SYDNEY LOCAL HEALTH DISTRICT CIE

Role of BME Engineering in Cochlear Implants

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SLHD- RPA Hospital

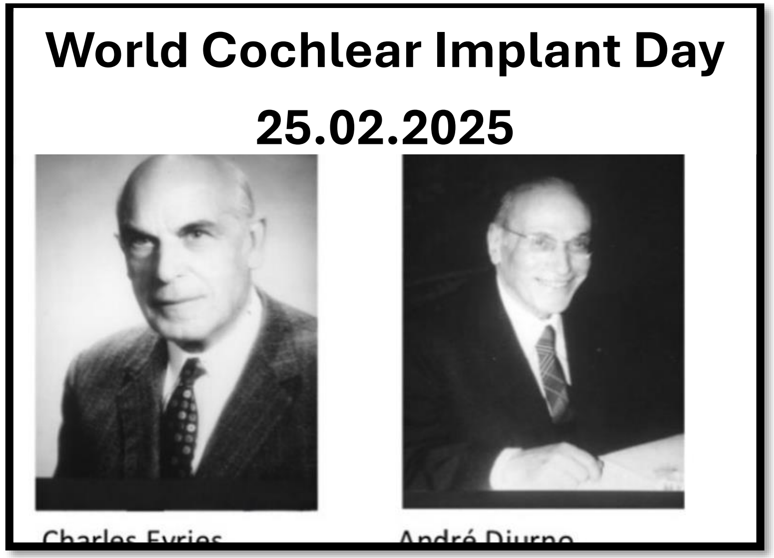
Sydney Cochlear Implant Program

- **Acknowledgment of Country:**

- I would like to begin by acknowledging the traditional custodians of the land on which we are meeting today, the Darug people. I pay my respects to their Elders, past, present, and emerging, and extend that respect to any Aboriginal and Torres Strait Islander people present here today.


WORLD HEARING DAY
3 MARCH 2025
CHANGING MINDSETS: EMPOWER YOURSELF
Make ear and hearing care a reality for all!
You can take steps today to ensure good hearing health throughout life.
World Health Organization


500 million people live
with disabling hearing loss


World Cochlear Implant Day
25.02.2025

- Acc to 2019-20 report from Deloitte Access Economics: The Social and Economic Cost of Hearing Loss in Australia: 3.95 million Australians live with some form of hearing loss.

- Acc to Australian Institute of Health and Welfare (AIHW), one in six Australians live with some form of hearing impairment.

Hearing Loss and Cochlear Implant

- **Type of Hearing Loss:**
  - Conductive Hearing Loss
  - Sensorineural Hearing Loss
  - Mixed Hearing Loss

- **Candidates for Cochlear Implants:**

  Criteria for cochlear implant candidacy may vary, but generally include:
  - Severe to profound sensorineural hearing loss in both ears.
  - Limited benefit from traditional hearing aids.
  - For children, typically not achieving speech milestones even with hearing aids.
  - Ability to undergo surgery and follow-up rehabilitation, as cochlear implants require both a surgical procedure and ongoing auditory training to maximize effectiveness.

In Australia:

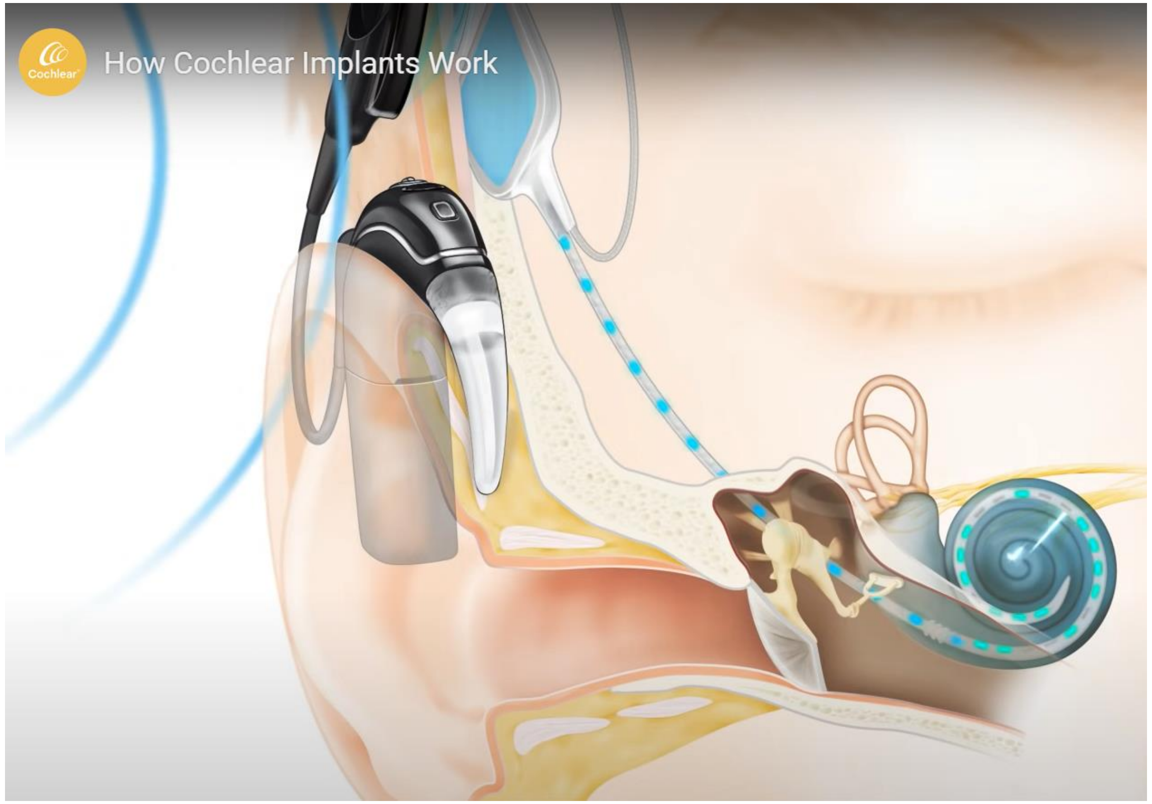
Around 90% of children who are eligible for a cochlear implant will receive one.

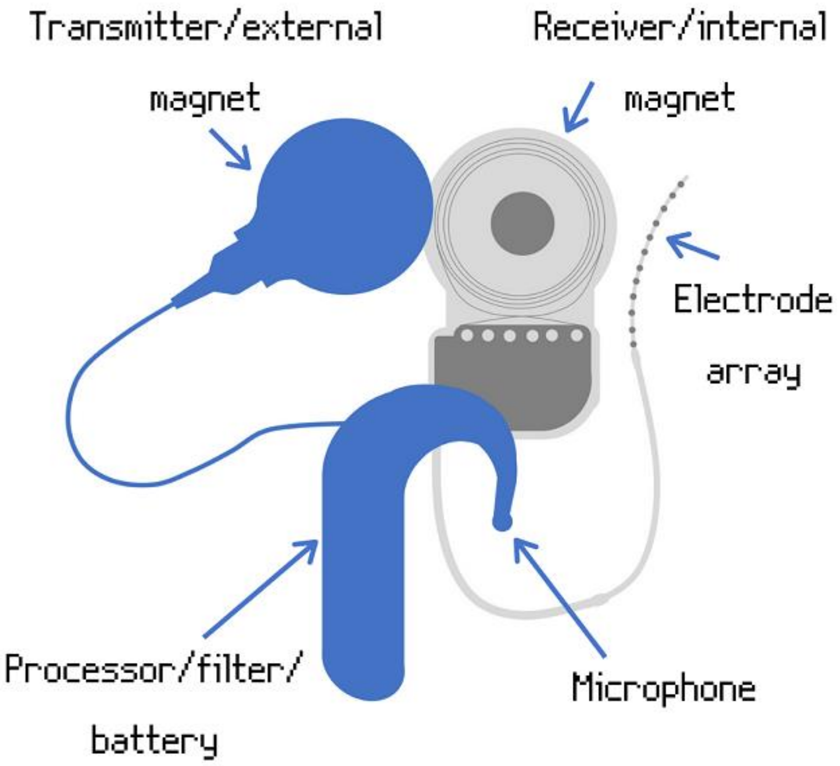
Only about one in 10 adults who could benefit from implants currently access them

Agenda

- Cochlear Implant structure,
- The beginning,
- Role of Biomedical Engineers in Bioengineering Cochlear Implants,
- Intraoperative testing of Cochlear Implants,
- Special Implants:
  - Auditory Brainstem Implants,
  - Vestibular Implants,
  - Drug Eluted CI,
- Genetherapy:
  - Gene Therapy.

Hoe does Cochlear implant work?





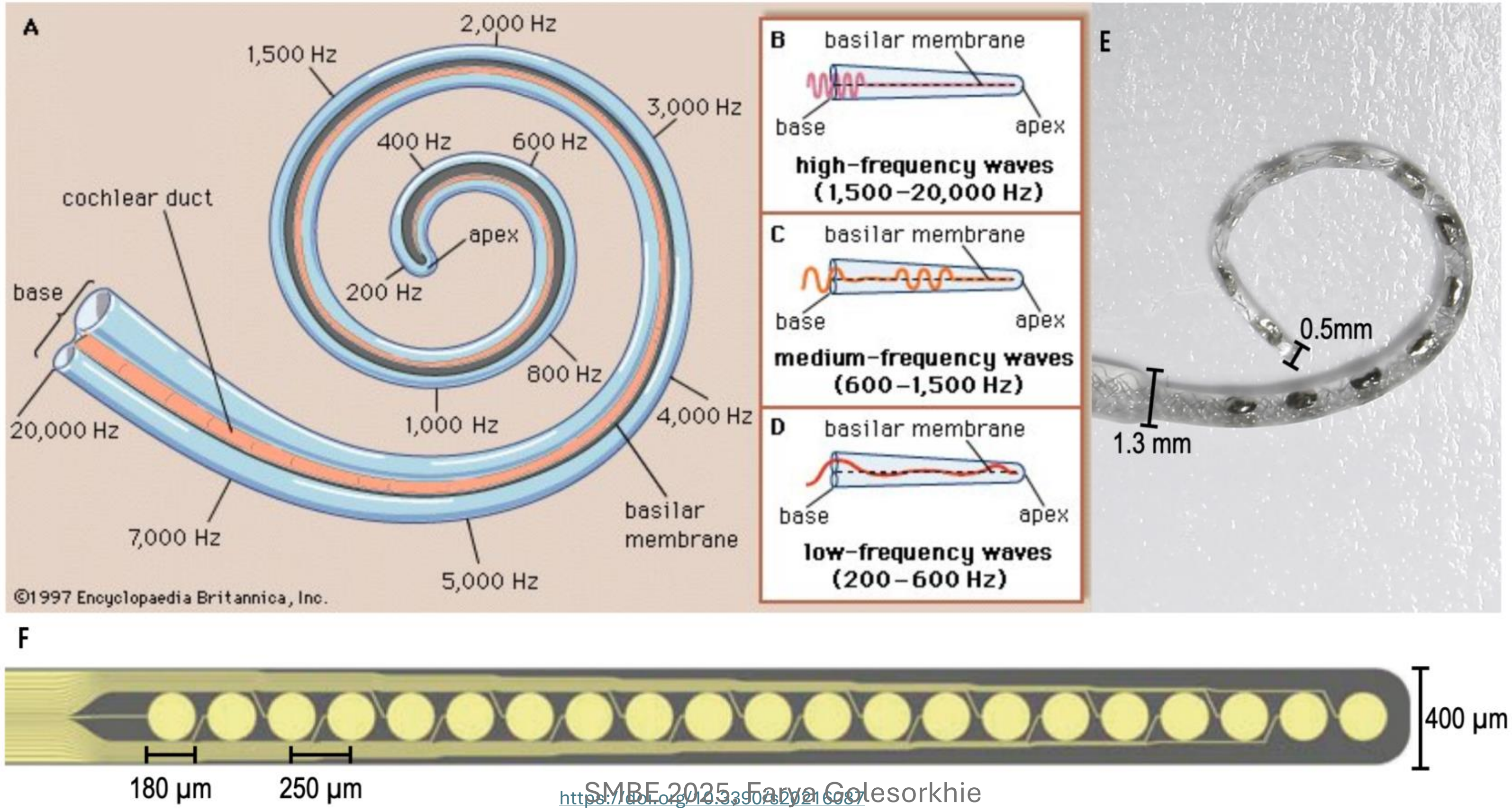
https://www.clearliving.com/hearing/technology/cochlear-implants/

Sends sound directly to the hearing nerve.

What is a CI?

The Array

~22 small platinum ring electrodes, < 400 µm diameter, distributed along a length of ~ 20 mm



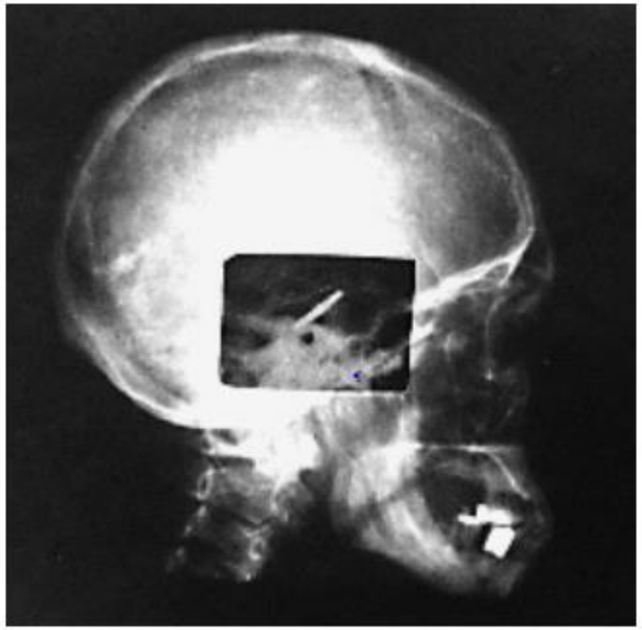
https://doi.org/10.3390/s21216087

Beginning

- First cochlear implant on 25th Feb 1957 in France by DJURNO (Engineer) and EYRES (Surgeon)- single electrode in the cochlea
- Four years later in 1964 William House and Doyle in USA,
- …
- 1978 Graeme Clark in Australia

- Graeme Clark developed a multi-channel implant with 10 electrodes in 1978. Three people who helped Graeme Clark were Jim Patrick who designed the array with 22 electrodes, Paul Trainer the CEO and founder of Nucleus, and Peter Seligman who designed the processor

Charles Eyries, André Djurno,



Now!

3 A current model cochlear implant. A. Transmitter. B. Transmitter coil. C. Microphone. D. Ear hook. E. Speech processor. F. Implant receiver/ stimulator. G. Multichannel electrode array

Courtesy of Cochlear Limited, Sydney.

CI632

CI622

22 Electrodes

COCHLEAR IMPLANT COMPARISON CHART

- **DISCLAIMER:** FTC provisions (16 CFR Part 255) regulate product endorsements, testimonials, and blogs, specifically in the Revised Endorsement Guides. This chart has been created and maintained by Tom Hannon, a bilateral Advanced Bionics recipient, and Howard Samuels, a bilateral Advanced Bionics recipient and a volunteer Bionic Ear Association (BEA) mentor; both are equally responsible for the concept, format, research, writing and editing, and neither are employed by a cochlear implant manufacturer. Information provided in this chart may vary on market location; more current information may be available from the manufacturer. Any errors or omissions are our own; contact us with any corrections. Please feel free to print or distribute this chart; the latest version will always be available at: CochlearImplantHELP.com Please note that this chart is for side-by-side feature reference only; please refer all technical discussion to your implant team.

	ADVANCED BIONICS	COCHLEAR	MED-EL	COMMENTS
	Advanced Bionics	Cochlear Cochlear [1]	MED-EL MED-EL	
CORPORATE OWNERSHIP	Owned by: Sonova Holding AG [2] Traded as: PHBN:GR SONVF:US SOON1:EB SOON:BQ SOON:TQ SONVY:US	Owned by: Cochlear Limited Traded as: COH:AU CHEOF:US OC5:GR CHEOY:US	Founded & privately owned by: Prof. Erwin Hochmair + Dr. Ingeborg Hochmair	
ESTABLISHED, LOCATION	AB: 1993 California, USA Sonova: 1947 Switzerland	1981 Australia	1990 Austria	Date the implant manufacturing company was formed.
US PATENTS (AS OF 1-JUN-21)	656	839	307	USA patents only to avoid global duplications: US Patent Office Quick Search by "*Assignee Name*" Google Patent Search
ESTIMATED GLOBAL MARKET SHARE	20%	55%	20%	Remaining 5% includes Oticon (Neurelec) & Nurotron. Market share percentages constantly change, and those stated are from a confidential industry analyst given to CochlearImplantHELP in 2019.

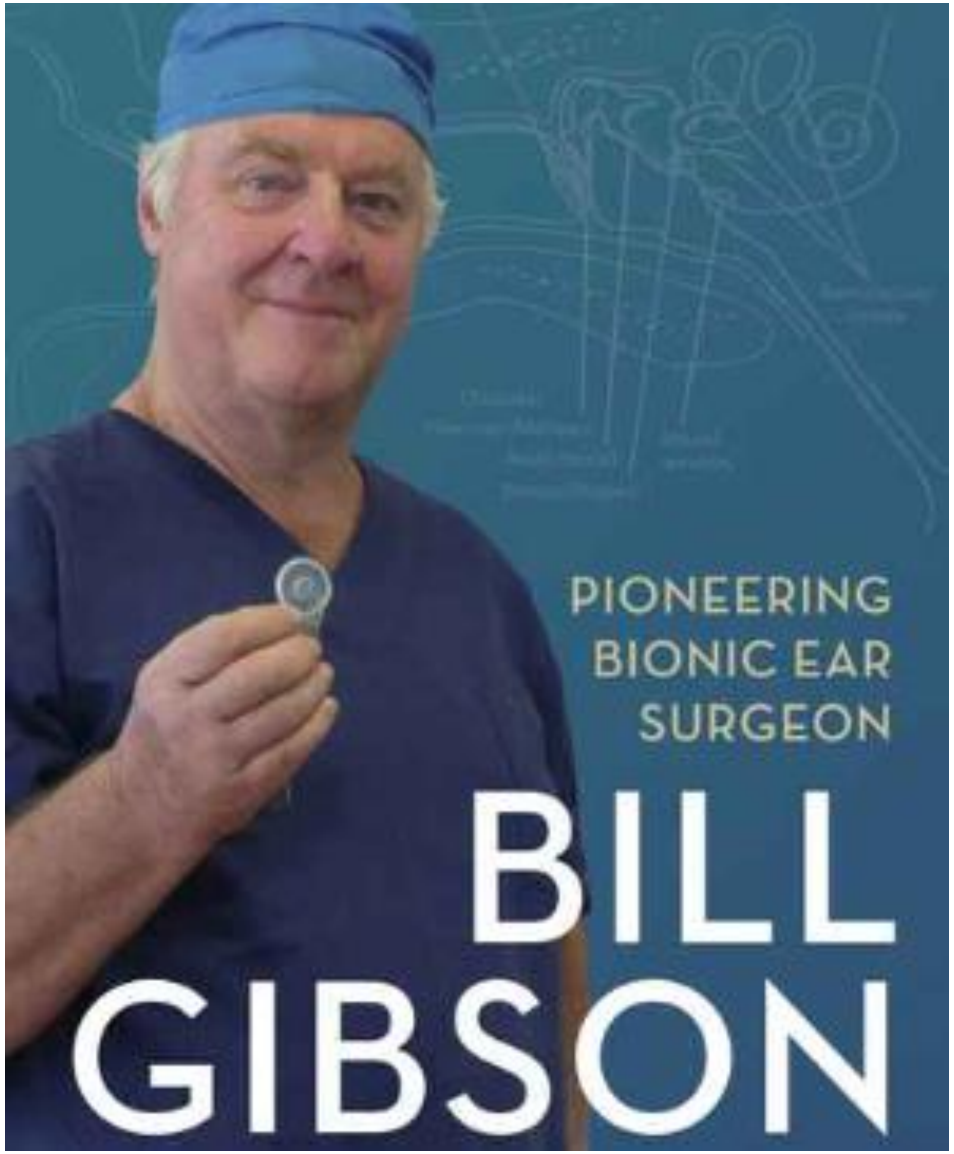
In August 1984, Susan Walters became the first cochlear implant recipient in New South Wales, Australia.

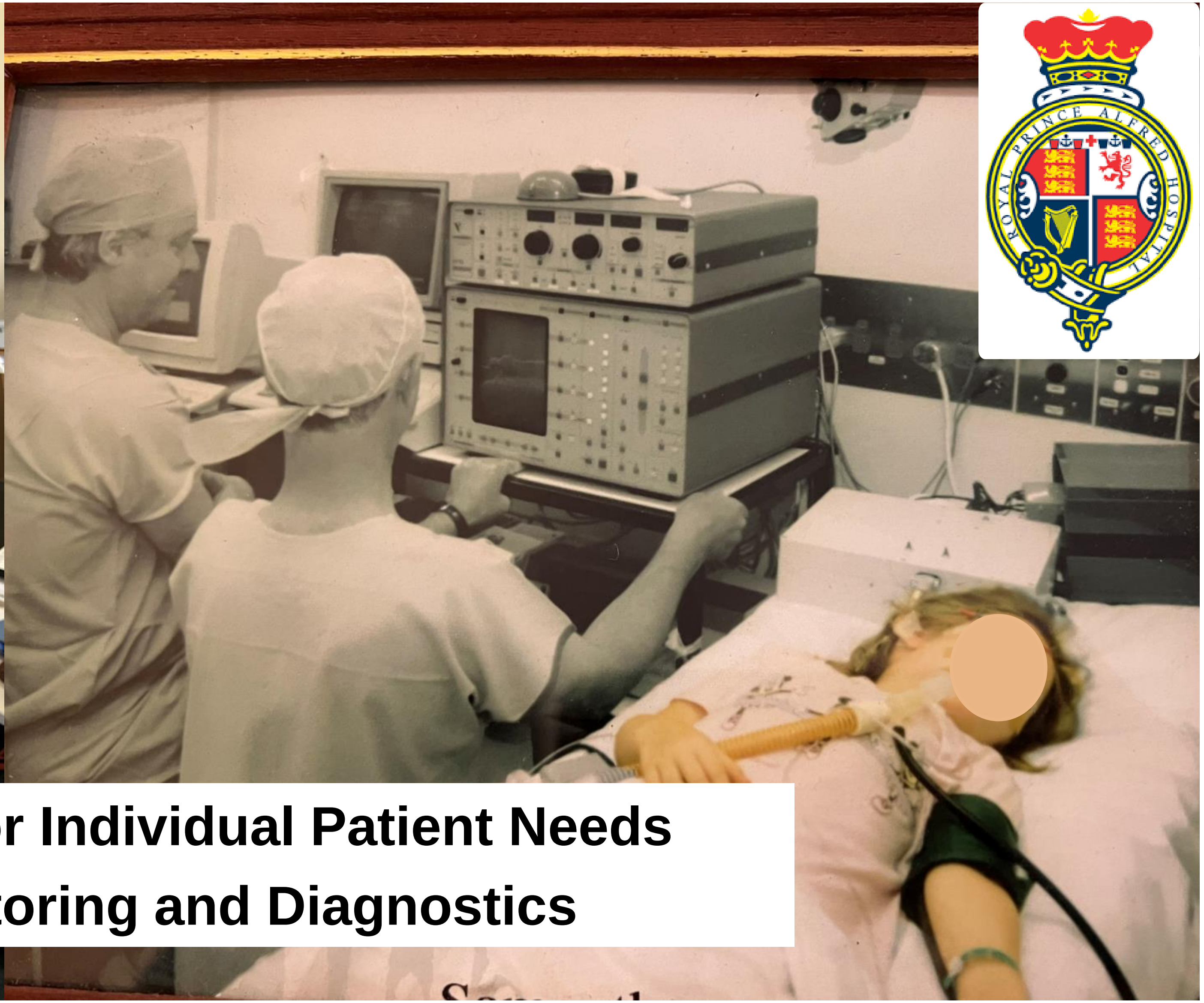
Restoring her hearing from profound deafness was nothing short of a miracle.

Six months later, Susan made history as the world's first deaf person to make a phone call using a cochlear implant sound processor...

Professor Gibson AO

- First Professor of Otology at the University of Sydney,
- He implanted first CI recipient in NSW in 1984 and by 1986 twenty adults received CI,
- In 1984 started a program for Cochlear implant at Royal Prince Alfred Hospital,
- This program later became NextSense (SCIC and RIDBC in the past).





- Customization for Individual Patient Needs
- Long-Term Monitoring and Diagnostics

Role of BME Engineers in Cochlear Implants

- Design and Development of Implantable Devices
- Signal Processing Algorithms
- Electrode Array Design
- Miniaturization of Components
- Biocompatibility and Materials Selection
- Power Management and Energy Efficiency
- Customization for Individual Patient Needs
- Integration with Other Assistive Technologies
- Long-Term Monitoring and Diagnostics
- Clinical Trials and Data Analysis

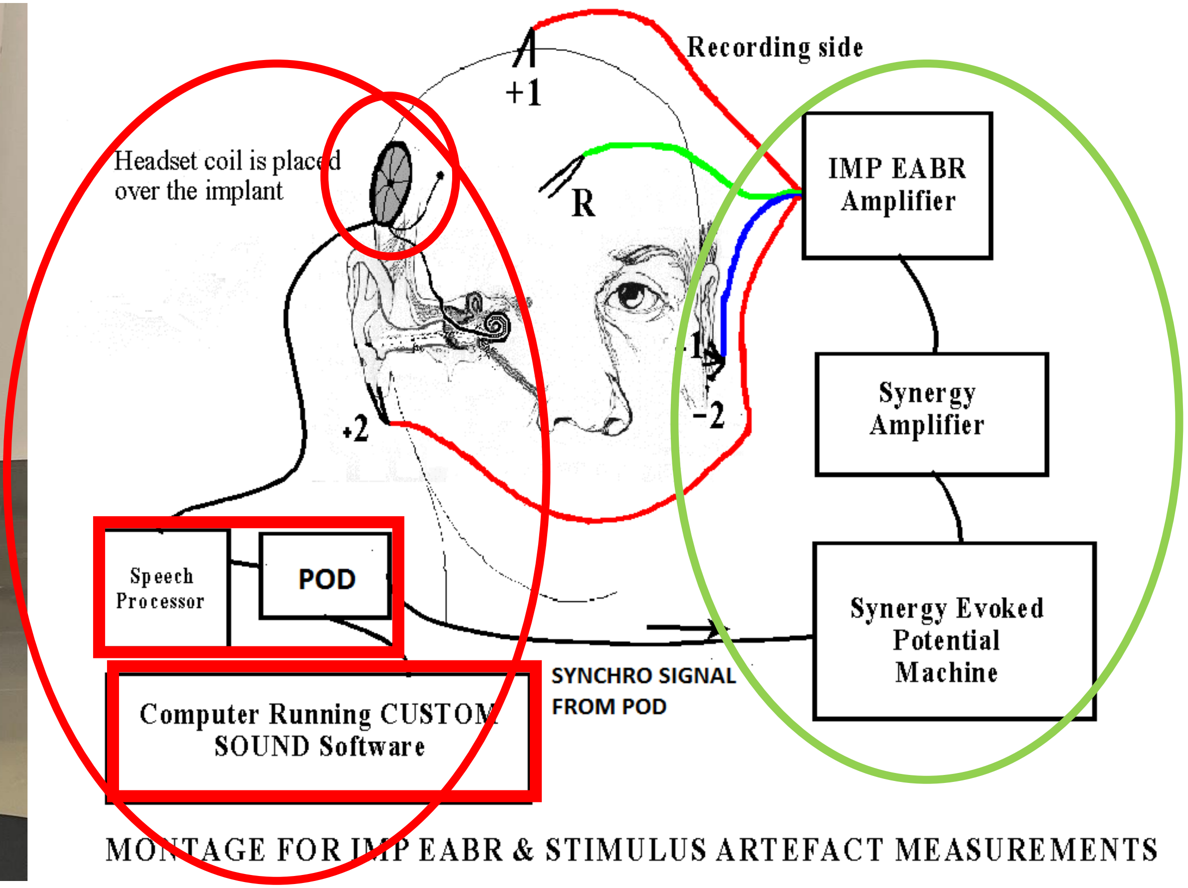
[1] OpenAI, "ChatGPT," *OpenAI*, Mar. 6, 2025. [Online]. Available: https://chat.openai.com/. [Accessed: Mar. 6, 2025].

- Real-Time Sound Processing and Noise Filtering
- Development of Smart Cochlear Implants
- Improvement of Speech Recognition
- Wireless Communication and Remote Control
- Development of Implantable Sensors
- Improvement in Implant Durability and Longevity
- Advancements in Electromagnetic Compatibility
- Neural Stimulation and Response Optimization
- Post-Surgery Rehabilitation and Training
- Patient Feedback Integration and Adjustment
- Acoustic-to-Electrical Signal Conversion
- Optimizing Frequency Mapping
- Developing Hybrid Cochlear Implants
- Post-Implantation Software and Firmware Updates
- Advanced Signal-to-Noise Ratio Enhancement
- Hearing Preservation Techniques
- Tinnitus Management Integration
- 3D Imaging and Mapping for Implant Placement
- Research in Cochlear Implant Nerve Interface
- Development of Multi-Channel Stimuli for Enhanced Hearing

Outline

- Intraoperative electrophysiology setup and protocol
- Intra-operative measures available:
  - Impedance
    - Interpreting impedance levels
    - Open circuit or air bubble?
  - Transimpedance Matrix (TIM)
    - Tip-foldover/ kinck
    - Guiding device position during surgery with TIM
  - Intraoperative Electrical Auditory Brainstem Response (EABR) and Artifacts
    - Neural integrity
    - Non-auditory stimulation
    - Extrachochlear Electrode
  - Neural Response Telemetry (NRT)
    - Absence of AutoNRT- What does that mean?
- Review of complicated and abnormal cases
- Interference sources
- Conclusion

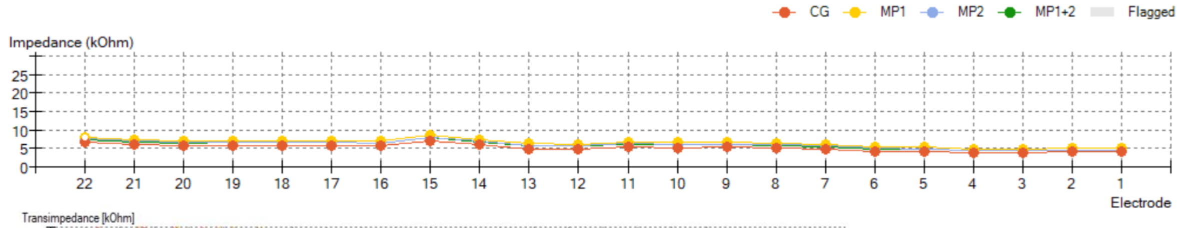
Setup



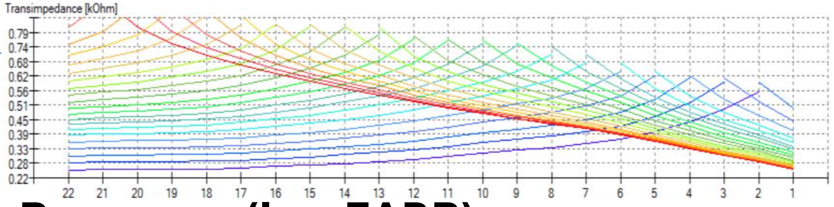
Recording side
+1
Headset coil is placed over the implant
R
IMP EABR Amplifier
Synergy Amplifier
-1
-2
+2
Speech Processor
POD
Synergy Evoked Potential Machine
SYNCHRO SIGNAL FROM POD
Computer Running CUSTOM SOUND Software
MONTAGE FOR IMP EABR & STIMULUS ARTEFACT MEASUREMENTS

Intra-operative measures available:

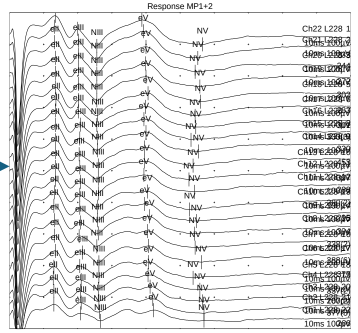
- **Electrode Impedances**



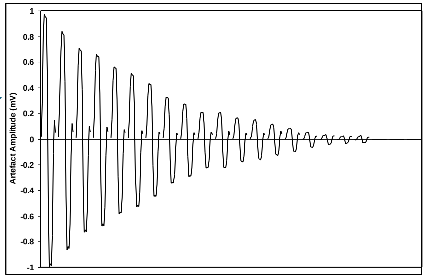
- **Trans-Impedance Matrix (TIM)**



- **Implant-Evoked Auditory Brainstem Response (ImpEABR)**

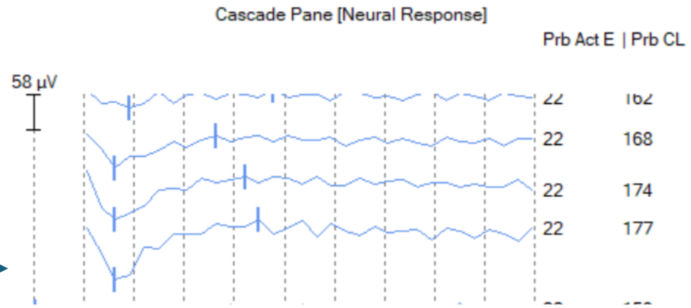


- **Stimulus artefact test**

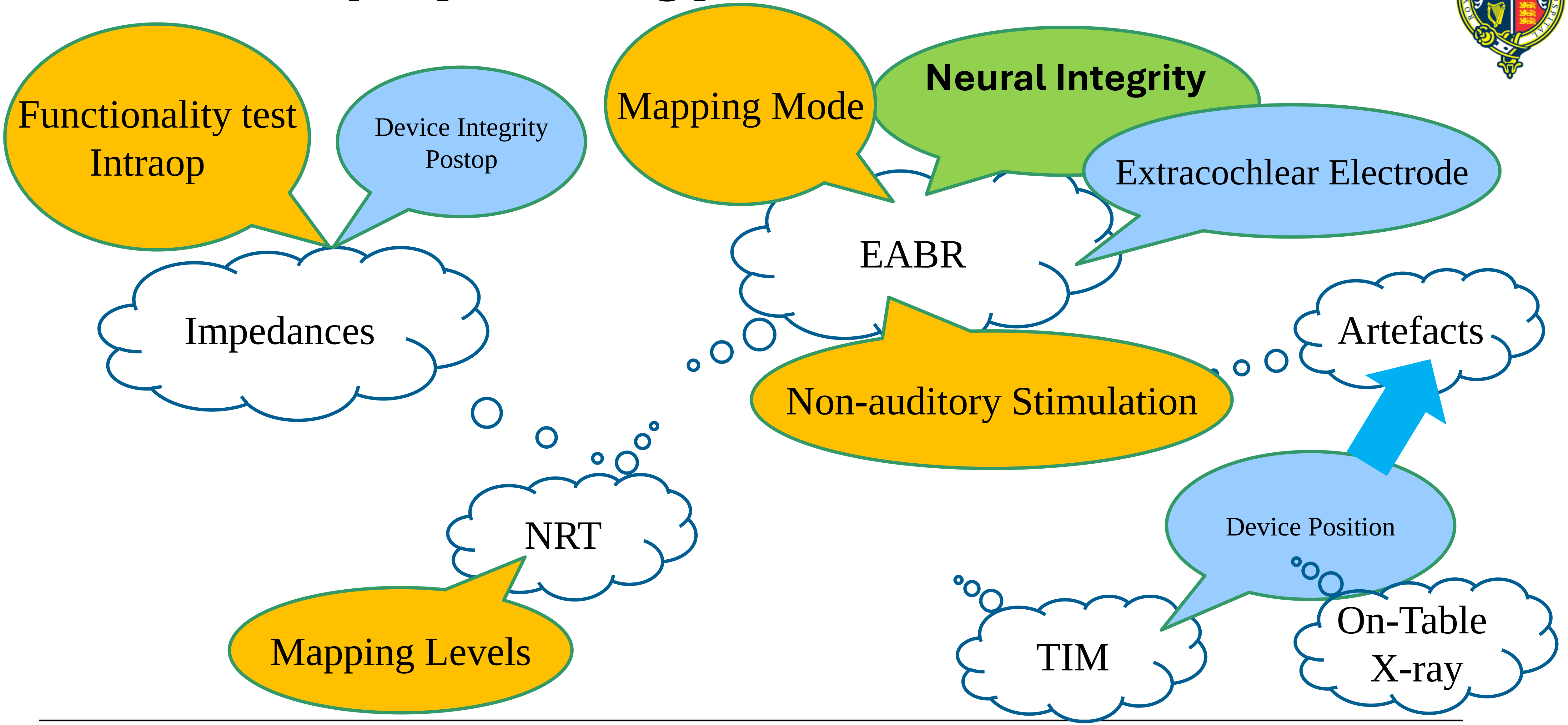


- **Stenver's view X-ray**

- **Neural Response Telemetry (Auto-NRT and Advanced Auto NRT)**



Electrophysiology measures

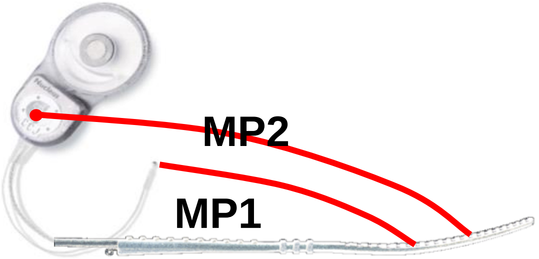


Electrical Impedance

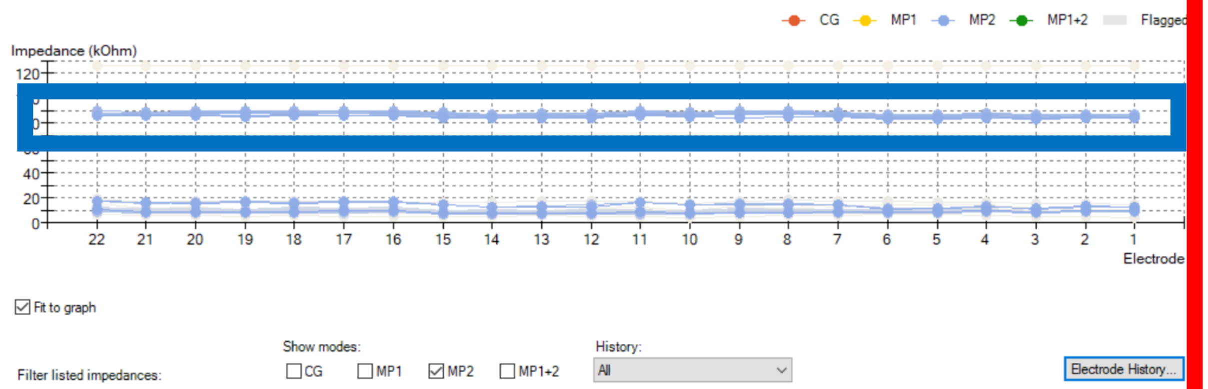
- Most important measure for functionality analysis,
- Impedances of the 22 electrodes are both tested intraoperatively (device integrity) and post operative,
- Open Circuit and Short Circuit.

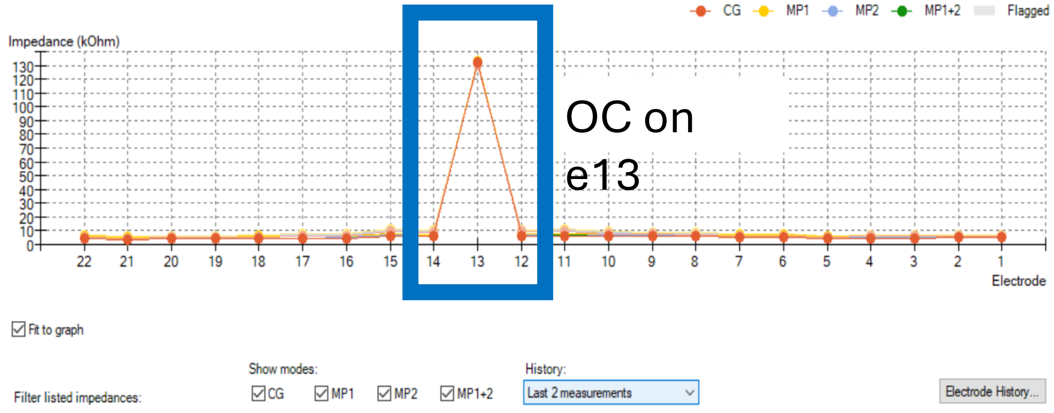
Monopolar: to determine biological resistance of the tissue

Common Ground: device integr

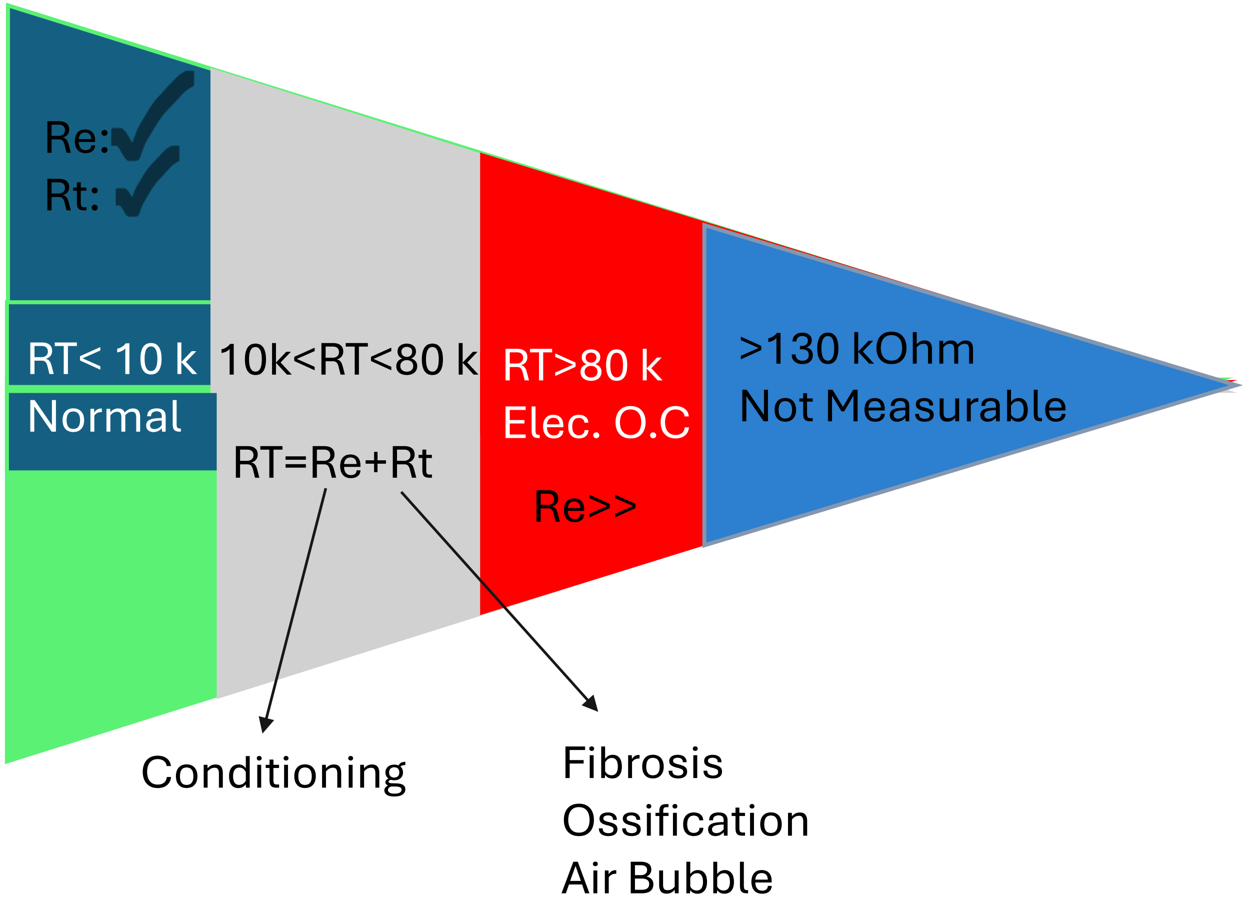


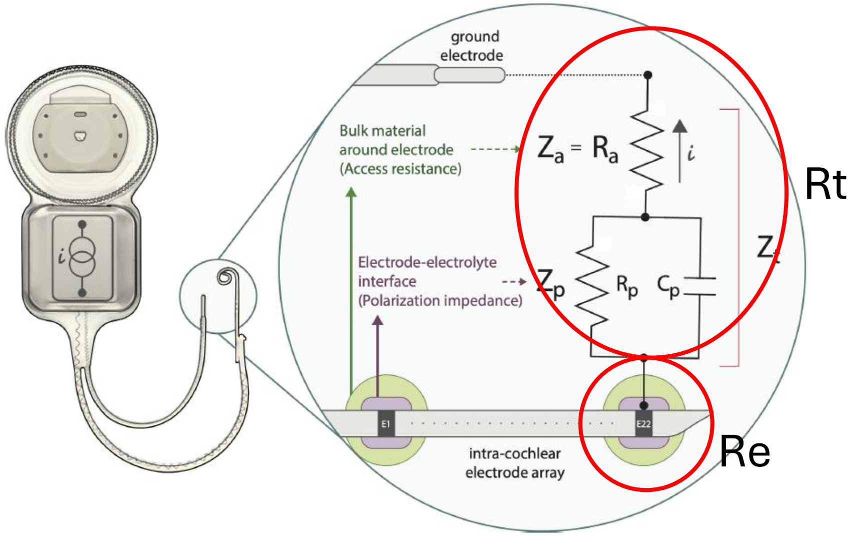
Monopolar



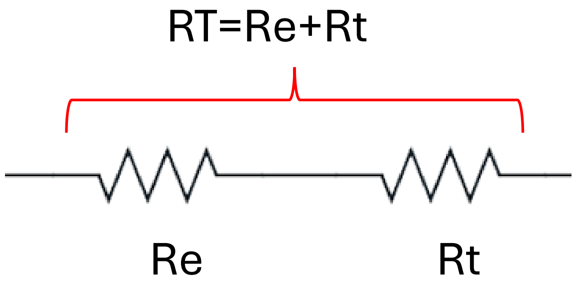


Interpreting Impedance levels:





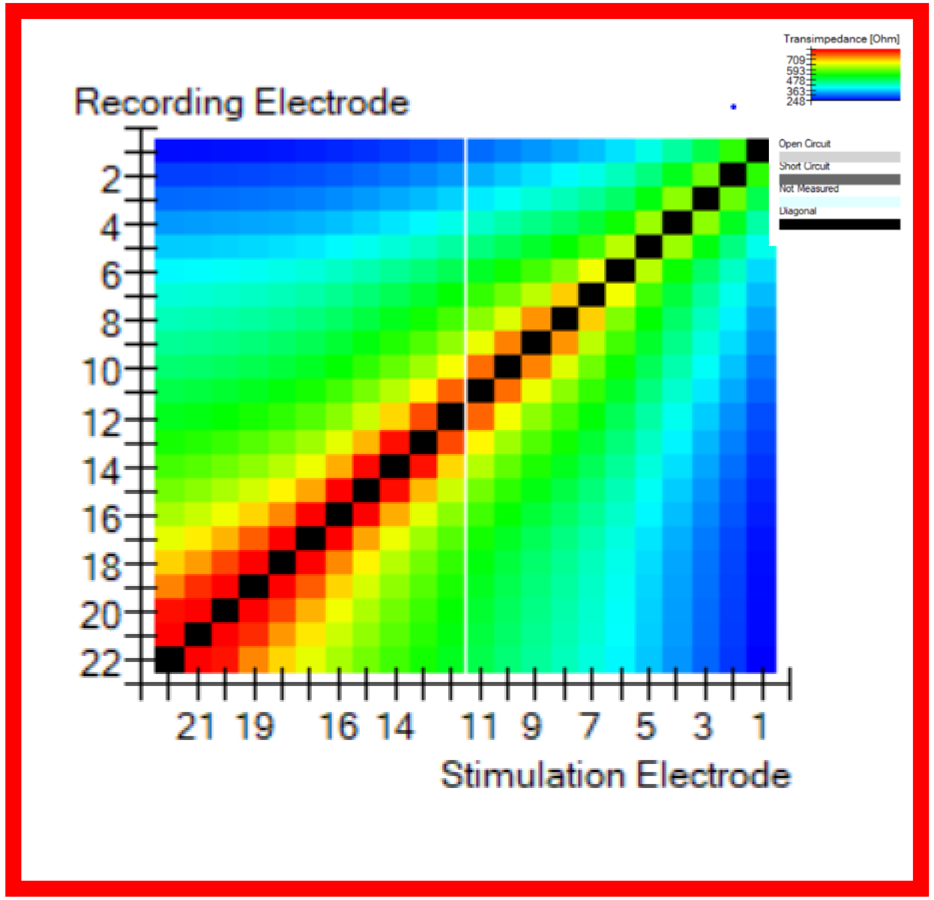
https://doi.org/10.3389/fbioe.2020.568690

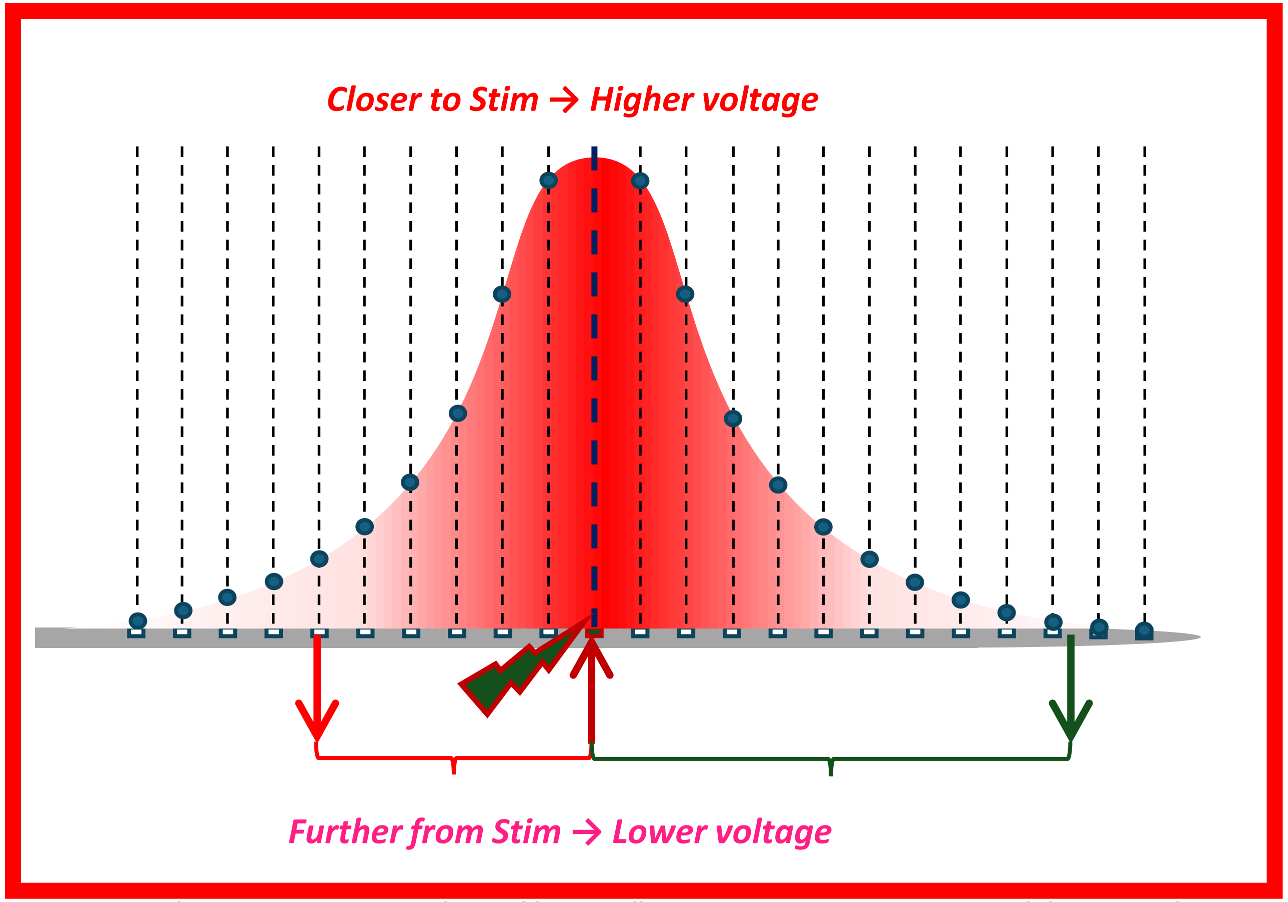


*<565 Ohm: Short Circuit

Trans Impedance Matrix (TIM)

- Essentially measures electric field intensity at (other) non-stimulating electrodes

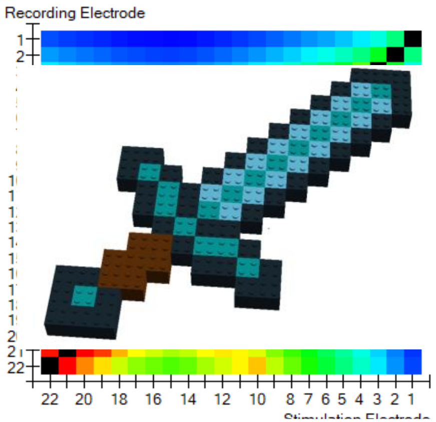


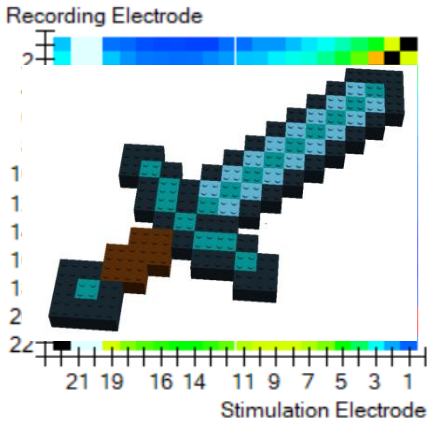


Hoppe U, et al A: Evaluation of a Transimpedance Matrix Algorithm to Detect Anomalous Cochlear Implant Electrode Position. Audiol Neurotol 2022;27:347-355. doi: 10.1159/000523784

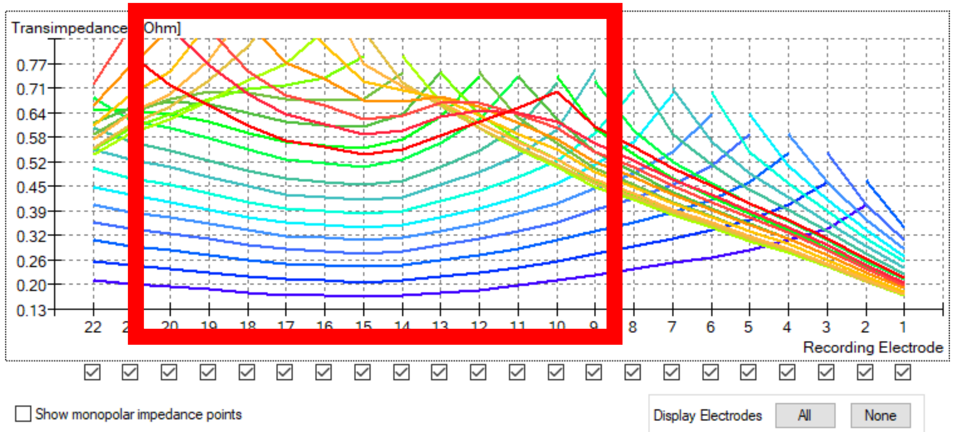
TIM used for Device position
Tip Fold Over

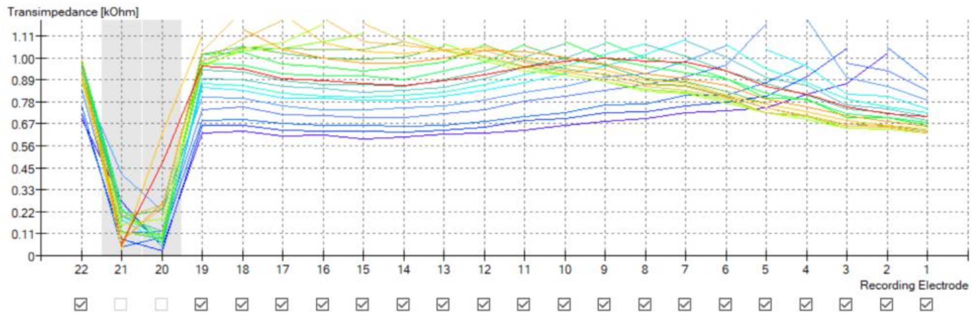
TIM HeatMap



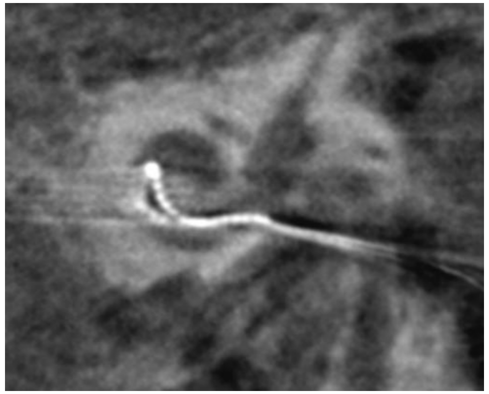


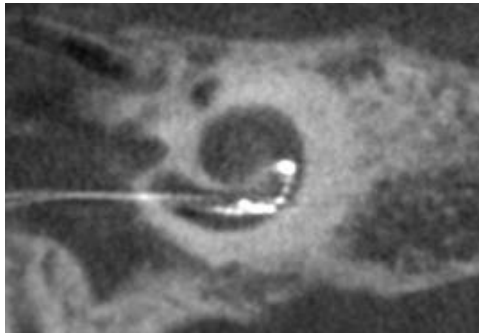
TIM LineGraph





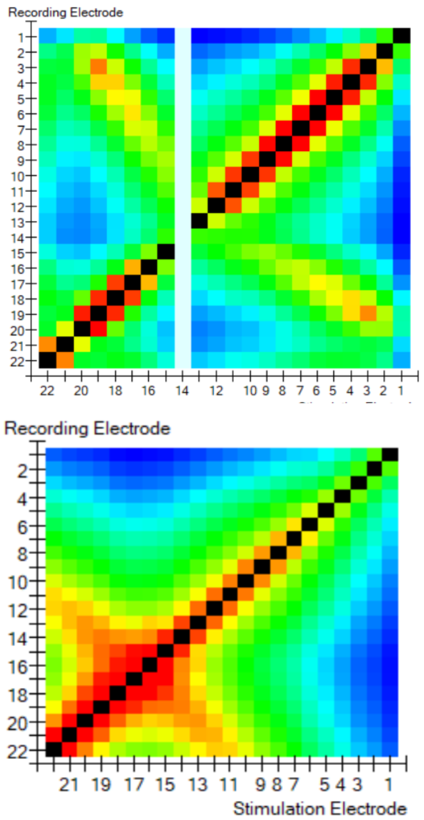
CB CT scan



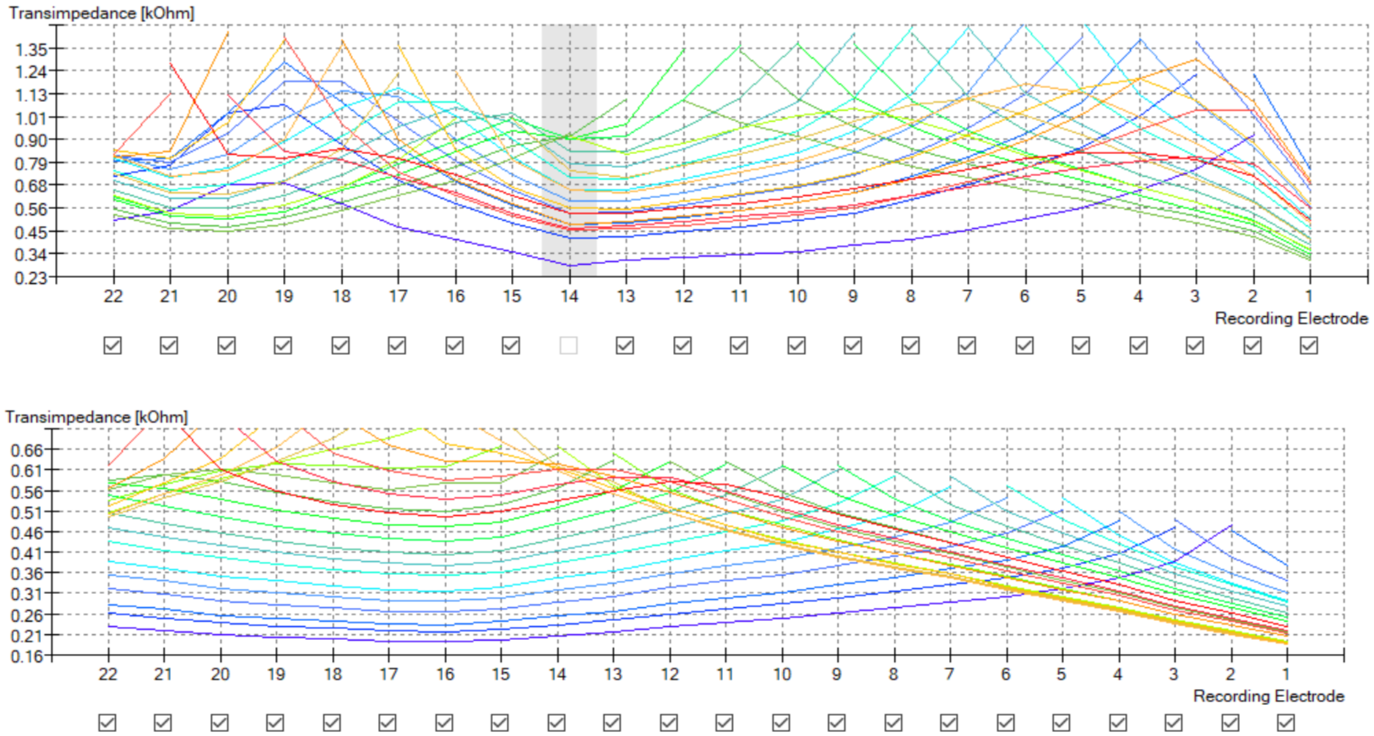


TIM used for Device position
Tip Fold Over

TIM HeatMap



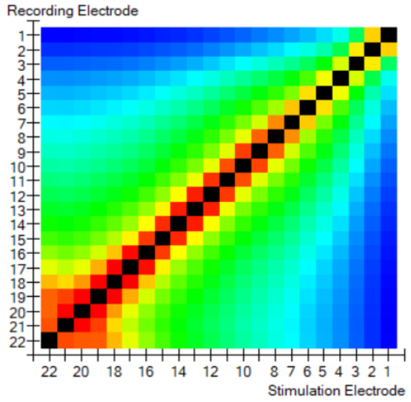
TIM LineGraph

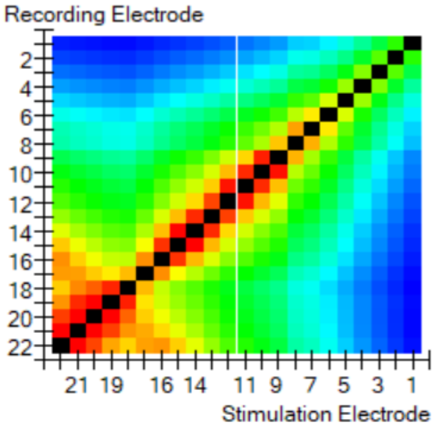


CB CT scan

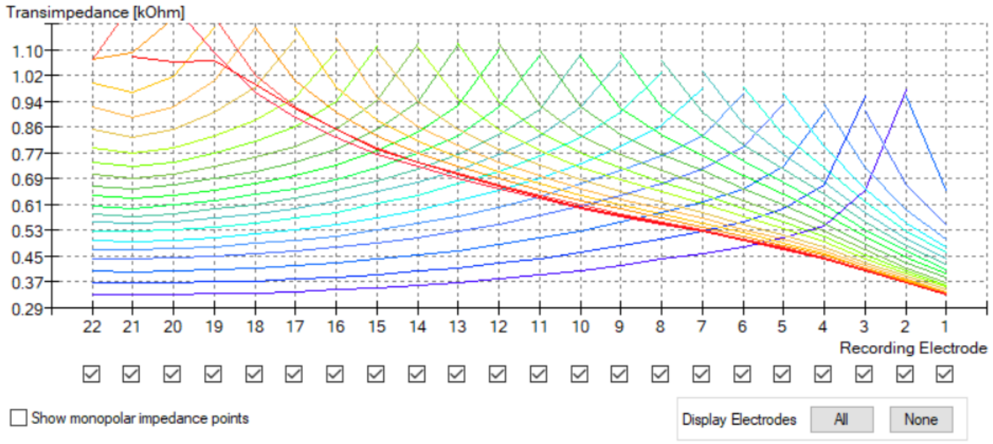
TIM used for Device position Tip Fold Over

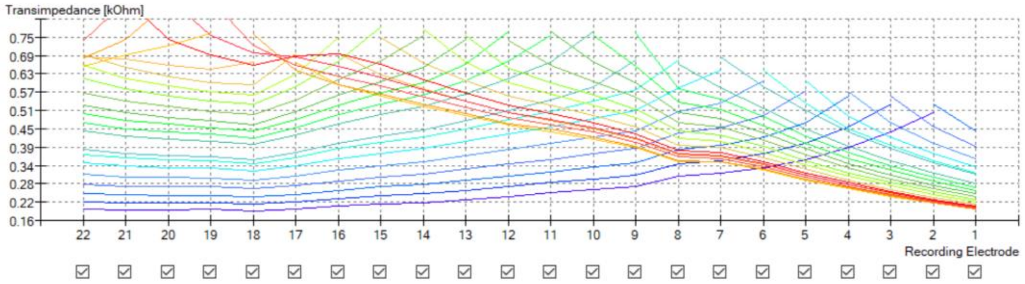
TIM HeatMap





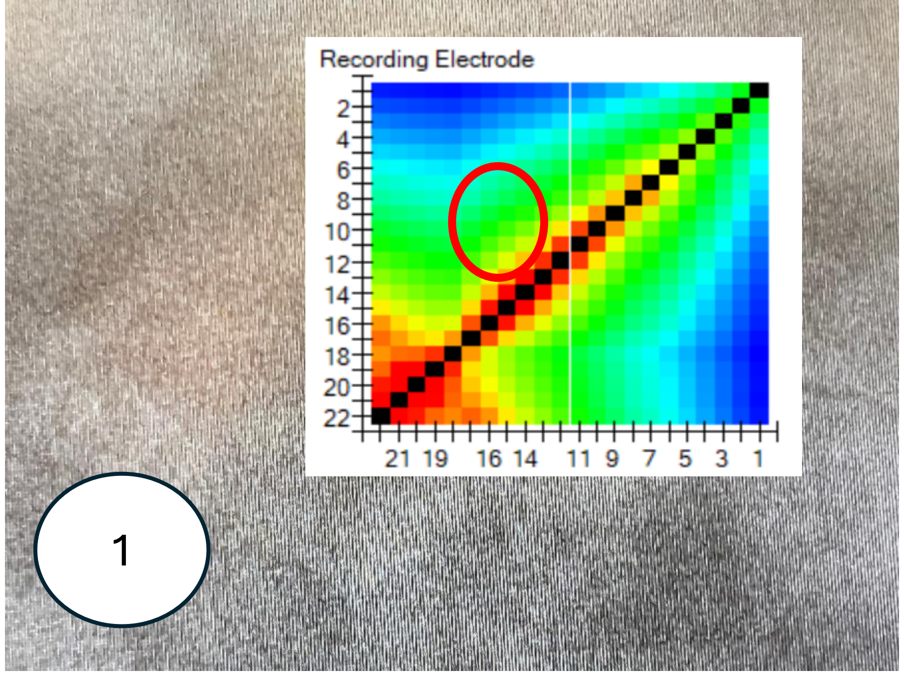
TIM LineGraph

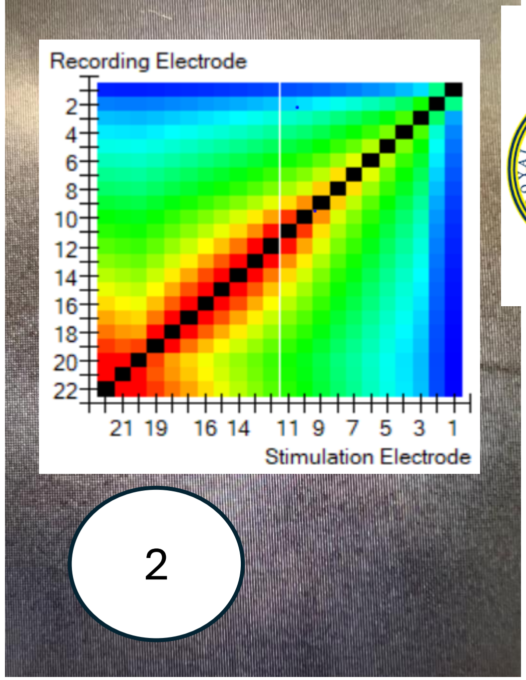


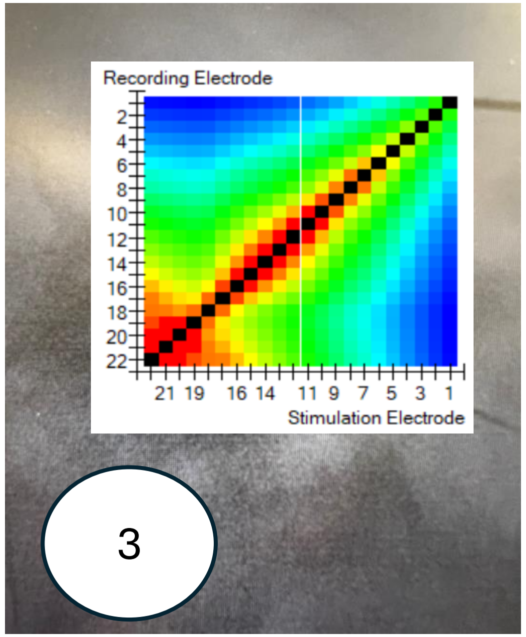


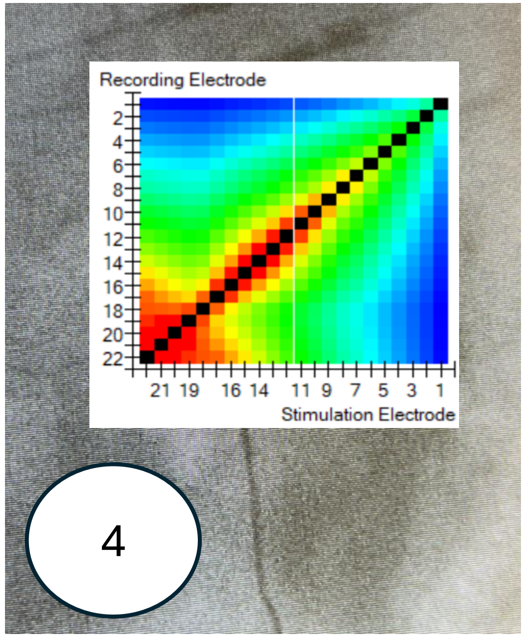
On-Table X-ray

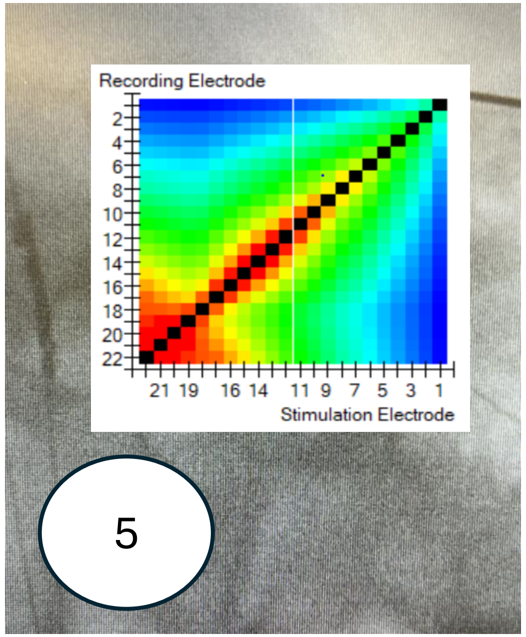
Guiding device positioning during surgery with TIM

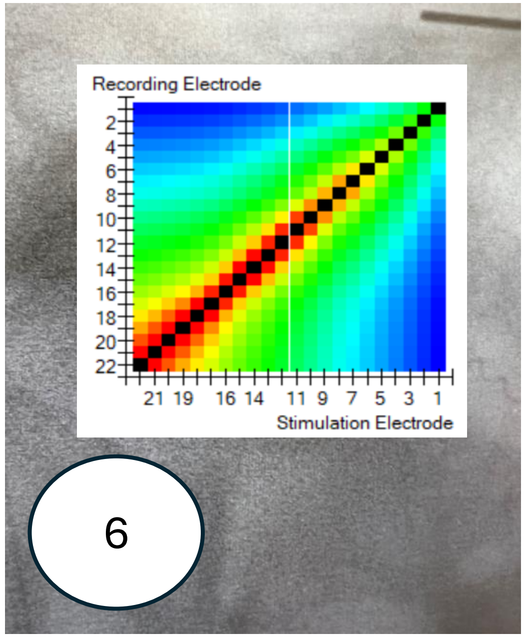






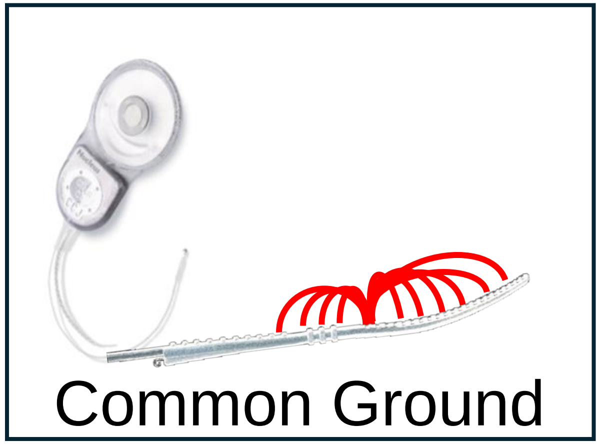


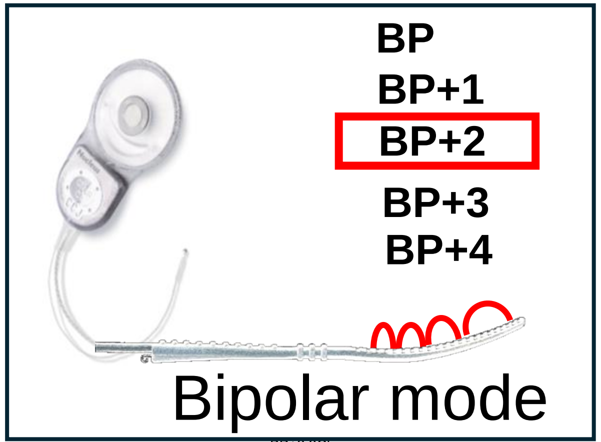


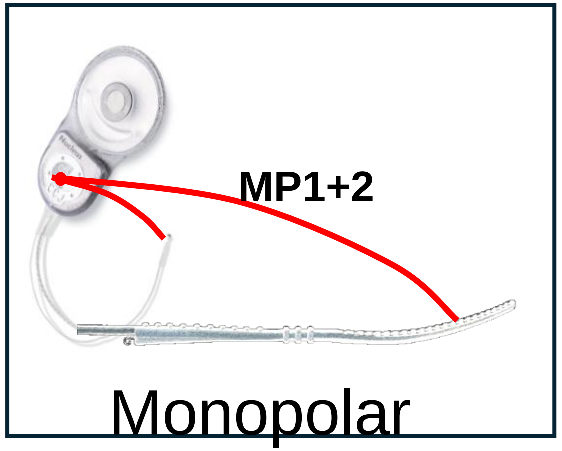


Intraoperative ImpEABR and Artifacts

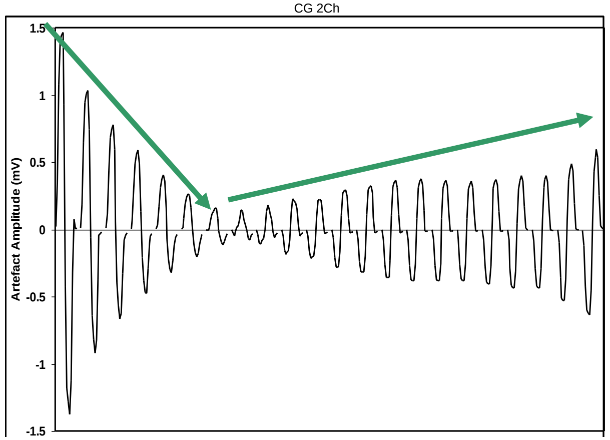
- results for normal insertion with good response:



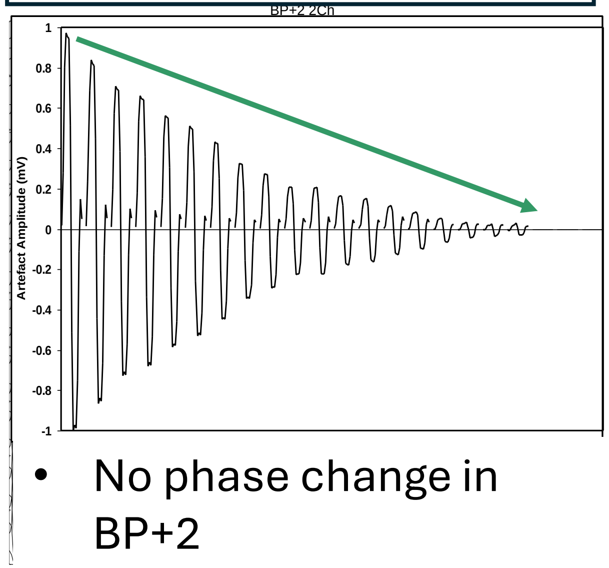




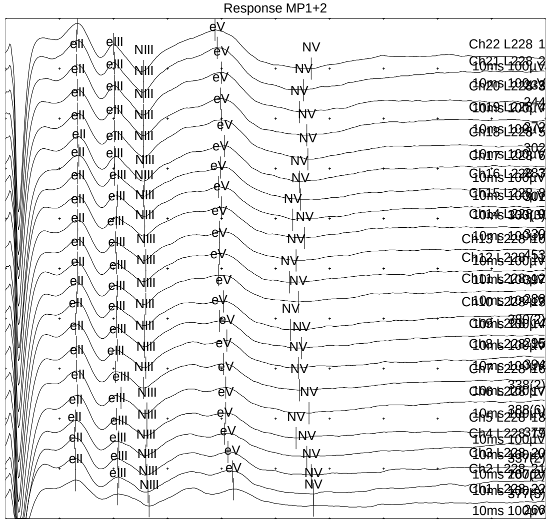
Implant **Evoked ABR** artefacts



- One phase change in CG
- Amplitude decreases and then increase



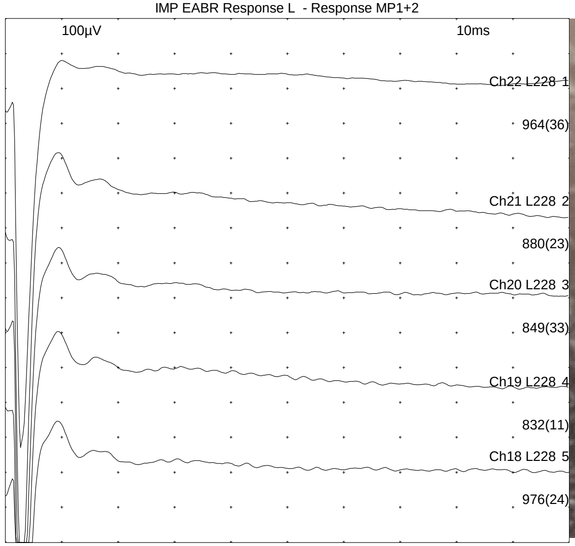
- No phase change in BP+2
- Amplitude decreases from ch1 to ch19

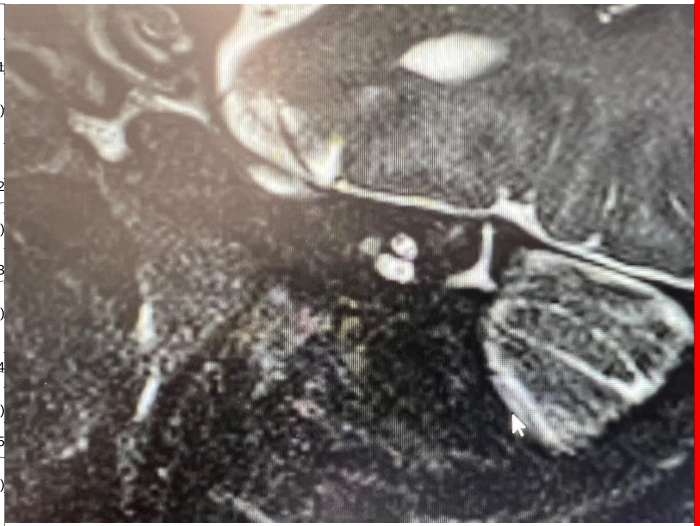


Intraoperative ImpEABR -Neural Integrity

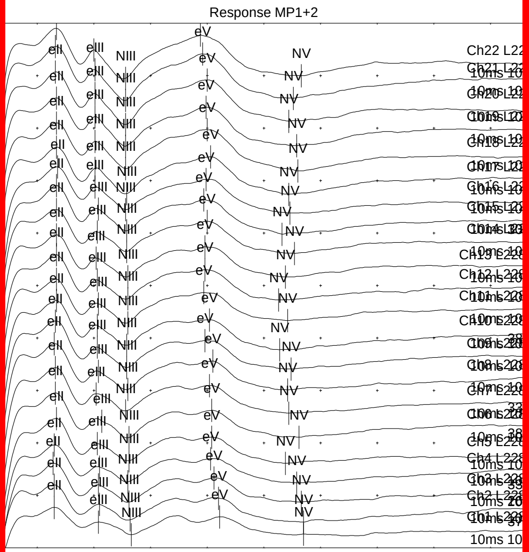
Hypoplastic Cochlear Nerve

MP1+2, CL:228, PW:25 µs, Ch:22,3-1

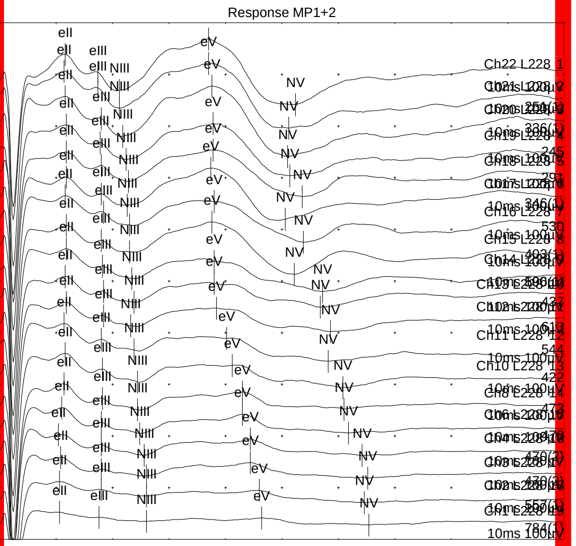




Normal



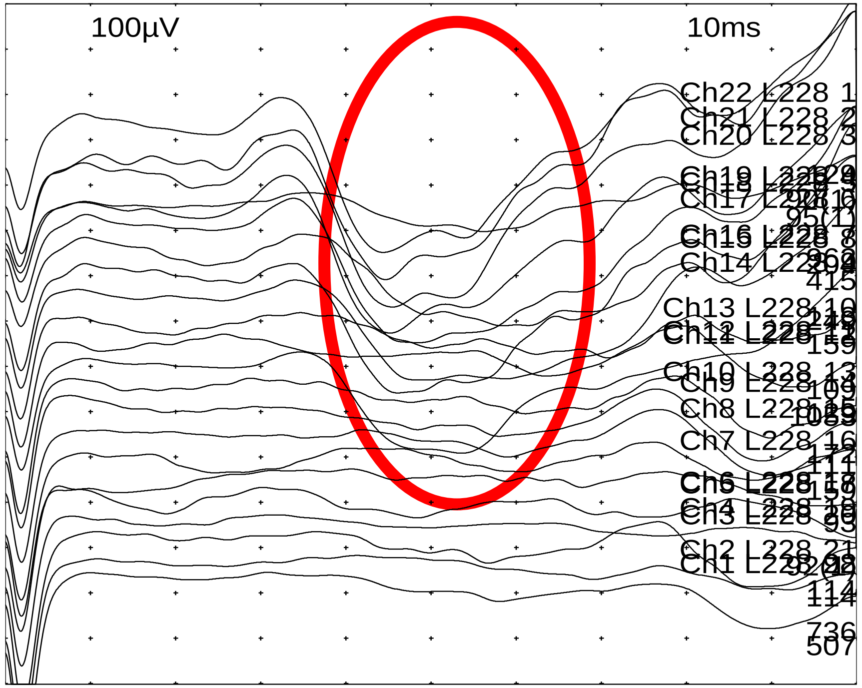
ANSD (normal CN)



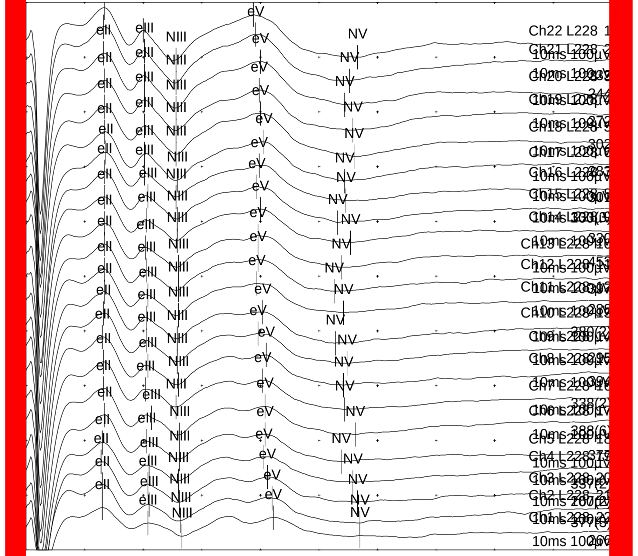
Intraoperative ImpEABR –Non-Auditory Stimulation

Facial Nerve Stimulation

L - Response MP1+2

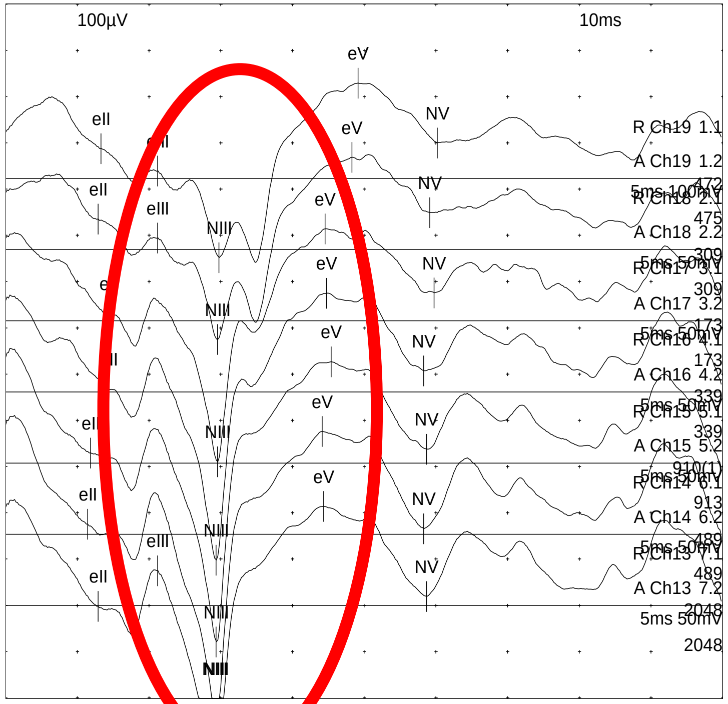


Normal



Vestibular Response

IMP EABR Response R - BP+2 2Ch

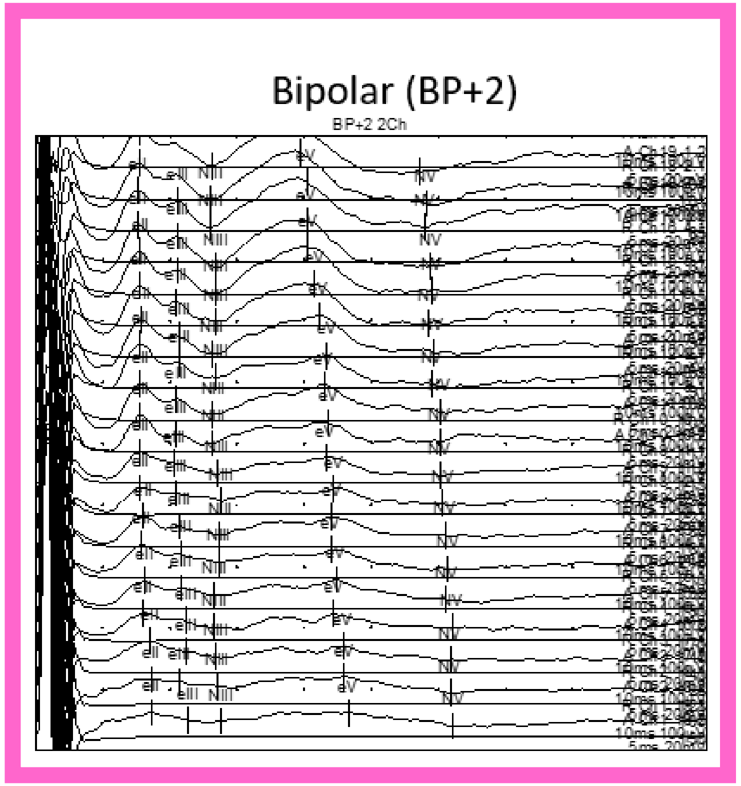


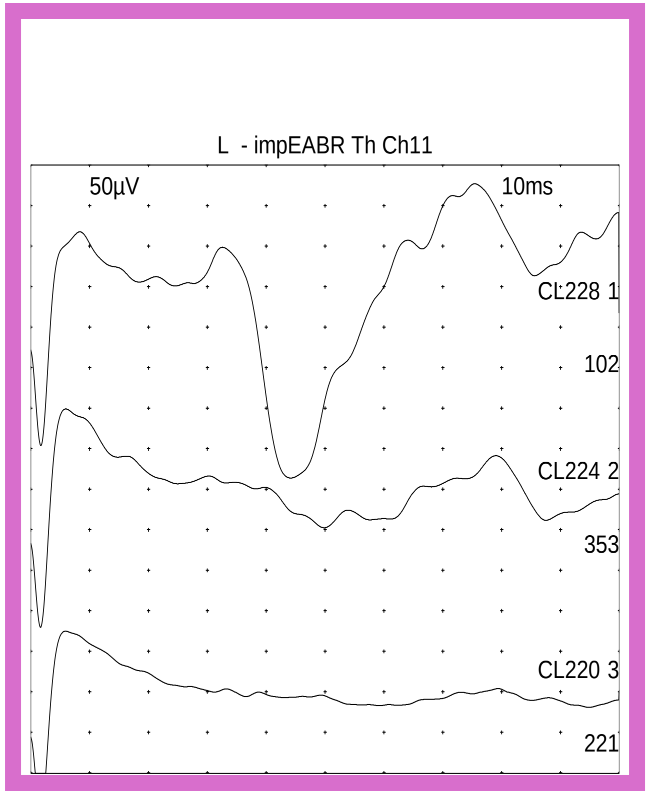
How do we use this information?

Intra-Op EP results can assist with selecting information regarding maximum stimulation levels and potentially switch on stimulation mode

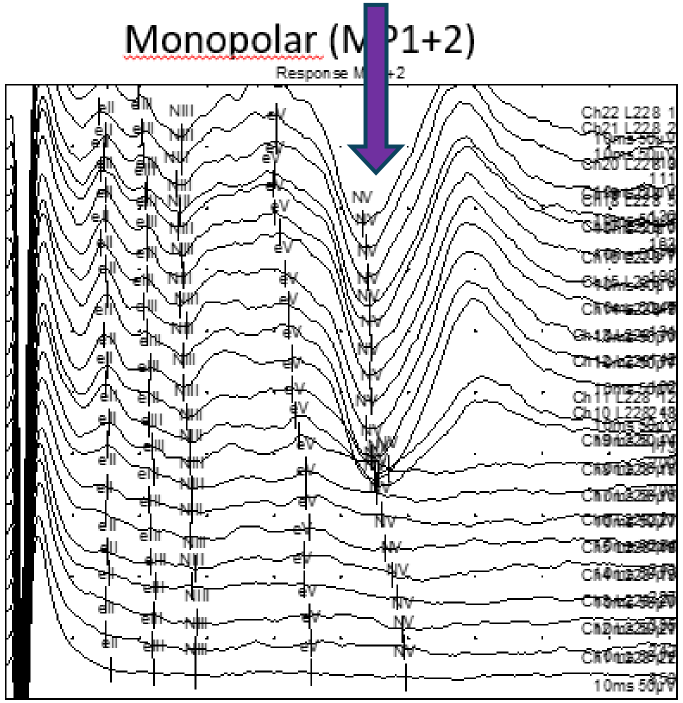
Measure the current level at which the facial nerve stimulation disappears.

No FNS in BP+2.

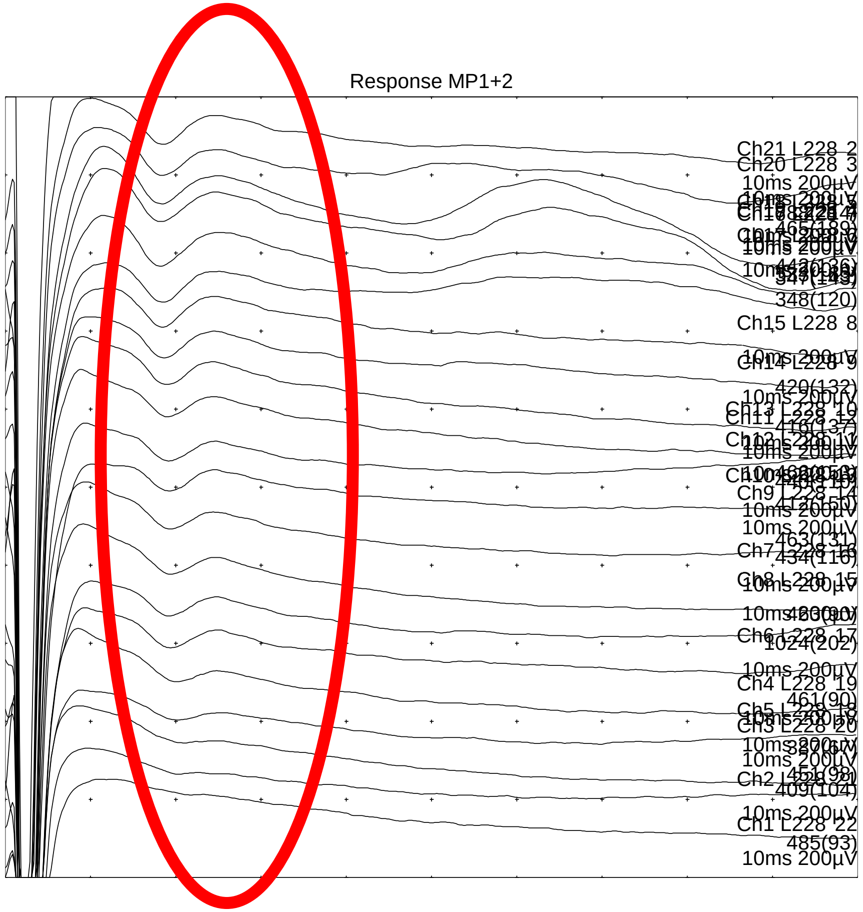


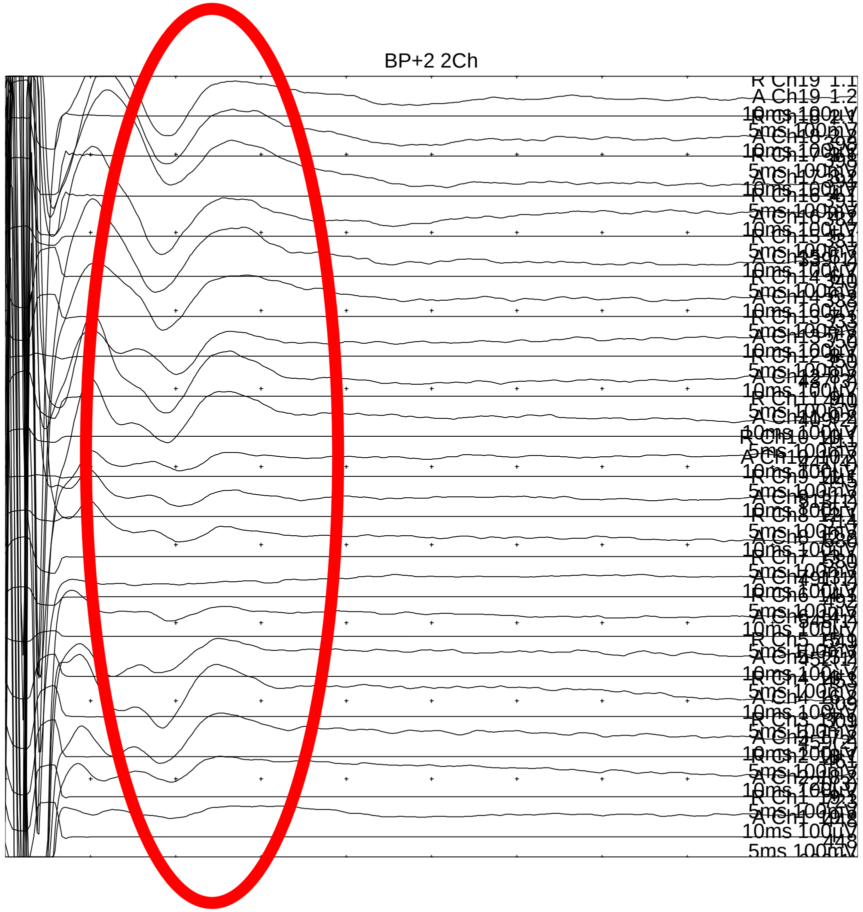


Facial nerve stim



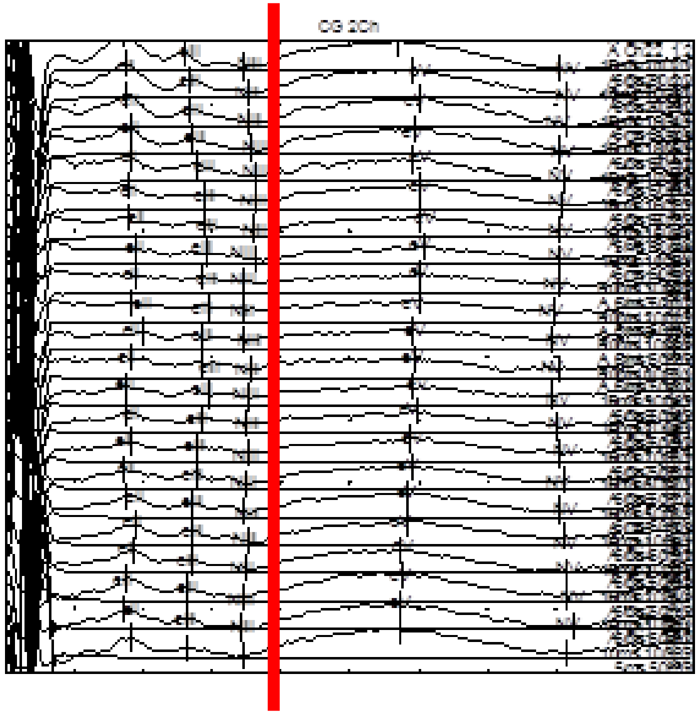
Vestibular Response

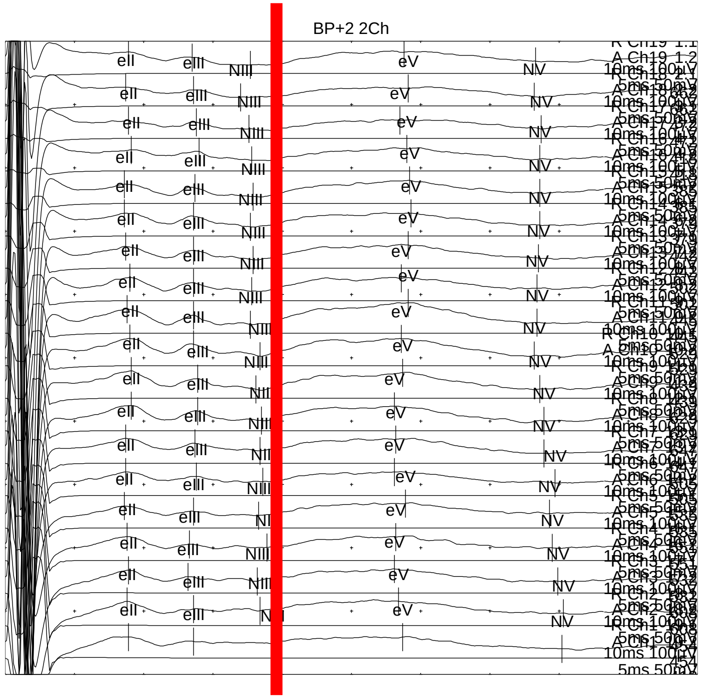


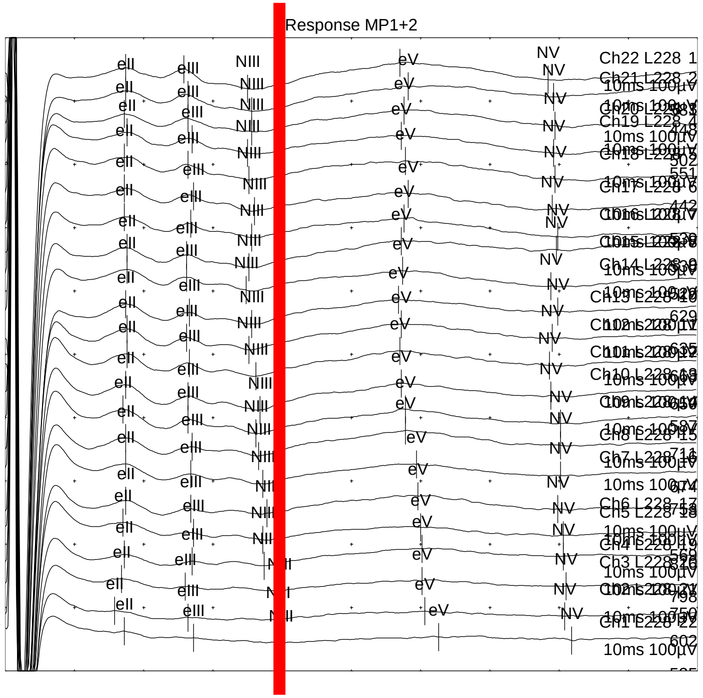


Late wave V latency

✓acoustic neuroma

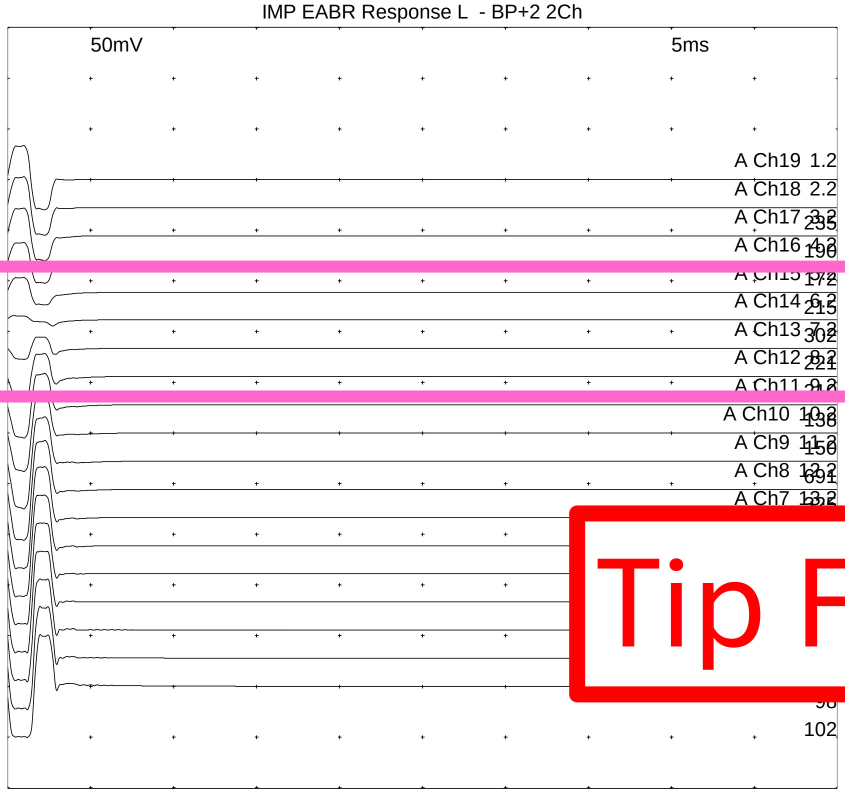




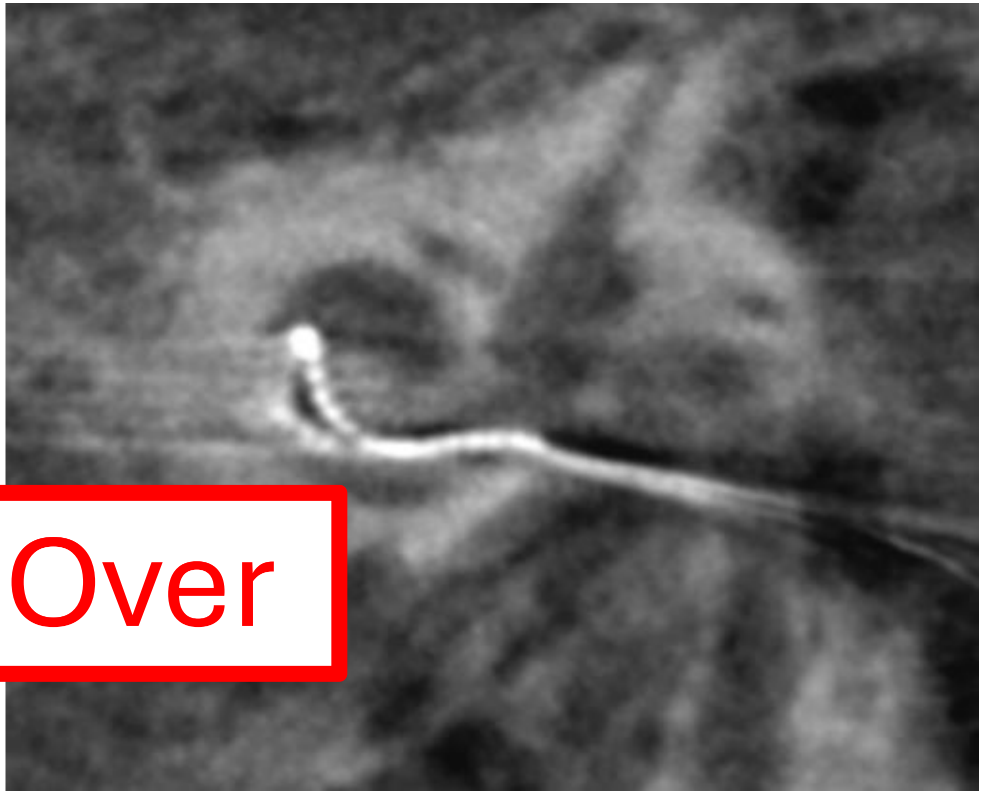


Device position-Artefacts

Artefacts



CT Scan

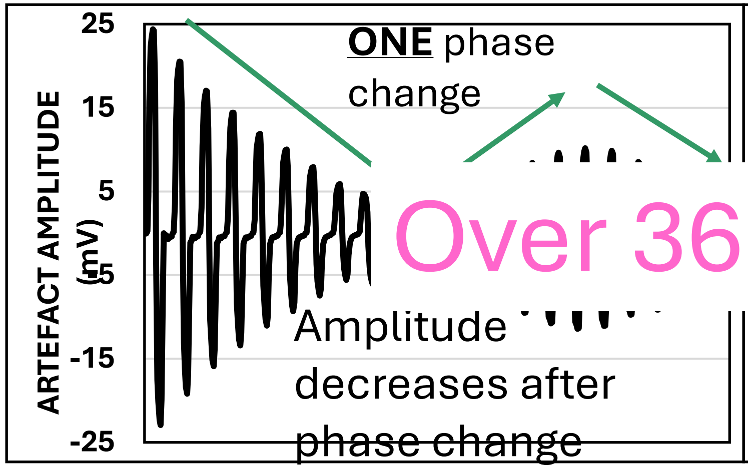


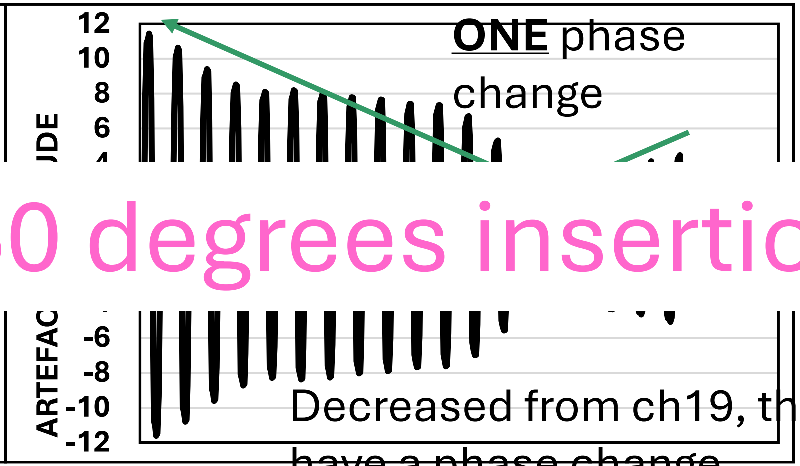
Tip Fold Over

Deep Insertion-Artefacts

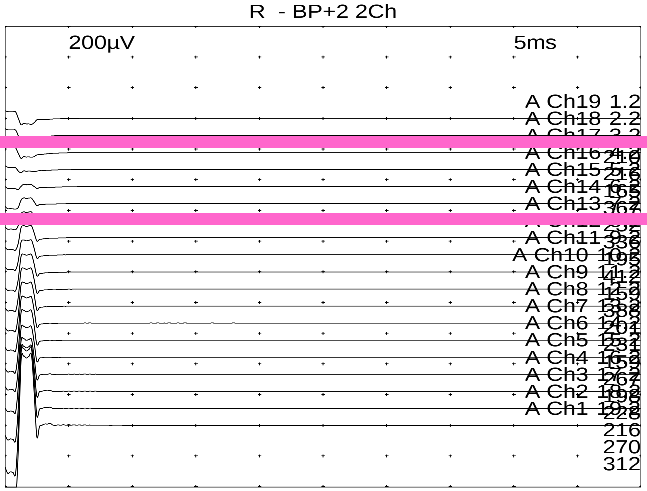
Common Ground (CG)

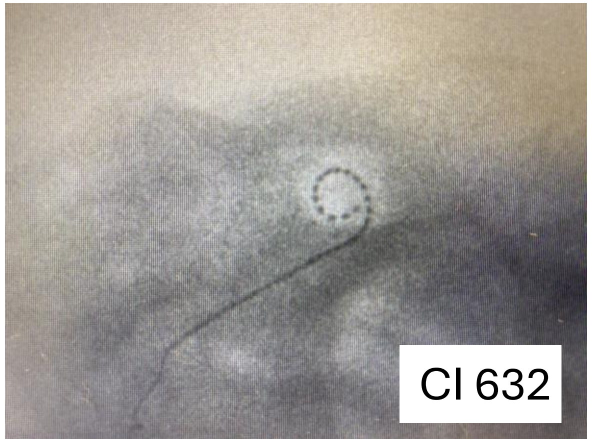
Bipolar (BP+2)





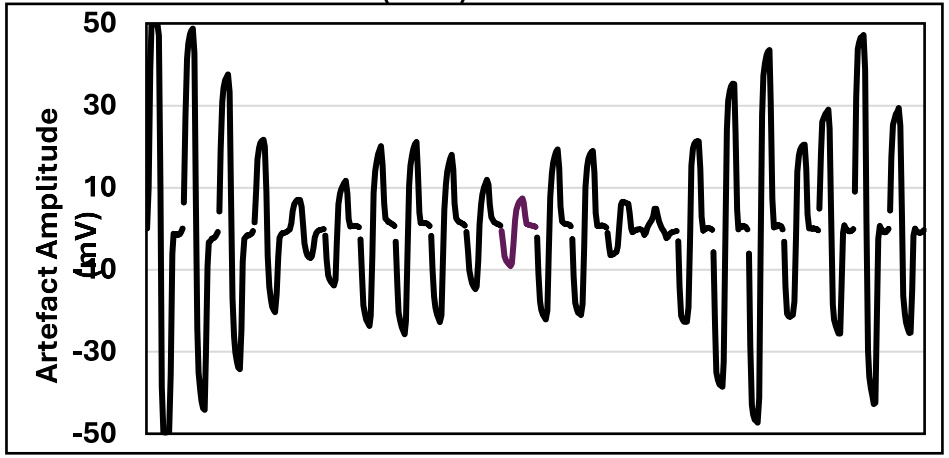
Over 360 degrees insertion



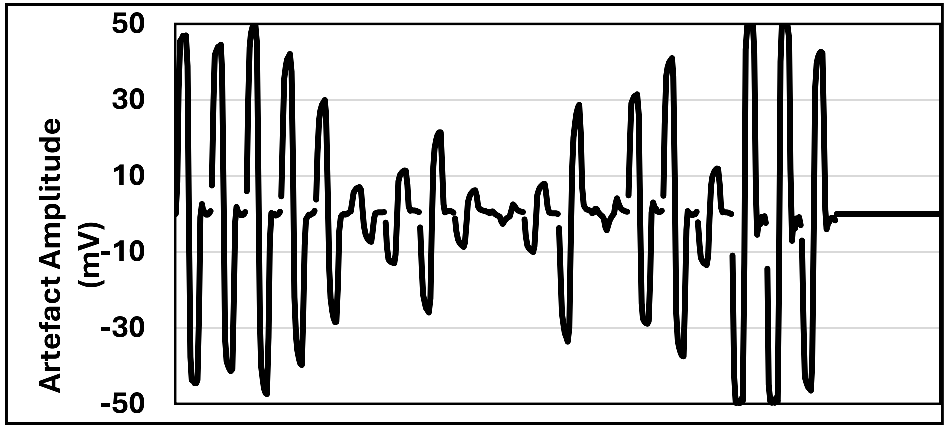


Vestibular response -Artefacts

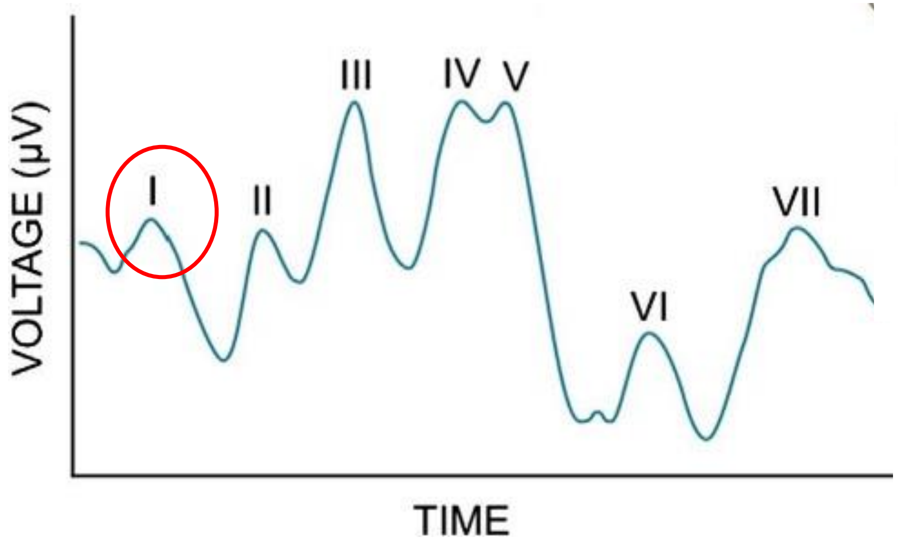
Common Ground (CG)

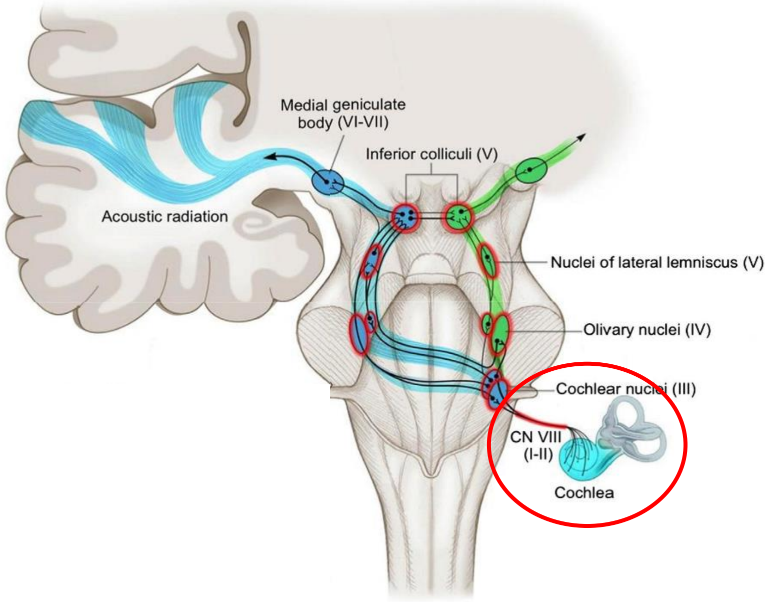


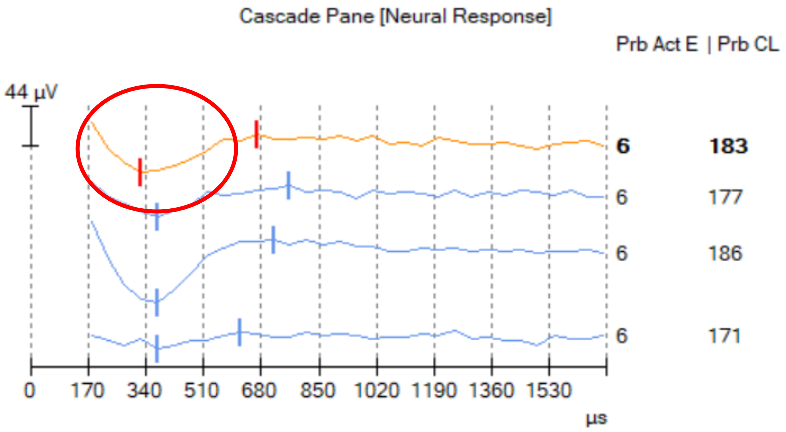
Bipolar (BP+2)

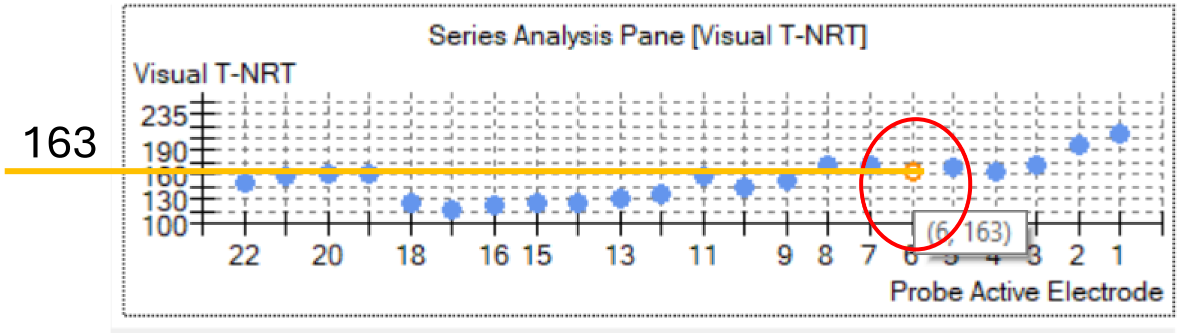


Neural Response Telemetry



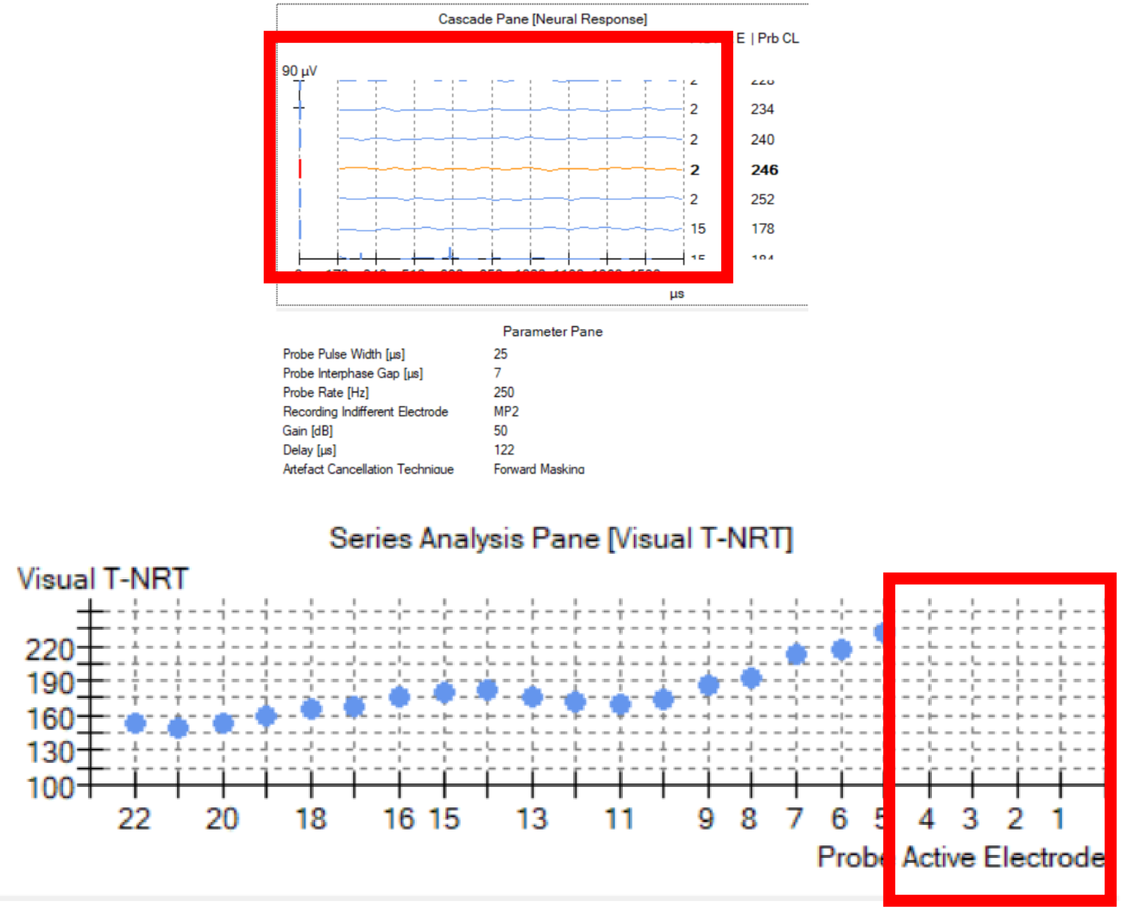


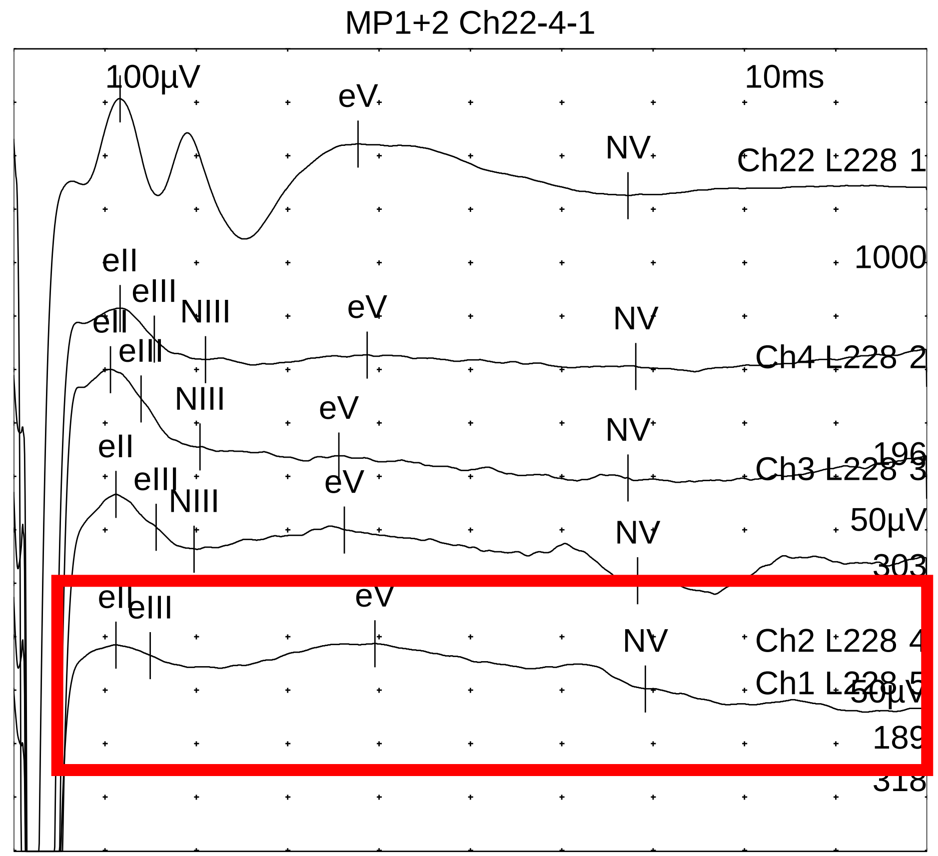




Absence of AutoNRT- What does that mean?

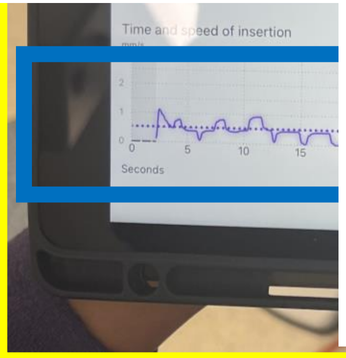
Mode: MP1+2, CL:228, PW:70 µs, Ch:22,4-1





Smart Nav

- Easy to export-import patient
- Security of patient data (password protected),
- Placement Check,
- Speed of Insertion,
- Advanced Auto NRT.

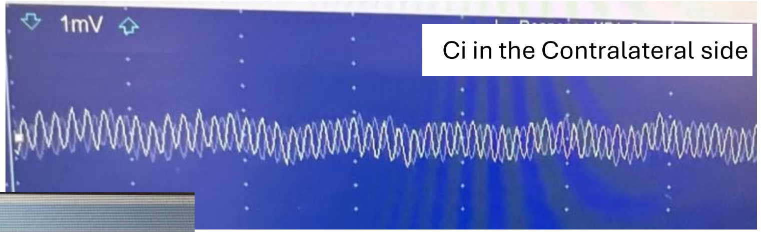


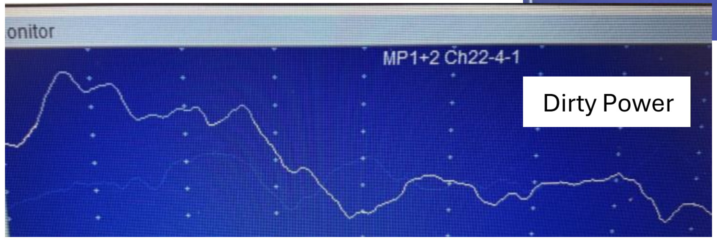
Surgical Considerations:

- First place the extracochlear electrodes in place before inserting the array,
- For second side cases make sure there is no processor on the contralateral side,
- For good magnet-coil connection, consider less draping layers,
- For abnormal Cochlea, do on-table X-ray.

Electrical Interference Sources

1) NIM Facial nerve monitor – Constant spikes
2) Surgical bed motor, bed warmer and hugger
3) Wire loops
4) Measurement needles disconnected
5) Hearing aid/CI on the contralateral ear is still on
6) Diathermy – Huge interference when bipolar is used during measurement
7) Patient is about to wake up
8) Movement artefact (patient cable moved)
9) MRI machine/Laser machine is nearby





Intra-operative testing Conclusion

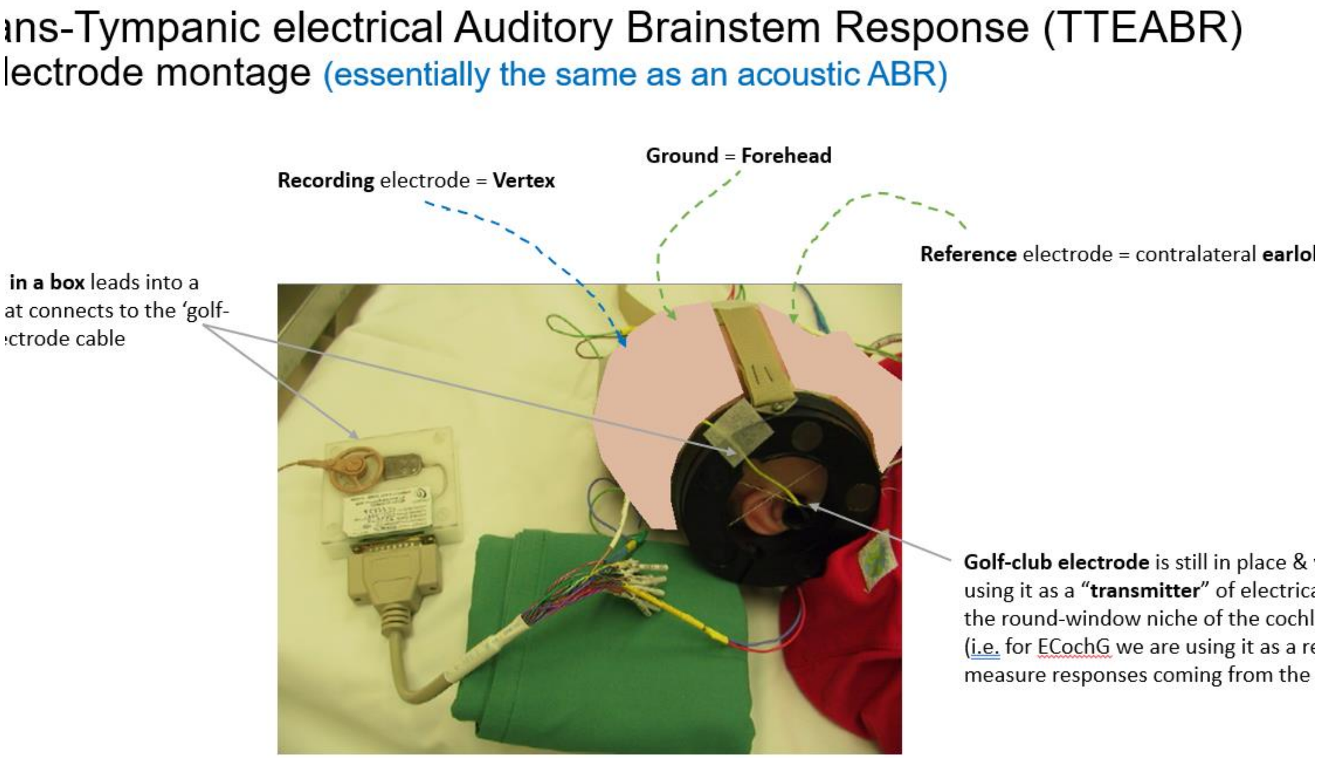
Intraoperative electrophysiological testing may include a suite of tests and approaches, supported when necessary with intraoperative radiological testing:

- ✓ Shows the implant is all working normally
- ✓ Allows decision making about changing over the implant or adjusting the position within the one operation
- ✓ In difficult cases- such as facial nerve stimulation or cochlear nerve dysplasia- allows adjustment of parameters to find the best response and advise the Audiologist for post- ive mapping

Next Sense

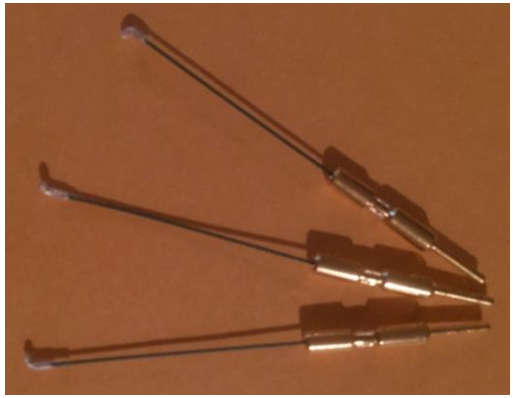
APSCI 2023_Birman and Golesorkhie

Trans Tympanic eABR



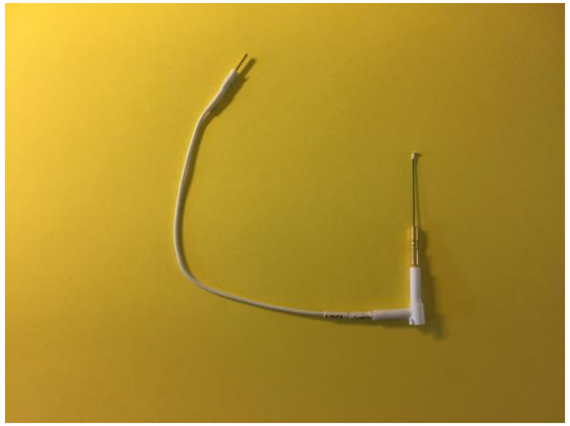
- To verify that the cochlea is stimulable
- the round window membrane at the round window niche is stimulated by a golf club electrode

ELECTRODES

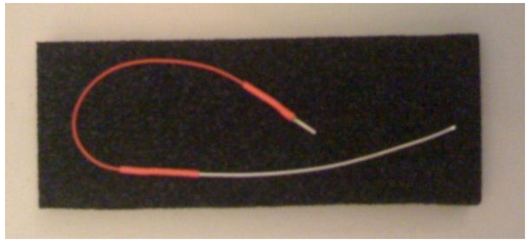


Golf Club Electrode

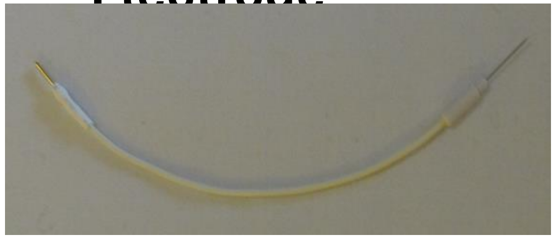
Electrode Holder



Golf Club Electrode & Electrode Holder Assembly



Silver Ball Electrode

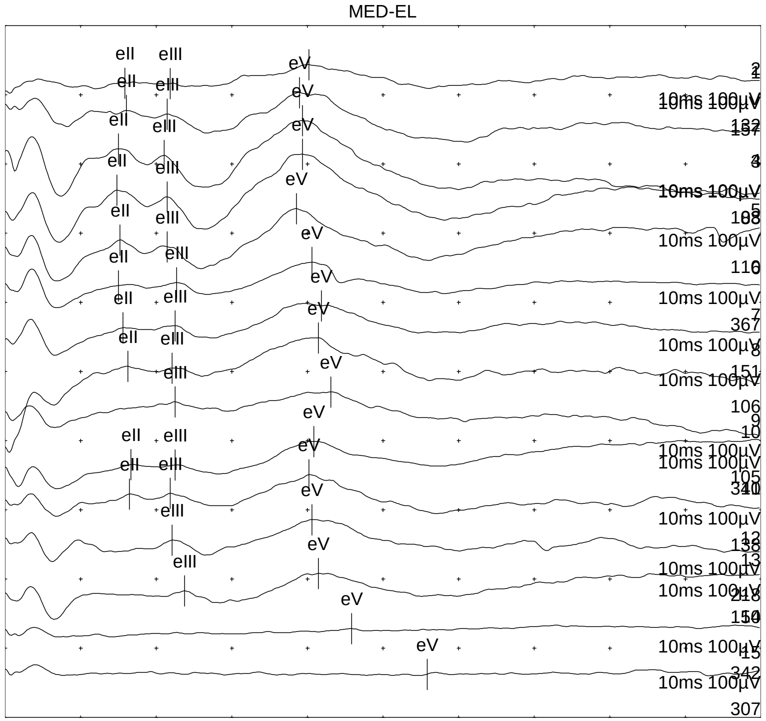


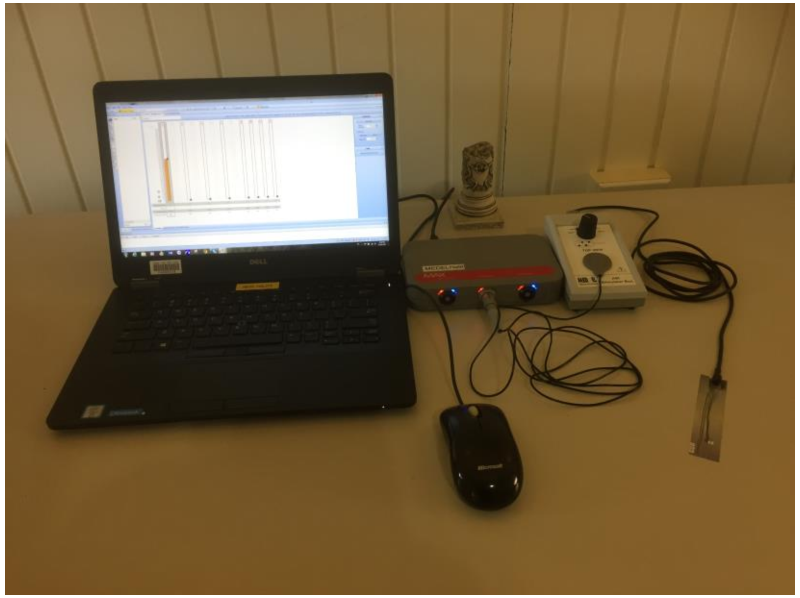
Needle recording electrode

Halit SANLI

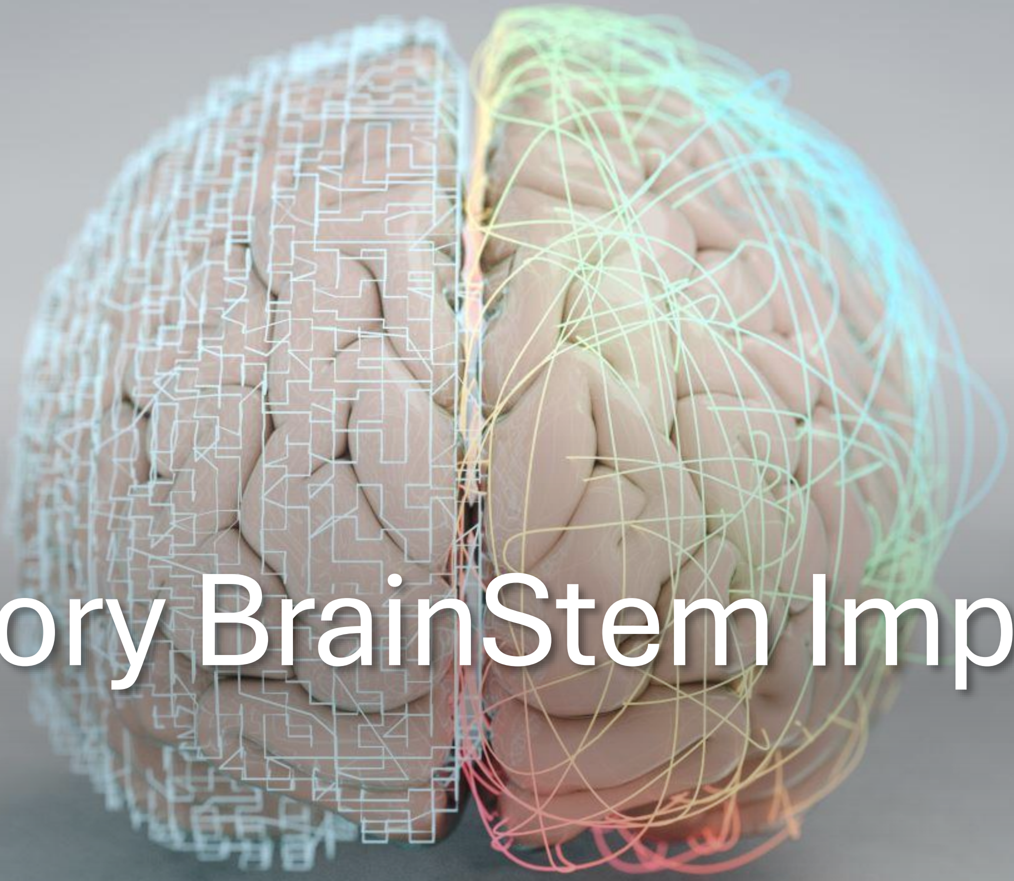
SCIRAN-Tumour Removal

MED-EL TEST ELECTRODE AND STIMULATOR SETUP





HALIT SANLI, 2017



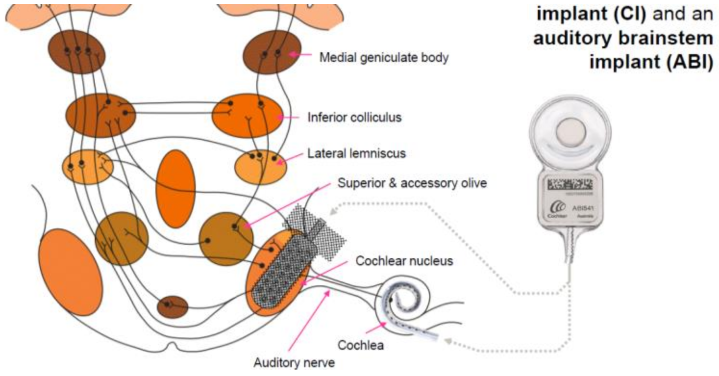
Auditory BrainStem Implants

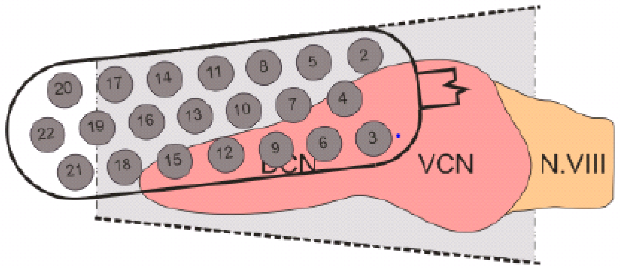
Auditory BrainStem Implants

- Direct Stimulation of Cochlear Nucleus
- In cases of acoustic tumors or total cochlea ossification

- Role of intraop testing:
  - Device position optimization.

- A multidisciplinary team needed





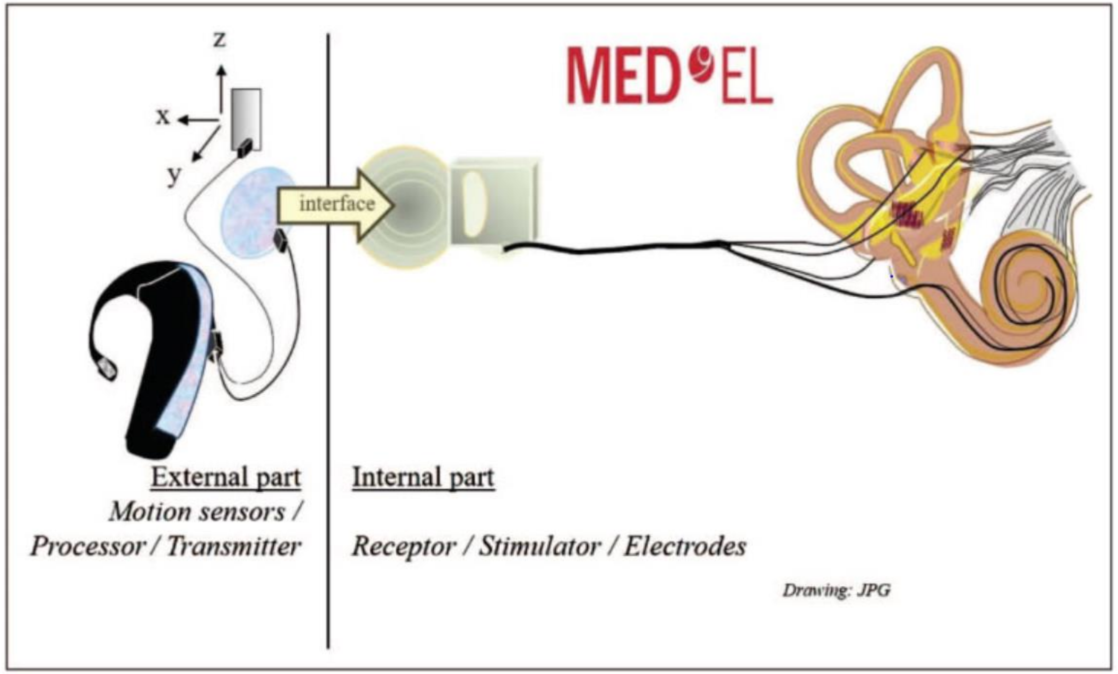
Clinical Trials

Dexamethasone Eluting Electrode

- **Dexamethasone-eluting implants** release a controlled dose of dexamethasone (anti-inflammatory) to reduce cochlear inflammation.
- **Improved electrode performance** by reducing fibrosis and lowering electrical impedance.
- **Enhanced post-operative outcomes**: Reduced inflammation, better speech recognition, and more stable electrode function.
- **Ongoing clinical trials** demonstrate positive results in reducing inflammation and improving hearing outcomes.
- **Potential for long-term benefits**: May improve the longevity and effectiveness of cochlear implants.
- **Current research**: Studies focus on safety, efficacy, and comparison with traditional implants.

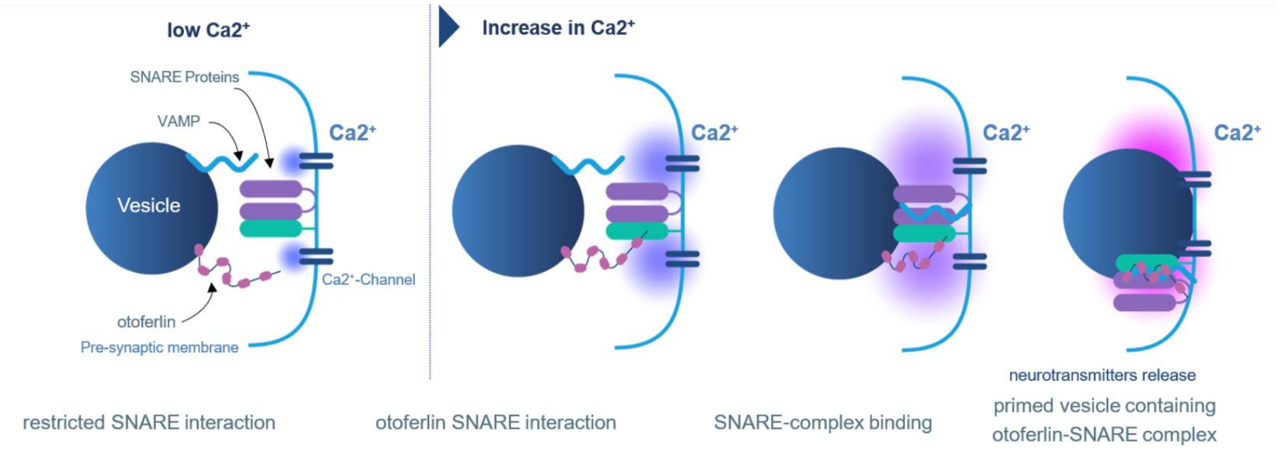
Vestibular Implants

- Used in patients with bilateral vestibular hypofunction (BVH).
- Similar in concept to cochlear implants for hearing, the vestibular implant uses electrical signals to mimic the natural function of the vestibular system.
- The device works by detecting head movements using an external sensor, which then converts these movements into electrical signals that stimulate the vestibular nerve.



Genetherapy-SENS51

- **Target**: Treats congenital hearing loss caused by **Otoferlin deficiency**.
- **Mechanism**: **AAV vectors** deliver the **functional Otoferlin gene** to cochlear cells.
- **Outcome**: Restores **Otoferlin protein** production, improving sound transmission.
- **Preclinical Results**: Mice with Otoferlin mutations showed **hearing restoration**.
- **Clinical Trials**: Ongoing **Phase 1/2 trial** in children to assess **safety and efficacy**.
- **Benefits**: **Non-invasive** treatment; targets root cause of hearing loss.
- **Challenges**: Long-term efficacy and **safety concerns** with viral vectors.

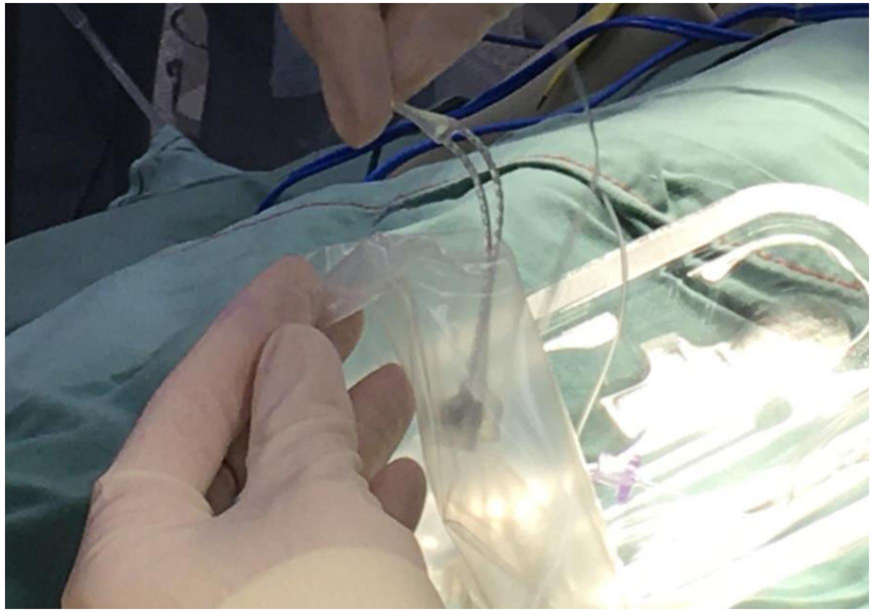


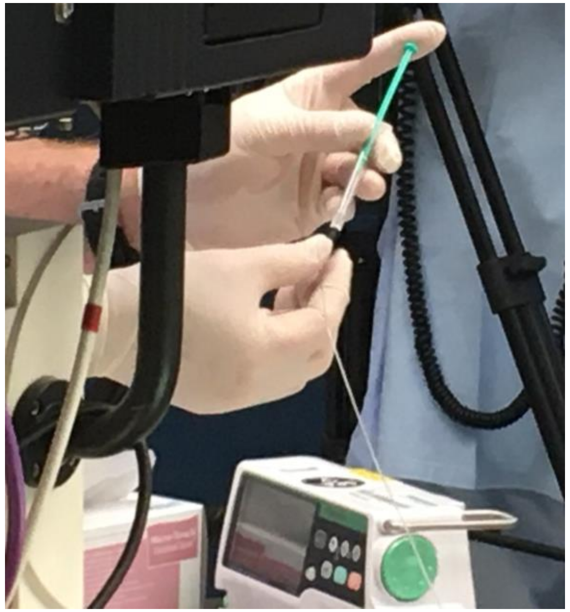
www.sensorion.com

Genetherapy-CIGT

Site:
RPAH

- UNSW- Cochlear implant neurotrophin gene therapy trial CIGT
- localized delivery of naked DNA to targeted cell groups using electric field
- to stimulate cochlear auditory nerve fibre re-growth and extension towards the electrodes





Thank you!

In 1984, Sue Walter was the first adult recipient of CI

In 1987, Holly was the first paediatric recipient of CI

https://youtu.be/hJd6Ar15dwU