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Revision History

Revision	Date	Software Version	Description
v1.0	13 Jan 2021	v3013	First publication of training manual for hearScope™.

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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™ device 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

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3. Getting started

3.1 What's in the box

	Item	Description
1		Smartphone digital otoscope with Micro USB cable
2		Micro USB to USB-C adapter
3		Reusable ear tips 2x Small; 2x Medium; 2x Large reusable ear tips included with initial purchase
4		Protective case
5		Phone stand
6		Dermal and throat adapter (<i>Optional</i>)

4. About the hearScope™

hearScope™ consists of a digital otoscope with a light source and ear tips of various sizes that connect to an Android smartphone or desktop. The device is housed in a protective, reclosable case.

The intended use of the 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 desktop, using the hearScope™ mobile application or desktop application software.

For a list of compatible smartphones/tablets or laptops go to <https://www.hearxgroup.com/hearscope>.

5. Using the hearScope™ hardware

5.1 Prepare the device

- Ensure that the device is fully charged and operational.

5.2 Using the device

- Ensure that the device is placed right side up and the text 'THIS SIDE UP' is pointing upwards.
- Point the hearScope™ 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 is controlled by turning the wheel attached to the cable, it is recommended to turn the intensity up to the maximum for first use. Use the cable to assist with the capturing of images during examinations.
- Select an ear tip to fit the hearScope™ so that your thumb fits comfortably on the focus wheel.

Note: The first time you use the device, you should push the ear tip onto the hearScope™ until you hear a 'click' sound.

For dermal and oral inspections:

- Using the adapter for **dermal inspection:** The same adapter is used to fit a tongue depressor. Insertion guides are available at the bottom of the adapter to assist with inserting the tongue depressor into the adapter. The length of the tongue depressor is flexible based on user preference. The hearScope™ has LED lighting at the tip to use it with throat inspections.
 - Using the adapter for **oral inspection:** The adapter is designed to be positioned with the edge of the adapter placed directly against the skin. The camera is positioned at the correct distance from the skin to simplify the zoom required to take images of moles and skin lesions effortlessly.
- To capture images of the 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 right ear. The facilitator or user should use their left hand to pull the top of the ear upwards and backwards. The hearScope™ in the cable should be held in the facilitator's right hand. Press to capture button to capture images. Ensure that the device is 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 in the hearScope™ application

Download and open the hearScope™ application. The hearScope™ mobile App is available for compatible Android devices. The hearScope™ application can be downloaded directly from the [hearScope™ website](https://www.hearxgroup.com/hearscope) or from the following stores:

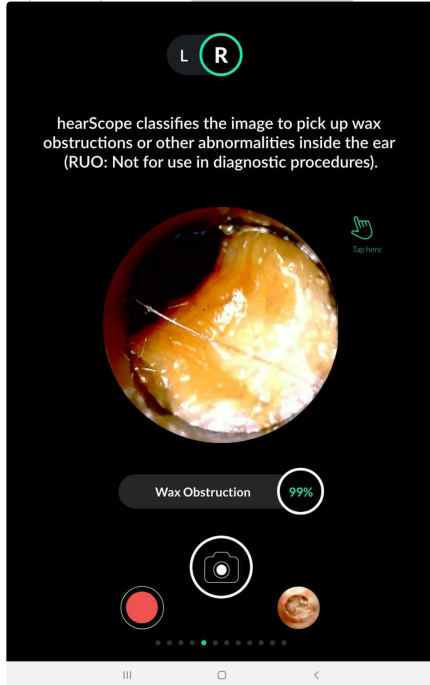
- Mobile use:
 - [Google Play](https://play.google.com/store/apps/details?id=com.hearx.hearscope)
- Desktop use:



- Linux and Windows: Download from the [hearScope™ website](#)
- Mac: [App Store](#)

PLEASE NOTE: If the device was purchased with the hearScope™ from hearX, the hearScope™ app will already be pre-installed on the smart device.

AI image classification



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

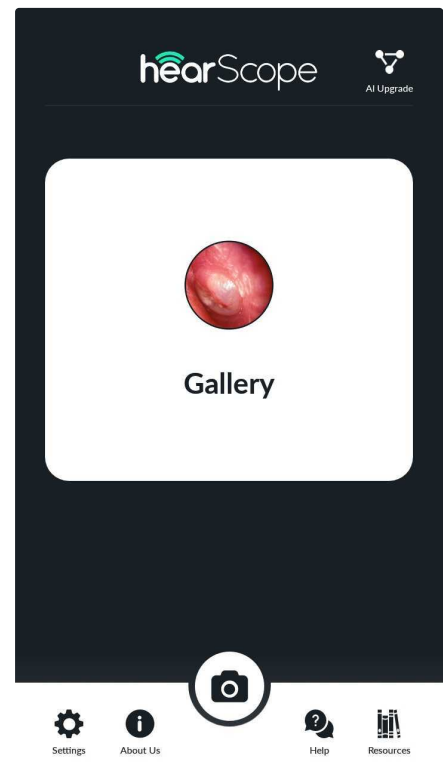
**BETA version available from 9 March 2020 - Please note that this is a free BETA version for research use only and is not intended to diagnose. Always seek medical attention from a healthcare professional when any symptoms are present.*

Our Artificial Intelligence 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 image classification feature can be enabled by selecting *AI Upgrade* in the top right corner of the application. Sign in with your hearX account or register a new 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.

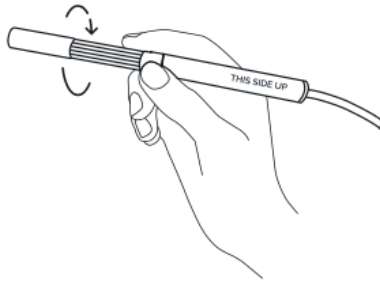
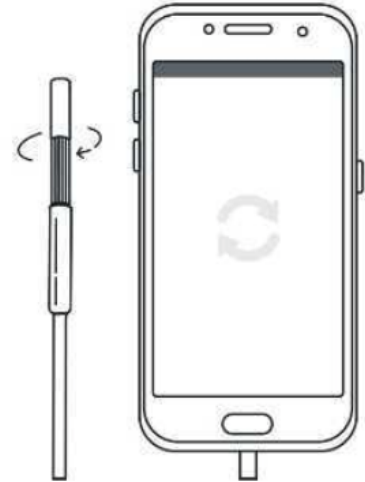
7. Capturing an image using the hearScope™ digital otoscope

Connect your hearScope™ to the smart device (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 desktop required by the hearScope™ software to ensure the correct functioning of the application.

Tap Allow for the following permissions:

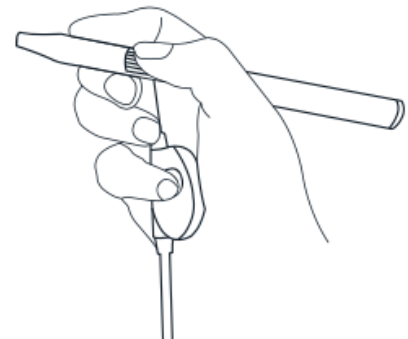
- Storage
- Camera
- Audio



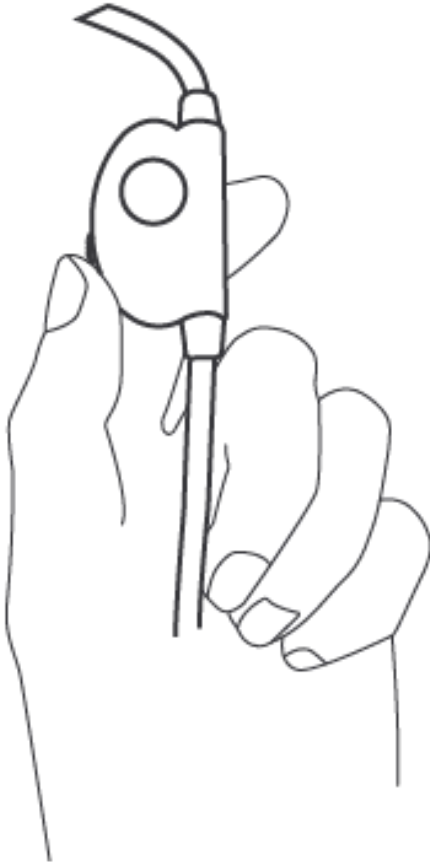
Orientate the hearScope™ right side up by ensuring the text on the hearScope™ device ('This side up') is pointing upwards. Point the hearScope™ at an object about 25mm from the front of the scope and adjust the focus wheel until the object is in focus to set initial focus.

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

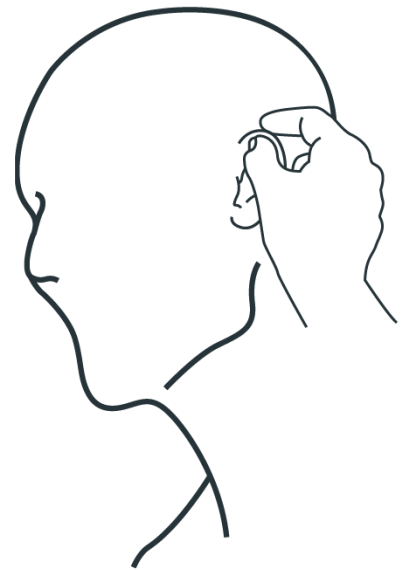
Note: The first few fits can be tight so push the ear tip onto the hearScope™ until you hear a 'click' sound.



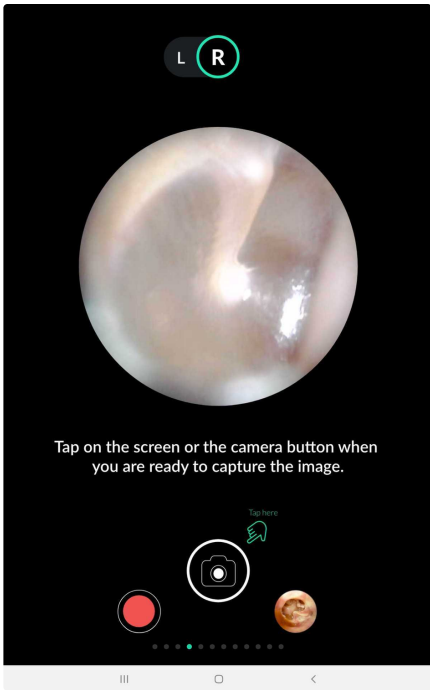
The light intensity can be adjusted by turning the wheel attached to the cable, it is recommended to turn the intensity up to the maximum for first use. Use the button on the cable to assist with the capturing of images during examinations.



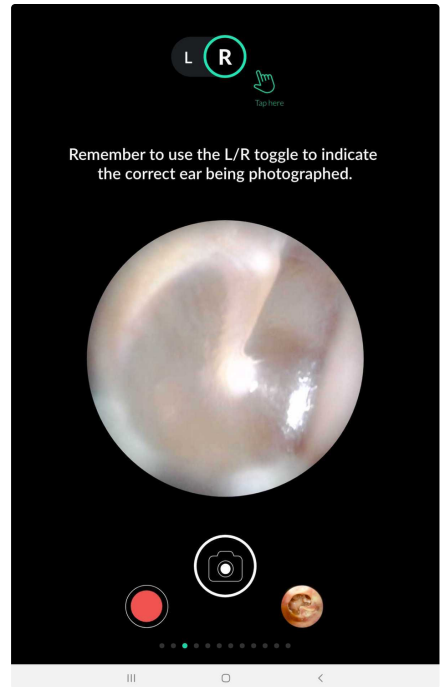
Tap on the CAMERA icon on the smart device to activate the camera view that displays the camera feed received from the hearScope device. Gently insert the device into the ear. The patient/test subject and/or facilitator should use their thumb to adjust the focus with the focus wheel. Do not insert the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



Use the capture button to start capturing images and/or videos. Images can also be captured by tapping on the screen of the smart device.

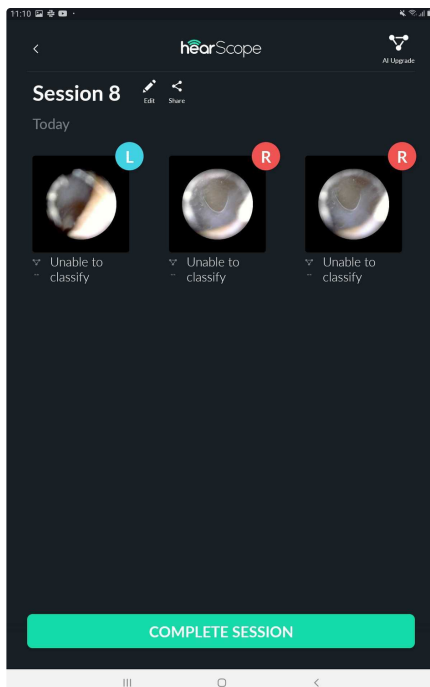
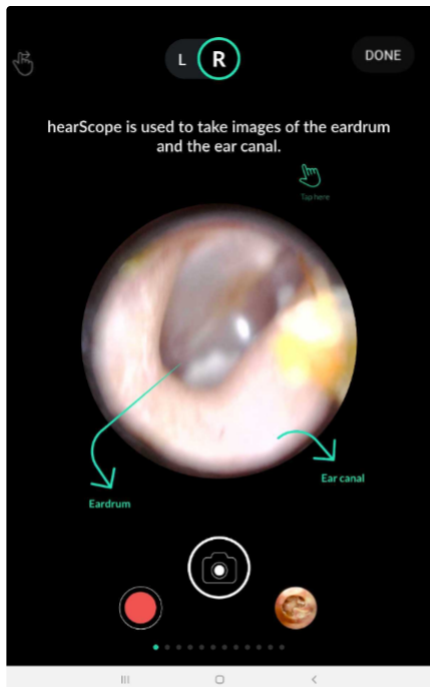


Ensure that the correct ear is selected by toggling the L or R at the top of the screen.



To capture a good quality image make sure to focus the hearScope™ on the eardrum.

Select DONE in the top right corner to view captured images and/or videos.



All the images captured will be displayed in that session.

Otoscopy images can be viewed, deleted, and cropped. It is also possible to add text/audio notes, and request AI image classification. To open the editing view, select the images within the session.

The session name can be changed by tapping on the 'Edit' icon. Sessions can be sent via email services or instant messaging services by tapping on the 'Send' icon. *Please note: It remains the responsibility of the user to ensure that patient's consent is obtained to share images.*

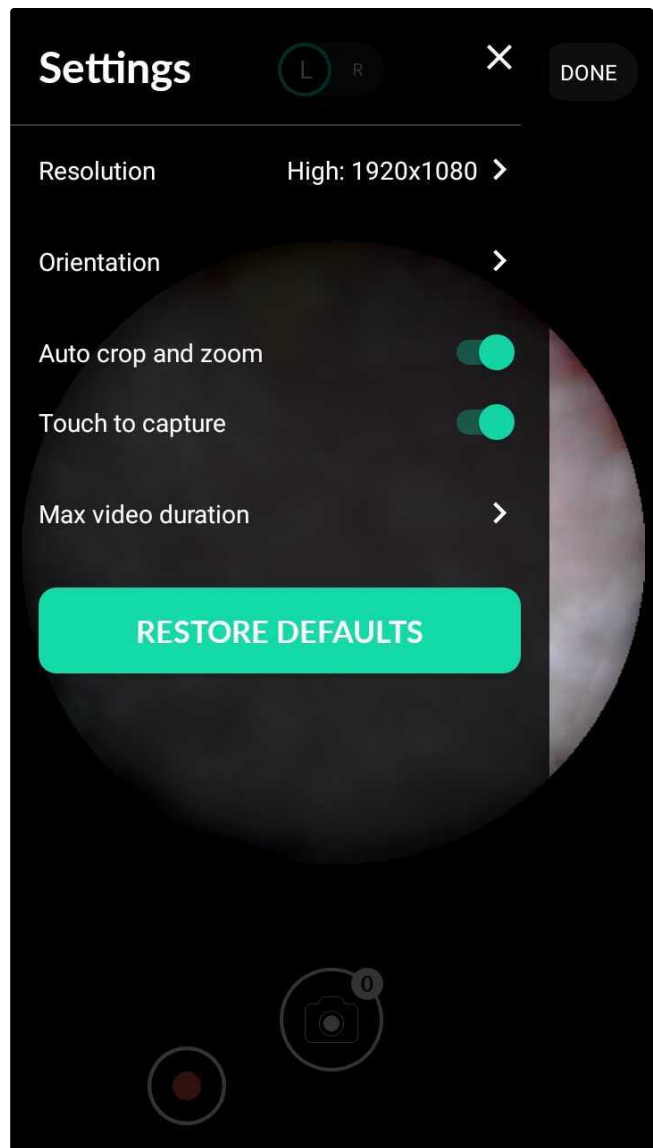
hearScope™ camera settings

The camera settings by tapping on the 'Settings' icon on the capture screen.

Camera settings that can be set include:

- **Resolution:** This will allow the facilitator to select the resolution (quality) in which the otoscopy image will be captured.
- **Orientation:** This will allow the facilitator to select if the smart device screen orientation should be as default on landscape, portrait, or on auto.

- **Auto-crop and zoom:** When enabled the hearScope™ image will automatically crop and zoom captured images.
- **Touch to capture:** When enabled it will allow the test subject/patient and/or facilitator to tap on the screen of the smart device to capture the image.
- **Max video duration:** This allows the facilitator to choose the maximum duration of the video.



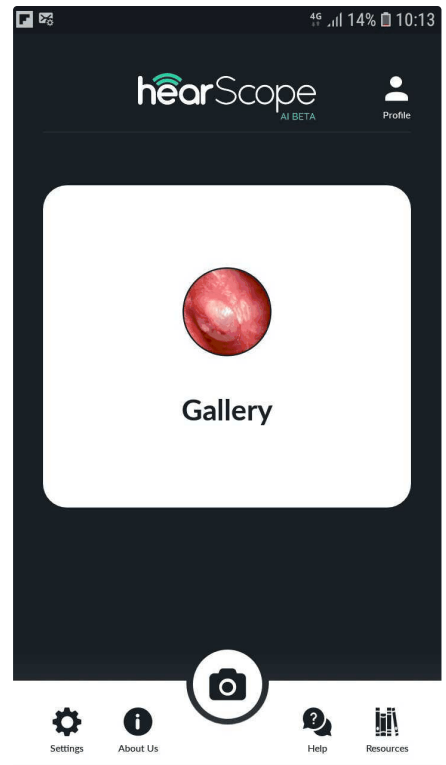
8. Viewing of a test subject's otoscopy image on the smart device

The hearScope™ app has a Gallery where all the hearScope™ sessions are stored. All the images will save to the hearScope™ Gallery after the facilitator has selected the DONE button and completed the session.

To view the otoscopy images:

- Launch the hearScope™ app on the smart device
- 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, text and voice notes can be added and images can be submitted to be classified by the AI image classification feature. To do this tap on a captured image.



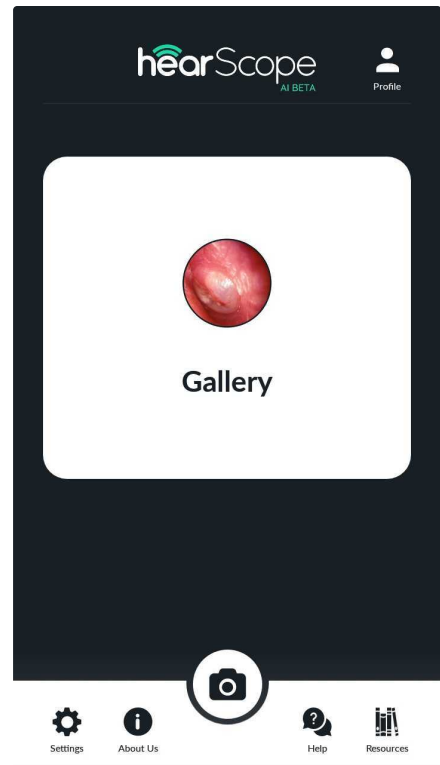
9. Support

9.1. hearScope™ Menu

Gallery: This will allow the facilitator to access the previously captured hearScope™ images.

Settings: The administrator can customize the following settings in the hearScope™ Mobile app:

- **Camera Settings:**
 - **Resolution:** This allows the administrator to select the resolution in which the otoscopy images are being captured. Should you experience any delays in the application, decrease the resolution to medium (640x480).
 - **Orientation:** This allows the administrator to select the orientation of the screen when capturing the otoscopy image.
 - **Auto-crop and zoom:** When enabled hearScope™ will automatically crop and zoom the otoscopy images. Should you experience any delays in the application, disable the auto-crop and zoom on the device.
 - **Touch to capture:** When enabled it allows the patient/test subject and or facilitator a simple touch on the smart device's screen to capture an otoscopy image.
- **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. The administrator can also choose if the images are shared when connected to WIFI only or connected WIFI and data.
- **Research mode:** This feature can only be enabled by research stakeholders to share images with additional data with hearX for research purposes. This feature requires a research code to be enabled.



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.

Help: This provides information such as new features, a tutorial on how to use the hearScope™, and a list of FAQ's.

Resources: The facilitator has access to additional information for each classification result when using the AI image classification feature. *(The AI image classification is currently in BETA testing.)*

10. Other

10.1 Maintenance

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

- Device restart is recommended daily.
- Ensure that the device cover and screen protector provided by the hearX Group is used at all times to protect the smart device from damage by accidental dropping or any other impact.
- 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's

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10.3 Contact

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