**hearX Self Test Kit**

**FAQ:**

# **How can the hearX Self Test Kit benefit me as an audiologist?**

The hearX Self Test Kit aims to equip healthcare professionals during these unprecedented times by providing a solution that allows adult patients to take a hearing test at home. The hearX Self Test Kit offers a test battery to 1) refer patients requiring a more comprehensive diagnostic assessment for suspected ear disease and; 2) support hearing aid fitting\*.
*\* The Purchaser remains responsible for adhering to the relevant territory regulations to implement the hearX Self Test Kit into their practice.*

# **What audiometric tests can be conducted using the hearX Self Test Kit?**

The comprehensive self-test solution allows healthcare providers to conduct the following tests towards successful hearing aid fitting in low-or no-touch models of care :

* Digital pure tone audiometry using hearTest, a certified CE and FDA registered audiometer (IEC 60645-1) with calibrated headphones offering rapid automated testing.
* Speech-in-noise testing using hearSpeech for a speech recognition threshold and to inform patient care, counselling and management of hearing aid expectations.
* hearRisk assessment detects the risk of ear disease and is based on i) Conductive loss risk algorithm (patent pending) with 95% accuracy; ii) Asymmetric loss screening; iii) FDA red flag questions. The CEDRA questionnaire is an optional assessment.
* Digital Artificial Intelligence (AI) otoscopy (optional) to provide a safe, simple way to capture images of the eardrum with validated AI image classification for diagnostic categories.

# **Is it possible to perform bone conduction audiometry?**

Usually, the diagnostic assessment for a patient with suspected ear disease requires air and bone conduction audiometry, which is required to be performed in a sound-treated room to ensure that reliable thresholds can be measured down to -10 dB HL. The challenge with a Self Test Kit, is that it requires hearing tests in environments which do not always comply with ideal testing environment standards. Apart from the environments not being ideal for bone conduction the challenge further is the ability to self-administer a bone conduction test is somewhat difficult to set up.

The problem that requires a solution is to differentiate patients who require traditional clinic-based services, i.e. cases with suspected ear disease or conductive hearing loss, from those with sensorineural hearing loss, who are likely candidates for hearing aids. Fortunately, some recent developments provide alternatives to conventional audiological testing, such as bone conduction audiometry and tympanometry, to identify the risk of ear disease.

We developed our hearRisk product, that provides a proprietary way of detecting conductive hearing loss risk with a 95% accuracy and can be used to flag those 3% of patients that can not be fitted with a hearing aid and then, if required, ask those patients to visit the clinic.

The hearX Self Test Kit does not offer bone conduction audiometry, but rather offers our hearRisk product.

We ask certain FDA recommended questions to detect ear disease and also offer the CEDRA questionnaire to detect if specific ear disease conditions are present.

# **How does the pure tone audiometry test, used as part of the hearX Self Test Kit, compare to pure tone testing conducted in an audiology practice?**

The hearTest pure tone audiometry test is a clinically validated CE and FDA registered test and results in various peer-reviewed articles have shown that hearTest provides similar results compared to the golden standard in audiometry. The outcome of this paper, [**Smartphone threshold audiometry in underserved primary health-care contexts,**](https://www.ncbi.nlm.nih.gov/pubmed/26795898) indicates that accurate air-conduction audiometry can be conducted in a sound booth and without a sound booth.

A recent article [**Accuracy and Reliability of Smartphone Self-Test Audiometry in Community Clinics in Low Income Settings: A Comparative Study**](https://journals.sagepub.com/eprint/PIA5RBZKY4FBKINPQHCQ/full)has also indicated that Smartphone self-test audiometry can provide accurate and reliable air conduction hearing thresholds with sensitivity for detection hearing loss >40 dB HL in one ear was 90.6% (n = 84 ears), and specificity 94.2% (n = 84 ears).
For more information on the research related to the hearX products please visit https://www.hearxgroup.com/research

# **Is an otoscope included in the solution?**

Yes, by purchasing the hearScope add-on, the hearX Self Test Kit can include the smartphone otoscope to be used by patients at home, as part of curb-side tests, or as part of counter-side testing. The user is guided by a detailed tutorial to take an image of the tympanic membrane to see if there are any obstructions in the ear canal that will hinder hearing aid fitting. The use of the otoscope in home testing is optional for patients and possible for significant others that may have the dexterity to handle the otoscope can be asked for assistance.
The otoscope works with specula that is significantly shorter than other clinical specula to protect the patient’s ear and further improve the ease of use of the otoscope.

# **The hearScope™ otoscope uses AI image classification. Does this mean the audiologist is not involved in the otoscopy?**

No, the audiologist is involved in the otoscopy. Even though hearScope™ includes the world's first AI image classification system, which instantaneously classifies captured images in the categories of normal, chronic perforation, wax obstruction or abnormal - which is a high probability of another pathology being present, it is the audiologist or physician's responsibility to interpret the images and decide on a course of action. The information is shown to the patient, but is also included as part of the test result with the image to the audiologist asynchronously..

The hearScope™ AI feature is currently in BETA-testing and not certified yet. Use this feature at your own risk. The use of hearScope™ should not replace your good judgment, common sense or healthcare experience. It is in your best health interest to use the feature in conjunction with medical advice obtained from a qualified healthcare professional, preferably one specialising in diagnosing diseases of the ear.

# **How can the audiologist make sure his patient is not in a noisy environment while performing the test?**

The hearX Self Test Kit includes a noise monitoring system and monitors the noise in the environment. We advise via the app if the environment is too noisy and the patient should find a quieter area. The testing also uses noise monitoring to pause the test and advise for a restart, if required. Additional quality control measures monitor the response times and false response counts to also indicate the test reliability. All quality measures are available alongside the test results to the audiologist.

# **How long should I wait before I can access my patients' test results?**

As long as the tablet is connected to a wifi network the test results will be received instantly through a secure cloud service and will be accessible on mHealth Studio Cloud. Test results are therefore accessible asynchronously and the audiogram and all relevant test data for the patient will be available for telesupport services. All data seamlessly integrates with cloud data management software.

**Which devices are compatible with the hearX Self Test Kit?**
The hearX Self Test Kit is sold with a standardised device to ensure the correct outputs are produced for audiometric testing. Only devices procured directly from hearX, for this purpose, can be used.

A Samsung Tab A tablet is included with the hearX Self Test Kit and adheres to the ANSI S3.6 standards required for a type 4 audiometer.

RSA only: The hearX Self Test Kit can be used on a Samsung Galaxy A3 device.

# **Where can I use the hearX Self Test Kit?**

The hearX Self Test Kit can be used in multiple environments, such as curb-side testing within a drive-through setting, home testing, or even counter-side testing to adhere to the required social distancing measures.

Ensure that you remain familiar and in compliance with all regulations applicable to your practice as they relate to remote fitting of hearing aid devices. Regulatory requirements in this area of practice are constantly evolving, including with regards to remote medical evaluations and practice of remote care. hearX makes no warranty or representation as to the Purchaser’s right and allowance to use the Product for its desired purpose, within the territory of use. It remains the Purchaser’s responsibility to adhere to the relevant territory regulations, which include both state and federal regulations.

# **Will my patients know how to use the self test?**

Yes, the easy step-by-step software will guide patients through a comprehensive hearing assessment. Software checks are included to ensure the headphones are fitted correctly before the test is started and tutorials are added at key points to ensure the patient can easily complete the hearing assessments.

# **Does the patient keep the tablet and headphones?**

No, the patient returns the kit to the audiologist who should then clean and disinfect the headphones and tablet for use with another patient.

# **Is there a warranty period for my devices?**

Yes, the hearX Self Test Kit comes with a 1 year out-of-box warranty. If a device fails within the first year then the supplier warranty applies. The time for the replacement of a smartphone device may take up to 3 months.

# **Are the headphones calibrated and how long is the calibration valid for?**

Yes, all headphones need to be calibrated on an annual basis. The calibration status of the headphones is shown on the tablet and a warning is lifted once the headphones are nearing calibration expiry. Once the headphone calibration has expired, the headphones need to be returned to the service center for recalibration. After receiving back the headphones, the calibrated headphones should be re-linked to the tablet and can be used for testing for another 12 month period.

# **Where should my headphones be calibrated?**

All headphones should be calibrated at a hearX calibration facility. Please email hearX at info@hearxgroup.com or contact the office during business hours (Monday to Friday from 9 am to 4 pm SAST) at: US: (415) 212-5500 or RSA: +27 (0) 12 030 0268, to schedule an appointment.

# **Who can I contact when I experience a problem or require support?**

Please feel free to send any support issues to support@hearxgroup.com. Our friendly support team will review your issue and get back to you within 24 hours.

If your issue can’t wait feel free to contact our offices during business hours (Monday to Friday, 9am to 4pm SAST) at:

US: (415) 212-5500

RSA: +27 (0) 12 030 0268.