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Program on Global Aging, Health, and Policy

LASI-DAD Wave 2 hearTest Protocol

HTST-MN-01 hearTest Instructions for Use Version 2.9

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g2aging.org

HTST-MN-01 hearTest IFU v2.9

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Revision History

Revision	Date	Description
v2.3	Nov 30, 2020	hearTest™ IFU PDF document transferred to Confluence. Updates to the supported hardware and addition of tablet devices. Removal of Samsung J5 Prime. Added Test Optimisation v1 (fast) and Test Optimisation v2 (fastest) test method explanations Added document approval section.
v2.4	Jul 1, 2021	Updated the IFU in accordance to the RadioEar DD 450 and DAC in section 3, section 4, section 9 and section 14 which replaced the

		Sennheiser HDA 300
v2.5	Sep 29, 2021	Removal of Samsung Tab A and Samsung J5 Prime Updated to the supported hardware and addition of tablet devices and headphones Added subjective Test, UK - HSE and USA - OSHA test protocols
v2.6	Nov 22, 2022	EU Authorized Representative added Intended use separated from description Updated DAC description Updated storage conditions
v2.7	Jan 20, 2023	DAC v3 is included when purchasing the Diagnostic Set C
v2.8	Sep 4, 2023	Added incident reporting to section 2.
v2.9	Feb 15, 2024	Rectified a typo in section 11 for PTA.

The hearTest Instructions for Use is available in paper format upon request.

1. Intended use and description

The intended use of hearTest™ is to determine patient hearing threshold levels.

hearTest™ is a type 4 audiometer intended to determine patient hearing thresholds by means of air conduction audiometry. The patient response to the tone presented is used to determine the hearing threshold levels at various frequencies. The hearTest device is a portable audiometer that can be used by both health care professionals and community health workers trained to operate the device.

2. General information

hearTest™ devices are designed to conduct hearing tests using calibrated headphones and standardised smart devices (smartphones and/or tablets). hearTest™ generates tones in the audible range (at each octave and limited inter-octave frequencies between 125Hz and 16 000Hz). The tones are presented at various sound pressure levels, one ear at a time. The test follows a rising-falling threshold seeking procedure. This technique is used to calculate hearing thresholds which are presented on a graph measured in decibels hearing level. This graph is known as an audiogram. The hearTest™ application guides the user through the test and displays the final results.

From software version 5009

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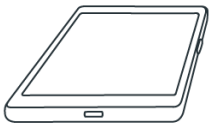
If in relation to the use of the device, a serious incident has occurred, please report this to hearX SA (Pty) Ltd. and the competent authority of your Member State.

3. Abbreviations

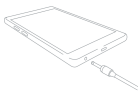
DAC	The **Digital-to-analog converter** converts a digital signal from the Smart Device to an electrical signal transferred to the headphones.
STS	**Standard Threshold Shift**, or STS, is defined in the occupational noise exposure standard at 29 CFR 1910.95(g)(10)(i) as a change in hearing threshold, relative to the baseline audiogram for that employee, of an average of 10 decibels (dB) or more at 2000, 3000, and 4000 hertz (Hz) in one or both ears.
PLH	**Percentage Loss of Hearing** (PLH) is a reference value for the hearing status of an individual against which loss can be measured.
RETSPL	**Reference equivalent threshold sound pressure levels** (RETSPLs) are used when calibrating audiometric equipment to a hearing threshold level of zero at various frequencies.
MPANL	**Maximum Permissible Ambient Noise Levels.** The American National Standards Institute (ANSI) specifies maximum permissible ambient noise levels (MPANLs) allowed in an audiometric test room to ensure that hearing thresholds obtained down to 0-dB HL will not be elevated due to masking by ambient noise.
PTA	**Pure tone audiometry** is a hearing test based on a patients' response to pure tones presented at selected frequencies. The results of a pure tone test provides us with the degree, type and configuration of the hearing loss, which directs the diagnosis and management of the hearing loss.

4. What's in the box?

	Samsung Galaxy Tab A7 (T505 / T500) tablet
	Sennheiser HD 280 PRO / RadioEar DD 450 / IP30 insert earphones & DAC (digital-to-analogue converter) v3 *(DAC v3 is included when purchasing the Diagnostic Set B, Diagnostic Set C, Occ Health Insert and/or Occ Health Over Ear hardware set)*
	Hardcover bag with protective foam inserts

5. Setting up your device

Connect the headphones to the smart device



Sennheiser HD 280 PRO: These headphones are connected to smart devices by means of the 3.5mm stereo aux connecter.

Sennheiser HD 280 PRO with a DAC: The Sennheiser HD 280 Pro has a 3.5mm stereo aux connector. When used in accordance with a DAC, ensure that the DAC is connected by using the USB-C port on the bottom of the smart device. Connect the headphones by inserting the stereo aux connector into the 1,75 mm aux port located between the **L** & **R** ports. Once you have been successful in connecting the headphones to the DAC, attach the DAC securely to the silver plate on the back of the tablet.

RadioEar DD 450 headphones / RadioEar IP 30 insert earphones with a DAC: Both the RadioEar DD 450 headphones and RadioEar IP 30 insert earphones has 6.3mm mono connectors and can only be used in accordance with the DAC. Ensure that the DAC is connected by using the USB-C port on the bottom of the smart device. Connect the headphones by inserting the Blue mono connector into the **L** port and the Red mono connector into the **R** port of the DAC. Once the headphones have been successfully connected to the DAC, attach the DAC securely to the silver plate on the back of the tablet.

NOTEWORTHY

Master Volume: The smart device's master volume needs to be set to maximum to conduct a hearTest™ test. Press the volume key (normally on the side of the smart device) to increase the master volume to its maximum.

Battery Operated Only: Device to be used without plugging into mains, i.e. battery operated only.

Operating Environment: The operating environment must be free from any distractions, both visual and audio. It is recommended that the smart device is on airplane mode before conducting a hearTest™ test. Also ensure that the smart device's Wi-fi, Bluetooth, and GPS are switched off. This can be done by swiping the screen downwards from the top and selecting airplane mode (airplane icon).

6. Perform a hearing test

Ensure you are in a quiet environment which will stay quiet for the test duration.

	**Step 1:** Fit the headphones correctly over both ears, ensuring the sides marked with "**L**" is on the left side and "**R**" on right over both ears.
	**Step 2:** Press the START button to perform a hearing test.
	**Step 3:** Instruct the patient to tap the RESPONSE button as quickly as possible when hearing a tone. Ensure that the patient lets go of the response button once they have responded.
	Step 4: Results: Press FINISH to view the result and SAVE to store it.

7. Limitations of use

The device must not be used when it is likely that the validity of the test results may be compromised. Do not conduct a hearing test on a patient who may have an ear infection with active drainage from the ear, as this may cause damage to the equipment or harm other patients. Pathology in the outer ear, such as excessive cerumen or middle ear infection may result in elevated hearing thresholds. For the purpose of hygiene, never use the headphones on broken skin. Patients who have a cardiac pacemaker should maintain a separation distance of at least 10 cm between the ear caps and cardiac pacemaker or implanted defibrillator, as the transducers of such devices generate permanent magnetic fields. Patients must be able to follow verbal instructions and cooperate to undergo pure tone audiometry. The device should not be used by children under the age of 7 years in the self-test mode. For children between the ages of 4-7 the device must be operated in ‘tester operate mode.' The device is not recommended to be used for children below the age of 4 years old.

8. Important safety warnings

The hearTest™ application should only be used by persons who have received adequate training and/or have thoroughly read through this user manual. The hearTest™ application should only be used with the smartphone or tablet and headphones, issued from hearX Group. The device has been calibrated and standardized according to the ISO standards to ensure that tests conducted are reliable.

Before conducting a hearing test; it is recommended that the smart device is switched to Airplane mode and is not charging. Also ensure that the smart device’s Wi-fi, Bluetooth, and GPS are switched off. EMC warning- guidance shall be provided with regards to the effects of electromagnetic fields, particularly from high powered medical devices on the performance of the audiometer.

All precautions relevant to a smart devices are applicable. Please refer to the “Quick Start Guide” enclosed in the smart device’s packaging for more information.

Refer to **Maintenance and cleaning** of this manual for the proper cleaning procedure of the device.

The instrument must be stored and operated within the specified temperature, pressure, and humidity ranges, see **Environmental Conditions** for further information.

Do not attempt to open, modify, or service the device. Return the device to the manufacturer or distributor for all servicing requirements. Opening the device will void the warranty. The device consists of sensitive parts, such as the screen, buttons and transducer, and should be handled with care. Do not drop or otherwise impact the device. If the device is dropped or damaged, return it to the manufacturer for repair and/or calibration.

The device requires calibration on an annual basis or as required by industry. If the device is dropped or damaged, the device must be returned to seller for re-calibration. It is the responsibility of the user to ensure that their devices are calibrated according to their work requirements.

When unpacking hearTest™, carefully check the equipment for any visible damage. Should any of the equipment suffer from visible damage, please return the content to the seller.

Ensure that the device is stored in a place of safety to avoid theft or the device being used by unauthorized persons. The application is secured with a password to ensure that the patient's personal information is kept confidential to the operator and/or the organization conducting the tests.

hearTest™ is classified as a Class IIa medical device according to Rule 10a, Council Directive 93/42/EEC of 14 June 1993.

hearTest™ is an automatic IEC 60645 Type 4 pure tone, air conduction audiometer intended for screening and monitoring. It meets or exceeds the following standards:

- ISO 389 Part 4,5,8, and 9. Acoustics - Reference zero for the calibration of audiometric equipment
- ISO 8253-1 (also known as SANS 8253-1) Acoustics - Audiometric test methods - Part 1: C Pure-tone air and bone conduction audiometry
- IEC 60645-1 Electroacoustics - Audiological equipment. Part 1 Equipment for pure-tone audiometry
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: Requirements for EMC compatibility
- IEC 62304 Medical device software
- ANSI S3.6 - Specification for audiometers (type 4 audiometer)

The following explains relevant symbols used in this manual and on the device:

	Manufacturer name and address
	Type B applied part. A part which provides protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current. The applied parts are the left & right earphones and the associated cables.
	Follow instructions for use.
	CE mark indicating conformity with Health and Safety requirements set out in European Directives.
	Authorised representative in the European Community.
	This symbol will be followed by the manufacturer's serial number.
	Not for general waste.
	Device is fragile.
	Keep product dry

9. Operating environment

hearTest™ should only be used in a noise-controlled environment as per ISO 8253-1 ambient noise levels. The environment must be free from distractions and the patient must be able to understand the communications instructed.

10. hearTest™ compatible devices

hearTest™ has been designed for use with a Samsung Galaxy Tab 7 (T505 / T500) tablet and Sennheiser HD 280 PRO / RadioEar DD 450 / IP30 insert earphones.

Note: A DAC is required when using the RadioEar DD 450 headphones and/or RadioEar IP 30 earphones

11. hearTest™ test and displays

hearTest™ has the following test methods:

When selected the hearTest™ will follow the **Threshold Ascending** test method as specified in ISO 82531:1. to determine hearing thresholds. For each frequency, the test will begin at 40 dB HL. If the patient hears the tone, the intensity is reduced by 10 dB and repeated,

if they do not, the intensity is increased in 5 dB steps until a response occurs. A threshold is determined by the minimum intensity at which a patient reliably responded twice.

Test Optimisation v1 (fast) and Test Optimisation v2 (fastest) uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed.

A hearTest™ test is performed as follows:

1. Sit the patient down and provide the test instructions before placing the headphones on the patient.
2. Ensure headphones are placed on the ears of the patient correctly - L for LEFT and R for RIGHT.
3. Press the 'START' button.
4. The default test mode requires the patient to hold the device throughout testing and respond by clicking the button when they hear a tone.

The initial results screen will indicate the patient's audiometric thresholds in dB HL (the softest intensity level at which they still responded reliably) at each frequency tested. A pure tone average (PTA), which is the average of the thresholds at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz and is provided for each ear. Furthermore, the severity of the hearing loss (if any) will also be indicated for each ear. The hearTest™ PTA categories are described in Table 1.

Table 1: PTA Categories (WHO)

PTA Category	Test PTA
Normal Hearing	<= 25 dB HL
Mild Hearing Loss	26 to 40 dB HL
Moderate Hearing Loss	41 to 60 dB HL
Severe Hearing Loss	61 to 80 dB HL
Profound Hearing Loss	>= 80 dB HL

Table 2: PTA Categories (UK)

PTA Category	Test PTA
Normal Hearing	<20 dB HL
Mild Hearing Loss	20 to 40 dB HL
Moderate Hearing Loss	41 to 70 dB HL
Severe Hearing Loss	71 to 95 dB HL
Profound Hearing Loss	>= 95 dB HL

Table 3: PTA Categories (USA)

PTA Category	Test PTA
Normal Hearing	< 15 dB HL
Slight Hearing Loss	16 to 25 dB HL
Mild Hearing Loss	26 to 40 dB HL
Moderate Hearing Loss	41 to 55 dB HL

Moderately Severe Loss	56 to 70 dB HL
Severe Hearing Loss	71 to 90 dB HL
Profound Hearing Loss	> 90 dB HL

The hearTest™ results are visually presented on an audiogram. An audiogram is a graphic display of the patient's hearing abilities in terms of frequencies tested and the intensities at which audiometric thresholds were obtained. It may be easier to visualize any asymmetry between the ears and the severity of the hearing loss using an audiogram.

Test reliability scores are also presented and gives the user an indication of the reliability of the test that has been conducted. The reliability scores will indicate whether there were any environmental noise concerns during the test (i.e. was the background noise too loud while the sound was being presented?), threshold concerns (i.e. is there a large disparity between condition tone and test tones outcomes (>10 dB)) and test stats (i.e. how many false responses, the mean response time and the duration of the test).

These results should only be interpreted by a qualified practitioner trained to do so.

12. hearTest™ protocols

12.1 Default protocol:

Protocol	Default
Frequencies	500 Hz, 1 000 Hz, 2 000 Hz, 4 000 Hz, 8 000 Hz
Min Testing Intensity	*Samsung T500/5 & Sennheiser HD 280 PRO:* 10 dB *Samsung T500/5, Sennheiser HD 280 PRO & DAC:* -10 dB *Samsung T500/5, RadioEar DD 450 & DAC:* -10 dB *Samsung T500/5, RadioEar IP 30 & DAC:* -10 dB
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.2 Default Self Test Protocol:

Protocol	Default Self Test Protocol

Frequencies	500 Hz, 1 000 Hz, 2 000 Hz, 4 000 Hz, 8 000 Hz
Min Testing Intensity	*Samsung T500/5 & Sennheiser HD 280 PRO:* 20 dB *Samsung T500/5, Sennheiser HD 280 PRO & DAC:* 20 dB *Samsung T500/5, RadioEar DD 450 & DAC:* 20 dB *Samsung T500/5, RadioEar IP 30 & DAC:* 20 dB
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.

12.3 Daily check protocol:

Protocol	**Daily Check**
Frequencies	500 Hz, 1 000 Hz, 2 000 Hz, 4 000 Hz, 8 000 Hz
Min Testing Intensity	*Samsung T500/5 & Sennheiser HD 280 PRO:* 10 dB *Samsung T500/5, Sennheiser HD 280 PRO & DAC:* -10 dB *Samsung T500/5, RadioEar DD 450 & DAC:* -10 dB *Samsung T500/5, RadioEar IP 30 & DAC:* -10 dB
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.4 SANS 10083 occupational health exit protocol:

Protocol	SANS 10083 Occupational Health Exit
Frequencies	500 Hz, 1 000 Hz, 2 000 Hz, 3 000 Hz, 4 000 Hz, 6 000 Hz, 8 000 Hz
Min Testing Intensity	A SANS 10083 Occupational Health Protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.

12.5 SANS 10083 occupational health baseline protocol:

Protocol	SANS 10083 Occupational Health Baseline
Frequencies	500 Hz, 1 000 Hz, 2 000 Hz, 3 000 Hz, 4 000 Hz, 6 000 Hz, 8 000 Hz
Min Testing Intensity	A SANS 10083 Occupational Health Protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring

Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.6 SANS 10083 occupational health screening protocol:

Protocol	**SANS 10083 Occupational Health Screening**
Frequencies	500 Hz, 1 000 Hz, 2 000 Hz, 3 000 Hz, 4 000 Hz, 6 000 Hz, 8 000 Hz
Min Testing Intensity	A SANS 10083 Occupational Health Protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.7 HSE compliant baseline protocol:

Protocol	**HSE compliant baseline protocol**
Frequencies	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz, 8000Hz
Min Testing Intensity	HSE Compliant protocol will only work in accordance with a DAC. The DAC supports two headphones:

	1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.8 HSE compliant screening protocol:

Protocol	**HSE compliant screening protocol**
Frequencies	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz, 8000Hz
Min Testing Intensity	HSE Compliant protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.

Calculations	Calculates PLH and STS

12.9 HSE compliant exit protocol:

Protocol	HSE compliant exit protocol
Frequencies	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz, 8000Hz
Min Testing Intensity	HSE Compliant protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.10 OSHA compliant baseline protocol:

Protocol	OSHA compliant baseline protocol
Frequencies	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz, 8000Hz
Min Testing Intensity	OSHA Compliant protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms

Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.11 OSHA compliant screening protocol:

Protocol	**OSHA compliant screening protocol**
Frequencies	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz, 8000Hz
Min Testing Intensity	OSHA Compliant protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.12 OSHA compliant exit protocol:

Protocol	**OSHA compliant exit protocol**

Frequencies	500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz, 8000Hz
Min Testing Intensity	OSHA Compliant protocol will only work in accordance with a DAC. The DAC supports two headphones: 1. RadioEar DD450 for EHF (up to 16kHz) 2. RadioEar IP30 (only to 8kHz). The lowest level we can present using a DAC is -10 dB SPL.
Max Pre-tone Waiting Period	4000 ms
Person Response Window After Tone	1500 ms
Optionals	Patient-operated Better ear question Smart-noise-monitoring
Testing Protocols	hearTest™ follows the Test Optimisation v1 (fast) test method. This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required.
Calculations	Calculates PLH and STS

12.13 Custom protocol options:

Protocol	**New Protocol Options**
Frequencies	125 Hz, 250 Hz, 500 Hz, 750 Hz, 1 000 Hz, 1 500 Hz, 2 000 Hz, 3 000 Hz, 4 000 Hz, 6 000 Hz, 8 000 Hz, 10 000 Hz, 12 500 Hz, 16 000 Hz
Min Testing Intensity	This is adjustable based on the requirements of the tester. *Samsung T500/5 & Sennheiser HD 280 PRO:* 10 dB *Samsung T500/5, Sennheiser HD 280 PRO & DAC:* -10 dB *Samsung T500/5, RadioEar DD 450 & DAC:* -10 dB *Samsung T500/5, RadioEar IP 30 & DAC:* -10 dB
Max Pre-tone Waiting Period	Adjustable 1500 ms - 4000 ms
Person Response Window After Tone	Adjustable 1500 ms - 4000 ms
Optionals	Patient-operated Smart noise monitoring

	Tone Info Visible Test Progress Visible Auto Contralateral Masking Better Ear Question
Testing Protocols	**Shortened Ascending:** hearTest™ will follow the Shortened Threshold Ascending method as specified in ISO 82531:1. to determine the hearing thresholds. For each frequency, the test will begin at 40 dB HL. If the patient hears the tone, the intensity is reduced by 10 dB and repeated, if they do not, the intensity is increased in 5 dB steps until a response occurs. Further optimisation have been added to ensure shorter testing times. **Test Optimisation v1 (fast) and Test Optimisation v2 (fastest):** This test method uses regression formulas to predict more accurate starting intensity based on age and gender inputs. The threshold tracking steps are optimised based on the number of responses received and the pre and post tone waiting times are set on the minimum time allowed. Contact hearX Group for further info if required. Contact hearX Group for further info if required.

13. hearTest™ measures

False Response Count	False response percentage divided by the total amount of responses. *False response % / Total responses = % False response count*
Mean Response Time	Average between the response time of all the responses.
Standard Deviation Response Time	A measure indicating the spread of response times from the mean. A higher standard deviation indicates higher variability in the response times of the patient. A standard deviation of greater than 1 should be considered fairly high and a cause for investigation.
Pure Tone Average	Average between thresholds at 500 Hz, 1 000 Hz, 2 000 Hz, and 4 000 Hz

14. hearTest™ features

Audiological Function	**When is this function useful?**	**Technical considerations**
Noise Check		
The noise check feature provides a real-time ambient noise monitor to	Before conducting a hearing test, it is important to determine the	The yellow line across the graph represents the maximum ambient

help analyse ambient noise levels before conducting a test. Users may also make use of the automated noise check feature by pressing the white microphone in the top right corner. This will average the noise over 5 seconds and indicate if the noise is too loud for testing	ambient noise to be confident that the environment in which you are testing is adequate for testing.	noise permissible for your selected testing protocol. The white dots along the yellow line are placed at frequencies corresponding to your selected protocol. The intensity of each white dot is calculated as the Headphone MPANL (Maximum permissible ambient noise level of your linked headphone at 0dB at a specific frequency) + selected protocol minimum testing intensity. If the ambient noise exceeds the yellow line at any of the frequencies used in your protocol, the ambient noise is considered too high for testing.
Test-Retest		
In line with requirements for ISO8253-1, a retest is performed on the 1000Hz tone (Or closest lowest frequency if 1000Hz not tested) to ensure retest threshold is within 5dB of first threshold.	Function acts as a test validator to help guard against inaccurate test scenarios.	A warning is shown to the user on the results screen (Under Test-Retest header on reliability tab) if thresholds differ by more than 5dB. Users should use their discretion as to whether or not the test should be conducted again.

Feature	Audiological Function	When is this useful?	Technical considerations
Protocol Name	The protocol settings can be adapted to suit your test situation. It is important to name your protocol accordingly.	This function is important to determine when to use the appropriate protocol for a specific test setting, e.g. Ototoxic monitoring.	
Ear-specific Selection of Frequencies	This function allows you to select the frequencies you wish to test and unselect the frequencies you wish to skip.	Default conditioning frequency is set to 1 000 Hz if 1 000 Hz is selected in the protocol. not, the lowest closest frequency to 1000Hz is used as the conditioning frequency.	
Adjustments			
Minimum testing intensity (dB)	The minimum loudness level	This level can be changed to speed up the	See Testing Intensities & Frequency Ranges

	in dB that will be presented to determine a threshold for that specific frequency.	test or to determine the actual thresholds of hearing.	section for more info
Maximum Pre-tone Waiting Period (ms)	The silent waiting period before a tone is presented. It is randomised between 1300 ms and the value that is selected by the tester.	You may wish to increase this value to lessen the predictability of the tone presentations.	Range 1500 ms - 4000 ms.
Person Response Window After Tone (ms)	The maximum of time where a person response is still valid after the tone has finished playing.	This function is useful when testing populations that may require additional time to respond, e.g. elderly persons or persons with physical disabilities.	Range 1500 ms - 4000 ms.
Optional			
Patient-operated	Patient-operated is the standard test mode where a person responds to the tones themselves by selecting the response button presented on the application. The person is then using the device themselves. This can be disabled to allow a tester to respond on behalf of the patient.	It is useful to disable this function when testing children (< 7 years), persons who are unfamiliar with technology, or persons who may not be able to use the technology, e.g. persons with disabilities. Patient-operated is the preferred option for adults who can respond independently in a reliable manner.	Mean response time, standard deviation response time and false responses are all set to 0 if user-assisted test mode is enabled.
Tone Info Visible	This function displays the tone frequency, intensity, and ear while presenting the tone.	Consider enabling when doing user assisted testing. NOT recommended for patient-operated testing.	
Test Progress Visible	This function displays how many steps of the test have been completed out of the total steps in the test.	This function gives the tester an indication of the time it will take to test the patient.	
Flight Mode Required	Flight mode is enabled to avoid disruptions during testing. We HIGHLY	This function prevents incoming calls or messages from	Test results will not be synced while flight mode is enabled. Remember to enable internet

	recommend enabling flight- mode during testing.	disrupting the test while it is running.	connection after your testing session to sync results to the cloud.
Better Ear Question	This function presents a pre-screen dialogue requesting the patient's better ear. The test will begin with the selected ear. If disabled, the test will always begin with the left ear.	By starting the test with the patient's better ear, it is easier to condition the patient to respond to the expected tone, by presenting it first to the better ear. Masking will be influenced by this selection.	

15. Device maintenance and cleaning

Before use, check the headset cables and connectors for signs of wear and/or damage. If found, please report the damage/fault immediately to the seller. It is important that the headphones are managed with care.

The ear cups are subject to a standard disinfecting procedure, as they will be exposed to direct contact with the patient/person who is being tested. Disinfection is necessary after every use. This will ensure infection control and reduce the risk of cross-contamination.

This includes physically cleaning and use of a recognized disinfectant. The specific manufacturer's instructions should be followed for use of this disinfecting agent to provide an appropriate level of cleanliness.

It is recommended to use a disinfectant that is alcohol-free, as continued exposure to alcohol dehydrates the leather on the ear cups, causing it to crack and/or tear. It is important to avoid moisture from entering the headphones during the cleaning process. E.g. Avoid the use of a soaked cloth.

The disinfecting procedure should include cleaning and checking of the microphone opening and the auxiliary port. This is to ensure the microphone remains open for noise monitoring and the auxiliary port is free from small objects or dust that may enter as the device is used.

hearTest™ Packaging	
Dimensions	350 mm x 270 mm x 120 mm
Net Weight (Contents: smart device, headphones, and charger)	< 1 Kg
Shipping Weight (Quantity=1)	1 Kg
Power Source	Internally Powered
Safety and Design Standards	IEC 60645-1 ; IEC 60601-1-2 ; IEC 62304
Medical Device class	Class IIa
Degree of Protection (electric shock)	Type B applied part
Warm-up Time	None
Protection Against Ingress (IP): Smart device Headphones	 IP 68 Not specified
Usage Environment	Professional Healthcare Environment
Smart Device Battery	

Type	Non-removable Lithium-Ion
Capacity	T500/5: 7040 mAh
Expected Lifetime	2 years of regular use
Indicator	Battery level is indicated on the screen
Method of Replacement	Please contact the seller for any replacements
Calibration	
The calibrated headphones supplied require annual calibration (depending on local requirements and specific area of use, it may be required more often). The application will not permit testing with headphones that have an expired calibration period. Please contact the seller to arrange for the re-calibration of your headphones.	

Tone	
Type	Pure Tone
Frequencies	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 10 000, 12 500, 16 000 Hz
Rise / Fall time	35 ms (-20 dBFS to -1 dBFS and vice versa)
Intensity Range	The minimum intensity and frequency range for: *Samsung T500/5 and Sennheiser HD 280 Pro:* minimum 10 dB HL from 125 - 8 000 Hz *Samsung T500/5, Sennheiser HD 280 Pro with a DAC:* minimum -10 dB HL from 125 - 8 000 Hz *Samsung T500/5, Sennheiser RadioEar DD 450 with a DAC:* minimum -10 dB HL from 125 - 16 000 Hz *Samsung T500/5, Sennheiser RadioEar IP 30 with a DAC:* minimum -10 dB HL from 125 - 8 000 Hz **The maximum levels for the Sennheiser HD 280 PRO:** 125 Hz 65 dB HL 250 Hz 80 dB HL 500 to 3000 Hz 90 dB HL 4000 Hz 85 dB HL 6000 Hz 80 dB HL 8000 Hz 70 dB HL **The maximum levels for the Sennheiser HD 280 PRO with a DAC:** 125 Hz 75 dB HL 250 Hz 90 dB HL 500 Hz 95 dB HL 750 to 4000 Hz 100 dB HL 6000 Hz 95 dB HL 8000 Hz 90 dB HL

	The maximum levels for the RadioEar DD450 with a DAC: 125 Hz 75 dB HL 250, 6000, 8000 Hz 90 dB HL 500 to 4000 Hz 95 dB HL 10 000 Hz 80 dB HL 12 500 Hz 75 dB HL 16 000 Hz 55 dB HL **The maximum levels for the RadioEar IP 30 insert earphones, Peltor headset with a DAC:** 125 Hz 80 dB HL 250 Hz 90 dB HL 500 to 4000 Hz 100 dB HL 6000, 8000 Hz 80 dB HL
SPL Accuracy	Within 3 dB across all frequencies
THD	< 2%

Narrow Band Masking		
Frequency (Hz)	Lower cut-off frequency (Hz)	Upper cut-off frequency (Hz)
125 250 500 750 1000 1500 2000 3000 4000 6000 8000 10 000 12 500 16 000	108 217 433 650 866 1300 1730 2595 3460 5200 6930 8660 10 825 13 850	145 289 578 867 1155 1730 2310 3470 4625 6935 9245 11 555 14 450 18 495

Headphones			
The RETSPLs of the RadioEar DD450, Sennheiser HD 280 Pro headphones and RadioEar IP 30 earphones for an IEC 60318-1 ear simulator. All the values are provided in dB.			
Static Force	Sennheiser HD 280 Pro	7 N	
	RadioEar DD 450	10 N ± 0.5 N	
	RadioEar IP 30	Not applicable	
Frequency	**Sennheiser HD 280 PRO**	**RadioEar DD 450**	**RadioEar IP 30**
125 250	37.2 13.5	30.5 18	28 17.5

500	6.8	11	9.5
750	1.8	6	6
1000	1.4	5.5	5.5
1500	3.7	5.5	9.5
2000	1.9	4.5	11.5
3000	-3.9	2.5	13
4000	2.2	9.5	15
6000	16	17	16
8000	29.4	17.5	15.5
10 000	-	22	-
12 500	-	27.5	-
16 000	-	56	-

The MPANLs of the RadioEar DD450, Sennheiser HD 280 Pro headphones and RadioEar IP 30 earphones with Peltor headset. All the values are provided in dB.

Frequency	**Sennheiser HD 280 PRO**	**RadioEar DD 450**	**RadioEar IP 30 with Peltor headset**
125	41	64	83
250	30	51	71
500	27	38	57
1000	31	38	50
2000	44	37	44
4000	43	51	55
8000	32	56	56

Environmental Conditions		
Operating	Temperature Humidity Ambient Pressure	15 to 35 ^{O}C 30 to 90 %RH Non-Condensing 98 to 104 kPa
Shipping and Storage	Temperature Humidity Ambient Pressure	0 to 30 ^{O}C 30% - 60% Non-Condensing 70 to 106 kPa

Electromagnetic Compatibility (EMC)		
Electrical medical equipment requires special precautions regarding EMC and requires to be put into service according to the guidance provided below.		
Guidance and manufacturer's declaration – electromagnetic emissions		
The hearTest™ audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the hearTest™ audiometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The hearTest™ audiometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are

		not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The hearTest™ audiometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity

The hearTest™ audiometer is intended for use in the electromagnetic environment specified below. The user of the hearTest™ audiometer should assure that it is used in such an environment.

Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	Not applicable, see note 2		
Surge IEC 61000-4-5	Not applicable, see note 2		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable, see note 2		
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	

NOTE:

Power supply or data line (input/ output part ports) tests are not applicable. If the presence of a USB connection is detected (either for data transfer or charging operations) the hearTest™ audiometer will not execute a test.

Guidance and manufacturer's declaration – electromagnetic immunity

The hearTest™ audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the hearTest™ audiometer should assure that it is used in such an environment.

Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz, and 6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz. 3 V/m 80 MHz to 2.7 GHz, including wireless communications equipment at other discrete frequencies [a].	6 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the hearTest™ audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 0.60 √P d = 0.35 √P 80 MHz to 800 MHz d = 0.70 √P 800 MHz tot 2.5 GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [b], should be less than the compliance level in each frequency range [c]. Interference may occur in the vicinity of equipment marked with the following symbol:

Notes:

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.

1. Tests conducted according to Table 9 of IEC 60601-1-2 2014.
2. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the hearTest™ audiometer is used exceeds the applicable RF compliance level above, the hearTest™ audiometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the hearTest™ audiometer.
3. Over the range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the hearTest™ audiometer

The hearTest™ audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the hearTest™ audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the hearTest™ audiometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz **d = 0.60 √P**	**80 MHz to 800 MHz** **d = 0.35 √P**	**800 MHz to 2.7 GHz** **d = 0.70 √P**
0.01	0.06	0.04	0.07
0.1	0.19	0.11	0.22
1	0.6	0.35	0.7

10	1.9	1.1	2.2
100	6	3.5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.			
NOTES: 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.			

16. Troubleshooting

- It is recommended to set up the device in an environment with internet access prior to testing in the field to ensure all controls are up to date and in place.
- Ensure the headphones are properly connected to the phone's headphone jack.
- It is recommended that the smart device be fully charged before commencing with testing.
- Ensure the headphones are still in calibration before conducting a test.
- Ensure tests are conducted within maximum ambient permissible noise levels.
- Ensure headphones are cleaned in between testing patients.
- Ensure that the correct headphone is on the correct ear and surrounds the pinna.
- Results will not upload to the cloud without a data connection.
- Ensure that you have the latest version of the software application installed on the smart device prior to testing.
- See *Frequently Asked Questions*

17. Frequently asked questions

What is the difference between hearScreen and hearTest?

hearTest is a diagnostic audiometer, testing thresholds that can be used for a hearing aid fitting.

hearScreen is a initial assessment conducted to determine if a patient is at risk for hearing loss and refers the patient go for additional testing and obtain further information.

Should equipment be checked on a regular basis?
Yes, it is important that the equipment you are using for your hearing screening/assessing is checked regularly. There are two checks required to ensure the equipment is in full working order:

- Annual calibration of headphones - the hearTest™ application is designed to be used with headphones calibrated specifically for this application, thus the headphones need to be calibrated by the hearX Group once every 12 months.
- Daily listening checks - conduct a hearing screening on yourself or somebody that you know has normal hearing at the beginning of each day, to ensure that their results are consistent, that there is no distortion in the tones presented, and that there are no defects in any of the major components of the device. The pre-set *Daily Check* protocol should be used to conduct a daily listening check. A setting is available to enforce the Daily Check is performed prior to testing commences each day.

What should the testing environment look like?
The screening environment should be as quiet as possible, ideally in a separate room with doors and windows closed. Try to stay away from anything that is making excessive noise, as this will affect the reliability and accuracy of the hearing screening/ assessment results.

How do you change the protocol?

- Select **MENU** button in the top left corner in the smart device. *(PLEASE NOTE: If the smart device is in the Self Test mode the menu is password protected and the same password used to log into the device should be entered to access the menu. The lock icon should be selected in the top right corner of the START screen to unlock the menu. Enter your password to unlock the menu)*
- Tap on **SETTINGS**, and select hearTest
- Tap on **MANAGE PROTOCOLS**.
- Click on **ADD+** in the top right top corner.
- Name the protocol under the frequencies tab.
- Select the frequencies under the **FREQUENCIES** tab which you would like to include in the test.
- Change settings in **ADJUSTMENTS** tab according to your prerequisites
- Change settings in **OPTIONALS** tab according to your prerequisites
- Tap on the **SAVE** button to save your new protocol.

Can I test children with hearTest™?
Yes, it has been validated for children older than 4 years

How do I update my hearTest™ application?
Application software updates available are indicated with a badge on the START screen.

- Ensure that the hearX device is connected to a stable internet connection.
- Select **MENU** button in the top left corner of the smart device. *(PLEASE NOTE: If the smart device is in the Self Test mode the menu is password protected and the same password used to log into the device should be entered to access the menu. The lock icon should be selected in the top right corner of the START screen to unlock the menu. Enter your password to unlock the menu)*
- Tap on **UPDATES**.
- A list will be displayed showing available updates. Select from the list which app you would like to update.
- A pop-up window will appear asking you if you would like to update the app. Tap on **UPDATE** to continue or **CANCEL** if you wish to cancel the update.

What is mHealth Studio Cloud?
mHealth is a centralised data management cloud portal that can be used to synchronise hearTest™ results and display on a web page for detailed result reporting. This can be accessed via cloud. mhealthstudio.com and requires a registered account to access the relevant test data.

18. Clinically validated research

The hearTest™ app has been clinically validated by means of research articles published in an international, peer-reviewed academic journal. The citations for these articles can be found below:

Field test of the Rapid Assessment of Hearing Loss survey protocol in Ntcheu district, Malawi. Bright T, Mulwafu W, Phiri M, Mwanaisha P, Fan J, Swanepoel D, Kuper H, Mactaggart I, Yip JLY, Polack S. International Journal of Audiology, 2020.
Access Article

Community health worker-based hearing screening on a mobile platform: A scalable protocol piloted in Haiti. Jayawardena ADL, Nassiri AM, Levy DA, Valeriani V, Kemph AJ, Kahue CN, Segaren N, Labadie RF, Bennett ML, Elisée CA and JL Netterville. Laryngoscope Investigative Otolaryngology, 2020.
Access Article

Rationale and feasibility of a combined rapid assessment of avoidable blindness and hearing loss protocol. Bright T, McCormick I, Phiri M, Mulwafu W, Burton M, Polack S, Mactaggart I,Yip JLY, Swanepoel D and Kuper H. PLoS ONE, 2020.
Access Article

Diagnostic accuracy of non-specialist versus specialist health workers in diagnosing hearing loss and ear disease in Malawi. Bright T, Mulwafu W, Phiri M, Ensink RJH, Smith A, Yip J, Mactaggart I, Polack, S. Tropical Medicine and International Health, 2019.
Access Article

Extended high frequency smartphone audiometry: validity and reliability. Bornman M, Swanepoel D, Biagio De Jager L, Eikelboom. Journal of the American Academy of Audiology, 2019.
Access Article

Automated Smartphone Threshold Audiometry: Validity and Time Efficiency. Van Tonder J, Swanepoel D, Mahomed-Asmail F, Myburgh H, Eikelboom R. Journal of the American Academy of Audiology, 2016.
Access Article

Smartphone threshold audiometry in underserved primary health-care contexts. Sandström J, Swanepoel D, Myburgh H, Laurent C. International Journal of Audiology, 2016.
Access Article

Document Approval

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