**State of Nevada**
**Speech-Language Pathology, Audiology and Hearing Aid Dispensing Board**

# NOTICE OF PUBLIC MEETING

## Advisory Committee on Fitting and Dispensing Hearing Aids

### Wednesday, July 17, 2024 ~ 4:30pm

**Location:** Board Office ~ 6170 Mae Anne Avenue, Suite 1, Reno, Nevada 89523

*Supporting materials relating to this meeting will be physically available but in an effort to reduce costs and preserve resources, attendees are encouraged to access electronic copies on the Board's website at https://www.nvspeechhearing.org/about/Minutes.asp*

### Teleconference Access

**ZOOM VIDEO & AUDIO:**
https://us02web.zoom.us/j/88201289884?pwd=bHMyKyt6OGpOSFpVSkxZNTJ0Nm1BZz09

**AUDIO ONLY BY TELEPHONE:** (669) 900-6833

**Meeting ID:** 882 0128 9884 **Passcode:** 521198

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## AGENDA

The **ADVISORY COMMITTEE ON FITTING AND DISPENSING HEARING AIDS** of the **NEVADA SPEECH-LANGUAGE PATHOLOGY, AUDIOLOGY AND HEARING AID DISPENSING BOARD** may: (a) address agenda items out of sequence (b) combine agenda items or (c) pull or remove items from the agenda at any time. The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of a person. (NRS 241.020, NRS 241.030). Action by the Committee on any item may be to approve, deny, amend, or table.

1. **Call to Order, Confirmation of Quorum**
2. **Public Comment**
   *No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020)*
3. **Approval of the Minutes: Advisory Committee on Fitting and Dispensing Hearing Aids of April 10, 2024** *(for possible action)*
4. **Review and Recommendation to the Board on Revisions to Hearing Aid Definitions and NRS 637B.055 "Practice of fitting and dispensing hearing aids" defined" to Permit Cerumen Management and Tinnitus Care** *(for possible action)*
   a. Additions/Revisions to Hearing Aid Definitions: New for OTC Hearing Aids and Revision to NRS 637B.044 *(for possible action)*
   b. NRS 637B.055 "Practice of fitting and dispensing hearing aids" defined. *(for possible action)*
      1) Cerumen Management & Definition *(for possible action)*
      2) Tinnitus Care & Definition *(for possible action)*

5. **Review and Recommendation to the Board on Revision to Examination Requirements in NRS 637B, NAC 637B, and/or Board Policy 03 – Dispensing Examinations for HAS License to Engage in the Practice of Fitting and Dispensing Hearing Aids** *(for possible action)*

6. **Review and Recommendation to the Board on Possible Revisions to NRS 637B.050 "Practice of Audiology" defined" to Clarify/Update Scope of Practice.** *(for possible action)*

7. **Review and Recommendation to the Board on Guidance Regarding Manual and Automated Audiometry Compliance with NRS 637B and NAC 637B** *(for possible action)*

8. **Reports from Committee Chair and Members**
   a. Report from Committee Chair and Board Members *(for possible action)*
   b. Next Meeting (possible dates): Wednesday October 2, 2024 October 9, 2024, or October 16, 2024 at 4:30pm; Other dates as proposed. *(for possible action)*
   c. Future Agenda Items *(for possible action)*

9. **Public Comment**

   *No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020)*

10. **Adjournment**
    *(for possible action)*

**PUBLIC COMMENT**

Public comment is welcomed by the Committee. Public comment will be limited to five minutes per person and comments based on viewpoint will not be restricted. A public comment time will be available prior to action items on the agenda and on any matter not specifically included on the agenda as the last item on the agenda. At the discretion of the Committee Chair, additional public comment may be heard when that item is reached. The Committee Chair may allow additional time to be given a speaker as time allows and in their sole discretion. (NRS 241.020, NRS 241.030). Prior to the commencement and conclusion of a contested case or a quasi-judicial proceeding that may affect the due process rights of an individual, the Board may refuse to consider public comment. (NRS 233B.126).

**ACCOMMODATIONS**

Persons with disabilities who require special accommodations or assistance at the meeting should contact the Board office at (775) 787-3421 or email at board@nvspeechhearing.org no later than 48 hours prior to the meeting. Requests for special accommodations made after this time frame cannot be guaranteed.

**AGENDA POSTING & DISSEMINATION**

This meeting has been properly noticed and posted in the following locations:

- Nevada Speech-Language Pathology, Audiology and Hearing Aid Dispensing Board
  - Board Office: 6170 Mae Anne Avenue, Suite 1, Reno, Nevada 89523
  - Board Website: www.nvspeechhearing.org
- State of Nevada Public Notices Website: www.notice.nv.gov

This agenda has been sent to all members of the Board and other interested persons who have requested an agenda from the Board. Persons who wish to continue to receive an agenda and notice must request so in writing on an annual basis.

**SUPPORTING MATERIALS**

Supporting material relating to public meetings of the Speech-Language Pathology, Audiology and Hearing Aid Dispensing Board is available at the Board's administrative office located at 6170 Mae Anne Avenue, Suite 1, Reno, Nevada 89523 on the Board's website at https://www.nvspeechhearing.org/about/Minutes.asp or by contacting Jennifer R. Pierce, Executive Director by phone at (775) 787-3421 or email at board@nvspeechhearing.org. Anyone desiring additional information regarding the meeting is invited to call the Board office at (775) 787-3421 or board@nvspeechhearing.org.

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 1

## Call to Order, Confirmation of Quorum

Call to Order, Confirmation of Quorum.

**Action:** Meeting Called to Order

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 2

## Public Comment

*No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020).*

**CHAIR: PLEASE READ PRIOR TO CALLING FOR PUBLIC COMMENT:**

I will now review the instructions for providing public comment during this meeting:

Any person wishing to make public comment may attend this meeting and provide public comment in one of the following ways:

1. Attend the meeting and provide public comment in-person at the physical location; OR

2. Attend the meeting and provide public comment virtually through the Zoom teleconference video link listed on the agenda; OR

3. Attend the meeting and provide public comment telephonically through the Zoom telephone number listed on the agenda. Please see additional public comment instructions at the end of the agenda.

Public comment is welcomed by the Committee.

- Public comment will be limited to five minutes per person and comments based on viewpoint will not be restricted.
- A public comment time will be available prior to action items on the agenda and on any matter not specifically included on the agenda as the last item on the agenda.
- At the discretion of the Committee Chair, additional public comment may be heard when that item is reached.
- The Committee Chair may allow additional time to be given a speaker as time allows and in their sole discretion.
- Prior to the commencement and conclusion of a contested case or a quasi-judicial proceeding that may affect the due process rights of an individual, the Committee may refuse to consider public comment.

**Action:** None – Informational Only

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 3

## Approval of the Minutes: Meeting of the Advisory Committee on Fitting and Dispensing Hearing Aids of April 10, 2024

The minutes of the meeting of April 10, 2024 are presented for approval.

**Attachments on next page:**

1. *Advisory Minutes Not Yet Approved 4 10 2024*

**Action:** Approve, Table, or Take No Action on the Matter

*Minutes have not yet been approved and are subject to revision at the next meeting.*

**State of Nevada**
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**

**MINUTES OF PUBLIC MEETING**
Advisory Committee on Fitting and Dispensing Hearing Aids

April 10, 2024

| | |
|---|---|
| **Members Present:** | Timothy Hunsaker; Lynee Anderson; Nanci Campbell; Jennifer Joy-Cornejo; Melissa Maestas |
| **Members Absent:** | None |
| **Staff Present:** | Jennifer Pierce, Executive Director<br>Stacey Whittaker, Licensing Coordinator<br>Henna Rasul, Sr. Deputy Attorney General<br>Izack Tenorio, Board Lobbyist |
| **Public Present:** | Laura "Wednesday" Fussell, Nancy Kuhles |

**Call to Order, Confirmation of Quorum**
Timothy Hunsaker called the meeting to order at 4:35pm. A roll call confirmed a quorum was present.

**Public Comment**
Timothy Hunsaker introduced this agenda item and read the following statement pursuant to AB219 (2023): "I will now review the instructions for providing public comment during this meeting: Any person wishing to make public comment may attend this meeting and provide public comment in one of the following ways: 1. Attend the meeting and provide public comment in-person at the physical location; OR 2. Attend the meeting and provide public comment virtually through the Zoom teleconference video link listed on the agenda; OR 3. Attend the meeting and provide public comment telephonically through the Zoom telephone number listed at the end of the meeting agenda with additional public comment instructions. Public comment is welcomed by the Board. Public comment will be limited to five minutes per person and comments based on viewpoint will not be restricted. A public comment time will be available prior to action items on the agenda and on any matter not specifically included on the agenda as the last item on the agenda. At the discretion of the Board Chair, additional public comment may be heard when that item is reached. The Board Chair may allow additional time to be given a speaker as time allows and in their sole discretion. Prior to the commencement and conclusion of a contested case or a quasi-judicial proceeding that may affect the due process rights of an individual, the Board may refuse to consider public comment."

Dr. Hunsaker then called for public comment. There was no oral public comment. Jennifer Pierce reported that a written public comment was received via email prior to the meeting and read the letter into the record as follows:

> "April 10, 2024 Re: Public Comment to the Advisory Committee on Fitting and Dispensing Hearing Aids Meeting. Dear Members of the Advisory Committee on Fitting and Dispensing Hearing Aids, Thank you for the opportunity to make a public comment, and thank you for serving on the committee. My name is Tenaya Watson. I hold a Certificate of Clinical Competence in Speech Language Pathology from the American Speech Language and Hearing Association and Nevada state license to practice Speech Language Pathology serving as

a practicum supervisor and school based speech language pathologist for Clark County School District. I also serve as the President of Nevada Speech-Language Hearing Association (NSHA). I am here to represent NSHA members' concerns surrounding proposed regulations regarding unlicensed audiology assistants. Although this evening's agenda does not include NAC 637B.0442, NSHA members believe bringing concerns to you now and asking for clarification would be beneficial to the Advisory Committee and the Nevada Speech-Language Pathology, Audiology and Hearing Aid Dispensing Board prior to the meeting on April 24, 2024 when LCB File R108-23 will be discussed. NSHA members are seeking further clarification and attention to the NRS stating who can conduct the infant screening, added regulation made by the workgroup and LCB located on page 10, Section 4 (h). According to the Division of Public and Behavioral Health Bureau of Child, Family, and Community Wellness Early Hearing Detection and Intervention (EHDI) Guidelines, all babies born in Nevada are offered a newborn hearing screening at birth prior to discharge from hospital care. This hearing screening is free of charge to caregivers. If screening is not passed, then an out-patient rescreen is recommended at the hospital. According to EHDI Guidelines, babies should have a diagnostic hearing evaluation by a licensed, pediatric audiologist if not passed. Additionally, Nevada Revised Statute CHAPTER 442 - MATERNAL AND CHILD HEALTH, specifically NRS 442.530 "Provider of hearing screenings" defined "Provider of hearing screenings" means a health care provider who, within the scope of his or her license or certificate, provides for hearing screenings of newborn children in accordance with NRS 442.500 to 442.590, inclusive. The term includes a licensed audiologist, a licensed physician or an appropriately supervised person who has documentation that demonstrates to the State Board of Health that he or she has completed training specifically for conducting hearing screenings of newborn children. NSHA's questions are as follows: How is the proposed regulation following Nevada's EHDI guidelines? How does the allowance of an unlicensed audiology assistant to perform a newborn universal screener align with the NV EHDI guidelines? How is the proposed regulation aligned with NRS 442.530? Thank you for the opportunity this evening to bring these concerns forward so the committee may have an opportunity to review the proposed regulations prior to the meeting on April 24, 2024. We are happy to provide any additional information and look forward to hearing how we can continue to advocate for these areas. We appreciate the consideration. Sincerely, Tenaya Watson M.Ed., CCC-SLP NSHA President"

**Approval of the Minutes: Meeting of the Advisory Committee on Fitting and Dispensing Hearing Aids of January 16, 2024 with Clarification on Recommendations Made for Revisions to NRS 637B and NAC 637B Regarding HAS License Requirements**

Timothy Hunsaker introduced this item and asked Ms. Pierce to summarize the issue regarding clarifying the minutes. Ms. Pierce explained that on page 2 of the minutes, regarding agenda item "a. Review and Recommendation to the Board on Possible NRS and/or NAC Revisions", the Committee had discussed and recommended maintaining the requirement that an Apprentice complete a minimum of 2 years on-site training, and that if the NBC-HIS requirement is removed in the 2025 BDR, NAC 637B should be revised to require that a Standard HAS applicant holding an out-of-state license must hold at least one year of experience. In the minutes as written, this is described as "*to require 1 year of dispensing experience for a Standard HAS applicant who is licensed or has prior training/experience in another state*." Ms. Pierce explained that after re-reviewing the meeting recording, the minutes should correctly reflect the intention that this experience be independent practice experience, not supervised training prior to obtaining a Standard HAS license. Ms. Pierce recommended that the minutes be corrected to add the words "*licensed independent*" as follows: "*to require 1 year of licensed independent dispensing experience for a Standard HAS applicant who is licensed or has prior training/experience in another state."* Timothy Hunsaker called for a motion. Melissa Maestas made a motion to approve the minutes with the recommended correction. Jennifer Joy-Cornejo seconded the motion. The motion passed unanimously.

**Review and Recommendation to the Board on Revisions to NRS 637B Related to Board Action to Pursue Repeal of NRS 637B.205 Requiring Dispensing Examinations and License Endorsement for an Audiologist to Fit and Dispense Hearing Aids**

Ms. Pierce explained that as a result of the Board's action to pursue repeal of NRS 637B.205 which would eliminate examination and endorsement requirement for an Audiologist to fit and dispense hearing aids, the following eight (8) sections of NRS 637B were identified for revision, specifically to remove references to the words "dispensing" audiologist or "endorsement": NRS 637B.050 "Practice of audiology" defined; NRS 637B.075 Sponsor" defined; NRS 637B.100 Creation; number, appointment and qualifications of members; terms; vacancies; NRS 637B.175 Fees; NRS 637B.191 Regulations concerning examinations for, period of validity of, renewal and reinstatement of licenses; placement of license on inactive status; NRS 637B.236 Apprentices: Supervision of and responsibility for work; selection of hearing aid; signing of audiogram or sales document; NRS 637B.242 Sale of hearing aids by catalog, mail or Internet: Conditions; records; regulations; and NRS 637B.243 Audiograms for use of physician or member of related profession. All eight (8) sections were presented as a set for a recommendation to revise. Timothy Hunsaker called for a motion. Lynee Anderson made a motion to recommend the Board approve the revisions as presented. Melissa Maestas seconded the motion. The motion passed unanimously.

**Review and Recommendation to the Board on Revisions to NRS 637B Definitions, and NRS 637B.055 "Practice of fitting and dispensing hearing aids defined" to Include "Ordering the Use of" Language, Cerumen Management, and Tinnitus Care**

Ms. Pierce explained that this item contained sections for consideration that would be taken separately.

**NRS 637B.044 "Hearing aid" defined and NRS 637B.NEW "Over-the-counter hearing aid" defined.**

Ms. Pierce summarized that following the FDA Final Rule on Over-the-Counter hearing aids and related NRS revisions already identified, this definition was identified for review, as well as a proposed new definition to add for "over-the-counter hearing aids". The current NRS hearing aid definition and sample definitions from the FDA, the Code of Federal Regulations (CFR), and North Carolina were presented for the Committee's consideration, and after some discussion the Committee came to consensus that the current definition should be retained but members liked the idea of adding the CFR definition. Timothy Hunsaker called for a motion. Jennifer Joy-Cornejo made a motion to recommend that the Board retain the current NRS definition of a hearing aid with the addition of the CFR definition and add the new over-the-counter hearing aid definition to the planned NRS revisions. Melissa Maestas seconded the motion. The motion passed unanimously.

**NRS 637B.055 "Practice of fitting and dispensing hearing aids" defined. (for possible action)**

Ms. Pierce explained that this section of NRS has been under review since 2021 with recommendations made for three separate revisions. Ms. Pierce directed the Committee to the most recently proposed revised version, reviewed by the Board at its January 2024 meeting, where concerns were raised specific to the addition of cerumen management and the matter was sent back to the Committee for further deliberation and recommendation. Ms. Pierce recommended that each revised section be discussed and considered for action separately.

**"Ordering the Use of" Added to "fitting and dispensing hearing aids"**

Ms. Pierce summarized that guidance from the FDA and IHS on the FDA Final Rule on Over-the-Counter Hearing Aids indicated that it did not necessitate a change to state laws & regulations to address "prescribing" traditional hearing aids, however IHS has recommended that states add this "ordering the use of" language to clarify scope of practice. Timothy Hunsaker called for a motion. Nanci Campbell made a motion to recommend that the Board include the revision with "ordering the use of" in the planned BDR. Melissa Maestas seconded the motion. The motion passed unanimously.

**Cerumen Management & Definition**

Ms. Pierce explained that cerumen management is not addressed as allowed or prohibited for Hearing Aid Specialists in NRS 637B or NAC 637B and questions have been raised on this matter through requests for guidance and complaint cases. There is also no reference in the NRS definitions of a Hearing Aid Specialist (NRS 637B.045) or the Practice of Fitting and Dispensing Hearing Aids (NRS 637B.055), though it is specifically included in the Practice of Audiology (NRS 637B.050).

Ms. Pierce directed the Committee to research indicating that the IHS Position Statement on the Practice of Hearing Aid Dispensing includes "administering cerumen management in the course of examining ears, taking ear impressions and/or fitting of hearing aids" in its scope of practice for Hearing Aid Specialists. Nationally, four states currently address cerumen management in laws and regulations (North Carolina, South Dakota, Tennessee, & Wisconsin), with a fifth state in progress (Nebraska). The Committee discussed the matter at length, citing a need to ensure the safety of the public while recognizing the practice as generally accepted and happening regularly as part of the HAS scope of work. Members discussed that practitioners would need to determine their readiness and ability to engage in the practice based on their experience and training. Concerns were noted around the potential risk of harm to patients should these procedures not be done correctly. It was also suggested that prohibiting the practice could exacerbate current healthcare access issues in many communities, should a patient have to be referred out to a physician or urgent care for treatment, with discussion around the level of training provided to medical assistants and others who provide treatment in urgent care and similar settings. Ms. Pierce agreed to conduct follow up research to determine if there are specific training courses on the topic and whether any states specifically prohibit the practice. The Committee discussed the thorough guidelines included in Tennessee regulation, and consensus was that cerumen management should be considered within the scope of practice but if allowed, prescribed guidelines like the example should be included with consideration to also address required training. Timothy Hunsaker called for a motion. Melissa Maestas made a motion to recommend that the Board consider adopting rules and regulations to allow cerumen management and consider the Tennessee example with a requirement for training included. Nanci Campbell seconded the motion. The motion passed, but not unanimously as Jennifer Joy-Cornejo voted against.

**Tinnitus Care & Definition**

Ms. Pierce explained that the Committee previously recommended adding this revision, but the matter was sent back by the Board for further consideration regarding the cerumen management section previously addressed. Tinnitus care is included in the IHS Scope of Practice for Hearing Aid Specialists and IHS offers a Tinnitus Care Provider Certificate that may be earned following a three-day training workshop culminating in an exam. Nationally, North Carolina is the only state that currently addresses tinnitus care in rules and regulations. Ms. Pierce also suggested that a new definition for tinnitus care be included in any recommendation the Committee makes to include this revision. The Committee discussed the matter and Melissa Maestas shared her experience with completing the IHS course. Timothy Hunsaker called for a motion. Jennifer Joy-Cornejo made a motion to recommend that the Board include the revision to include tinnitus care in the scope of practice with verbiage that includes a requirement for a practitioner to have completed "a Board-approved certification or course in tinnitus care", as well as a new definition for tinnitus care. Nanci Campbell seconded the motion. The motion passed unanimously.

**Review and Recommendation to the Board on Possible Revisions to Examination Requirements in NRS 637B and NAC 637B for HAS License to Engage in the Practice of Fitting and Dispensing Hearing Aids**

Ms. Pierce summarized that following the discussions on HAS training and licensing requirements at the January 2024 Committee and Board meetings, the Board office received a request from IHS for the Board to consider waiving both the written and practical dispensing examinations for an applicant holding current NBC-HIS

certification. IHS suggests that since NBC-HIS certification includes an exam demonstrating skills and knowledge, a person who has passed that exam and is maintaining board certification should be able to move from one state, where licensed, to another without taking the entry licensure exam. Florida's HAS license requirements were cited as an example, though Florida does not require a practical examination. Ms. Pierce further summarized that 40 states currently require a HAS applicant to pass both a written and practical examination, and 9 states require only a written examination. Many states indicate some level of reciprocity granted, but the number of states that fully waive examination requirements for those holding NBC-HIS certification and/or out-of-state licensure is unknown. Ms. Pierce also explained that in addition to a waiver for NBC-HIS certification, the Committee might also consider whether to recommend a waiver for either exam when an applicant has passed the same IHS version of either exam in another state. Currently, NAC 637B allows the Board to accept a passing score within the past 12 months on the Written ILE exam, and this has been identified to extend to 24 months in the Board's current revision in LCB File R108-23 scheduled for a public hearing later this month. There was much discussion with the general consensus being that it seemed reasonable to consider accepting a score on the same or a "substantially equivalent" exam from an applicant holding an out-of-state license in good standing, and to consider accepting current NBC-HIS certification in lieu of the Written ILE exam. The matter was tabled, and the Committee asked Ms. Pierce to draft possible NRS and NAC revisions to better visualize the changes and further consider recommendations at the next meeting. No action was taken.

**Reports from Committee Chair and Members**

Jennifer Pierce reported that the contract with IHS for the new revised dispensing examination has been approved and she will be working with IHS and reaching out to exam proctors regarding availability for a training session. The next meeting was confirmed for Wednesday, July 17, 2024 at 4:30pm.

**Public Comment**

Timothy Hunsaker called for public comment. There was no public comment.

**Adjournment**

Timothy Hunsaker adjourned the meeting at 6:05pm.

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 4

## Review and Recommendation to the Board on Revisions to Hearing Aid Definitions and NRS 637B.055 *"Practice of fitting and dispensing hearing aids" defined* to Permit Cerumen Management and Tinnitus Care

**a. Additions/Revisions to Hearing Aid Definitions: New for OTC Hearing Aids and Revision to NRS 637B.044**
At its April 10, 2024 meeting, the Committee recommend the following:

- The Board retain the current NRS definition of a hearing aid in NRS 637B.044 with addition of CFR definition language; and
- Add a new definition for over-the-counter hearing aids.

As such, the following revisions are presented for the Committee's review and recommendation:

**NRS 637B.NEW "Over-the-counter hearing aid" defined.**
"Over-the-counter hearing aid" means any device as defined in 21 C.F.R. § 800.30(b).

**NRS 637B.044 "Hearing aid" defined. "Hearing aid" means any:**

1. Device worn by a person who suffers from impaired hearing for the purpose of amplifying sound to improve hearing or compensate for impaired hearing, including, without limitation, an earmold, as defined by the United States Food and Drug Administration in 21 C.F.R. § 800.30 and is not an over the counter (OTC) hearing aid as defined in 21 C.F.R. § 800.30.; and
2. Part, attachment or accessory for such a device.

**Action:** Approve, Table, or Take No Action on the Matter

**b. NRS 637B.055 "Practice of fitting and dispensing hearing aids" defined.**

**1) Cerumen Management & Definition**
At its April 10, 2024 meeting, the Committee recommended the Board consider adopting rules and regulations to allow cerumen management in this scope of practice and consider language used in Tennessee that includes a training requirement. The motion passed, but not unanimously and Board Staff were asked to conduct follow up research to determine if there are specific training courses on the topic and whether any states specifically prohibit the practice.

- According to IHS, "Most states do not specifically mention cerumen management in their statutes; however, licensing laws, in general, authorize the performance of services that involve at least a limited degree of cerumen management in the performance of said services, such as otoscopic evaluation, taking ear impressions for ear molds, and cleaning hearing aids. The following states include a specific reference and/or authorize hearing aid specialists to perform cerumen management: Alabama, Arizona, Colorado, Florida, Georgia, Idaho, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Mississippi, North Carolina, Tennessee, and Utah."

- Four states currently allow and prescribe guidelines for a HAS to engage in cerumen management: North Carolina, South Dakota (January 2024), Tennessee, and Wisconsin.

- Nebraska is currently pursuing legislation that would allow both cerumen management and tinnitus care, which is opposed by the American Academy of Audiology.

- There does not appear to be one standard for cerumen management training available, though some found online appear to be 5-6 hours in length, and Tennessee's regulations require 6 hours of training.

- The IHS Position Statement on the Practice of Hearing Aid Dispensing includes "administering cerumen management in the course of examining ears, taking ear impressions and/or fitting of hearing aids" in its scope of practice for Hearing Aid Specialists.

Should the Committee recommend this revision, potential language is drafted below for review and consideration. It would be most appropriate to permit the practice in NRS with guidelines added to NAC that outline parameters for practice and training required (adopted from Tennessee regulations). The last section also includes consideration of rules for HAS Apprentices.

**NRS 637B.NEW "Cerumen Management" defined.**
"Cerumen Management" means the removal of cerumen for the purpose of inspecting the ears, making impressions, and/or fitting and maintaining hearing aids.

**NRS 637B.055 "Practice of ordering the use of, fitting, and dispensing hearing aids" defined.**
9. Providing cerumen management removal as prescribed by regulation of the Board.

**NAC 637B NEW "Cerumen Management" * D R A F T ***
A licensed hearing aid specialist shall comply with the following regarding the practice of cerumen management:
1. The indications for cerumen management for a licensed hearing aid specialist include:
   (a) Enabling audiometric testing;
   (b) Making ear impressions;
   (c) Fitting hearing protection or prosthetic devices; and
   (d) Monitoring continuous use of hearing aids;
2. The licensed hearing aid specialist shall refer a patient who exhibits any of the following contraindications to cerumen removal for medical consultation or medical intervention to an otolaryngologist or a licensed physician:
   (a) An age less than twelve (12) years of age;
   (b) A perforated tympanic membrane;
   (c) History of pain, active drainage, or bleeding from the ear;
   (d) Evidence of congenital or traumatic deformity of the ear;
   (e) Ear surgery within the last six (6) months;
   (f) Tympanostomy tubes, such that irrigation should not be used;
   (g) A bleeding disorder;
   (h) Actual or suspected foreign body in the ear;
   (i) Stenosis or bony exostosis of the ear canal;
   (j) Cerumen impaction that totally occludes the ear canal;
   (k) Cerumen located medial to the cartilaginous external auditory canal; or
   (l) A tympanic membrane that the licensee is unable to see;
3. In performing cerumen removal, a licensed hearing aid specialist shall only remove cerumen lateral to the external auditory canal using the following instruments:

(a) Cerumen loop;
(b) Cerumenolytic liquid;
(c) Irrigation, for patients with intact tympanic membranes and a closed mastoid cavity, no tympanostomy tubes, no recent ear surgery, and no recent dizziness; or
(d) Suction used lateral to the bony canal, only for patients with no recent surgery, intact tympanic membranes and no clear otorrhea;

4. If the patient, while undergoing cerumen management that did not present contraindications, complains of significant pain, exhibits uncontrolled bleeding or a laceration of the external auditory canal, or notices the acute onset of dizziness or vertigo or sudden hearing loss, then the licensed hearing aid specialist shall immediately stop the procedure and refer the patient to an otolaryngologist or a licensed physician;
5. The licensed hearing aid specialist shall maintain the following proper infection control practices:
   (a) Universal health precautions;
   (b) Decontamination;
   (c) Cleaning, disinfection, and sterilization of multiple use equipment; and
   (d) Universal precautions for prevention of the transmission of human immunodeficiency virus (HIV), hepatitis B virus, and other bloodborne pathogens, as defined by occupational safety and health standards promulgated pursuant to 29 CFR 1910;
6. The licensed hearing aid specialist who performs cerumen management shall maintain a case history for every patient and informed consent signed by the patient as part of the patient's records;
7. The licensed hearing aid specialist shall carry appropriate professional liability insurance before performing cerumen removal;
8. The licensed hearing aid specialist is prohibited from requiring patients to sign any form that eliminates liability if the patient is harmed.
9. A licensed hearing aid specialist who engages in cerumen management under NRS 637B.055 must have completed a cerumen management course approved by the International Hearing Society, the American Academy of Otolaryngology-Head and Neck Surgery, or another organization approved by the Board. The course must:
   (a) Be overseen by a physician, preferably an otolaryngologist;
   (b) Consist of at least six (6) hours of a participant practicing removing cerumen from an ear canal model using a variety of safe techniques; and
   (c) Result in a certificate of completion and attestation of competence signed by the overseeing physician.
10. A licensed hearing aid specialist apprentice may/may not XXXXXXXX

**Action:** Approve, Table, or Take No Action on the Matter

**2) Tinnitus Care & Definition**

At its April 10, 2024 meeting, the Committee recommended the Board revise NRS 637B.055 include tinnitus care in the scope of practice with verbiage that includes a requirement for a practitioner to have completed "a Board-approved certification or course in tinnitus care", as well as a new definition for tinnitus care.

- The use of hearing aids for tinnitus masking and treatment is not the same as fitting hearing aids for hearing loss, as tinnitus treatment requires training and counseling beyond the initial hearing aid fitting.
- The IHS Position Statement on the Practice of Hearing Aid Dispensing includes "determining candidacy for hearing aids, tinnitus management devices, and other assistive listening devices" in its scope of practice for Hearing Aid Specialists.
- IHS offers a Tinnitus Care Provider Certificate earned during a three-day training workshop and assessment that culminates in a Tinnitus Care Provider certificate. IHS also advises practitioners using the title "Tinnitus Care Provider" to include "Holding a Certificate from the International Hearing Society." IHS also advises that the certificate title does not replace the job title and practitioners should check their state rules, regulations and scope of practice regarding providing tinnitus care. IHS Tinnitus Care Provider Certificate Program participants and certificate holders are expected to understand and abide by all applicable local, state/provincial, and federal laws and rules governing scope of practice, licensure/registration requirements, and permissible titles.
- Nationally, only North Carolina currently addresses tinnitus care in rules and regulations:

  *§ 93D-1.1. "Hearing aid specialist; scope of practice. The scope of practice of a hearing aid specialist regulated pursuant to this Chapter shall include the following activities: (7) Providing hearing aid, tinnitus management device, and assistive device recommendations and selection.*

Should the Committee recommend this revision, it is proposed that the recommendation also include a new definition for tinnitus care, as suggested below for consideration and revision:

**NRS 637B.NEW "Tinnitus Care" defined.**
"Tinnitus Care" means the assessment of tinnitus symptoms and advising patients on sound therapy techniques and other strategies to address tinnitus symptoms.

**NRS 637B.055 "Practice of ordering the use of, fitting, and dispensing hearing aids" defined.**
10. Providing tinnitus management, only when holding a tinnitus care provider certificate awarded by the International Hearing Society or its successor organization, or another equivalent program approved by the Board.

**Action:** Approve, Table, or Take No Action on the Matter

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 5

## Review and Recommendation to the Board on Revision to Examination Requirements in NRS 637B, NAC 637B, and/or Board Policy 03 – Dispensing Examinations for HAS License to Engage in the Practice of Fitting and Dispensing Hearing Aids

The current matter is before the Committee to consider a recommendation to the Board regarding waiving the written and/or practical dispensing examinations for a HAS applicant who is licensed out of state and may also hold NBC-HIS certification.

At its April 10, 2024 meeting, the Committee's discussion ended in consensus that it would be reasonable to accept a score on the same or a "substantially equivalent" exam from an applicant holding an out-of-state license in good standing, and to consider accepting current NBC-HIS certification in lieu of the Written ILE exam. The matter was tabled, and the Committee asked Board Staff to draft possible NRS and NAC revisions to better visualize the changes and further consider recommendations at the next meeting.

**Background**

- The matter is specifically brought to address reciprocity for experienced practitioners who are licensed in another state, removing the burden of the examination process if they were taken many years before or never required in the home state.
- IHS suggests that since NBC-HIS certification includes an exam demonstrating skills and knowledge, a person who has passed that exam and is maintaining board certification should be able to move from one state, where licensed, to another without taking the entry licensure exam. As an example, Florida only requires the written ILE exam and allows a waiver when licensed out of state and holding NBC-HIS certification.
- 40 states currently require a HAS applicant to pass both a written and practical examination, and 9 states require only a written examination. Many states indicate some level of reciprocity granted, but the number of states that fully waive examination requirements for those holding NBC-HIS certification and/or out-of-state licensure is unknown.

**Hearing Aid Dispensing Examinations for HAS License by State**

| | | | | | |
|---|---|---|---|---|---|
| **Written + Practical** (40) | Alabama<br>Arizona<br>Arkansas<br>California<br>Connecticut<br>Georgia<br>Idaho<br>Illinois | Indiana<br>Kansas<br>Kentucky<br>Louisiana<br>Maine<br>Michigan<br>Minnesota<br>Mississippi | Missouri<br>Montana<br>Nebraska<br>Nevada<br>New Hampshire<br>New Jersey<br>New Mexico<br>New York | North Carolina<br>North Dakota<br>Ohio<br>Oklahoma<br>Oregon<br>Rhode Island<br>South Carolina<br>South Dakota | Tennessee<br>Texas<br>Utah<br>Virginia<br>Washington<br>West Virginia<br>Wisconsin<br>Wyoming |
| **Written Only** (9) | Colorado<br>Delaware<br>Florida*<br>Hawaii<br>Iowa | Maryland<br>Massachusetts<br>Pennsylvania<br>Vermont | | | |
| **None** (2) | Alaska<br>DC | | | | |

**Exam waived when holding NBC-IHS certification*

| **Exam Versions Used** *(# of states)* | **Written** | **Practical** |
|---|---|---|
| **IHS** | 43 | 23 |
| **IHS or State** | 1 | 0 |
| **State** | 5 | 17 |

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

**Draft Revision Options for Consideration**

1. Revision to Board Policy 03 - Dispensing Examinations

The Committee may recommend this revision to expand reciprocity for those who have been previously licensed in Nevada but are outside the 3 year time limit to reinstate their license:

**3. Special Circumstances**

**c. Reinstatement of License** or Re-Licensure in Nevada

A Dispensing Audiologist or Hearing Aid Specialist requesting license reinstatement or applying for a new Nevada license past the 3 year reinstatement period must retake both the written and practical examinations unless one (1) of the conditions below applies:

1) They passed the examinations within the past five (5) years; OR
2) They did not pass the examinations within the past five (5) years but are currently licensed and actively practicing in another state.

2. Revision to NAC 637B.0373 to Accept NBC-HIS Certification or Exam(s) Passed Elsewhere

This revision would expand the current NAC allowance to accept a passing score within the past 24 months regardless of out of state licensure.

**NAC 637B.0373 Examination for license to engage in practice of fitting and dispensing hearing aids: Contents; eligibility; passing score; authorization to retake upon payment of fee.**

1. The examination prescribed by the Board pursuant to NRS 637B.194 must consist of a written portion and a practical portion. The examination may also include a portion that tests the familiarity of an applicant with the provisions of this chapter and chapter 637B of NRS and all other federal laws and regulations relevant to the practice of fitting and dispensing hearing aids in this State.
2. To be eligible to take the examination set forth in subsection 1, an applicant must:
   (a) File a completed application with the Executive Director of the Board; and
   (b) Pay the examination fee prescribed by NAC 637B.030.
3. The Board will establish the passing score for the examination set forth in subsection 1.
4. If an applicant does not achieve a passing score on the examination set forth in subsection 1, as established by the Board pursuant to subsection 3, he or she may retake the examination not sooner than 30 days after the date of the previous examination upon payment of the examination fee prescribed by NAC 637B.030.
5. The Board may approve and accept a passing score obtained on a written examination taken within the immediately preceding 24 months if the examination taken by the applicant was substantially the same as the written portion of the examination prescribed by the Board.
6. The Board may approve and accept a passing score obtained on a written examination without limitation if all of the following conditions are met:
   (a) The applicant holds a corresponding valid and unrestricted license in the District of Columbia or any state or territory of the United States; and
   (b) Either of the following are met:
      i. The applicant holds current certification from the National Board for Certification in Hearing Instrument Sciences; or
      ii. The examination taken by the applicant was substantially the same as the written portion of the examination.
7. The Board may approve and accept a passing score obtained on a practical examination without limitation if all of the following conditions are met:
   (a) The examination taken by the applicant was substantially the same as the practical examination required by the Board; and
   (b) The applicant holds a corresponding valid and unrestricted license in the District of Columbia or any state or territory of the United States.

3. Revision to NRS 637B.193(2) to waive one or both exams.
   This would allow for waiver of one or both exams for those who are licensed in good standing in another state and/or holding current NBC-HIS certification.

   **NRS 637B.193 Hearing aid specialists: Qualifications of applicants.**
   An applicant for a license to engage in the practice of fitting and dispensing hearing aids must:
   2. Pass the examination prescribed pursuant to NRS 637B.194. One or both examinations may be waived if the applicant holds a current, unrestricted license in good standing in the District of Columbia or any state or territory of the United States and has either:
      (a) Achieved a passing score on a substantially equivalent version of the examination in Nevada or another state at any time; OR
      (b) Holds current certification from the National Board for Certification in Hearing Instrument Sciences.

4. Revision to NRS 637B.203 & .204 to Include HAS in License by Endorsement and waive one or both exams.
   Guidance may be needed to determine if this would be sufficient by itself to allow waiver or if it should also be included in NRS 637B.193 as outlined above.

   **NRS 637B.203 Expedited license by endorsement to practice audiology, [or] speech-language pathology, or ordering the use of, fitting, and dispensing hearing aids: Requirements; procedure for issuance.**
   **NRS 637B.204 Expedited license by endorsement to practice audiology , [or] speech-language pathology, or ordering the use of, fitting, and dispensing hearing aids for active member of Armed Forces, member's spouse, veteran or veteran's surviving spouse: Requirements; procedure for issuance.**
   3. An applicant for an expedited license by endorsement as a Hearing Aid Specialist wishing to fit and dispense hearing aids may be exempt from passing the examination required pursuant to NRS 637B.160 and NRS 637B.194 if they meet all requirements set forth in subsections 1 and 2 and either:
      (a) Has achieved a passing score on a substantially equivalent version of the examination in Nevada or another state at any time; or
      (b) Hold a current certification from the National Board for Certification in Hearing Instrument Sciences.
   OR
   3. The written examination may be waived if the applicant holds a current, unrestricted license in good standing in the District of Columbia or any state or territory of the United States and current certification from the National Board for Certification in Hearing Instrument Sciences.

5. Other recommendations identified by the Committee.

6. Affirm the current examination requirements with no revisions recommended.

**Action:** Approve, Table, or Take No Action on the Matter

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 6

## Review and Recommendation to the Board on Possible Revisions to NRS 637B.050 "Practice of Audiology" defined" to Clarify/Update Scope of Practice.

It was brought to the attention of Board Staff that in May 2024, Maryland passed two bills intended to align its audiology practice act with the education, training, and qualifications of audiologists practicing in the State. As the Board is pursuing a BDR in 2025, this matter is brought to the Committee for feedback on whether similar changes to Nevada's scope of practice are warranted.

The Maryland bills were supported by the Academy of Doctors of Audiology and passed with overwhelming bi-partisan support, allowing audiologists to "evaluate, diagnose, manage, and treat auditory or vestibular conditions in the human ear" in the State of Maryland with the following added to the scope of practice:

- Prescribe, order, sell, dispense, or externally fit a sound processor to an osseo-integrated device for the correction or relief of a condition for which osseo-integrated devices are worn.
- Prescribe, order, sell, dispense, or externally fit a sound processor to a cochlear implant for the correction or relief of a condition for which cochlear implants are worn.
- The conducting of health screenings.
- The removal of a foreign body from the external auditory canal that is not impacted to the point it requires anesthesia.
- The removal of cerumen from the external auditory canal that is not impacted to the point it requires anesthesia.
- The ordering of cultures and bloodwork testing as it relates to the auditory or vestibular conditions in the human ear.
- The ordering and performing of in-office nonradiographic scanning or imaging of the external auditory canal.
- The ordering of radiographic imaging as it relates to the auditory or vestibular conditions in the human ear.

Nevada's current scope of practice is as follows:

**NRS 637B.050 "Practice of audiology" defined.** "Practice of audiology" means the application of principles, methods and procedures relating to hearing and balance, hearing disorders and related speech and language disorders and includes, without limitation:

1. The conservation of auditory system functions;
2. Screening, identifying, assessing and interpreting, preventing and rehabilitating auditory and balance system disorders;
3. The selection, fitting, programming and dispensing of hearing aids, the programming of cochlear implants and other technology which assists persons with hearing loss and training persons to use such technology;
4. Providing vestibular and auditory rehabilitation, cerumen management and associated counseling services;
5. Conducting research on hearing and hearing disorders for the purpose of modifying disorders in communication involving speech, language and hearing;
6. Providing referral services for medical diagnosis and treatment; and
7. At the request of a physician, participating in the diagnosis of a person.

**Action:** Approve, Table, or Take No Action on the Matter

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 7

## Review and Recommendation to the Board on Guidance Regarding Manual and Automated Audiometry Compliance with NRS 637B and NAC 637B

The Board office received a request for guidance regarding the use of automated audiometry and whether it is allowable in Nevada under NRS 637B and NAC 637B. A number of recent research articles on the subject are included at the end of this packet for reference.

NAC 637B.0446(1)(b) appears to address this as follows, but guidance is needed to clarify what is allowable:

**NAC 637B.0446 Case history and minimum procedures required for prospective candidate for hearing aid; exception. (NRS 637B.132)**

1. Except as otherwise provided in subsection 3, a hearing aid specialist or dispensing audiologist shall take the pertinent case history of, and perform personally the following minimum procedures bilaterally on, each prospective candidate for a hearing aid:
   (a) Pure-tone audiometry, including air-conduction testing and bone-conduction testing through an annually calibrated system.
   (b) Live voice audiometry, only if a separate sound-treated room is available, or recorded voice audiometry, including speech-reception threshold testing, most comfortable and uncomfortable level testing, and speech discrimination testing presented through a speech audiometer.
   (c) When applicable, effective masking.
   (d) Before a hearing test and an ear impression is performed, an otoscopic examination of the ear canal in which the tympanic membrane is visualized.
   (e) After an ear impression is performed, an otoscopic examination in which the tympanic membrane is visualized.
2. A hearing aid specialist or dispensing audiologist shall perform each procedure set forth in subsection 1 in a proper environment to obtain accurate results.
3. The minimum procedures set forth in subsection 1 are not required if the person supplies the hearing aid specialist or dispensing audiologist with complete results of the required tests which have been given within the immediately preceding 6 months by a qualified tester who is licensed pursuant to the provisions of this chapter and chapter 637B of NRS.

**Attachments – located at the end of the packet:**

1. *Audiometry Literature Review*
   - *Liu, et al*
   - *Mahomed, et al*
   - *Ramatsomaa & Koekemoera*
   - *Serpanos,et al*
   - *Shojaeemend & Ayatollahi*
   - *Storey, et al*

**Action:** Approve, Table, or Take No Action on the Matter

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 8

## Reports from Committee Chair and Members

a. Report from Committee Chair and Board Members

b. Next Meeting (possible dates):
- Wednesday, October 2, 2024 at 4:30pm
- Wednesday, October 9, 2024 at 4:30pm
- Wednesday, October 16, 2024 at 4:30pm
- Others as proposed

c. Future Agenda Items

**Action:** Approve, Table, or Take No Action on the Matter

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 9

## Public Comment

*No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020)*

**Action:** None – Informational Only

State of Nevada
**Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board**
**Advisory Committee on Fitting and Dispensing Hearing Aids**

# AGENDA ITEM 10

## Adjournment

**Action:** Meeting Adjourned

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# Clinical comparison of two automated audiometry procedures

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**Objective:** Automated pure-tone audiometry has been shown to provide similar hearing threshold estimates to conventional audiometry, but lower correlations were reported at high and low frequencies in audiometric tests than those of manual tests, while the correlations were better in the middle frequencies. In this paper, we used the same equipment and different test procedures for automated testing, and compared the results with manual test results.

**Design:** One hundred subjects aged 18–36 years were randomly divided into two groups to perform air-conduction pure-tone audiometry (0.25, 0.5, 1, 2, 4, 8 kHz) using the ascending and shortened ascending protocols built-in to the automated audiometer, respectively. Recorded testing time, the total number of responses and the subject's preference tests were compared with those of manual tests.

**Results:** Significant difference was found at 250 Hz regarding the distribution of the absolute difference between the two automated and the manual thresholds. The testing time spend in the ascending method (9.8 ± 1.4 min, mean ± SD) was significantly longer than in the shorted ascending method (5.8 ± 0.9 min). The total numbers of responses of the ascending method (90.5 ± 10.8 times) and shorted ascending method (62.0 ± 11.4 times) were significantly different. Finally, no significant difference was found in preferences between automated and manual procedures.

**Conclusion:** The shorted ascending method can save lots of testing time. The difference between the two automated thresholds at 250 Hz is caused by the different test procedures, and the difference at 8,000 Hz between the automated test and the manual test can be due to the transducer types and allowable differences in calibration.

KEYWORDS

**automated audiometry, audiometry, KUDUwave, ascending method, shortened ascending method**

## Introduction

More than 1.5 billion people worldwide are living with some degree of hearing loss, equivalent to 20% of the total population. At least 430 million of them have moderate or higher levels of hearing loss, also known as disabling hearing loss (World Health Organization [WHO], 2021). In China, according to the results of the Second National Sample Survey on Disability, 27.8 million people had hearing disabilities, of which 20.04 million people were suffering from hearing disability alone and 7.76 million were suffering from multi-disabilities (Xi-bin et al., 2008). Given the large number of people with hearing loss, China is experiencing an extreme lack of experts who can provide high-quality hearing services (Chadha et al., 2021). Currently, only 10,000 audiologists provide hearing services for 1.37 billion people in China (1:137000) (Chung et al., 2014).

Pure-tone audiometry is the gold standard for a clinical hearing assessment. For many years, pure-tone audiometry has always relied on traditional manual audiometry. However, pure-tone audiometry is a test based on sequence and step inspection, which is particularly suitable for the automation (Margolis and Morgan, 2008). Automation is a powerful enabler for alternative diagnostic pathways, which can reduce testing costs without trained audiologists (Eksteen et al., 2019) and testing outside a sound booth (Brennan-Jones et al., 2016; Magro et al., 2020), and potentially benefit people with hearing loss in remote and economically underdeveloped areas (Visagie et al., 2015; Sandström et al., 2020), to address the global need for an accessible hearing loss diagnosis (Swanepoel et al., 2019; Sidiras et al., 2021; Wasmann et al., 2022).

There is a high correlation between the manual and automated pure-tone audiometry, with an overall average difference of 0.4 ± 6.1 dB regarding the air conduction threshold (Mahomed et al., 2013). However, lower correlations in automated thresholds at high (6,000 or 8,000 Hz) and low (250 or 500 Hz) frequencies were reported in previous studies. Compared with the standard methods, the threshold difference varied from 8.7 to 17 dB at the low or high-frequency points, significantly higher than those at overall frequencies (Abu-Ghanem et al., 2016; Brennan-Jones et al., 2016; Corry et al., 2017; Sandström et al., 2020). In the studies of automated audiometry, the explanation of this phenomenon varied due to different testing environments and different types of equipment. The differences in low frequencies were interpreted as the effect of ambient noise levels and suboptimal fitting of the earphones (Abu-Ghanem et al., 2016; Corry et al., 2017), whereas the differences in high frequencies were susceptible to variations in the coupling of headphones or earphones and individual physiological differences (Brennan-Jones et al., 2016; Corry et al., 2017; Sandström et al., 2020). However, there are no reports on whether such variability is due to the difference in automated audiometry procedures.

There are three methods for automated measurement of pure-tone thresholds: the automated method of adjustment, the automated method of limits, and the automated adaptive method (Jerger, 2018). According to a scoping review, in the last decade, about 74% of published studies on automated tests utilized the modified Hughson-Westlake procedure, which is based on the classical method of limits (Wasmann et al., 2022). Two kinds of threshold-seeking procedures were recommended in the modified Hughson–Westlake protocol by ISO 8253-1:2010, i.e., ascending and shortened ascending procedures. The ascending procedure stipulated that when three reactions occurred at the same test sound level during a maximum of five ascents, then this sound level was determined as the hearing threshold level. For the shortened ascending method, the hearing threshold level was identified as at least two reactions that occurred at the same level out of three ascents. In the current literature, some automated tests use the shortened method, and some studies do not specify the test method. In ISO 8253-1-2010, it is stated that the shortened and ascending method can obtain almost identical results. The guidelines do not state whether the same consistent results can be obtained when using both methods for automated testing. In manual testing, the shortened method can be used for special subjects, such as those who cannot concentrate for long periods of time, where the test time is more important than the reliability of the threshold.

In clinical testing, the subject's response profile is complex and variable. During manual testing, an experienced audiologist will make observations of the subject's behavior. Whether the ascending or the shortened ascending method is used, the audiologist will guarantee the reliability of the test results. However, in the programmed automated test, although the correlation between the results of the automated and the manual test, in terms of the overall (average of the hearing thresholds for all frequencies), was good; the correlation was poor in the lower and higher frequencies. There are no clinical data on whether the use of the shortened ascending method in automatic testing will sacrifice reliability at certain frequencies. In this study, two automated audiometry protocols, ascending and shortened ascending methods, were used to compare the results with manual audiometry, respectively, to observe the correlation between the two methods at all testing frequencies and to investigate the effect of different automated methods on the test results.

## Materials and methods

### Subjects

One hundred normal hearing participants (56 females) ranged 18–36 years (median age was 27 years) from the

Otolaryngology Clinic of Beijing Tongren Hospital were recruited in this study. The inclusion criteria were: (World Health Organization [WHO], 2021) aged 18 years or above, (Xi-bin et al., 2008) no known cognitive disorder, (Chadha et al., 2021). Mandarin as a first language, (Chung et al., 2014) four-frequency average (500, 1,000, 2,000, and 4,000 Hz) air-conduction thresholds of both ears ≤15 dB HL, (Margolis and Morgan, 2008) normal otoscope examination. This study was approved by the Ethics Committee of Beijing Tongren Hospital, Capital Medical University. The participants all provided written informed consent before the test.

## Equipment

The clinical diagnostic audiometer (Otometrics Conera) was used for the manual pure-tone hearing threshold test with TDH-39 supra-aural earphones. The calibration was conducted according to ISO 389-1: 2017. Automated audiometry was conducted using the KUDUwave (GeoAxon, Pretoria, South Africa) audiometer, which used insert earphones for air conduction thresholds testing. The circumaural headphones of KUDUwave are placed above the insert earphones to increase the attenuation of ambient sound, meanwhile, the audiometer monitors background noise levels *via* an external microphone (outside of the circumaural headphone cup) and an internal microphone (inside of the circumaural headphone cup) to ensure testing compliance (Swanepoel de et al., 2010). As noted by Storey et al. (2014), with this combination of attenuation and monitoring, patients can be reliably tested to −10 dB HL at 55 dB ambient noise and to 0 dB HL at 70 dB ambient noise. The KUDUwave was connected to the computer through the USB port, and the test process was controlled by the software installed in the notebook computer. The KUDUwave was measured and calibrated before use in accordance with ISO 389-2: 1994. All tests were carried out in an American National Standards Institute (ANSI) certified double-walled sound-treated booth.

## Test methods

The otoscope examination, tympanic admittance measurement and manual air conduction hearing threshold test were performed for all participants. The participants who met the inclusion criteria were numbered in the order of 1–100, the participants with odd numbers were tested by the ascending program (Group A) for automated testing, and even-numbered participants were tested by the shortened ascending program (Group S) for automated testing.

The manual audiometry was conducted by an audiologist with at least 30 years of testing experience. The test requirements were fully explained to the participant before the test. The participants were asked to quickly press and release the response button whenever the tone is heard in either ear, no matter how faint it may be. After the participants fully understood the test requirements, they wore air conduction headphones, and the hearing thresholds were determined according to the standard clinical procedure (modified Hughson–Westlake, ISO 8253-1). The test frequency was at octave frequencies from 250 to 8,000 Hz.

The automated test process was completed by an undergraduate student in audiology. The participants were informed of the test process and requirements, which were the same as the manual test. Insert earphones were deeply inserted and the end of the insert foam tips were flush with the opening of the external auditory meatus. The circumaural earcups of KUDUwave were placed over insert earphones to increase the attenuation of environmental sound, and ensured comfort and stability. The conditioning page interface was presented to play stimulus to the participant and observe the response time. After the subject fully understood the test requirements, the automated test was started to determine the hearing thresholds. The test frequency was at octave frequencies from 250 to 8,000 Hz.

The ascending and shortened ascending procedures of the KUDUwave automated test program were adopted. The initial intensity of each frequency was 30 dB HL, and the sound duration lasted for 1,000 ms. A valid response was considered as pressing the response button within 2,500 ms after delivering the pure tone, or it will be marked as a false positive response by KUDUwave. After the test, KUDUwave automatically reports the percentage of false positives, the number of times the subject responded to the pure tone and the response time the subject pressed the response button after the pure tone is delivered. A detailed description of the automated and manual protocols was listed in the (**Supplementary Table 1**).

The test time required for manual testing and automated testing was manually recorded and compared. The time for explaining test requirements, wearing headphones, and familiarizing with the sound test process were not included in the recorded test time. The participants were asked about their preference for manual and automated testing methods after the test finished, preferred the automated test, preferred the manual test, or had no preference. To avoid differences in the background noise of the test environment from affecting the test results, all manual and automated tests were conducted in one sound booth.

## Data processing

Descriptive measures illustrated the difference between the thresholds of manual and automated audiometry, described as mean ± SD. The test time required for manual and automated audiometry and the total number of reactions were described

as mean ± SD. The preference for the test methods was described as a percentage. A paired *t*-test was employed across the frequencies of 250–8,000 Hz to test whether there is a significant difference between the thresholds of manual and automated audiometry. Comparisons between Groups A and S were evaluated using independent *t*-tests, including the testing time and the total number of reactions. The chi-squared test is used to determine whether there is a significant difference in the distribution of the difference of threshold between Groups A and S. The chi-squared test is also used to test the difference in the participants' preference for two automated procedures. An ANOVA test was conducted to test the effect of gender and age on the thresholds of the pure tone audiometry. All statistical analyses were performed by SPSS 25 (SPSS Inc., Chicago, IL, USA). A *p*-value of less than 0.05 was considered statistically significant.

## Results

In order to compare the automated and manual test results, the difference values were calculated between clinical audiometer thresholds and the KUDUwave thresholds for the two automated procedures. As shown in **Table 1**, the two automated test methods were more accurate at the range of 500 to 4,000 Hz, while the accuracy at 250 and 8,000 Hz were poor. Nevertheless, the automated thresholds at all frequencies had a good correlation with the manual thresholds at all frequencies.

The distribution of the absolute difference between the manual and the automated thresholds was shown in **Figure 1**. Only a significant difference was found at 250 Hz ($p = 0.002$), the number of thresholds difference within 5 dB in Group S was higher than that in Group A, while the number of threshold differences within 0 dB in Group S was less than that in Group A. The correlation of the automated thresholds at 8,000 Hz between the two groups was low, and the percentage compared with the manual test results less or equal to 5 dB was smaller than that at other frequencies. However, no statistical difference was observed between the two groups at 8,000 Hz.

The differences in test time, participants' preferences, and the total number of reactions between the two automated groups were listed in **Table 2**. The automated test time in Group S was significantly shorter than in Group A (Group A: 9.8 ± 1.4, Group S: 5.8 ± 0.9, $p < 0.001$). Accordingly, the total number of reactions in Group S was also less than in Group A, because Group S used shortened ascending method. Most of the participants did not favor automated tests, and the main feedback was that the headphones of the automated audiometer were heavier, especially in Group A, because the test time was much longer than in Group S. However, no significant difference existed in preference between automated and manual procedures.

In addition, we analyzed the effect of gender and age on the results of the automated test. According to the ANOVA test, no significant differences between automated and manual audiometry thresholds were found regarding the gender or age of the subjects, the results were listed as (**Supplementary Table 1**).

## Discussion

In this study, we tested two automated audiometry procedures, ascending and shortened ascending methods, and compared the automated thresholds with manual test results. Similar to previous reports, the automated audiometry correlated well with the manual test. However, we found lower correlation at 250 and 8,000 Hz than at the other frequencies.

Hearing thresholds obtained from two automated procedures showed a greater variation at 8,000 Hz compared to manual tests. There were a larger number of hearing threshold differences of 10 dB or above at 8,000 Hz. Other studies also reported higher mean threshold differences for automated tests at 8,000 Hz than other frequencies (Storey et al., 2014; Brennan-Jones et al., 2016; Barbour et al., 2019; Sandström et al., 2020). The reason for this is likely to be systematic differences in transducer types, and allowable differences in the calibration (Sandström et al., 2020). The use of insert earphones may have introduced additional variation at high frequencies compared to supra-aural headphones (Brennan-Jones et al., 2016). In this study, the insert earphones were used for the automated test and supra-aural headphones for the manual test. Although thresholds obtained from two automated procedures showed greater variations at 8,000 Hz, compared with the manual test, there was no significant difference between the two automated thresholds. Therefore, it was considered that the variation at 8,000 Hz was due to the difference in transducer types.

Hearing thresholds obtained at 250 Hz also showed a greater variation between automated and manual audiometry. It was thought to be possibly due to the non-sound treated environments or to the suboptimal fitting of the insert earphones (Abu-Ghanem et al., 2016; Corry et al., 2017; Barbour et al., 2019; Sandström et al., 2020). However, this did not explain the variation at 250 Hz in this study. Both the manual and automated audiometry were tested in a soundproof room, and circumaural headphones were placed above the insert earphones to increase the attenuation of ambient sound when tested for automated audiometry. More than 40% of thresholds difference at 250 Hz in Group A were equal to 0 dB, compared with only 20% in Group S. It is possible that low-frequency tone is not easily recognized by human ears and requires more attention to obtain an accurate threshold. The ascending method used in Group A, which presented more tones than Group S, facilitated the reliable hearing threshold at 250 Hz. The difference at 250 Hz between the two automated procedures was

TABLE 1 The difference and correlations between manual and automated audiometry thresholds.

| Hz | 250 | 500 | 1,000 | 2,000 | 4,000 | 8,000 |
|---|---|---|---|---|---|---|
| **Ascending method** | | | | | | |
| M difference in dB (SD) | −3.52 (4.77) | −0.46 (5.08) | 0.61 (4.14) | −0.46 (5.18) | 2.04 (4.97) | 5.61 (6.27) |
| Abs M difference in dB (SD) | 4.03 (4.35) | 3.32 (3.86) | 2.76 (3.14) | 3.83 (3.50) | 4.08 (3.47) | 6.63 (5.17) |
| Correlations | 0.88 | 0.89 | 0.96 | 0.95 | 0.96 | 0.95 |
| **Shortened ascending method** | | | | | | |
| M difference in dB (SD) | −4.26 (4.12) | −1.02 (5.09) | −0.17 (4.32) | −0.68 (5.42) | 0.80 (5.14) | 6.99 (7.49) |
| Abs M difference in dB (SD) | 4.94 (3.26) | 3.75 (3.58) | 2.78 (3.29) | 4.09 (3.60) | 3.75 (3.58) | 8.01 (6.37) |
| Correlations | 0.91 | 0.90 | 0.95 | 0.95 | 0.95 | 0.95 |

M difference: the average value of the difference between the manual and the automated thresholds (manual minus automated values); Abs M difference: the average of the absolute value of the difference between the manual and the automated threshold; Correlation: the correlation coefficients between manual and automated test results.

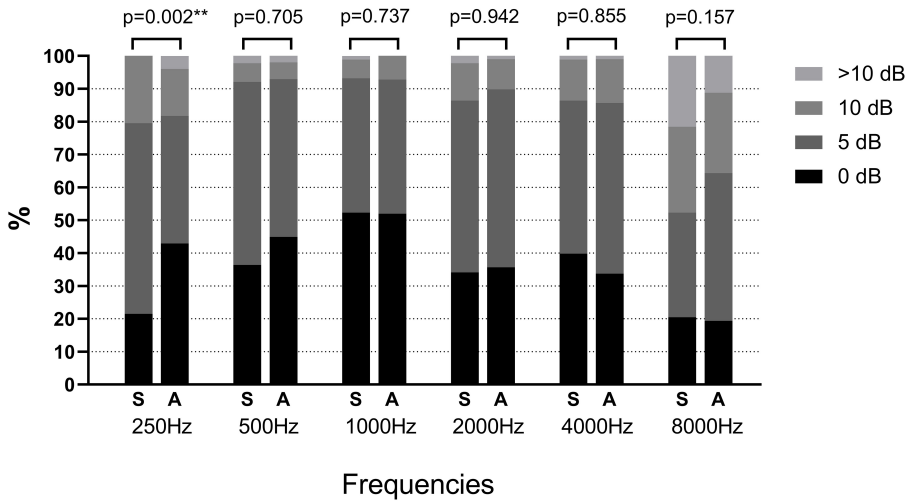


FIGURE 1
Distribution of the absolute differences between each type of automated test threshold (Groups A and S) and the manual test threshold at each frequency. Asterisk values indicate a statistically significant difference with a *p*-value less than 0.05. S, shortened ascending method; A, ascending method.

TABLE 2 Differences in test time, preference on the testing methods, and the total number of reactions between Groups A and S.

| | Testing time (min) | Preference (%) | | | Total number of reactions |
|---|---|---|---|---|---|
| | Automated | Manual | Automated | Whatever | Automated |
| Group S | 5.8 ± 0.9 | 31.6 | 21.1 | 47.4 | 62.0 ± 11.4 |
| Group A | 9.8 ± 1.4 | 36.7 | 16.3 | 46.9 | 90.5 ± 10.8 |
| *P*-values | $P < 0.001$* | | $p = 0.795$ | | $P < 0.001$* |

Asterisk values indicate a statistically significant difference with a *p*-value less than 0.05.

an intriguing issue which could be explored in further research in the field of automated audiometry.

In this study, both the testing time and the total number of reactions in Group S were significantly lower than those in Group A. The long-time testing would also aggravate the uncomfortable feelings of the subjects. Participants who were more willing to accept the manual audiometry most had a longer testing time, and they felt ear stuffy from insert earphones or heaviness from earphone cups. In a previous study (Storey et al., 2014), subjects also reported discomfort from the weight and pressure of the headset over time. In this study, only air conduction thresholds were performed, and it would have taken longer if the bone conduction had also been measured.

Although the correlation was lower at low and high frequencies than at medium frequencies, these errors were still within acceptable limits when clinically explaining the test

results. Therefore, in large-scale screening settings, or in some special populations, such as subjects with short attention spans, the shortened ascending method should be a better choice in automated testing. In mass screening and in areas with inadequate medical facilities, where the testing environment often does not meet the standard requirements. KUDUwave has been shown to obtain comparable results to manual testing in a free-field environment (Visagie et al., 2015), with the application advance in clinically heterogeneous populations (Brennan-Jones et al., 2016), and in bone-conduction test (Swanepoel de and Biagio, 2011), the automated audiometry device has great potential for service delivery in low- and middle-income countries and in rural and remote areas lacking medical facilities, which is an important direction for our future research.

## Study limitations and future directions

One of the limitations of this study is that the testing sequence of the manual and automated methods was not counter-balanced, the manual testing was conducted firstly, which could cause an order effect. Secondly, all subjects in this manuscript were with normal hearing, and the correlation between the results of the shortened/ascending and manual method was good, but further research is needed to determine whether the correlation is still accepted when the automated hearing test was conducted in people with different degrees of hearing loss. Thirdly, all the pure tone audiometry tests in this study were conducted in the sound booth, the subsequent studies need to be conducted to compare the hearing thresholds of subjects with different degrees of hearing loss in a non-isolated environment.

## Conclusion

In normal hearing subjects, there is a high correlation between automated and manual audiometry thresholds, but the variation was higher at 8,000 Hz. The test time was shorter using the shortened ascending method than the ascending method, but the accuracy of the two automated procedures differed statistically at 250 Hz. A more delicate threshold-seeking, the ascending procedure, may address this problem when testing low frequencies.

## Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

## Ethics statement

The studies involving human participants were reviewed and approved by the Beijing Tongren Hospital, Capital Medical University. The patients/participants provided their written informed consent to participate in this study.

## Author contributions

HL, BL, and XF designed the experiments. HL and BD carried out the experiments. HL, YW, and XF analyzed the experimental data. HL wrote the manuscript. XF, BL, and YW reviewed the manuscript. All authors contributed to the article and approved the submitted version.

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## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## Publisher's note



## Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fnins.2022.1011016/full#supplementary-material

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# VALIDITY OF AUTOMATED THRESHOLD AUDIOMETRY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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**ABSTRACT**

**Objectives:** A systematic literature review and meta-analysis on the validity (test–retest reliability and accuracy) of automated threshold audiometry compared with the gold standard of manual threshold audiometry was conducted.

**Design:** A systematic literature review was completed in peer-reviewed databases on automated compared with manual threshold audiometry. Subsequently a meta-analysis was conducted on the validity of automated audiometry. A multifaceted approach, covering several databases and using different search strategies was used to ensure comprehensive coverage and to cross-check search findings. Databases included: MEDLINE, SCOPUS, and PubMed with a secondary search strategy reviewing references from identified reports. Reports including within subject comparisons of manual and automated threshold audiometry were selected according to inclusion/exclusion criteria before data were extracted. For the meta-analysis weighted mean differences (and standard deviations) on test–retest reliability for automated compared with manual audiometry were determined to assess the validity of automated threshold audiometry.

**Results:** In total, 29 reports on automated audiometry (method of limits and the method of adjustment techniques) met the inclusion criteria and were included in this review. Most reports included data on adult populations using air conduction testing with limited data on children, bone conduction testing, and the effects of hearing status on automated audiometry. Meta-analysis test–retest reliability for automated audiometry was within typical test–retest variability for manual audiometry. Accuracy results on the meta-analysis indicated overall average differences between manual and automated air conduction audiometry (0.4 dB; 6.1 SD) to be comparable with test–retest differences for manual (1.3 dB; 6.1 SD) and automated (0.3 dB; 6.9 SD)

audiometry. No significant differences ($p$ > 0.01; summarized data analysis of variance) were seen in any of the comparisons between test–retest reliability of manual and automated audiometry compared with differences between manual and automated audiometry.

**Conclusions:** Automated audiometry provides an accurate measure of hearing threshold, but validation data are still limited for (a) automated bone conduction audiometry; (b) automated audiometry in children and difficult-to-test populations; and (c) different types and degrees of hearing loss.

**Keywords:** automated threshold audiometry, validation, test-retest reliability, accuracy.

## INTRODUCTION

Automated healthcare services may include screening, diagnostic, and intervention procedures that can be conducted without the necessary healthcare professional's direct involvement. In situations where specialist healthcare personnel are limited or unavailable, this approach may ensure that services and healthcare resources are optimized (Margolis & Morgan 2008; Swanepoel et al. 2010). Automated threshold audiometry has existed for many years; however, it has not been used widely in clinical practice apart from occupational healthcare settings (Margolis & Morgan 2008).

The earliest record of automated threshold audiometry was in the seminal report of Georg von Békésy (1947). This self-recording threshold audiometer automatically increased and decreased the sound intensity while sweeping through the test-frequency range and became known as "sweep frequency Békésy audiometry." The patient is required to press a response button when the test signal is heard and release it when he or she loses perception of the signal. This method of determining the threshold is commonly known as the "method of adjustment." Subsequent systems used derivations of this technique with fixed-frequency threshold-seeking algorithms, referred to as fixed or discreet frequency Békésy audiometry, where a sweep in intensity occurs within a fixed frequency based on the patient's behavioral response relayed through a response switch (Meyer-Bisch 1996; Franks 2001).

In later years automated audiometry systems were programmed according to conventional manual audiometry procedural steps (Sparks 1972), typically using versions of the Hughson and Westlake threshold-seeking method (Hughson & Westlake 1944). The audiometer automatically makes adjustments to the intensity of the presented signal, up or downward depending on the response or lack of response. This method is known as the "method of limits." This method has also been modified in some cases to include forced-choice responses from the patient. Here the listener is required to listen and make a response that either indicates that a sound was heard or not. This can be done, for example, by pressing the

appropriate “button” on a touch-screen monitor after a signal is presented (Franks 2001; Margolis & Morgan 2008).

Pure-tone threshold audiometry measures are especially suited to automation because they are based on predetermined sequenced steps (Margolis & Morgan 2008). In addition, when using a computer, results can be recorded automatically enabling all the advantages of electronic record keeping, such as reduced paperwork, transfer to other clinicians, and tracking change over time. In addition, automated testing can incorporate quality monitoring mechanisms to ensure consistent and reliable results as has recently been demonstrated (Margolis et al. 2007, 2011). Automation may also potentially improve standardization of tests protocols and procedures across clinics and even within clinics.

At present, the need for hearing healthcare services globally far outweighs the current capacity to deliver the services (Goulios & Patuzzi 2008; Fagan & Jacobs 2009; Swanepoel et al. 2010; Margolis et al. 2010, 2011). Automated audiometry has been proposed as a way to increase the reach of audiometry in underserved areas especially when conducted within asynchronous telehealth framework (Swanepoel et al. 2010; Swanepoel & Hall 2010). An automated audiometer cannot replace an audiologist, but a system that can determine pure-tone hearing thresholds with similar accuracy to that of manual audiometry may be beneficial in addressing the demand for hearing health services. Optimizing limited professional resources by incorporating automation may improve the reach of current audiological services and can improve the efficiency of current hearing healthcare resources (Margolis & Morgan 2008; Swanepoel et al. 2010).

Although automated threshold audiometry has existed for many decades, it has been used almost exclusively in industry as part of mass hearing screening and baseline monitoring and for research purposes. Clinical audiological practices, in contrast, have almost exclusively relied on conventional manual audiometry. This may partly be attributed to perceived concerns regarding the accuracy and reliability of automated air conduction (AC) and bone conduction (BC) audiometry and the availability of validation studies (Sparks 1972; Margolis & Morgan 2008). However, being a behavioral test procedure manual audiometry presents with normal variability in threshold determination (test– retest or intertester differences) due to subject factors such as fatigue and concentration as well as due to different transducers and test environments used (ANSI 1996; Margolis et al. 2007). Normal variability in audiometry has typically been quantified by test–retest reliability and occasionally by intertester reliability (Margolis et al. 2007; Ishak et al. 2011).

In the light of the potential benefits of automation in threshold audiometry, its long history, and the apparent lack of summative evidence supporting its use, the present study aimed to systematically review the current body of peer-reviewed publications on the validity (test–retest reliability and accuracy) of automated threshold

audiometry. In addition the study included a meta-analysis, using results from published reports, to quantify the test–retest reliability and accuracy of automated threshold audiometry.

## MATERIALS AND METHODS

### Systematic Review

A systematic review of peer-reviewed literature was conducted to determine the validity, as measured by the accuracy and reliability, of automated threshold audiometry compared with manual threshold audiometry. Accuracy is defined as the indirect method of measurement between two different techniques measuring the same variable of which one is the gold standard (Bland & Altman 1999). Manual audiometry served as the gold standard and automated audiometry as the comparison method for determining auditory thresholds. Test–retest reliability refers to the ability of a test to give similar results when applied more than once on the same subjects under the same conditions (Dobie 1983).

A varied search strategy was used across several electronic databases to identify relevant research reports (excluding editorials, notes, and short surveys) from peer-reviewed literature. For inclusion reports were required to include some within-subject comparison of automated threshold audiometry to manual threshold audiometry (accuracy). Test–retest reliability information was also captured from the identified reports.

A multifaceted approach, covering several databases and using different search strategies, was used to ensure comprehensive coverage and cross-checking of search findings (White & Schmidt 2005). An initial search strategy was undertaken using the following databases and search engines: MEDLINE, SCOPUS, and PubMed. Searches were conducted on July 20, 2012 and included all relevant reports published until this date. Supplemental Digital Content 1 (see Table, links.lww.com/EANDH/A100) indicates the databases, search strategy, and search terms used.

The MEDLINE database search used a strategy of relevant key words to determine all records relating to the study aim (Supplemental Digital Content 1, Table, links.lww.com/EANDH/A100). The second database, PubMed, was searched using available Medical Subject Heading terms. SCOPUS, the third database included in the search strategy, is the world's largest abstract and citation database of peer reviewed literature also indexing MEDLINE. This served as a cross-check for reports from PubMed and MEDLINE databases.

Inclusion and exclusion criteria: only reports of a comparative nature between automated and manual threshold audiometry, written in English were included.

Descriptions of automated audiometry without these comparisons, reviews, articles, notes, and short surveys were not included.

The first author reviewed the abstracts of all reports resulting from the searches to determine whether the report complied with the inclusion criteria. If any queries arose the second author also reviewed the abstracts. Where an abstract was unavailable, the full article was reviewed (Table 1). After all duplicates and unrelated reports had been excluded, the remaining reports were reviewed in full to determine whether they met the inclusion criteria. A secondary search was used to supplement the findings of the primary search. This involved reviewing the reference lists of all reports already identified for inclusion during the primary search strategy for additional reports not identified with the primary search.

**Table 1. Results from the applied search strategies**

| Procedural steps | Number of reports | Description |
|---|---|---|
| 1. Database search results | 1932 | 3 Databases (Medline, PubMed, Scopus). |
| 2. Database results excluding duplicates | 1311 | 621 duplicates omitted. |
| 3. Database results excluding non-English reports | 1072 | 223 reports omitted. |
| 4. Database results excluding reviews, short surveys and notes omitted | 971 | 101 reports omitted. |
| 5. Database results related to scope of review based on abstract and title | 63 | 971 titles and abstracts reviewed for relevance, 908 records omitted, 63 complete articles reviewed. |
| 6. Database results within scope of review based on full article | 26 | 37 reports omitted based on inclusion/exclusion criteria. One could not be tracked due to incorrect indexing on the journal archive. |
| 7. Additional reports within scope of review | 3 | 3 reports identified from secondary search strategy surveying reference lists of 26 identified reports. |
| 8. Final reports | 29 | Reports utilized in systematic review. |
| 9. Reports utilized in meta-analysis | 12 | Reports with data appropriate to meta-analysis aims |

The reports selected for review were carefully scrutinized and categorized according to the audiological threshold-seeking method used (method of adjustment or method of limits), type of evaluation (diagnostic or screening), AC or BC thresholds, type of transducers and audiometer used, age and hearing status of participants, type of statistical analysis for accuracy, test– retest reliability, and the conclusions drawn by the article.

**Meta-Analysis**

A meta-analysis was conducted to combine and quantify the results of individual reports so that an overall assessment of test–retest reliability and accuracy based on existing evidence could be made for automated audiometry. To be included in the

meta-analysis, reports had to meet the following criteria: (a) The report had to include data comparing manual and automated audiometry in terms of accuracy; (b) Data had to be reported in the form of mean differences (real or absolute) and standard deviations with the number of observations reported.

Mean differences and standard deviations were documented. Weighted averages, using reported real and absolute average differences and standard deviations were determined for validation (test–retest reliability and accuracy) across studies, taking into account the number of observations reported. Furthermore, a comparison of test– retest threshold differences for manual and automated threshold audiometry, indicative of normal variability, was made with the difference between automated and manual audiometry (accuracy) using an analysis of variance (ANOVA) test (http://statpages.org/anovalsm.html). A significant difference in variability was noted by a $p < 0.01$.

## RESULTS

### Systematic Review

The systematic review procedural outcomes are summarized in Table 1. After excluding duplicates, reviews, short surveys, notes, and non–English-language records, 971 reports remained. Sixty-three reports were identified and subsequently the full-text was reviewed. One report (Raza 2008) could not be traced because its indexing on all databases did not correspond to the actual journal listing. Despite efforts to contact the authors and the journal the report could not be sourced. A total of 26 full reports were identified, which met the inclusion/exclusion criteria.

The second stage of the search strategy, involving a review of the reference lists of identified reports, revealed three additional reports, bringing the total number to 29 reports.

The final list of reports included in the systematic review date from 1956 to 2011 (Fig. 1). Supplemental Digital Content 2 (Table, http://links.lww.com/EANDH/A101) provides a summary of all reports included according to authors, year of publication, subject descriptions, test parameters, automated threshold-seeking method (method of limits/method of adjustment), research findings (accuracy or test–retest reliability), and conclusions.

Of the 29 reports, 15 used the method of adjustment and 13 the method of limits whereas one report used both methods (Harris 1979). The majority of reports covered diagnostic audiometry whereas four reports included screening applications of automated audiometry (one for method of limits; three for method of adjustment).

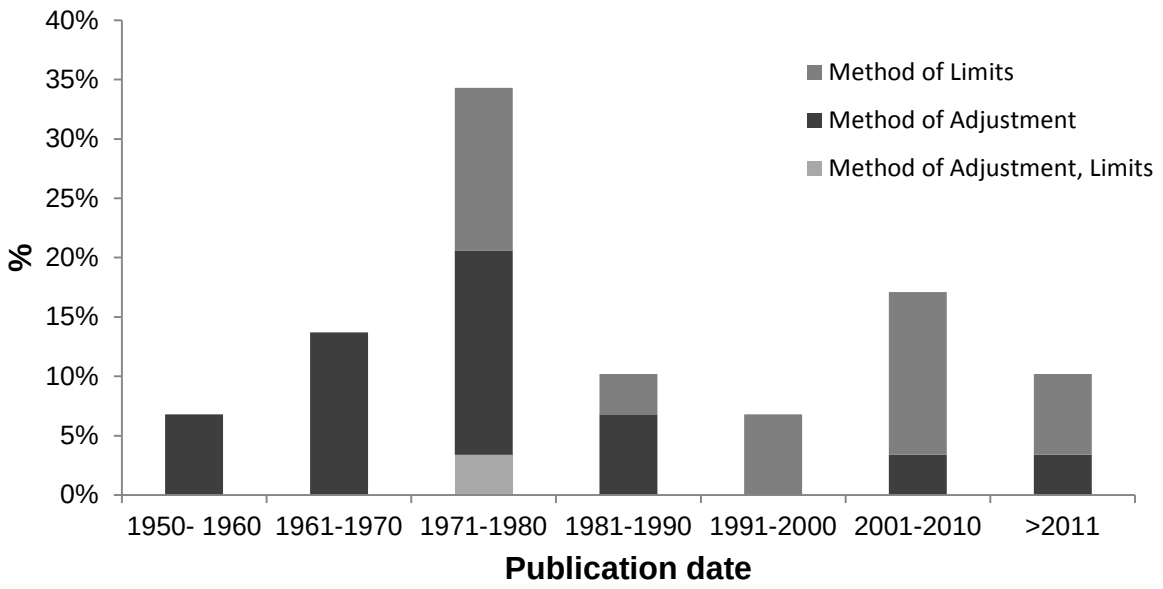


**Figure 1. Distribution of reports included in systematic review (n=29) date of publication and type of automated audiometry (method of limits; method of adjustment, method of limits and adjustment).**

Table 2 provides a description of data on accuracy and test– retest reliability included in the systematic review records. Test–retest reliability was included by 11 reports (7 for method of adjustment and 4 for method of limits). Ten of these included only AC audiometry, whereas one included both AC and BC audiometry. Of these 10 reports, three included participants with a hearing loss, whereas four did not indicate the hearing status of participants (Table 2).

Records obtained reported data using a variety of statistical analyses (Supplemental Digital Content 3, Table, http://links.lww.com/EANDH/A102). The most common presentation of test–retest data was presented in terms of average differences and standard deviations (n = 4) and average thresholds and standard deviations (n = 3).

All 29 reports provided information on the accuracy of automated threshold audiometry. Twenty-six records reported results for adult populations, 19 of these included AC audiometry only, whereas seven included AC and BC audiometry. Six of the 26 adult reports included persons with hearing loss only, five included persons with normal hearing, whereas six included persons with normal hearing or a hearing loss, and nine did not indicate the hearing status of their samples. Furthermore, only five of the studies reported results on children, two of which included AC and BC results.

Various techniques were used to document the accuracy, referred to as validity in records, of automated audiometry (Supplemental Digital Content 3, Table, http://links.lww.com/EANDH/A102). The most commonly used measures of accuracy were average differences between automated and manual audiometry with accompanying standard deviations (n = 11) and average thresholds and standard

deviations (n = 11). Less commonly used techniques included absolute average differences and SDs (n = 6), t test (n = 4), and ANOVA analysis (n = 2).

**Table 2. Distribution of air and bone conduction data for adults and children reported across studies identified in the systematic review (n=29)**

| Type of hearing | Accuracy | | | | Test-retest reliability | | | |
|---|---|---|---|---|---|---|---|---|
| | Normal hearing | Hearing loss | ⁎Both | Not indicated | Normal hearing | Hearing loss | ⁎Both | Not indicated |
| ***Adults*** | | | | | | | | |
| AC testing | 5 | 3 | 3 | 8 | 2 | 3 | 1 | 4 |
| AC and BC testing | - | 3 | 3 | 1 | - | - | - | 1 |
| **Subtotal** | **5** | **6** | **6** | **9** | **2** | **3** | **1** | **5** |
| ***Children*** | | | | | | | | |
| AC testing | 1 | - | 1 | 1 | - | - | - | - |
| AC and BC testing | - | - | 2 | - | - | - | - | - |
| **Subtotal** | **1** | **-** | **3** | **1** | **0** | **0** | **0** | **0** |
| **TOTAL** | **6** | **6** | **9** | **10** | **2** | **3** | **1** | **5** |

*⁎Indicating that both hearing and hearing loss subjects were included in the study.*
*AC, air conduction; BC, bone conduction.*

## Meta-Analysis

The meta-analysis used mean differences (real and absolute) and standard deviations at each frequency extracted from the reports, if available. In some reports the mean differences and standard deviations across all frequencies were not determined and thus were calculated when possible (i.e., if the number of observations were included). Supplemental Digital Content 4 (Table, http://links.lww.com/EANDH/A103) and Supplemental Digital Content 5 (see Table, http://links.lww.com/EANDH/A104) indicate summaries of the data obtained for test–retest reliability and accuracy across individual studies used in the meta-analysis. Weighted average calculations were subsequently obtained across these studies (Tables 3 and 4).

Only five reports provided data on test–retest reliability in the form of mean differences (real and absolute) and standard deviations for automated testing and manual testing. Test–retest variability for automated threshold audiometry indicated average differences that ranged between −1.1 and 2.2 dB with the standard deviation ranging between 6.2 and 10.4 dB for individual test frequencies, whereas the absolute average differences ranged between 2.0 and 4.9 dB with a standard deviation of 3.0 to 4.8 dB (Table 3).

**Table 3. Meta-analysis weighted average test-retest reliability differences for manual and automated audiometry**

| Frequencies | 125 Hz | 250 Hz | 500 Hz | 1000 Hz | 2000 Hz | 3000 Hz | 4000 Hz | 6000 Hz | 8000 Hz | All |
|---|---|---|---|---|---|---|---|---|---|---|
| **MANUAL THRESHOLD AUDIOMETRY** | | | | | | | | | | |
| **Average differences and standard deviations (3 reports)** | | | | | | | | | | |
| Average difference | - | - | 2.3 | 2.1 | 1.5 | 2.0 | -0.4 | -1.7 | - | 1.3 |
| N | - | - | 500 | 500 | 500 | 40 | 500 | 40 | - | 532 |
| Standard deviation | - | - | 6.7 | 4.8 | 5.0 | 4.7 | 6.9 | 7.6 | - | 6.1 |
| N | - | - | 500 | 500 | 500 | 40 | 500 | 40 | - | 532 |
| **Absolute average differences and standard deviations (2 reports)** | | | | | | | | | | |
| Absolute average difference | 4.8 | 3.4 | 2.9 | 3.2 | 2.7 | - | 2.8 | - | 3.0 | 3.2 |
| N | 60 | 80 | 80 | 80 | 80 | - | 80 | - | 80 | 80 |
| Standard deviation | 5 | 3.7 | 3.7 | 3.4 | 3.6 | - | 3.5 | - | 4.3 | 3.9 |
| N | 60 | 60 | 60 | 60 | 60 | - | 60 | - | 60 | 60 |
| **AUTOMATED THRESHOLD AUDIOMETRY** | | | | | | | | | | |
| **Average differences and standard deviations (3 reports)** | | | | | | | | | | |
| Average difference | - | - | 0.3 | -1.1 | 0.0 | 2.1 | 0.7 | 1.7 | - | 0.3 |
| N | - | - | 500 | 500 | 500 | 40 | 500 | 40 | - | 532 |
| Standard deviation | - | - | 7.1 | 6.8 | 6.4 | 6.2 | 7.1 | 10.4 | - | 6.9 |
| N | - | - | 500 | 500 | 500 | 40 | 500 | 40 | - | 532 |
| **Absolute average differences and standard deviations (2 reports)** | | | | | | | | | | |
| Absolute average difference | 4.9 | 3.4 | 2.9 | 2.6 | 2.6 | - | 2.3 | - | 2.0 | 2.9 |
| N | 60 | 80 | 80 | 80 | 80 | - | 80 | - | 80 | 80 |
| Standard deviation | 4.8 | 3.5 | 3.6 | 3.2 | 4.1 | - | 3.0 | - | 3.2 | 3.8 |
| N | 60 | 60 | 60 | 60 | 60 | - | 60 | - | 60 | 60 |

**Table 4. Weighted average differences and standard deviations between manual and automated threshold audiometry (manual minus automated)**

| Frequencies | 125 Hz | 250 Hz | 500 Hz | 1000 Hz | 2000 Hz | 3000 Hz | 4000 Hz | 6000 Hz | 8000 Hz | All |
|---|---|---|---|---|---|---|---|---|---|---|
| **AVERAGE DIFFERENCES AND STANDARD DEVIATIONS** | | | | | | | | | | |
| **Combined (10 reports)** | | | | | | | | | | |
| Average difference | -2.5 | -3.5 | -1.5 | -1.2 | -0.1 | 2.1 | -3.6 | -2.1 | -5.0 | 0.4 |
| N | 232 | 360 | 796 | 796 | 796 | 428 | 796 | 556 | 384 | 820 |
| Standard deviation | 8.6 | 6.7 | 5.4 | 5.3 | 5.5 | 6.1 | 5.7 | 7.7 | 8.7 | 6.1 |
| N | 232 | 420 | 766 | 766 | 526 | 578 | 526 | 466 | 420 | 798 |
| **Method of limits (3 reports)** | | | | | | | | | | |
| Average difference | - | -0.4 | -0.7 | 0.4 | -1.3 | -0.8 | 3.8 | -1.3 | -1.7 | 0.3 |
| N | - | 60 | 84 | 84 | 24 | 24 | 84 | 24 | 84 | 116 |
| Standard deviation | - | 5.1 | 4.4 | 5.3 | 5.8 | - | 4.9 | - | 7.0 | 5.5 |
| N | - | 60 | 60 | 60 | 60 | - | 60 | - | 60 | 92 |
| **Method of adjustment (7 reports)** | | | | | | | | | | |
| Average difference | -2.0 | -2.3 | 0.5 | 0.3 | 2.1 | 1.1 | 0.1 | -1.0 | -3.1 | 0.8 |
| N | 232 | 360 | 796 | 796 | 796 | 428 | 796 | 556 | 384 | 796 |
| Standard deviation | 8.6 | 6.9 | 5.4 | 5.3 | 5.5 | 6.1 | 5.8 | 7.7 | 9.0 | 6.2 |
| N | 232 | 360 | 706 | 706 | 466 | 578 | 466 | 466 | 360 | 706 |
| **ABSOLUTE AVERAGE DIFFERENCES AND STANDARD DEVIATIONS** | | | | | | | | | | |
| **Combined (4 reports)** | | | | | | | | | | |
| Absolute Average Difference | 4.2 | 3.6 | 3.4 | 3.5 | 3.4 | - | 2.9 | - | 3.1 | 4.2 |
| N | 136 | 196 | 196 | 196 | 196 | - | 196 | - | 196 | 360 |
| Standard deviation | 4.0 | 3.5 | 3.9 | 3.6 | 3.8 | - | 3.2 | - | 4.5 | 5.0 |
| N | 136 | 196 | 196 | 196 | 196 | - | 196 | - | 196 | 345 |

Table 4 provides a summary of weighted average differences between manual and automated audiometry in the adult population. Results indicate that the overall (n = 10) average differences between automated and manual audiometry ranged between −5.0 and 2.1 dB across the frequency spectrum with the standard deviations ranging from 5.3 to 8.7 dB. Furthermore, the average differences obtained between the automated method of limits and manual audiometry ranged between −1.7 and 3.8 dB with standard deviations between 4.4 and 7 dB. In addition, method of adjustment audiometry yielded lower results at 0.125, 0.25, 6, and 8 kHz (−0.1 to −2.3 dB) whereas manual audiometry yielded higher results at the remaining frequencies, with the standard deviations ranging from 5.3 to 9 dB. The combined absolute differences ranged from 2.9 to 4.2 dB with standard deviations ranging from 3.2 to 4.5 dB.

Last, it should be noted that data from the two studies on children (4 to 10 years of age) were excluded from the meta-analysis as only one study using the method of adjustment (Békésy fixed-frequency testing) reported results in the form of average differences. These ranged between 3.6 and 20.3 dB with standard deviations ranging from 2.6 to 7.2 dB for 0.25, 1 and 4 kHz (Hartly & Siengenthalar 1964). Another study reported results in terms of absolute differences across all frequencies (4.1 dB), with a standard deviation of 1.7 dB (Margolis et al. 2011), when using an automated method of limits technique.

ANOVA comparisons of the meta-analysis weighted averages were conducted between the test–retest differences for manual and automated audiometry and the average difference between manual and automated thresholds (accuracy comparison) for the real and absolute differences. This was done for the combined category (method of limits and method of adjustment) and between method of adjustment and method of limits average differences. No statistically significant differences ($p > 0.01$; summarized data ANOVA) were obtained between any of the comparisons of test–retest (manual and automated) threshold differences and automated compared with manual threshold differences.

**DISCUSSION**

Comparison of two audiometric threshold techniques, such as automated and manual audiometry, has been performed using a variety of statistical analyses (Supplemental Digital Content 3, Table). Measures of agreement determined by the two threshold-seeking methods most commonly included the average difference (with standard deviation), average thresholds (with standard deviation), and average absolute differences (with standard deviation). The average difference is valuable in showing a systematic effect but negative and positive differences may cancel each other out even when large differences in either direction exist. Bland and Altman (1986) recommend the use of absolute average differences and standard deviation as a more appropriate measure of correspondence because it provides an indicator of the expected spread in variability. With this in mind, the meta-analysis was

conducted using average differences (real and absolute) and standard deviations to draw conclusions regarding the validity of automated audiometry when compared with manual audiometry.

**Automated Audiometry Test–Retest Reliability**

Test–retest reliability is defined as the repeatability of a technique and allows comparison of techniques to determine which is more precise (Bland & Altman 1986). Eleven reports in this systematic review included results on test–retest reliability, of which four used the method of limits and seven the method of adjustment for threshold audiometry. In each case, reported test–retest reliability for automated audiometry was indicated to be within typical variability when compared with the test– retest reliability of manual audiometry (Burns & Hinchcliffe 1957; Gosztonyi et al. 1971; Formby et al. 1996; Robinson & Whittle 1973; Erlandsson et al. 1979a, b; Lutman et al. 1989; Fautsi et al. 1990; Ho et al. 2009; Ishak et al. 2011; Swanepoel et al. 2011). Only Ishak et al. (2011) reported higher test–retest variability with Bèkèsy sweep-frequency audiometry, but reported that using a slower sweep rate of 20 seconds per octave would improve the acquired test–retest reliability.

Several reports indicated that the second test session produced slightly lower (i.e., better) thresholds than the first session when manual and automated audiometry were used (Burns & Hinchcliffe 1957; Gosztonyi et al. 1971; Robinson & Whittle 1973; Erlandsson et al. 1979a; Lutman et al. 1989; Fautsi et al. 1990; Fromby et al. 1996; Ho et al. 2009; Ishak et al. 2011, Swanepoel et al. 2011). Several of the reports attributed the lower thresholds during the second session to the learning effect (Erlandsson et al. 1979a, b; Lutman et al. 1989; Ishak et al. 2011). This suggests that subsequent studies should consider randomizing the order of testing techniques and control the previous experiences participants had with audiometric testing.

The meta-analysis showed overall test–retest variability to be similar for automated (5 reports) and manual AC audiometry (5 reports). Average differences obtained for manual and automated test–retest audiometry respectively were 1.3 dB (6.1 SD) and 0.3 dB (6.9 SD) and absolute differences of 3.2 dB (3.9 SD) and 2.9 dB (3.8 SD). The meta-analysis test–retest difference for automated compared with manual audiometry (Table 3) demonstrated no statistically significant difference (ANOVA; $p > 0.01$). Higher variability was noted at 6 kHz for both automated and manual AC audiometry, but this was because only one article reported data at 6 kHz (Burns & Hinchcliffe 1957). Burns and Hinchcliffe (1957) reported a high variability for 6 kHz, with standard deviations of 3 to 4 dB, higher than those obtained at the other tested frequencies in the study (Supplemental Digital Content 4, see Table, http:// links.lww.com/EANDH/A103).

Meta-analysis test–retest results are consistent with previously reported standard deviations of average test–retest differences for manual audiometry, ranging between 4.4 and 6.2 dB for a group of adults and children (Stuart et al. 1991). A recent report (Swanepoel & Biagio 2011) on manual audiometry obtained absolute average test–retests differences (3.6 dB; 3.9 SD) that were in line with the meta-analysis results (2.9 dB; 3.8 SD). The AC test–retest threshold differences for automated audiometry fall well within present test–retest limits.

Ho et al. (2009) was the only study to report on automated BC test–retest reliability. Results were reported in terms of paired thresholds; the study concluded that test–retest reliability of automated BC audiometry was appropriate (Ho et al. 2009) and within typical manual BC test–retest reliability (Laukli & Fjermedal 1990; Margolis et al. 2010; Swanepoel & Biagio 2011).

**Automated Audiometry Accuracy**

Over the six decades since the first description of automated audiometry, only 29 reports (15 on method of adjustment, 13 on method of limits, and 1 using both method of limits and adjustment) have reported on the validation of automated audiometry by comparing results with the gold standard of manual audiometry.

The meta-analysis showed that overall average differences between manual and automated AC audiometry (0.4 dB; 6.1 SD) correspond to test–retest difference for manual (1.3 dB; 6.1 SD) and automated (0.3 dB; 6.9 SD) audiometry. No statistically significant difference (ANOVA; $p > 0.01$) was evident between overall absolute differences for manual and automated audiometry (4.2 dB; 5.0 SD) and the test–retest absolute differences for manual (3.2 dB; 3.9 SD) and automated (2.9 dB; 3.8 SD) audiometry (Table 3).

Average differences for manual and automated BC audiometry were only reported by nine studies. These studies used varied forms of analyses in terms of agreement (Supplemental Digital Content 3, Table) and as a result weighted averages for BC threshold audiometry could not be determined across studies.

**Method of Adjustment**

As demonstrated in Figure 1 the method of adjustment was the first type of automated threshold audiometry. Overall, 16 reports were identified including comparisons of manual and method of adjustment automated threshold audiometry. The manual audiometry threshold determination techniques in these reports included the modified Hughson-Westlake method and some variations thereof (Corso 1956; Burns et al. 1957; Hartley et al. 1964; Knight 1965; Jokinen 1969; Robinson & Whittle 1973; Erlandsson et al. 1979a; 1979b; Ishak et al. 2011) as indicated in Supplemental Digital Content 2 (see Table, http://links. lww.com/EANDH/A101).

Several reports included in the systematic review indicated that automated audiometry using the method of adjustment (Békésy sweep or Békésy fixed-frequency method) generally yields lower (i.e., better) thresholds compared with manual audiometry (Burns & Hinchcliffe 1957; Knight 1965; Jokinen 1969; Maiya & Kacker 1973; Robinson & Whittle 1973; Erlandsson et al. 1979a, 1979b; Harris 1979; Frampton & Courter 1989; Ishak et al. 2011). A single report showed manual audiometry having lower thresholds than the method of adjustment technique at certain frequencies (0.25, 6, and 8 kHz). The authors reported that the reason for this phenomenon was probably the threshold-seeking method used (Ishak et al. 2011).

The meta-analysis showed an average differences of 0.8 dB (6.2 SD) between automated (method of adjustment) and manual AC audiometry. There was no statistically significant difference (ANOVA; $p > 0.01$) when these results were compared with test–retest reliability of both manual (1.3 dB; 6.1 SD) and automated threshold audiometry (0.3 dB; 6.9 SD). The accuracy of automated (method of adjustment) threshold audiometry is therefore within the normal variability as defined by test–retest reliability. Margolis et al. (2010) compared automated and manual threshold differences between two audiologists using manual audiometry as opposed to test–retest reliability. The intertester differences (0.6 dB; 5.5 SD) for manual audiometry were similar to the average differences (0.8 dB; 6.2 SD) between manual and automated audiometry results obtained in the meta-analysis.

Four reports included screening audiometry, comparing manual and automated thresholds (method of adjustment). Three of these studies used children (Hartly & Siengenthalar 1964; Delany et al. 1966; McPherson et al. 2010) and one used an adult population (Gosztonyi et al. 1971). Delany et al. (1966) indicated that automated audiometry for participants provided results substantially in agreement with manual audiometry, however, as observed with adults, automated audiometry tends to produce thresholds that are slightly lower (−0.8 to −3.3 dB) than manual testing. In addition, the authors (Hartly & Siengenthalar 1964; Delany et al. 1966; McPherson et al. 2010) indicated that automated audiometry can produce useful threshold data with children down to the age of 6 years. As age decreases, however, a greater proportion of children are either unable to perform the test at all or frequently lose concentration so that portions of the test need to be repeated at a later stage to obtain a full audiogram.

Gosztonyi et al. (1971) reported on industrial screening conducted on salaried and hourly workers (N = 38 ears). This study indicated that manual audiometry thresholds may be significantly lower than automated thresholds but the authors later discovered that the reason for this phenomenon was the fact that all participants were involved in medicolegal cases. Thus the phenomenon of nonorganic hearing loss significantly increased the threshold differences obtained between manual and automated audiometry.

Although findings on the application of automated audiometry using the method of adjustment are promising, limited data are available for pediatric populations and BC testing. An important reason for no BC data in the method of adjustment technique is attributed to the difficulty in using masking with this method. It is challenging to use a masking noise on the contralateral ear as the narrowband noise level should theoretically change with the tested frequency (Meyer-Bisch 1996). In addition to the technical difficulties of such an operation, the test may become difficult to follow for the patient (Meyer- Bisch 1996).

**Method of Limits**

In the 1970s the focus of research on automated audiometry started to shift from method of adjustment techniques to the method of limits (Fig. 1). Overall, 13 reports used the method of limits for automated audiometry compared with manual audiometry. All the studies obtained in the systematic literature review reported no statistically significant difference for AC between manual and automated audiometry.

Meta-analysis weighted average difference (0.3 dB; 5.5 SD) obtained when comparing automated method of limits technique with manual audiometry was similar to the weighted average difference for the method of adjustment and manual audiometry (0.8 dB; 6.2 SD); no statistically significant difference was noted (ANOVA; $p > 0.01$). These findings correspond to test–retest reliability results of automated (1.3 dB; 6.1 SD) and manual (0.3 dB; 6.9 SD) audiometry, indicating no statistically significant difference (ANOVA; $p > 0.01$). The accuracy of method of limits automated audiometry is within normal variability as defined by test–retest reliability.

Seven of the 13 reports included findings on BC audiometry (Sparks, 1972; Wood et al. 1973; Picard et al. 1993; Margolis et al. 2007; Ho et al. 2009; Margolis et al. 2010; Margolis & Moore 2011). No statistically significant difference between manual and automated BC audiometry was noted across these studies. Margolis and Moore (2011) indicated a statistically significant difference between AC thresholds for manual and automated audiometry. The difference was partly attributed to the different transducers used (manual—TDH 50; automated— Sennheiser HDA 200) and the differential effect of low and high frequencies being tested.

**CONCLUSIONS**

Automated threshold audiometry has developed over six decades from method of adjustment (Békésy methods) automated procedures incorporating conventional manual audiometry (method of limits) threshold-seeking methods. Present evidence demonstrates similar test–retest reliability for automated compared with manual threshold audiometry, and automated audiometry thresholds being within typical test–retest and intertester variability of manual thresholds. Despite its long history, however, validation is still limited for (a) automated BC audiometry; (b) automated

audiometry in children and difficultto- test populations, and (c) different types and degrees of hearing loss.

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The authors declare no conflict of interest.

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**Supplemental Digital Content 1**. Table (Databases and search strategy details)

| Database | Search strategy | Identifiers | Results | Limiters |
|---|---|---|---|---|
| Medline | Reports indicating findings of automated audiological testing. Terms occurring in the title, abstract, or keywords of articles. | “Automatic” OR “computerized” OR “computer-based”OR "pc-based" OR "automation" OR "automated" OR “audioscan” AND "audiometry" OR "hearing measurement" OR "hearing thresholds" OR "auditory thresholds" OR "hearing assessment" OR "hearing evaluation" | 463 | Reports published prior to 1946 not included |
| PubMed | MeSH terms related to automated audiological testing, occurring in the title and abstract. | “automatic” OR “computerized” OR “computer-based” OR “pc-based” OR “automation” OR “automated” OR “audioscan” AND “audiometry” | 195 | MeSH terms utilized only |
| Scopus | Reports indicating findings of automated audiological testing. Terms occurring in all fields. | “automatic” OR “computerized” OR “computer-based” OR “pc-based” OR “automation” OR “audioscan” OR “automation” “automated”, “self-recording”, “self-recorded” OR “Békésy” AND “audiometry”, “hearing measurement”, “hearing thresholds”, “auditory thresholds”, “hearing assessment” and “hearing evaluation”. | 1274 | None |

**Supplemental Digital Content 2.** Table (Summary of reports included in review)

| Author | Year | Subject description | Test parameters | Automated audiometry threshold seeking method | Research findings | | Conclusion |
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| | | | | | Accuracy | Test-retest | |
| Corso | 1956 | 105 subjects (210 ears), 17-25 years old.<br><br>Normal hearing adults | Diagnostic AC audiometry.<br>Frequencies: .25, .5, 1, 1.5, 2, 3, 4, & 8 kHz).<br>Transducers:<br>Auto- oscillator type 1011 manual-oscillator type 1304-A<br>Audiometer:<br>Manual-Bekesy type audiometer, Reager Model,<br>Automated-ADC audiometer, Model 50-E2 | Method of Adjustment-Békésy fixed frequency.<br>Frequency range of 2-8 kHz, starting at 40 dB.<br>Testing time: 10min per ear was used with 0.5 dB rate per second.<br>Thresholds obtained by the intersection of the midpoint curves and specific frequency lines. | - Average absolute thresholds and standard deviations<br>-Test of significance (t-ration).<br>-Difference in variability (F-ratio).<br>-Pearson product-moment correlation coefficient. | - | Manual testing obtained thresholds that were lower than for automated testing (midpoint Békésy testing).<br>Less variability in thresholds was noted between .25 and 2 kHz when manual testing was utilized.<br>A low statistically significant positive correlation was noted at given frequencies between manual and automated audiometry. |
| Burns & Hichcliffe | 1957 | 20 subjects (40 ears), 20-58 years of age.<br><br>Hearing status not indicated | Diagnostic AC testing.<br>Frequencies: .5, 1, 2, 3, 4, 6 kHz.<br>Transducer:<br>Standard Telephones Model 4026 | Method of Adjustment -<br>Békésy sweep frequency.<br>Frequency range of .5-6 kHz was swept with a continuous tone, in 7 min 55 sec, paper speed of 1cm/min. | - Average difference and standard deviation<br>- t-Test values | - Average difference and standard deviations<br>- Product moment | Overall, manual and automated (Békésy) threshold audiometry gives essentially similar results.<br>A significant difference was noted at 1000Hz, where Bekesy testing yielded a lower threshold of approximately 3 dB. |

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| | | | | Rate of change of intensity, increasing and decreasing, approximately 2 dB/sec.<br>Thresholds obtained by the intersection of the midpoint curves and specific frequency lines. | | correlation coefficients.<br>-t-Test | Reliability was satisfactory at all frequencies utilizing both audiometric testing methods, besides at 500 Hz where the second automated test yielded a lowering of thresholds of 1-2 dB. |
| Hartely *&* Siengent halar. | 1964 | 30 subjects (60 ears)<br>13 children: 4 - 5 years old;<br>17 children: 8-10 years old.<br><br>Normal hearing children. | Diagnostic AC Testing.<br>Frequencies: .25, 1, 4 kHz.<br>Audiometer: Manual-Audiovox Model 7-B, automated-Granson-Stadler Model E-800, | Method of Adjustment-Békésy fixed frequency.<br>1 min fixed frequency tracing (timed to begin after 3 reversals on the tracing) were obtained.<br>Thresholds read using the mean mid-point between peaks and valleys. | - Average thresholds<br>- Average difference and Standard deviations<br>-t-Test<br>-Within subject variability – t-Test | - | Better standard of acuity for manual compared to automated threshold audiometry were obtained. The difference was greater for younger children than older children.<br>Within subject variability for automated threshold testing was higher than manual testing. Significant difference of variability at .25 kHz for the older group and at 4 kHz for the younger group. |
| Delany *et al.* | 1966 | 66 ears, 17-29 years old.<br><br>Hearing status not indicated. | Diagnostic AC testing.<br>Frequencies: .5, 1, 2, 3, 4, 6 kHz.<br>Transducer: 4026A earphones<br>Audiometer: | Method of Adjustment -<br>Békésy fixed frequency.<br>Frequencies tested at kHz/sec.<br>Tone burst | - Average difference | - | Automated threshold audiometry gives results substantially in accord with manual audiometry. The differences over most frequencies are small, but automated threshold |

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| | | | Automated-mobile audiometric laboratory, manual-not indicated | presentation rate: 2 tones/sec. | | | audiometry gives lower threshold levels. |
| Knight | 1965 | 66 ears.<br><br>Normal hearing subjects. | Diagnostic AC testing.<br>Frequencies: .5, 1, 2, 3, 4, 6 kHz.<br>Audiometer: Manual and automated-Grason-Stadler model E 800 | Method of Adjustment.<br>Attenuator speed: 5 dB/sec, tone pulsed 2/sec. | -Average difference and standard deviation | - | Manual and automated audiometry is equivalent, as they yield threshold levels on average that are within 1 dB. |
| Jokinen | 1969 | **4 groups*:***<br>1) 19 subjects (30 ears), 19-24 years old, inexperienced, normal hearing subjects.<br>2)15 subjects (30 ears), 19-24 years old, experienced outpatients, normal hearing.<br>3) 9 subjects | Diagnostic AC testing.<br>Frequencies: .125 .25, .5, 1, 2, 3, 4, 6, 8 kHz.<br>Audiometer: Manual- Madsen Model OB 60, Automated-Granson Stdler model E800 | Method of Adjustment -<br>Békésy fixed frequency.<br>Tones presented for 30 sec at a frequency, first with 200 msec pulsed tones, secondly with a continuous tone.<br>Tone pulse, rise and fall time of 25 msec, with on and off ratio of 1: 1.<br>Intensity changes: 0.25dB steps, rate: 2.1 dB/sec. | -Average differences and standard deviations | - | Various differences were seen in the 4 groups.<br>The normal hearing, inexperienced and experienced groups, obtained better results with automated testing (both continues and pulsed tones) than with manual testing.<br>The presbycusis group, with and without the acoustic trauma, indicated that manual and continues Békésy testing obtained the same results, however, pulsed Békésy testing obtained better thresholds |

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| | | (17 ears), 52-73 years old, presbycusis with drop at 4000Hz indicating an acoustic trauma.<br>4) 22 patients (39 ears), 53-81 years old, subjects had presbycusis | | | | | than manual testing. |
| Gosztonyi et al. | 1971 | ***Accuracy***<br>19 subjects.<br><br>***Test-retest reliability***<br>46 salaried employees and 25 hourly employees.<br><br>All noise exposed adults. | Industrial screening AC testing.<br>Frequencies: .5, 1, 2, 4, 8 kHz.<br>Audiometer: Automated-self-recording audiometer, manual-standard clinical audiometer. | Method of Adjustment. | - Average thresholds | - Average difference | Manual testing produced better thresholds than automated testing , there was a difference of 10 dB between the two.<br>Test- retest reliability for salaried employees indicated a difference no more than 10 dB.<br>In this study it was investigated that the reason for the great difference between thresholds was as a result of subjects either being influenced to claim for HL or had compensation cases or had compensation legislations in progress. |
| Sparks | 1972 | 15 subjects. | Diagnostic AC | Method of limits. | | - | It was apparent that if |

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| | | Bi-modal population of mild or severe hearing loss participants used. | and BC testing, with masking. Frequencies: .25, .5, 1, 2, 4, 8 kHz. Transducers: AC- TDH-39 housed in a MX-41 AR cushion. BC- Radioear B-70A oscillator Audiometer: Manual and automated- Beltone 15-C | A computer program using Hughson-Westlake procedure for threshold seeking, masking programmed according to Hood (1960). Computer program provided instructions, which were followed by an assistant who was familiar with the use of Teletype system. If a response was elicited the assistant would type 1, no response the assistant would type 2. The computer would indicate next step. | -Average thresholds and standard deviations. -t-Test conducted on mean values. -Product moment correlation coefficient. | | subjects were consistent in their response, automated testing could obtain thresholds similar to that of manual testing. The t-test: no significant difference between AC and BC values between two methods of testing. Correlation coefficients: high correlation between the two methods of testing. |
| Maiya, & Kacker. | 1973 | 20 subjects, 15-30 years.<br><br>Normal hearing subjects. | Diagnostic AC testing. Frequencies: .125, .25, .5, 1, 2, 4, 6, 8 kHz. Audiometer: Manual- Maico-MA-8, Automated- Grason-Stadler Company model E- 800. | Method of Adjustment - Békésy sweep frequency. Rate: 1 octave/min, chart travel period of 6 2/3 min. Rate of change of intensity: 2.5dB/sec. Thresholds read using the mid-point mean value between | - Average thresholds | - | Automated and manual testing yielded similar thresholds, however automated testing seemed to be more sensitive than manual testing. |

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| | | | | ascending or descending tracing at the frequency level. | | | |
| Robinson & Whittle | 1973 | ***Accuracy:*** 64 subjects (128 ears), 26-73 years old. ***Test-retest reliability:*** 48 subjects (96 ears), 29-73 years old.<br><br>Hearing status not indicated. | Diagnostic AC testing. Frequencies: .25, .5, 1, 2, 4, 6, 8 kHz. Transducers: TDH-39 earphones and MX-41-AR cushions. Audiometer: Manual and automated- Rudmose type ARJ-5 | Method of Adjustment - Békésy fixed frequency. Pulsed tones with a repetition rate: 2 Hz, cycle consisting of a silent period of 185 ms and a tone pulse with 65 ms rise, fall times and a dwell of 185 ms at maximum amplitude, attenuator: 5dB/s. Thresholds read as the mid-point of the excursions, extraneous deviations being ignored. | - Average differences and standard deviations -Linear regression and correlation coefficients. - Estimation of asymptomatic data. | - Average differences and standard deviations of initial test - Average differences and standard deviations of second test | Automated threshold yield better results than manual testing, except at .25 kHz where no diff was noted. Test-retest reliability: manual and automated testing yield lower thresholds when tested for the second time. |
| Wood *et al.* | 1973 | 20 subjects, 7-72 years old.<br><br>Hearing status of subjects included: 1 normal hearing | Diagnostic AC, BC testing with masking. Frequencies: .25, .5, 1, 2, 4, 8 kHz. Audiometer: Automated- Grason Stadler model 829E, manual- not | Method of limits. Functional generator controlled frequency of tonal signal. Rise and fall time: 30 sec, duration of the tone: 1500msec. ***Unmasked air and bone:*** Tones presented using | - Average deviations | - | A high positive relationship between manual and automated testing for air and bone testing was noted. Automated testing reduces examiner bias and causes direct standardization of testing. Additionally, the use of computerized program will |

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| | | subject, 14 sensorineural , 4 conductive and 1 mixed hearing loss subject/s. | indicated. | an initial bracketing of 10 dB, then a bracketing of 5dB.<br>***Masking:***<br>AC Masking- 40dB gap between AC of test ear and BC of non-test ear.<br>BC Masking- if AC of the test ear exceeded the midline BC by more than 10dB.<br>Minimal effective masking (Martin 1976) was used / if patient did not respond to minimal masking than platue masking was administered. | | | give the audiologist time for direct patient contact, counselling and aural rehabilitation. |
| Almqvist & Aursnen | 1978 | 82 subjects (41 ears), 7-82 years.<br><br>Hearing status not indicated. | Screening AC, Frequencies: .5, 1, 2, 3, 4, 6 Hz. Audiometer: Manual- not indicated, Automated- minicomputer, type PDP-8. | Method of limits. Computer program utilized principles based on manual audiometry. | -Standard deviation | - | Automated audiometry appeared to be a fast and a reliable method for screening audiometry.<br>A total standard deviation of 4.8 dB was noted between manual and automated audiometry, standard deviation varied across frequencies and was the smallest in the speech frequencies. |

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| Sakabe *et al.* | 1978 | ***2 groups used:*** 1) 31 subjects (62 ears), 19- 22 years old. Normal hearing subjects. 2) 124 subjects (248 ears).<br><br>Hearing status not indicated. | Diagnostic AC testing. Frequencies: .125, .25, .5, 1, 2, 4, 6, 8 kHz. | Method of limits. Automatically interrupted tone, on-off time: 2sec, rise- fall time: 25ms. Tone presented at 30dB, if not heard, raised to 60dB, if heard lowered again to 30dB and increased by 5dB till heard again. The tone is lowered to 30dB again and raised in 5dB steps till a response is elicited. Once a response is obtained a comparison between the 2 'thresholds' are made. The smaller value is the threshold obtained at that frequency. | - Error analysis | - | Automated audiometry has sufficient accuracy for practical use. Automated audiometry coincides with manual audiometry within 10 dB. Additionally it would take 5-15min to conduct. |
| Erlandsson *et al.* | 1979 | ***Accuracy :*** 115 subjects (230 ears), 25 to 63 years.<br><br>***Test-retest reliability:*** 10 subjects (20 ears). | Diagnostic AC. Frequencies: .25, .5, 1, 1.5, 2, 3, 4, 6, 8 kHz. Transducers: Manual- TDH-39M with MX-41/AR cushions. Automated- TDH-49P with MX- | Method of adjustment- Békésy sweep frequency. Attenuation rate: 2.5 dB/s, pulsed tone-presentation; sweep time from .25 -10 kHz was 400s. | - Regression equations and α and β coefficients. - | -standard deviations | Automated audiometry yields a lower and more reliable hearing threshold than manual audiometry. Manual audiometry SD are about twice as much for automated testing. Test-retest reliability of automated audiometry indicated that the standard |

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| | | All subjects were noise exposed shipyard workers. | 41/AR cushions. Audiometer: Manual- Madsen OB60, automated- Type Delmar 120. | | Estimated standard deviations | | deviations between the 5 successive tests had their lowest values for 1 kHz, increasing slowly towards lower and higher frequencies. |
| Erlandsson *et al.* | 1979 | ***Accuracy :*** 115 subjects (230 ears), 25 to 63 years.<br><br>***Test-retest reliability:*** 10 subjects (20 ears).<br><br>All subjects were noise exposed shipyard workers. | Diagnostic AC. Frequencies: .5, 1, 1.5, 2, 3, 4, 6, 8 kHz. Audiometer: Manual- Madsen OB60, automated- Type Delmar 120. | Method of adjustment- Békésy sweep frequency. Attenuation rate: 2.5 dB/s with a pulsed tone-presentation, sweep time from .25-1 kHz was 400s. | - Regression equation<br>- Estimated standard deviations | - Average thresholds and standard deviations | Automated audiometry yields a lower and more reliable hearing threshold than manual audiometry. Test-retest reliability of automated audiometry indicated that the standard deviations between the 5 successive tests had their lowest values for 1 kHz, increasing slowly towards lower and higher frequencies. |
| Harris | 1979 | 12 subjects (24 ears), 20 - 26 years old.<br><br>Hearing status not indicated. | Diagnostic AC. Frequencies: .5, 1, 2, 3, 4, 6, 8 kHz. Audiometer: Manual- Tracor Model RA-115, automated- Self-recording- Tracor Model | Method of adjustment- Békésy fixed frequency. Tone pulse rate: 2.5pulses/sec was used; tones were presented for 30sec at each frequency. Attenuation rate of 5dB/sec in 0.25dB | - Average threshold and standard deviation<br>- Average differences | - | Automated audiometry, utilizing the method of limits, indicated results that agree more with manual than automated audiometry utilizing the method of adjustment. At all frequencies, automated audiometry utilizing the method of |

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| | | | ARJ-4C, Microprocessor-Tracor Moder RA-40<br><br>** Two automated methods compared to manual testing. | steps.<br>Thresholds read as the mid-point of the excursions at each frequency.<br>Method of limits.<br>An 800msec tone presented at random intervals of 1,2, sec.<br>The Hughston-westlake method was utilized by the computer program. | | | adjustment showed lower thresholds than the other 2 tests.<br>Automated audiometry utilizing the method of limits showed higher thresholds for all frequencies except 4 KHz, over manual audiometry.<br>The two automated audiometry tests differed significantly at the 0.01 level in all frequencies.<br>Time differences between each test were less than a minute. |
| Frampton & Counter | 1989 | 42 subjects (84ears).<br><br>All subjects were noise exposed adults. | Diagnostic AC testing.<br>Frequencies: .5, 1, 2, 3, 4, 6, 8 kHz.<br>Audiometer: Manual-Grason Stadler GSI 10, automated-Grason sStadler 1703 B | Method of Adjustment -<br>Békésy sweep frequency.<br>7 frequency sweep with a pulsed tone mode. | - Average differences | - | Automated audiometry produced lower thresholds than manual testing.<br>Automated audiometry is reliable and sensitive in the 'real world' setting.<br>It allows large numbers of audiograms to be collected quickly by medical assistants with no training. |
| Lutman *et al.* | 1989 | 120 subjects (240 ears), 40 – 65 years old. | Diagnostic AC thresholds.<br>Frequencies: .5, 1, 2, 3, 4 kHz. | Method of adjustment-Békésy fixed frequency.<br>Stimulus tone pulsed | - Average thresholds and | - Average differences and | Automated audiometry produced better results than manual audiometry.<br>Overall automated |

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| | | Hearing status not indicated.<br><br>Longitudinal study, subjects retest 2-3 years later. | Transducers: Manual- TDH-39P with MX 41/AR cushions Automatic- TDH-49P with MX -41/AR cushions | at a rate: 2.5pulses/sec, with duration of 200ms (3dB down points). The tracking procedure : 2dB step occurring every 2 pulses. Tracking at each frequency lasted 40sec, 50 levels were visited for each frequency. | standard deviations - Ranges of thresholds - Average difference | standard deviations - Standard of variance | audiometry was 4.4 dB better than manual audiometry; the difference was lower at .5 kHz and increased as the frequency increased. Test-retest reliability- manual audiometry indicated a worsening of hearing at .5,1, 2 kHz and an improvement at 4 kHz. Automated audiometry produced correlation coefficients which were statistically significant, however it suggests the shift is due to random measurement error rather than actual shifts in the threshold. |
| Fausti *et al.* | 1990 | 20 subjects (40 ears), 18-25 years old.<br><br>Normal hearing adults. | Diagnostic AC testing. Frequencies: .25, 0.5, 1, 2, 4, 8 kHz. Audiometer: Manual- GS1701, Automated- V320 | Method of limits. V 320 Audiometer used, tones presented: 50% duty cycle, duration: 250 ms , rise-fall time: 25-50ms. Modified Hughson Westlake Ascending-descending audiometric test technique . | - Two-way analysis of variance with repeated measures on frequency and system s - Sheffé's | - Average absolute differences | No significant difference was noted between automated and manual testing over all test frequencies. Test-retest reliability: indicated no significant difference between the two tests conducted. |

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| | | | | | to determine statistical significance. | | |
| Picard *et al.* | 1993 | ***3 groups used:*** 1) 420 subjects (840 ears), 18-64 years old. Noise exposed workers. 2) 36 elderly subjects (72 ears), 65-80 years old. Hearing status not indicated. 3) 12 subjects (24 ears), 7.5- 12 years old. Normal hearing children. | Diagnostic AC and BC testing with masking. Frequencies: AC- .5, 1, 2, 3, 4, 6 kHz. BC- .5 ,1, 2, 4 kHz. Audiometer: Automated- MADSEN, Model OB 822, manual not indicated. | Method of limits- BOBCAT. Tone duration of 700ms, 2s time interval. The computer program made use of the ascending- descending method (ISO 6189). ***Masking:*** Hood technique of masking used. AC Masking- 40dB gap between AC of test ear and BC of non-test ear. BC Masking- AC of the test ear exceeded the midline BC by more than 10dB. | - Reliability coefficients using Hoyt's solution. - Average thresholds and standard deviation - Dispersion relationships | - | Manual and automated procedures produce similar results, regardless of subject age, degree of hearing loss or nature of hearing loss. Mean thresholds across the populations comparable between automated and manual testing. Automated testing with the child population did not reveal consistent results when compared to manual audiometry, especially at 2 and 6 kHz. Automated testing takes longer to determine thresholds than manual testing (automated- 42 sec, manual- 34 sec). It was noted as population changed to 'difficult to test' patients (children) manual testing started to take more time. It was also noted that examiner takes shortcuts to |

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| | | | | | | | obtain results but automated testing maintains rigid adherence to full procedure. |
| Fromby *et al.* | 1996 | ***Accuracy:*** 101 subjects (202 ears), mean age of 43 years. Noise exposed workers.<br><br>***Test-retest reliability:*** 20 subjects (39 ears), Mean age of 43 years. Noise exposed workers. | Diagnostic AC testing. Frequencies: .25. .5, 1, 2, 3, 4, 6, 8 kHz Transducer: Telephonics TDH-39. Audiometer: Manual-Madsen, model OB822, automated-digital-to-analog converter (DAC) (TDT, model Quikki QDA1). | Method of limits-Maximum likelihood method was used (ML). Threshold for each frequency was measured in 15-trial block to yield 60% correct detection. On a trial, a 200msec pure-tone signal presented in a visually cued 200msec observation interval. Signals: 10-msec rise-fall times as part of the nominal durations. Subjects had 1000 msec to make a "yes-only" response which attenuated the signal level. If the subject did not respond during the 1000-msec response period, the computer assumed a "no" response for the trial, and the signal level was increased | - Average threshold<br>- Standard error bars | - Average threshold<br>- Standard error bars | Automated testing and manual testing yielded similar results. Threshold differences between the two methods were not statistically significant at any test frequency except .25 kHz, automated threshold was higher, but was within 3 dB of the threshold obtained manually. Test- retest reliability for automated testing: no significant test-retest differences at any test frequency. Additionally, manual testing took less time than automated testing (manual-3 min 46 sec, auto-6 min 43 sec). |

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| | | | | according to the ML algorithm. | | | |
| Margolis *et al.* | 2007 | ***3 groups:*** 1) 120 subjects, 16-93 years old. Hearing status varied. 2) 8 subjects, 64- 85 years old. Varying degrees of hearing loss. 3) 6 subjects, 13- 86 years old. Varying degrees of hearing loss. | Diagnostic AC, BC and masking. Frequencies: not indicated. Transducers varied for different groups tested. ***Group 1 and 2:*** Manual- TDH-50, automated- prototype, non-occluding circumaural earphones ***Group 3:*** Manual- TDH-50 (not test ear occluded during BC testing), automated- insert earphones ER3A (both ears occluded during BC testing) | Method of limits- AMTAS. Tonal stimuli presented in a temporal observation interval that is visually marked for the listener, following the observation interval, the listener responds YES or NO by touching 'buttons' on a touchscreen monitor. The signal level is changed in an adaptive fashion to find the threshold of audibility. A threshold is obtained using a bracketing procedure. Masking noise presented to the non-test ear at levels that are selected to maximize the likelihood that neither under-masking nor over-masking will occur. | -Average absolute differences (QAave) - Regression coefficients - QUALIND - Correlation coefficients | - | The aim of this study was to develop a quality assessment method (QUALIND) based on a comparison of audiograms obtained utilizing automated (AMTAS) and manual testing. A predictive equation was derived from a multiple regression of a set of quantitative quality indicators on a measure of test accuracy, defined as the average absolute difference between automated and manually tested thresholds. For a large subject sample (n=120), a strong relationship was found between predicted and measured accuracy. The predictive equation was cross validated against two independent data sets. The results suggest that the predictions retain their accuracy for independent data sets if similar subjects |

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| | | | | | | | and methods are employed, and that new predictive equations may be required for significant variations in test methodology. The method may be useful for automated test procedures when skilled professionals are not available to provide quality assurance. |
| Ho *et al*. | 2009 | ***3 groups used:*** 1) 16 subjects (32 ears), 20- 80 years old. 2) 16 subjects (32 ears), 23-80 years old. 3)16 subjects (32 ears), 23-81 years old.<br><br>Hearing status of all 3 groups unknown. | Diagnostic AC and BC testing with masking. Frequencies: AC- .25, .5, 1, 2, 3, 4, 6, 8 kHz. BC- .5,1, 2, 4 kHz Transducer: EAR 5A. Audiometer: Manual- not indicated, Automated- Otogram. | Method of limits- Otogram. Assesses AC and BC thresholds, administers masking when appropriate. Uses touch-screen technology programmed according to the Hughson-Westlake algorithm. | - Average Differences and standard deviations. - Levels of agreement were analysed and expressed by weighted κ coefficients, using SPSS version 15 and StatXact version 8.0. | - Average Differences and standard deviations. - Levels of agreement were analysed and expressed by weighted κ coefficients, using SPSS version | AC and BC results when tested with automated and manual testing produced similar results. AC thresholds when tested using automated and manual testing indicated 94% of automated thresholds that fell within 10 dB of those obtained manually and indicated 10 paired thresholds that fell within 15 dB of manual testing. BC unmasked thresholds showed that 93% of automated thresholds fell within 10 dB of each other and 96% fell within 15 dB of each other. BC masked thresholds between the 2 tests showed |

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| | | | | | | 15 and StatXact version 8.0. | a lower level of agreement but still a good level of agreement.<br>Test-retest reliability indicated good intrarater agreement between the automated and manual testing conducted. |
| McPherson *et al.* | 2010 | 80 subjects (160 ears), 7-8 years old. | Screening AC tested.<br>Frequencies: .5, 1, 2, 3, 4 kHz.<br>Transducers: Manual- Circumaural ME-70 enclosures over TDH-39 supra-aural earphones. Automated- Circumaural headphone Ovann OV880V.<br>Audiometer: Manual- Madsen Micromate, automated- IBM ThinkPad laptop PC, model T22. | Methods of adjustment.<br>Békésy fixed frequency.<br>Continues tones of 1 sec were presented in left ear at .5 kHz at 40 dB, and were raised or lowered in 3dB steps depending on response. Thereafter 1-4 kHz tested. | -$X^2$-test<br>-Sensitivity or specificity analysis<br>- Individual test results for each ear was compared using kappa values of agreement<br>. | - | Automated screening procedure produced higher referral rate than manual screening (56% versus 13%). However, when .5 kHz was excluded from the data the referral rate between the two methods indicated no significant difference.<br>The reason for .5 kHz producing errors could be as a result of ambient environmental noise and that automated audiometry started at .5 kHz and subjects were unfamiliar to test procedures. |
| Margolis *et al.* | 2010 | ***Accuracy:*** 30 subjects (60 ears). | Diagnostic AC, BC and masking.<br>Frequencies: AC- | Method of limits- AMTAS (see Margolis *et al*, 2007). | - Average differences | - | The differences between automated and manual testing were compared to |

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| | | Hearing status:<br>5 normal hearing subjects, 25 hearing loss subjects.<br><br>***Test-retest reliability:***<br>18 subjects (36 ears).<br>Hearing status:<br>3 normal hearing subjects, 15 sensorineural hearing loss subjects. | .25, .5, 1, 2, 3, 4, 6, 8 kHz.<br>BC- .5, 1, 2, 4 kHz<br>Transducer: AC- Sennheiser HDA200<br>BC manual- Radioear B71(mastoid placement)<br>BC automated- B71 vibrator (forehead placement).<br>Audiometer: Manual and automated- Madsen Conera. | | -Average Absolute differences<br>- Confidence intervals | | differences obtained when the same subjects are tested manually by two audiologists.<br>AC thresholds obtained by manual and automated testing indicated similar differences that were obtained when the same patients were tested manually by two audiologists.<br>BC thresholds obtained with automated testing were lower than thresholds obtained with manual testing. The difference could be due to the placement of the bone conductor. |
| Swanepoel *et al.* | 2010 | ***2 groups used:***<br>1) 30 subjects (60 ears), 18- 31 years old. Normal hearing adults. | Diagnostic AC and masking.<br>Frequencies: .125, .25, .5, 1, 2, 4, 8 kHz.<br>Audiometer: Manual and automated- KUDUwave 5000. | Method of limits. Modified Hughson-Westlake method. Software presented a tone for 1.25s, subjects had to respond within 1.5 s before the next tone was presented. | - Absolute average differences and standard deviations<br>- Two sided | - Absolute average differences and standard deviations | Thresholds determined by manual and automated testing were within 5 dB of each other, indicating no significant difference between the two test procedures, in both the hearing and hearing loss group. |

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| | | 2) 8 subjects (16 ears), average age of 55 years old. Subjects had a sensorineural hearing loss ranging from mild to severe hearing loss. | | Threshold was accepted if there was a minimum of 3 responses. Software automatically determined if contralateral masking was necessary and applied when required in an adaptive manner. | paired *t*-test - Pearson correlation coefficients | - Two sided paired *t*-test - Pearson correlation coefficients | Test-retest reliability of automated testing indicated reliability equivalent to that of manual testing. Additionally, both manual and automated testing took more or less the same time to administer (manual- 7.2-7.7 min, automated- 7.2-7.4 min). |
| Ishak *et al.* | 2011 | ***Accuracy:*** 13 subjects (13 ears), a8-60 years old. Normal hearing adults. ***Test-retest reliability:*** 21 subjects (21 ears), 18-60 years old. Normal hearing adults. | Diagnostic AC testing. Frequencies: .25, .5, .75, 1, 1.5, 2, 3, 4, 6, 8 kHz. Audiometer: Manual and automated- Essilor Audioscan system. ** Test-retest reliability was determined by testing subjects 4 times with each test producer. | Method of adjustment-Békésy sweep frequency and Audioscan. ***Békésy:*** Sweep rate: 15 s per octave, pulse rate: 2.5 pulses/s, attention rate: 2.5dB/s was used. Hearing thresholds determined by calculating averaged values of three consecutive audiometric data obtained around each octave or half-octave frequencies. | - Repeated measures ANOVA - Contrasts analysis to compare mean thresholds. | - Thresholds from each test session were subtracted - Variance of hearing threshold ($\sigma^2$) | The results showed that the thresholds obtained with Békésy testing were significantly better than those obtained from the manual testing at most frequencies. Audioscan produces better thresholds than Békésy, showing no significant differences in hearing thresholds at frequencies from .5 kHz- 4 kHz. Hearing thresholds obtained from Audioscan were significantly poorer than manual testing at frequencies of .25, 6 and 8 kHz. This was probably due |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | These values were rounded to the nearest 5dB for the analysis.<br>***Audioscan:***<br>Sweep rate: 15sec/octave, tones swept 1- 8 kHz, back to 1 kHz and swept again from 1 kHz to .25 Hz.<br>A straight line was produced when the subjects pressed the response button. The level was then increased by 5dB at frequencies to which the subjects did not respond. | | | to the threshold seeking procedure, which does not allow the intensity level to go either higher or lower than the current screening intensity level.<br>High test-retest reliability for manual and audioscan testing, however, Békésy testing indicated poor test-retest reliability. |
| Margolis *et al.* | 2011 | ***2 groups:***<br>1) 68 subjects (136 ears),<br>4- 8 years old (1 group of 4-5 year olds and another group of 6-8 year olds).<br>Normal hearing | Diagnostic AC testing.<br>Frequencies: .5, 1, 2, 4, 8 kHz.<br>Transducers:<br>Automated- HDA 200<br>Manual- TDH-50.<br>Audiometer: Manual and automated (children)- Benson CCA-100 | Method of limits- AMTAS was used for the adult group (see Margolis *et al*, 2007). KIDTAS was used for the child population. It differed from AMTAS, used a smiley and sad face and a visual reinforcement picture for a correct response. Additionally, QUALIND was used. QUALIND is | - Average absolute average difference and standard deviation | - | The differences obtained between automated testing (AMTAS/KIDTAS) and manual testing produces thresholds with variability that is comparable to thresholds obtained using manual testing by two audiologists, only if QUALIND identifies and excludes 'poor' audiograms. No significant differences between manual and |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | children.<br>2) 15 subjects , Adults.<br>Hearing status:<br>11 normal hearing, 1 unilateral hearing loss, 3 mild-to-moderate bilateral hearing loss subjects. | Mini.<br>Manua (adults)l-Grason Stadler, automated-Benson CCA.<br><br>**Different transducers were only used in the adult population. | a method for estimating accuracy by tracking variables that are known to predict agreement between automated and manual thresholds, and calculating the predicted average absolute difference with a formula derived from a regression analysis of the relationship between the quality indicators and the measured average absolute differences. The strength of the regression coefficient indicates the degree to which accuracy can be predicted by QUALIND. | | | automated thresholds were noted when using different earphones in the adult subjects. |
| Margolis & Moore | 2011 | 13 subjects (19 ears), 21-65 years old.<br><br>All subjects had a sensorineural | Diagnostic AC, BC and masking.<br>Frequencies: .25, .5, 1, 2, 4, 8 kHz.<br>Audiometer:<br>Manual- Grason Stadler | Method of limits-AMTAS (see Margolis *et al*, 2007). | - Average thresholds<br>-Average differences<br>-Average absolute | - | Automated testing produced thresholds similar to those obtained by manual testing results. Automated thresholds were higher than those obtained manual by 7 dB at .25, .5, 1, 2 kHz, with |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | hearing loss. | GSI 61, Automated-Madsen Aurical. | | differences -Analysis of variance (ANOVA) | | smaller differences at higher frequencies. According to Margolis et al (2010) results between manual and automated testing should be similar, thus it was concluded by this study that the difference noted between the two test results was due to the use of different earphones. |

**Supplemental Digital Content 3**. Table, Statistical measures of accuracy and test-retest reliability employed in systematic review reports (n=29)

| Type of analysis | Number of studies |
|---|---|
| ***Accuracy (threshold comparison with manual audiometry)*** | |
| Average differences and standard deviation | 11 |
| Average thresholds and standard deviation | 11 |
| Absolute average differences and standard deviation | 6 |
| t-Test | 4 |
| Linear regression and correlation coefficients | 4 |
| Pearsons product | 3 |
| Standard deviations only | 3 |
| ANOVA analysis | 2 |
| Average deviation | 1 |
| Error analysis | 1 |
| Contrast analysis | 1 |
| $X^2$ Test | 1 |
| Sensitivity and specificity analysis | 1 |
| Comparison of Kappa values of agreement | 1 |
| Standard error bars | 1 |
| Test of significance | 1 |
| Within subject variability test | 1 |
| F-ratio | 1 |
| Two way analysis of variance | 1 |
| Reliability coefficients- Hoyts solution | 1 |
| Sheffe's test of statistical significance | 1 |
| Dispersion relationships | 1 |
| K-coefficients | 1 |
| Confidence intervals | 1 |
| Estimation of asymptomatic data | 1 |
| ***Test-retest reliability*** | |
| Average differences and standard deviation | 4 |
| Average thresholds and standard deviation | 3 |
| Absolute average differences and standard deviation | 2 |
| t-test | 2 |
| Pearson Product moment correlation coefficients | 2 |
| Standard deviation | 1 |
| Standard of variance | 1 |
| Standard error bars | 1 |
| k-coefficients | 1 |
| Repeated ANOVA | 1 |
| Variance of hearing threshold ($\sigma^2$) | 1 |

**Supplementary Digital Content 4.** Table (Summary of data included in meta-analysis, test-retest reliability)

| | Author | Year | Number of ears | Statistical analysis | Frequencies (Hz) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 125 | 250 | 500 | 1000 | 2000 | 3000 | 4000 | 6000 | 8000 | All |
| MANUAL TESTING | **AVEARAGE DIFFERENCES** | | | | | | | | | | | | | |
| | Burns & Hichcliffe. | 1957 | 40 | Average differences | - | - | 1.0 | 2.2 | 1.5 | 2.0 | 1.4 | -1.7 | - | 1.0 |
| | | | | Standard deviation | - | - | 4.9 | 4.2 | 4.7 | 4.7 | 4.7 | 7.6 | - | 5.1 |
| | Lutman et al. | 1989 | 460 | Average differences | - | - | 2.4 | 2.1 | 1.4 | - | -0.5 | - | - | 1.3 |
| | | | | Standard deviation | - | - | 6.9 | 4.8 | 5 | - | 7.1 | - | - | 6.1 |
| | Ho et al. | 2009 | 32 | Average differences | - | - | - | - | - | - | - | - | - | 1.8 |
| | | | | Standard deviation | - | - | - | - | - | - | - | - | - | 6.6 |
| | **ABSOLUET AVERAGE DIFFERENCES** | | | | | | | | | | | | | |
| | Fausti et al. | 1990 | 20 | Absolute Average difference | - | 2.3 | 2 | 1.8 | 1.8 | - | 2.3 | - | 2.3 | 2.1 |
| | Swanepoel et al. | 2010 | 60 | Absolute Average difference | 4.8 | 3.8 | 3.3 | 3.7 | 3.0 | - | 3.0 | - | 3.3 | 3.6 |
| | | | | Standard deviations | 5 | 3.7 | 3.7 | 3.4 | 3.6 | - | 3.5 | - | 4.3 | 3.9 |
| AUTOMATED TESTING | **AVERAGE DIFFERENCES** | | | | | | | | | | | | | |
| | Burns & Hichcliffe. | 1957 | 40 | Average differences | - | - | 1.0 | 2.0 | 1.0 | 2.1 | 1.2 | 1.7 | - | 1.5 |
| | | | | Standard deviation | - | - | 6.4 | 5.2 | 3.8 | 6.2 | 6.4 | 10.4 | - | 6.4 |
| | Lutman et al. | 1989 | 460 | Average differences | - | - | 0.2 | -1.3 | -0.1 | - | 0.6 | - | - | 0.1 |
| | | | | Standard deviation | - | - | 7.2 | 6.9 | 6.6 | - | 7.2 | - | - | 7.0 |
| | Ho et al. | 2009 | 32 | Average differences | - | - | - | - | - | - | - | - | - | 0.3 |
| | | | | Standard deviation | - | - | - | - | - | - | - | - | - | 5.9 |
| | **ABSOLUTE AVERAGE DIFFERENCES** | | | | | | | | | | | | | |
| | Fausti et al. | 1990 | 20 | Absolute Average difference | - | 2.3 | 1.8 | 1.8 | 1.8 | - | 2.0 | - | 1.5 | 1.9 |
| | Swanepoel et al. | 2010 | 60 | Absolute Average difference | 4.9 | 3.8 | 3.2 | 2.8 | 2.8 | - | 2.4 | - | 2.2 | 3.2 |
| | | | | Standard deviations | 4.8 | 3.5 | 3.6 | 3.2 | 4.1 | - | 3.0 | - | 3.2 | 3.8 |

**Supplementary Digital Content 5**. Table (Summary of reports included in the meta-analysis, accuracy)

| | Author | Year | Number of ears | Statistical analysis | Frequencies | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 125 | 250 | 500 | 1000 | 2000 | 3000 | 4000 | 6000 | 8000 | All |
| | **AVERAGE DIFFERENCES** | | | | | | | | | | | | | |
| | Burns & Hichcliffe | 1957 | 40 | Average differences | - | - | -1.1 | 3.2 | 1.3 | 1.6 | 1.2 | -0.5 | - | 1.0 |
| | | | | Standard deviation | - | - | 5.5 | 5.1 | 4.7 | 6.0 | 7.1 | 9.2 | - | 6.3 |
| | Knight J.J. | 1965 | 66 | Average differences | - | - | -0.3 | 1.0 | 1.5 | 1.1 | 1.3 | -0.1 | - | 0.8 |
| | | | | Standard deviation | - | - | 4.2 | 4.9 | 4.9 | 4.9 | 3.8 | 5.3 | - | 4.7 |
| | Delany et al. | 1966 | 66 | Average differences | - | - | 1.2 | -0.8 | -0.9 | -1.4 | -1.5 | -3.3 | - | -1.1 |
| **METHOD OF ADJUSTMENTS** | Jokinen K | 1969 | 30 | Average differences | 5.1 | 2.1 | -0.6 | -0.6 | 2.3 | 4.9 | -2.5 | -0.6 | -2.7 | 0.8 |
| | | | | Standard deviation | 7.0 | 6.0 | 5.0 | 5.6 | 7.0 | 4.4 | 5.4 | 6.6 | 6.4 | 5.9 |
| | | | 30 | Average differences | -1.7 | -3.1 | -3.3 | -2.8 | -0.6 | 4.1 | -4.4 | -4.5 | -5.5 | -2.4 |
| | | | | Standard deviation | 8.1 | 6.1 | 4.2 | 4.9 | 5.2 | 5.6 | 5.3 | 6.4 | 7.9 | 6.0 |
| | | | 17 | Average differences | -8.4 | -7.7 | -5.4 | -7.8 | -4.4 | 2.6 | -10 | -5.6 | -3.9 | -5.6 |
| | | | | Standard deviation | 6.3 | 6.4 | 6.4 | 3.8 | 6.2 | 7.4 | 5.6 | 6.7 | 6.4 | 6.1 |
| | | | 39 | Average differences | -5.2 | -7.0 | -5.6 | -6.4 | -4.1 | -1.0 | -12.6 | -8.1 | -12.3 | -6.9 |
| | | | | Standard deviation | 9.9 | 9.5 | 6.7 | 7.0 | 7.6 | 7.4 | 7.0 | 9.0 | 11.5 | 8.4 |
| | | | 30 | Average differences | 4.3 | 0.3 | -2.0 | -0.4 | 1.2 | 5.6 | -2.0 | -0.7 | -3.6 | 0.3 |
| | | | | Standard deviation | 7.7 | 7.2 | 5.5 | 5.7 | 6.8 | 5.2 | 7.0 | 8.1 | 8.5 | 6.9 |
| | | | 30 | Average differences | -4.0 | -5.7 | -4.1 | -2.8 | -1.5 | 3.2 | -5.1 | -6.1 | -4.8 | -3.4 |
| | | | | Standard deviation | 8.9 | 6.1 | 4.0 | 5.2 | 5.1 | 6.8 | 5.9 | 7.4 | 8.2 | 6.4 |
| | | | 17 | Average differences | -6.4 | -6.0 | -2.1 | -3.0 | 0.9 | 8.5 | -3.6 | 1.9 | 2.0 | -0.9 |
| | | | | Standard deviation | 6.7 | 6.7 | 8.4 | 5.0 | 7.3 | 6.8 | 4.8 | 7.2 | 6.1 | 6.6 |
| | | | 39 | Average differences | -3.1 | -4.7 | -0.2 | -1.7 | -0.5 | -4.2 | -4.9 | -2.8 | -10.0 | -3.6 |
| | | | | Standard deviation | 11.4 | 10.0 | 7.9 | 7.7 | 6.6 | 8.1 | 8.2 | 10.1 | 14.6 | 9.4 |
| | Robinson & Whittle | 1973 | 128 | Average differences | - | 0.4 | 2.9 | 1.5 | 2.8 | - | 2.7 | 4.2 | 2.1 | 2.4 |
| | | | | Standard deviation | - | 5.9 | 4.4 | 4.1 | 4.3 | - | 5.3 | 8.2 | 8.5 | 5.8 |
| | Harris | 1979 | 24 | Average differences | - | - | -2.1 | -4.0 | -5.6 | -4.0 | -9.0 | -1.0 | -2.9 | -4.1 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Lutman et al. | 1989 | 240 | Average differences | - | - | 3.0 | 2.8 | 6.4 | - | 5.3 | - | - | 4.4 |
| | | | | Standard deviation | - | - | 5.8 | 5.6 | 5.2 | - | 6.1 | - | - | 5.8 |
| METHOD OF LIMITS | **AVERAGE DIFFERENCES** | | | | | | | | | | | | | |
| | Harris | 1979 | 24 | Average differences | | | -3.5 | -2.3 | -1.3 | -2.9 | 3.8 | -4.4 | -0.2 | -1.5 |
| | | | | Standard deviation | - | - | 6.4 | 5.2 | 3.8 | 6.2 | 6.4 | 10.4 | - | 6.4 |
| | Ho et al. | 2009 | 32 | Average differences | - | - | - | - | - | - | - | - | - | 0.76 |
| | | | | Standard deviation | - | - | - | - | - | - | - | - | - | 5.7 |
| | Margolis et al. | 2010 | 60 | Average differences | - | -0.4 | 0.4 | 1.5 | 1.4 | - | 0.1 | - | -2.3 | 0.1 |
| | | | | Standard deviation | - | 5.1 | 4.4 | 5.3 | 5.8 | - | 4.9 | - | 7.0 | 5.4 |
| | **ABSOLUTE AVERAGE DIFFERENCES** | | | | | | | | | | | | | |
| | Sparks | 1972 | 15 | Absolute Average differences | - | - | - | - | - | - | - | - | - | 4.5 |
| | | | 60 | Absolute Average differences | 4.8 | 3.8 | 3.8 | 3.7 | 3.2 | - | 2.9 | - | 2.8 | 3.6 |
| | | | | Standard deviation | 4.1 | 3.4 | 4.5 | 3.7 | 3.3 | - | 3.5 | - | 4.5 | 3.9 |
| | Swanepoel et al. | 2010 | 60 | Absolute Average differences | 4.2 | 3.8 | 3.6 | 3.8 | 3.3 | - | 2.2 | - | 2.3 | 3.3 |
| | | | | Standard deviation | 4.2 | 3.5 | 4.5 | 3.1 | 4.0 | - | 3.0 | - | 3.6 | 3.8 |
| | | | 16 | Absolute Average differences | 2.3 | 3.3 | 2.2 | 2.2 | 2.2 | - | 2.8 | - | 1.4 | 2.4 |
| | | | | Standard deviation | 3.2 | 2.4 | 2.6 | 2.6 | 2.6 | - | 3.1 | - | 3.1 | 2.8 |
| | Margolis et al. | 2010 | 60 | Absolute Average differences | - | 3.2 | 3.0 | 3.3 | 4.0 | - | 3.7 | - | 4.5 | 3.6 |
| | | | | Standard deviation | - | 4.0 | 3.2 | 4.4 | 4.4 | - | 3.2 | - | 5.8 | 4.2 |
| | Margolis et al. | 2011 | 15 | Absolute Average differences | - | - | - | - | - | - | - | - | - | 3.9 |
| | | | | Standard deviation | - | - | - | - | - | - | - | - | - | 1.7 |

AJA

Research Article

# Validation of a Bilateral Simultaneous Computer-Based Tympanometer

Hlologelo Ramatsoma[a] and Dirk Koekemoer[a]

**Purpose:** This study aimed to investigate the accuracy of bilateral simultaneous tympanometric measurements using a tympanometer with two pneumatic systems inside circumaural ear cups.
**Method:** Fifty-two adults (104 ears), with a mean age of 32 years (*SD* = 12.39, range: 18–60 years) were included in this study. A within-subject repeated-measures design was used to compare tympanometric measurements yielded with the investigational device in unilateral and bilateral simultaneous conditions compared with an industry-standard tympanometer.
**Results:** No significant bias ($p > .05$) was found between the mean of the differences of tympanometric measurements yielded by the two devices, except for a significant bias ($p < .05$) of the mean of the differences for ear canal volume measurements (0.05 $cm^3$). The Bland–Altman plots showed overall good agreement between the tympanometric measurements between the two instruments. In all 104 ears, the tympanogram types of the KUDUwave TMP were compared with the reference device. The results were highly comparable with a sensitivity and specificity of 100% (95% CI [86.8%, 100%]) and 92.3% (95% CI [84.0%, 97.1%]), respectively.
**Conclusions:** The investigational device is a suitable instrument for unilateral or bilateral simultaneous tympanometric measurements in adults and demonstrates the potential of decentralized and accessible tympanometry services.

The collection of case history to identify middle ear disorders is often difficult and of little value (Burke, 1989). Otoscopy is often used in conjunction with case history collection and pure-tone audiometry in order to increase the accuracy of diagnosing middle ear disorders. However, otoscopic examination relies heavily on the knowledge and expertise of the clinician (Bluestone & Cantekin, 1979; Karma et al., 1988). In addition, pure-tone audiometry alone has a low accuracy in identifying middle ear disorders (Wegner et al., 2013; Yockel, 2002). As a result, certain pathologies, such as otitis media, are often not diagnosed or misdiagnosed and consequently not treated appropriately, which may potentially lead to serious complications (Asher et al., 2005; Buchanan & Pothier, 2008; Legros et al., 2008). The incidence of middle ear pathologies in the developing world such as sub-Saharan Africa and South Asia are up to eightfold higher than in developed regions of the world (Acuin, 2004; Monasta et al., 2012). Access to equipment for the diagnosis of middle ear disorders is significantly limited in developing countries (Fagan & Jacobs, 2009). Thus, the development of equipment to facilitate the diagnosis of middle ear pathologies in underserved regions is of immense need.

The development of objective test procedures to aid hearing health care professionals to reliably diagnose auditory disorders dates back to as early as the 1920s. Tympanometry is an objective measure that was introduced in the early 1970s as a clinical procedure to assess middle ear status (Katz et al., 2015). Since then, there has been extensive research confirming the validity and reliability of tympanometry as a method to identify and differentiate middle ear disorders (De Melker, 1992; van Balen & De Melker, 1994). Various studies have shown that, when tympanometry is performed with a 226-Hz probe tone, the resulting sensitivity and specificity range from 80% to 100% and from 70% to 100%, respectively (Anwar et al., 2016; De Melker, 1992; Harris et al., 2005; Ozturk et al., 2011). Therefore, tympanometry is accepted as being a sensitive and specific indicator of the middle ear status, which is often not evident through visual examination (Bluestone & Cantekin, 1979; Paradise et al., 1976; Toner & Mains, 1990; van Balen & De Melker, 1994). Consequently, tympanometric assessment of middle ear function has formed a routine part of the audiological test battery for individuals of all ages in developed countries such as the United States (Martin

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et al., 1994). The objective nature of tympanometry allows for minimal user training, ease of use, and interpretation of test results (Abbott et al., 2014).

Nevertheless, a major concern, especially in developing countries, is the lack of affordable diagnostic equipment, such as tympanometers, in primary health care clinics and remote environments (Fagan & Jacobs, 2009; Naidoo, 2006). Naidoo (2006) investigated audiological practices and service delivery among 148 hearing health care professionals across South Africa. The use of tympanometry among the respondents was low, with 37.5% and 16.22% of the respondents from the public and private sectors, respectively, indicating that they never perform tympanometry. Over 80% of the respondents who did not conduct tympanometry indicated the lack of equipment as a primary reason. This is not surprising given that tympanometers are relatively expensive; that is, more than 15 years ago, the price of desktop and handheld tympanometers ranged from $2,000 to $3,500 (USD; Onusko, 2004).

The lack of tympanometers in audiological clinics is concerning as the use of tympanometry will improve diagnostic accuracy, follow-up, and treatment of middle ear pathologies. Referrals can then be optimized, thus decreasing the overall burden on the health care system. A strong case can be motivated for tympanometry as an integral piece of equipment that should be part of every ear and hearing clinic. It is therefore desirable that affordable, contextual, and clinically accurate medical equipment is developed to address auditory-related conditions, such as middle ear pathologies, as these are important contributors to health and economic development.

Developing countries are challenged by limited resources in the hearing health care sector, such as scarcity of specialist clinicians and appropriate audiological infrastructure such as sound-treated booths. Many advances have been made to increase accessibility of hearing health care through boothless audiometry, tele-audiology, and automated diagnostic audiometry (Swanepoel et al., 2010, 2015). An automated computer-based audiometer (KUDUwave, eMoyo) with increased passive attenuation and the potential to be incorporated into tele-audiology practices has been validated to provide access to diagnostic audiometry in underserved environments with a shortage of audiologists and audiological equipment such as sound booths (Swanepoel et al., 2015). The investigational device, the KUDUwave TMP (eMoyo), is the most recent configuration of this computer-based audiometer, which integrates immittance audiometry. In this study, the novel tympanometer, the KUDUwave TMP, was used to validate bilateral computer-based tympanometry. The investigational device serves as an example of a more cost-effective and accessible piece of equipment that can facilitate the diagnosis of middle ear pathologies, thus offering comprehensive audiological services in the more resource-stricken areas.

Among its characteristics, the KUDUwave TMP is integrated with validated boothless automated diagnostic audiometry (Swanepoel et al., 2015), making it well suited for use in tertiary institutions and hospitals, as well as in underserved and remote areas where audiological resources are typically unavailable. Furthermore, mobile screening, tele-audiology, and primary health care clinics can be set up to reach those without access to centralized audiological care. The KUDUwave TMP bilateral simultaneous tympanometry feature allows for ease of middle ear evaluation, especially in difficult-to-test patients by assessing both ears simultaneously. One common anecdote is that difficult-to-test-patients, such as children, may not allow the clinician to obtain tympanometric measurements in the second ear as they have experienced the unfamiliar pressure with the first ear being tested. This type of technology opens up the possibility of assessing both ears at the same time, thus potentially saving clinical time. Unlike conventional tympanometers, the setup of the KUDUwave TMP on the test subject ensures that an airtight seal is achieved and maintained (using the circumaural ear cups to keep the probe in place), ensuring accurate measurements (Keefe et al., 2000) as a result of effective probe sealing. One of the major benefits of this device is that it has two tympanometers; this does not only allow for bilateral simultaneous tympanometry but also ensures that a hearing care clinic still continues to operate should one tympanometer stop functioning. This will benefit remote areas that may not be in proximity to the device's manufacturer.

To date, only one study has been conducted on the feasibility and effectiveness of tympanometry using the KUDUwave TMP. Chouhan and Petersen (2018) found a very strong agreement between consecutive measures made with the KUDUwave TMP and a perfectly positive agreement between the KUDUwave TMP and the industry standard, reference tympanometer, with regard to the identification of tympanogram type. However, Chouhan and Petersen's subjects only consisted of individuals with normal middle ear status and auditory functions. In addition, no validation of the investigational device's bilateral simultaneous tympanometry was reported. Therefore, the aim of this study was to determine the reliability and validity of the KUDUwave TMP's unilateral and bilateral simultaneous tympanometry by comparing it with a conventional industry-standard tympanometer.

## Method

Ethical approval for the study was granted by the Biomedical Research Ethics Committee of the University of Kwazulu-Natal. This study employed a within-subject repeated-measures design. In all cases, subjects provided informed consent prior to participation.

### *Participants*

A sample of 52 participants (104 ears), with a mean age of 32 years ($SD$ = 12.39, range: 18–60 years), was used in this study. The inclusion criteria were based on an otoscopic examination of the ear canal showing the following characteristics: the absence of impacted cerumen, absence of otorrhea, and absence of structural abnormalities such

as atresia. If necessary, the ear was cleaned of excessive cerumen by the clinical audiologist prior to participation. The participants of this study consisted of outpatients receiving audiological care at Dr. George Mukhari Academic Hospital, North of Pretoria, South Africa.

### *Equipment*

A GSI TympStar Version 1 Middle Ear Analyzer (Grason-Stadler) was used as the industry-standard tympanometer and as a reference device for this study. The KUDUwave TMP (eMoyo) used in this study, as the investigational device, was a portable, computer-controlled, Type 3 aural acoustic immittance instrument (International Electrical Commission 60645-5, 2004) and was operated by a laptop (HP Pavilion PC, Windows 10, Hewlett-Packard Inc.). The investigational device was powered by the USB ports of the laptop while test measurements were displayed on the screen. Bilateral simultaneous tympanometry testing was made possible with the KUDUwave TMP's circumaural ear cups that housed two pneumatic pumps (one in each cup; see Figure 1). The circumaural ear cups were placed over the subjects' ears and probe tips during testing, as shown in Figure 2.

The test parameters of both devices were set to the same values to avoid any parameter effects on the test results (Margolis & Heller, 1987). Both instruments used a probe tone of 226 Hz, with a pump speed set at 200 daPa/s. Additionally, the pressure range was from positive +200 daPa to negative −400 daPa. Tympanometry was conducted using single-use ear tips, specifically the KR and MF series (Grason & Associates, LLC), for the KUDUwave TMP and the GSI Tympstar Version 1 Middle Ear Analyzer. Both devices were set to detect a seal automatically, and the tester was then responsible for starting the test as soon as the probe tip was inserted into the ear canal and formed an airtight seal. The two tympanometers indicated when there was a blockage (e.g., probe pressed against the ear canal wall) or air leakage to prevent false test results.

**Figure 1.** The KUDUwave TMP and probe ear tips.

Prior to data collection, the tympanometers were calibrated in accordance with International Electrical Commission 60645-5 (2004). The calibration of the equipment was checked daily with the probe tips of each tympanometer inserted into the calibration cavities supplied by the corresponding manufacturers. The volumes of the calibration cavities were 0.5, 2.0, and 5.0 $cm^3$. In accordance with suggested good practice (British Society of Audiology, 2013), a subject with ears known to produce normal tympanograms was tested daily prior to data collection in order to verify the performance of each device.

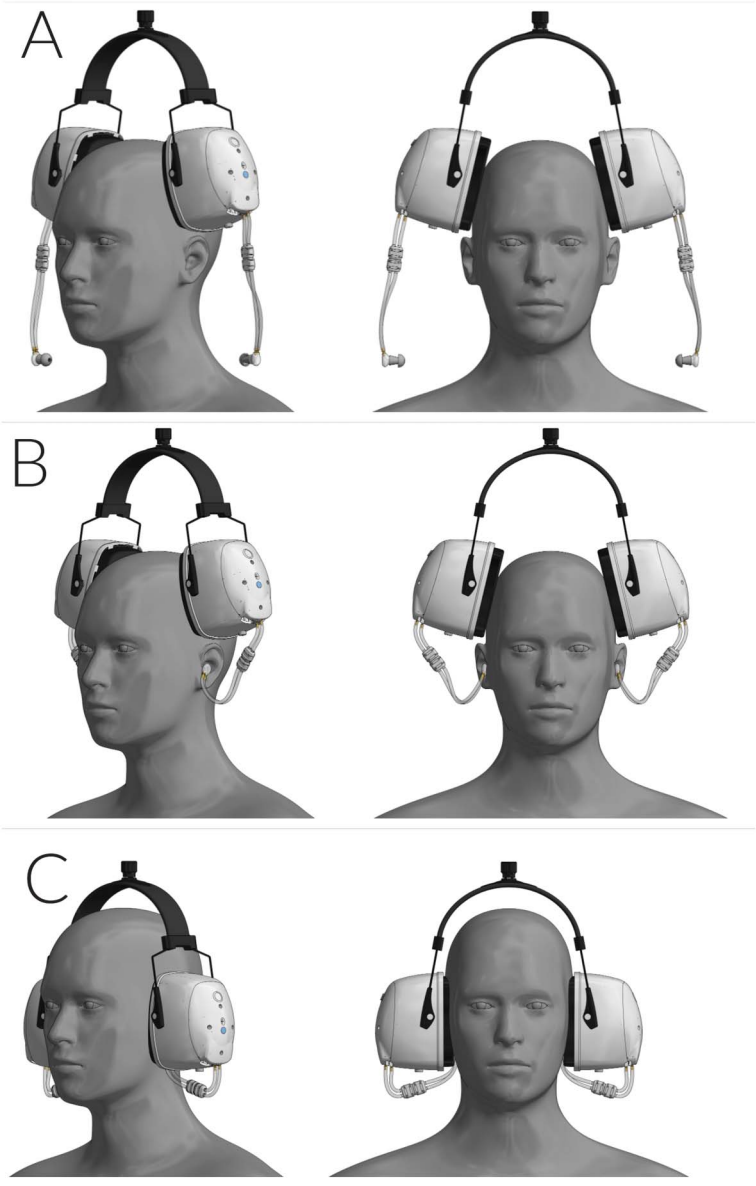
### *Measurements*

All subjects were tested on the reference device and on the investigational device. Throughout the study, the investigational device was operated by the principal researcher, a qualified audiologist, and the reference device was operated by two public hospital clinical audiologists. The ear tips of the two devices were inserted in the subject's ear canals by the audiologists. In all cases, the clinicians selected the appropriate ear tip size, as per their clinical expertise, to ensure that an adequate seal was maintained and that the testing was comfortable for the test subject. The order of testing (unilateral vs. bilateral simultaneous tympanometry using the KUDUwave TMP and tympanometry [unilateral] using the GSI TympStar Version 1 Middle Ear Analyzer) was counterbalanced, and all of the testing on individual patients was conducted on the same day.

The clinicians used different test rooms to ensure that they were blinded to the tympanometry test results of the previous tests of each participant. The uniform verbal instructions provided to all the subjects were the following: (a) to refrain from talking, swallowing, or yawning once the probe tip was inserted in the ear; (b) to sit still during the testing; and (c) not to modify the insertion of the probe once inserted. Measures of equivalent ear canal volume (ECV), tympanometric peak pressure (TPP), and peak compensated static acoustic admittance (static admittance [SA]) were obtained and recorded for all subjects. The same units were used for all the measurements on both tympanometers, where SA was measured in terms of acoustic ($cm^3$), ECV ($cm^3$), and TPP (daPa).

All subjects participated in five tympanometric test sessions in a randomized order, following otoscopic examination. Subjects had a 5-min break after every session to avoid an increase in tympanic membrane compliance as a result of tympanic membrane preconditioning (Gaihede, 1996). Each of the five sessions had a specific aim: Session 1 was used to obtain unilateral tympanometry test results for both ears using the reference device, Session 2 was used to obtain unilateral tympanometry test results for both ears using the investigational device, Session 3 was used to determine test–retest reliability of unilateral tympanometry test results of the investigational device, Session 4 was used

**Figure 2.** The KUDUwave TMP bilateral simultaneous tympanometry testing setup. (A) The circumaural ear cups are initially placed over the subject's ears. (B) The probe tip with ear tips are inserted into the subject's ear canals. (C) The KUDUwave TMP ear cups are finally placed over the subject's ears and the probe tips.




to obtain bilateral simultaneous tympanometry test results using the investigational device, and Session 5 was used to determine test–retest reliability of bilateral simultaneous tympanometry test results of the investigational device.

### *Analysis*

Raw data were first captured on Google Sheets (Google LLC). MedCalc Version 19.1 software tool (MedCalc Software) was used to statistically analyze the data. Descriptive statistics, including percentages and frequency calculations, were used to describe the sample's characteristics.

The statistical method described by Bland and Altman (1986) was performed to determine whether ear measurements (ECV, SA, and TPP) obtained with the investigational device in consecutive measures (repeatability) and the results obtained in unilateral and bilateral simultaneous conditions were in agreement. In addition, the Bland–Altman limits of agreement analysis was performed to determine whether ear measurements of the reference device compared to the investigational device were in agreement. A one-sample *t* test was used to determine whether the mean of the differences of the ear measurements, in consecutive measurements for the investigational device and between the two devices, did not deviate significantly from 0 ($p > .05$).

The sensitivity and specificity of the KUDUwave TMP were determined using the GSI TympStar tympanometer as the reference instrument. This was achieved by comparing the tympanogram types identified by the investigational device to those of the reference device. Tympanometry results were classified as per the Jerger's classification of tympanograms (Jerger, 1970) using the Margolis and Heller normative data (Margolis & Heller, 1987). The tympanogram classifications were categorized as follows: Type A (including Types As and Ad), Type B, and Type C. Kappa statistics were used to determine the agreement between the tympanogram types yielded by the investigational and reference device.

## Results

The study consisted of 52 adults (104 ears) between the ages of 18 and 60 years. The sample, as detailed in Table 1, included 38% men and 62% women, with a mean age of 32 years (*SD* = 12.39). More than 55% of the participants were between the ages of 18 and 29 years. In all subjects, otoscopic examination was conducted, and ear measurements were taken using the investigational and reference device. Probe sealing was achieved with both devices, resulting in the statistical analysis comprising 104 ears.

### *Test–Retest Reliability of the KUDUwave TMP*

Fifty-two participants were tested 4 times with the KUDUwave TMP: twice unilaterally (one ear at a time) and twice in a bilateral simultaneous condition (both ears at the same time). Ear measurements from both ears were included in the analysis, resulting in data from 104 ears for each ear measurement (ECV, SA, and TPP).

Table 2 reports the repeatability of measurements with the investigational device in its unilateral mode. The mean of the differences between repeated measures of ECV (0.00 $cm^3$), SA (−0.02 $cm^3$), and TPP (−1.46 daPa) was found to have not deviated significantly from 0 ($p \geq .98$, $p \geq .05$, and $p \geq .21$). Similarly, Table 3 shows repeated measures with the KUDUwave TMP in bilateral simultaneous mode. The mean of the differences for ECV (0.00 $cm^3$), SA (−0.01 $cm^3$), and TPP (0.56 daPa) did not deviate significantly from 0 ($p \geq .21$, $p \geq .28$, and $p \geq .39$).

**Table 1.** Summary of subject demographics.

| Factors | Variables | % | *N* = 52 |
|---|---|---|---|
| Gender | Males | 38 | 20 |
| | Females | 62 | 32 |
| Age (years) | 18–29 | 56 | 29 |
| | 30–39 | 19 | 10 |
| | 40–49 | 12 | 6 |
| | 50–60 | 13 | 7 |

*Note.* Age range: 18–60 years old, with a mean age of 32 years old and an *SD* of 12.39.

**Table 2.** Precision of unilateral tympanometry results of the KUDUwave TMP.

| Variable | ECV ($cm^3$) | SA ($cm^3$) | TPP (daPa) |
|---|---|---|---|
| *M* | 0.00 | –0.02 | –1.46 |
| *SD* | 0.04 | 0.09 | 11.76 |
| *p* | .98 | .05 | .21 |

*Note.* ECV = ear canal volume ; SA = static admittance ; TPP = tympanometric peak pressure.

Figure 3 plots the differences in ECV (Plot A), SA (Plot B), and TPP (Plot C) against their means. Between one to two data points were out of range on each plot, but were retained for this analysis. No relationship was found between the differences and their means. Therefore, no systematic difference between consecutive measurements was found.

In Figure 4, the Bland and Altman plots showed constant variability around the mean of the three measurements: ECV (Plot A), SA (Plot B), and TPP (Plot C). In all three plots, a maximum of three data points were out of range, however, and were not omitted for the data analysis. No relationship was found between the differences and their means.

### *Reliability Between Unilateral and Bilateral Simultaneous Conditions*

The reliability of the KUDUwave TMP's ear measurements yielded in unilateral mode against bilateral simultaneous tympanometry was determined. A one-sample *t*-test analysis revealed that the mean of the differences for ECV and TPP did not deviate significantly from 0 ($p > .05$ and $p > .42$), as shown in Table 4, between consecutive measurements made with the KUDUwave TMP. However, the mean of the differences of SA (−0.02 $cm^3$) was found to have deviated significantly from 0 ($p \leq .02$) when comparing unilateral and simultaneous bilateral tympanometric measurements.

Bland–Altman plots shown in Figure 5 were generated for each test measurement (ECV, SA, and TPP). It was found that no proportional bias was present and the measurements could therefore be considered equivalent. The data points from all three ear measurements that fell outside the limits of agreement were retained during the analysis.

**Table 3.** Precision of bilateral simultaneous tympanometry results of the KUDUwave TMP.

| Variable | ECV ($cm^3$) | SA ($cm^3$) | TPP (daPa) |
|---|---|---|---|
| *M* | 0.00 | –0.01 | 0.56 |
| *SD* | 0.04 | 0.09 | 6.58 |
| *p* | .21 | .28 | .39 |

*Note.* ECV = ear canal volume ; SA = static admittance ; TPP = tympanometric peak pressure.

**Figure 3.** Bland–Altman plots showing the reliability of measurements of the KUDUwave TMP test results in unilateral mode. Dotted lines depict 95% limits of agreement. Mean difference of 0 (*SD* = 0.04) for Plot A, –0.02 (*SD* = 0.09) for Plot B, and –1.46 (*SD* = 11.76) for Plot C. ECV = ear canal volume; TPP = tympanometric peak pressure.

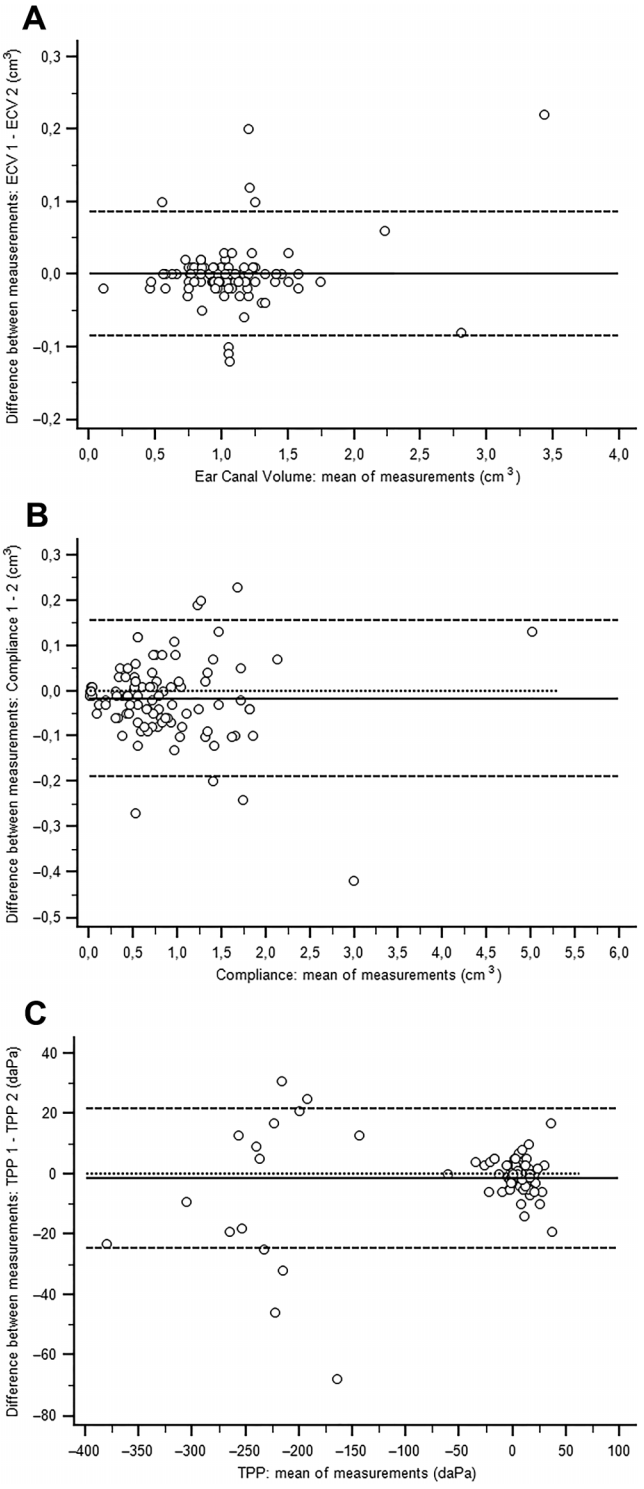


**Figure 4.** Bland–Altman plots showing the reliability of measurements of the KUDUwave TMP test results in bilateral simultaneous mode. Dotted lines depict 95% limits of agreement. Mean difference of 0 (*SD* = 0.04) for Plot A, −0.01 (*SD* = 0.09) for Plot B, and 0.56 (*SD* = 6.58) for Plot C. ECV = ear canal volume; TPP = tympanometric peak pressure.

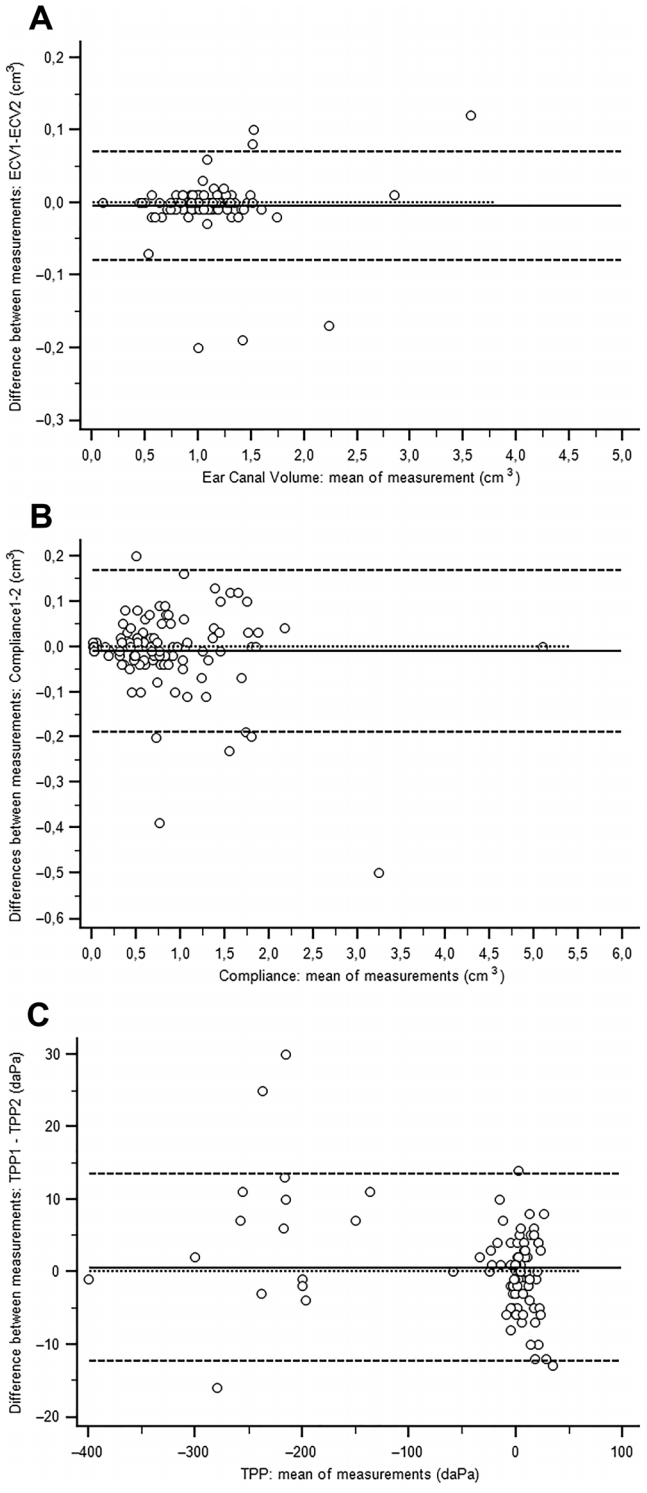


**Table 4.** Agreement between unilateral and bilateral simultaneous tympanometric measurements using the KUDUwave TMP.

| Variable | ECV ($cm^3$) | SA ($cm^3$) | TPP (daPa) |
|---|---|---|---|
| *M* | −0.01 | −0.02 | −0.84 |
| *SD* | 0.07 | 0.09 | 10.44 |
| *p* | .05 | .02[a] | .42 |

*Note.* ECV = ear canal volume ; SA = static admittance ; TPP = tympanometric peak pressure.

[a]Indicates that the mean of differences deviated significantly ($p < .05$) from 0.

### *Agreement Between the Investigational and Reference Device*

The test results of the investigational (in its unilateral condition) and reference device were compared in 104 ears. Figure 6 shows the differences in ECV measurements plotted against their means. Although four data points fell out of range, they were retained for data analysis. The mean of the differences of the two measurements was 0.05 $cm^3$, which deviates significantly from 0 (see Table 5; $p \leq .01$). Therefore, a systematic difference between the two measurements was found. The differences between the two measurements were not related to the mean of the measurements as depicted in Figure 6. Hence, for both low and higher values of ECV, the investigational device and reference device yielded similar values when measuring ECV on both devices. In addition, 95% of differences plotted were less than 2 *SD*s away from the mean. The difference that occurred within the ± 1.96 *SD* range was not clinically significant.

Figure 7 displays a Bland–Altman plot of the difference in the SA measurements against their mean. The mean of the differences (−0.03 $cm^3$) did not deviate significantly from 0 (see Table 5; $p \geq .19$), and the difference between the measurements did not relate to the mean of measurements (see Figure 7).

For TPP measurements, the mean of the differences (−0.84 daPa) did not deviate significantly from 0 (see Table 5; $p \geq .42$) as shown in Figure 8. No relationship was found between the difference and the means with this measurement.

The sensitivity and specificity of the KUDUwave TMP were calculated with the GSI TympStar Version 1 Middle Ear Analyzer as a reference and golden standard device. In the context of this study, sensitivity was a measure of the investigational device's ability to correctly identify those with the disease being tested for, and specificity was a measure of the investigational device's ability to correctly identify those without the disease by generating negative results for individuals who did not present the condition being tested for.

Out of the 104 tympanogram types yielded by both devices, a total of 16 tympanograms resulted in Type Ad and As tympanograms. Type Ad and As tympanograms obtained using standard tympanometry have been observed in individuals with normal middle ears and ears with lesions, such as in cases of otosclerosis and ossicular discontinuity (Browning et al., 1985; Colletti, 1975, 1976, 1977; Lilly, 1984; Shahnaz & Polka, 1997). Consequently, previous validation studies on the KUDUwave TMP excluded these tympanogram types from the analysis. However, for this study and the calculation of sensitivity and specificity of the investigational device, these tympanograms were classified as abnormal. Therefore, the analysis was conducted on all 104 tympanograms. The results of the investigational device were highly comparable with those of the reference device with the sensitivity being 100% (95% CI [86.8%, 100%]) and the specificity being 92.3% (95% CI [84.0%, 97.1%]), as shown in Table 6. On the other hand, Table 7 shows the comparison between the tympanogram type classifications yielded by the KUDUwave TMP and that of the GSI TympStar in all 104 ears. Cohen's kappa ($\kappa = 0.77$) indicated good agreement between the two measures.

## Discussion

The aim of this study was to determine the reliability and validity of a novel bilateral simultaneous tympanometer by comparing it with an industry-standard tympanometer. All outliers on the Bland–Altman plots were retained for data analysis. This study demonstrated overall good agreement between the investigational and reference device results, specifically when determining the tympanogram type.

### *Test–Retest Reliability of the KUDUwave TMP*

When determining the agreement between two different clinical devices, the repeatability of each individual device is important, since poor repeatability of either device can lead to poor agreement between the independent devices (Bland & Altman, 1986). Both unilateral and bilateral simultaneous tympanometric ear measurements (ECV, SA, and TPP) of the investigational device showed good repeatability: The mean of the differences between measurements did not deviate significantly from 0 (see Tables 2 and 3). The precision of the investigational device was found to be similar in either unilateral and bilateral simultaneous mode when measuring ECV and SA, since the standard deviation of the two measurements were similar (ECV: 0.04 $cm^3$ and SA: 0.09 $cm^3$), as summarized in Tables 2 and 3. However, the precision of the KUDUwave TMP when measuring TPP was higher in the bilateral simultaneous mode as the standard deviation in this mode was found to be lower (6.58 daPa) than in unilateral measurement mode (11.76 daPa). Overall, the results showed good repeatability between consecutive measures with the investigation device in both modes of measurement.

**Figure 5.** Bland–Altman plots showing agreement between unilateral and bilateral simultaneous measurements of the KUDUwave TMP. Data points outside the limits of agreements (1.96 *SD*s from the mean) were retained for data analysis purposes. Mean difference of –0.01 (*SD* = 0.07) for Plot A, –0.02 (*SD* = 0.09) for Plot B, and –0.84 (*SD* = 10.44) for plot C. TPP = tympanometric peak pressure.

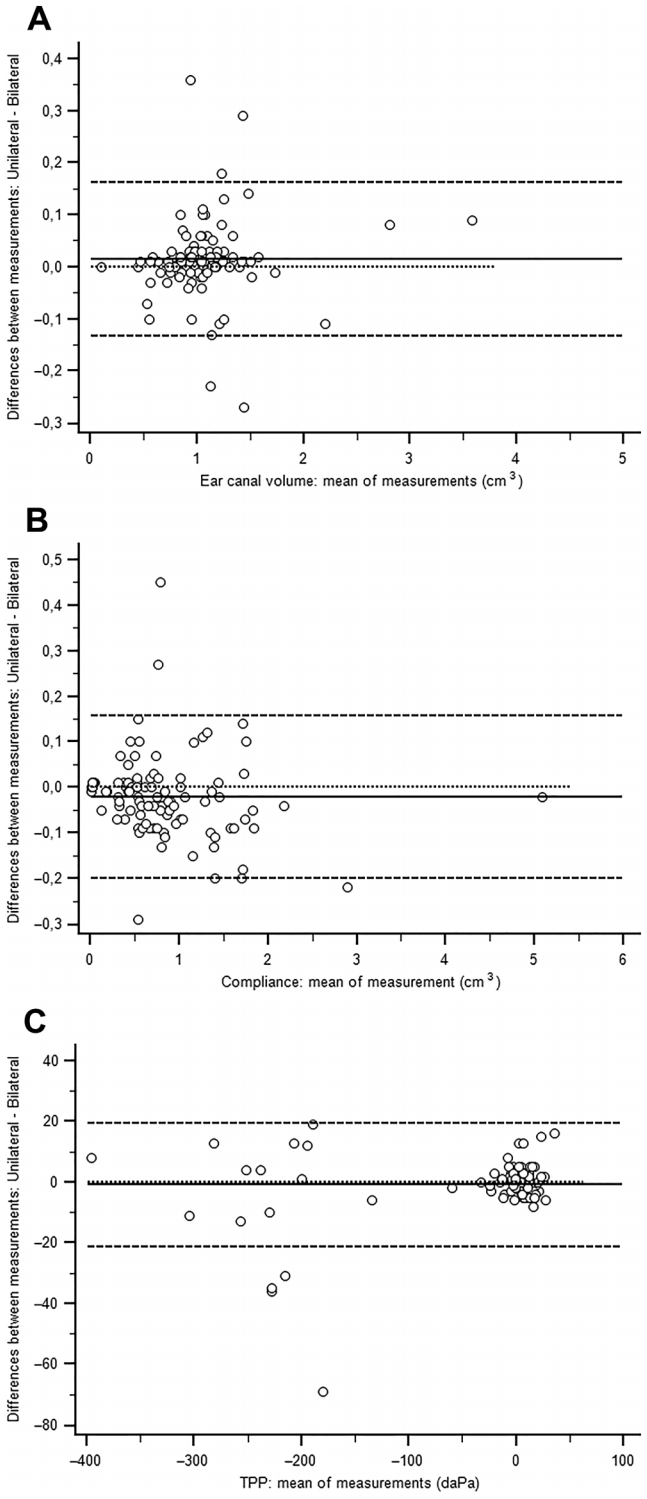


**Figure 6.** Difference in ear canal volume against their means. Mean of the differences (0.05 $cm^3$) between the measurements deviates significantly from 0 (see Table 5; $p \leq .01$). Four points are out of range but were still retained for the data analysis ($n = 104$).

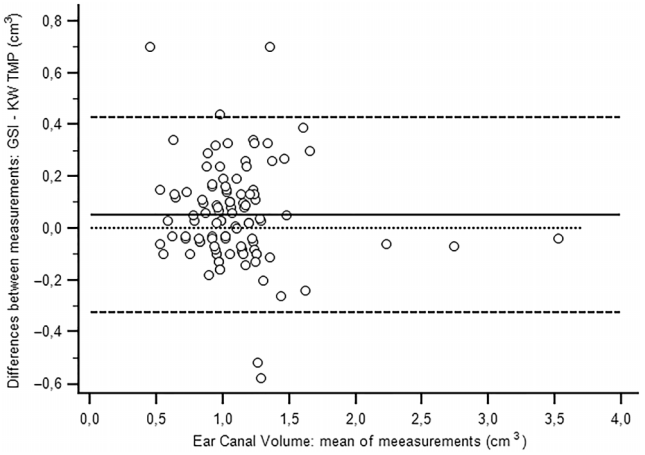
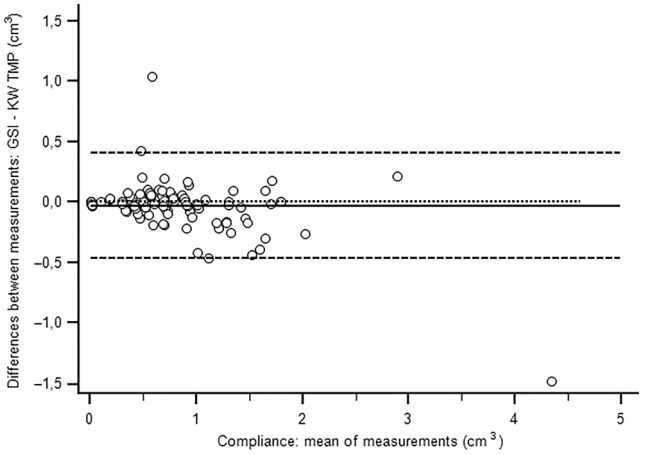



**Figure 7.** Difference in static admittance against their means. Mean of the differences (–0.03 $cm^3$) between the measurements does not deviate significantly from 0 (see Table 5; $p \geq .19$). One point is out of range but was retained for data analysis ($n = 104$).




### *Reliability Between Unilateral and Bilateral Simultaneous Conditions of the KUDUwave TMP*

In the interest of evaluating the reliability between ear measurements of the unilateral and bilateral simultaneous conditions of the investigational device, only the first measurements of both conditions were compared in each ear. No significant bias ($p \geq .05$) between measurements in the different conditions was found, except for SA ($p \leq .05$; see Table 4). A factor contributing to this variation of measurement could be preconditioning of the tympanic membrane (Gaihede, 1996), although the sequence of the testing was random and 5-min breaks were given between measurements. Other authors found that the increase in tympanic membrane conductance and susceptance after repetitive measurements on the first day recovered over a period of 24 hr (Gaihede, 1996; Osguthorpe & Lam, 1981). However, a 24-hr recovery period could not be given in this study as the participants were walk-in outpatients at the data collection site. The overall agreement of SA measured in the two conditions was determined by the limits of agreement, which is the range of ± 1.96 *SD*s of the difference between measurements (Bland & Altman, 1986). Figure 5 indicates the range of agreement where 95% of the data points occur. Thus, the interval of ± 0.18 $cm^3$ represents the range where 95% of the unilateral and bilateral simultaneous measurements, in terms of SA, will be found. This interval is small, clinically insignificant, and unlikely to result in a different tympanogram type when either measurement is used.

ECV and TPP showed good agreement between the two measurements with an interval of ± 0.14 $cm^3$ and ± 20.46 daPa, respectively (the limits of agreement). The difference that occurred within the ± 1.96 *SD* range was not clinically significant in all three measurements. Resultantly, the two measurements always generated the same tympanogram type with an accuracy of 100%. Thus, the small intervals did not affect the type of tympanogram yielded

**Table 5.** Agreement between the KUDUwave TMP and the GSI TympStar.

| Variable | ECV ($cm^3$) | SA ($cm^3$) | TPP (daPa) |
|---|---|---|---|
| *M* | 0.05 | −0.03 | 8.33 |
| *SD* | 0.19 | 0.22 | 46.07 |
| *p* | .01[a] | .19 | .07 |

*Note.* ECV = ear canal volume ; SA = static admittance ; TPP = tympanometric peak pressure.

[a]Indicates that the mean of differences deviated significantly ($p < .05$) from 0.

**Figure 8.** Difference in tympanometric peak pressure against their means. Mean of the differences (–0.84 daPa) between the measurements does not deviate significantly from 0 (see Table 5; $p \geq .42$). One point is out of range but was retained for data analysis ($n = 104$).

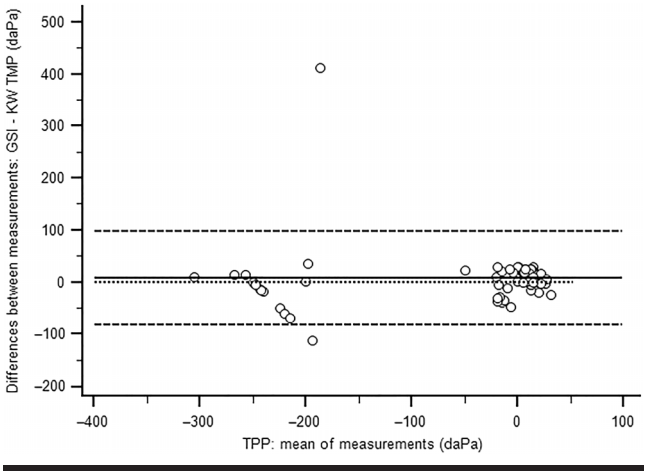


**Table 6.** Tympanometry comparison between KUDUwave TMP and GSI TympStar Version 1 Middle Ear Analyzer ($n$ = 104 ears).

| KUDUwave TMP | | GSI TympStar | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Abnormal | | | | | Normal | | |
| | | B | C | Ad | As | Subtotal | A | Subtotal | All |
| Abnormal | B | 10 | — | — | — | 10 | — | — | 10 |
| | C | — | 5 | — | — | 5 | 1 | 1 | 6 |
| | Ad | — | — | 8 | — | 8 | 4 | 4 | 12 |
| | As | — | — | — | 3 | 3 | 1 | 1 | 4 |
| Normal | A | — | — | — | — | — | 72 | 72 | 72 |
| All | | | | | | 26 | | 78 | 104 |

*Note.* Sensitivity: 26/26 = 100. Specificity: 72/78 = 92.31.

between the measurements (see Table 8). The overall good agreement between the measurements generated by the KUDUwave TMP in the two conditions indicated that bilateral simultaneous tympanometric measurements are a clinically effective method for conducting tympanometry.

### *Agreement Between Investigational and Reference Device*

When comparing the KUDUwave TMP to the GSI TympStar Middle Ear Analyzer, the investigational device's unilateral condition measurements were used. ECV measurements showed a significant bias (see Table 5; 0.05 $cm^3$). Thus, the mean of differences between ECV measurements for the two devices deviated significantly from 0 ($p \leq .05$). The significant bias found for ECV was expected, given the fact that different sizes of ear tips and the insertion depth of the ear tip could result in a difference in ECV measurement (Lous et al., 2012). During the study, the sequence of measurements with both devices was randomized. This may have resulted in the clinical audiologists using different ear tip sizes and insertion depth even for the same subject. Another factor that may have contributed to the difference in ECV was the variation in ear canal pressure. Shanks and Lilly (1981) demonstrated that ear canal pressure variation is a source of the difference in ECV and that the volume change is attributed to the movement of the probe tip, tympanic membrane, and the walls of the ear canal. The limits of agreements on the Bland–Altman plot (see Figure 6) were

**Table 7.** KUDUwave TMP tympanogram types compared with GSI TympStar Version 1 Middle Ear Analyzer ($n$ = 104 ears).

| KUDUwave TMP | GSI TympStar | | | | | |
|---|---|---|---|---|---|---|
| | A | As | Ad | B | C | Total all |
| A | 72 | — | — | — | — | 72 |
| As | 1 | 3 | — | — | — | 4 |
| Ad | 4 | — | 8 | — | — | 12 |
| B | — | — | — | 10 | — | 10 |
| C | 1 | — | — | — | 5 | 6 |
| Subtotal | 78 | 3 | 8 | 10 | 5 | 104 |

**Table 8.** KUDUwave TMP tympanogram types comparison between unilateral and simultaneous measurement ($n$ = 104 ears).

| KUDUwave TMP unilateral | KUDUwave TMP bilateral | | | | | |
|---|---|---|---|---|---|---|
| | A | As | Ad | B | C | Total all |
| A | 72 | — | — | — | — | 72 |
| As | — | 3 | — | — | — | 3 |
| Ad | — | — | 13 | — | — | 13 |
| B | — | — | — | 10 | — | 10 |
| C | — | — | — | — | 6 | 6 |
| Subtotal | 72 | 3 | 13 | 10 | 6 | 104 |

calculated from the mean of the differences to determine the overall agreement of ECV measurements. This calculation indicated that the GSI TympStar may have given results 0.43 $cm^3$ above the KUDUwave TMP or −0.33 $cm^3$ below (see Figure 6). While there was statistical disagreement between the ECV measurements for both devices, they were still within the range that generated the same tympanogram type (see Table 5). Thus, differences within ± 1.96 *SD*s of the mean were not of clinical importance. This suggests that ECV data obtained from both devices can be readily compared and yield the same clinical results.

Both the SA and TPP ear measurements showed no significant bias ($p \geq .05$) between the results of the devices (see Table 5). The two measurements (SA and TPP) showed good agreement, independent from the mean values (see Table 5 and Figures 7 and 8), between the two devices. When observing the overall agreement of SA using the limits of agreement for both measurements, the interval in which 95% of the differences between the devices are found is ± 0.43 $cm^3$. SA is one of the most important variables used when classifying the tympanogram type as either Type A, Ad, or As. It is therefore important that there is no clinically significant difference between the measurements of the devices, as this may lead to misdiagnosis. Table 7 indicates that the investigational device has yielded 12 Type Ad tympanograms compared to the reference device (eight) for the same subjects. This variation cannot be explained by preconditioning of the tympanic membrane (Gaihede, 1996). Preconditioning is a biomedical phenomenon where the SA becomes higher as a result of pressure loads during tympanometry. As mentioned previously, the sequence of the testing was random, thus counterbalancing the testing states. Nonetheless, the overall accuracy of the investigational device has been affected to a smaller degree by this (see Table 6).

Regarding the TPP measurement of both devices, the range in which 95% of the differences between the devices was found is ± 90.30 daPa. This range did not result in any clinically significant variation with regard to the type of tympanogram obtained from both devices. This measurement is important when classifying all the variations of tympanogram types. As indicated in Table 7, the investigational device generated Type B tympanograms in 10 out of 10 cases and Type C tympanograms in five out of six cases when compared to the reference device. It was thus concluded that both instruments (specifically the KUDUwave TMP,

in this case) could be readily used without any bias for the SA and TPP measurements.

This study had numerous impacts on the assessment and management of middle ear pathologies. As previously reported, subjective ear examination has proven to be a difficult skill to learn and master, and pure-tone audiometry alone is not accurate enough in the identification of middle ear pathologies (De Melker & Burke, 1988; Reves et al., 1985; Wegner et al., 2013; Yockel, 2002). The current study indicated a sensitivity of 100% and a specificity of 92.3% when comparing the tympanogram type generated by the devices (see Table 6). Furthermore, current findings indicated that the tympanogram types obtained by the two devices were comparable with kappa statistics of .77, suggesting substantial agreement between the two measures (McHugh, 2012). In comparison, the current study was in agreement with a previous study conducted on the KUDUwave TMP beta. The study ($n$ = 113) showed a 100% agreement between the KUDUwave TMP and a reference device regarding the tympanogram type yielded (Chouhan & Petersen, 2018). However, only subjects with normal middle ear status (Type A) were included. The findings of this study supplement the existing scientific evidence on the validation of the KUDUwave TMP.

Findings from this study provided evidence that valid tympanometric assessments could be conducted using the KUDUwave TMP, either in unilateral or bilateral simultaneous conditions. The tympanometric assessment of two ears simultaneously did not affect the results yielded in the other ear. In addition, it was demonstrated that the setup of the investigational device allows for hands-free tympanometry as a result of effective probe sealing. This may be particularly useful in the case where the operator is conducting tympanometric assessments in the bilateral simultaneous condition.

Hearing-related disorders are a significant public health concern. Individuals and communities are faced with inaccessibility to hearing health care services as a result of limited hearing health care specialists and lack of audiological equipment. Implementation and provision of hearing health care services in underserved areas require addressing both the unavailability of appropriate equipment and hearing health professionals. The current study is the first to validate the novel bilateral simultaneous tympanometer with integrated automated diagnostic audiometry and increase ambient noise attenuation. This novel device could offer an inexpensive possibility to decentralize and improve accessibility to comprehensive hearing health care services by addressing the global shortage of hearing health care resources.

One limitation to this study is that, while being conducted, there was no ear tip size and insertion depth uniformity between the devices and the same subjects. This may have affected the ECV measurements yielded by the two devices in some cases. However, the clinical audiologists who were operating the tympanometers are highly experienced; thus, the variability of the size of the ear tips used may have been small. A consideration when using this technology is the new way of placement of the device on the patient—this may need some training and experience from the user.

## Conclusions

This study was part of a validation series for the KUDUwave TMP. The KUDUwave TMP was found to be comparable with the gold standard reference device and produced high sensitivity and specificity scores between the tympanogram type yielded by the two devices. The current study findings demonstrated the ability to assess middle ear status accurately using the investigational device—either unilaterally or in its bilateral simultaneous condition.

## Acknowledgments

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ASHA American Speech-Language-Hearing Association

AJA

Research Article

# Adapting Audiology Procedures During the Pandemic: Validity and Efficacy of Testing Outside a Sound Booth

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ABSTRACT

**Purpose:** This investigation aims to provide outcomes from a clinical perspective on the validity and efficacy of a wireless automated audiometer system that could be used in multiple settings when a sound booth is not accessible. Testing was conducted in a clinical setting under modified protocols meeting safety precautions during the COVID-19 pandemic.

**Method:** Four doctoral students in audiology served as examiners. Participants were 69 adults between the ages of 20 and 69 years, with normal hearing (≤ 25 dB HL; $n$ = 110 ears) or hearing loss (> 25 dB HL; $n$ = 25 ears). Two versions of a pure-tone air-conduction threshold test following a modified Hughson-Westlake approach were performed and compared at 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz (a) in a sound-treated test booth using standard manual audiometry and (b) in a quiet, nonsound-treated clinical room (sound booth free) using automated KUDUwave audiometry. Participants were asked to complete a five-item feedback questionnaire, and examiners were interviewed to report on their experience.

**Results:** Clinical validity to within ±10 dB of standard audiometry was demonstrated for 94.5% of the total thresholds ($n$ = 937) measured with the sound booth–free approach. Less accuracy (73.3%) was observed using a ±5 dB comparison. When comparing the mean thresholds, there were significant differences ($p$ < .01) between the mean thresholds at most frequencies, with mean sound booth thresholds being higher than the sound booth–free mean thresholds. A strong threshold correlation (.91–.98) was found between the methods across frequencies. Participant and examiner feedback supported the efficacy of the sound booth–free technology.

**Conclusions:** Findings support sound booth–free, automated software-controlled audiometry with active noise monitoring as a valid and efficient procedure for pure-tone hearing threshold assessment. This method offers an effective alternative when circumstances require more transportable hearing assessment technology or do not allow for standard manual audiometry in a sound booth.

The coronavirus (COVID-19) pandemic has disrupted the provision of essential and elective health care services globally (B. Stuart, 2020; World Health Organization, 2020). Innovative and alternative approaches that minimize the spread of COVID-19 have become necessary to ensure safe health care delivery. The Centers for Disease Control and Prevention (Centers for Disease Control and Prevention, 2020) issued guidance for health care facilities on managing effective and safe operations during COVID-19. Adjustments of current health care delivery practices were recommended, such as optimizing telehealth services and reducing in-person visits when appropriate. In-person care should follow infection prevention control guidelines that include screening for COVID-19 symptoms upon entry into a health care facility,

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use of well-fitted face masks, and scheduling appointments to minimize direct patient interaction to mitigate risks of infection (Centers for Disease Control and Prevention, 2020).

Traditional audiology services are close contact, mostly offered face to face in enclosed clinical spaces and in sound-treated test booths, but the pandemic has required practices to shift to alternative forms of service delivery (Swanepoel & Hall, 2020). The American Speech-Language-Hearing Association (ASHA, n.d.) *Audiology Service Delivery Considerations in Health Care During COVID-19* outlined suggestions for in-person services and those using telehealth (teleaudiology). An assessment of the needs, goals, and readiness of the practice is recommended when planning to implement teleaudiology care (ASHA, n.d.). Current models of teleaudiology use asynchronous, synchronous, automated, and hybrid technologies for hearing screening and diagnostic services, and aural rehabilitation for amplification device programming and counseling (Krumm, 2014). However, effective teleaudiology practices may be restricted by state laws and regulations, insurance coverage, maintaining privacy of patient records, budgeting expenses, acquiring the necessary equipment, and access to secure high-speed Internet connections and technological support (ASHA, n.d.; Muñoz et al., 2020). An international survey of 269 audiologists revealed that despite positive attitudes, less than 25% had adopted teleaudiology services in clinical practice (Eikelboom & Swanepoel, 2016). Moreover, remote testing practices may not be preferable by all patient populations. A survey of hearing health perceptions in older U.S. adults showed a majority preferred in-person hearing health care visits (Gaeta, 2020).

Because of the limitations in adopting teleaudiology approaches, clinical settings are faced with challenges to deliver audiological services in person that meet adequate health and safety requirements. Specifically, precautions for disinfection and ventilation need to be in place for testing inside a sound booth (American Academy of Audiology, 2020; ASHA, n.d.). Smartphone and tablet-based hearing assessment applications (apps) have been developed that allow for automated self-administered tests, with the advantage of portability and testing outside a sound booth. However, these systems have shown mixed findings on accuracy due to transducer differences, issues with calibration, and difficulty controlling the background noise environment (Barczik & Serpanos, 2018; Shojaeemend & Ayatollahi, 2018). Moreover, these self-hearing test apps do not have capability for performing complete diagnostic testing including pure-tone bone-conduction testing, effective masking, and speech audiometry.

Recent technology was designed for performing hearing testing outside a sound booth using a software-controlled audiometer operated through a headset with built-in sound attenuation and active noise monitoring (KUDUwave 5000; eMoyo Technologies, n.d.). The system is mobile and offers adaptability for manual or automated in person or remote testing in synchronous or asynchronous modes. The KUDUwave system has capability for performing complete diagnostic hearing evaluation including pure-tone air- and bone-conduction testing, speech audiometry, and masking, in addition to tympanometry. The headset (Ambidome) interfaces with a computer via a USB port and consists of circumaural earphones connected with insert earphones to increase sound attenuation. External and internal microphones on the headset continually monitor background noise levels, and testing is only performed during periods when ambient noise falls below the noise floor limit (Storey et al., 2014). System specifications indicate that the combined ear-cup and ear-insert technology provides 31–52.3 dB of sound attenuation with operational background noise levels ranging up to < 50 to < 70 dB SPL to test down to 0 dB HL from 125 to 8000 Hz (KUDUwave User Manual EM-KW-SW-IFU Revision: 19; eMoyo Technologies, n.d.).

Reports on the validity of the KUDUwave system used in a teleaudiology approach have been positive. Swanepoel, Koekemoer, and Clark (2010) and Visagie et al. (2015) found that average air-conduction hearing thresholds measured in adults with the remote synchronous software-based system were within 5 dB and not significantly different ($p > .01$) from those measured with conventional in-person audiometry. Reliable and accurate hearing findings using KUDUwave audiometry have also been reported in a sound booth (Swanepoel & Biagio, 2011; Swanepoel, Mngemane, et al., 2010) as well as in nonstandard test environments with noise and outside a sound booth in children (Swanepoel et al., 2013) and adult populations.

Maclennan-Smith et al. (2013) performed manual KUDUwave testing on 147 elderly adults presenting with normal hearing or varying degrees of hearing loss. Testing was performed in two locations: in a nonsound-treated room of a retirement facility with average ambient noise levels of 47–54 dBA, then in a sound booth at an audiology clinic. Thresholds were reported to correspond within 5 dB between the two settings in 95% of air-conduction (250–8000 Hz) and 86% bone-conduction comparisons (250–4000 Hz). The investigators concluded that valid hearing measures are possible in natural sound environments. Storey et al. (2014) evaluated pure-tone air-conduction thresholds obtained in quiet and in a background noise typical of a level in a nonsound-treated environment (40 dBA) using automated KUDUwave audiometry in adolescents and adults with normal hearing or with hearing loss. Outcomes showed that the background noise did not affect accuracy using the computer-based system, with 92% of thresholds from 250 to 8000 Hz within 5 dB of conventional sound booth audiometry. Swanepoel et al. (2015) demonstrated a significant improvement of attenuation across frequencies

using the combined circumaural earcups and inserts of the KUDUwave headset when evaluated with standard ER-3A insert earphones and TDH-39 supra-aural transducers. Audiometry using the automated mode of KUDUwave was performed in a natural environment and compared with standard audiometry in a sound booth for 23 adult listeners with normal hearing and re-administered in a subgroup. No significant differences ($p > .05$) were found between the air- or bone-conduction thresholds measured inside or outside the test booth. Test–retest threshold differences using the computer-based system outside the sound booth were similar to those measured by standard audiometry (Swanepoel et al., 2015).

This study aimed to provide outcomes from a clinical perspective on the validity and efficacy of a wireless automated audiometer system that could be used in multiple settings when a sound booth is not accessible. Specifically, this investigation compared procedures using standard manual pure-tone air-conduction performed in a sound-treated test booth and KUDUwave audiometry in a quiet nonsound treated clinical room (sound booth free) in an existing clinical setting under modified protocols meeting safety precautions during the COVID pandemic. Information from this study can assist clinicians when considering alternative technology for hearing assessment outside a sound booth.

## Method

The study was designed to compare hearing threshold results for two test conditions, using standard manual pure-tone air-conduction performed in a sound-treated test booth and KUDUwave audiometry in a quiet nonsound-treated clinical room (sound booth free). Participant recruitment and assessments were conducted from November 2020 through February 2021. Study methods were approved by the Institutional Review Board of Adelphi University, Garden City, NY.

### Participants

Eligible participants included English-speaking adults between the ages of 20 and 69 years. Participants were recruited from the university and clinical population of Adelphi University. Each participant completed a COVID-19 screening questionnaire prior to entering the clinic, gave oral and signed informed consent prior to testing, and was offered monetary compensation for their time at the completion of the study session.

### Study Procedures

Test procedures were conducted in a single 45-min session at the Hy Weinberg Center for Communication Disorders, Adelphi University. Four doctoral students in audiology served as examiners. The examiners completed a 2-hr training using the KUDUwave online training materials (eMoyo Technologies, n.d.) to learn how to use the equipment and completed at least two practice tests prior to conducting any assessments. COVID-19 protocols followed institutional guidelines and required passing a temperature check and COVID-19 self-check screening, wearing of face masks by examiners and participants throughout the test session, appropriate room ventilation, and disinfection of the equipment and furniture surfaces following each session.

A brief questionnaire, otoscopy (Welch Allyn 25020A; Welch Allyn), and tympanometry (Titan Version 2; Interacoustics) were performed to identify exclusionary conditions in individual ears including ear drainage, pain, infection, or excessive ear canal obstruction. The questionnaire also gathered demographic information on age and gender. Two versions of a pure-tone air-conduction threshold test followed a modified Hughson-Westlake approach and were performed at 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz (a) in a sound-treated test booth using standard manual audiometry and (b) in a quiet, nonsound-treated clinical room (sound booth free) using automated, software controlled KUDUwave audiometry with active noise monitoring (eMoyo Technologies, n.d.).

The order of the pure-tone assessment (either in the sound booth or sound booth free) was randomly assigned. A retest hearing threshold at 1000 Hz within 10 dB of the first threshold was a criterion for test consistency and inclusion in the study. A representative sample of the background ambient noise levels of the test environments was measured using a calibrated portable Type 1 sound level meter (SLM; B&K SLM 2250; B&K Pistonphone Type 4231; Bruel and Kjaer) set on an A frequency and fast time weighting. The SLM was positioned with the microphone (B&K Type 4189; Bruel and Kjaer) at 0° azimuth in the center of the room 1.2 m from the floor, approximating a seated ear-level position. For each test environment, an average of five separate recordings at random intervals within an hour period represented the sample ambient noise levels and is reported below.

#### Sound Booth Standard Pure-Tone Test

The sound booth standard manual air-conduction pure-tone test was performed following ASHA (2005) recommended protocols in a two-room suite with the participant seated in a double-walled sound-treated test room (IAC RS 253; IAC Acoustics). The examiner was seated in the adjoining single-walled room where the calibrated audiometer (GSI 61; Grason-Stadler Inc.) was housed and operated. An exception to the ASHA (2005) guideline was that the doors in the test room and examiner room remained open during testing in compliance with the site COVID-19 protocol for ventilation. Insert earphones were

used to mitigate the effects of ambient noise in accordance with the ASHA (2005) guidelines for pure-tone threshold audiometry during open-door sound booth testing.

A quiet room setting in the test suite was ensured by an unoccupied space (with exception of the participant and examiner) and no external sound source. Representative ambient noise samples within the sound booth measured 17.3 dBA (doors closed) and 20.0 dBA (doors open); both levels met the maximum permissible ambient noise level (MPANL) requirements for audiometric test rooms with ears covered using supra-aural or insert earphones as specified by the American National Standards Institute (American National Standards Institute, 2018). Participants were instructed, and responses were indicated using a hand-held response button. Insert earphones (3 M E.A.RTONE 3A) with disposable foam insert tips were fitted as deeply into the ear canals as possible.

### Sound Booth–Free Computerized Automated Pure-Tone Test

The sound booth–free computerized automated air-conduction pure-tone test was performed in a quiet (see criteria above), nonsound-treated clinical room. Hearing threshold testing outside sound-isolated test booths is not considered standard practice (ASHA, 2005). The representative ambient noise sample measured 34.6 dBA met the ANSI S3.1–1999 (R2018) MPANLs specified for ears covered but exceeded the MPANL requirements for ears not covered.

Testing was conducted using the KUDUwave 5000 (eMoyo USA, LLC) audiometer, composed of the hardware (KUDUwave headset and response button) and operated and recorded using the software downloaded onto a Windows-operated laptop computer (see KUDUwave User Manual EM-KW-SW-IFU Revision: 19; eMoyo Technologies, n.d.). A system self-check calibration of the hardware was verified prior to each day of testing. The participant was seated, instructed, and provided with the response button. The examiner remained in the vicinity to oversee procedures during the session. The examiner positioned the KUDUwave headset by first inserting the KUDUwave disposable foam ear tips as deeply as possible in the ear canals and then placed the circumaural earcups over the ears. The examiner initiated the automated air-conduction pure-tone test through the computer.

### Poststudy Assessment

After completing the study, participants were asked to complete a five-item feedback questionnaire to report on their experience with the pure-tone tests. They were asked to indicate the comfort of the KUDUwave headset using a 3-point scale (not at all comfortable, somewhat comfortable, or comfortable) and to indicate their preference between the sound booth and sound booth–free procedures. A debriefing was conducted with the examiners to assess their experiences administering the tests.

### Analysis

Individual ears with asymmetrical hearing loss requiring masking were excluded from the analysis. Descriptive analysis was used to evaluate the validity of the pure-tone thresholds measured in the sound booth–free condition. Mean thresholds, standard deviations (*SD*s), and 95% confidence intervals (CIs) were calculated for the sound booth and the sound booth–free approach across frequencies. The absolute mean difference thresholds and absolute mean difference *SD*s was computed by frequency for each condition. The standard pure-tone test in the sound booth was treated as the baseline. Threshold accuracy was assessed by the differences between the two testing conditions for each frequency and identifying the percentage of sound booth–free thresholds that were within clinical accuracy of ±5 and ±10 dB. A paired sample $t$ test was conducted to analyze whether there was a statistically significant difference ($p < .01$) between mean thresholds for the sound booth and sound booth–free results. Correlations between the two approaches were computed. The efficacy of the sound booth–free method was assessed by a qualitative evaluation of the participant and examiner feedback.

## Results

Sixty-nine adults ($M_{age}$ = 37 years; women = 44; men = 25) completed both the sound booth and sound booth–free (KUDUwave) testing. A total of 135 ears were included in the analysis. Three ears were omitted from evaluation due to asymmetry requiring masking. Ears were classified as normal hearing (defined by thresholds ≤ 25 dB HL; $n$ = 110) or hearing loss (defined by thresholds > 25 dB for at least two frequencies; $n$ = 25). By counterbalancing the test order, we effectively minimized test order effects, $F(1, 133) = 1.494$, $p = .224$. Table 1 provides a summary of the participants by hearing status for age, gender, and pure-tone average (calculated from the thresholds at 500, 1000, and 2000 Hz measured with standard audiometry).

### Accuracy of Thresholds

Of the total air conduction thresholds ($n$ = 937), 94.5% were within 10 dB and 73.3% were within 5 dB in comparisons between the standard and sound booth–free approaches. Figure 1 shows the distribution of absolute differences between thresholds recorded with the sound booth and sound booth–free approaches. The thresholds

**Table 1.** Participant characteristics (*N* = 69).

| Variable | Hearing loss | Normal hearing |
|---|---|---|
| Overall (*n* ears) | 25 | 110 |
| Age | | |
| Mean age | 36 years | 37 years |
| *SD* | 16.90 | 16.76 |
| Range | 20–69 | 20–69 |
| Gender | | |
| Females (*n* ears) | 10 | 76 |
| Males (*n* ears) | 15 | 34 |
| Pure-tone average | | |
| Mean | 27 dB | 8 dB |
| *SD* | 23.27 | 6.29 |
| Range | –10 to 95 | –10 to 25 |

*Note.* Pure-tone averages were calculated from thresholds (in dB HL) at 500, 1000, and 2000 Hz collected during the sound booth portion of the exam.

measured using the sound booth–free method to within ±10 dB of those measured in the sound booth were accurate 90% or better for all but the 6000 Hz frequency, which was 88.5% accurate. With greater precision at ±5 dB, the sound booth–free approach was accurate at least 80% but below 89% for the frequencies of 500, 1000, 2000, and 3000 Hz. However, the accuracy to within ±5 dB dropped to between 53% and 64.9% in the higher frequencies of 4000, 6000, and 8000 Hz.

Table 2 displays the mean thresholds for the sound booth and sound booth–free approaches, mean absolute differences, 95% CIs, and the accuracy of audiometric thresholds by frequency. Mean thresholds measured in the sound booth across the frequencies ranged from 10.6 to 16 dB and from 7.1 to 10.5 dB in the sound booth–free condition. The mean *SD*s across frequencies were 12.8–22.2 (sound booth) and 13.1–21.8 (sound booth free). The absolute mean threshold differences between the measures ranged from 1.1 to 4.4 dB at 500, 1000, 2000, and 3000 Hz, and from 6.5 to 6.9 dB at 4000, 6000, and 8000 Hz. The absolute mean threshold difference *SD*s were 4.4–6.3 dB. There were significant differences ($p < .01$) between the thresholds at all frequencies except for 500 Hz ($p = .02$). Threshold correlation coefficients across the frequencies between the sound booth and sound booth–free approaches were between 0.91 and 0.98.

Table 3 displays the threshold accuracy and 95% CIs across frequencies for the booth-free testing compared with the sound booth testing for participants with normal hearing and with hearing loss. Absolute mean threshold differences between the sound booth and booth-free measures at 500, 1000, 2000, and 3000 Hz ranged from −0.6 to 4.8 dB for the group with hearing loss and 1.5 to 4.7 dB for those with normal hearing. At 4000, 6000, and 8000 Hz, the absolute mean threshold differences ranged from 6.4 to 8.6 dB for those with hearing loss and 6.3–6.6

**Figure 1.** Distribution of absolute differences between thresholds recorded with the sound booth and sound booth–free approaches (*N* = 135 ears).

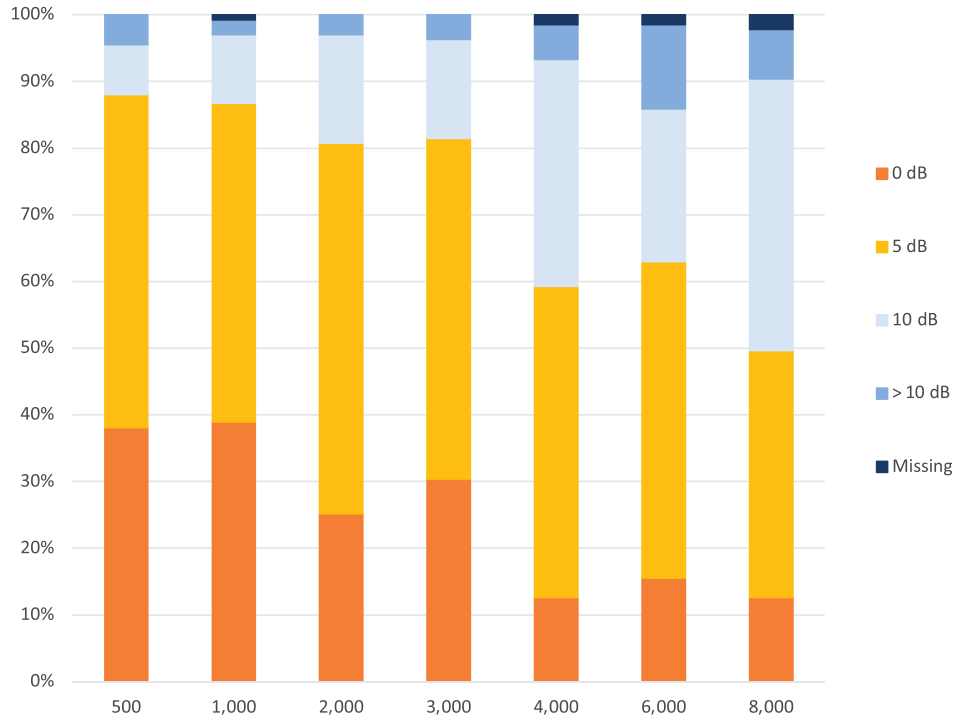

**Table 2.** Mean threshold (in dB HL) outcomes and accuracy by frequency for the sound booth–free testing compared with the sound booth testing.

| Hz | % Thresholds ±10 dB | % Thresholds ±5 dB | Mean thresholds sound booth (*SD*) | Mean thresholds sound booth–free (*SD*) | *t* (*p* value) | Absolute mean threshold difference (*SD*) | 95% CI | Correlation |
|---|---|---|---|---|---|---|---|---|
| 500 | 90.3% | 88.1% | 10.55 (12.76) | 9.44 (13.34) | −2.361 (.020) | 1.07 (5.51) | [0.18, 2.05] | .912 |
| 1,000 | 97.8% | 87.4% | 11.70 (13.72) | 8.78 (13.09) | −7.55 (< .001) | 2.93 (4.50) | [2.17, 3.69] | .944 |
| 2,000 | 97.0% | 80.7% | 13.15 (13.98) | 8.74 (14.20) | −11.30 (< .001) | 4.41 (4.53) | [3.64, 5.17] | .948 |
| 3,000 | 96.3% | 81.2% | 14.48 (15.81) | 10.52 (15.62) | −8.70 (< .001) | 3.96 (5.29) | [3.07, 7.33] | .943 |
| 4,000 | 94.7% | 60.2% | 14.40 (17.18) | 7.82 (17.55) | −17.20 (< .001) | 6.51 (4.41) | [5.83, 7.33] | .968 |
| 6,000 | 88.5% | 64.9% | 13.78 (19.94) | 7.10 (18.24) | −14.88 (< .001) | 6.85 (6.29) | [5.17, 7.31] | .962 |
| 8,000 | 92.4% | 53.0% | 15.98 (22.18) | 9.28 (21.75) | −15.49 (< .001) | 6.88 (4.97) | [5.86, 7.55] | .975 |

*Note.* Thresholds recorded in the sound booth–free approach were subtracted from those recorded in the sound booth; CI = confidence interval.

dB for the group with normal hearing. The absolute mean threshold difference *SD*s were 3.4–6.8 dB for the group with hearing loss and 3.9–5.5 dB for the group with normal hearing. Within 10 dB of consistency to standard audiometry, the mean sound booth–free thresholds for the group with hearing loss were 86% accurate at the 6000 Hz frequency; 96% accurate at 500, 2000, and 3000 Hz; and 100% accurate at 1000, 4000, and 8000 Hz. For the group with normal hearing, thresholds within 10 dB of standard audiometry were 89% accurate at the 6000 Hz frequency, 91% and 94% accurate at the 8000 and 4000 Hz frequencies respectively, and 95%–97% at the other frequencies. Significant differences ($p < .01$) between the sound booth and booth-free thresholds were observed across all frequencies for the group with normal hearing and for 1000, 3000, 4000, 6000, and 8000 Hz for the participants with hearing loss.

## Effect of Age

To test if age was a factor in increased variability between measurements, correlations were calculated between the participants' age and the absolute value of differences between the sound booth and booth-free thresholds for each frequency. No significant correlations were found for the 500, 1000, and 2000 Hz frequencies; however, correlations were significant ($p < .01$) at 3000 Hz and higher. Table 4 displays the results of these correlation calculations.

## Participant and Examiner Feedback

Participant (64) and examiner (four) feedback was evaluated to determine the efficacy of the computerized sound booth–free method. More participants (37.5%) preferred the standard sound booth testing compared with 28.4% who preferred the sound booth–free test, and 34.1% had no preference. Participants were asked to report on the comfort of the KUDUwave headset on a 3-point scale (*not at all comfortable*, *somewhat comfortable*, and *comfortable*). Outcomes showed that 84.4% reported that the equipment was either somewhat comfortable or comfortable, whereas 15.6% reported that it was not at all comfortable. No participants asked to stop the exam due to their discomfort. Examiners reported positive feedback on the ease of training and operation of the KUDUwave system. The initial challenges they experienced included slight difficulty putting in and taking out the ear insert while lifting the circumaural earcup of the headset off the participant's head, but this improved with practice and testing. The examiners did not observe any extreme negative reactions to the computerized sound booth–free testing experience.

# Discussion

The need for adaptable technology in hearing assessment was made necessary for the provision and continuity of services during the global COVID-19 pandemic. This study provided a clinical perspective on the validity and efficacy of KUDUwave audiometry, an automated software-based system with active noise monitoring, as an alternative to sound booth testing in a clinical setting. Clinical validity to within ±10 dB of standard audiometry was demonstrated for 94.5% of the total threshold measurements and for ≥ 88.5% of thresholds measured at 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz with the computerized, automated sound booth–free approach. Overall, the mean thresholds tested in the sound booth–free condition were lower at all frequencies, suggesting better thresholds than those tested using standard audiometry in the sound booth. The corresponding mean threshold *SD*s revealed a similar variability by frequency within the standard audiometry and sound booth–free approaches across participants. Accurate comparisons by hearing status were difficult due to the smaller number of ears with hearing loss ($n = 25$) than normal hearing ($n = 110$).

**Table 3.** Threshold (in dB HL) accuracy by frequency for the sound booth–free testing compared with the sound booth testing for participants with normal hearing and with hearing loss.

| | Hearing loss | | | | | Normal hearing | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Hz | % thresholds ±10 dB (range of differences) | *n* ears | *T* (*p* value) | Absolute mean difference in dB (*SD*) | 95% CI | % thresholds ±10 dB (range of differences) | *n* ears | *T* (*p* value) | Absolute mean difference in dB (*SD*) | 95% CI |
| 500 | 96% (–15 to 10) | 25 | 0.59 (.559) | –0.60 (5.07) | [–2.56, 1.36] | 95% (–20 to 15) | 109 | –2.85 (.005) | 1.51(5.55) | [0.47, 2.56] |
| 1,000 | 100% (–5 to10) | 25 | –4.32 (< .001) | 3.80 (4.40) | [1.84, 5.76] | 97% (–15 to 20) | 110 | –6.32 (< .001) | 2.73 (4.52) | [1.88, 3.57] |
| 2,000 | 96% (–25 to10) | 25 | –2.43 (.023) | 3.20 (6.60) | [1.24, 5.16] | 97% (–5 to 15) | 110 | –12.57 (< .001) | 4.68 (3.91) | [3.95, 5.41] |
| 3,000 | 96% (–10 to 30) | 25 | –3.51 (.002) | 4.80 (6.84) | [2.84, 6.76] | 96% (–10 to 20) | 110 | –8.09 (< .001) | 3.77 (4.89) | [2.86, 4.69] |
| 4,000 | 100% (0 to 10) | 25 | –9.44 (< .001) | 6.40 (3.39) | [4.44, 8.36] | 94% (–5 to 25) | 108 | –14.87 (< .001) | 6.62 (4.63) | [5.75, 7.49] |
| 6,000 | 86% (–30 to 25) | 22 | –7.85 (< .001) | 8.64 (5.16) | [6.68, 10.60] | 89% (–5 to 25) | 108 | –12.95 (< .001) | 6.28 (5.06) | [5.33, 7.23] |
| 8,000 | 100% (0 to 10) | 24 | –8.95 (< .001) | 7.08 (3.88) | [5.12, 9.034] | 91% (–10 to 20) | 108 | –13.24 (< .001) | 6.62 (5.20) | [5.63, 7.60] |

*Note.* CI = confidence interval.

**Table 4.** Correlation between participant age and the absolute value of differences between the sound booth and sound booth–free thresholds by frequency.

| Hz | Correlation | *p* value |
|---|---|---|
| 500 | .165 | .056 |
| 1,000 | .030 | .726 |
| 2,000 | .120 | .020 |
| 3,000 | .242 | .005 |
| 4,000 | .344 | < .001 |
| 6,000 | .265 | .002 |
| 8,000 | .477 | < .001 |

However, a similar percentage of accuracy to within ±10 dB of standard audiometry across frequencies was demonstrated in the mean hearing thresholds measured in the sound booth–free condition between the groups. Likewise, the absolute mean threshold difference *SD*s showed a similar variability between participants with normal hearing and hearing loss.

The overall threshold outcomes were not as precise to those found in other investigations of adults using KUDUwave audiometry in a sound booth–free environment that showed > 90% accuracy using a more stringent ±5 dB criterion (Maclennan-Smith et al., 2013; Storey et al., 2014; Swanepoel et al., 2015). Our findings across participants showed greater absolute mean threshold differences between the sound booth and sound booth–free measures at 4000–8000 Hz (6.5–6.9 dB) than at the lower frequencies (1.1–4.4 dB). The largest absolute mean threshold difference *SD* was 6.3 dB at 6000 Hz, indicating greater variability at that frequency, with less variability (*SD* = 4.4–5.5 dB) at the other frequencies. Similarly, Storey et al. (2014) reported greater variability at 6000 and 8000 Hz (*SD* > 7.1 dB) and the largest threshold difference (5.7 dB) at 8000 Hz.

However, the range of absolute mean threshold differences (1.1–6.9 dB) and *SD*s (4.4–6.3) between the sound booth and sound booth–free conditions found across participants in our study is within acceptable clinical variation. Typical pure-tone air conduction test–retest differences have been shown to range from 5 to 10 dB (Peterson & Bell, 2008; A. Stuart et al., 1991). Our study findings also showed a high correlation (≥ .91) between the thresholds measured using standard audiometry and the sound-booth free approach across all frequencies, as has been reported previously (Maclennan-Smith et al., 2013; Storey et al., 2014).

Subjective reports on the fitting and use of the KUDUwave headset have been mixed. Our outcomes that showed about 28% preferred the sound booth–free test, which differed from Swanepoel, Mngemane, et al. (2010), who noted that the majority (63%) of their participants preferred the automated pure-tone test using KUDUwave audiometry. However, our results supported that 62% of participants either preferred or were neutral to the sound booth–free test when compared with standard audiometry. Although most participants (84%) in our study reported the KUDUwave headset as somewhat comfortable or comfortable, previous investigators have reported average user ratings of slightly uncomfortable, suggesting that the pressure of the headset worn over time may be problematic for some (Storey et al., 2014).

The COVID-19 pandemic required many practices to shift their modes of hearing service delivery quickly to stay in business and to meet the needs of patient care safely, transforming hearing health care approaches during the pandemic and beyond (Swanepoel & Hall, 2020). The strength of our study is that it was conducted during the COVID-19 crisis in a clinic setting that was challenged with providing continuity of hearing services. Our experience supported that the computerized sound booth–free system is a practicable option. Compared with the expense of a diagnostic audiometer and sound booth used for the standard audiometry portion of this study, the KUDUwave equipment was approximately one third of the cost. The software can be downloaded for free from the manufacturer website (eMoyo Technologies, n.d.) onto multiple computers. Since the audiometer is software based with active noise monitoring occurring within the headset, the system is portable when using the software on a laptop, and we were able to conduct the training and testing in several different nonsound-treated room locations.

The examiner feedback from our study indicated that the KUDUwave system was easy to learn and operate. Our examiners were trained to perform KUDUwave audiometry within one day. Furthermore, the KUDUwave system can be used in varying modes. Although not directly evaluated during our study, the technology does have adaptable capability for testing in person using manual or automated audiometry as well as for use in teleaudiology testing remotely in synchronous or asynchronous platforms (eMoyo Technologies, n.d.). While only pure-tone air conduction testing was assessed in this study, the KUDUwave is a comprehensive system with capability for complete diagnostic hearing assessment including pure-tone air and bone conduction, speech audiometry, effective masking, and tympanometry.

There were several limitations that may have contributed to the outcomes of this study. There was a large age range in the participant cohort (i.e., 20–69 years), and when correlating the absolute value differences between the sound booth and KUDUwave measures with age, the correlations were significant at 3000 Hz and higher. This indicates, for this sample, that the differences in measurements are more variable for these frequencies as age increases. Previous investigations have shown accuracy of air conduction thresholds measured with KUDUwave audiometry to within 5 dB of standard measures across age groups ranging from children to older adults but did

not report on age effects: 5–8 years (Swanepoel et al., 2013), 18–31 years (Swanepoel, Mngemane, et al., 2010), 19–77 years (Swanepoel & Biagio, 2011), and 20–75 years (Swanepoel et al., 2015). Maclennan-Smith et al. (2013) compared KUDUwave audiometry in a natural environment to a sound booth in older adults age 65–94 years and found absolute air-conduction threshold differences (2.7 ± 3.1 dB) and *SD*s (2.6–4.0 dB) within previously reported values for the same audiometer (Swanepoel & Biagio, 2011; Swanepoel, Mngemane, et al., 2010). Storey et al. (2014) reported no significant age effect in the accuracy of KUDUwave results in participants 15–80 years of age; however, no correlation value was provided. The statistical differences and variability in hearing thresholds between the standard and sound booth–free measures found in our study and in comparisons with previous reports may be explained by the challenges imposed by COVID-19 and by procedural differences. The hearing thresholds measured in the sound booth during the standard audiometry task may have been affected by the open sound booth doors. The lower (better) hearing thresholds measured with KUDUwave audiometry in our study may be explained by a lower ambient noise attenuation that was provided by the combined insert earphone and circumaural headphone headset technology (Storey et al., 2014). Variation in examiner performance may have also been a factor. We used four examiners to conduct assessments, whereas other studies used single examiners (i.e., Maclennan-Smith et al., 2013; Storey et al., 2014; Swanepoel et al., 2015), and achieved greater internal validity in their findings.

Overall, the outcomes from this study support the use of sound booth–free, automated software-controlled audiometry with active noise monitoring as a valid and efficient procedure for hearing threshold measurement. This method offers an effective alternative when circumstances require more transportable hearing assessment technology or do not allow for standard manual audiometry in a sound booth.

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# Automated Audiometry: A Review of the Implementation and Evaluation Methods

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**Objectives:** Automated audiometry provides an opportunity to do audiometry when there is no direct access to a clinical audiologist. This approach will help to use hearing services and resources efficiently. The purpose of this study was to review studies related to automated audiometry by focusing on the implementation of an audiometer, the use of transducers and evaluation methods. **Methods:** This review study was conducted in 2017. The papers related to the design and implementation of automated audiometry were searched in the following databases: Science Direct, Web of Science, PubMed, and Scopus. The time frame for the papers was between January 1, 2010 and August 31, 2017. Initially, 143 papers were found, and after screening, the number of papers was reduced to 16. **Results:** The findings showed that the implementation methods were categorized into the use of software (7 papers), hardware (3 papers) and smartphones/tablets (6 papers). The used transducers were a variety of earphones and bone vibrators. Different evaluation methods were used to evaluate the accuracy and the reliability of the diagnoses. However, in most studies, no significant difference was found between automated and traditional audiometry. **Conclusions:** It seems that automated audiometry produces the same results compared with traditional audiometry. However, the main advantages of this method; namely, saving costs and increased accessibility to hearing services, can lead to a faster diagnosis of hearing impairment, especially in poor areas.

**Keywords:** Audiometry, Audiology, Hearing Loss

## I. Introduction

Automated healthcare services are used in the field of screening, diagnosis and intervention, in particular, when there is no direct access to specialists. This approach will help people to use health care services and resources more efficiently and effectively. Automated audiometry is an example of an automated healthcare service used for the automatic recording of hearing thresholds [1].

Bekesy audiometer was the first instrument used for automated audiometry and was introduced in the late 1940s [2]. This audiometer has been used in numerous studies, particularly to study the effect of noise on hearing. The new Bekesy audiometer automatically adjusts the sound intensity in the audio frequency range, and the patient presses a button when she/he hears a sound signal. This method is known as the method of adjustment. Another method used

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in automated audiometry is in concordance with performing manual or traditional audiometry. In this method, the audiometer increases or decreases the intensity of the signal automatically depending on the patient's response. This method is also known as the method of limits [1].

Generally, automated audiometry is increasingly used to improve access to care, to save time and costs, and to cover the lack of a specialist and to provide services to poor areas [3,4]. Automated audiometry is usually used in behavioral tests. These tests are divided into three categories: absolute detection thresholds, feature discrimination thresholds, and speech recognition testing. The first category is also called pure-tone audiology which is the main focus of this review study. The feature discrimination threshold test and speech recognition testing are used to obtain supplementary information about pure-tone audiograms [5].

The pure-tone threshold test is the most commonly used hearing test. This test is conducted in two ways: recording the air-conduction and the bone-conduction thresholds. In the air-conduction method, an earphone is used, and an audio signal passes through the outer and middle passageway and reaches the cochlea. In the bone-conduction method, an electromechanical earphone is placed on the skull, which stimulates the cochlea through a mechanical vibrator without the need to pass the audio signal through the outer and middle ear canal. Determining the threshold levels of air-conduction and bone-conduction help to differentiate between two types of hearing loss: sensorineural hearing loss and conductive hearing loss [6]. It is notable that automated audiometry needs to be evaluated in terms of diagnostic accuracy and reliability. There are a number of methods for evaluating automated audiometry to determine the quality of the tests when an audiologist is absent. These methods help to obtain high quality and accurate results which can be easily used in practice [4].

Although many studies have focused on the design, implementation and evaluation of automated audiometry [1], few studies have reviewed and compared the implementation and evaluation methods. The aim of this study was to review and summarize the latest studies related to automated audiometry by focusing on the implementation of an audiometer, the use of transducers and evaluation methods. This study can help to gain a better understanding of the topic by discussing the strengths and weaknesses of these methods.

## II. Methods

This review study was conducted in 2017. In this study, papers related to the design and implementation of automated audiometry were searched in the following databases: Science Direct, Web of Science, PubMed, and Scopus. The keywords were tele-audiometry, automated audiometry, audiometry and telehealth, audiometry and telemedicine. The time frame for the papers was between January 1, 2010 and August 31, 2017 to focus on the latest studies related to the implementation of an audiometer, transducers, and evaluation methods used for automated audiometry. The language was restricted to English. Initially, 143 papers were obtained; however, 71 papers were removed because of duplication, and one paper was removed because the abstract was unavailable. The remaining 71 papers were screened in terms of their relevancy to the research objective. In this phase, 53 papers were removed due to poor consistency with the aim of this study. In fact, any paper unrelated to pure-tone audiometry and automated audiometry was excluded from the study. In addition, papers that only focused on remote audiometry in the presence of an audiologist, remote consultation, and behavioral tests other than pure-tone audiometry, such as feature discrimination thresholds and speech recognition testing were excluded.

Finally, 18 papers remained; however, the full text was not available for two of them. As a result, 16 papers were included in the study. The process of selecting the papers for this research is shown in Figure 1.

## III. Results

As previously noted, 16 papers were selected for this study. These studies had been conducted in the United States (8 studies), South Africa (5 studies), Australia (2 studies), and Poland (1 study). In this study, different methods for the implementation of automated audiometry, transducers and evaluation methods are discussed (Table 1).

### 1. Implementation Methods

A review of the literature revealed that there are three ways to implement automated audiometry. These are software solutions [2,7-12], hardware solutions [13-15], and smartphone/tablet solutions [3,5,16-19]. Each of these solutions is discussed below.

#### 1) Software solutions

In a number of studies, a test called AMTAS (Automated Method for Testing Auditory Sensitivity) has been proposed for automated recording of pure-tone audiograms which includes both the air-conduction and bone-conduction thresh-


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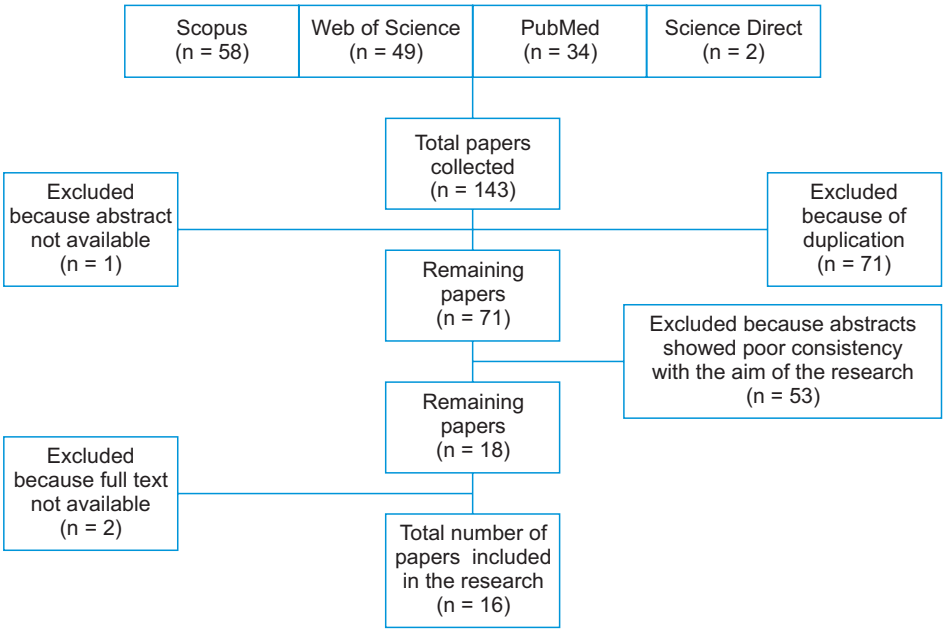


Figure 1. The process of selecting papers for the research.

olds. In this method, the patient uses 'Yes' and 'No' buttons on a touch screen to indicate whether she/he is hearing or not hearing an audio signal. The signal level differs according to the responder's response to determine the level of hearing threshold of the patient. When generating a signal, sound masking is produced on the ear that is not tested. Circumaural transducers are used in this test to reduce the level of ambient noise. This enables the test to be done in a quiet room instead of a soundproofed room [2,7-10].

In a study conducted by Margolis et al. [8], 30 participants (5 people with a normal hearing status and 25 individuals with hearing impairment) took part in the AMTAS test. The results showed that for air-conduction thresholds, the differences between the test values in the traditional method and the AMTAS were approximately similar to the differences in the values reported by two audiologists. However, for the bone-conduction thresholds, the differences between the recorded values with the AMTAS method and the manually recorded values were larger than the differences between the values reported by the two audiologists. Two reasons mentioned for these differences were incorrect reference-equivalent threshold force levels for bone-conduction through the forehead bone and a differential effect of middle ear diseases on the forehead and mastoid bone-conduction thresholds. Some studies showed that forehead bone-conduction thresholds are less affected by middle-ear diseases than mastoid thresholds for patients with conductive hearing loss. In another study conducted by Eikelboom et al. [2], the AMTAS test was performed in a quiet room for 44 participants with different levels of hearing impairment. The results indicated that the audiometry changes with the air-conduction and bone-conduction methods were within an acceptable level for the automated and manual methods. Although the AMTAS thresholds were higher compared to the manual methods, no significant difference was reported.

In another study, a software program called the Home Hearing Test (HHT) was developed to record the air-conduction thresholds at home. The purpose of this study was to compare the results of the tests performed by the patients with the results of the automated audiometry in a clinical setting. The difference between the HHT and manual thresholds was slightly higher than the recorded thresholds by two audiologists and the measured difference between the AMTAS results and the manual method in a clinical setting. Some of the reasons for this difference were a long time interval between the HHT test at home and the manual test in a clinic (53 days), the probability of environmental noise affecting the thresholds of the HHT and the differences among the participants in terms of the severity of hearing impairment [10].

The software solution is not limited to AMTAS, and different software has been developed for automated audiometry. For example, in Poland, web-based audiometer software was developed. Three tests were performed to evaluate the software: a manual test, an audiometry test under the supervision of an audiologist in a sound insulation room, and a test which could be done by the patient at home. There was no limitation for the type of earphones used to do the test at home. The results revealed that a web-based audiometer can be used in screening tests. Although performing audiom-

Table 1. Selected papers for research

| | Author, year | Country | Objective | Methods | Results |
|---|---|---|---|---|---|
| 1 | Meinke et al., 2017 [16] | USA | To assess the test–retest variability of hearing thresholds obtained with a mobile WAHTS to test industrial workers at a worksite compared to standardized automated hearing thresholds obtained in a mobile trailer sound booth. | System development and evaluation study | On average, the WAHTS resulted in equivalent thresholds as the mobile trailer audiometry at 1,000, 2,000, 3,000, and 8,000 Hz, and the thresholds were within ±5 dB at 500, 4,000, and 6,000 Hz. |
| 2 | van Tonder et al., 2017 [17] | South Africa | To validate the threshold version (hearTest) of the validated hearScreen smartphone based application using inexpensive smartphones (Android operating system) and calibrated supra-aural headphones. | System development and evaluation study | Within the adult sample, 94.4% of the thresholds obtained through a smartphone and conventional audiometry corresponded within 10 dB or less. Within the adolescent sample, 84.7% of the thresholds obtained at 0.5, 2, and 4 kHz with the hearTest and conventional audiometry corresponded within ≤5 dB. At 1 kHz, 79.3% of the thresholds differed by ≤10 dB. |
| 3 | Margolis et al., 2016 [10] | USA | To compare air-conduction audiograms obtained by the Home Hearing Test (HHT) to results obtained in a clinic. | System development and evaluation study | Threshold differences (clinic vs. HHT) were slightly larger than the differences between the thresholds obtained by two audiologists and AMTAS versus manual threshold differences obtained under laboratory conditions. The differences were not statistically significant. |
| 4 | Whitton et al., 2016 [5] | USA | To compare hearing measurements made at home using self-administered audiometric software against audiological tests performed on the same subjects in a clinical setting. | System development and evaluation study | Remote, automated audiograms were statistically equivalent to manual, clinic-based testing from 500 to 8,000 Hz ($p \leq 0.02$); however, the 250 Hz thresholds were elevated when collected at home. |
| 5 | Sandstrom et al., 2016 [3] | South Africa | To validate a calibrated smartphone-based hearing test in a sound booth environment and in primary healthcare clinics. | System development and evaluation study | In the sound booth, conventional thresholds exceeding 15 dB HL corresponded to the smartphone thresholds within ≤10 dB in 80.6% of the cases with an average threshold difference of –1.6 dB (SD 9.9). In the primary healthcare clinics, conventional thresholds exceeding 15 dB HL corresponded to the smartphone thresholds within ≤10 dB in 92.9% of the cases with an average threshold difference of –1.0 dB (SD 7.1). |
| 6 | Brennan-Jones et al., 2016 [14] | Australia | Examine the accuracy of automated audiometry in a clinically heterogeneous population of adults using the KUDUwave automated audiometer. | Evaluation study | The absolute mean differences ranged between 5.12–9.68 dB (air-conduction) and 8.26–15 dB (bone-conduction). A total of 86.5% of the manual and automated 4 FAs (thresholds at 0.5, 1, 2, and 4 kHz) were within 10 dB (i.e., ±5 dB); 94.8% were within 15 dB. However, there were significant ($p < 0.05$) differences between the automated and manual audiometry at 250, 500, 1,000, and 2,000 Hz (air-conduction) and 500 and 1,000 Hz (bone-conduction). |

Table 1. Continued 1

| | Author, year | Country | Objective | Methods | Results |
|---|---|---|---|---|---|
| 7 | Masalski and Krecicki, 2013 [11] | Poland | To determine the measurement error of the hearing threshold determined with an application of self-administered web-based pure-tone audiometry conducted at home and to identify and analyze factors influencing its value. | System development and evaluation study | The evaluation of the hearing threshold was made in three series: (1) tests on a clinical audiometer, (2) self-tests done on a computer under the supervision of an audiologist, and (3) self-tests conducted at home. The average difference between the value of the hearing threshold determined in series 1 and 2 was –1.54 dB (SD 7.88) and a Pearson correlation coefficient of 0.90. Between the first and third series, these values were –1.35 ± 10.66 dB and 0.84, respectively. In series 3, the SD was most influenced by the error connected with the procedure of hearing threshold identification (6.64 dB), calibration error (6.19 dB), and additionally at a frequency of 250 Hz. |
| 8 | Eikelboom et al., 2013 [2] | Australia | To validate the air-conduction and bone-conduction AMTAS automated audiometry system. | Evaluation study | For test-retest reliability, the overall difference in the air-conduction hearing thresholds was 0.5 dB. The spread of the differences was 4.9 dB. For the bone-conduction thresholds, the overall difference was –0.2 dB, and the spread of the differences was 4.5 dB. For the accuracy, the overall difference in the air-conduction hearing thresholds between the two techniques was 0.1 dB. The spread of the differences was 6.4 dB. For the bone-conduction thresholds, the overall difference was 0 dB, and the spread of the differences was 7.7 dB. |
| 9 | Khoza-Shangase and Kassner, 2013 [18] | South Africa | To determine the accuracy of uHear, a downloadable audiometer on an iPod Touch, when compared with conventional audiometry. | Evaluation study | Using the paired *t*-test, it was determined that there was a significant statistical difference between the hearing screening thresholds obtained from conventional audiometry and uHear. The difference in the thresholds may be attributed to the differences in the transducers used, the ambient noise levels and the lack of calibration for uHear. |
| 10 | Foulad et al., 2013 [19] | USA | To determine the feasibility of an Apple iOS-based automated hearing testing application and to compare its accuracy with conventional audiometry. | System development and evaluation study | On average, 96% of the threshold values obtained using the automated test in a sound booth were within 10 dB of the corresponding threshold values obtained using conventional audiometry. When the automated test was performed in a quiet room, 94% of the threshold values were within 10 dB of the threshold values obtained using conventional audiometry. Under standardized testing conditions, 90% of the subjects preferred the iOS-based audiometry as opposed to conventional audiometry. |

Table 1. Continued 2

| | Author, year | Country | Objective | Methods | Results |
|---|---|---|---|---|---|
| 11 | Swanepoel and Biagio, 2011 [13] | South Africa | To validate a computer-based, diagnostic air and forehead bone conduction audiometry when compared with conventional industry standard audiometry in a sound booth environment. | Evaluation study | Air conduction thresholds for two audiometers corresponded within 5 dB or less in more than 90% of instances, with an average absolute difference of 3.5 dB (SD 3.8). Bone conduction thresholds for the two audiometers corresponded within 10 dB or less in 92% of instances, with an average absolute difference of 4.9 dB (SD 4.9). |
| 12 | Margolis and Moore, 2011 [7] | USA | To measure the occlusion effect produced by three earphones (circumaural, supra-aural, and insert) and to compare air- and bone-conduction thresholds obtained with manual and automated methods for subjects with sensorineural hearing loss. | Evaluation study | The supra-aural earphone produced the largest occlusion effects, followed by the insert and circumaural earphones. Some systematic differences in the air-conduction thresholds were found for the two procedures that may be attributable to the earphone differences. |
| 13 | Margolis et al., 2011 [9] | USA | To evaluate an AMTAS for 4- to 8-year-old children, and a quality assessment method (QUALIND) that predicts the accuracy of the test. | Evaluation study | For most subjects (93% of the adults and 91% of the children), the differences between the AMTAS and manual thresholds were similar to the differences that occur when two experienced audiologists test the same subjects. QUALIND detected the inaccurate audiograms with a sensitivity of 71% and a specificity of 91%. When the inaccurate audiograms identified by QUALIND were excluded, the accuracy of the AMTAS was similar to the accuracy of the manual audiometry. |
| 14 | Yao et al., 2010 [12] | USA | To evaluate a web-based service, distributed pure-tone hearing assessment system that improves accessibility of traditionally poor groups to audiology care and to compare with conventional audiometry. | System development and evaluation study | Paired *t*-test results demonstrated that the remote hearing assessment is equivalent in effectiveness to its conventional counterparts at all tested frequencies (*p*-values are in the range of [0.12, 0.94]). |
| 15 | Swanepoel et al., 2010 [15] | South Africa | To investigate the reliability, accuracy, and time efficiency of automated hearing assessment using a computer-based telemedicine-compliant audiometer. | Evaluation study | Manual audiometry test-retest correspondence was 5 dB or less in 88% of the thresholds compared to 91% for automated audiometry. Thresholds for automated audiometry did not differ significantly from manual audiometry with 87% of the thresholds in the normal-hearing group and 97% in the hearing-impaired group, corresponding within 5 dB or less to each other. Both techniques were equally time efficient in the normal-hearing population, and 63% of the subjects preferred the automated threshold-seeking method. |

Table 1. Continued 3

| | Author, year | Country | Objective | Methods | Results |
|---|---|---|---|---|---|
| 16 | Margolis et al., 2010 [8] | USA | To evaluate the validity of the AMTAS, an automated method for obtaining an audiogram, including air- and bone-conduction thresholds with masking noise presented to the non-test ear. | Evaluation study | For air-conduction thresholds, the AMTAS manual differences were similar to the inter-tester differences between the audiograms for the paired audiologists, but for the bone-conduction thresholds, the former was larger. |

AMTAS: automated pure-tone audiometric procedure, WAHTS: wireless automated hearing-test system.

etry tests requires basic knowledge in the context of hearing thresholds or frequencies, a user friendly interface can be used when an audiologist is not available [11].

Another study was conducted in the United States in which a web-based distributed pure-tone hearing assessment system was developed. It had a three-layer architecture, which increased the scalability of the system to be integrated with other audiometry services. Moreover, the audiometry data were stored in a standardized database, which could be integrated with Electronic Medical Records. In terms of clinical effectiveness, the results showed that the web-based software worked similar to the traditional method at all frequencies. Moreover, the bandwidth required for the system was less than 1 MB/s [12].

### 2) Hardware solutions

In a number of studies, hardware solutions have been proposed to be used in automated audiometry. According to the literature, the KUDUwave portable audiometer [13-15] and an earphone designed to remove environmental noise [16] were among the hardware solutions proposed for performing automated audiometry. The KUDUwave is a portable audiometer that makes real-time audiogram recording possible. This audiometer controls the noise attenuation by using earphones and circumaural ear-cups and provides an opportunity for performing hearing tests down to zero dB with an environmental noise up to 59 dB SPL. Moreover, the environmental noise levels are continuously monitored, and if the environmental noise level exceeds the limit, the audiometry test will be stopped. Therefore, this test can be performed outside a sound insulation room [13]. The KUDUwave uses sound masking when it is needed. If the difference between the air conduction thresholds in the test and non-test ear is 75 dB or more when the frequencies are smaller than or equal to 1,000 Hz, or if the difference is 50 dB or more when the frequencies are larger than 1,000 Hz, a masking level of 30 dB is used above the non-test ear. For bone conduction thresholds, a continuous masking level of 20 dB is used above the non-test ear [13,14].

In a study conducted by Swanepoel and Biagio [13], the performance of the KUDUwave was evaluated for 30 individuals aged 19 to 77 years. The results indicated that the air-conduction thresholds had a difference of around 5 dB from the values recorded by the traditional method for 90% of the participants. The bone-conduction thresholds had a difference of around 10 dB from the values recorded by the traditional method for 92% of the participants. However, all the values reported by the KUDUwave were clinically ac-

ceptable. A small difference was seen in the test–retest. The results of the test–retest were approximately the same in 91% of cases when the KUDUwave audiometer was used and the difference range was 15 dB. For the traditional audiometer, the results were approximately the same in 92% of cases with a difference range of 10 dB. The reason for the small difference was unknown. However, it might be due to the bone vibrator attachment to the circumaural earphones that produces more static forces in the displacements [13].

In another study in Australia, the hearing status of people was evaluated by using the KUDUwave in the traditional and automated tests. The traditional test was done in a soundproof room, and the automated test was conducted in a room without sound insulation. The bone vibrator was placed on the mastoid bone in the traditional test, while it was on the forehead bone in the automated test. These factors, along with environmental noise, could affect the results. However, the results showed that the difference in the hearing thresholds was low. The results suggested that 86.5% of the recorded thresholds were in a 10-dB range. Although the differences in the thresholds became statistically significant, further research is needed to identify whether these differences are clinically meaningful [14].

The KUDUwave audiometer was also examined in South Africa. The air-conduction hearing thresholds of 30 participants with normal hearing status and 8 participants with hearing impairment were recorded using both automated and traditional methods. The results showed that the automated audiometry is a stable, accurate, and time efficient method to evaluate the hearing status of adults with normal hearing or hearing impairment. The combination of the automated audiometry with an asynchronous telehealth model, especially for poor areas with little access to hearing specialists, would be beneficial to improve health care services [15]. In a study conducted by Meinke et al. [16], a mobile wireless automated hearing-test system (WAHTS) was designed to reduce the environmental noise and to be used to record the hearing thresholds in a non-sound proof environment. The system performance was evaluated by examining the air-conduction thresholds of 20 workers in six locations, and the results were compared with the results of another test conducted by using computer-controlled audiometry in a mobile trailer sound booth. Overall, the difference between the thresholds obtained by WHATS and the thresholds obtained in the mobile trailer sound booth was within 5 dB [16].

### 3) Smartphone/tablet solutions

In a study conducted by Whitton et al. [5], a tablet-based application was developed in the United States. The test algorithm followed the same rules of the clinical test. The audio tones were provided for a time interval of 3 to 7 seconds, and the participants' responses were considered to be a correct answer even up to 2.5 seconds later. The test was conducted in a home and clinical environment. The difference between the mean values recorded at home and at the clinic was small. The thresholds recorded at home had increased for very low frequencies (≤250 Hz). This increase could be due to an increase in the ambient noise at low frequencies in a home environment. This study showed that it is possible to monitor hearing impairments outside a clinical environment.

In another study, a version of the hearScreen smartphone app was used to record the hearing thresholds. The exclusion criteria was a unilateral hearing loss of more than 40 dB HL to avoid inter-aural effects because contralateral masking was not considered in the prototype of the smartphone app. Conventional thresholds exceeding 15 dB HL corresponded to smartphone thresholds within ≤10 dB in 80.6% of the cases. This study suggested that air-conduction audiometry can be performed accurately by a smartphone-based audiometer in a soundproof room or outside a sound insulation room and in the healthcare clinics of poor areas [3].

The hearTest application was another app developed for Android smartphone-based audiometry. This app was used with a supra-aural earphone. However, no significant difference was seen between the app results and the traditional thresholds except for a 4 kHz frequency. In total, 70.6% of the thresholds calculated by the app and the traditional method had less than a 5 dB difference. Moreover, the duration of the test was not significantly different for the two methods [17].

uHear audiometer was another application developed by Khoza-Shangase and Kassner [18] in South Africa, and its accuracy was compared with the traditional approach. uHear is an automated screening test which is downloadable for iPod and iPhone. The participants of the study were 86 primary school students. The differences between the results obtained from uHear and the traditional method were significant at all frequencies. In this test, non-calibrated insert earphones were used for automated testing. The advantage of insert earphones compared to supra-aural earphones is reducing environmental noise with greater accuracy. However, this advantage can only be obtained if the earphones are correctly and recently calibrated. Because the study was conducted in a school environment, environmental noise could affect the outcomes. That might be the reason why


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uHear was not as accurate as the traditional audiometry in determining the hearing thresholds for primary school children. This study showed that caution should be exercised in using uHear and that further research evidence is needed to use it at a general level.

Another iOS-based application was developed to be used on the iPhone, iPod touch and iPad. The hearing thresholds were recorded with an automated method in a quiet room as well as in a sound insulation room. Sound masking was applied automatically when the difference between the threshold values of the two ears was greater than or equal to 35 dB. The sound masking included a narrowband noise centered at the frequency that was tested. The results showed that on average, 96% of the thresholds recorded in the sound insulation room with the automated test had a difference in the range of 10 dB compared to the thresholds recorded in the sound insulation room with the traditional method. In a quiet room, this amount reached 94%. The results indicated that the obtained thresholds were close to traditional audiometry results, and the iOS-based tools provided a platform for conducting automated audiometry with no need for additional equipment [19].

## 2. Transducers

A review of the studies showed that the most important transducers used in the implementation of an automated audiometry system included earphones and a bone vibrator which are discussed below separately.

### 1) Earphones

Having reviewed the literature, it was revealed that there are two important factors regarding the choice of earphones or their design when using them for audiometry tests. The first factor is related to reducing environmental noise, and the second factor is related to the occlusion effect of the earphone. It is notable that the background noise in the test room is called environmental noise. Because the automated audiometry test might be performed in an environment outside a sound insulation room, the environmental noise levels must be minimized to be able to record the hearing thresholds precisely. The ambient noise level should be much lower than the test signal level, so that the listener can distinguish the test signal from the environmental noise [16]. The occlusion effect causes a change in the values recorded for the bone-conduction thresholds (usually an incremental change) due to the obstruction of the ear canal. The skull vibration is transmitted to the walls of the external ear canal and tympanic membrane. When the ear canal is not clogged, the ear canal acts as a high-pass filter, and low-frequency sounds are removed. When the canal is clogged, the low-frequency energy falls to the trap and transmitted into the inner ear [20].

The standard procedure for measuring the bone-conduction thresholds is to perform the test in a condition in which the ear canals are not clogged. On the other hand, earphones are used to record the air-conduction thresholds. If the earphone does not produce the occlusion effect, the earphones can be kept on the ears during the test. This feature enables recording the air-conduction and bone-conduction thresholds with no need to switch earphones and causes no interruptions during the test [7]. In general, noise reduction techniques improve the value for hearing thresholds for low frequencies by using two active and passive modes. The passive technique attempts to prevent the environmental noise from entering the ear canal. In the active noise elimination technique, a microphone is used to measure the amount of noise in the environment, which is neutralized by using environmental noise opposing signals [5].

The available earphones can be divided into three main categories: circumaural, supra-aural, and insert earphones. Figure 2 shows how each earphone couples to the external ear. The KUDUwave audiometer is powered by circumaural ear cups with insert earphones to control the environmental noise. Moreover, there are microphones in the inner and outer parts of the earphones to monitor the ambient noise, and if the level of ambient noise exceeds the limit, the audiometry test is stopped. These features help to perform the evaluation with a better quality in an environment outside of a soundproof room [13].

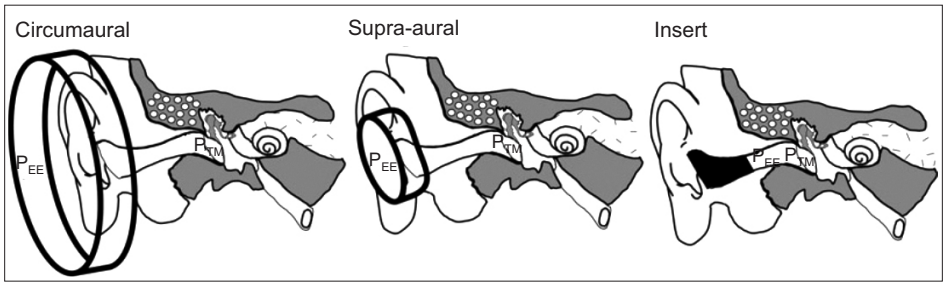


Figure 2. Different types of earphones.

In a study conducted by Meinke et al. [16], a headset was designed to reduce the environmental noise and to be used to accurately record the hearing thresholds outside an insulating room and in an industrial environment. The headset was relatively large and heavy to do passive attenuation. It had multiple layers to eliminate environmental noise by a passive technique. The ear cup with thick polyurethane foam, a speaker, a plastic face plate, a thin protective fabric and an ear seal from hearing protectors were lined to eliminate noises. The test–retest reliability results were equal or better than the results from the supra-aural, insert and circumaural earphones.

In another study, the occlusion effects created by earphones were highlighted. One of the important points in performing an automated audiometry test is to prevent the occlusion effects created by earphones. Supra-aural earphones produce a significant occlusion effect at frequencies of 1 kHz or lower. Insert earphones also produce a significant occlusion effect unless completely inserted into the ear canal and into its bony part. Putting the earphones in this way is not possible in routine tests due to the lack of comfort and safety; however, if the earphone is put around the ear and a large volume of air is placed inside, it can eliminate the occlusion effect. The results of this study showed that the occlusion effect produced by circular earphones for frequencies above 500 Hz is so insignificant, and the thresholds recorded in the bone-conduction test with this type of earphone are similar to the thresholds recorded without earphones. Therefore, according to the results, the circumaural, insert and supra-aural earphones had a better performance in not generating the occlusion effect, respectively [7].

#### 2) Bone vibrator

One of the important technical factors in an automated audiometry test is the location of placing the bone vibrator. The vibrator is used to generate signals for determining the bone-conduction thresholds. The two common methods for producing these signals are the use of the mastoid bone and the forehead bone. The mastoid bone is used mostly in traditional audiometry techniques [7]. In the case of using the mastoid bone, the vibrator needs to be placed on the left and right ears and between the ears. To increase the efficiency, it is better not to move the oscillation tool from one ear to another ear. The forehead bone is preferred in automated testing, since there is no need to change the vibrator placement during the test [8].

The KUDUwave audiometer uses a bone vibrator that is placed on the forehead bone. In this audiometer, the insert earphones are used during the testing of the bone-conduction thresholds. As previously mentioned, the earphones should be deeply inserted into the bone part of the ear canal to avoid the occlusion effect of insert earphones. According to the results, the correlation between the bone-conduction thresholds in the test–retest is slightly less than the measured values in the traditional audiometry tests, although they were within acceptable limits. The reason for this small difference was unknown. It might be partly due to the bone vibrator which was attached to the circumaural earphone and generated more static force in the movements [13].

In the case of using the forehead bone, the earphones are used on both ears. When testing each ear, sound masking is produced on the other ear. Therefore, it is important that the earphones create a small amount of obstruction to have no effect on the bone-conduction thresholds. The difference between the two traditional and automated methods in the bone-conduction thresholds is greater than that of the air-conduction mode. This difference can be due to the difference in the position of the vibrator on the mastoid bone and the forehead bone or due to middle ear diseases, which affect the sensitivity of the bone-conduction thresholds in both the mastoid and forehead methods. The forehead method estimates the cochlea sensitivity with a higher accuracy [8].

### 3. Evaluation of Automated Audiometry

To evaluate the accuracy of automated audiometers, the results of automated and traditional methods can be compared. The traditional method is selected as the gold standard, and the results of the automated method are compared to the gold standard. Audiometry tests can be performed with traditional or automated methods either consecutively or at intervals. In the consecutive method, it is better to have a balance between the tests due to the possible impact of learning, fatigue, attention and motivation on the results of the tests. According to World Health Organization definitions, the assessment of people's hearing levels can be divided into normal hearing, disabling hearing impairment, conductive hearing impairment and unilateral hearing impairment. Then, the level of agreement can be calculated between the traditional and automated methods [21]. In a study, the results of automated audiometry were compared with the traditional method for a sample of patients to examine the reliability and generalization of the test results. The selected sample included patients with chronic tinnitus disorder who had from a normal hearing status to severe hearing impairment. According to the findings, the results of both methods were similar at the frequencies of 500 to 8,000 Hz [5].


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The test–retest method is another method used to evaluate the reliability of the hearing tests. In this method, the test–retest difference value of a standard audiometer is calculated [5,13]. In another method, the difference between the automated approach and the traditional method is compared with each other. Moreover, the mean value of the hearing thresholds can be compared between two audiologists on a participant and by using the traditional method. The mean value can be compared to the result of an automated test to measure the accuracy of this test, too. If the difference between the automated method and the traditional method is not greater than the mean value, it means that the automated method does not have much of a difference from that of the traditional method of audiometry. The mean value can also be used as a criterion to measure the reliability of the traditional method [8].

The results of automated audiometry can also be evaluated by using qualitative methods. In the traditional method, it is assumed that a skilled audiologist can observe the specific characteristics and behaviors of a patient and can use them to predict the validity of the test. In an automated test, there is a need to use an alternative method to evaluate the quality and accuracy of the test results, mainly due to the absence of an audiologist. To achieve this, a method called QUALIND has been proposed. This is a qualitative assessment method for determining the accuracy of the automated test results by using measurable factors, such as the behaviors and characteristics of a patient. In an automated test, the following factors can be used to predict the validity of the results: patient's age and gender, the duration of the test, the average time for determining each frequency, the rate of wrong warnings, the difference between the test–retest and the number of cases in which the difference between the air and bone conduction thresholds was more than 50 dB [22]. In a study conducted by Margolis et al. [9], the QUALIND method was used to assess the AMTAS results of children. This method detected incorrect audiograms with a sensitivity of 71% and a specificity of 91%. After removing the incorrect audiograms, the AMTAS accuracy was similar to the manual audiometry accuracy. This method can reduce the costs and increase the efficiency and accessibility of audiometry test.

## IV. Discussion

The audiometry of pure-tone thresholds is based on a series of distinct steps and can be implemented in the form of an automated process [4]. In addition, if a computer is used, the results are automatically recorded and can be transferred to other professionals easily. Moreover, performing automated audiometry can improve the standardization of the test procedures [1] and facilitate patient monitoring in poor areas [23].

The results of the current study showed that different software and hardware solutions have been used for automated audiometry. As smartphones become ubiquitous, new opportunities have arisen for presenting innovative solutions, especially in poor and remote areas [19], and a variety of audiometry applications have been developed to be able to record the audiograms at different times and places by using a smartphone [3]. The smartphone application can be an affordable and a valid method to determine the air-conduction hearing thresholds [17]. Although the use of technology has some advantages, the limitations of technology should not be underestimated. For example, due to the limitation of smartphones in generating different audio frequencies and intensities, these applications can only be used for general screening programs when traditional audiometry tests are not available [19]. Another limitation is about sound calibration. Unlike an audiometer, the output sound of smartphones is not calibrated, and it may not meet the requirements of audiometry. Moreover, the hardware of smartphones and audiometers is different, and the accuracy of the results should be examined [24]. It seems that more studies are required to identify the strengths and limitations of computerized solutions for automated audiometry to be able to design more effective solutions in the future.

According to the results, two important audiometric transducers are earphones and bone vibrators. As one of the challenges of using automated audiometry is environmental noise, especially at low-frequencies [10], different types of earphones can be used to reduce the environmental noise through active or passive techniques [5]. These features help to perform a high quality test outside of a sound proof room [13]. Moreover, the literature review showed that the bone-conduction thresholds should be measured along with the air-conduction thresholds to diagnose the type of hearing impairment [5]. In traditional audiometry, earphones are removed from the ear for a bone-conduction hearing test to prevent them from producing occlusion effects, while in automated audiometry, due to the absence of an audiologist, it is better to keep the earphones on the ears to record the bone-conduction hearing thresholds. This approach can increase the test quality [7]. However, there are different types of transducers, and the use of each type may affect the results of the automated audiometry and hearing impairment diagnosis. Therefore, it is essential to use those transducers

that have been previously tested and can produce results as accurate as the tests conducted by clinicians.

The results showed that the benefits of automated audiometry are only achieved when the quality of the produced audiograms is at least similar to that of traditional audiograms. Inaccurate audiograms may lead to test repetition, increased costs, and a waste of time [4]. To assess the validity of the automated audiometry test, there are different methods for evaluation. For example, the difference between the threshold values reported in traditional and automated audiometry have been calculated in different studies, and the reported values in a range of 5–10 dB have been considered acceptable [2,3,13-17,19]. In another study, the correlation coefficient between the values obtained from the automated and the traditional method was calculated [11]. In other studies, the difference between the values reported by the automated and the traditional method was compared with the difference between the values reported by two audiologists [8-10]. In most studies, the results of automated audiometry were similar to the traditional approach, and it seems that traditional audiometry can be replaced with an automated approach. However, as mentioned before, different automated solutions and different transducers may produce different results, and as a result, conducting evaluations are inevitable.

In conclusion, automated audiometry produces clinically acceptable results compared with traditional audiometry. The two main advantages of automated audiometry are saving costs and improving accessibility to hearing care, which can lead to a cost-effective and rapid diagnosis of hearing impairment, especially in poor areas. The use of automated audiometry may have some challenges, such as measuring the impact of environmental noise on the test results, recording bone-conduction hearing thresholds with the possibility of generating occlusion effects by the earphones, and ensuring the quality of the automated audiometry test results. Further studies need to be conducted to compare the characteristics of different computerized solutions and related challenges for automated audiometry. Because the performance of transducers are different, evaluation studies are needed to compare their performance to be able to choose the best one for automated audiometry.

## Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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**Original Article**

# Ambient noise impact on accuracy of automated hearing assessment

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The Nordic Audiological Society
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## Abstract

*Objective:* The aim of this study was to determine the effect of ambient noise on the accuracy of thresholds obtained using the KUDUwave portable clinical audiometer as compared to those obtained using a GSI-61 clinical audiometer in a sound booth. *Design:* Pure-tone air conduction thresholds were obtained in three conditions: (1) with a clinical audiometer in a quiet sound booth, (2) with the KUDUwave in a quiet sound booth, and (3) with the KUDUwave with 40 dBA of background noise. *Study sample*: A total of 31 individuals ranging in age from 15 to 80 years participated in the study, 21 with normal hearing and ten with hearing loss. *Results:* Eighty-nine percent of thresholds obtained with the KUDUwave in quiet, and 92% of thresholds obtained with the KUDUwave in background noise were within 5 dB of those obtained with the clinical audiometer. Accuracy was poorer at 250 Hz and 8000 Hz. *Conclusion:* Ambient noise typical of that found in a non-sound-treated room, did not affect the accuracy of air conduction hearing thresholds obtained with the KUDUwave. The KUDUwave may be a viable method of testing when a clinical audiometer and sound booth are not available.

**Key Words:** Behavioral measures; instrumentation; medical audiology; noise

Throughout the world, 360 million people suffer from moderate to profound hearing loss (World Health Organization [WHO], 2013). Hearing loss can be debilitating, causing communication difficulties and consequent isolation and depression. Fortunately, it is also treatable through careful diagnosis, medical care, and the use of amplification. However, more than two-thirds of those with hearing loss, live in low- and middle-income countries with limited access to treatment (WHO, 2013). One promising answer to this problem is tele-audiology testing in real-time through video conferencing. Although remote audiology is a means to provide audiological care in underserved areas, the availability of proper equipment, such as an audiometer and sound booth, remains an obstacle.

GeoAxon Holdings, a South African company, has developed one potential solution to address these difficulties: the KUDUwave audiometer. This portable hearing assessment unit consists of sound-attenuating headphones that contain a fully functional audiometer inside the headset. The KUDUwave has an automatic mode as well as the capability to test manually or remotely via the internet (GeoAxon KUDUwave 5000 audiometer, South Africa).

Other automated hearing assessment solutions have also been recently developed and tested. Foulad et al (2013) compared air conduction thresholds using EarTrumpet (an Apple iOS-based application) in a sound booth and in a quiet room to thresholds obtained using a standard audiometer in a sound booth. The iPhone application was accurate within ± 5 dB for 88% of the time in a quiet room. Margolis et al (2010) studied the Automated Method for Testing Auditory Sensitivity (AMTAS$^{R}$) system by testing 30 individuals. Five participants had hearing loss and 25 participants had normal hearing. They compared inter-tester threshold differences and threshold differences measured between AMTAS and a clinical audiometer. The inter-tester differences were measured by comparing thresholds found by a tester in one location to those found for

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**Abbreviation**

AMTAS Automated method for testing auditory sensitivity

the same individual by a different tester in a different location. They found the difference between AMTAS and manual testing with clinical audiometers (−0.1 dB) to be smaller than the mean inter-tester difference (0.6 dB) using clinical audiometers.

A potential benefit of the KUDUwave is that it was designed to be used where a sound booth is not available by attenuating background noise and by incorporating monitoring of ambient noise levels. The KUDUwave unit consists of foam insert earphones that are then surrounded by circumaural noise-attenuating headphones. The attenuation provided, as determined at the University of Pretoria, South Africa, is slightly lower than that of a sound booth (See Appendix A in the online version of the journal. Please find this material with the direct link to the article at: http://informahealthcare.com/doi/abs/10.3109/14992027.2014.920110.) (GeoAxon: KUDUwave 5000 audiometer). In addition, using multiple external and internal SPL sound meters, the KUDUwave continually monitors ambient noise (e.g. traffic, people talking, environmental sounds) and only tests during periods when ambient noise falls below the noise floor limit. GeoAxon's specifications indicate that through this combination of attenuation and monitoring, a patient can be tested reliably to −10 dB HL in 55 dBA of ambient noise, and to 0 dB HL in 70 dBA of ambient noise (GeoAxon: KUDUwave 5000 audiometer).

Studies using the KUDUwave audiometer have shown comparable audiological results between the KUDUwave unit and a clinical audiometer. Swanepoel, Mngemane and colleagues (2010) compared the accuracy of KUDUwave's automated mode with manual audiometry in a quiet sound booth. They tested 30 normal-hearing individuals and eight individuals with hearing loss and found that 91% of thresholds obtained using the KUDUwave's automated mode, were within 5 dB of those obtained using the manual mode. Swanepoel, Koekemoer and Clark (2010) used the KUDUwave to test 30 normal-hearing individuals remotely and face-to-face in a quiet sound booth. Using a physician as the facilitator at a test site in South Africa, an audiologist in North America tested air and bone-conduction thresholds. Thresholds obtained remotely were within 10 dB of those obtained in person 96% of the time.

A recent study used the manual mode of the KUDUwave to compare threshold accuracy in the presence of background noise to those obtained in a sound booth (Maclennan-Smith & Hall, 2013) They compared thresholds for 147 hearing-impaired individuals obtained using the KUDUwave in its manual mode in a retirement facility with ambient noise levels of 47–54 dBA of background noise with those obtained using the KUDUwave in a quiet sound booth. They found that 95% of air conduction thresholds and 86% of bone conduction thresholds were within ±5 dB. The purpose of the present study was to investigate the accuracy of pure-tone air conduction thresholds obtained by the KUDUwave in its automated mode with a controlled level of background noise at a level that would typically be present in a closed non-sound-treated room.

## Methods

A cross-sectional design was used to compare hearing threshold results for three test conditions. Utah State University Internal Review Board (IRB) approval was obtained for the study and participants signed an informed consent prior to testing.

### *Participants*

Individuals were recruited for this study from the Utah State University Hearing Clinic and local community. Inclusion criteria were (1) age, 13 years and older, (2) English-speaking, (3) normal or impaired hearing (thresholds greater than 20 dB at two frequencies, and (4) no outer- or middle-ear pathology. Participants were excluded if they had ear pain or drainage, recent changes in hearing or balance, outer ear blockage as determined using a Welch Allyn clinical otoscope, middle-ear dysfunction as determined with tympanometry using the GSI Tympstar immittance bridge, and asymmetrical hearing loss requiring masking. Participants were paid $10 for their time.

### *Study procedure*

A brief case history was completed followed by otoscopy and tympanometry to determine the participant's eligibility. Pure-tone air conduction hearing thresholds were obtained in three conditions: (1) with a GSI-61 clinical audiometer in an American National Standards Institute (ANSI) certified double-walled sound treated booth, (2) with the KUDUwave in a quiet ANSI-certified sound booth, and (3) with the KUDUwave inside an ANSI-certified sound booth with 40 dBA of background noise present. Audiometry in all three conditions included all octave and inter-octave frequencies between 250 and 8000 Hz for a total of 10 frequencies per ear for each condition. Manual pure-tone air conduction audiometry followed the guidelines as outlined by the American Speech Language and Hearing Association (ASHA, 2005). The KUDUwave is controlled by EMOYO, a proprietary PC-based software application which has a manual option and automatic screening, diagnostic pure tone, and speech testing options. The KUDUwave was set to its automatic diagnostic mode, which used a bracketing threshold search method similar to the Hughson-Westlake method to automatically obtain subject thresholds. The order of the testing methods (i.e. clinical audiometer, KUDUwave in quiet, KUDUwave in noise) was counterbalanced to control for test order effects. Test order was assigned to each participant systematically to ensure that each test order combination was used the same number of times. Testing for each patient was completed in a one-hour session.

The examiner, a graduate student in audiology, was blind to the results obtained from the KUDUwave to minimize tester bias during hearing threshold measurement using the clinical audiometer. To accomplish this, a separate research assistant facilitated the KUDUwave testing and recorded the results. The same graduate student and research assistant conducted testing for all of the subjects. The graduate student instructed the participants for each test procedure.

At the end of each session, the participant was asked to rate the overall comfort of the KUDUwave headset on a 10-point scale (1 = extremely comfortable, to 10 = extremely uncomfortable).

### *Equipment & test procedures*

Testing was completed in a double-walled sound-treated booth for all conditions to ensure controlled conditions for testing. Calibration of all audiometric equipment was performed as recommended by ASHA according to ANSI specifications, within one year prior to testing. Pure-tone air-conduction thresholds were obtained for each ear using a GSI-61 clinical audiometer and 3A insert earphones with foam tips. For consistency in probe placement, the probe tip was inserted into the ear canal until the end of the probe tip was

flush with the opening of the external auditory meatus. The subjects were seated in the sound booth facing away from the examiner and responded to the pure tones using a response button.

The automated audiometric testing was completed using the Geo Axon KUDUwave 5000 portable audiometer. The test process was automated and recorded on a laptop computer. Testing was completed inside the sound booth both in quiet and with calibrated 16-talker babble (Department of Speech and Hearing Sciences, University of Illinois, 2003) being introduced into the room through three sound field speakers located 32 inches from the participant's chair at 0 and 45 degree horizontal azimuth. The background noise was gated and its level was controlled through the second channel of the clinical audiometer. The intensity of the background noise was 40 dBA as measured prior to the study by a Larson Davis (Provo, USA) 800b Type 1 sound-level meter at the location and approximate level where a patient's head would be. The 40 dBA level was determined by measuring ambient noise levels in a variety of educational and medical settings in Utah. These sound-level meter readings are outlined in Appendix B, available in the online version of the journal. Please find this material with the direct link to the article at : http://informahealthcare.com/doi/abs/10.3109/14992027.2014.920110. (GeoAxon: KUDUwave 5000 audiometer). Based on these measurements, the 40 dBA noise level was determined to be achievable in actual testing situations by testing in a closed non-sound-treated room. Neither the clinical audiometer testing condition nor the KUDUwave testing conditions exceeded the maximum permissible ambient noise levels (MPANLS) for insert earphones (3M™ E-A-RTONE™ 3a). Since the KUDUwave provides greater attenuation than inserts, it was determined that MPANLs were not exceeded during any of the study conditions.

To reduce set-up time and increase consistency, the testing protocol selections were saved in the EMOYO software's macro function, which enabled protocol parameters to be pre-programmed. The set-up selections contained in the macro are outlined in Appendix C available in the online version of the journal. Please find this material with the direct link to the article at: http://informahealthcare.com/doi/abs/10.3109/14992027.2014.920110. (GeoAxon: KUDUwave 5000 audiometer). The examiner placed the insert earphones and headset on the subjects. The research assistant monitored the progress of the test and was available in case the KUDUwave malfunctioned or the test ended prematurely.

### *Analysis*

To determine threshold accuracy, differences were calculated between testing conditions for each frequency and percentages of accurate thresholds were calculated; mean threshold differences were calculated for each frequency; correlations between results from the clinical audiometer and the KUDUwave were calculated; and an independent sample t-test was used to analyse by group (i.e. normal hearing, hearing impaired). SPSS (v21) software was used for analyses.

## Results

Thirty-five individuals ages 15 to 80 were recruited for testing. Three participants did not complete testing due to a KUDUwave software malfunction that caused a failure to record any thresholds despite numerous responses by the participant. This software failure occurred at 3000 Hz at −10 dB HL. One participant became ill and could not complete testing, resulting in 31 participants (62 ears) that were included in the analysis. Participant demographics are provided in Table 1. The mean thresholds and ranges for the cohort at each frequency are shown in Figure 1. Three ears demonstrated large negative differences between the clinical audiometer and the KUDUwave across all frequencies, indicating the KUDUwave systematically recorded significantly poorer thresholds for those participants. Table 2 shows the age and threshold differences for the outliers. All three outlier subjects were college-educated individuals with normal cognitive and language ability. Two had mild to moderately-severe sensorineural hearing loss and one had normal hearing. Results were reported both with and without the outliers. Test order effects were not present ($F$ (5,54) = .564, $p$ = .73).

**Table 1.** Participant demographics.

| | *N (ears)* | *Percent* | *Mean* | *SD* | *Range* |
|---|---|---|---|---|---|
| Age | | | | | |
| Hearing loss | 20 | | 35 | 22.18 | 15 to 80 |
| Normal hearing | 42 | | 23 | 4.53 | 19 to 53 |
| Females | | | | | |
| Hearing loss | 10 | 50 | | | |
| Normal hearing | 28 | 67 | | | |
| Males | | | | | |
| Hearing loss | 10 | 50 | | | |
| Normal hearing | 14 | 33 | | | |
| Pure-tone average | | | | | |
| Hearing loss | 20 | | 35 | 26.76 | 0 to 90 |
| Normal hearing | 42 | | 6 | 5.45 | −2 to 22 |

Note. Pure-tone averages were calculated from thresholds at 500 Hz, 1000 Hz, and 2000 Hz obtained using the clinical audiometer.

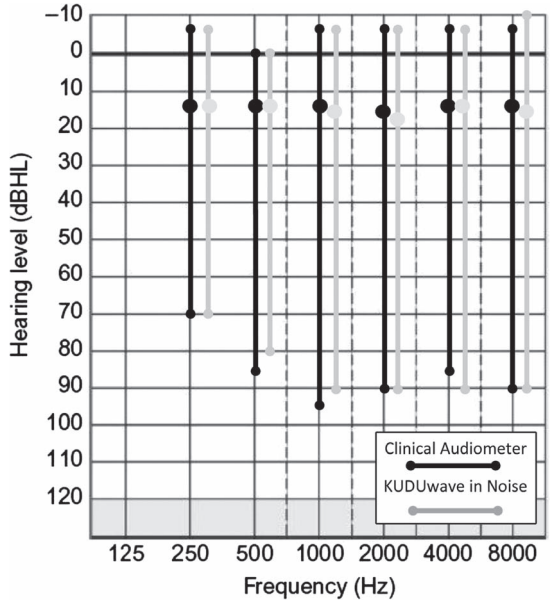


**Figure 1.** Mean, minimum and maximum audiometric thresholds by frequency. Means are indicated by large circles. Minimums and maximums are indicated by small circles. Thresholds using a clinical audiometer in quiet are shown in black, and thresholds obtained using the KUDUwave in noise are shown in grey.

**Table 2.** Outlier threshold difference data.

| *Subject #, and ear* | *Age of participant* | *Condition* | *250* | *500* | *750* | *1000* | *1500* | *2000* | *3000* | *4000* | *6000* | *8000* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 9, right | 49 | Quiet | −25 | −20 | −20 | −10 | −15 | −20 | −25 | −20 | −20 | −20 |
| | 49 | Noise | −35 | −25 | −20 | −10 | −25 | −20 | −20 | −25 | −20 | −20 |
| 10, right | 25 | Quiet | −60 | −55 | −55 | −50 | −45 | −65 | −50 | −50 | −55 | −60 |
| 30, left | 80 | Quiet | −40 | −35 | −30 | −20 | −10 | −20 | −15 | −10 | −15 | −25 |

Note. Differences between the clinical audiometer and the KUDUwave. Negative differences indicate the KUDUwave had higher (poorer) thresholds.

*Accuracy of thresholds*

The percentage of accurate thresholds was calculated by comparing thresholds obtained by the KUDUwave in quiet and in noise to those obtained with the clinical audiometer. An accurate threshold was defined as any KUDUwave threshold that was within ±5 dB of those obtained using the clinical audiometer. The KUDUwave produced accurate thresholds 89% of the time in the quiet condition and 92% of the time in the noise condition. When the outliers were not included, the percentages were 96% and 94% respectively for the quiet and noise conditions. The percentage of accurate thresholds, the means and standard deviations of the differences, and the mean absolute value of the differences between the KUDUwave and the clinical audiometer are shown in Table 3. Figure 2 shows the median difference scores, inter-quartile ranges and 95% confidence intervals for the noise and quiet conditions. The statistical outliers (ears with larger mean differences) are indicated by circles and asterisks above and below the box plots.

*Differences by frequency*

To determine differences in accuracy of the KUDUwave based on stimulus frequency, percentages of accurate thresholds were calculated for each of the 10 frequencies for each testing condition (quiet and noise). As can be seen in Table 4, thresholds were more accurate in the mid-frequency region from 500 to 6000 Hz. The standard deviations were also larger at 250 and 8000 Hz, indicating greater variation at those frequencies. Correlations were high between thresholds obtained using the clinical audiometer and the KUDUwave for all frequencies.

*Effect of hearing status*

To determine the effect of hearing loss on the accuracy of KUDUwave thresholds, a percentage of accurate thresholds was calculated for those with normal hearing and those with hearing loss in each of the conditions (quiet and noise). Table 5 shows overall percentages of accurate thresholds and overall mean threshold differences for the two groups as well as the percentage of accurate thresholds by frequency for the two groups.

A t-test was conducted between the mean threshold differences of those with hearing loss and those with normal hearing. The results were not statistically significant ($t\ (60) = 0.22$, $p = .83$ in quiet; and $t\ (60) = -0.55$, $p = .58$ in noise). However, with the outliers removed, the difference between the groups reached the level of significance for the noise condition $t\ (57) = -2.51$, $p = .02$, indicating that the mean difference between the KUDUwave and the clinical audiometer for the normal group was statistically significantly greater than for the group with hearing loss. In the quiet condition, the difference was still not significant even with the outliers removed ($t\ (53) = 0.38$, $p = .70$), indicating that the observed differences in accuracy of thresholds between the two groups fell within the range of error.

*Effect of age*

To determine whether age played a factor in the accuracy of KUDUwave results, a correlation was calculated between subject age and the mean absolute value of differences between the standard audiometer and the KUDUwave in both the quiet and noise conditions. No significant correlations were found with or without outliers included.

*Comfort of the KUDUwave headset*

At the end of each testing session, the participant was asked to complete a rating form to indicate their comfort level during testing. Comfort of the KUDUwave headset was rated on a 10-point scale (1 = extremely comfortable and 10 = extremely uncomfortable). The average rating was 5.4, which fell between "slightly comfortable" and "slightly uncomfortable." Those who rated the KUDUwave to

**Table 3.** Accurate thresholds and mean threshold differences.

| | *N ears* | *% Thresholds within 5 dB* | *M difference in dB* | *SD* | *M Abs difference in dB* | *Range of differences* |
|---|---|---|---|---|---|---|
| Quiet condition | 62 | 88.54 | −2.20 | 8.00 | 4.39 | −60 to 30 |
| Excluding outliers | 59 | 95.71 | −0.68 | 2.44 | 2.99 | −35 to 30 |
| Noise condition | 62 | 91.77 | −1.08 | 3.73 | 3.47 | −35 to 35 |
| Excluding outliers | 59 | 94.11 | −0.68 | 2.61 | 3.12 | −25 to 25 |

Note. Negative values indicate the KUDUwave had higher (poorer) thresholds and positive values indicate the KUDUwave had lower (better) thresholds. M Abs difference is the mean of the absolute value of the differences between the clinical audiometer thresholds and the KUDUwave thresholds for each condition.

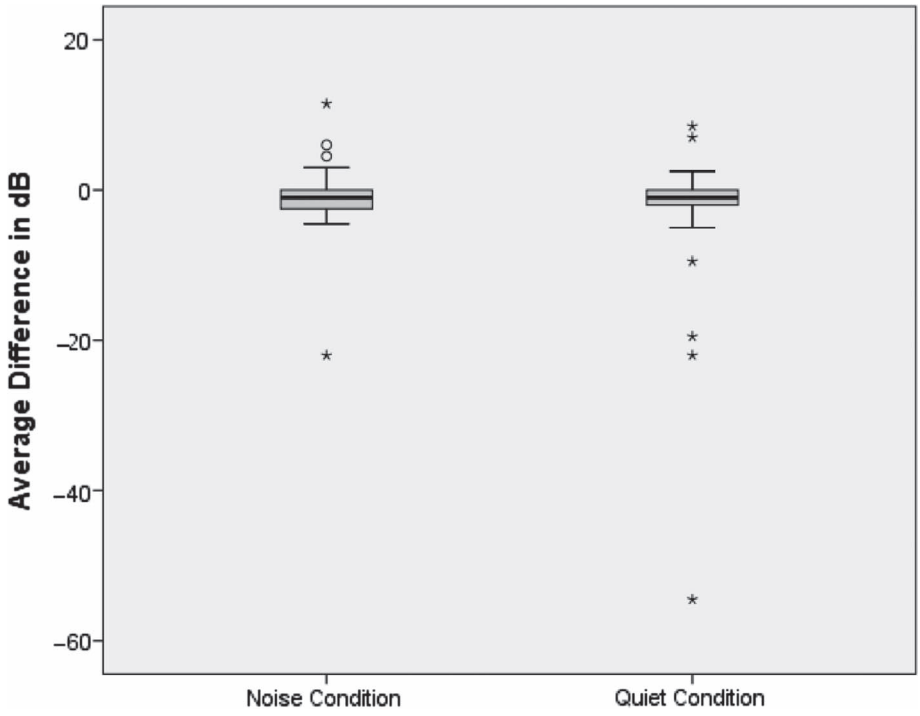


**Figure 2.** Mean threshold differences between the KUDUwave and clinical audiometer in the noise and quiet conditions. The heavy line indicates the median, the boxes represent the interquartile range, and the whiskers represent the 95% confidence interval for the mean difference. The circles and stars represent ears that were statistical outliers.

be uncomfortable commented that the weight and pressure of the headset became uncomfortable over time.

## Discussion

Throughout the world, many individuals with hearing loss do not have access to adequate hearing care due to a scarcity of equipment and certified professionals. A possible solution to this global problem is the KUDUwave audiometer, which is designed for automated hearing testing without the need for a sound booth.

The findings from the current study, similar to the Swanepoel et al (2010) study, revealed that the KUDUwave in the automatic mode accurately obtained pure-tone air conduction thresholds in a quiet sound booth when compared to thresholds obtained with a clinical audiometer. The current study found that overall, 89% of thresholds obtained with the KUDUwave in quiet were accurate (within 5 dB of those found with a clinical audiometer). Swanepoel et al found similar results, 91% accuracy (N = 38) using a ±5 dB criteria. When the outliers were removed in the present study, the percentage of accurate thresholds in quiet increased to 96%.

The KUDUwave audiometer also performed similarly to other commercially available automated systems available. Using the EarTrumpet iPhone application, Foulad et al reported 88% accuracy using a ±5 dB standard. It should be noted that the output for this phone/tablet-based system is limited to approximately 45 dB HL in the high frequencies and 65 dB in the low frequencies. The KUDUwave was slightly less accurate than the AMTAS system. Margolis et al reported a −0.1 dB mean difference, while the mean KUDUwave difference found in the current study in quiet with outliers excluded was −0.6 dB. Neither Margolis et al, or Foulad et al addressed the difficulties of testing in a noisy environment.

Findings from the current study revealed the KUDUwave produced accurate thresholds 92% of the time in the presence of background noise. The level of noise used in this study was typical for a fairly quiet room with the door closed (e.g. physician's office). Further research is needed to determine the accuracy of thresholds obtained using the automated mode in environments with variable noise levels such as may be found in warm climates where facilities often have open windows and higher levels of ambient noise.

The majority of thresholds obtained with the KUDUwave were within ±5 dB (89% and 92% in quiet and noise respectively). However, it is important to note that 5% of the ears tested exhibited large test result differences in thresholds obtained with the KUDUwave compared to the clinical audiometer, and varied by as much as 60 dB from those obtained with the clinical audiometer. These large differences were generally due to higher (poorer) thresholds from the KUDUwave than the standard audiometer. Even though this is a relatively small percentage, these individuals would be misdiagnosed and potentially fitted with hearing aids, a mistake that could cause permanent hearing damage. Large threshold differences were also reported by Swanepoel et al (2010), who reported that 2% of threshold differences were greater than 15 dB both when retesting in manual mode or comparing manual thresholds to automatic thresholds. The reason for these differences in the current study could not be specifically determined. However, because test conditions were counterbalanced, participant fatigue is unlikely the reason, as this problem appeared only in the KUDUwave test conditions. Because the KUDUwave requires placement of an insert and subsequent placement of the headset, it is possible that the tubing for the inserts was pinched or that the pressure from the headset caused

**Table 4.** M differences and M absolute value of differences by frequency, percent of accurate thresholds, and correlations for the KUDUwave compared to the clinical audiometer.

| *Hz* | *250* | *500* | *750* | *1000* | *1500* | *2000* | *3000* | *4000* | *6000* | *8000* |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | *Quiet condition* | | | | | |
| Accurate thresholds % | 85.7 | 90.3 | 85.7 | 88.7 | 90.3 | 88.7 | 90.3 | 91.9 | 88.7 | 75.8 |
| Excluding outliers % | 91.5 | 94.9 | 98.3 | 93.2 | 94.9 | 93.2 | 94.9 | 96.6 | 93.2 | 79.7 |
| M difference in dB | −1.21 | −1.13 | −0.97 | −2.34 | −2.10 | −2.90 | −2.85 | −0.65 | −1.37 | −3.47 |
| (SD) | (6.63) | (4.65) | 6.33 | (7.88) | (6.87 | (9.56) | (8.410 | (8.32) | (9.67) | (11.44) |
| M excluding outliers | −0.09 | −0.63 | −1.34 | −1.10 | −1.02 | −1.27 | −.42 | .68 | .10 | −1.86 |
| (SD) | (4.21) | (3.57) | (4.71) | (4.26) | (3.57) | (4.11) | (4.48) | (4.59) | (6.11) | (8.20) |
| Abs M difference dB | 4.92 | 3.71 | 4.35 | 4.27 | 3.23 | 4.19 | 4.44 | 3.87 | 4.60 | 6.37 |
| (SD) | (9.56) | (8.73) | (8.56) | (7.00) | (6.41) | (9.06) | (7.36) | (7.38) | (8.60) | (10.09) |
| Abs M excluding outliers | 3.05 | 2.03 | 2.80 | 3.14 | 2.20 | 2.63 | 3.14 | 2.71 | 3.31 | 4.92 |
| (SD) | (3.48) | (3.23) | (3.86) | (3.07) | (2.98) | (3.39) | (3.20) | (3.75) | (5.13) | (6.79) |
| Correlations | .84 | .91 | .92 | .94 | .96 | .91 | .94 | .94 | .93 | .90 |
| Excluding outliers | .96 | .98 | .98 | .98 | .99 | .98 | .98 | .98 | .98 | .95 |
| | | | | | *Noise condition* | | | | | |
| Accurate thresholds % | 88.7 | 95.1 | 91.9 | 93.5 | 95.1 | 93.5 | 95.1 | 96.8 | 91.9 | 75.8 |
| Excluding outliers % | 91.1 | 96.4 | 92.9 | 94.9 | 96.6 | 94.9 | 98.3 | 98.3 | 93.2 | 78.0 |
| Difference in dB M | −1.21 | −1.13 | −0.97 | −1.37 | −1.69 | −1.37 | −1.05 | 0.40 | −0.08 | −2.34 |
| (SD) | (6.63) | (4.65) | (6.33) | (4.45) | (5.58) | (4.26) | (4.35) | (5.06) | 8.32 | (8.90) |
| Excluding outliers M | −0.68 | −0.68 | −0.51 | −1.27 | −1.44 | −1.02 | −0.59 | 0.85 | 0.36 | −1.78 |
| (SD) | (5.34) | (3.53) | (5.92) | (4.31) | (4.74) | (3.57) | (3.49) | (3.85) | (8.09) | (8.65) |
| Abs M difference dB | 3.95 | 2.58 | 3.55 | 3.31 | 3.31 | 2.50 | 2.66 | 3.31 | 3.81 | 5.73 |
| (SD) | (5.44) | (4.02) | (5.31) | (3.26) | (4.78) | (3.71) | (3.59) | (3.26) | (7.38) | (7.18) |
| Abs M excluding outliers | 3.39 | 2.20 | 3.22 | 3.14 | 2.97 | 2.20 | 2.29 | 2.88 | 3.58 | 5.34 |
| (SD) | (3.76) | (2.82) | (4.98) | (3.20) | (3.95) | (2.98) | (2.68) | (2.66) | (7.25) | (7.00) |
| Correlation | .93 | .97 | .95 | .98 | .97 | .98 | .98 | .98 | .95 | .94 |
| Excluding outliers | .96 | .98 | .96 | .98 | .98 | .99 | .99 | .96 | .96 | .95 |

Note. Negative values indicate that the KUDUwave produced higher (poorer) thresholds than the clinical audiometer. The correlations shown are between the clinical audiometer thresholds and the KUDUwave thresholds for each condition. The difference values are the mean difference between clinical audiometer thresholds and the KUDUwave thresholds for each condition. The Abs M Difference values are the mean of the absolute value of differences between the clinical audiometer thresholds and the KUDUwave thresholds for each condition. Any KUDUwave threshold that was within + 5 dB of the clinical audiometer thresholds was considered to be an accurate threshold.

**Table 5.** Percent accurate thresholds for subjects with hearing loss and with normal hearing by frequency in the quiet and noise conditions.

| *Hz* | *N Ears* | *250* | *500* | *750* | *1000* | *1500* | *2000* | *3000* | *4000* | *6000* | *8000* | *Overall* | *M difference In dB Overall* | *Abs M difference In dB Overall* | *Range of differences In dB Overall* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | *Accurate threshold % In quiet* | | | | | | | | |
| Hearing loss | 20 | 100.0 | 100.0 | 93.3 | 70.00 | 80.00 | 80.00 | 80.00 | 80.00 | 70.0 | 50.0 | 76.5 | −2.52 | 5.58 | −40 to 30 |
| Excluding outliers | 18 | 94.4 | 94.4 | 94.4 | 77.8 | 88.9 | 88.9 | 88.9 | 88.9 | 77.8 | 55.6 | 85.0 | −0.50 | 3.89 | −35 to 30 |
| Normal | 42 | 88.1 | 92.9 | 97.6 | 97.6 | 95.2 | 92.9 | 95.2 | 97.6 | 97.6 | 88.1 | 94.3 | −2.05 | 3.81 | −65 to 10 |
| Excluding outliers | 41 | 90.2 | 95.1 | 100.0 | 100 | 97.6 | 95.1 | 97.6 | 100.0 | 100.0 | 90.2 | 96.6 | −0.77 | 2.57 | −15 to 10 |
| | | | | | | | *Accurate threshold % In noise* | | | | | | | | |
| Hearing loss | 20 | 85.0 | 95.0 | 85.0 | 80.0 | 95.0 | 90.0 | 95.0 | 95.0 | 80.0 | 50.0 | 85.0 | −0.70 | 4.80 | −35 to 45 |
| Excluding outliers | 18 | 88.9 | 95.1 | 88.9 | 83.3 | 100.0 | 94.4 | 100.0 | 100.0 | 83.3 | 55.6 | 88.9 | 0.56 | 3.06 | −25 to 35 |
| Normal | 42 | 90.5 | 95.2 | 95.2 | 100.0 | 95.2 | 95.2 | 95.2 | 97.6 | 97.6 | 88.1 | 95.0 | −1.26 | 2.84 | −25 to 10 |
| Excluding outliers % | 41 | 90.2 | 95.1 | 95.1 | 100.0 | 95.1 | 95.1 | 97.6 | 97.6 | 97.6 | 87.8 | 95.1 | −1.22 | 2.78 | −25 to 10 |

Note. Negative values indicate that the KUDUwave produced higher (poorer) thresholds than the clinical audiometer. The difference scores are the mean difference between clinical audiometer thresholds and the KUDUwave thresholds for each condition and each group. Any KUDUwave threshold that was within ±5 dB of the clinical audiometer thresholds was considered to be an accurate threshold.

the insert earphone to be pushed against the ear canal. A computer malfunction for KUDUwave testing in the automatic mode should also be considered.

The results of the current study showed a difference in the overall accuracy of the KUDUwave across the frequencies that were tested. The best accuracy was found in the mid-frequency ranges (500–6000 Hz). The percentage of accurate thresholds was lowest at 8000 Hz (77% in quiet) and 250 Hz (75% in noise). Swanepoel et al did not report poorer threshold accuracy at 8000 Hz. They reported smaller absolute value threshold differences at 8000 Hz (2.8 and 2.3 dB) than for all the frequencies combined (3.6 and 3.3 dB). However, the mean threshold differences reported by Margolis et al (2010) between AMTAS and a clinical audiometer were also greater at 8000 Hz (2.3 dB) than for 500 Hz (−0.4 dB), 1000 Hz (−1.5 dB), 2000 Hz (−1.4 dB), and 4000 Hz (−0.1 dB). Although accuracy at all frequencies is desirable, an accurate range between 500 and 6000 Hz is encouraging because this information would allow for accurate diagnosis of degree of hearing loss. Further research is needed to determine accuracy of the bone conduction and masking capabilities, and speech audiometry components of the KUDUwave in a noisy environment.

Although the present study found the KUDUwave to be accurate for adults and adolescents, research is needed to determine the viability of this testing unit for a younger pediatric population. When asked to rate the overall comfort of the KUDUwave headset, the participants in this study rated it to be "slightly uncomfortable." The reported discomfort from the weight and pressure of the headset over time could make the KUDUwave difficult to use with a younger population.

## Conclusion

Solutions such as the KUDUwave are needed to provide hearing care in areas where audiologists and equipment are not readily available. This study replicated previous findings regarding the accuracy of the KUDUwave in quiet. However, the cause for highly inaccurate thresholds, for a small percentage of ears, needs further investigation. This study also found that background noise, typical of an enclosed non-sound-treated room, did not affect the accuracy of thresholds obtained using the KUDUwave. More research is needed in realistic settings to determine the accuracy of the KUDUwave in environments with louder and more variable noise levels.

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## Supplementary material available online

Supplementary Appendix A, B, & C.

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