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.
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 for tympanometry and electrophysiology devices.
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

Headphone Maximum Permissible Ambient Noise Levels

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


Bose Quiet Comfort 35 Wired Active

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.

© INTERLINK MEDIA, 2016
Inner fidelity, Tyll Hertsens, 2016
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
The Promise of Portable Automated Rapid Testing (PART)
Technology and Industry Convergence regarding Audibility

Apple Air Pods Pro

IQ Buds Boost

Etymotic

Bose HearPhones

Made for IPhone
# Technology and Industry Convergence regarding Audibility and Functionality

One company’s opinion

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<table>
<thead>
<tr>
<th>FEATURES</th>
<th>IQbuds BOOST</th>
<th>High End EAR BUDS*</th>
<th>PSAP**</th>
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| 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.
This research was supported by:
Dept. of Veterans Affairs, Rehabilitation Research and Development, National Institutes of Health/National Institute for Deafness and Communication Disorders


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


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


**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
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.

Our GREAT VETERANS can now connect w/ their VA healthcare team from anywhere, using #VAVideoConnect - available at: mobile.va.gov/appstore.

We are expanding the ability of veterans to connect w/ their VA healthcare team from anywhere using a mobile app on their phone/computer. This will significantly expand access to care for our HEROES!
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.
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• **Clinical Video Telehealth (CVT)**
  – Remote diagnostics, fittings, and follow ups
  – Audiolologic 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.
VA has collected 16,903 Tele-Audiology outcomes.

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<th>Ben</th>
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<td>All Veterans</td>
<td>4.47</td>
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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
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
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
Welcome to
GSI-AMTAS™
Self Administered Automated Audiogram

Get Started
• AC/BC (including all interoctaves)
• Brief Instructions
VIDEO OTOSCOPY
EXTERNAL EAR IMAGES
**External Ear Images**

**Measurement in mm converted to RIC sizes**

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<th>RIC Conversion Chart</th>
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<td>3 = 32+ mm</td>
<td>1 = 29-32 mm</td>
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<td>5 = 39+ mm</td>
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<td><strong>Resound</strong></td>
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<td>3 = 31+ mm</td>
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<td>5 = 31+ mm</td>
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AUDIOGRAM-QUALITY INDICATORS
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
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