



Cochlear™ Neural Response Telemetry

Amy Isaacs Donaldson, AuD, CCC/A
Regional Clinical Training Manager
Cochlear Americas

Hear now. And always.



Learning Objectives

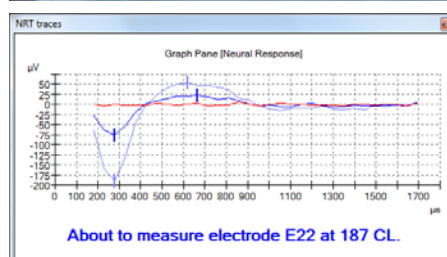
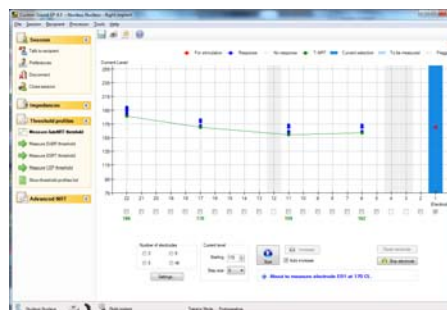


- Participants will be able to describe telemetry and impedance measurements in the Nucleus Cochlear implant system and list their clinical uses.
- Participants will be able to list the characteristics of Neural Response Telemetry (NRT) and explain its clinical use.
- Participants will be able to explain how to use Custom Sound software to measure both impedances and NRT in the Nucleus Cochlear Implant System.

Topics:



- Nucleus® 6 System
- History of NRT
- Measuring impedances
- Clinical use of impedances
- Neural Response Telemetry (NRT®)
- Performing AutoNRT® in Custom Sound® EP Software
- Clinical use of NRT
- Case Studies
- NEW! CR220 Intraoperative Remote Assistant



Cochlear™ Nucleus® 6 System:

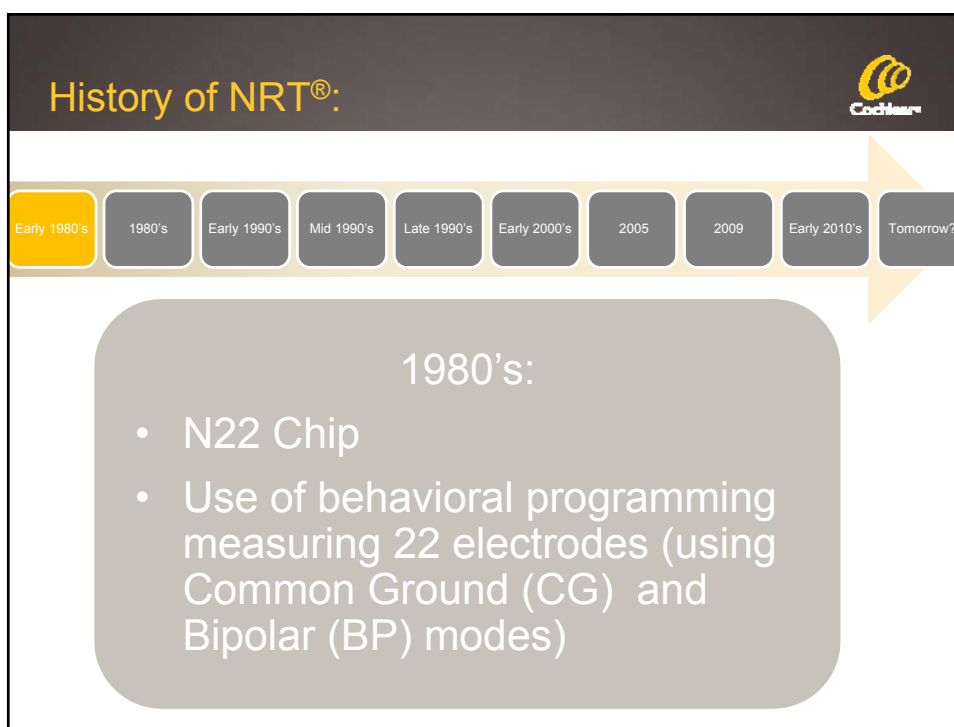


- Cochlear™ Nucleus® Profile is the world's thinnest cochlear implant with a portfolio of electrode arrays available:
 - Coutour Advance® Electrode (CI512) - the industry's only perimodiolar array for optimum performance¹
 - Slim Straight® Electrode (CI522) – the industry's thinnest full length electrode²
 - Hybrid™ Electrode – the industry's only electrode for hearing preservation
- Smartest and smallest sound processor with industry-first automatic scene classifier, datalogging, wireless accessories and the industry's only water proof ear-level option when rechargeable batteries are used³

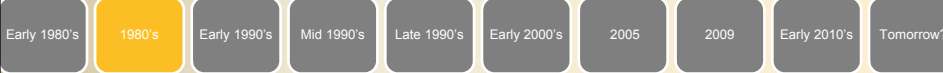

¹Holden et al, Ear and Hearing, 2013

²40% thinner than other implant manufacturers electrodes, measurements according to manufacturers' electrode specifications

³IP68 rating with the Aqua+ accessory with rechargeable battery



History of NRT®:

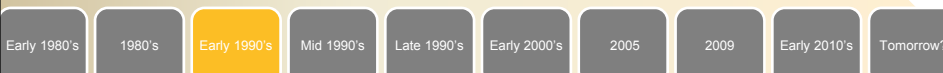



Timeline labels: Early 1980's, 1980's, Early 1990's, Mid 1990's, Late 1990's, Early 2000's, 2005, 2009, Early 2010's, Tomorrow?

1980's:

- Begin implanting children (using CG and BP Modes)
- Research into objective measures

History of NRT®:

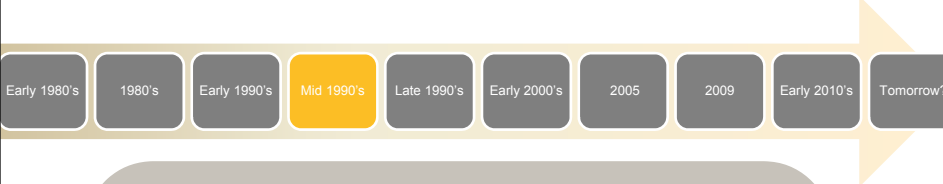


Timeline labels: Early 1980's, 1980's, Early 1990's, Mid 1990's, Late 1990's, Early 2000's, 2005, 2009, Early 2010's, Tomorrow?

Early 1990's:

- Research with ECAP and NRT
- Use of loudness scales and Counted T's approach

History of NRT®:

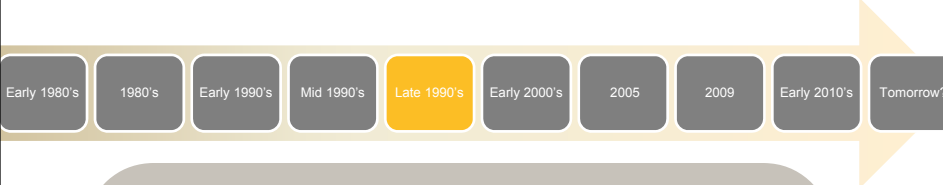


Early 1980's 1980's Early 1990's **Mid 1990's** Late 1990's Early 2000's 2005 2009 Early 2010's Tomorrow?

Mid 1990's:

- Launch of CI24M (CIC3 Chip)(with NRT amplifier and monopolar modes)
- Research into reducing number of measured electrodes (and interpolating intermediate electrodes)
- New reimbursement models starting to emerge

History of NRT®:

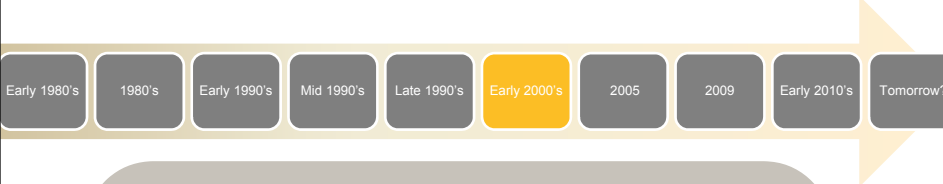


Early 1980's 1980's Early 1990's Mid 1990's **Late 1990's** Early 2000's 2005 2009 Early 2010's Tomorrow?

Late 1990's:

- Launch of commercially available NRT software
- Use of NRT intraoperatively (IOP)

History of NRT®:

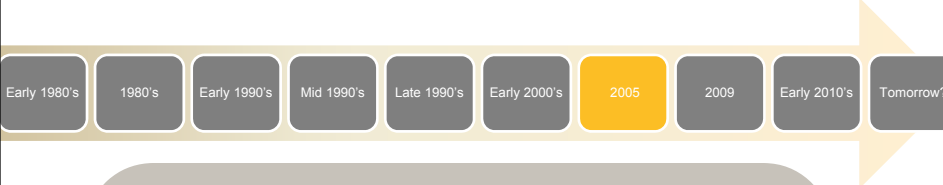


Early 1980's 1980's Early 1990's Mid 1990's Late 1990's **Early 2000's** 2005 2009 Early 2010's Tomorrow?

Early 2000's:

- Cafarelli et al (2005): looking at ECAP profiles and shift and tilt functions (and setting levels using live voice)
- Objective offset method also used in programming

History of NRT®:




Early 1980's 1980's Early 1990's Mid 1990's Late 1990's Early 2000's **2005** 2009 Early 2010's Tomorrow?

2005:

- CIC4 Chip
- Nucleus® Freedom® system launched with AutoNRT®

History of NRT®:




Timeline: Early 1980's, 1980's, Early 1990's, Mid 1990's, Late 1990's, Early 2000's, 2005, 2009, Early 2010's, Tomorrow?

2009:

- Launch of Nucleus 5 with Remote Assistant
- CR120 IOP Remote Assistant introduced

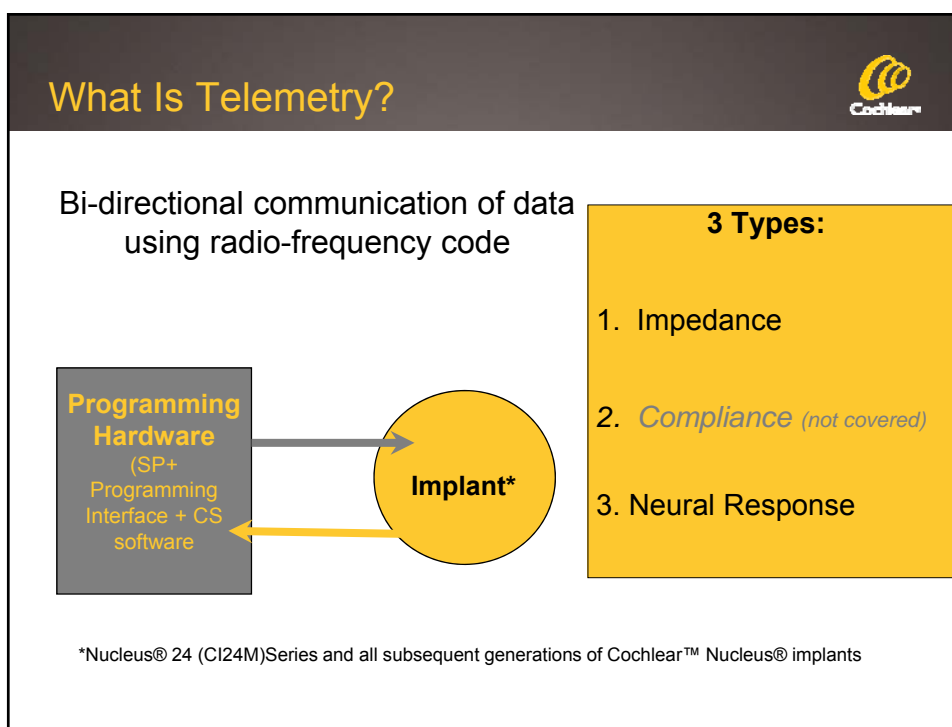
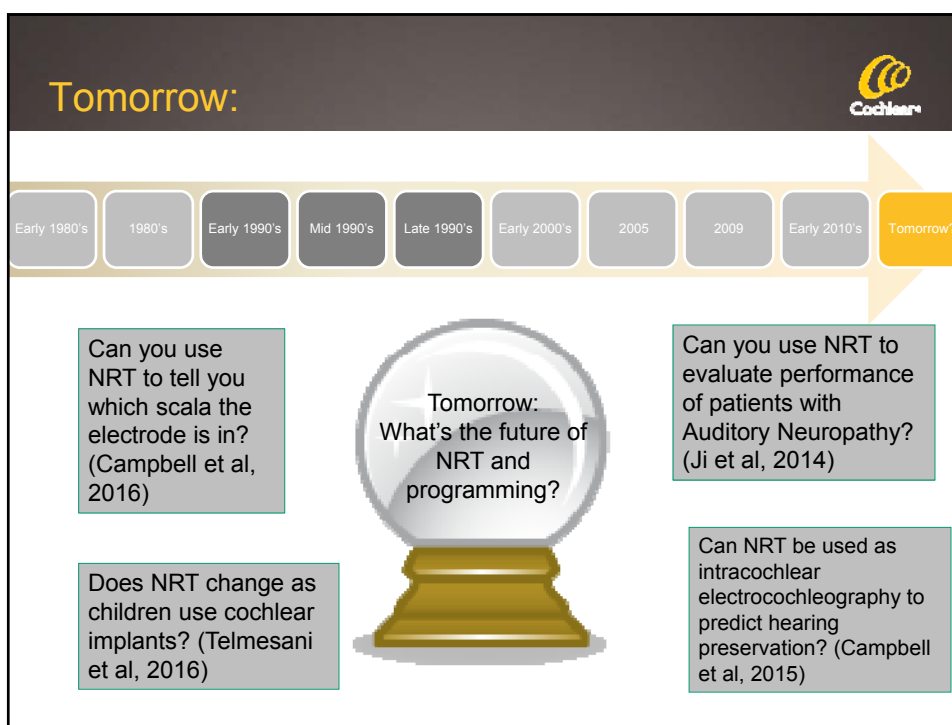
History of NRT®:



Timeline: Early 1980's, 1980's, Early 1990's, Mid 1990's, Late 1990's, Early 2000's, 2005, 2009, Early 2010's, Tomorrow?

Early 2010's

- Botros and Psarros (2010) publish ECAP profile scaling model research
- CR220 intraoperative remote is introduced



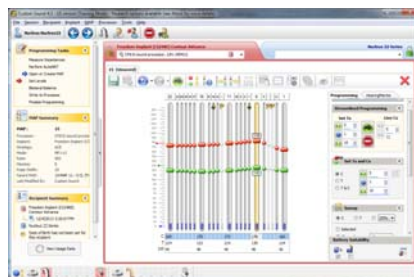
Why is Telemetry Useful?



- Provides information about the functioning of the internal device
- Impedances can provide information about the substrate around the electrode (i.e. fluid, fibrous tissue, bone, etc.)
- NRT can provide confirmation of neural response, assistance with mapping, a measure of neural response over time

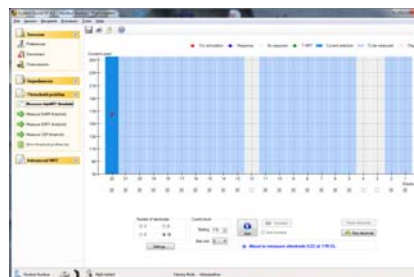


Custom Sound® Suite:



Custom Sound:

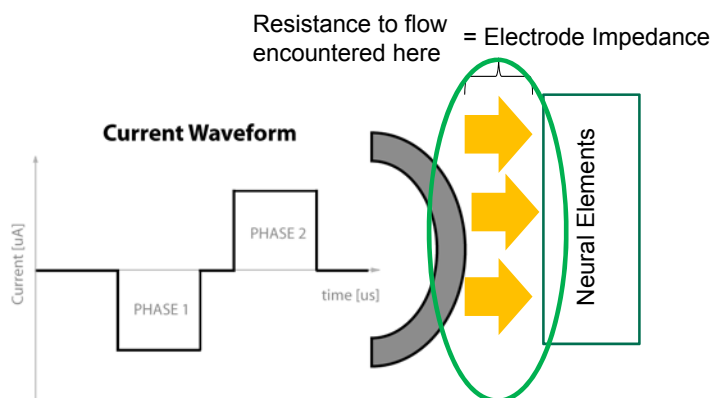
- CI mapping
- Programming of SP
- Acoustic Component programming
- Impedances and AutoNRT



Custom Sound EP:

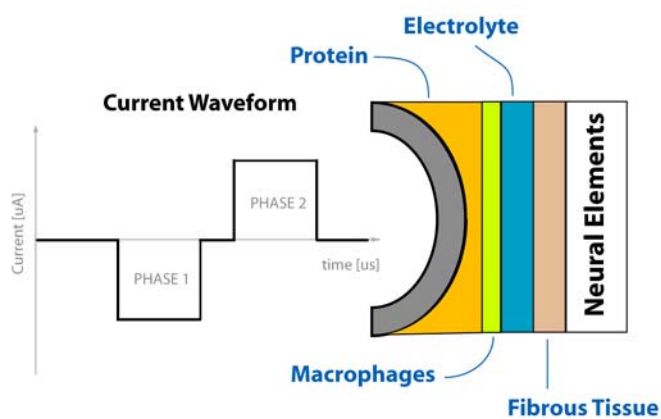
- Intraoperative testing
- Impedances
- AutoNRT and Advanced NRT
- Other objective measures (ESRT, CEP, EABR)

What is Electrode Impedance?

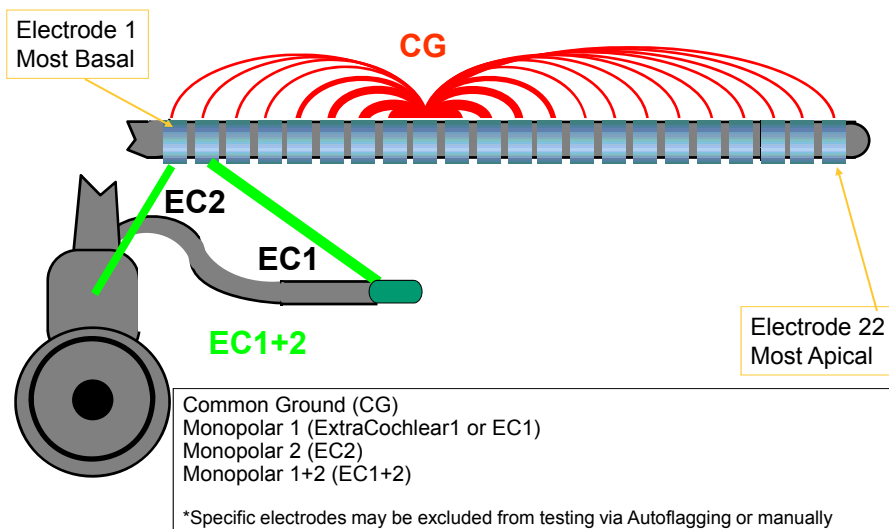


- Electrode impedance measures the resistance to the flow of electrical current through any particular medium
- Measured in ohms
 - Impedance = voltage/current

What is Electrode Impedance?



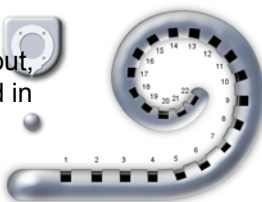
Impedance Test Modes:



Impedance in Custom Sound®



- Coil must be on device in order to measure impedance
- If measure button is greyed out, confirm processor is selected in drop down
- All four modes measured sequentially



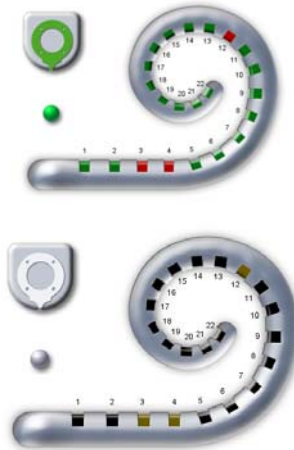
Measure



Impedance in Custom Sound:



- **Green**
 - Within operating range
- **Red**
 - Short or open circuit
- **Brown**
 - Previously flagged
 - Electrodes are flagged automatically if short/open or can be flagged manually (ie, if outside cochlea)
- *In training mode e3 & 4 are always short circuit and e 12 is always open circuit*

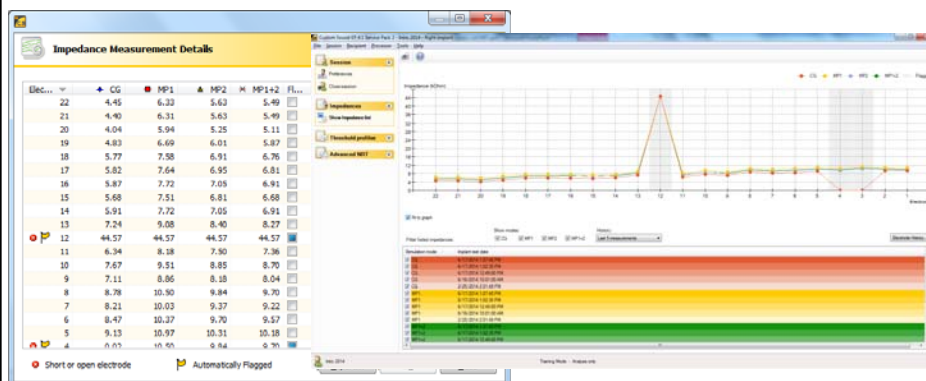


Impedance Reporting:



Custom Sound

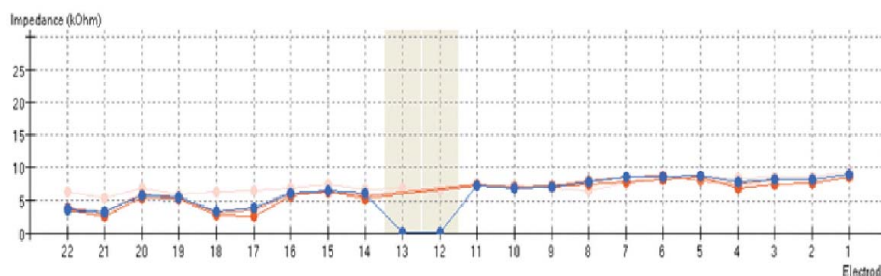
Custom Sound EP



Short Circuits:



- Short-circuit electrodes are defined as electrode contacts having an impedance less than ($<$) 565Ω as measured in Custom Sound
- A low impedance value ($<565\Omega$) suggests that the electrode or the wire attached to it, may be in contact with another electrode or wire



Open Circuits:



- Open-circuit electrodes are defined as electrode contacts having an impedance greater ($>$) than:
 - **20k Ω for full-band** electrode arrays (Nucleus® 24M)
 - **30k Ω for half-band** electrode arrays (Contour Advance™, Slim Straight (CI422) and Hybrid (L24) electrode arrays)
- Due to smaller surface area for the electrode contacts of half-band arrays, a higher limit is used

Reminders about open and short-circuits:



- May be intermittent
- Custom Sound automatically flags and excludes electrodes that meet the short or open-circuit criteria
- Not generally re-introduced into recipient's program (unless not registering as short or open-circuit for period of time)
- If open-circuit identified in surgery, remeasure at later point in time as may be result of air bubble (typically resolves).

Summary of Key Factors:



Factor	Impact on electrode impedances
Environment - fluid contact, proximity to bone etc	If there is not good fluid contact or there is fibrosis/ossification there will be more resistance to the current (therefore higher impedances).
Medical, pharmaceutical (drugs), hormonal changes	Rx and hormonal fluctuations change the conductive nature of the fluid the current passes through (and therefore may change the resistance or impedance value).
CIS (unused channels) Disabled channels	Due to conditioning of the electrode with the surrounding environment, unused or disabled channels will typically have higher impedance values.
Time of day measurement taken	Impedance values will typically be lower after a period of stimulation due to conditioning of the electroneural interface.

Basic Overview of NRT:



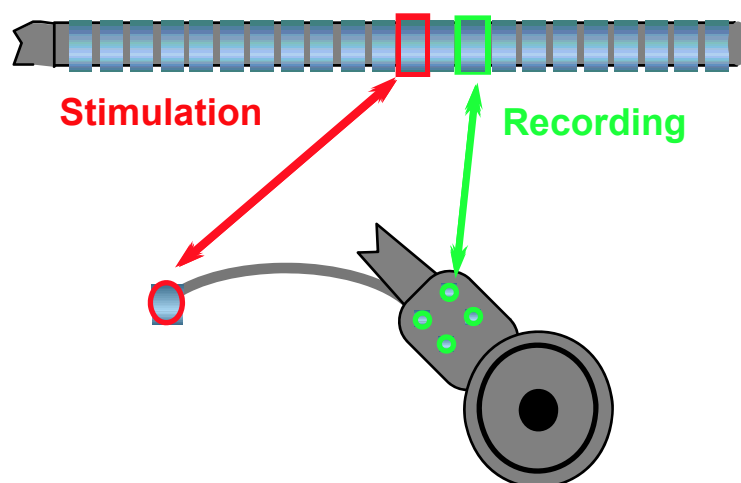
- Brief set of electrical pulses are delivered to stimulating electrode
- Neural activity is obtained by recording electrode
- Recorded evoked potentials are amplified, digitized and then transmitted to the external speech processor
- NRT software receives this telemetry signal, averages it and displays on computer screen
- Result is Electrically Evoked Compound Action Potential (ECAP)

What does NRT show you?

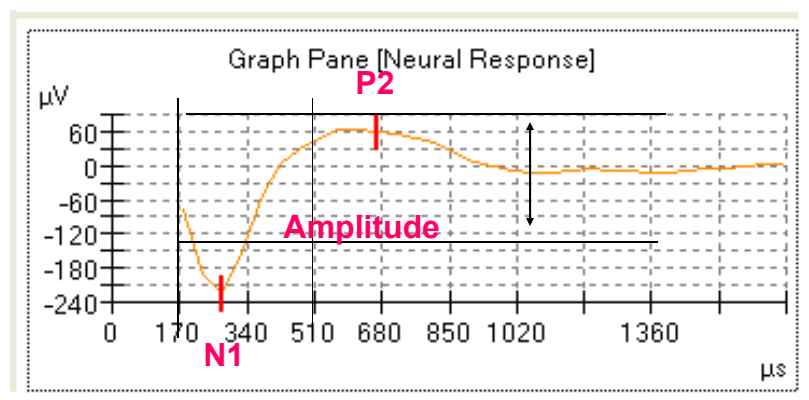


- Compound action potentials generated by **specific neural populations** in the cochlea
- Its amplitude and recovery show you how responsive that neural population is to electrical stimulation

Stimulating & Recording Modes for NRT:

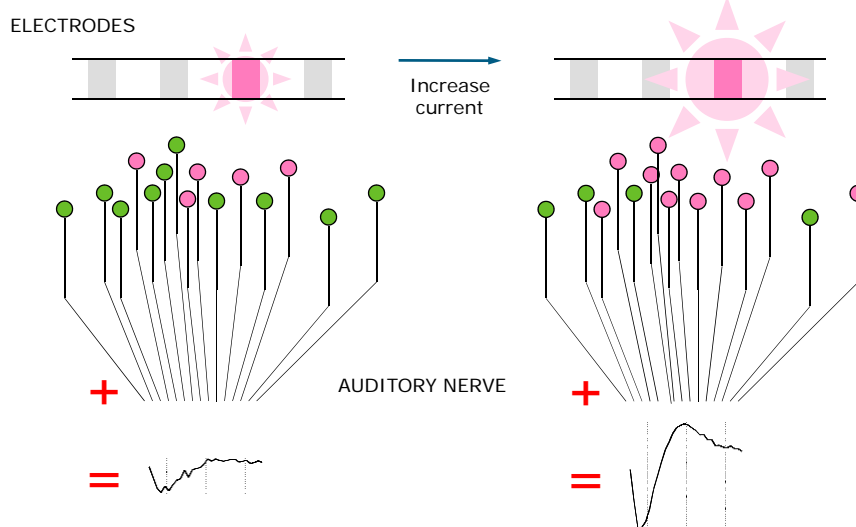


ECAP Characteristics:



Ref: Abbas et al. (1999). Summary of results using the Nucleus 24M implant to record the electrically evoked compound action potential. *Ear and Hearing*, 20(1): 45-59.

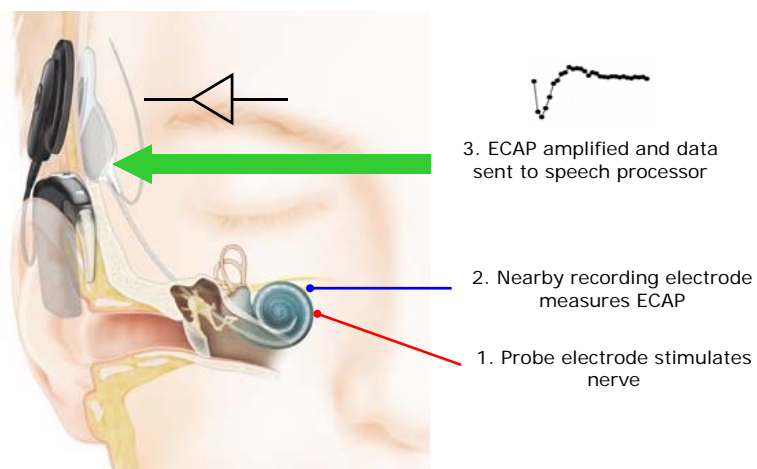
Biologic Changes with Increasing Current:



How NRT is measured:



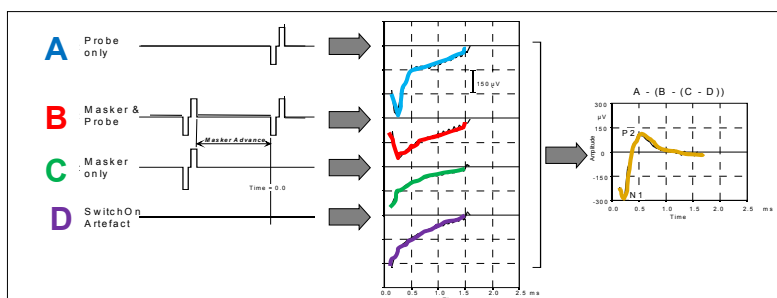
- **Cochlear™ Nucleus® 24 Family** of implants allow the recording of electrically-evoked compound action potentials (ECAP)



Subtraction Paradigm:



- Typical neural potential is small (~100 uV) but stimulus used is much larger in amplitude and close to the evoked neural response
- Forward-masking (or subtraction paradigm) is used to measure



$$\text{Response} = A - (B - (C - D))$$

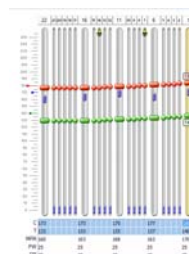
What does NRT tell you?



**Ability of Auditory
Nerve to fire
synchronously**



**Correlation with
audibility;
estimation of C-
levels**



**Objective
Assessment of
Changes Over Time**



What NRT does **not** tell you:



- NRT is NOT a test of implant function
 - Impedance telemetry for electrode faults
- Absent NRT \neq Implant malfunction
- Possible reasons for absent NRT:
 - AutoNRT is possible in about 90% of cases (Botros, 2007 & Gordon, 2004)
 - Pulse width greater than that which can be used for NRT is necessary for auditory response (ie, $> 50 \mu\text{S}$)
 - May be absent intra-operatively due to asynchrony of the neural fibers but appear post-operatively with device use (deMoura, 2014)

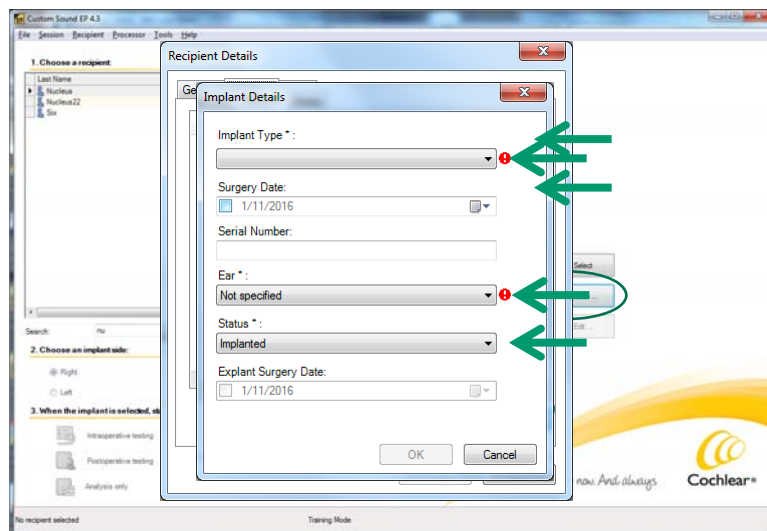
Auto NRT[®]:



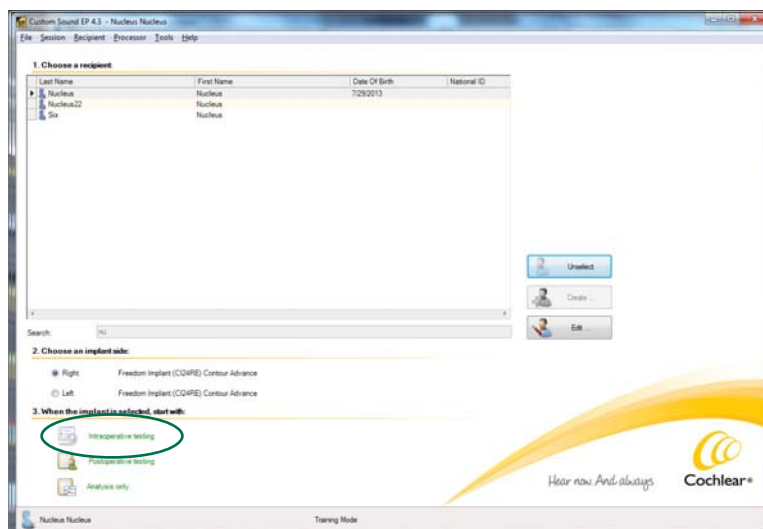
- Auto NRT* is an easy way to collect NRT data automatically
- One button push and the computer automatically does the work for you
- Can be done in the OR
- Can be done post-operatively in the clinic
- Data is automatically available for use in programming in Custom Sound

*AutoNRT is only available for CI24 (RE) and following implants

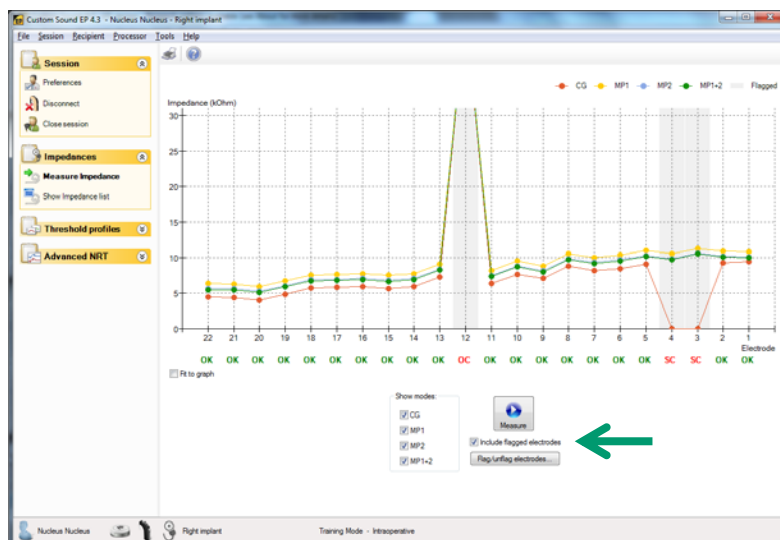
Custom Sound EP:



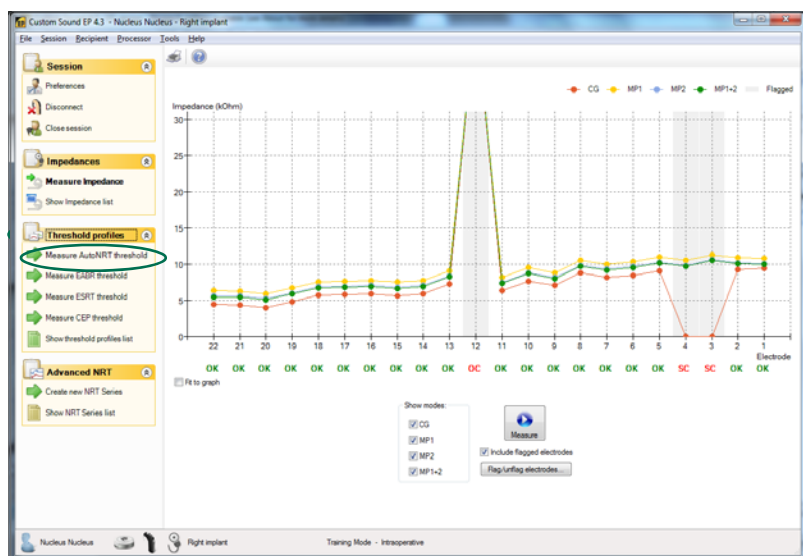
Custom Sound EP:



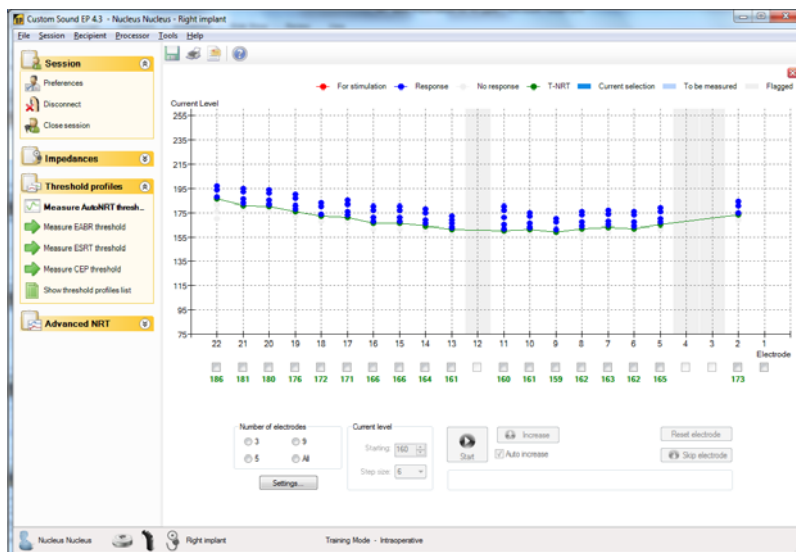
Custom Sound EP:



Custom Sound EP:



Custom Sound EP:

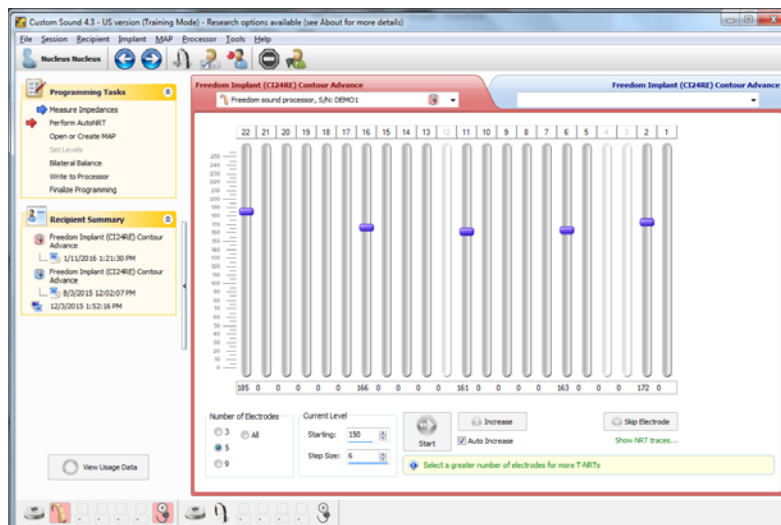


NRT- IOP Decisions:



- No Link With Device
 - Check equipment
 - Call Audiology On Call at 800-523-5798
- Impedance Telemetry Absent
 - Check equipment
 - Call Audiology On Call at 800-523-5798
- Impedance Telemetry
 - Short circuited (SC) electrodes are rare – will likely be permanent
 - Open electrodes (OC) check electrode placement - if OK then may have been air bubble
- Absent NRT

AutoNRT through Custom Sound:

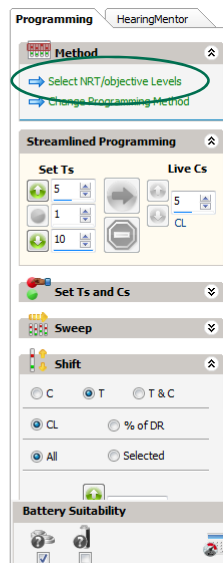
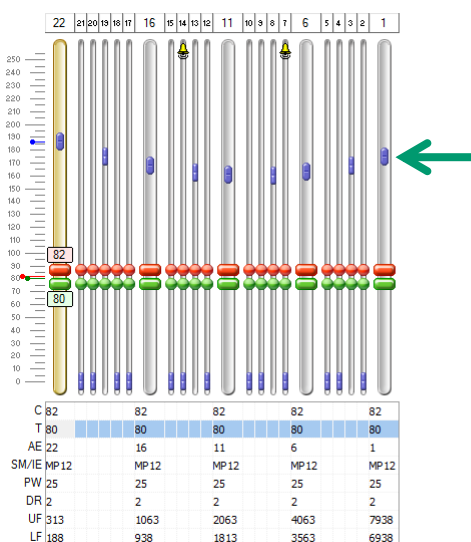


Post-operative uses of NRT:



- NRT levels are correlated with T and C levels
 - Combining NRT and behavioral information allows for a stronger correlation (Brown et al, 2000)
 - The “profile” of the NRT can be used to generate a “scaled threshold profile” of the T and C levels with the absolute T- and C-levels determined by behavioral measures² (Botros & Psarros, 2010)
- NRT can be present post-operatively even if not present intra-operatively (deMoura et al, 2014)
- NRT thresholds will tend to decrease over the first few months of device use then stabilize (Molisz et al, 2015)

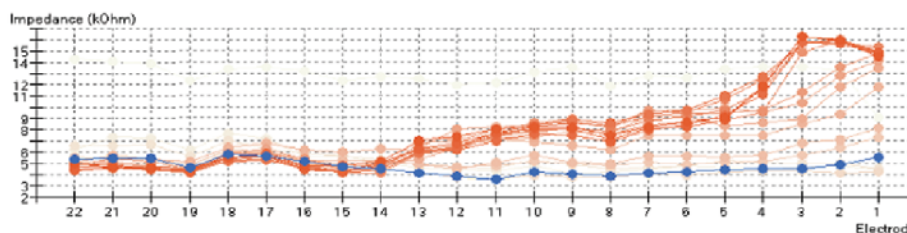
Creating an NRT-based Map:



Case Study 1:



- **Case history:** 52 year old male recipient, implanted with a CI24R(ST) on the left ear. Implanted for eight years and wearing the processor daily for about 12 hours on average. Over time during regular scheduled follow ups, the clinician noticed rising impedances. The recipient reports no symptoms of deterioration in sound quality or battery life.
- **Electrode impedances:** In last six to eight programming sessions, there has been a gradual rise in electrode impedance values in the basal electrodes. However, the values are still not considered an open-circuit ($>20\text{k}\Omega$ for fullband electrode arrays as with the CI24R(ST) device).



Case Study 1 (continued):

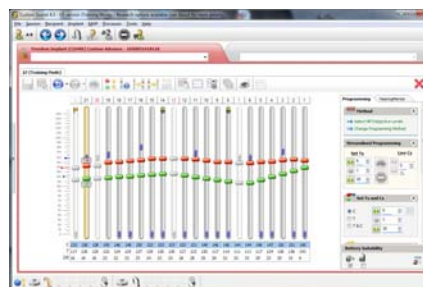
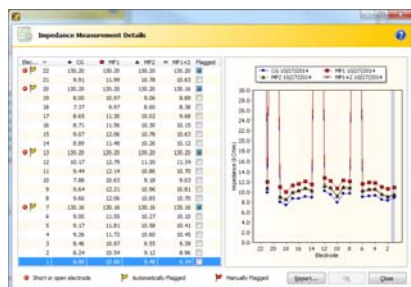


- **Troubleshooting** information: Wears the Freedom BTE processor and changes microphone protectors regularly. Processor checked and sound quality good with monitor earphones. Link between implant and processor is okay with no intermittencies reported.
- **Medical history:** Diagnosed with progressive noise induced hearing loss about 10 years ago. Recipient wore bilateral hearing aids for two years before being implanted. No other significant medical history.
- **Imaging:** Radiography revealed ossification in the basal region of the implanted cochlea. All intracochlear electrodes insitu in cochlea.
- **Programming information:** Programs all operational. Currently all C-levels within compliance. Recipient reports wanting sound a bit louder in the 'higher pitched' area.
- **Hearing performance:** Scores 86% on CNC words and 97% on sentence testing in noise. Recipient is happy with his outcomes and how the system is enhancing his quality of life.

Case Study 2:



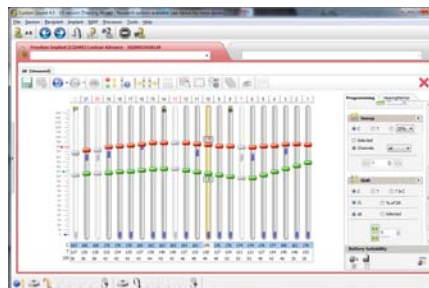
- **Case History:** 7 year old girl, implanted with a CI24RE device one year ago (at age 6). Parents report she is wearing the device daily, but they are not seeing many responses from her. The clinic reports inconsistent response in the soundfield and during mapping.
- **Map evaluation:** Mapped in ACE, 900 Hz map. Impedances have been stable but open circuits are noted on E7, E13, E20 and E22. These electrodes are off in the map.



Case Study 2 (continued):



- **Troubleshooting:** Datalogging confirmed device use was full time. Testing in the soundfield suggested elevated thresholds with the device on (40-45 dB across the array)
- **Imaging:** X-ray revealed device is appropriately placed in cochlea.
- **Programming information:** AutoNRT had been run and results suggested NRT thresholds were above C levels. There had been some adverse reaction to sound early on (at the one week follow-up post-activation) and the clinic was hesitant to increase C levels. Mapping session completed with CTM present and clinic increased C levels significantly; T levels were also set at behavioral levels and came up slightly. Child was tolerant of map increase.
- **Hearing Performance:** Immediate improvement in soundfield thresholds. Increase in responses to sound at home and at school over next several weeks. No further concerns about device function.



NEW! Introducing the Cochlear™ Nucleus® CR220 Intraoperative Remote Assistant



The Cochlear Nucleus CR220 Intraoperative Remote Assistant is a hand-held device that enables surgeons, clinicians, audiologists or any trained operating room staff to perform:

- Electrode impedances
- Automatic Neural Response Telemetry (AutoNRT®)

Benefits of the CR220



- Fast and easy intraoperative measurements
- Immediate operational feedback of the implant
- Confidence the electrode is positioned correctly
- Reduces infection risk
- Reduces time patient is under anesthetic*
- May prevent additional tests or imaging



Export CR220 measurements into Custom Sound for use in the clinic



Conclusions:



- Telemetry allows communication with the implant
- Impedance measures provide the clinician with information about the function of the internal device
- AutoNRT can be used in the operating room and post-operatively to quickly measure NRT thresholds
- NRT can be useful in device programming and monitoring auditory status in patients



References



- Brown et al (2000) The relationship between EAP and EABR thresholds and levels used to program the nucleus 24 speech processor: data from adults. *Ear Hear*, 21(2):151-63.
- Botros et al (2007) AutoNR: an automated system that measures ECAP thresholds with the Nucleus Freedom cochlear implant via machine intelligence. *Artif Intell Med*, 40(1): 15-28.
- Botros & Psarros (2010) Neural response telemetry reconsidered: I. The relevance of ECAP threshold profiles and scaled profiles to cochlear implant fitting. *Ear & Hearing*, 31(3):367-79.
- Cafarelli et al (2005) Normative findings of electrically evoked compound action potential measurements using the neural response telemetry of the Nucleus CI24M cochlear implant system. *Audiol Neurotol*, 10(2):105-16.
- Campbell L, Kaicer A, Briggs R, O'Leary S. (2015) Cochlear response telemetry: intracochlear electrocochleography via cochlear implant neuralresponse telemetry pilot study results, *Otol Neurotol*. Mar;36(3):399-405
- Campbell L(1), Kaicer A, Sly D, Iseli C, Wei B, Briggs R, O'Leary S. (2016) Intraoperative Real-time Cochlear Response Telemetry Predicts Hearing Preservation in Cochlear Implantation. *Otol Neurotol*. 2016 Feb 6.

References



- deMoura et al (2014) Longitudinal analysis of the absence of intraoperative neural response telemetry in children using cochlear implants. *Int Arch Otolaryngol*, 18(4):362-368.
- Gordon et al (2004) Toward a battery of behavioral and objective measures to achieve optimal cochlear implant stimulation levels in children. *Ear & Hearing*, 25(5):447-63.
- Holden et al (2013) Factors affecting open-set word recognition in adults with cochlear implants. *Ear and Hearing*, 2013
- Ji F, Li JN, Liu K, Jiao QS, Sun L, Hong MD, Chen AT, Li SY, Yang SM. (2014) NRT test in auditory neuropathy patients with cochlear implants. *Acta Otolaryngol*. Sep;134(9):930-42.
- Molisz et al (2015) Postimplantation changes of electrophysiological parameters in patients with cochlear implants. *Audiol Neurotol*, 20(4):222-8.
- Telmesani LM, Said NM. (2016) Electrically evoked compound action potential (ECAP) in **cochlear** implant children: Changes in auditory nerve **response** in first year of **cochlear** implant use. *Int J Pediatr Otorhinolaryngol*. Mar;82:28-33.



Hear now. And always

©Cochlear Limited 2016. All rights reserved. Hear now. And always and other trademarks and registered trademarks are the property of Cochlear Limited.

Cochlear Americas is pleased to provide this guidance on insurance coverage about Cochlear's products and technology, but please realize that this information is provided as guidance only. Cochlear Americas makes no representation, warranty or guarantee regarding the fitness for your particular situation of the guidance provided or that following these guidelines will result in any form of coverage or reimbursement. Please be sure to seek legal advice and consult with your own reimbursement advisors to confirm the applicability of our guidance to your particular needs. And remember that all services or products billed to an insurance company or payer must be medically necessary, actually performed or purchased, and appropriately documented.