
# HEARSCREEN

Instructions For Use

03/26/2025.

hearScreen®

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# REVISION HISTORY

| REVISION | DATE | DESCRIPTION | BUSINESS ANALYST |
|---|---|---|---|
| v1.0 | 20 Nov 2023 | Drafted document | @William Ward |
| v1.1 | 05 Jun 2024 | Updated intended use and description with intended user | @William Ward |
| 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 |

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 warrants further testing to be conducted for the test subject to ensure the degree of hearing loss is confirmed. hearTest, another hearX software product, can be used as a hearing screening test to determine the slope of hearing loss and obtain an audiogram for the patient / test subject.

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**

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 within your country.

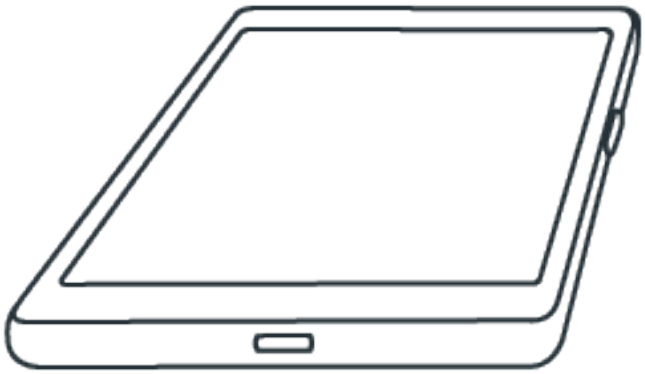
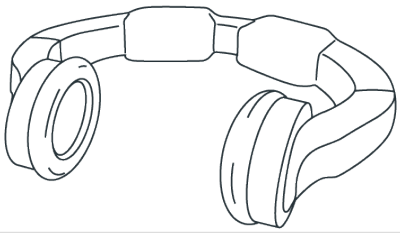
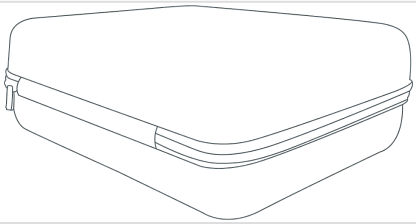
# 3. ABBREVIATIONS

| | |
|---|---|
| **RETSPL** | **Reference equivalent threshold sound pressure levels** (RETSPLs) are used when calibrating audiometric equipment to a hearing threshold level of zero at various frequencies. |

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

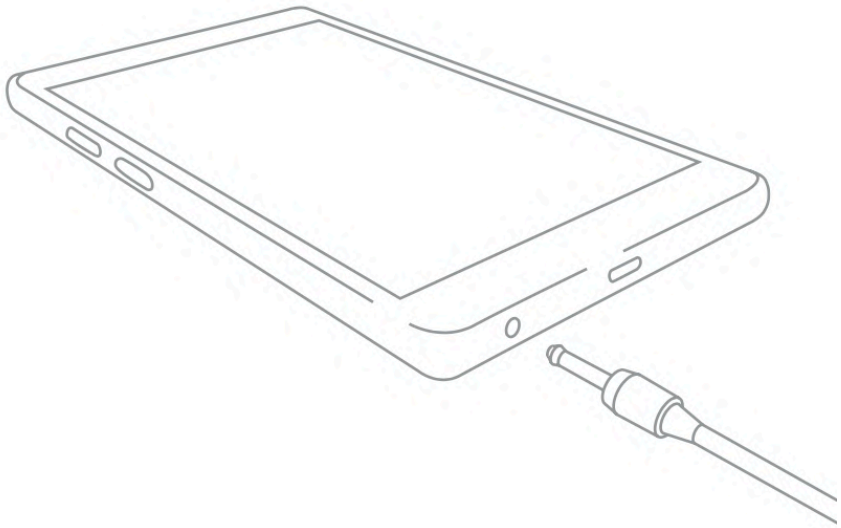
| | |
|---|---|
| **MPANL** | **Maximum Permissible Ambient Noise Levels.** The American National Standards Institute (ANSI) specifies maximum permissible ambient noise levels (MPANLs) allowed in an audiometric test room to ensure that hearing thresholds obtained down to 0-dB HL will not be elevated due to masking by ambient noise. |

## 4. WHAT'S IN THE BOX?

| | |
|---|---|
|  | Samsung Smart Device:<br>(T510 / T515 /T503) tablet or<br>(A320F /A045F / A042M /A042) smart phone |
|  | Sennheiser HD 280 PRO |
|  | 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.

**NOTEWORTHY**

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

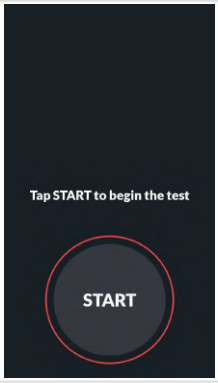
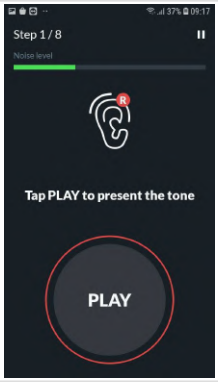
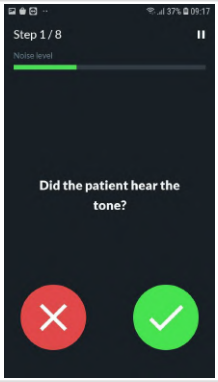
**Battery Operated Only:** Device to be used without plugging into mains, i.e. battery operated only.

**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 hearScreen® screening. 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 SCREENING 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 screen. |
|  | **Step 3:** The screener stands behind the patient and presents the tones by tapping on the "Play" button on the screen. The test subject indicates if they hear the tone. |
|  | **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 when it is likely that the validity of the test results may be compromised. Do not conduct a hearing screen 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 and wounds. 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 is not recommended to be used for children below the age of 4 years old.

# 8. IMPORTANT SAFETY WARNINGS

The hearScreen® application should only be used by persons who have received adequate training and/or have thoroughly read through this user manual. The hearScreen® application should only be used with the 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 screening test, ensure that the smart device is not charging. Certain precautions must be taken to minimize the effect of electromagnetic fields (particularly from high powered medical devices), as EMC can negatively impact the performance of the audiometer. Specific EMC information is provided later in this guide. This device should be kept at least **0.15 meters (15 cm)** away from sources of proximity magnetic fields to prevent potential interference or operational issues.

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 hearScreen®, 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.

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.<br>The applied parts are the left & right earphones and the associated cables. |
|  | Follow instructions for use. |
|  | 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

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 patient must be able to understand the communications instructed.

## 10. HEARSCREEN® COMPATIBLE DEVICES

hearScreen® has been designed for use with a @and Sennheiser HD 280 PRO.

## 11. HEARSCREEN® TEST AND DISPLAYS

hearScreen® is administered by a school health nurse, community health worker or tester and the only thing they require to do is tap on a button when the tone should be presented.

Before the hearScreen® screening test starts, you have the opportunity to view the following under the different tabs:

- Noise check: Here you will see a graphic representation of the ambient noise as monitored by the device in real-time. This is monitored throughout the screening test.
- Practice: The conditioning function allows the patient to experience the sounds which are presented before the test commences.
- Protocols: As the trained health worker, you have the ability to customize and add required protocols in addition to the default protocol as provided by the software. With this functionality, specific frequencies can be configured and the minimum testing intensities can be adjusted for both adults and children.

As soon as the hearScreen® hearing screening test starts, tones are presented at different frequencies, either as per the default protocol at 1000; 2000 and 4000 Hz or as per your preference set up in your customized protocols. The frequencies will be presented at 35 dB for adults and 25 dB for children by default.

The screener stands behind the patient and presents the tones by tapping on the "Play" button on the screen. The test subject indicates if they hear the tone. If the tone was heard, the green button is selected to confirm, if not, the red button should be selected.

The screening test has a Pass or Refer result and all data is uploaded to the EHR once the test is saved.

## 12. HEARSCREEN® PROTOCOLS

| PROTOCOL | 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<br>Display tone step in test<br>Shortened rescreen<br>Better ear question |
| Testing Protocols | Default or custom protocol setup<br>Default:<br>• Default protocol (500, 1000, 2000, 4000, 8000 Hz)<br>Custom:<br>• Select up to 9 frequencies as part of a screening protocol<br>• Various protocols can be set up and saved. |
| Additional Settings | • Optional severity classification via the severity protocol feature<br>• On-screen test information and progress visibility<br>• Severity classification up to 70 dB HL |

## 13. HEARSCREEN® MEASURES

| | |
|---|---|
| False Response Count | False response percentage divided by the total amount of responses.<br>*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. |

# 14. HEARSCREEN® FEATURES

| Audiological Function | When is this function useful? | Technical considerations |
|---|---|---|
| **Noise Check** | | |
| The noise check feature provides a real-time ambient noise monitor to help analyse ambient noise levels before conducting a test.<br><br>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 | Before conducting a hearing test, it is important to determine the ambient noise to be confident that the environment in which you are testing is adequate for testing. | The yellow line across the graph represents the maximum ambient 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.<br><br>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. | |

| FEATURE | AUDIOLOGICAL FUNCTION | WHEN IS THIS USEFUL? | TECHNICAL CONSIDERATIONS |
|---|---|---|---|
| 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 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 gives the tester an indication of the time it will take to test the patient. | |
| 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 patient to retest frequencies that have been referred | |
| 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.

| **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):<br>Smart device | IP 68 |
| Usage Environment | • Hearing screening in schools, research and project environments<br>• Hearing screening service in clinical practice |
| **Smart Device Battery** | |
| Type | Non-removable Lithium-Ion |
| Capacity | A320F: 2350 mAh<br>T510/5: 6150 mAh<br>T503: 7040 mAh<br>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. 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 Hz |
| Rise / Fall time | 35 ms (-20 dBFS to -1 dBFS and vice versa) |
| Intensity Range | The minimum intensity and frequency range for:<br>*Samsung T500/5 and Sennheiser HD 280 Pro:* 20 to 70 dB HL from 500 - 8 000 Hz<br>**The maximum levels for the Sennheiser HD 280 PRO:**<br>125 to 3000 Hz 90 dB HL<br>4000 Hz 85 dB HL<br>6000 Hz 80 dB HL<br>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** | | |
|---|---|---|
| Operating | Temperature<br>Humidity<br>Ambient Pressure | 15 to 35 °C<br>30 to 90 %RH Non-Condensing<br>98 to 104 kPa |
| Shipping and Storage | Temperature<br>Humidity<br>Ambient Pressure | 0 to 30 °C<br>30% - 60% Non-Condensing<br>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)<br>IEC 61000-4-2 | ± 8 kV contact<br>± 15 kV air | ± 8 kV contact<br>± 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<br>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<br>IEC 61000-4-11 | Not applicable, see note 2 | | |
| Power frequency (50/ 60 Hz) magnetic field<br>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 |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Conducted RF<br><br>IEC 61000-4-6<br><br>Radiated RF<br><br>IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz, and<br><br>6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz.<br><br>3 V/m 80 MHz to 2.7 GHz, including wireless communications equipment at other discrete frequencies [a].<br><br>10 V/m | 6 Vrms | 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.<br><br>**Recommended separation distance**<br><br>d = 0.60 √P<br><br>d = 0.35 √P 80 MHz to 800 MHz<br><br>d = 0.70 √P 800 MHz tot 2.5 GHz<br><br>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).<br><br>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].<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |

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 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**<br>**d = 0.60 √P** | **80 MHz to 800 MHz**<br>**d = 0.35 √P** | **800 MHz to 2.7 GHz**<br>**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 is one check required to ensure the equipment is in full working order:

- Annual calibration of headphones - the hearScreen® 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.

**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.

**How do you change the protocol?**

- Launch hearScreen® application.
- Click on **PROTOCOLS**
- Click on **ADD+** to add new protocol
- 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 hearScreen®?**
Yes, it has been validated for children older than 4 years

**How do I update my hearScreen® 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.
- 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 hearScreen® results and display on a web page for detailed result reporting. This can be accessed via cloud. *mhealthstudio.com*[3] and requires a registered account to access the relevant test data.

3 http://mhealthstudio.com

# DOCUMENT APPROVAL

| ROLE | NAME | DATE | SIGNATURE |
|---|---|---|---|
| Product Owner: Business | Danielle Snyman | 12 Mar 2025 | @Danielle Snyman |
| Senior Quality Assurance Officer | Jade Blanchard | 13 Mar 2025 | @Jade Blanchard |