*NOTE: Use the most powerful head-worn sound processor that is available for this test, as the skin will attenuate the signal by on average 10-15 dB in a band fitting.*

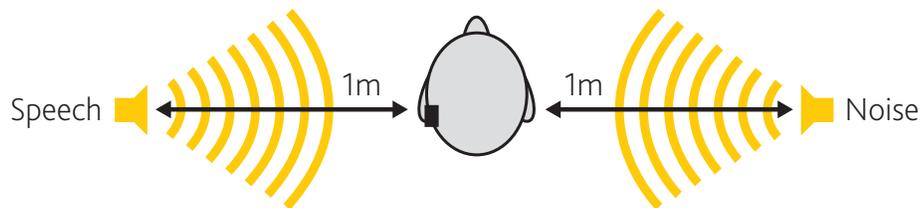


Image A. Set-up of hearing in noise test for SSD candidates.

---

## LISTENING TEST FOR SSD CANDIDATES

To evaluate the benefit of a Baha System for SSD candidates, a longer trial or testing opportunity away from the sound booth is crucial. This will usually provide a good indication of the benefits a candidate can expect.

### Key things to consider when performing a listening test:

- Select the latest available sound processor to help provide the most benefit in terms of signal processing.
- If the candidate needs more audibility, use a more powerful sound processor.
- It is useful to measure the BC direct to get an understanding of the transcranial attenuation.
- Instruct the candidate on how to handle the sound processor and fit a non-surgical option.
- Instruct the candidate to test the sound processor in the situations and environments where they normally struggle.<sup>21</sup>
- Use the Baha home trial log to let the candidate note their experience during the trial, this will help when following up after the test.



# Evaluation of Pediatric candidates

The Baha System can be fitted to infants and children in need of hearing amplification through bone conduction.\* The evaluation of their need is generally the same as for adults. (*Candidates should have sufficient bone quality and quantity to support successful implant placement*).<sup>22</sup>

As in adult candidate evaluations, the child's bone conduction thresholds are the most relevant factor in an audiological assessment. Use the air-bone gap as a guide to the benefits that can be expected from choosing the Baha System. There may also be medical indications which show that a bone conduction implant system will be the best solution. If possible, compare the results of the functional gain measurements in the sound field booth, with and without the sound processor.

We recommend fitting infants and children who are not ready for implantation with the Baha SoundArc or Baha Softband. This can instantly improve the child's hearing and support language development, which is a very good introduction to the possible benefits, both for the child and their parents or carers. The decision to implant the child can then be postponed to a later date, and it is usually an easier decision once the benefits for the child have been observed.

---

## ADDITIONAL CONSIDERATIONS

### Early Baha sound processor fitting

Early access to sound is critical for a child's speech, language and educational development. Yoshinaga-Itano reports that children who receive hearing rehabilitation before the age of six months perform significantly better in language tests at the age of three to four years than children who are treated later. The Yoshinaga-Itano study concludes that delay in intervention may lead to a permanent language deficit.<sup>23</sup>

### Recommended age for implantation\*

Implantation must wait until the child has developed sufficient bone thickness and bone quality. The time this takes can vary from child to child.<sup>22,24</sup> In the United States and Canada, the placement of a bone-anchored implant is contraindicated in children below the age of 5. When fitting a child with the Baha Attract System, a skin thickness of at least 3 mm is required. For children where such conditions are not met, the SoundArc or Softband can be used from infancy.

\*In the USA and Canada, the FDA approves implantation for children aged five years and older.

### **Sound processor considerations when fitting a Baha SoundArc or Baha Softband**

In order to achieve optimal results, the correct sound processor is required. Early access to sound is crucial. When a Baha sound processor is fitted using the SoundArc or Softband, sound signals may be weakened by 10-15 dB due to skin attenuation, some of which may be compensated with extra amplification by fitting the infant or child with the Baha Fitting Software.

Consider using a more powerful sound processor than indicated by the fitting range for pre-operative testing as that may help overcome the attenuation from the skin. The benefit of a more powerful processor is most noticeable at higher sound frequencies because these are weakened to a greater extent than low frequencies when passing through the skin.<sup>18</sup>

### **Bilateral or unilateral aiding**

Clinical research suggests that children with binaural conductive hearing loss should be fitted with bilateral sound processors on a SoundArc or Softband, preferably before the age of six months.<sup>23,25</sup> If bilateral fitting is contraindicated, fit the side with the best bone conduction thresholds. For children with SSD, the sound processor should be placed on the deaf side.

### **Counseling**

Parents of hearing-impaired children have a great need for counseling. They may have questions about hearing loss and how it will affect their child's development. They need guidance about how to help their child achieve the best possible results, especially in speech and language development. They will want to know why a Baha System is the best solution for their child. In addition, counseling should cover the treatment process from both a short and long-term perspective. Therefore, the Baha SoundArc or Baha Softband and the prospect of surgery should be discussed.



#### **Use age appropriate tests to evaluate audibility:**

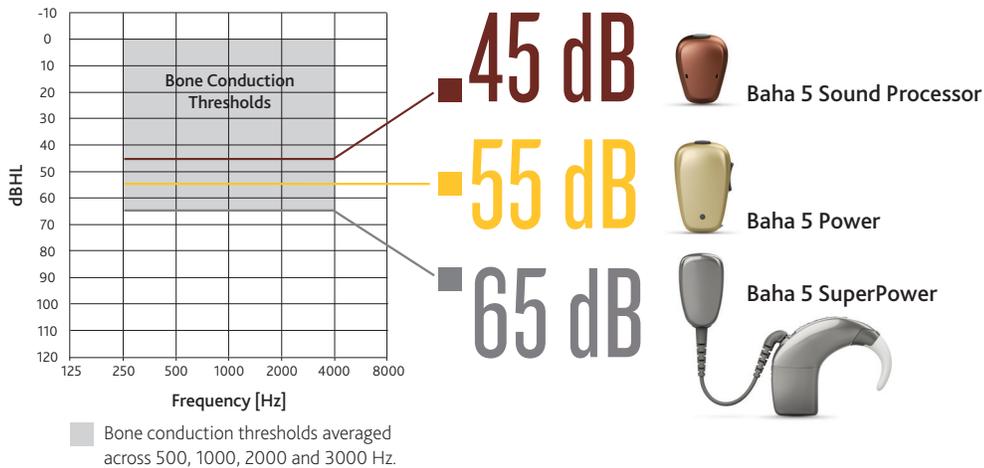
- Behavioral Observational Audiometry (BOA): Infants
- Visual Reinforcement Audiometry (VRA): Children from about six months to two/three years
- Play audiometry: Children between three and five years\*

*\* Play audiometry can be carried out with warble tones, speech or animal sounds.*

# Selecting the sound processor

The Cochlear™ Baha® 5 sound processor portfolio offer your candidates more possibilities for a lifetime of better hearing.

Use the candidate's air-bone gap as a guide to the expected benefits of a Baha sound processor. A comparison of sound field speech tests, with and without the sound processor, will also be useful. A field test with a sound processor fitted on a SoundArc or Softband allows the candidate to trial the system before surgery. For a realistic experience, allow the candidate to use the device in different sound environments, preferably in every day activities or by taking a walk around the hospital/clinic or the surrounding area.



## Conductive hearing loss

For candidates with purely conductive loss, we recommend focusing on the sound processor which offers the most benefit to the candidate and provides sufficient amplification based on their hearing loss needs.

## Mixed hearing loss

The fitting range of the selected sound processor must cover the extent of the sensorineural loss. In common with other hearing devices, the clinical rule of thumb is: if the hearing loss is in the lower third of the fitting range, a more powerful sound processor may produce better outcomes.

When using the Baha Attract System, soft tissue attenuation must be taken into account (see section on "Choosing the right Baha System").

## SSD

In some cases, the sound processor may need to be capable of delivering added amplification to provide sufficient audibility in the contralateral ear. SSD candidates may benefit from a more powerful head-worn processor when there is:

- Larger than expected interaural attenuation. Extra amplification will be required to ensure audibility in the good ear.
- Sensorineural hearing loss developing in contralateral ear over time.



### Direct-to-device connection

The candidate can have a hands-free or voice-activated connection to their iPhone®, iPad® or iPod®, without any extra devices. With Apple, the new Made for iPhone (MFi) technology allows the candidate to enjoy phone conversations, watch movies, listen to music on the go or have the ability to stream audio with a FaceTime® call directly to their sound processors.



### Hear in challenging and noisy situations as well as over distance

There may be circumstances where additional audibility is needed. A sound processor connected wirelessly to a Mini Microphone 2 or a Mini Microphone 2+, located closer to the sound source, will help dramatically increase the signal to noise ratio. Alternatively, a more powerful processor can help make sounds (*especially those in higher frequencies, such as 's' and 'sh'*) easier to understand. This will also enable better hearing at a distance, in a restaurant or meeting room, for example. Accessories such as the Telecoil should also be considered as a means of improving hearing at a distance.

### Connection to smartphones and any Bluetooth® devices

The candidate can connect wirelessly to their Android™ device or any other smartphone, by using the Phone Clip and simultaneously connect and enjoy other Bluetooth enabled devices, to listen to music, podcasts or movies.

### Watching TV couldn't be easier

Candidates are able to enjoy stereo sound directly from their TV to their sound processors while still being able to take part in conversations.

### Discreet control

The sound processor can be controlled through the use of apps via the candidate's smartphone or connected wirelessly to remote control, for times when they would like to discreetly change programs or their volume. They can personalize their listening experience directly from their iPhone® or Android™. For more information, visit [www.Cochlear.com/Apps](http://www.Cochlear.com/Apps)



Cochlear Wireless Mini Microphone 2 and 2+



Cochlear Wireless TV Streamer



Cochlear Wireless Phone Clip

## Benefits and Features Overview

	Baha 5 Sound Processor	Baha 5 Power	Baha 5 SuperPower
	 <p>Program/streaming button 312 battery CS44 connector Tamper proof battery door available</p>	 <p>Program/streaming button Visual indicator Volume rocker CS44 connector 675 battery Tamper proof battery door</p>	 <p>Decoupled transducer Program/streaming/volume buttons Adaptable earhook Visual indicator Rechargeable battery</p>
Patient profile	Conductive hearing loss	Conductive hearing loss with risk of progressive SNHL	Moderate-severe mixed hearing loss
	Mild mixed hearing loss	Mixed hearing loss	SSD with high frequency hearing loss
	SSD	SSD with large transcranial attenuation	Progressive SNHL
Fitting range	Up to 45 dB SNHL	Up to 55 dB SNHL	Up to 65 dB SNHL
Battery type	312	675	Rechargeable 2 sizes
No. of programs	4	4	4
Visual status indicator (LED)	N/A	✓	✓
Tamper-proof	Available	Built-in	Built-in
Feedback Analyser	✓	✓	✓
Data logging	✓	✓	✓
FM Compatible	Through Mini Mic 2+	Through Mini Mic 2+	Through Mini Mic 2+
Colors			

## Enhancing the performance of the Baha 5 System

	Baha 5 Sound Processor	Baha 5 Power	Baha 5 SuperPower
2.5 GHz Wireless Connectivity	✓	✓	✓
Bluetooth-enabled	✓	✓	✓
Made for iPhone® (MFi)	✓	✓	✓
Audio/music streamed directly from iPhone®, iPad® or iPod® to your sound processor, no extra streaming devices	✓	✓	✓
Listening over distance in meetings or lecture halls	With Mini Microphone 2, 2+	With Mini Microphone 2, 2+	With Mini Microphone 2, 2+
Listening to one-on-one conversations in noisy environments	With Mini Microphone 2, 2+	With Mini Microphone 2, 2+	With Mini Microphone 2, 2+
Discreet control of sound processor	Via apps, Remote control and or Phone Clip	On device, via apps, Remote control and or Phone Clip	On device, via apps, Remote control and or Phone Clip
Hands-free or voice-activated connection to smartphone	With Phone clip	With Phone clip	With Phone clip
Audio streaming to any Bluetooth enabled device	With Phone clip	With Phone clip	With Phone clip
Listen to TV with sound directly to sound processor	With TV Streamer	With TV Streamer	With TV Streamer



# Listening through the Baha System

The Baha® SoundArc and the Baha Softband are proven solution to provide either an amplification option for children or an evaluation system for those considering the Baha Attract or Connect Systems.

## SOUND PROCESSOR PRE-OPERATIVE TESTS

There are test devices which allow candidates to have the listening experience of the Baha sound processor.



### Test Rod

This is a simple device for quick evaluations. A sound processor is connected to the rod which can then be pressed against the bone behind the ear.



### Baha SoundArc

The Baha SoundArc is a new innovative bone conduction solution for your patients. It provides a comfortable and effective demo experience and offers patients a stylish solution prior to surgery.



### Baha Softband

The Baha Softband is not only a hearing solution for children who have yet to or are unable to undergo surgery, it is also a solution for candidate evaluation.

---

## SOUND PROCESSOR CONSIDERATIONS FOR PRE-OPERATIVE TESTS

Consider using a more powerful sound processor than indicated by the fitting range for pre-operative testing as that may help overcome the attenuation from the skin. If the candidate needs more audibility, change to a more powerful sound processor.

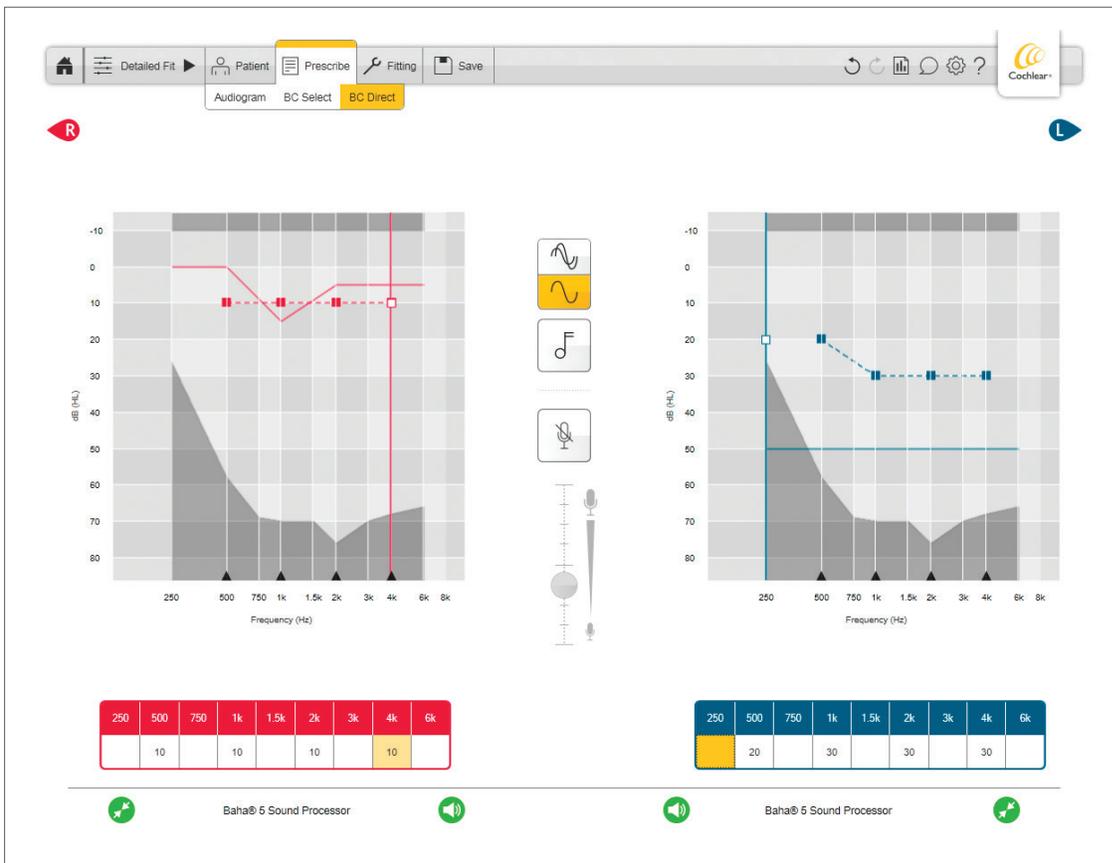
For SSD candidates, a head-worn sound processor should be used, as a body-worn device will not help alleviate the head shadow effect due to its microphone placement.

While factory settings may be a starting point for quick demonstrations, it is suggested that the processor is programmed using Baha Fitting Software to ensure the best possible experience for the candidate. Baha Fitting Software offers several features which may help optimize demonstrations with a Baha SoundArc or Softband.

**To program the sound processor for a demonstration, follow these steps:**

- Select your sound processor in the HomeScreen to start the relevant fitting software.
- If using NOAH, make sure that the unmasked BC thresholds have been transferred from the NOAHAud into the Baha Fitting Software. If in stand-alone mode, enter the patient's unmasked BC thresholds or use the import function to import threshold data stored in the Baha Data Bank.
- Place the SoundArc or Softband on the candidate's head and attach the sound processor to the connector disc and connect the sound processor to the fitting software.
- The feedback measurement is performed during connection, before BC Select.
- In BC Select, select SoundArc or Softband and Demo as the connection type.
- Perform a BC Direct measurement.
- Make sure to click Save before disconnecting the sound processor.

*NOTE: For more details on how to fit a Baha System please refer to the Software User Guide.*



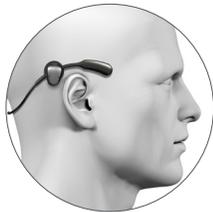
# Fitting the Baha SoundArc

The Cochlear™ Baha® SoundArc is a non-surgical bone conduction device; it is designed to sit above the ears and be worn behind the head, with the Baha sound processor attached to the connector disc just behind the ear.

Make sure the Baha SoundArc is fitted correctly prior to programming the sound processor with the Fitting Software.

## / 01

Choose the right size SoundArc (S, M, L, XL) for the head by making sure the tips rest slightly in front of the ears and the disc is placed above and behind the ear.



## / 02

Slide the disc to position shown in image. It should not wobble. Attach a Baha SoftWear™ Pad to the connector disc of the SoundArc. Ensure that the entire area of the disc sits flush against the skin of the head. To reduce the risk of feedback, the sound processor should not touch the ear.



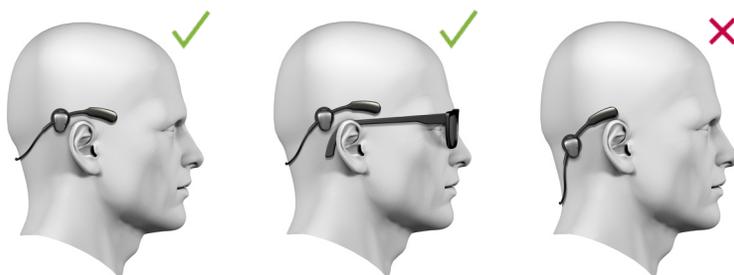
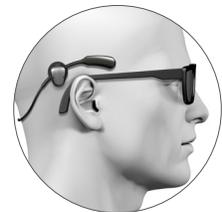
## / 03

If the Baha SoundArc falls backwards, does not stay on or there is a gap between the SoundArc and the back of the head. Bend open at **point A** and inwards at **B**. Fit again and check placement of disc and soft tips.



## / 04

Fit the SoundArc with any accessories (glasses etc.) in place, so that they can be removed without affecting the position of the SoundArc.



### TIPS

- Have your patient practice taking the Baha SoundArc on and off.
- Counsel your patient on proper placement of the disc.
- Instruct your patient on how to adjust and bend the Baha SoundArc.
- Inform your patient to gradually increase wearing time over the first few days.
- For some patients, a slightly higher placement of the disc can improve the sound transmission.

# Fitting the Baha Softband

It is important for an infant, child or adult to have a positive first experience with the Baha Softband.

## / 01

Attach a Baha SoftWear™ Pad to the connector disc of the Baha Softband.

## / 02

Test that the sound processor works by first putting the Softband around your own head, covering your ears and introducing sound.

## / 03

Program the sound processor for the individual hearing loss using the Baha Fitting Software. Optimize the sound processor fitting by selecting suitable parameters in the BC Select screen. Also, whenever possible, conduct BC Direct measurements, which are in-situ bone conduction thresholds, once the Softband has been fitted.

## / 04

Put the Softband around the patient's head, quite loosely at first. It may be helpful to let the candidate familiarize themselves with the Softband before putting it on their head.

## / 05

Place the plastic snap connector disc against the mastoid or another bony location on the skull. Avoid placing it on the temple, as this may be uncomfortable. Check that the entire snap connector disc is in contact with the skull.

## / 06

Tighten the Softband until it is close-fitting enough to ensure effective sound transmission, while also loose enough so as not to cause discomfort. Make sure you can fit one finger between the head and the Baha Softband – this will ensure it is not too tight.

## / 07

Ask the parent, carer or adult to talk to the candidate to familiarize themselves with the hearing experience.



**NOTE:** Once the Baha Softband is tight enough to transmit sound effectively, additional tightening will only increase the sound marginally.<sup>26</sup>

# Choosing the right Baha System

Both the Baha Attract and Baha Connect systems are indicated for conductive hearing loss, mixed hearing loss and SSD. The following guidelines may help you select the best system for your patient's individual needs.

## Baha Connect System

Mixed hearing loss, SSD with large transcranial attenuation. Candidates with progressive hearing loss.



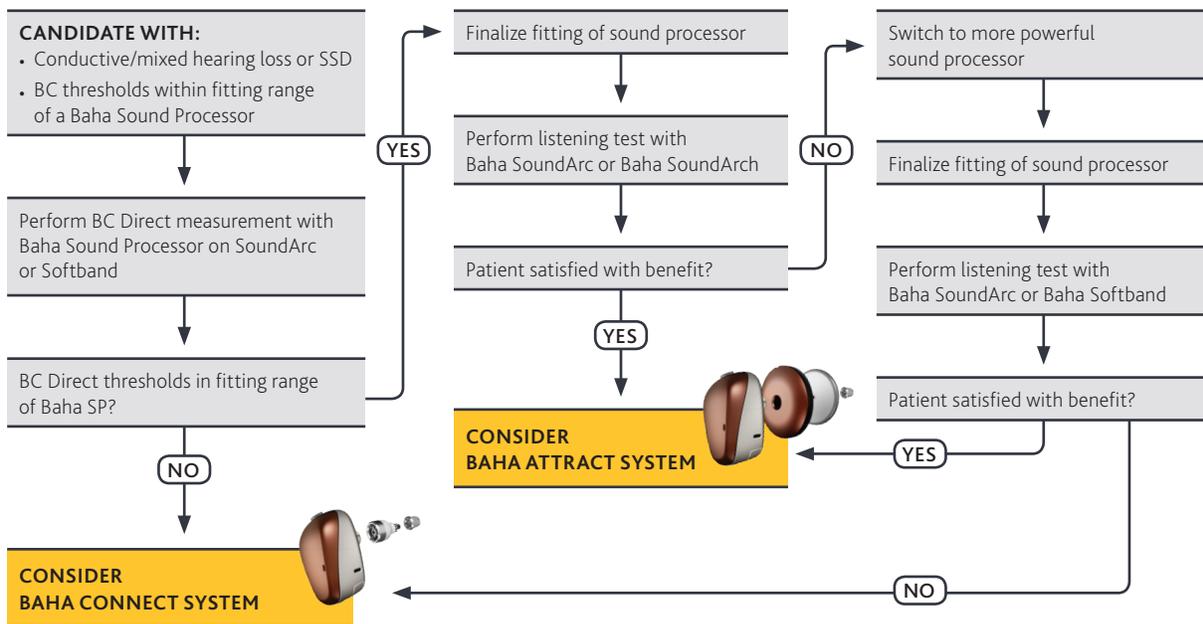
## Baha Attract System

Conductive hearing loss, mild mixed hearing loss and SSD with low transcranial attenuation.



### SYSTEM SELECTION GUIDE

Performing a listening test with the sound processor fitted on a Baha SoundArc or Baha Softband will provide valuable input during the evaluation. If the candidate needs more audibility, change to a more powerful sound processor. If the candidate is in the criteria for a SuperPower sound processor, the wearing options need to be considered before choosing the most suitable Baha system.



## SYSTEM BENEFITS

### Baha Connect System

#### Maximum performance

For candidates who want or need maximum amplification with direct bone conduction.

#### Soft tissue condition

For candidates where the pressure from a magnet connection may cause skin problems, i.e. patients with very thin tissue or poor vascularity.

#### Maximum retention

For candidates whose active life makes retention a top priority.

#### MRI up to 3 T

For candidates who will need to undergo regular MRI or need to have scans where the anatomy close to the implant site needs to be visible.

### Baha Attract System

#### Maximum discretion

For candidates who value the discreet look of a magnetic system.

#### No wound care

For candidates who can't or don't want to manage the maintenance of an abutment connection.

#### Minimal risk of skin infections

For candidates with higher risk of skin infection, e.g. certain medical conditions, living or working in high humidity, dusty environments.

#### Maximum ease

For candidates with dexterity challenges who value or benefit from easy sound processor attachment and removal.

#### MRI at 1.5 T\*

For candidates who are unlikely to require an MRI close to the implant site. *(On scans with a Baha Attract System the image around the implanted magnet will be shadowed.)*

#### Less risk of implant loss due to trauma

For candidates with a higher risk of implant loss due to trauma, e.g. children and people who participate in contact sports.

---

## ADDITIONAL CONSIDERATIONS REGARDING SYSTEM SELECTION

### Conductive hearing loss

Both the Baha Attract System and the Baha Connect System may provide good audiological outcomes.

### Mixed hearing loss

The degree of sensorineural hearing loss will determine the system selection.

### SSD

SSD candidates with a large transcranial attenuation or a sensorineural hearing loss developing in the hearing ear may benefit from the additional amplification provided by the Baha Connect System.

\* The Baha Attract implant magnet (BIM400) can be removed if an MRI over 1.5T is needed.

## WEARING OPTIONS FOR BAHHA 5 SUPERPOWER SOUND PROCESSOR

Selection of the candidate's primary option is dependent on their individual needs in terms of gain requirements and feedback limitations, the position of the implant (*in relation to the pinna*) and lifestyle factors (*e.g. use of eyeglasses and hats*). You can set up multiple programs to allow candidates to switch between wearing options should they want to use more than one. The following guidelines will help you select the primary option for your candidate in three easy steps. All options can be used with both the Baha Attract System and the Baha Connect System.

To select the best wearing option for your candidate, consider the position of the implant versus the pinna.



**Same ear  
Behind-the-ear  
(BTE)**



**Same ear  
Under-the-ear  
(UTE)**



**Other ear  
Behind-the-ear  
(BTE)**



**Other ear  
Under-the-ear  
(UTE)**

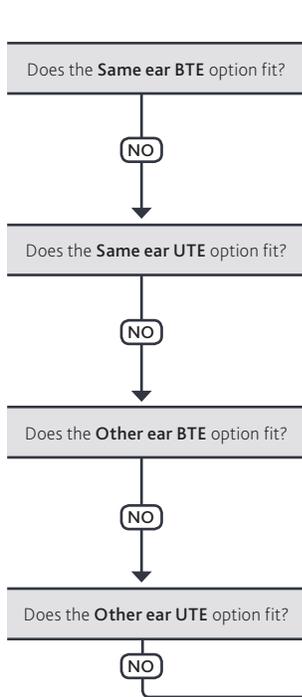


**Clip-on**

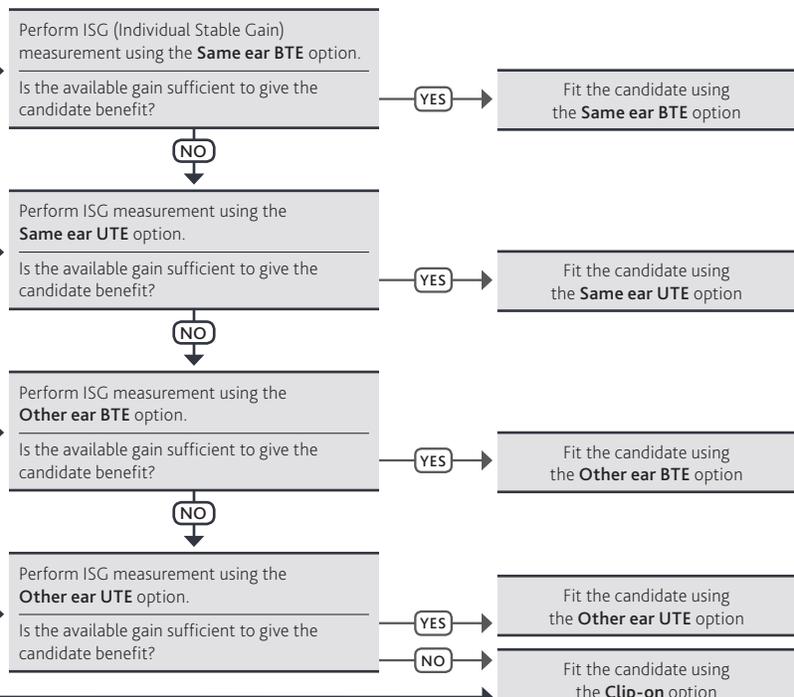
### Candidate with:

- Conductive/mixed hearing loss with BC thresholds up to 65 dB
- Baha Connect System, Baha Attract System, SoundArc or Softband
- SSD with large transcranial attenuation

### / 1 Evaluation



### / 2 ISG measurement



### / 3 Fitting



*Shelly — Baha Connect user*

# Counseling candidates

Before receiving treatment, candidates should be motivated, well-informed and carefully counseled to achieve realistic expectations of their Baha system experience. During counseling, it is important to understand an individual's diagnostic background so that advice is given to meet their particular needs.

## THE MAIN AREAS THAT SHOULD BE COVERED DURING COUNSELING ARE:

- Benefits of the Baha System in relation to the individual's own needs
- Risks and potential complications
- The complete treatment process
- Expectations of hearing improvement
- Aftercare
- Costs/reimbursement/funding

## BENEFITS OF A BAHA SYSTEM FOR CANDIDATES

### Conductive/mixed hearing loss

The use of an implantable bone conduction solution provides several unique advantages over other treatments for conductive/mixed hearing loss. In most cases, the Baha System will help deliver significantly improved sound quality, comfort and speech intelligibility.

### SSD

As SSD candidates may have specific expectations due to their type of hearing loss, it is important to ensure these expectations are realistic. The audiologist or physician can help individuals understand their perceived handicap and, more importantly, their motivation for better hearing.

**NOTE: After fitting, the full restoration of directional hearing should not be expected as all sounds will be processed by the remaining functioning cochlea.<sup>5</sup>**

## TREATMENT PROCESS

Once candidates have had an opportunity to test the Baha System, they should be informed of the treatment process.

- Emphasize that the surgical procedure is considered minor and routine and may be performed in an outpatient setting under local or general anesthetic.
- Explain that a small titanium implant will be placed just behind the ear.
- Clarify that the implant will be connected either to an abutment or a magnet. The abutment will protrude through the skin, while the magnet will be hidden beneath the skin. At this point, showing an actual implant may reduce any anxiety.
- Inform candidates that there will be a dressing over the implant site when they come from surgery, and that the dressing will be removed after a few days.
- Explain how the sound processor will be fitted on to their magnet or abutment.

**NOTE: Emphasize that there is no risk of damage to the candidate's hearing from the surgery and point out that the procedure is fully reversible. More detailed information about the surgical procedure should be provided by the surgeon.**

## EXPECTATIONS

Ensure the candidate has realistic expectations of hearing improvement. Preoperative testing is essential in this respect and listening through a sound processor on a Softband will give candidates an experience comparable to that of the post-surgical outcome.

## AFTERCARE

Candidates who will have the Baha Connect System must be able to maintain and clean the area around the abutment, either by themselves or with help from others. With children, explain to parents or carers that hygiene will be their responsibility. No special aftercare is necessary for the Baha Attract System, however, users should check the magnet site to ensure that there are no pressure issues arising from the sound processor magnet.

## COST, REIMBURSEMENT AND FUNDING

Reimbursement of the cost of a Baha System is an important issue and this should be discussed during the preoperative counseling. Terms and conditions for reimbursement and funding vary between countries and/or regions. For information about the terms and conditions applicable in your area, please consult your local Cochlear representative.

- 
1. Snik AF, Mylanus EA, Proops DW, Wolfaardt J, Hodgetts WA, Somers T, Niparko JK, Wazen JJ, Sterkers O, Cremers CW, Tjellström A. Consensus statements on the Baha system: where do we stand at present? *Ann Otol Rhinol Laryngol*. 2005 Dec;114(195):1-12.
  2. Hol MK, Snik AF, Mylanus EA, Cremers CW. Long-term results of bone-anchored hearing aid recipients who had previously used air-conduction hearing aids. *Archives of Otolaryngol Head Neck Surg*. 2005;131(4):321-5.
  3. McDermott AL, Dutt SN, Reid AP, Proops DW. An intra-individual comparison of the previous conventional hearing aid with the bone-anchored hearing aid: The Nijmegen group questionnaire. *J Laryngol Otol*. 2002;116 Suppl. 28:15-9.
  4. De Wolf MJ, Hedrix S, Cremers CW, Snik AF. Better performance with bone anchored hearing aid than acoustic devices in patients with severe air-bone gap. *Laryngoscope*. 2011;121:613-16.
  5. Flynn MC, Sammeth CA, Sadeghi A, Cire G, Halvarson G. Baha for Single-Sided Sensorineural Deafness: Review and Recent Technological Innovations. *Semin Hear*. 2010; 31(4) 326-49.
  6. Kunst SJW, Hol MKS, Snik AFM, Bosman AJ, Mylanus EAM, Cremers CWRJ. Baha in patients with acquired and congenital unilateral inner ear deafness (Baha CROS): clinical evaluation of 56 cases. *Ann Otol Rhinol Laryngol*. 2010;119(7):447-54.
  7. Pai I, Kelleher C, Nunn T, Pathak N, Jindal M, O'Connor A, Jiang D. Outcome of bone anchored hearing aids for single-sided deafness: A prospective study. 2012 *Acta Otolaryngol*. 2012 Jul;132(7):751-5.
  8. Wazen JJ, Van Ess MJ, Alameda J, Ortega C, Modisett M, Pinsky K. The Baha system in patients with single-sided deafness and contralateral hearing loss. *Otolaryngol Head Neck Surg*. 2010;142(4):554-9.
  9. Hol MK, Kunst SJ, Snik AF, Cremers CW. Pilot study on the effectiveness of the conventional CROS, the transcranial CROS and the Baha transcranial CROS in adults with unilateral inner ear deafness. *Eur Arch Otorhinolaryngol*. 2010 Jun;267(6):889-96.
  10. McLoed B, Upfold L, Taylor A. Self-reported hearing difficulties following excision of vestibular schwannoma. *Int Journal of audiology*. 2008 Jul; 47(7): 420-30.
  11. Watson GJ, Silva S, Lawless T, Harling JL, Sheehan PZ. Bone anchored hearing aids: a preliminary assessment of the impact on outpatients and cost when rehabilitating hearing in chronic suppurative otitis media. *Clin otolaryngol*. 2008 Aug;33(4):338-42.
  12. Lieu JEC et.al. Unilateral hearing loss is associated with worse speech language scores in children. *Pediatrics* 2010; 125 (6),1348-55.
  13. Sheehan PZ, Hans PS. UK and Ireland experience of bone-anchored hearing aids (Baha) in individuals with Down syndrome. *Int J Pediatr Otorhinolaryngol*. 2006;70(6):981-6.
  14. Marres HA, Cremers CW, Marres EH. The Treacher Collins syndrome. Management of major and minor ear anomalies. *Rev Laryngol Otol Rhinol*. 1995;116, 2:105-108.
  15. Van der Pouw CTM, Snik AFM, Cremers CWRJ. The Baha HC200/300 in comparison with conventional bone conduction hearing aids. *Clin Otolaryngol Allied Sci*. 1999 Jun;24(3):171-6.
  16. Marres HA. Hearing Loss in the Treacher Collins Syndrome. *Adv otorhinolaryngol*. 2002;61:209-15.
  17. McDermott AL, Williams J, Kuo MJ, Reid AP, Proops DW. The role of bone anchored hearing aids in children with Down Syndrome. *Int J Pediatr Otorhinolaryngol*. 2008;72(6):751-7.
  18. Håkansson B, Tjellström A., Rosenhall U. Hearing thresholds with direct bone conduction versus conventional bone conduction. *Scand Audiol*. 1984;13(1):3-13.
  19. Janssen RM, Hong P, Chadha NK. Bilateral Bone-Anchored Hearing Aids for Bilateral Permanent Conductive Hearing Loss: A Systematic Review. *Otolaryngol Head Neck Surg*. 2012;147(3):412-22.
  20. Snapp HA, Fabry DA, Telishi FF, Arheart KL, Angeli SI. A clinical protocol for predicting outcomes with an implantable prosthetic device in patients with SSD. *J Am Acad Audiol*. 2010;21:654-662.
  21. Desmet J et. al. Clinical need for a Baha trial in patients with single-sided sensorineural deafness. Analysis of a Baha database of 196 patients. *Eur Arch Otorhinolaryngol*. 2012;269(3):799-805.
  22. Davids T, Gordon KA, Clutton D, Papsin BC. Bone-anchored hearing aids in infants and children younger than 5 years. *Arch Otolaryngol Head Neck Surg*. 2007;133(1):51-5.
  23. Yoshinaga-Itano C. Early Intervention after universal neo-natal hearing screening: impact on outcomes. *Dev Disabil Res Rev*. 2003;9(4):252-66.
  24. Tjellström A, Håkansson B, Granström G. Bone-anchored hearing aids: current status in adults and children. *Otolaryngol Clin North Am*. 2001;34(2):337-64.
  25. Dun CA, de Wolf MJ, Mylanus EA, Snik AF, Hol MK, Cremers CW. Bilateral bone-anchored hearing aid application in children: The Nijmegen experience from 1996 to 2008. *Otol Neurotol*. 2010;31(4):615-23.
  26. Hodgetts WA, Scollie SD, Swain R. Effects of applied contact force and volume control setting on output force levels of the Baha Softband. *Int J Audiol*. 2006;45(5):301-8.

# Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people with moderate to profound hearing loss. We have helped over 450,000 people of all ages live full and active lives by reconnecting them with family, friends and community.

We aim to give our recipients the best lifelong hearing experience and access to innovative future technologies. For our professional partners, we offer the industry's largest clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

As your partner in hearing for life, Cochlear believes it is important that you understand not only the benefits, but also the potential risks associated with any cochlear implant or Hybrid implant. You should talk to your hearing healthcare provider about who is a candidate for a cochlear implant or a Hybrid implant. Before any surgery, it is important to talk to your doctor about CDC guidelines for pre-surgical vaccinations. Cochlear implants and Hybrid implants are contraindicated for patients with lesions of the auditory nerve, active ear infections or active disease of the middle ear. Cochlear implantation and Hybrid implantation are surgical procedures, and carry with them the risks typical of surgery. You may lose residual hearing in the implanted ear. Electrical stimulation may result in some side effects, including ringing in the ear, stimulation of the facial nerve; in rare cases this may cause pain. Though rare, it is possible that additional surgery may be required at some point to resolve complications with a cochlear implant or Hybrid implant. Information contained in this document is provided as a guide only, and does not constitute medical advice from Cochlear. Please consult with your health care provider for all applicable medical questions. For complete information about risks and benefits of cochlear implantation, please refer to the Nucleus Package Insert available at [www.Cochlear.com/US/NucleusIndications](http://www.Cochlear.com/US/NucleusIndications)

©Cochlear Limited 2018. All rights reserved. Hear now. And always and other trademarks and registered trademarks are the property of Cochlear Limited or Cochlear Bone Anchored Solutions AB. The names of actual companies and products mentioned herein may be the trademarks of their respective owners.

Views expressed by Cochlear recipients are those of the individual. Consult your hearing health provider to determine if you are a candidate for Cochlear technology. Outcomes and results may vary.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Cochlear is under license.

©2017. Apple, the Apple logo, iPhone, iPad and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

Android and Google Play are registered trademarks of Google Inc.

The Nucleus Smart App is compatible with iPhone 5 (or later) and iPod 6th generation devices (or later) running iOS 10.0 or later.

The Nucleus 7 Sound Processor is compatible with iPhone 8 Plus, iPhone 8, iPhone 7 Plus, iPhone 7, iPhone 6s Plus, iPhone 6s, iPhone 6 Plus, iPhone 6, iPhone SE, iPhone 5s, iPhone 5c, iPhone 5, iPad Pro (12.9-inch), iPad Pro (9.7-inch), iPad Air 2, iPad Air, iPad mini 4, iPad mini 3, iPad mini 2, iPad mini, iPad (4th generation) and iPod touch (6th generation) using iOS 10.0 or later. Apple, the Apple logo, FaceTime, Made for iPad logo, Made for iPhone logo, Made for iPod logo, iPhone, iPad Pro, iPad Air, iPad mini, iPad and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc., registered in the U.S. and other countries.

Information accurate as of January, 2018

[www.Cochlear.com/US](http://www.Cochlear.com/US)

Follow us on   

**Cochlear Americas**  
13059 East Peakview Avenue  
Centennial, CO 80111 USA  
Telephone: 1 303 790 9010  
Support: 1 800 483 3123

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



BUN070 ISS4 JAN18

