Build Practice Success with Hearing Aid Verification

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Speaker Disclosure

- Relevant Financial Relationships:
 - Employee of Audioscan

- Relevant Nonfinancial Relationships:
 - -None



Learning Objectives

- Why verification services are needed
- How verification services can build practice success
- New tools supporting accurate & efficient verification
- Verification workflow considerations



Build Practice Success

Why verification services are needed



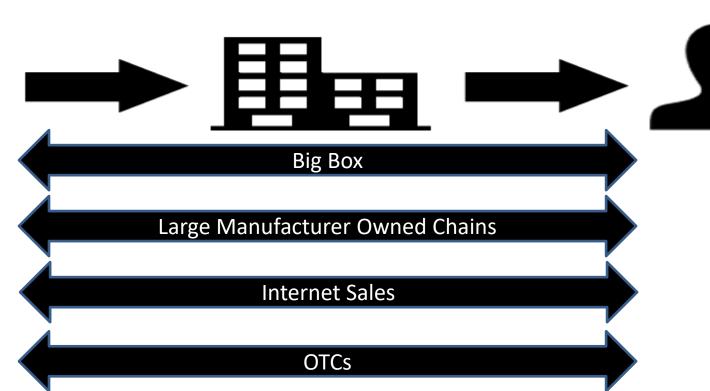
Evolving Product and Service Delivery

Manufacturer

"Historic" Distribution (Private, Hosp., VA, Clinics, Small Chains)

Consumer





Evolving Product and Service Delivery

- Expected to...
 - Provide improved access to "hearing aids"
 - Offer lower cost alternatives than historically available
 - Drive consumer focus towards product as the sole solution



How to address 'product focus', differentiate and build practice success?

Verification Services

"Real-ear measurement"



REM associated with...

- Improved audibility
- Improved listening outcomes
- Improved patient satisfaction
- Improved patient loyalty
- Improved perceived quality of services
- Improved fitting efficiency (reduce fitting visits)



^{*}See Valente et al. (2018); Amlani et al. (2016, 2017); Abrams et al. (2012); Aazh & Moore (2007), etc.

"Prescribed gain (output) from a validated prescriptive method should be verified using a probe-microphone approach that is referenced to ear canal SPL."

American Academy of Audiology Best Practice Guidelines (2006)

Ethical Considerations

"Members shall use all resources to provide the best possible service."

"Members shall evaluate services and products rendered to determine effectiveness".

Principle 1: ADA Code of Ethics "Members shall provide only those procedures, products and services that are in the best interests of the patient."

Principle 3: ADA Code of Ethics

Are we conducting REM?





Mueller (1999); Mueller (2003); Mueller (2005); Mueller & Picou (2010); Mueller (2014); Valente (2022)



Some Reasons for NOT using REMs...

- "The fitting software will set it right, shows me what I need."
- "Patients don't like it at target."
- "Too time consuming"
- "Too difficult"
- "Doesn't make a difference" [to my patients or my practice]



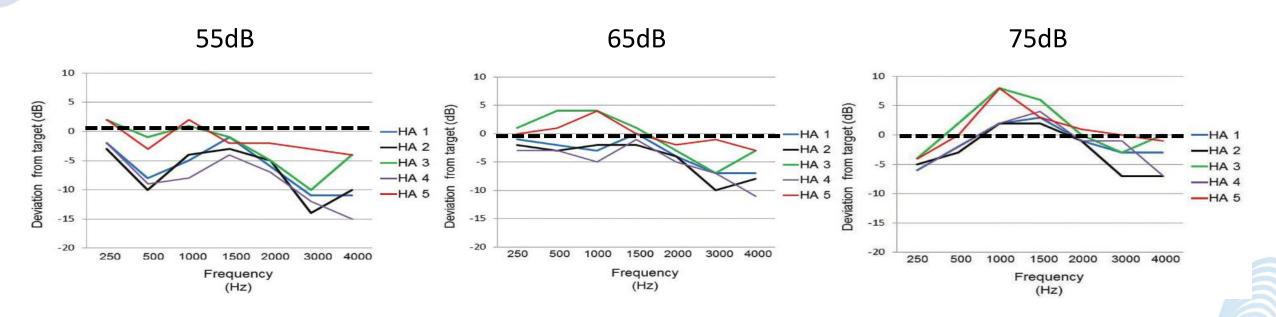
Many studies have shown quick-fit underamplifies, including...

- Swan and Gatehouse (1995)
- Hawkins and Cook (2003)
- Aarts and Caffee (2005)
- Aazh and Moore (2007)
- Aazh et al (2012)
- Abrams et al (2012)
- Boymans and Dreschler (2012)

- Leavitt and Flexer (2012)
- Munro et al (2015)
- Sanders et al (2015)
- Amlani et al (2017)
- Valente et al (2018)
- Folkeard et al (2018)
- Pumford and Mueller (2020)
- •



NAL-NL2 REAR Results Using 5 Different Manufacturers' Programming Software

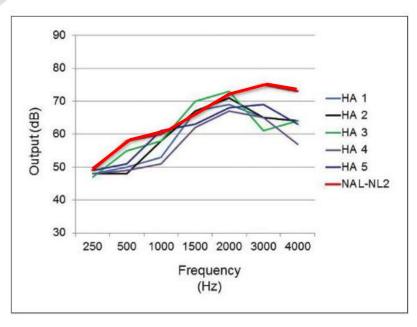


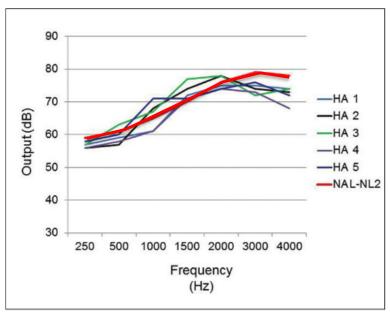
Fitting software showed match within 1 dB!

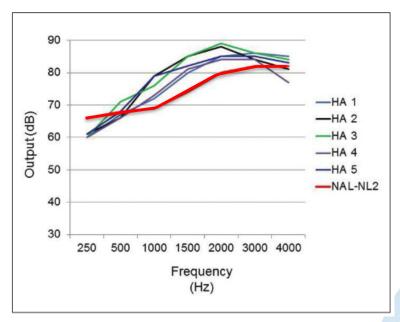
Sanders, J., Stoody, T., Weber, J., Mueller, H., "Manufacturers' NAL-NL2 Fittings Fail Real Ear Verification" Hearing Review, March 2015; 21(3): 24-32



NAL-NL2 Comparison to 5 Different Manufacturers' Proprietary Fittings







75dB

55dB

65dB

N = 16

Sanders, J., Stoody, T., Weber, J., Mueller, H., "Manufacturers' NAL-NL2 Fittings Fail Real Ear Verification" Hearing Review, March 2015; 21(3): 24-32



Importance of 'Verified' Audibility

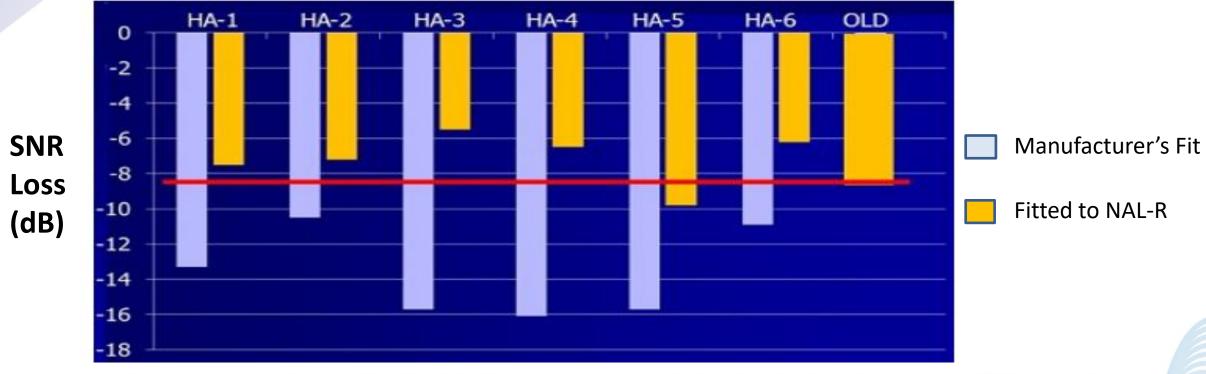
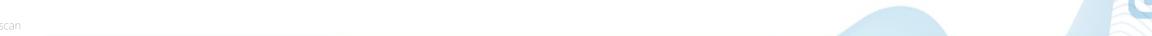


Figure 7. Performance for the aided QuickSIN presented in soundfield at 57 dB SPL. Bars indicate SNR loss. The average SNR disadvantage as compared to individuals with normal hearing. (Adapted from Leavitt & Flexer, 2012).

N = 5

Leavitt R., & Flexer, C. (2012). The importance of audibility in successful amplification of hearing loss. H Review, 19(13), 20-23. From Mueller, H.G. (2014, January). 20Q: Real-ear probe-microphone measures - 30 years of progress? AudiologyOnline,



Importance of Verified Audibility – Real world

- Valente et al. (2018)
 - Double-blind randomized cross-over design
 - -N = 24 New users; Mild to Mod losses
 - Fitted w/'Premium' RICs
 - REM (NAL-NL2) or Quick-Fit to Proprietary (~4 wks)
 - Verified NAL-NL2 fittings significantly better
 - Lab (e.g., speech recognition in quiet)
 - Real-world (e.g., APHAB)
 - Preference (19 of 24; ~ 80% preferred verified NL2 fitting)

Valente, M et al. (2018). Differences in word and phoneme recognition in quiet, sentence recognition in noise, and subjective outcomes between manufacturer first-fit and hearing aids programmed to NAL-NL2 using real-ear measures. JAAA, 29(08), 706-721.



Effect of Service Delivery on Hearing Aid Outcomes

- 154 Older Adults; Mild-to-Mod SNHL
- Mini-BTE HI's (6 wk trial)
 - Best practice (BP) (REM, HAO)
 - OTC (no REM, no HAO)
 - Placebo (REUG, HAO)
- BP and OTC provided benefit
 - PHAB, CST, HHIE
- However,
 - BP higher satisfaction than OTC
 - BP more likely to purchase (81%) than OTC (55%)
 - Placebo purchased by <u>36%</u>



Research Article

The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial

Larry E. Humes, a Sara E. Rogers, Tera M. Quigley, Anna K. Main, Dana L. Kinney, and Christine Herring

Objectives: The objectives of this study were to determine efficacy of hearing aids in older adults using audiology best practices, to evaluate the efficacy of an alternative over-the-counter (OTC) intervention, and to examine the influence of purchase price on outcomes for both service-delivery models. Design: The design of this study was a single-site,

prospective, double-blind placebo-controlled randomized trial with three parallel branches: (a) audiology best practices (AB), (b) consumer decides OTC model (CD), and (c) placebo devices (P). Outcome measures were obtained after a typical 6-week trial period with follow-up 4-week AB-based trial for those initially assigned to CD and P groups.

Setting: Older adults from the general community were recruited via newspaper and community flyers to participate at a university research clinic.

Participants: Participants were adults, ages 55–79 years,

Participants: Participants were adults, ages 55–79 years, with mild-to-moderate hearing loss. There were 188 eligible participants: 163 enrolled as a volunteer sample, and 154 completed the intervention.

Intervention(s): All participants received the same highend digital mini-behind-the-ear hearing aids fitted bilaterally. AB and P groups received best-practice services from audiologists; differing mainly in use of appropriate (AB) or placebo (P) hearing aid settings. CD participants self-selected their own pre-programmed hearing aids via an OTC model. Primary and Secondary Outcome Measures: Primary outcome measure was a 66-item self-report, Profile of Hearing Aid Benefit (Cox & Gilmore, 1990). Secondary outcome measure was the Connected Speech Test (Cox, Alexander, & Gilmore, 1987) benefit. Additional measures of hearing-aid benefit, satisfaction, and usage were also obtained.

Results: Per-protocol analyses were performed. AB service-delivery model was found to be efficacious for most of the outcome measures, with moderate or large effect sizes (Cohen's d). CD service-delivery model was efficacious, with similar effect sizes. However, CD group had a significantly (p < .05) lower satisfaction and percentage (CD: 55%; AB: 81%; P: 36%) likely to purchase hearing aids after the trial.

Conclusions: Hearing aids are efficacious in older adults for both AB and CD service-delivery models. CD model of OTC service delivery yielded only slightly poorer outcomes than the AB model. Efficacious OTC models may increase accessibility and affordability of hearing aids for millions of older adults. Purchase price had no effect on outcomes, but a high percentage of those who rejected hearing aids paid the typical price (85%).

Trial Registration: Clinicaltrials.gov: NCT01788432; https://clinicaltrials.gov/ct2/show/NCT01788423

Humes et al. (2017). Effects of service delivery model and purchase price on hearing aid outcomes in older adults.... American Journal of Audiology.

OTC: 'Self-fit' vs 'Validated NAL-NL2'

		Best for subject based on NAL-NL2			
	Device / Setting	X	Υ	Z	
Selected by subject	X	12	41	10	63
	Υ	1	13	11	
	Z	2	8	4	



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RESEARCH

Improving Patient Perception of Clinical Services Through Real-ear Measurements

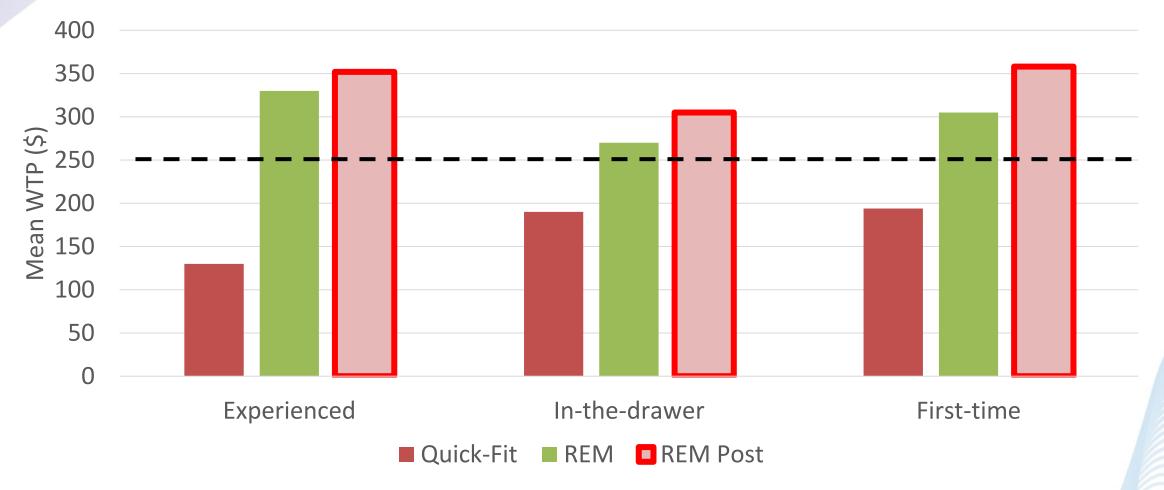
Published on November 22, 2016

Research | December 2016 Hearing Review

REM builds patient loyalty and is viewed as valuable to a wide range of patients

By Amyn M. Amlani, PhD, John Pumford, AuD, and Erich Gessling

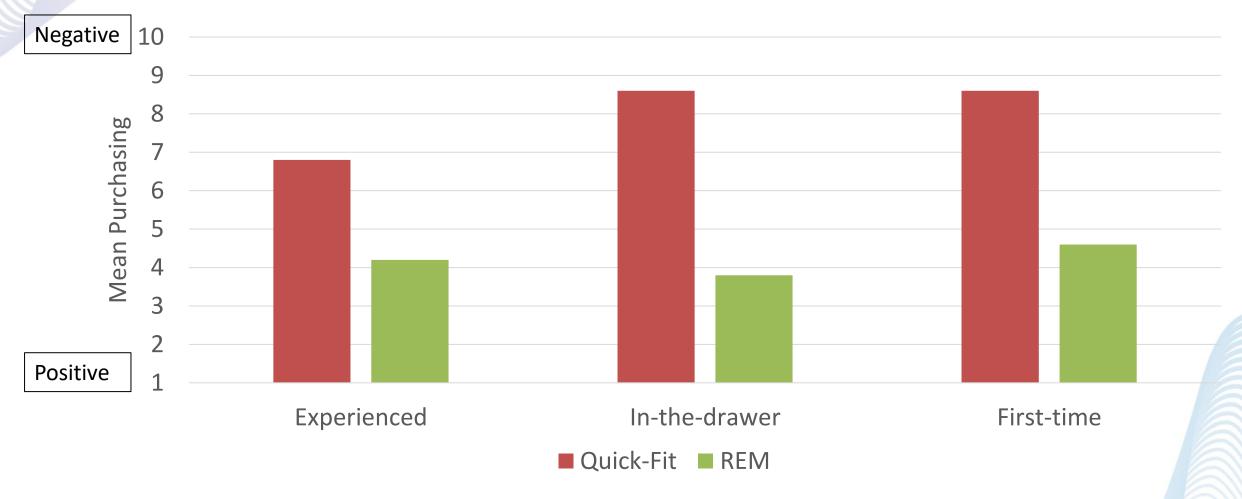
Willingness-to-Pay



"The average cost to provide services for a hearing aid fitting is \$250 per hour. Assuming no reimbursement assistance of any kind, how much would you be willing-to-pay for the services you were provided?"



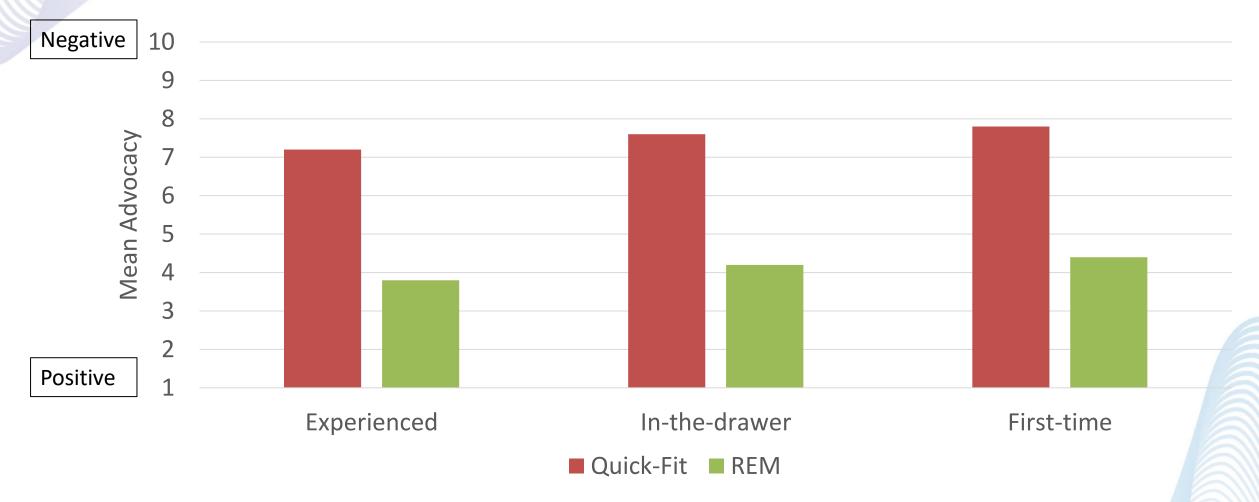
Loyalty



"What is the likelihood that you would expand your purchase of <u>additional</u> services offered by this provider?"



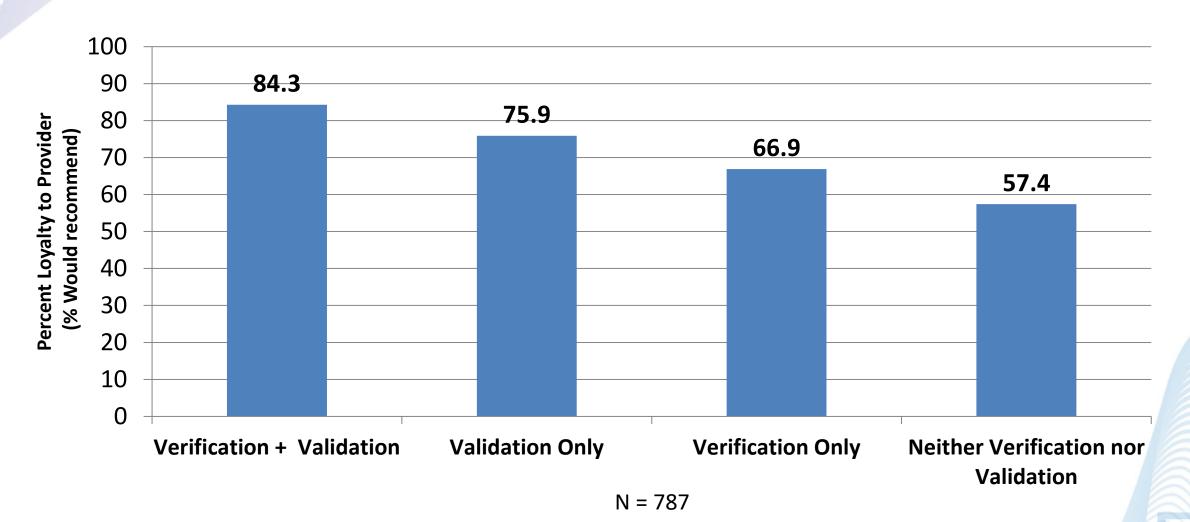
Loyalty



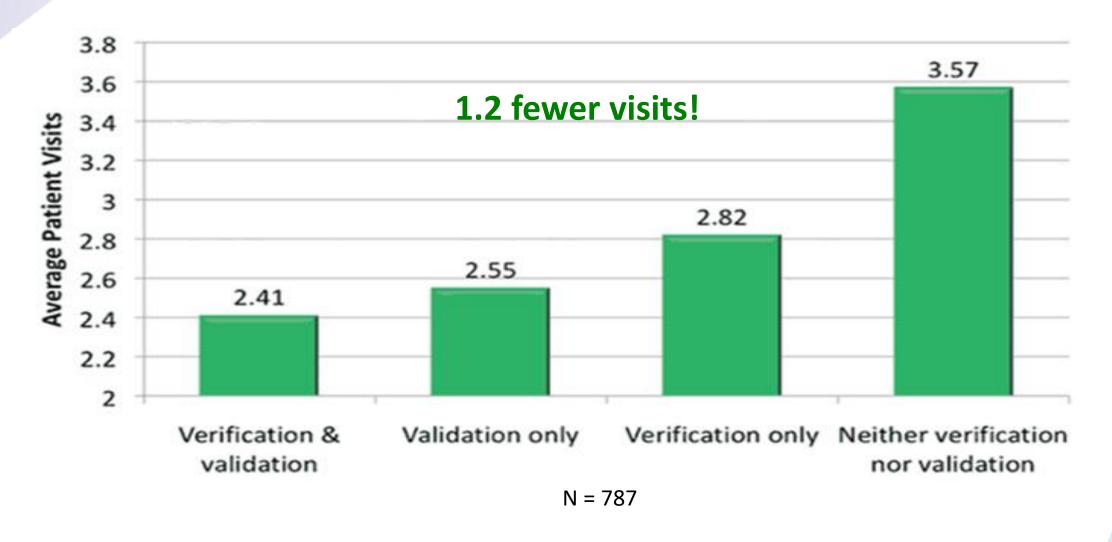
"What is the likelihood that you would recommend this provider to family and friends?"



Best Practice and Patient Loyalty



Best Practice and Patient Visits





Build Practice Success

Verification has never been easier, more accurate or more efficient

Leverage Verification Efficiency Options



Software-assisted Probe Tube Placement



Automated Verification to Target (AutoREMfits)



Pre-fitting devices via simulated REM (Test-Box)



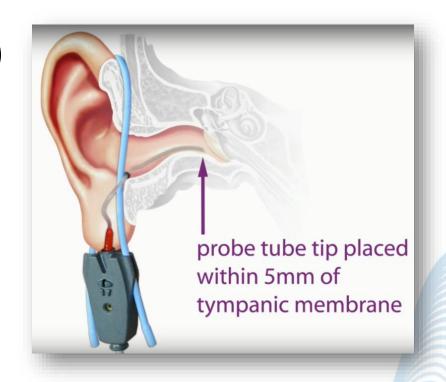
Simultaneous bilateral measurements



Typical REM fitting < 10 mins

Probe Tube Placement

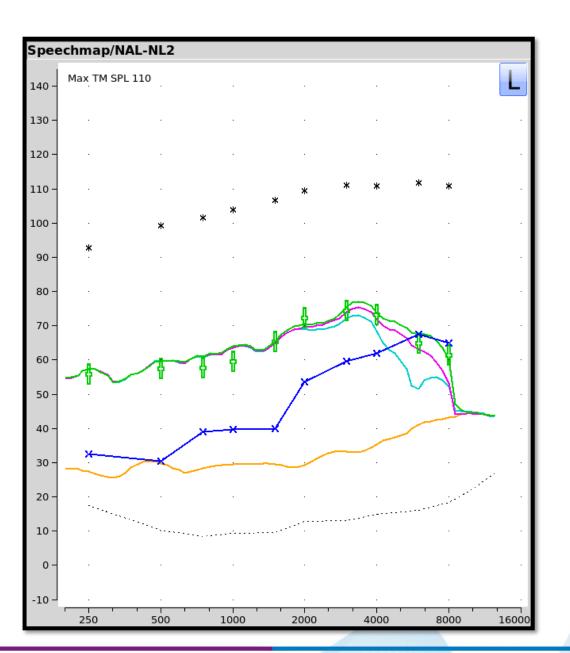
- Location near TM required for accuracy (~5mm)
- Minimizes contamination of 'standing waves'
- Challenging
 - Too deep = patient discomfort
 - Too shallow = measurement error





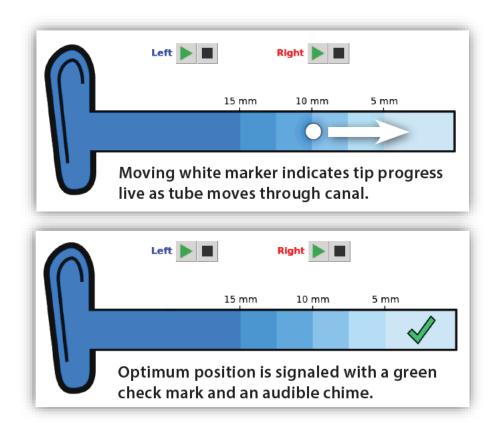
Impact of probe tube location

- Green Curve = within 5mm of TM
- Purple Curve = extracted ~ 5mm
- Blue Curve = extracted ~ 10 mm
- Orange Curve = fully plugged

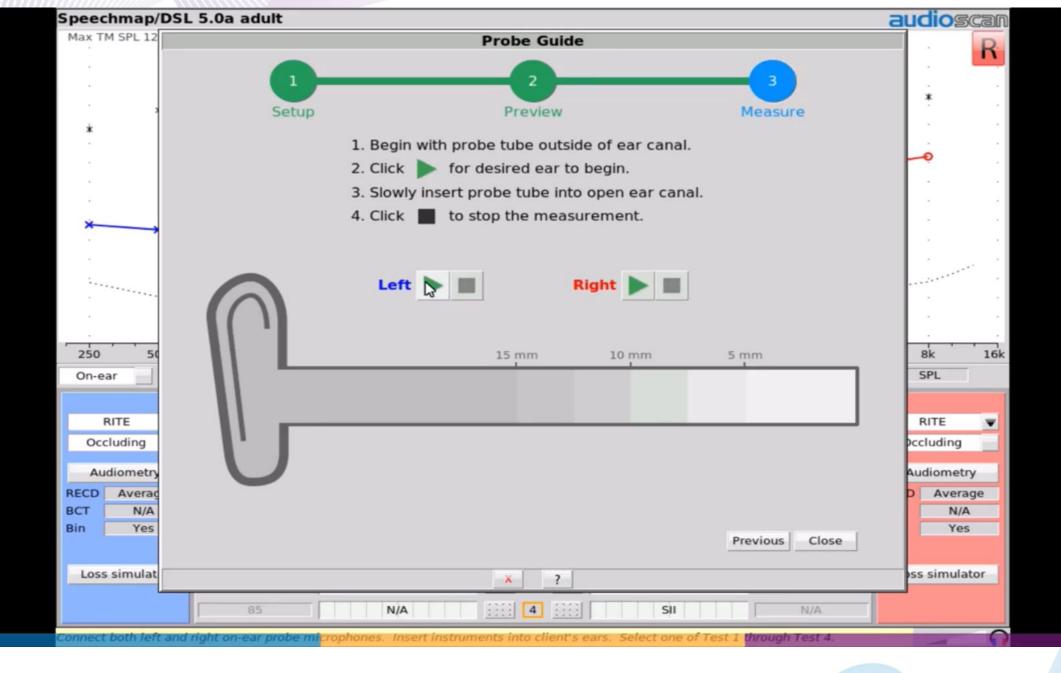


Probe *GUIDE*

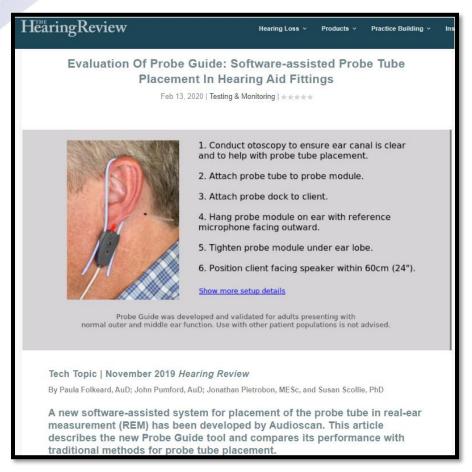
- Software-assisted probe tube placement system
- Analyzes sound waves in ear canal to determine probe tube location & guide placement
- Real-time measures compared to acoustic model to indicate when probe tube ~ 5mm of TM







How well does it work?



Key Takeaways

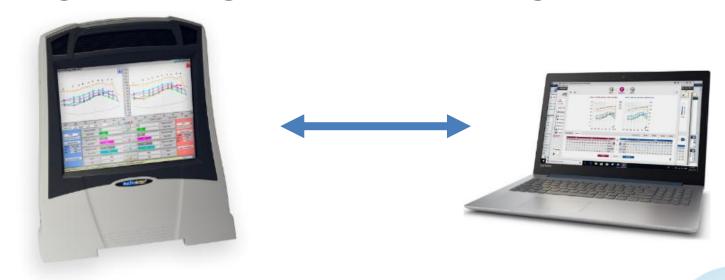
- PG equivalent to experienced clinician using typical visual method
 - Acoustic Measures
 - Marked Depth
 - Visual Inspection
 - Lack of Eardrum Contact

Folkeard P, Pumford J, Pietrobon J, Scollie S. Evaluation of Probe Guide: Software-assisted probe tube placement in hearing aid fittings. Hearing Review. 2019;26(11).



autoREMfits

- Automatically measure and adjust hearing aid to targets
- Fitting software and REM system exchange data
- Clinician conducts some initial background programming
- Actual programming of device to target done automatically



Some reasons to consider autoREMfits:

- Faster fit to target than manual
- Potential for improved target match
 - –Unfamiliar products / software
 - Inexperienced verifiers



How well does it work?



Key Takeaways

- Better target match than quick fit
- Equivalent target match as experienced clinician using manual methods
- Less time to verify to target (~50% less)

Folkeard P, Pumford J, Abbasalipour P, Willis N, Scollie S. A comparison of automated real-ear and traditional hearing aid fitting methods. Hearing Review. 2018;25(11):28-32.



How well does it work?

Using autoREMfit for Hearing Aid Fitting and Verification: Evidence of Accuracy and Reliability

This clinical study examines the new autoREMfit application of Audioscan VerifitLINK as integrated into Signia Connexx hearing aid fitting software. The results reveal good fit-to-target accuracy (RMSE ~2 dB; 65 dB SPL input) for two different audiograms and coupling systems. Test-retest reliability was excellent with no value greater than 1 dB at any frequency Clinical benefits of this autoREMfit collaboration are discussed.

hearing aids (HA) is ensuring that the is necessary for all hearing aid fittings.



tainly one of the most critical aspects This evidence leads to the logical conclusion fication equipment, assessing the difference related to the fitting and dispensing of that real-ear probe-microphone verification

gain and output have been optimized for a Probe-microphone (aka real-ear) meagiven user across frequencies. While to some sures, as we know them today, have been get is obtained. The HCP still has to make extent, this is patient-specific, we do know clinically available for 35 years. The use of some pre-fitting decisions in the HA fitting that on average, the best starting point is a this verification approach has been part of all software, ensure that the patient is seated validated prescriptive fitting method, such as dinical guidelines from professional organic correctly and the probe tube placement is the NAL-NL21 or the DSLv5.0.2 Research has 2 attorns that have been written since that time. appropriate, but the fit-to-target itself is autoshown that a verified fitting to either of these Some documents, in fact, go so far as to state matic, Today, there are at least five different validated generic fitting formulas will provide what frequency-specific dB deviations from verification equipment companies that have increased benefit when compared to alterna- prescriptive targets are allowable. Despite partnered with four leading hearing aid mantive choices, such as the manufacturers' proprietary fittings in both adults and pediatrics the support from professional organizations, autoREMfit option.12 Overall. research with (see Mueller, Ricketts, and Bentler3 for a many hearing care providers (HCPs) do not these different autoREMfit approaches has review). Clinical studies have also shown that conduct this testing at all, or do not use it to shown them to be reasonably accurate and the manufacturers' versions of these validated verify prescriptive targets. Surveys from past reliable, 13-36 generic fitting formulas typically do not result vears indicate that probably no more than in targeted behavior in the real-ear (including 30-40% of HCPs fitting hearing aids routinely when there is a perfect match to target dis- conduct probe-mic measures, and many who First, the fit-to-target most likely is faster do, do not use them for validating prescrip- than that accomplished with traditional HCP

plexity of the hearing aid programming that fitting. would be involved, the HCP is not skilled in or the real-ear fit-to-target process is perceived as too time consuming.

partnered to develop an automated method fitting software, not those of the verification

refer to as autoREMfit (each company tends to have their own name for the procedure; see Mueller and Ricketts for a review10). AutoREMfit isn't something new; it has been around for 20 years,11 but there recently has been an increased interest. In principle, with autoREMfits, the hear-

ing aid manufacturers' software exchanges measurement and control data with the veribetween the real-time measured output and gramming adjustments until a match to tar-

As reviewed by Mueller, 12 there are several potential advantages to using autoREMfit. programming, even for an experienced pro-There are many reasons why verification vider.14.15 For someone who is new to proto prescriptive targets is not a routine practice gramming hearing aids, the autoREMfit is likely more accurate and consistent than the ing to think that ownership of the equipment HCP-fit. The procedure also comes in handy is a major factor. This doesn't appear to be when the need arises to program hearing aids true, as examined in the Mueller and Picou that the HCP normally doesn't work with. survey.8 We can, however, come up with Finally, the automated procedure is indeed several possible reasons why these disparate — impressive, and could be used as a sales tool. findings exist, including: the perceived com- helping to ensure patient confidence in the

probe-mic techniques and procedures, and/ cerns.10 Some autoREMfit implementations fit only to the REIG, not to output targets (ie, the REAR), some systems only fit to average-To address in part these issues, hearing aid level inputs, and several autoREMfit systems and real-ear equipment manufacturers have use the prescriptive targets from the HA

Key Takeaways

- Better target match than quick fit
- Good fit to target accuracy (RMSE ~2dB) for 2 different audiograms / couplings (open and closed)
- Excellent test-retest reliability (<=1 dB)

Pumford J, Mueller HG. Using autoREMfit for hearing aid fitting and verification: Evidence of accuracy and reliability. Hearing Review. 2020;27(8):24-27.



Pre-Fitting in the Test Box

Simulated Real-Ear Measurements (S-REM)

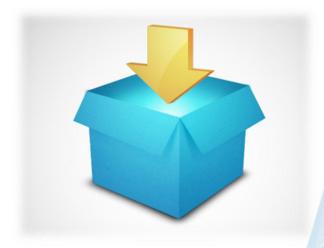


Benefit of Speechmap Test Box (Simulated REM)

Program devices to target without the patient

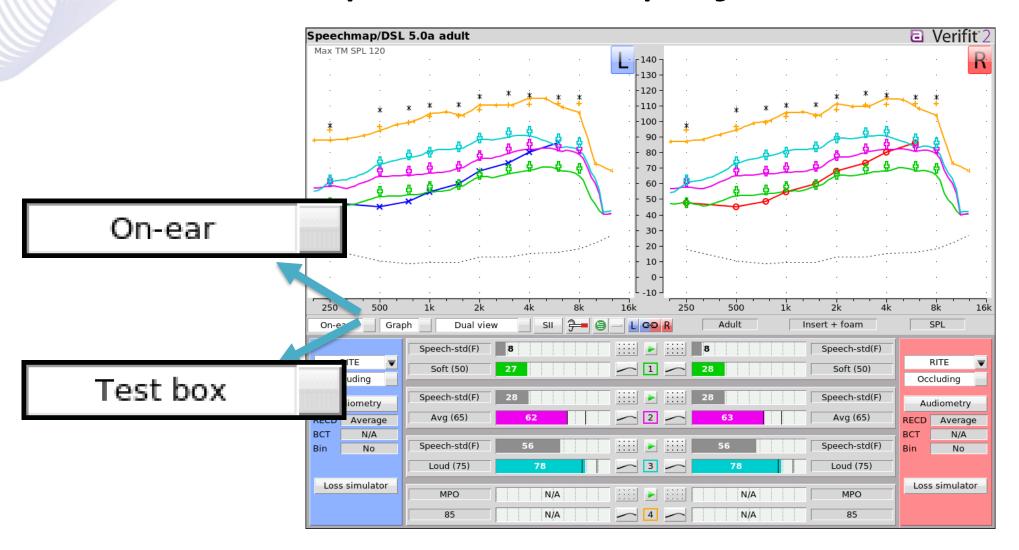




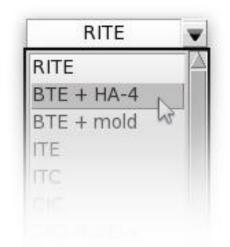




Same Speechmap, just in the box



Instrument type-specific MLE added to input signal





Patient-specific RECD added to coupler measurement

Audiometry

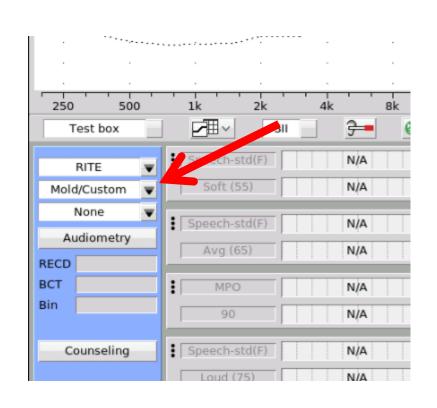
RECD Entr+foam

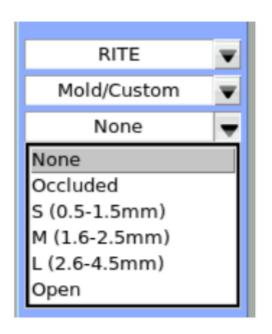
BCT N/A

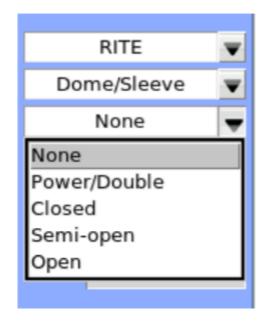
Bin Yes



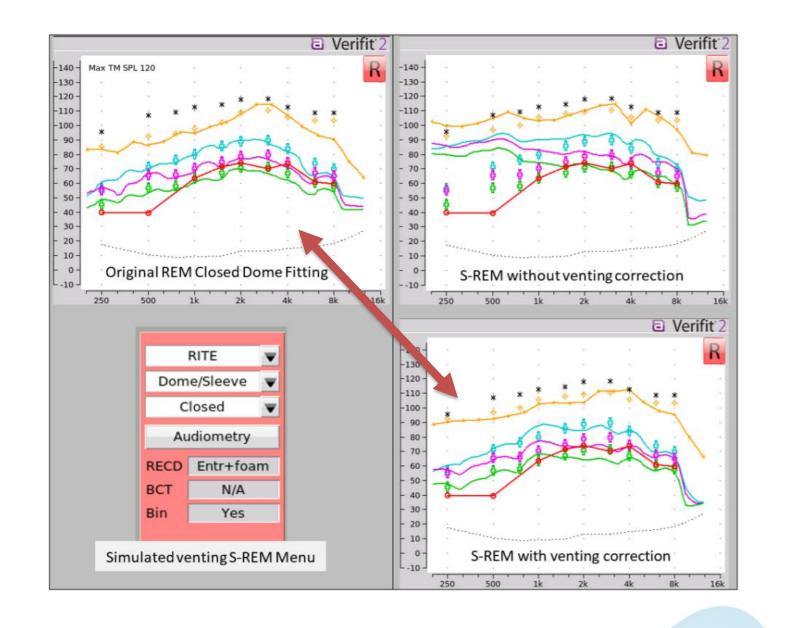
Venting Corrections in S-REM











How well does it work?

Accepted Manuscript

Submission Date: Accepted Date: Publication Date: 2021-09-16 2022-03-17

Journal of the American Academy of Audiology

Venting corrections improve the accuracy of coupler-based simulated real-ear verification for use with adult hearing aid fittings

Susan Scollie, Paula Folkeard, John Pumford, Parvaneh Abbasalipour, Jonathan Pietrobon.

Affiliations below.

DOI: 10.1055/a-1808-1275

Please cite this article as: Scollie S, Folkeard P, Pumford J et al. Venting corrections improve the accuracy of coupler-based simulated real-ear verification for use with adult hearing aid fittings. Journal of the American Academy of Audiology 2022. doi: 10.1055/a-1808-1275

Conflict of Interest: John Pumford and Jonathan Pietrobon are employees of Audioscan. Funding in support of this work was provided through matching funds from Audioscan to Dr. Scollie as Co-PI on a grant from the Ontario government (ORF-RE-08-072).

This study was supported by Ontario Research Fund, RE08-072

Abstract:

Background: Hearing aid responses can be verified with the Real Ear Aided Response (REAR). Procedures for predicting the REAR from coupler-based verification exist, but have not incorporated corrections for venting, limiting their use and validity for vented and open fittings. A commercially-available system for including venting effects in simulated real-ear measurement (S-REM) has recently been developed.

Purpose: To evaluate the accuracy of a vent-corrected S-REM for predicting the REAR across test levels, for fittings with a wide range of coupling styles including modular domes.

Research design: This was a within-subjects comparison study using technical measures. Retrospective file review was used to obtain previously-measured REARs from 104 fittings in 52 adults and three hearing aid styles. Prospective data collection was used to re-measure each fitting at three test levels using S-REM with and without venting corrections. Comparison of differences by frequency band were performed to assess the impact of the venting correction.

Results: The vent model reduced low-frequency error by up to 11 dB, and the effects were consistent with the expected effects of venting in hearing aid fitting: fittings with more open dome or tip styles had a larger improvement when the vent model was added. A larger sample of fittings was obtained for dome/sleeve couplings than for custom fittings.

Conclusions: The vent-corrected S-REM system evaluated in this study provides improved fitting accuracy for dome or sleevefitted hearing aids for adults and supports the use of vented S-REM for open fittings. Further study to examine a representative sample of custom tip or mold fittings, and fittings for children are future directions.

Key Takeaways

- Vent correction significantly improved accuracy of S-REM prediction of REM
- Particularly in LF's, average error reduced by ~ 10-15 dB for semi-open, open and vented earmold styles

Scollie, Folkeard, Pumford, Abbasalipour, Pietrobon (2022). Venting corrections improve the accuracy of coupler-based simulated real-ear verification for use with adult hearing aid fittings. JAAA. doi: 10.1055/a-1808-1275.

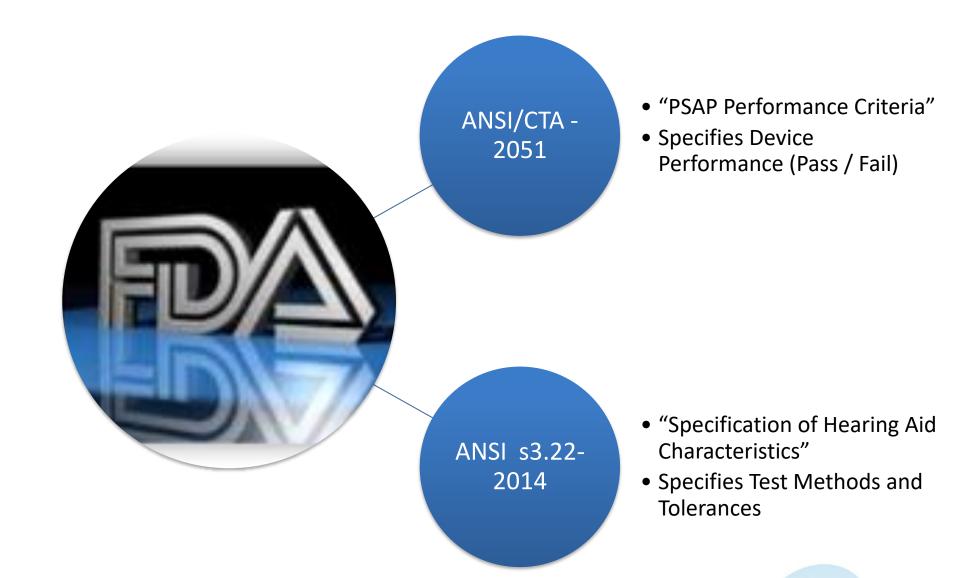


Build Practice Success

Verification workflow considerations with direct-to-consumer hearing devices



FDA OTC Final Rule and Verification

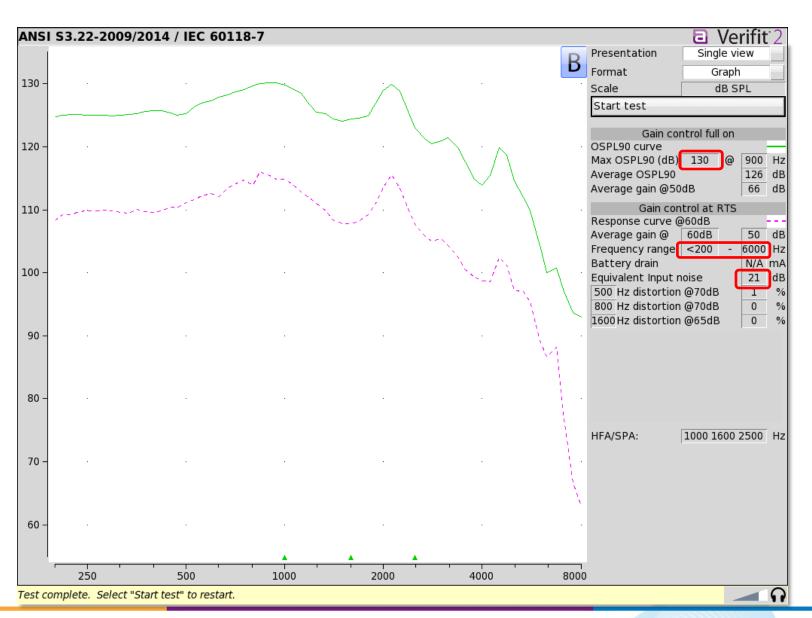


FDA OTC Final Rule – Technical Requirements

• Information <u>must</u> appear in user documentation

Measure	Requirement
Maximum output (OSPL90)	Not greater than 111 dB SPL peak (General) Not greater than 117 dB SPL peak (IC active)
Full-on gain (FOG50)	No limit
Total Harmonic Distortion (THD)	Not greater than 5%
Self-generated (internal) noise	Not greater than 32 dBA
Bandwidth	<=250 Hz up to 5000 Hz or greater
Latency	Not greater than 15 msec
Smoothness (Frequency response)	No peak in $1/3^{rd}$ octave > 12 dB above average levels of adjacent $1/3^{rd}$ octaves

Now: ANSI Test



But what about audibility?



Procedure:

- Evaluated a range of Hearing Aids and PSAPs re: target match capability
- Devices adjusted for best NAL-NL2 REAR target match
 - Soft (50) & Average (65) speech
- Determined % of total targets within +/- 5 dB from 250 – 6000 Hz

Concluded:

- Hearing Aids able to meet targets (suitable) for a range of hearing losses
- Most PSAPs able to meet targets (suitable) for only slight to mild hearing losses
- These OTC-like devices would not meet stated criteria that are suitable for mild to moderate losses

% of NAL-NL	.2 Targets Met	Flat-Moderately Sloping				
DEVICE	CATEGORY	VERY MILD	MILD	MODERATE	MODERATE- SEVERE	SEVERE
Phonak Audeo Q30 312	ENTRY LEVEL Hearing Instrument	100%	100%	100%	94%	94%
Phonak Audeo Q90 312T	PREMIUM Hearing Instrument	100%	100%	100%	94%	72%
Widex Unique Fashion 440	PREMIUM Hearing Instrument	78%	89%	89%	94%	89%
Widex Unique Fashion 110	ENTRY LEVEL Hearing Instrument	78%	78%	83%	89%	72%
AST Etimbre+ R1	INTERMEDIATE PSAP	94%	89%	56%	17%	0%
Plaid	INTERMEDIATE PSAP	94%	72%	67%	44%	17%
VitaSound		100%	78%	50%	28%	0%
Soundhawk*	ADVANCED PSAP	78%	78%	67%	11%	0%
Nuheara IQbuds	ADVANCED PSAP	78%	78%	61%	22%	0%
ExSilent Qleaf Lite		89%	83%	50%	0%	0%
ExSilent YTango Lite		44%	78%	61%	11%	0%
Tune Amp Tweak	INTERMEDIATE PSAP	83%	67%	67%	44%	33%
Etymotic Bean		39%	72%	83%	28%	0%
Sound World Solutions CS10	ADVANCED PSAP	67%	67%	50%	61%	22%
Austar AST Finner Group CIC*		6%	22%	28%	28%	56%
AST E33 Rechargeable	INTERMEDIATE PSAP	33%	28%	39%	56%	56%
Austar AST FE62*	INTERMEDIATE PSAP	67%	50%	72%	50%	44%

What to consider...

- Establish objective vetting procedure for OTCs to identify possible devices for adults w/mild to moderate HL
- Establish off-the-shelf OTC purchase procedure distinguishable from traditional hearing aid dispensing models
- Establish an OTC servicing plan for current and new patients (i.e., OTC purchased elsewhere) with clear fee schedule for services



Mock example for including OTCs

	OTC	Low	Mid	High
	Choosing device	Choosing device	Choosing device	Choosing device
	Expectation / uses	Programming –	Programming –	Programming –
	[Basic Verification	minimal features	several features	many features
	(ANSI)]	Verification	Verification	Verification
	Orientation – insertion, removal,	Pre-fit subjective outcome measure	Pre-fit subjective outcome measure	Pre-fit subjective outcome measure
	battery, cleaning	Orientation,	Orientation,	Orientation,
	~ 20 minute fitting	expectation, trial	expectation, trial	expectations, trial
	Audiology Assistant	period, care/use	period, care/use	period, care/use
	Cost = device + orientation	Cost = device + orientation + verification + programming	Cost = device + orientation + verification + programming	Cost = device + orientation + verification + programming
	e.g., (\$400x2) + 50 = \$650	e.g., (\$450x2) + \$1500 = \$2400	e.g., (\$850x2) + \$1500 = \$3200	e.g., (\$1300x2) + \$1500 = \$4100
Adapted from Palmer, C. (2018 hearing aids - opportunity or d				

Going Forward...

- The future impact of OTCs on the existing professional care environment is unclear
- Verification is a valuable clinical service we can use today to engage with prescription hearing aids <u>and</u> OTC devices



Summary

- Research and professional guidelines support the value of verification for patients and providers
- New verification tools can make the process easier and more efficient
- Verification services can be included in your workflow with traditional and OTC devices
- Verification services highlight clinician value in addressing hearing healthcare needs and support practice success

Thank You

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