Pediatric Evaluation and Fitting Guide
for the Cochlear™ Baha® Softband System
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>03</td>
</tr>
<tr>
<td>Candidacy</td>
<td>05</td>
</tr>
<tr>
<td>Medical Indications</td>
<td>07</td>
</tr>
<tr>
<td>Pediatric Evaluation</td>
<td>08</td>
</tr>
<tr>
<td>Selecting the Sound Processor</td>
<td>09</td>
</tr>
<tr>
<td>Fitting the Baha Softband</td>
<td>11</td>
</tr>
<tr>
<td>Fitting Validation</td>
<td>12</td>
</tr>
<tr>
<td>Accessories</td>
<td>14</td>
</tr>
<tr>
<td>Wireless</td>
<td>14</td>
</tr>
<tr>
<td>Baha 3 and Baha 3 Power Accessories</td>
<td>21</td>
</tr>
<tr>
<td>FM System Tips</td>
<td>22</td>
</tr>
</tbody>
</table>
Introduction

This Pediatric Evaluation and Fitting Guide provides information to help you identify, evaluate and counsel pediatric patients and their parents who may benefit from a bone conduction solution. This guide is focused on the Baha® Softband System but the evaluation and validation tools can easily be used for any implantable bone conduction system.

Advantages of the Baha Softband System:

- Early access to sound for children within the indications
- Comfortable solution which encourages use
- Helps children and parents become familiar with the sound processor prior to implantation
- May be a stepping stone to implantable bone conduction systems

The main advantages of bone conduction implants are:

- Reduced need for amplification as conductive component is bypassed
- Excellent sound quality
- Proven performance, backed by numerous published clinical results
- Minimally invasive surgery, without risk of further damage to hearing
- No occlusion of the ear canal
- Ability to test the system before surgery
Using bone conduction, sound is conducted naturally through the bone directly to the cochlea, independent of the outer and middle ear. The Baha System uses this natural process by amplifying sound signals, converting them into vibrations and transmitting them to the working cochlea. There are two basic pathways to the cochlea, through the skin (Baha Softband or Baha Attract System) or directly to the bone (Baha Connect System). The Baha System is an effective hearing solution for children with conductive or mixed hearing loss because it bypasses any problems associated with the outer or middle ear. The system can also help children with single-sided sensorineural deafness by transmitting sound received on the deaf side directly to the hearing ear.

Once you have identified, evaluated and counseled potential candidates for a Baha System, they must be referred to an ENT specialist for a consultation. Several Baha Systems are available to suit the individual needs of each child:

The Baha Attract System* transmits sound vibrations to the inner ear through a magnetic connection between the sound processor and the implant under the skin. The benefit being that there is no skin penetrating abutment, providing a good aesthetic outcome with no need for daily care.

The Baha Connect System** transmits vibrations through an abutment which connects the sound processor to the implant. Using the DermaLock™ technology the skin is left intact around the abutment. Here the major benefit is the efficient transmission of vibrations, providing maximum amplification.

The Baha Softband uses a flexible headband to hold the sound processor, which transmit vibrations to the bone through the skin. This system facilitates early aiding of children before surgery is warranted, and can also help people for whom surgery is contraindicated.

A complete portfolio of sound processors is available to cater for varying degrees of hearing loss, skin attenuation and lifestyle.

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** The Baha Connect System consists of: Cochlear® Baha® BIL300 Implant, Cochlear® Baha® BA400 Abutment DermaLock™, Cochlear® Baha® Sound Processor.
Candidacy

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

Conductive hearing loss

Most children with conductive hearing loss will benefit from a Baha System. As the Baha System sends sound directly to the cochlea via bone conduction, the conductive element of the hearing loss is effectively bypassed. This means that less amplification is required compared to other solutions.

Selection criteria:

- Degree of conductive hearing loss - studies suggest that candidates with an air-bone gap of more than 30 dB (PTA at 0.5, 1, 2, and 3 kHz) will experience significant advantages from the Baha System, compared to using a hearing aid.

Possible causes of conductive loss in children:

- Atresia/Microtia
- Treacher Collins Syndrome
- Down Syndrome
- Chronic Otitis Media

Mixed hearing loss

Many children with mixed hearing loss are suitable candidates. 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 implantable bone conduction system. Studies suggest that candidates with an air-bone gap of more than 30-35 dB (PTA at 0.5, 1, 2, and 3 kHz) derive greater benefit from a Baha System than a hearing aid.

- Extent of the sensorineural hearing loss – those with a mild-to-moderate sensorineural component in their hearing loss are suitable Baha candidates. The Baha sound processor can compensate for some of the sensorineural loss but, as the conductive part of the loss is bypassed, only modest amplification is required – much less than is necessary with conventional hearing aids. 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 Sensorineural Deafness (SSD)

Children with SSD and normal hearing in their good ear may benefit from a Baha System. The Baha sound processor picks up sound on the deaf side and sends it via bone conduction to the contralateral cochlea, overcoming the head shadow effect. This gives improved speech understanding and 360° sound awareness.3-5

Selection criteria:

• The level of hearing in the good ear should be assessed. Candidates with normal hearing in their good ear will benefit from a Baha System. In cases where there is a more pronounced 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.

Possible causes of SSD in Children:

• Congenital factors
• Genetic factors
• Ototoxic drugs
• Sudden deafness
• Surgical interventions
• Trauma

Additional considerations

Early amplification

Early access to sound amplification is crucial 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.5 The Yoshinaga-Itano study concludes that delay in intervention may lead to a permanent language deficit.5

Recommended age for implantation

The Baha Softband can be used from infancy. Baha implantation must wait until the child has developed sufficient bone thickness and bone quality. How long this takes can vary from child to child but, according to studies, the child should be more than two years old and have a skull bone at least 2.5 mm thick. When fitting a child with the Baha Attract System, a skin thickness of at least 3 mm is required. The Baha Attract System is a natural step from a Baha Softband into an implantable bone conduction system.

In the USA and Canada, Baha implantation is indicated for children five years of age or older.
**Medical Indications**

When evaluating candidacy in conductive/mixed hearing losses 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, regardless of the size of the air-bone gap.

**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 device maintains an open ear canal.

**Congenital malformations**

For most children with congenital ear malformations, surgical intervention or a bone-conduction (BC) hearing aid is often prescribed because an AC hearing aid is simply not an option. Baha Systems have several advantages over conventional BC hearing aids and, compared to surgical reconstruction, bone conduction implants provide a reliable and cost effective solution.

**Draining ears**

A common problem for otologists when treating middle ear disease is difficulty in ensuring a dry ear canal. If the child uses an AC hearing aid, the ear mold in the ear canal may aggravate this condition. With a Baha System, the ear canal remains open at all times, thus allowing the ear to dry.

**Ear canal stenosis**

Children with stenosis of the ear canal are not suitable for a surgical intervention, and the use of conventional hearing aids can also be difficult due to the presence of an ear mold. With a Baha System, the ear canal is bypassed.

**Previous ear surgery**

Children 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.

**Syndromic hearing losses**

Children with syndromes such as Down, Goldenhar, and Treacher Collins can be suitable children for a Baha System. Treatment of these individuals often requires special consideration and counseling. A personal counseling plan which takes account of the type of syndrome, the severity of the condition and the individual’s general abilities is recommended. For such candidates, parents or caregivers will often play an active role in the maintenance of the system, so they will need to be involved early on in the candidate selection process.
Pediatric Candidacy

The Baha System can be fitted to infants and children in need of hearing amplification through bone conduction. The indications of their need are generally the same as for adults. In the USA and Canada, Baha implantation is indicated for children aged five years of age or older.

As in adult patient evaluations, the child's bone conduction threshold is 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 a 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 Softband. This will instantly improve the child's hearing and is a very good introduction to the benefits, both for the child and parents or caregivers. The decision to implant the child is usually made easily once the benefits for the child have been observed.

**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
- Conditional Play audiometry: Children between three and five years
  - Frequency specific stimuli
  - Speech Audiometry

**Physiologic assessments:**
- Acoustic immittance, including tympanometry and acoustic reflexes
- Otoacoustic emissions (OAE) testing
- Electrophysiologic Audiometry:
  - Auditory Brainstem Response (ABR)
  - Auditory Steady State Response (ASSR)
Selecting the Sound Processor

Sound processor considerations when fitting the Baha Softband

Early access to sound amplification is crucial. In order to achieve good results, the sound processor should be programmed using Baha Fitting Software. Follow the procedure outlined in the Baha Fitting Quick Guide.

Type of hearing loss

Conductive hearing loss

For children with a purely conductive loss, we recommend focusing on the sound processor which offers the features most suitable for the child’s own requirements as any Baha device can provide sufficient amplification.

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 page 4 for details on the different systems).

Single-sided sensorineural deafness (SSD)

For most children with SSD, the choice of sound processor can simply be based on which device they find offers the most useful features. In some cases, however, 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 progressively developing in the 'good' ear due to presbycusis or noise exposure. Extra gain will be required to amplify the sound above the candidate’s thresholds.
Additional considerations regarding sound processor selection

Improved audibility in difficult listening situations
There may be circumstances where additional audibility is needed. A sound processor with wireless connectivity may provide benefits through the use of a remote microphone which can dramatically increase the signal-to-noise ratio. Alternatively, a more powerful processor can make sounds (especially those in higher frequencies, such as ‘s’ and ‘sh’) easier to understand. A processor with a specific noise program may also ensure audibility and comfort.

Listening at a distance
A sound processor with wireless connectivity can provide benefits through the use of a remote microphone located closer to the sound source, which can dramatically increase the signal-to-noise ratio. A more powerful sound processor can amplify soft sounds so they become more audible, enabling better hearing at a distance, in a church, for example.

Sound processor handling
A sound processor with wireless connectivity may provide the benefit of a remote control for those who find it difficult to manipulate the buttons on the sound processor.

Accessories
For children, a processor with wireless accessories like the mini microphone can be very useful for parents to communicate with their child in noisy environments like traffic or in the playground. A remote control may also be a very useful tool for the parent to monitor the status and settings of their child’s sound processor.
Fitting the Baha Softband

It is important for a child to have a positive first experience with the Baha Softband.

1. Program the sound processor for the child’s 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, using the child’s processor.

2. Attach the sound processor to the plastic snap connector disc.

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

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

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

6. Tighten the Softband until it is close-fitting enough to ensure effective sound transmission (able to fit one finger between the head and the Baha Softband) while also loose enough so as not to cause discomfort. Once the Baha Softband is tight enough to transmit sound effectively, additional tightening will only increase the sound marginally.

7. Ask the parent or caregiver to talk to the child or sing a song to provide a pleasant hearing experience. Watch for the child’s reaction.

* In infants, mastoid placement may not be possible until the child has sufficient head control. Forehead placement may be appropriate, especially during stroller or rides in a car seat.
Any validation measure that is used for traditional hearing aid or cochlear implant fitting with children can work well for a Softband and/or implanted Baha System measure. The following tools are suggested but do not encapsulate the entire scope of materials available for pediatric amplification validations.

<table>
<thead>
<tr>
<th>Tool</th>
<th>Age</th>
<th>Who</th>
<th>Type and Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Listening Function (ELF)(^{13})</td>
<td>0-3 years</td>
<td>Parents</td>
<td>Observational responses to 12 listening activities at home. Helps establish child’s “listening bubble” empowering parents to influence the communication opportunities at home.</td>
</tr>
<tr>
<td>Children’s Home Inventory for Listening Difficulties (CHILD)(^{14})</td>
<td>3-12 years</td>
<td>Parents</td>
<td>Parents rate the child’s listening ability in different situations.</td>
</tr>
<tr>
<td>Children’s Auditory Performance Scales (CHAPS)(^{15})</td>
<td>School age</td>
<td>Teachers</td>
<td>Compares children of similar age and background on listening tasks in quiet, noise, auditory memory and auditory attention.</td>
</tr>
<tr>
<td>Listening Inventory for Education (LIFE)(^{16})</td>
<td>School age</td>
<td>Student/ Teacher</td>
<td>Used as pre-and post-test evaluations for effectiveness of amplification.</td>
</tr>
<tr>
<td>Self-assessment of Communication – Adolescent (SAC)(^{17})</td>
<td>Teenage</td>
<td>Self</td>
<td>Self-report questionnaire designed to measure the effect of hearing loss and hearing solution outcomes.</td>
</tr>
<tr>
<td>Functional Listening Evaluation (FLE)(^{18})</td>
<td>Child - Adult</td>
<td>Professional</td>
<td>Used to determine how listening is effected by noise, distance, and visual input.</td>
</tr>
</tbody>
</table>

Validation for children with SSD may require different measures. The greatest concerns with SSD are localization, hearing in noise, and head shadow effect. Therefore, the measurement tool should be specific enough to gather sufficient data to determine benefit with the amplification system. However, although a Baha System cannot restore localization, it may provide 360 degree sound awareness. The following are recommended:

**Speech in Noise**
- Body parts
- SRT/SAT
- WIPI

**Spondee words**
- Outcome measures
- Early Listening Function
- CHILD
- FLE
**Period of Use**

1. Initially, keep the Baha Softband on for very short periods of time (10–15 minutes).
2. Use for longer periods once the child accepts the Baha Softband.
3. Change the position of the plastic snap connector disc regularly.
4. Reduce the time of use if there is any sign of discomfort. This is to ensure that the child maintains positive associations with using the Baha Softband.

The amount of sound transferred is based on both the volume setting and the contact area of the plastic snap connector disc.

**NOTE:** The position of the plastic snap connector disc should be changed regularly to avoid discomfort and soreness. If soreness arises, avoid placing the plastic snap connector disc on this area for several days. Should the soreness persist, discontinue use of the Baha Softband for a couple of days or until soreness is gone. Once the Baha Softband is tight enough to transmit sound effectively, additional tightening will only increase the sound marginally. Never use the safety release (disc) to open or close the Baha Softband.

**Care Instructions**

The Baha Softband can be washed by hand at 104°F (104°C) or cooler. Use a mild soap but avoid fabric softeners. Do not tumble dry or iron. The disc(s) can be cleaned with a small brush. Never use any strong chemical solutions.

**Warning!** A Baha sound processor contains small parts. Constant adult supervision is required for Baha users under 3 years of age.

**NOTE:** If the wearer has an implant, do not place the Baha Softband directly over the implant/abutment during the healing period as this may hinder osseointegration.
Accessory Overview

Wireless

A number of accessories have been developed for Baha sound processors. The accessories are designed to maximize access to technologies that make listening easier in specific environments.

The Cochlear 2.4 GHz wireless technology used in the Baha 4 Sound Processor enables simple-to-use and robust connectivity to speech and audio sources without the need for intermediate devices. With the Cochlear 2.4 GHz system, the Baha user may connect directly to up to three streaming accessories, such as the TV Streamer and/or the Mini Microphone, plus a Remote Control and Phone Clip. In addition, several Baha users may share the signal transmitted from one wireless accessory. In addition, the Cochlear Wireless Accessories portfolio provides direct speech and audio streaming and new means of changing and monitoring sound processor status. The wireless accessories can easily be paired manually or by using the Baha Fitting Software.

Cochlear Wireless Mini Microphone

The Mini Microphone is a versatile solution in many situations when the patient needs to hear over a distance or where background noise is problematic. It can provide benefit in situations for children such as:

- In a classroom, when listening to a teacher.
- When travelling by car, listening to someone in the front seat.
- Dining at a restaurant.
- Participating in a class at the gym.

The Mini Microphone is a small, lightweight, portable personal audio streamer that transmits sound directly to the Baha 4 Sound Processor. It may be clipped onto clothing and will transmit speech wirelessly to the Baha sound processor over a distance of up to 21 feet. It allows several students in the same classroom to be connected to the same Mini Microphone. When used as an audio streamer, the Mini Microphone can be placed next to a sound source such as a television speaker or connected directly to an audio device such as an MP3 player via a 3.5 mm cable.

Troubleshooting

<table>
<thead>
<tr>
<th>Question</th>
<th>Background</th>
<th>Possible solution/Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A sound processor unintentionally drops out of the streaming program.</td>
<td>At least one of the causes described for the 'no sound' symptom above has persisted for more than 5 minutes. The battery in the sound processor is so depleted that it no longer supports audio streaming.</td>
<td>Take the necessary corrective action as described for the 'no sound' symptom on page 24 and activate streaming again. Replace the battery in the sound processor with a new one and activate streaming again.</td>
</tr>
<tr>
<td>The sound from the Mini Microphone is too high or is distorted.</td>
<td>An audio device has been connected to the Line-in plug and the audio level from this device is too high.</td>
<td>Adjust the volume using the &quot;+&quot; and &quot;-&quot; keys on the Mini Microphone or use the volume control on the external audio device itself until the best sound level and quality is obtained.</td>
</tr>
<tr>
<td>The sound from the Mini Microphone is still either too low or too high.</td>
<td>The audio volume level of the sound processors is not suitable for listening.</td>
<td>Adjust the volume on the sound processor itself or alternatively, using the &quot;+&quot; and &quot;-&quot; keys on the Remote Control.</td>
</tr>
<tr>
<td>Question</td>
<td>Background</td>
<td>Possible solution/Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The sound level from the Mini Microphone is very low.</td>
<td>The Mini Microphone is not being worn correctly by the speaker. The sound received by the microphone is very low. An audio device has been connected to the Line-in plug and the audio level from this device is too low.</td>
<td>Clip the Mini Microphone on the speaker’s jacket or other clothing or hang it around the speaker’s neck using the lanyard so that the device is within 6-8 inches of the speaker’s mouth. Increase the volume using the “+” key on the Mini Microphone. Adjust the volume using the “+” and “-” keys on the Mini Microphone or use the volume control on the external audio device until the best sound level and quality is obtained.</td>
</tr>
<tr>
<td>The sound from the Mini Microphone is distorted or drop-outs occur frequently.</td>
<td>The Mini Microphone and sound processors are at the edge of the wireless range. The Mini Microphone and sound processors do not have sufficient line of sight.</td>
<td>Ensure that the Mini Microphone and sound processors are within wireless range. Ensure that streaming is not obstructed between the Mini Microphone and the sound processor.</td>
</tr>
<tr>
<td>Pressing the streaming button on the Remote Control has no effect.</td>
<td>The Mini Microphone and sound processor have not been paired. The Remote Control and sound processor are not within wireless range.</td>
<td>Carry out the pairing process. Ensure that the Remote Control and sound processor are within wireless range and activate streaming again.</td>
</tr>
<tr>
<td>Pressing the streaming button on the sound processor for more than 3 seconds has no effect.</td>
<td>The Mini Microphone and sound processor have not been paired.</td>
<td>Carry out the pairing process.</td>
</tr>
<tr>
<td>When pressing the pairing button on the Mini Microphone, no pairing melody is played in the sound processor.</td>
<td>The Mini Microphone and sound processor are not within wireless range. The Mini Microphone and sound processor have not been in pairing mode simultaneously.</td>
<td>Ensure that the Mini Microphone and sound processor are within wireless range and repeat the pairing process. Repeat the pairing process and ensure that your sound processor is turned on within 20 seconds after the pairing button has been pressed on the Mini Microphone.</td>
</tr>
<tr>
<td>The streaming button on the Remote Control has been pressed but no streamed audio signal is found when searched for (indicated by an ‘X’ icon on the display).</td>
<td>The Mini Microphone and sound processor are not within wireless range. The Mini Microphone is not switched on. The battery level of the Cochlear Mini Microphone is too low to support streaming. An audio device has been connected to the Line-in plug but the device is switched off or the output has been muted.</td>
<td>Ensure that the Mini Microphone and sound processor are within wireless range and activate streaming again. Switch on the Mini Microphone and activate streaming again. Charge the battery. Switch on or unmute the external audio device.</td>
</tr>
<tr>
<td>There is no sound in the sound processors although they are still in the streaming program.</td>
<td>The Mini Microphone and sound processor are not within wireless range. The Mini Microphone is no longer switched on. The battery level of the Mini Microphone has become too low to support streaming. An audio device has been connected to the Line-in plug but the device has been switched off.</td>
<td>Ensure that the Mini Microphone and sound processor are within wireless range again. Switch on the Mini Microphone and activate streaming again. Charge the battery. Switch on or unmute the external audio device.</td>
</tr>
</tbody>
</table>
Cochlear Baha Remote Control

The Remote Control simplifies the daily use of the Baha 4 Sound Processor. With easy to use buttons, it provides parents a way to monitor the child’s sound processor from a distance.

- Allows discreet adjustment of the sound processor, reduces the risk of feedback.
- Provides large buttons for simple volume or program changes.
- Makes streaming to other wireless accessories easier.

The display gives a clear overview of the settings of the sound processor and allows users, parents and caregivers to monitor the sound processor battery status and settings. The operating range between the Remote Control and the sound processor is approximately 3 feet.

Troubleshooting

<table>
<thead>
<tr>
<th>Question</th>
<th>Background</th>
<th>Possible solution/Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>No information is shown in the display after it has been activated.</td>
<td>The Remote Control and sound processors have not been paired.</td>
<td>Carry out the pairing process.</td>
</tr>
<tr>
<td>The pairing button on the Remote Control has been pressed but the 'search' icon on the display is not replaced by the status of the sound processor.</td>
<td>The Remote Control and sound processor are not within wireless range. The Remote Control and sound processor have not been in pairing mode simultaneously.</td>
<td>Ensure that the Remote Control and sound processor are within wireless range and repeat the pairing process. Repeat the pairing process and ensure that the battery is inserted in the sound processor within 20 seconds after the pairing button has been pressed on the Remote Control.</td>
</tr>
<tr>
<td>The 'search' icon on the Remote Control is displayed constantly.</td>
<td>The Remote Control and sound processor are not within wireless range. The sound processor is not switched on. The battery in the sound processor is depleted.</td>
<td>Ensure that the Remote Control and sound processor are within wireless range. Switch on the sound processor. Replace the battery in the sound processor with a new one.</td>
</tr>
<tr>
<td>Two different program numbers or icons are shown on the display.</td>
<td>The two sound processors are not in the same program. There can be several reasons for this, e.g. that one of the sound processors was not within wireless range when a command was given from the Remote Control or because you have changed programs on one of the sound processors by pressing its button.</td>
<td>Align the sound processor program using the Remote Control or the program button on the sound processor.</td>
</tr>
<tr>
<td>When changing volume on the sound processors using the &quot;+&quot; or &quot;-&quot; keys, the volume does not change on one of the sound processors.</td>
<td>Volume control is activated for one sound processor only (i.e. only one of the &quot;&lt;&quot; and &quot;&gt;&quot; arrows are shown on Remote Control display).</td>
<td>Press the &quot;&lt;&quot; or &quot;&gt;&quot; key as appropriate to also activate the volume control for the other sound processor.</td>
</tr>
</tbody>
</table>
Cochlear Wireless Phone Clip

The Phone Clip can make talking on the phone easier for Baha users. It is a small and lightweight clip-on accessory with a built-in microphone and Bluetooth® capability. It links the Baha sound processor to any Bluetooth-enabled telephone, thereby allowing the user to hear the telephone directly through the Baha 4 Sound Processor.

- Hands-free calling direct to the Baha 4 Sound Processor.
- Discreetly adjust the Baha 4 Sound Processor by using the Phone Clip as a remote control.
- Stream music from a Bluetooth-enabled device.

In addition, the Phone Clip will pick up speech from the user and transmit it to the telephone so that the user may communicate freely on the phone without holding the handset, even with the handset several feet away. In this way the Baha processor in combination with the Phone Clip will act as a wireless headset.

Troubleshooting

<table>
<thead>
<tr>
<th>Question</th>
<th>Background</th>
<th>Possible solution/Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Phone Clip does not respond to any (long or short) presses on the answer/hang-up button.</td>
<td>The battery in the Phone Clip is depleted.</td>
<td>Charge the battery.</td>
</tr>
<tr>
<td>The pairing button on the Phone Clip has been pressed but no pairing melody is played in the sound processor after the battery is inserted.</td>
<td>The Phone Clip and sound processor are not within wireless range. The Phone Clip and sound processor have not been in pairing mode simultaneously.</td>
<td>Ensure that the Phone Clip and sound processors are within wireless range and repeat the pairing process. Repeat the pairing process and ensure that the battery is inserted on the sound processor within 20 seconds after the pairing button has been pressed on the Phone Clip.</td>
</tr>
<tr>
<td>The Phone Clip cannot be found by the mobile phone when searching for it in the Bluetooth menu.</td>
<td>The Phone Clip and mobile phone are not within wireless range. The Phone Clip is not in Bluetooth pairing mode.</td>
<td>Ensure that the Phone Clip and mobile phone are within wireless range and repeat the Bluetooth pairing process. The Phone Clip is only in Bluetooth pairing mode for 120 seconds after having been activated. Repeat the Bluetooth pairing process.</td>
</tr>
<tr>
<td>Bluetooth pairing failed.</td>
<td>The Phone Clip left Bluetooth pairing mode before the mobile phone completed the pairing process. The wrong 4-digit PIN code has been entered.</td>
<td>Repeat the Bluetooth pairing process and ensure that the process is completed within 120 seconds after having been activated in the Phone Clip. Repeat the Bluetooth pairing process and if a PIN code is requested, enter 0000 (four zeros).</td>
</tr>
</tbody>
</table>
Cochlear Wireless TV Streamer

The TV Streamer sends stereo sound directly to the Baha 4 Sound Processor from up to 21 feet away. The Baha 4 wearer is able to hear a balance of sound from the sound processor and the TV so that they can follow conversations while watching TV. The TV Streamer allows the Baha user to adjust the sound level from the TV so that they can watch without turning up the TV volume to levels that might disturb others. The TV Streamer can easily be connected to a TV, stereo, computer or other audio source and the long range allows users to move around freely while enjoying high quality sound. The low latency of the Cochlear 2.4 GHz technology virtually eliminates the risk of echo effects and lip sync issues. Due to the unique properties of the Cochlear 2.4 GHz system, several users can enjoy TV together using a single TV Streamer. For convenience, streaming between the TV and the Baha 4 Sound Processor will be automatically reconnected if the user leaves the room and returns within 5 minutes.

Troubleshooting

<table>
<thead>
<tr>
<th>Question</th>
<th>Background</th>
<th>Possible solution/Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressing the streaming button on the Remote Control has no effect.</td>
<td>The TV Streamer and sound processors have not been paired.</td>
<td>Carry out the pairing process. Ensure that the Remote Control and sound processors are within wireless range and activate streaming again.</td>
</tr>
<tr>
<td>Pressing the button on the sound processor for more than 3 seconds has no effect.</td>
<td>The TV Streamer and sound processor have not been paired.</td>
<td>Carry out pairing process.</td>
</tr>
<tr>
<td>No pairing melody is played in the sound processor when the button on the TV Streamer has been pressed.</td>
<td>The TV Streamer and sound processor are not within wireless range. The TV Streamer and sound processor have not been in pairing mode simultaneously.</td>
<td>Ensure that the TV Streamer and sound processors are within wireless range and repeat the pairing process. Repeat the pairing process and ensure that the battery on both sound processors are inserted within 20 seconds after the pairing button has been pressed on the TV Streamer.</td>
</tr>
<tr>
<td>When the streaming button on the Remote Control has been pressed, no streamed audio signal is found when searched for (indicated by an ‘X’ icon on the display).</td>
<td>The TV Streamer and sound processors are not within wireless range. The TV Streamer cables are not connected correctly to the TV. The TV Streamer is switched off or the sound from the TV output has been muted.</td>
<td>Ensure that the TV Streamer and sound processors are within wireless range and activate streaming again. Check that the cables between the TV Streamer and the TV are connected correctly and activate streaming again. Switch on the TV Streamer or unmute the TV and activate streaming again.</td>
</tr>
<tr>
<td>There is no sound in the sound processor although it is in streaming mode.</td>
<td>The TV Streamer and sound processors are not within wireless range. The TV might have been switched off or the sound from the TV has been muted.</td>
<td>Ensure that the TV Streamer and sound processors are within wireless range. Switch on or unmute the TV.</td>
</tr>
<tr>
<td>The sound from the TV Streamer is distorted.</td>
<td>The audio input level from the TV is too high.</td>
<td>Adjust the volume using the volume button on the TV Streamer until the sound is no longer distorted.</td>
</tr>
<tr>
<td>Question</td>
<td>Background</td>
<td>Possible solution/Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The volume level from the TV Streamer is very low.</td>
<td>The audio input level from the TV is too low.</td>
<td>Adjust the volume on the sound processor first, then adjust the volume using the “+” and “-” keys on the TV Streamer until the sound is sufficiently loud.</td>
</tr>
<tr>
<td>The sound from the TV Streamer is distorted or drop-outs occur from time to time.</td>
<td>The TV Streamer and sound processors are on the edge of the wireless range. The TV Streamer and sound processors do not have sufficient line of sight.</td>
<td>Move a little closer to the TV Streamer, ensure that it is placed in a suitable position and that streaming is not obstructed.</td>
</tr>
<tr>
<td>The sound from the TV Streamer is not synchronized with the TV picture.</td>
<td>Your TV cannot synchronize the sound from the selected audio outputs and the picture.</td>
<td>If possible, try using another audio output from your TV. Audio streaming from the TV Streamer has almost no latency and does not contribute to any lip sync errors.</td>
</tr>
<tr>
<td>The sound from the TV Streamer is not synchronized with the sound from the TV loudspeakers.</td>
<td>Your TV is not able to synchronize sound from the selected audio outputs with the sound from the TV loudspeakers.</td>
<td>If possible, try using another audio output from your TV. Audio streaming from the TV Streamer has almost no latency and does not contribute to any echo effects. If the problem persists, refer to the TV Streamer User Manual for instructions about fixing latency issues.</td>
</tr>
<tr>
<td>The sound from the sound processor is either too low or too high.</td>
<td>The audio input level is not suitable for listening.</td>
<td>Adjust the volume on the sound processor first, then adjust the volume using the “+” and “-” keys on the TV Streamer until the sound level is suitable. Alternatively, use the “+” and “-” keys on the Remote Control (optional) for this operation.</td>
</tr>
<tr>
<td>A sound processor unintentionally drops out of the streaming mode.</td>
<td>The TV Streamer and sound processor have been out of wireless range for more than 5 minutes. The battery in the sound processor is so depleted that it no longer supports audio streaming.</td>
<td>Ensure that the TV Streamer and sound processors are within wireless range and activate streaming again. Replace the battery in the sound processor.</td>
</tr>
</tbody>
</table>
How to pair the Wireless Accessories

1. Make sure that the Wireless Accessory battery is fully charged.

2. Turn off the Baha 4 Sound Processor by either removing the battery or pressing the "volume down" button.

3. Turn on the Wireless Accessory.

4. Remove the silver cap (where applicable) from the Wireless Accessory.

5. Press the pairing button on the Wireless Accessory once using the tip of a pen or similar object. The LED will flash yellow every two seconds and the device will now be in pairing mode for 20 seconds.

6. While pairing mode is active, turn on the sound processor either by inserting the battery or pressing the "volume up" button.

7. Successful pairing will be indicated by an audible melody played in the sound processor.
Baha 3 and Baha 3 Power Accessories

NOTE: These accessories connect to the compatible sound processor through the Direct Audio Input (DAI).

Audio adapter

The audio adapter allows direct input from personal stereos, TVs, MP3 players and other external audio equipment. The audio adapter also protects sound processors from sudden power peaks.

Warning! It is extremely dangerous and potentially fatal to connect any equipment that is plugged into a 110 and/or 220 V power supply without using the Audio adapter. Only connection cables supplied by Cochlear should be used. Non-standard connection cables can cause damage to the sound processor(s) and injury to the patient. Cochlear is not liable for any damage resulting from incorrect use or connecting incorrect equipment.

Telecoil unit

The telecoil unit is specifically designed to improve sound when using telephones. In addition, with the head-worn devices, it enables access to loop facilities in homes and public buildings.
FM System Tips

**FM Receiver**

FM technology makes it possible to improve signal to noise ratio in situations like:

- Listening in background noise *(a child in a noisy classroom)*
- Listening from a distance *(when listening to a presentation in a large conference room)*

Both the Phonak and Oticon FM systems have been tested with the Baha 3 and Baha 4 Sound Processors by Cochlear. There have also been successful installations with the Comfort Audio system. Dynamic FM (a feature from Phonak) automatically varies gain in the FM receiver according to changes in the ambient noise levels. Traditional FM systems use only fixed gain settings. The Phonak Microlink FM receiver enables the use of most Phonak FM transmitters. For more information about the FM receivers and orders, please contact Phonak at www.phonak.com.

**Ear-level FM receivers**

An FM receiver is connected directly to the sound processor through the DAI port and wirelessly communicates with the transmitter when connected either automatically or manually. Use of an ear-level receiver can reduce the Baha sound processor’s battery life by 10-40% depending on the hearing loss and type of FM receiver used. Dynamic FM receivers use more power than traditional ear-level FM receivers.

**Neckloop Systems**

A neckloop is a necklace-size loop of covered wire that includes FM. The Cochlear Baha telecoil accessory is used to pick up the electromagnetic field that the neckloop produces and activates automatically when connected to the sound processor via the DAI port. An FM neckloop receiver is worn around the neck of someone who has a sound processor with telecoil. When the transmitter and receiver are turned on, the wireless connection is established either automatically or manually.

**Body-worn Systems**

An FM cable connects the Baha sound processor to a commercially available body-worn FM receiver through the DAI port on the sound processor. Body-worn FM receivers are used with an FM transmitter and microphone, which picks up the speaker’s voice. Once the transmitter and the receiver are turned on, the wireless connection is established between the two devices either automatically or manually.
To consider when fitting an FM system

- Depending on the child's age, Cochlear recommends at least 3-6 months of Baha sound processor experience prior to FM use. This gives a younger child time to develop some basic listening skills and allows the clinician to measure baseline speech perception performance.

- Given the known interference issues with FM systems in general, children under five years of age may not be appropriate FM candidates unless they are closely monitored.

- To evaluate if sufficient power is available from the Baha sound processor to support use of an FM system, perform a BC Direct measurement.

- Consider fitting a more powerful sound processor and/or decreasing gain or MPO in lower frequencies in the DAI program.

- Prepare for the school or other external environment at the clinic. Try to use the same FM system as would be used in the classrooms during fitting in the clinic. It is also recommended that a parent, therapist, audiologist or teacher be trained to conduct daily listening checks to ensure that the quality of sound is optimal and to verify proper operation of the FM equipment.

- Address performance expectations and impact on expected battery life prior to fitting. It is important that users and parents/caregivers understand when and how to operate the FM system to ensure optimal hearing benefit and satisfaction.

Fitting an FM receiver

1. Turn all equipment off.

2. Plug the FM receiver into the Baha sound processor.

3. Switch on the Baha sound processor.

4. For Baha 3 sound processors in all programs except for the DAI program, the output of the FM receiver is mixed with the signal of from the sound processor microphones. For the Baha 4 Sound Processor, you will need to create a DAI+Mic program as there is no mixing in the Everyday or Noise programs for that processor.

5. Test the patient's speech recognition in quiet with the sound processor alone and then through the wireless FM system using the DAI program. Performance should be similar between these two conditions.

NOTE: If the Phonak FM is too loud or too soft, the FM programming software, Phonak FM SuccessWare, may be required to optimize the FM volume level. The MLxi on/off button is configurable in Phonak FM SuccessWare. By default this option is disabled but can be enabled to allow manual adjustment of the power setting for the MLxi.
# Frequently Asked Questions

## Sound Processor Troubleshooting

<table>
<thead>
<tr>
<th>Question</th>
<th>Possible solution/Answer</th>
</tr>
</thead>
</table>
| No sound or weak sound.                            | - Try a new battery.  
- Check the program settings and/or adjust the volume.  
- Check the gain settings and make sure that they are optimized according to the patient's preference.  
- If a Baha Connect System is used try rotating the abutment to check that it is stable. If the abutment connection seems loose, refer the patient to a trained health care professional to have it tightened. |
| Poor sound quality (distorted/intermittent/crackling/buzzing sound). | - Try a new battery.  
- Perform a Feedback Analyzer test and analyze the result and see if the optimization of gain resolved the issue.  
- Redo the BC Direct test.  
- If a Baha Connect System is used try rotating the abutment to check that it is stable. If the abutment connection seems loose refer the patient to a trained health care professional to have it tightened. |
| Feedback problems.                                 | - Check that items such as hats and glasses do not come in contact with the Baha sound processor.  
- Ensure that neither the head nor the ear come in contact with the sound processor.  
- If a Baha Connect System is used, try rotating the abutment to check that it is stable. If the abutment connection seems loose, refer the user to a trained health care professional to have it tightened.  
- Perform a Feedback Analyzer test and analyze the result and see if the optimization of gain resolved the issue.  
- Redo the BC Direct test.  
- Adjust the volume. |
| Echo from the user's own voice ("talking with the head in a barrel"). | - Decrease gain in the low frequency area.  
- Decrease gain in the mid frequency area. |
| Sound processor has become damp/wet.               | - Immediately open the battery door and remove the battery.  
- Put the sound processor in a container with drying capsules. Leave the device to dry overnight. Drying kits are available from most hearing health care professionals. |
| Sound processor will not start.                    | - Make sure high quality zinc-air batteries are used (the batteries provided in the sound processor box is Cochlear's latest recommendation).  
- Make sure the surface on the battery is clean.  
- Try to reinsert the battery as straight as possible using the battery insertion/removal tool. |
### BFS 4.0

<table>
<thead>
<tr>
<th><strong>Question</strong></th>
<th><strong>Background</strong></th>
<th><strong>Possible solution/Answer</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Devices programmed with BFS 4.0 will not connect to BFS 2.0 SR2 or older fitting software versions.</td>
<td>A sound processor that has been programmed using the BFS 4.0 contains the new standard and can therefore not communicate with older standards.</td>
<td>You will need to reset the sound processor to factory settings in BFS 4.0. Disconnect the sound processor without clicking “Save” before you can connect to an older fitting software version. You will lose all programming parameters. Consider updating to the Baha Fitting Software 4.0.</td>
</tr>
<tr>
<td>Connected a Baha 4 Sound Processor and then cannot connect a BP100 or BP110 device in the same session.</td>
<td>Constraints related to the new Platform.</td>
<td>Restart the Baha Fitting Software.</td>
</tr>
<tr>
<td>Is it possible to benefit from the increased speed of the HI-PRO 2 with the BFS 4.0?</td>
<td>N/A</td>
<td>Yes, when programming Baha 4 Sound Processors. If you program a Baha 3 device, the speed will be similar to HI-PRO USB.</td>
</tr>
<tr>
<td>The feedback manager shows measurements above full on gain.</td>
<td>N/A</td>
<td>Which means the risk of feedback is minimal at those frequencies.</td>
</tr>
<tr>
<td>A patient wearing a BP110 Power fitted with BFS 4.0 that was previously fitted using BFS 2.0 complains that the sound is weaker.</td>
<td>The gain settings for the BP110 Power have been recalibrated the output for BP110 Power was reduced by 2-3 dB. Please note that this is not a gain limitation, only a correction to the prescription.</td>
<td>If you would like to have an output similar to the previous one, increase gain.</td>
</tr>
<tr>
<td>The shape of the full on gain curve is different for Baha 4 Sound Processors compared to the BP100.</td>
<td>The stable gain curve is different in Baha 4 Sound Processors due to improvements in the platform. The prescription however, is the same for all devices.</td>
<td>N/A</td>
</tr>
<tr>
<td>In Data logging/Program/Volume change view, there is only data for program 1.</td>
<td>This is a known constraint from the new platform. It only supplies data on volume changes for program 1.</td>
<td>Future software feature.</td>
</tr>
<tr>
<td>The patient has been fitted with a Baha 4 Sound Processor with 4 programs but only 3 programs are available.</td>
<td>This only occurs for Baha 4 Sound Processors and only if the device was disconnected before the programming was saved.</td>
<td>Connect the Baha 4 Sound Processor to the BFS, making sure that the 4 programs are selected and save the session before disconnecting the sound processor.</td>
</tr>
</tbody>
</table>
General fine-tuning recommendations with FM systems

<table>
<thead>
<tr>
<th>Parameter</th>
<th>When to adjust</th>
<th>Recommendation</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Everyday program in the Baha 3 sound processor will provide mixing between sound processor microphones and FM when receiver is inserted: recommended for children. DAI program may be used for dedicated listening, mainly in adults. The Baha 4 Sound Processor requires a DAI+Mic program for FM use.</td>
<td>For children mixing between microphones and FM receiver may improve communication and safety. Program settings can be optimized for use with FM.</td>
<td></td>
</tr>
<tr>
<td>MPO</td>
<td>To increase battery life and reduce risk of sound processor power down.</td>
<td>Reduce MPO in 2 dB steps by up to 10 dB in low frequencies (250-1000 Hz) particularly for BP100 and Baha 4 Sound Processors.</td>
<td>Decreasing the MPO reduces peaks in the current consumption to lower the risk of power down/dropped connection. This has a limited impact on the hearing performance.</td>
</tr>
<tr>
<td>Gain</td>
<td>To improve sound quality.</td>
<td>Reduce low frequency gain (250, 500 &amp; 750 Hz) by 2 dB, repeat in further 2 dB steps if problems persist. Use a more powerful sound processor in cases where needed gain is close to limit while using FM.</td>
<td>Devices set at max gain may show poorer sound performance as the signal can become distorted due to the increased current consumption when combined with FM.</td>
</tr>
<tr>
<td>Mic Relative DAI</td>
<td>To prioritize FM input for children.</td>
<td>For children: 6 dB For adults: 0 dB</td>
<td>Children use FM mostly in noisy classrooms and may need to prioritize the teacher’s voice while still capturing questions from the class. Adults tend to select dedicated listening through a DAI program or use another program when requiring more awareness of surroundings.</td>
</tr>
<tr>
<td>Battery</td>
<td>To reduce risk of sound processor power down.</td>
<td>Zinc-air Rayovac or other premium brand with 4-ventilation holes (with or without mercury)</td>
<td>Maintains necessary battery oxygenation when using FM to avoid power downs.</td>
</tr>
<tr>
<td>Question</td>
<td>Answer Sound processor</td>
<td>Answer FM receiver</td>
<td>Answer FM transmitter</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------</td>
<td>-------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>No sound.</td>
<td>Check batteries. Check connections. Check sound processor microphones. Make sure telecoil is inserted if you are using a neck loop receiver. Replace interface that connects to FM receiver (Europlug, cables etc.).</td>
<td>Check battery (if appropriate). Ensure within operating range. Check connection of device. Plug the FM receiver into an amplifier speaker and speak into the transmitter microphone. The FM receiver should work by itself. Check to see that the receiver and transmitter are set to the same channel. Check that settings (e.g. volume) are correct.</td>
<td>Check connections. Check position of microphone. Check microphone is not muted. Check battery. Ensure within operating range. Check synchronization channel. Change channels and resynchronize. Check that settings are correct.</td>
</tr>
<tr>
<td>Poor sound quality.</td>
<td>Check mic/DAI program settings. Change batteries. Reduce MPO by up to 10 dB in low frequencies (250-1000 Hz). Reduce gain by up to 6 dB in low frequencies (250-750 Hz).</td>
<td>Check connections. Ensure use within operating range and no interference. Check volume setting. Check battery life (if appropriate). Ensure cables are not frayed or kinked (if appropriate). Ensure compatible technology used with transmitter.</td>
<td>Change position of microphone. Ensure within operating range. Ensure cables are not frayed or kinked (if appropriate). Use sound check function (if available on transmitter).</td>
</tr>
<tr>
<td>Connection lost repeatedly in the FM System.</td>
<td>Ensure use of Rayovac batteries with 4-ventilation holes. Reduce MPO by up to 10 dB in low frequencies (250-1000 Hz). Reduce gain by up to 6 dB in low frequencies (250-750 Hz). Replace interface that connects to FM receiver (Europlug, cables etc.).</td>
<td>Check connections. Ensure within operating range and no interference. Check volume setting. Check battery life (if appropriate). Ensure cables (if appropriate) are not frayed or kinked.</td>
<td>Change position of microphone. Ensure within operating range. Ensure cables (if appropriate) are not frayed or kinked. Change channels and resynchronize. Ensure compatible technology is used with transmitter. Consider testing with Phonak Inspiro if issue is with zoomlink or smartlink.</td>
</tr>
</tbody>
</table>
As the leading global expert in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. For thirty years, Cochlear has pioneered this technology, helping more than a quarter of a million people reconnect to their families and friends.

Along with the industry’s largest investment in research and development, we continue to partner with leading international researchers and hearing professionals, ensuring that we are at the forefront of hearing science.

For our customers, that means access to our latest technologies throughout their lives, and the ongoing support they need.

REFERENCES


As your patient’s partner in hearing for life, Cochlear believes it is important to convey not only the benefits, but also the potential risks associated with a Baha procedure.

Not everyone with hearing loss is a candidate for a Baha System. The Baha System is contraindicated in patients with inadequate bone quality or quantity to provide stability and support for the implant, or in patients who will be unable to maintain and clean the skin around the abutment. In the U.S., use of the implanted fixture is also contraindicated in children under age 5 years.

All surgical procedures include an element of risk, and it is impossible to guarantee success. The device may fail to osseointegrate for a number of reasons, including physiological and surgical issues as well as traumatic impact to the implant site. On rare occasions the skin around the abutment may become inflamed from a mild infection or the skin may grow back towards its original thickness. For complete information regarding the risks and benefits of a Baha procedure, please refer to the Instructions for use for the Baha Implant available at www.Cochlear.com/US/BahaIndications.

www.Cochlear.com/US

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