Boothless Audiometry

Comparing Point of Care Hearing Testing Options and Considerations for their use.

Part 1: Engineering Perspectives and Learnings
Samuel Gordon

Part 2: Survey of Boothless Audiometric Devices and Telehealth Policies from the VA perspective
Dr. Chad Gladden

Boothless Audiometry Part 1

Engineering Perspectives and Learnings

Disclosure Statement:
Any specific organization, manufacturer, or product discussed in this presentation does not represent an endorsement by the speaker or the U.S. Department of Veterans Affairs. The presenter has no financial or non-financial relationships with any public or private business entity discussed in this presentation.

Samuel Y. Gordon, BSEE
Research Biomedical Engineer
U.S. Department of Veterans Affairs
National Center for Rehabilitative Auditory Research
Portland, Oregon

Boothless Audiometry Part 1

- Engineering Perspectives and Learnings

Presentation Contents

Discussion of ANSI/ASA Standards that apply to Boothless Audiometry

Applying Standards to testing in non-ideal settings

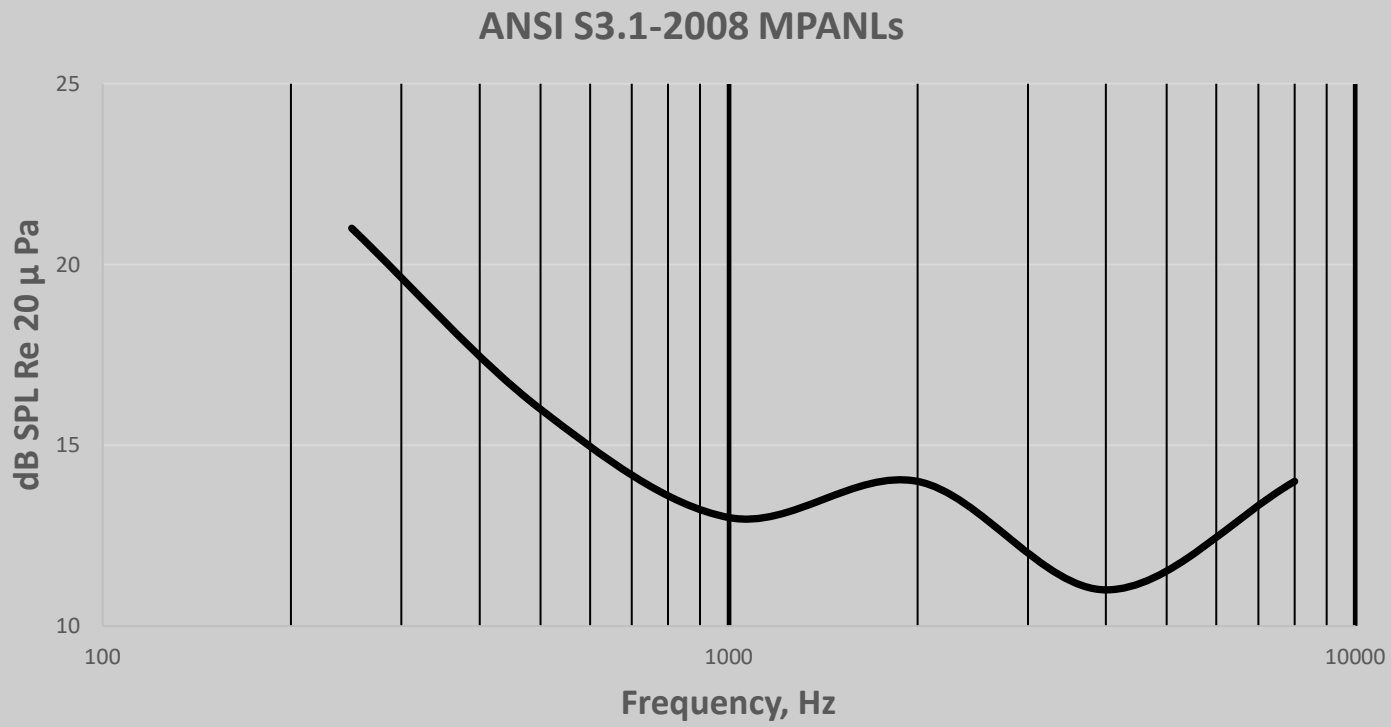
Measuring the Acoustical Spectral Signature of the boothless testing area

Understanding and Dealing with unavoidable noise in the test area

Summary of key Boothless Audiometer requirements

Future directions in Audio, Therapeutic Audio, and Audiometric devices

Maximum Permissible Ambient Noise Levels ANSI/ASA S3.1-2008



ANSI specifies the maximum amount of noise that is permitted in an auditory test booth for successful hearing threshold measurements.

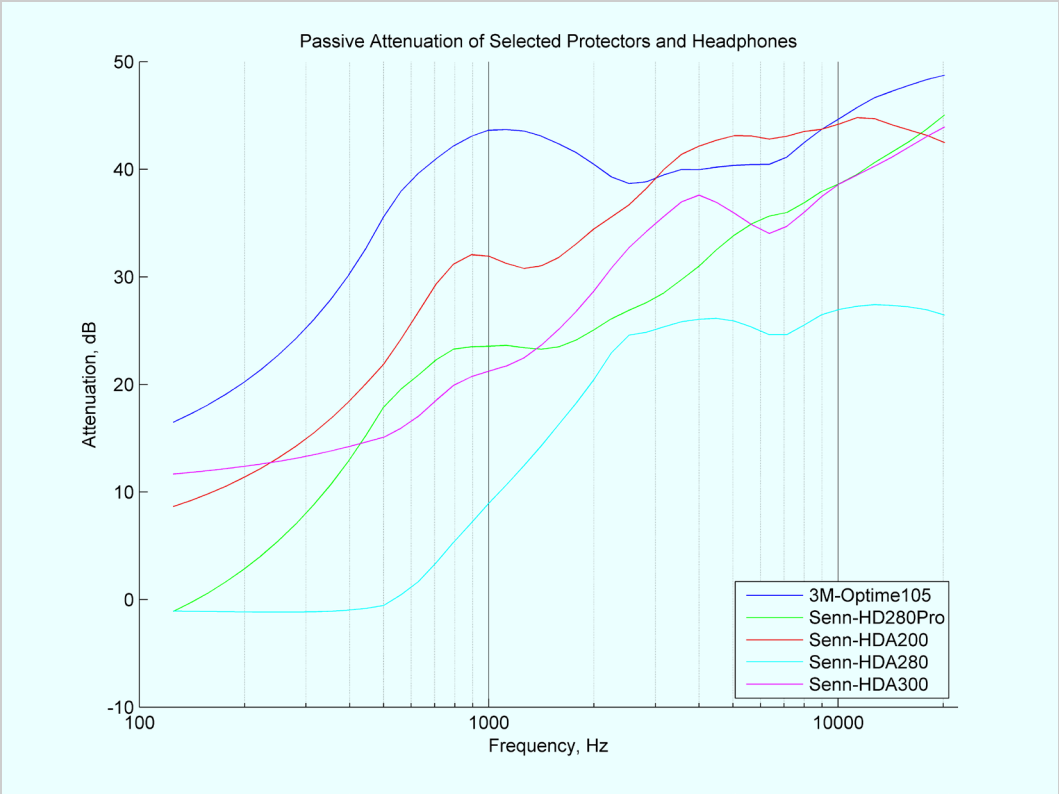
Specification for Audiometric Devices ANSI/ASA S3.6-2018

The ANSI Standard specifies:

- **The labelling of Audiometric Medical Devices (e.g. 1HFA)**
- **The functionality and performance requirements for Audiometric Medical Devices.**

If the device is compliant with the Standard, FDA 510k not required but FDA GMP compliance by the manufacturer of the device is required in the USA. Pre-Market Approval by the FDA is still required tympanometry and electrophysiology devices.

Passive Attenuation of Hearing Protection Devices ANSI/ASA S12.42-2010



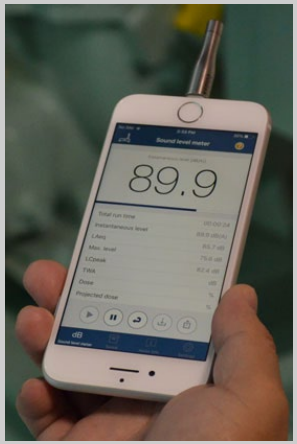
ANSI specifies the allowable methods to be used to measure the Passive Attenuation of hearing protection devices.

USAARL Report No. 2012-14, Robert Williams, (Use of Head and Torso Simulator)

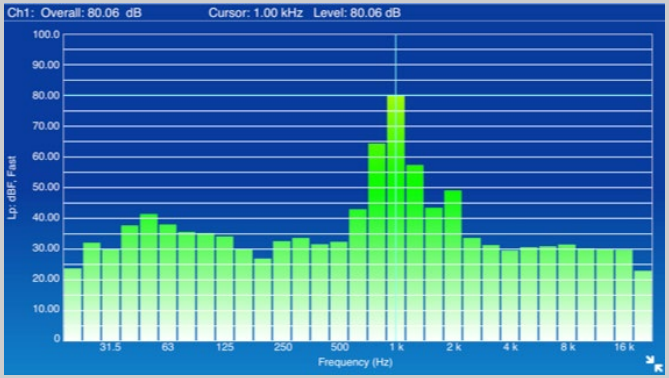
Measuring Acoustical Spectral Signature

Two Examples:

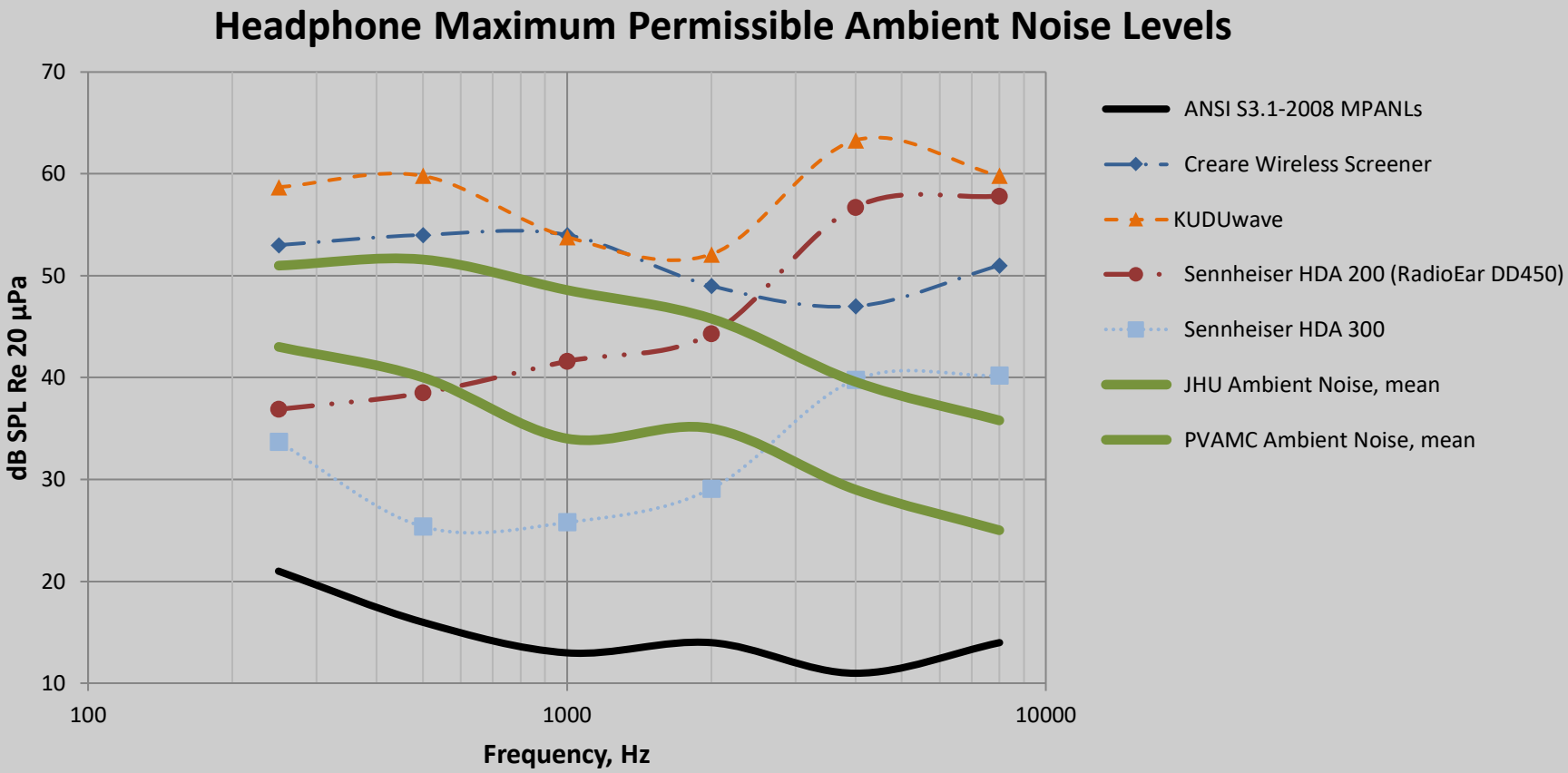
- NIOSH Sound Level Meter App
  - Developed by CDC
  - Meets Type 2 requirements of IEC 61672:3 SLM standard when used w/ external microphone.
  - MicW calibrated microphone



- Sound Meter Pro App for IOS
  - Faberacoustical.com



Acoustical Spectral Signatures Auditory Isolation Performance



Brungart, et. al. Using tablet-based technology to deliver time-efficient ototoxicity monitoring, 2017, International Journal of Audiology

Calibration Considerations

Sennheiser HD 280 Pro, $100

MicW I series boundary mic, $100

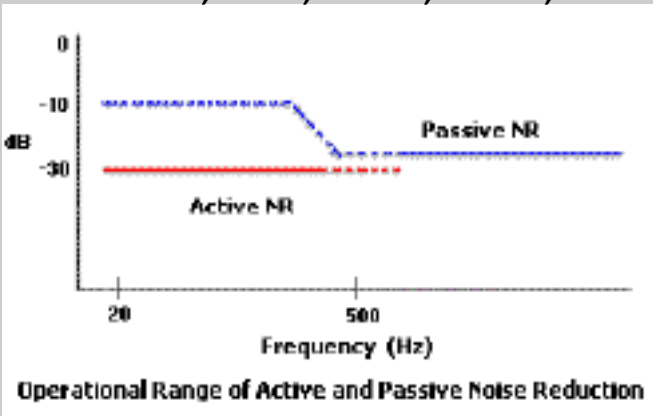
Listen for the tone? Too Noisy to test!

Active Ambient Noise Monitoring prior to making the measurement

- Ambient and impulsive noise
- Broadband
- Narrowband (frequency selective)

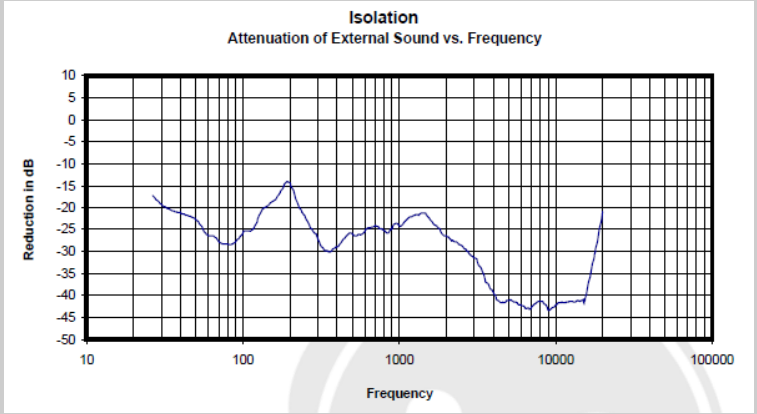
Active Noise Suppression

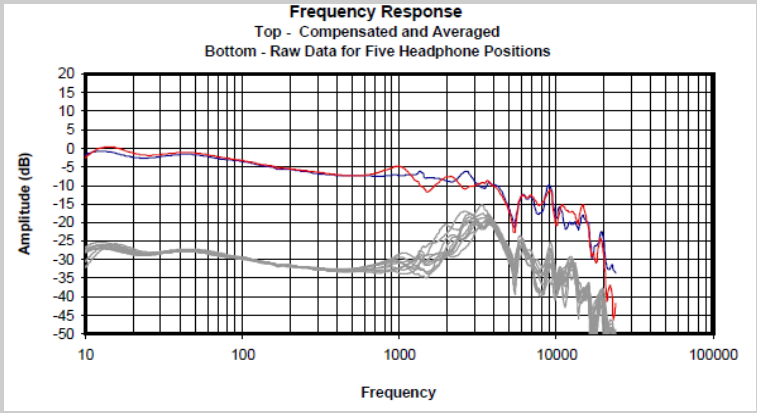
Amar Bose, PhD, 1978, 1989, 2009



Amar Bose PhD, The World is a Noisy Place, 2009
Wu, et al., Noise Cancelling Headphones, 2014

Bose Quiet Comfort 35 Wired Active





© INTERLINK MEDIA, 2016
Inner fidelity , Tyll Hertsens, 2016

Publications of Interest:

Accuracy of Mobile-Based Audiometry in the Evaluation of Hearing Loss in Quiet and Noise, Saliba et. Al, 2016, Otolaryngology-Head and Neck Surgery

Note: This is presented for example purposes only and does not represent an endorsement of any individual product by the NCRAR or the presenter.

Boothless Testing Device Requirements

(Partial List)

- ANSI S3.6 Compliant Device with HF capability
- 100 dB SPL output from 250 to 20,000 Hz (ototoxicity)
- Accurate threshold determination in environmental noise conditions up to 55 dB SPL
- Active wide and narrow band ambient noise monitoring
- Manual, Automatic, Local, and Remote testing capabilities
- Auto Threshold and SRO screening test
- Middle Ear Testing
- Word and Speech intelligibility testing
- Test and Subject confidence rating system
- Secure Local Machine subject data storage
- Secure Cellular Modem and/or Network data transmission
- VA IT Network/Applications Evaluation Group approval (VA only)

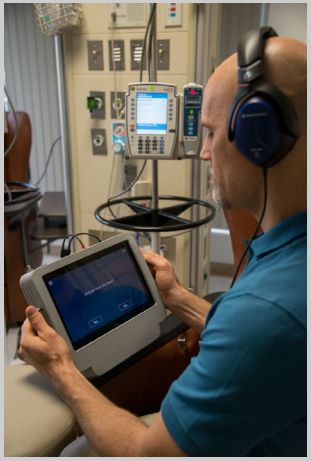
Platform Evolutions: OtoID and others

2006

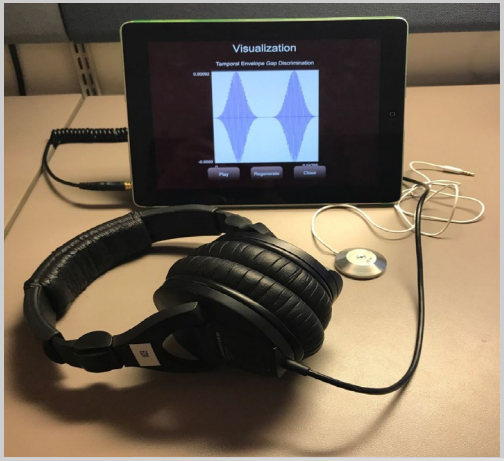
2011

2013

2015

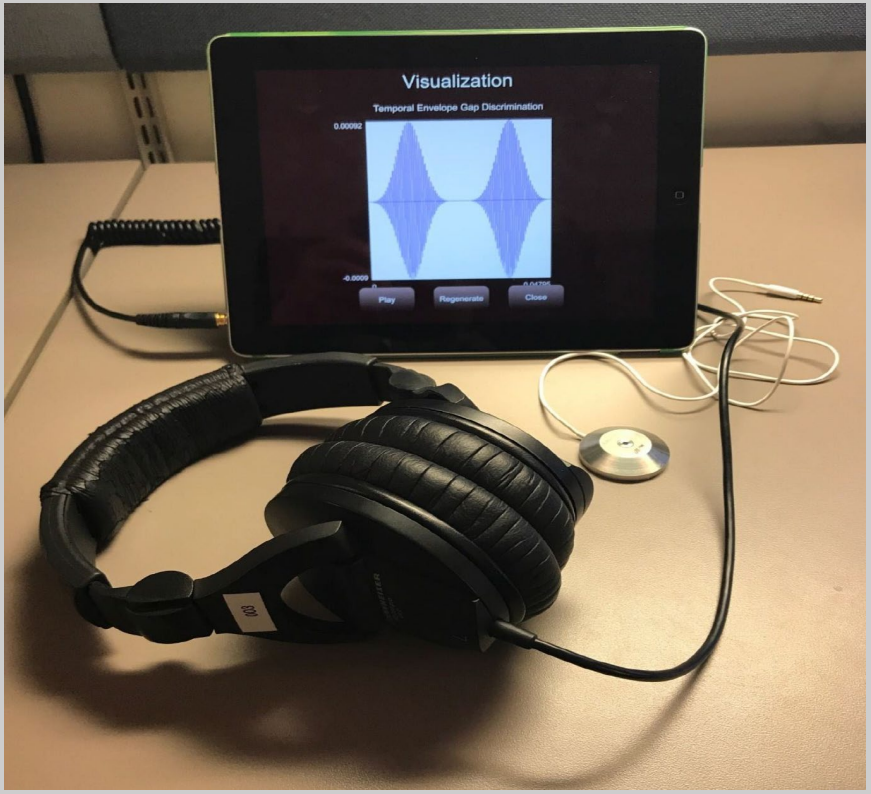


2017



Beyond

The Promise of Portable Automated Rapid Testing (PART)

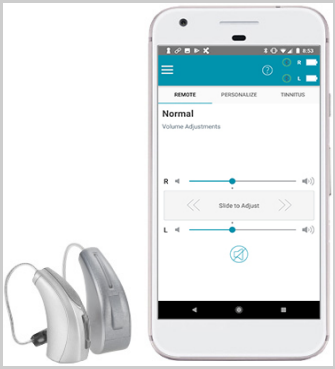


VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research & Development

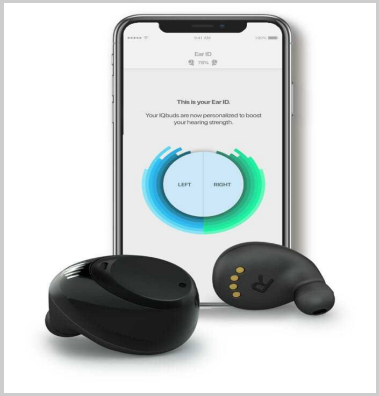
https://bgc.ucr.edu/games

Technology and Industry Convergence regarding Audibility

Apple Air Pods Pro



Made for IPhone



IQ Buds Boost

Etymotic

Bose HearPhones

Technology and Industry Convergence regarding Audibility and Functionality
One company's opinion

FEATURES				
	IQbuds BOOST	High End EAR BUDS*	PSAP**	HEARING AID†
Bluetooth Connectivity	✓	✓	✗	✗ PO
Take Calls & Stream Music	✓	✓	✗	✗ PO
Rechargable	✓	✓	Some ($300+)	✗ PO
Sound Amplification	✓	✗	✓	✓
Conversation Enhancement	✓	✗	✗	✓
External Noise Supression	✓	✗	✗	✗
Directional Microphone	✓	✗	✗	✓
Personalization / Calibration	✓ IH	✗	✗	✓ IC
Tap Touch Controls	✓	✗	✗	✗
Usage	Situational	Leisure	All Day	All Day
Pricing°	**$499**	**$150+**	**$50-299**	**$4000+**

** Personal Sound Amplification Products

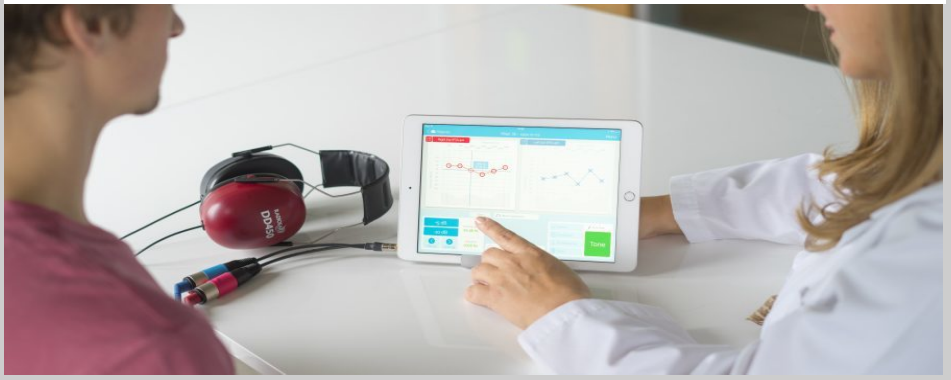
† Prescription Only

Summary

- Automated testing outside of the booth has been occurring for over 20 years for NCRAR research.
- Boothless Audiometry has been in use for many years and is a common practice in the world community.
- The technologies that support tele-audiology and tele-medicine are rapidly evolving to shape the future of “Point of Care” diagnosis and therapeutics.

Important solutions that you will learn about today!

Note: This is presented for example purposes only and does not represent an endorsement of any individual product by the VA, NCRAR, or the presenters.



Acknowledgements and Citations

This research was supported by :

Dept. of Veterans Affairs, Rehabilitation Research and Development,
National Institutes of Health/National Institute for Deafness and Communication Disorders

Brungart D, Shurman J, **Konrad-Martin D,** Watts K, Buckey J, Clavier O, Jacobs PG, **Gordon S, Dille M.** Using tablet-based technology to deliver time-efficient ototoxicity monitoring. Int J Audiol, Early Online, 2017 September:1-9. http://dx.doi.org/10.1080/14992027.2017.1370138

Jakien KM, Kampel SD, Gordon SY, Gallun FJ. (2017) The benefits of increased sensation level and bandwidth on spatial release from masking. Ear Hear 38(1), e13-e21.

Konrad-Martin D, Poling G, **Garinis AC,** Ortiz C, Hopper J, **O'Connell Bennett K, Dille MF.** Applying U.S. national guidelines for ototoxicity monitoring in adult patients: Perspectives on patient populations, service gaps, barriers and solutions. Int J Audiol, 2017 Nov; epub ahead of print:1-16. https://doi.org/10.1080/14992027.2017.1398421

Dille M. New Device Helps Halt Hearing Loss for Cancer Patients. VA Research Currents. 2015 (Winter): 8-9

Ellinger RL, Jakien KM, Gallun FJ. (2017) The role of interaural differences in speech intelligibility in complex multitalker environments. J Acoust Soc Am, 141 EL170

Jakien KM, Kampel SD, Gordon SY, Gallun FJ. (2017) The benefits of increased sensation level and bandwidth on spatial release from masking. Ear Hear 38(1), e13-e21.

Jakien, K. M., Kampel, S. D., Stansell, M. M., & Gallun, F. J. Validating a Rapid, Automated Test of Spatial Release From Masking. American Journal of Audiology, 1-12, September, 2017.

Srinivasan NK, Stansell MM, Gallun FJ. (2017) The role of early and late reflections on spatial release from masking: Effects of age and hearing loss J Acoust Soc Am, 141 EL185 http://dx.doi.org/10.1121/1.4973837

Ellingson, R. M., Gallun, F. J., Bock, G. (2015). "Measurement with verification of stationary signals and noise in extremely quiet environments – measuring below the noise floor." Journal of the Acoustical Society of America. 137(3):1164-1179. http://scitation.aip.org/content/asa/journal/jasa/137/3/10.1121/1.4908566

Dille MF, Jacobs PG, Gordon SY, Helt W, McMillan GP. (2013) OtoID: New extended frequency, portable audiometer for ototoxicity monitoring. JRRD. 50(7): 997-1006. PMID: 24301436

Jacobs PG, Silaski G, Wilmington D, **Gordon S, Helt W, McMillan G, Fausti S, Dille M**. Development and evaluation of a portable audiometer for high frequency screening of hearing loss from ototoxicity in homes/clinics IEEE Trans Biomed Eng. 2012; 59(11):3097-3103.

Ellingson RM, Helt WJ, Helt PV, Wilmington DJ, **Gordon JS, Fausti SA**, Mobile, personalized-SRO, serial monitoring system supports early detection of hearing loss, full frequency range testing, Accepted for publication in Proceedings of the 2011 IEEE International Instrumentation and Measurement Technology Conference (I2MTC), May 10-12, 2011, Binjiang, Hangzhou, China.

Konrad-Martin D, James KE, **Gordon JS, Reavis KM,** Phillips DS, Bratt GW, **Fausti SA.** Evaluation of audiometric threshold shift criteria for ototoxicity monitoring, J Am Acad Audiol, 21(5):301-314; quiz 357, 2010.

Fausti SA, Helt WJ, Gordon JS, Reavis KM, Phillips DS, Konrad-Martin D. Audiologic monitoring for ototoxicity and patient management, In: KC Campbell ed. Pharmacology and Ototoxicity for Audiologists. New York: Thomson Delmar Learning, 230-251, 2007.

Jacobs PG, Saunders GH. (2013). Leveraging smart phone technology to realize a system of teleaudiology. Invited article for Hearing Views@Hearing health 7 technology Matters! http://hearinghealthmatters.org/hearingviews/2013/leveraging-smart-phone-technology-to-realize-a-system-of-teleaudiology/

Jacobs PG, Saunders GH. (2014). New opportunities and challenges for teleaudiology within the VA. Guest editorial. J Rehabil Res Dev, Sept; 51(5):vii–xii.

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research & Development

U.S. Department of Veterans Affairs

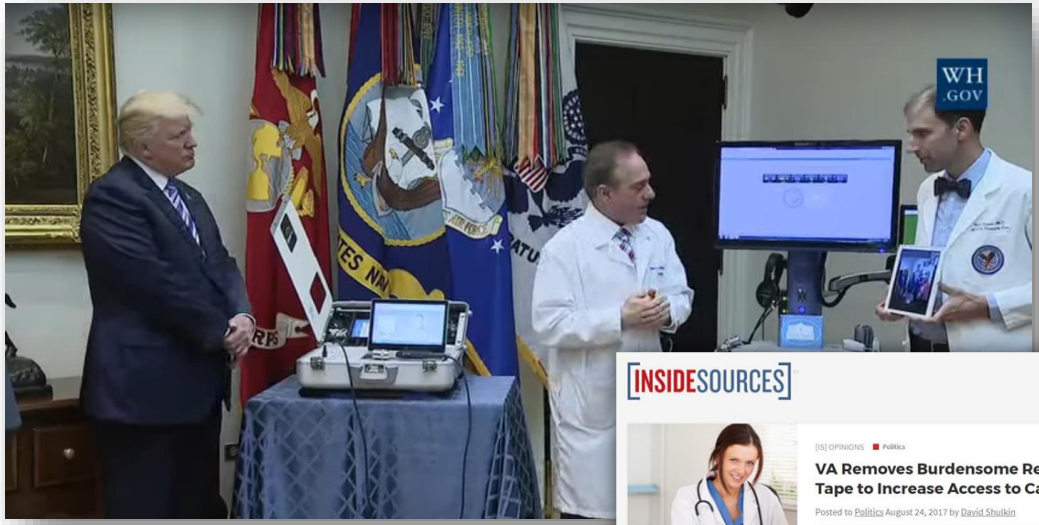
NCRAR Seminar
Nov 19, 2020

Chad Gladden, Au.D., CCC-A
Audiology Telehealth Coordinator
Audiology and Speech Pathology National Program Office

VA Telehealth Definitions

- **Telehealth:**
  - The use of electronic information or telecommunications technologies to support clinical health care, patient and professional health-related education, public health, and health administration at a distance.
- **Telehealth Modalities:**
  - **Clinical Video Telehealth (CVT)**
    - Real-time videoconferencing between VA medical centers and CBOCs that replicates face-to-face care between patient and provider
    - CVT to Home (CVTHm) - Real-time videoconferencing between VA providers into the patient's home to replicate face-to-face care between patient and provider
  - **Store-and-Forward Telehealth (SFT)**
    - Acquisition, storage, and forwarding of clinical images to experts for review
  - **Home Telehealth (Remote Monitoring)**
    - Monitors patients and manages diseases through video into the home and use of mobile devices for acute and chronic management and health promotion/disease prevention

Anywhere to Anywhere



ANYWHERE TO ANYWHERE TOGETHER

[INSIDESOURCES]

[IS] OPINIONS ■ Politics

VA Removes Burdensome Red Tape to Increase Access to Care

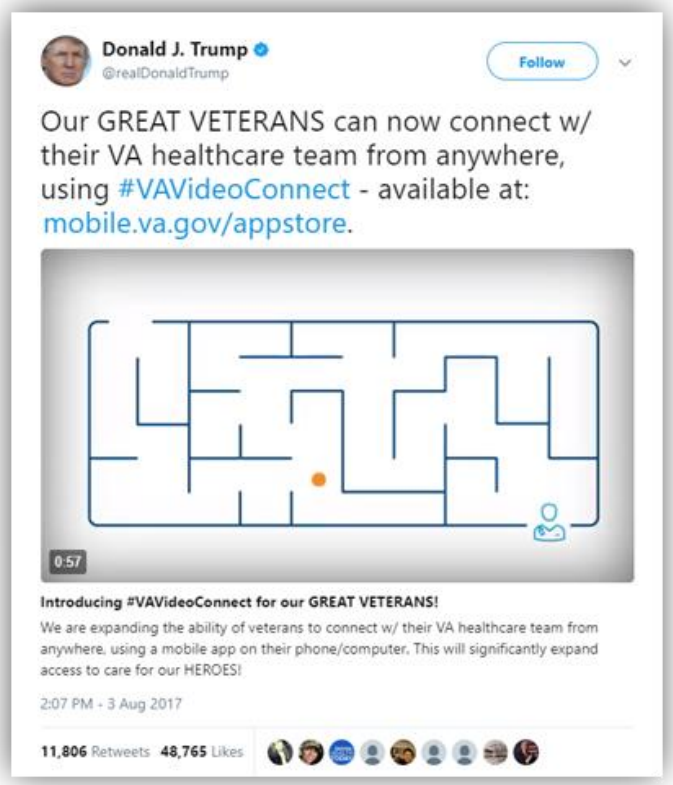
Posted to Politics August 24, 2017 by David Shulkin

Email Print Share This Tweet This

Imagine the day that you can see your medical provider from anywhere in the country including from the comfort of your own home. You wouldn't have to take a full day off of work, travel long distances, or spend hours in a hospital waiting room. Thanks to the age of smart phones and other advanced technology, that day has come. And it couldn't have come at a more critical moment.

Across the nation, wait times in the private sector for new patient appointments have increased 30 percent in the past three years including major cities such as Seattle, Boston, Denver and Los Angeles, according to a recent survey.

Telehealth technology is revolutionizing how Americans access healthcare. Healthcare professionals have been utilizing this technology for years, but with significant limits. Only a few states allow medical providers to use telehealth to practice across state lines, severely limiting the potential impact of this technology.



Legal Authority

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ06

Authority of Health Care Providers To Practice Telehealth

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

(b) *Health care provider's practice via telehealth.* (1) Health care providers may provide telehealth services, within their scope of practice, functional statement, and/or in accordance with privileges granted to them by VA, irrespective of the State or location within a State where the health care provider or the beneficiary is physically located. Health care providers' practice

https://www.federalregister.gov/documents/2018/05/11/2018-10114/authority-of-health-care-providers-to-practice-telehealth

1. Anywhere to Anywhere Telehealth Legislation signed into law as part of the VA MISSION Act on June 6, 2018. The June 6 law and the June 11 regulation/rule (see 2. below) will eventually merge.
2. Anywhere to Anywhere Telehealth Regulation published as final in the Federal Register with effective date of Monday June 11, 2018.

Summary

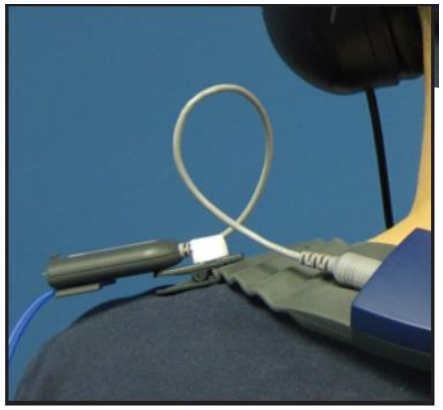
	KUDUwave Prime	KUDUwave Pro	KUDUwave Tymp	AMTAS Pro	AMTAS Flex	Edare	SHOEBOX PRO	SHOEBOX STANDARD	SHOEBOX Quicktest
AC Diagnostic	✓	✓	✓	✓	✓	✓	✓	✓	
AC Screening	✓	✓	✓	✓	✓	✓	✓	✓	✓
BC Screening		✓	✓	✓			✓		
BC Diagnostic		✓	✓	✓			✓		
Speech SRT		✓	✓	✓			✓		
Speech WRS		✓	✓	✓			✓		
Masking	✓	✓	✓	✓	✓		✓	✓	
Automated	✓	✓	✓	✓	✓	✓	✓	✓	✓
Manual	✓	✓	✓	✓			✓		
HC technician/provider	✓	✓	✓		✓	✓		✓	
Audiologist	✓	✓	✓	✓		✓	✓		
Tympanometry			✓						

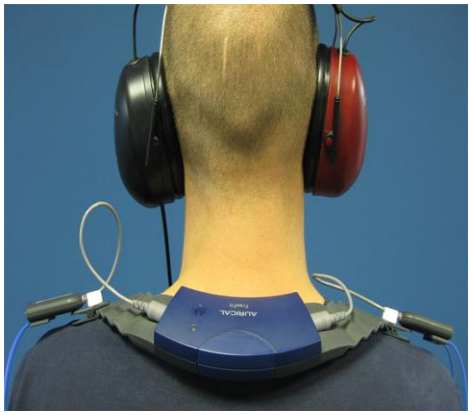
Teleaudiology Portfolio

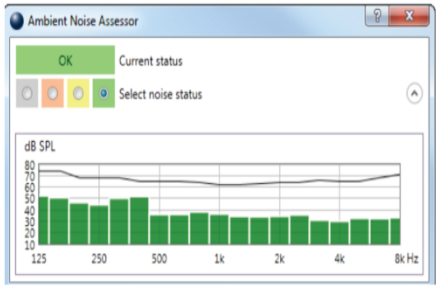
- Clinical Video Telehealth (CVT)
  - Remote diagnostics, fittings, and follow ups
  - Audiologic Rehab and Tinnitus Education
  - Remote Cochlear Implant Programming
- Clinical Video Telehealth to Home (CVTHm)
  - Remote fine-tuning for hearing aids
- Store and Forward Telehealth (SFT)
  - Asynchronous hearing testing with images

Clinical Video Telehealth

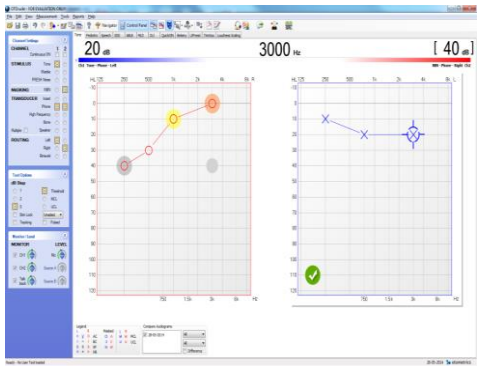
Clinical Video Telehealth

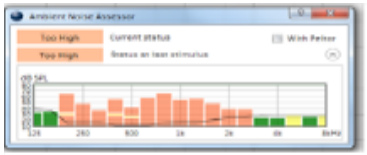






View of ANA, as seen by the VAMC-based audiologist during speech testing.





TeleAudiology Outcomes-IOI-HA

VA has collected 16,903 Tele-Audiology outcomes.

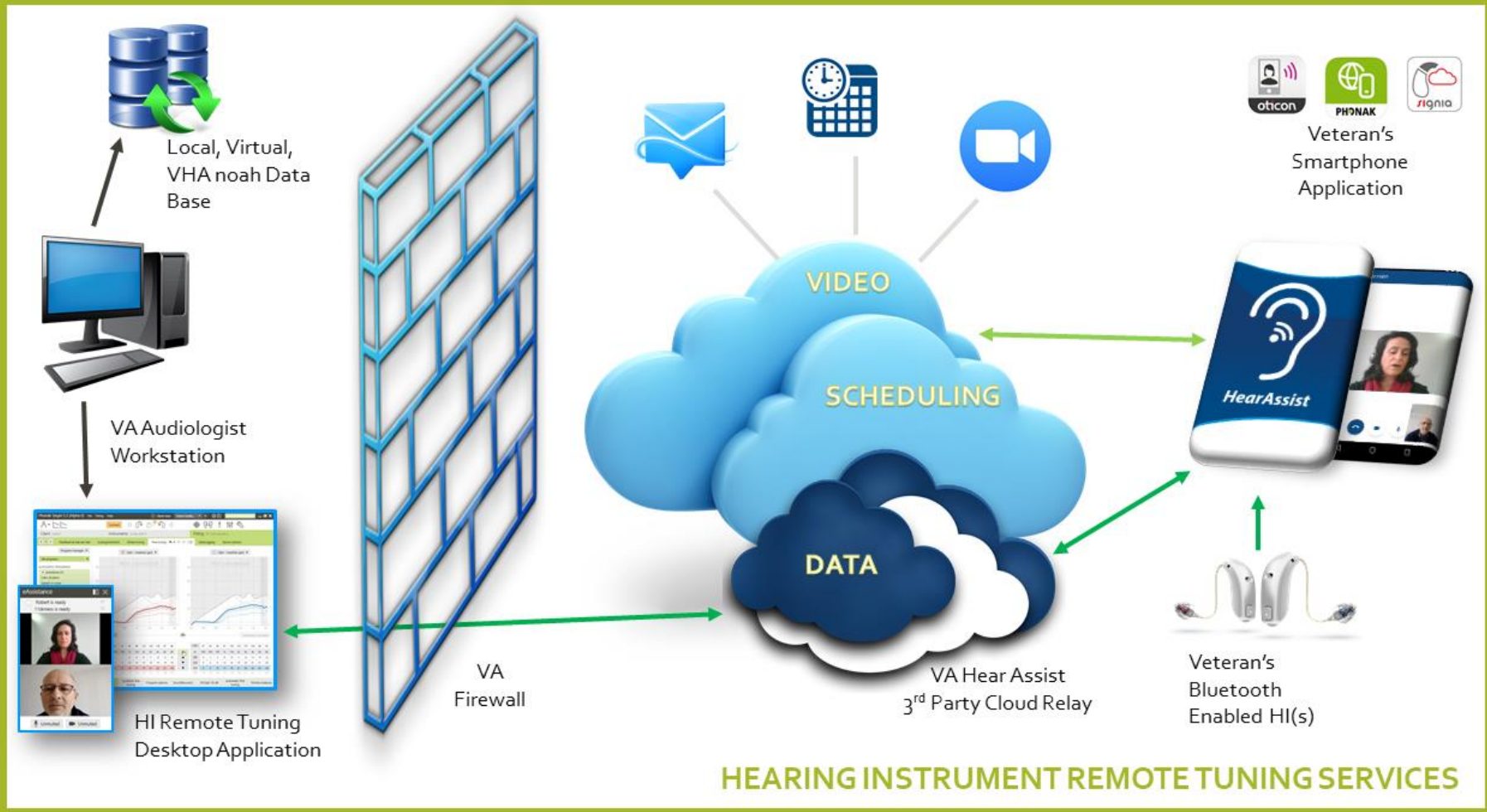
	Use	Ben	ActLim	Sat	PartRest	ImpOth	QOL
All Veterans	4.47	4.10	3.87	4.43	3.87	3.93	4.07
Telehealth	4.53	4.18	3.97	4.51	4.03	4.04	4.12

Scoring: 1=poorest outcome, 5=best outcome

Tele-Audiology outcomes are as good as, or better than, traditional face-to-face encounters.

Cochlear Implants

Enterprise Remote Tuning of Hearing Instruments (ERTHI)



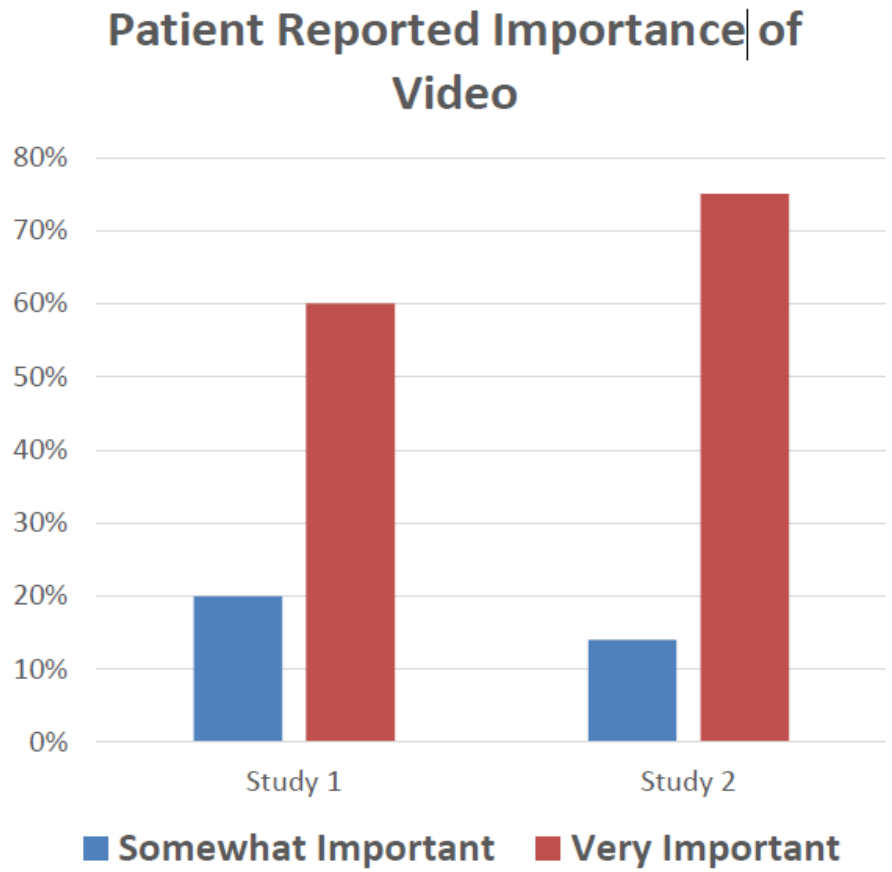
Enterprise Remote Tuning of Hearing Instruments CVTHm

- Increases Veterans' access to care by enabling remote access to VA hearing aid services from the Veteran's home via smartphone or tablet
- Reduces inconvenience and costs related to medical travel
- Synchronous methods:
  - Oticon, Phonak, Resound, Sivantos

VA workstation

Veteran's Telephone

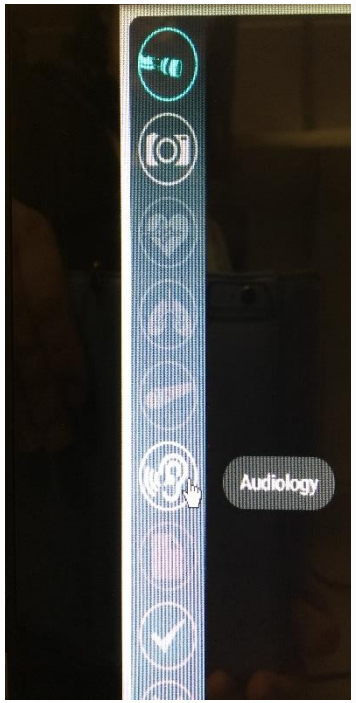
IMPORTANCE OF VIDEO



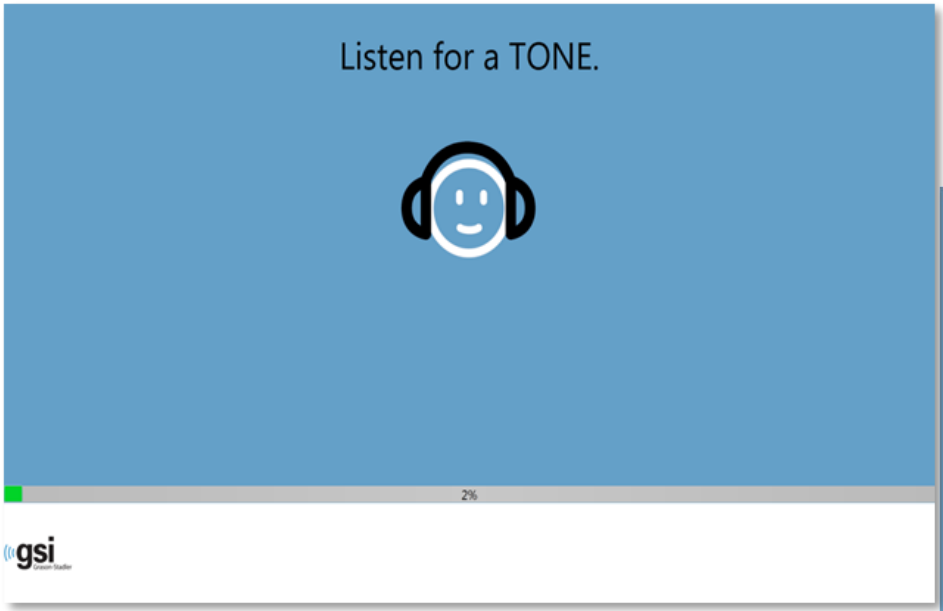
- In two recent studies where rural Veterans received mental health care over video (study 1, n=30; study 2, n=84), the majority of patients reported seeing their provider over video was somewhat or very important.
- *Source:* *Jan.Lindsay2@va.gov*

50

AUDIOLOGY SFT-AUTOMATED AUDIOMETRY

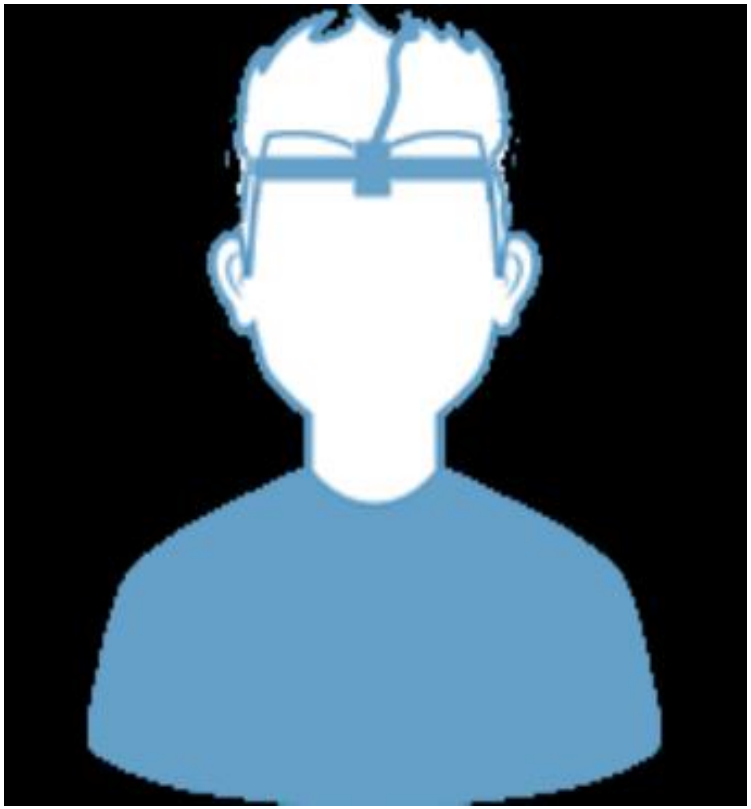


AUTOMATED AUDIOMETRY

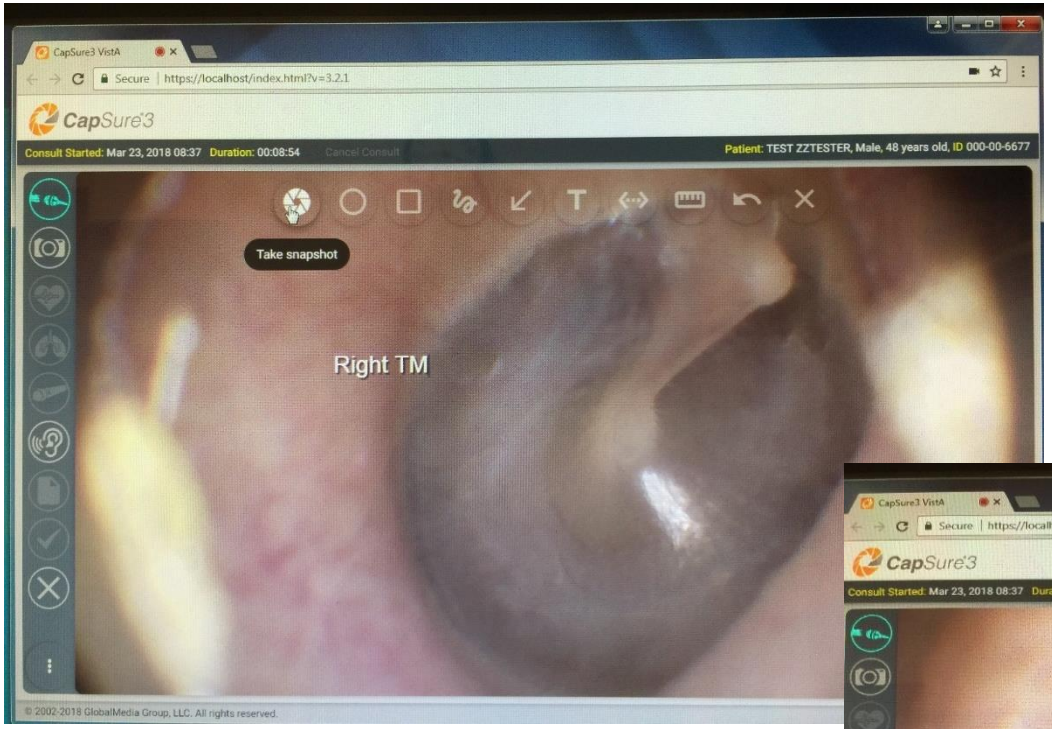


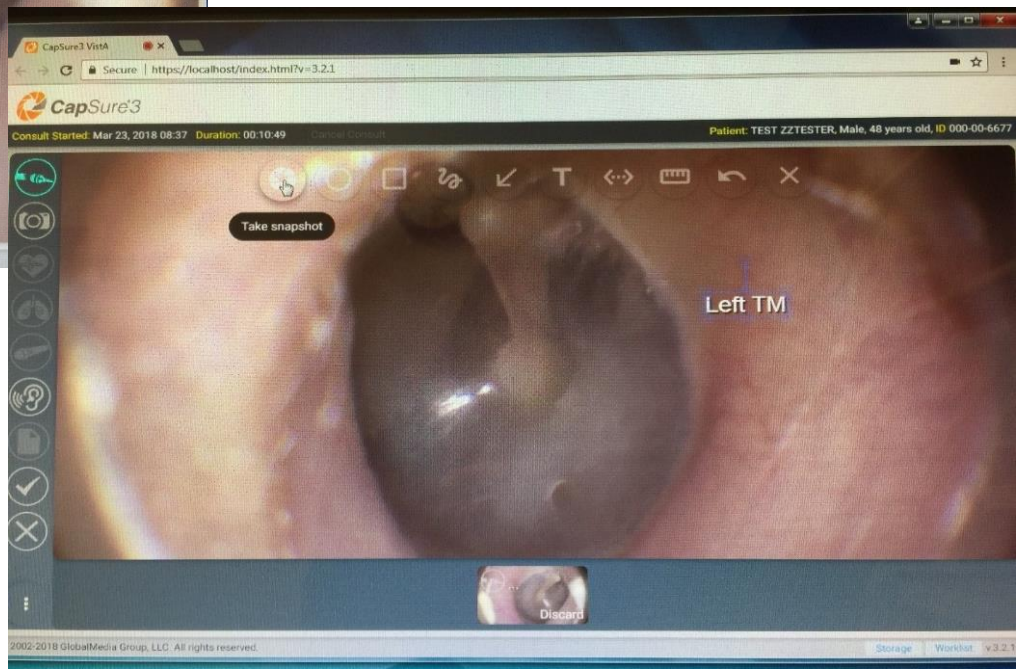
- AC/BC (including all interoctaves)
- Brief Instructions

Transducer Placement



VIDEO OTOSCOPY



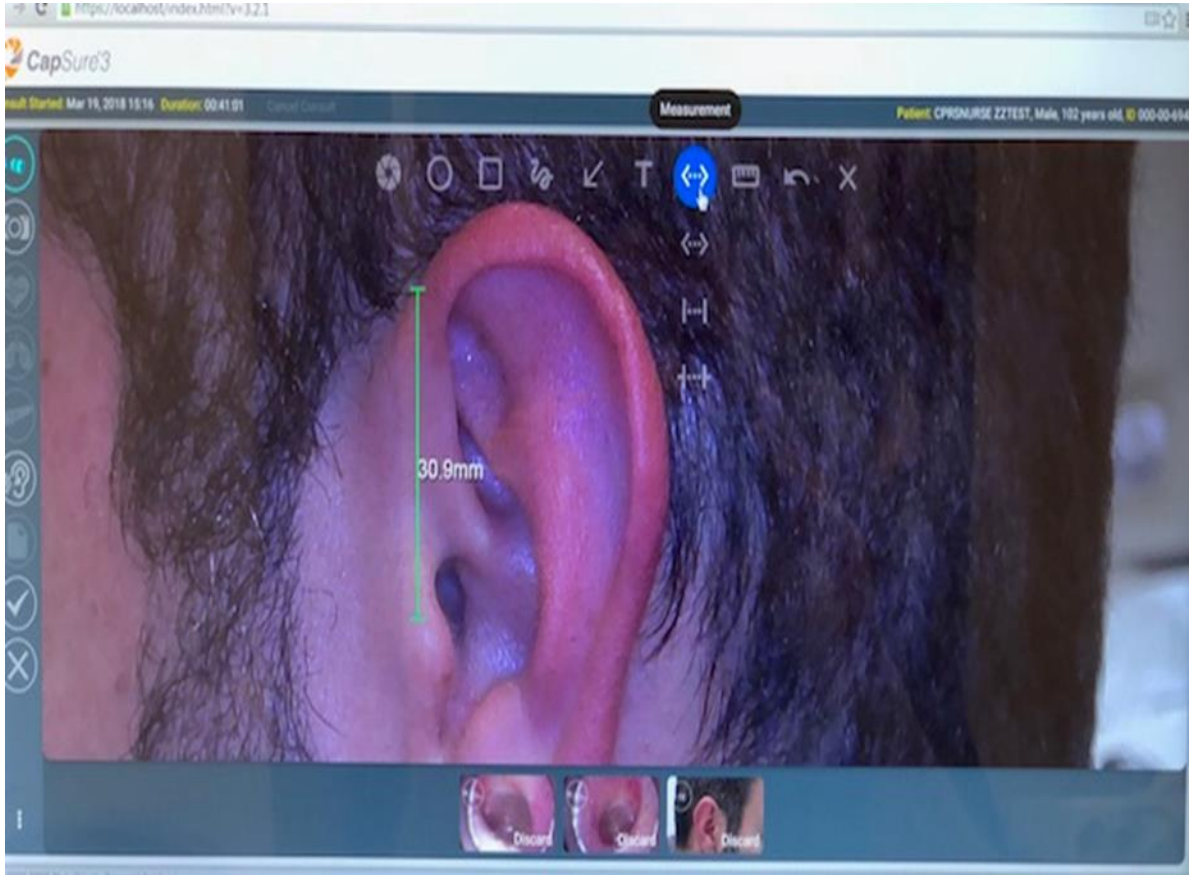


EXTERNAL EAR IMAGES

EXTERNAL EAR IMAGES

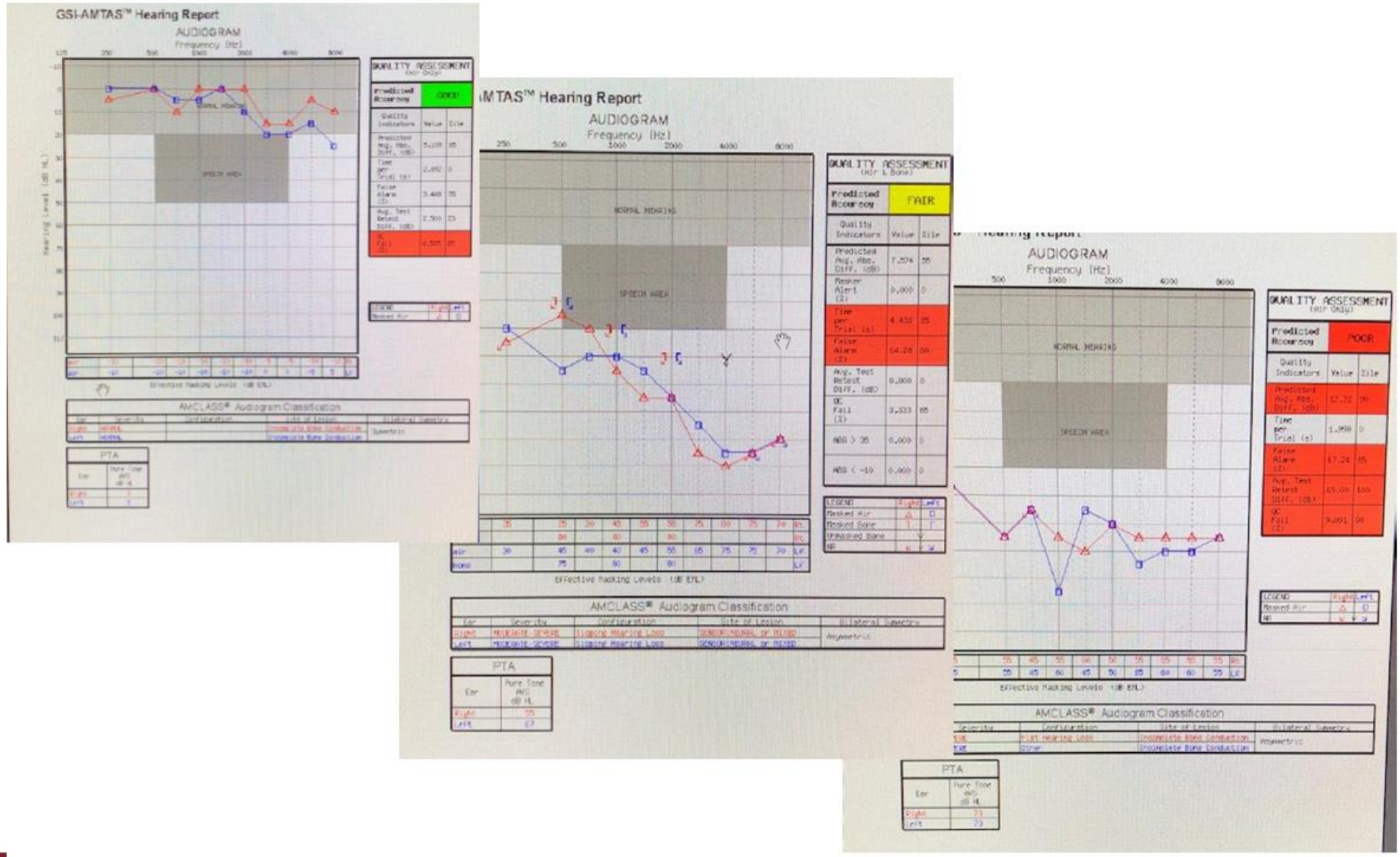
RIC Conversion Chart

Phonak	Widex
0 = 15-20 mm	-2 = 17-20 mm
1 = 21-26 mm	-1 = 21-24 mm
2 = 27 – 31 mm	0 = 25-28 mm
3 = 32+ mm	1 = 29-32 mm
Oticon	2 = 33-36 mm
1 = 15-20 mm	3 = 37-40 mm
2 = 21-26 mm	4 = 41-44 mm
3 = 27-32 mm	5 = 44+ mm
4 = 33- 38 mm	
5 = 39+ mm	
Resound	**Siemens**
0 = 19-22 mm	0 = 19- 23 mm
1 = 23-26 mm	1 = 24 - 28 mm
2 = 27-30 mm	2 = 29-33 mm
3 = 31+ mm	3 = 33+ mm
Starkey	
1-2 = 22-26 mm	
3-4 = 26-30 mm	
5 = 31+ mm	



Measurement in mm converted to RIC sizes

AUDIOGRAM-QUALITY INDICATORS



VISN Clinical Resource Hubs

Telehealth Interim Staffing

- Virtual float providers offer same-day or short term contingency coverage
- Staffing: contact center, telehealth hub, facility partnership
- Facilitating timely, convenient access to care

Clinical Resource Hub-VISN 19

What are we trying to add to our Virtual toolbox?

- Otoscopy
  - Personal otoscopes that hook to a tablet or smartphone
- In situ audiometry
- Fitting verification methods
- Portable, reusable diagnostics units to ship to the home

- **Purpose/Mission:** The DoD and VA Boothless Audiometry Networking Group (BANG) collaborates, shares, and gathers information from Audiology leaders, clinicians, and researchers to increase awareness, understanding, and capabilities, and to leverage boothless audiometry to provide timely (or on time) access to hearing health services.

- **Goals:**
  - Develop a centralized list of current DoD and VA boothless audiometry projects and studies to ensure greater awareness and visibility of all studies and avoid duplication of effort.
  - Gather information about how boothless audiometry is currently being used, or has been used previously, in various settings: clinical audiology, deployed, remote, and other medical settings, e.g., waiting areas, diabetes clinics, outpatient clinics).
  - Evaluate Boothless Audiometry Technology State of the Science from published research, industry, and stakeholders to gain knowledge of the use and capabilities of boothless audiometry products and smart phone hearing test Apps.
  - Review FDA-approved boothless audiometry products and maintain a current, accessible database, including detailed technical and operational capabilities of each product.
  - Determine and develop a boothless audiometry best practice guideline and toolkit for DoD and VA hearing health professionals.

TO CARE FOR HIM WHO SHALL
HAVE BORNE THE BATTLE AND
FOR HIS WIDOW, AND HIS ORPHAN

A. LINCOLN