



The “Perfect Storm” of Technology, Demographics and Changing Distribution Models

Dave Fabry, Ph.D.
Vice President, Global Medical Affairs, GN Hearing

The Regents of
The University of Minnesota

on recommendation of the faculty
have conferred upon

David Alan Fabry

the degree of

Master of Arts

with all its privileges and obligations

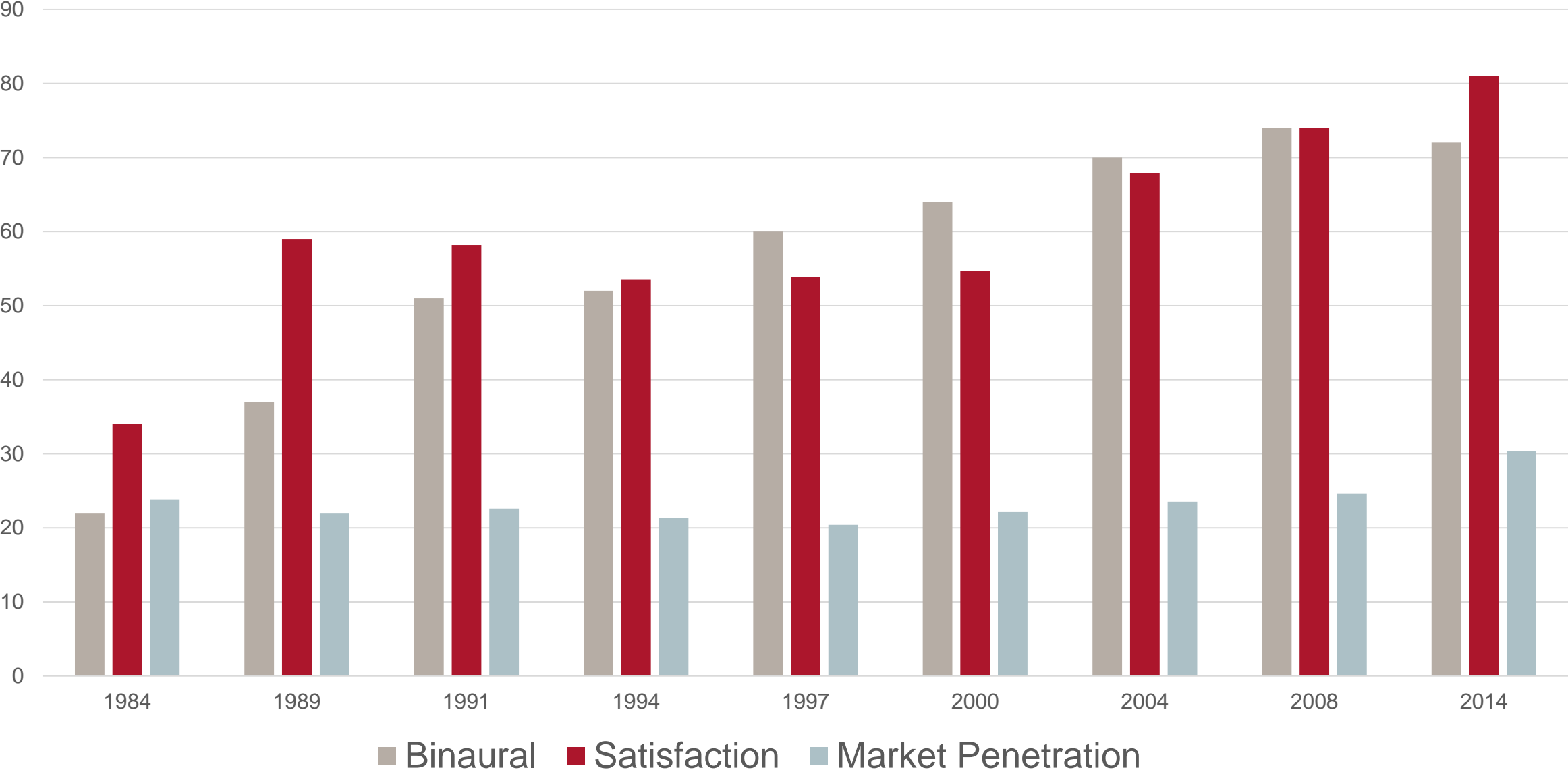
Given in Minneapolis, in the State of Minnesota,
the seventeenth day of March, nineteen hundred eighty-four.

Dwaine A. Wilson
SECRETARY



C. Peter Magrath
PRESIDENT

US Hearing Aid Binaural Fitting Rate (%) , Satisfaction (%) and Market Penetration (%), by Year

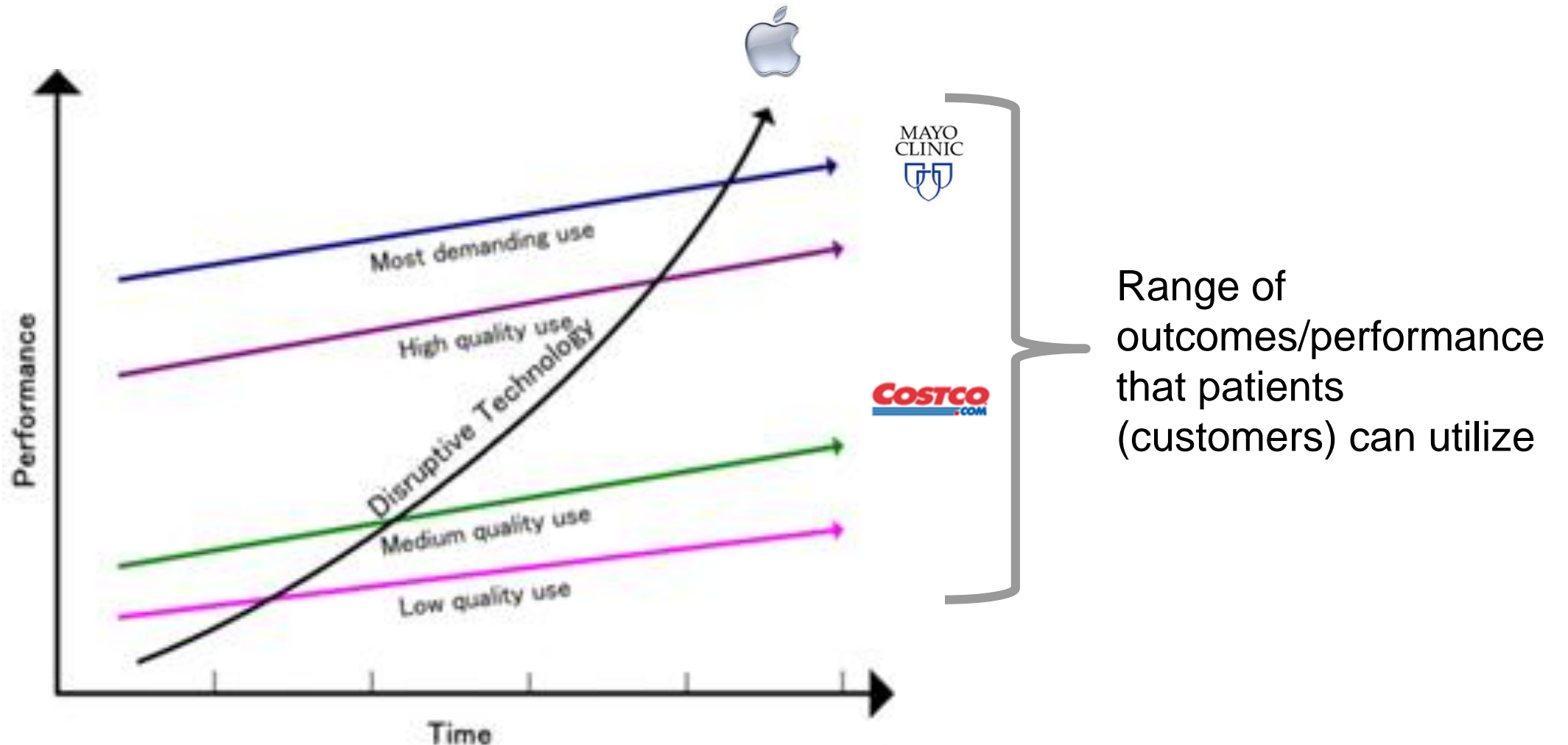




Threats vs. Opportunities



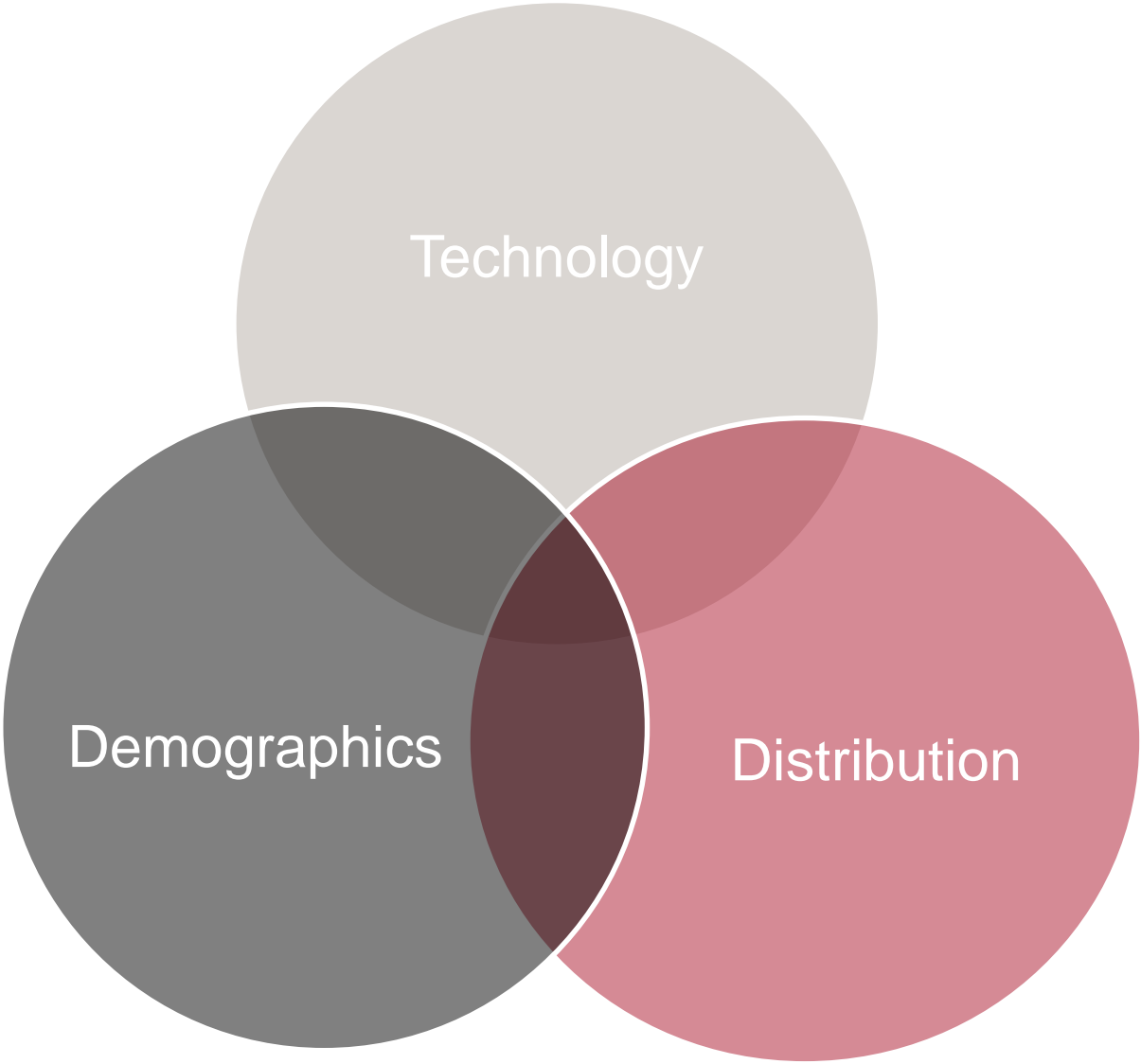
Disruptive Innovation Model

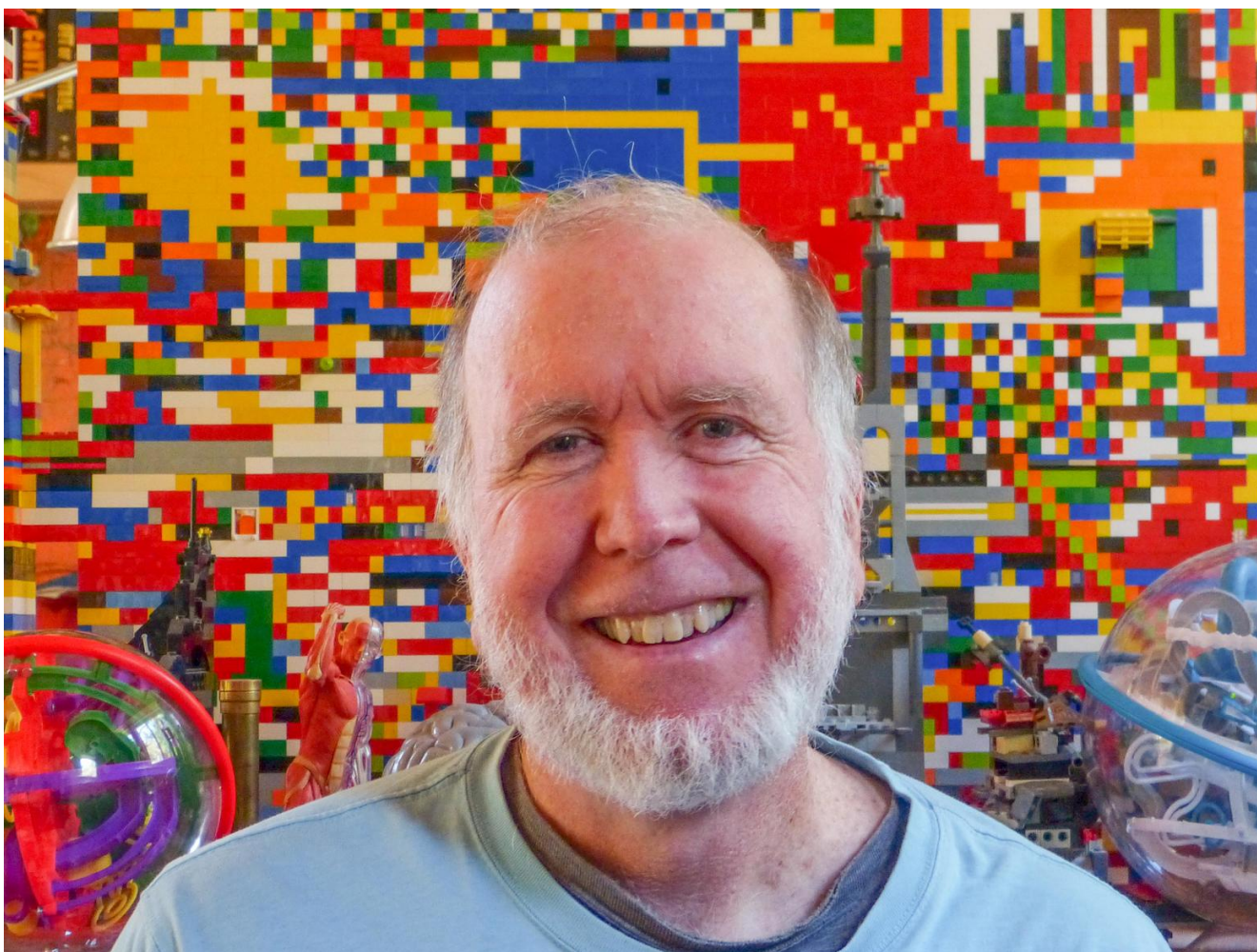
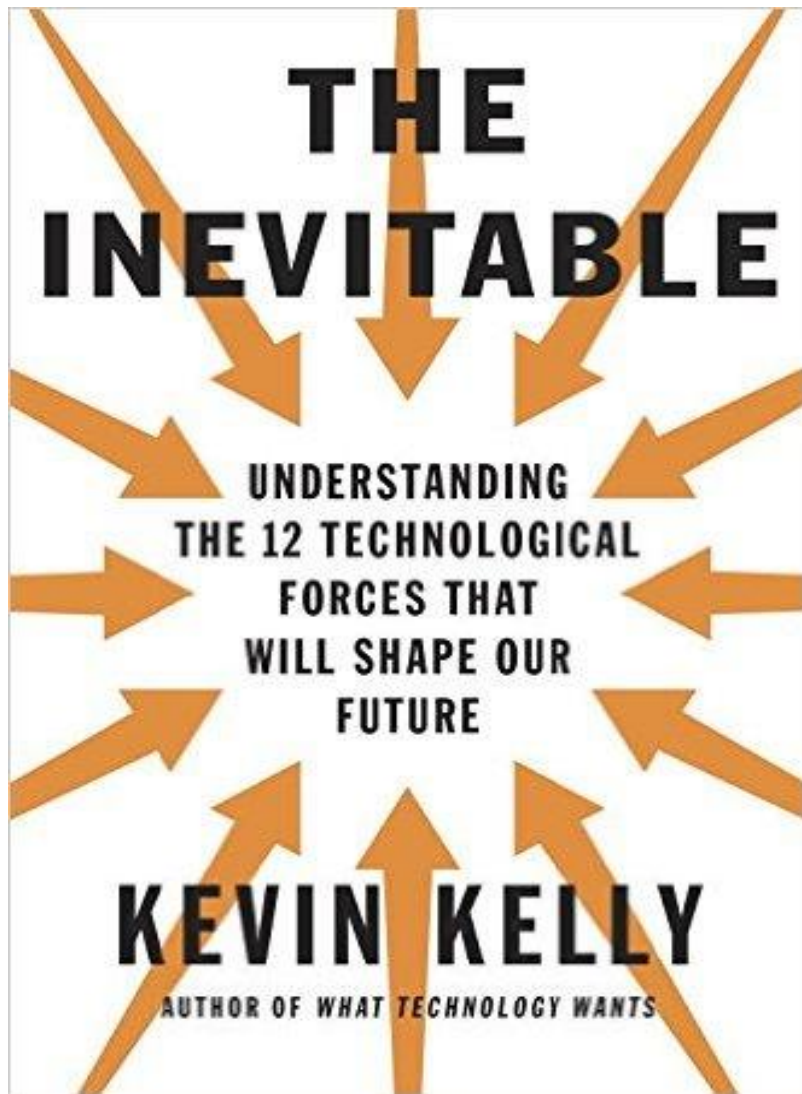


***“You can’t read
the label,
when you are
sitting
inside the jar”***

- Mike Maddock







12 Technological Forces

Becoming

Cognifying

Flowing

Screening

Accessing

Sharing

Filtering

Remixing

Interacting

Tracking

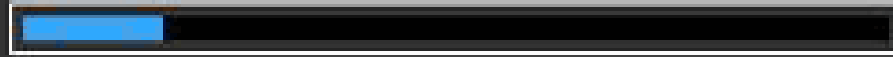
Questioning

Beginning

Fabry (2016) Seminars in Hearing



Updating Software



Cancel

12 Technological Forces

Becoming

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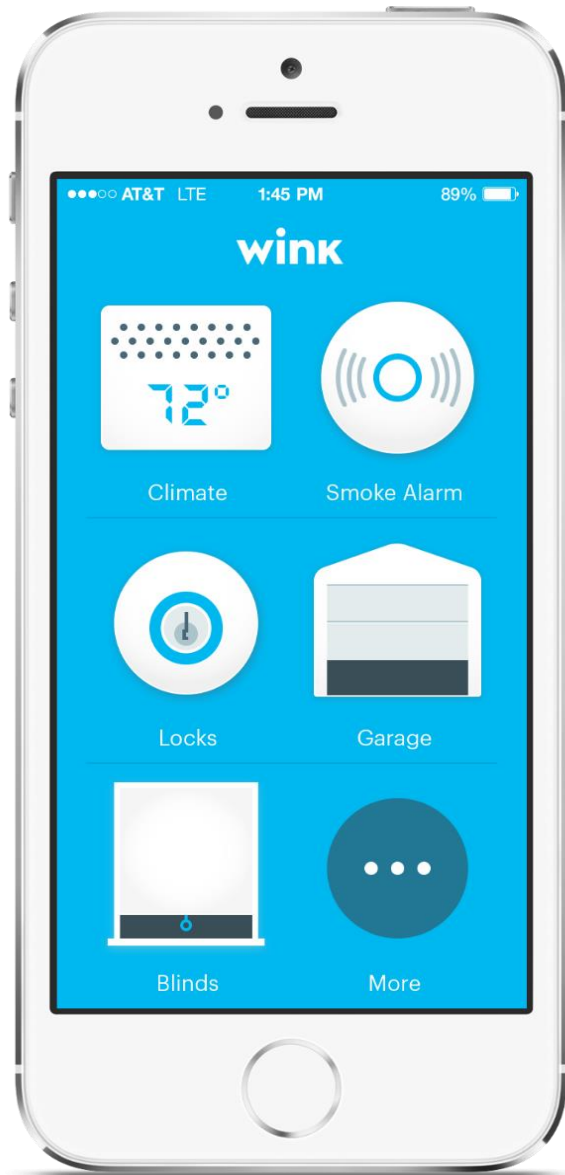
Tracking

Questioning




Beginning

Fabry (2016) Seminars in Hearing





GE LINK BULBS

 <p>60w replacement* 12w SOFT WHITE</p>	 <p>65w replacement 10w SOFT WHITE</p>	 <p>90w replacement 13w BRIGHT WHITE</p>
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*This 12-watt bulb provides nearly the same light output as a 60-watt soft white incandescent bulb (800 lumens vs. 840 lumens).

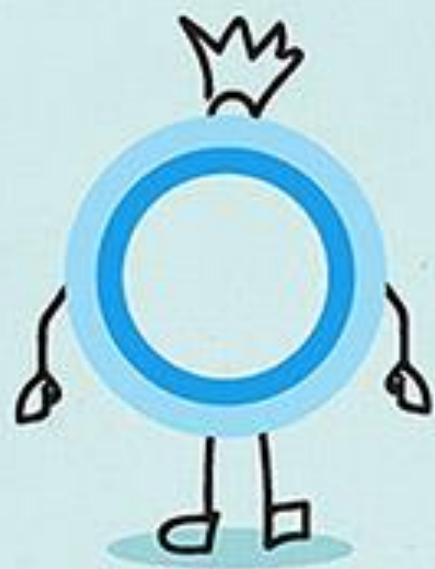
wink







Siri



Cortana



Alexa



Google Now







12 Technological Forces

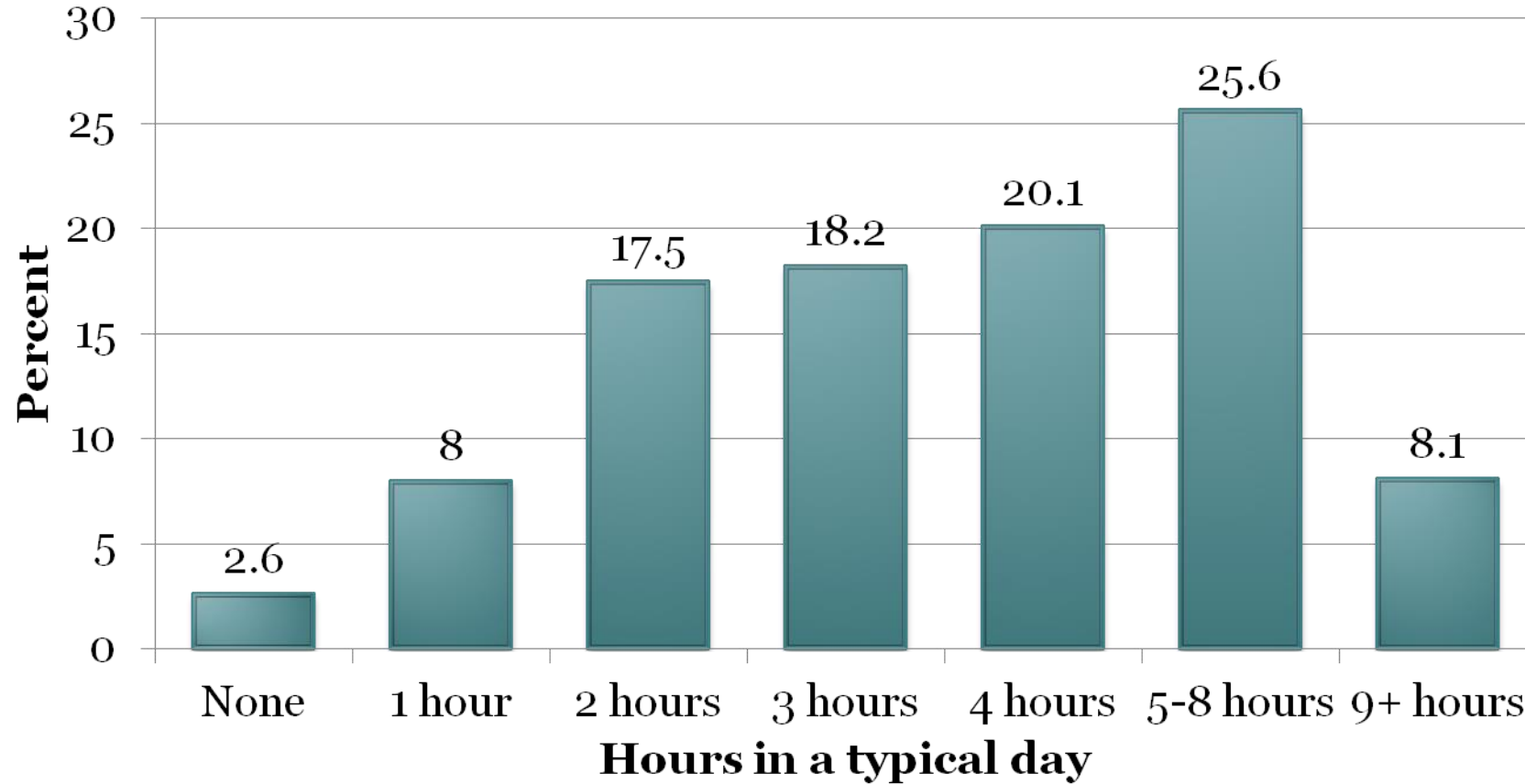
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Beginning

Fabry (2016) Seminars in Hearing



Media habits – total HL population
Media = watching television





ALLSEEN ALLIANCE



PREMIER MEMBERS



COMMUNITY MEMBERS



SPONSORED MEMBERS





Bluetooth[®]
SMART





Apple tv



AirPods

Wireless. Effortless. Magical.



12 Technological Forces

Becoming

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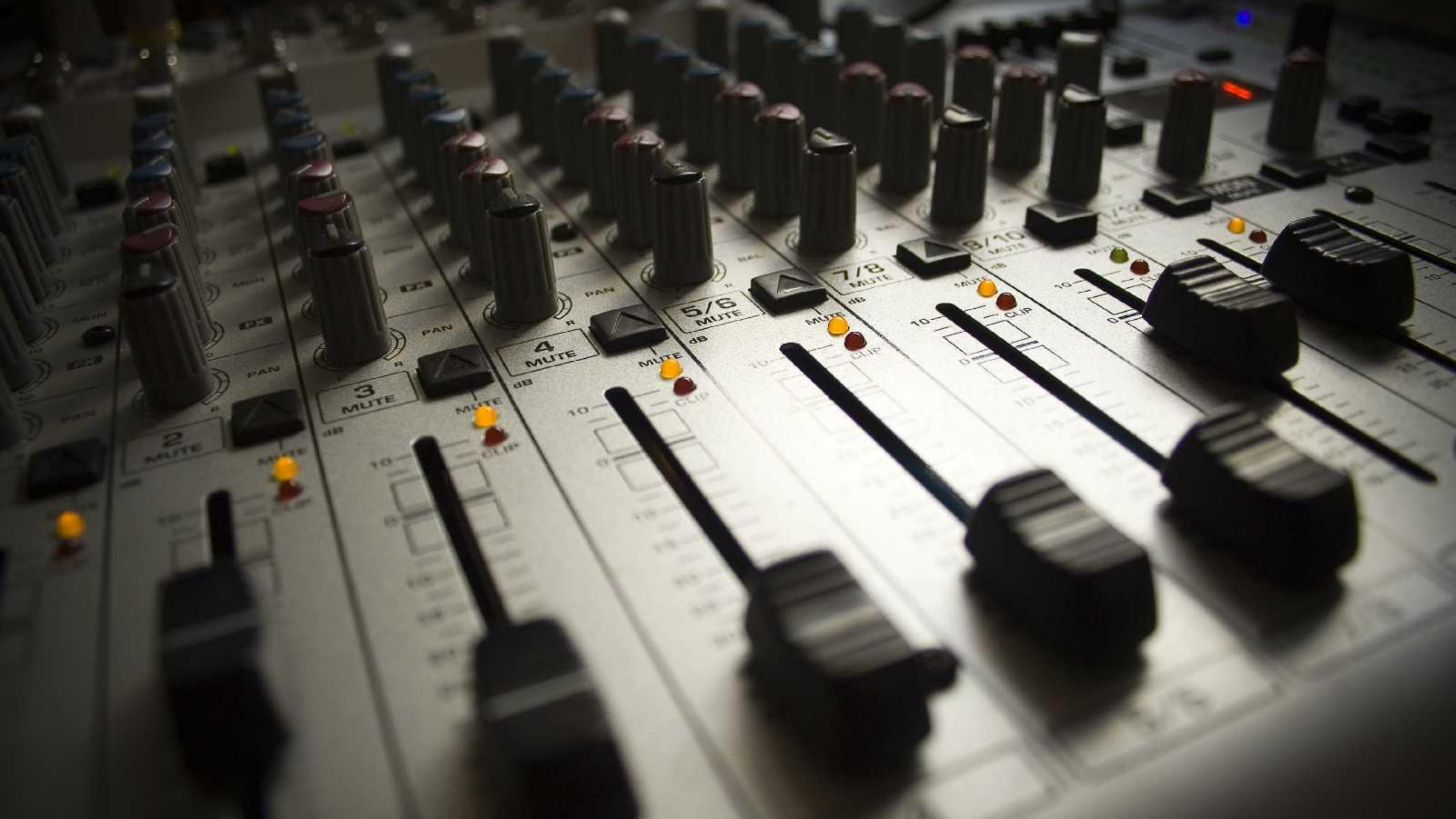
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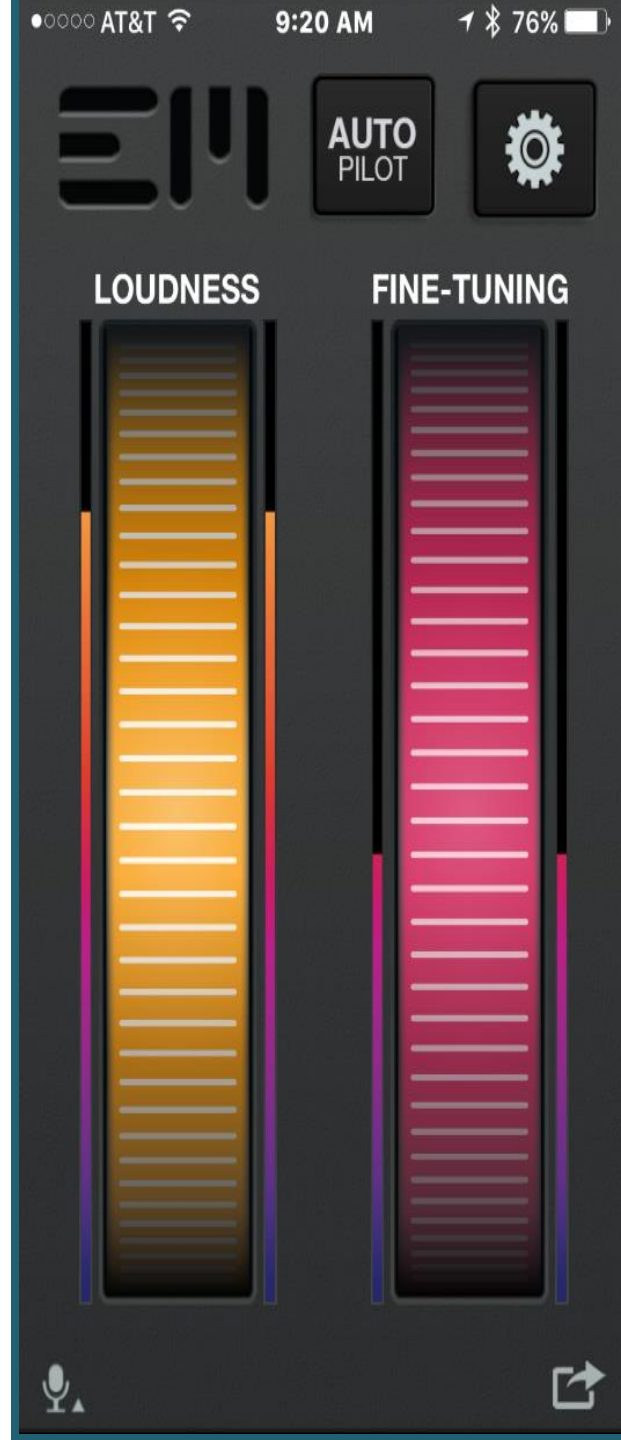
Beginning

Fabry (2016) Seminars in Hearing



AirPods

Wireless. Effortless. Magical.



Fennex – Augmented Hearing App


[View More by This Developer](#)

By FENNEX AG

Open iTunes to buy and download apps.



[View in iTunes](#)

 This app is designed for both iPhone and iPad

Free

Category: [Health & Fitness](#)

Updated: Jul 31, 2017

Version: 1.0.2

Size: 52.9 MB

Language: English

Seller: FENNEX AG

© 2017 FENNEX AG

Rated 4+

Compatibility: Requires iOS 10.0 or later. Compatible

Description

Fennex™ is a hearing aid app that provides augmented hearing by turning your Apple headphones (EarPods or AirPods) into a personal hearing amplifier. Firstly, take a quick hearing test that indicates your hearing abilities. Secondly, use the hearing test results to personalize your hearing experience. Thirdly, select a listening scene

[FENNEX AG Web Site](#) ▶ [Fennex – Augmented Hearing App Support](#) ▶

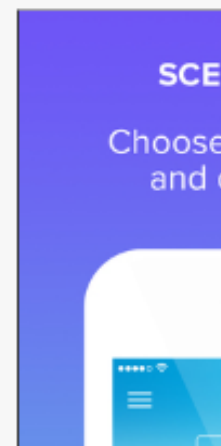
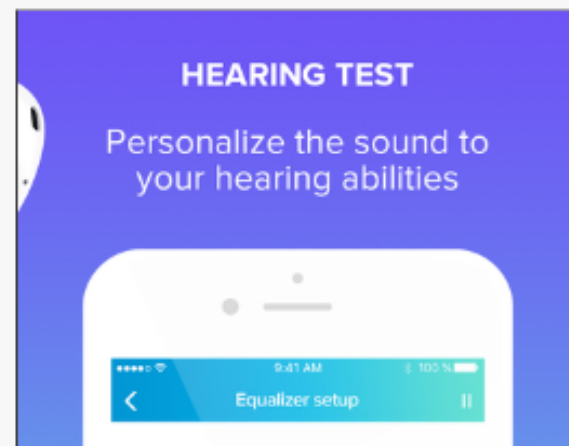
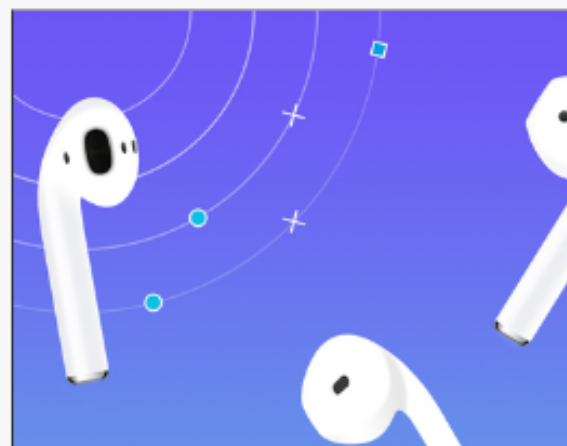
[...More](#)

What's New in Version 1.0.2

* Improved sound quality with 48% better performance versus previous version

Screenshots

[iPhone](#) | [iPad](#)



12 Technological Forces

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Interacting

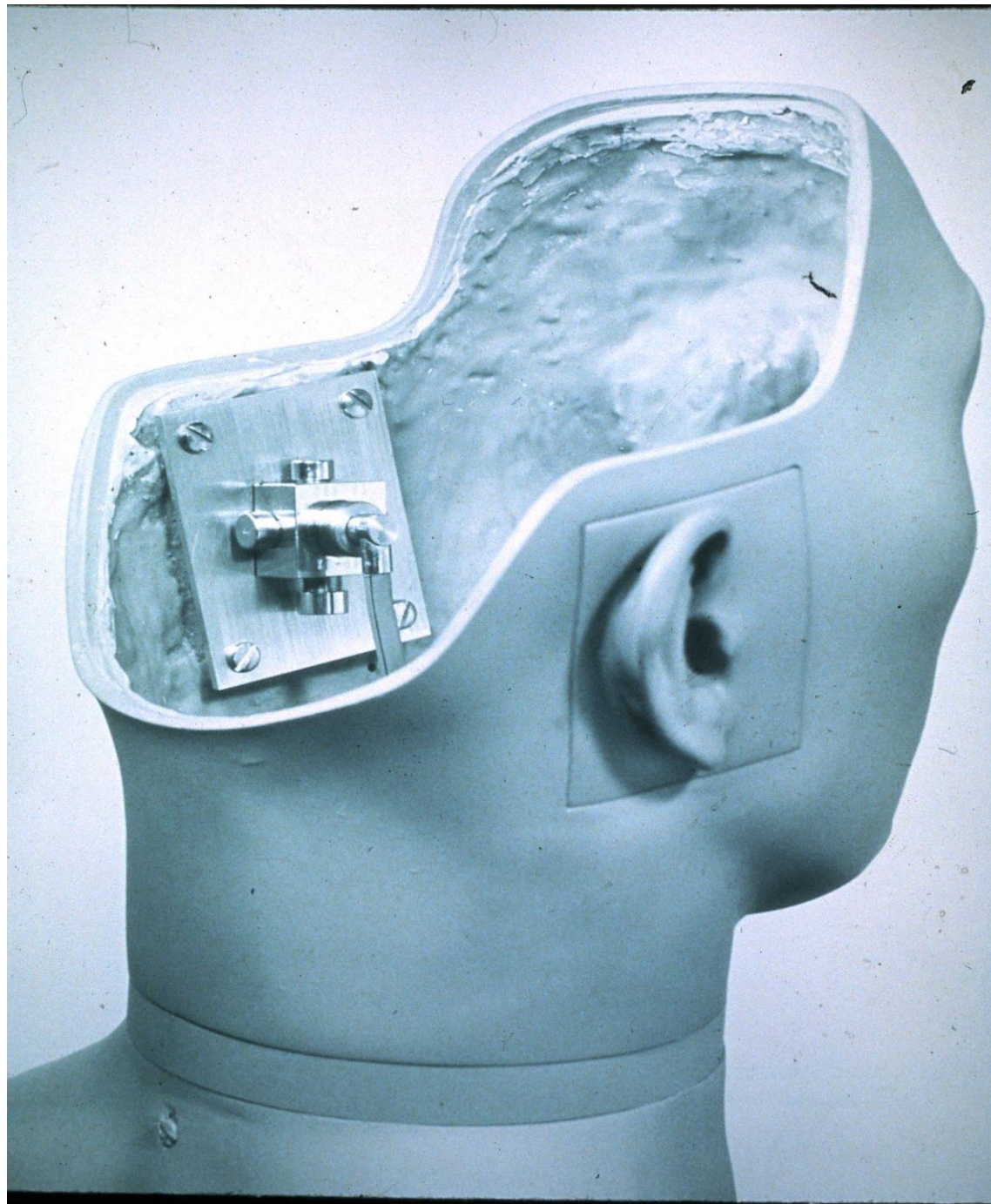
Tracking

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Beginning

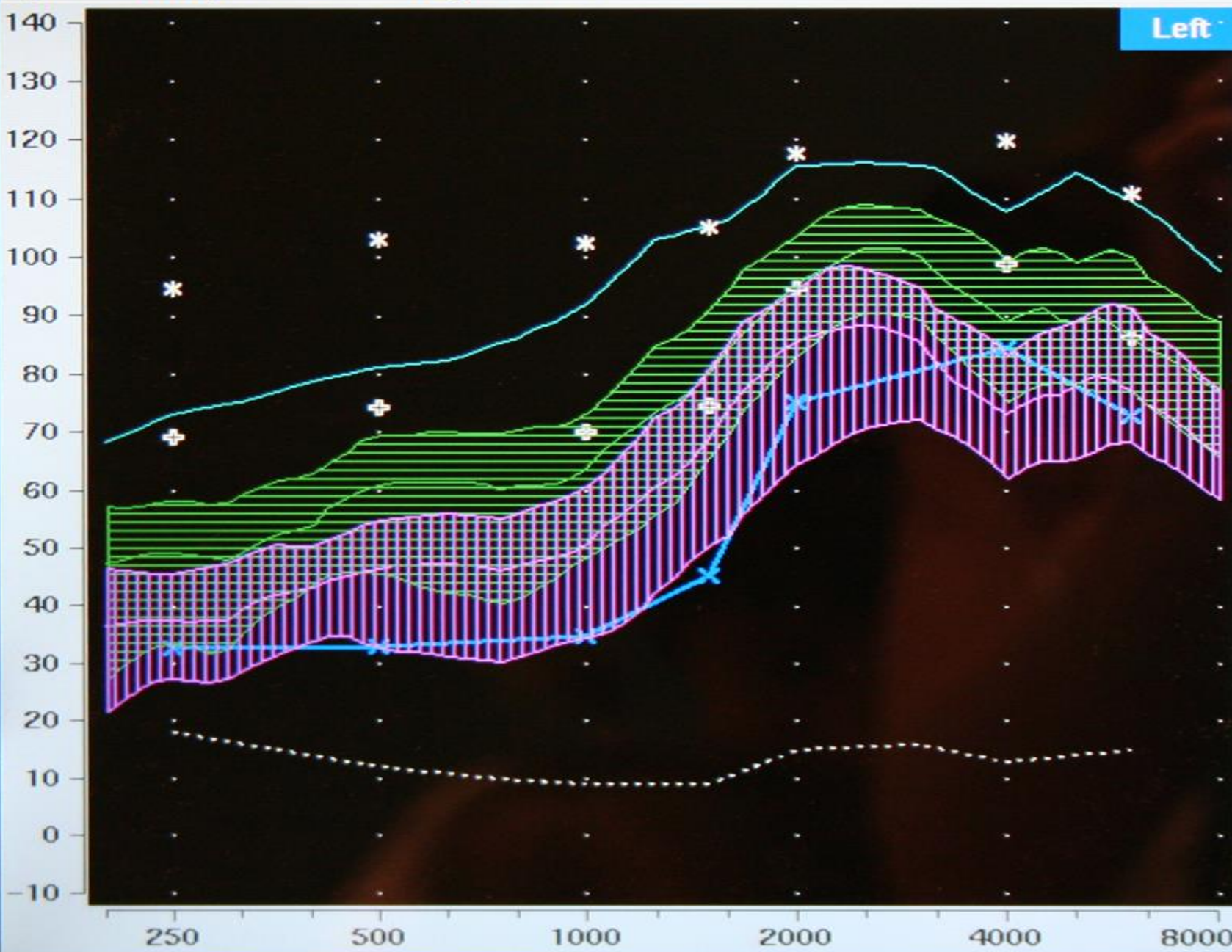
Fabry (2016) Seminars in Hearing





Speechmap/DSL - Single view

Left



- Instrument
- Mode
- Presentation
- Format
- Scale (dB)

- Audiometry**
- Age
 - Transducer
 - UCL
 - RECD
 - REDD

REAR	Stimulus	Level	SII
<input type="radio"/> 1	Speech-shape	Avg (70)	82
<input type="radio"/> 2	Speech-shape	Soft (55)	64
<input type="radio"/> 3	MPO	90	N/A
<input type="radio"/> 4			

LTASSu

Curve

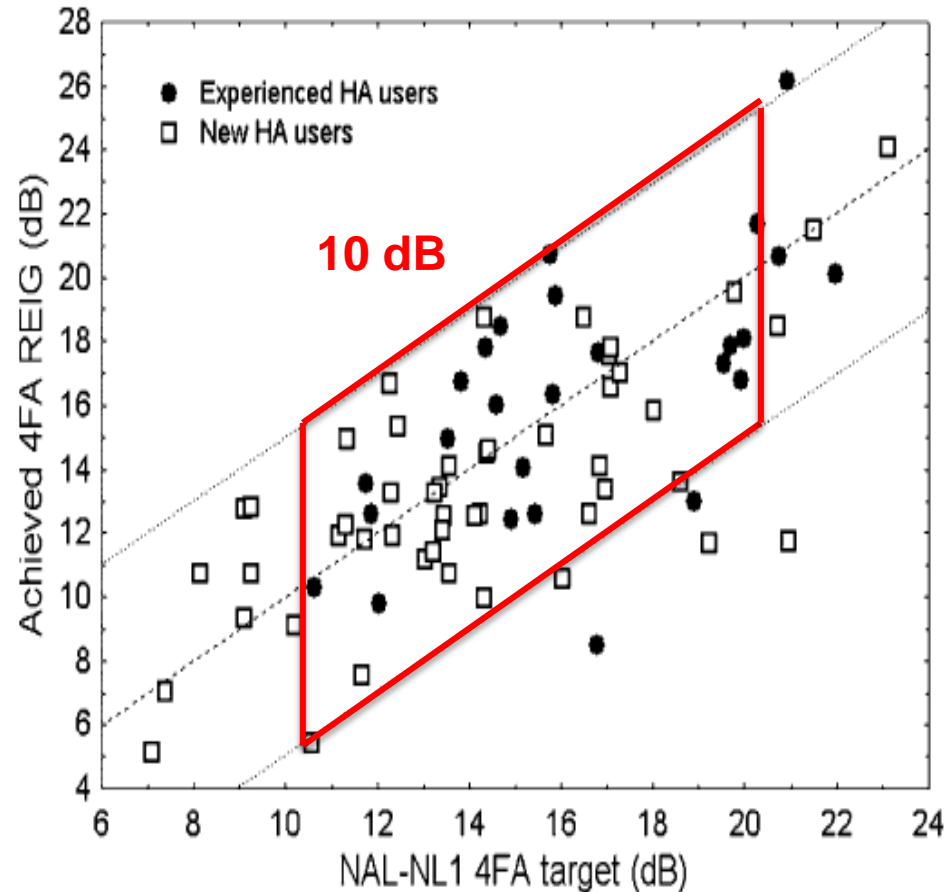
Is first fit the final fit?

Kiedser et al, 2008

New and experienced wearers show a range of gain preference

Patients' judgment of loudness will change with time

Starting gain may affect preferred final gain (Mueller et al, 2008)



Auditory Ecology

The range of **acoustical environments** that a person experiences, the **auditory demands** of those environments, and the **importance** of those demands to an individual's daily life.

(Gatehouse et al., 1999)

Potential Predictors of Benefit

Hearing Thresholds

Loudness Discomfort Level

Susceptibility to Upward Spread of Masking

Broadened psychophysical tuning

Spectral and Temporal smearing

Noise dosimetry measurement

Lifestyle and Demand questionnaire

Cognitive function

Speech in noise testing

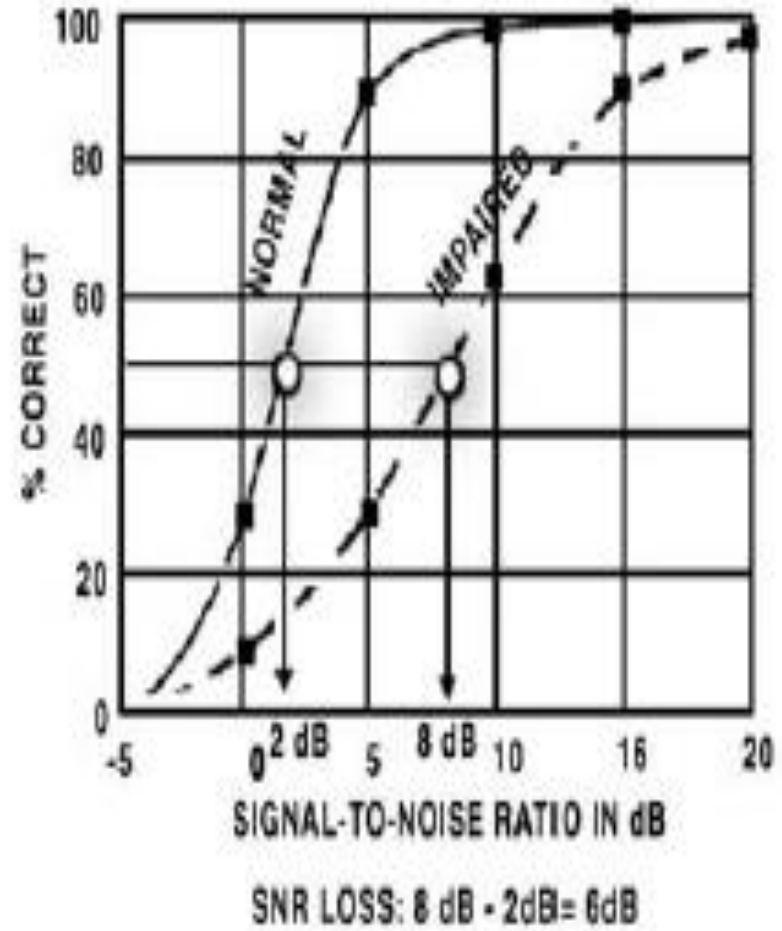
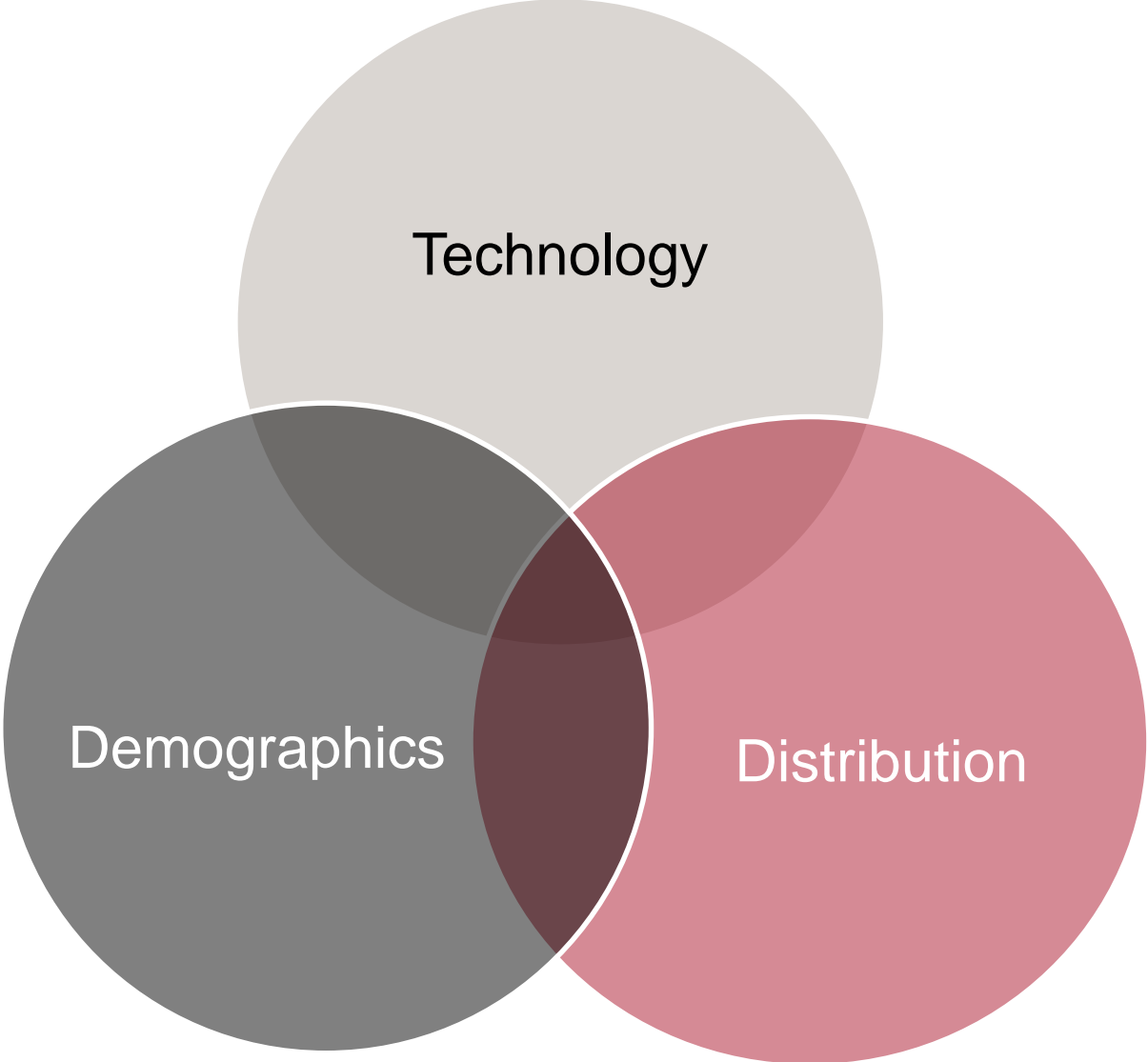


Figure 1 (From Killion, 2002)

Using SNR Loss Measures to assist with Selection of HA Technology

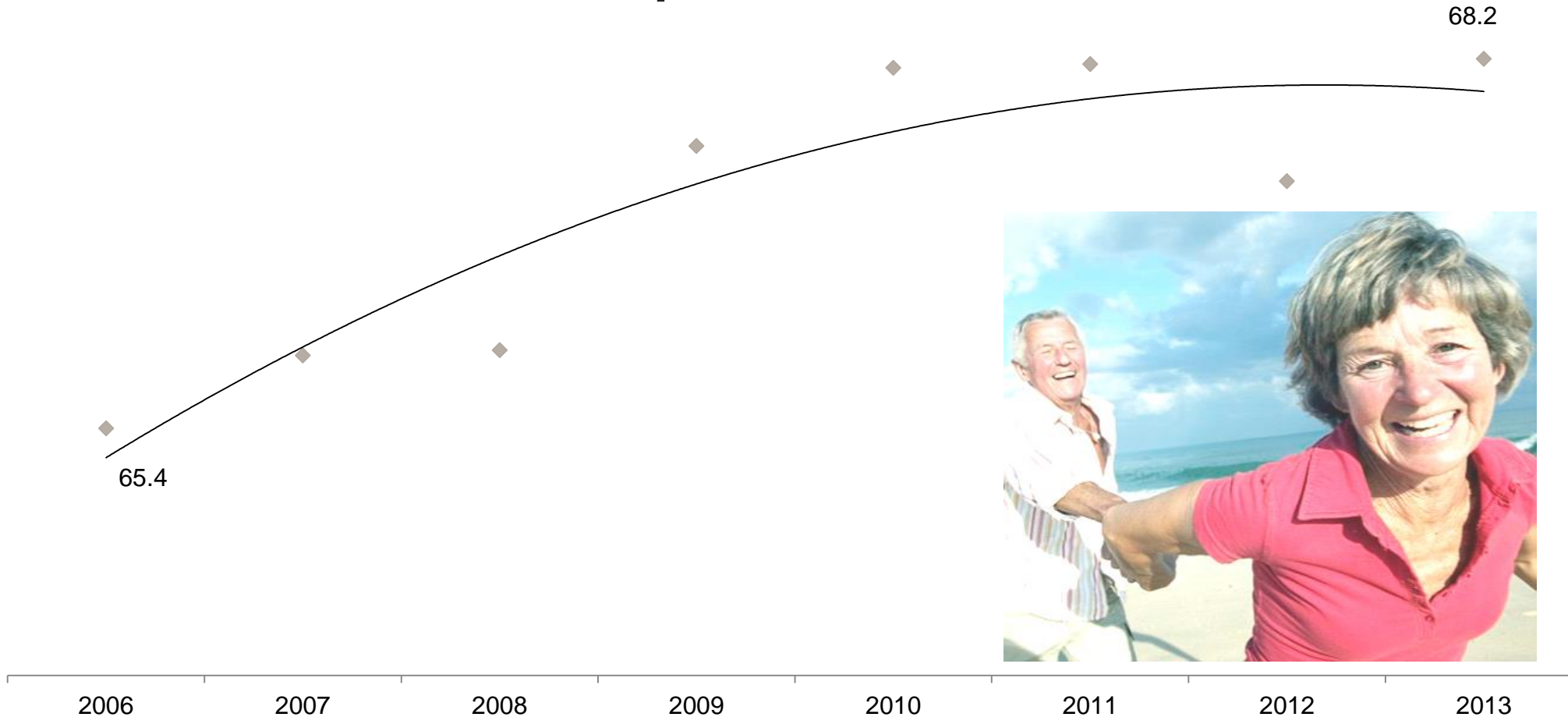
SNR LOSS	CATEGORY	TECHNOLOGY NEEDS
0 - 2 dB	Normal	Omni-directional microphones (CIC/ITC)
2 – 7 dB	Mild	Fixed/Dynamic Directional mics
7 – 15 dB	Moderate	Dynamic/Adaptive directional mics
> 15 dB	Severe	FM/Remote Microphone system



A photograph of a middle-aged man with short, light-colored hair, smiling warmly. He is wearing a light blue, long-sleeved button-down shirt and is seated on a light-colored upholstered chair. The background shows a window with a grid pattern. The entire image is overlaid with a semi-transparent teal color. Centered over the image is the text "Boomers are already here!" in a white, sans-serif font.

Boomers are already here!

A Positive, Optimistic View of Life



% Boomers indicating at what age the feel 'old age' begins

Open-Minded & In Pursuit of Knowledge



They are more likely than the population to describe themselves as “knowledge-seeking”

Have adapted to and adopted new technologies, with 7 in 10:

- Comfortable using new technologies and devices
- Using technology to stay connected with family on a regular basis

More Boomers than younger generations agree they...



...Are taking more responsibility for their health compared to 10 years ago

81%



...Will take whatever means necessary to control their own health

64%



**READ LESS MINDS.
ASK MORE QUESTIONS.**

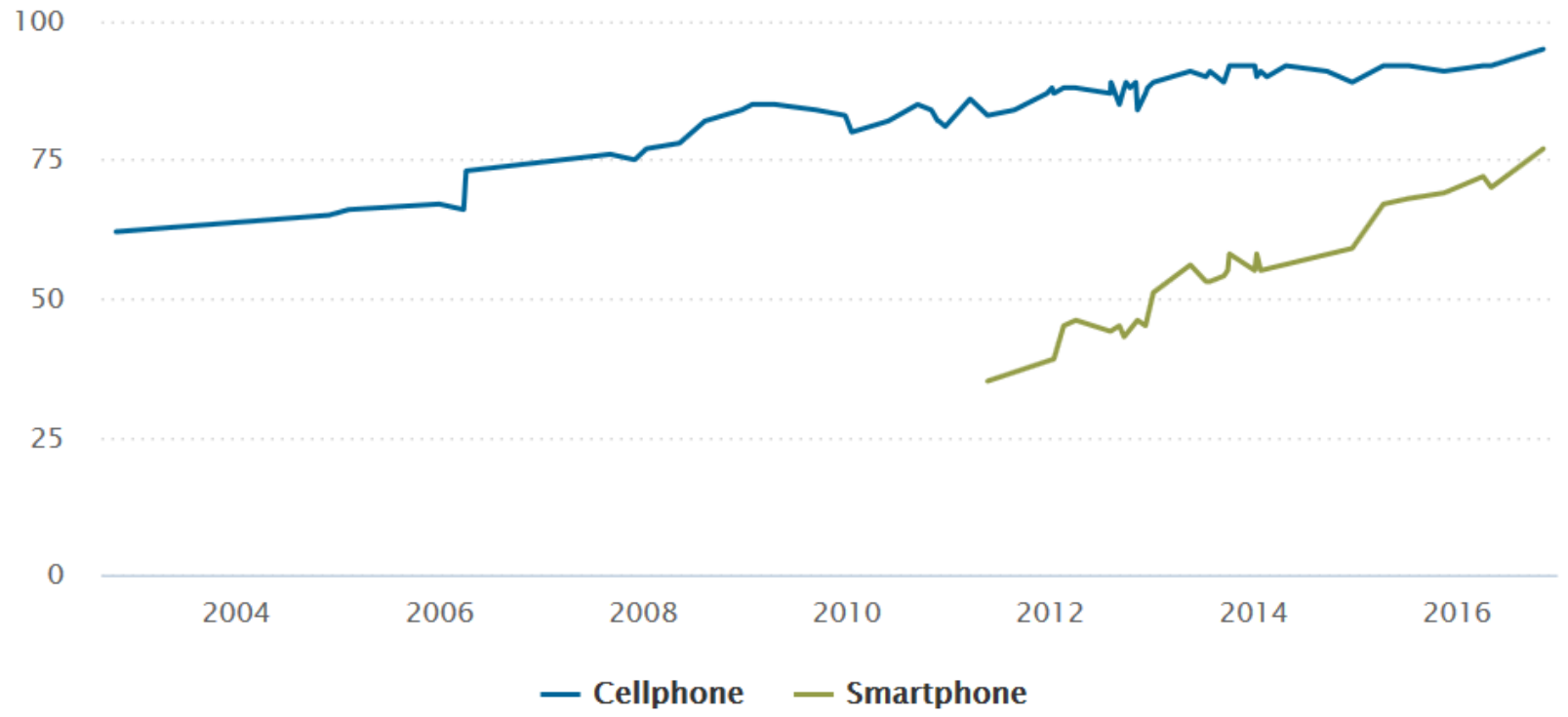
Key Survey Findings

Technology and tele-health is emerging as a driver of consumers' healthcare decision making

- **Approx. 86% of respondents see value in incorporating tele-health care into a healthcare regimen**

They have the technology!

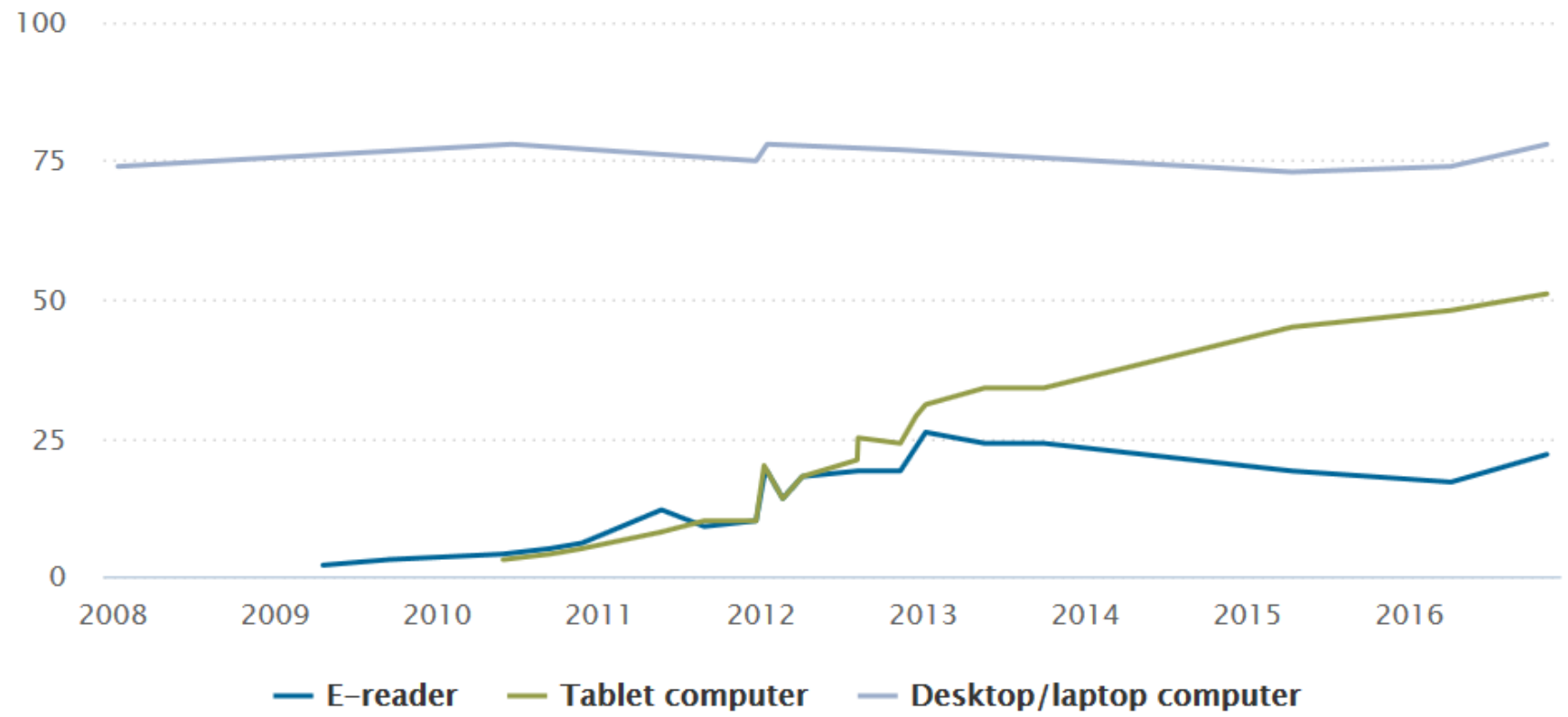
% of U.S. adults who own the following devices



Source: Pew Research Center, January 12, 2017

Survey Findings: They have the technology

% of U.S. adults who own the following devices



Source: Pew Research Center, January 12, 2017

Key Survey Findings

The future hearing aid wearer can be expected to choose a brand that offers tele-health

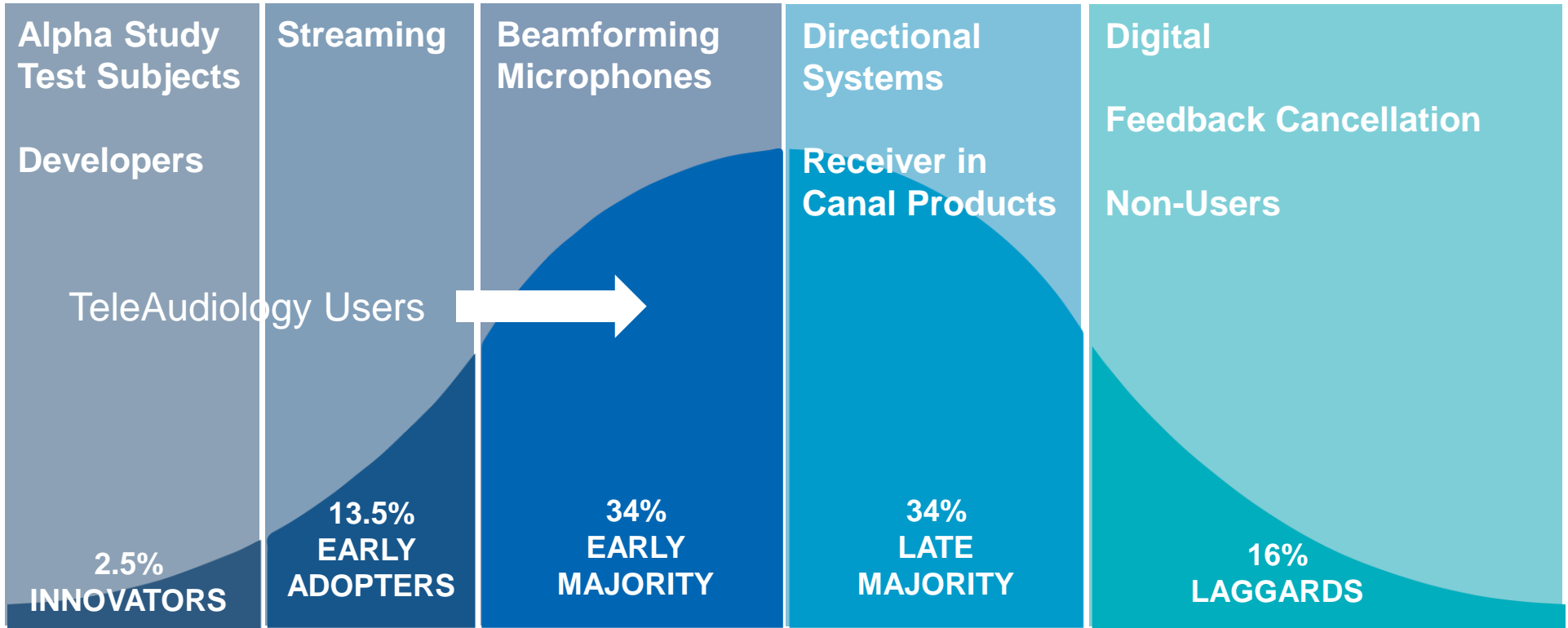
- Of the 35-54 year-old age group **20%** answered that they were **very likely** to change their hearing aids or other hearing assistance device to a brand that provides a telepresence function that links them directly to a healthcare professional
- **30%** of the **35-54 year olds** answered that **telepresence is the future of the healthcare industry**

Key Survey Findings

The users see benefits of TeleAudiology - and are online

- **22% of all respondents would be very or somewhat likely to communicate with their audiologist or other healthcare professional through telepresence. This is 39% for the age group 35-54 year old**

TECHNOLOGY TRENDS



Key Survey Findings

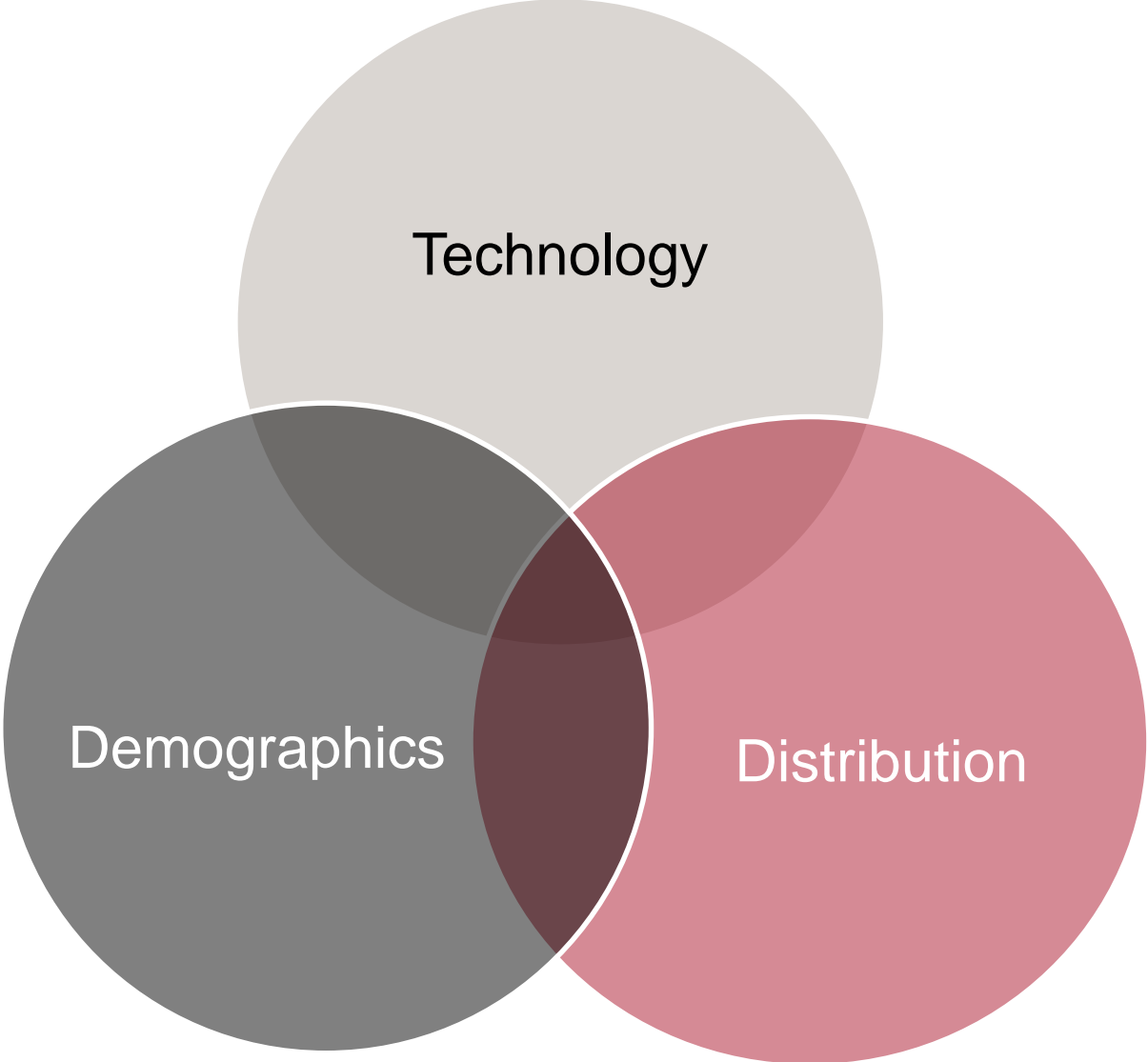
The users expect their health professionals to be flexible and on the forefront of technology. Of those not satisfied with their hearing care professional (HCP):

- **30% said it was due to the HCP not offering the most recent technology available**
- **23% stated that it was too hard to schedule an appointment**
- **31% felt that the doctor's office was too far away – and they were all in the +55 year age group**



EMPATHY

Understanding what someone
needs and acting on it.

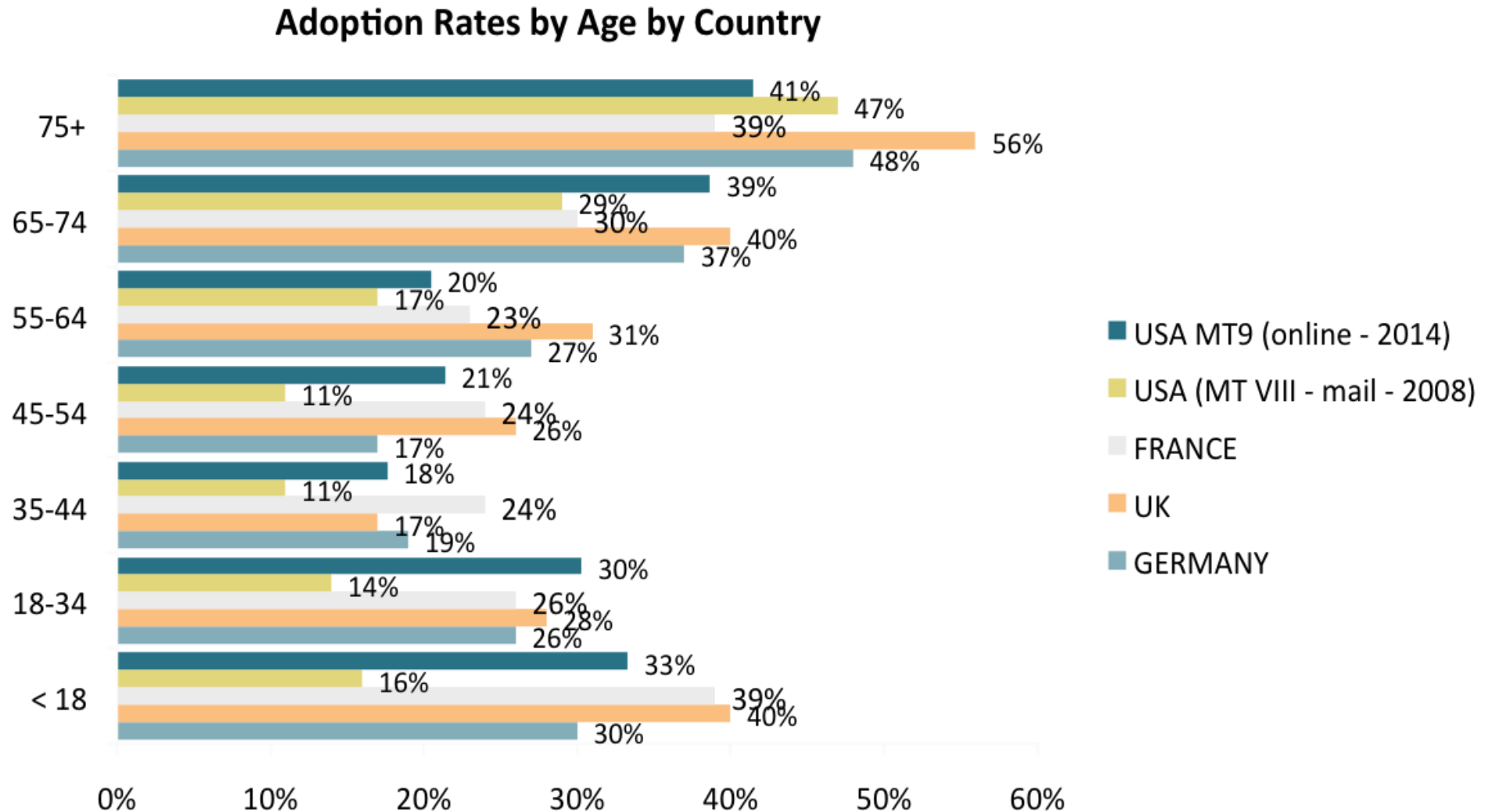


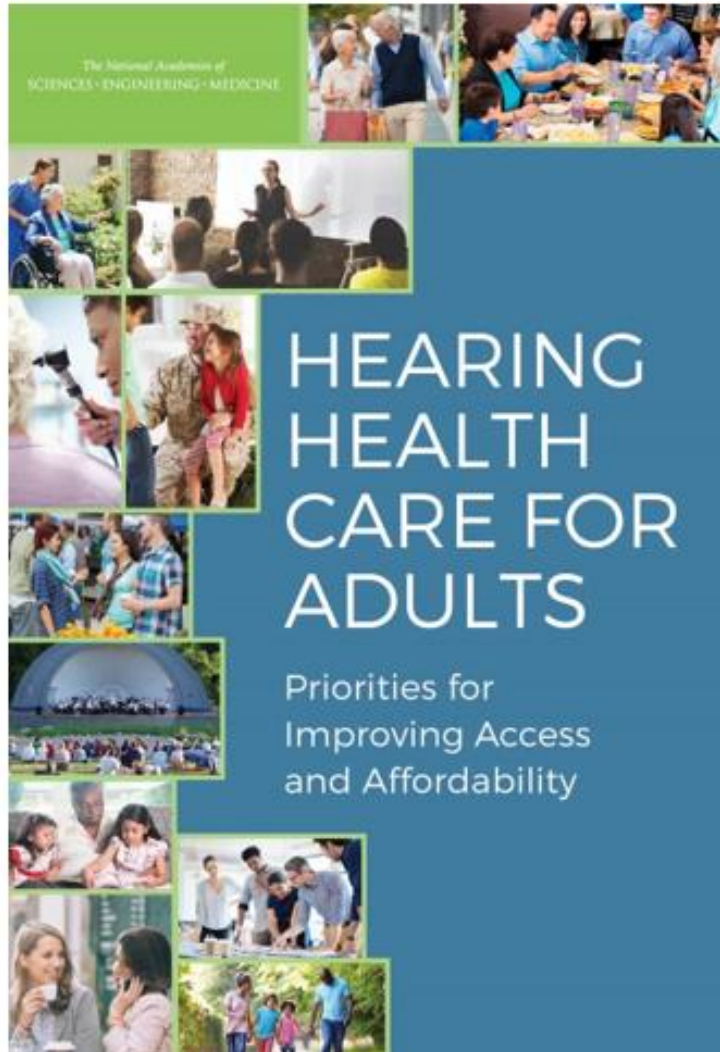
Technology

Demographics

Distribution

Hearing Aid Adoption: US and Europe (MT9 and EuroTrak)





Hearing Health Care for Adults: Priorities for Improving Access and Affordability

Suggested citation: National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Washington, DC: The National Academies Press.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Over-the-Counter Hearing Aid Legislation



Over-the-Counter Hearing Aid Legislation

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

Mr. GRASSLEY, Mr. HASSAN, and Mr. ISAKSON (in-
terim) introduced this bill, which was read twice and referred to the Com-
mittee on Labor, and Pensions



A BILL

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

Over-the-Counter Hearing Aid Legislation

S. 670/ H. 1652 includes changes from original legislation S. 9

Strengthens language specifying OTC hearing aids are intended to be used for adults “over the age of 18”

Direct Secretary of HHS to take steps to ensure safety and efficacy

- Requirements to establish output limits appropriate for OTC devices
- Requirements for appropriate labeling; reporting adverse affects, listing contradictions, and advising to consult with physician if present

Preempts state law

- Finalize rather than withdraw PSAP guidance

Senate Follows House Action; Passes FDA User Fee Bill with OTC Hearing Aid Provision

Today at 1:42 PM



AUGUST 2017

Senate Follows House Action; Passes FDA User Fee Bill with OTC Hearing Aid Provision

On August 3, the US Senate passed the FDA Reauthorization Act, legislation reauthorizing the FDA's user fee programs for prescription drug, medical device, generic drug, and biosimilar biological products. The legislation also contains a provision that would direct the FDA to develop a category of over-the-counter (OTC) hearing aids for adults with perceived mild to moderate hearing loss. The US House of Representatives [passed](#) this legislation on July 12. This legislation will now go on to the President to be signed into law.

As this legislation progressed through Congress, the Academy met with lawmakers to share the Academy's statements on [OTC Devices](#) and [Accessibility and Affordability for Hearing Care](#) and to reinforce the important role of audiologists in optimizing hearing-care outcomes for patients. On the passage of this OTC hearing aid legislation, Academy President Ian Windmill, PhD said, "Throughout the legislative process, the Academy advocated for changes to the OTC hearing aid legislation to allow for consumers to self-direct their care in a safe and appropriate manner. While the legislation is not perfect, it is a substantial improvement over previous iterations of the bill. We will continue to engage with

The final passage of the OTC hearing aid legislation comes after nearly two years of national dialogue prompted by the release of the President's Council of Advisors on Science and Technology (PCAST) [report](#) on age-related mild to moderate hearing loss. The National Academy of Sciences, Engineering, and Medicine (NASEM), formerly the Institute of Medicine (IOM), also convened public and private stakeholder meetings as they prepared and released their own recommendations in their [report](#) entitled *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. The US Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) hosted workshops and other events to solicit stakeholder feedback on this topic.

Academy President Windmill went on to say, "During many of the national discussions on age-related hearing loss, audiologists were frequently identified as leaders in advancing policies to improve access to services and devices for consumers. Audiologists can provide guidance to the consumer on determining if an OTC hearing aid device or other amplification product can offer the best results for hearing loss treatment. With the passage of the OTC legislation, we, as audiologists, must continue to lead through consumer education, outreach to other providers, and partnerships with federal agencies. Our efforts will now shift towards directly engaging with the FDA and FTC to shape new OTC hearing aid device regulations that will be developed and implemented in the coming months and years."

The Academy will keep members up-to-date on next steps regarding the development of a category of OTC devices as more information becomes available. Visit the Academy's website for the latest in [Government Relations News](#).



What's the 411 on TELEMEDICINE?



Telemedicine is a healthcare service provided to a patient by a healthcare professional from a different location through the use of telecommunications technology.

TELEMEDICINE COULD BE...

Connecting with your doctor over video

Conducting a follow-up appointment online

Participating in a virtual consultation

OVER 20 MILLION

patients will
benefit from a
remote service
by the end of 2017



LEADING MEDICAL SERVICES USING TELEMEDICINE

- Radiology
- Mental Health
- Pathology
- Primary and Urgent Care
- Intensive Care Unit Monitoring
- Chronic Care Monitoring
- Wellness Applications

TYPES OF TELEMEDICINE DELIVERY

- Live Video
- Voice
- Mobile Devices
- Store and Forward
- Provider-to-provider Consultation
- Direct to Consumer
- Artificial intelligence



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info@americantelemed.org | @AmericanTelemed



115TH CONGRESS
1ST SESSION

H. R. 2550

To amend title XVIII of the Social Security Act to provide for an incremental expansion of telehealth coverage under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2017

Mr. THOMPSON of California (for himself, Mrs. BLACK, Mr. WELCH, and Mr. HARPER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

Medicare Telehealth Parity Act of 2017 would phase in expansion of telehealth services by:

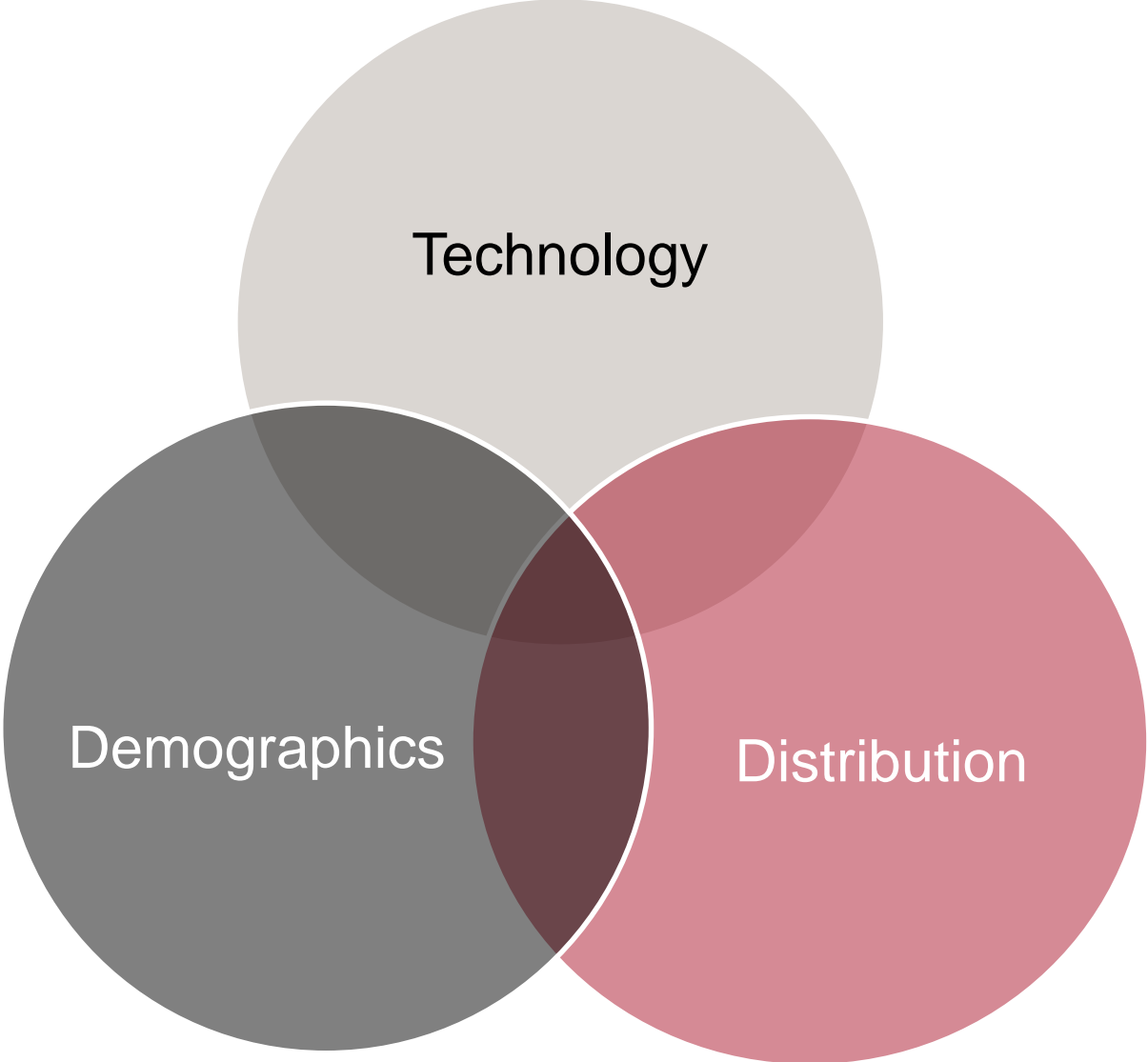
- Expanding the list of eligible providers and related covered services to include audiologists, speech-language pathologists, respiratory therapists, physical therapists, and occupational therapists;
- Removing the geographic barriers under current law and allowing for the provision of telehealth services in rural, underserved, and metropolitan areas;
- Expanding access to telestroke services, regardless of where the patient is located;
- Allowing remote patient monitoring (RPM) for patients with chronic conditions such as heart failure, chronic obstructive pulmonary disease (COPD), and diabetes; and
- Allowing the beneficiary's home to serve as a site of care for home dialysis, hospice care, eligible outpatient mental health services, and home health services.

Telemedicine State Licensure Compact Legislation Tracking

TELEMEDICINE ASSOCIATION

2017 State Licensure Compact Legislation Tracking (as of July 2017)

State	<u>Interstate Medical Licensure Compact</u>	<u>Enhanced NLC</u>	<u>APRN Compact</u>	<u>PSYPACT</u>	<u>PTLC</u>	<u>N</u>
Alabama	✓					
Alaska						
Arizona	✓	✓		✓	✓	
Arkansas		✓				
California						
Colorado	✓	Proposed*			✓	
Connecticut						
Delaware		✓				
DC	Proposed					
Florida		✓			Proposed	



Technology

Demographics

Distribution



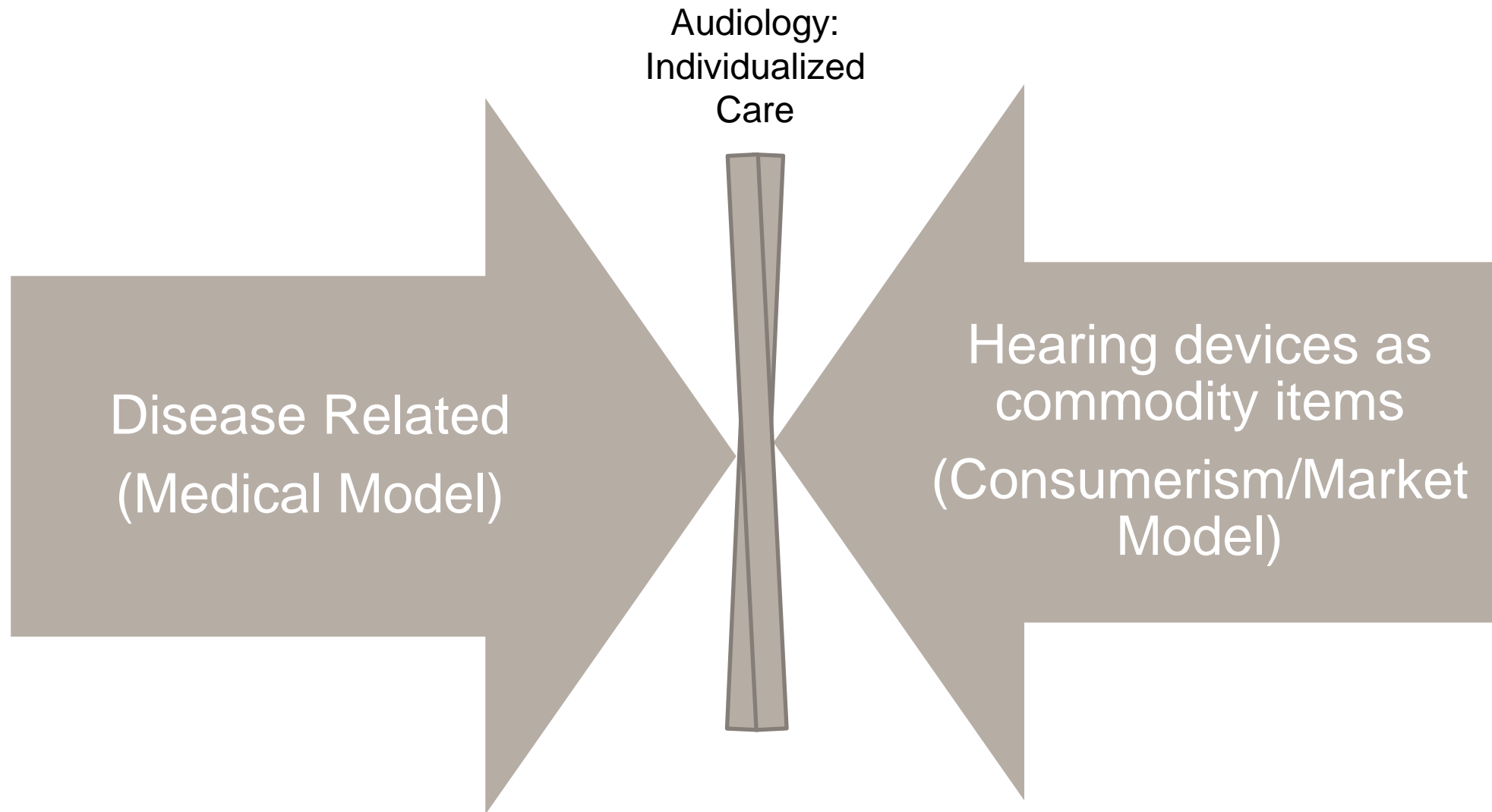
SUCCESS

FAILURE

Healthcare Future Shifts

From Treatment to Prevention

Note Pressures on Hearing Healthcare Definition



What Should Insurance Pay For...?

Audiology

Healthcare
Practitioner /
Medical Model

Wellness Care
Consumer / Market
Model

Disease
Detection,
Diagnosis &
Progression

Auditory
Rehabilitation
following
disease

Auditory
Rehabilitation
for Age &
lifestyle
hearing
problems

Hearing
Conservation

Consumer
Electronics &
“Internet of
things”

Product
Design

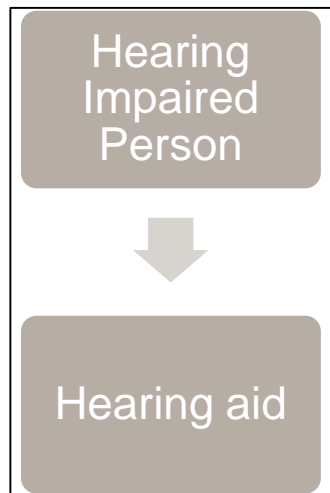
Which Model Has the Best Outcomes?

Cost / diagnosis?

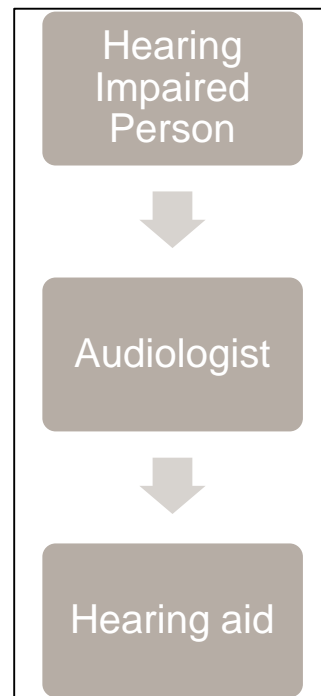
Cost / hearing Aid?

Cost / hearing benefit?

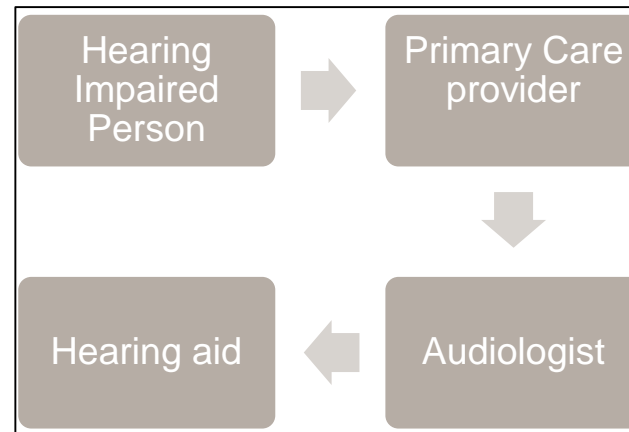
Option #1



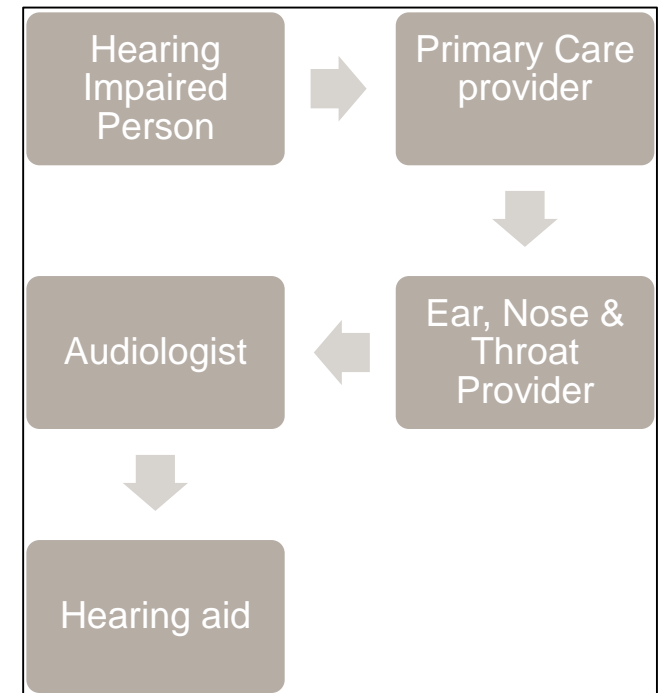
Option #2



Option #3



Option #4



Fennex – Augmented Hearing App


[View More by This Developer](#)

By FENNEX AG

Open iTunes to buy and download apps.



[View in iTunes](#)

 This app is designed for both iPhone and iPad

Free

Category: [Health & Fitness](#)

Updated: Jul 31, 2017

Version: 1.0.2

Size: 52.9 MB

Language: English

Seller: FENNEX AG

© 2017 FENNEX AG

Rated 4+

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[FENNEX AG Web Site](#) ▶ [Fennex – Augmented Hearing App Support](#) ▶

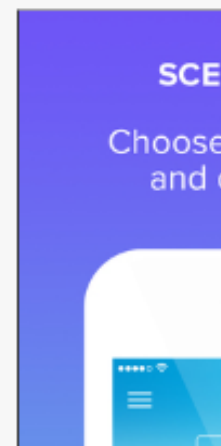
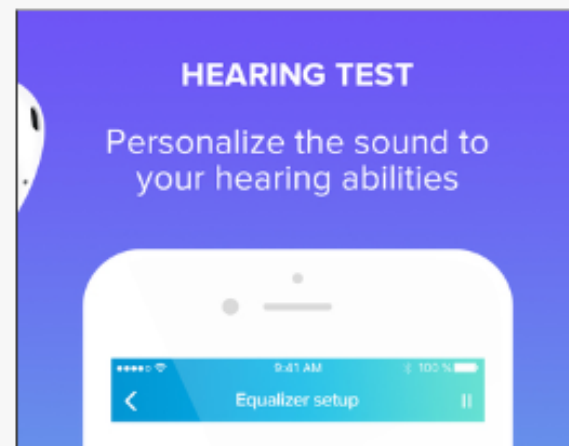
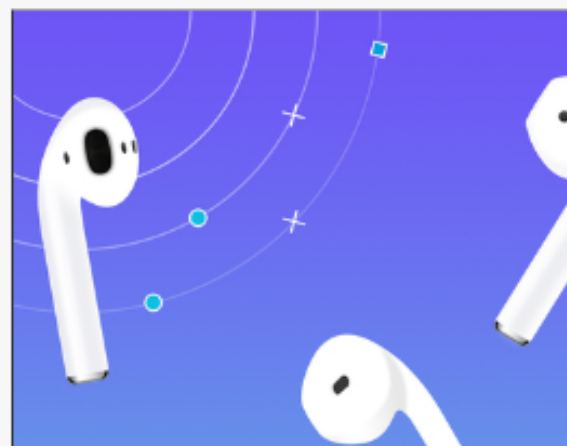
[...More](#)

What's New in Version 1.0.2

* Improved sound quality with 48% better performance versus previous version

Screenshots

[iPhone](#) | [iPad](#)



Did you know?

74% of adults have their vision examined every two years? (Glaucoma Research Foundation)

62% of adults see their dentist annually? (CDC & Prevention)

23% of adults receive hearing screenings during physical examination? (Better Hearing Institute)

Healthcare Future Shifts

From Treatment to Prevention

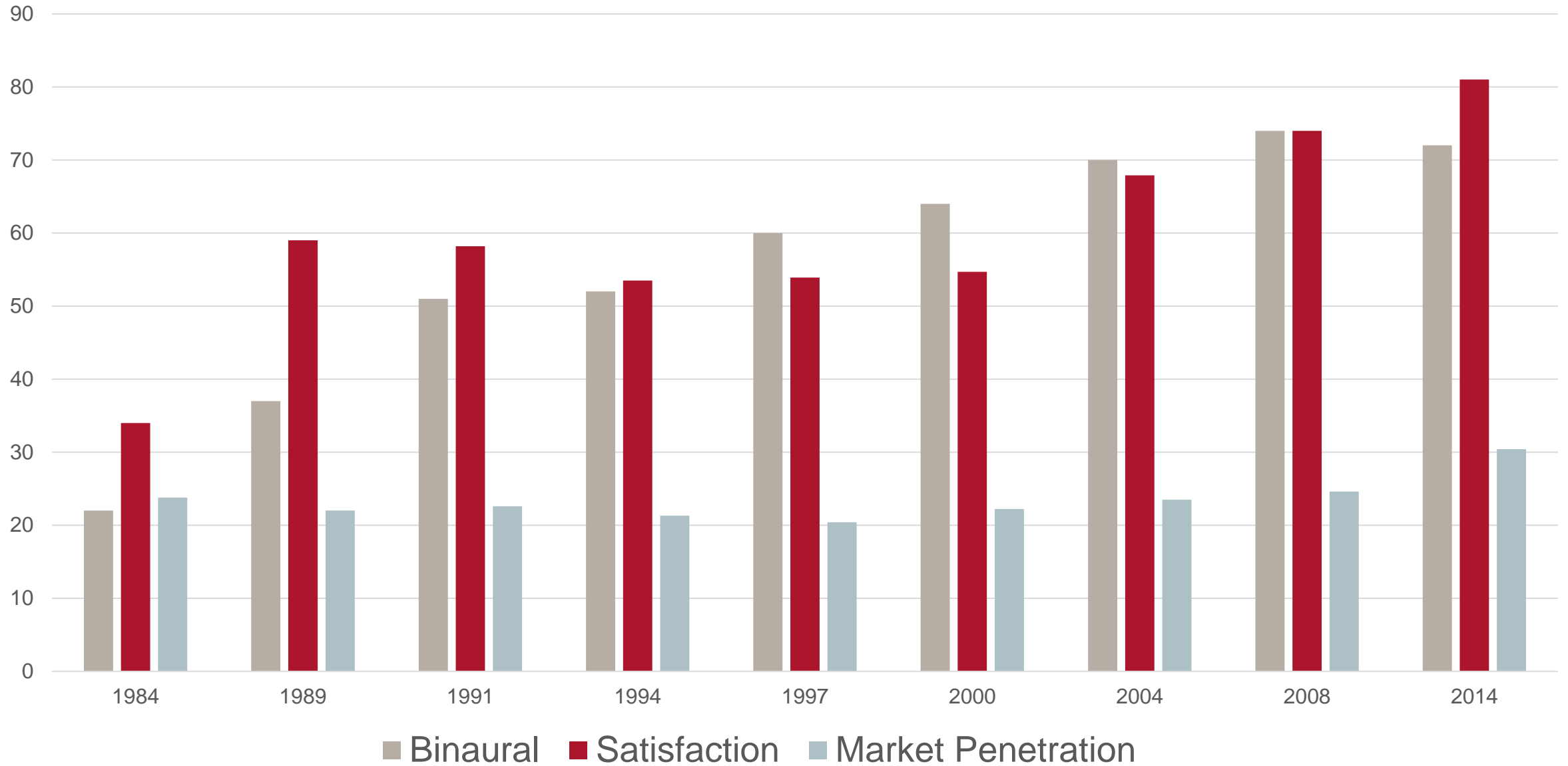
From Provider Centric to Patient Centered





Mayo's primary value:
"The needs of the
patient come first"

US Hearing Aid Binaural Fitting Rate (%) , Satisfaction (%) and Market Penetration (%), by Year



Approaches



Self-Global based System
Synchronous Forward,
Asynchronous tools

Goal

- Increase **access**
- Convenient **services**
- Continuity of **care**
- Reduce **cost**

AAA

- Provided by **qualified** practitioner
- **Primarily** for persons with limited access
- **Validate** before implementation

ASHA

- **Assure service quality**
- **Validate efficacy and cost-effectiveness**
- **Meet needs of patients who need greater access to services**

Issues

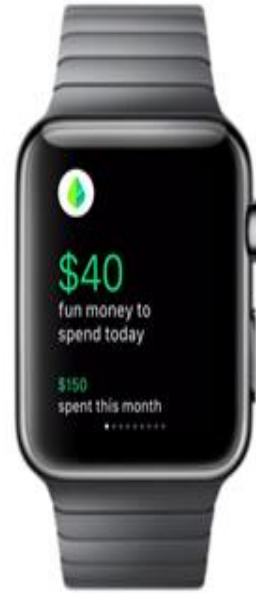
- **License** defines legal requirements to practice
- **State laws** may vary
- **Few Boards** have addressed
- **“Mutual recognition”** model

Healthcare Future Shifts

From Treatment to Prevention

From Provider Centric to Patient Centered

From Bureaucracy to Innovation



Data Privacy

Information about an individual's health, e.g. hearing loss is considered **sensitive personal information**.

The processing of all personal information is regulated by data privacy laws and regulations, including the EU General Data Protection Regulation (GDPR), the US Health Insurance Portability and Accountability Act of 1996 (HIPAA), and local data protection laws in each country.

These laws and regulations contain provisions on processing of personal information, and stricter provisions on processing of sensitive personal information

FDA vs. FTC: Who does what?

The FDA:

Has a broad charge that includes regulation of food, drugs, biologics, vaccines, medical devices, electronic products, cosmetics, veterinary products, tobacco products, etc.



The FTC:

A federal agency that regulates many types of advertising. The FTC protects consumers by stopping unfair, deceptive or fraudulent practices in the marketplace.



FDA-Regulated Medical Hearing Devices

Class I (low risk)	Class II (moderate risk)	Class III (high risk)
AC Hearing Aids	Wireless AC Hearing Aids (special controls)	Cochlear Implants
		Implantable Middle Ear Devices

Not Regulated
PSAPs "Hearables"

Over-The-Counter Hearing Aid Act of 2017

Senate = S.670

House = HR 1652

OTC hearing aid:

- Same technology as AC or wireless AC hearing aid
- For use by adults over 18 to compensate for perceived mild to moderate hearing impairment
- May use wireless technology or include tests for self-assessment of hearing loss
- Is available OTC, without involvement of a licensed person, to consumers through in-person transactions, by mail, or online

Over-The-Counter Hearing Aid Act of 2017

FDA is required to generate regulations that:

- Establish or adopt appropriate output limits
- Include reasonable assurance of safety, efficacy, AND privacy/security!

Healthcare Future Shifts

From Treatment to Prevention

From Provider Centric to Patient Centered

From Bureaucracy to Innovation

From disconnected to Hyper-connectivity



Perceptions Toward Internet-Based Delivery of Hearing Aids among Older Hearing-Impaired Adults

DOI: 10.3766/jaaa.15058

Navshika Chandra*

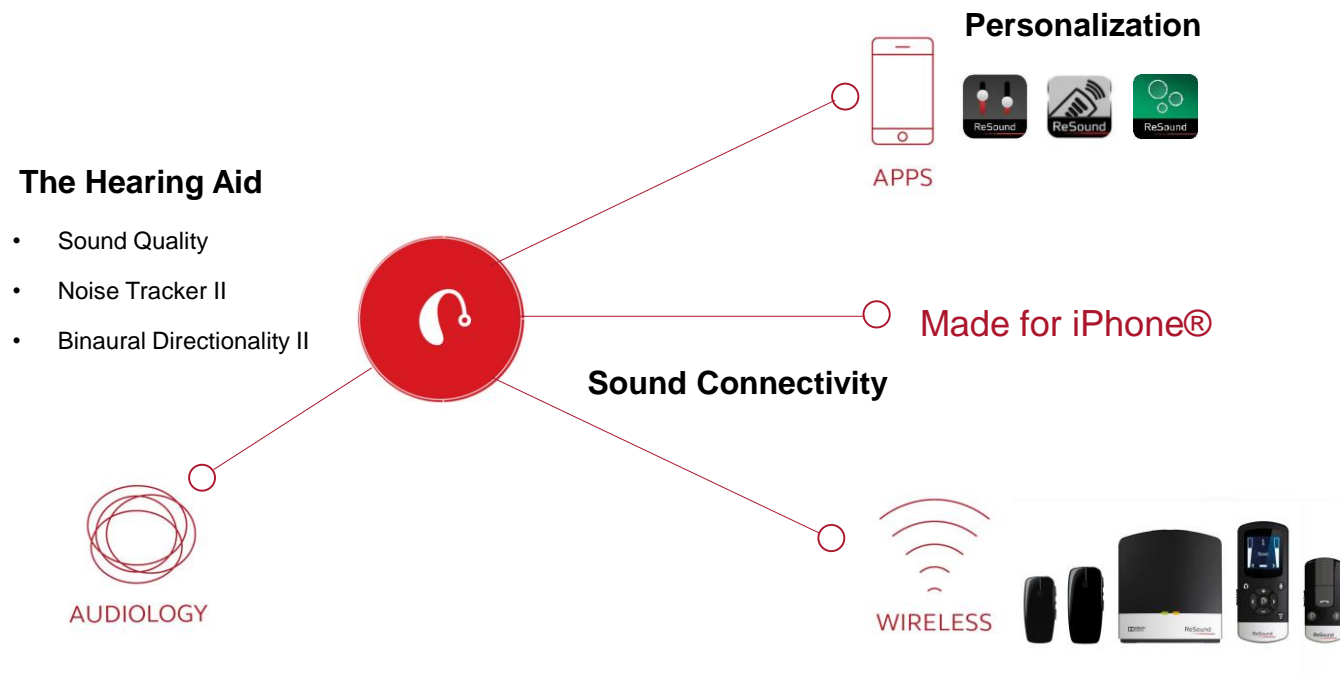
Grant D. Searchfield*†

Abstract

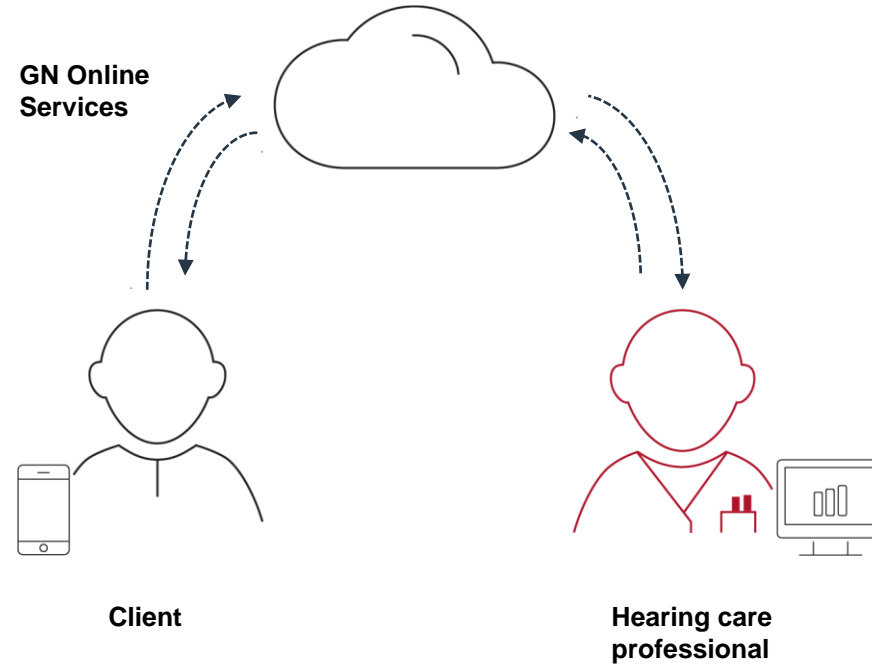
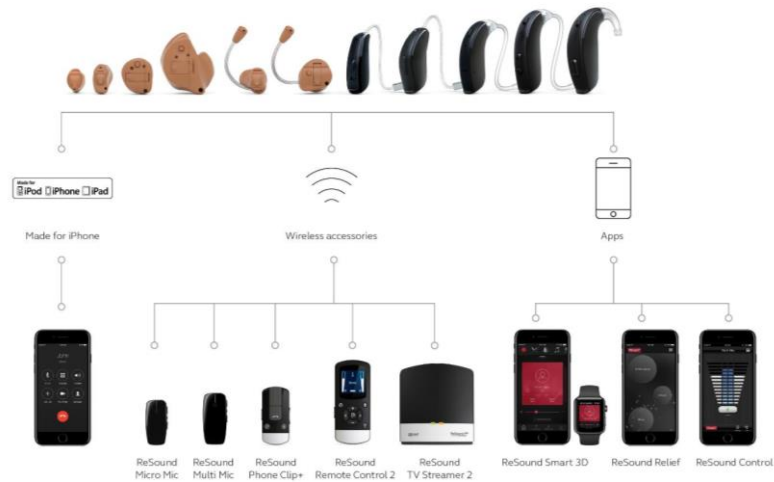
Background: Despite evidence that hearing aids can improve the social and psychological functioning of older hearing-impaired adults, hearing aid uptake is low. High cost of hearing aids and poor access to audiology services in rural areas are potential barriers to hearing aid acquisition. Methods of hearing aid delivery deviating from the traditional clinician-based model have been available to consumers for many years. One such method is Internet hearing aid sales. However, research exploring Internet-based hearing aid delivery, as a method to improve hearing aid uptake in this population, is limited.

Purpose: The purpose of this study was to explore the perceptions of older hearing aid users (aged ≥ 65 yr) toward Internet-based hearing aid delivery.

The Hearing Ecosystem

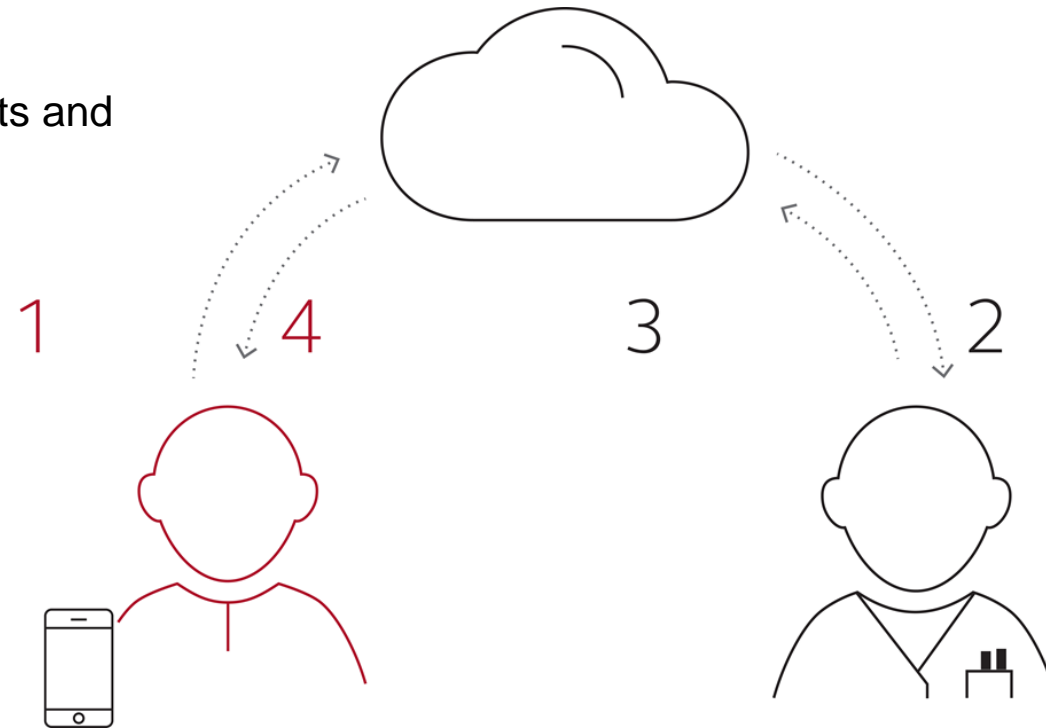


TeleAudiology as an Engagement Tool

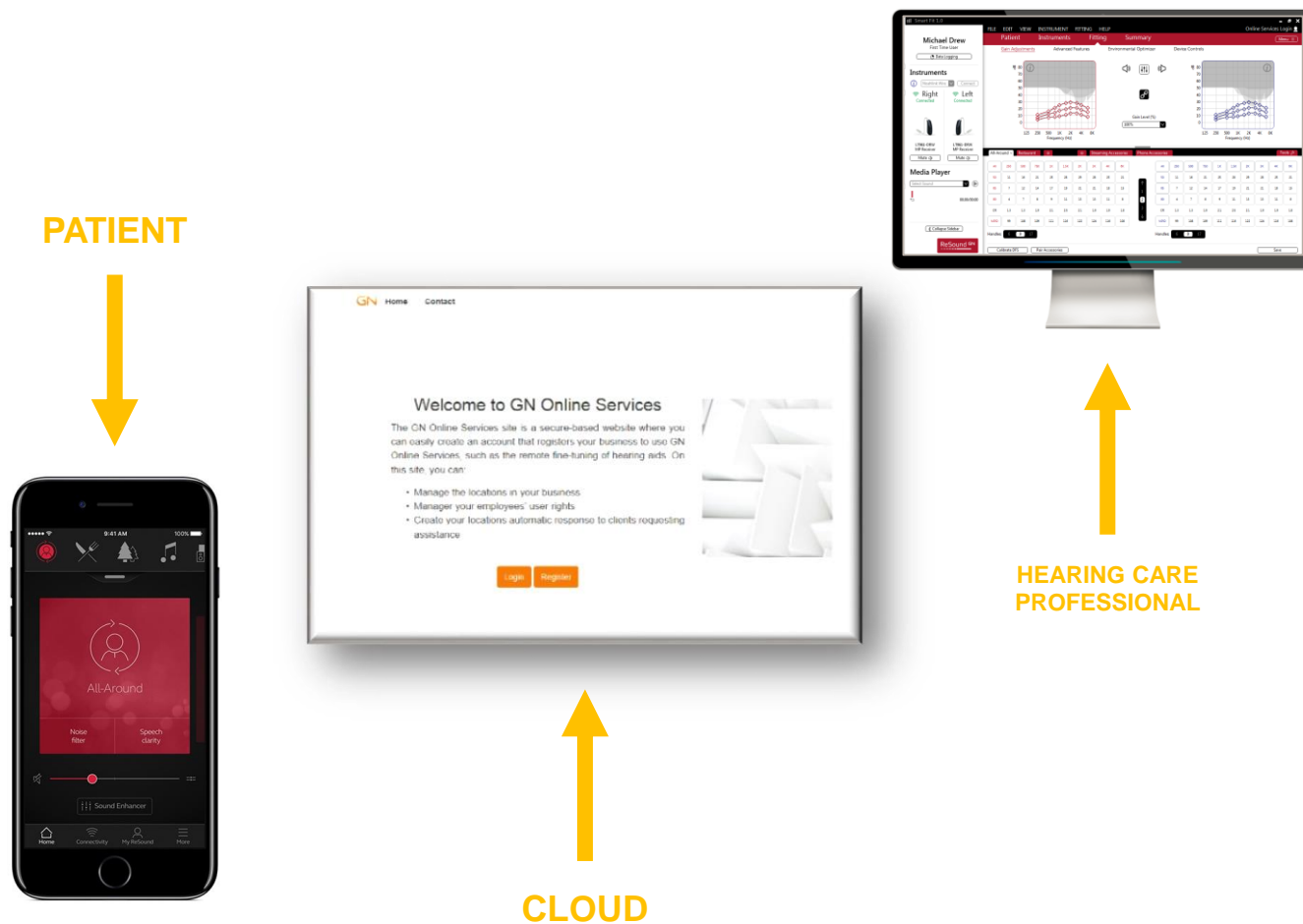


ReSound Assist

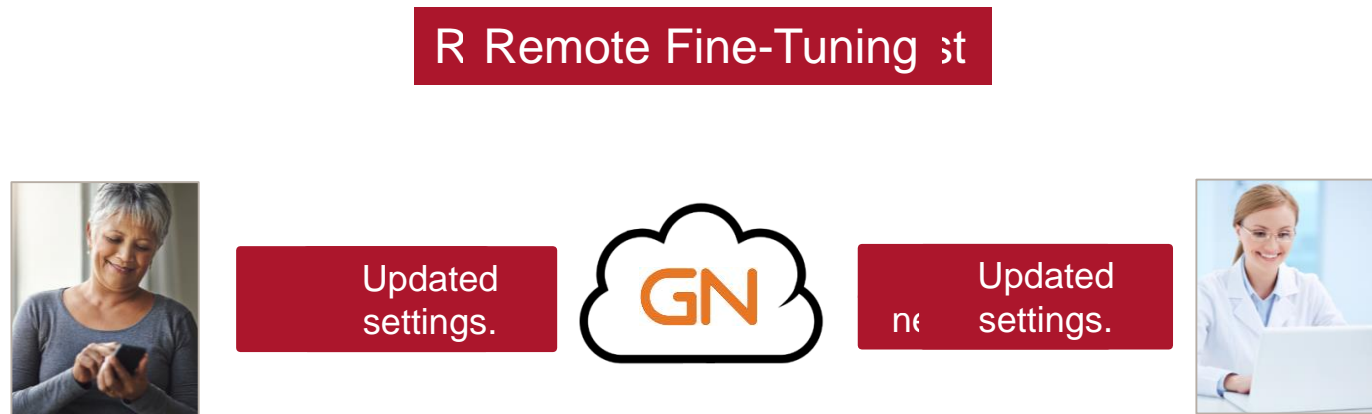
- Easy access for your patients
- Remotely make fine-tuning adjustments after the first fit in your office
- Less time scheduling appointments and more time supporting patients

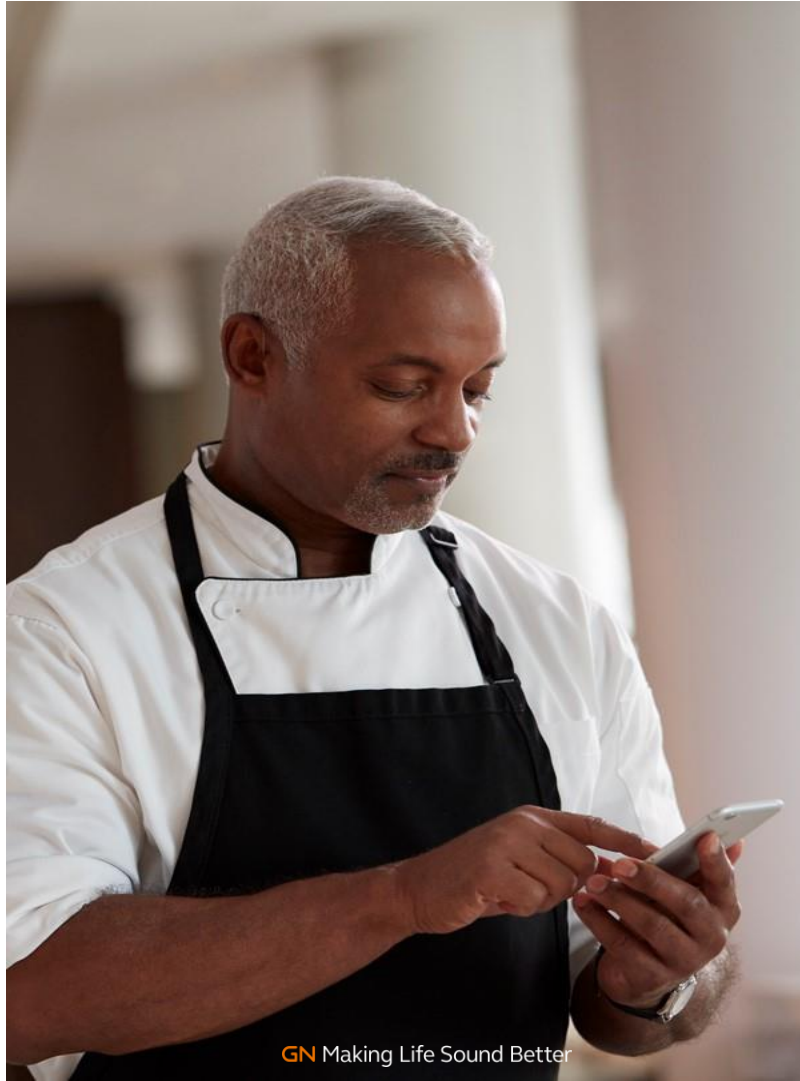


What is ReSound Assist?



How does ReSound Assist work?





Benefits of ReSound Assist

For Patients

- Convenience
- Real-time feedback to hearing care professional in challenging hearing situations
- Hearing instruments can be adjusted based on real world patient experience




Benefits of ReSound Assist

For Hearing Care Professionals

- Improved patient engagement
- Enhanced level of care
- Reduced number of appointments for fine-tuning adjustments

Providing Patient Consent

Patient Consent [X]

 **Patient Consent Needed**

The sharing of health information requires patient consent. Review the document with the patient and Start Consent.

Introduction

The purpose of this document is to allow you to take full advantage of all the features and functionalities in your hearing instruments manufactured by GN Hearing. To realize all the benefits from these advanced hearing instruments, your hearing care professional and GN Hearing must be able to receive and handle information related to your hearing loss via the GN Online Services.

When using the GN Online Services, information related to your hearing loss will be transmitted to enable direct communication, remote fine tuning and other services that enable you to hear more, do more and be more.

It is required by law that the manufacturer of your hearing instruments, GN Hearing, and your hearing care professional receive a consent from you prior to processing your personal information. All your information will be handled carefully, securely, and in accordance with the law. If you wish to review your personal information, or should you later wish to withdraw your consent, this can be done at any time. Details on information collection and purposes for processing are included below.

Declaration of client consent to

a) allow your Hearing Care Professional to disclose personal information to the manufacturer of your hearing instrument, GN Hearing A/S, and

 Print Consent

Start Consent

Reject & Save

Healthcare Future Shifts

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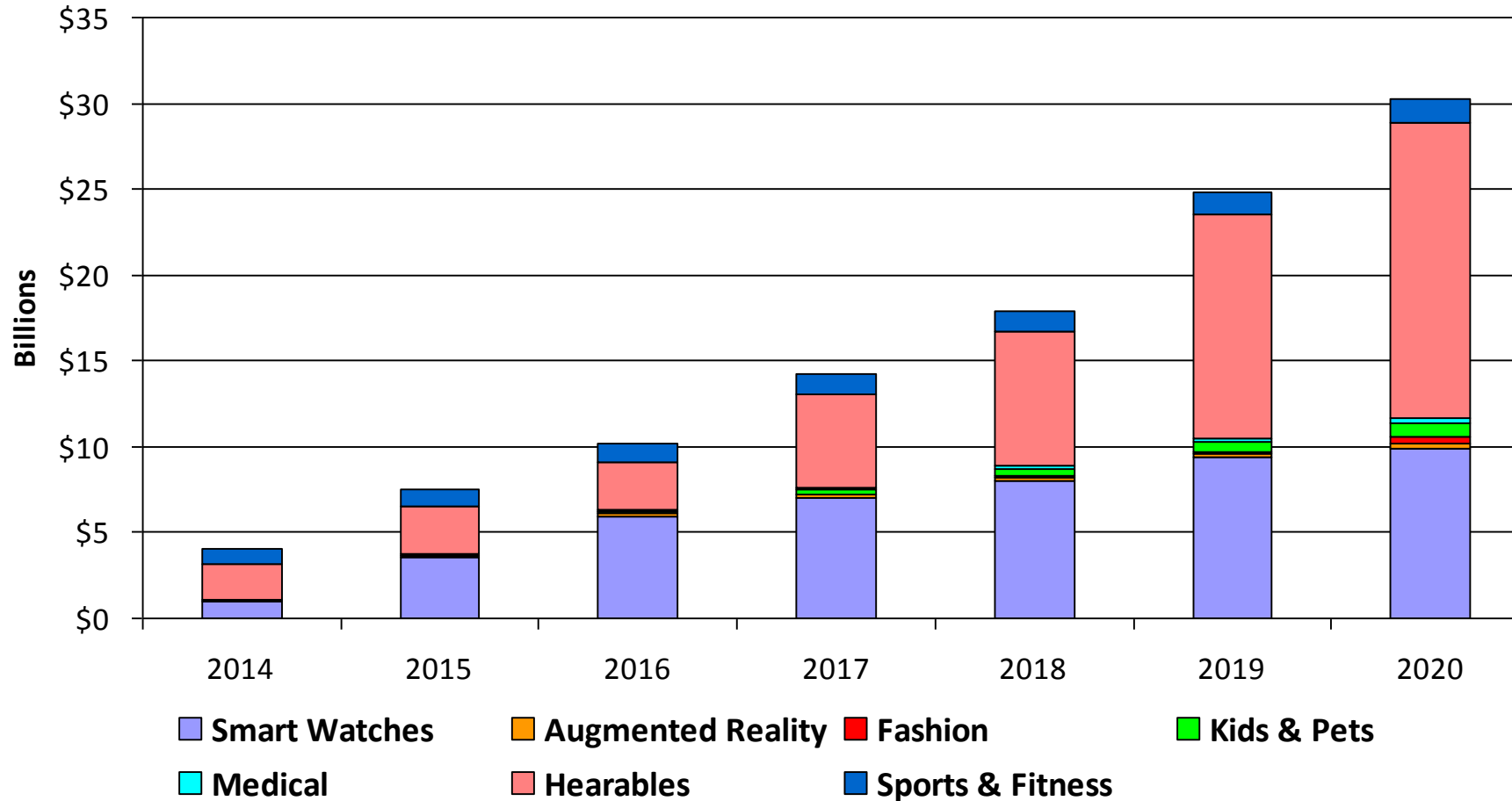
From Hearing “Aids” to “Hearables”

The Ear is Prime Real Estate for Sensing

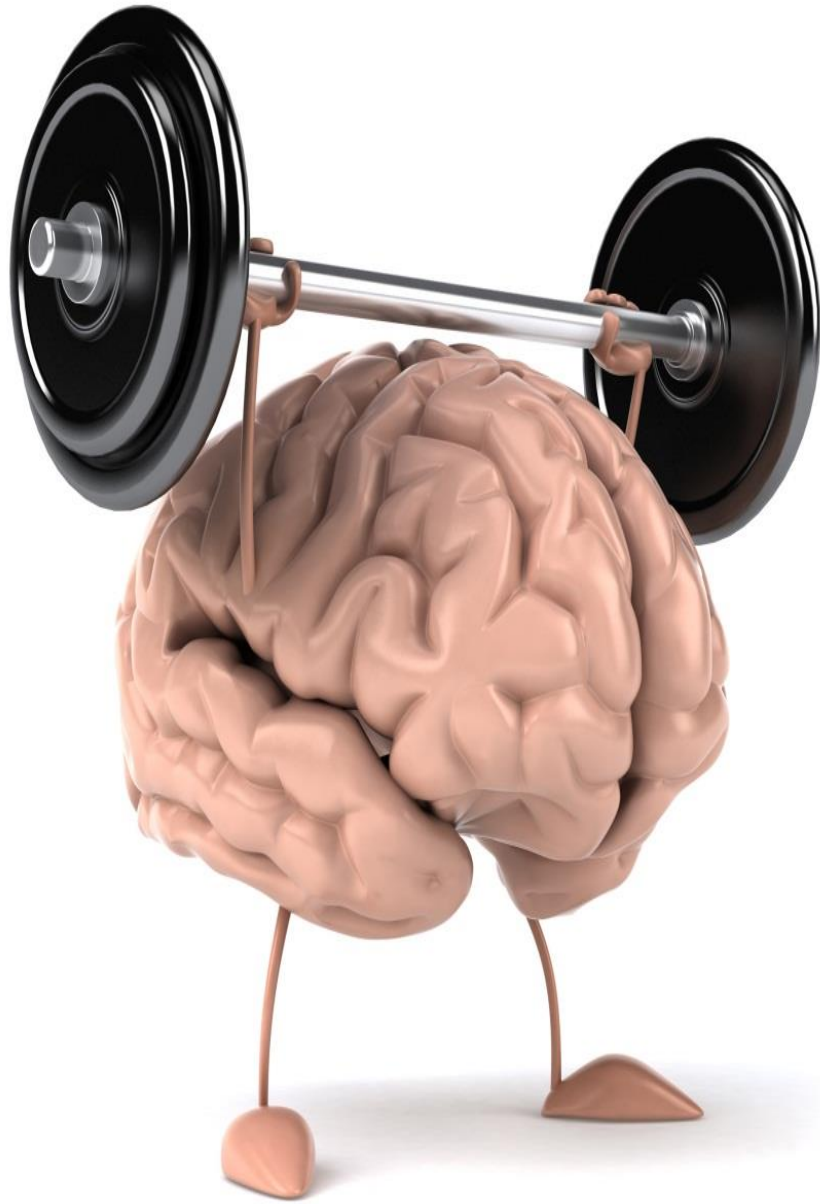


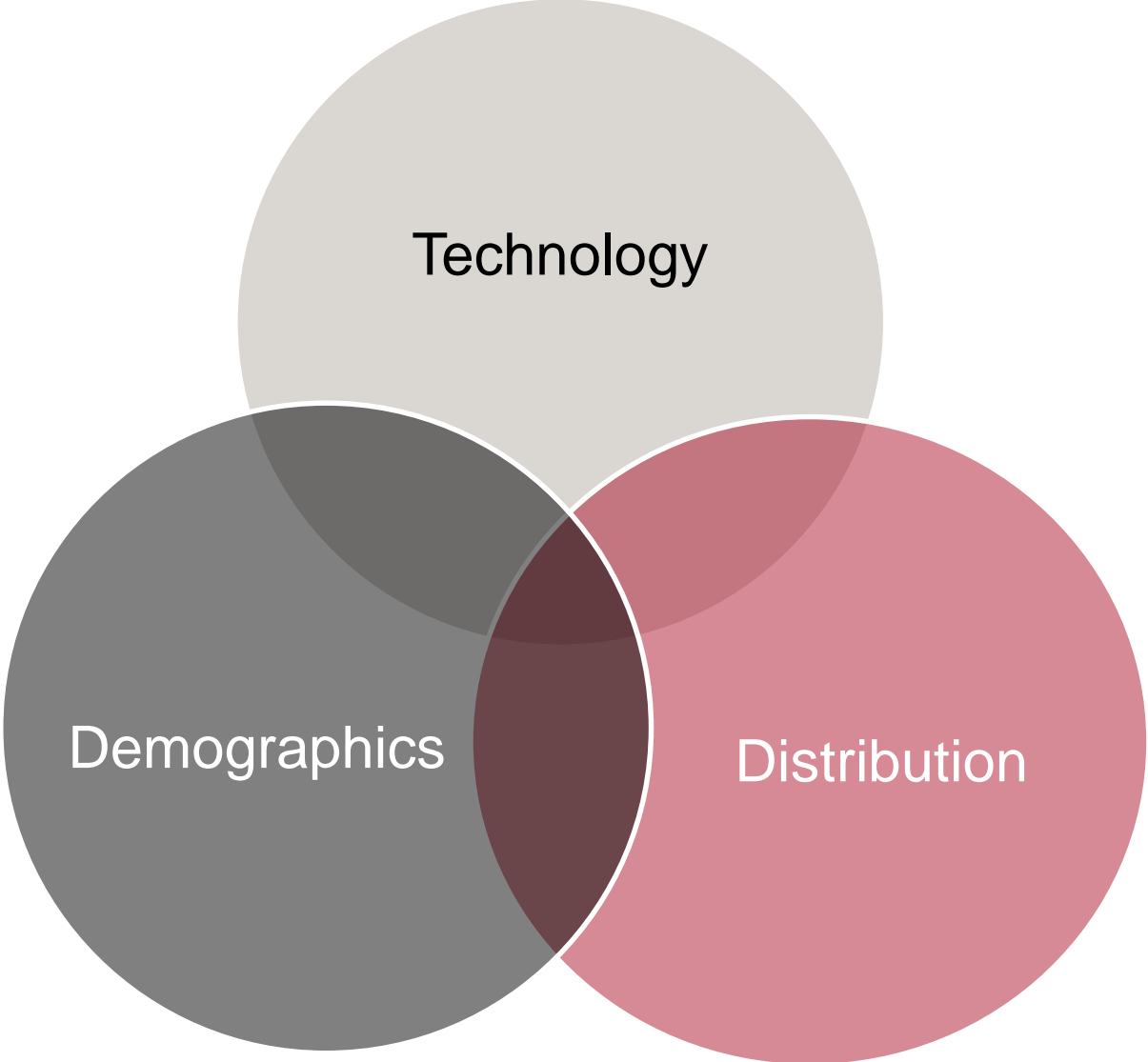
- **Biometrics and health**
- **Location , position and vibration**
- **Two way communications**

The global market for smart wearables



For more details, download the report from www.bit.ly/smartwear



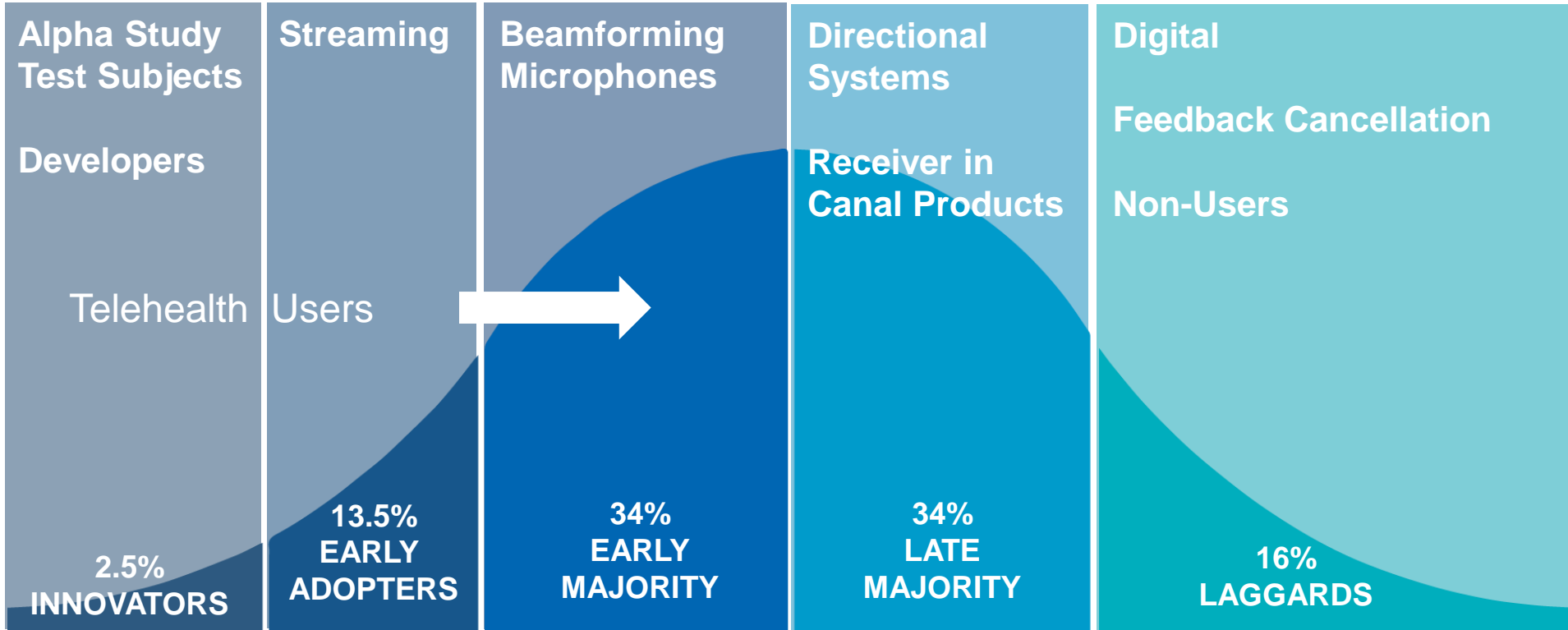


Technology

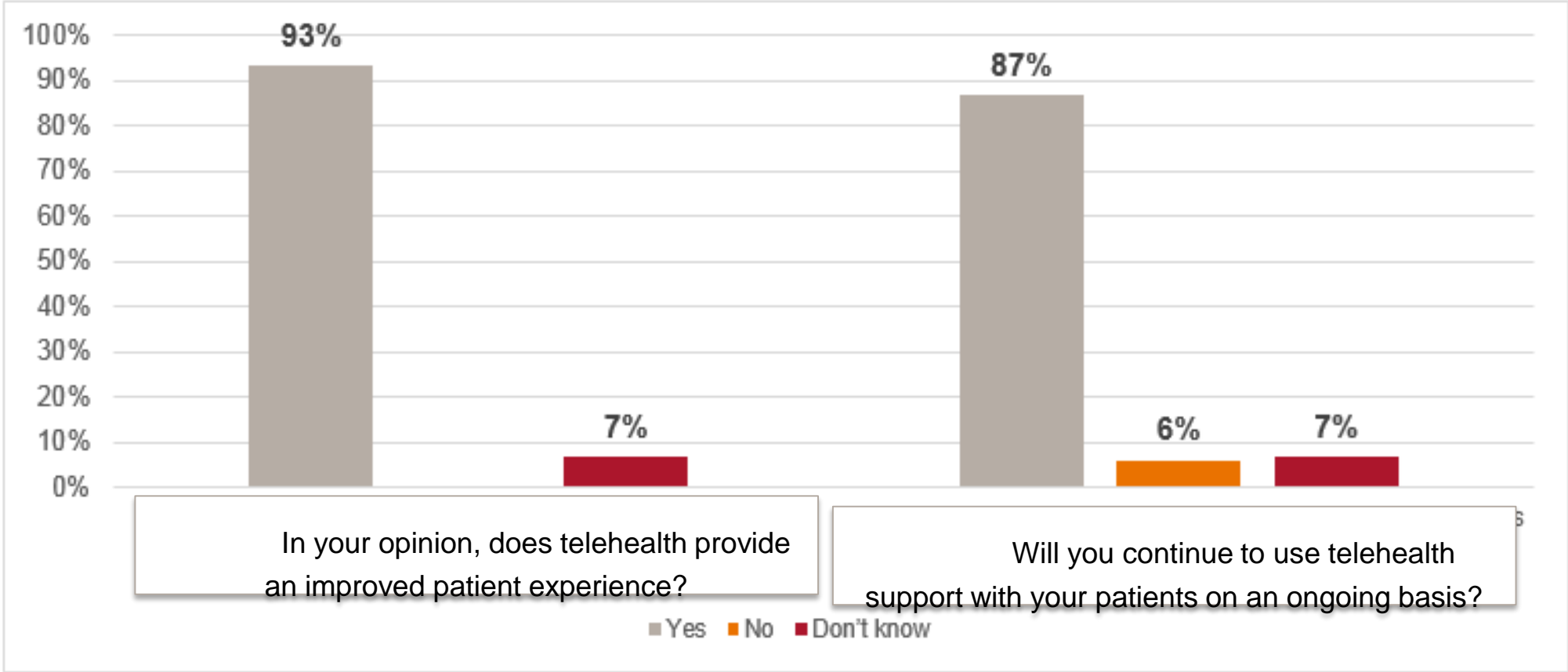
Demographics

Distribution

TECHNOLOGY TRENDS



Initial survey results from a telehealth support model



Market test April-June 2017 in US, Italy, Netherlands and Denmark with participation of 15 Audiologists (Wilke)

Create a patient experience that over-delivers value at *every* patient contact

Appointment 1 – First Fit and verification of initial fitting targets

Appointment 2 – Real-time adjustments – Deliver practical improvements to the patients hearing aids based on their feedback in real-world environments.

Appointment 3 – Using apps – now is the chance to showcase the control the patient can have over their technology and how to make it suit their lifestyle further using manufacturer and third-party apps. Demonstrate use of telehealth support (in office)

Appointment 4 – TeleHealth – Now use telehealth to address real-world challenges *in-situ*. Holding this back ensures the patient sees this as a huge convenience as opposed to an overwhelming resource. In addition – this moment provides an opportunity to make the optional subscription available to more patients.

Appointment 5 – Showcase the ecosystem – Have a wireless accessory pre paired to allow you to introduce an enhanced experience to the patient through connecting further devices to their devices.

Thank you
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