



The future of Hearing Conservation

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During the 1980's, audiometer manufacturers began embracing microprocessor technology. Since then, technological innovation has introduced smart phones, tablets, and the mobile internet which has led to commercially available tablet audiometers. They are advertised as “easy-to-use audiometer(s) designed for non-Audiologists to conduct automated diagnostic hearing testing outside of a sound booth”¹. Manufacturers of these devices claim that they are clinically validated, ANSI and ISO compliant, NOAH Certified, HIPAA compliant and cost effective². So, how do these tablets and apps compare with conventional hearing conservation testing systems using microprocessor audiometers, electro-acoustic simulators and noise attenuating sound booths? Are they ready to be embraced by hearing conservation professionals?

Tablet Audiometers

Tablet audiometers pair tablets such as the Apple iPad with a proprietary audiometer application(app). Tablets are inexpensive, lightweight, portable and widely-available devices. Their simplicity of initial setup, low cost, widespread availability and popularity suggest that they offer a viable alternative to microprocessor audiometers and hearing booths currently found in hearing conservation testing environments.

Traditional Audiometers

Traditional audiometers meet the criteria of a medical diagnostic device. With an 8-10-15 year lifecycle, audiometers are stable, can be reset to factory specifications, can be enhanced with firmware updates and can interface with many occupational health management programs. The audiometer, handswitch and headset are checked daily - most often by using an electro-acoustic simulator. OSHA annual and exhaustive calibrations are performed using more sophisticated calibration instruments.

The Food and Drug Administration defines an audiometer as an “electroacoustic device that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders”³ and it is classified as a Class II device. Are tablets designed to be operated as medical devices?

1 Shoebox. (2018, September 3) The iPad Audiometer [Advertisement]. Shoebox Audiometry homepage. Shoebox. Retrieved from <http://www.shoebbox.md>

2 Shoebox. (2018, September 3) Clinical Validation [Advertisement]. Shoebox Audiometry Validation page. Shoebox. Retrieved from <http://www.shoebbox.md/clinical-validation>

3 U.S. Food and Drug Administration (2017, April 1) CFR - Code of Federal Regulations Title 21. Title 21-Food And Drugs, Chapter I - Food And Drug Administration, Department of Health and Human Services, Subchapter H-Medical Devices, US Food and Drug Administration. Retrieved from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=874.1050>

Tablet Models

While traditional audiometers have a life cycle of approximately 8-15 years, the life cycle for a tablet model is considerably shorter. New tablet models arrive every year, and each model lasts 2 or 3 years. [At the time of publishing] there have been at least sixteen Apple iPad models since 2010 (more if you include options). When tablet models change, their hardware, firmware, memory and operating systems change. These changes may affect the performance of applications that were designed to operate with a specific model. Hardware changes and updates can disable important audio functions or affect linearity and volume levels.⁴

Tablet Operating Systems

When tablet manufacturers modify their operating systems, new modifications can affect tablet performance and application stability. Software designed to run on a particular operating system, Windows XP for example, may not function under Windows 7 or Windows 10. What assurance is there that an older app will run properly on a newer operating system? Will support for older tablets or apps be available for 10 or 15 years?

With a conventional audiometer, there is one manufacturer involved with production, distribution and service. With tablet audiometers, hardware, product service and firmware upgrades may be handled by the tablet manufacturer or one of hundreds of distributors. Audiometer application issues may be handled separately by the application designer or their service/distribution network. Should the device fail, who determines if the application, the tablet or any of the accessories (earphones, cables, headbands, etc.) has failed?

Daily Calibration Checks

Daily calibration checks are often made with an electro-acoustic ear since response levels are stable, reliable and faster than a human counterpart. Audiometers interface with electro-acoustic ears via the audiometer response button jack. But some tablet audiometers do not have response buttons and therefore a human biological reference must be used to conduct the daily bio-acoustic check.

Hearing conservationists should recognize that a patient who handles the tablet audiometer is holding the entire hearing testing system in their hand and this introduces the possibility of physical damage to the tablet; e.g. dropping the tablet, spilling liquids onto the tablet, damaging the touch screen from excessive force, banging jewelry against the tablet, using a pen or hard object against the screen, etc.

OSHA Mandated Calibrations

Annual and exhaustive calibration procedures validate the integrity of the entire audiometric testing system - the audiometer, the audiometer/

4 https://www.reddit.com/r/ipad/comments/6h3vfm/ipad_pro_105_volume_level/

sound booth cables and jacks, the headphone cables, headband, earphone cushions and elements. A failure of any of these components will compromise hearing threshold results. OSHA audiometer calibration procedures are very specific. The audiometer AND its associated headset must be acoustically calibrated annually. What may be misleading are statements that suggest that adjusting a tablet, (independent of the actual headset used for hearing testing) or that sending a “calibrated headset” (independent of the testing tablet) complies with OSHA and ANSI calibration. These methodologies of “calibration” do not meet OSHA hearing conservation program requirements for annual or exhaustive calibration.

Validation

When new technology suggests use of an alternative and better diagnostic tool, invariably the new tool is compared with a corresponding gold standard. “The gold standard is the best single test (or combination of tests) that is considered the current preferred method of diagnosing a particular disease.”⁵ For hearing professionals, “formal audiometric testing is the gold standard for diagnosing hearing loss and monitoring treatment.”⁶ In occupational hearing conservation programs, it is the identification of patient baseline hearing thresholds and the monitoring of changes in thresholds that are inherent in evaluating standard threshold shifts and identifying occupational hearing loss.

Validity by definition is the “degree to which it measures what it purports to measure (Kerlinger & Lee, 2000; Thorndike et al 1991)^{7,8}. For hearing conservationists, the medical diagnosis of primary concern is hearing loss that is the result of excessive occupational noise exposure and this is often revealed with evaluating standard threshold shifts. Further analysis determines whether this standard threshold shift is temporary, permanent, OSHA recordable or non-recordable. Any procedure for validation in a hearing conservation environment involves the use of a calibrated audiometer, a competent technician or hearing professional in an OSHA compliant hearing testing environment.

When manufacturers declare that their hearing test system has been clinically validated for use in hearing conservation programs, it suggests that trials have been conducted to verify that patients who have been diagnosed with a standard threshold shift, (using a conventional audiometer), have been confirmed as having a standard threshold shift using the newer tablet technology. The measures that are used to evaluate how well the new technology provides a correct diagnostic classification are known as test sensitivity and specificity.

Sensitivity

A sensitive test helps rule out disease (when the result is negative).

If a test is highly sensitive and the test result is negative, you can be nearly certain that they don’t have disease.

5 Gold Standard, U.S. National Library of Medicine, Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636062/>

6 National Institute of Health (2013, September 13) What the Numbers Mean: An Epidemiological Perspective on Hearing, Measuring Hearing Loss, *National Institute of Health*, Retrieved from <https://www.nidcd.nih.gov/health/statistics/what-numbers-mean-epidemiological-perspective-hearing>

7 Kerlinger, F.N. & Lee, (2000), *Foundations of behavioral research* (4th ed.) New York: Harcourt Brace.

8 Thorndike, R.M., Cunningham, G.K., Thorndike, R.I., & Hagen, E.P. (1991). *Measurement and evaluation in psychology and education* (5th ed.) New York: Macmillan.

Specificity

A very specific test rules in disease with a high degree of confidence

If the test result for a highly specific test is positive you can be nearly certain that they actually have the disease.⁹

For hearing conservationists, a validation study for STS that has poor specificity or sensitivity will fail to identify individuals whose hearing has changed and may incorrectly identify a number of individuals whose hearing has not changed. Specificity and sensitivity values of 90 and 89 percent in an STS study would suggest that at least 10 percent of patients will be misdiagnosed as having an STS when they don’t AND at least 10 percent of patients tested will be misdiagnosed as not having an STS when they do.

A number of tablet “validation studies” investigate how well a tablet audiometer is able to identify hearing loss; i.e. does the patient being evaluated have a mild or moderate hearing impairment. While hearing loss is always a concern for hearing conservationists, the more important issue is whether an employee’s hearing has CHANGED. Hearing loss is not the same as a change in hearing thresholds. Tablet based hearing conservation systems need to validate their studies based on STS and not on hearing loss classification.

If a tablet manufacturer cites a study as an endorsement, does it mean that the device is as good as the gold standard? One study by the Mayo Clinic found that 4.8% of results from the tablet device differed by 10 dB or greater than those determined by conventional audiometry, and that crosstalk and linearity failed in initial assessments¹⁰. Another study had sensitivity as low as 86.5 suggesting that almost 14% of patients were not diagnosed correctly.¹¹ A tolerance of +/- 10dB for audiometer output levels would suggest that the audiometer is not suitable for determining STS’s. Excessive crosstalk and non-linearity problems means that these tablets were not ANSI and OSHA compliant at the time of initial testing. This raises hardware quality control concerns. So, is a new diagnostic tool (tablet audiometer) that is not always OSHA and ANSI compliant, has a tolerance of +/-10dB and misdiagnoses 14% of the test population better or even equivalent to the gold standard?

Regarding the use of sound booths for testing, audiologists look at several factors that can influence hearing thresholds. The frequency of background noise and upward spread of masking play a significant role with low frequency sounds - especially when noise is intermittent or periodic in nature. Auditory vigilance is an issue when competing speech, music or environmental sounds influence concentration. Noise that affects the task at hand - responding appropriately to the auditory stimulus - need not be loud to be influential. Studies that validate noise cancellation strategies should be conducted in industrial noise environments where the noise spectrum is varied, intermittent, often low in frequency and where environmental sounds can affect task performance.

9 <https://www.med.emory.edu/EMAC/curriculum/diagnosis/sensand.htm>

10 Thompson GP, Sladen DP, Borst BJ, Still OL, “Accuracy of a Tablet Audiometer for Measuring Behavioural Hearing Thresholds in a Clinical Population”, *Journal of Otolaryngology Head and Neck Surgery*, 2015, Nov, 153(5):838-42.

11 Saliba J, Al-Reefi M, Carriere JS, Varma N, Provencal C, Rappaport JM. “Accuracy of Mobile-Based Audiometry in the Evaluation of Hearing Loss in Quiet and Noisy Environments” *Journal of Otolaryngology Head and Neck Surgery*, 2017, Apr; 156(4):706-11.

While tablet technology offers promise as an additional tool for hearing conservationists, there are no studies that examine their specificity and sensitivity when evaluating standard threshold shifts. The methodology for OSHA calibration compliance may be flawed and quality control issues were found in referenced validation studies. A tolerance of +/-10dB is unacceptable for STS determination. More studies need to be conducted that evaluate the effectiveness of STS determination when noise cancelling devices alone are used in intermittent low frequency industrial noise environments. As such, I believe there is insufficient evidence to suggest that tablet audiometers and noise reduction technologies are currently suitable for use in occupational hearing conservation programs.

Biography

Robert Dietz is a clinical audiologist and strategic medical surveillance consultant specializing in occupational noise exposure measurement, medical surveillance data acquisition, employee health data analysis and computerized health management systems integration. Since 1975, he has been responsible for the development, implementation and maintenance of occupational hearing conservation programs for leading fortune 500 companies nationwide. Dr. Dietz received his Au.D. and his M.B.A. degrees from the University of Connecticut. He holds a B.S. Degree in Electrical Technology from New York Institute of Technology and a A.S. Degree in Engineering Science from the State University of New York at Farmingdale. Dr. Dietz is a member of the American Speech-Language Hearing Association with a certificate of clinical competence in audiology.

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