



TytoPro

Tyto Stethoscope

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.

 **Note:** The Tyto Stethoscope is a class II device intended for use under prescription.

Product Overview

The **Tyto Stethoscope™** is a user-friendly, electronic stethoscope that digitally records heart, lung and other internal auscultation, and transmits this sound data to a medical professional in another location.

The Tyto Stethoscope connects to your Apple (iOS) devices to facilitate the process of communicating data and video with the clinician. Computer software manages the process on the clinician's end.

This Tyto Stethoscope is designed for use either in a home environment or at a clinic. It can be used in a number of scenarios and on any person:

- By a clinician/healthcare professional from a remote location, via live video conference.
- By a clinician/healthcare professional with the patient physically present in the clinic.
- By an adult at home, to perform an examination on themselves or others, with the results submitted for subsequent review by a clinician.
- By an adult at home, to initiate a live virtual visit with a clinician and enable examination during the video conference.

⚠ Warning: Users must have a basic understanding of smartphone operation to ensure proper use of the product.

⚠ Warning: Users must have sufficient vision and hearing to follow the prompts on the product to ensure proper use.

Intended Use and Indications for Use

The Tyto Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds 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. The Tyto Stethoscope is intended for use by professional users in a clinical environment or in conjunction with patients or lay users in a non-clinical environment.

Rx Only

⚠ Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Before the Exam

Connect the Stethoscope Tip

Before you start an exam, connect the Tyto Stethoscope tip to the Tyto device using the blue dot guiding marks:





Note: As the Tyto Stethoscope is placed directly on the skin, please use alcohol wipes to disinfect the membrane of the Tyto Stethoscope (black surface touching the skin) before each use.

User Role: Performing Guided and Unguided Exams

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


Guided exams are intended for use by any person who is not a healthcare professional, or a healthcare professional who is not qualified to perform auscultation and/or a physical exam, and who requires a more detailed, step-by-step approach to the exam. Guided exams lead the user through the process of performing and viewing exams. See Section [Guided Exams](#) for more information.

Unguided exams are intended for healthcare professionals, who have medical knowledge, and are proficient in heart and lungs auscultation. Unguided exams provide a streamlined approach allowing more flexible recording and faster operation, with minimal instructions for use. See Section [Unguided Exams](#) for more information.

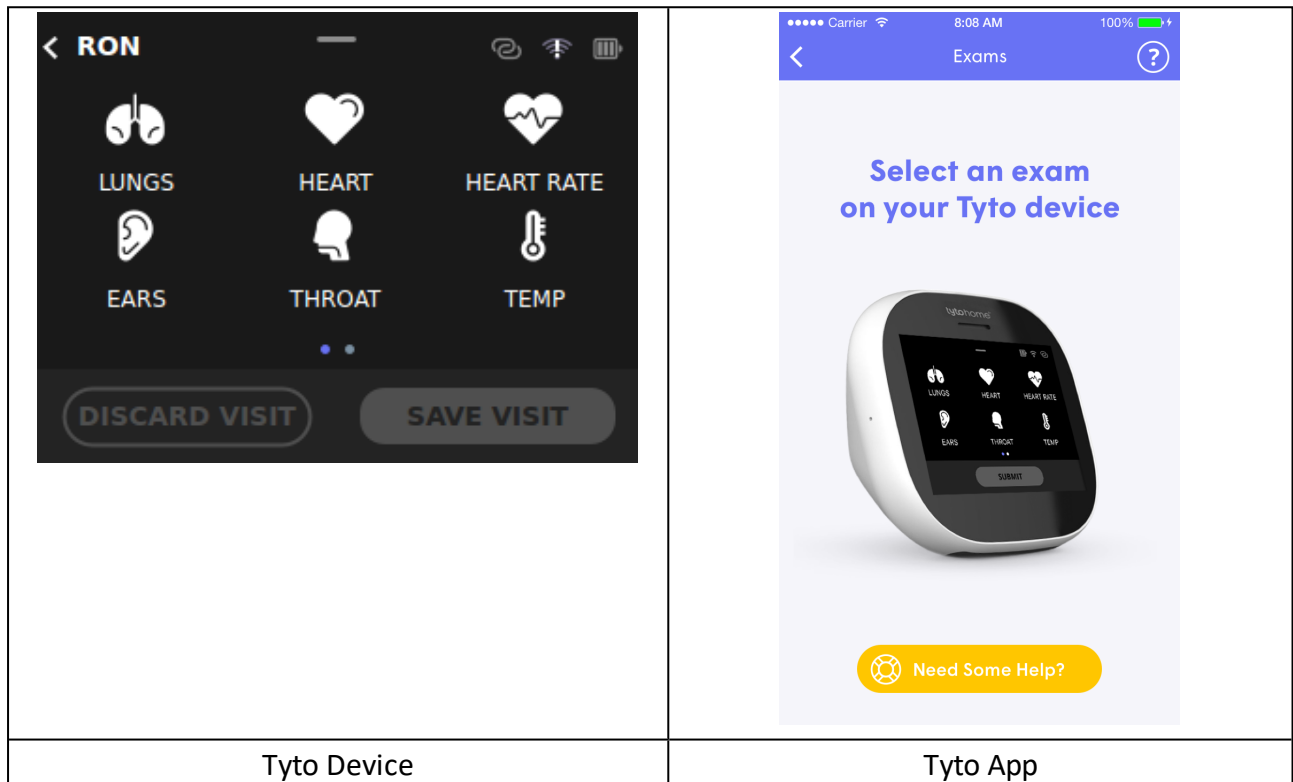
The type of user role, guided or unguided, is defined by the System Administrator when your user was created.

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.

Exam Menu

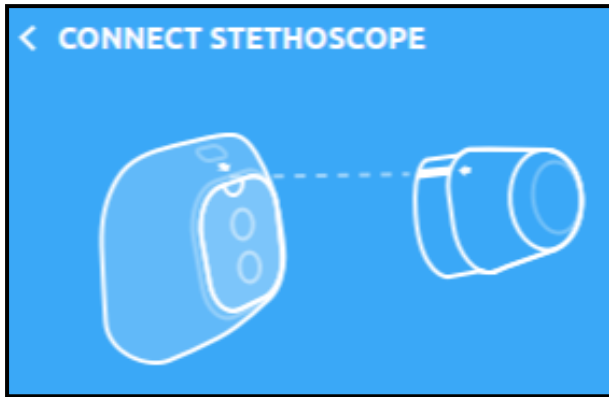
 **Note:** Refer to the *TytoPro™ General Operation User Guide* for preliminary instructions on logging in to the system and viewing the Exam menu.


To start one of the Tyto Stethoscope exams, please select the relevant exam from the exams selection screen in the Tyto device, as shown below:



The Tyto Stethoscope tip is used to perform the following four types of exams:

- The Lungs exam enables lungs auscultation, listening to both the front and the back of the body
- The Heart exam enables heart auscultation
- The Heart Rate exam measures heart rate
- The General Audio Exam enables general body auscultation, such as bowel sounds, carotid blood flow etc.



 **Note:** Make sure the Tyto Stethoscope tip is connected prior to starting the exam. If it's not, you'll see a message asking you to connect it:

Guided Exams

Heart Exam and Lungs Exam



To avoid confusion between left and right sides, in the Heart exam and the Lungs exam you will first be asked to confirm which is the patient’s right arm. This will help you in positioning the stethoscope correctly on the correct points.

Then tap **NEXT** on the device. You will see a picture with the first measurement point highlighted on the screens of both the Tyto device and the Tyto App.

When the Tyto Stethoscope is positioned on the desired point, tap **NEXT** on the device to begin the recording.


| | |
|--|---|
| <p>The screenshot shows a close-up of a person's chest. There are four white circles on the chest: one on the upper left, one on the upper right, one on the lower left, and one on the lower right. The word 'RIGHT' is written in white on the left side of the chest, and 'LEFT' is written in white on the right side. At the bottom center is a blue rounded rectangle with the word 'NEXT' in white.</p> | <p>The screenshot shows a mobile app interface. At the top, it says 'Lungs Front'. Below is a photo of a person's chest with a white crosshair. There are four blue dots on the chest: one on the upper right, one on the upper left, one on the lower left, and one on the lower right. Below the photo, there is text: 'Please put Tyto on top right part of the chest, between the collarbone and nipple.' At the bottom center is a yellow rounded rectangle with a white question mark icon and the text 'Need Help?'.</p> |
| <p>Tyto Device</p> | <p>Tyto App</p> |


Using the Tyto Stethoscope for Heart and Lungs

When using and placing the Tyto Stethoscope on the body, please take special care to note the placement positioning — the left or right side — as indicated by the software.

When performing a lung exam on another person, you first perform the exam on the back of the patient's body and only afterwards on the front, as guided by the software. During the lung exam, the person being examined should breathe in and out deeply and slowly.

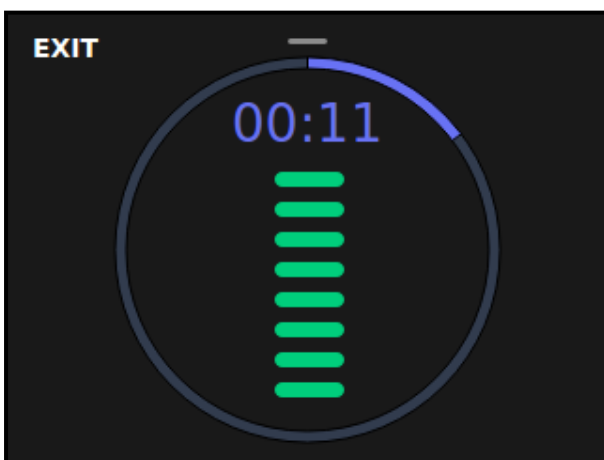
- Place the Tyto Stethoscope firmly on the patient's body at the indicated position. Place the device directly on the skin, if possible. Otherwise it may be used over thin clothing (e.g. a shirt).
- Place the Tyto Stethoscope in full contact with the patient's body or clothing. Hold the Tyto Stethoscope steady during recording, and don't move the device until the countdown completes. Try to remain as quiet as possible, eliminating external sounds.

 **Note:** In order to achieve a high quality and clear recording of the lungs sound, please make sure the patient breathes deeply and slowly, through the mouth, and sits in an upright position. In addition, please make as little noise as possible during the exam, to prevent ambient noise from disturbing the lungs sound recording.

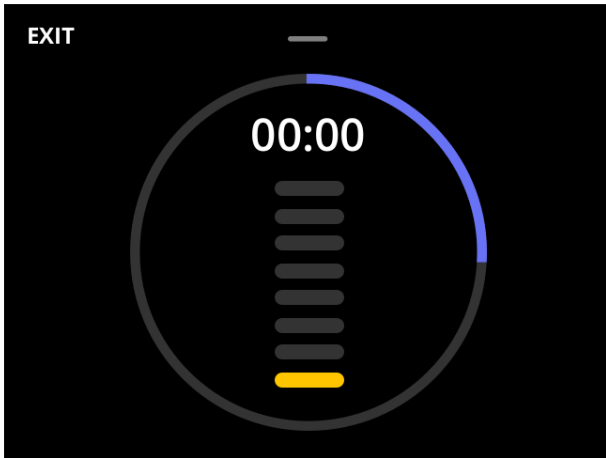
 **Note:** Please make sure that the surface of the Tyto Stethoscope is parallel to the patient's skin, and the entire membrane touches the patient's skin. This is necessary to achieve strong signal strength.

Signal Strength

During the recording, a signal strength bar will be displayed, indicating the quality of your recording.

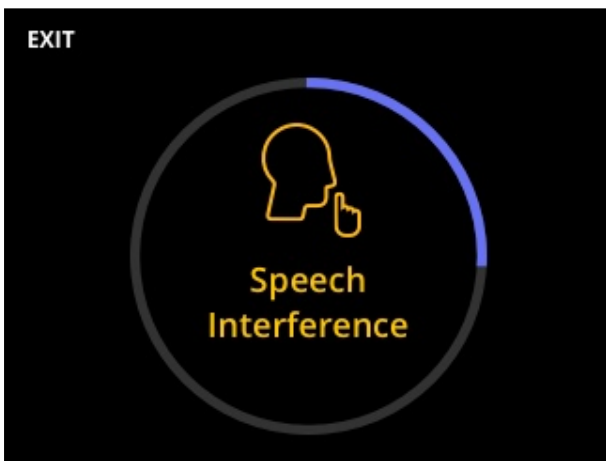


Try to keep the bar high and green.

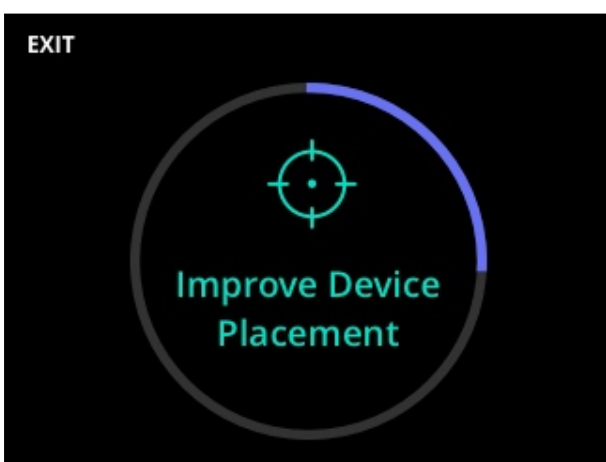


If it turns yellow or isn't displayed, check that you're in the right spot and that Tyto is attached properly to the body.

Tyto will alert you if there are interfering noises during the recording, such as voices talking, device movement, lots of noise in the room, or if the device is pressed to hard against the body:



Speech Interference

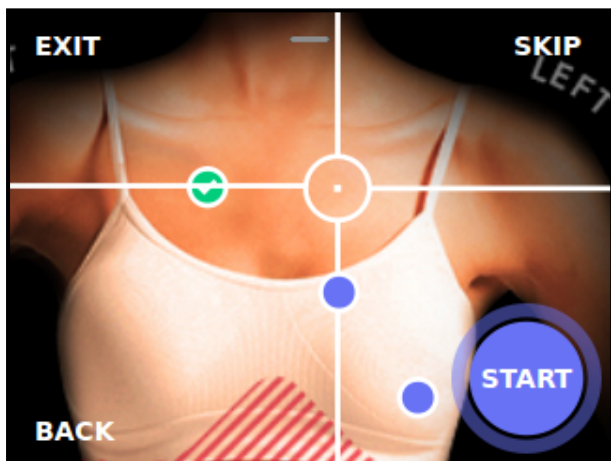


Improve Device Placement



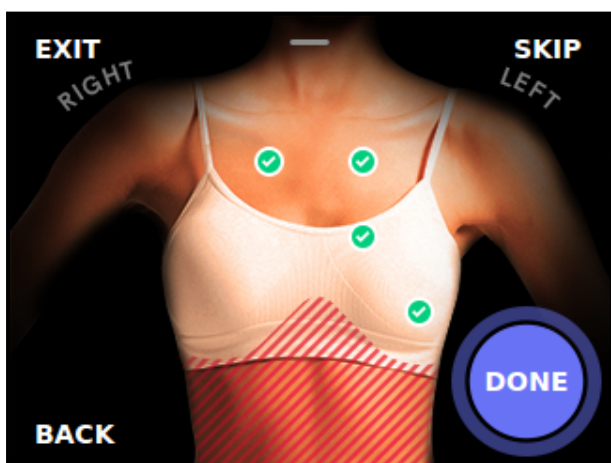
Reduce Pressure

Move on to the Next Examination Point

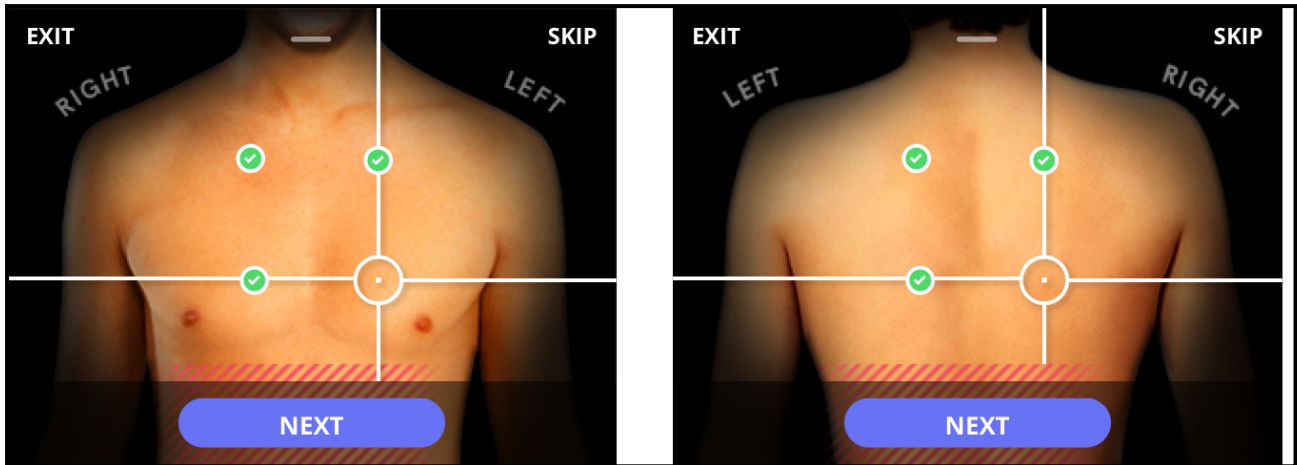


Once the countdown is over and the point recording is complete, Tyto device labels the point with a green label, and the exam moves automatically to the next measurement point in the sequence.

Continue until you complete all measurement points. There are four measurement points for the heart exam, and eight for the lungs exam: four on the front and four on the back.



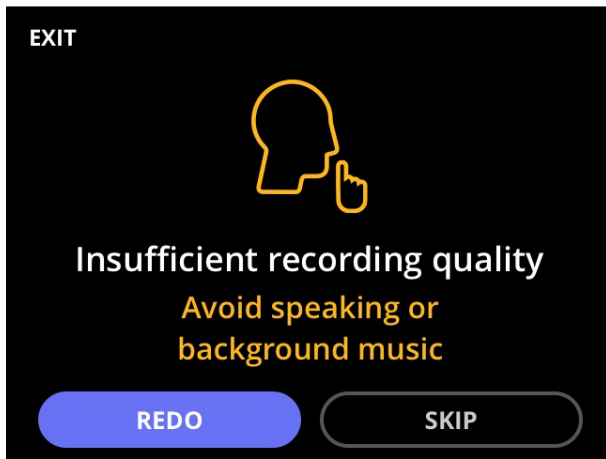
Heart Exam [4 points]



Front & Back Body Lungs Exam [4 points]

Redoing an Examination Point

Once the countdown ends, Tyto analyzes the recording.

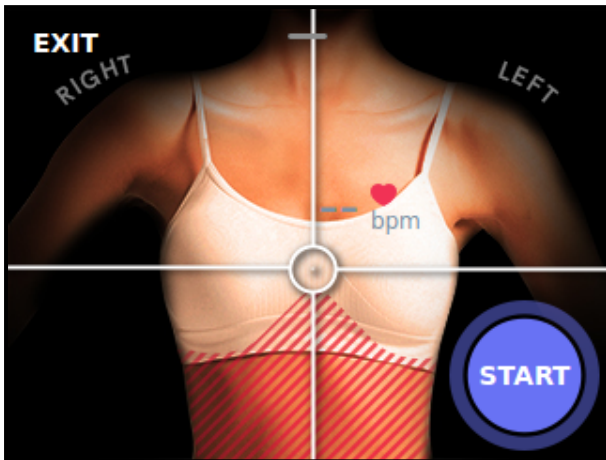


If the recording needs improvement, try again. Tyto will recommend how to improve.

Tap **REDO** to redo the same point.

You can also choose to move to the next point by tapping **SKIP**.

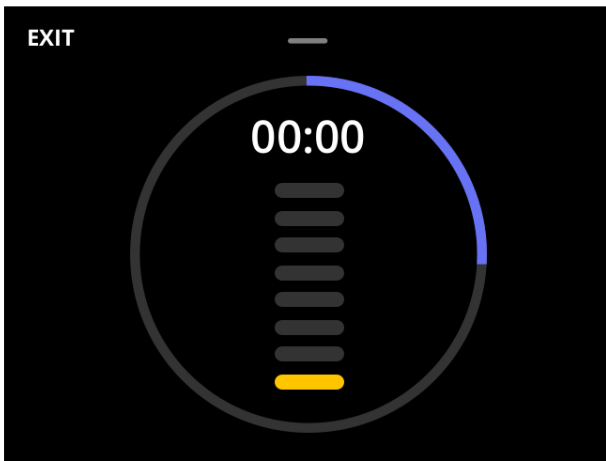
Heart Rate Exam



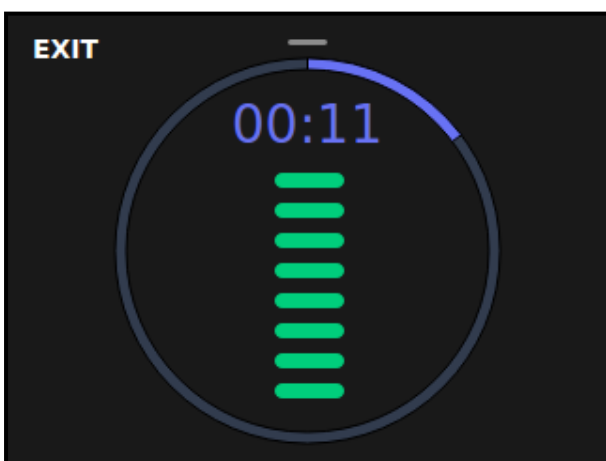
In the Heart Rate exam, place the Tyto Stethoscope on the middle of the chest (on the sternum), as indicated on the device and App. Tap **START** on the device to begin the exam.

Please conduct the exam silently, as speaking or other external noise may cause the measurement to fail.

During the 20-second exam, you will see an indication of the signal quality received by the system:

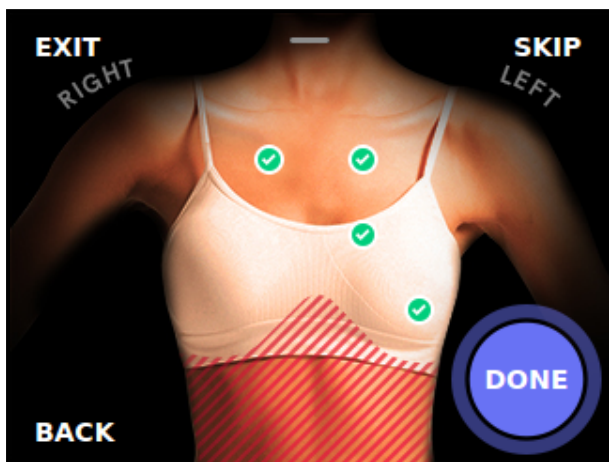



Poor signal quality

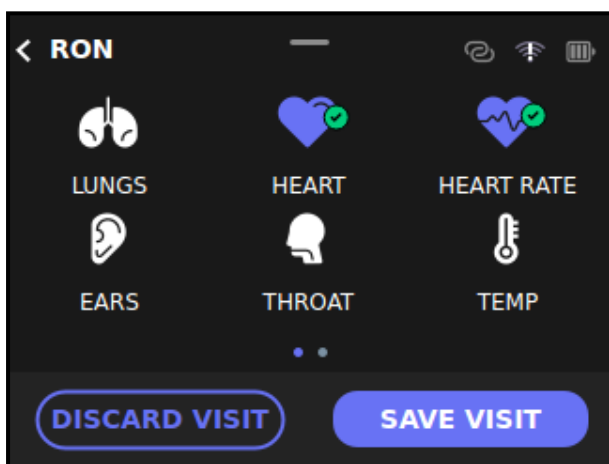


Good signal quality

Completing the Exam



Once you have collected data from all measurement points, tap  (**DONE**) to complete the exam.



The Exams screen will show the completed exam in purple (Heart and Heart Rate exams in this example) to indicate that data was collected. At this point, you can choose to collect data for additional exams.


Completing the Visit

To complete the visit, refer to [Section - Completing the Exam](#), [Section - Completing the Exam](#), and [Section - Sending the Store-and-Forward Data to the Clinician](#), in the Tyto Device User Guide.

Unguided Exams

Connecting Headphones to the Device

To listen to the auscultation sounds directly, connect headphones to the Tyto device audio jack, which is located at the bottom of the device, usually covered by a rubber band, as shown in the images below. Prior to entering the exam (heart, heart rate or lungs) a notification will be shown until the headphones are connected. Once connected, the exam will continue.

 **Note:** The headphones must meet the following specifications:

- Impedance minimum: 16 ohm, typical 32 ohm
- Frequency response: minimum 20 – 10,000Hz
- Plug jack: 3.5mm stereo

Please make sure you insert the headphones into the correct socket, as the charger socket is located next to the headphones jack.

Please note that you can also insert the headphones into the audio jack, located on the Tyto Stethoscope tip itself.

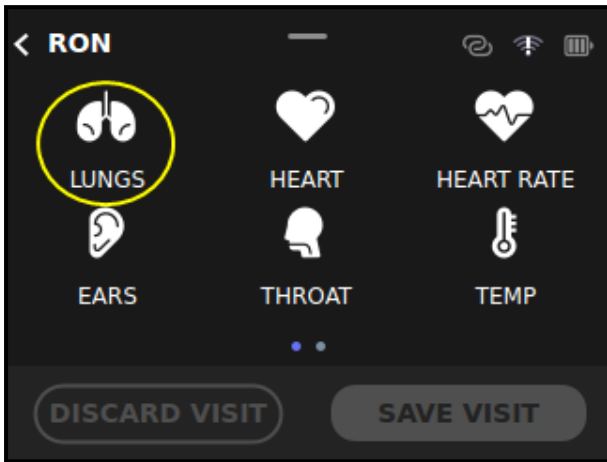


Connect headphones to the Tyto device.



Headphones connected.

Lungs Exam

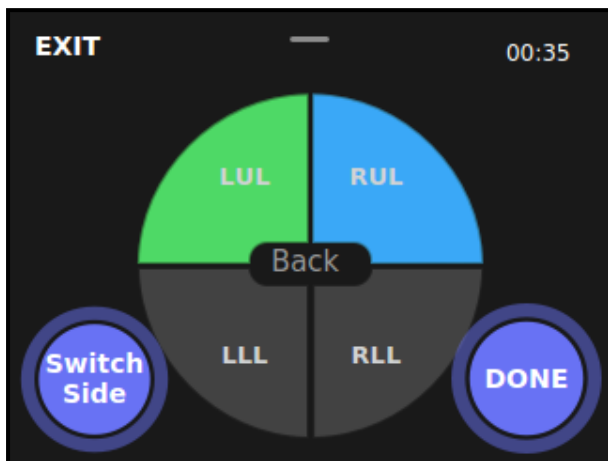


Tap **LUNGS** to begin the examination.

The device will **immediately** begin to record lungs auscultations. The red blinking dot, located at the upper-right corner of the device, as well as in the App, indicates that sound recording is activated.

| | |
|---|--|
| <p>The device screen shows a circular diagram divided into four quadrants representing lung lobes: LUL (top-left, green), RUL (top-right, blue), LLL (bottom-left, grey), and RLL (bottom-right, grey). Navigation buttons include 'EXIT' at the top left, 'Switch Side' at the bottom left, 'DONE' at the bottom right, and 'Back' in the center. A timer in the top right corner shows '00:35'.</p> | <p>The app interface shows a chest diagram with lung lobes labeled: RUL, LUL, RML, RLL, and LLL. A red recording indicator and a timer showing '00:33' are visible. Below the diagram, instructions are provided: 'Sit Straight Don't Speak' and 'Breath Deeply & Slowly'.</p> |
| <p>Tyto Device.</p> | <p>Tyto App</p> |

Lung Lobes Tagging





Example of an exam where **LUL** was examined at least once, and **LLL** is being examined now.

To indicate where on the chest or back you are placing the Tyto Stethoscope (which lung lobe you are currently listening to), press on the appropriate tag (**LUL**, **RUL**, etc.) to indicate the area of auscultation. This tagging is essential to allow the diagnosing physician, who will listen to the recorded sound remotely, to know which lobe he is listening to at a given moment. Every time you move the Tyto Stethoscope to a different area, make sure you accompany this action by pressing the relevant lobe in the device.

This tagging information will be displayed to the clinician when he listens to the recorded exam.

Note that the selected lobe, the area being recorded, will be marked in blue. A green tag indicates an area that has already been examined at least once. Press on **SWITCH SIDE** to toggle between back and front.

 **Note:** In order to achieve a high quality and clear recording of the lungs sound, please make sure the patient breathes deeply and slowly, using his mouth, and sits in an upright position. In addition, please minimize noise during the exam, to prevent ambient sounds from affecting the recording.

 **Note:** Please make sure the surface of the Tyto Stethoscope is parallel to the patient's skin, and that the entire membrane touches the patient's skin. This is necessary to achieve strong signal strength.

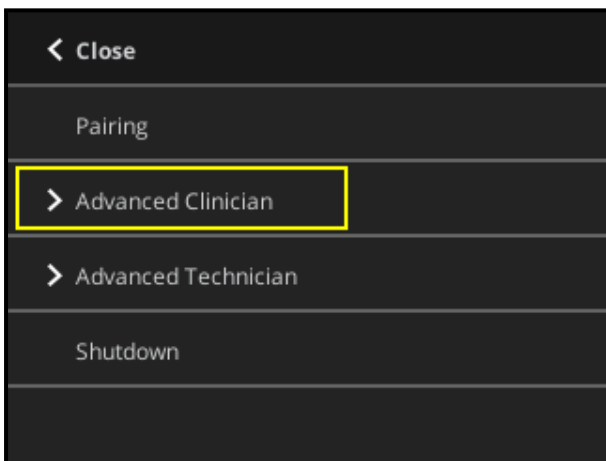
Volume and Sound Filters

To access the Advanced Clinician options of the device Settings menu, swipe down on the device. These settings can be used to change the default audio filters. The default audio filter for heart / heart rate exam is Bell and for lungs exam is Diaphragm.

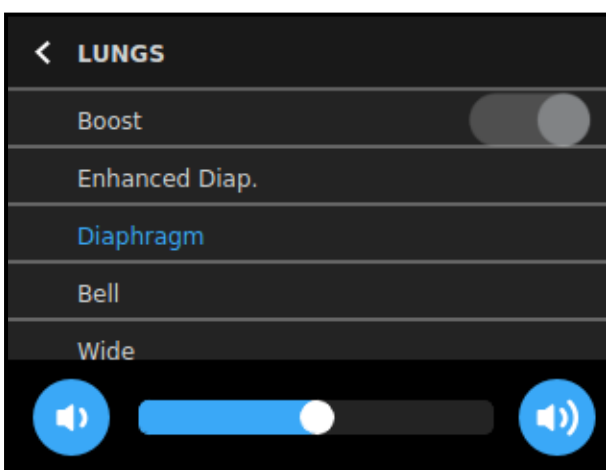
Other optional filters for lungs sounds are Wide for amplification of a wider range of frequencies, or Enhanced Diaphragm, which amplifies the lungs sound frequencies and lowers other frequencies, such as the heart sounds.

In addition, you have a Boost option, which amplifies the sound acquisition. The Boost is helpful in cases of shallow breathing or low breathing sounds. The Boost option is enabled by default for the Lungs exam. If you wish to reduce the sound amplification, turn off the Boost option.

Additionally, the volume of sound heard via the headphones can also be controlled by swiping down the device screen anytime during the recording, and moving the volume slider at the bottom to the right or left




Tap 'Advanced Clinician'



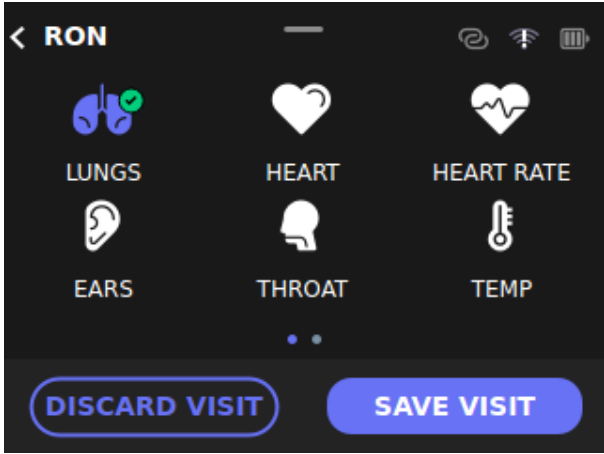
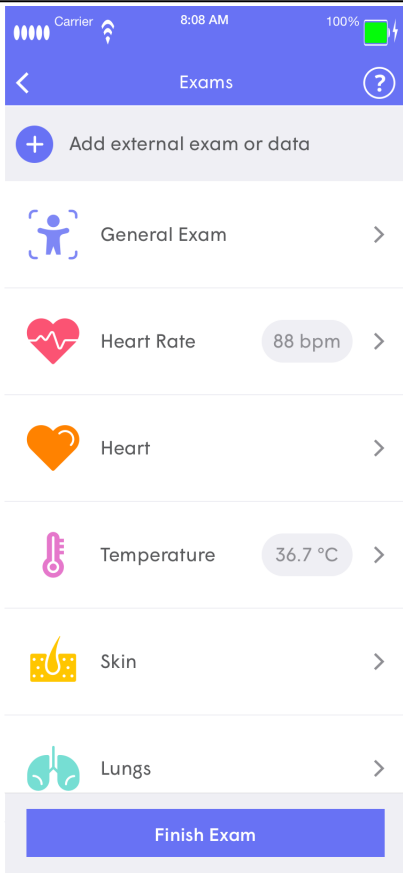
Tap Audio Filter and Adjust Volume

Completing the Lungs Exam

When you have performed the necessary auscultations, and have recorded all necessary locations on back and front, tap  (**DONE**) on the device. This will stop the sound recording and exit the Lungs exam.

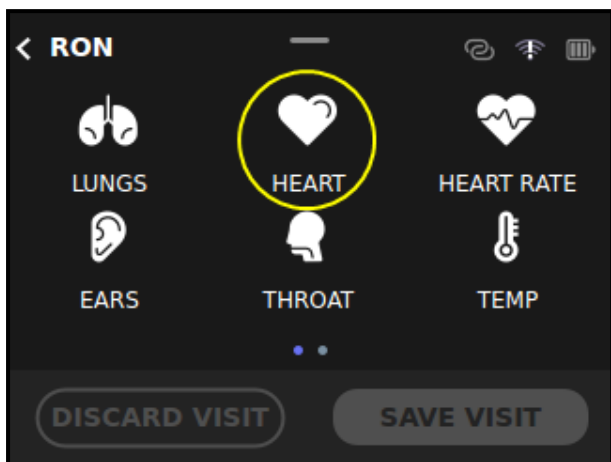
The device will indicate with a green check mark that the lungs exam was recorded.

The App displays the recorded lungs exam, and enables listening to the exam. Please note that the back and front sides will be displayed as separate recordings/lines.

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

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

Heart Exam



Tap **Heart** to begin the examination.

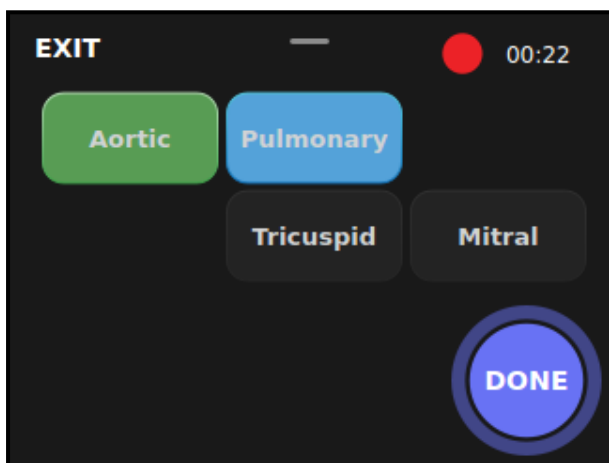
The device will **immediately** begin to record heart auscultations. The red blinking dot, located at the upper-right corner of the device, as well as in the App, indicates that sound recording is activated:

| | |
|---|---|
| A screenshot of the Tyto device interface. It shows a dark screen with the word 'EXIT' at the top left and a red dot with a timer '00:04' at the top right. Below are four buttons: 'Aortic', 'Pulmonary', 'Tricuspid', and 'Mitral'. A large blue circular button with the word 'DONE' is at the bottom right. | A screenshot of the Tyto app interface. At the top, it says 'RON'S HEART EXAM' and shows a timer '00:14'. Below is a diagram of a human chest with four points labeled 'A', 'P', 'T', and 'M'. The text 'Please keep quiet' is displayed below the diagram. At the bottom, there is a line drawing of a person's head and shoulders with a hand pointing towards the chest. |
| <p>Tyto Device.</p> | <p>Tyto App</p> |

Heart Auscultation Areas Tagging

To indicate on which heart auscultation area (heart valve) you place the Tyto Stethoscope, tap on the appropriate tag (**Aortic**, **Pulmonary**, **Tricuspid** or **Mitral**). This tagging is essential to allow the diagnosing physician, who will listen to the recorded sound remotely, to know which auscultation area he is listening to at a given moment. When you move the Tyto Stethoscope to a different area, **make sure** you tap the relevant valve area in the device. This tagging information will be displayed to the clinician when he listens to the recorded exam.

The area being recorded is marked blue. A green tag indicates an area that has been examined at least once.



Example of an exam where Aortic area was examined at least once, and Pulmonary area is being examined now.

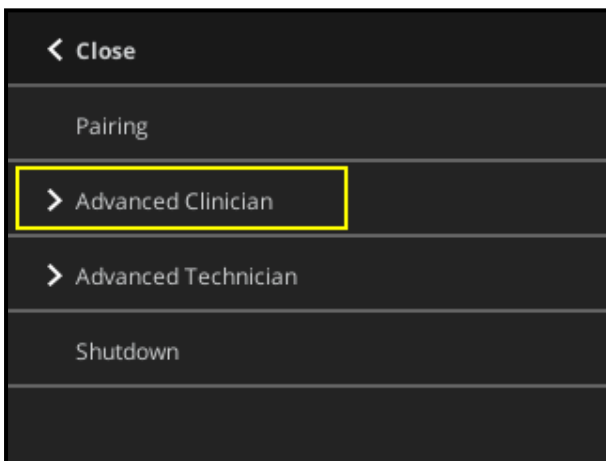
Volume and Sound Filters

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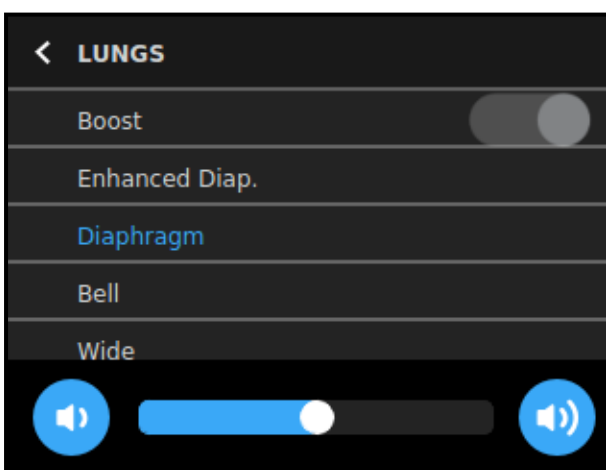
Other optional filters for lungs sounds are Wide for amplification of a wider range of frequencies, or Enhanced Diaphragm, which amplifies the lungs sound frequencies and lowers other frequencies, such as the heart sounds.

In addition, you have a Boost option, which amplifies the sound acquisition. The Boost is helpful in cases of shallow breathing or low breathing sounds. The Boost option is enabled by default for the Lungs exam. If you wish to reduce the sound amplification, turn off the Boost option.

Additionally, the volume of sound heard via the headphones can also be controlled by swiping down the device screen anytime during the recording, and moving the volume slider at the bottom to the right or left




Tap 'Advanced Clinician'



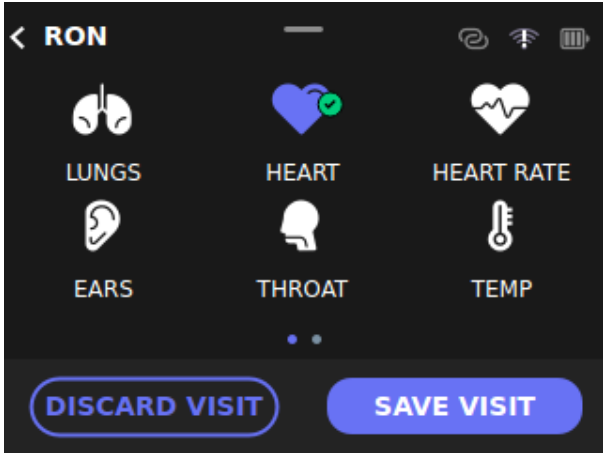
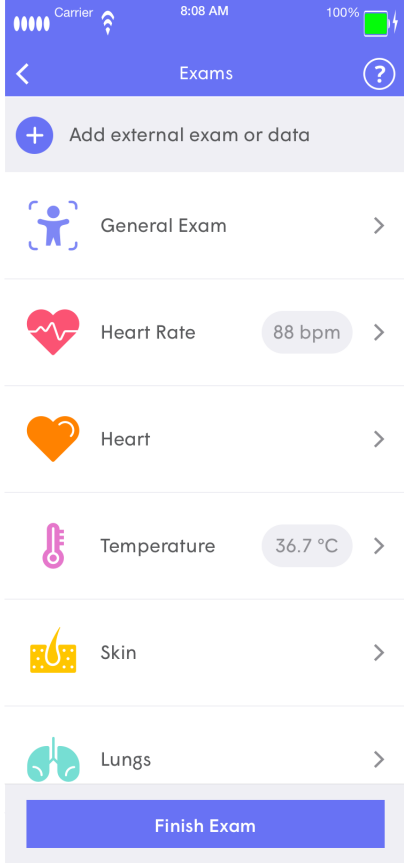
Tap Audio Filter and Adjust Volume

Finishing the Heart Exam

When you have completed the necessary heart auscultations, and have recorded all necessary locations, tap  (DONE) on the device. This will stop the recording and exit the Heart exam.

The device indicates with a green check mark that the heart and lungs exams were recorded.

The App displays the recorded heart exam, and enables listening to the exam, if necessary, or deleting it if the recording was not as desired.

| | |
|---|---|
|  |  |
| <p style="text-align: center;">Tyto Device</p> <p>The device indicates with a green check mark that the heart and lungs exams were recorded.</p> | <p style="text-align: center;">Tyto App</p> <p>The App displays the recorded heart exam, and enables listening to the exam, if necessary, or deleting it if the recording was not as desired</p> |

Heart Rate Exam

Please refer to [Section - Heart Exam](#) for instructions on performing this examination.

General Audio Exam

The general Audio exam enables general body auscultation, such as for bowel sounds, carotid blood flow (bruit) sounds, etc. The Audio exam is accessed using the second screen of the exam selection in the device (next to the Skin exam). Swipe right to navigate to the second screen, and then press the Audio icon.

Please insert the stethoscope before starting the exam, as in heart and lungs exams. Then, place the stethoscope on the required position, depending on the clinical need. Tap **Start** to begin audio recording, and **Done** when finished.