HSCP-MN-03 hearScope™ Desktop Training Manual v1.0

Table of contents:

Revision History

Revision	Date	Software Version	Description
v1.0	4 Feb 2021	v1.1.6	First publication of training manual for hearScope™ Desktop.
v1.1	14 Nov 2022		Update relevant sections on how to capture a hearScope image.

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1. Scope of this manual

This manual provides instructions for use of the hearScope™ hardware and software applications. This manual will guide the audiologist or hearing health professional on how to operate the hearScope™ otoscope hardware and explain all software features included for optimal use within a clinical and/or home-testing setting. The instruction for use of hearScope™ is an extension of the instructions for use of hearScope™ covered in HSCP-MN-EN hearScope IFU v3.1.

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 What’s in the box

	Item	Decription
1		Digital otoscope with Micro USB cable
2		Reusable ear tips 2x Small (3mm); 2x Medium (4mm); 2x Large (5mm) reusable ear tips included with initial purchase
3		Protective case
4		Dermal and throat adapter *(Optional)*

4. About hearScope™

hearScope™ consists of a handheld video-otoscope with a light source and ear tips of various sizes that connects to an Android smartphone, laptop, or personal computer (PC). The device is supplied with a protective, reclosable case. The intended use of hearScope™ is to visually inspect the outer ear canal and tympanic membrane under magnification. Imaging of the outer ear canal and tympanic membrane is viewed on the smartphone or laptop/PC, using the hearScope™ mobile application or web app software.

For a list of compatible Android smartphones/tablets or desktops go to hearScope by hearX Group - Digital video otoscope with AI image classification .

5. Using the hearScope™ hardware

5.1 Using the otoscope

- Ensure that the hearScope™ is used right side up and the text ‘THIS SIDE UP’ is pointing upwards.
- Point the hearScope™ at an object about 25mm from the front of the scope and adjust the focus wheel until the object is in focus to set initial focus.
- The light intensity can be adjusted by turning the wheel attached to the cable, it is recommended to turn the intensity up to the maximum for first use.
- Select an ear tip and fit it onto the hearScope™ so that your thumb fits comfortably on the focus wheel.

  Note: The first few fits can be tight so push the ear tip onto the hearScope™ until you hear a ‘click’ sound.

  For dermal and throat adapter instructions:

  - Using the attachment for throat inspection: The same adapter is used to fit a tongue depressor. Insertion guides are available at the bottom of the adapter to simplify inserting the tongue depressor into the adapter. The length of the tongue depressor is flexible based on user preference. hearScope™ has LED lighting at the tip to use it with throat inspections.
  - Using the attachment for dermal inspection: The adapter is designed to be positioned with the edge of the adapter placed directly on the skin. It positions the camera the correct distance from the skin to simplify the zoom required to take images of moles and skin lesions effortlessly.
- To capture images/videos of a patient/test subject’s right ear, use the right hand to hold the device and take your left hand over the patient/test subject's head to the right ear. The facilitator or user should use their left hand to pull the top of the ear upwards and

backwards. Either press to capture button located on the hearScope Desktop Application OR tap on the Spacebar on your keyboard to capture images. Ensure that the specula are not inserted too deeply into the ear canal. If the patient/test subjects experience any discomfort, remove the device from the ear.

6. Set up instructions for hearScope™

Download and open the hearScope™ application. The hearScope™application can be downloaded directly from the hearScope™ website or from the following stores:

- Mobile use:
  - Google Play Store
- Desktop use:
  - Linux and Windows directly from the hearScope™ website
  - Mac: App store

AI image classification

Anyone, anywhere can capture images of tympanic membranes with hearScope™ and request an AI image classification result within seconds.

**BETA version available from 9 March 2020 - Please note that this is a free BETA version for research use only and is not intended to diagnose. Always seek medical attention from a healthcare professional when any symptoms are present.*

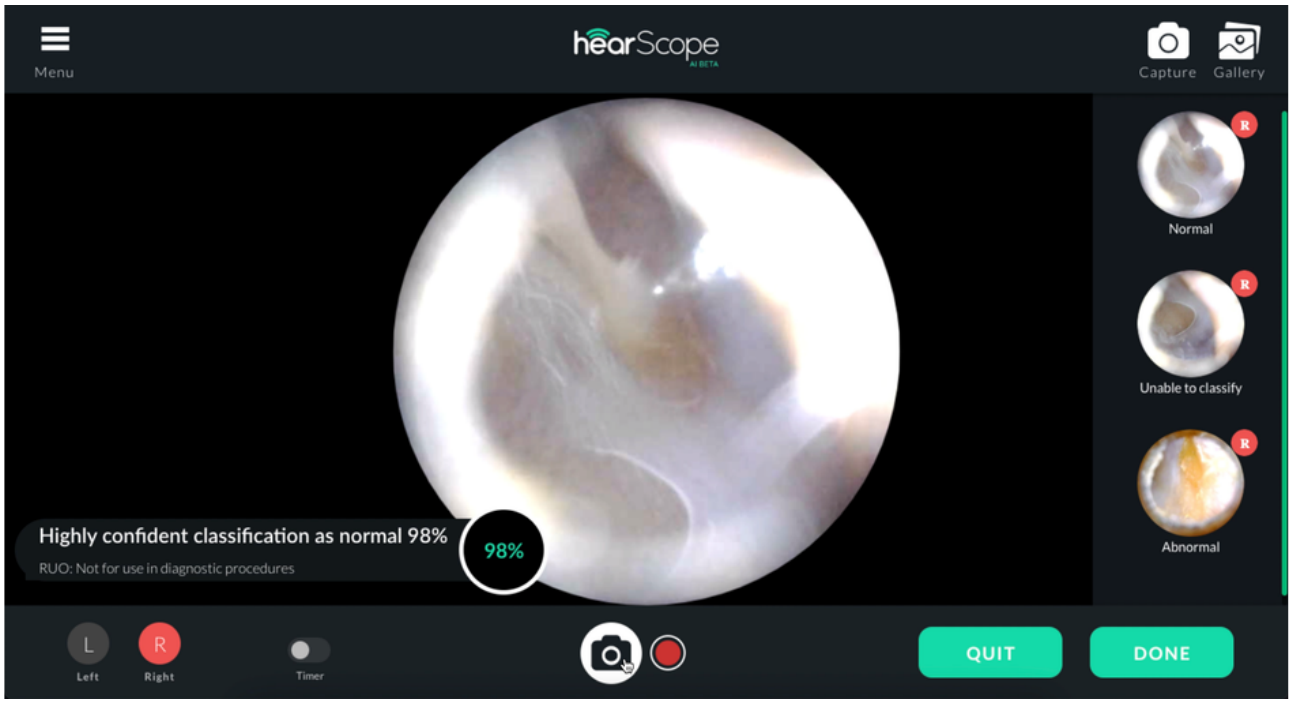
Our Artificial Intelligence image classification system applies machine learning to provide an accurate image classification for the most common ear disease categories.

Key features:

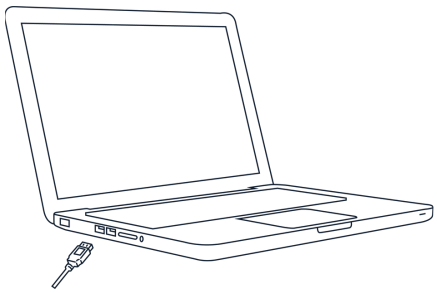
- **Instantaneous AI image classification:** Receive an instantaneous AI image classification when taking an image.
- **Confidence rating:** Be sure about the provided confidence rating for the classification result.
- **Classification explanation:** Read through additional information for each classification result.

The AI feature can be enabled by clicking on the MENU button in the top left corner and selecting AI Upgrade. Sign in with your hearX account or register an account. When enabled the test/subject and or facilitator can capture images of tympanic membranes with hearScope™ and request an AI image classification result within seconds. Our Artificial Intelligence system applies machine learning to provide an accurate image classification for the most common ear disease categories.

Note: The image classification does not replace the opinion of a health practitioner, always consult a health practitioner for a diagnosis.



7. Capturing a hearScope™ otoscopy image

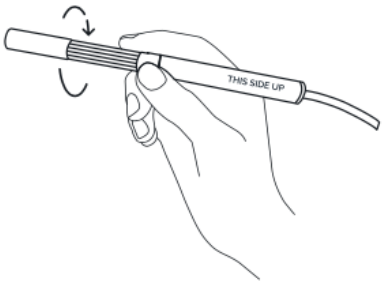


Connect your hearScope™ to the laptop or PC (use the micro USB or USB-C adapter) and launch the hearScope™ App.

A pop-up notification will appear once the hearScope™ app has been opened, requesting permission to use the application functions on the laptop/pc required by the hearScope™ software to ensure the correct functioning of the application.

Tap Allow for the following permissions:

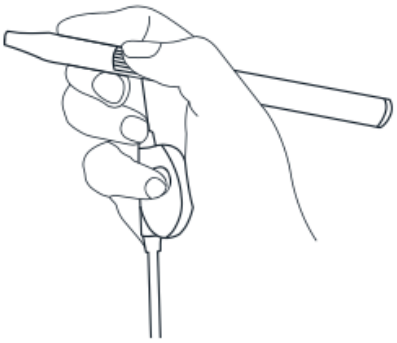
- Storage
- Camera
- Audio



Orientate the hearScope™ right side up by ensuring the text on the hearScope™ device ('This side up') is pointing upwards. Point the hearScope™ at an object about 25mm from the front of the scope and adjust the focus wheel until the object is in focus to set initial focus.

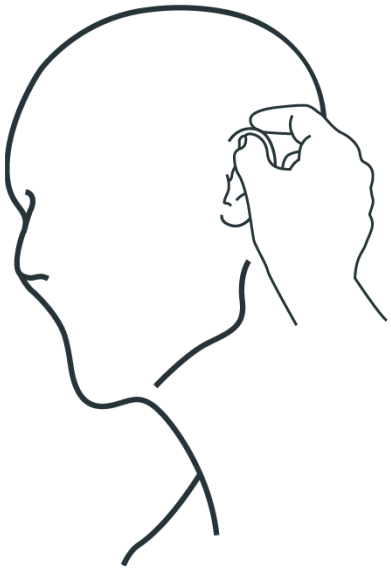
Select an ear tip (speculum) to place on the hearScope™. Refer to the numbers in the ear tips. Size 4 is generally used for adult examinations. Ensure that your thumb fits comfortably on the focus wheel.

Note: The first few fits can be tight so push the ear tip onto the hearScope™ until you hear a ‘click’ sound.

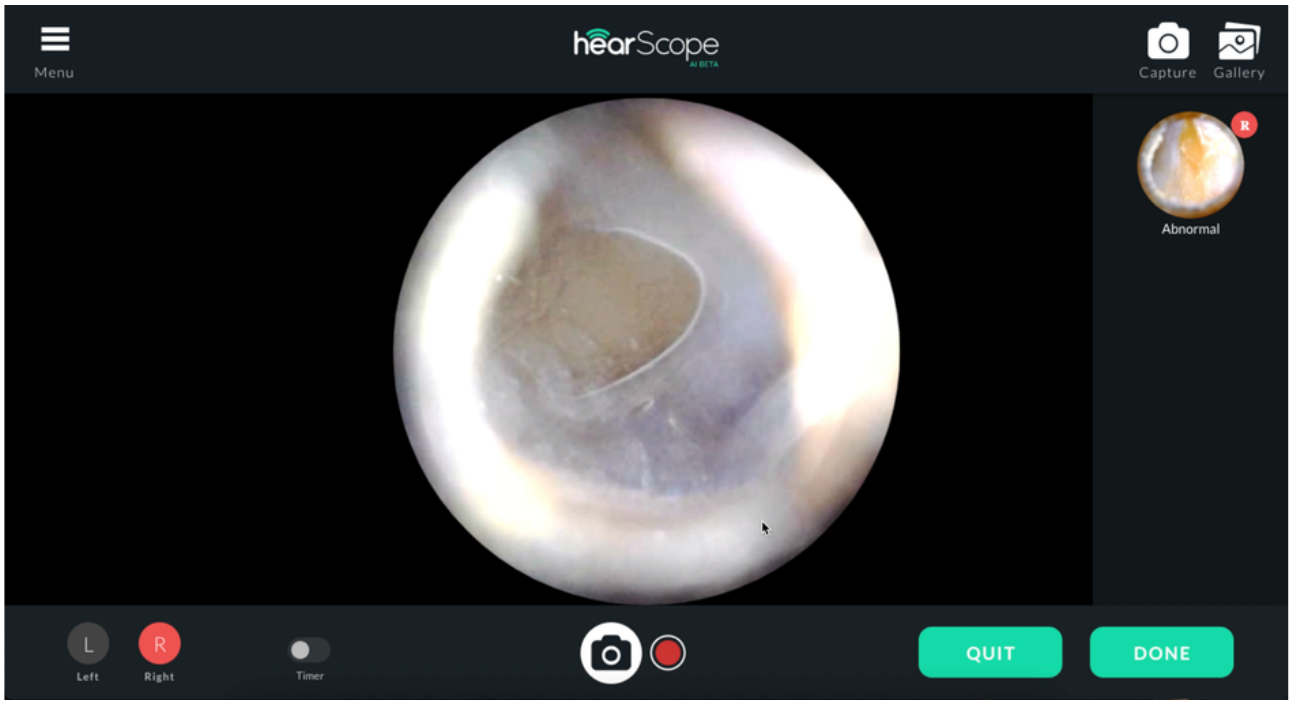


The light intensity can be adjusted by turning the wheel attached to the cable, it is recommended to turn the intensity up to the maximum for first use. Use the button on the cable to assist with the capturing of images during examinations.

Tap on the CAMERA icon on the smart device. Gently insert the device into the ear. The patient/test subject and/or facilitator should use their thumb to adjust the focus with the focus wheel. Do not insert the hearScope™ too deep, as this may cause damage to the eardrum.



Use the CAMERA button to start capturing images and/or videos. Images can also be captured by pressing the space bar on your keyboard. The facilitator also has the option to add a timer where the image will be captured automatically every 8s, 10s, or 12s depending on the settings which have been applied (time can be set in the settings menu, accessed via the home screen).

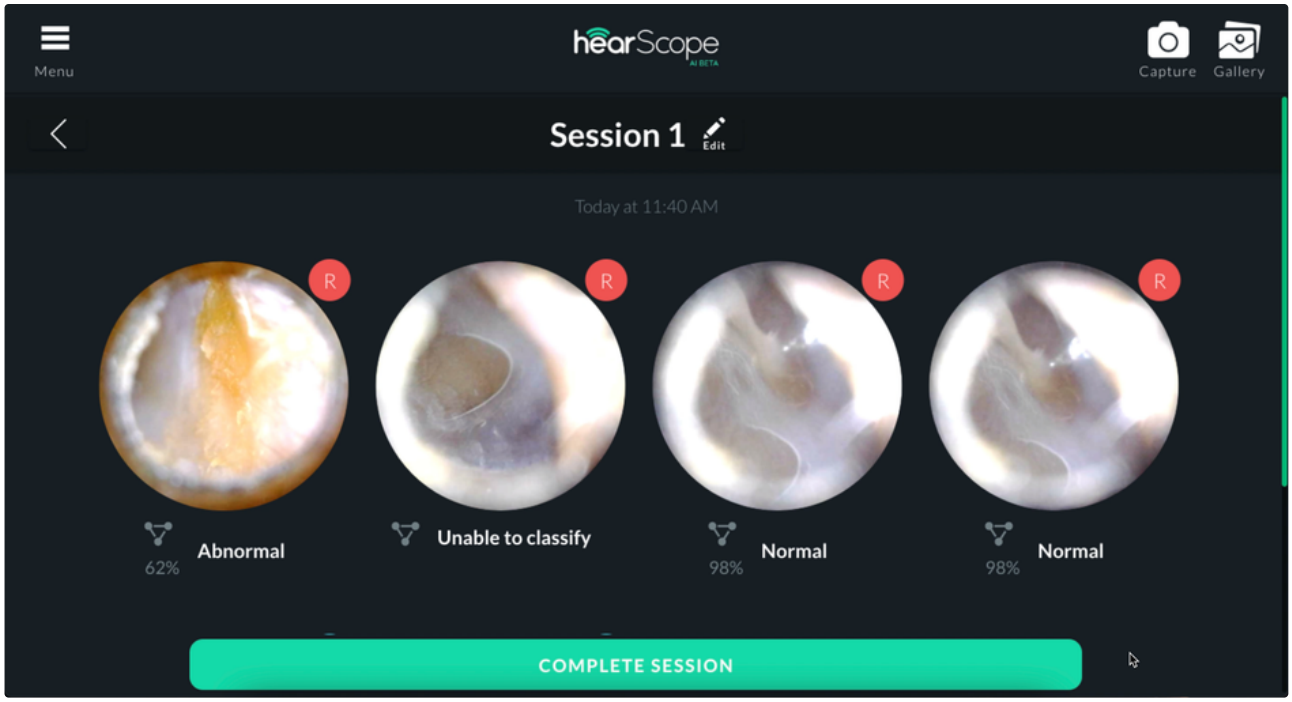


Ensure that the correct ear is selected by toggling the L or R at the bottom of the screen.

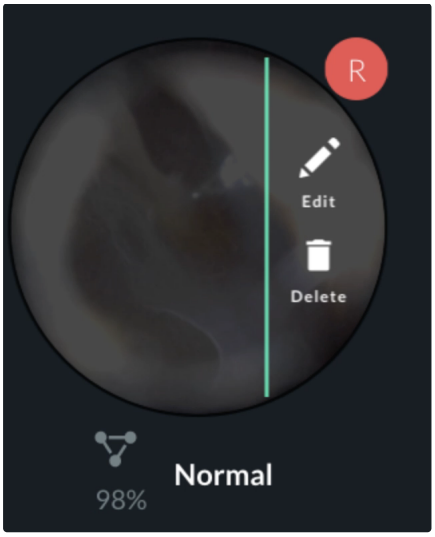
To capture a good quality image make sure to focus the hearScope™ on the eardrum. Select DONE in the bottom right corner to complete the session and view the captured images.

Once the images have been captured it will display all the images which have been captured in that session. The session name can be changed by tapping on the ‘Edit’ button. change session name, add text/audio notes, and request AI image classification.

The session name can be updated by selecting the EDIT icon next to the session name.



Otoscopy images can be viewed, deleted, and cropped. To do this hover over the captured image and click on EDIT.



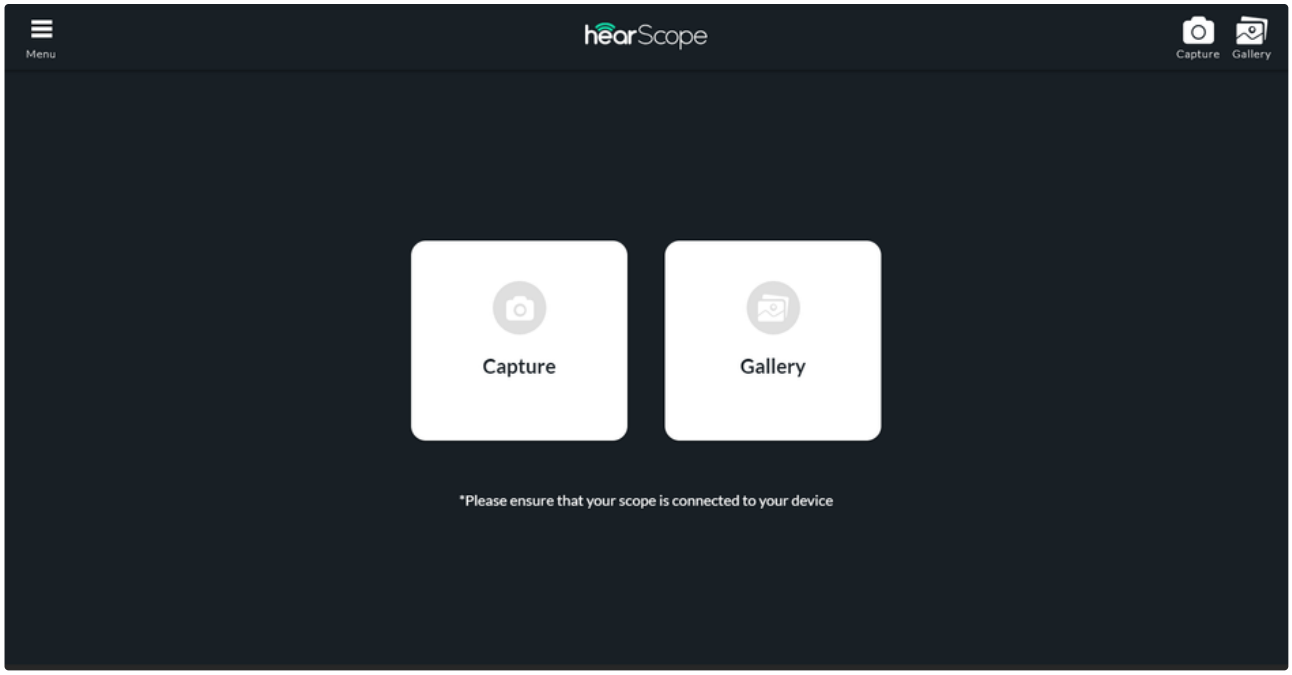
8. Viewing of a test subject's otoscopy image

The hearScope™ Desktop app has a Gallery where all the hearScope™ sessions are stored. These images are saved in a specific directory folder on the laptop/PC. The storage location of the images on the desktop can be changed by accessing the location settings. All the images will save to the hearScope™ Gallery after the facilitator has selected the DONE button when a session has been completed.

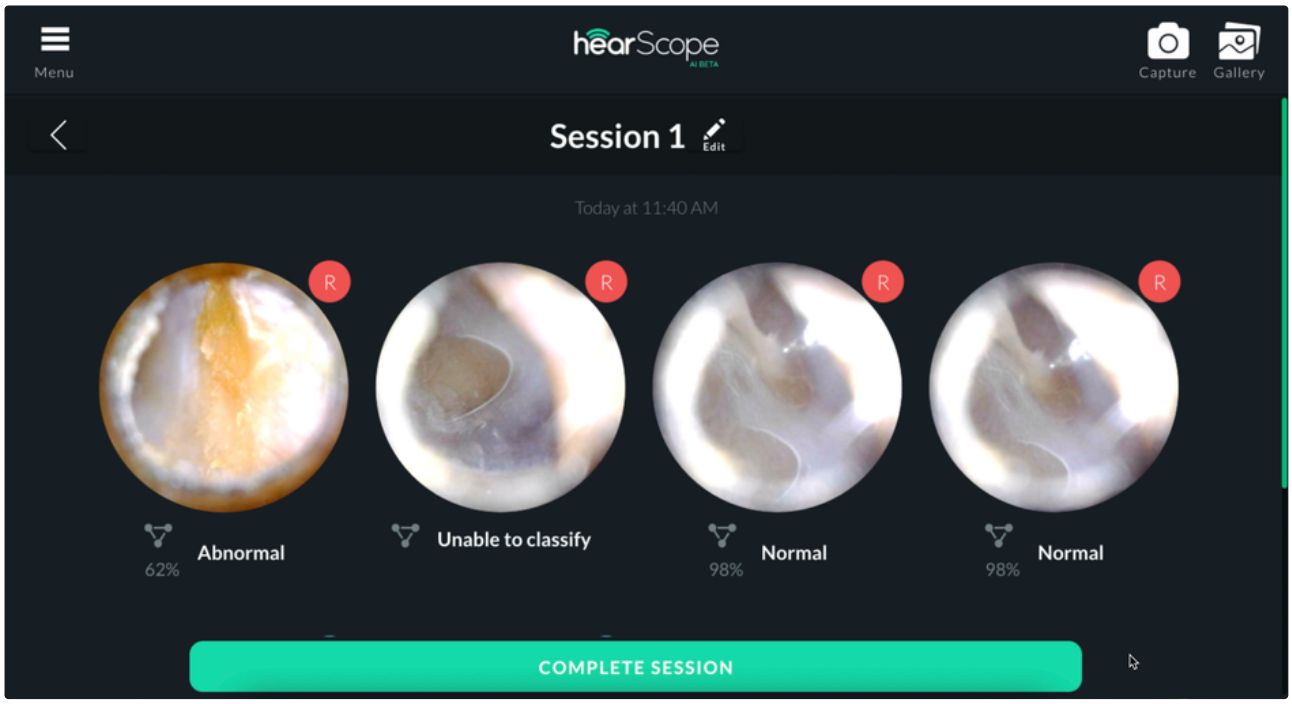
To view a patient's otoscopy images:

- Launch the hearScope™ App on the desktop.
- Tap on Gallery. This will allow the facilitator to either view all sessions or view the session. which have been captured on the same day.
- Tap on the session which images would like to be viewed.

The session name can be changed by tapping on the EDIT button next to the session name.

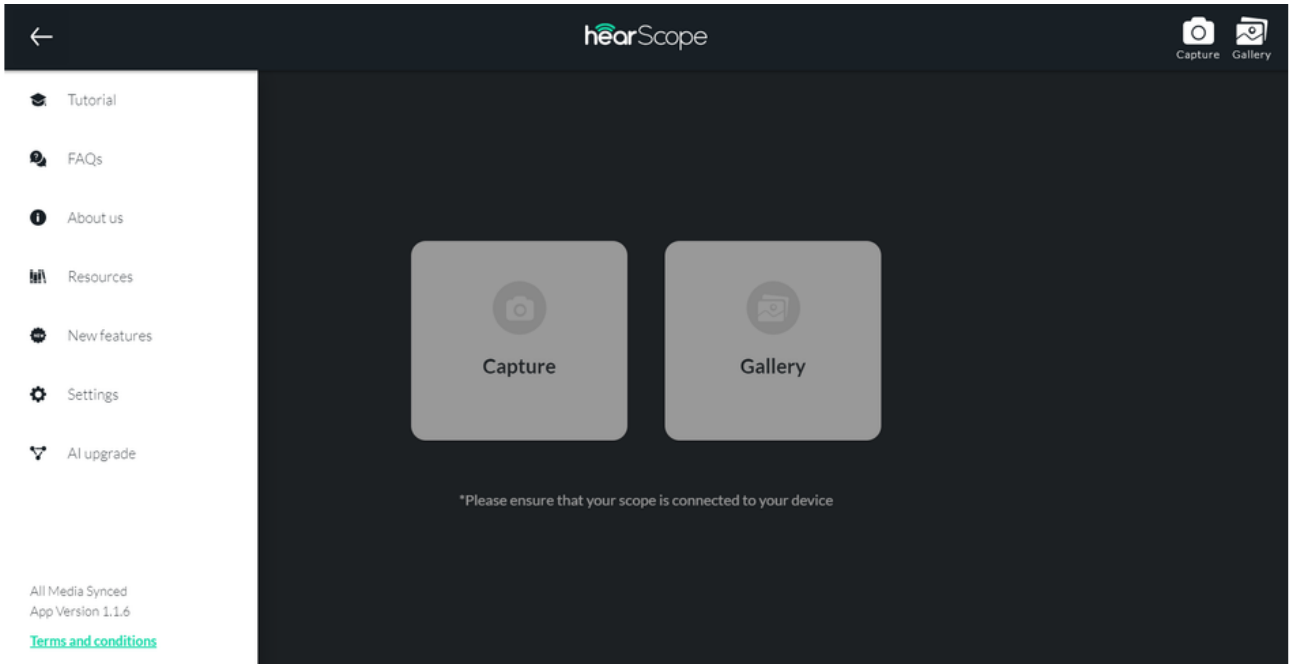


The facilitator can view, delete, and crop otoscopy images. To do this tap on a captured image. The facilitator can also add text notes and request AI image classification.

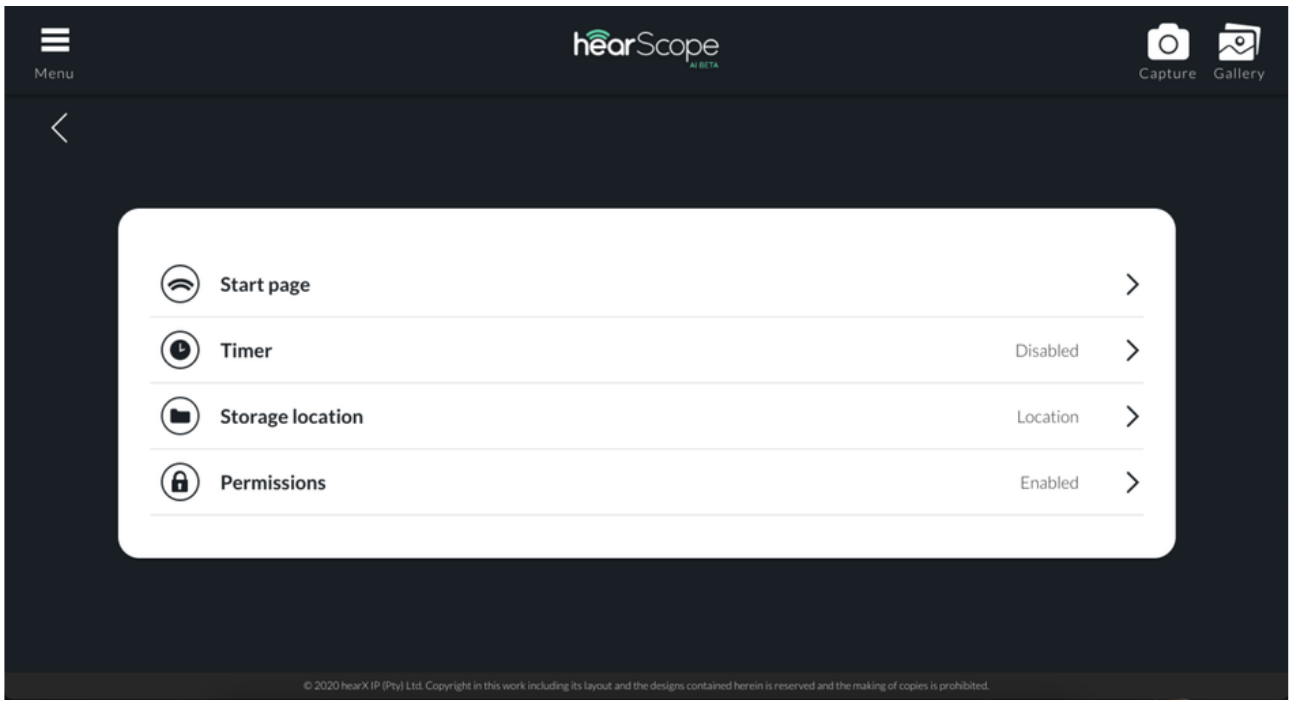


9. Support

9.1. hearScope™ Menu



Tutorial: Provides set-by-step instructions on how to use and operate the hearScope™.
FAQ's: Provides a list of Frequently asked questions.
About us: This provides information such as the App version installed on the smart device, hearScope™ user manual, list of third-party licenses, hearX Group company information, and contact details.
Resources: The facilitator has access to additional information for each classification result when using the AI image classification feature - *Please note that the AI image classification feature is a free BETA version for research use only and is not intended to diagnose. Always seek medical attention from a healthcare professional when any symptoms are present.*
New features: Proved a list of all the new features which has been added to the currently installed version of the hearScope™ Dekstop App.
Settings: The administrator can customize certain settings in the hearScope™ Desktop app:



- **Start page:** This allows the facilitator to choose which page must be displayed when launching the hearScope™ app.

- **Timer**: This allows the facilitator to change the timer to either be disabled or set to capture images automatically after every 8s, 10s, or 12s.
- **Storage location:** The gallery in the hearScope™ desktop app references this folder to show all the images and sessions. This also allows the facilitator to select a specific folder on their laptop/PC where the captured images will be saved to.
- **Permissions:** This allows the administrator to choose whether or not they would like to anonymously share the images which are captured with the hearX group to use for research purposes.

AI Upgrade: Allows the facilitator to sign in with their hearX account or register an account to enable the AI image classification feature. When enabled the test/subject and or facilitator can capture images of tympanic membranes with hearScope™ and request an AI image classification result within seconds. Our Artificial Intelligence system applies machine learning to provide an accurate image classification for the most common ear disease categories.

10. Other

10.1 Maintenance

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

- Before use, check the cables and connectors for signs of wear and/or damage. If found, please arrange for servicing or checking by the seller before continuing with the use of the device. No further maintenance is required.
- The hearScope™ body and case can be disinfected with a cloth dampened with EPA-approved alcohol. The use of improper cleaning methods or solutions may damage the device. If the lens becomes dirty carefully wipe the lens with a dry, non-scratching microfiber cloth. Take care to ensure all components of the hearScope™ are dry before the next use.
- The reusable ear tips should be disinfected after every use. Submerge the ear tips in rubbing alcohol (minimum 70% isopropyl alcohol) for 20 minutes and wipe excess debris and moisture off before next use. **Warning:** Do not use Chlorhexidine-based cleaning solutions on the hearScope™ as it may cause deafness.

10.2 FAQ

1. Why would I choose hearScope™ over a traditional otoscope?

The hearScope™ is a low-cost digital otoscope that connects directly to a smartphone. Images and videos are immediately available to show to the patient or upload to an electronic health record. Showing patients the pathology that is present in their ear canal or eardrum in real-time, makes hearScope™ a powerful patient counseling tool. hearScope™ is also an effective academic training tool while teaching students aspects of ear anatomy and pathology.

2. Which devices are compatible with hearScope™?

The hearScope™ mobile application is compatible with most Android smartphones and tablets. Please view the compatibility list here (if your Android device is not on the list, please contact hearX for assistance). iPhone is currently not compatible with the hearScope™.

The hearScope™ desktop application is compatible with Windows, Mac, and Linux.

3. Who can use the hearScope™?

hearScope™ is a low-risk medical device that is easy to use. Typical users include medical practitioners, community health workers and nurses. The device can be used by non-professionals if in accordance with instructions in the user- manual and with appropriate training (please contact hearX for training inquiries).

4. Is it safe to use the hearScope™?

The hearScope™ has been designed and manufactured according to medical device standards, including good manufacturing practices as per ISO 13485. The hearScope™ is safe to use and poses no unintended risks to the user if used in accordance with instructions in the user- manual and with appropriate training (please contact hearX for training inquiries).

5. Can the hearScope™ be used only on adults?

hearScope™ is shipped standard with 2 x small (3 mm), 2 x medium (4 mm), and 2 x large (5 mm) reusable specula (tips), which are appropriate for use on most ear sizes. Typically, these sizes will be sufficient to accommodate the use of hearScope™ on persons over the age of 5 years old, although exceptions may apply based on the size, length, and curvature of an individual's ear canal.

6. When will the AI image classification feature be available?

hearX has released a BETA version of the AI image classification feature in 2020. The AI image classification feature is able to classify normal tympanic membranes, wax obstruction, chronic perforations, and abnormal tympanic membranes. Abnormal refers to a high possibility of pathology being present.

Please note that this is a free BETA version for research use only and is not intended to diagnose. Always seek medical attention from a healthcare professional when any symptoms are present.

7. What ear conditions will be diagnosed using AI image classification feature?

The conditions include normal eardrums, wax obstructions, chronic perforations, and abnormal tympanic membranes. We are continuously improving this feature to be able to classify more pathologies, such as acute otitis media and otitis media with effusion.

Please note that this is a free BETA version for research use only and is not intended to diagnose. Always seek medical attention from a healthcare professional when any symptoms are present.

8. How accurate will the hearScope™ AI automated diagnostic support system be?

The AI image classification feature can diagnose images with an accuracy of more than 90%.

9. How do I assemble, use and clean the hearScope™?

Please consult the instruction manual to learn how to assemble, use and clean the hearScope™ and its components. To access a digital copy of the hearScope™ user manual, click here or visit hearScope by hearX Group - Digital video otoscope with AI image classification .

10. Where can I find the hearScope™ user manual?

A digital copy of the hearScope™ user manual can be accessed by clicking here or visit the hearScope™ website: hearScope by hearX Group - Digital video otoscope with AI image classification

11. What are specula (ear tips) made of and are they reusable? Can I order more?

Yes, ear tips are reusable and are made of medical-grade Polypropylene. To order additional ear tips please contact hearX for assistance.

12. How do I clean the specula (ear tips)?

The reusable ear tips should be disinfected after every use. Submerge the ear tips in rubbing alcohol (minimum 70% isopropyl alcohol) for 20 minutes and wipe excess debris and moisture off before next use.

WARNING: Do not use Chlorhexidine-based cleaning solutions as it may cause deafness.

13. How do I connect my hearScope™ to a phone with a USB-C connection?

A micro USB to USB-C adaptor is included in the box.

14. Why is the light not on or the image of the ear so dark?

The LED light intensity can be adjusted (and turned on/off) by turning the dial attached to the hearScope™ cable.

15. How do I focus the device?

Focus the hearScope™ by adjusting the focus wheel at the front of the device.

16. Why is the image upside down?

Please make sure you orientate the hearScope™ before you insert it into the ear. Use the “THIS SIDE UP” mark on the device as a guide.

17. What image/video format does the hearScope™ app generate?

PNG format is used for images. MP4 is used for videos.

18. Are my hearScope™ image and video files accessible outside of the hearScope™ app?

Yes! Simply browse to your device's internal image storage directory and access the “hearScope™” folder to view all your generated files. Mobile usage example: My Files > Internal Storage > DCIM > hearScope™.

19. What image resolution does the hearScope™ mobile application produce?

Images are captured with 640x480 or 1920x1080 resolution.

20. What is the warranty period of the hearScope™ device?

hearScope™ comes with a limited one-year out-of-box warranty.

21. Which EHR platforms do hearScope™ support?

Currently, otoscopy images can be viewed as part of test results for hearScreen, hearTest, hearTest Occ Health, and hearX Self Test Kit on an electronic health record (EHR) platform (mHealth Studio).

Should you require your own EHR platform to integrate with hearScope™, our mHealth Studio application provides generic integration possibilities. Please contact hearX for more information.

22. How does hearScope™ complement other hearX products?

- hearScreen: The hearScope™ may be used as a pre or post-screening tool to assist in identifying any conditions, which are likely to have an effect on the refer result. The hearScope™ is a powerful counseling tool to motivate patients to seek to follow up services if pathology is present.
- hearTest Occ Health: Otoscopy is part of the screening implemented for occupational health. Proof of an ear examination is easily provided with the eardrum images.

10.3 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)*