

The logo for hearScope features the word "hear" in a lowercase, sans-serif font, followed by "Scope" in a larger, uppercase, sans-serif font. Above the "ear" portion of "hear" are three curved lines of increasing size, resembling a signal or sound wave icon.

hearScope

USER MANUAL



hearScope™ - Ground Floor, Building 2, Ashlea
Gardens Office Park, 180 Garsfontein Road, Ashlea
Gardens, Pretoria, 0081, South Africa

hearScope v2.

HSCP-MN-EN hearScope IFU v1.0

For more information visit www.hearxgroup.com or
contact hearX: info@hearxgroup.com

ZA: +27 12 030 0268

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Congratulations! This is your hearScope™ smartphone video-otoscope.

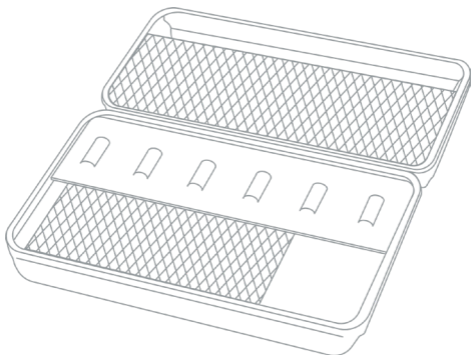
Please read this guide carefully to ensure correct setup and safe operation.

WHAT IS hearScope™?

hearScope™ consists of a handheld video otoscope with a light source and ear tips of various sizes that connects to an Android smartphone (can be user-supplied). The device is supplied with a protective 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, using the hearScope™ application.

For a list of compatible Android smartphones go to www.hearxgroup.com/hearscope

1 Protective case

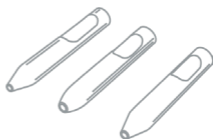


2 hearScope™ *Smartphone video otoscope with Micro USB cable*



3 Reusable ear tips

*2x Small, 2x Medium and 2x Large
reusable ear tips included with
initial purchase.*



4**Micro USB to USB-C adaptor***Required for some phone models***5****Phone stand**

SET UP INSTRUCTIONS

- Switch on the smartphone, download and open the hearScope™ application.

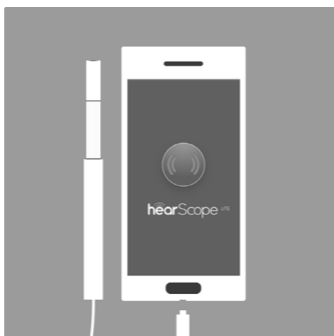


<https://play.google.com/store/apps/details?id=com.hearxgroup.hearscope>

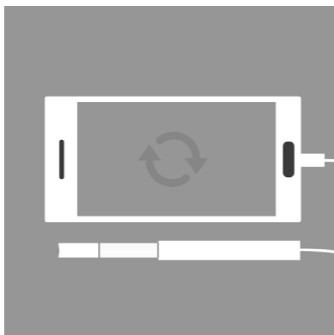
- Connect the hearScope™ to your smartphone (use the micro USB to USB-C adaptor if required).
- Grant your smartphone permission to access the hearScope™.

Please refer to the in-app tutorial for operating instructions with images. Go to Menu/Tutorial.

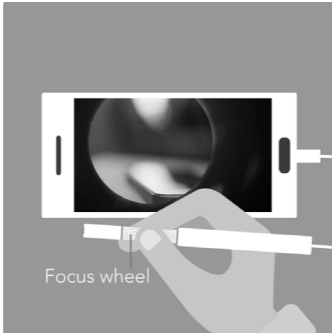
1. Open the hearScope™ application on your smartphone.



2. Orientate your hearScope™ right side up by pointing it at an object and rotating the hearScope until the image on the hearScope™ application is the right way up.

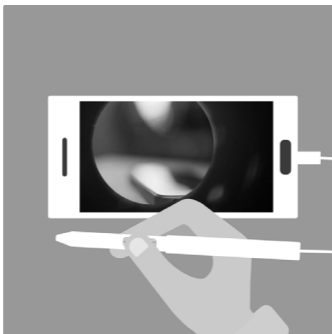


3. Point the hearScope™ at an object about 25mm from the front of the scope and adjust the focus wheel until the object is in focus to set initial focus.



4. The light intensity can be adjusted by turning the wheel attached to the cable, it is recommended to turn the intensity up to maximum for first use.

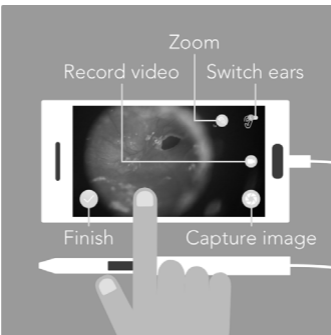
5. Select an ear tip and fit it to your hearScope™ so that your thumb fits comfortably on the focus wheel. Note: The first few fits can be tight so push the ear tip onto the hearScope™ until you hear a 'click' sound.



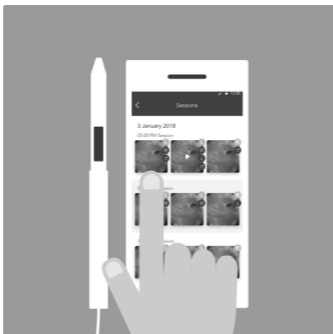
6. Gently insert the ear tip into the ear. Use your thumb to make small focus adjustments as needed. Take caution in not inserting the tip too deeply.



7. View the image on the screen of the smartphone. Use the on screen buttons to capture images, record video, zoom in and out, switch ears and finish the session.



8. After finishing the session select images to crop, add text/audio notes and request diagnostic support (coming soon).




9. All images are saved automatically, press-and-hold to delete multiple images.

CONTRAINDICATIONS

hearScope™ should not be used in individuals with visible obstructions of the outer ear canal. In individuals with fluid draining from the outer ear canal, hearScope™ should be used with caution, with strict infection control protocols in place. hearScope™ should not be used for any purpose other than visually inspecting the outer ear canal and tympanic membrane.

SAFETY PRECAUTIONS

 To ensure optimum and safe use of the hearScope™ smartphone video otoscope, please read carefully through the following safety precautions:

- Although the hearScope™ may aid in diagnosing conditions of the outer ear and tympanic membrane, it does not replace the advice of and prescribed treatment by a medical professional.
- hearScope™ ear examinations should only be conducted by individuals who have received appropriate training on using an otoscope.
- Examine the device thoroughly for damage before every use. Do not use the device if any damage or irregularities are found.
- Ensure that appropriately-sized tips are used and that they are not inserted too deeply into the outer ear canal. Deep insertion may result in harm to the outer ear canal or tympanic membrane.
- Ensure strict infection control by disinfecting each ear tip after use. Do not use a single ear tip on more than one patient at a time.
- Store the hearScope™ and its parts out of reach of infants, small children and pets.
- Avoid exposing the device to any fluid and/or dust.
- All precautions relevant to a smartphone device are applicable. Please refer to the smartphone manufacturer's documentation for more information.
- Do not use the hearScope™ anywhere where the usage of a smartphone is not permitted. hearScope™ was not tested for electromagnetic disturbance or immunity and may not function in an environment where electromagnetic disturbances are present.
- Do not use this device in the presence of flammable anesthetics or pressurised oxygen.
- Follow local rules and regulations regarding

disposal or recycling of this device and its components.

- No modification of this device is allowed.

STORAGE & HANDLING

Ensure that the hearScope™ is disconnected from the smartphone when not in use. Turn off the light to preserve the LED lamp life. Store the device in the provided protective case at all times to avoid damage. The device and ear tips should be disinfected prior to storage. Avoid exposing the device to any fluid and/or dust. Be careful not to touch the hearScope™ lens.

DEVICE MAINTENANCE & CLEANING

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. No modifications or repairs should be made to the device by anyone other than the seller.

The hearScope™ body and case can be disinfected with a cloth dampened with EPA-approved alcohol. 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.

TROUBLESHOOTING

For Troubleshooting tips and answers to Frequently Asked Questions, please visit www.hearxgroup.com/hearscope.

WARRANTY

hearScope™ comes with a limited out-of-box 2 year warranty. Within the limited range of the warranty, defective products or parts will be repaired or replaced by the manufacturer or authorised technical service groups to the extent permitted by law.

Faults on the hearScope™ must be reported to the Manufacturer within 60 days of discovering the fault for the warranty to be applicable. This warranty is non-transferable and does not cover damages due to negligence, accidents, abuse, misapplication, modification and repairs not made by the manufacturer or authorised service groups. This warranty does not cover shipping costs associated with repairs or replacements.








TRADEMARK INFO

hearScope™ is a trademark owned by hearX SA (Pty) Ltd. Trademarks of other products and companies are registered trademarks of that company and should be treated as such.

TECHNICAL DESCRIPTION

Packaging as shipped (approximate)	
Dimensions	200mm x 55mm x 125mm
Weight	± 220g
hearScope™ body	
Dimensions	135mm x Ø11mm
Weight	± 61g
Ear Tip (speculum)	
Dimensions	72mm x Ø11mm
Weight	± 2g
Camera	2 MP CMOS
Light source	LED, variable intensity
Power source	Powered via the smartphone battery
Operating conditions	
Temperature	10°C to 40°C
Relative humidity	15% to 75% Non-Condensing
Shipping/storage conditions	
Temperature	-20°C to 50°C
Relative humidity	15% to 90% Non-Condensing

SYMBOL GLOSSARY

-  Manufacturer name and address
-  Caution/Precaution.
-  CE mark indicating conformity with Health and Safety requirements set out in European Directives.
-  Not for general waste.
-  Device is fragile
-  Keep product dry
-  Consult instructions for use