

# A Comparative Analysis of Technical Performance and Effectiveness of Multiple Over-the-Counter Hearing Aids

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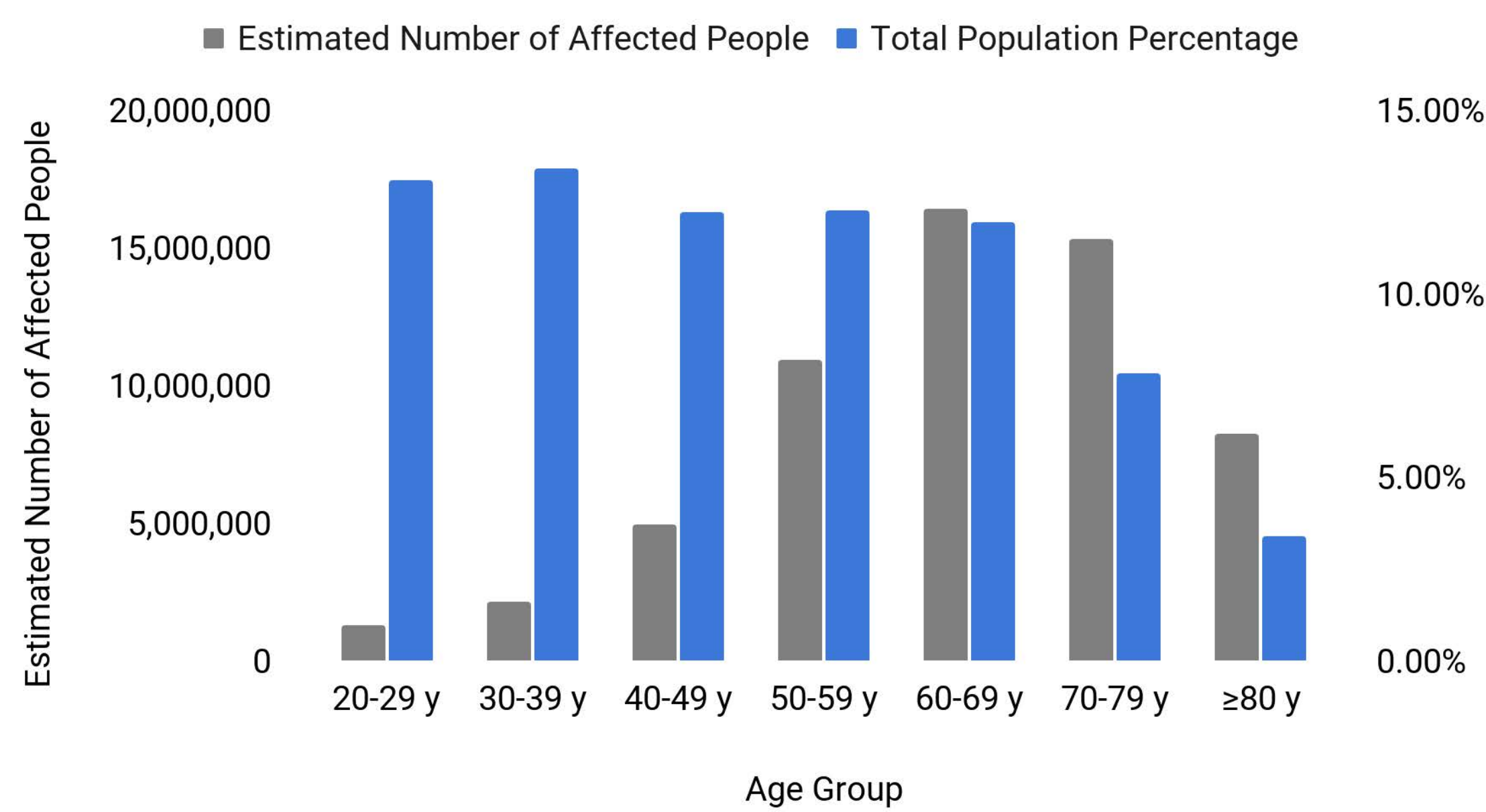
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## Problem Background

The FDA's October 2022 rules for over-the-counter (OTC) hearing aids (HA) offer adults with mild to moderate hearing loss (MMHL), defined as only hearing in or above the 26-40 dB and 41-55 dB ranges respectively (ASHA, 2024), an easier way to acquire them without prescriptions. (FDA, 2022) Despite increased accessibility, consumers face challenges in choosing from the vast array of available models due to limited pre-purchase information. Details are often only accessible through aftercare or apps after buying, which can lead to unmet expectations. Additionally, the absence of professional audiologist guidance in the OTC process means consumers miss out on personalized tuning and hearing assessments, which could affect the hearing aid's performance.

MMHL Statistics vs. Age Group



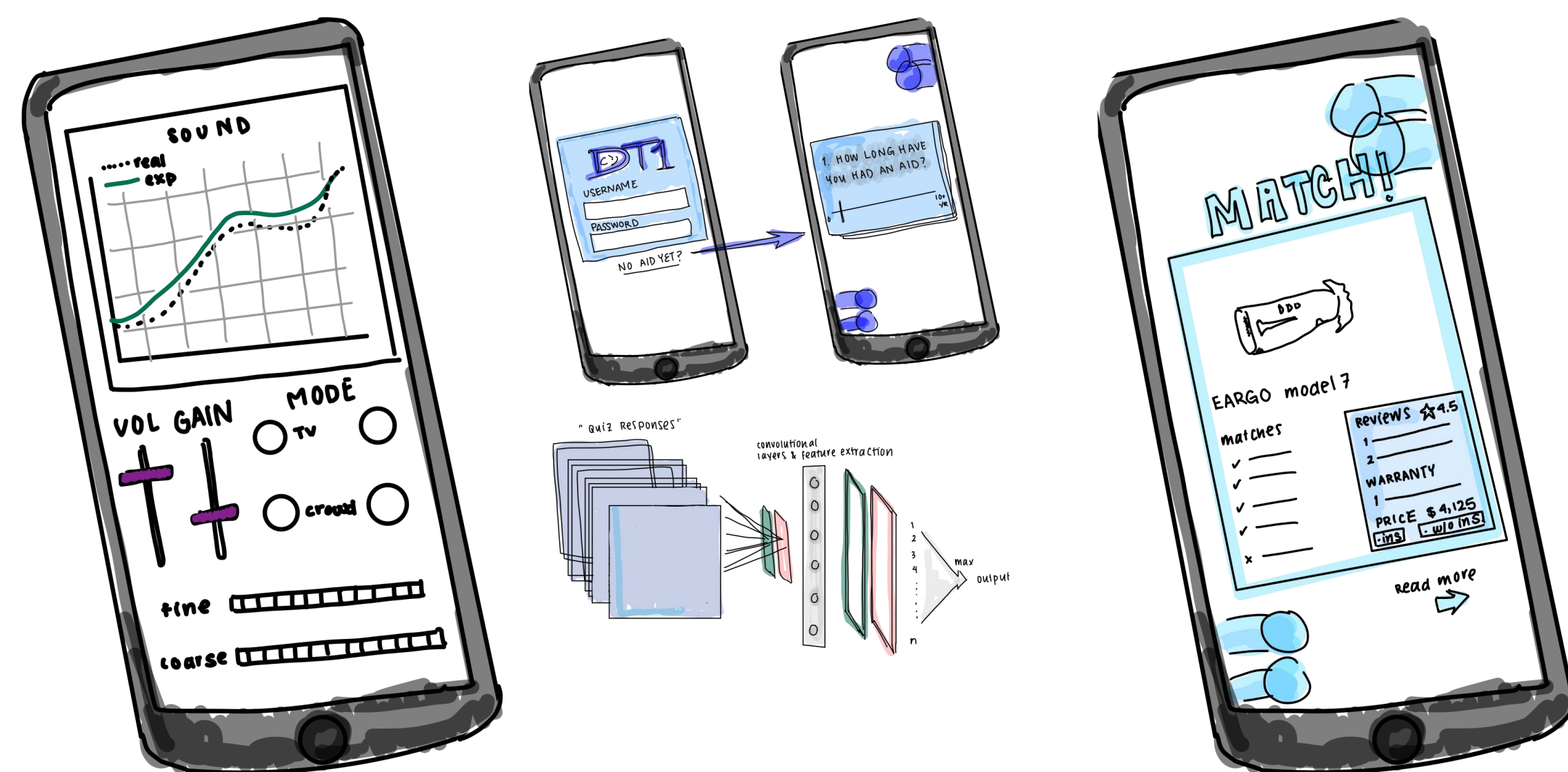
**Figure 1:** Population project of people with MMHL based on 2023 US census and a 2016 study. About 59.36 million Americans today suffer from unilateral or bilateral MMHL (Goman & Lin, 2016)

## Need Statement

Adults with MMHL need an improved method for monitoring their hearing, obtaining and maintaining their OTC HAs to enhance their hearing experience, attract new users and encourage continued usage of these devices.

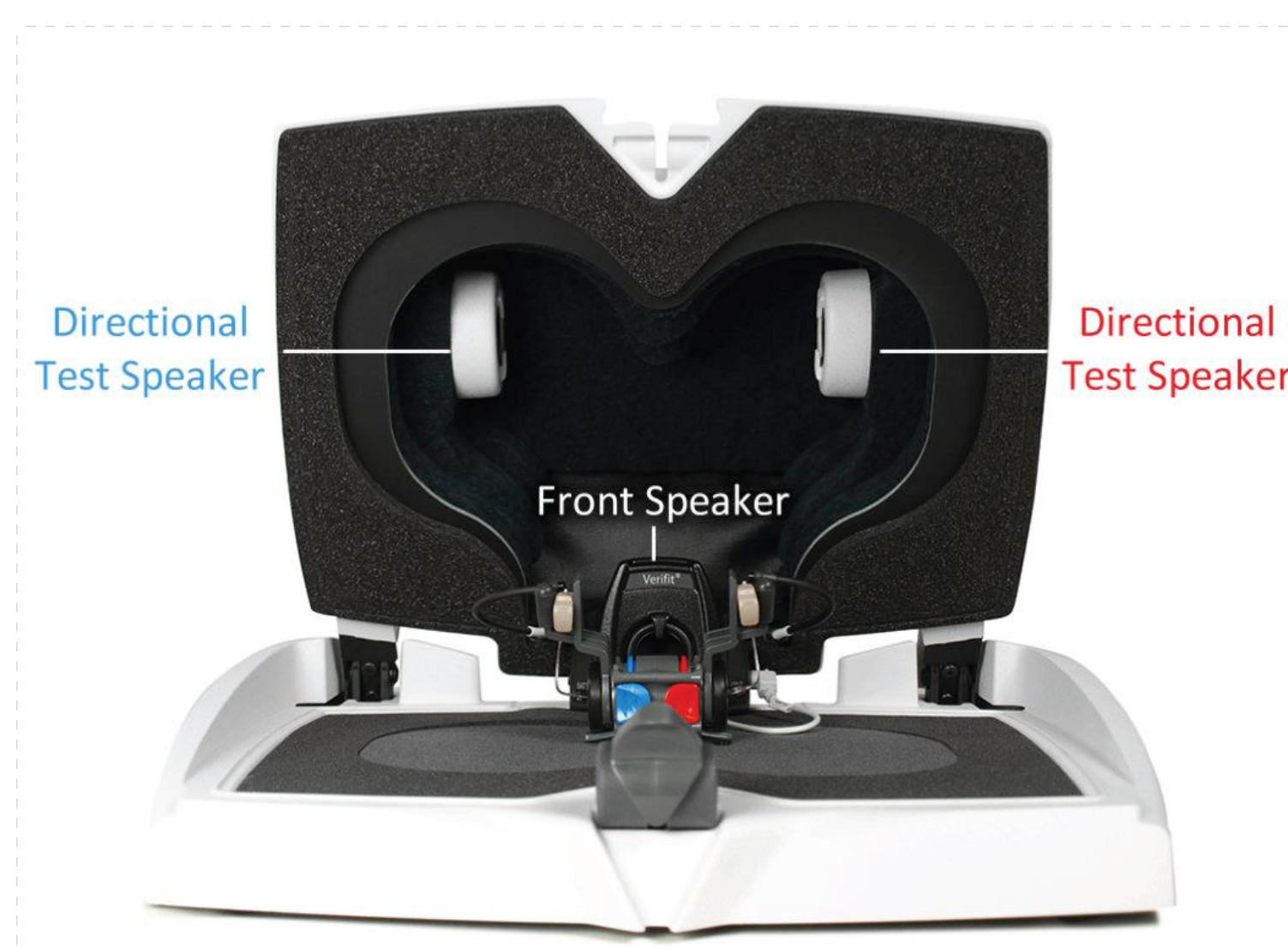
## Solution Objective

Perform regulatory compliance tests on OTC HAs to evaluate them against FDA published standards and manufacturer's specifications. Data collected will allow us to develop a solution ensuring users receive the most suitable HA pairing.



**Figure 2:** A graphical representation of the OTC HA matching process, enabling convenient access and accurate matching for the users.

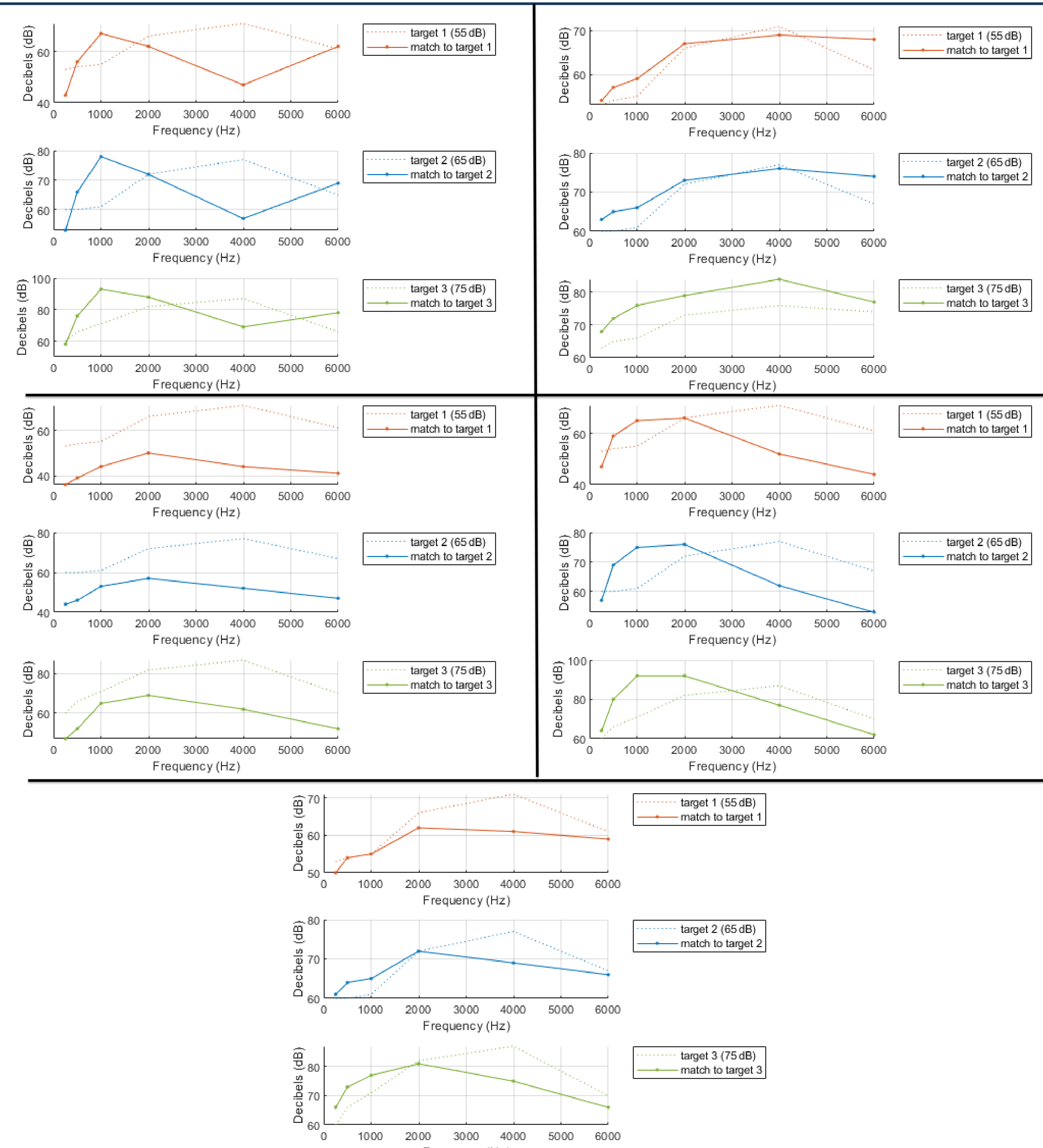
## Verification and Testing: Materials and Methods



**Figure 3:** Test box calibration set up. This is the apparatus used to conduct the various tests.

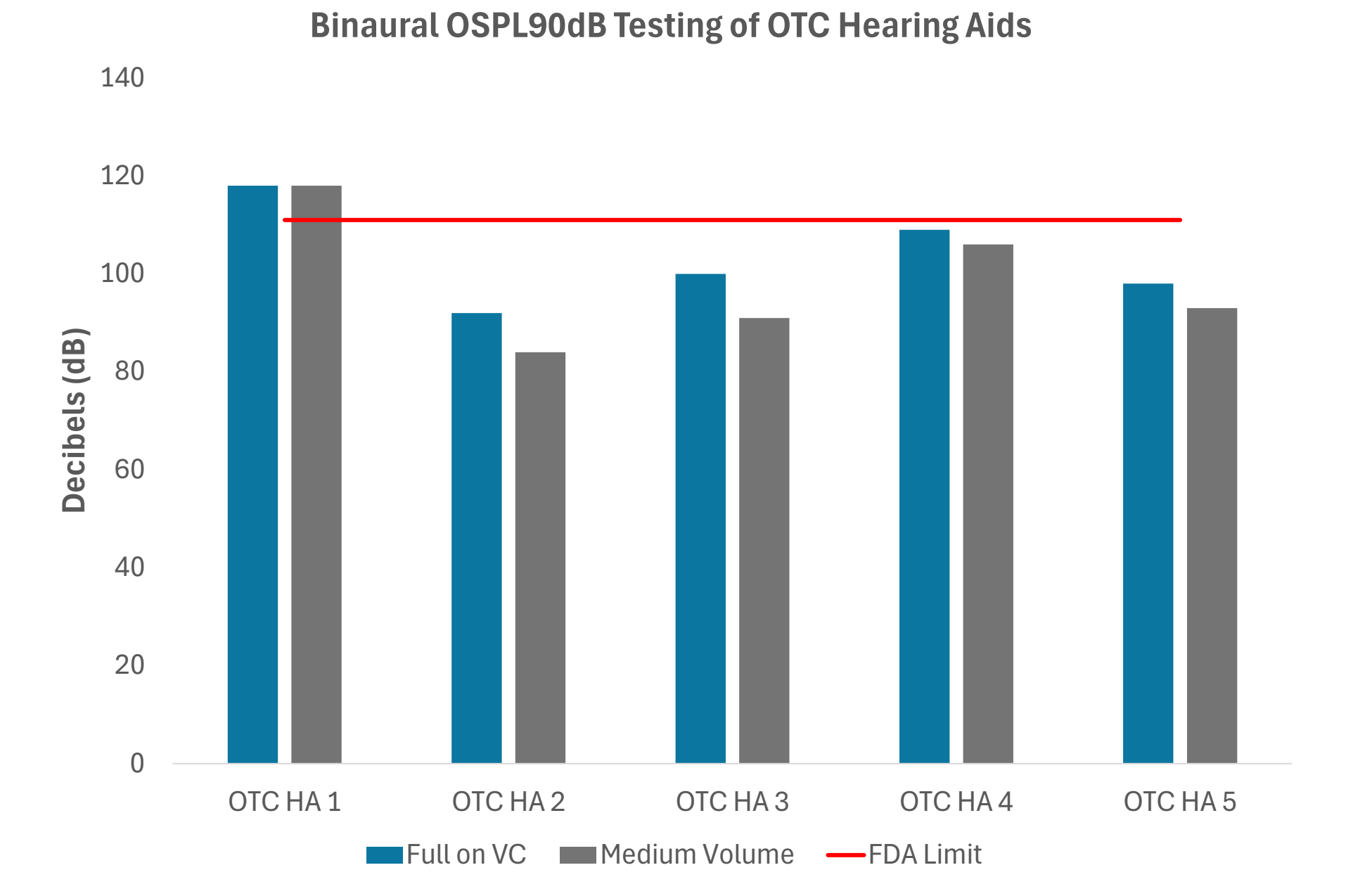
Audioscan Verifit 2 was used to evaluate several OTC hearing aid models, focusing on FDA-required descriptors and user usability for adults with MMH. ANSI tests were conducted simultaneously, assessing **OSPL-90dB**, **full-on gain**, and **harmonic distortion** using a blue 2cc coupler inside a test box. Additionally, speech mapping tests simulated mild to moderate hearing loss at various speech levels to check the OTC device outputs, using a silver 0.4cc coupler for setup.

## Preliminary OTC HA Speech Mapping Testing



**Figure 4:** Speech mapping test results of several OTC hearing aids. Tests performed for target 1 (soft 55 dB), target 2 (medium 65 dB) and target 3 (loud 75 dB) speech inputs. The dotted lines are the target output levels, whereas the solid lines are the measured output levels. Expected measured output levels should be within 5-10 dB of the target output levels, ideally above the target output levels.

## OSPL90dB, Binaural Full-on Gain Testing



**Figure 5:** Binaural OSPL90dB Measurement. This figure displays the maximum output sound pressure level achieved by a model of OTC HA when the input signal is at 90 dB SPL, highlighting the device's peak loudness capabilities. The columns represent the peak SPL recorded for the device, emphasizing their performance in potentially loud environments. Left shows output given full volume input, while right shows output given a medium volume input. Full on volume control is when the HA's volume is turned to max; same follows for medium volume.

## OTC HA Measurements vs. FDA Requirements

	OTC HA 1 Test Box Measures	OTC HA 2 Test Box Measures	OTC HA 3 Test Box Measures	OTC HA 4 Test Box Measures	FDA Required Specs
<b>OSPL 90dB</b>	118 dB	100 dB	109 dB	98 dB	111 dB SPL or 117 dB SPL
<b>Full-On Gain</b>	26 dB	17 dB	24 dB	10 dB	N/A
<b>Frequency Range</b>	<200-5000 Hz	<200-7100 Hz	300-4760 Hz	<200-8000 Hz	<250-5000 Hz
<b>Harmonic Distortion</b>	1%	1%	2%	0%	<= 5% at 500 Hz (67 dB & 97 dB)

**Figure 6:** OTC HA Performance. This table displays the results from the ANSI testing done several OTC HA devices. Each test done is compared to the specifications provided by the manufacturer as well as the required specifications by the FDA.

## Conclusion

Our preliminary analysis has pinpointed distinct functional capabilities among OTC hearing aids, enabling us to discern performance variations. We are expanding our testing to refine these findings and examining patient profiles more closely to optimize our hearing aid matching process.

## Acknowledgements

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