



USER MANUAL

v4.1



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HSCP-MN-EN hearScope IFU v3.1

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Congratulations! This is your hearScope digital AI 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 specula of various sizes that connects to an Android smartphone, laptop, or personal computer (Windows, Linux or Mac). The device is supplied with a protective, reclosable case.

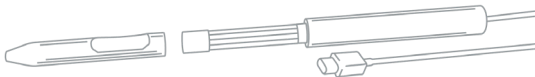
The intended use of hearScope is to visually inspect the outer ear canal and tympanic membrane under magnification. Imaging of the outer ear canal and tympanic membrane is viewed on the devices on the smart device, using the hearScope mobile application or web app software.

For a list of compatible devices go to <https://www.hearxgroup.com/hearscope>.

WHAT'S IN THE BOX?

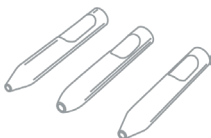
1 hearScope

Digital video otoscope with Micro USB cable



2 Reusable specula

2x Small (3mm); 2x Medium (4mm); 2x Large (5mm) reusable specula are included with the initial purchase of the digital video otoscope.



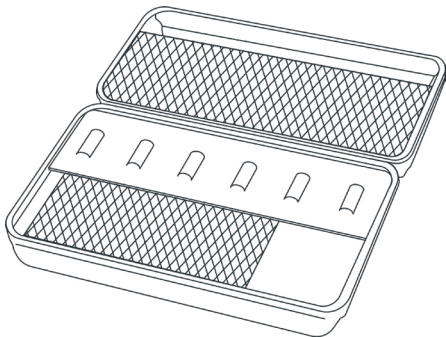
3 Micro USB to USB-C adaptor

Required for some phone models



4 Phone stand





SET UP INSTRUCTIONS

- Switch on the smart device, download and open the hearScope application.



- Connect the hearScope to your smart device (use the micro USB to USB-C adaptor if required).
- Grant your smart device 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 smart device.
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 speculum and fit it to your hearScope so that your thumb fits comfortably on the focus wheel.
6. Hold the hearScope in a pencil grip. Gently pull the pinna (outer flap) of the ear backwards and upwards to straighten the ear canal.
7. Gently insert the speculum into the ear and use your thumb to make small focus adjustments as needed. Bridge your little finger against the patient's cheek. Take caution in not inserting the tip too deeply.
8. View the image on the screen of the smart device. Zoom in and out of the image using the "zoom" button on the hearScope.
9. To indicate that images were taken in the right or left ear, select the ear icon in the corner of the device screen to switch between ears.
10. Capture an image by selecting the camera icon on the smartphone screen. Video footage may be


captured by selecting the video camera icon the smart device screen (video feature only available in PRO version).

11. End the session by selecting "Finish".
12. Press-and-hold images to crop, add text/audio notes, automated diagnostic support (automated diagnostic support and specialist diagnosis features coming soon).
13. Save images by selecting them and pressing "Save".
14. Saved images can be viewed by accessing the "Gallery" from the home screen.

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, as well as to inspect throats or skin.

SAFETY PRECAUTIONS

 To ensure optimum and safe use of the hearScope device 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 speculum 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 smart 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 smart device 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 smart device 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 specula 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 specula should be disinfected after every use. Submerge the specula 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/or support related assistance, please contact our support at support@hearxgroup.com

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.

TECHNICAL DESCRIPTION

Packaging as shipped (approximate)	
Dimensions	200mm x 55mm x 125mm
Weight	+/- 220g
hearScope body	
Dimensions	135mm x (diameter) 11mm
Weight	+/- 61g

Speculum	
Dimensions	72mm x (diameter) 11mm
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