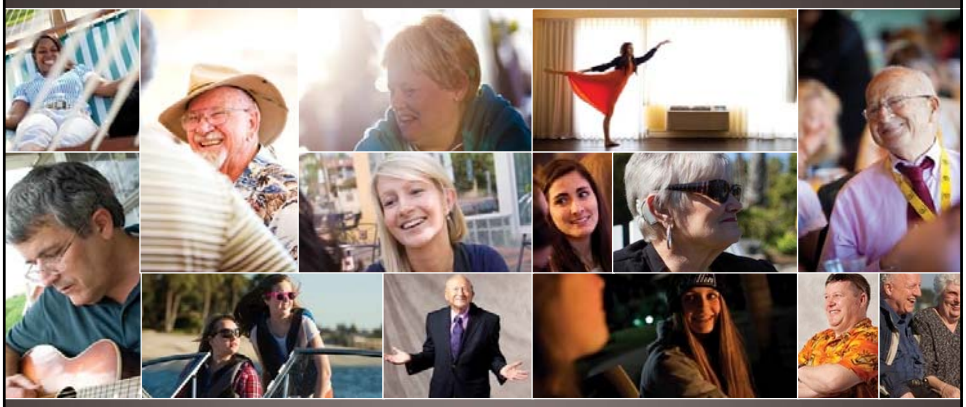

Hybrid L24 Study Update: Where Are They Now?

Ginger Grant, AuD

Audiology Online: January 18, 2017

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Cochlear

Learning Objectives

1. After the completion of this course participants will be able to list the benefits of acoustic hearing.
2. After the completion of this course participants will be able to describe the expanded indications for the Nucleus® Hybrid™ system.
3. After the completion of this course participants will be able to outline the steps to programming a Nucleus Hybrid device.

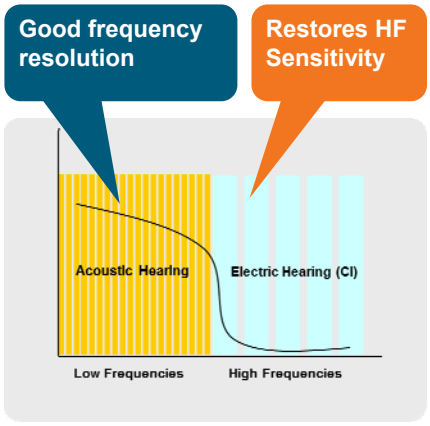
Why Hybrid?

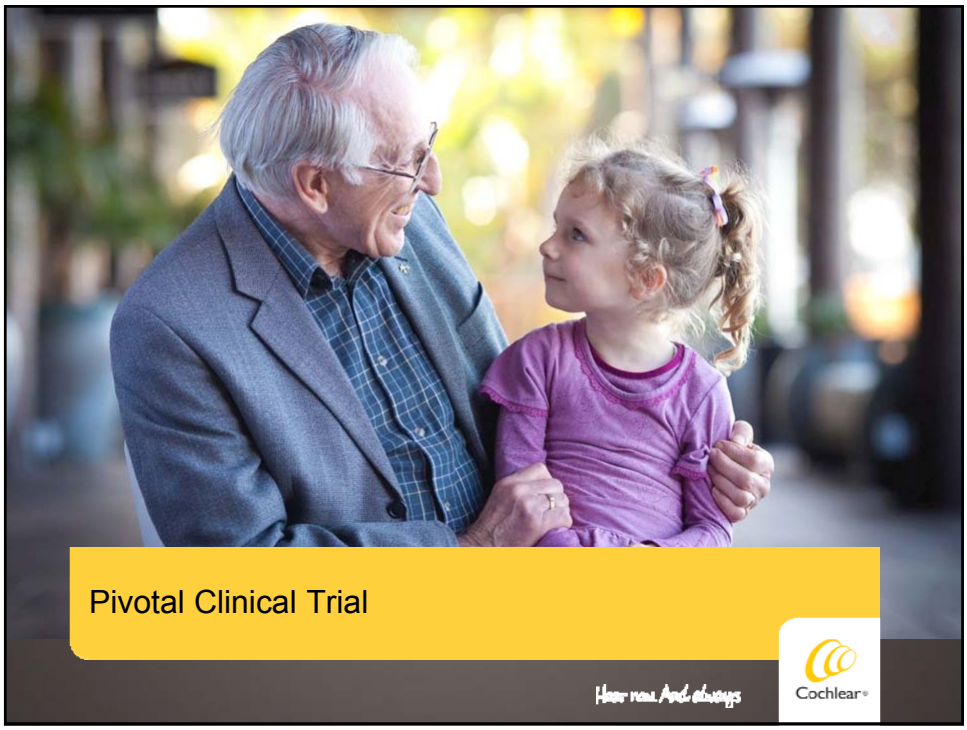
Audibility 125 → 8000Hz

High frequency electric hearing is critical for improved speech understanding

Benefits of Acoustic Hearing

- ✓ Enhanced sound quality
- ✓ Improved understanding in background noise
- ✓ Fundamental frequency cues for both pitch and vowel discrimination
- ✓ Interaural timing difference cues





Background

More than 15 years of research
- 8 year FDA trial of 50 adult subjects

FDA-approved March 2014
- 1st Hybrid implant system (U.S.) April 16, 2014
- 1st cochlear implant labeled for potential preservation of residual hearing
- 1st Indication using CNC words
- 1st Integrated Electric + Acoustic Sound Processor

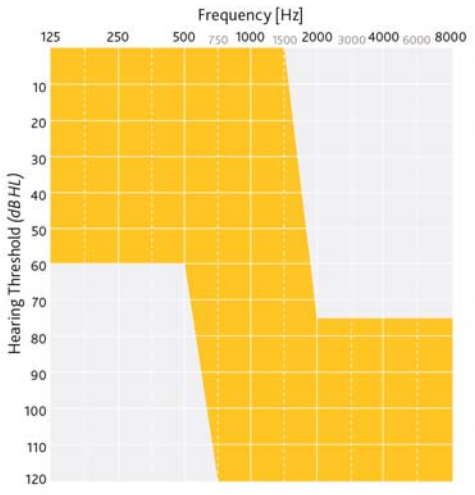
Study Design

- Multicenter pivotal trial
- 14 surgeons at 10 US-based implant centers
- 50 adult subjects implanted
- Primary endpoint was 6 months postactivation

Pivotal IDE Study

Subject Demographics	N=50
Gender Male Female	 25 (50%) 25 (50%)
Mean Age at Implantation (yrs)	64.1 [37-86]
Mean Duration Hearing Loss (yrs)	28.1 [3-74]
Mean Duration Sev/Prof Loss (yrs)	13.1 [2-30]
Mean Preoperative CNC Score CI Ear	28.4% [9-64%]
Mean Preoperative AzBio Sentence Score CI Ear	16.3% [0-64%]

Hybrid L24: An Expanded Indication



Ear to be Implanted
- Aided CNC word score between 10% and 60% correct, inclusively

Contralateral Ear
- Aided CNC word score better than ear to be implanted but less than 80% correct

Audiometric
- Severe to profound HF SNHL bilaterally

Adults
- aged **18 years** and older

Key Findings of Pivotal Study

United States Multicenter Clinical Trial of the Cochlear Nucleus Hybrid Implant System

J. Thomas Roland Jr, MD; Bruce J. Gantz, MD; Susan B. Waltzman, PhD; Aaron J. Parkinson, PhD; The Multicenter Clinical Trial Group

Published results demonstrate:

- Significant improvement in speech understanding in quiet and noise
- Expanded indications for individuals with severe high frequency hearing loss
- Increased satisfaction, consistent with speech perception results

Laryngoscope. 2016 Jan; 126(1): 175-81.

Reimbursement

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Reimbursement Success

Since August 2016…

142,000,000

Covered Lives Now Have Access To Hybrid Coverage

BlueCross BlueShield
62 Million

Anthem
40 Million

Aetna
23 Million

TRICARE
9 Million

FEHB
Federal Employees Health Benefits Program
8 Million

Acoustic Component

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Cochlear™ Hybrid Hearing™

- Amplify low frequency hearing and provide access to high frequencies via electrical stimulation
- The Acoustic Component is compatible with all N6 Sound Processors (CP910 and CP920)
- No processor exchange needed
- Available for use by all recipients, pediatric and adult, with **all Nucleus implants**

The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality. Not available for the Nucleus 22 series of implants.

Hybrid™ Hearing Availability Today:

Nucleus® Hybrid™ Hearing Now FDA Approved for **ALL** Nucleus Implants

Cochlear™ Nucleus® Profile Slim Modiolar Electrode

Cochlear™ Nucleus® Contour Advance®

Cochlear™ Nucleus® Slim Straight

Cochlear™ Nucleus® Full–Band Straight

Cochlear™ Nucleus® Hybrid™ L24

*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 Clinical Trial Outcomes Update

Hear now. And always

Background:

- All Hybrid implant subjects upgraded to the N6 sound processor
  - 39/50 (78%) consented to long term follow-up and upgrade study
- Questions:
  1. What does long-term hearing preservation look like?
  2. What does Hybrid performance look like?
     - Electric Alone?
     - Electric + Acoustic?

Hearing Preservation

Established Definitions:

1. Preservation of measurable[1,2] acoustic hearing
   - Definition used by industry and in most publications
   - Measure of detection/audibility but not usability

2. Preservation of functional[1,2] acoustic hearing
   - A **severe or better** degree of hearing loss post-implantation that may provide a level of acoustic hearing to enhance electrical stimulation

1. Lenarz et. Al (2013) European Multi-center Study of the Nucleus Hybrid L24 cochlear implant. International Journal of Audiology. 1-11
2. Roland, et AL (2015) United States Multicenter Clinical Trial Cochlear Nucleus Hybrid Implant System. Laryngoscope, 2-7

Evolution of Sentence Materials

- CUNY Sentences were used in our earliest clinical trials (1999) with Hybrid implants but many recipients quickly topped out
- Members of AAA and AAO-HNS established use of HINT sentences in noise as part of the Minimum Speech Test Battery developed in 1996
- AzBio Sentences were developed by Spahr and Dorman in 2004
- Cochlear's Hybrid L24 trial was implemented with use of AzBio Sentences in noise in an attempt to avoid ceiling effects
- The recommended MSTB protocol was updated in 2011 to replace HINT sentences with AzBio Sentences

Power of the Nucleus® 6:

ACOUSTIC

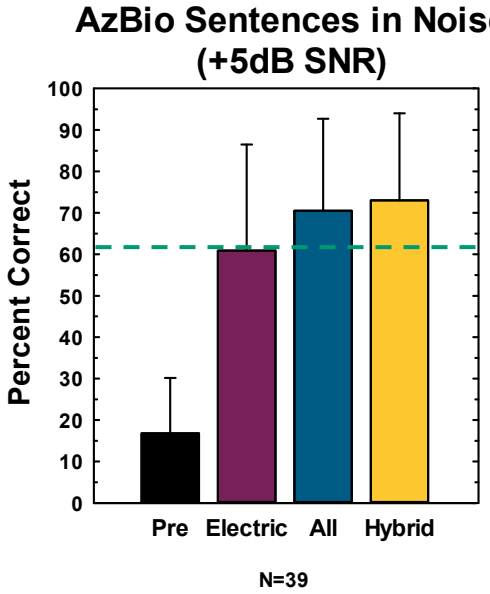
- ASC
- **SCAN**
- **Wind Noise Reduction**

ELECTRIC

- ADRO®
- ASC
- **SCAN**
- **Wind Noise Reduction**
- **Background Noise Reduction**
- Whisper™

TRUE WIRELESS

Speech Perception in Noise



Next Steps

- Long term follow up post approval study
  - Original pivotal Hybrid L24 subjects followed to 5 years postactivation
  - The majority of subjects have completed all requirements
  - Publication planned
- Newly implanted post approval study
  - Cochlear's initiative to gather even more 5 year data
  - 19 implant centers currently enrolling subjects
  - Data collection and analysis ongoing


Programming Considerations
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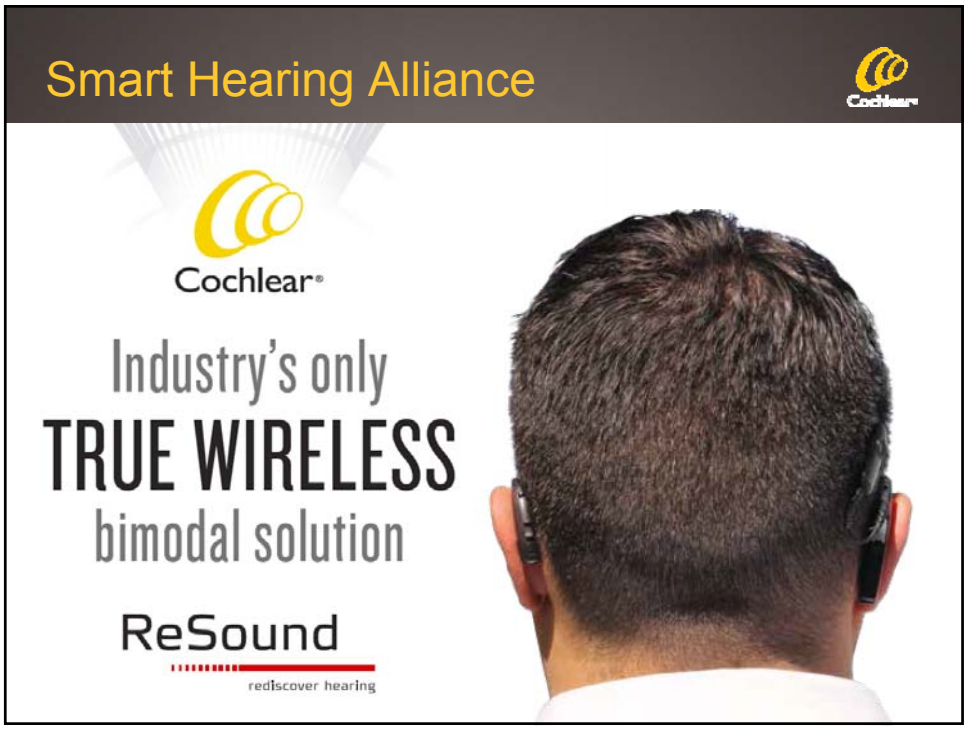
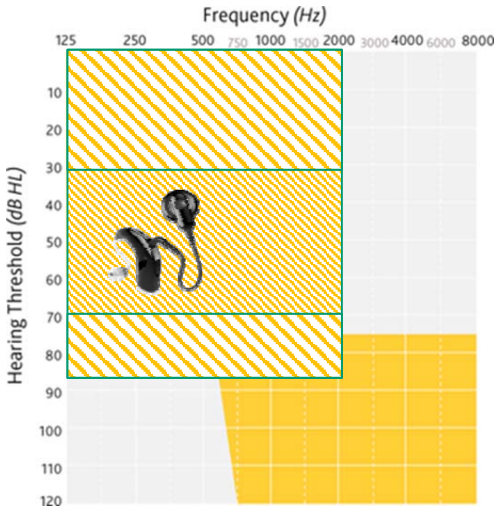

Smart Hearing Alliance
Cochlear
Industry's only
TRUE WIRELESS
bimodal solution
ReSound
rediscover hearing

What have we learned about programming?



Hybrid Mode: Cut-off Frequency

What's changed in Custom Sound® 4.4?

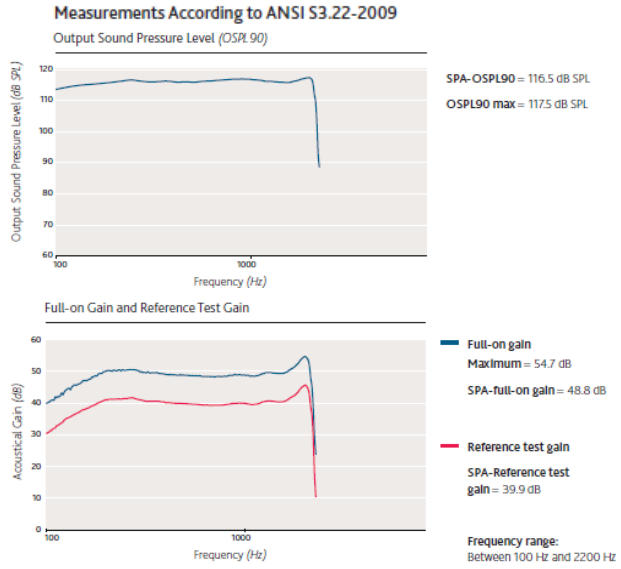
Now each stimulation mode has its own cut-off frequency. We no longer have what we called a 'cross-over frequency'.

- **Acoustic** cut-off at ≤90 dB HL up to 2 kHz *remains unchanged*
- **Electric** cut-off has been *lowered* to >70 dB HL up to 2 kHz

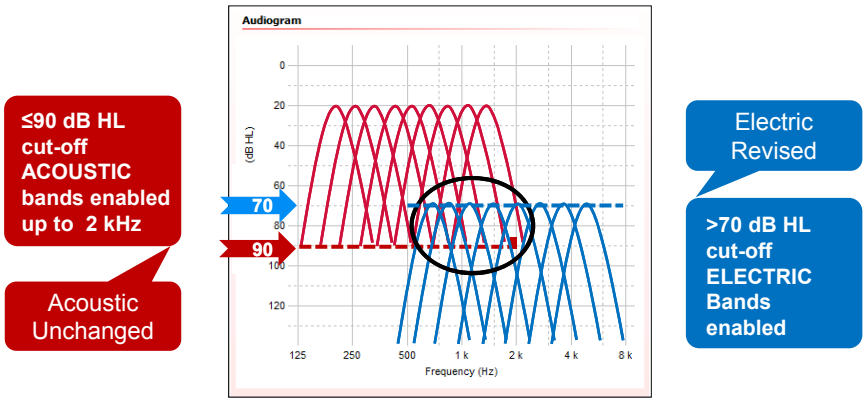
This results in more overlap for some audiograms between acoustic and electric stimulation, especially for shallow sloped audiograms.

NOTE: This change *only applies when creating new MAPs* (for existing or new recipients). The software uses the currently entered audiogram and applies the above calculations.

Acoustic Component Specifications



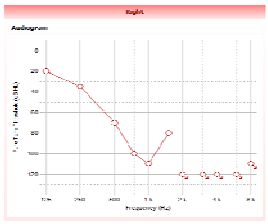
Hybrid Mode: Frequency Bands

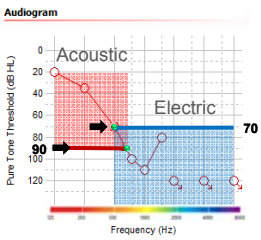


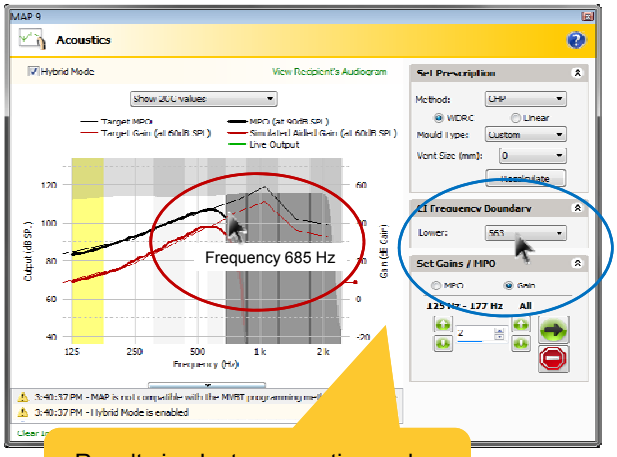
Robust Custom Sound algorithm:

- Checks the Acoustic cut-off frequency at 90 dB HL, up to 2 kHz
- Checks the Electric cut-off frequency at 70 dB HL, up to 2 kHz

Electro-Acoustic Cross-over Ranges



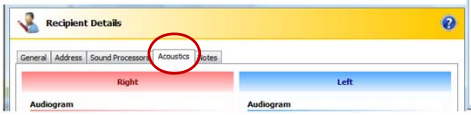


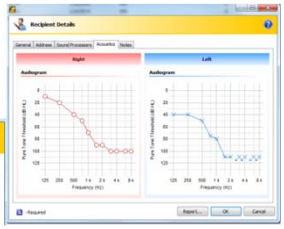


Results in electro-acoustic overlap between 563 Hz and 685 Hz

Steps in Programming

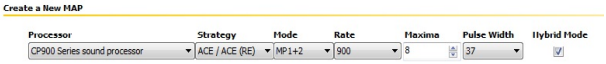
1. **Create a new recipient**



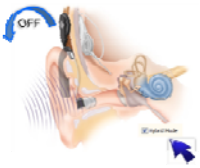


2. **Measure Impedances**

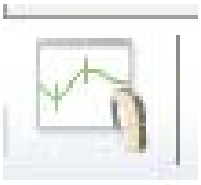
3. **Create a New MAP (will default to 37 PW) & check the box for Hybrid**



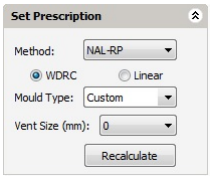
Steps in Programming



4. Remove the coil from the head

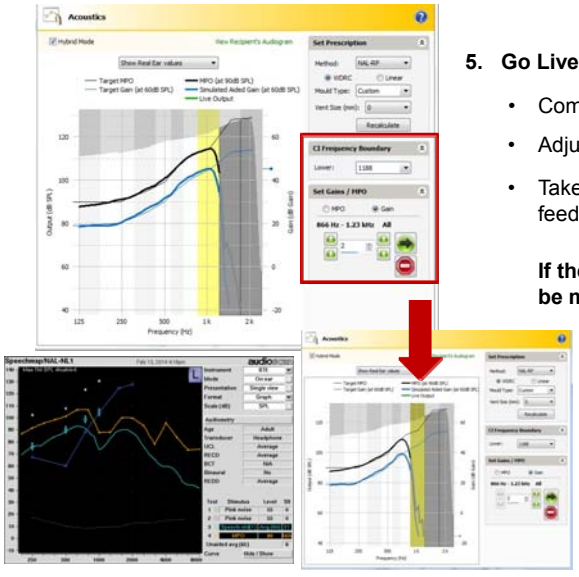


- Open the Acoustics screen



- Select the fitting prescription, mold type, compression and vent size.

Steps in Programming



5. Go Live with acoustic stimulation only

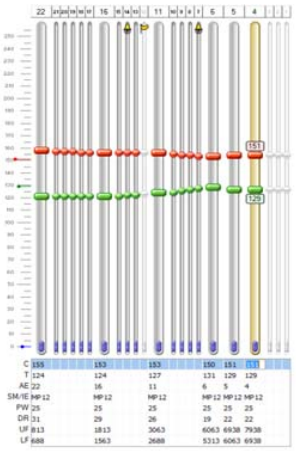
- Complete Real Ear measurements
- Adjust gain and MPO if needed
- Take into account the subjective feedback of the recipient.

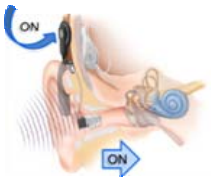
If the desired gain cannot be met acoustically:

- enable adjacent channel to obtain additional gain
- disable acoustic channels not meeting target
- the lower CI frequency boundary may need to be lowered further in the next step

Steps in Programming

6. Measure T levels using the streamlined programming method. Go live to obtain C levels so sound is comfortably loud.





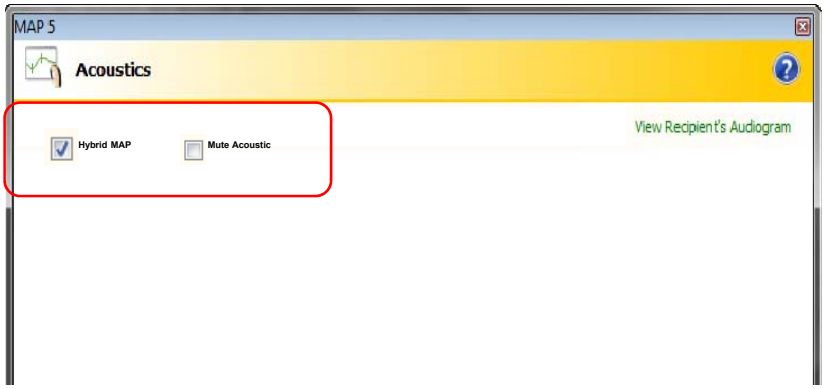
Coil must be on the head

7. Loudness Balance C levels

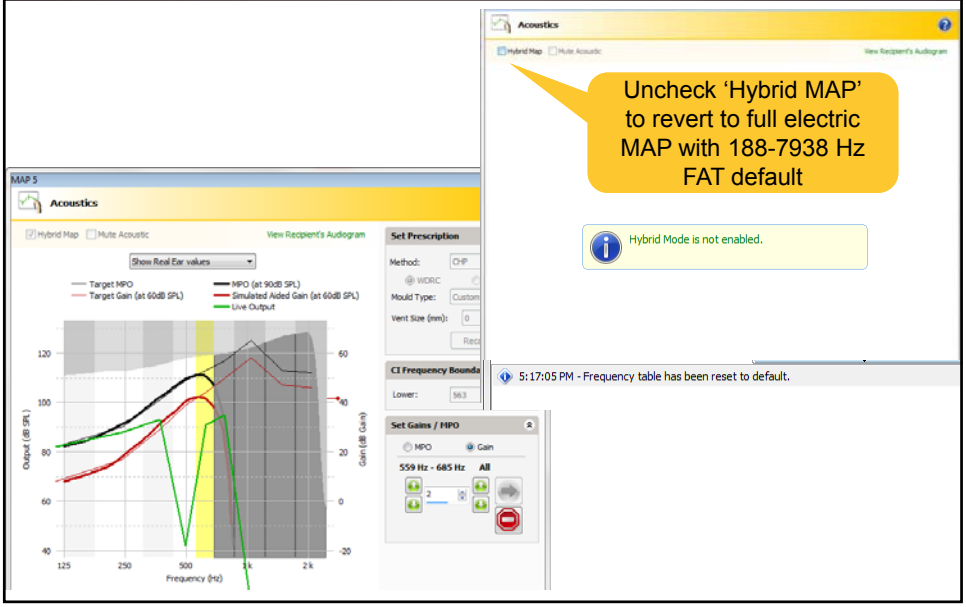
Acoustics Panel Options

What's new in the Acoustics panel in CS 4.4?

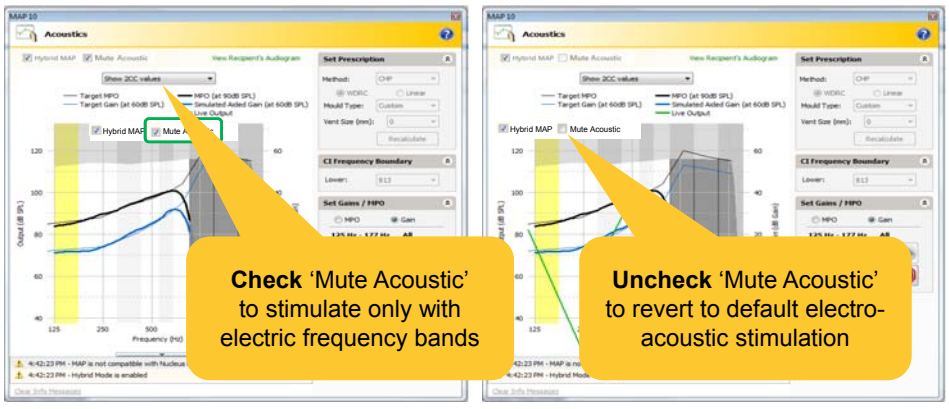
It is now possible to make very quick loudness comparisons between Hybrid mode and full electrical mode.



Hybrid MAP Checkbox

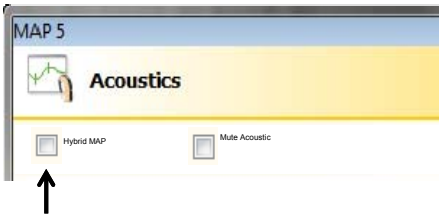


Mute Acoustic Checkbox



Summary of Quick Loudness Checks

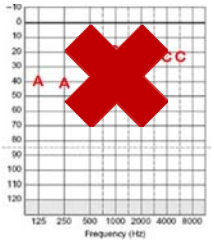
CI only
(full frequency allocation)

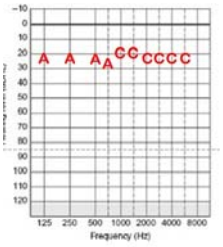


Listen in CI mode

Finalize Programming

8. Check battery suitability and personalize MAPs by adding SmartSound® iQ
   - Program 1 primary MAP with SCAN
   - Program 2 default
   - Program 3 and 4 can be used to try other cut offs with SCAN.
9. Write MAPs to the processor and finalize
10. Verification of audibility



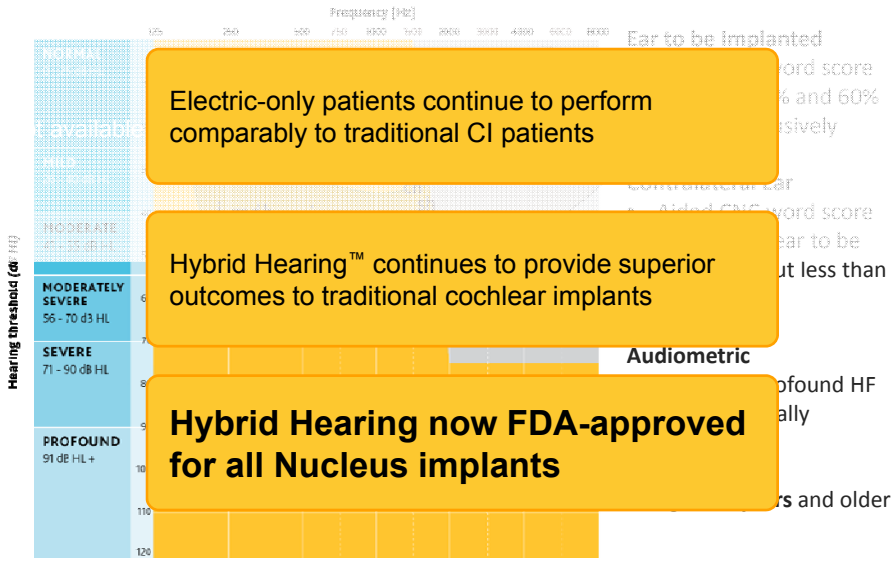


Summary

- Hybrid indication is continuing to gain momentum
- Programming of both the electric and acoustic portions can be completed with Custom Sound® Software
  - Overlap between acoustic and electric stimulation will vary by patient
- Hybrid L24 + Nucleus 6
  - 95% of subjects perform the same or better on AzBio +5 dB SNR

Gilden et al (2015). Improved hearing in noise using new signal processing algorithms with the Cochlear Nucleus 6 sound processor. Jour of Otol 10: 51-56.

Summary



References

1. Dorman MF & Spahr, A.J. Speech perception by adults with multichannel cochlear implants. In Cochlear Implants, S.B. Waltzman & J.T. Roland (Eds.) Thieme Medical Publishers, NY, Stuttgart, 2006.
2. Ebrahimi-Madiseh et al (2016). Speech perception scores in cochlear implant recipients: An analysis of ceiling effects in the CUNY sentence test (Quiet) in post-lingually deafened cochlear implant recipients. Cochlear Implants Int 2016 17(2): 75-80.
3. Gifford RH and Dorman MF. The Psychophysics of Low-Frequency Acoustic Hearing in Electric and Acoustic Stimulation (EAS) and Bimodal Patients. J Hear Sci 2012 May 1; 2(2): 33-44.
4. Gilden et al (2015). Improved hearing in noise using new signal processing algorithms with the Cochlear Nucleus 6 sound processor. Jour of Otol 10: 51-56.
5. Lenarz et. Al (2013) European Multi-center Study of the Nucleus Hybrid L24 cochlear implant. International Journal of Audiology. 1-11
6. Roland, et al (2016) United States Multicenter Clinical Trial Cochlear Nucleus Hybrid Implant System. Laryngoscope, 126(1): 175-81.
7. Sheffield SW, Jahn K, Gifford RH. Preserved Acoustic Hearing in Cochlear Implantation Improves Speech Perception. J Am Acad Audiol 2015 Feb; 26(2): 145-154.

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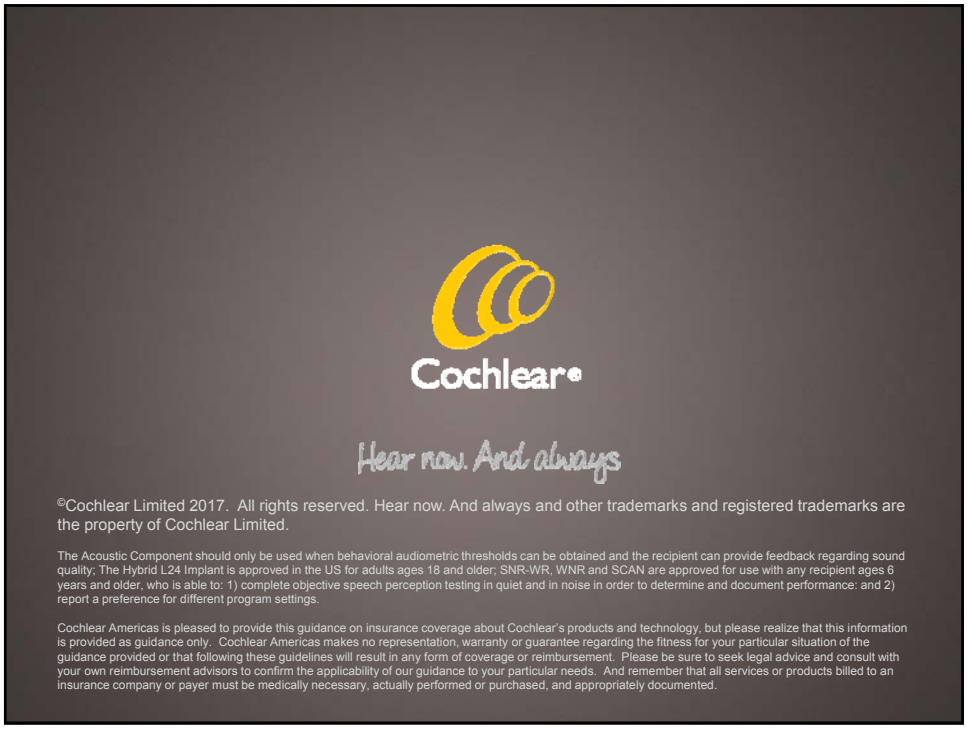

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The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality; The Hybrid L24 Implant is approved in the US for adults ages 18 and older; SNR-WR, WNR and SCAN 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: and 2) report a preference for different program settings.

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