Cochlear®
Hear now. And always

Candidacy, evaluation and fitting protocol

Cochlear™ bone conduction hearing systems

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Initial evaluation

Goals

- Identification of hearing loss with site of lesion (Conductive or Mixed Hearing Loss, Single Sided Deafness)
- Determine the impact on speech communication and quality of life
- Collect a baseline for continued monitoring of hearing outcomes
- Develop a treatment plan including medical and audiological pathways

Suggested tasks

Audiological evaluation

- ☐ Case history
- ☐ Otoscopic examination of the ear and ear canal
- ☐ Tympanometry for both ears
- ☐ Acoustic reflex measures (optional)
- ☐ Otoacoustic emissions (optional)
- ☐ Standard audiometric assessment including unaided air conduction, bone conduction, and speech recognition testing using insert earphones (preferred, if possible) for both ears

Medical examination

- ☐ Medical consultation to determine etiology and medical treatment (if needed)

Tip

Clinical data indicates that patients with an air-bone gap of more than 30 dB pure-tone average (PTA) will experience significant advantages from a bone conduction system as compared to using an air conduction hearing aid.[1]

Indications

Conductive or mixed hearing loss (CHL/MHL)

PTA bone conduction threshold ≤65 dB sensorineural hearing loss (SNHL)
(500, 1000, 2000, 3000 Hz)

Air conduction thresholds are not considered.

The audiometric air-bone gap (ABG) is a strong indicator of candidacy for a bone conduction solution. The greater the ABG, the greater the benefit of a bone conduction solution compared to an air conduction hearing aid.[1]

Non-surgical considerations

- ☐ Use during medical treatment to address hearing loss during treatment, before surgery or during healing period
- ☐ Lack of stable hearing can impact speech acquisition for pediatrics or impact daily life for adults

Implantable bone conduction considerations

- ☐ Use post medical treatment once the ear is stable

Bilateral CHL/MHL

On average:
PTA bone conduction threshold within a 10 dB difference

OR

At individual frequencies:
PTA bone conduction threshold up to 15 dB difference

Air conduction thresholds are not considered.

Single-sided deafness (SSD)

Poor ear:
Non-functional hearing
(i.e. profound hearing loss)

Good ear:
PTA air conduction threshold ≤20 dB SNHL
(i.e. normal hearing, 500, 1000, 2000, 3000 Hz)

Additional indications

- ☐ Patients who cannot or will not use an air conduction CROS hearing aid
- ☐ Patients with contraindications for cochlear implantation such as:
  - Duration of deafness
  - Reimbursement landscape
  - Age of recipient
  - Recipient anatomy (cochlear nerve deficiencies, inner ear malformations, congenital loss, etc.)
  - Active chronic otitis media
  - Air-bone gap
  - Tinnitus
  - Patient expectations
  - Patient goals (e.g., hearing in noise, hearing in specific situations, localization)

Bone conduction demonstration and evaluation

Goals

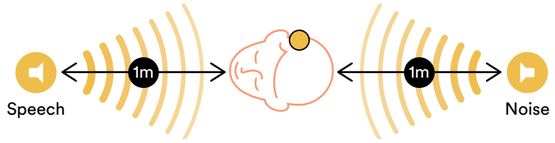
- Demo the bone conduction system
- Complete the bone conduction evaluation
- Provide recommendations based on evaluation results and other considerations
- Create audiological treatment plan in conjunction with medical treatment plan to address hearing needs of the patient

Equipment

- ☐ Baha® 6 Max Sound Processor
- ☐ Baha test rod, Softband and/or SoundArc™
- ☐ Cochlear™ Baha Fitting Software installed on fitting computer along with NOAHlink® Wireless Programing Interface
- ☐ Audiometric test equipment with soundfield capability
- ☐ Recorded speech testing material

Recommended setup for evaluation

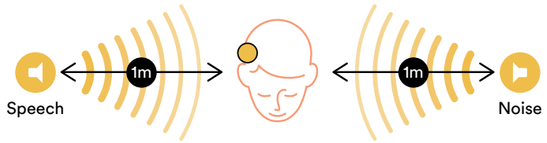
Conductive or mixed hearing loss



Option 1:
Speech from the front speaker and noise from the rear speaker (shown)

Option 2:
Speech from the front speaker and noise from the side speaker (90°)

Single-sided deafness



Speech from the speaker on the side of the ear to be implanted
Noise from the speaker on the side of the better hearing ear

Suggested tasks: Bone conduction evaluation

Unaided soundfield testing of ear to be implanted

- ☐ The non-test ear should be plugged or muffed to mitigate testing artifact, especially if that ear has better air conduction sensitivity than the treatment ear
- ☐ Soundfield unaided audiogram 500 Hz through 6000 Hz using narrow band noise stimuli
- ☐ Consider measuring unaided thresholds with the Ling 6(HL) test (v2.0) with calibrated, pre-recorded Ling 6 sounds[5]
- ☐ Unaided CNC Words at 65 dBA SPL
- ☐ Unaided adaptive sentences noise test (ex. BKB SIN, HINT, or QUICK SIN) at 65 dBA

Tip

For pediatric patients, use age-appropriate tests and questionnaires to evaluate audibility and speech understanding[5]

Aided soundfield testing of ear to be implanted

- ☐ The non-test ear should be plugged or muffed to mitigate testing artifact especially if the non-test ear has better air conduction sensitivity than the treatment ear
- ☐ Couple the Baha Sound Processor to a Softband and/or Sound Arc and place on the patient's head
- ☐ Program the Baha 6 Max in the fitting software for use by the patient to demo and to complete the aided portion of the testing
- ☐ Soundfield aided audiogram 500 Hz through 6000 Hz using narrow band noise stimuli
- ☐ Consider measuring aided thresholds with the Ling 6(HL) test (v2.0) with calibrated, pre-recorded Ling 6 sounds
- ☐ Aided CNC Words at 65 dBA SPL
- ☐ Aided adaptive sentences noise test (ex. BKB SIN, HINT, or QUICK SIN) at 65 dBA

Demonstration with a Baha® 6 Max Sound Processor

Demonstration using a Baha 6 Max Sound Processor on a test rod, Softband or SoundArc is a counseling tool that can give a candidate a sense of hearing through bone conduction and they can begin to understand the possible benefits.

Tip

For a more real-world experience, allow the candidate to listen with the Baha 6 Max Sound Processor in different sound environments—for example by taking a walk around the hospital/clinic or during a home trial.

Tip

It's important to counsel patients about the expected improvement in sound quality a patient can receive with a surgical bone conduction solution like Osia®, compared to a demonstration with non-surgical solution using the Baha 6 Max Sound Processor. A surgical solution has direct access to the bone conduction path with no skin attenuation to overcome. Additionally, Osia technology is uniquely suited to transmitting high frequency sounds to help patients hear better, especially in challenging situations like noisy environments.

Baha 6 Max Sound Processor preset program options

Program 1: Conductive hearing loss
Set up demo patient file using BC PTA of 10 dB

Program 2: Mixed hearing loss
Set up demo patient file using BC PTA of 35 dB

Program 3: SSD
Set up demo patient file identically to Program 1 but with low frequency gain reduced by 10 to 12 dB in the frequencies below 750 Hz

Bone conduction demonstration and evaluation

Baha 6 Max Sound Processor

Test rod

Test rod demonstration

	Out of box settings
Use	A simple, easy demonstration to give a candidate a first impression of hearing through bone conduction.
Clinic setup	Put a fresh battery in the Baha 6 Max Sound Processor. Snap the sound processor to the test rod and manually hold to the head.
Benefits	The fastest demo style. Easy to implement and can also demo for significant others.
Outcomes^	Provides a first impression of sound quality and function.
Predictability of post surgical experience	● LOWEST

Baha Softband

Baha SoundArc

Baha Softband or SoundArc™ demonstration and evaluation options

	Out of box settings	Preset programs (see progrms at left)	Custom program
Use	A quick demonstration to give a candidate a sense of hearing through bone conduction.	A demonstration by category of hearing loss type to get a closer approximation of the candidate's performance with a bone conduction solution.	A full demonstration and evaluation of the candidate's performance with bone conduction to predict outcomes.
Clinic setup	Put a fresh battery in the Baha 6 Max Sound Processor. Fit the Softband to the candidate and snap the processor to the softband.	Put a fresh battery in the Baha 6 Max Sound Processor. Fit the Softband to the candidate, snap the processor to the softband, and select the program that matches the candidates hearing loss profile.	Put a fresh battery in the Baha 6 Max Sound Processor. Fit the Softband to the candidate, snap the processor to the Softband, create a custom program for the candidate using Baha Fitting Software, and complete unaided and aided testing in the booth.
Benefits	Quick demo to allow the patient to wear the device for a longer period.	Quick demo to allow the patient to wear the device for a longer period and provide a closer estimate to sound quality.	Full demonstration and evaluation to allow the patient to wear the device for a longer period, provide a more specific demonstration of sound quality, and can measure outcomes.
Outcomes^	Provides a general sense of sound quality, since the programming is not customized for the loss type or the individual hearing loss.	Provides a closer approximation of sound quality.	Provides the closest approximation of sound quality. Provides predictable hearing and speech perception outcomes.[4]
Predictability of post surgical experience	●○○○○ LOW	●●●○○ MODERATE	●●●●● HIGHEST

^ Clinical studies have shown that a non-surgical bone conduction solution, like Baha Start, is an effective method for predicting outcomes before bone conduction implantation.[2-3]

Counseling

Goals

- For CHL/MHL patients: address the need for reliable hearing during the disease cycle and provide consistent hearing regardless of state of the outer/middle ear
- For SSD patients: address the need to reduce the head shadow effect as well as improve hearing in noise

Tip

Continue to re-evaluate the patient for bone conduction amplification over the course of medical treatment.

Suggested tasks: Counseling

Take into consideration

- ☐ Bone conduction evaluation results
- ☐ Short term vs. long term vs. intermittent use of the bone conduction solution
- ☐ Patient health plan benefits and coverage
- ☐ Patient hearing goals
- ☐ Patient age and lifestyle
- ☐ Daily use and maintenance of a bone conduction device
- ☐ Patient impression from demo

Provide recommendations based on results and discuss appropriate expectations

- ☐ Counsel on the optimal option for the patient (surgical or non-surgical)
- ☐ Many factors contribute to improved hearing performance. Setting appropriate expectations is not only important in the candidacy process, but on an ongoing basis in order to help patients see their successes, identify their challenges, and continue to make progress.
- ☐ For SSD patients: counsel that hearing in the deaf ear will not be restored but the bone conduction sound processor will send sound from the deaf side to the opposite cochlea

Next steps

- ☐ Review Bone Conduction Guide to Preparing for Surgery (BUN535)
- ☐ Provide Engagement Manager contact information to the candidate
- ☐ Complete order form
- ☐ For Baha 6 Max Sound Processor patients: Discuss Remote Care via Remote Assist* to supplement in-clinic care to complete follow-up appointments with programming, perform troubleshooting, make minor adjustments, set up replacement devices or complete an upgrade fitting

Bone conduction solution recommendations

Patient qualifications	Patient qualifications	Patient qualifications
• CHL/MHL with bone conduction threshold PTA less than 55 dB • Meets age requirement^† • Motivated to proceed with a surgical hearing implant solution	• SSD • Meets age requirement^† • Motivated to proceed with a surgical hearing implant solution	• CHL/MHL with bone conduction threshold PTA less than 55 dB • No age requirement • Motivated to proceed with a non-surgical hearing solution
Recommendation	**Recommendation**	**Recommendation**
Cochlear Osia System†	**Cochlear Osia System†** OR Conduct a cochlear implant evaluation for a **Cochlear Nucleus® System§**, more info at www.cochlear.us/cicandidacy	**Cochlear Baha Start with Baha 6 Max Sound Processor** worn with a SoundArc or Softband

Additional recommendations for specific cases

Patient with factors that preclude an Osia 2 System	**Cochlear Baha Connect System with Baha 6 Max Sound Processor**	
Patient with bone conduction PTA threshold between 55–65 dB	Option 1: **Cochlear Baha Connect System with Baha 5 SuperPower Sound Processor**	Option 2: Conduct a cochlear implant evaluation for a **Cochlear Nucleus System**, more info at www.cochlear.us/cicandidacy
Baha Solution patient requiring additional clearance between their skin and the sound processor	Consider the **Baha 6 Max Sound Processor with the 2mm Extended snap coupling**, instead of the LowPro™ snap coupling	

* Clinic must be enrolled in Remote Care to participate. Remote Assist for Baha is intended for a follow-up adjustment or setup of a replacement or upgrade sound processor for suitable qualified patients based on clinical judgment. For compatibility information visit www.cochlear.com/compatibility.

^ In the United States and Canada, the placement of a bone-anchored implant is contraindicated in children below the age of 5.

† In the United States, the Osia System is cleared for children ages twelve and older. In Canada, the Osia System is approved for children ages five and older.

§ In the United States and Canada, the Nucleus System is approved for children with single sided deafness ages five and older. For more information on general Nucleus candidacy criteria, please visit https://www.cochlear.com/us/en/home/diagnosis-and-treatment/how-cochlear-solutions-work.

Activation and programming

Goals

- Provide improved sound quality and speech intelligibility with comfortable wear for the recipient to use the device to the maximum potential

Equipment

Baha System

- ☐ Cochlear Baha Fitting Software installed on fitting computer
- ☐ NOAHlink Wireless Programing Interface

Osia System

- ☐ Cochlear Osia Fitting Software installed on fitting computer
- ☐ Hi-Pro 2 wired interface with the Cochlear CS45 fitting cables
- ☐ NOAHlink Wireless Programing Interface

Suggested tasks: Site check

- ☐ At every visit, complete a site check
- ☐ Counsel the patient to perform regular site checks and report any issues immediately

Baha Start

- ☐ Check fit and placement of Softband or SoundArc
  - Softband: The connector disc should fit flush against the skin on the mastoid or another bony location on the skull. It should be close-fitting to ensure effective sound transmission, while also loose enough so as not to cause discomfort. Make sure you can fit one finger between the head and the Softband—this will ensure it is not too tight.
  - SoundArc: The connector disk should fit flush against the skin on the head above and behind the ear. Adjust the shape of the SoundArc so that it does not wobble. The entire soft tip should rest slightly in front of the ear and feel comfortable on both sides.

Osia System and Baha Attract

- ☐ Check magnet strength
  - Cochlear Baha and Osia Sound Processor magnets are available with a variety of strengths. It is very important to choose a magnet strength that is appropriate for each patient.
  - If the magnet is too weak, the sound processor may fall off.
  - If the magnet is too strong, the patient may feel discomfort or experience soreness and irritation of the skin.
  - If skin compression or irritation is present, reduce magnet strength.
  - If required magnet strength is in-between, consider fitting a Cochlear SoftWear™ pad.
- ☐ The patient should contact the clinic immediately if they experience any pain, soreness, itching or warmth, or notice redness or irritation at the site

Baha Connect

- ☐ Check skin around abutment for irritation or infection
  - Regular cleaning is the most effective way to prevent skin reactions. Patients who are not able to appropriately conduct their own skin care should get assistance from their family or caregiver.
- ☐ The patient should contact the clinic immediately if they experience any pain, soreness, itching or warmth, notice redness or irritation at the site, or notice the abutment is loose

Tip

The Baha 6 Max Sound Processor with the LowPro snap coupling is suitable for most patients, but the 2mm Extended snap coupling may be considered for patients requiring additional clearance.

Suggested tasks: Programming the device

Select the programming workflow

Several activities are available in Baha and Osia Fitting Software for simple navigation and streamlined efficiency in programming for different fitting scenarios such as a first fitting, follow-up fitting, or set up a replacement processor. Each activity has a customized workflow to guide you through the session and complete the needed fitting tasks. The connection flow and recommended steps will differ depending on the activity chosen.

Programming steps

- ☐ In the Patient Information screen, patient information can be entered or displayed
  - When accessing the software through an office system (like Noah®), Patient information and Audiogram screens will automatically be filled in.
- ☐ The Connection screens walk through steps to connect a sound processor
- ☐ The Digital Link Calibration (Osia only) measures the individual implant calibration and the coil-to-coil distance
- ☐ The Feedback Analyzer measures the patient's individual feedback path and reduces the risk of feedback
- ☐ The Prescribe screens are the basis for the recipient's prescription
  - Audiogram, BC Select, and BC Direct configure the sound processor to match the patient's thresholds, profile and listening needs. These parameters are required before moving to the fitting step in order to apply the appropriate prescription and sound processor settings.
- ☐ The Fitting screens allow adjustment of gain and features of the sound processor to match patient preferences
  - Access Hearing Mentor, Fine Tuning, Active Gain and Program Settings and view the gain graph. Wireless devices may also be paired to the sound processor.
- ☐ The Save screen offers a summary of the settings to be saved to the device and provides the options to save to the sound processor and/or file system, reset or continue datalogging, and review and/or print the session report

Tip

Technical measurement for Baha 6 Max Sound Processors

For clinics interested in conducting device verification of the Baha 6 Max Sound Processor, the Technical Measurement workflow in Baha Fitting Software 6.1 will set up the sound processor to allow you to measure and compare the device to the published specification using Audioscan® Verifit and skull simulator.

Technical measurement settings are not for patient use and will only be temporarily available in the sound processor during verification testing. The sound processor will return to its previous state when disconnecting and restarting the sound processor.

Recommended activation interval

Baha Start

Immediately

Baha Connect

12 weeks post-surgery

Baha Attract

4 weeks post-surgery

Osia System

4–6 weeks post-surgery

Device registration

Baha System

Register implant and sound processor

Osia System

Register implant and sound processor

Suggested tasks: Activation and upgrade visits

Site check

- ☐ If swelling at activation, check again in 2 weeks

Programming

- ☐ Complete programming workflow for a first fitting
- ☐ Enable datalogging to review at the next visit
  - Cochlear datalogging provides greater insight into the environment experienced by your patient, helping you track usage patterns, make adjustments to the sound processor, and form customized goals to suit their individual needs.
- ☐ Consider using Remote Assist for an upgrade activation

Counseling

- ☐ Counsel the patient on proper site maintenance and to report if they experience any pain, soreness, itching or warmth, or notice redness or irritation at the site
- ☐ Practice attaching and taking off device and review basic device use
- ☐ Provide Recipient Solutions Manager contact information (www.cclr.me/welcome)
- ☐ Review what's in the patient kit and introduce accessories based on the recipient's hearing goals if a Recipient Solutions Manager is not being utilized
- ☐ Set up the Baha or Osia Smart App and create a Cochlear Account. A Recipient Solutions Manager may also assist the recipient with this step
- ☐ Discuss communication strategies and rehabilitation resources (i.e., orientation in noise environments, listening to podcasts, environmental sound awareness and identification, etc.)
- ☐ Discuss hearing in different situations including options for challenging listening environments

Activation and programming

Recommended follow-up intervals

Adult

- 2 weeks
- 6 months (optional)
- 12 months
- Then annually

Note: In cases of patients with magnets, check the site at least once in the immediate post-activation period from 2 weeks–3 months to assess the magnet strength for appropriate retention and modification if found to be too tight or too loose.

Pediatric[6]

- 1 month
- 3 months
- 6 months
- 9 months
- 12 months
- 18 months
- 24 months
- Then annually

Note: Please take age and developmental needs of the child into account when planning post-activation follow-up. For example, a young infant or child may need more extensive follow-up, while an older child or teenager may follow a more adult-type follow-up schedule.

Additional

- Follow-up as needed based on clinical judgement or patient request for clinical management or troubleshooting
- Upgrade as appropriate

Suggested tasks: Follow-up visits

Site check

- ☐ As appropriate for the device, check the site for placement, skin compression, pain, redness, swelling or other signs of irritation or infection

Programming

- ☐ Consider using Remote Assist for follow-up and troubleshooting visits for Baha 6 Max sound processors
- ☐ Review Datalogging
- ☐ Complete programming workflow for a follow-up fitting

Counseling

- ☐ Review goals, record progress and revise goals as needed
- ☐ Re-train on device and accessory use and maintenance as needed
- ☐ Re-educate on listening strategies as needed

Remote Care for patients with a Baha 6 Max System

Your patient, your care, anywhere

With Cochlear Remote Care*, you can offer your patients the convenience of quality hearing care without the need to visit the clinic.

You have the flexibility to manage patient progress remotely and the ability to offer care to more patients, including those who may be limited by location, health, mobility, or school or work commitments.

Cochlear Remote Assist^ for Baha 6 Max Sound Processors allows patients to meet with you remotely via a video appointment through their Baha Smart App, where you connect to their sound processor through the Baha Fitting Software to complete a full fitting, make adjustments to a program, or just check in with your patient.

- Remote Assist is an option for accessing care remotely to complete follow up appointments with programming, provide counseling to your patient, perform troubleshooting, make minor adjustments, set up replacement devices or complete an upgrade fitting.
- Remote Assist for Baha allows access to all fitting workflows in Baha Fitting Software, including BC Direct and Feedback Analyzer, so it may be used to complete a first fitting, fine-tuning, and enable programs and processor and/or program features.
- Because of this access to the features and tools in the fitting software, Remote Assist is flexible to fit anywhere into your clinical model to supplement in-clinic care.

For more information contact your Cochlear Representative

* Clinic must be enrolled in Remote Care to participate.

^ Remote Assist for Baha is intended for a follow-up adjustment or setup of a replacement or upgrade sound processor for suitable qualified patients based on clinical judgment. For compatibility information visit www.cochlear.com/compatibility.

Outcomes evaluation

Goals

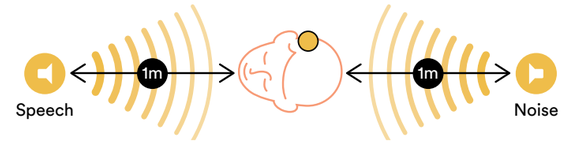
- Evaluate performance with fitted bone conduction device
- Compare aided testing to unaided baseline at candidacy evaluation
- Compare aided testing to last visit

Equipment

- ☐ Audiometric test equipment with soundfield capability
- ☐ Recorded speech material

Recommended setup for evaluation

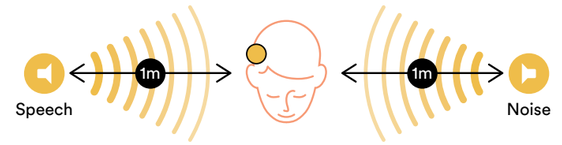
Conductive or mixed hearing loss



Option 1:
Speech from the front speaker and noise from the rear speaker (shown)

Option 2:
Speech from the front speaker and noise from the side speaker (90˚)

Single-sided deafness



Speech from the speaker on the side of the ear to be implanted
Noise from the speaker on the side of the better hearing ear

Suggested tasks: Aided evaluation

- ☐ The non-test ear should be plugged or muffed to mitigate testing artifact especially if the non-test ear has better air conduction sensitivity than the treatment ear
- ☐ Soundfield aided audiogram 500 through 6000 Hz using narrow band noise stimuli
- ☐ Consider measuring aided thresholds with the Ling 6(HL) test (v2.0) with calibrated, pre-recorded Ling 6 sounds
- ☐ Aided CNC Words at 65 dBA SPL
- ☐ Aided adaptive sentences noise test (ex. BKB SIN, HINT, or QUICK SIN) at 65 dBA

Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 700,000 devices and helped people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

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

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