HEARSCREEN

Instructions For Use

07/09/2025.

hearScreen®

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REVISION HISTORY

REVISION	DATE	DESCRIPTION	BUSINESS ANALYST
v1.0	20 Nov 2023	Drafted document	@William Ward (Unlicensed)
v1.1	05 Jun 2024	Updated intended use and description with intended user	@William Ward (Unlicensed)
v1.3	21 Feb 2025	Section 8 important safety warnings updated for effects of electromagnetic fields, updated smart device info, updated frequency range and testing intensity	@William Ward (Unlicensed)
v1.4	28 May 2025	Updated all references from mHealth to hearX Cloud and/or hearX App to reflect product rebranding. Reviewed and updated general grammar and tone for clarity and consistency.	@Huzaifa Patel @Belinda Beukes

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

1. INTENDED USE AND DESCRIPTION

The intended use of hearScreen® is to perform hearing screening tests in a community, school and/or clinical setting.

hearScreen® is a clinically validated digital smart device screening audiometer with cloud data management using Electronic Health Record (EHR) software. The hearScreen® can be used by both healthcare professionals and community health workers trained to operate the device.

2. GENERAL INFORMATION

hearScreen® devices are designed to conduct hearing tests using calibrated headphones and standardized smart devices. hearScreen® generates tones in the audible range (usually at each octave between 250 Hz and 8000Hz). The tones are presented at various sound pressure levels, one ear at a time.

The results are indicated as a simple pass or refer outcome. A referral means that further testing is needed to confirm the extent of hearing loss in the person being screened. hearTest, another software product by hearX, can be used as a hearing screening tool to determine the slope of hearing loss and generate an audiogram for the individual being tested.

hearScreen® is available in English, Spanish and French.

For more information visit: *www.hearxgroup.com*[1] or contact hearX SA: *info@hearxgroup.com*[2]

ZA: **+27 12 030 0268** | US: **+1 415 212 5500**

In the event of a serious incident related to the use of the device, the incident must be reported to hearX SA (Pty) Ltd. and the competent authority in the respective country.

1 http://www.hearxgroup.com
2 mailto:info@hearxgroup.com

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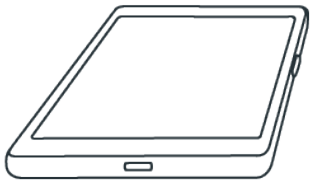
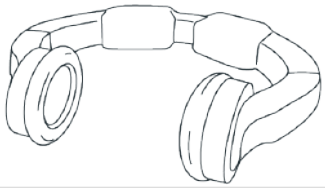
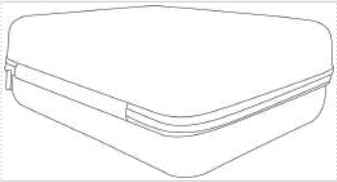
3. ABBREVIATIONS/DEFINITIONS

ABBREVIATION	DEFINITION
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.
Operator	The person responsible for setting up the device and facilitating the hearing screening test.

4. WHAT'S IN THE BOX?

ILLUSTRATION	ITEM	MODEL(S)	DESCRIPTION
	Smart Device	Samsung Tablet: • T510 • T515 • T503 Samsung Smartphone • A320F • A045F • A042M • A042	Used to operate hearX software applications
	Headphones	Sennheiser HD 280 PRO	Calibrated headphones for accurate hearing screening
	Carry Case		Hardcover bag with protective foam inserts for safe equipment transport

5. DEVICE SETUP

Begin device setup by connecting the headphones (Sennheiser HD 280 PRO) to the smart device using the 3.5 mm stereo AUX connector.. Simply insert the headphone jack into the audio port of the tablet or smartphone. Ensure the connection is secure before launching the hearX application.

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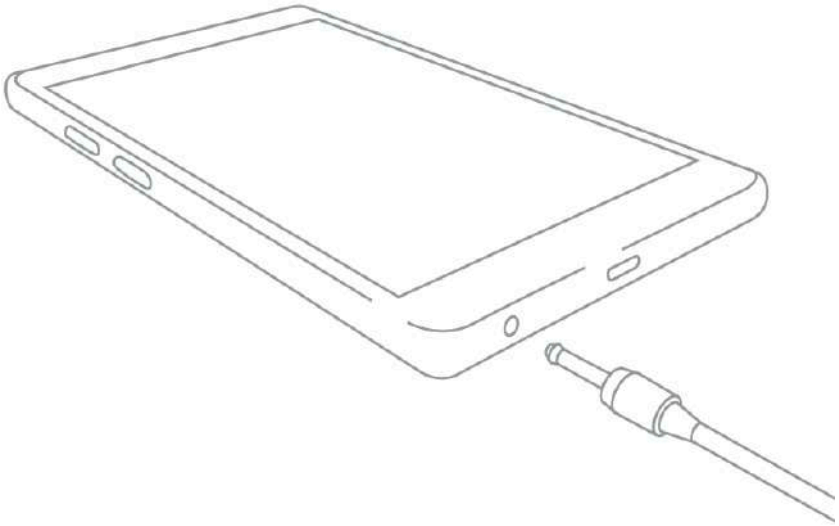

Device Setup Requirements

Before conducting a hearScreen® screening, ensure the smart device's **master volume is set to maximum** by pressing the volume key (usually located on the side of the device). The device should be used in **battery-operated mode only**—do not connect it to a power source during use. The **screening environment** must be free of visual and auditory distractions.

6. PERFORM A HEARING SCREENING TEST

Ensure the testing environment is quiet and will remain quiet for the duration of the test.

Step 1: Fit the headphones securely over both ears, ensuring the side marked "**L**" is placed on the left ear and the side marked "**R**" on the right ear.

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	**Step 2:** Press the START button to perform a hearing screen.
	**Step 3:** The screener stands behind the individual being tested and presents the tones by tapping the **"Play"** button on the screen. The individual indicates whether they hear the tone.

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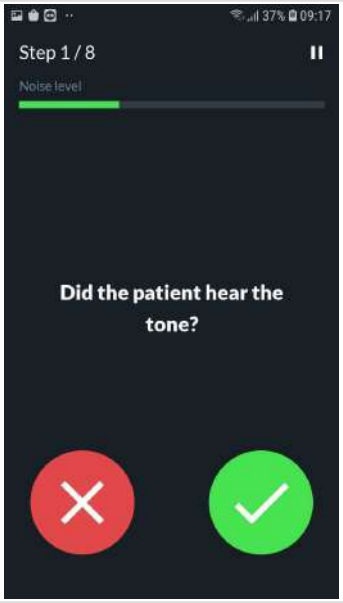
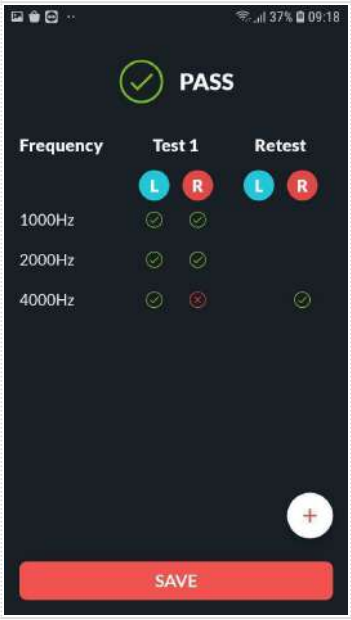


Step 4: If the tone was heard, the green button is selected to confirm, if not, the red button should be selected.



Step 5: The Results screen will show automatically after the completion of the screening. Press SAVE to continue and save the results.

7. LIMITATIONS OF USE

- The device must **not be used** in situations where the **validity of test results may be compromised**.
- Do **not conduct a hearing screening** on individuals showing signs of **ear infections with active drainage**, as this may **damage the equipment** and pose a **risk of cross-contamination**.
- Conditions such as **outer ear pathology**, including **excessive cerumen** or **middle ear infections**, may result in **elevated hearing thresholds** and affect the accuracy of results.
- For **hygiene and safety**, do not use the headphones on individuals with **broken skin or open wounds**.
- Individuals with a **cardiac pacemaker** or **implanted defibrillator** must maintain a **minimum distance of 10 cm** between the ear caps and the device, as the headphones contain **permanent magnetic fields**.
- The individual being tested must be able to **follow verbal instructions** and **cooperate** throughout the screening process.
- The device is **not recommended for use in children under the age of 4 years**.

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8. IMPORTANT SAFETY WARNINGS

- The hearScreen® application should only be operated by individuals who have received adequate training and/or have thoroughly reviewed this user manual. It must be used exclusively with the tablet and headphones provided by hearX, as these components have been calibrated and standardized according to ISO standards to ensure reliable and accurate test results.
- Before conducting a hearing screening test, ensure that the smart device is not connected to a charger. Precautions must be taken to minimize the effects of electromagnetic interference (EMI), particularly from high-powered medical devices, as this can negatively affect the performance of the audiometer. The device should be kept at least 0.15 meters (15 cm) away from sources of magnetic fields to prevent potential interference or operational issues. More detailed EMC (Electromagnetic Compatibility) information is provided later in this guide.
- All precautions relevant to a smart devices apply. For more information, please refer to the "Quick Start Guide" included in the smart device's packaging.
- Refer to **Maintenance and cleaning** of this manual for the proper cleaning procedure of the device.
- The equipment 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 annually** or as specified by industry standards. If the device is dropped or damaged, it must be returned to hearX for re-calibration. Users are responsible for ensuring their devices are calibrated according to their specific work requirements.
- When unpacking hearScreen®, carefully check the equipment for any visible damage. Should any of the equipment suffer from visible damage, please return the content to hearX.
- 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 PHI/PII (Personal Health Information/Personal Identification Information) is kept confidential to the operator and/or the organization conducting the tests.
- hearScreen® is a self-testing tone audiometer:
    - 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.

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EC REP	Authorised representative in the European Community.
SN	This symbol will be followed by the manufacturer's serial number.
	Not for general waste.
	Device is fragile.
	Keep product dry

9. OPERATING ENVIRONMENT

hearScreen® 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 individual being tested must be able to understand the communications instructed.

10. HEARSCREEN® COMPATIBLE DEVICES

The hearScreen® application has been designed for use with the following devices:

- Samsung Tablet: T510 / T515 / T503
- Samsung Smartphone: A320F / A045F / A042M / A042
- Sennheiser HD 280 PRO headphones

11. HEARSCREEN® TEST AND DISPLAYS

The hearScreen® hearing screening test is conducted by a trained school health nurse, community health worker, or tester. The operator's primary responsibility is to present tones by tapping a button and record whether the individual being tested hears each tone.

Before starting the hearScreen® hearing screening, the following options are available to review:

- **Noise Check:** Displays a graphic representation of ambient noise, monitored in real-time by the device. Noise levels are continuously monitored throughout the screening test.
- **Practice:** The conditioning function allows the individual being tested to experience the sounds which are presented before the test commences.
- **Protocols:** The trained health worker can customize and add protocols in addition to the default protocol provided by the software. Specific frequencies and minimum testing intensities can be configured separately for adults and children.

During the hearing screening test starts, tones are presented at various frequencies according to the default protocol (1000, 2000, and 4000 Hz) or as defined in customized protocols. Frequencies are presented at 35 dB for adults and 25 dB for children by default.

The operator facilitating the test stands behind the individual being tested and initiates tone presentation by tapping the "Play" button on the screen. The individual indicates whether the tone is heard. If the tone is heard, the green button is selected to confirm; if not, the red button is selected.

The screening test produces a Pass or Refer result. All data is uploaded to the Electronic Health Record (EHR) once the test is saved.

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12. HEARSCREEN® PROTOCOLS

Default hearScreen Protocol:

SETTING	DEFAULT
Frequencies	500 Hz, 750 Hz, 1 000 Hz, 1500 Hz, 2 000 Hz, 3000 Hz, 4 000 Hz, 6000 Hz, 8000 Hz
Testing Intensity	20 - 70 dB (Adjustable per age group adult/child)
Optionals	• Display tone info in test • Display tone step in test • Shortened rescreen • Better ear question
Testing Protocols	Default or custom protocol setup Default: • Default protocol (500, 1000, 2000, 4000, 8000 Hz) Custom: • Select up to 9 frequencies as part of a screening protocol • Various protocols can be set up and saved.
Additional Settings	• Optional severity classification via the severity protocol feature • On-screen test information and progress visibility • Severity classification up to 70 dB HL

13. HEARSCREEN® 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 signifies greater variability in the response times of the individual being tested. A standard deviation greater than 1 is considered high and should prompt further investigation.

14. HEARSCREEN® FEATURES

Audiological Function	When is this function useful?	Technical considerations
Noise Check		

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The noise check feature provides a real-time ambient noise monitor to help analyse ambient noise levels before conducting a test. Operators 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	Before conducting a hearing test, it is important to assess the ambient noise level to ensure the testing environment is adequate.	The yellow line across the graph represents the maximum ambient noise level allowed by the selected testing protocol. White dots along the yellow line correspond to the frequencies in the selected protocol. The intensity of each white dot is calculated as the headphone **MPANL** (Maximum Permissible Ambient Noise Level of the linked headphone at 0 dB for a specific frequency) plus the minimum testing intensity of the selected protocol. If the ambient noise exceeds the yellow line at any frequency used in the selected 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 operator on the results screen (Under Test-Retest header on reliability tab) if thresholds differ by more than 5dB. Operators 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 the test situation. It is important to name each 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 selection of frequencies to be tested and deselection of frequencies to be skipped.	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			

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FEATURE	AUDIOLOGICAL FUNCTION	WHEN IS THIS USEFUL?	TECHNICAL CONSIDERATIONS
Minimum testing intensity (dB)	The minimum loudness level in dB that will be presented to determine a threshold for that specific frequency.	This level can be changed to speed up the test or to determine the actual thresholds of hearing.	See **Testing Intensities & Frequency Ranges** section for more info
Optional			
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 provides the operator with an indication of the time required to test the individual being tested.	
Shortened rescreen	After first screening is conducted, if any frequencies resulted in a refer, a rescreen will be initiated. This setting enables rescreen only on the failed frequencies	This function allows the individual being tested to retest frequencies that have been referred.	
Better Ear Question	This function presents a pre-screen dialogue requesting selection of the better ear. The test will begin with the selected ear. If disabled, the test will always begin with the left ear.	Starting the test with the better ear facilitates conditioning the individual being tested 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 hearX. It is important that the headphones are managed with care.

The ear cups are subject to a standard disinfecting procedure, as they come into direct contact with the individual being tested. Disinfection is required after every use to 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.

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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.

hearScreen® 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	N/A
Degree of Protection (electric shock)	Type B applied part
Warm-up Time	None
Protection Against Ingress (IP): Smart device	IP 68
Usage Environment	• Hearing screening in schools, research and project environments • Hearing screening service in clinical practice
Smart Device Battery	
Type	Non-removable Lithium-Ion
Capacity	A320F: 2350 mAh T510/5: 6150 mAh T503: 7040 mAh A042F: 5000 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. Contact hearX to arrange re-calibration of the headphones.	
Tone	

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Type	Pure Tone
Frequencies	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 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:* 20 to 70 dB HL from 500 - 8 000 Hz **The maximum levels for the Sennheiser HD 280 PRO:** 125 to 3000 Hz 90 dB HL 4000 Hz 85 dB HL 6000 Hz 80 dB HL 8000 Hz 70 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)
500	433	578
750	650	867
1000	866	1155
1500	1300	1730
2000	1730	2310
3000	2595	3470
4000	3460	4625
6000	5200	6935
8000	6930	9245

Headphones

Sennheiser HD 280 Pro

Static Force	7 N

Frequency	**RETSPL**	**MPANL**
500	6.8	27
750	1.8	-
1000	1.4	31
1500	3.7	-
2000	1.9	44
3000	-3.9	-
4000	2.2	43
6000	16	-
8000	29.4	32

Environmental Conditions

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Operating	Temperature Humidity Ambient Pressure	15 to 35 °C 30 to 90 %RH Non-Condensing 98 to 104 kPa
Shipping and Storage	Temperature Humidity Ambient Pressure	0 to 30 °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 hearScreen® audiometer is intended for use in the electromagnetic environment specified below. The customer or user of the hearScreen® audiometer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The hearScreen® 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 hearScreen® 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 hearScreen® audiometer is intended for use in the electromagnetic environment specified below. The user of the hearScreen® 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		

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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 hearScreen® audiometer will not execute a test.

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance

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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 hearScreen® 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.

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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 hearScreen® audiometer is used exceeds the applicable RF compliance level above, the hearScreen® 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 hearScreen® 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 hearScreen® audiometer

The hearScreen® audiometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the hearScreen® audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the hearScreen® 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 field testing to ensure all controls are up to date and functional.
- Verify that the headphones are properly connected to the smart device's headphone jack
- Ensure the smart device is fully charged before commencing testing.
- Confirm that the headphones are within calibration before conducting a test.
- Conduct tests only within maximum permissible ambient noise levels.
- Clean the headphones between testing individuals to maintain hygiene.
- Verify that the correct headphone is positioned on the correct ear and properly surrounds the pinna.
- Results will not upload to the cloud without an active data connection.

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- Ensure the latest version of the software application is installed on the smart device before testing.
- Refer to the Frequently Asked Questions for additional guidance.

17. FREQUENTLY ASKED QUESTIONS

1. What is the difference between hearScreen® and hearTest™?
   hearTest™ is a diagnostic audiometer that measures hearing thresholds and can be used for hearing aid fittings. hearScreen® is an initial assessment designed to identify whether the individual being tested is at risk for hearing loss. If risk is indicated, hearScreen® refers the individual for additional testing to obtain further diagnostic information.
2. Should equipment be checked on a regular basis?
   Yes. It is important that the equipment used for hearing screening is checked regularly. One key check is required to ensure the equipment remains in full working order:
   - **Annual calibration of headphones** – The hearScreen® application is designed to be used with headphones that are specifically calibrated for the software. Therefore, headphones must be re-calibrated by hearX once every 12 months.
3. 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 results.
4. How can the protocol be changed?
   To change or add a new protocol in the hearScreen® application, follow these steps:
   a. Launch the hearScreen® application.
   b. Tap on PROTOCOLS.
   c. Select ADD+ to create a new protocol.
   d. In the FREQUENCIES tab, enter a name for the protocol.
   e. Select the frequencies to be included in the test.
   f. Adjust the necessary settings in the ADJUSTMENTS tab.
   g. Configure any additional options in the OPTIONALS tab.
   h. Tap SAVE to store the new protocol.
5. Can children be tested with hearScreen®?
   Yes. hearScreen® has been validated for use with children aged 4 years and older.
6. How are hearScreen® application updates installed?
   Available software updates are indicated by a badge on the START screen.
   To install updates manually:
   a. Ensure the smart device is connected to a stable internet connection.
   b. Tap the MENU icon in the top left corner of the screen.
   c. Select UPDATES.
   d. A list of available updates will be displayed. Select the relevant application to update.
   e. A confirmation pop-up will appear. Tap UPDATE to proceed or CANCEL to exit the update process.
   Note: If the smart device is managed through a Mobile Device Management (MDM) system, updates are installed automatically when the device is connected to the internet.
7. What is hearX Cloud?
   hearX Cloud is a centralised electronic health record (EHR) platform that stores and manages hearScreen® test data. It allows synchronisation of screening results from the hearScreen application and provides a secure, web-based interface for viewing detailed reports.
   Access to hearX Cloud requires a registered account.

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DOCUMENT APPROVAL

ROLE	NAME	DATE	SIGNATURE
Business Analyst	Belinda Beukes	28 May 2025	@Belinda Beukes
RAQA Officer	Jeresa Govender	02 Jun 2025	@Jeresa Govender

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