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DESIGN CONSIDERATIONS FOR OTC HEARING AIDS

ANDREW SABIN PH.D.
RESEARCH LEAD, BOSE HEAR. BOSE CORPORATION
FOR: AUDIOLOGY ONLINE. DECEMBER 16, 2020

*Any opinions expressed are my own, not those of Bose Corporation

Andrew Sabin, PhD

Andrew Sabin, PhD leads the research division of the hearing aid group at Bose Corporation. Prior to this he had a startup (Ear Machine) focusing on hearing aid self-fitting. He completed a Ph.D. in Communication Sciences and Disorders at Northwestern University in 2010.

- **Presenter Disclosure**: Financial: Andrew Sabin is employed by Bose. He received an honorarium for presenting this course. Non-financial: Andrew Sabin has no relevant non-financial relationships to disclose.
- **Content Disclosure**: This learning event does not focus exclusively on any specific product or service.
- **Sponsor Disclosure**: This course is presented by the American Auditory Society in partnership with AudiologyOnline.

Learning Outcomes

After this course, participants will be able to:

1. Describe the current state of federal regulation of OTC Hearing Aids.
2. Describe a variety of criteria that can be used to evaluate the quality of a self-fit hearing aid.
3. Provide an estimated percentage of individuals with hearing impairment that can be fit with a limited set of gain profiles.

1. WHAT IS THE CURRENT REGULATORY LANDSCAPE?

2. HOW DOES A USER FIT AN OTC HEARING AID?

3. HOW DO WE KNOW IF THAT FIT IS ANY GOOD?

1. WHAT IS THE CURRENT REGULATORY LANDSCAPE?

2. HOW DOES A USER FIT AN OTC HEARING AID?

3. HOW DO WE KNOW IF THAT FIT IS ANY GOOD?

THE OLD REGS

THE OLD REGS

HEARING AID	PSAP
CAN MAKE MEDICAL CLAIMS	CAN NOT MAKE MEDICAL CLAIMS

THE NEW REGS

HEARING AID

- OVER THE COUNTER HEARING AID
  - 
- SELF FIT HEARING AID
  - BOSE
- TRADITIONAL HEARING AID
  - Starkey
  - WIDEX high definition hearing
  - PHONAK
  - signia Life sounds brilliant.
  - oticon PEOPLE FIRST
  - ReSound

THE NEW REGS

HEARING AID

OVER THE COUNTER HEARING AID

SELF FIT HEARING AID

BOSE

TRADITIONAL HEARING AID

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WIDEX high definition hearing
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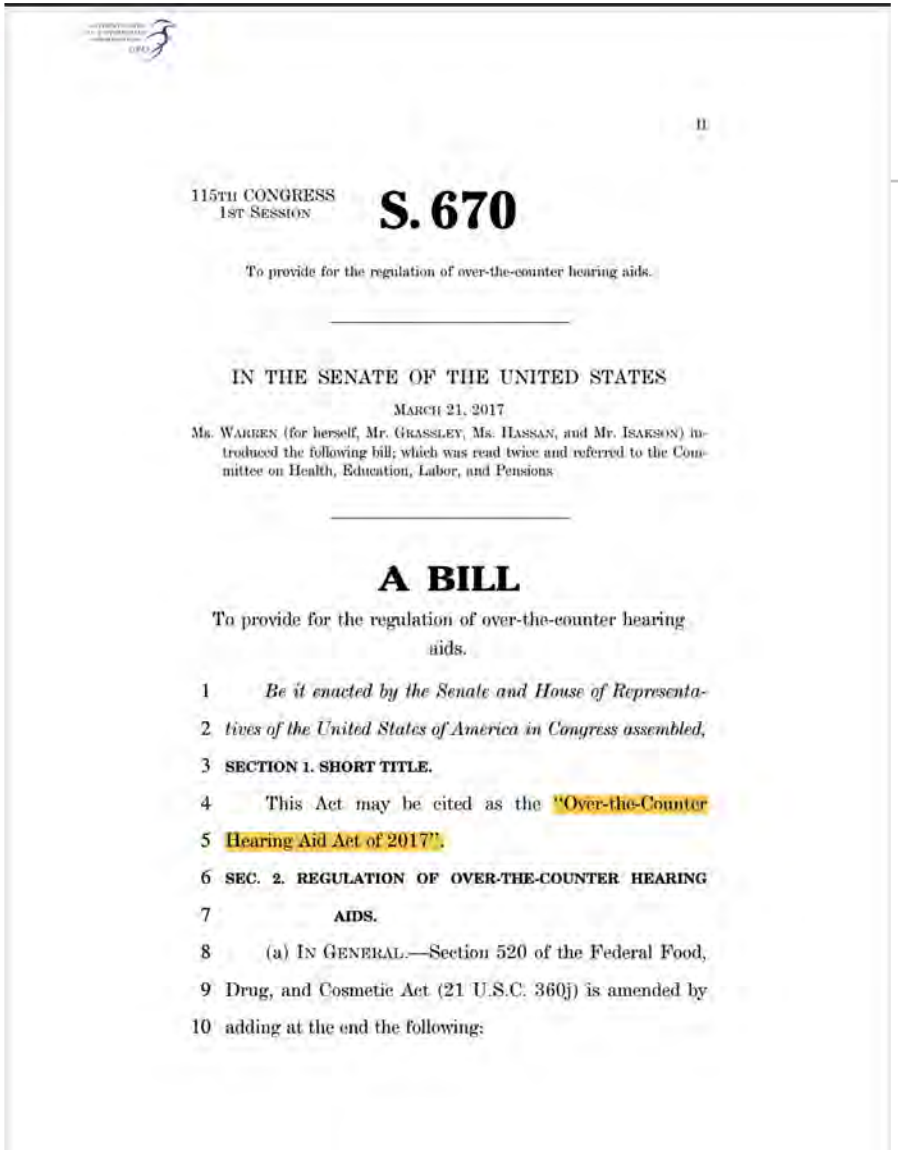

II

115TH CONGRESS
1ST SESSION

S. 670

To provide for the regulation of over-the-counter hearing aids.

IN THE SENATE OF THE UNITED STATES

MARCH 21, 2017

MS. WARREN (for herself, Mr. GRASSLEY, Ms. HASSAN, and Mr. ISAKSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for the regulation of over-the-counter hearing aids.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Over-the-Counter Hearing Aid Act of 2017".

SEC. 2. REGULATION OF OVER-THE-COUNTER HEARING AIDS.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

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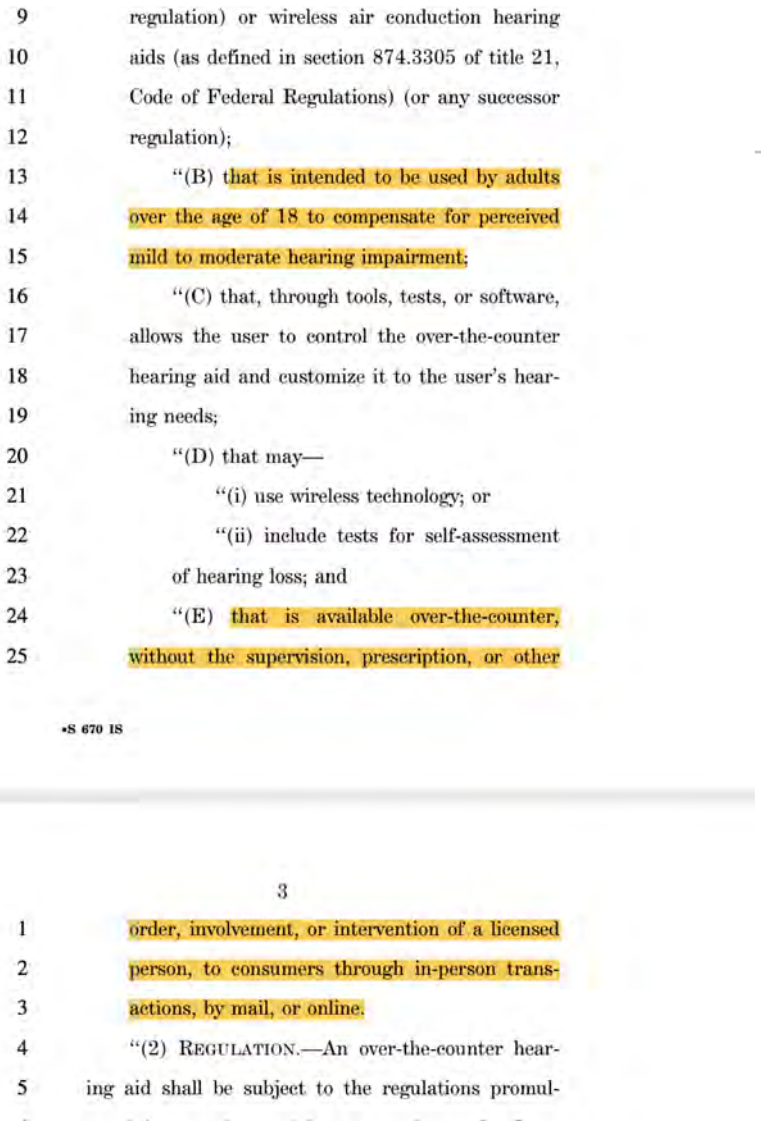

regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

"(B) that is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment;

"(C) that, through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

"(D) that may—

"(i) use wireless technology; or

"(ii) include tests for self-assessment of hearing loss; and

"(E) that is available over-the-counter, without the supervision, prescription, or other

•S 670 IS

3

order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

"(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promul-

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a report under section 510(k) to provide reasonable assurance of safety and effectiveness.

(4) EFFECT ON STATE LAW.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically applicable to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids (as defined in section 520(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by subsection (a)) through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids.

(c) NEW GUIDANCE ISSUED.—Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update and finalize the draft guidance of the Department of Health and Human Services entitled, "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products",

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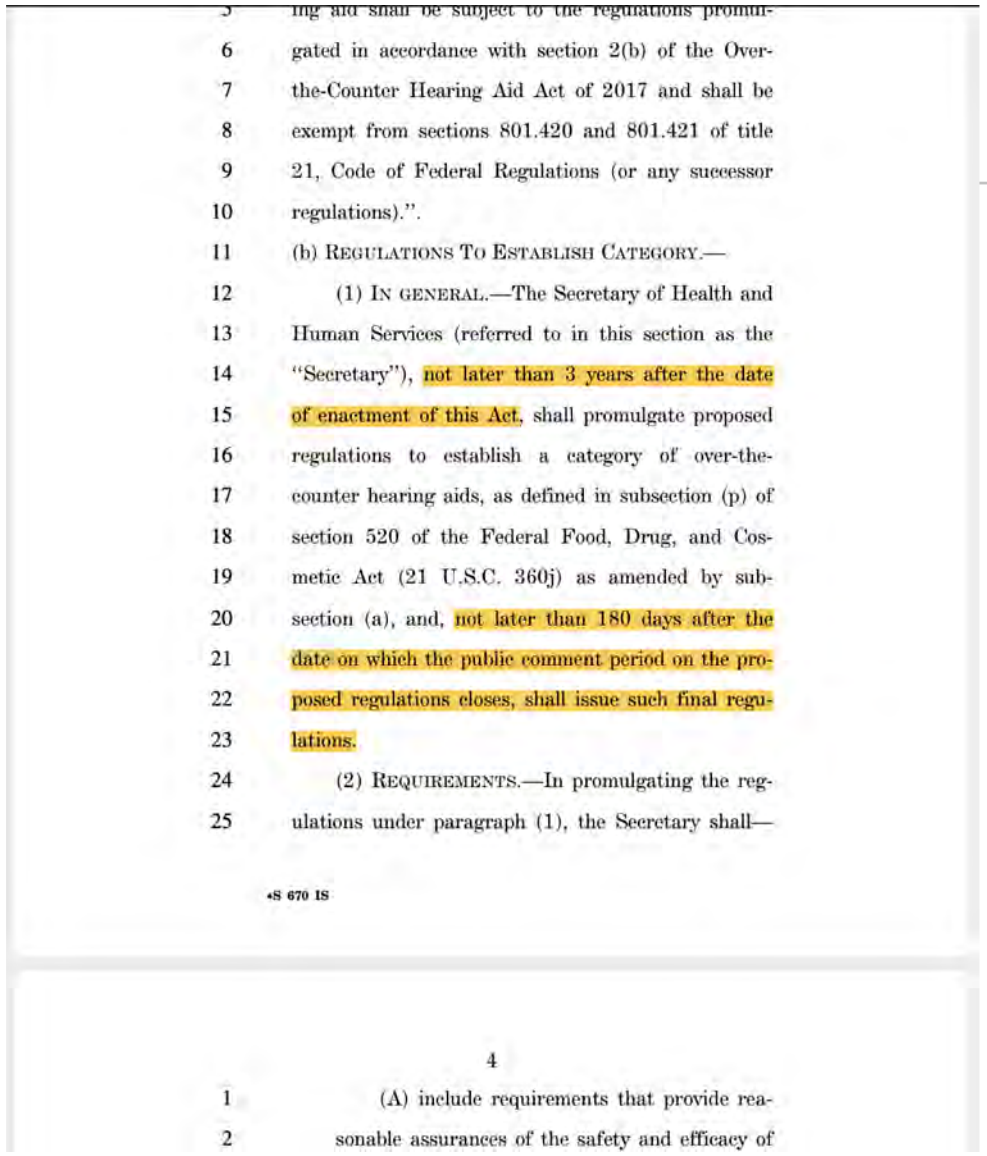

ing aid shall be subject to the regulations promulgated in accordance with section 2(b) of the Over-the-Counter Hearing Aid Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).".

(b) REGULATIONS TO ESTABLISH CATEGORY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), not later than 3 years after the date of enactment of this Act, shall promulgate proposed regulations to establish a category of over-the-counter hearing aids, as defined in subsection (p) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) as amended by subsection (a), and, not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.

(2) REQUIREMENTS.—In promulgating the regulations under paragraph (1), the Secretary shall—

•S 670 IS

4

(A) include requirements that provide reasonable assurances of the safety and efficacy of

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Sen. Warren Urges FDA to Initiate Overdue Rulemaking So Hearing Aids Can Be Made Available Over-the-Counter

November 16, 2020 editor hearing aides, Over-the-Counter Hearing Aid Act, Sen. Elizabeth Warren, U.S. Food and Drug Administration (FDA)

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THE NEW REGS

HEARING AID

OVER THE COUNTER HEARING AID

SELF FIT HEARING AID

BOSE

TRADITIONAL HEARING AID

Starkey
WIDEX high definition hearing
PHONAK
signia Life sounds brilliant.
oticon PEOPLE FIRST
ReSound

continued

DE NOVO CLASSIFICATION REQUEST FOR BOSE® HEARING AID

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Self-fitting air-conduction hearing aid. A self-fitting air-conduction hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings.

NEW REGULATION NUMBER: 21 CFR 874.3325

CLASSIFICATION: Class II

PRODUCT CODE: QDD

BACKGROUND

DEVICE NAME: Bose® Hearing Aid

SUBMISSION NUMBER: DEN180026

DATE OF DE NOVO: May 11, 2018

CONTACT: Bose Corporation
The Mountain
Framingham, MA 01701

INDICATIONS FOR USE

The Bose Hearing Aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

LIMITATIONS

The Bose Hearing Aid is subject to labeling and conditions for sale requirements under 21 CFR 801.420 and 801.421.

Limitations on device use are included in the Instructions for Use as "Important Information" and "Warnings, Precautions, and Safety Considerations."

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SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the self-fitting air-conduction hearing aid is subject to the following special controls:

1. Clinical data must evaluate the effectiveness of the self-fitting strategy.
2. Electroacoustic parameters, including maximum output limits, distortion levels, self-generated noise levels, latency, and frequency response, must be specified and tested.
3. Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device.
4. Software verification, validation, and hazard analysis must be performed.
5. If the device incorporates wireless technology:

(A) Performance testing must validate safety of exposure to non-ionizing radiation;

(B) Performance data must validate wireless technology functions; and

(C) Labeling must specify instructions, warnings, and information relating to wireless technology and human exposure to non-ionizing radiation.

6. Usability testing must demonstrate that users can correctly use the device as intended under anticipated conditions of use.
7. Patient labeling must include the following:

(A) Information on how a patient can self-identify as a candidate for the device;

(B) Information about when to seek professional help;

(C) A warning about using hearing protection in loud environments;

(D) A warning about staying alert to sounds around the user of the device;

(E) Technical information about the device, including information about electromagnetic compatibility; and

(F) Information on how to correctly use and maintain the device.

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significantly correlated with professionally-selected gain and user gain was on average only 1.9 dB less than professional, indicating that the self-selected gain settings were appropriate for subjects' hearing loss and comparable to a professionally derived fitting; 2) benefit experienced by the Self-Fit Group was significantly non-inferior to that experienced by the Pro-Fit Group as measured by two standard questionnaires (APHAB & SSQ-12) and by a speech-in-noise test (QuickSIN) test; and 3) subjects in the Self-Fit Group were satisfied with/preferred their own settings to the professionally-selected settings more than were/did subjects in the Pro-Fit Group. The human factors study demonstrated that the usability of the Bose hearing aid was analyzed, verified, and validated for its intended use, and the implemented mitigations for user training and device labeling are adequate. The technology in the Bose Hearing Aid that allows it to be effectively fit, customized, and used without the involvement of a hearing healthcare professional provides additional options for patients with perceived mild to moderate hearing loss.

Patient Perspectives

Patient perspectives considered for the Bose Hearing Aid during the review include: 1) blind A/B comparisons of the user-derived listening settings with the professionally-derived listening settings, 2) patient-reported outcome measures captured by the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial, and Qualities of Hearing Scale for clinical use (SSQ-12) questionnaires, and 3) patient satisfaction and preferences for the user-derived settings over the professionally-derived settings.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> The Bose Hearing Aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

The probable benefits outweigh the probable risks for the Bose Hearing Aid. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Bose Hearing Aid is granted and the device is classified as follows:

Product Code: QDD
Device Type: Self-fitting air-conduction hearing aid
Regulation Number: 21 CFR 874.3325
Class: II

https://www.accessdata.fda.gov/

THE NEW REGS

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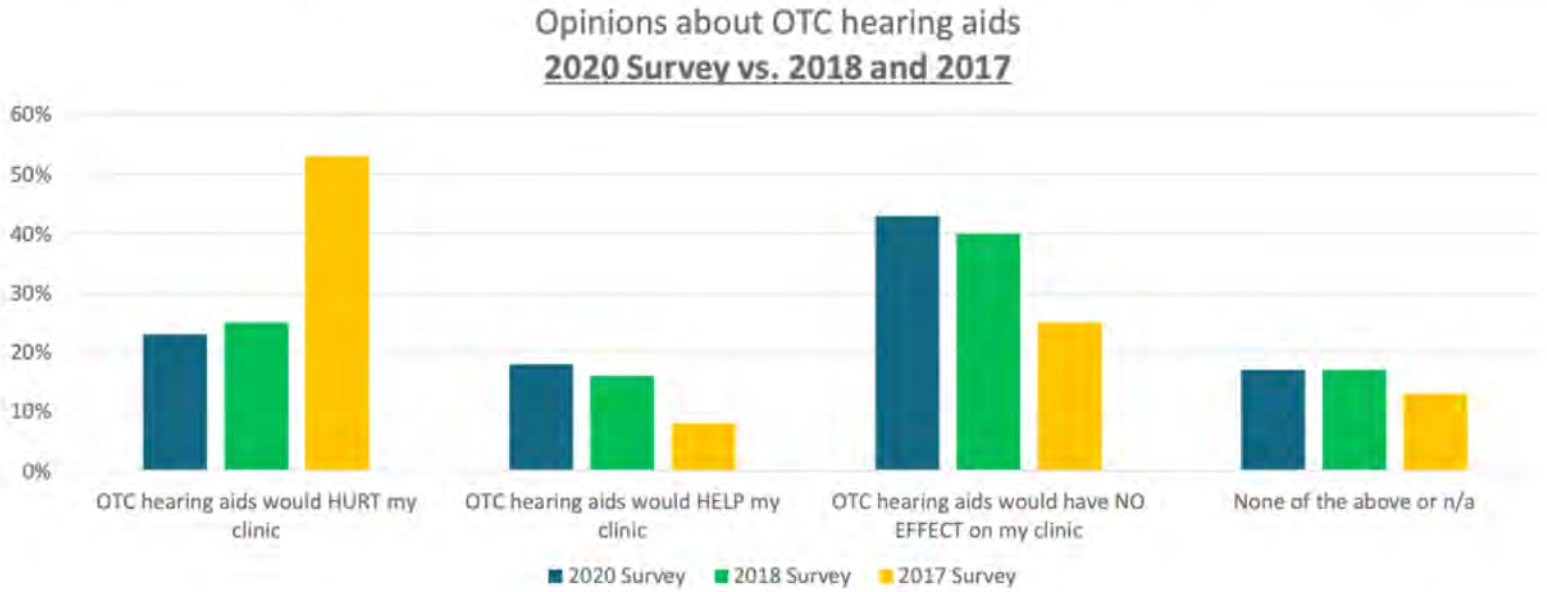
PSAP

BOSE

Starkey · WIDEX high definition hearing · PHONAK · signia Life sounds brilliant. · oticon PEOPLE FIRST · ReSound

16b. Which of the following responses best matches your feeling about OTC hearing aids



Survey from Hearing Health and Technology Matters

1. WHAT IS THE CURRENT REGULATORY LANDSCAPE?

2. HOW DOES A USER FIT AN OTC HEARING AID?

3. HOW DO WE KNOW IF THAT FIT IS ANY GOOD?

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3. HOW DO WE KNOW IF THAT FIT IS ANY GOOD?

2. HOW DOES A USER FIT AN OTC HEARING AID?

WHAT DOES THE BALANCE OF COVERAGE VS SIMPLICITY LOOK LIKE?

C

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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National Center for Health Statistics

CDC > NCHS

- National Health and Nutrition Examination Survey
- About NHANES
- What's New
- Questionnaires, Datasets, and Related Documentation
- Survey Participants
- Biospecimen Program

nhanes National Health and Nutrition Examination Survey

Survey Participants

If you were selected, learn more about participating

Survey Data and Documentation

Access data, documentation & response rates

Publications and Products

National Health and Nutrition Examination Survey

2009-2010 Data Documentation, Codebook, and Frequencies

C

Audiometry (AUX_F)

Data File: AUX_F.xpt

First Published: June 2012

Last Revised: NA

Component Description

The NHANES 2009-2010 Audiometry Examination Component consists of four parts:

1) A pre-exam audiometric questionnaire: This is a series of questions to identify conditions that would affect how audiometric testing is conducted, or how results are interpreted. Questions include whether the subject has ear tubes, a current cold or ear problem, or recent loud noise exposure. Note that more extensive data relating to a study subject's hearing status including information regarding occupational noise exposure are contained in the audiometry questionnaire (AUQ) section of the NHANES Sample Person Interview Questionnaire.

2) A brief otoscopic screening (physical) exam of the ear canals and eardrums: This was performed by the Health Technician to identify abnormalities which would require alternate audiometric procedures or influence interpretation of test results, and to identify conditions which might require medical referral. The exam screened for excessive or impacted ear cerumen (wax), physical abnormalities, or collapsing external ear canals.

3) Tympanometry: This is an objective assessment of middle ear function by testing the mobility of the eardrum in response to changes in air pressure within the ear canal. It is used to identify middle ear pathologies that might contribute to hearing loss. Tympanometric data, included in the AUX_F Audiometry data file consists of quantitative measurement variables for middle ear volume, pressure, compliance, and gradient, and tympanogram data quality ratings. The raw data for the examinee's tympanometric curves is released separately (AUXTYM_F).

4) Pure tone air conduction audiometry: This measures hearing sensitivity by presenting pure tone signals to the ear through earphones and by varying the intensity of the signals until a subject's hearing threshold at that frequency is determined. Testing is performed at frequencies across the range of human hearing.

Eligible Sample

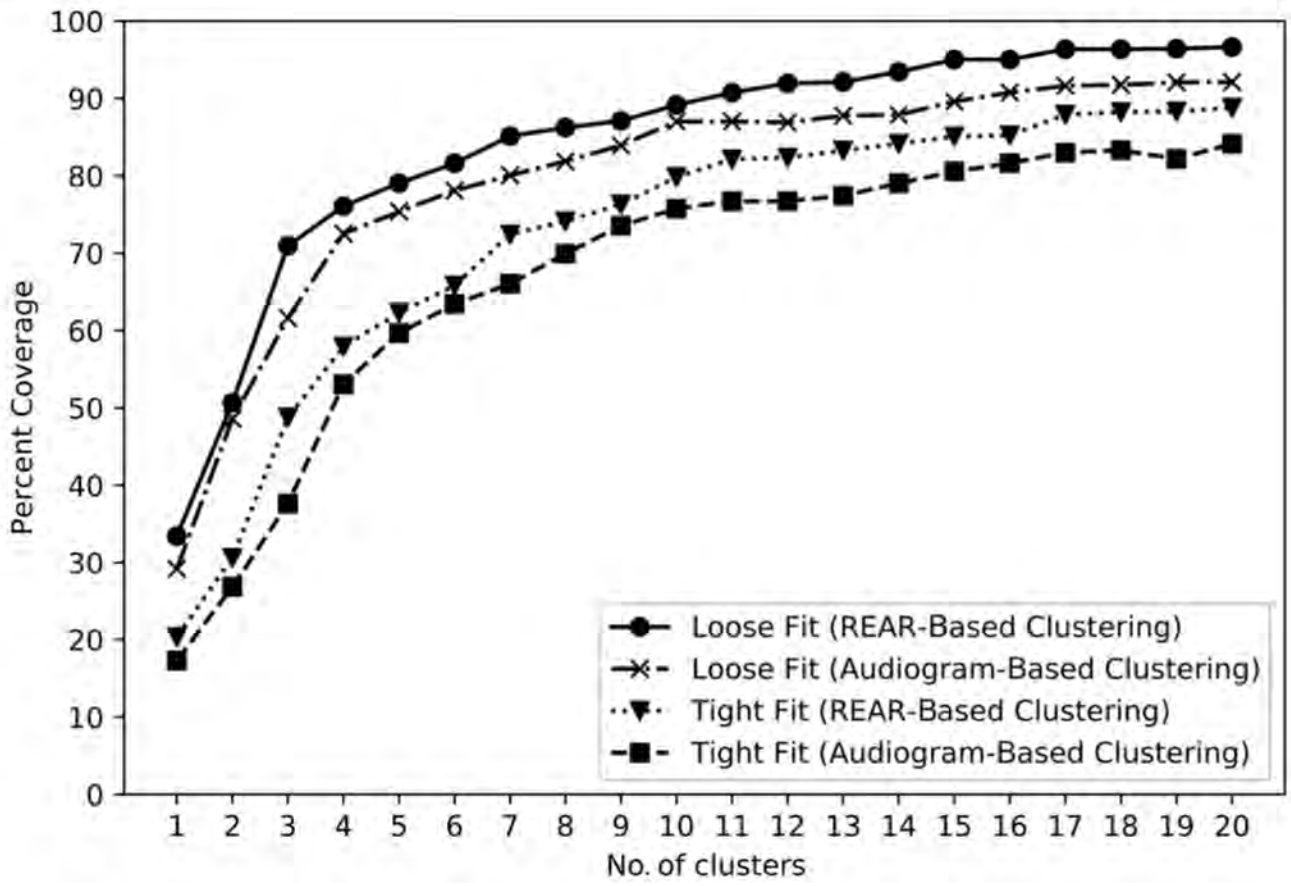
The NHANES 2009-2010 Audiometry Component tested full samples of U.S. adolescents ages

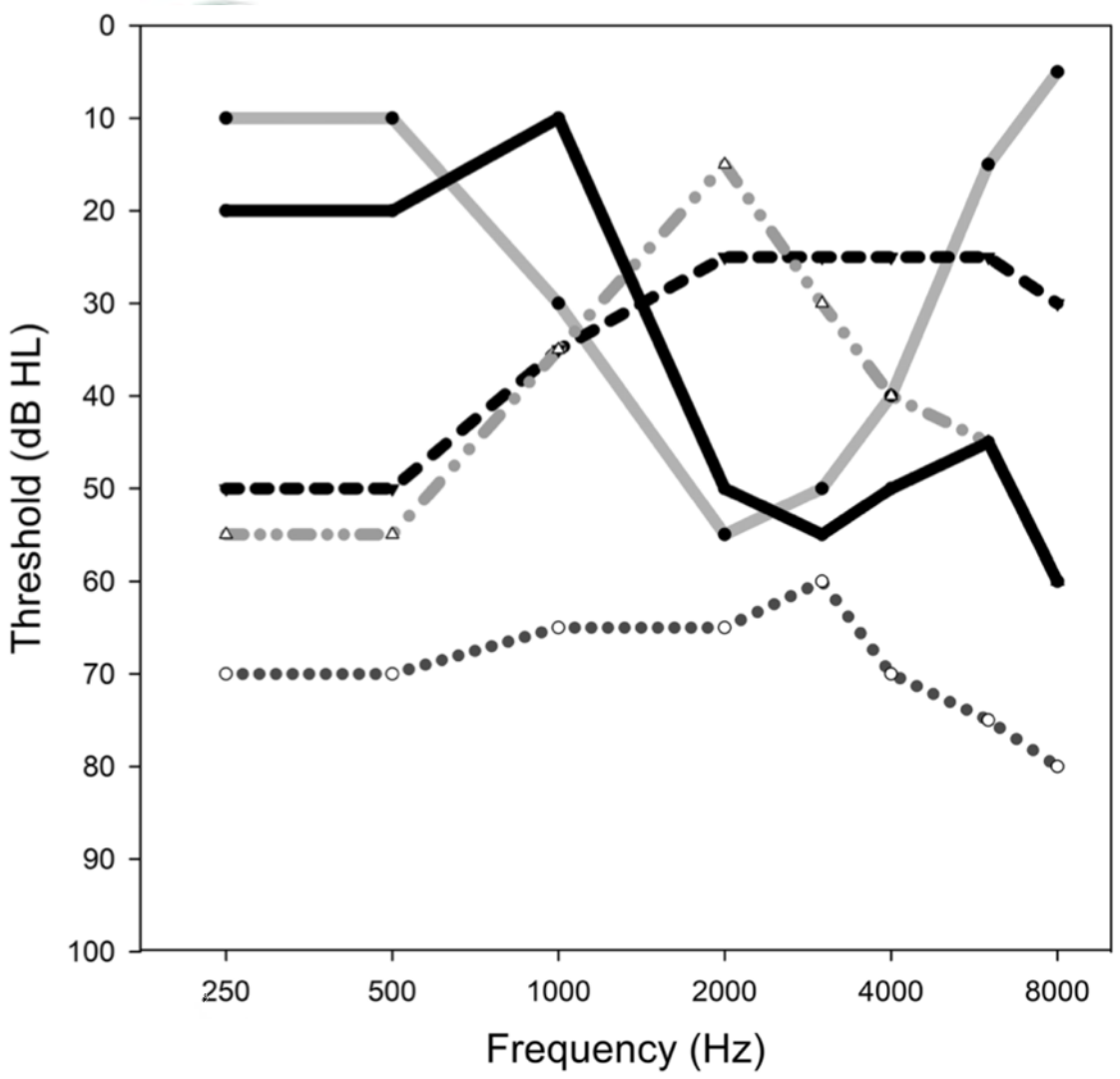
TABLE OF CONTENTS

CDC.gov

HOW MUCH OF THE POPULATION CAN A DEVICE WITH A FEW PRESETS COVER?

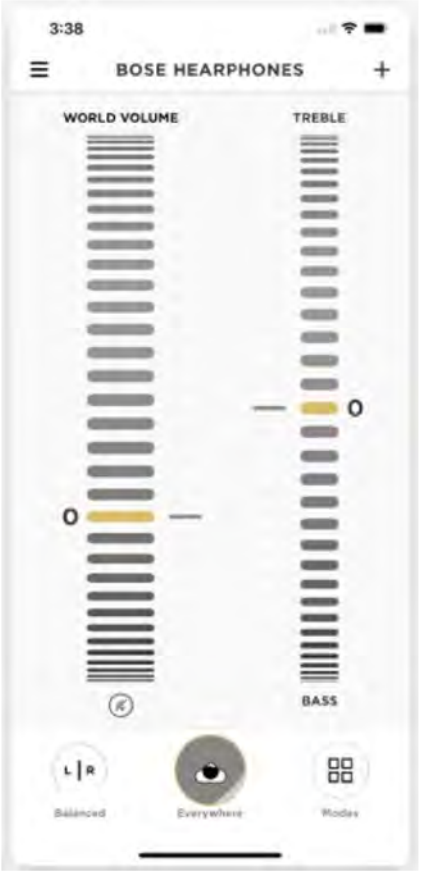
Jensen, J., Vyas, D., Urbanski, D., Garudari, H., Chipara, O., & Wu, Y. (2020). Common Configurations of Real-Ear Aided Response Targets Prescribed by NAL-NL2 for Older Adults With Mild-to-Moderate Hearing Loss. American Journal of Audiology, 29(3), 460–475. https://doi.org/10.1044/2020_AJA-20-00025


Percent Coverage
No. of clusters
Loose Fit (REAR-Based Clustering)
Loose Fit (Audiogram-Based Clustering)
Tight Fit (REAR-Based Clustering)
Tight Fit (Audiogram-Based Clustering)



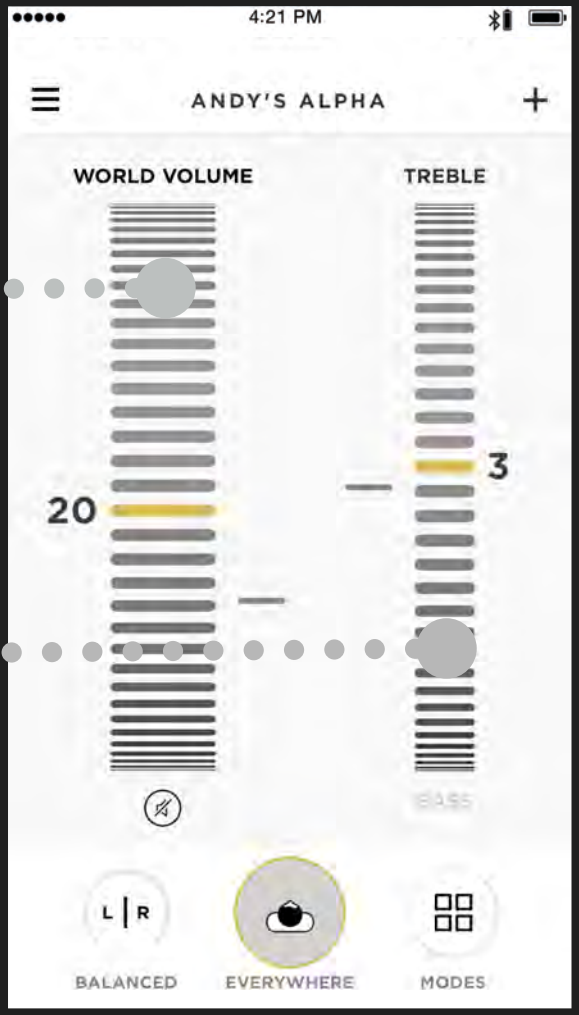
Jensen et al. 2020 IJA

HOW MUCH OF THE POPULATION CAN A DEVICE WITH A FEW ~~PRESETS~~ SIMPLE UI CONTROLS COVER?



1. Fit to WDRC targets

2. Fine Tune



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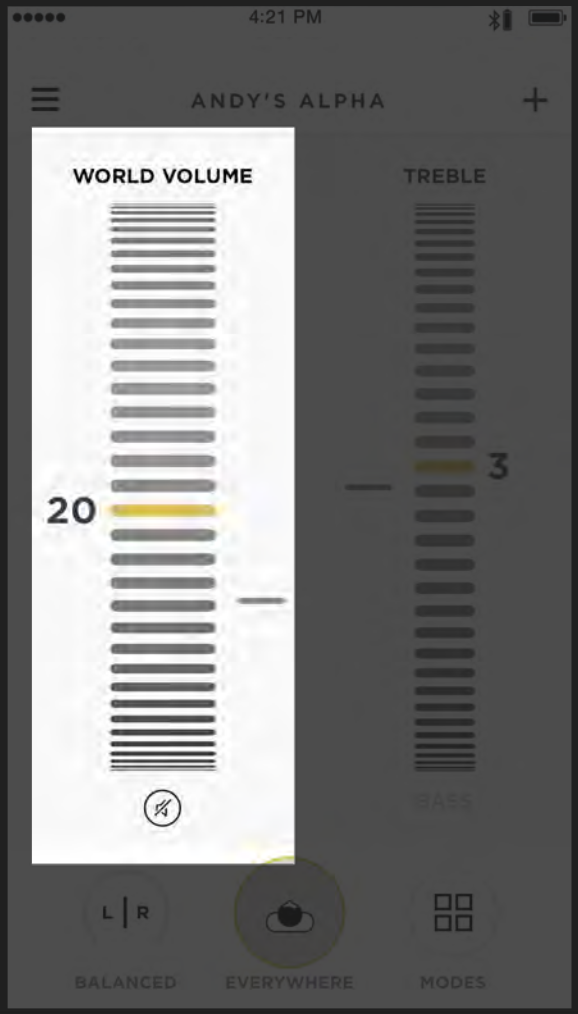

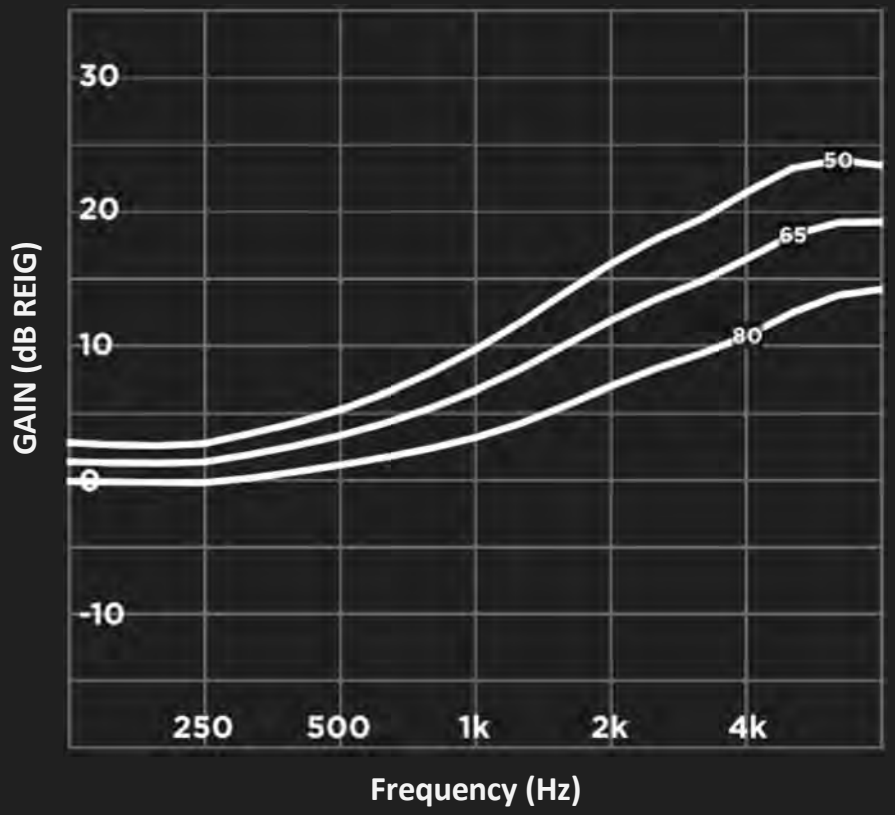

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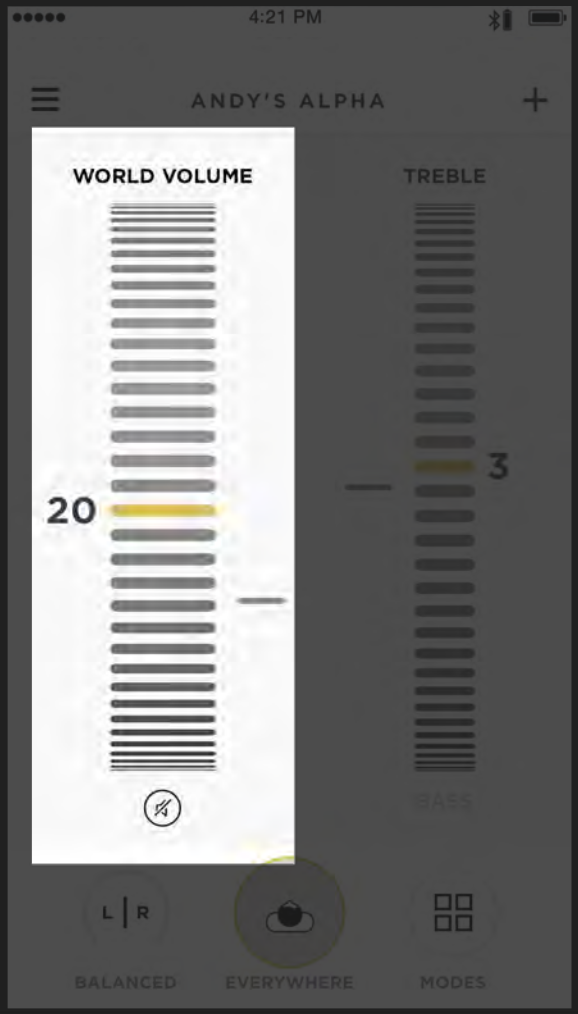

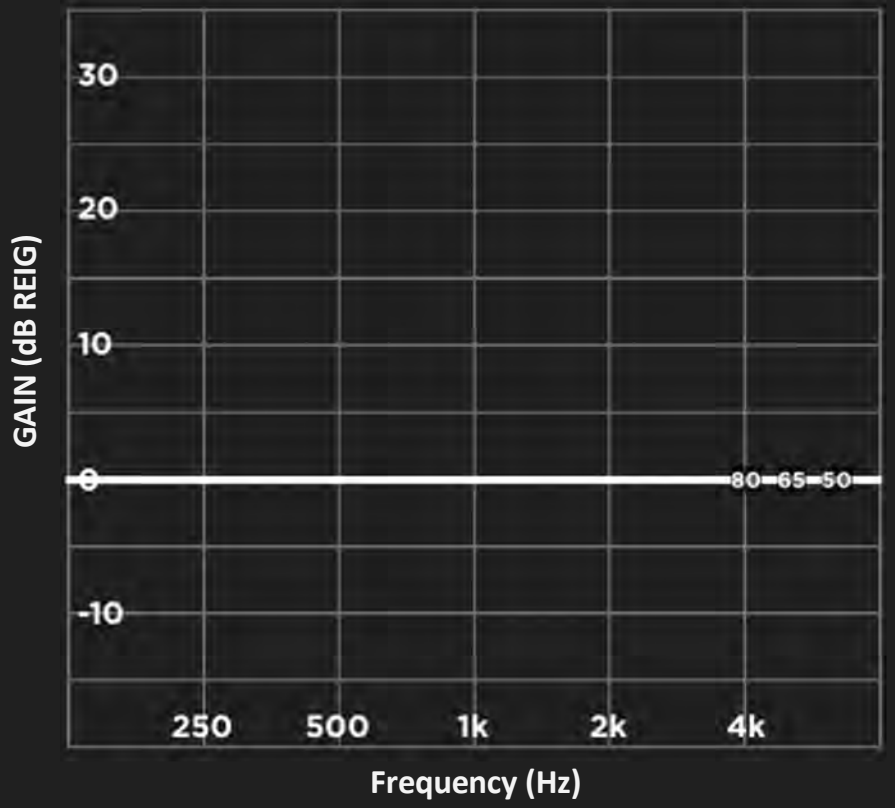

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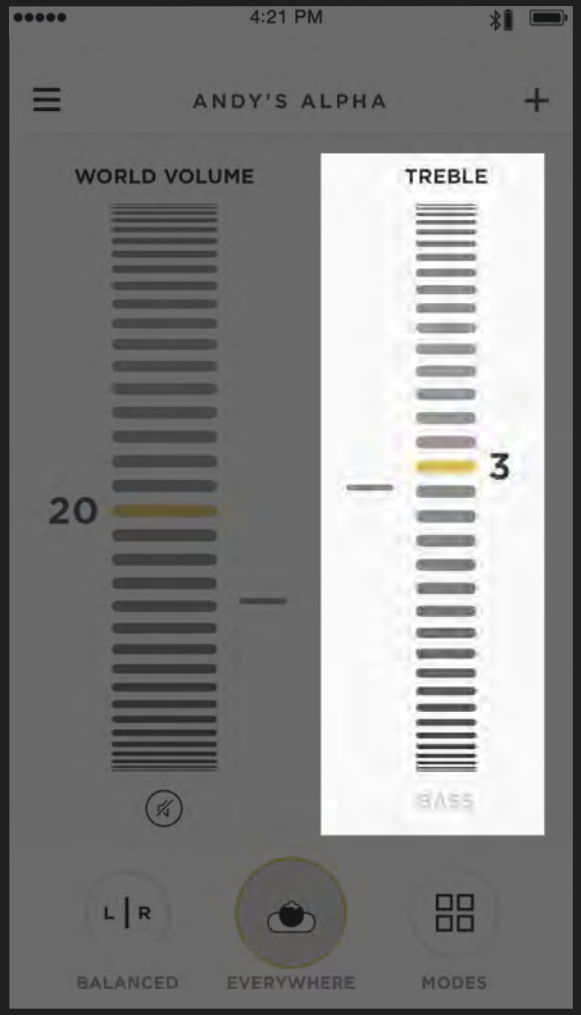

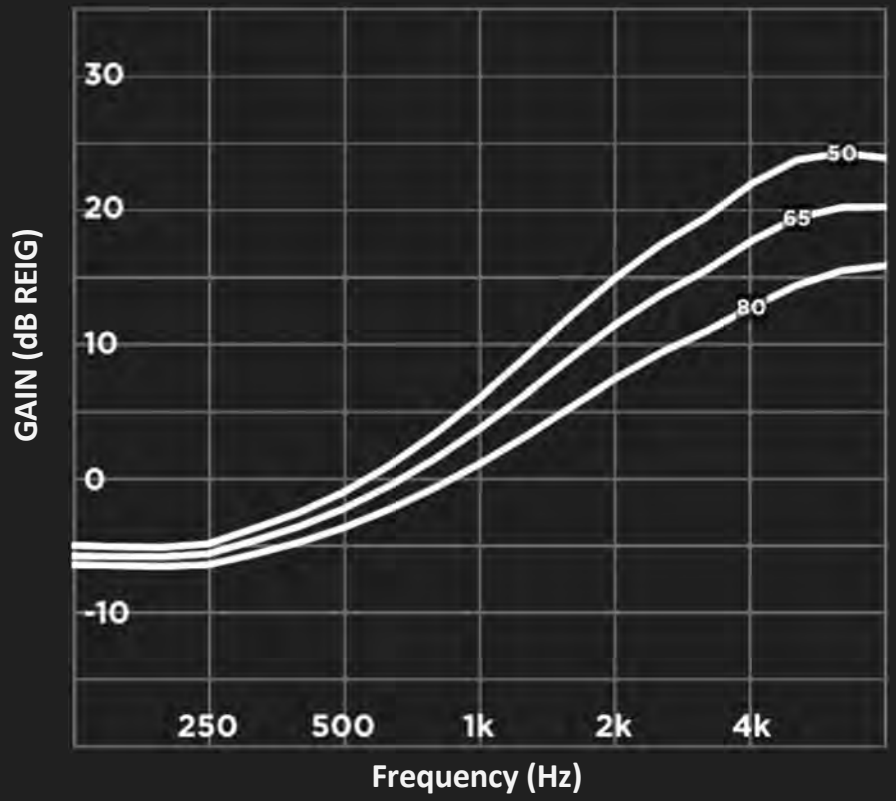

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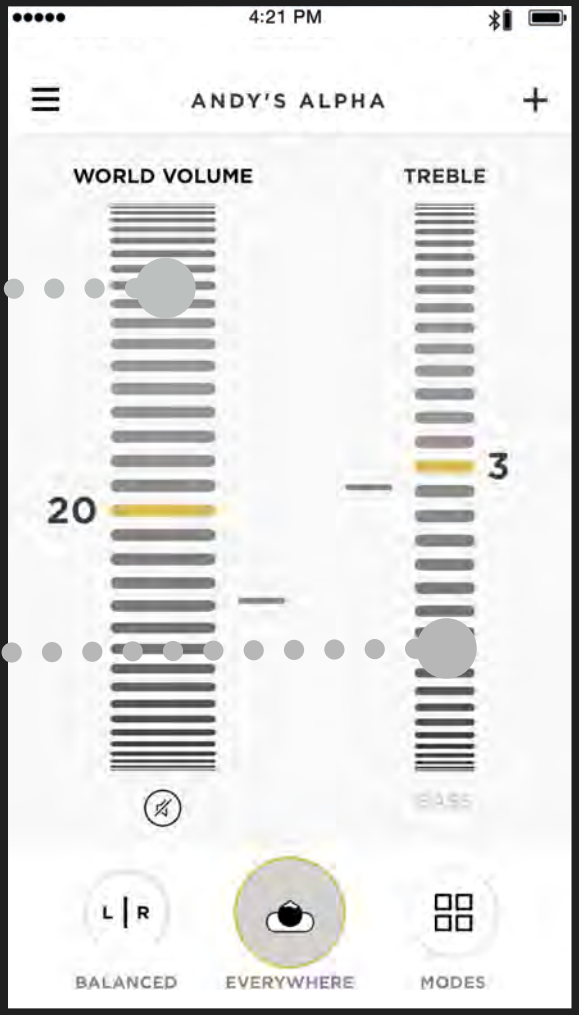
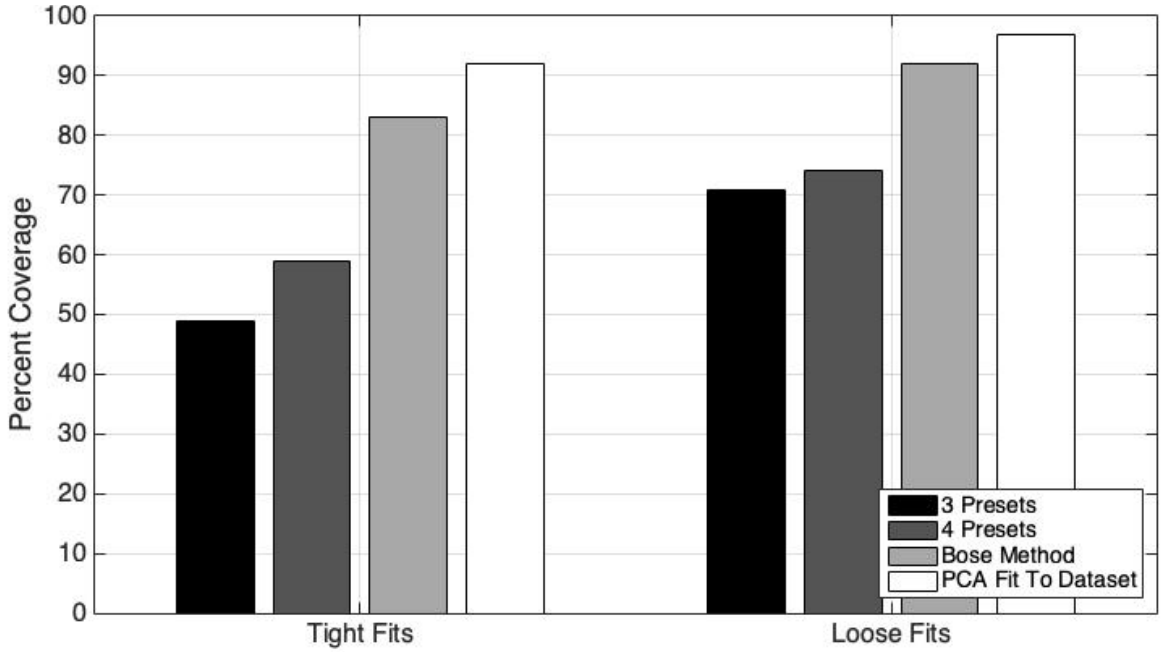


HOW MUCH OF THE POPULATION CAN A DEVICE WITH A FEW ~~PRESETS~~ SIMPLE UI CONTROLS COVER?



Sabin et al. In Preparation

1. WHAT IS THE CURRENT REGULATORY LANDSCAPE?

2. HOW DOES A USER FIT AN OTC HEARING AID?

3. HOW DO WE KNOW IF THAT FIT IS ANY GOOD?

2. [redacted]

3. HOW DO WE KNOW IF THAT FIT IS ANY GOOD?

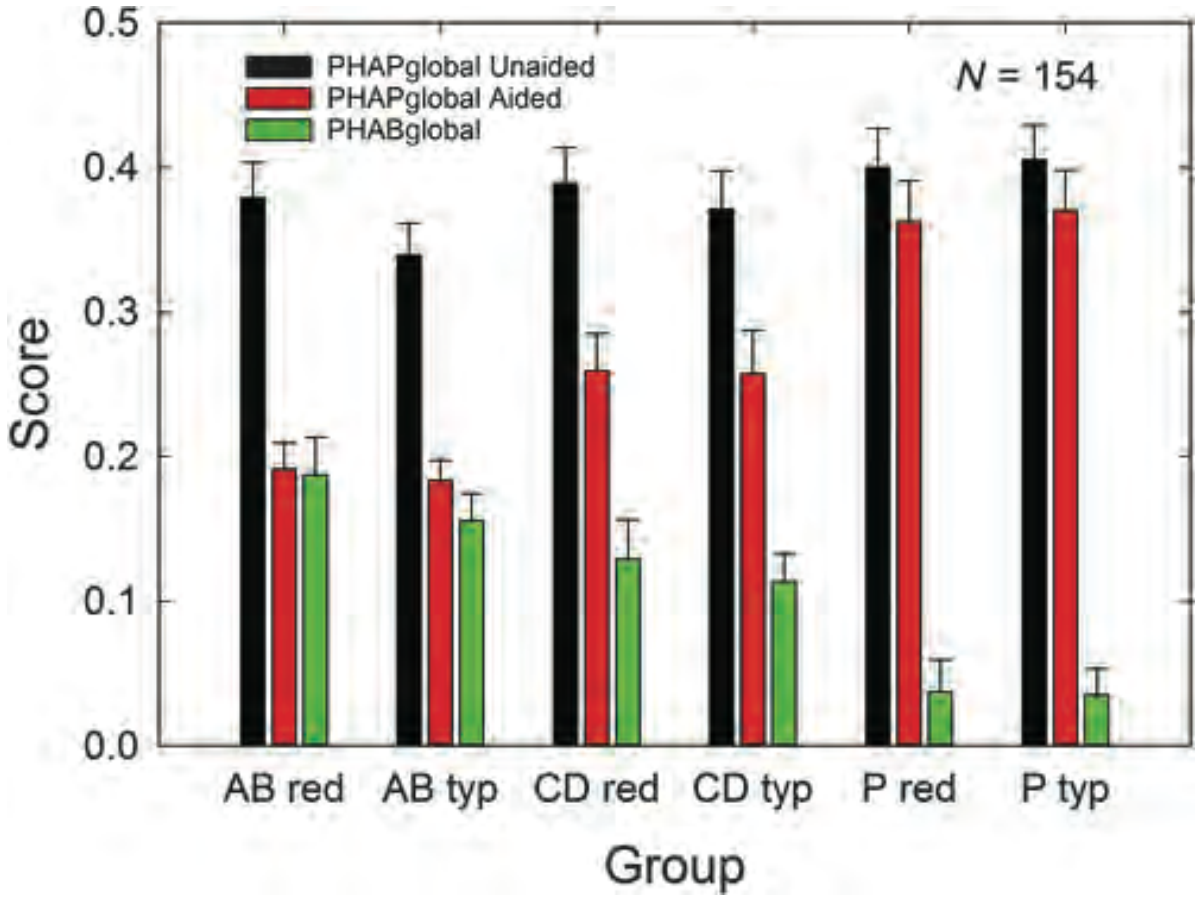
HERE: PRESETS, SIMPLE UI CONTROLS

ELSEWHERE: AT HOME AUDIOGRAM, ADAPTIVE FORCED CHOICE PROCEDURES, COMBINATIONS… ETC

WHAT ARE HA OUTCOMES LIKE IN PRESET DEVICES?

Humes LE, Rogers SE, Quigley TM, et al.: The effects of service-delivery model and purchase price on hearing-aid outcomes in older adults: a randomized double-blind placebo-controlled clinical trial. Am J Audiol 2017; 26:53–79

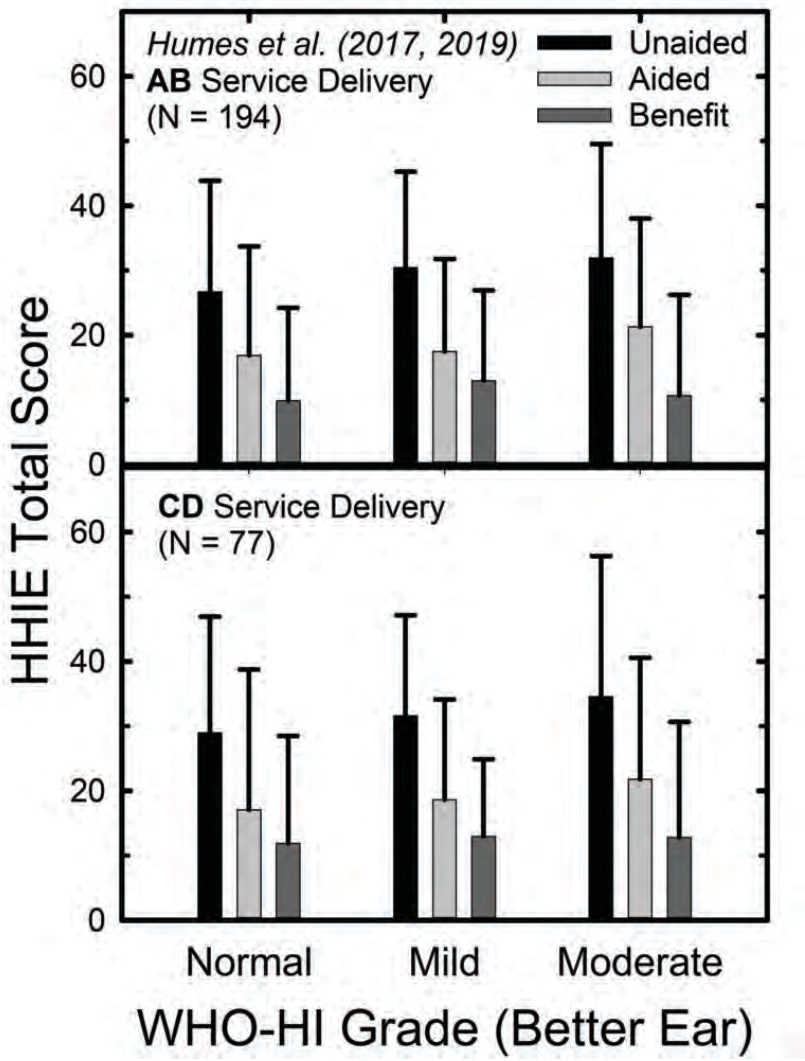
Humes et al. 2017 AJA



Humes et al. 2017 AJA

WHAT IS NORMAL HEARING AND HOW DOES THAT RELATE TO HA BENEFITS?

Humes, L. E. (2020). What is “normal hearing” for older adults and can “normal-hearing older adults” benefit from hearing care intervention? Hearing Review, 27(7), 12–18.



Humes 2020 Hearing Review

WHAT ARE HA OUTCOMES LIKE IN CONTROLLER-BASED DEVICES?

Sabin AT, Van Tasell DJ, Rabinowitz B, Dhar S. Validation of a self-fitting method for over-the-counter hearing aids. Trends Hearing. 2020;24:1-19.

	CLINICAL GROUP	OTC GROUP
SAMPLE SIZE	37	38
4FA HEARING LOSS Avg(sd)	29(9) dB HL	33(12) dB HL
AGE Avg(sd)	62(13) Years	66(12) Years
HEARING AID EXPERIENCE	33 New Users	28 New Users

CLINICAL FIT

CLINICAL FIT

SELF FIT

FIRST FIT

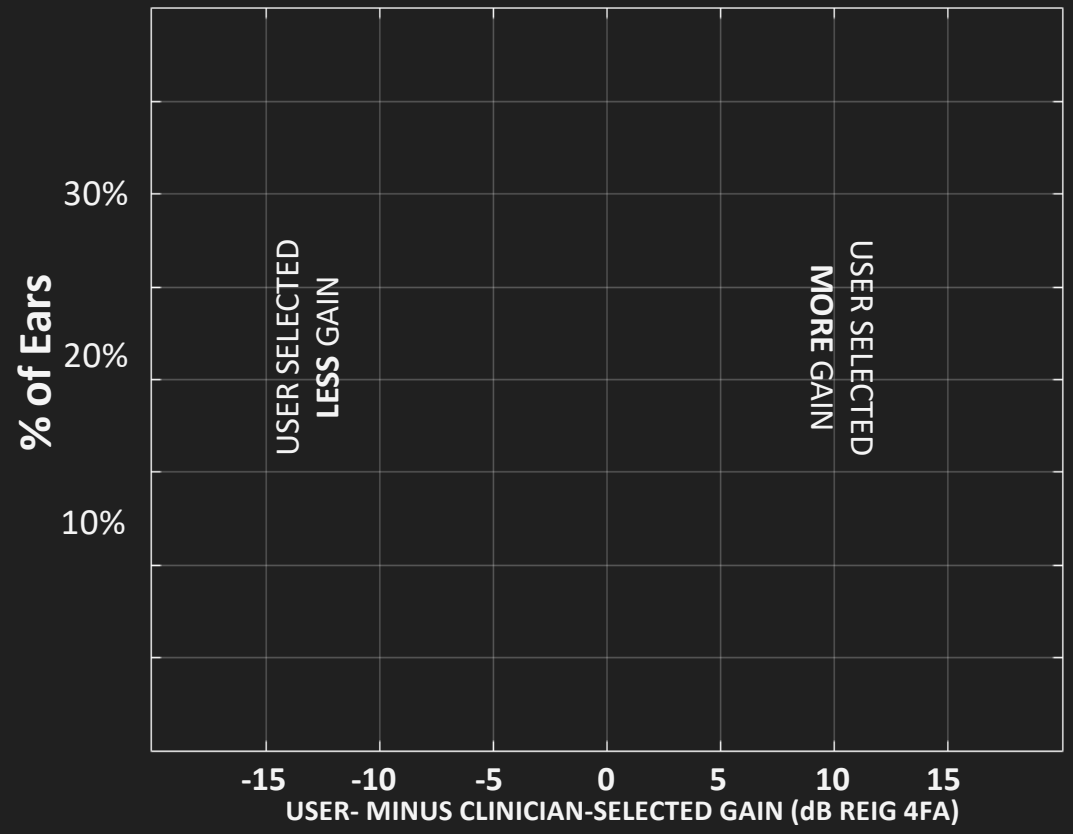
FINE TUNING

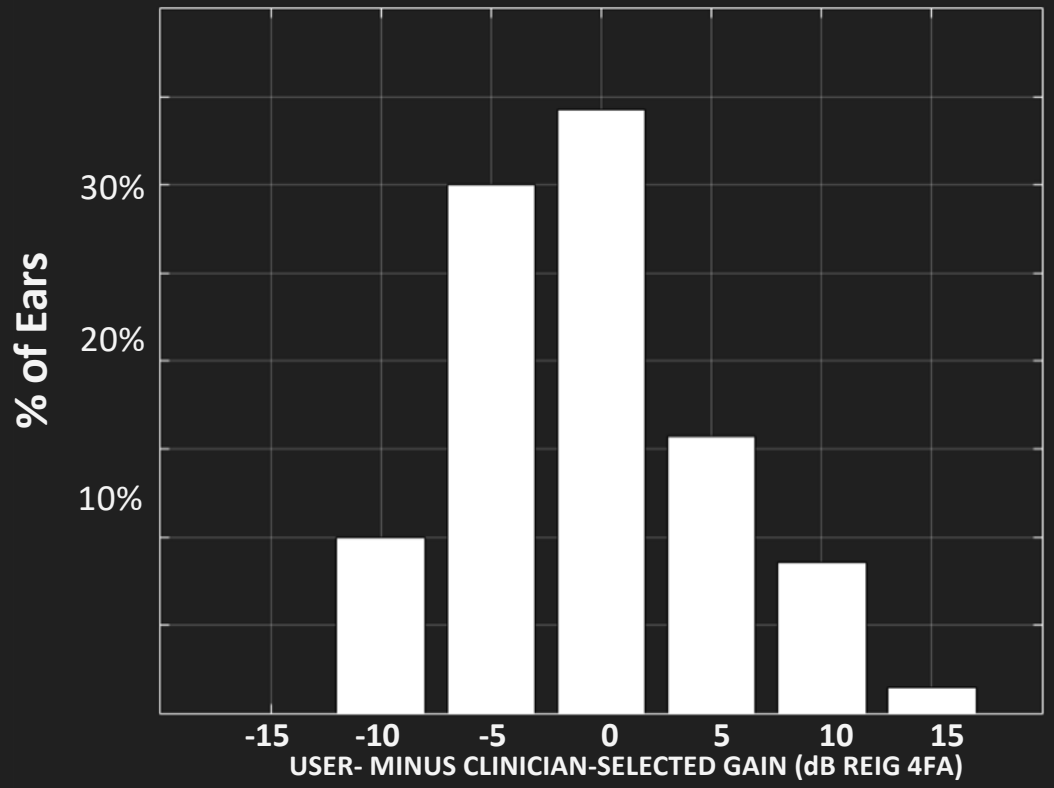
USER ADJUSTMENT IN EVERYDAY LIVES

~30 DAYS

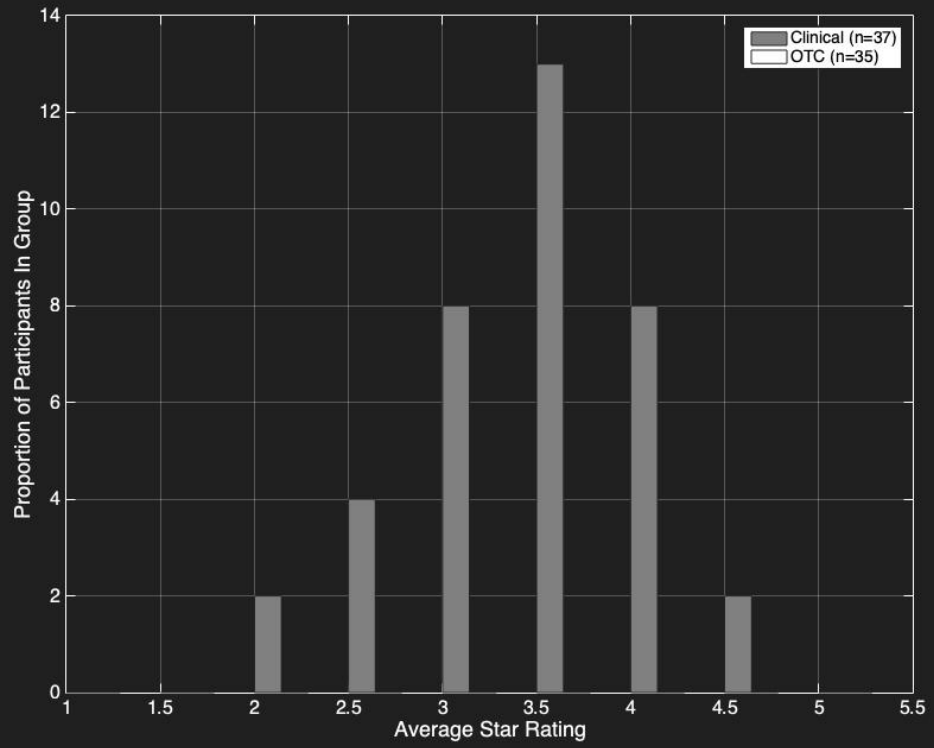
TIME

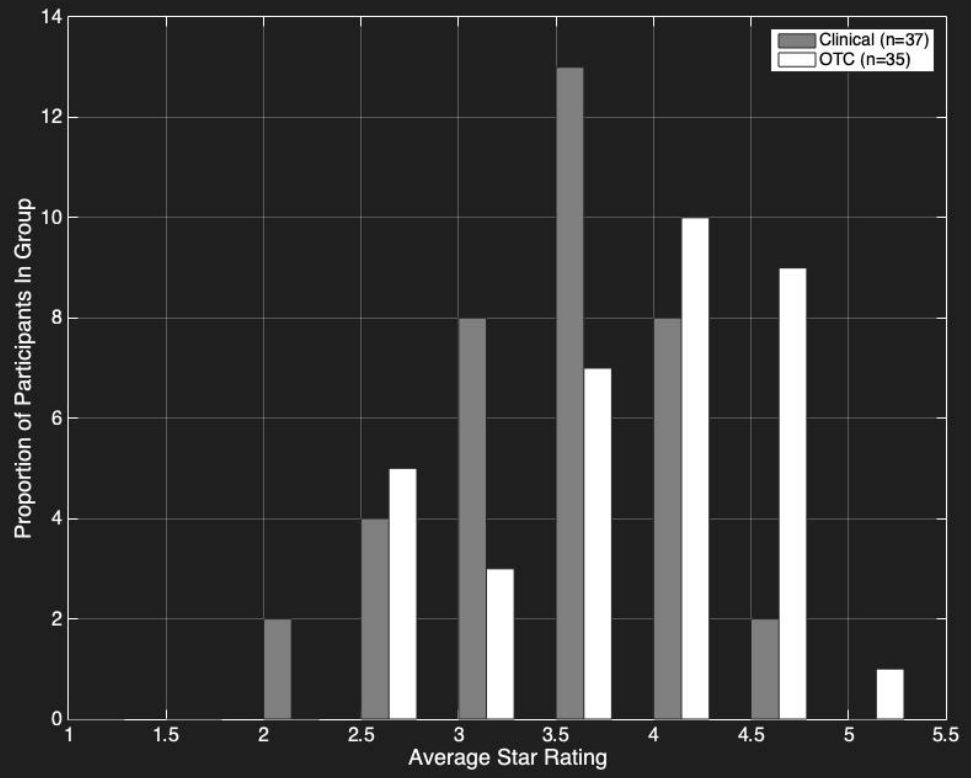
GAIN


% of Ears
30%
20%
10%
USER SELECTED LESS GAIN
USER SELECTED MORE GAIN
-15
-10
-5
0
5
10
15
USER- MINUS CLINICIAN-SELECTED GAIN (dB REIG 4FA)


% of Ears
30%
20%
10%
-15
-10
-5
0
5
10
15
USER- MINUS CLINICIAN-SELECTED GAIN (dB REIG 4FA)

SOUND QUALITY


Clinical (n=37)
OTC (n=35)
Proportion of Participants In Group
Average Star Rating
0
2
4
6
8
10
12
14
1
1.5
2
2.5
3
3.5
4
4.5
5
5.5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2
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4.5
5
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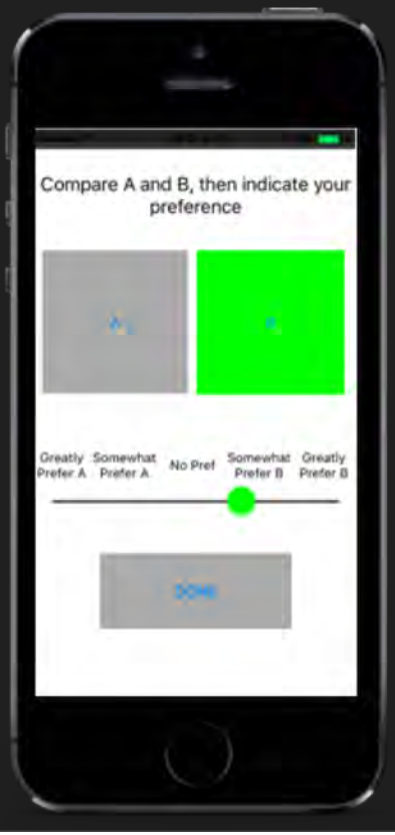
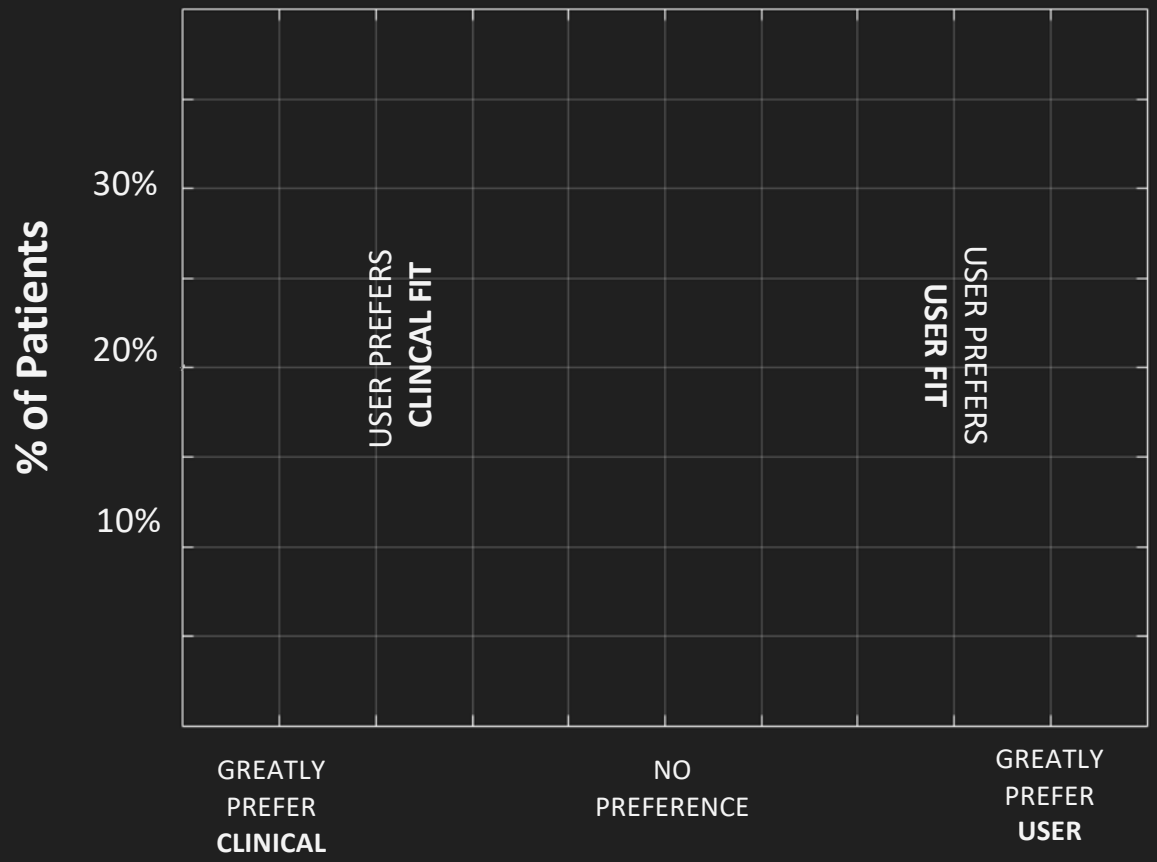
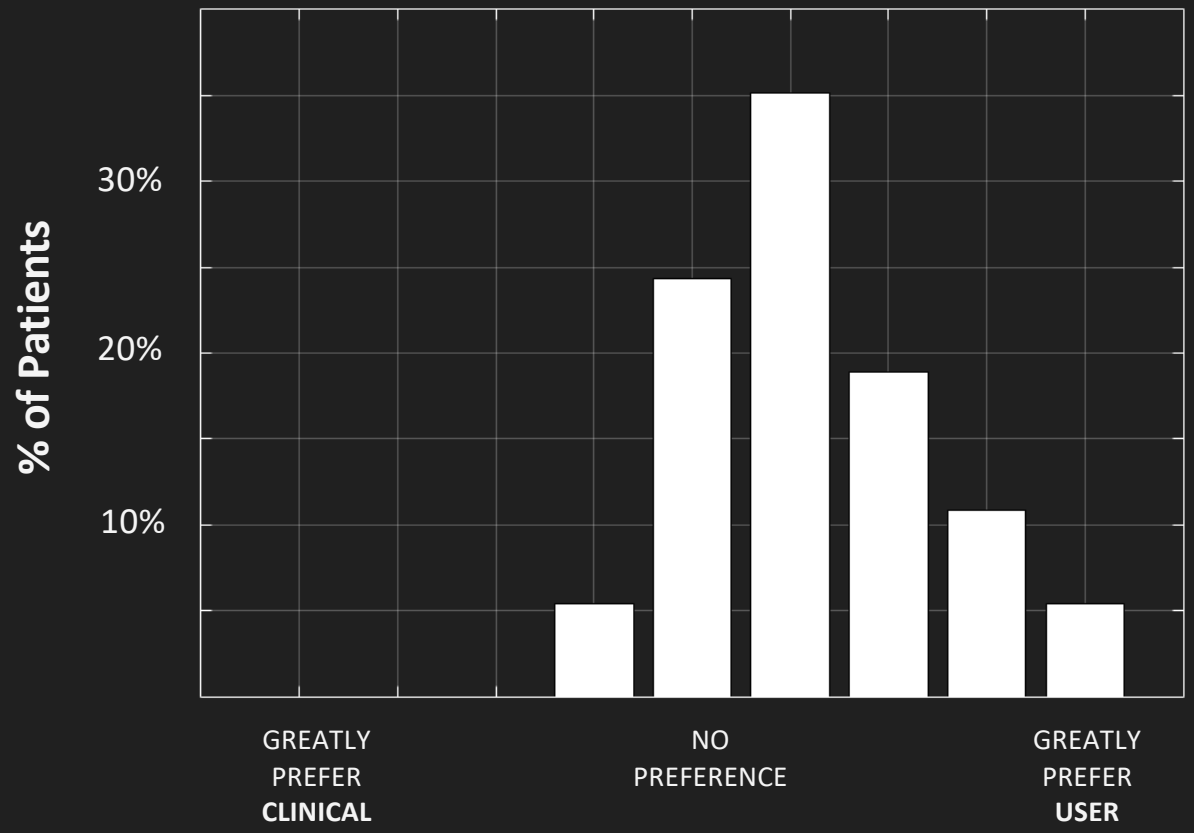
SOUND QUALITY




% of Patients
30%
20%
10%
USER PREFERS
CLINCAL FIT
USER PREFERS
USER FIT
GREATLY
PREFER
CLINICAL
NO
PREFERENCE
GREATLY
PREFER
USER


% of Patients
30%
20%
10%
GREATLY PREFER **CLINICAL**
NO PREFERENCE
GREATLY PREFER **USER**

BENEFIT

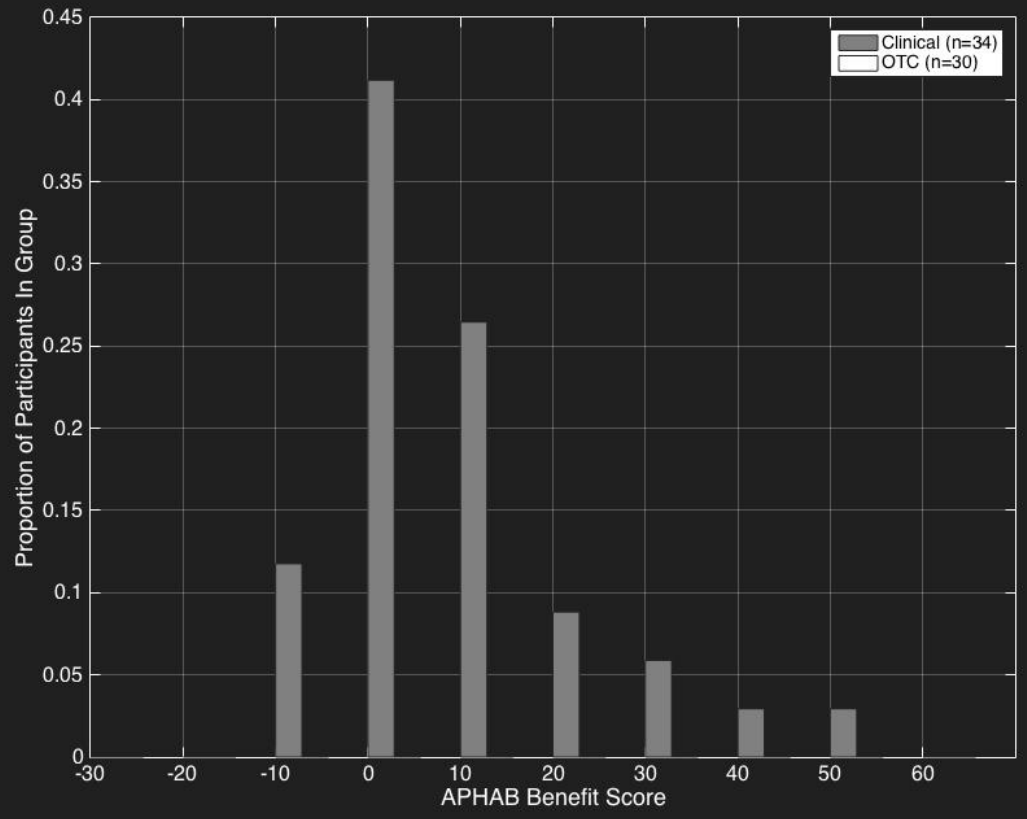
ABBREVIATED PROFILE OF HEARING AID BENEFIT
FORM A

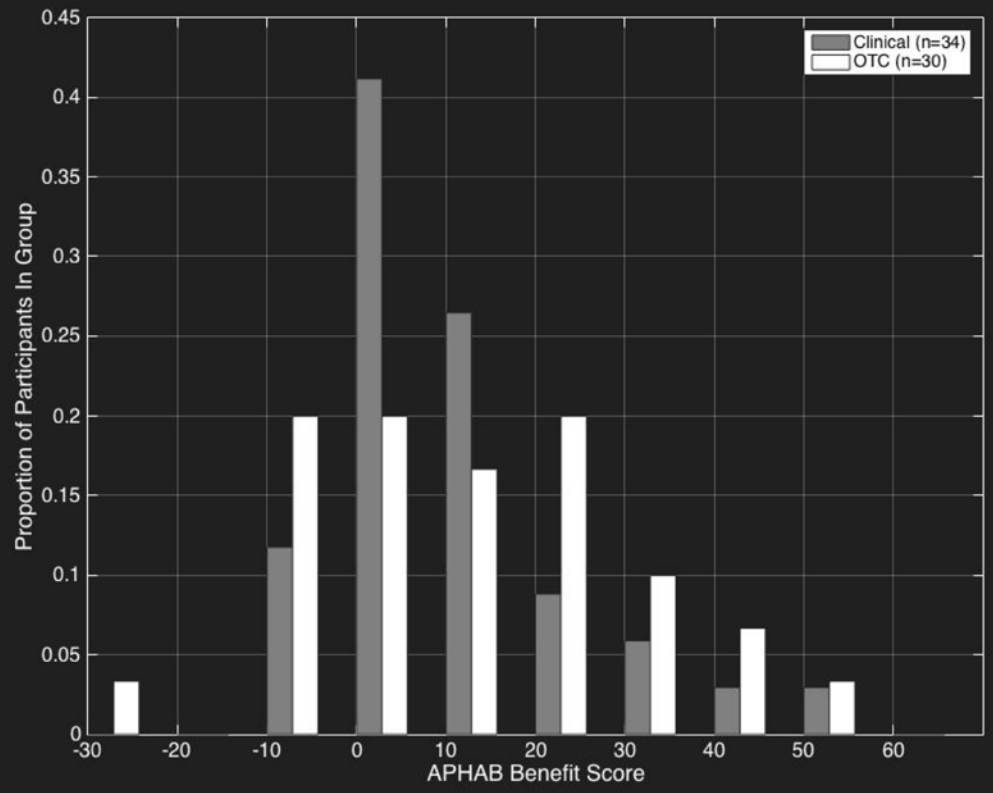
INSTRUCTIONS:

Please circle the answers that come closest to your everyday experience. Notice that each choice includes a percentage. You can use this to help you decide on your answer. For example, if the statement is true about 75% of the time, circle C for that item. If you have not experienced the situation we describe, try to think of a similar situation that you have been in and respond for that situation. If you have no idea, leave that item blank.

A	**Always (99%)**
B	**Almost Always (87%)**
C	**Generally (75%)**
D	**Half-the-time (50%)**
E	**Occasionally (25%)**
F	**Seldom (12%)**
G	**Never (1%)**

		Without Hearing Aids	**With** Hearing Aids
1.	When I am in a crowded grocery store, talking with the cashier, I can follow the conversation.	A B C D E F G	A B C D E F G
2.	I miss a lot of information when I'm listening to a lecture.	A B C D E F G	A B C D E F G
3.	Unexpected sounds, like a smoke detector or alarm bell are uncomfortable.	A B C D E F G	A B C D E F G
4.	I have difficulty hearing a conversation when I'm with one of my family at home.	A B C D E F G	A B C D E F G
5.	I have trouble understanding the dialogue in a movie or at the theater.	A B C D E F G	A B C D E F G
6.	When I am listening to the news on the car radio, and family members are talking, I have trouble hearing the news.	A B C D E F G	A B C D E F G
7.	When I'm at the dinner table with several people, and am trying to have a conversation with one person, understanding speech is difficult.	A B C D E F G	A B C D E F G
8.	Traffic noises are too loud.	A B C D E F G	A B C D E F G
9.	When I am talking with someone across a large empty room, I understand the words.	A B C D E F G	A B C D E F G
10.	When I am in a small office, interviewing or answering questions, I have difficulty following the conversation.	A B C D E F G	A B C D E F G


Clinical (n=34)
OTC (n=30)
Proportion of Participants In Group
0.45
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
-30
-20
-10
0
10
20
30
40
50
60
APHAB Benefit Score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0.15
0.1
0.05
0
-30
-20
-10
0
10
20
30
40
50
60
APHAB Benefit Score

1. WHAT IS THE CURRENT REGULATORY LANDSCAPE?

2. HOW DOES A USER FIT AN OTC HEARING AID?

3. HOW DO WE KNOW IF THAT FIT IS ANY GOOD?