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## Revision History

Revision	Date	Software Version	Description
v1.0	4 Nov 2020	v6003	First publication of training manual for hearScreen™.
v1.1	30 Nov 2020	v6004	New menu items with descriptions added in section: 12.1 mHealth Menu.
v1.2	8 Dec 2020	v6004	Updated screenshot in Section 8 and 9.
v1.3	23 Dec 2020	v6004	'How-to' videos updated in section 6, section 7, and section 8.
v1.4	20 Jan 2021	v6005	Updated screenshots in sections: 8 (step 2), 4.3, 9 and 10. Updated section 10.1, subsection: Add an otoscopy image.
v1.5	18 Jun 2021	v6005	Updated section 10.1 and updated screenshots in section 11

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## 1. Scope of this manual

This manual provides instructions for use of the hearScreen™ hardware and software applications. This manual will guide the audiologist or hearing health professional to operate the hearScreen™ screening audiometer software and explain all software features included for optimal use within a clinical and/or community setting.

## 2. Definitions

In this training manual the following terms are referred to:

<b>Owner</b>	Refers to the person who owns the smart device.
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<b>Administrator</b>	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.
<b>Facilitator</b>	Refers to the audiologist or hearing health professional who facilitates the test with the patient / test subject.
<b>Patient / Test subject</b>	Refers to the person who executes the test.

### 3. Getting started

#### 3.1 What's in the box

	Item	Decription
1	 <p>OR</p> 	Samsung J5 Smartphone with charger OR Samsung Galaxy Tab A Tablet SM-T510 with charger. Pre-installed software for mHealth and hearScreen
2		Sennheiser HD 280 Pro

### 3.2 Test environment recommendations

It is recommended that the test environment be as quiet as possible with limited background noise. If performed in a clinical setting, the test can be conducted in a soundproof booth (if available). The smart noise monitoring feature can be used to determine if noise levels are within range for reliable testing. The test environment should be free from distractions to ensure reliable results and patient concentration.

## 4. About hearScreen

hearScreen™ is a world-first clinically validated digital smartphone screening audiometer with cloud data management using mHealth software. The intended use of hearScreen is to perform hearing screening tests in a community, school and/or clinical setting.

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 diagnostic hearing screening test to determine the slope of hearing loss and obtain an audiogram for the patient / test subject.

## 5. Using the hearScreen 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 has internet access for the initial set up and when uploading of data is required.



### 5.2 Using the

#### Circumaural headphones



- Pull the ear cups apart to fit the headphones over the test subject'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 test subject'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@hearxgroup.com](mailto:no-reply@hearxgroup.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 audiologist or hearing health professional should open [https://cloud.mhealthstudio.com/members/sign\\_in](https://cloud.mhealthstudio.com/members/sign_in) and tap on the **Sign in with hearX** button.

**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 mHealth Studio Cloud portal when logging in with the hearX account. This video will show the administrator how to add a Tester account to access the smart device.

hearX group

mHealth Studio  
How to add a Tester account on  
mHealth Studio Cloud and mHealth Studio App

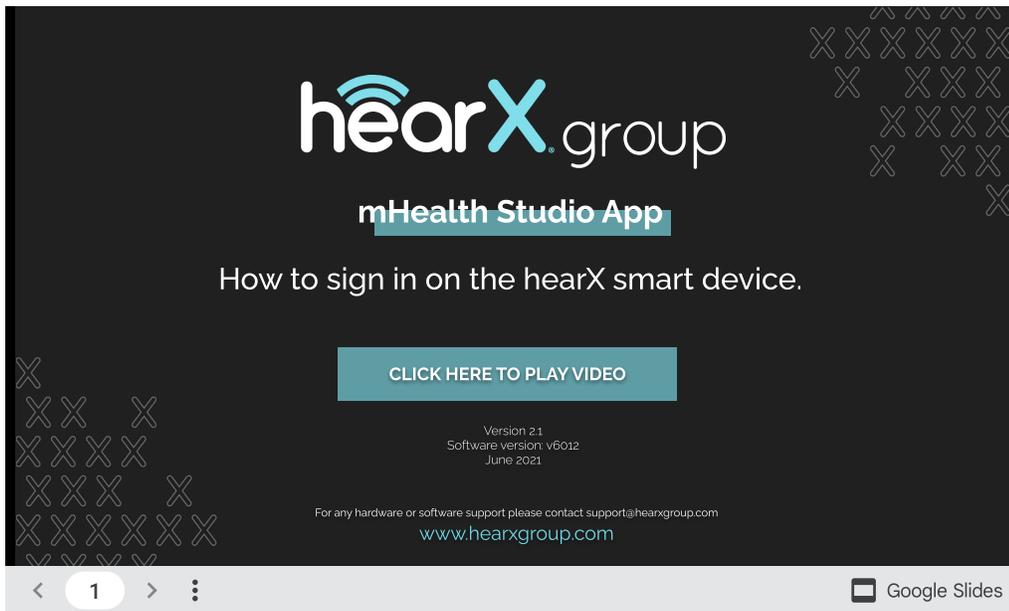
CLICK HERE TO PLAY VIDEO

Version 1.2  
February 2021

For any hardware or software support please contact [support@hearxgroup.com](mailto:support@hearxgroup.com)  
[www.hearxgroup.com](http://www.hearxgroup.com)

< 1 > ⋮ Google Slides

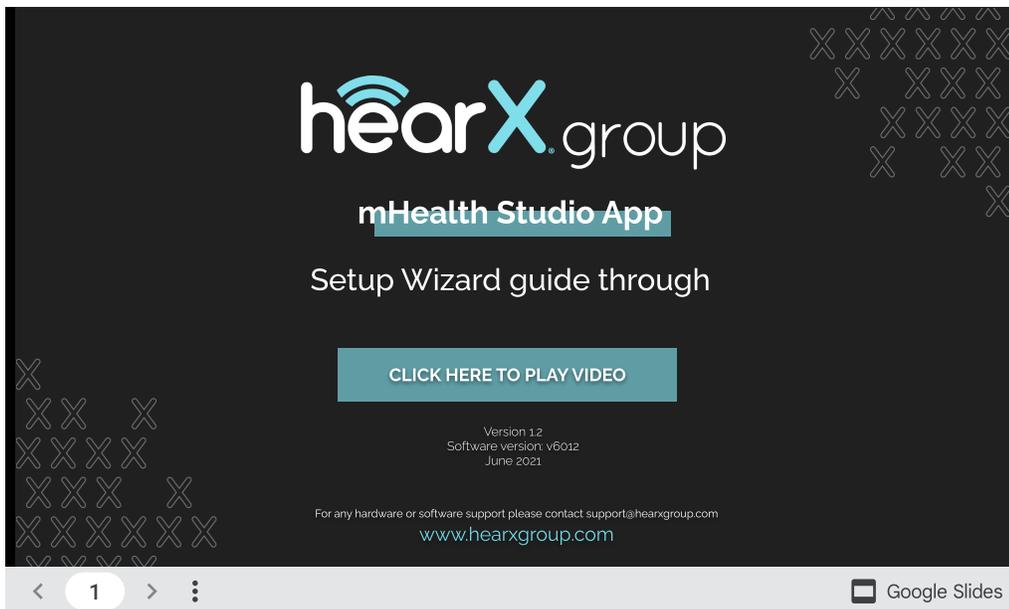
### Step 3: Sign in on the hearX smart device



Should the facilitator have forgotten their password, the 'Forgot password?' link will indicate that they must go to <http://cloud.mhealthstudio.com>. Access mHealth Studio Cloud to update the password via the Testers menu.

## 7. Follow the *Setup Wizard* on the hearX smart device

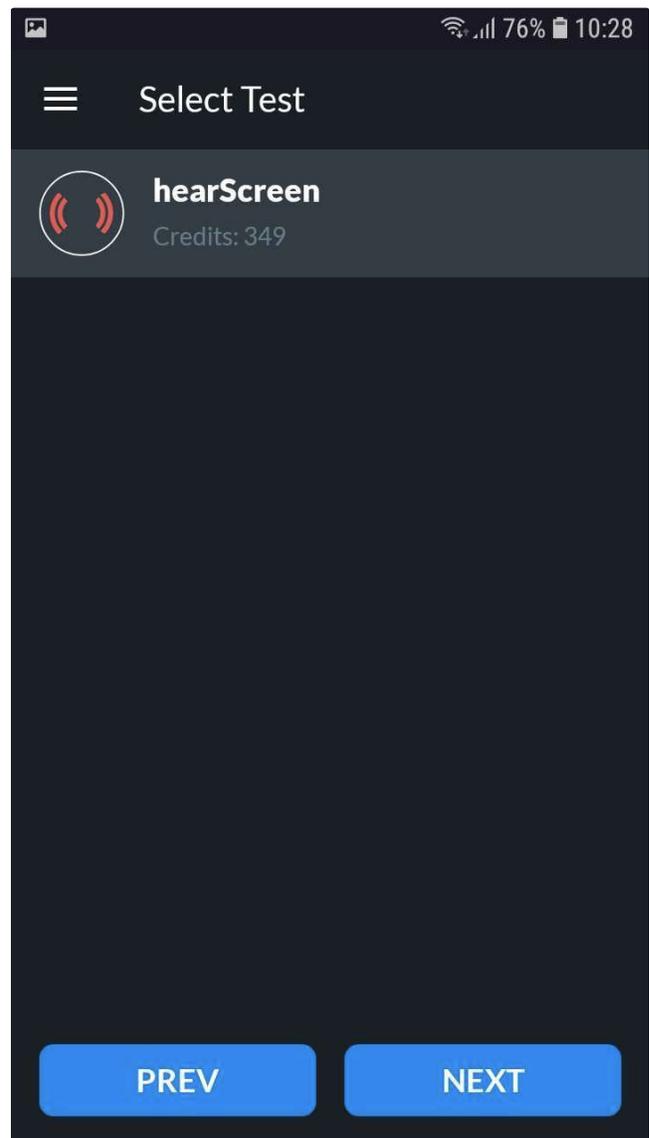
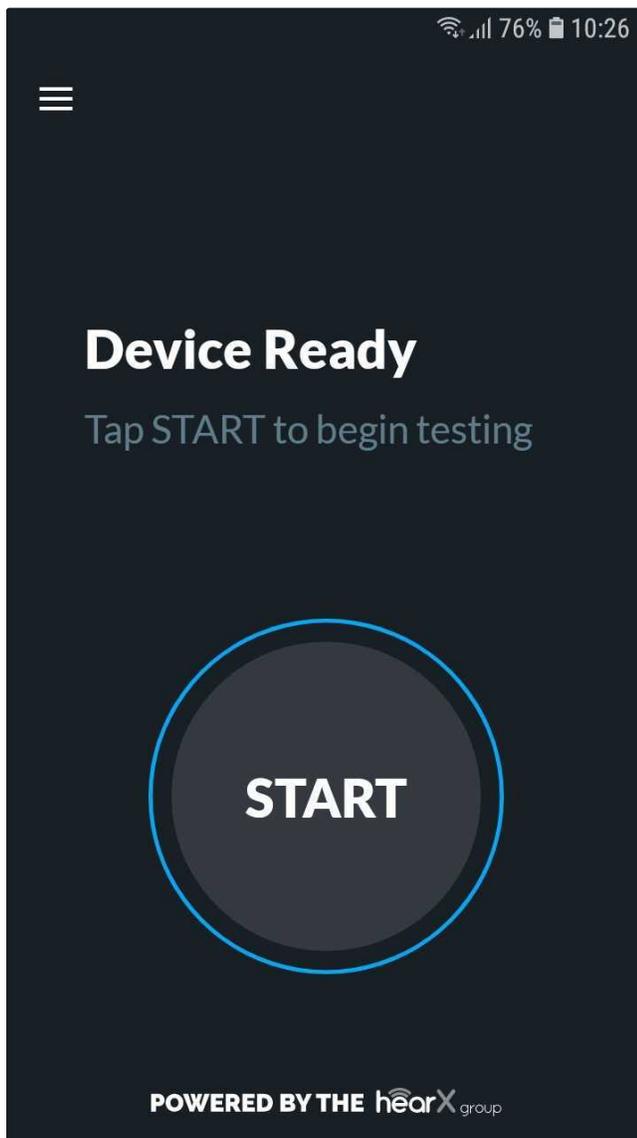
The *Setup Wizard* will guide the administrator to set up the device for test mode and complete all the required steps before handing over the device to the facilitators for testing.



Self test mode is only available for the hearX Self Test Kit. For more information regarding our Self Test Kit, please visit our website: <https://www.hearxgroup.com/stk>

## 8. How to conduct a hearScreen test

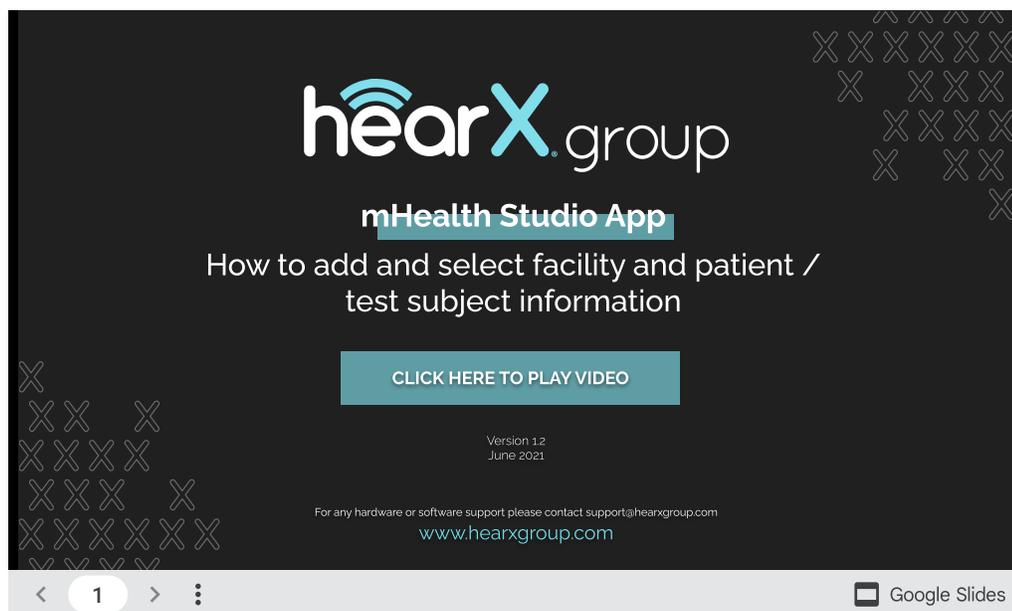
**Step 1:** Press the start button on the home screen.



The facilitator should select the correct test option that will be conducted and tap the NEXT button.

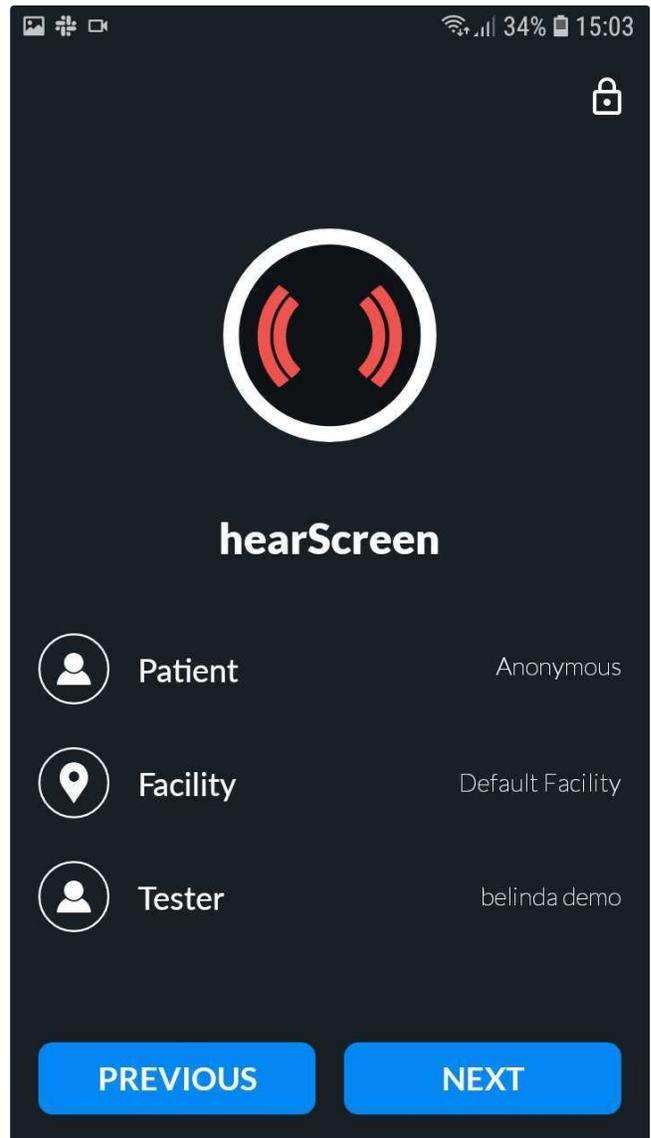
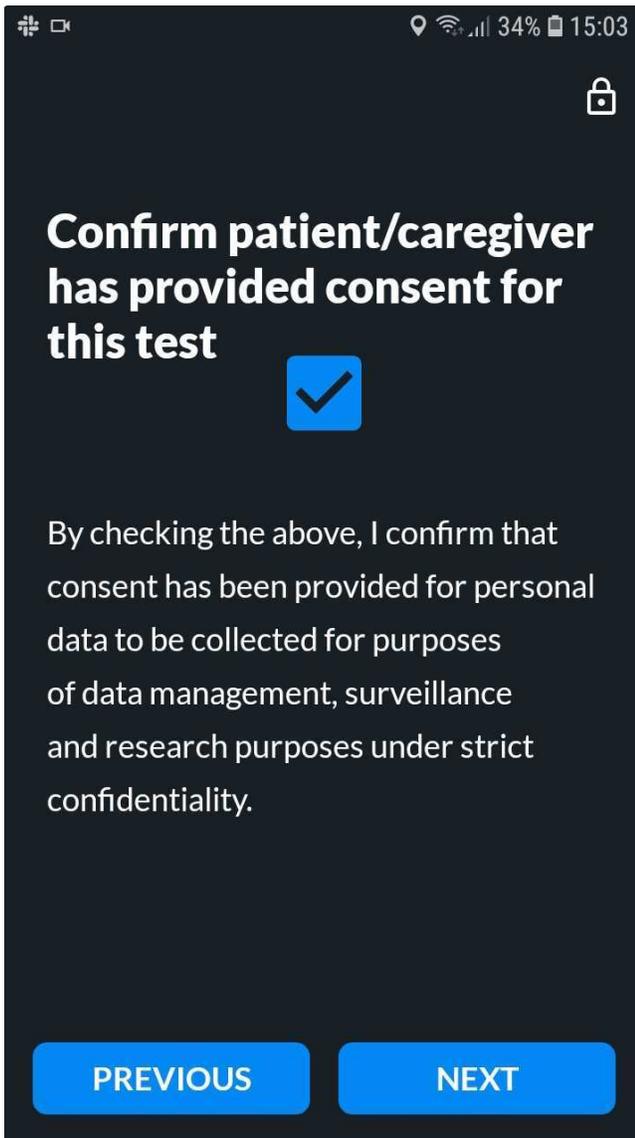
In the case of using hearScreen, the facilitator needs to select hearScreen from the list of available tests. This tests types listed on this screen is a function of all the different software licenses available and linked to the hearX smart device.

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



## Step 3: Summary and consent form

The summary page provides a summary of the name of the patient/test subject, the facility, and the facilitator that will be doing the test. It is important to determine that all the information has been correctly entered. The PREV button can be used to navigate back to correct any information or restart with selecting the facility / patient information. All patients/test subjects need to give consent before the session can begin. Click on the checkbox (See illustration below) and select NEXT.



#### Step 4: hearScreen pre-test checks

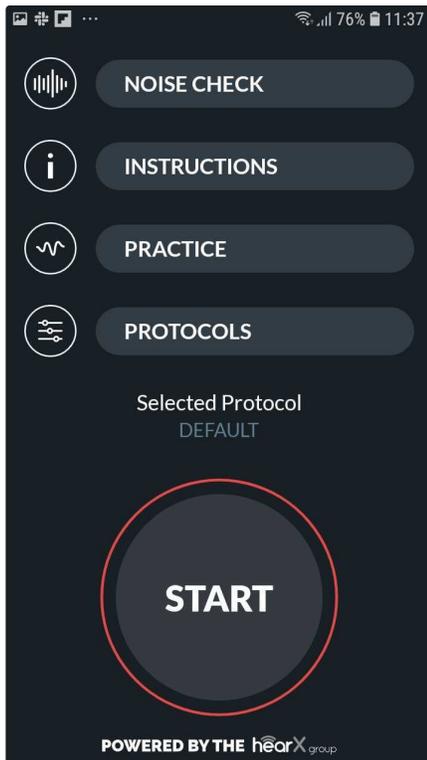
The START button will appear, the facilitator can proceed and start the test. Above the START button, there are four pre-test functions that can be used to enhance the test experience:

**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**



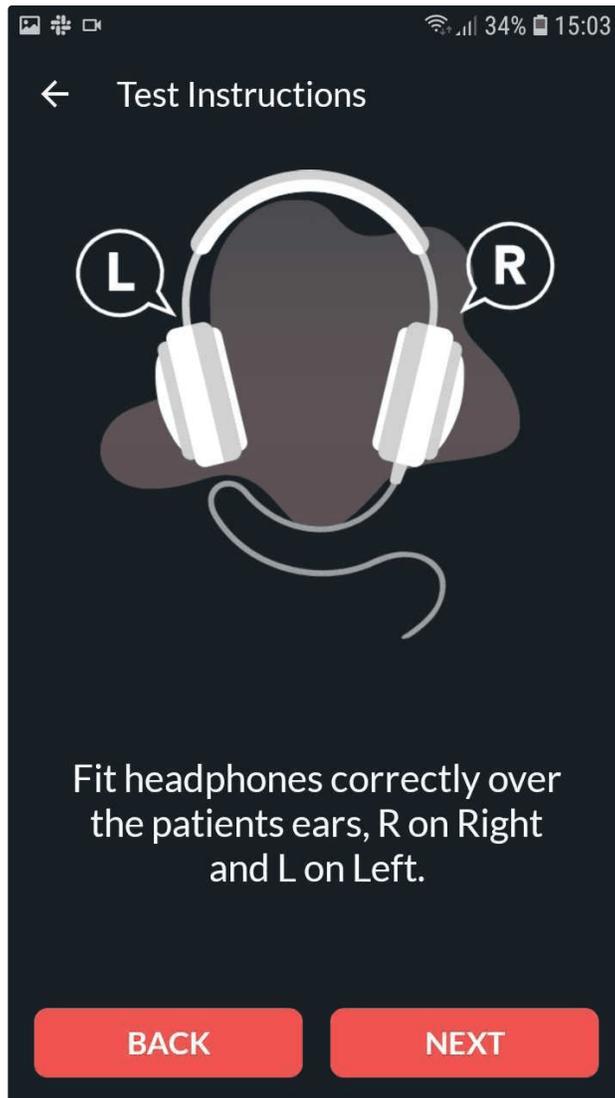
#### 4.1 Do a NOISE CHECK (Optional)

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 are provided with a visual representation.



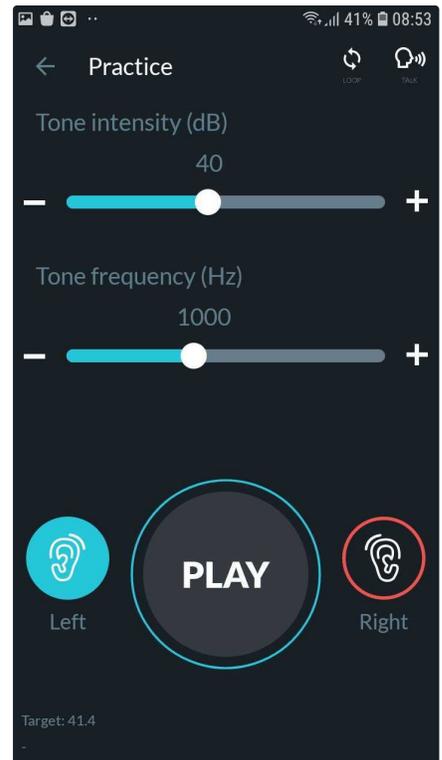
The facilitator should provide the test subject with instructions before starting the test. The test instructions should request that the patient respond to the tone presented. An example is provided below:

*'I am going to put these headphones on your ears and then you will hear various tones being presented. Some of the tones will be high pitched whilst others will be lower in pitch. These tones will start loudly and slowly start becoming softer so you need to listen carefully at all times. As soon as you hear a tone I want you to raise your hand and then put it back down so that I know you have heard it. Only raise your hand if you hear the sound. We will first start with one ear and then move on to the other. Let me know if you have any questions before we start'*

#### **4.3 PRACTICE function (Optional)**

To condition the test subject 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 test subject does not respond and then decreased as the test subject responds so that the test subject understands that the tone is expected to become softer until a hearing threshold is obtained.

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



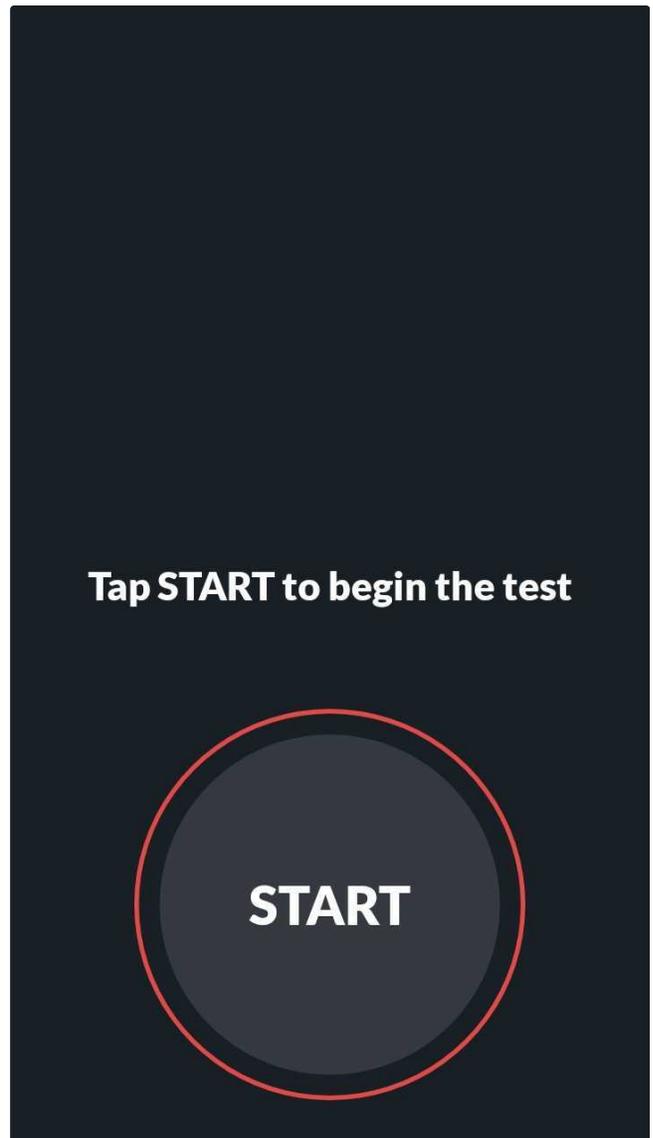
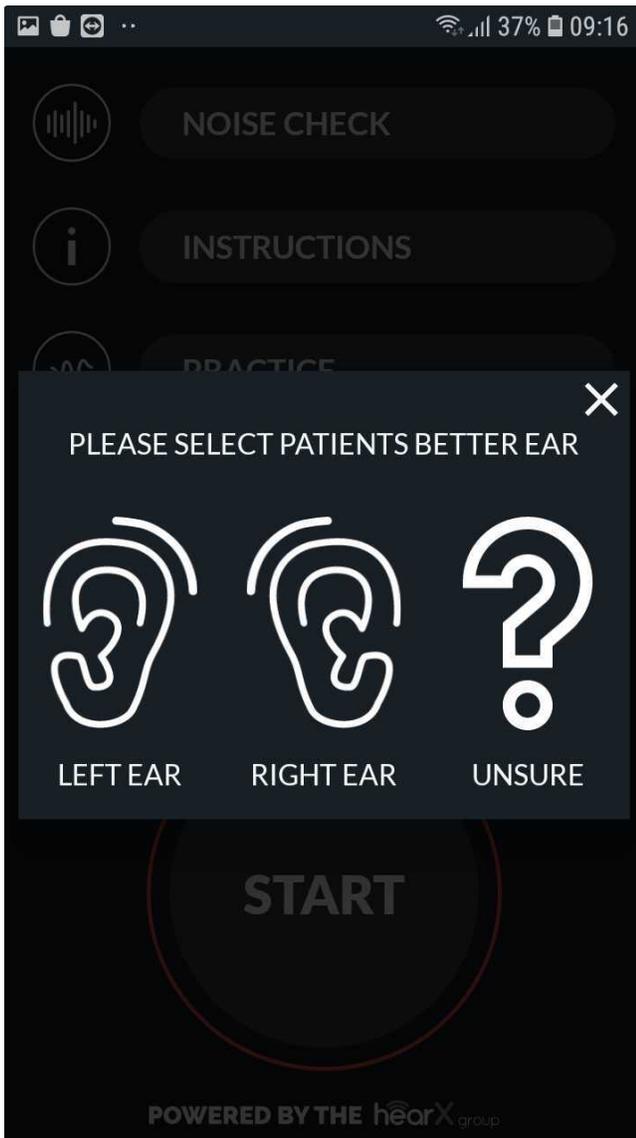
#### 4.4 Select the required PROTOCOL

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. hearScreen testing in progress

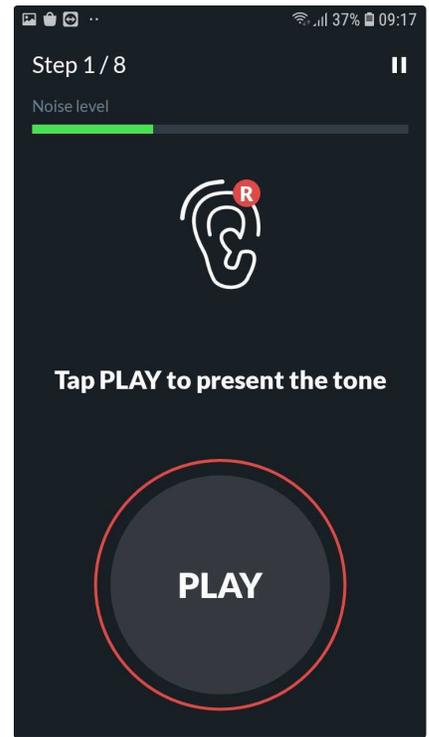
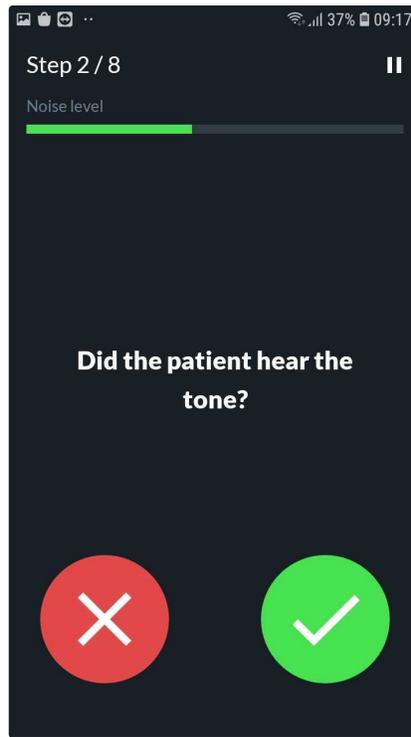
The test is operated as follows:

Before the test starts the facilitator will be presented with a pop-up question asking to select the test subjects better ear. They can select either 'LEFT' or 'RIGHT' ear. If the test subject is unsure, select 'UNSURE'. Tap 'START' to begin the test.



The facilitator will present the tone by clicking on the play button. When the test subject responds, the facilitator will click on the green tick. If the test subject does not respond, the facilitator will click on the red cross. In the event that the test subject does not hear the tone presented, the intensity of the tone will increase until it is a level that is audible to the test subject. In cases of profound hearing loss, the test subject may not respond to the tone at an increased intensity, due to the severity of the hearing loss.

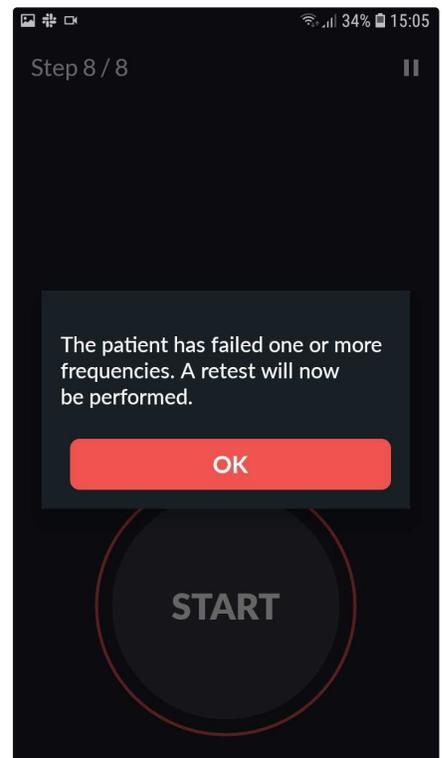
Following the input from the facilitator, the test will proceed to the next step.



In the event that the test subject fails the initial test, a retest is performed to increase accuracy on the final test outcome.

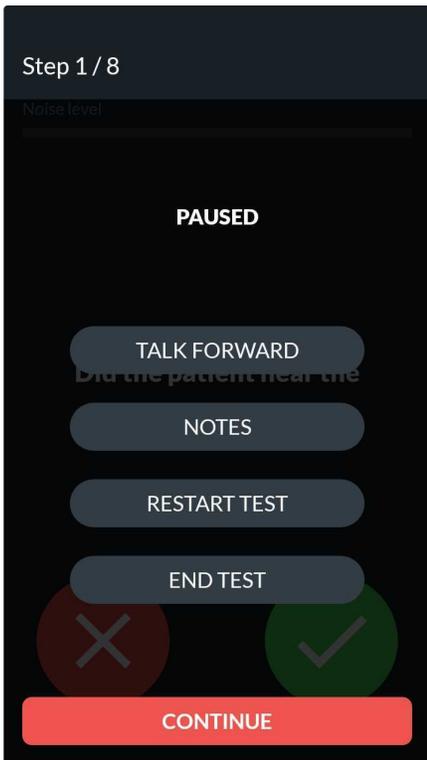
An immediate retest will be performed where those failed frequencies will be retested. This is based on the setting as set on the selected protocol to enable a retest. Only once the retest has been performed, will the final result appear.

The smart noise monitoring feature will display the external sound levels during testing. The bar will run green when the noise levels are safe and red when the noise levels are excessive and will impact the test reliability.



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:

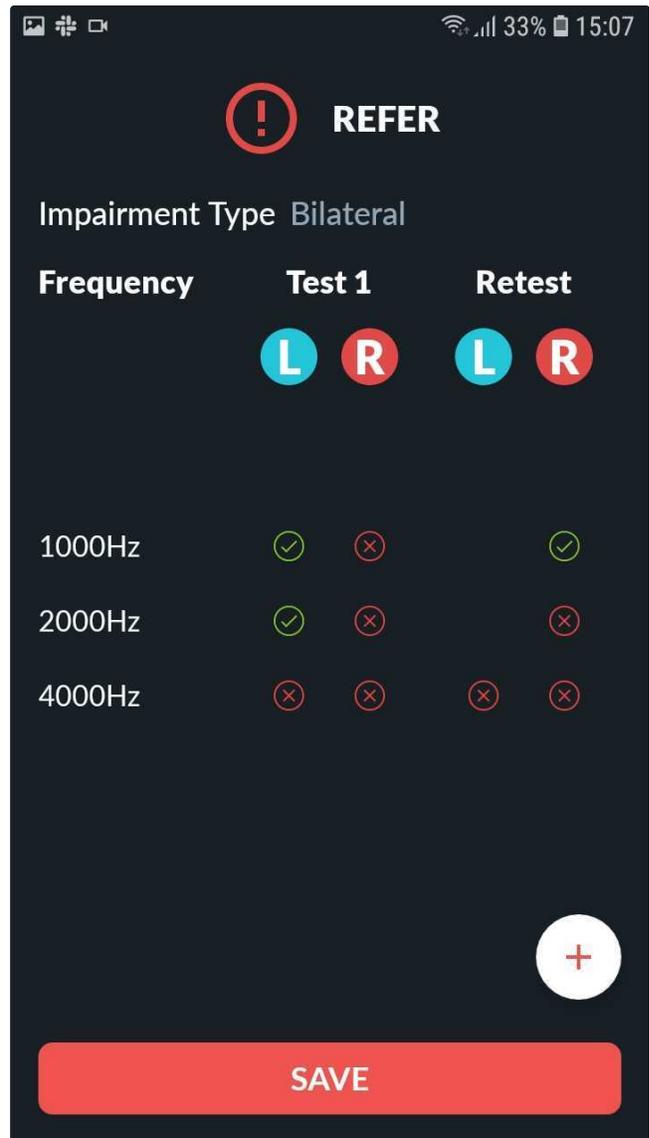
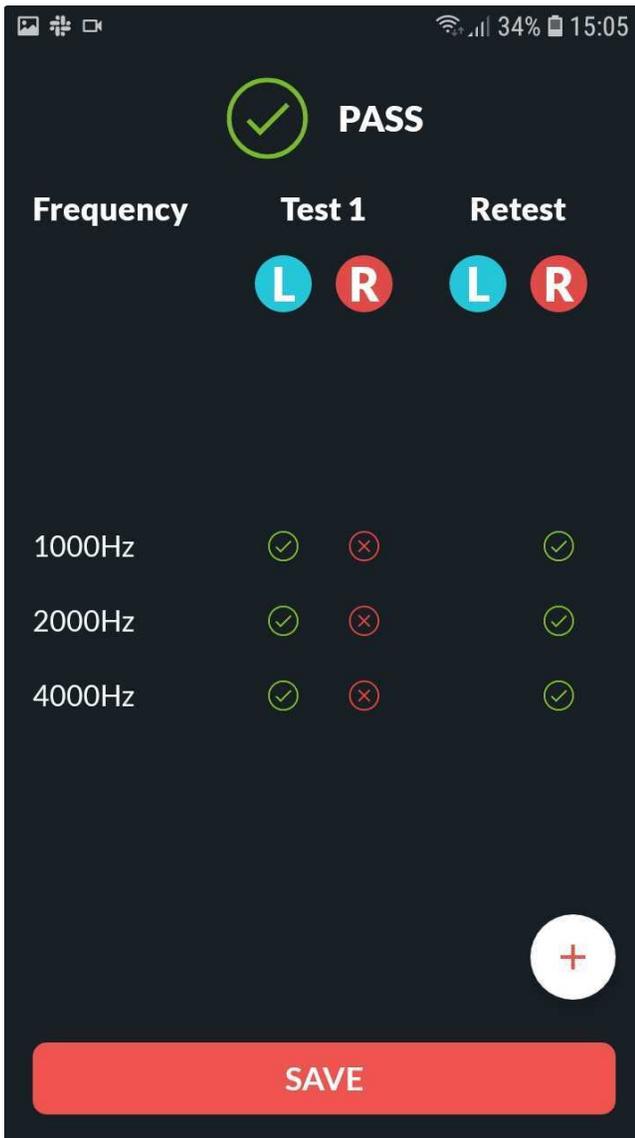
- Talk forward: Allows the facilitator to speak to the test subject via the headphones.
- Notes: Allows the facilitator to add notes.
- Restart Test: Allows the facilitator to restart the test.
- End Test: Allows the facilitator to end the test.



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

## 10. hearScreen test results

The test results are presented in the form of a "Pass" or "Refer" outcome.



**Please note:** The “Pass” outcome is dependent on the settings selected in the test protocol. [See the protocols section for more information.](#)

A “Pass” in the default protocol indicates that the test subject heard all the tones.

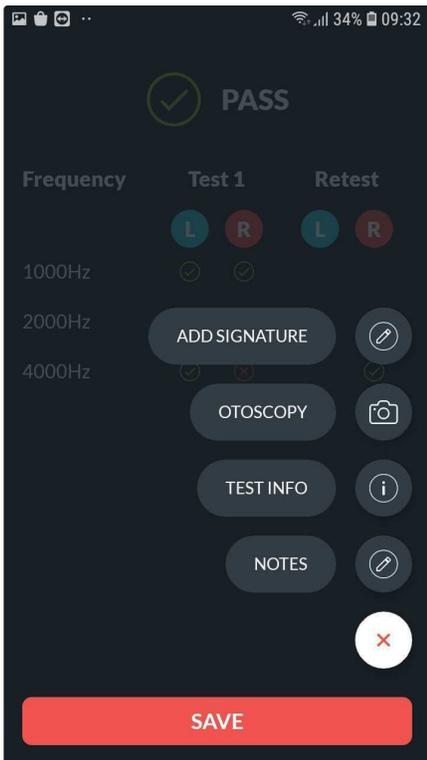
A “Refer” in the default protocol indicates that the test subject did not hear one or more tones irrespective of the ear and it could be different frequencies for different ears.

In the event that a retest was performed the results will display the outcomes of both the initial test and the retest clearly marking the failed frequencies with a ‘X’. The final result will be presented at the top of the screen. The pass requires no further action, whereas a refer outcome requires further assessment and diagnostic testing.

### 10.1 Additional menu on 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 test subject's signature to their results.
- [Test information](#) - This will allow the facilitator to view the test information such as test subject name, protocol used, test date, the headphones which were used and the test duration.

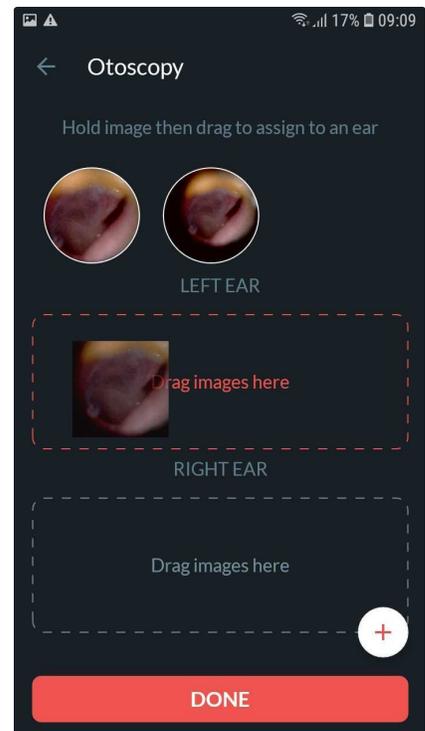
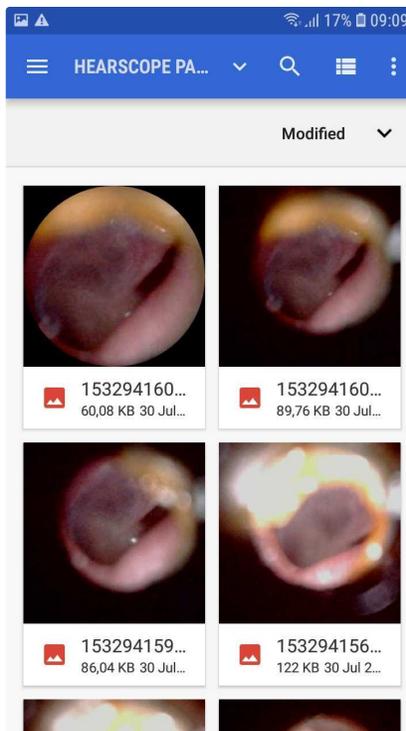
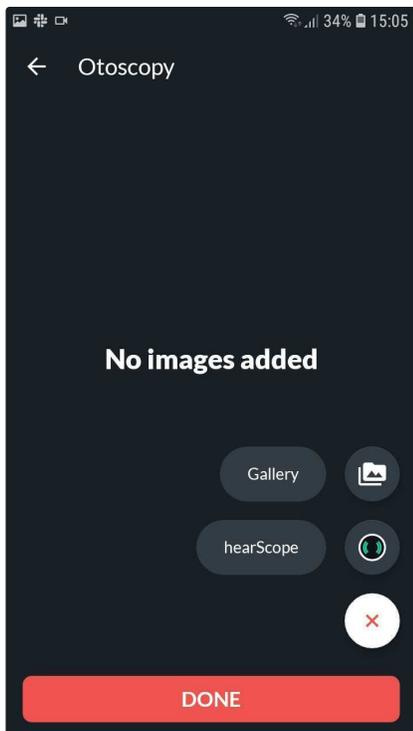


- Notes - This allows the facilitator to add notes.

- 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.

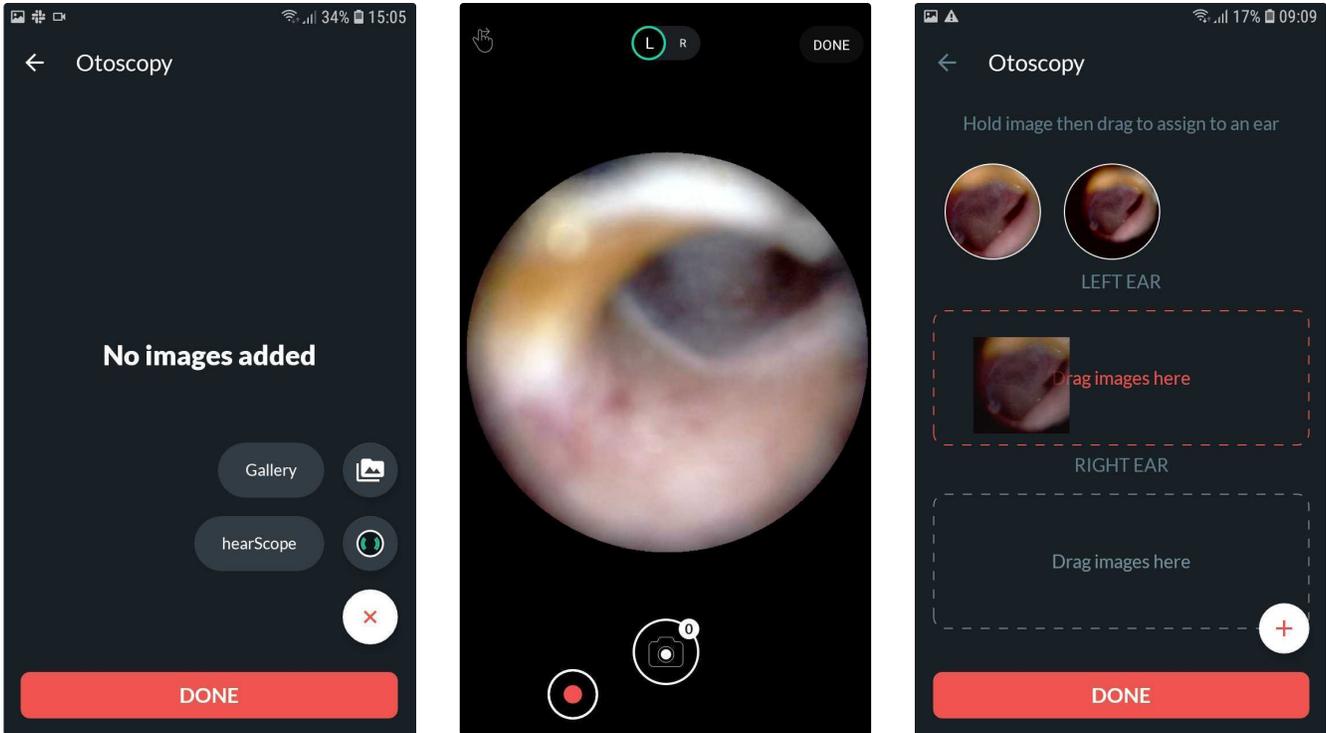
**Gallery:** To add an otoscopy image that has been previously captured, tap on the Gallery option and select the otoscopy images relevant to the patient. Once selected, assign the image to the right or left ear box by holding and dragging the image to the relevant box. Once completed, select 'DONE'.

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 left or right 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 an 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: <https://www.hearxgroup.com/hearscope>.



hearScope

## 11. Viewing of a test subject'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/test subject data remains limited to that of the owner of the hearX account used in Step 1 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 hearScreen in the menu on the left menu bar to see the latest tests synced to the portal. Once the test grid view opens the:
  - List of hearScreen test results that have been performed. It will display the date the test was performed, the name and surname of the patient/test subject, the name of the facilitator, location, result, as well as 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 mHealth Studio Cloud interface. On the left is a dark sidebar menu with the mHealth logo and navigation options: Admin, Testers, Facilities, Patients, hearScreen, hearTest, Self Test Kit, Vision, Devices, and Settings. The main content area is titled 'hearScreen Tests' and features a search bar with 'Add filter' and buttons for 'Columns', 'Download', and 'Bulk update status'. Below these is a table of test results.

	Test Date	First Name	Last Name	Tester	Location	Result	Status
	06/17/2021, 5:42 PM	Johan	Kleynhans	johandemo johandemo	Pretoria, South Africa	Referred	None
	04/08/2021, 12:49 PM	Test	Test	David Howe	Pretoria, South Africa	Referred	None
	04/04/2021, 10:41 AM	Pcprinsloo	N	PC Prinsloo		Referred	None
	03/24/2021, 10:31 AM	Anonymous	Anonymous	Michelle Bailey	Pretoria, South Africa	Pass	None
	03/18/2021, 10:22 AM	Prod	Test	PC Prinsloo	Kempton Park, South Africa	Pass	None
	03/04/2021, 11:45 AM	Willie	Van Zyl	Johan Kleynhans	Pretoria, South Africa	Pass	Refer for hearTest
	02/25/2021, 11:03 AM	Johan	Kleynhans	Johan Kleynhans	Pretoria, South Africa	Referred	Refer for hearTest
	02/23/2021, 3:53 PM	Johan	Kleynhans	Johan Kleynhans	Pretoria, South Africa	Referred	None

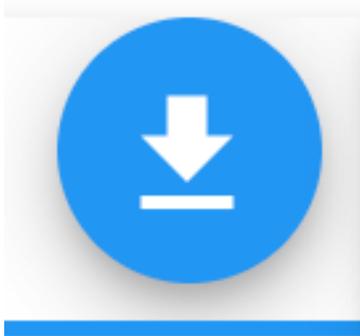
- Click on the EYE icon located on the left of the row as shown in the table to get a detailed view of the test results.

The screenshot displays the mHealth mobile health study interface. On the left is a dark sidebar menu with options: Admin, Testers, Facilities, Patients, hearScreen, hearTest, Self Test Kit, Vision, Devices, and Settings. The main content area is divided into several sections:

- PATIENT:** Name: Anonymous Anonymous; Gender: Male; Email: -; Contact Number: -.
- FACILITY:** Patient Language: English; Identity Number: -; Date of Birth: 1980-10-15; Reference Number: -.
- GENERAL:** Test Date: 03/24/2021, 10:31 AM; Duration: 0 Minutes 40 Seconds; Known Hearing Impairment: Unsure; Final Result: Pass.
- TEST RESULTS:** A table showing results for Left and Right ears across frequencies of 1000 Hz, 2000 Hz, 4000 Hz, and 8000 Hz. All results are 'Pass' at 35 dB.
- OVERALL TEST DETAILS:** Test Date, Duration, Known Hearing Impairment, Final Result.
- NOTES:** Age when tested: 40; Protocol: Test1; Hearing Impairment: Normal.
- SIGNATURES:** Empty section.
- OTOSCOPY:** Empty section.

A map of Pretoria is visible at the top of the interface. A blue download icon is located above the audiogram section.

- 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.

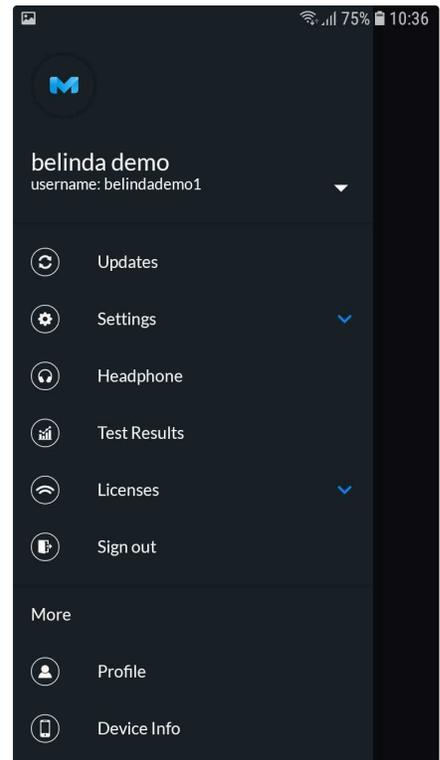


## 12. Support

### 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 (drop down):** 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:** 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:** Allows the facilitator to view existing licenses and linking of 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.
- **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.
- **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
- **Contact us:** Provides the contact details to get in touch with the hearX Group.
- **Changelogs:** Provides a summary of changes made to the application with each update.

## 12.2. Detailed settings of the hearX smart device

### 12.2.1 hearScreen Settings

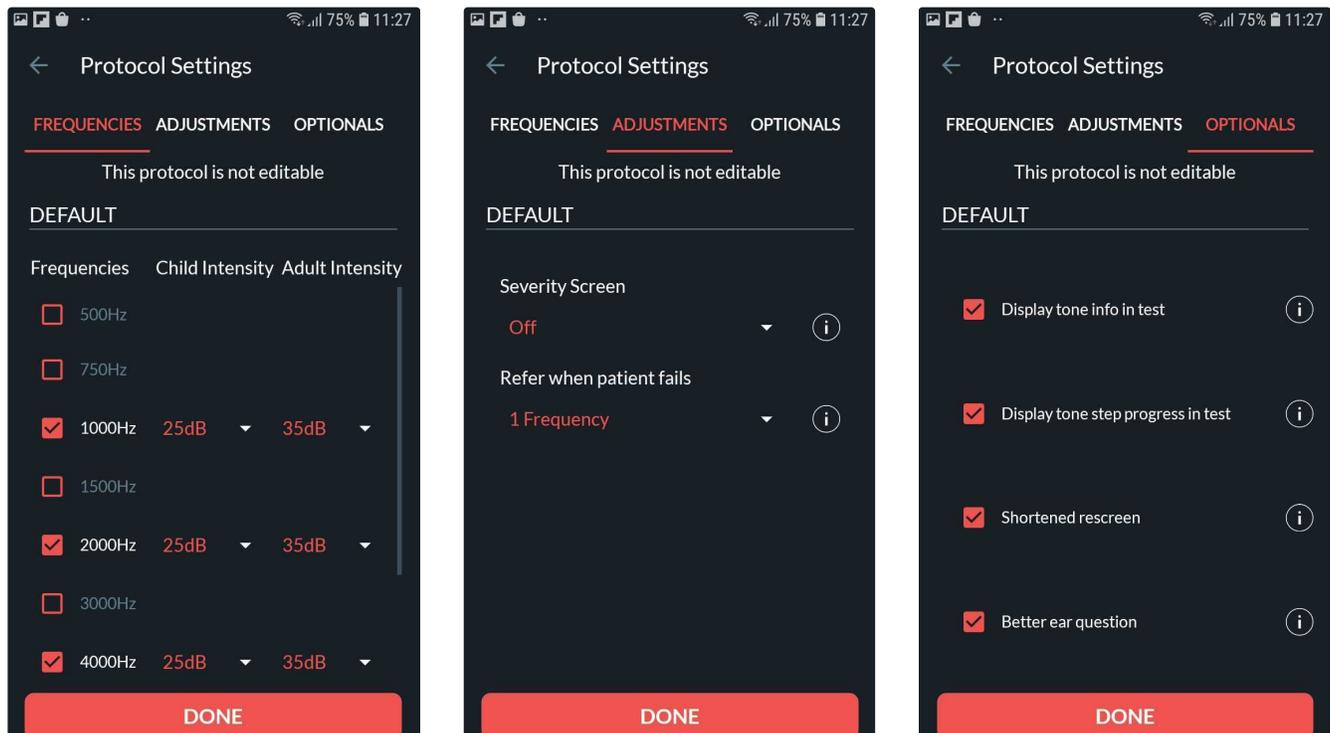
#### 12.2.1.1 General Settings

Enforce patient signature collection - This forces the patient/test subject to sign once the screening has been completed.

#### 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. Protocols can vary, for example, in some protocols, the patient needs to fail 2 or more frequencies before he/she can have a “refer” outcome.

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 required to include in the test and the pass level for screening adults and children.
- **Adjustments:** Activate or deactivate features like:
  - Severity Screen: Upon completion of the rescreen, this setting enables an ascending tone presentation in discreet intensity intervals on failed frequencies until a response is recorded. This provides an indication of the severity of the possible hearing loss. The severity is categorized into 5 levels where response occurs, namely Slight (30 dB HL), Mild (40dB HL), Moderate (55 dB HL), Moderate-Severe (70 dB HL), and Severe (no response at 70 dB HL).
  - Refer when patient fails: Frequencies for the left and right ear should be counted individually when setting the number of frequencies to evaluate a refer result. i.e: 1 Frequency = 1000Hz Left ear; 2 Frequencies = 1000Hz Left ear + 2000Hz Right ear.
- **Optionals:** Activate or deactivate features like:
  - Display tone info in test - Tone information such as ear, frequency and intensity are displayed on the screen during each tone presentation.
  - Display tone step progress in test - The test step is displayed in the top left corner throughout testing.
  - Shortened rescreen - After the first screening test is conducted, if any frequencies resulted in a refer, a rescreen will be initiated. This setting enables rescreen only on the failed frequencies.

- **Better ear question** - If enabled, a pre-screen dialog requesting patients/test subject better ear will be presented. Test will begin on selected ear. If disabled, the test will always begin in the left ear.

The **default** protocol available within the hearScreen software has been set with the following parameters:

- **Frequencies tested:** 1000, 2000 and 4000Hz in the left and right ears, with a 25dB pass level for children and a 35dB pass level for adults
- **Adjustments:**
  - **Severity screen:** This function has been deactivated.
  - **Refer when patient fails:** Frequencies This function is set to 1 frequency. A drop-down option in which the audiologist or hearing health professional can select the number of frequencies to fail in order to warrant a refer outcome.
- **Optionals:**
  - **Tone information visible:** This option is activated. one being presented to the facilitator on the screen.
  - **Test progress visible:** This option is activated. The test progress shows how many steps of the test have been completed during the testing process.
  - **Shortened rescreen:** This option is activated. In the event that the patient fails one or more frequencies, those frequencies that failed are retested again to confirm the fail result.

**Better ear question:** This option is activated. It asks the patient which ear he/she hears better with and starts the test on the better ear.

### 12.2.2 Detailed settings for mHealth App

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

1. **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.*)
2. **Facilitated:** The device is setup for use in settings where the facilitator is present and administers the test.

#### mHealth settings for **Self Test mode:**

If the smart device is in the Self Test mode the menu is **password protected** and the same password used to log into the device should be entered to access the menu. The lock icon should be selected in the top right corner of the START screen to unlock the menu. Enter your password to unlock the menu

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.

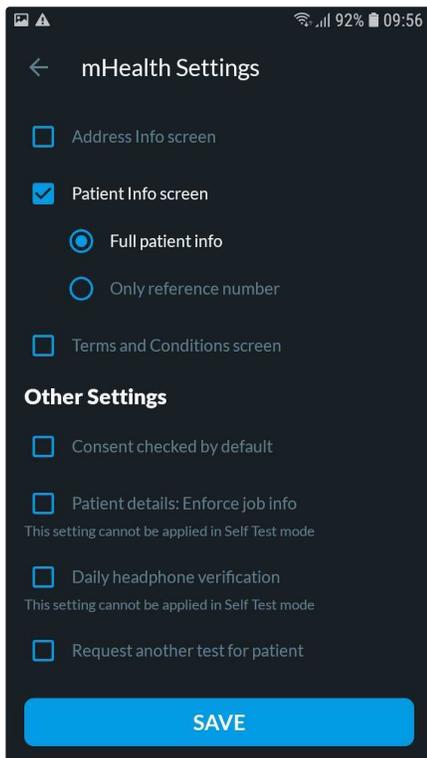
1. **Address info screen**- requires the patient to capture address information as part of the testing workflow.

2. **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:
  - a. **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.
  - b. **Only reference number** which results in capturing a unique identifier to keep patient information anonymous.
3. **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

1. 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.
2. Patient details: Enforce job info - *This setting cannot be applied in Self Test mode*
3. Daily headphone verification - *This setting cannot be applied in Self Test mode*
4. 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.

#### mHealth settings for Facilitated mode:

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

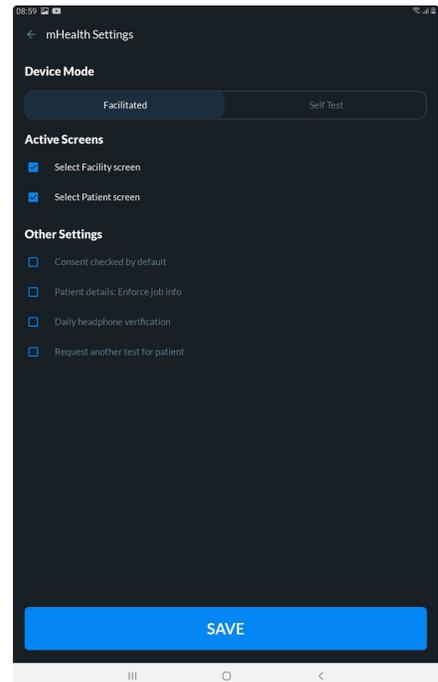
#### Active Screens

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.

1. 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.

2. 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

1. 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.
2. 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.
3. 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.
4. 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.

## 13. Other

### 13.1 Calibration

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](mailto:support@hearxgroup.com)

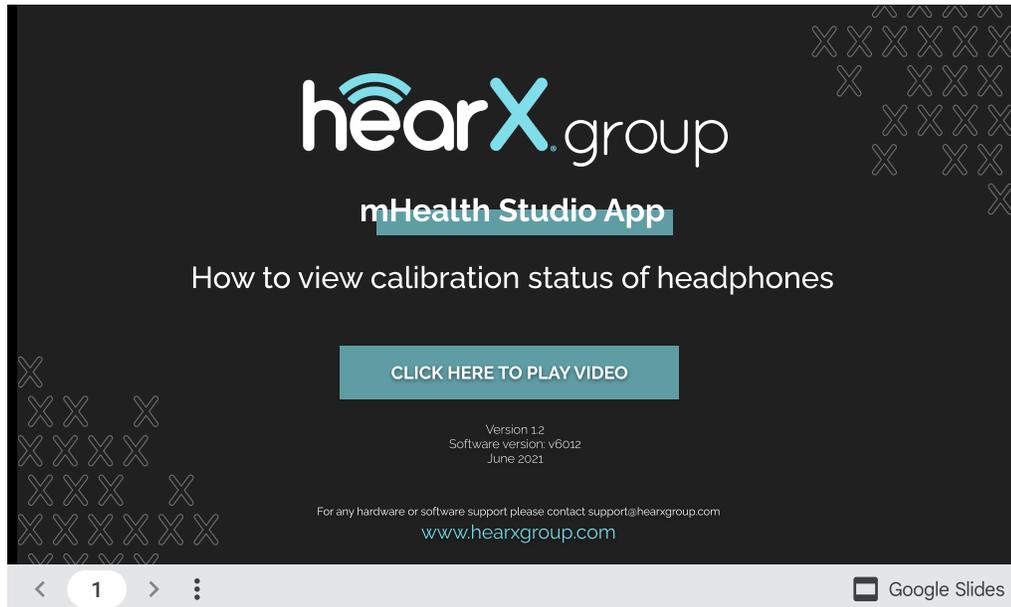
Costs associated with calibration will be quoted for as is based on the current priceless relevant at the time. Shipping costs may vary greatly and this will be for the customer's own account. Ensure the headphones are packed safely and securely with sufficient protective material to ensure the headphones 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

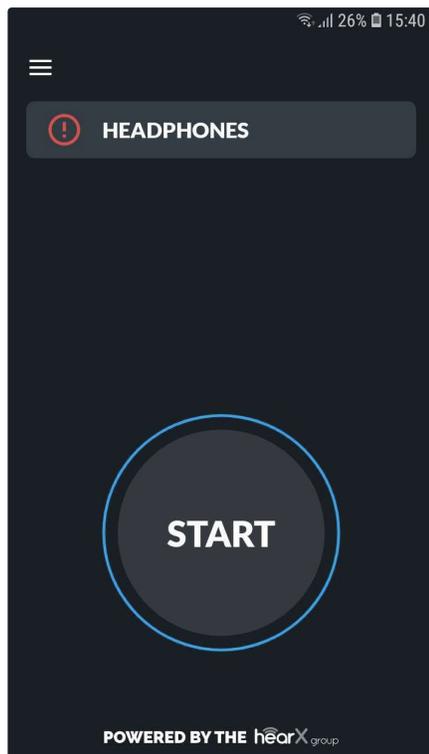
The hearX software will provide headphone notification on the START page prior to the date of calibration to inform the facilitator when the headphones are due for calibration. These notifications are displayed up to 80 days in advance. To view the details about the calibration and next calibration date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

## View calibration status of the headphones

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



## 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.

hearX group

mHealth Studio App

How to relink headphones

CLICK HERE TO PLAY VIDEO

Version 1.2  
Software version: v6012  
June 2021

For any hardware or software support please contact support@hearxgroup.com  
www.hearxgroup.com

1 Google Slides

### View calibration certificate on mHealth Studio Cloud

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mHealth Studio Cloud

How to view/download calibration certificate

CLICK HERE TO PLAY VIDEO

Version 1.0  
November 2020

For any hardware or software support please contact support@hearxgroup.com  
www.hearxgroup.com

1 Google Slides

## 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

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### 1. What frequencies can I test on hearScreen?

The default protocol has been set to test 1kHz, 2kHz and 4kHz in both ears as prescribed by the best practice standards. The user has the option to set his/her own protocol, with the following frequencies available for testing: 0.5, 0.75, 1.5, 2, 3, 4, 6 and 8 KHz.

There are two types of default protocols: “Default” which tests 1,2 and 4kHz in both ears and then the “Default Severity” which runs the “Default” test in addition to seeking a threshold estimation around the frequencies failed to determine the degree of potential hearing loss.

The user has the ability to create custom protocols. The protocols can be named as preferred. Please refer to the hearX Training Platform for instructions on how to add a custom protocol.

### 2. What is the ‘Smart Noise Monitoring’ feature and how does it work?

hearScreen has a ‘smart noise monitoring’ function that makes use of the microphone of the smart device to detect environmental noise and provide a warning to the tester when the noise levels have exceeded safe levels that allow for reliable testing.

The smart noise monitoring is displayed on a bar at the top of the screen, which, similar to a traffic light displays green when the noise is acceptable for reliable testing, orange as warning and red when the noise levels are not safe for reliable testing.

### 3. How is the quality of hearScreen facilitator evaluated?

In hearScreen, during a tester-administered screening, one tone is falsely presented in order to determine whether the tester is responding reliably to the patient’s responses or if they are trying to influence the test results by skipping through the steps. If the tester responds incorrectly to this falsely presented tone, they would be marked with a negative quality index (QI) score. The score is averaged over a month period. Hence if no improvement in a score is seen, the tester can undergo retraining until the QI score improves. Ideally, the score range should be  $\geq 80\%$ .

### 4. What is the difference between “verifying” and “linking” the headphones?

The headphones are required to be “linked” the first time that the headphones are used with the app. When “linking” the headphones an internet connection is required to download the calibration codes that link the specific headphone to the account and then to the specific phone or tablet being used with those headphones. A headphone “link” is required each time a user logs out and then back into the app. Verification of the headphones is required once the headphone has already been linked and is meant to confirm that the user is still using the same headphone that was initially linked to the phone. An internet connection is not required during the verification process. The frequency of this headphone verification action can be set in the app settings.

#### **5. Can I install hearScreen on my own smart device?**

While we use commercially available, off-the-shelf hardware as the base of our solution, the smart device used for hearScreen is standardized in order to comply with certain pre-set, industry-specific standards, to allow the output of the device, that generates the pure tones for screening, to be calibrated.

This is required to ensure the decibel level truly is what it says it should be. For a personal smart device, hearX cannot guarantee a reliable or definite sound level, as it has not been standardized and calibrated. The headphones used also need to be calibrated according to industry standards.

#### **6. Can I use hearScreen without the mHealth Studio App?**

hearScreen, hearTest, hearTest Occ Health, Vula Vision, and hearX STK need to be used within the mHealth Studio App, while hearScope can be used within the mHealth Studio App or as stand-alone applications. Please see the mHealth Studio FAQ's for additional information: [mHealth Studio FAQ's](#)

## **13.4 Contact**

Contact the hearX Group for any further information required:

**Email:** [support@hearxgroup.com](mailto:support@hearxgroup.com)

**US:** (415) 212-5500 | **RSA:** +27 (0) 12 030 0268