



▼ Table of contents:

- 1. Scope of this training guide
- 2. Definitions
- 3. Getting Started
 - 3.1 Quick Start Guide
 - 3.1 What is in the box?
- 4. About hearTest™
- 5. Using the hearTest™ hardware
 - 5.1 Prepare the smart device
 - 5.2 Using of headphones
- 6. Set up access accounts for mHealth Studio Cloud and hearX smart device.
 - Step 1: Setup the account to use the software via mHealth Studio Cloud
 - Step 2: Create a tester account to access the smart device
 - Step 3: Sign in on the hearX smart device
- 7. Follow the Setup Wizard on the hearX smart device
- 8. How to conduct a hearTest™ session
 - Step 1: Press the start button on the home screen.
 - Step 2: Select the relevant facility and patient/test subject information
 - Step 3: Consent form, Questionnaire, and summary
 - Step 4: hearTest™ guide through
 - 4.1 Do a NOISE CHECK (Optional)
 - 4.2 Use INSTRUCTIONS to guide patient (Optional)
 - 4.3 PRACTICE function (Optional)
 - 4.4 Select the required PROTOCOL
- 9. hearTest™ testing in progress
- 10. hearTest™ test Results
 - 10.1 Additional menu on the results screen
- 11. Viewing of patient's results on mHealth Studio Cloud
- 12. Support
 - 12.1 mHealth Menu
 - 12.2. Detailed settings of the hearX smart device
 - 12.2.1 hearTest™ settings
 - 12.2.1.1 General Settings
 - 12.2.1.2 Manage Protocols
 - 12.2.2 Detailed mHealth settings
 - mHealth settings for Self Test mode:
 - mHealth settings for Facilitated mode:
- 13. Other
 - 13.1 Calibration certificate
 - Calibration notification on mHealth Studio App

- Relinking of recalibrated headphones
- View calibration status of the headphones
- 13.2 Maintenance
- 13.3 FAQ
- 13.4 Contact
- Copyright Notice
- Trademarks

▼ Revision History

Revision	Date	Software Version	Description
v1.0	19 Nov 2020	v6008	First publication of training manual for hearTest™.
v1.1	3 Dec 2020	v6009	Updated screenshot in section 4.2, section 9. Added description of these methods in section 12.2.1.2
v1.2	8 Dec 2020	v6009	Updated screenshot in Section 8 and section 10.
v1.3	14 Dec 2020	v6008	Updated link for the HTST-MN-01 hearTest IFU v2.3 document
v1.4	22 Dec 2020	v6008	'How-to' videos in section 6, section 7, and section 8 updated.
V1.5	11 Jan 2021	v6019	Updated section 10.1, subsection: Add an otoscopy image. Updated the headphones to RadioEar DD450. Added DAC v3 and also updated the screenshots throughout the whole document.

1. Scope of this training guide

This manual provides instructions for use of the hearTest™ hardware and software applications. This manual will guide the facilitator to operate the hearTest™ audiometer software and explain all software features included for optimal use within a clinical and/or community setting. The instruction for use of hearTest™ is an extension of the instructions for use of hearTest™ covered in <https://hearxgroup.atlassian.net/l/c/7Q31adrm>

2. Definitions

In this training manual the following terms are referred to:

Owner	Refers to the person who owns the smart device.
Administrator	Refers to the person responsible for the set-up of the hardware and software. This can typically also be the owner of the hardware that oversees all tests results across multiple devices where applicable.
Facilitator	Refers to the audiologist or hearing health professional who facilitates the test with the patient / test subject.
Patient / Test subject	Refers to the person who executes the test.

3. Getting Started

3.1 Quick Start Guide

QUICK START GUIDE

FOR MHEALTH STUDIO APP

STEP 1



SET UP YOUR HEARX ADMIN ACCOUNT

Visit cloud.mhealthstudio.com on your laptop/PC and click on **sign in with hearX**. Enter your hearX admin account email address and the password.

STEP 3



CONNECT YOUR HEARX TABLET TO A STABLE INTERNET CONNECTION

On your tablet tap on the **i** **ICON** > tap **SETTINGS** > **Wi-Fi** > select the relevant network and enter the password.

STEP 5



SIGN IN USING YOUR USER ACCOUNT USERNAME AND PASSWORD

STEP 2



CREATE A TESTER ACCOUNT TO ACCESS YOUR HEARX TABLET

On the menu list click on **TESTER** > **ADD TESTER** > Add your desired username and password > Click on **CREATE**.

STEP 4



LAUNCH THE MHEALTH STUDIO APP

STEP 6



FOLLOW THE MHEALTH APP SETUP WIZARD

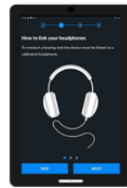
LINK YOUR SOFTWARE LICENSE

Tap on the license/s which you would like to the link to your hearX tablet > Once selected tap on LINK



LINK YOUR HEADPHONES

You can link your headphones to your hearX tablet by either scanning the QR code or by manually entering the serial number located in the band of your headphone



ENTER YOUR PROFILE INFORMATION

You can add a Professional Registration Number and/or Signature to your tester account.



SELECT YOUR INTENDED USE

If you have purchased the hearX Self Test Kit software select the Self test Kit as your intended use. If you have purchased the hearTest, hearTest Occ Health, or hearScreen software select General Testing as your device mode.

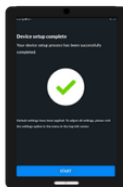


SELECT YOUR COUNTRY

Select the relevant country



ALL DONE!



3.1 What is in the box?

Item	Description
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4. About hearTest™

hearTest™ is a world-first certified digital smartphone audiometer with cloud data management using mHealth software. The intended use of hearTest™ is to determine patient hearing threshold levels. The device presents pure tones by means of air conduction only.

hearTest™ devices are designed to conduct hearing tests using calibrated headphones and standardized smartphones. hearTest™ generates tones in the audible range (usually at each octave 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 the 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 facilitator through the test and displays the final results.

i hearTest™ is also available for use in Occupational Health. For more information on this, see hearTest™ <https://www.hearxgroup.com/hearTest-occupational-health-solution>.

Furthermore, hearTest™ is available in a version that offers extended high-frequency testing, commonly used for ototoxicity monitoring. For more information visit <https://www.hearxgroup.com/hearTest>.

5. Using the hearTest™ hardware

5.1 Prepare the smart device

- Ensure that the device is fully charged and operational.
- Ensure that the media volume on the phone has been turned to maximum.
- Ensure that the device is connected to the internet for the initial set up and when uploading of data is required.

5.2 Using of headphones

Circumaural headphones



Sennheiser HD 280



RadioEar DD450 circumaural headset

- Pull the ear cups apart to fit the headphones over the patient's head.
- Ensure that the ear cups correspond with the correct ear (Red-right ear and Blue-left ear).
- Adjust the headband to fit according to the patient's head size. To expand the headband, push the sides of the headband up to increase the fitted size. Push the headband downwards to decrease the size of the headband.
- Ensure that the ear cups cover the ears completely.

6. Set up access accounts for mHealth Studio Cloud and hearX smart device.

Step 1: Setup the account to use the software via mHealth Studio Cloud

Upon successful purchase of the hearX software the email address selected to link the software subscription, will be used to create the hearX account. The hearX account is used to link all software subscriptions for use on the smart devices and is also assigned as the admin account for mHealth Studio Cloud. mHealth Studio Cloud consists of mHealth Studio App which is the launching platform used to operate the hearX software on the smart device, administer tests credits, handle secure account login and sync test results to the cloud platform named mHealth Studio Cloud™.

The administrator will receive an email from hearX Group (no-reply@hearsgroup.com) prompting to set a password for the newly created hearX account. The hearX account and password will be used to login to mHealth Studio Cloud™ to view all the session results.

Once the password has been set, the hearing health professional should open <https://cloud.mhealthstudio.com> and tap on the **Sign in with hearX** button.

The administrator should login to their newly created hearX account via the mHealth Studio App. To do this the administrator should follow the steps below:

1. Open the mHealth Studio App. **RadioEar DD450 circumaural headset**
2. Enter their email address in the username/email address field.
3. Enter a password.
4. A pop-up message will appear confirming that the hearX account email has been detected but no password has been set and will ask the administrator to either 'SET PASSWORD' or 'CANCEL'. If you tap on 'SET PASSWORD' you will be redirected to a page where the administrator is able to set their password.

FOR AUSTRALIAN CUSTOMERS

Please use <https://auscloud.mhealthstudio.com> to access the Australian version of mHealth. The mHealth link will not automatically redirect and access to mHealth should be registered on the Australian instance.

Please note: The hearX account provides the administrator with access to the hearX software and the web portals to view results. Any subscription to the hearX software will be linked to this account. When purchasing any other or new software on the hearX website this account must be used to complete the transaction in order for subscriptions to be linked to the correct hearX account.

Step 2: Create a tester account to access the smart device

To access the mHealth Studio App on the device and to start testing, a tester account is required for sign-in. A tester account is created on the mHealth Studio Cloud portal when you create the hearX account. This video will show the administrator how to add a Tester account to access the smart device.



CLICK HERE to watch how to add a Tester account using mHealth Studio Cloud and mHealth Studio App

Step 3: Sign in on your smart device



CLICK HERE to watch how to sign in on your hearX device

Should the administrator forget their password, the 'Forgot password?' link will indicate that they must go to <http://cloud.mhealthstudio.com> to update the password via the Testers menu.

7. Follow the Setup Wizard on the hearX smart device



CLICK HERE to watch the Setup Wizard guide through

OR



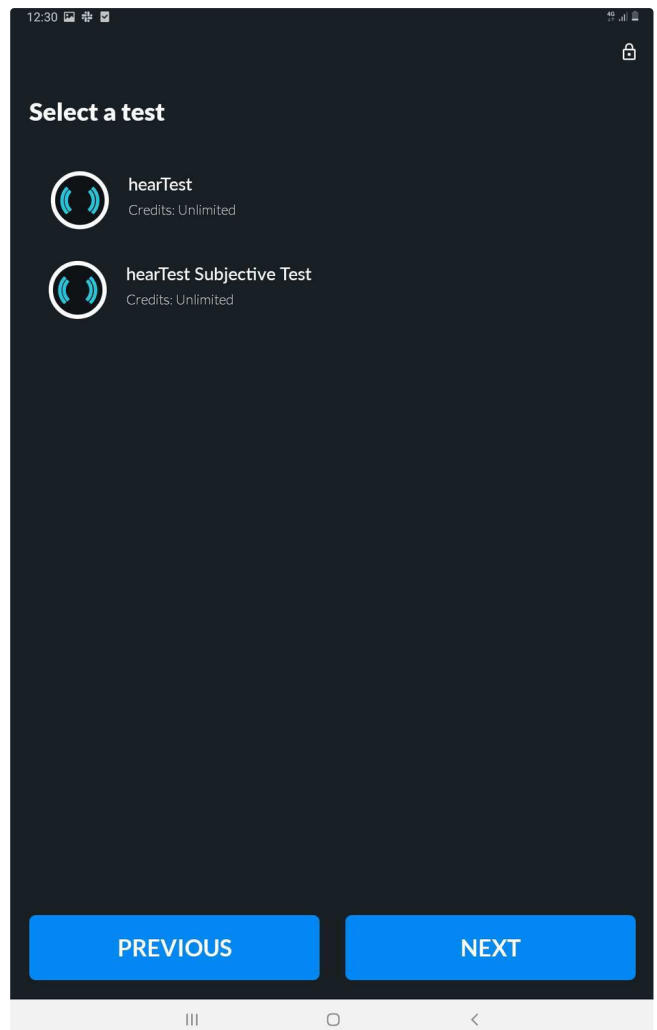
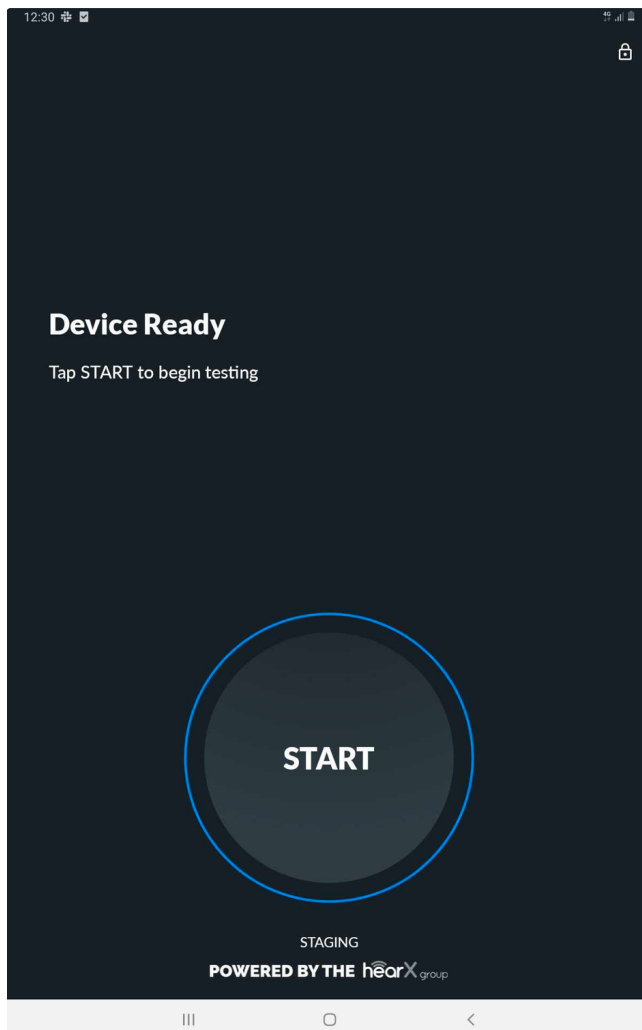
Self test kit
[X Self Test](#)

kit. For more information regarding our Self Test Kit, please visit our website: [hear.cn](#)

8. How

session

Step 1: Press the start button on the home screen.



The facilitator should select the correct test option that will be conducted and select 'Next'.

In the case of using hearTest™, the facilitator needs to select hearTest™ from the list of available tests. This is a function of all the different software licenses available of the hearX smart device that enables the different tests which can be conducted.

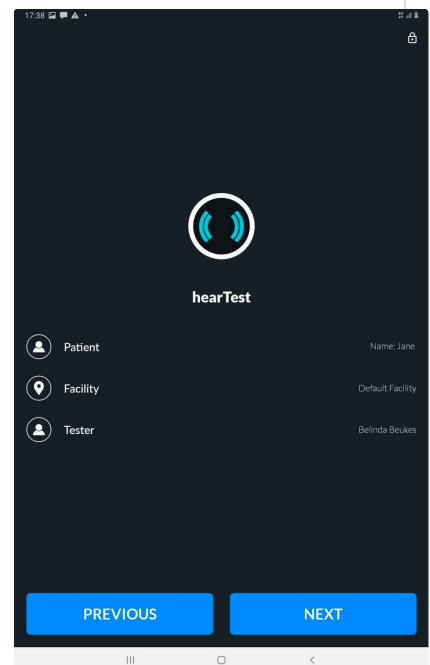
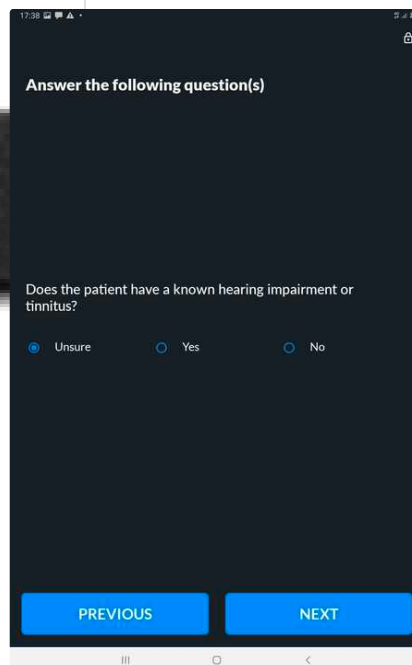
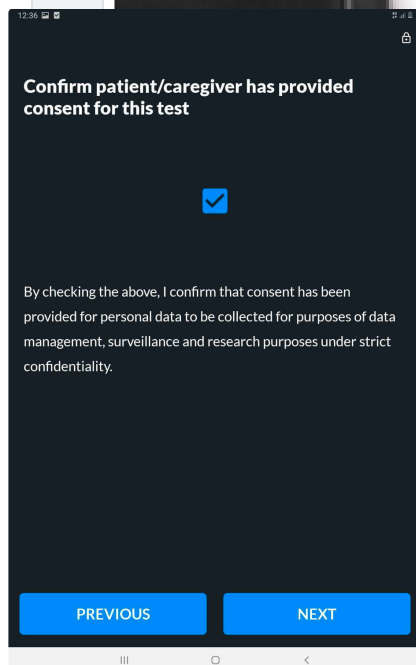
Step 2: Select the relevant facility and patient/test subject information



CLICK HERE to watch how to add and select Facility and Patient information

Step 3: Questionnaire, and summary

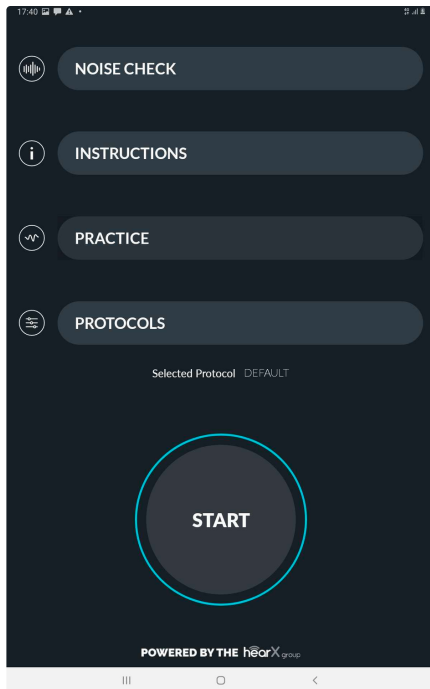
All patients must complete the questionnaire before the session can begin. Click on the check box (See illustration below) and select 'NEXT'. If the patient is not activated the patient will be asked if they have a known hearing impairment. If unsure, keep to the default and select 'Unsure'. The summary page provides a summary of the name of the patient, the facility, and the facilitator that will be conducting the test. The summary page also provides a 'PREV' button to determine that all the information has been correctly entered. The PREV button can be used to navigate back to the questionnaire or restart with selecting the facility / patient information.



Step 4: hearTest™ guide through

The START button will appear, the facilitator can proceed and start the test. Above the START button, there are four pre-test functions that can be used to enhance the test experience:

- 4.1 Do a NOISE CHECK (Optional)
- 4.2 Use INSTRUCTIONS to guide patient (Optional)
- 4.3 PRACTICE function (Optional)
- 4.4 Select the required PROTOCOL



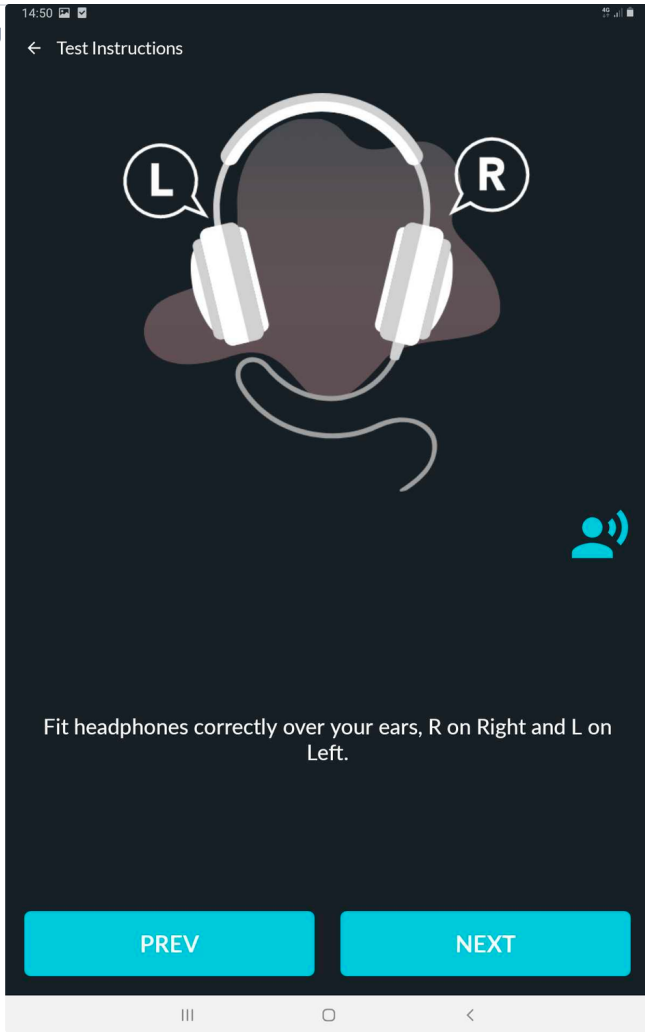
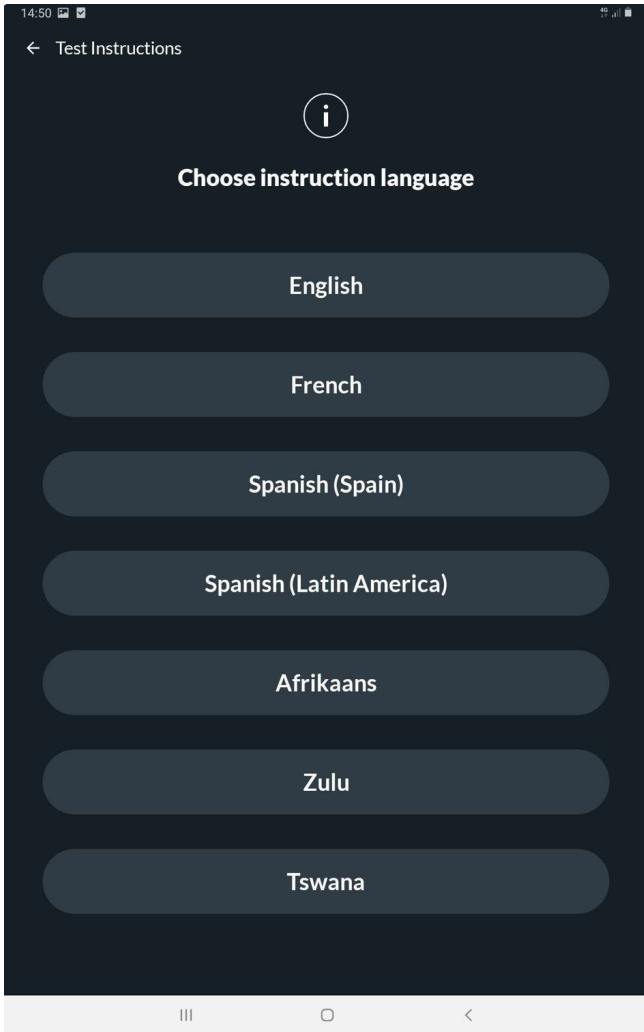
4.1 Do a NOISE CHECK (Optional)

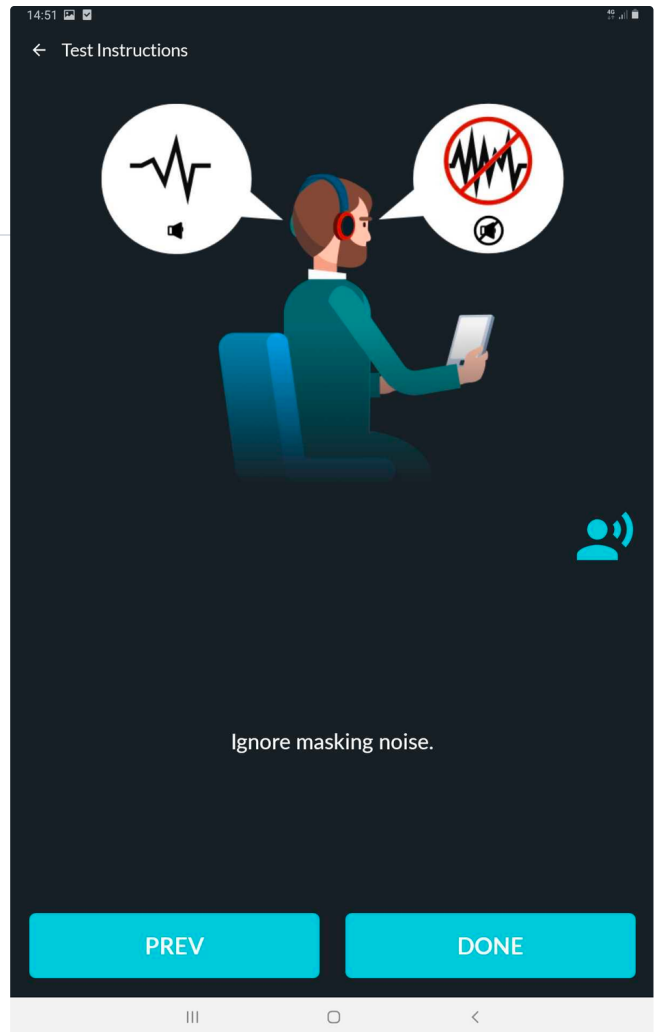
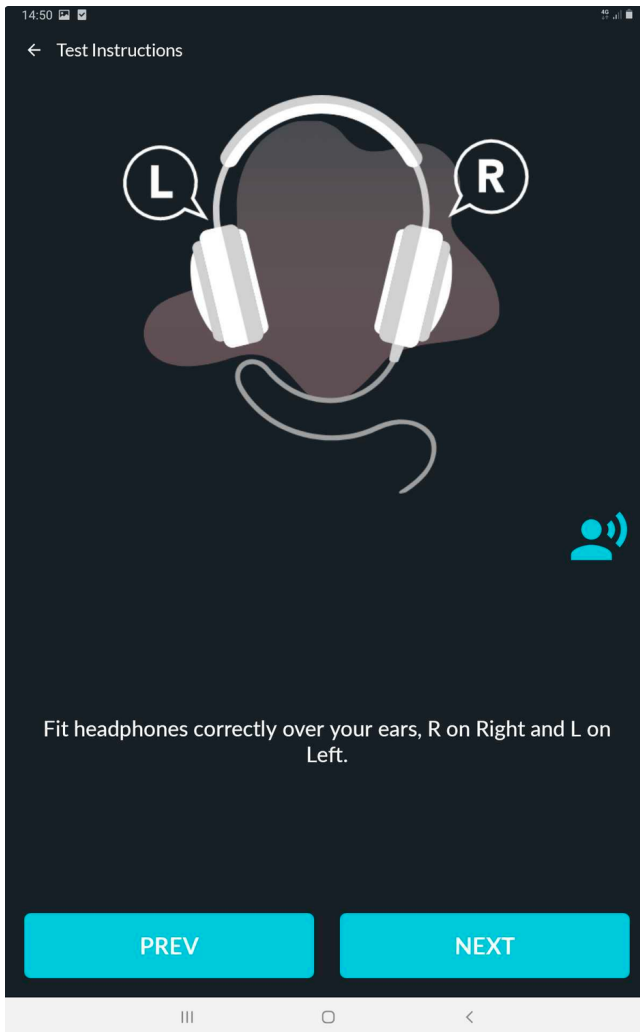
To ensure that the environmental noise levels are not excessive.

Please note: This is not a sound level meter and should not be used to officially certify the sound environment but is rather a precautionary measure for the facilitator to provide an alert when noise levels are excessive and may affect test results.

4.2 Use INSTRUCTIONS to guide patient (Optional)

Step by step test instructions, available in an audio presentation of 7 languages namely English, French, Spanish (Spain), Spanish (Latin American), Afrikaans, Zulu, and Tswana.

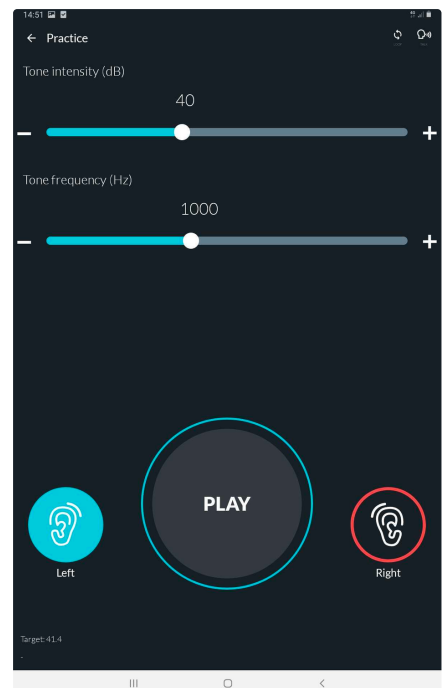




4.3 PRACTICE function (Optional)

To condition the patient on the tones that will be presented and train them on the desired response. The conditioning tone can be adjusted in frequency and intensity. It is recommended to condition a patient at 1000Hz with a 40dB intensity. The intensity can be increased if the patient does not respond and then decreased as the patient responds so that the patient understands that the tone is expected to become softer until a hearing threshold is obtained.

The facilitator can also speak to the patient via the headphones, whilst on the conditioning page. The facilitator should select the talk forward icon to speak to the patient via the headphones.



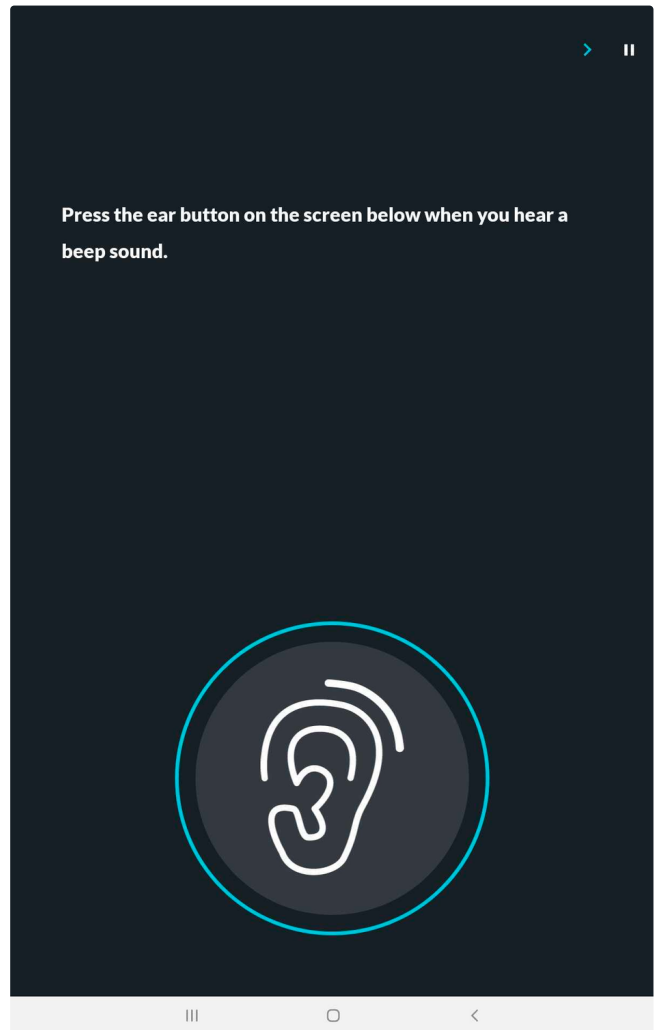
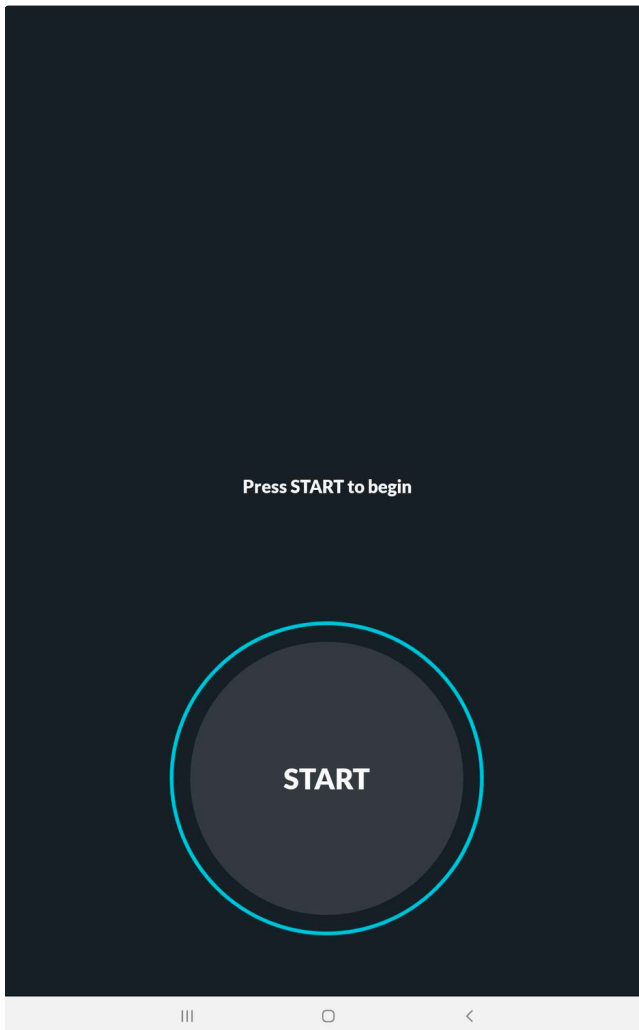
4.4 Select the required PROTOCOL

The facilitator has the option of creating their own protocols and adjusting it as per preference to the features available, or they can select the default protocol which is pre-set. To adjust the default protocol or to add an additional protocol please see: [Manage Protocols](#)

9. hearTest™ testing in progress

The test is operated as follows:

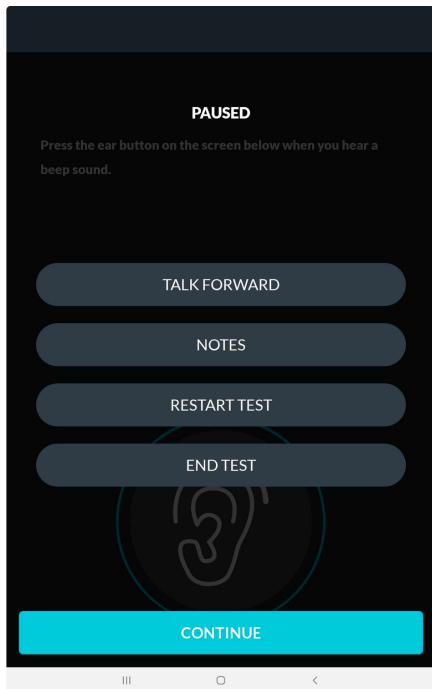
Before pressing the START button the facilitator must hand the smart device to the patient.



The patient should proceed with the pure tone audiometry test by selecting the START button to begin. For the duration of the test the patient will tap on the ear icon button. The patient should tap on the ear button when they hear a beep sound. The test duration is estimated to be between 5 - 10 mins depending on the severity of the patient's loss in hearing ability.

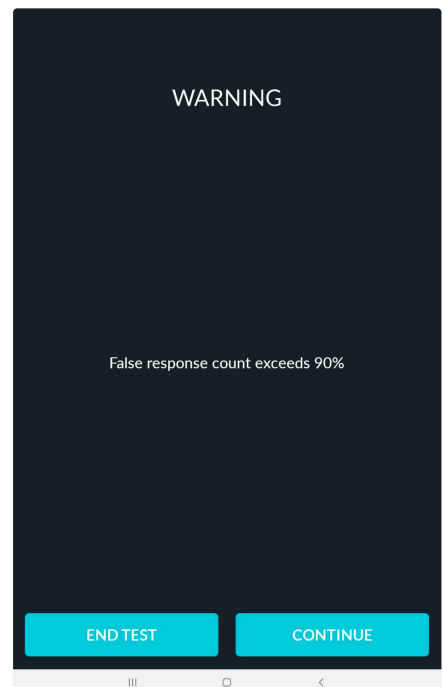
The test can be paused at any time during by pressing the || button in the upper right corner. By pausing the test it allows the facilitator to:

- [Talk forward](#): Allows the facilitator to speak to the patient via the headphones.
- [Notes](#): Allows the facilitator to add notes.
- [Restart Test](#): Allows the facilitator to restart the test.
- [End Test](#): Allows the facilitator to end the test.



Should the facilitator want to continue with the current test, select the 'CONTINUE' button.

Note: If the patient responds inconsistently, the application will flag this by playing a warning tone that will be heard on the loudspeaker by the facilitator. The facilitator is then given the option to resume the test or end the test.



Once the test is completed it will display the patient's test results.

10. hearTest™ test Results

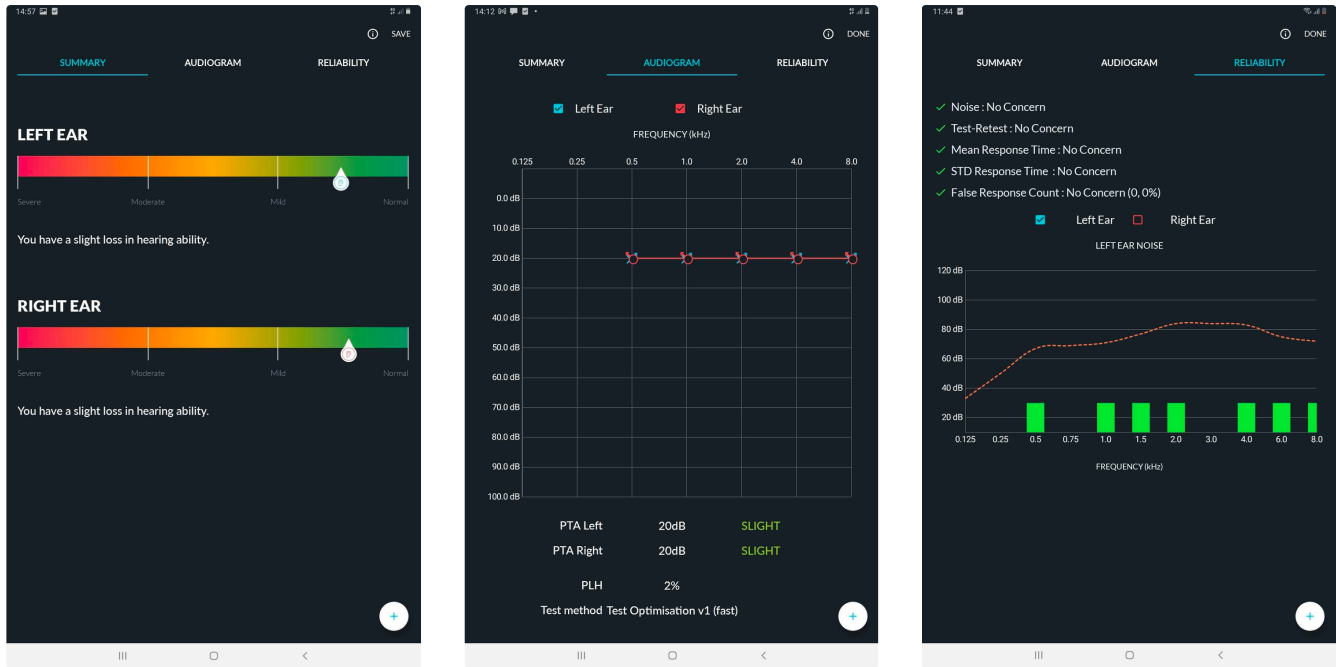
Once the patient completes the pure tone audiometry test the results summary is displayed.

The test results are divided into 3 tabs:

- Summary
- Audiogram

- Reliability

The patient's audiogram is available in the second tab on the result screen and all the test reliability metrics are displayed in the reliability tab (see below).



Summary: The summary result screen provides information on the shift between the last relevant baseline test and this test. The summary screen can be enabled in the hearTest settings in mHealth. refer to the degree of hearing loss is based on the World Health Organisation's grades of hearing impairment and is shown in the table below.

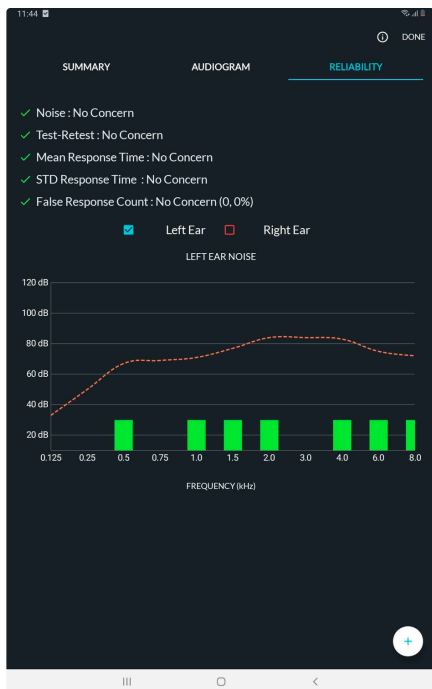
Pure Tone Category	Test PTA
Normal Hearing	0 to 25dB
Mild Hearing Loss	26 to 40 dB
Moderate Hearing Loss	41 to 60 dB
Severe Hearing Loss	61 to 80 dB
Profound Hearing Loss	>= 80 dB

Audiogram: The results PTA Category is recorded as a graph that represents the hearing thresholds called an Audiogram. The interpretation of the Audiogram will be presented at the bottom of the page in terms of the estimated degree of hearing loss. The facilitator can get the definition of each symbol in the audiogram by pressing the **i** icon on the top left corner of the screen.

Reliability: The reliability metrics look at the test validity as well as noise concerns that may affect the test result. The orange dotted line illustrates the average noise concerns per frequency determined by the maximum permissible ambient noise levels (MPANLs).

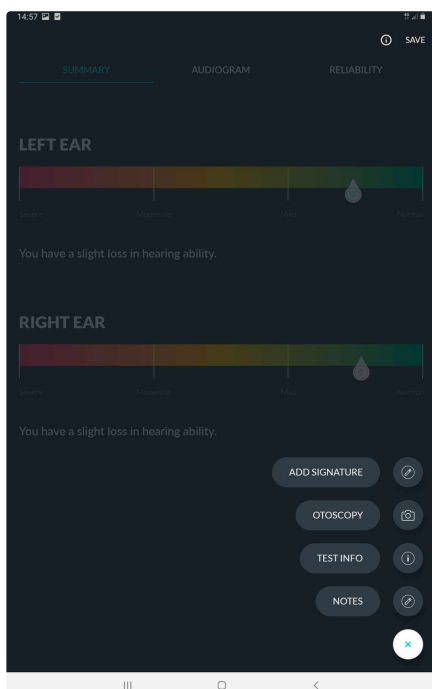
On the reliability screen, there is a different graph for each ear and can be selected to view that when selecting the Left or Right ear tick box above the graph.

The green bars indicate the ambient noise at a safe level. The orange bars indicate that the ambient noise exceeds the allowable levels at the testing frequency. Other metrics displayed include False response count as well as the mean and standard deviation on response times - if a concern is present for the specific test



10.1 Additional menu on the results screen

The facilitator can access the additional menu options on the results screen by selecting the + button at the bottom right corner of the page.

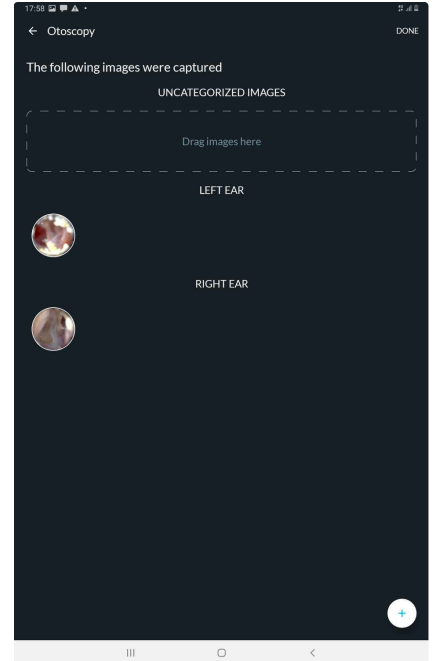
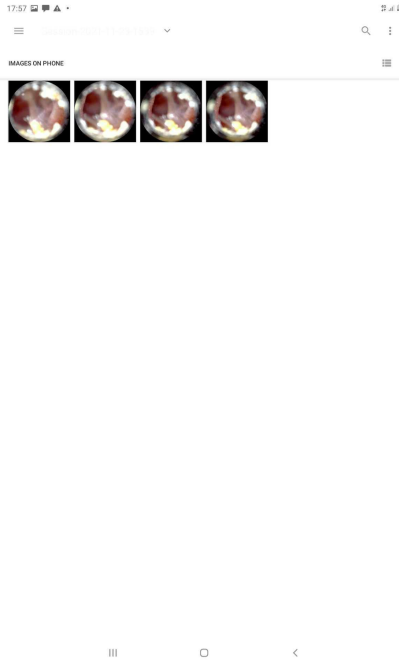
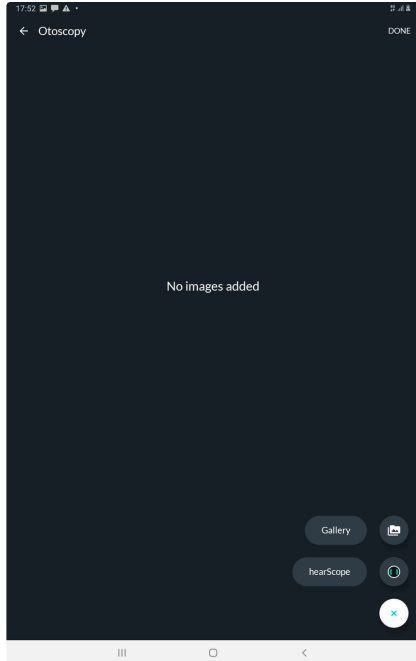


- **Add signature** - This will allow the facilitator to add the patient's signature to their results.
- **Test info** - This will allow the facilitator to view the test information such as patient name, the protocol used, test date, the headphones which were used, and the test duration.
- **Notes** - This allows the facilitator to add notes.
- **Add an otoscopy image** - This allows the facilitator to add an otoscopy image. Previously captured images can be attached from the Gallery or by opening the hearScope application from the mHealth Studio App and capturing new otoscopy images to attach to the test.

- **Gallery:** To add an otoscopy image that has been previously captured, tap on the Gallery option and select the otoscopy images relevant to the patient. Once selected, assign the image to the right or left ear box by holding and dragging the image to the relevant box. Once completed, select 'DONE'.

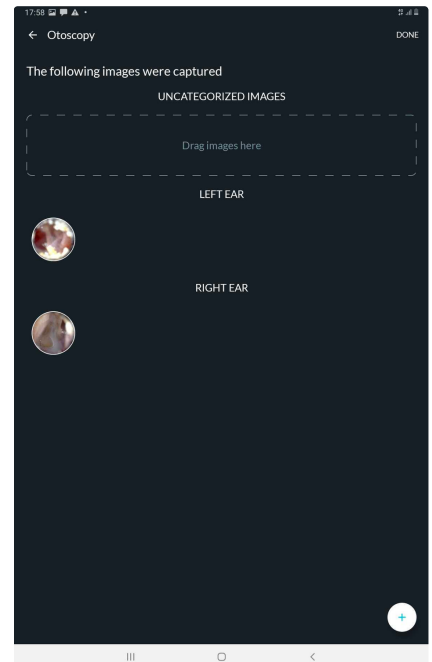
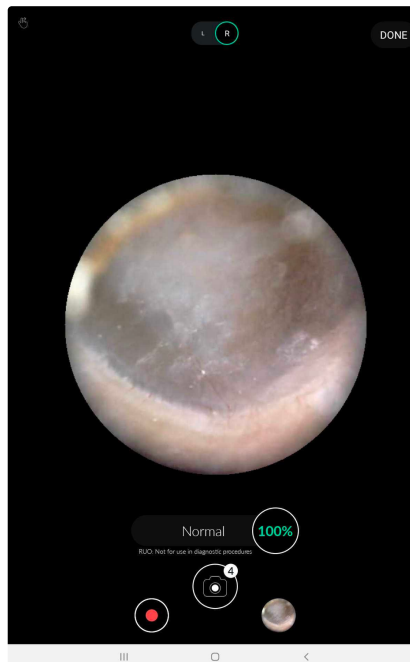
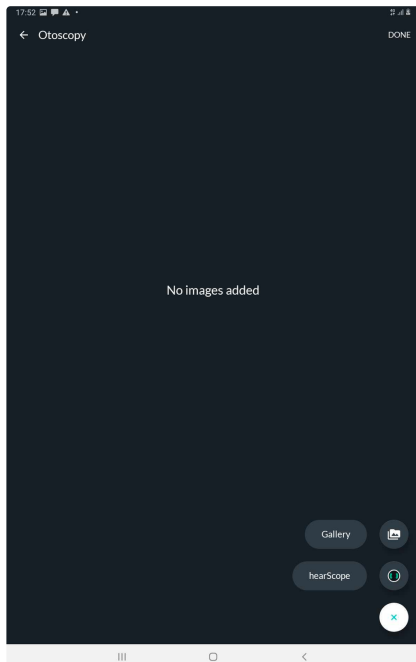
If previously captured images are not visible in the gallery make sure to tap on the three 'vertical dots' at the top right of the screen to make sure that the correct source of images is selected. Each hearScope session will be saved in its own folder. The folder name is the same as

the session name which is given at the end of each hearScope session. If no session name is entered the folder name will be the date and time when the session was conducted.



hearScope: (This option is only available if the hearX hearScope hardware has been purchased and the hearScope app is installed on the device.) To capture a new otoscopy image tap on the hearScope option. This will redirect the facilitator to the hearScope App. Connect the hearScope otoscope to the smart device to capture the otoscopy images. Once captured, tap on 'DONE' on the top right corner.

When capturing the otoscopy image through the hearScope app, the image will automatically assign to the relevant ear in mHealth Studio App. *Note: When capturing images in hearScope, remember to toggle the L and R to the relevant ear.*



The facilitator should select 'SAVE' to save the results. The save action starts the upload and syncing of test results to mHealth Studio Cloud backend if a stable network connection is available.

NEW: hearX hearScope is an easy to use, digital video otoscope that plugs into the same tablet. It consists of auto-zoom and auto-crop functionality that simplifies taking an image of your own eardrum. The hearScope also comes with a Artificial Intelligence (AI) image classification feature (Currently in BETA testing, for research use only) that provides a classification result within seconds for either normal, wax obstruction, chronic perforation or abnormal (indicates a high probability for a pathology being present).

For more information on hearScope visit: [hearScope by hearX Group - Digital video otoscope with AI image classification](#)



11. Viewing of patient's results on mHealth Studio Cloud

mHealth Studio Cloud provides a detailed test view for the results for a test session. All test results will sync with the mHealth Studio Cloud portal after the facilitator has selected the SAVE button when the session has been completed.

Access to mHealth Studio Cloud remains free even after the software subscription licenses on the device have expired. Access to patient data remains limited to that of the owner of the hearX account used in **Step 1:** Setup the account to use the software via mHealth Studio Cloud. to log on, who also is the owner of the medical data.

To view the test results:

- Sign-in on mHealth Studio Cloud
- Select the hearTest tab on the left menu bar to see the latest tests synced to the portal. Once the test grid view opens the:
 - List of hearTest results that have been performed. It will display the date the test was performed, the test type, the name and surname of the patient, the name of the facilitator, location, the result for both left and right ear, and status.
 - Columns can be added to the grid view by selecting the COLUMNS button and are also searchable by typing any specific search criteria in the search bar to the right of the screen.

The screenshot shows the 'hearTest' application interface. On the left is a dark sidebar with navigation options: Admin, Testers, Facilities, Patients, hearScreen, hearTest (selected), Self Test Kit, Vision, Devices, and Settings. The main area is titled 'hearTest' and contains a filter 'Result Left: Is Mild' and an 'Add filter' button. Below this are buttons for 'Columns', 'Download', and 'Bulk update status', along with a search bar 'Search records'. A table displays test results with columns: Test Date, Test Type, First Name, Last Name, Contact Number, Tester, Result Left, Result Right, and Status. The table contains 8 rows of data, each with an eye icon on the left.

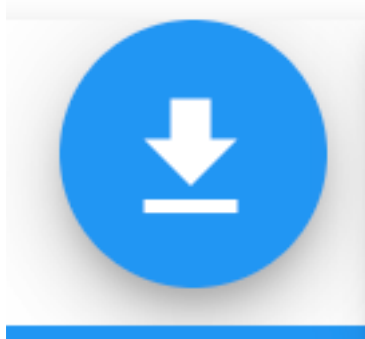
Test Date	Test Type	First Name	Last Name	Contact Number	Tester	Result Left	Result Right	Status
03/20/2020, 3:54 PM	hearTest	Anonymous	Anonymous	-	David Howe	Mild 40 dB	Moderate 50 dB	None
12/04/2019, 1:57 PM	hearTest	Anonymous	Anonymous	-	David Howe	Mild 40 dB	Mild 40 dB	None
12/04/2019, 2:09 PM	hearTest	Anonymous	Anonymous	-	David Howe	Mild 40 dB	Mild 40 dB	None
12/12/2019, 4:12 PM	hearTest	Anonymous	Anonymous	-	David Howe	Mild 40 dB	Mild 40 dB	None
12/12/2019, 4:35 PM	hearTest	Anonymous	Anonymous	-	David Howe	Mild 40 dB	Mild 40 dB	None
03/20/2020, 3:50 PM	hearTest	Anonymous	Anonymous	-	David Howe	Mild 40 dB	Moderate 50 dB	None
03/20/2020, 4:07 PM	hearTest	Anonymous	Anonymous	-	David Howe	Mild 40 dB	Moderate 50 dB	None

- Click on the EYE icon located on the left of the row as shown in the table to get a detailed view of the test results.

The screenshot shows the detailed view of a test result. It includes a map of the location, patient information, facility details, and test results. The patient information includes Name (Anonymous Anonymous), Gender (Male), Email (-), and Contact Number (-). The facility information includes Name (Anonymous Anonymous), Patient Language (English), Identity Number (-), Date of Birth (1980-10-15), and Reference Number (Migration Run). The test results section shows a line graph of Intensity (dB) vs Frequency (Hz) for both Left and Right ears. The graph shows a peak at 1000 Hz and a dip at 2000 Hz. Below the graph are sections for THRESHOLDS, RELIABILITY, and STS. The THRESHOLDS section shows Left Ear (dB) and Right Ear (dB) for the current test. The RELIABILITY section shows Frequency (Hz) and the STS section shows Test Current.

THRESHOLDS	RELIABILITY	STS
Left Ear (dB)	Frequency (Hz)	Right Ear (dB)
Test Current	500	Test Current
0		15

- The test result is also downloadable as a pdf report. The download icon in the blue circle above the audiogram will open the pdf report.

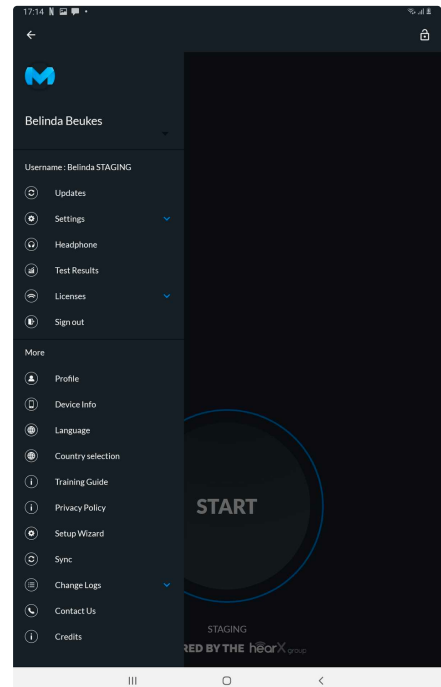


12. Support

12.1 mHealth Menu

App Menu

- **Updates:** Application software updates available are indicated with a badge. Open the menu item to see which software requires an update.
- **Settings:** This is where the user can access the settings to mHealth Studio App settings as well as settings related hearX software which has been installed on the device. [See Section for mHealth Settings](#)
- **Headphones:** This provides technical information about the headphones, as well as the calibration information. Below this, there are two buttons that provide the facilitator with the option to link or verify the headphones as stated in [Linking headphones](#)
- **Test results:** This allows the facilitator to view the test results conducted on the device. The facilitator can select the patient/test subject whose results they would like to view.
- **Licenses:** This allows the facilitator to view existing licenses that are linked to the device as well as linking any new licenses. (if available).
- **Sign out:** Allows the facilitator to sign out of the application



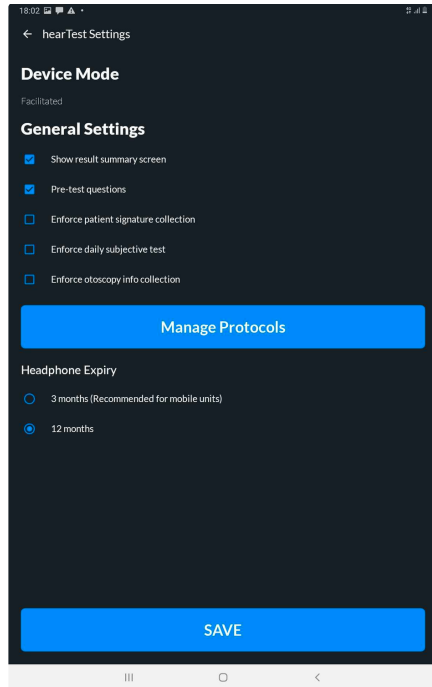
More

- **Profile:** This provides information about the facilitator, such as their name, professional registration number (if applicable), and signature. The professional registration number refers to a medical registration number for the audiologists or occupational health registered professionals.
- **Device info:** This provides technical information about the smart device, as well as the installations such as the application versions, device identifiers, calibration status, sync status, and test counts.
- **Language:** This allows the facilitator and/or administrator to change the language in which the software is being operated. The facilitator and/or administrator can choose between English, French, Spanish, and Spanish (Latin America). **PLEASE NOTE:** The selected language only applies to the mHealth, hearScreen & hearTest software and any other hearX software application will remain in English on the smart device.
- **Country selection:** This allows the facilitator to change the country selection in which the device is being used to perform tests. This is to ensure that the protocols and settings used, comply to the relevant regulations which is applicable in the selected country.
- **Training Guide:** This allows the facilitator and/or administrator to easily access the necessary training material to understand the products and features that can be used and setup to optimally use the products in various settings.
- **Privacy Policy:** This provides information regarding hearX® Group privacy policy as well as terms and conditions.
- **Setup Wizard:** This allows the administrator to set up the device from the start as explained in 'Follow the Setup Wizard on the hearX smart device'
- **Sync:** This allows for manual syncing of test result data if required. Background syncing is always on and if an internet connection is available the data will sync to the mHealth Studio Cloud portal
- **Change Logs:** Provides a summary of changes made to the application with each update.
- **Contact us:** Provides the contact details to get in touch with the hearX Group.

12.2. Detailed settings of the hearX smart device

12.2.1 hearTest™ settings

12.2.1.1 General Settings



General hearTest™ settings required for the smart device needs to be checked and includes:

- **Show summary result view.** This provides a more user-friendly interpretation of the Pure Tone Average for each ear on a bar graph with a gradient indicating the hearing loss categories based on the PTA values
- **Impairment pre-test questions.** This asks the patient if they have a hearing loss in the left, right or both ears.
- **Enforce patient signature collection.** This setting will force the patient to add their signature after the test has been completed. can not be applied in Self Test mode
- **Enforce daily subjective test -** This function forces the facilitator to perform a daily check to ensure that the headphones and audiometer are producing correct and reliable results.
- **Enforce otoscopy info collected.** This function will force the facilitator to add otoscopy images to the patient's results.

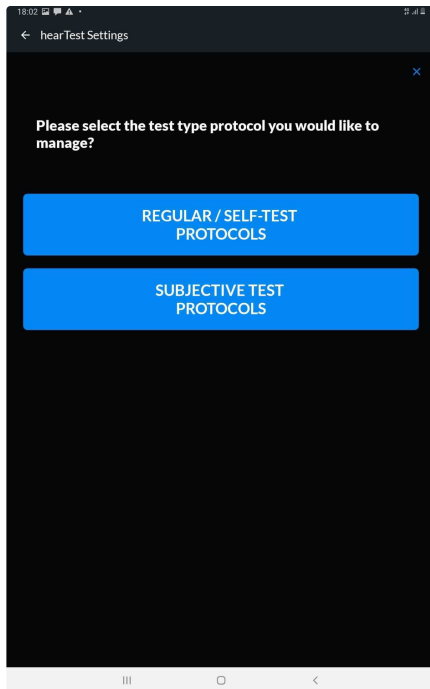
To access the protocol settings to be used for the pure tone audiometry test to be performed select the **Manage Protocols** button on the hearTest™ Settings

12.2.1.2 Manage Protocols

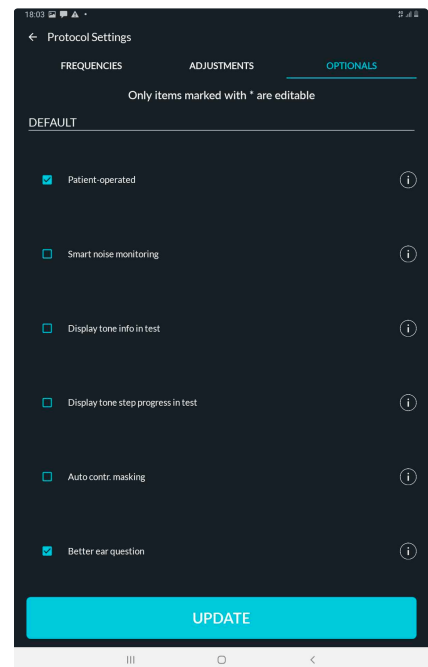
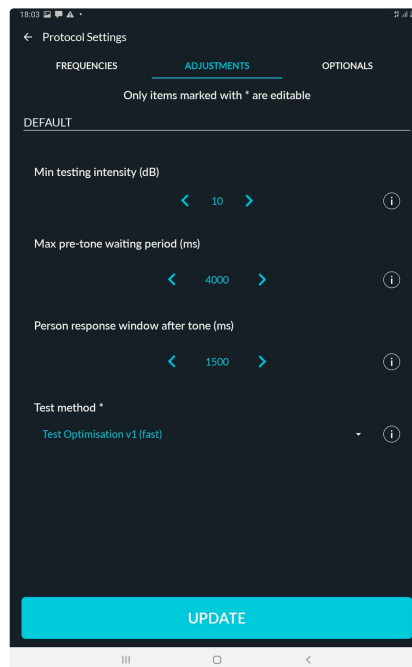
Both the administrator and facilitator have the option of creating their own protocols and adjusting it as per preference to the features available, or they can select the default protocol which is pre-set.

There are two pre-set protocols already loaded on the smart device:

1. Regular / Self-Test Protocols
2. Daily Subjective Test Protocols



For creating custom protocol setup select the + in the top right corner of the screen. The setup of a custom protocol is divided into 3 tabs:



- **Frequency:** The administrator should select the frequencies they wish to include in the test.
- **Adjustments:** Select the starting points and time adjustments in tone presentation during testing such as:
 - Minimum testing intensity
 - Maximum pre-tone waiting period
 - Person response window after tone
 - Test methods:
 - **Shortened Ascending:** 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):** The **Test Optimisation v1 (fast) and v2 (fastest)** test methods 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.


- **Optionals:** Activate or deactivate features like:

- Patient-operated - This means that the test is automatically presented and the test response is provided by the patient. If the patient-operated mode is deactivated, the user interface will appear in the patient-operator mode. A facilitator-operated test requires a tester to respond on behalf of the person.
- Smart noise monitoring - Smart noise monitoring will in addition to regular noise monitoring, pause testing with a warning if ambient noise levels exceed MPANL twice in a row on a no response.
- Display tone info in test - Tone information such as ear, frequency and intensity are displayed to screen during each tone presentation.
- Display tone step progress in test - This test step is displayed in the top left corner throughout testing..
- Auto control masking - This function automatically presents a masking noise when there is a gap in the results obtained between the thresholds of the left and right ears.
- Better ear This - It asks the patient which ear he/she hears better with and starts the test on the better ear.

Once the facilitator has selected their desired protocols that must click on the 'SAVE' button to save their new protocol.

 The **Default** protocol has been set on the following parameters:

- **Frequencies tested:** 500, 1000, 2000, 4000 and 8000Hz in the left and right ears.
- **Adjustments:**
 - The *minimum testing intensity* is 10dB. This means that each frequency will be tested right up to 10db until a threshold is obtained.
 - The *maximum pre-tone waiting period* is set to 4000ms. This is the amount of time provided before each tone presentation.
 - The *person response window* after the tone presentation has been set to 1500ms. This is the time provided to the patient to respond before the next tone is presented.
 - The *test method* is set on Test Optimisation V1 (fast)
- **Optionals:**
 - Patient-operated - the patient-operated option is activated.
 - Smart noise monitoring - this option is deactivated.
 - Display tone info in test - This option is deactivated.
 - Display tone step progress in test - This option is deactivated.
 - Auto control masking - this option is deactivated.
 - Better ear This option is activated. It asks the patient which ear he/she hears better with and starts the test on the better ear.

 The **Default-SelfTest** protocol has been set on the following parameters:

- **Frequencies tested:** 500, 1000, 2000, 4000 and 8000Hz in the left and right ears.
- **Adjustments:**
 - The *minimum testing intensity* is 20dB. This means that each frequency will be tested right up to 20db until a threshold is obtained.
 - The *maximum pre-tone waiting period* is set to 4000ms. This is the amount of time provided before each tone presentation.
 - The *person response window* after the tone presentation has been set to 1500ms. This is the time provided to the patient to respond before the next tone is presented.
 - The *test method* is set on Test Optimisation V1 (fast)


- **Optionals:**
 - Patient-operated - the patient-operated option is activated.
 - Smart noise monitoring - this option is deactivated.
 - Display tone info in test - This option is deactivated.
 - Display tone step progress in test - This option is deactivated.
 - Auto control masking - this option is deactivated.
 - Better ear This option is deactivated

 The **Subjective Test** protocol has been set on the following parameters:

- **Frequencies tested:** 500, 1000, 2000, 4000 and 8000Hz in the left and right ears.
- **Adjustments:**
 - The *minimum testing intensity* is 10dB. This means that each frequency will be tested up to 10db until a threshold is obtained.
 - The *maximum pre-tone waiting period* is set to 4000ms. This is the amount of time provided before each tone presentation.
 - The *person response window* after the tone presentation has been set to 1500ms. This is the time provided to the patient to respond before the next tone is presented.
 - The *test method* is set on Test Optimisation V1 (fast)
- **Optionals:**
 - Patient-operated - the patient-operated option is activated.
 - Smart noise monitoring - this option is deactivated.
 - Display tone info in test - This option is deactivated.
 - Display tone step progress in test - This option is deactivated.
 - Auto control masking - this option is deactivated.
 - Better ear This option is activated.

The protocol required for hearTest to function optimally should include at least 500, 1000, 2000 and 4000 Hz for pure tone testing. These frequencies are also included for PTA calculations.

12.2.2 Detailed mHealth settings

 The smart device can be set up in two different device modes:

Self test: The device is setup for use in settings where the patient completes the test without a facilitator being present to assist in administering the test. (*Self Test mode can only be used when the Self Test software license was purchased and the Self Test Toggle is enabled on your Tester account on mHealth Studio Cloud.*)

Facilitated: The device is setup for use in settings where the facilitator is present and administers the test.

mHealth settings for Self Test mode:

Your smart device's 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

To review the default settings that have been applied to the device select the menu in the top left corner. Tap on Settings and select mHealth.

Test Required

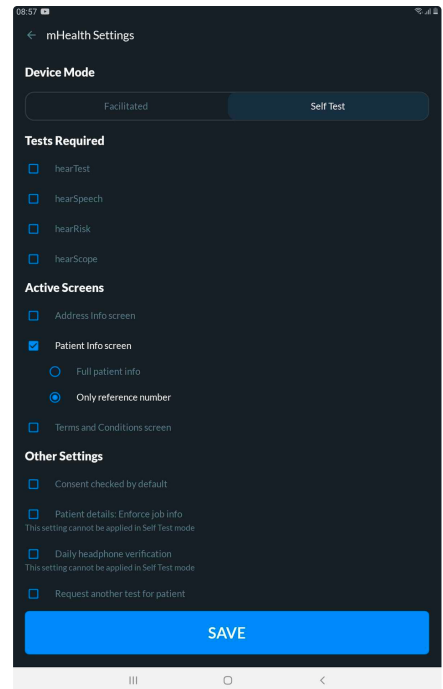
Once the Self Test mode is selected as the device mode the default apps are automatically selected to be included in the software. These apps are selected under

Tests Required. The test marked active under Tests Required are included in the test battery which the patient / test subject will complete

In case a hearScope is included make sure to also tick hearScope in this list to make use of capturing otoscopy / eardrum images when the patient is completing the test.

Active Screens

These settings allow for various screens to be inactive when progressing through the testing workflow, meaning it will not present within the sequence of screens required to conduct a test in Self Test mode.



- **Address info screen** - requires the patient to capture address information as part of the testing workflow.
- **Patient info screens** - can be deactivated and are often not required to be captured to proceed with the test. There is an option if this patient info is presented to either use:
 - **Full patient info** patient screen, the user will have to provide the required patient information for each test. The mandatory information required by the patient are: First Name, Last Name, and Birthdate. Additionally, gender, email address, contact number, and reference number can also be completed.
 - **Only reference number** which results in capturing a unique identifier to keep patient information anonymous.
- **Terms and Conditions Screen** - If the audiologist or hearing health professional requires the patient to accept any additional terms and conditions that are published on a public website and pertains to another third party service which the patient is signing up for, or based on the type of hearing device that can potentially be prescribed, this allows for capturing this consent in the patient journey.

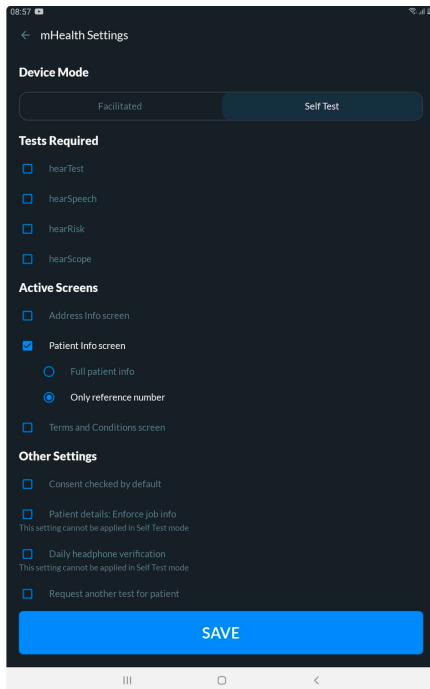
NOTE: The audiologist or hearing health professional needs to enable this in the mHealth Studio app by ticking the Terms and Conditions tick box in the Settings in the menu of the app **as well as set up the correct URL that can be shown in the app** in the mHealth Studio Cloud accessed.

How to set up Terms and Conditions URL on mHealth Studio Cloud:

1. Login to mHealth Studio Cloud with your admin account details.
2. Select the Settings > Self Test item in the side menu.
3. Paste the relevant public terms and conditions URL in the input bar provided.

Other Settings

- **Consent checked by default** - this option will have the page that requested consent automatically completed so that the facilitator can proceed to the next step with minimum interruptions before testing.
- **Patient details: Enforce job info** - *This setting cannot be applied in Self Test mode*
- **Daily headphone verification** - *This setting cannot be applied in Self Test mode*
- **Request another test for patient** - *This setting cannot be applied in Self Test mode*
- **Auto sync patients** - *This setting cannot be applied in Self Test mode*



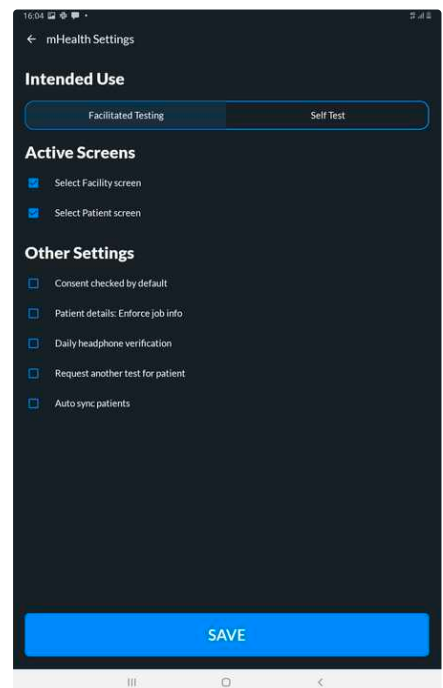
mHealth settings for Facilitated mode:

Your smart device's menu is **password protected** and the same password used to log into the device should be entered to access the menu. Tap on Settings and select mHealth.

Active Screens

These settings allow for various screens to be inactive, meaning it will not present within the sequence of screens required to conduct a test in Self Test.

- **Select Facility screen** - this option allows the facilitator to add a new facility, search for an existing facility, and select the facility before starting the session to know where the tests are being conducted.
- **Select Patient Screen** - this option allows the facilitator to add a new patient/test subject or search for an existing patient/test subject before starting the screening. When this option is deactivated the patient data will be anonymous.



Other Settings

- **Consent checked by default**- this option will have the page that requested consent automatically completed so that the facilitator can proceed to the next step with minimum interruptions before testing.

- **Patient details: Enforce job info** - To make capturing of additional job information compulsory when adding a test subject. This is more relevant when using the product within Occupational Health context.
- **Daily headphone verification** - this option allows the facilitator to opt for a daily headphone verification to make sure the same headphone is still used with the smartphone to ensure the same headphone calibration needs to apply for testing. If the headphone verification fails the new headphone linking should be done which requires the smart device to be connected to the internet to download the calibration information before testing can proceed. This ensures accurate testing at all times.
- **Request another test for patient** - this option will show the facilitator a pop-up message asking to confirm testing the same patient/test subject as previously tested.
- **Auto sync patients** - this option allows for the device to automatically sync all patient data from the mHealth Studio Cloud to the mHealth Studio Application when connected to a internet connection.

13. Other

13.1 Calibration certificate

Certified audiometers require calibration to be performed annually. The calibration for the hearX audiometer is required annually but depending on the territory in which the hearX audiometer, the calibration requirements can differ for using the hearX hardware within a mobile testing environment for occupational health. The calibration interval could be specified to be performed every three (3) months.

hearX offers calibration facilities for headphone calibration in South Africa, United States of America and Australia.

To arrange for headphone calibration send an email to support@hearxgroup.com

Costs associated with calibration will be quoted for as is based on the current priceless relevant at the time. Shipping costs may vary greatly and this will be for the customer's own account. Ensure the headphones are packed safely and securely with sufficient protective material to ensure the headphones are not damaged in transit. We recommend a minimum amount of at least four layers of bubble wrap and/or protective covering, placed inside a box for shipping to the calibration facilities. hearX can not be held responsible for any damaged headphones received at any calibration facilities caused during transit.

Calibration notification on mHealth Studio App

The hearX software will provide headphone notification on the START page prior to the date of calibration to inform the facilitator when the headphones are due for calibration. These notifications are displayed up to 80 days in advance. To view the details about the calibration and next calibration date refer to the Headphone menu on mHealth Studio App. (As explained below)

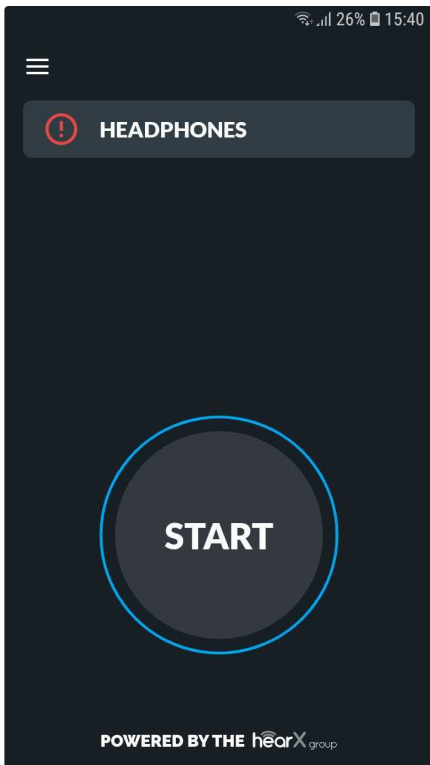


CLICK HERE to watch how to view calibration status of your headphones

Relinking of recalibrated headphones

A warning is displayed once the headphone is near calibration expiry. Once the headphone calibration has expired, the headphones need to be returned to the service center for recalibration. All headphones should be calibrated at a hearX calibration facility.

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.



To relink the headphones, go to HEADPHONE in the menu. Select LINK to start re-linking the headphones. Two options are available to link the headphones:

1. Scan the QR code on the headphone band with the QR reader, or
2. Insert the serial number of the headphone, which is available on the headphone band, and select GO.



CLICK HERE to watch how to relink your headphones

View calibration status of the headphones

The calibration status of the headphones can be viewed by accessing HEADPHONE in the menu.



CLICK HERE to watch how to view and/or download your calibration certificate from mHealth Studio

13.2 Maintenance

 These are some helpful tips to keep the smart device in good condition and ensure optimal functioning:

- Device restart is recommended daily. The mHealth Studio App software will force a device restart after 7 days.
- Ensure that the device cover and screen protector provided by the hearX Group is used at all times to protect the smart device for damaging by accidental dropping or any other impact.
- Use alcohol-free disinfectant wipes to clean the headphones around the ear cups and headband.
- Package the headphones tightly in the foam insert of the hardcover bag for extra protection, especially when transporting the equipment.
- Handle the headphones and insert plugs with care to avoid stretching or damaging of the headphone cable.

13.3 FAQ

What is the difference between mHealth Studio Cloud™ and mHealth Studio Mobile™ application?

mHealth Studio Cloud™ is the cloud-based database that stores and manages the data uploaded from the mHealth Studio Mobile™ application that is operated on a smartphone device.

What is the difference between hearScreen™ and hearTest™?

hearScreen™ is a quick automated hearing screening test. The results are reflected as a "Pass" or "Refer". hearScreen is typically used in school screening and for large scale hearing screening projects.

hearTest™ is a pure tone air conduction hearing test. hearTest™ takes longer to administer and is used to seek a hearing threshold over a range of frequencies. The results from hearTest™ are reflected in the form of a graph called an Audiogram. hearTest™ is used as a follow-up tool and at clinics. hearTest™ is also available with extended high-frequency testing as well as a version for occupational health testing.

13.4 Contact

Contact the hearX Group for any further information required:

Email: support@hearxgroup.com

US: (415) 212-5500 (*Support available from 3pm - 11pm SAST*)

RSA: +27 (0) 12 030 0268 (*Support available from 8am - 4pm SAST*)

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