Cochlear™ Baha® Systems

Candidate Selection Guide

Hear now. And always

Cochlear®

This Candidate Selection Guide provides information to help you identify, evaluate and counsel candidates who may benefit from an implantable bone conduction solution.

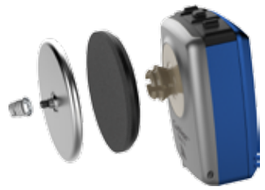
The main advantages of bone conduction implants are:

- **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**

Introduction

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 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 by transmitting sound received on the deaf side directly to the hearing ear.

Once you have identified, evaluated and counselled 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 candidate:



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 head band to carry the sound processor, which transmit vibrations to the bone through the skin. This system facilitates early aiding of children before surgery is carried out, 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.

***The Baha Attract System consists of:** Cochlear Baha BI300 Implant, Cochlear Baha BIM400 Implant Magnet, Cochlear Baha SP Magnet, Cochlear Baha sound processor.
****The Baha Connect System consists of:** Cochlear Baha BI300 Implant, Cochlear Baha BA400 Abutment (DermaLock), Cochlear Baha sound processor.

Full instructions for use, indications, contraindications and warnings can be found in the Instructions For Use for the respective product.

Identifying candidates

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

Conductive hearing loss

Most candidates with conductive hearing loss will benefit from a Baha System. As Baha 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:

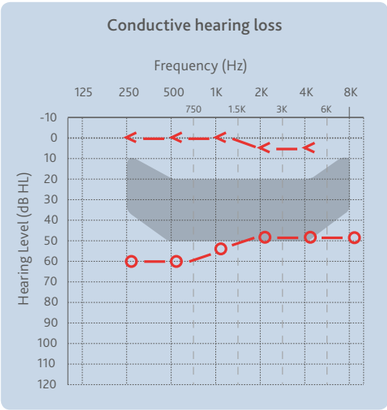
- Degree of conductive hearing loss - studies suggest that candidates with an air-bone gap of more than 30 dB (PTA_4) will experience significant advantages from the Baha System, compared to using an air conduction (AC) hearing aid.[1-3]

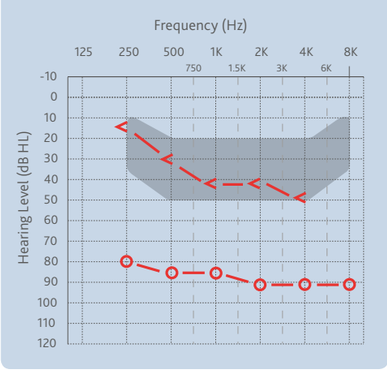
Mixed hearing loss

Many individuals 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_4) derive greater benefit from a Baha System than a hearing aid.[4]
- 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).



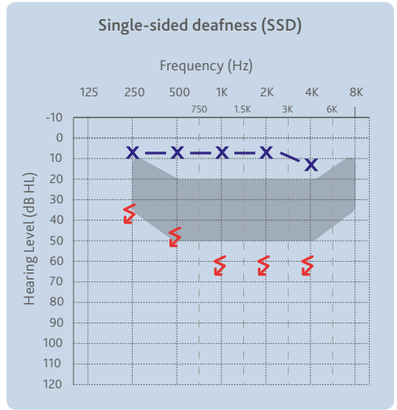


Single-sided Sensorineural Hearing Loss (SSD)

Candidates with SSD and normal hearing in their good ear will benefit from a Baha System.[12] 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.[5-7]

Selection criteria:

- The level of hearing in the good ear should be assessed. Candidates with normal hearing or a mild hearing loss in their good ear will benefit from a Baha System.[8] 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:

- Acoustic neuroma tumours
- Congenital factors
- Genetic factors
- Ménière's disease
- Neurological degenerative disease
- Ototoxic drugs
- Sudden deafness
- Surgical interventions
- Trauma

Treatment benefits

Compared to a CROS aid:[13]

- No occlusion of the hearing ear
- Proven solution backed by long term studies
- No need to wear hearing devices on both ears

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 mould. In contrast, a Baha device maintains an open ear canal.

Congenital malformations

For most candidates 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 provides a reliable and cost effective solution.[9]

Draining ears

A common problem for otologists when treating middle ear disease is difficulty in ensuring a dry ear with good hearing. If the candidate uses an AC hearing aid, the ear mould 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.[1]

Treatment benefits in conductive/mixed hearing loss

Compared to conventional air conduction (AC) hearing aids:[2-4]
- 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

Compared to middle ear surgery and middle ear implants:[1]
- Safe and reliable means of restoring hearing
- A reversible intervention
- No risk of additional hearing impairment
- Opportunity to evaluate benefit prior to surgery

Compared to conventional bone conductors:[9,14]
- Comfortable solution
- Better sound quality
- More aesthetic solution

Ear canal stenosis

Individuals 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 mould. With a Baha System, the ear canal is bypassed.

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 mould without feedback problems. The Baha System is a good solution because an ear mould is not required.

Radical cavity

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

Syndromic hearing losses

Individuals with syndromes such as Down,[10] Goldenhar and Treacher Collins,[12-15] can be suitable candidates for a Baha System. Treatment of these individuals often requires special consideration and counselling. A personal counselling 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 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 selection process.[10-12]

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 functional gain measurements in their sound field, with and without the sound processor, will also be useful.

Field testing of a Baha sound processor fitted on a Softband or headband allows the candidate to hear through a Baha device before surgery. 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 the surrounding area).

Recommended tests:

- Pure tone audiometry (average bone thresholds at 500, 1000, 2000, and 3000 Hz)
- Listening test, evaluation on a Softband, testband or headband (Please refer to the section "Listening through the Baha System" for a detailed description about how to perform listening tests).
- Speech audiometry, use words or speech in noise tests
- Sound field testing (Baha sound processor worn on a test band or test rod for short-term testing, and a head band or Baha Softband for longer trials)

Please refer to the section below, Listening through the Baha System, for a detailed description about how to perform listening tests.

Bilateral or unilateral fitting

Bilateral fitting

For candidates with binaural hearing loss, a bilateral fitting of Baha sound processors is recommended as this improves speech understanding, sound localisation, and general candidate satisfaction.[17] To optimize the benefit from a bilateral fitting, bone conduction thresholds should be symmetrical, with an average difference of less than 10 dB (PTA_4) 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.[17]

Unilateral fitting

The general recommendation is to choose the side with the best cochlea function, ie. 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 sensorineural deafness (SSD)

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, allowing testing of a Baha 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 preformed 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 Baha sound processor fitted on a test band or a Baha 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.[18]

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.

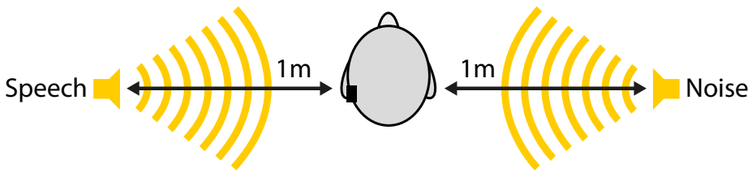


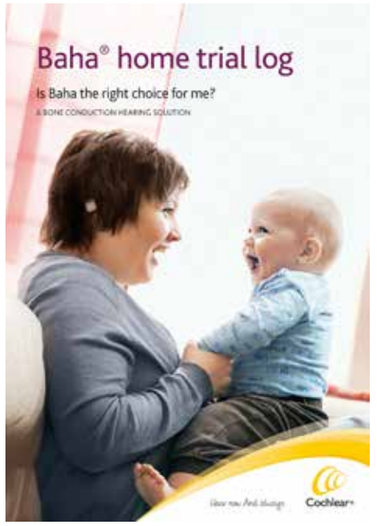
Image A. Set-up of hearing in noise test for SSD candidates.

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. The candidate should be instructed to test the solution in situations where they normally struggle.[19]

Key things to consider when performing a listening test:

- Select the latest available sound processor as that will provide the most benefit in terms of signal processing.
- If the candidate needs more audibility, use a more powerful sound processor.
- Program the sound processor to the candidates hearing loss and connection type (see section on "Listening through a Baha" for further information)
- Instruct the candidate on how to handle the sound processor and fit the Baha Softband.
- Instruct the candidate to test the sound processor in the situations and environments where they normally struggle.
- 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.



Paediatric candidacy and fitting

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, the FDA approves Baha implantation for children aged five years and 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 carers. The decision to implant the child can then be postponed to a later date, and it is usually made easy once the benefits for the child have been observed.

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.[21] The Yoshinaga-Itano study concludes that delay in intervention may lead to a permanent language deficit.[21]

Recommended age for implantation

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.[24,25] 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 Baha Softband can be used from infancy.

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

WARNING! A Baha sound processor contains small components and constant adult supervision is required for Baha users under three years of age

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 Software User Guide (included in Baha Fitting Software Media Pack Art. No. 94799).

Choosing the right Baha System

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

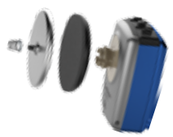
Candidacy

Baha Connect System

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

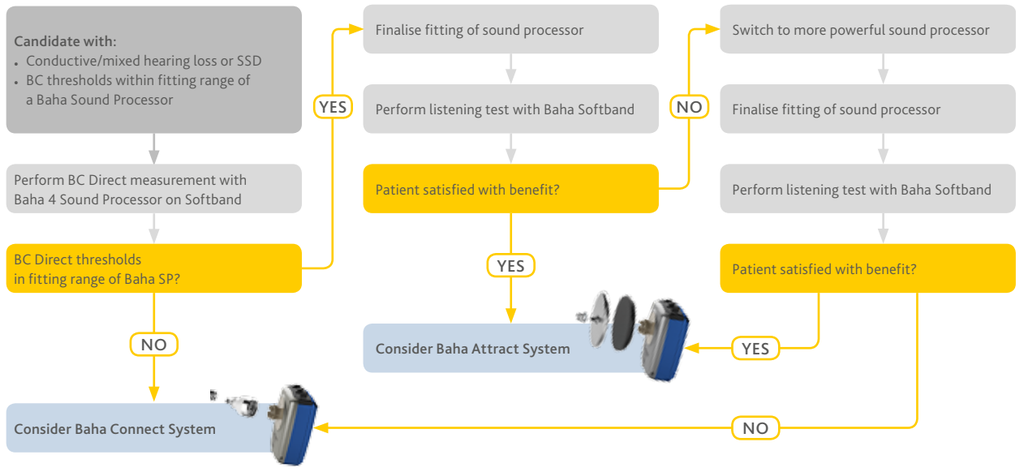
Baha Attract System

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



Suggested evaluation process

Performing a listening test with the sound processor fitted on a Baha Softband will provide valuable input during the evaluation.



NOTE: For this evaluation the most recent sound processor may provide benefits in terms of signal processing and wireless capabilities. If the client needs more audibility, change to a more powerful sound processor.

Additional considerations regarding system selection

Conductive HL

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

Mixed HL

Selection will depend on the amount of sensorineural hearing loss to compensate for.

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.

System benefits

Baha 4 Connect System	Baha 4 Attract System
Maximum performance For patients who want or need maximum amplification with direct bone conduction.	**Maximum discretion** For patients who value the discreet look of a magnetic system.
Soft tissue condition For patients where the pressure from a magnet connection may cause skin problems, i.e. patients with very thin tissue or poor vascularity.	**No wound care** For patients who can't or don't want to deal with the maintenance of an abutment connection, e.g. patients with poor personal hygiene.
Maximum retention For patients whose active life makes retention a top priority.	**Minimal risk of skin infections** For patients with higher risk of skin infection, e.g. certain medical conditions, living or working in high humidity, dusty/dirty environments.
MRI up to 3 T For patients who will need to undergo regular MRI's or need to have scans where the anatomy close the implant site needs to be visible.	**Maximum ease** For patients with dexterity problems who value or benefit from easy sound processor attachment and removal.
	MRI up to 1.5 T* For patients who are unlikely to require an MRI close to the implant site. (Due large artefact/ shadow on scans with a magnetic system)
	Less risk of implant loss due to trauma For patients with a higher risk of implant loss due to trauma, e.g. children and people who practice contact sports.

* The Baha Attract implant magnet (BIM400) can be removed for MRI over 1.5 T.

Selecting the sound processor

Type of hearing loss

Conductive hearing loss

For candidates with a purely conductive loss, we recommend focusing on the sound processor which offers the features most suitable for the candidate's own requirements. Any Baha device will 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. Providing a second device for situations where more power is required could also be considered.

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

Single-sided sensorineural deafness (SSD)

For most candidates 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 will provide benefits through the use of a remote microphone which can dramatically increase the signal-to-noise ratio. Alternatively; a more powerful processor will make sounds (especially those in higher frequencies, such as 's' and 'sh') easier to understand. A processor with a specific noise programme will also ensure audibility and comfort.

Listening at a distance

A sound processor with wireless connectivity will 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 will amplify soft sounds so they become more audible, enabling better hearing at a distance, in a church, for example. Accessories such as the Telecoil should also be considered as a means of improving hearing at a distance.

Sound processor handling

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

Paediatric considerations

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 childs' sound processor.

Listening through the Baha System

There are several test devices which allow candidates to listen through 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.

Testband

This is a spring-loaded head band designed for short tests, mainly inside the clinic, as the pressure of the plastic connector plate against the head is quite firm.

Baha Headband

This has a softer spring than the testband, which makes it suitable for longer term tests.

Baha Softband

The elastic Baha Softband is designed to allow long term use by children who are not candidates for surgery. It is available with bilateral or unilateral connectors.

To fit band devices:

1. Attach a sound processor to the plastic snap connector disc.
2. Make sure the sound processor is working by first fitting the band around your own head and then covering your ears while introducing sound.
3. Put the band on the candidate's head, placing the plastic snap connector disc against the selected mastoid.
4. Position the sound processor behind the ear. To avoid feedback, make sure the processor doesn't touch the ear or skin.
5. When using the Baha Softband, tighten it until it is tight enough to ensure effective sound transmission, but loose enough so as not to cause discomfort.

NOTE: For candidates with bone defects or other problems where a testband/ headband is not suitable, the Baha Softband may provide a better testing solution.

Sound processor considerations for pre-operative tests

We recommend using the most recent sound processor available for this test as it may provide benefits in terms of signal processing and wireless capabilities. If the client 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 head band or Baha Softband.

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

- If using NOAH, make sure that the BC thresholds has been transfered from the NOAHAud into the Baha Fitting Software. If in stand-alone mode, enter the patients BC thresholds or use the import function to import threshold data stored in the Baha Data Bank.
- Select your sound processor in the Selection Screen and click on the detect button.
- Place the band on the candidate's head and attach the sound processor to the plastic snap connector disc.
- In BC Select, select Demo as the connection type.
- Run a Feedback Analyser measurement if supported by the sound processor.
- 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 Baha Fitting Guide and instructions for use.

Selection of implant side

Clinical research suggests that children with binaural conductive hearing loss should be fitted with bilateral sound processors on a Baha Softband, preferably before the age of six months.[21,22] If bilateral fitting is contraindicated, fit the side with the best bone conduction thresholds. For children with SSD, the Baha sound processor should be placed on the deaf side.

Counselling

Parents of hearing-impaired children have a great need for counselling. 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, counselling should cover the treatment process from both a short and long-term perspective. Therefore, both the Baha Softband and the prospect of surgery should be discussed.

Device selection

Due to weakening of the sound signal as it passes through the skin, the gain from a Baha sound processor fitted on the Softband will be reduced by 10-15 dB, some of which may be compensated with extra amplification by fitting the child with the Baha Fitting Software. We recommend using the most recent sound processor as it may provide benefits in terms of signal processing and wireless capabilities. If the child needs more audibility, change to a more powerful sound processor. The benefit of a stronger processor is most noticeable at higher sound frequencies because these are weakened to a greater extent than low frequency signals when passing through the skin.[20]

Use age appropriate tests to evaluate audibility:

- Behavioural 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.

Fitting the Baha Softband for children

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 familiarise itself with the Softband before putting in on the 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, while also loose enough so as not to cause discomfort.
7. Ask the parent or carer to talk to the child or sing a song to provide a pleasant hearing experience. Watch for the child's reaction.

Make sure your can fit one finger between the head and the Baha Softband – this will ensure it is not too tight.

NOTE: Once the Baha Softband is tight enough to transmit sound effectively, additional tightening will only increase the sound marginally.[23]

Counselling of candidates

Before receiving treatment, candidates should be motivated, well informed and carefully counselled about having realistic expectations of their Baha System. During counselling, 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 counselling are:

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

Benefits of 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 deliver significantly improved sound quality, comfort and speech intelligibility.

Single-sided sensorineural deafness (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.[5]

Treatment process

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

- You should tell the candidate that they will need to have surgery. Emphasise that the surgical procedure is considered minor and may be performed in an outpatient setting under local or general anaesthetic.
- 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 provides a connection without a skin penetrating abutment. At this point, showing an actual implant may reduce any anxiety.
- Inform candidates that there will be dressing and pressure bandage over the abutment when they come from surgery, and that the dressing will be changed five to seven days later and removed completely after 10 to 14 days.
- Explain how the sound processor will be fitted.

NOTE: Emphasise that there is no risk of damage to the candidate's hearing from Baha 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 Baha testing is essential in this respect and listening through a Baha sound processor on a test band or Baha 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. Careful consideration must therefore be given to the candidate's ability to maintain proper hygiene. With children, explain to parents or carers that hygiene will be their responsibility. No special aftercare is necessary for the Baha Attract System.

Cost, reimbursement and funding

Reimbursement of the cost of a Baha System is an important issue and this should be discussed during the preoperative counselling. 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.

NOTE: Please contact your Cochlear representative for details of cost, reimbursement and funding available in your country.

Case histories

Case history 1

Patient: Male

Age: 70

Occupation: Retired

Type of hearing loss: SSD

Diagnosis: Sudden Sensorineural Deafness and Tinnitus since 1998.

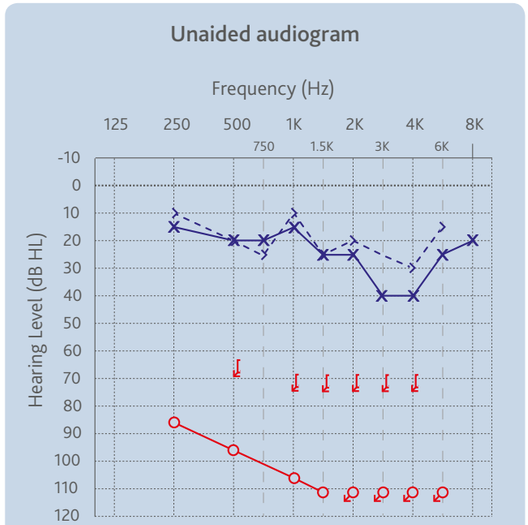
Aided side: Right

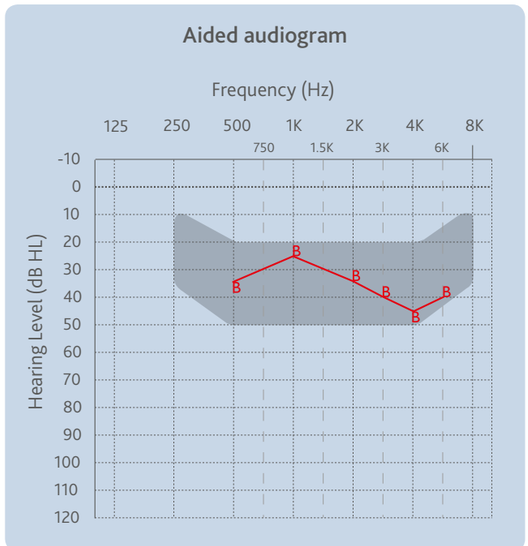
Baha System: Baha 4 Attract System

Sound processor: Baha BP110 Power

History: Patient has been deaf on his right ear since 1998, received a Baha 4 Attract System in 2013. Fitted with the Baha BP110 Power sound processor and Sound Processor Magnet 3. Speech perception increased from 6 – 84% at 65dB. Very happy with the outcome.

PTA_4 improvement: N/A





B = Aided threshold with Baha in soundfield testing

Case history 2

Patient: Female

Age: 48

Occupation: Office worker

Type of hearing loss: Unilateral conductive.

Diagnosis: CSOM since 2008, Left side AN surgery, deaf since 2006.

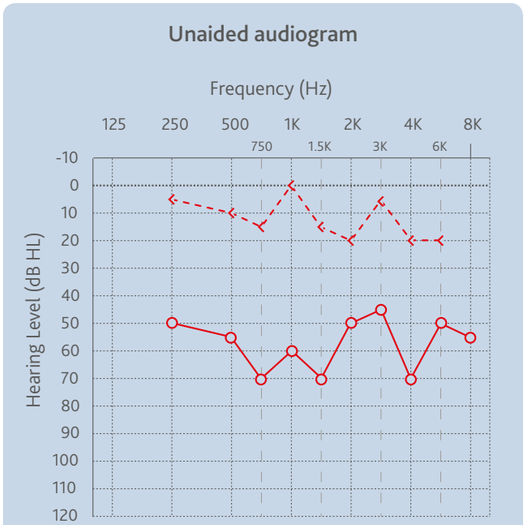
Aided side: Right

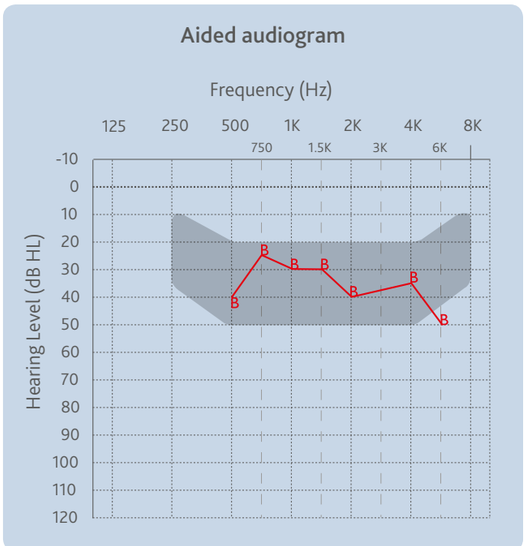
Baha System: Baha 4 Attract System

Sound processor: Baha 4 Sound Processor

History: Patient has been deaf in her left ear since 2006 after an acoustic neuroma surgery. Chronic suppurative otitis media in the right ear since 2008. Received a Baha 4 Attract System in 2013. Fitted with the Baha 4 sound processor and Sound Processor Magnet 5. Speech perception increased from 0 – 66% at 65dB.

PTA_4 improvement: 59 to 36 dB





B = Aided threshold with Baha in soundfield testing

Case history 3

Patient: Male

Age: 53

Occupation: Nurse

Type of hearing loss: Bilateral mixed hearing loss

Diagnosis: Chronic otitis media, middle ear bones removed after osteomyelitis, tympanic membranes ruptured bilaterally.

Aided side: Right

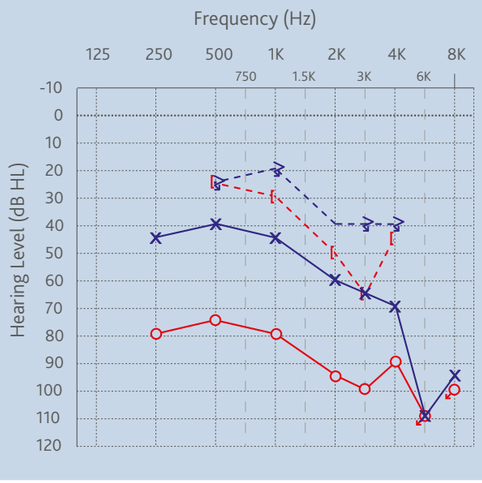
Baha System: Baha 4 Connect System

Sound processor: BP110 Power

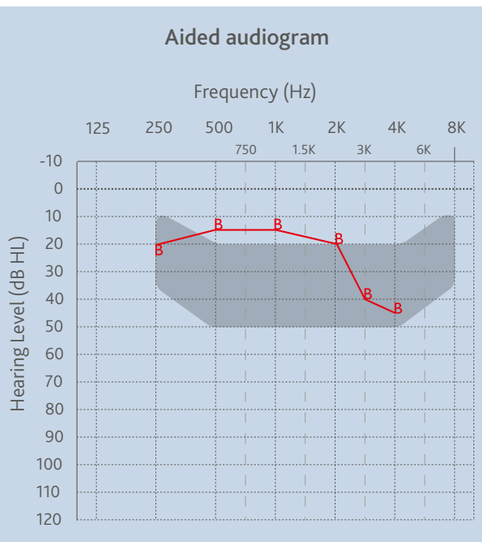
History: The client has had hearing problems his entire life. The client received his Baha in 2004. In 2007 he received a new implant after losing the original due to trauma. He uses his Baha constantly and is extremely pleased with the sound.

PTA_4 improvement: 85 to 24 dB

Unaided audiogram



Aided audiogram



B = Aided threshold with Baha in soundfield testing

Case history 4

Patient: Female

Age: 13

Occupation: Student

Type of hearing loss: Bilateral Conductive hearing loss.

Diagnosis: Treacher Collins syndrome.

Aided side: Left

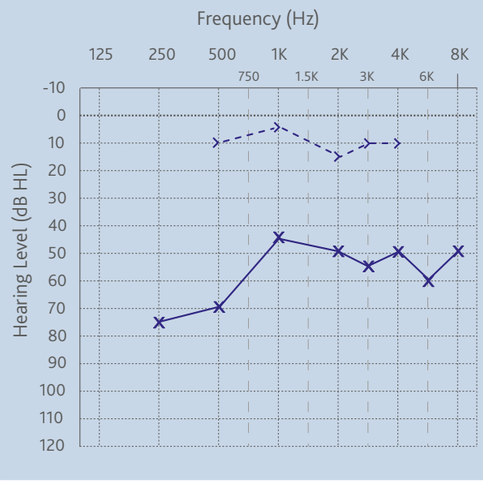
Baha System: Baha 4 Connect System

Sound processor: Baha 4 Sound Processor

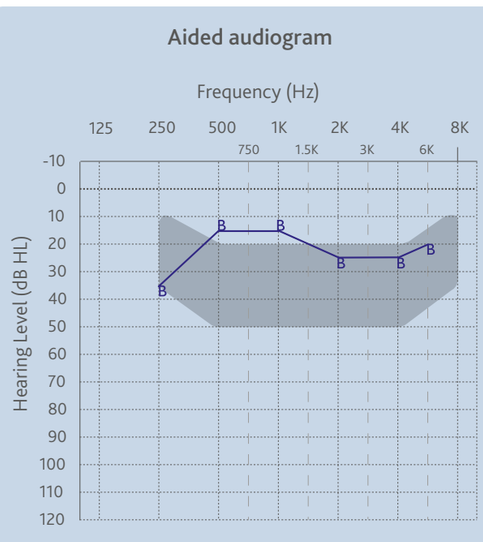
History: The client has used Baha since she was 3 years old. She experiences great benefit from the Baha in classroom situations.

PTA_4 improvement: 54 to 20 dB

Unaided audiogram



Aided audiogram



B = Aided threshold with Baha in soundfield testing

NOTE: Results obtained in case studies are not predictive of results in other cases, which may vary from those detailed.

Hear now. And always

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.

That is why seven out of ten people worldwide who choose a cochlear implant choose Cochlear as their hearing partner.

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