VIDEO OTOSCOPE

v3.0

25/02/2020

hearScope is a trademark of the hearX Group IP

Congratulations with the purchase of your hearScope smartphone and/or web app video otoscope. Please read this guide carefully to ensure the correct setup and safe operation.

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Pretoria, 0081, South Africa

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

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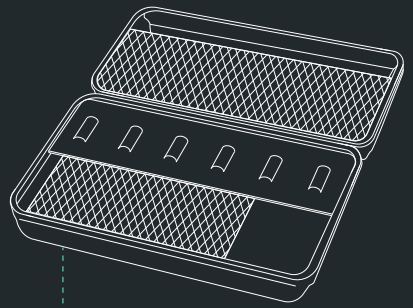
hearScope™ v3
HSCP-MN-EN hearScope IFU v1.0

WHAT IS HEARSCOPE

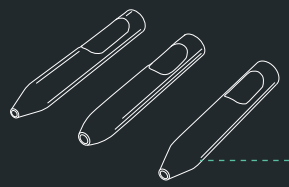
hearScope consists of a handheld video-otoscope with a light source and ear tips of various sizes that connects to an Android smartphone, laptop or personal computer (PC). The device is supplied with a protective, reclosable case. The intended use of hearScope is to visually inspect the outer ear canal 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 laptops go to: www.hearxgroup.com/hearScope.

WHAT IS IN THE BOX?

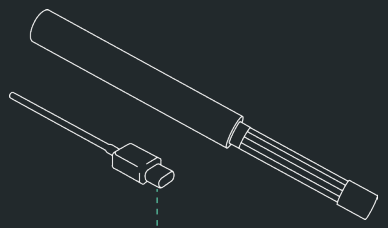


Protective case



Reusable ear tips

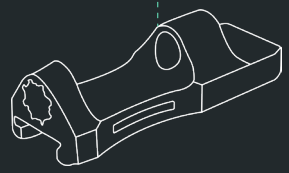
2x Small; 2x Medium; 2x Large reusable ear tips included with initial purchase



Smartphone video-otoscope with Micro micro USB cable (Smartphones)

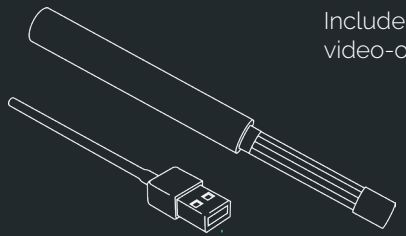
Micro USB to USB-C adapter

Included with smartphone video-otoscope



Dermal and throat adapter

*optional



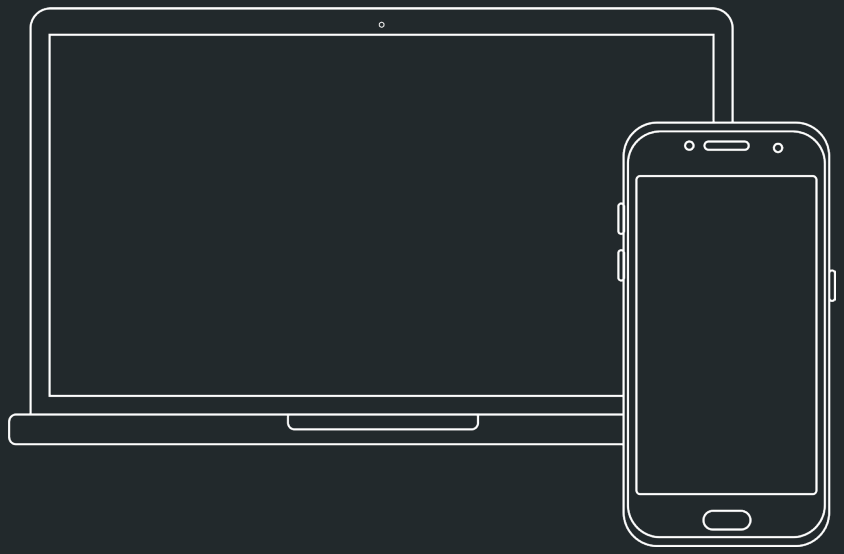
Smartphone video-otoscope with USB cable (laptop/PC)

Phone stand

Included with smartphone video-otoscope

SETUP INSTRUCTIONS

1



Download and open the hearScope application.

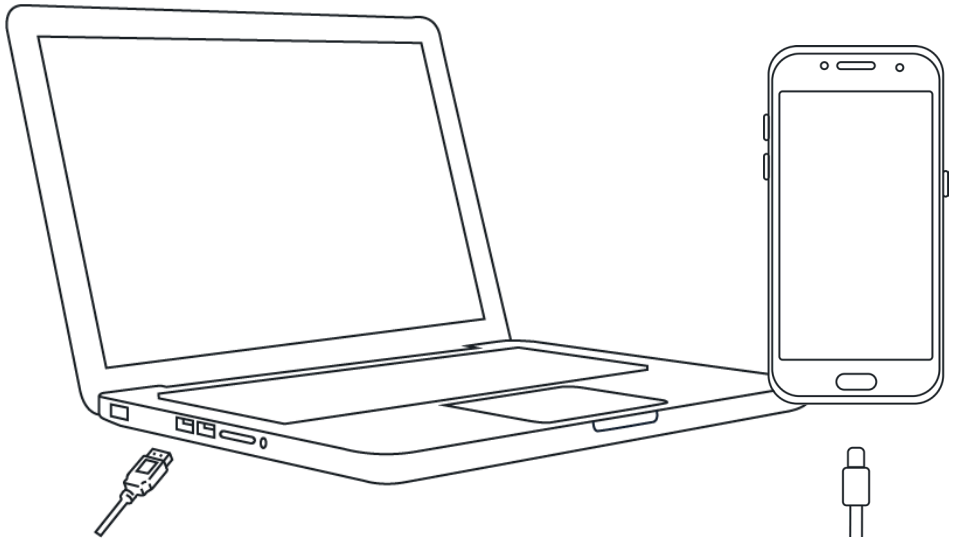
Mobile app:

https://play.google.com

Web app:

*Coming soon

2

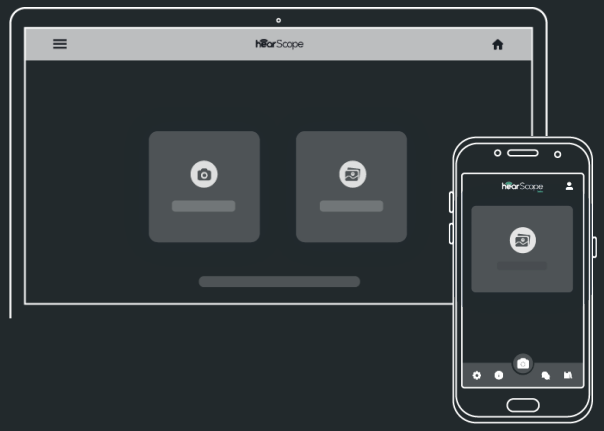


Connect your hearScope to your smartphone (use the micro USB or USB-C adapter), or to your laptop/PC (plug in the USB cable in the USB port of the laptop/PC) and grant your smartphone, laptop or PC permission to access the hearScope.

SETUP INSTRUCTIONS

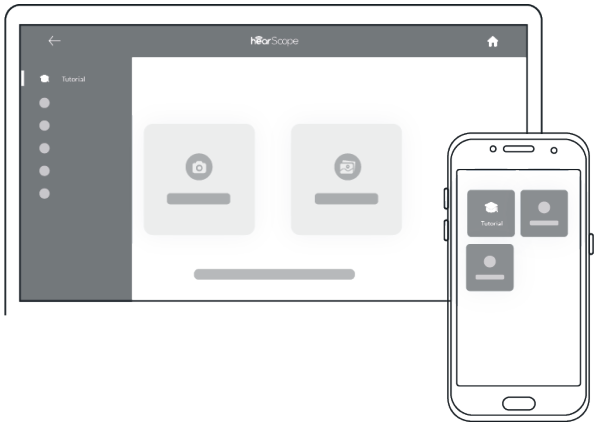
Please refer to the in-app tutorial for operating instructions.

3



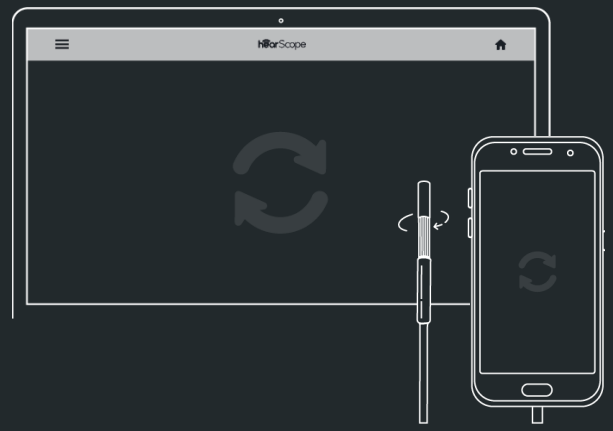
Open your hearScope application on your smartphone, laptop or PC.

4



On the Home Page go to Help and then select Tutorial.

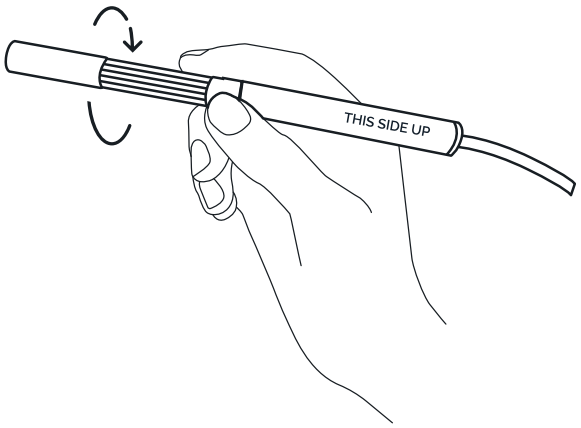
5



Orientate your hearScope right side up by ensuring the text on the hearScope device ('This side up') is pointing upwards.

SETUP INSTRUCTIONS

6

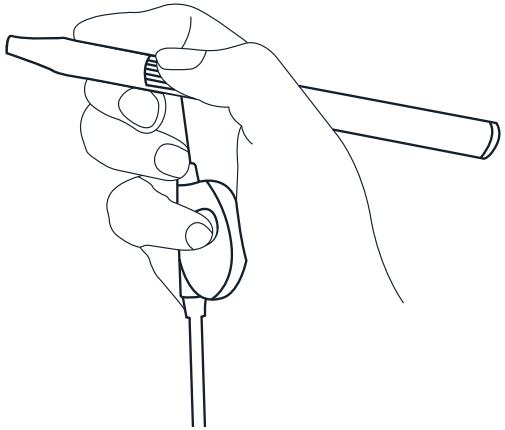


Point the hearScope at an object about 25mm from the front of the scope and adjust the focus wheel until the object is in focus to set initial focus.

7

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.

8



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:
Please see "Attachment" section on page 6.

SETUP INSTRUCTIONS

Please refer to the in-app tutorial for operating instructions.

9

When inserting the hearScope, gently pull the pinna of the ear upwards and towards the back. Do not insert the hearScope too deep, as this may cause damage to the eardrum.

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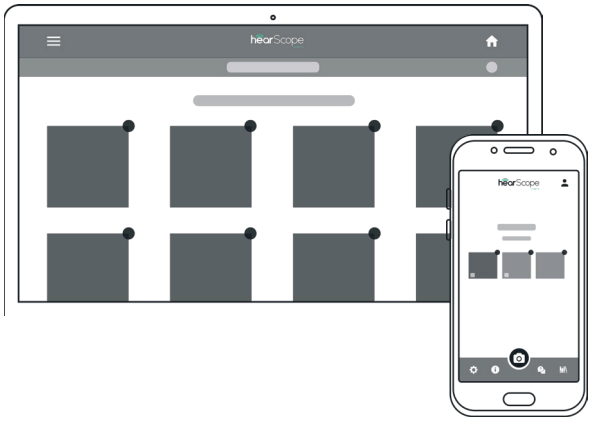
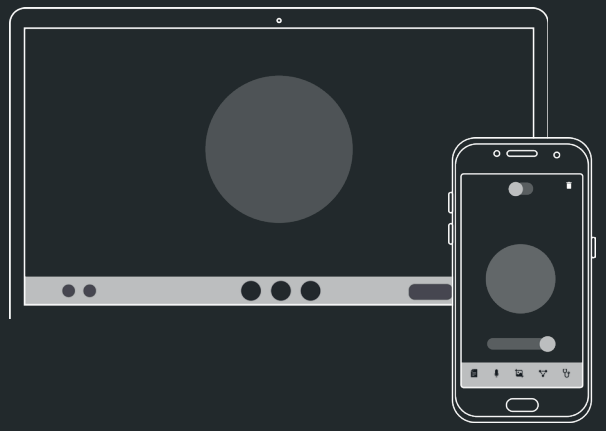


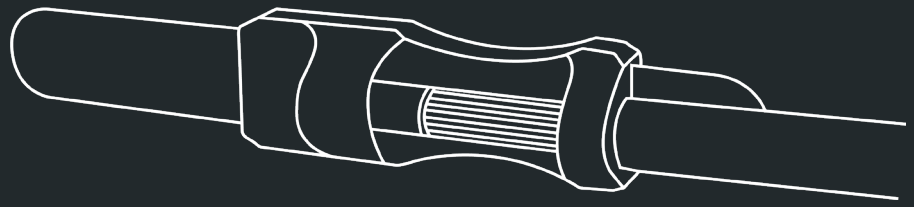
Saved images can be viewed by accessing the 'Gallery'.

11



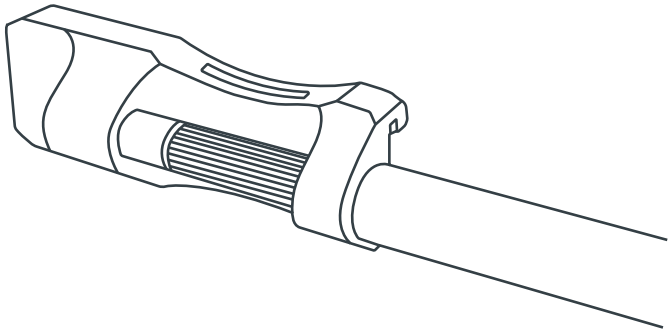
All images can be edited, as well as deleted.

ATTACHMENT



Using the attachment for throat inspections:

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 as a laryngoscope and assists with throat inspections.



Using the attachment for dermal images

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. This enables the use of hearScope™ as a dermascope.

CONTRAINDICATIONS

hearScope should not be used on 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.

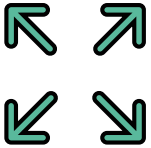
SAFETY PRECAUTIONS

To ensure optimum and safe use of the hearScope video otoscope, please carefully read 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 provided by a medical professional.

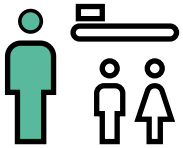
hearScope ear examinations should only be conducted by individuals who have received appropriate training on the use of an otoscope.

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 fluids and/or dust.

Do not use this device in the presence of flammable anesthetics or pressurized oxygen.

Follow local rules and regulations regarding disposal or recycling of this device and its components.

No modification of this device is allowed.

⚠ Please note the following:

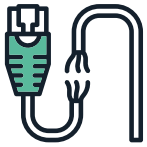
- The device is not to be used to screen for the presence of diseases or conditions beyond its indicated uses.
- The device provides a screening diagnosis only and it is critical the patient be advised to receive follow-up care.
- The device does not treat the disease.

STORAGE AND HANDLING

Ensure that the hearScope is disconnected from the smartphone or laptop/PC when not in use. Unplug the cable from the smartphone or laptop/PC to turn off the light to preserve the LED lamp life. Store the hearScope 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

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



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. 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.

TROUBLESHOOTING

For troubleshooting tips and answers to frequently asked questions, please visit www.hearxgroup.com/hearscope

WARRANTY

hearScope comes with a limited 1 year warranty. Within the limited range of the warranty, defective products and/or parts will be replaced and repaired by the manufacturer of 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 damage 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 IP (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
Maximum resolution	1920 x 1080 pixels
Light source	LED, Variable intensity
Power source	Powered via the smartphone battery or the laptop/PC battery
Operating conditions	Temperature: 10°C to 40°C Relative humidity: 15% to 75% Non-Condensing
Shipment/ storage conditions	Temperature: -20°C to 50°C Relative humidity: 15% to 90% Non-Condensing

SYMBOL GLOSSARY

Manufacturer

Caution

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.