



TytoPro

Tyto Otoscope

User Guide

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Important Notice

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General Safety Messages/Product Overview

General Safety Messages

 **Warning:** A warning indicates precautions to avoid the possibility of personal injury or death.

 **Caution:** A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.

 **Note:** A note provides other important information.

Disclaimer

Information provided by TytoCare is believed to be accurate and reliable. However, TytoCare assumes no responsibility for the use of such information, nor for any infringements of patents or other rights of third parties, that may result from its use.

Intended use

The Tyto Otoscope is an electronic otoscope that enables capturing and transmission of video and still images of the external ear canal and tympanic membrane, whereby a clinician at one location on an IP network can view images and videos of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations.

Product Overview

The **Tyto Otoscope™** is a user-friendly, electronic otoscope that digitally records video imaging of the ear canal and eardrum.

The otoscope tip connects to your Tyto Device to facilitate the process of communicating data and video with other clinicians or healthcare professionals. Recorded data may be forwarded for diagnosis by another clinician in a different location.

The Tyto Otoscope is designed for use in a clinical or home environment. It can be used in a number of scenarios:

- By an individual clinician/healthcare professional
- By a clinician/healthcare professional, who forwards exam data to another clinician/healthcare professional for later diagnosis
- By a clinician/healthcare professional, who collaborates online with another healthcare professional during or after the examinations.

Before the Exam

Cleaning Instructions

Clean the device before use. The cleaning should be done using 70% isopropyl alcohol wipes or cloth/swabs (e.g. q-tips) dipped in 70% alcohol. Clean the outer surface by swabbing or wiping the surface with the alcohol wipes. Use the q-tip swab, dipped in 70% alcohol, on narrow and less accessible surfaces, such as the otoscope lens, located at the front of the otoscope.



Note: Do not use any other cleaning materials or chemicals to use the otoscope.

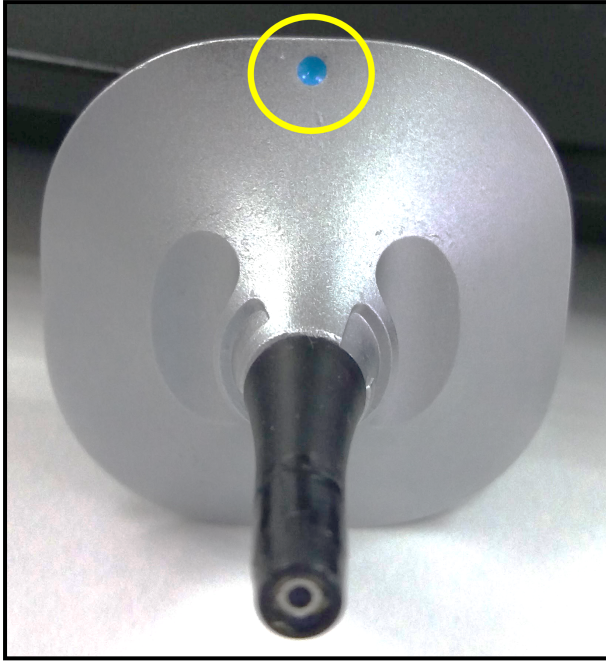
Do not use a brush to clean the otoscope’s lens, as it might scratch it.

Connect Otoscope Tip and Disposable Speculum

Before you start using the device, it is important to connect the otoscope tip correctly. Connect the otoscope tip to the Tyto device using the blue dot guiding marks:



Tyto Device




Otoscope Tip




Otoscope Tip and Tyto Device connected




After connecting the otoscope tip, place a disposable speculum on the tip and lock it in place by rotating it:

 **Note:** Choose the correct size of disposable specula: for adults use the shorter specula with wider opening (4.0mm), which enables a wider Field of View; for small children use the longer specula with the narrower opening (3.0mm).

 **Note:** Do not use an otoscope disposable speculum that has cracks or contains sharp objects.

 **Note:** Discard the disposable speculum after use.

 **Note:** In case you feel pain or discomfort during the ears exam, stop the exam, retract the Tyto Otoscope and update the clinician if you're using it during an online visit.

User Role: Performing Guided and Unguided Exams


Two methods can be used for examinations conducted with the TytoPro™ system.

Guided exams are intended for any person who is not a healthcare professional, and is not qualified for performing an ear examination, or who requires a more detailed, step-by-step approach. Guided exams lead the user through the process of performing and viewing exams. See [Section - Guided Exam](#).

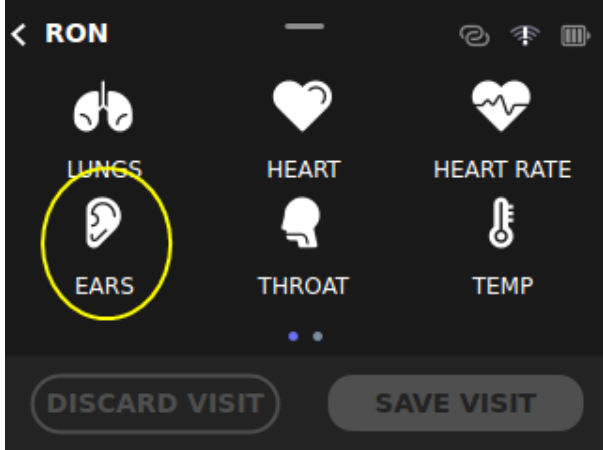

Unguided exams are intended for healthcare professionals who have medical knowledge, and are proficient performing ears exams. Unguided exams provide a streamlined approach allowing more flexible recording and faster operation, with minimal instructions for use. See [Section - Unguided Exam](#)

The type of user role, guided or unguided, is defined by the System Administrator when your user was created. Contact the System Administrator of your TytoCare system to determine whether your user is defined as Guided or Unguided, or in case you wish to change your user role.

Exams Menu

 **Note:** Refer to the TytoPro™ General Operation User Guide for preliminary instructions on logging in to the system and viewing the Exam menu.

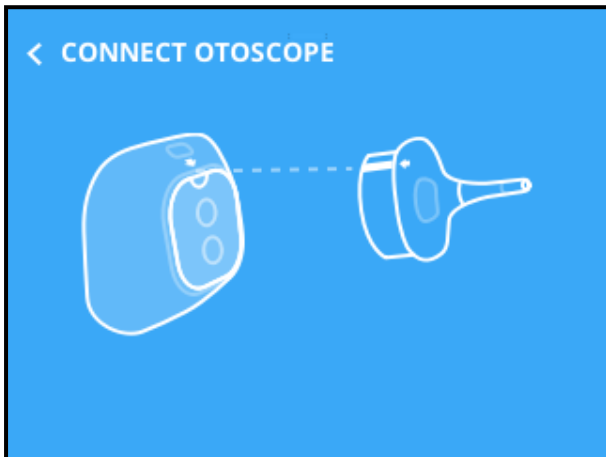
To start an ear exam, tap **EARS** from the examination selection screen, as shown below:


	
<p>Tyto Device.</p>	<p>Tyto App</p>

Guided Exam

Select Which Ear to Exam

The Ears selection screen allows you to select the ear you are about to exam, and shows which ears have been examined. Initially, the display indicates that no recordings have been made.




 **Note:** Make sure the Tyto Otoscope tip is connected. If it is not connected, a message will display:



When performing the exam, you can start with either the right or left ear. It is highly recommended to always examine both ears, even if only one ear aches.

Tap Right or Left ear.

In the example below, we tap RIGHT EAR.

 **Warning:** it is important to select the correct ear (left or right), and to correctly identify the side that you are recording. Note that patient's sides are mirrored. Mixing between sides could mislead the diagnosing clinician.

Video Tutorial and Animation

The **first time** you do the exam, a **video tutorial** will be displayed on the App, guiding you in performing an ears examination. This tutorial is required when you do your first ear exam. It is always available when performing later exams, and can be viewed by clicking the **?** (**question mark**) on top of the Tyto App screen.

Every time you perform an ear exam, a short **animation** displays, reminding you of the key considerations that should be taken into account during the ear examination. As only the video tutorial has the detailed instructions, it is recommended to always watch the tutorial before use. Once you are ready to perform the ear exam and start video recording, tap **Start**.

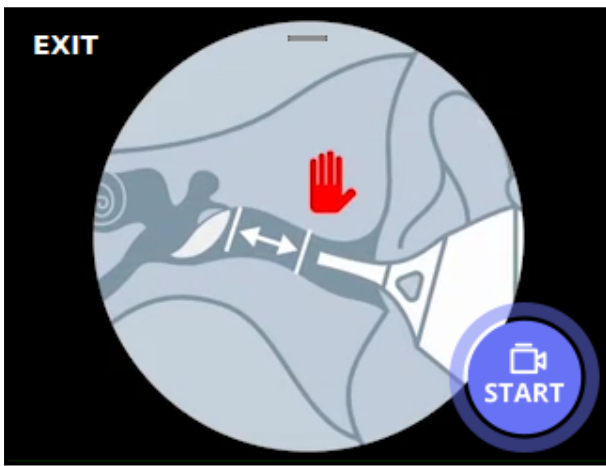


Figure 1-1. Device screen showing the Start button. Tap Start when you are ready to begin the ear exam (see below [Section - Before You Start: How to Conduct the Exam](#)).

Preparing the Patient Before the Exam

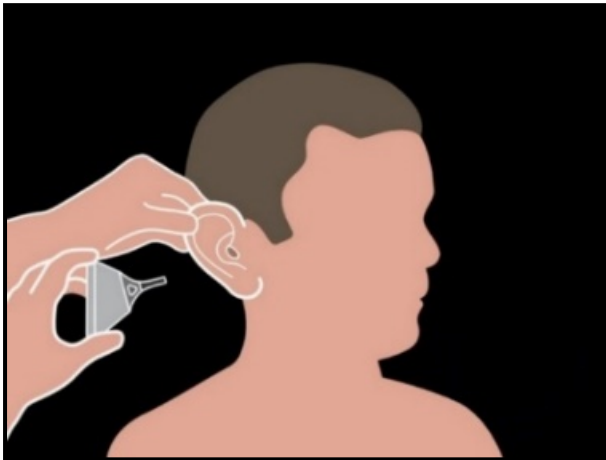
Before starting the exam, the patient should sit comfortably, and be encouraged to not move their head during the exam.

For small children under the age of three, another adult can hold the child's head to prevent sudden movement during the exam. For babies, it's advisable to lay the baby on its back and move the head to one side, while the other adult holds the baby and prevents head movement.

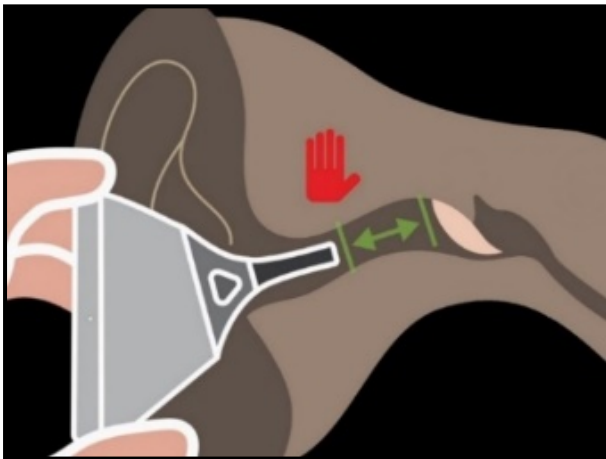
Distracting the child's attention during the exam, using a TV show or toy, can also be helpful.

Before You Start: How to Conduct the Exam

Before starting the exam, please take few moments to review the basic steps of the exam.



1. Pull back gently on ear to straighten ear canal. For small children, pulling the ear back and down can be more effective.



2. Insert the Tyto Otoscope into the ear canal.

⚠ Warning: Be Careful NOT TO TOUCH EARDRUM. In case the canal is blocked or obstructed by wax / cerumen, stop the examination and pull back the Tyto Otoscope.



3. Example of an eardrum:

⚠ Warning: Stop once you get a view of the eardrum. Do not push the Tyto Otoscope any further! You can use the yellow dotted circle as a guide to know when you are too close to the eardrum. During an online visit, update the clinician when you see the eardrum.

Guidelines for Recording

The video must be recorded continuously, from before the Tyto Otoscope enters the ear canal, until after it is withdrawn. DO NOT start or stop the exam when the Tyto Otoscope tip is inside the ear.

Observe the video carefully. Aim the Tyto Otoscope tip towards the darker area, which indicates a deeper part of the ear canal, and follow this direction until the eardrum becomes visible.

Inserting the otoscope tip deeper into the ear canal should be performed **gently, slowly** and **gradually**.

⚠ Warning: DO NOT let the tip of the Tyto Otoscope get too close to the eardrum. It must NOT touch the eardrum.

If the image is blurred, it's probably because wax is attached to the camera lens (usually seen as a yellow area on the camera). In that case, pull the Tyto Otoscope tip out of the ear canal. Clean the lens (located at the front of the Tyto Otoscope) carefully using alcohol wipes, until the image is clear again.

DO NOT insert the Tyto Otoscope tip further if the ear canal is blocked with wax, if you detect a foreign body in the ear canal, the image is blurred, the patient feels pain or discomfort, the quality

of the video in the App is low, or when you cannot identify the path in the ear canal towards the eardrum. In the event of pain or discomfort, pull the Tyto Otoscope slowly backwards.

Warning: When performing an online exam while the clinician experiences poor network conditions, the App might stop displaying the video. In case of self-examination it is important to tap **ACTIVATE VIDEO** to resume the Otoscope video playback.

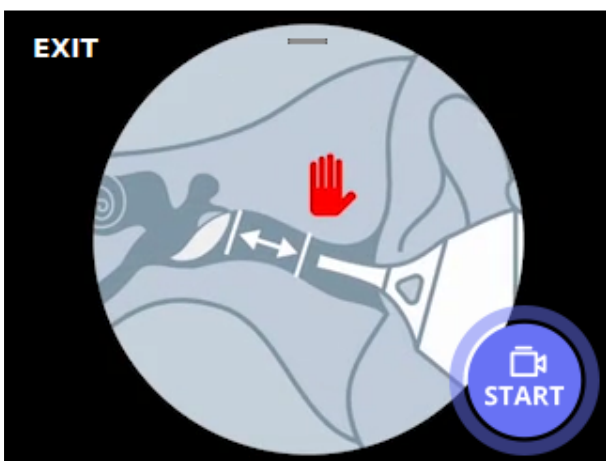
If video is not displayed, either in the App or on the device, remove the Tyto Otoscope from the ear.

If you do not succeed in reaching the eardrum, it may help to rotate the Tyto Otoscope tip, to achieve a better viewing angle of the eardrum.

Please note that the Tyto Otoscope tip may become warm after long period of continuous recording (above 30 seconds). In case the environment (ambient) temperature exceeds 95°F (35°C) during operation, the otoscope may get heated even faster. If the patient feels discomfort in their ear, pull the Tyto Otoscope tip out, stop the recording, and wait a few minutes for the tip to cool down.

Start Recording


Once you're ready to begin the ear exam, tap **Start** on the device. The device will immediately begin recording video for the ear exam. Then, position the Tyto Otoscope as shown in [Section - Before You Start: How to Conduct the Exam](#) above.



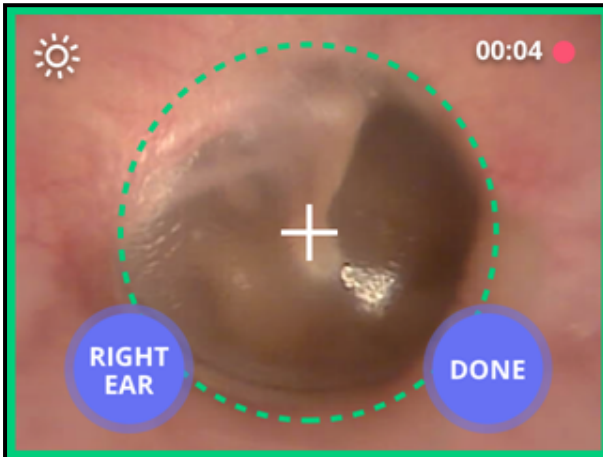
Tap **Start** on the Device to begin recording video for the Ear exam.

Changing the Illumination Strength of the Otoscope

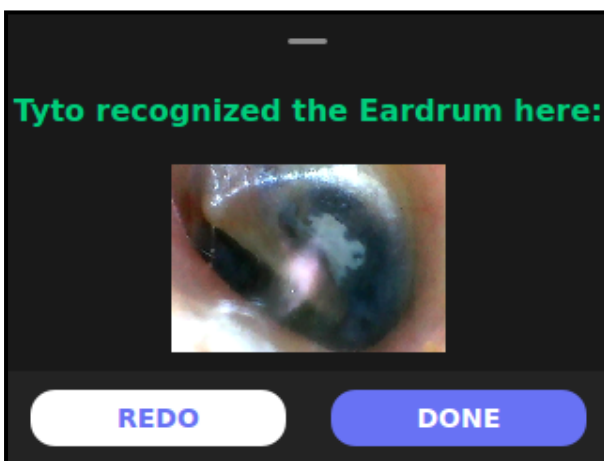
The Tyto Otoscope tip includes built-in illumination. You can adjust the strength of the illumination by **swiping down** on the device screen during the video recording, and then increasing or decreasing the strength using the bottom slider. This illumination level will be kept for future ear examinations.

Once reaching the ear drum, it is possible to enrich the color detail of the image by tapping the  icon. Recommended when the otoscope is stabilized towards the ear drum. Note that in this mode, fast motion will result with a blurry image.


Stop Recording



1. Tap **Done** on the device after the tip is completely removed from the ear canal, and the desired video of the eardrum has been captured.



2. The Device will display a confirmation message.

 **Note:** After 45 seconds the video recording stops automatically, to prevent unduly long video recording and subsequent over heating of the Tyto Otoscope. If this happens, pull the otoscope tip out of the ear canal, and retake the exam. It is suggested to wait a minute between ear exams.



After Recording the First Ear


After you record the first ear, you have several choices:

- Review the recording, and delete it if desired through the Tyto App
- Take another recording of the same ear using the Repeat button on the device
- Take a recording of the other ear using the Next Ear button on the device
- View the Ears screen and end the exam by pressing the Back arrow on the device

Review or Delete the Recording

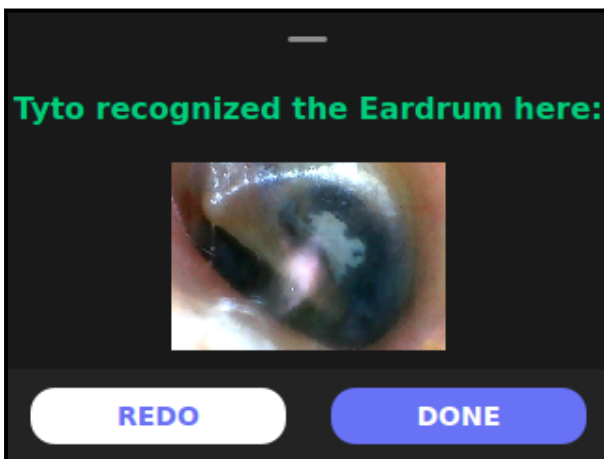
From the Tyto App, you can view or delete the recording:

- Tap  **Play** on the App to view the recording.
- Tap  (**Delete**) on the App to delete the recording.

 **Note:** After the video is captured, it will be displayed in the App. Please review the video in the App, and verify that the image is clear and sharp.

Take Another Recording of the Same Ear


From the Device, you can take another video of the same ear. You can have several videos of each ear.

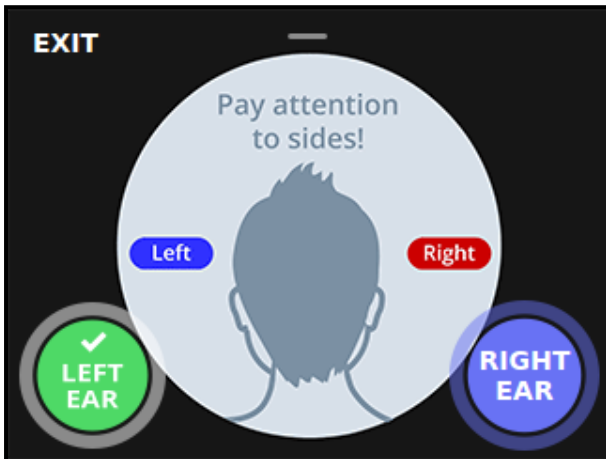


Tap **Redot** (in picture here Add) on the Device to record an additional video.

Exam the Other Ear

From the Tyto Device, you can examine the other ear.

 **Note:** It is recommended to always record exams for both ears.



Tap **Right Ear** (in this example) on the Device to record the next ear.

Review the Ears Screen

From the Device screen, tap the **back arrow** to see the Ears screen:




In this example, the green background and check mark next to **RIGHT EAR** indicates that at least one recording was made for the right ear. The purple background under **LEFT EAR** indicates that no recording was made for that ear.

You now have two options:

- Tap the Right or Left Ear icons to record or re-record an exam.
- Tap the back arrow to return to the Exam Selection screen.

Finishing the Ear Exam

When you have completed the necessary video recordings, tap  (**DONE**) on the device. This will stop the video recording and exit the Ears exam.

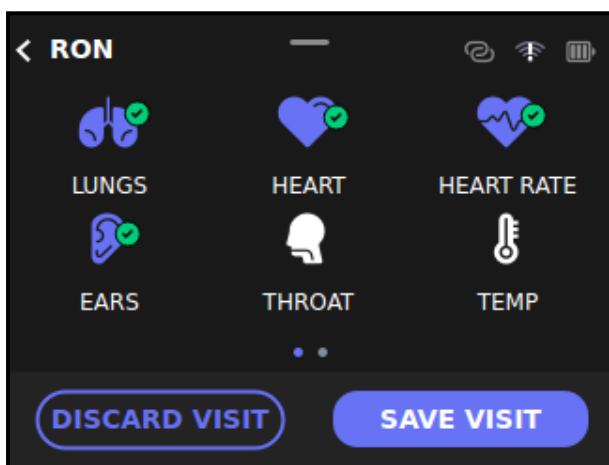
When you tap **DONE**, if you have not recorded videos for both ears, a warning screen appears.

- Tap **Exit** to end the exam anyway.

OR

- Tap the button on the right to record a video for the ear that was not recorded


The device will indicate with a green check mark that the ear exam was recorded:



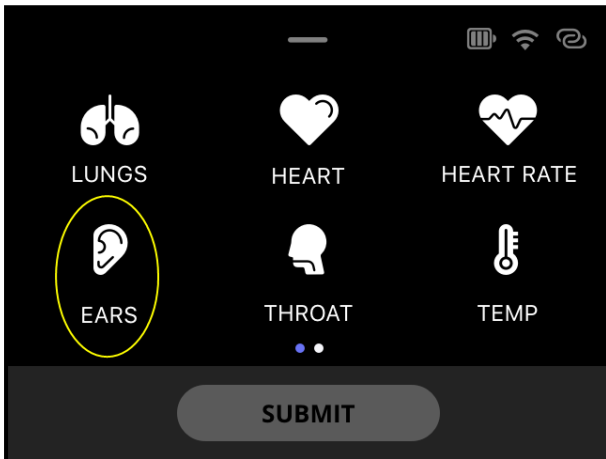
If you review the recorded video in the app, and decide that you do not want to share it or keep it, tap the Trash Can icon to delete the selected video.

Please refer to [Section - After the Exam](#) in the General Operation User Guide for further instructions.

Unguided Exam

 **Note:** Refer to the TytoPro General Operation User Guide for preliminary instructions on logging in to the system and viewing the Exam menu.

Exam Menu

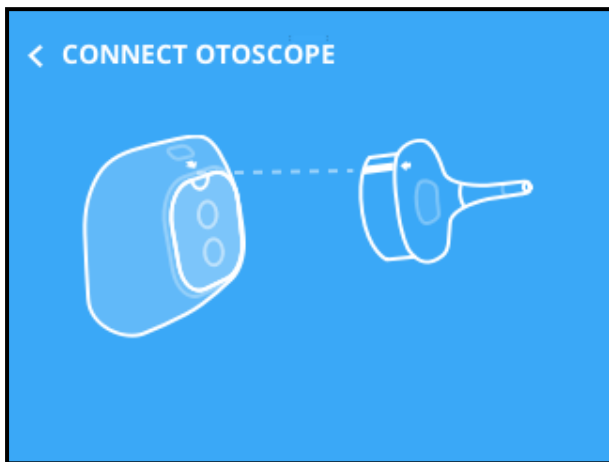


1. Tap **EARS** to begin the examination.



2. Tap which ear to begin with.

Recording the Video of the Ear Examination



Note: Make sure the Tyto Otoscope tip is connected prior to starting the exam (choosing left or right ear). If it is not connected, this message will display.

1. When you choose an ear, the device will **immediately** begin to record video. The red blinking dot, located at the upper-right corner of the device, as well as in the app, indicates video recording is activated.
2. When you have completed the examination of the first ear, you will normally tap **NEXT EAR** to record the other ear.
3. Tap (**DONE**) to end the examination.

Changing the Illumination Strength of the Otoscope

The Tyto Otoscope tip includes built-in illumination. You can adjust the strength of the illumination by **swiping down** on the device screen during the video recording, and then increasing or decreasing the strength using the bottom slider. This illumination level will be kept for future ear examinations.

Important Notes for Performing the Ear Exam:

1. Do not perform the exam if the patient is not calm.
2. Pull back ear to straighten ear canal.
3. Insert the Tyto Otoscope gently and slowly until the eardrum is visible.
4. Do not insert the Tyto Otoscope tip further if the patient feels pain or discomfort, or if the quality of the video in the App is low. In the case of pain or discomfort, pull the otoscope slowly backwards.
5. If cerumen blocks or hides the eardrum, or you detect a foreign body in the ear canal, stop the exam and remove the Tyto Otoscope. Do not push further, which will risk pushing the cerumen in or damaging the eardrum.

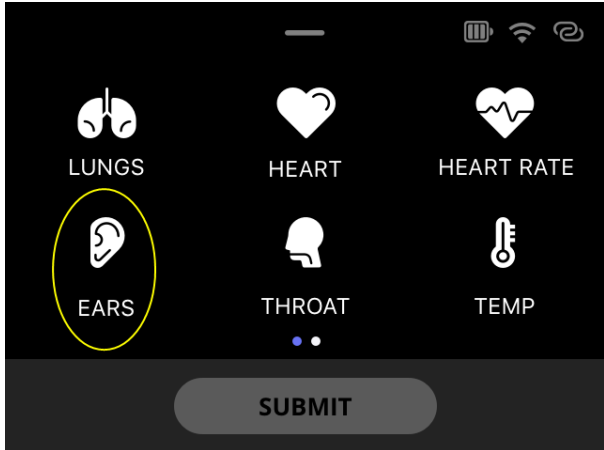
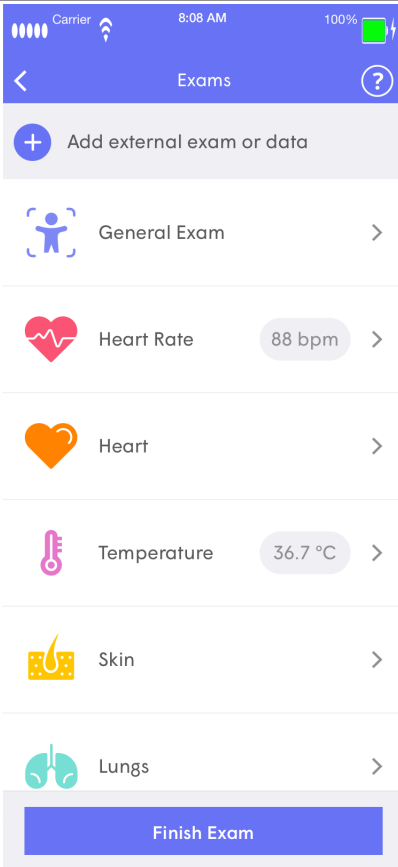
6. Be careful not to push the Tyto Otoscope too deep, which will risk damaging or rupturing the eardrum, which can cause hearing impairment.
7. If the image is blurred, it is probably because cerumen is attached to the speculum. Remove the otoscope tip outside of the ear, and clean the camera lens using alcohol wipes.
8. If video is not displayed, remove the Tyto Otoscope from the ear.
9. It is normal procedure to record both ears, even if only one ear aches.

Finishing the Unguided Ear Exam

When you have completed the necessary video recordings, tap **Submit** on the device. This will stop the video recording and exit the Ears exam.

The device will indicate with a green check mark that the ear exam was recorded. In addition, the App will display the recorded ear exam, and enable viewing the exam video, if necessary.

Please refer to [Section - After the Exam](#) in the Tyto device User Guide for further instructions on reviewing recorded exams.

	
Tyto Device	Tyto App