Cochlear Americas

Implantable Hearing Solutions

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Presentation Overview

- Cochlear and Implantable Solutions
- The Cochlear™ Nucleus® & Hybrid™ Systems
- The Cochlear™ Baha® System
- Cochlear Resources
- Conclusion - Questions & Answers

Cochlear’s Implantable Solutions

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Cochlear Implantable Solutions

Cochlear Nucleus® System

A system that helps individuals* with severe to profound sensorineural hearing loss who only receive limited benefit from amplification

Cochlear Nucleus Hybrid System

Hybrid Hearing delivers maximum long-term performance outcomes for patients with severe to profound high frequency hearing loss**

Cochlear Baha® System

An osseointegrated auditory implant system for individuals† with unilateral profound hearing loss (single-sided deafness), mixed or conductive hearing loss

***** Children 2-17: severe-to-profound SNHL, children 1-2 years: profound SNHL, adults: moderate-to-profound SNHL ** Hybid L24 approved for recipients 18 and older. The Cochlear Nucleus Hybrid acoustic component is not compatible with the Kanso Sounds Processor. The Kanso Sound Processor is not intended to be used by Hybrid L24 Cochlear Implant recipients who receive benefit from the acoustic component. †Implant appropriate for aged >5 years old. Younger children may use the Baha Softband system

The Cochlear™ Nucleus® & Hybrid Systems

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Cochlear Implant Basics

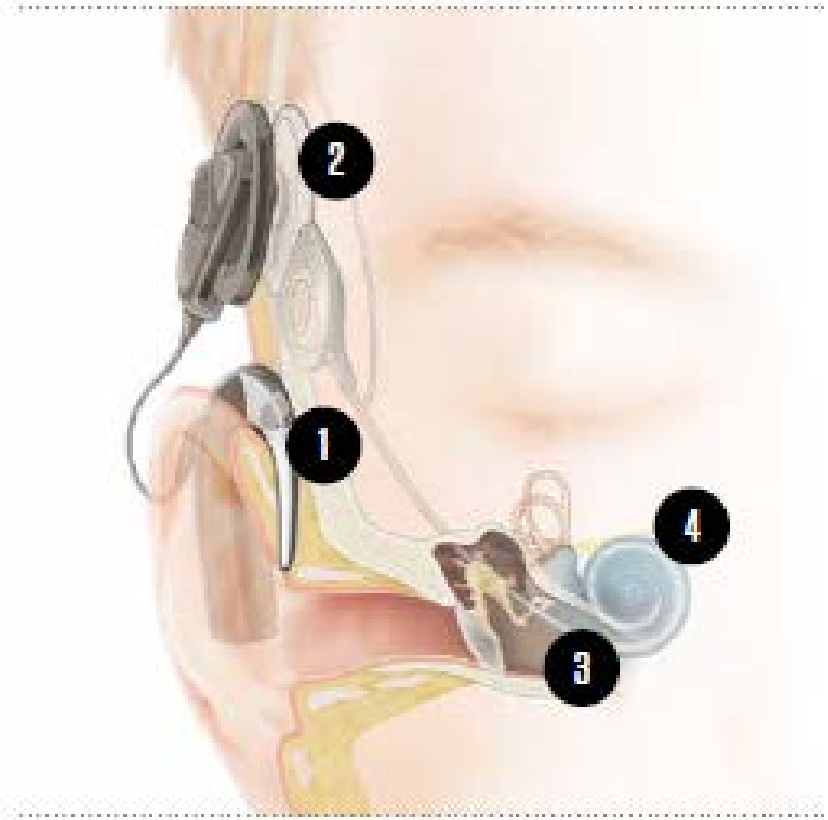
There are two main parts of the Nucleus Implant System:

An External Sound Processor

&

An Internal Implant

Hearing with a cochlear implant



1. Microphones on the sound processor pick up sounds and the processor converts them into digital information
2. This information is transferred through the coil to the implant just under the skin
3. The implant sends electrical signals down the electrode into the cochlea
4. The hearing nerve fibers in the cochlea pick up the signals and send them to the brain, giving the sensation of sound

Indications for Nucleus Hearing Implants

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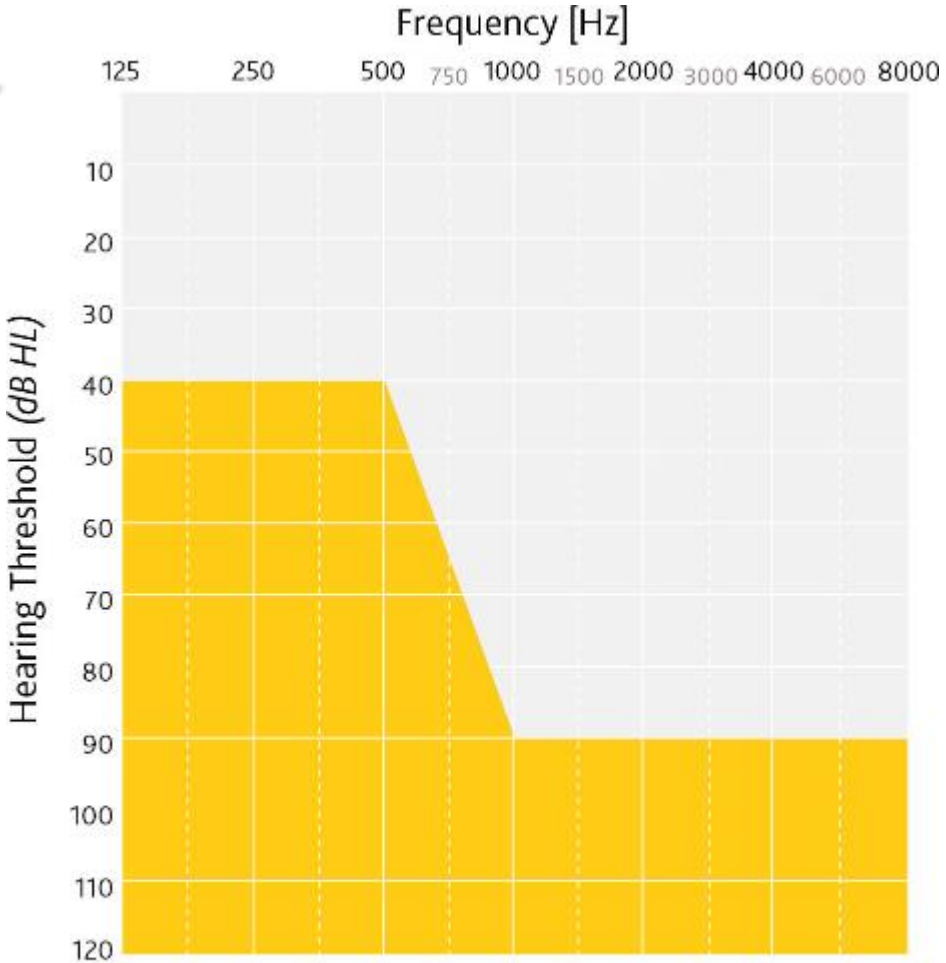
Nucleus® Cochlear Implant Indications for Adults



Cochlear Implant:

Sentence Score no better than 50% in the ear to be implanted and no better than 60% in the best aided condition

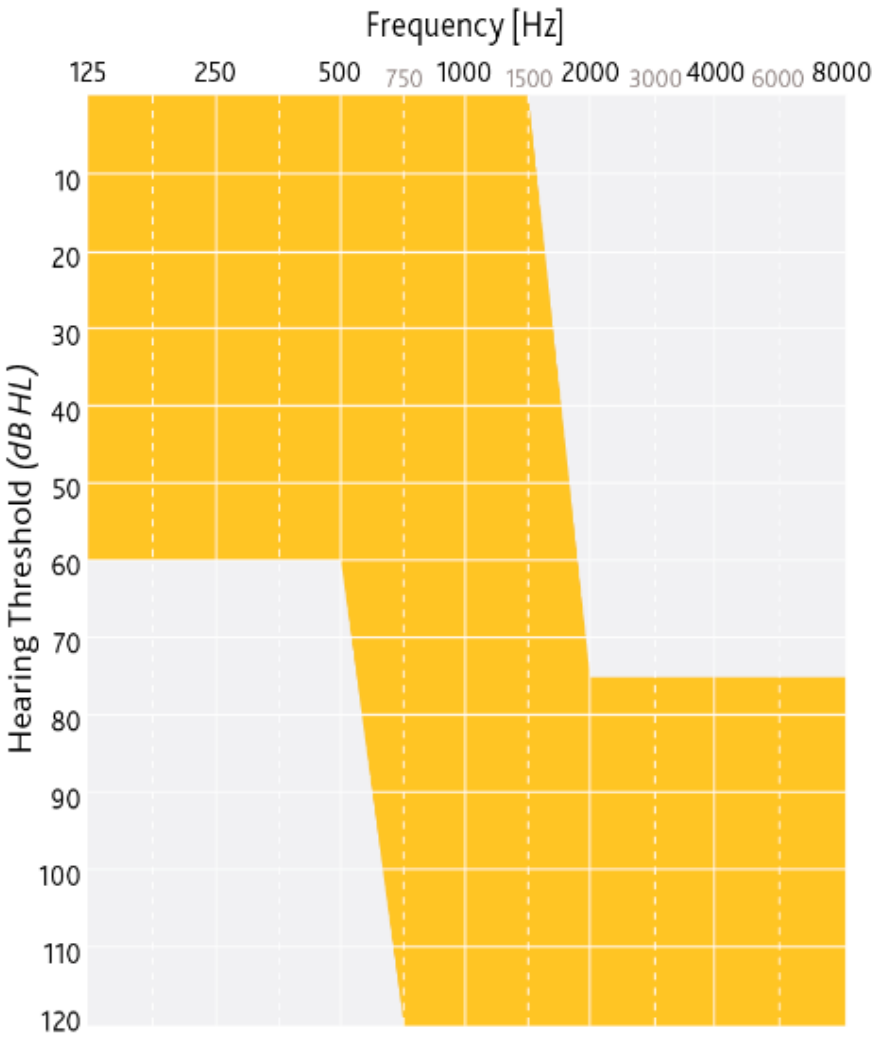
Medicare National Coverage Determination:

Sentence Score no better than 40% (best aided) unless enrolled in a clinical trial

Current opportunity: Evaluation of Revised Indications for Cochlear Implant Candidacy for the Adult CMS Population

https://clinicaltrials.gov/ct2/show/NCT02075229

Hybrid™ L24: An Expanded Indication



Ear to be Implanted

- Aided CNC word score between 10% and 60% correct, inclusively
- Normal to moderate SNHL in the low frequencies; PTA of 2k, 3k, 4k $\geq$ 75 dB HL

Contralateral Ear

- Aided CNC word score better than ear to be implanted but less than 80% correct
- PTA of 2k, 3k, 4k, $\geq$ 60 dB

Adults

- aged 18 years and older
- unilateral implantation of poorer ear

*The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality
Hybrid L24 implant is approved for use in adults ages 18 and older

Summary of Cochlear™ Nucleus® Indications

For Hybrid L24*: BEST AIDED

Word *(CNC)* score ≥10% and ≤60% in the poorer ear (ear to be implanted)
PTA of 2k, 3k, 4k ≥ 75 dB HL

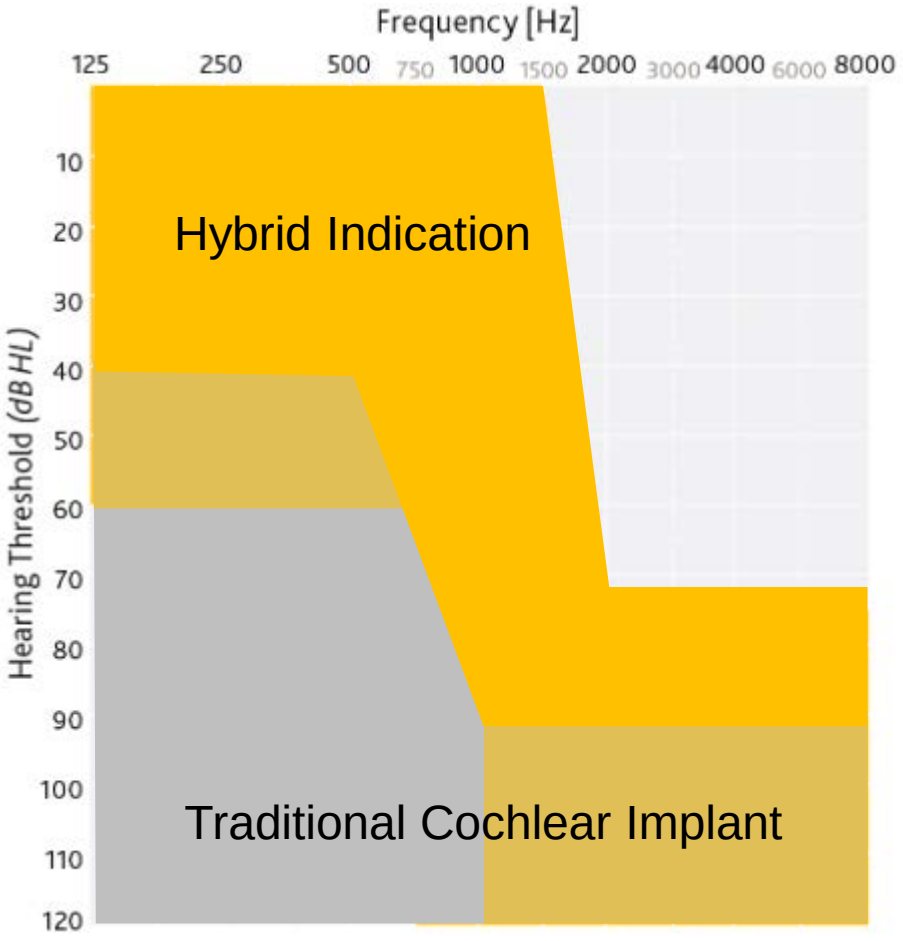
Word *(CNC)* score ≤ 80% in the opposite ear (better ear)
PTA @ 2k,3k, 4k ≥ 60 dBHL

For Traditional CI: BEST AIDED

Sentence score ≤ 50% in the poorer ear

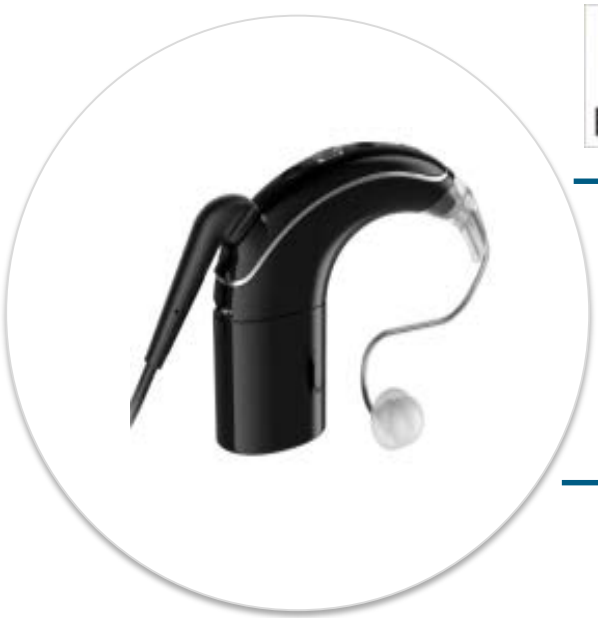
Sentence score ≤ 60% in the best listening condition

Medicare: Sentence Score no better than 40% (best aided) unless enrolled in a clinical trial



*The Hybrid L24 Implant is approved in the US for adults ages 18 years and older for unilateral use only

Nucleus 7 Hybrid™ Mode



3 Receiver Sizes

Domes - instant fit, covering all recipient needs

Clinics can order custom earmolds from external supplier

*The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality.

Current Nucleus Technology

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The Nucleus 7 Sound Processor

Nucleus 7 is the **smallest** and only **Made for iPhone** cochlear implant processor which delivers proven **hearing performance**[1].

HearYourWay™

1 - Cochlear Limited. D1190805. CP1000 Processor Size Comparison. 2017, Mar. Data on file

Nucleus 7 Sound Processor Features

Smallest BTE

Improved Wearing Options

Made for iPhone

SmartSound® iQ & MFi

True Wireless

Up to 50% more battery life

Nucleus Smart App

Aqua+ for Nucleus 7

Hybrid*

*The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality.

SmartSound iQ with SCAN

A range of technologies working together to meet user needs in every hearing situation

Automatically adjusts to the hearing situation

Industry first scene classifier (SCAN)*

Background noise reduction (SNR-NR)*

Wind noise reduction (WNR)*

*SNR-NR and WNR are approved for use with any recipient ages 6 years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings. SCAN is FDA approved for use with any recipient age 6 years old and older, to be used at the discretion of the recipient/parent/caregiver.

ConnectYourWay™

Nucleus 7 is the first and only **Made for iPhone** cochlear implant processor[1]

Bluetooth® LE and MFi for Hearing Device technology from Apple® lets patients connect directly to Apple iOS devices and stream music, phone calls and more.

2. Apple Inc. Use Made for iPhone hearing aids [Internet]. Apple support. 2017 [cited 24 February 2017]. Available from:

Nucleus Smart App

Nucleus Smart

Advanced control of the sound processor and wireless accessories, personalization and support –
directly from your iOS device*

*devices running iOS 10 and later

Available on the App Store

MFi Enables
More Access to Hearing Than Ever Before

- First ever CI product with direct audio streaming from a compatible Apple device, bimodally too.
- No app required!

Direct Audio Streaming and Control

Listen on Apple Podcasts

YouTube

NETFLIX

MFi is just the first step …

iOS

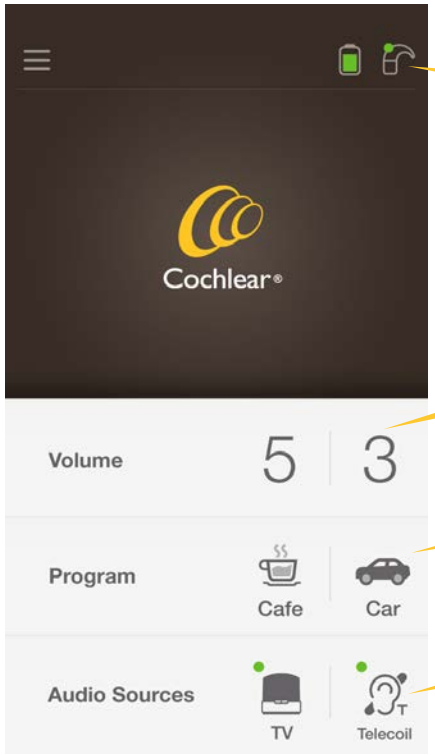
MFi Capability =
Pairing to Apple Device & Basic Controls

Nucleus Smart

Nucleus Smart App =
CR230-type functionality for Nucleus 7; and much more!

Nucleus Smart App Control and Monitoring

Home Screen Controls



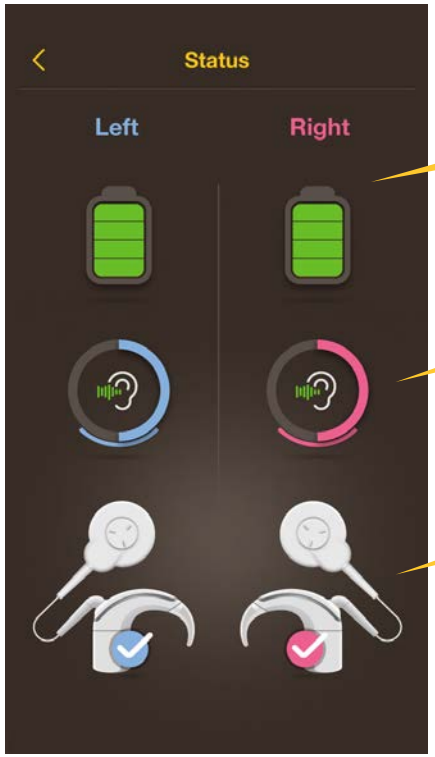
Tap to go to Status screen
(shown on next slide)

Controls for Volume, Sensitivity, MVBT

Controls for Program

Controls for audio sources and mixing

Status Screen Controls

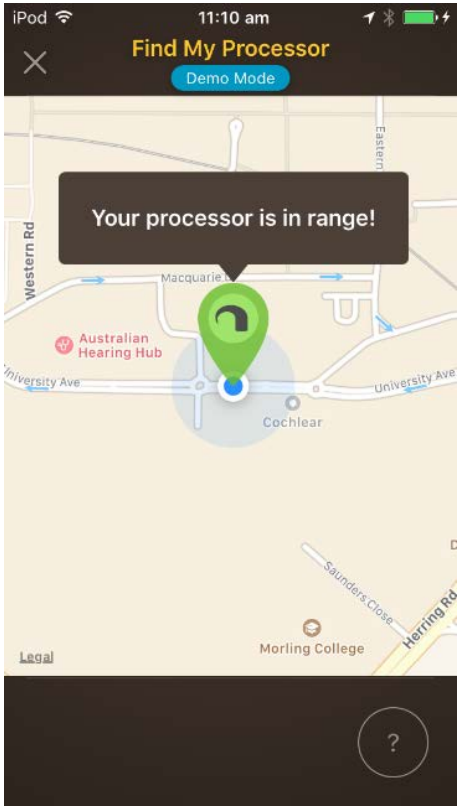


Battery level

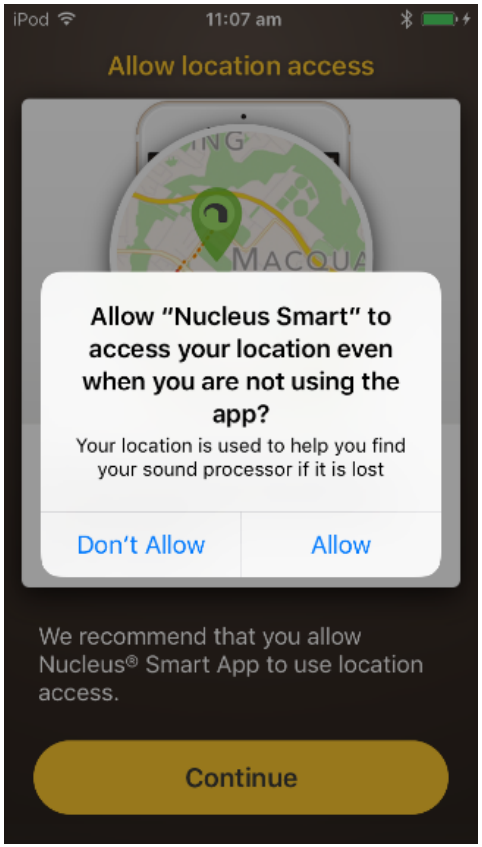
Audio level meter

Sound Processor Status

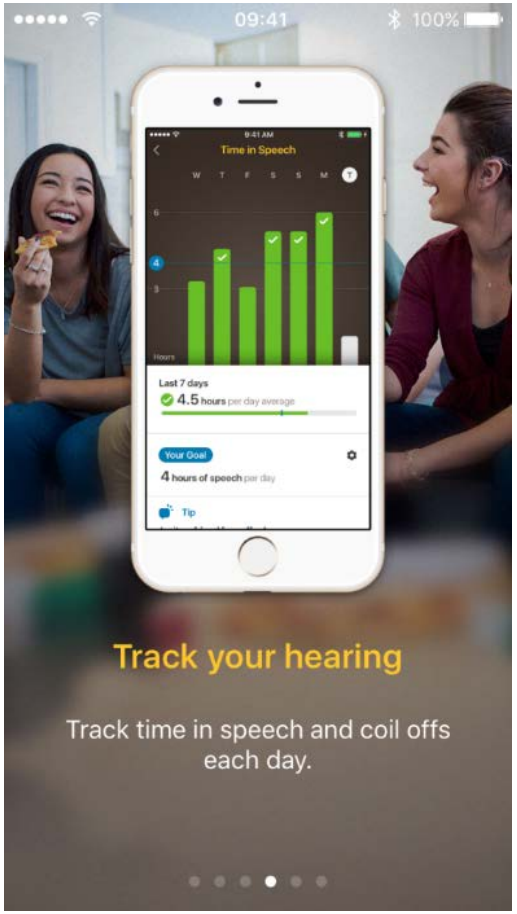
Find My Sound Processor



Uses GPS to track when the phone last had contact with the sound processor



Hearing Tracker

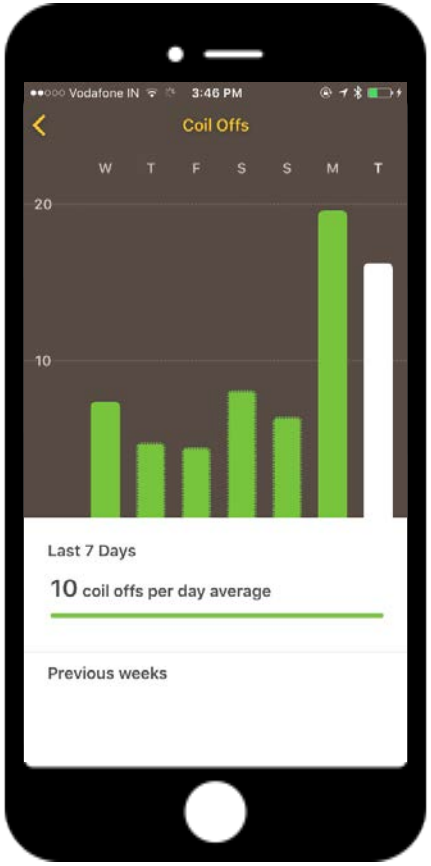


What does it show?

Time in Speech

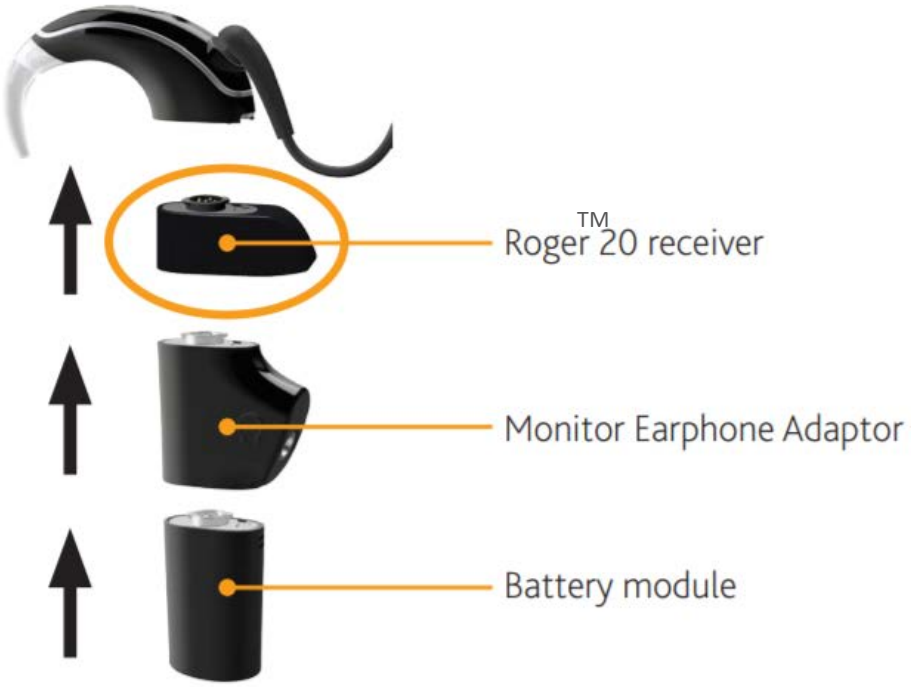
What does it show?

Coil Offs



Monitor Earphone Adaptor

Processor only



FM Connectivity

CP1000 does not have an accessory port

The World's Only Smart Bimodal Solution that's Made for iPhone®

Nucleus® 7

Cochlear

LiNX 3D
ENZO 3D

ReSound GN

+

Made for iPhone

True Wireless Accessories

KANSO®

Kanso®: Smart, simple, discreet

SMART

The benefits of Nucleus 7 hearing technology in an off-the-ear solution

SIMPLE

Easy-to-use single unit, cable free, one button set and forget

DISCREET

Smallest and lightest off-the-ear sound processor[1,2]

1. Cochlear Limited. CP950 Kanso Sound Processor User Guide. Data on file, July 2016.
2. MED-EL. Rondo. The World's First CI Single-Unit Processor. [PDFInternet] [as of August 2016]. Available from: http://s3.medel.com/pdf/US/ flbr/23710_21RONDO+US+Factsheet.pdf.

Kanso is Smart

Uncompromised Hearing Performance

The world's first off-the-ear processor with ***SmartSound® iQ with SCAN*** *and* ***dual microphones***.

Dual microphones enhance a recipient's ability to hear in noisy environments by up to 30%.[1-3]

SNR-NR and WNR are approved for use with any recipient ages 6 years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings. SCAN is FDA approved for use with any recipient age 6 years old and older, to be used at the discretion of the recipient/parent/caregiver

1. Amlani AM. Efficacy of directional microphone hearing aids: a meta-analytic perspective. *J Am Acad Audiol* 2001;12(4):202-14.
2. Bentler RA. Effectiveness of directional microphones and noise reduction schemes in hearing aids: a systematic review of the evidence. J Am Acad Audiol. 2005 Jul-Aug;16(7):473-84.
3. Cochlear Limited, A clinical comparison of the Cochlear™Nucleus®5 noise management options, Cochlear White Paper; 2010, N34545F JUN10 ISS1.

Kanso Sound Processor Uses Nucleus® 6 Technology

SmartSound® iQ with SCAN*

For the best hearing outcomes, recipients need a system that can manage different types of sound automatically. SmartSound® iQ has a range of individual technologies that are designed to work together seamlessly.

Dual microphones

Kanso is the only off-the-ear sound processor with dual microphones, which enhances a recipient's ability to hear in noisy environments by up to 30%.[1-3]

* SNR-NR and WNR are approved for use with any recipient ages 6 years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings. SCAN is FDA approved for use with any recipient age 6 years old and older, to be used at the discretion of the recipient/parent/caregiver.

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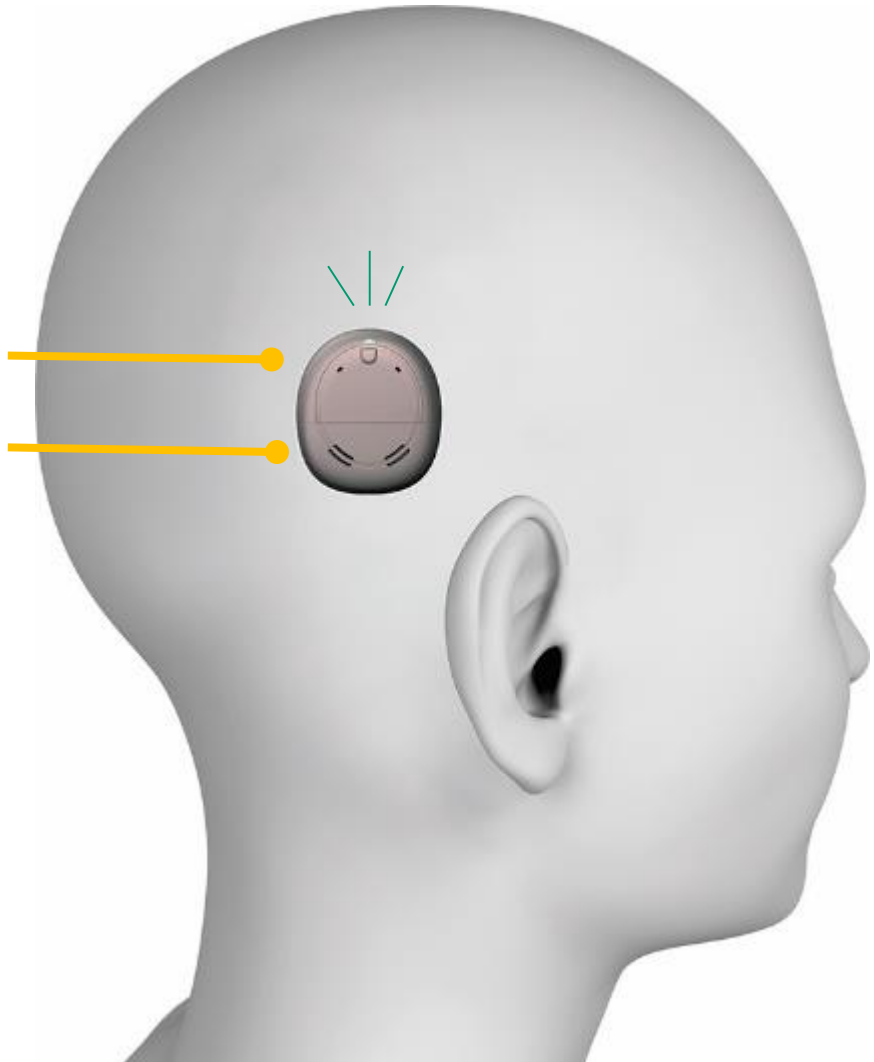
3. Cochlear Limited, A clinical comparison of the Cochlear™Nucleus®5 noise management options, Cochlear White Paper; 2010, N34545F JUN10 ISS1.

Kanso is Simple



- Kanso is a cable free, single unit with one button to set and forget
- No need to change programs with SmartSound iQ with SCAN
- Indicator light can be set as desired

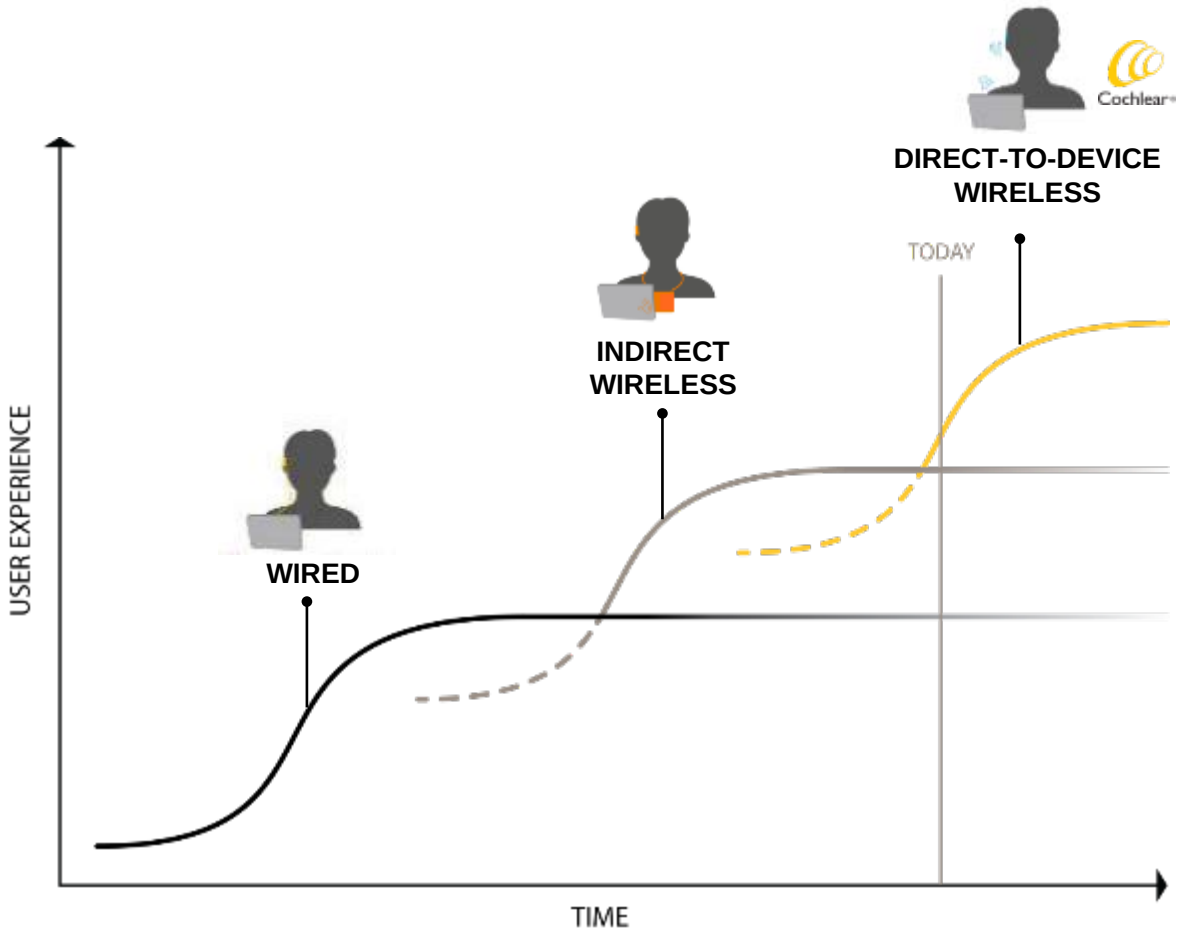
Kanso is discreet and comfortable

Kanso is the smallest[1,2] off-the-ear sound processor in the industry

1 Cochlear Limited. CP950 Kanso Sound Processor User Guide. Data on file, July 2016
2 MED-EL Medical Electronics. RONDO User Manual. Las accessed July 2016. Available at: http://www.mede.com/int/rondo.

Cochlear™ True Wireless™ technology

The evolution of wireless connectivity has incrementally improved the overall user experience (e.g. sound quality, ease of use) and reduced dependencies on extra equipment (cords, neck loops, etc.).



Experience freedom

True Wireless™ devices

- Cochlear is the only hearing implant company delivering True Wireless freedom – no cords, no wires, no bulky neck-worn components.
- Remotes allow recipients to manage their hearing discreetly.

True Wireless Accessories

Phone Clip

- Stream phone calls directly to the sound processor.
- Answer and adjust the volume just by pushing a button.
- Works with many Bluetooth® enabled devices and MP3 music players.

Mini Mic 2/2+

- Hear better over a distance and in noisy listening situations
- Place near the source of the sound
- Helpful for sounds coming from the side opposite the sound processor.

TV Streamer

- Watch TV without blasting sound all through the house.
- Or constantly ask, “What did they say?”
- The sound processor works like a second, wireless speaker for the TV.

Mini Microphone 2+

Optimized for both one-to-one and group communication.

- FM compatibility
- Built-in Telecoil
- Line-in connector
- Range up to 82 feet (25 meters)*
- Up to 11 hours battery life
- Directional microphones
- Table Mic Mode
- Drop detection mute feature
- Volume lock and volume indicators
- Battery status indicator
- Swivel clip

3 x the range[1]

FM & Loop connectivity

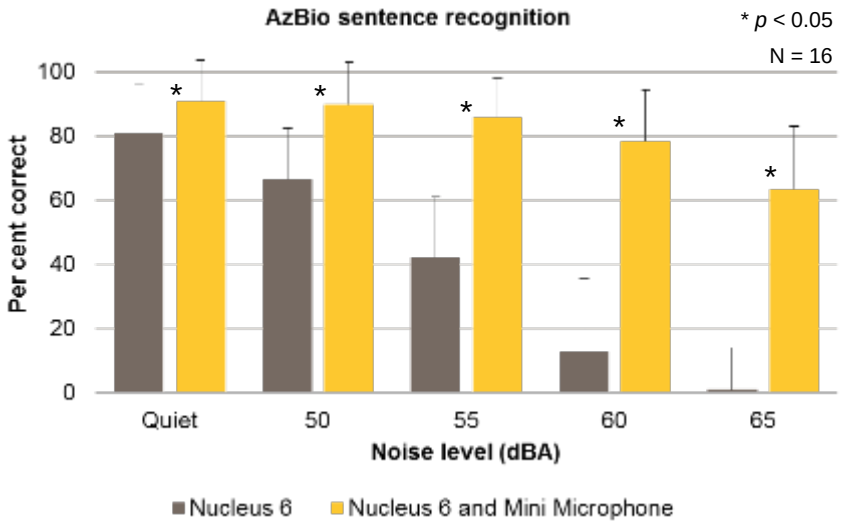
50% longer battery life[1]

1. Compared to Cochlear Wireless Mini Microphone
* Clear line of sight

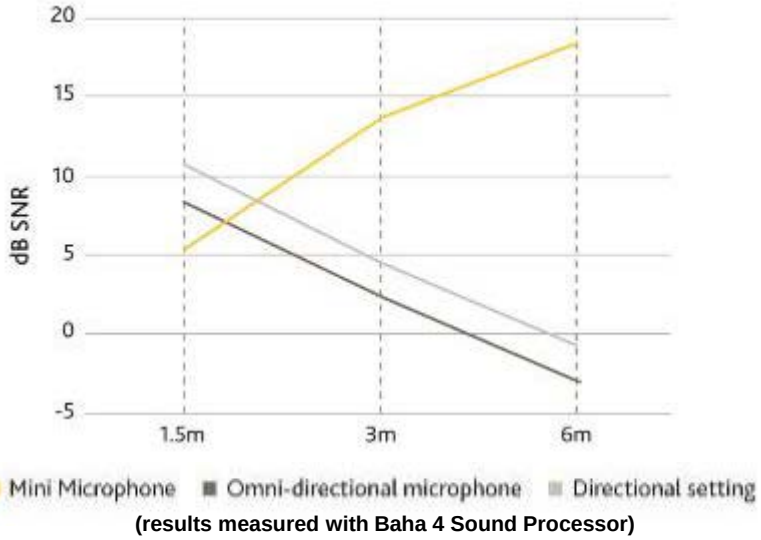
Improved hearing performance

The Cochlear Wireless Mini Microphone provides significantly better speech recognition in noise and quiet[1] and improves the SNR over distance[2].

Better speech understanding in Noise[1]



+23 dB improvement in SNR at 19 feet (six meters)[2]



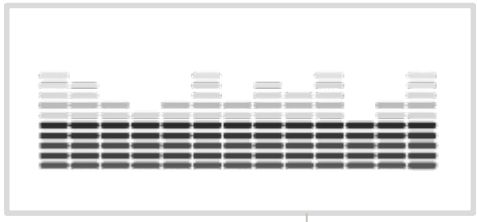
(results measured with Baha 4 Sound Processor)

1. Wolfe J, Morais M, Schafer E. Improving hearing performance for cochlear implant recipients with use of a digital, wireless, remote-microphone, audio-streaming accessory. J Am Acad Audiol. 2015 Jun;26(6):532-9.
2. Hoffmann J, Andersson J, Agat T, Hedin A, Flynn MC. Hearing benefits of the Cochlear™ Wireless Mini Microphone for Cochlear Baha 4 Sound Processors. Sweden: Cochlear Bone Anchored Solutions; 2014. E83101.

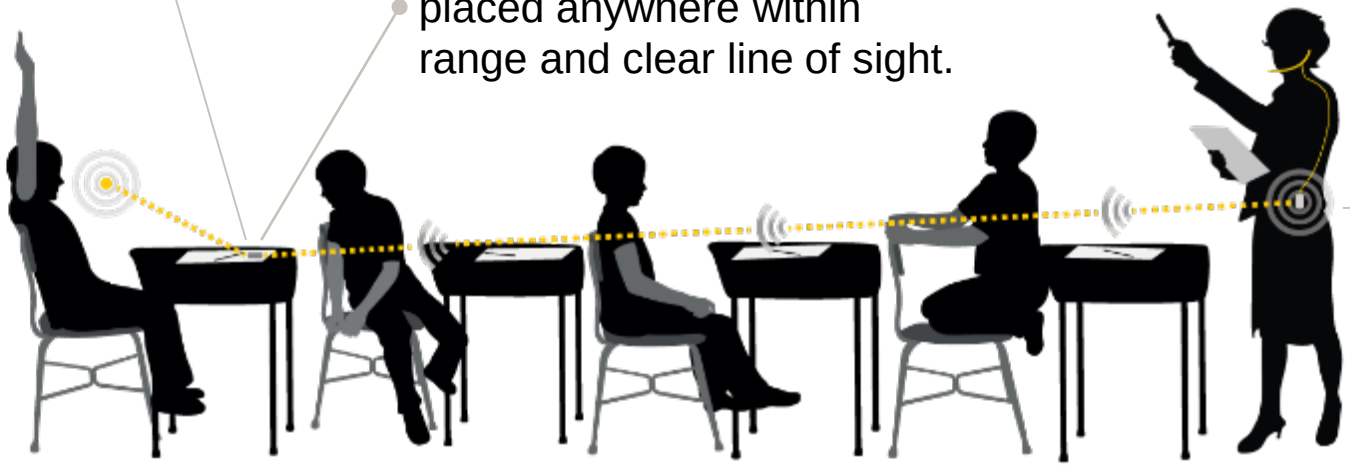
Multiple FM classroom configurations

Only one FM receiver required for bilateral or multiple users.

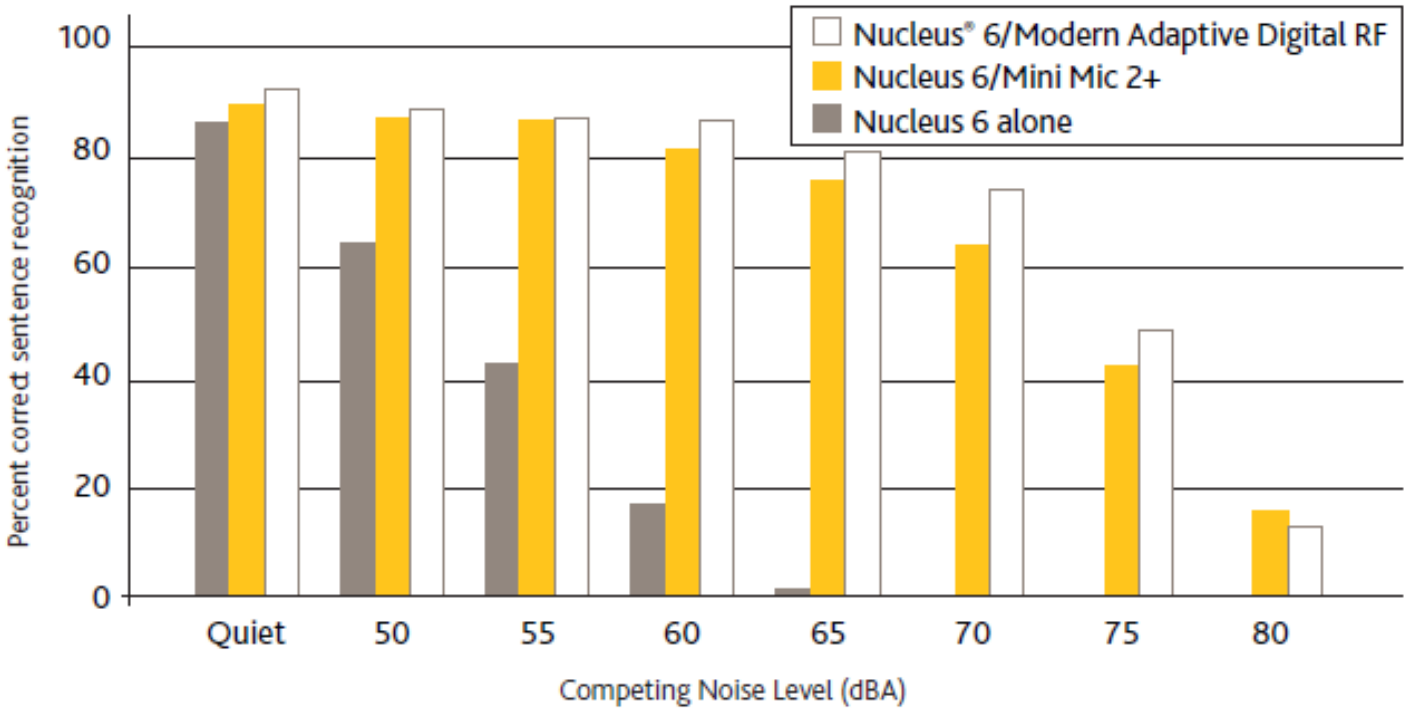
Maintains dynamic FM signal across wireless connection.



Mini Microphone can be placed anywhere within range and clear line of sight.



Mini Mic 2+ in the classroom



N=15, no significant difference at any competing noise level

Wolfe et al., "True Wireless and Bimodal/Bilateral Fittings." Presented at ACIA 2016, Toronto, ON.

The Cochlear™ Baha® System

Hear now. And always

Cochlear®

A Lifetime of Innovation…

1970's
Researchers at the University of Gothenburg discover osseointegration and create the Baha® System

1995
FDA approves the Baha® System for use in the US (approved for SSD in 2002)

2010
Baha® 3 Systems set new standards for implant stability

2012
Cochlear's DermaLock™ abutment is designed to further improve patient outcomes and surgical procedure

2013
Cochlear introduces the Baha® Attract

2014
True wireless is introduced to Baha recipients with the innovative Baha® 4

2015
Baha® 5 is introduced – incredibly small, unbelievably smart

TODAY
Baha 5 Systems expanded to offer more power and more choices

Osseointegration

- The process by which living bone tissue bonds with titanium
- Makes direct bone conduction possible
- Provides the basis of long-term predictability and success of the Baha® System

Surgical options

Processor

Baha 5 suite of processors attach for incredibly smart, unbelievably powerful hearing

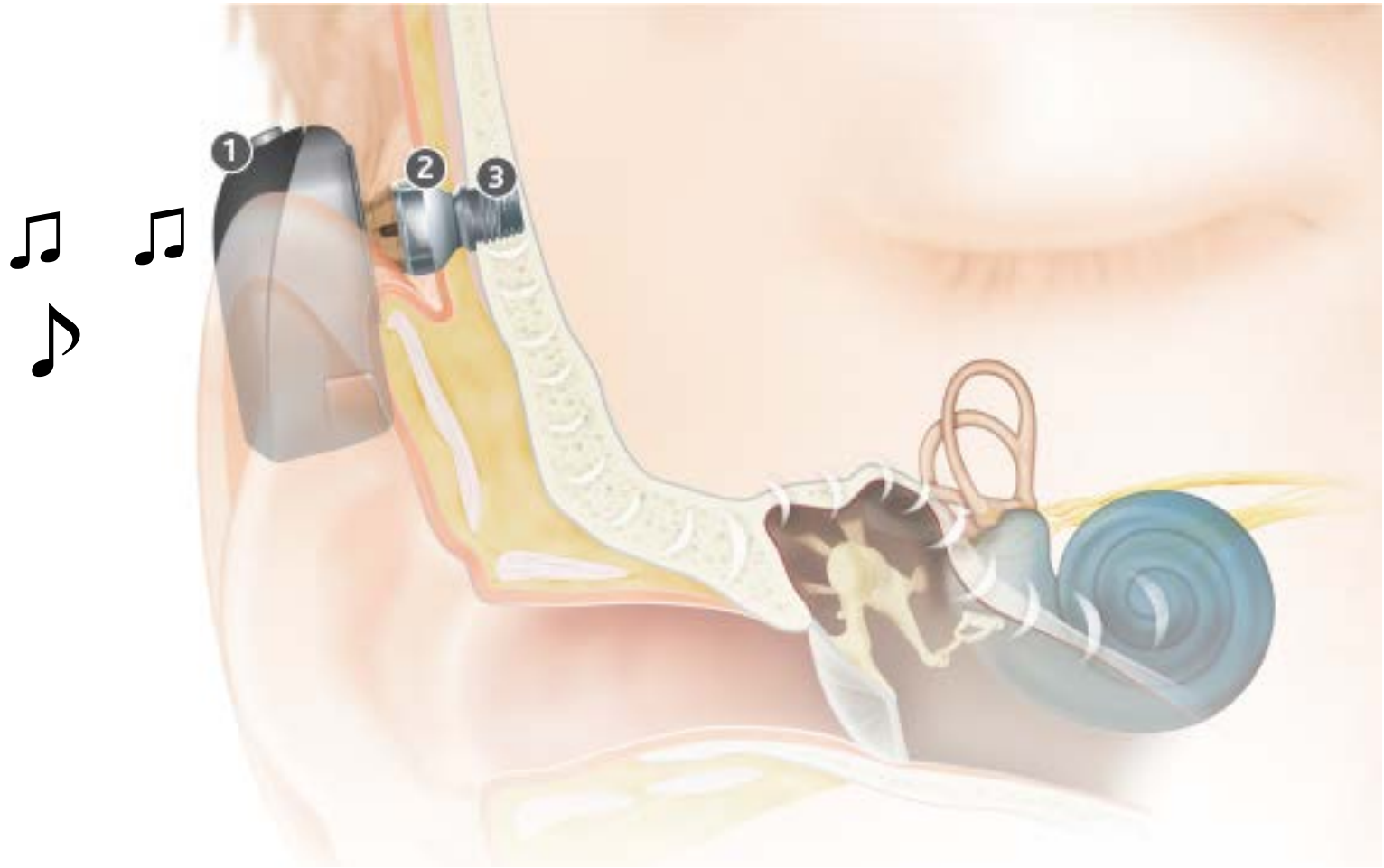
Connection

BIM400 Implant Magnet or BA400 Abutment connect recipients for a lifetime of hearing

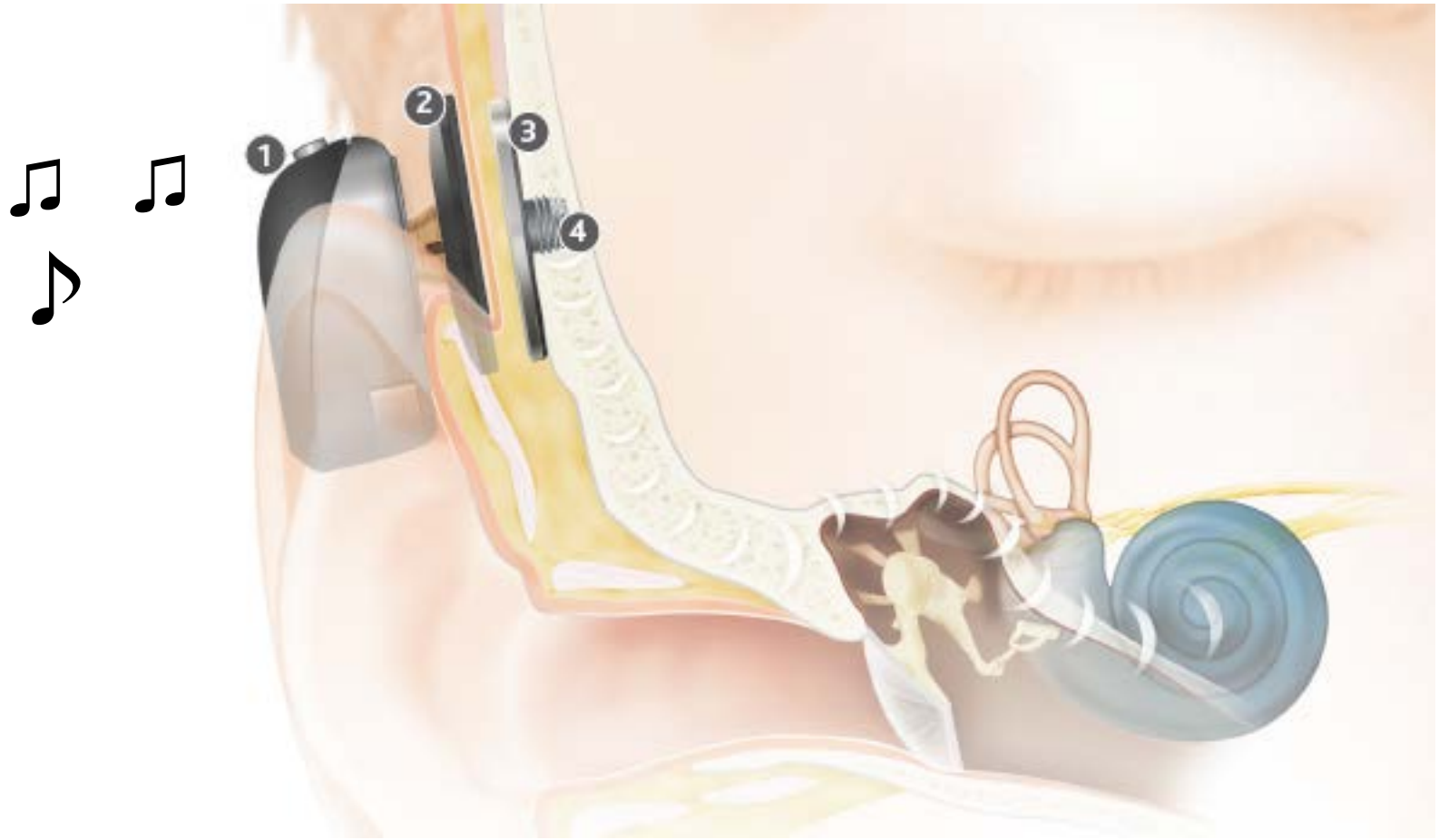
Implant

BI300 Implant provides a strong foundation

How the Baha® Connect System works



How the Baha® Attract System works



One Implant. Two Systems.

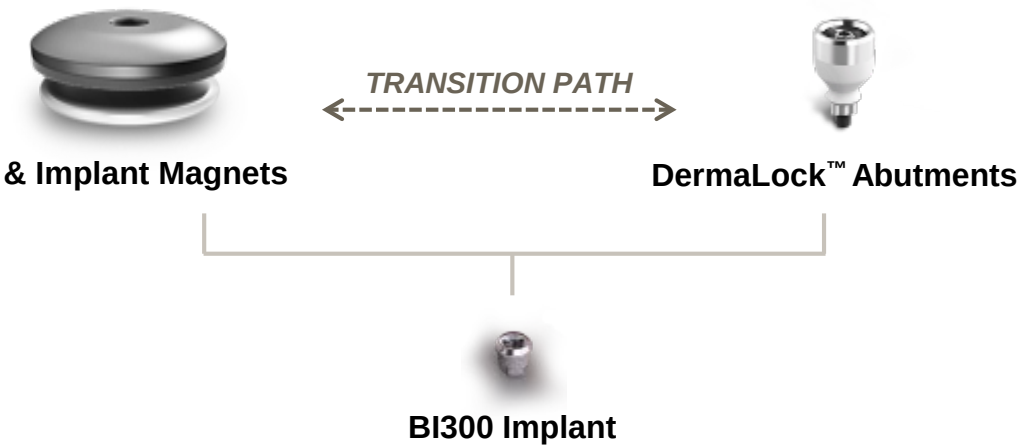
Baha Attract

Cosmetically appealing
Less risk of soft tissue reaction
MRI safe (up to 1.5 Tesla)

Baha Connect

Maximizing hearing performance
No soft tissue reduction
MRI safe

Baha Surgical Transition Path



Non-surgical Options for Baha

Baha SoundArc

Good performance, comfortable, stylish and discreet

Baha Softband

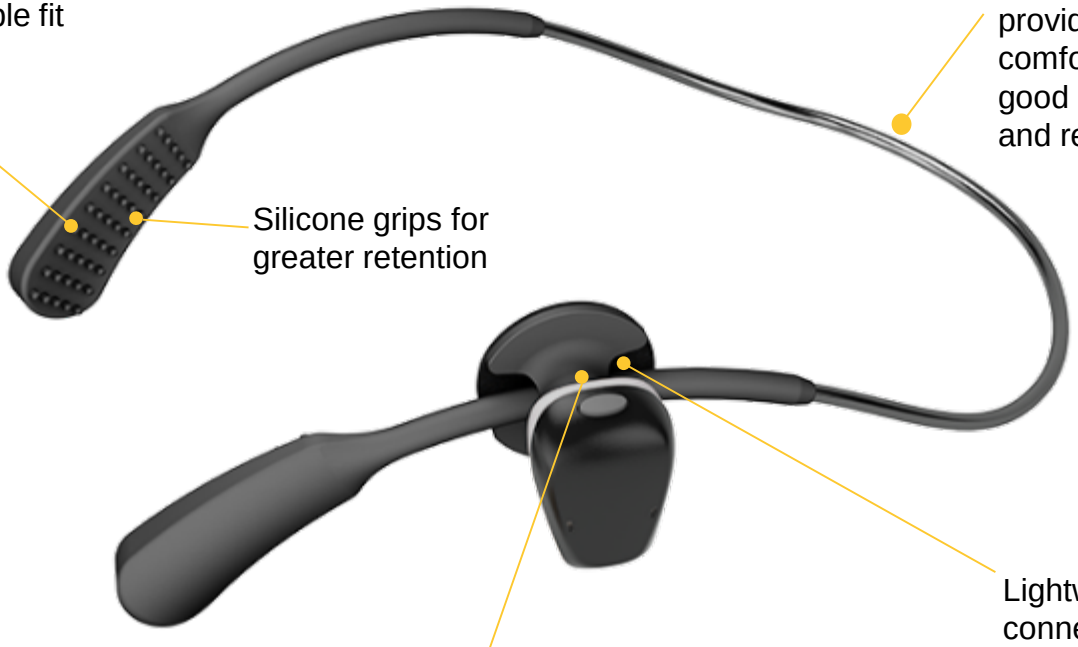
Good performance, comfortable, optimal for young children

Baha SoundArc

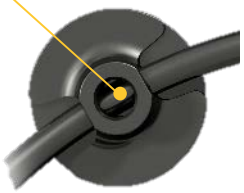
Soft silicone tips create a snug and comfortable fit

Custom fit spring steel band fits neatly around the head, providing optimal but comfortable pressure for good sound transmission and retention.

Silicone grips for greater retention



Secure coupling, minimizes risk of feedback



Connector disc design allows easy attachment to Baha sound processors.

Lightweight aluminum connector disc, compatible with Baha SoftWear™ Pad which improves comfort and sound transmission

Candidacy for Baha® Systems

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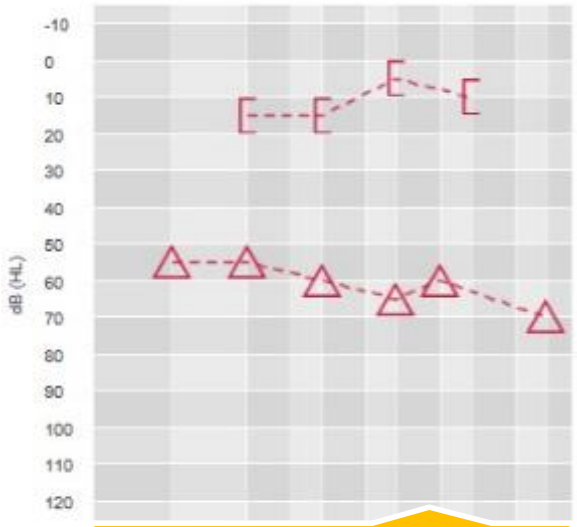
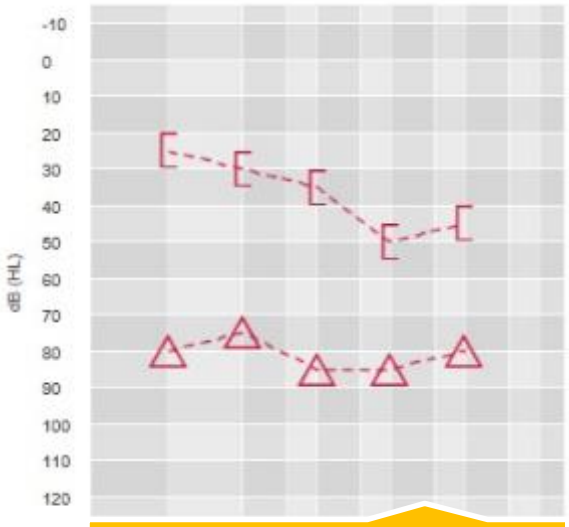
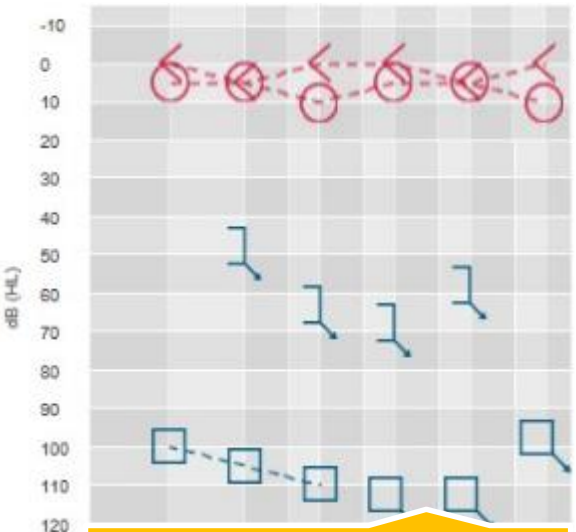
Baha System Candidacy



Conductive Hearing Loss



Mixed Hearing Loss

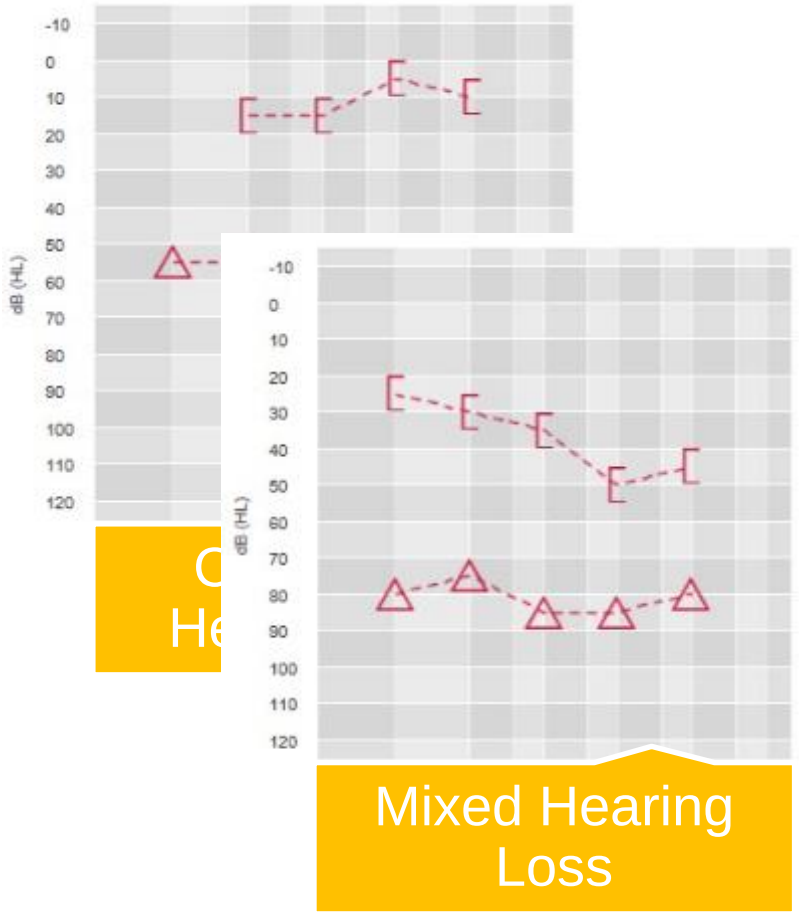


Single-Sided Deafness (SSD)

FDA Indication for Implantation

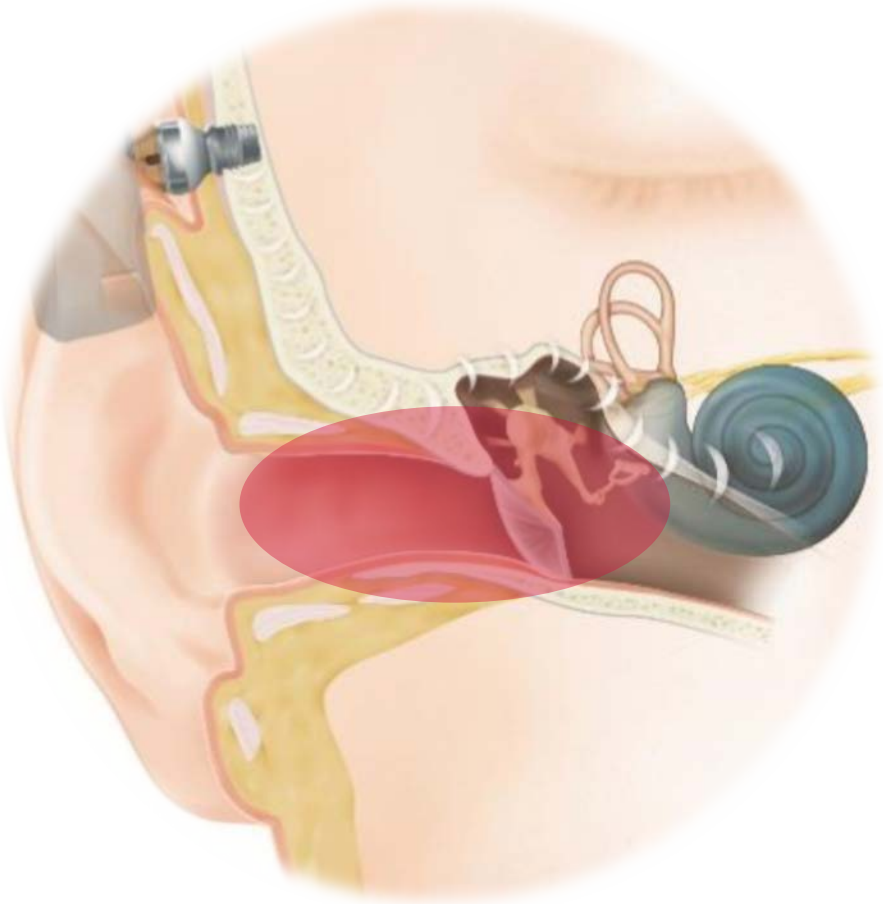
Mixed & Conductive Hearing Loss

- ≥ 5 years of age
- ≤ 65 dB HL Bone Conduction PTA
  - PTA of 0.5, 1, 2 & 3 kHz
- For bilateral fitting, symmetric bone conduction thresholds are defined as less than 10 dB difference on average (0.5, 1, 2 & 3 kHz) or less than 15 dB at individual frequencies

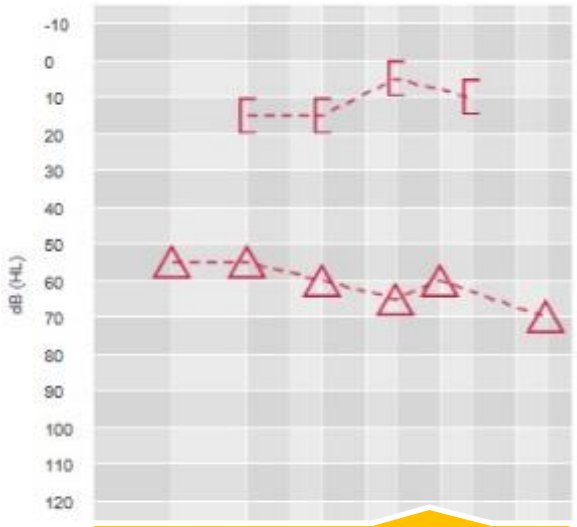


Baha Solutions: Conductive & Mixed Hearing Loss

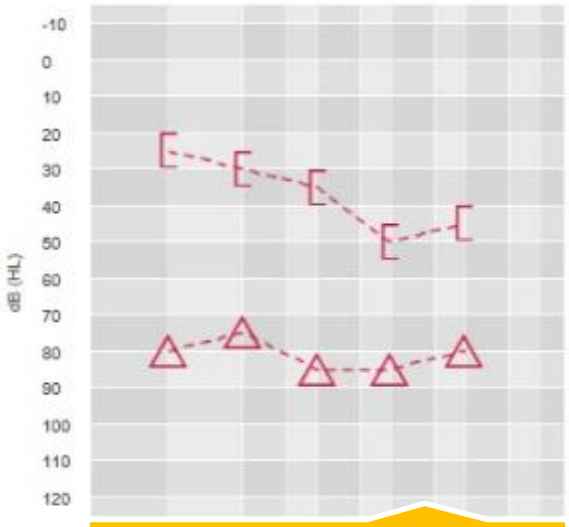
- Direct bone conduction bypasses the outer and middle ear
- Baha solutions treat conductive & mixed hearing loss
  - Atresia
  - Chronic middle ear disease
  - Cholesteatoma
  - Congenital abnormalities
- Baha devices do not have to overcome conductive component, only amplify for any sensorineural component



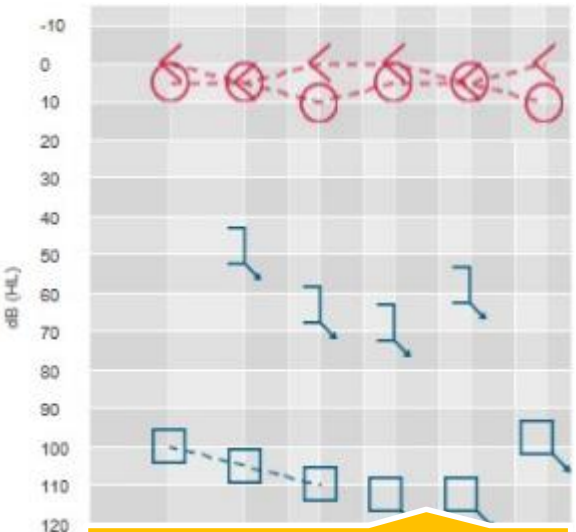
Baha System Candidacy



Conductive Hearing Loss



Mixed Hearing Loss

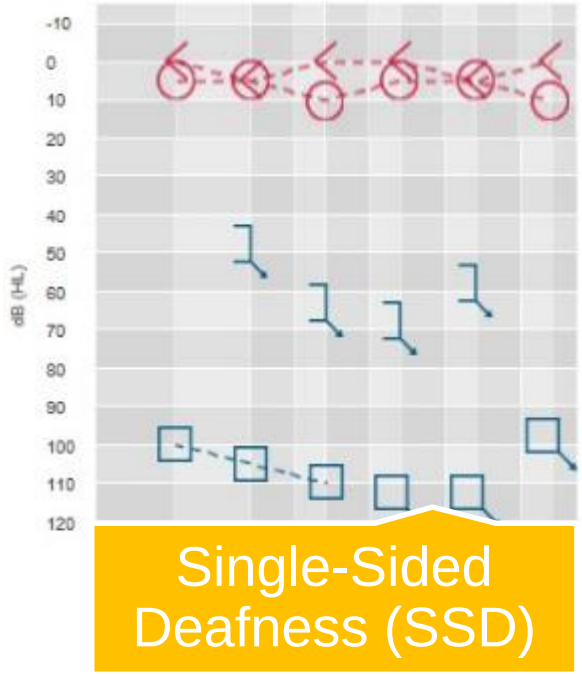


Single-Sided Deafness (SSD)

FDA Indication for Implantation

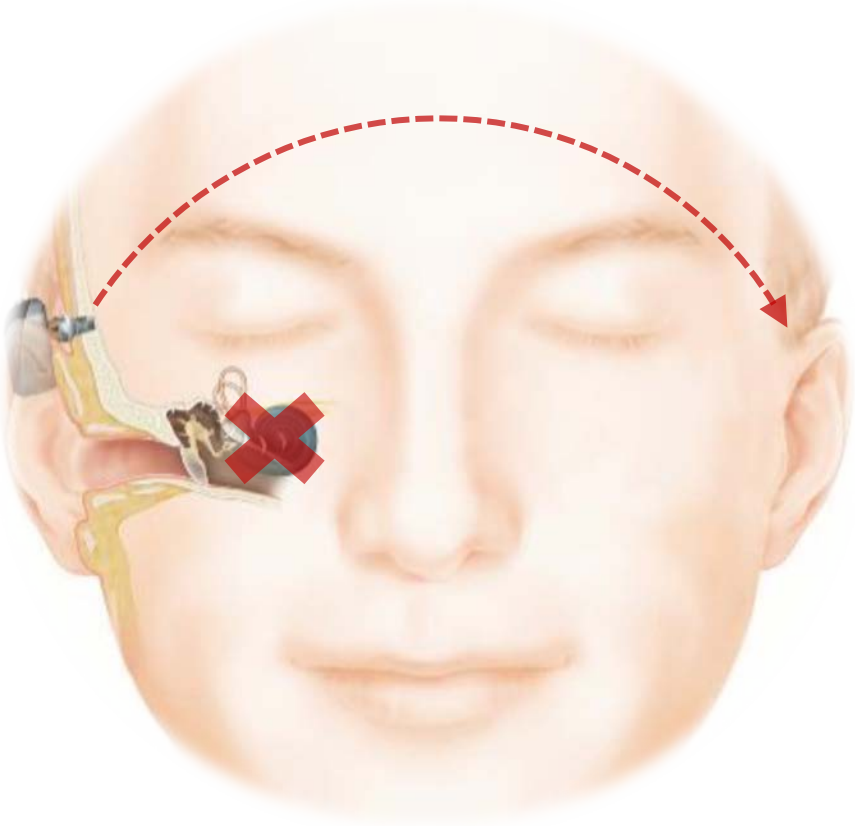
Single-sided Deafness

- ≥ 5 years of age
- Normal Hearing in the contralateral ear
  - Defined as PTA Air Conduction thresholds equal to or better than 20 dB at 0.5, 1, 2 & 3 kHz
- Functions by transcranial routing of the signal



Baha Solutions: Single-Sided Deafness

- Sound travels via direct bone conduction to stimulate the better hearing cochlea
- Baha technology can bypass the deaf ear and bring sound from the bad side to the good side
- Reduces the head shadow effect
- Direct stimulation of cochlea and no device in the better hearing ear



Baha® 5 Portfolio

Hear now. And always

Cochlear®

Small. Smart. Powerful.

Baha® 5 Sound Processors share the same unique technology building blocks to deliver a smart and seamless hearing experience to all patients.

- The industry's smallest sound processor.[1]
- The only smart processors with direct-to-device wireless streaming and control.
- Two power sound processors including the industry's most powerful solution.[2]

1. Flynn MC. Smart and Small – innovative technologies behind the Cochlear Baha 5 Sound Processor. Cochlear Bone Anchored Solutions AB, 629761, 2015.
2. Norrman, J, Review of fitting ranges. Cochlear Bone Anchored Solutions AB, D773528, 2015.

Bluetooth SMART

Made for iPod iPhone iPad

SmartSound® iQ Signal Processing

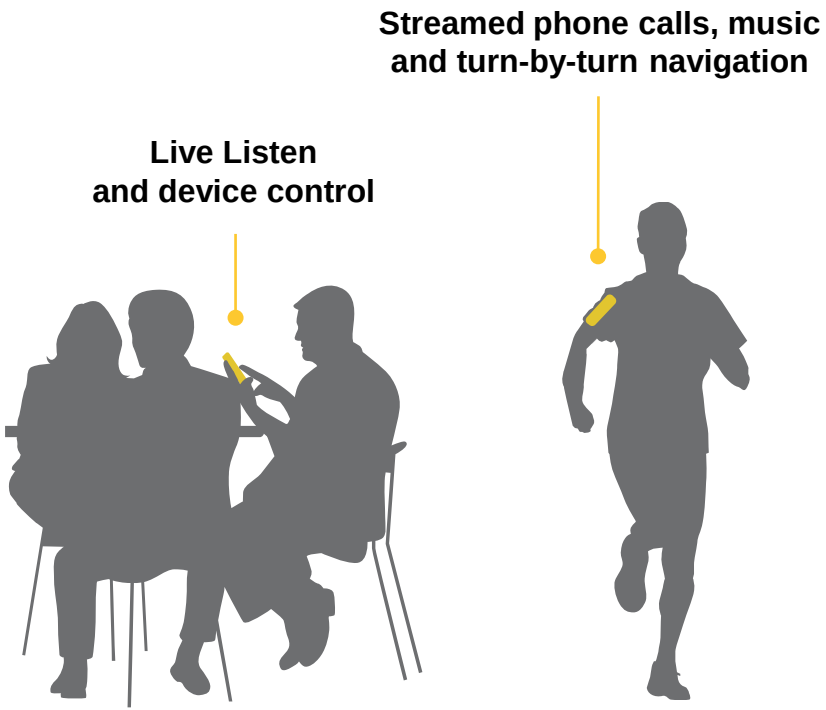
The Scene Classifier II in SmartSound® iQ measures the input sound level and signal-to-noise ratio to define and categorize the patient's acoustic environment.

It selects the best signal processing strategy utilizing:

- Active Gain
- Active Balanced Directionality
- Noise Manager II

Smart Connectivity for Direct-to-Device Communication

With new Bluetooth® technology designed by Apple, Baha 5 sound processors are the hearing implant industry's only Made for iPhone Hearing Devices.



Bluetooth SMART

Made for iPod iPhone iPad

The First Smart App for Bone Conduction

Advanced control of sound processor and wireless accessories, personalization and support – directly from iPhone®, iPad®, iPod touch® and **now also Android™ smartphones**.

Available on the App Store

GET IT ON Google Play

True Wireless™ Accessories

Cochlear™ Wireless
TV Streamer

Cochlear™
Wireless
Phone Clip

Cochlear™ Wireless
Mini Microphone 2+

Cochlear™ Wireless
Mini Microphone 2

One smart solution. The power to choose.

Apps & True Wireless™

Baha 5 sound processors

Baha Fitting Software

Baha SoundArc
& Softband

Baha Connect System

Baha Attract System

Baha BI300 Implant

Bluetooth SMART

Made for iPod iPhone iPad

Cochlear Americas Resources

Hear now. And always

Cochlear®

Support Meetings in the Phoenix Area

Second Wednesday of the month in Phoenix

Courtyard Marriott on Camelback

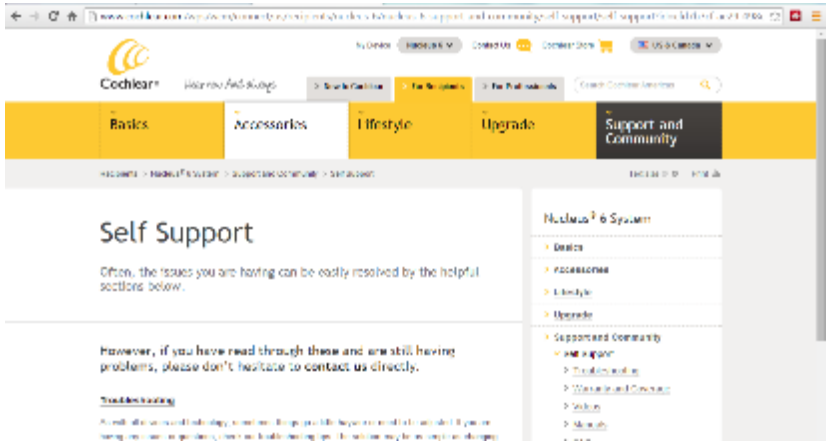
- “Bring Your Box”
  - Assistance with devices and accessories for those already implanted
- Informational Cochlear Implant Meetings
  - For those considering a cochlear implant or Baha solution

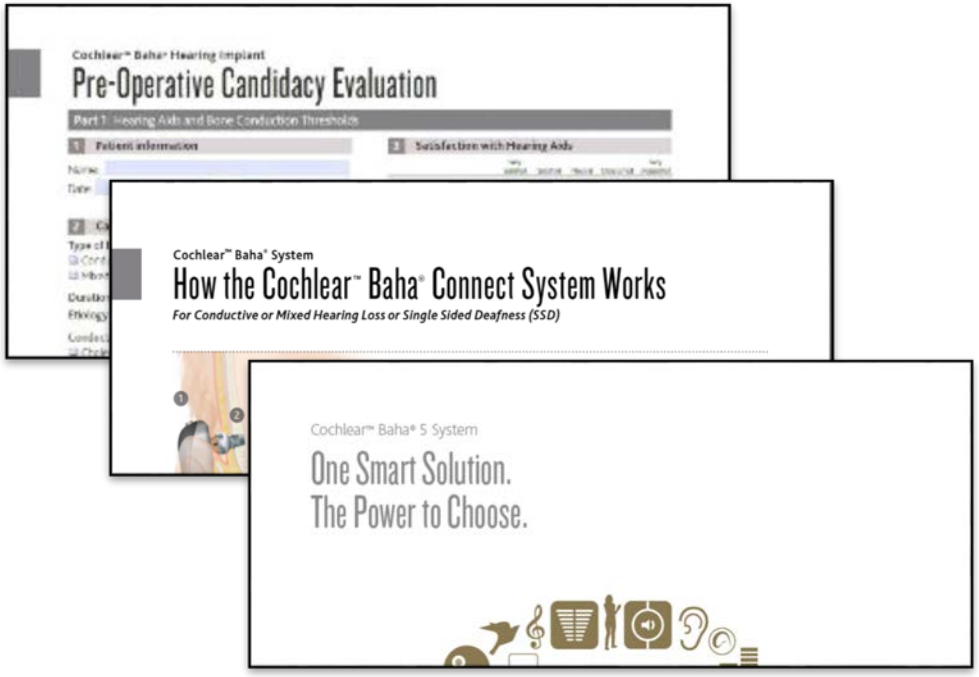
Coffee Chats in East Valley and West Valley

- Small group setting for those to learn about implantable solutions

myCochlear

- Cochlear's website: www.cochlear.com/us
- myCochlear Clinic: www.mycochlear.com
- Sign up for Cochlear's professional newsletters and follow us on social media for the latest updates





Cochlear Family

- Your patient’s online portal for all things Cochlear
- Access to information on all equipment registered to them, including warranty information
- Cochlear Store
- Troubleshooting videos and guides
- Promotions and discounts
- Care service plans
- Online support

Communication Corner

- Online resource providing age-appropriate tools to help maximize your or your loved one's hearing
- The training programs include fun and engaging activities from early listening to more complex conversations to use of technology
- Telephone with Confidence
- Sound Foundations
- Programs for every age
- Professional and parent / patient courses online

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Hear now. And always

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