



# **TytoHome**

# **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 mobile 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 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.
- 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.

**⚠ 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:



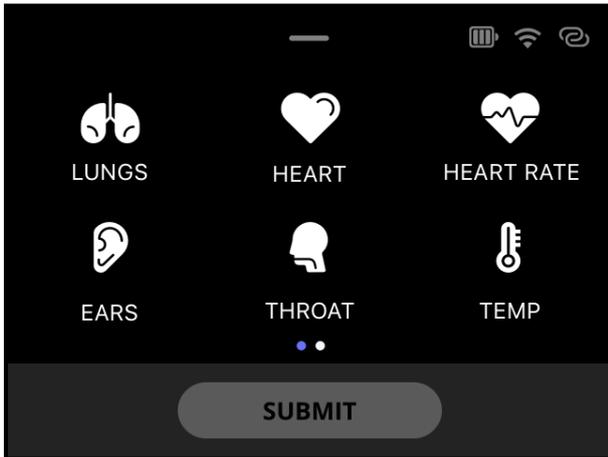


 **Note:** As the Tyto Stethoscope is placed directly on the skin, please use alcohol wipes to disinfect the membrane of the Tyto Stethoscope (black surface touching the skin) before each use.

## Exam Menu

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

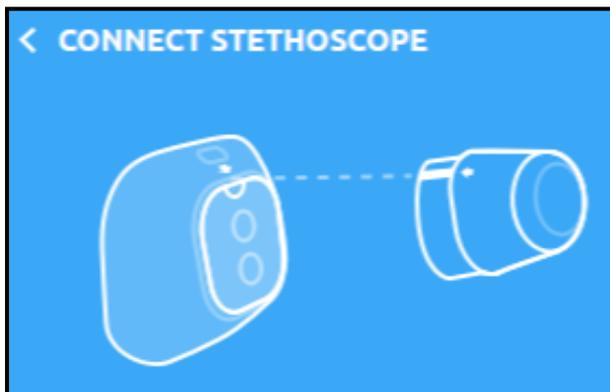
To start one of the Tyto Stethoscope exams, please select the relevant exam from the exams selection screen in the Tyto device, as shown below:



Tyto Device

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

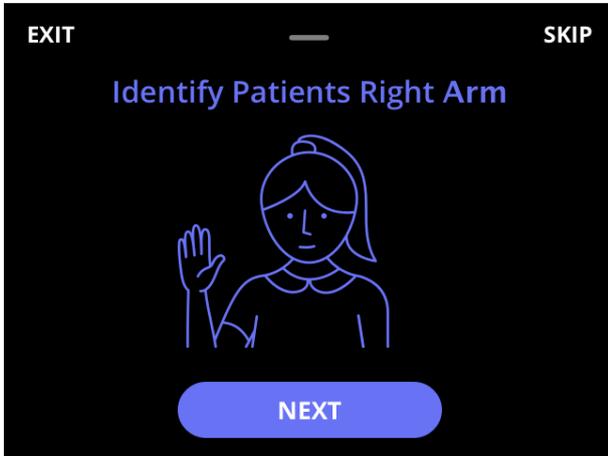
- The Lungs exam enables lungs auscultation, listening to both the front and the back of the body
- The Heart exam enables heart auscultation
- The Heart Rate exam measures heart rate



 **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:

## Performing the 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. The words 'RIGHT' and 'LEFT' are written in white on the left and right sides of the chest respectively. There are four circular markers on the chest: a white circle with a dot in the center on the upper right, and three blue circles on the upper and lower right and lower left. At the bottom center is a blue rounded rectangular button with the word 'NEXT' in white capital letters.</p> | <p>The screenshot shows a mobile app interface. At the top, it says 'Carrier', '8:08 AM', and '100%' with a battery icon. Below that is a blue header with a back arrow and the text 'Lungs Front'. The main image shows a person's chest with 'RIGHT' and 'LEFT' labels. There are four green checkmarks on the chest: two on the upper right and two on the lower right. Below the image is the text: 'Please put Tyto on top right part of the chest, between the collarbone and nipple.' At the bottom center is a yellow rounded rectangular button with a gear 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.

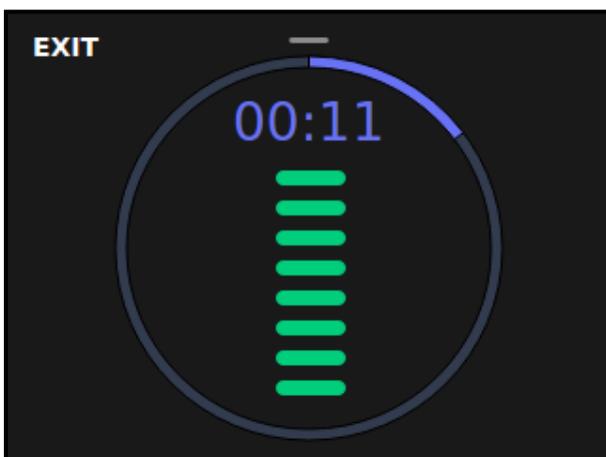
- Place the Tyto Stethoscope firmly on the patient's body at the indicated position. Place the device directly on the skin, if possible. Otherwise it may be used over thin clothing (e.g. a shirt).
- Place the Tyto Stethoscope in full contact with the patient's body or clothing. Hold the Tyto Stethoscope 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.

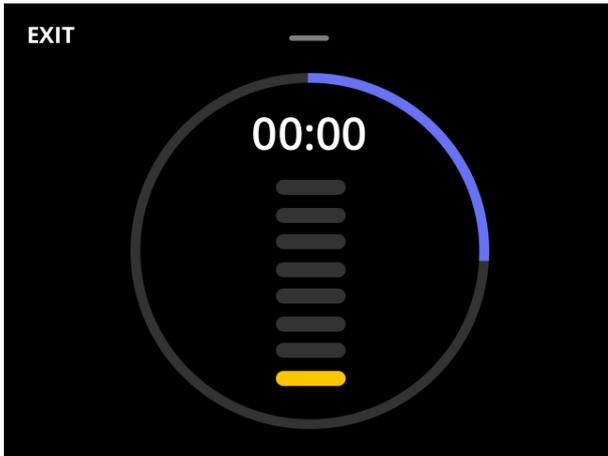
 **Note:** Please make sure that the surface of the Tyto Stethoscope is parallel to the patient's skin, and the entire membrane touches the patient's skin. This is necessary to achieve strong signal strength.

### Signal Strength

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

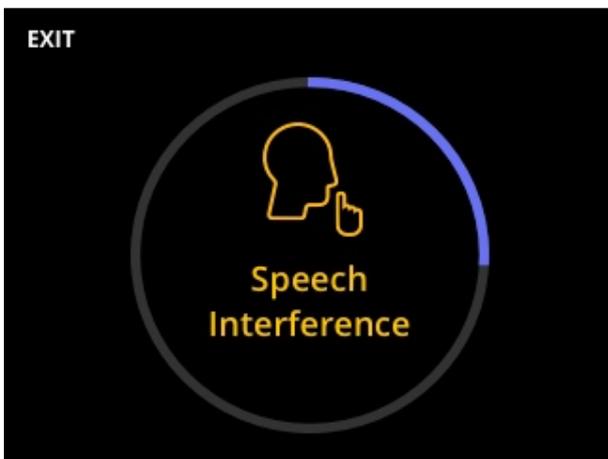


Try to keep the bar high and green.

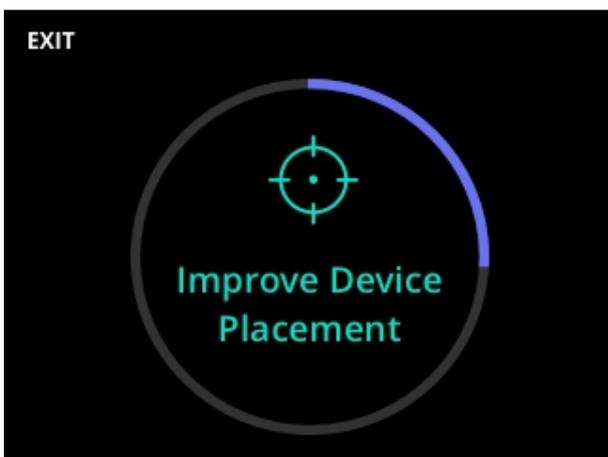


If it turns yellow or isn't displayed, check that you're in the right spot and that Tyto is attached properly to the body.

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**

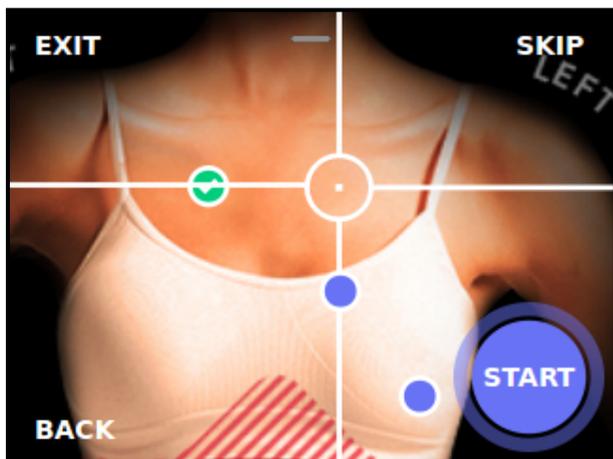


**Improve Device Placement**



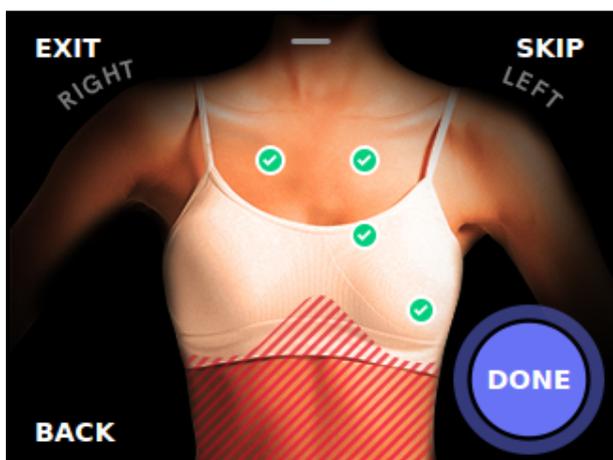
### Reduce Pressure

## Move on to the Next Examination Point

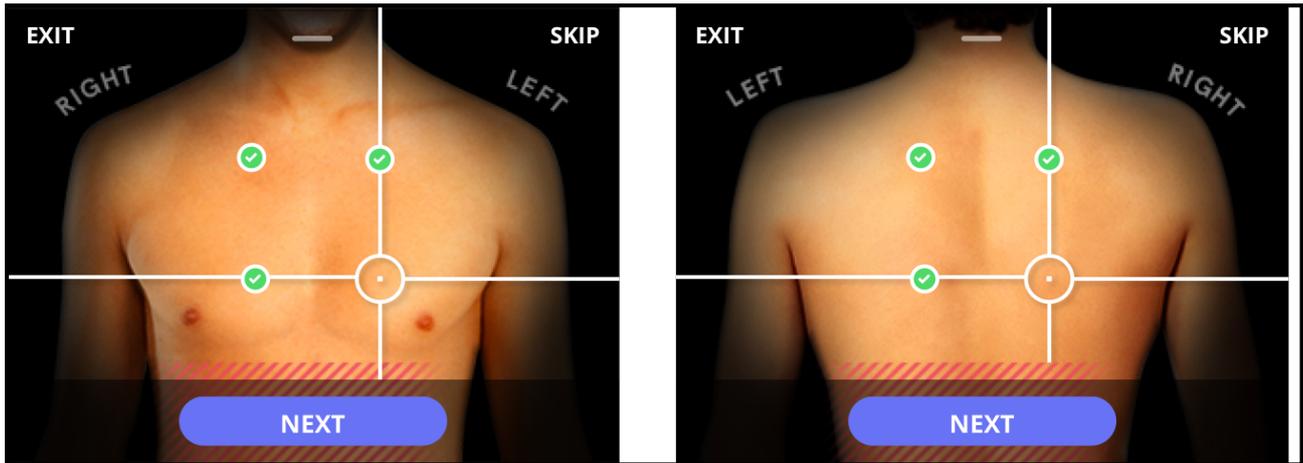


Once the countdown is over and the point recording is complete, Tyto device labels the point with a green label, and the exam moves automatically to the next measurement point in the sequence.

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.



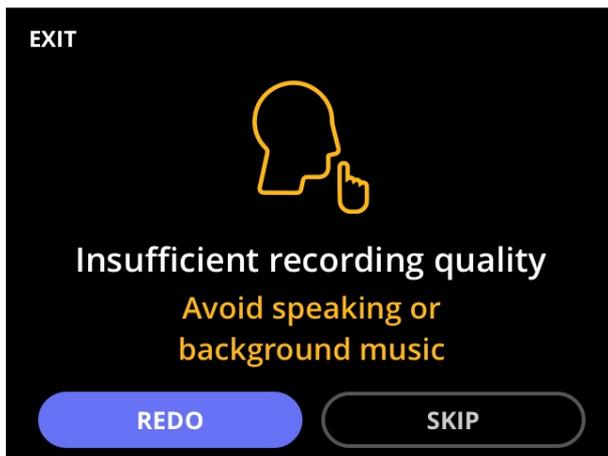
### Heart Exam [4 points]



Front & Back Body Lungs Exam [4 points]

## Redoing an Examination Point

Once the countdown ends, Tyto analyzes the recording.

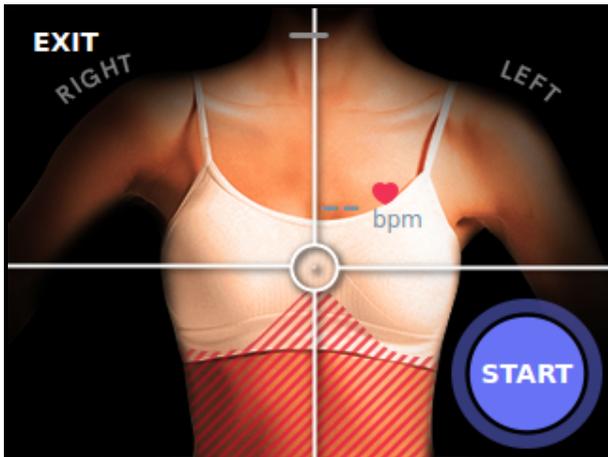


If the recording needs improvement, try again. Tyto will recommend how to improve.

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

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

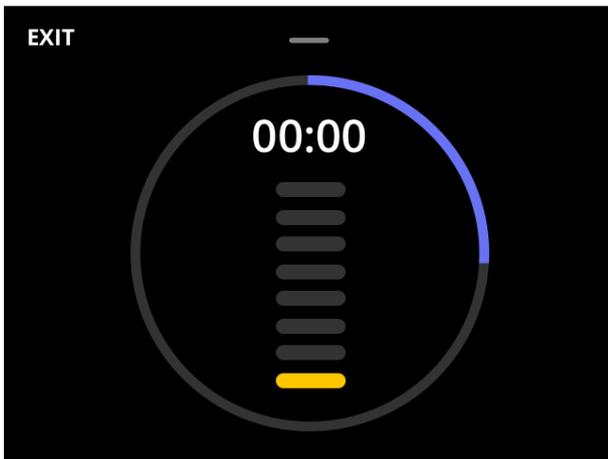
## Heart Rate Exam



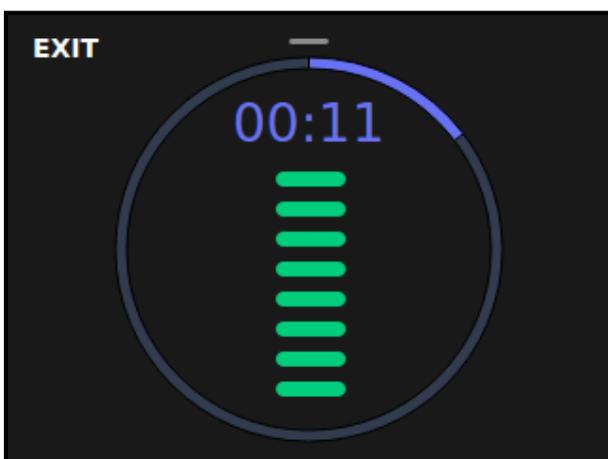
In the Heart Rate exam, place the Tyto Stethoscope on the middle of the chest (on the sternum), as indicated on the device and App. Tap **START** on the device to begin the exam.

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:

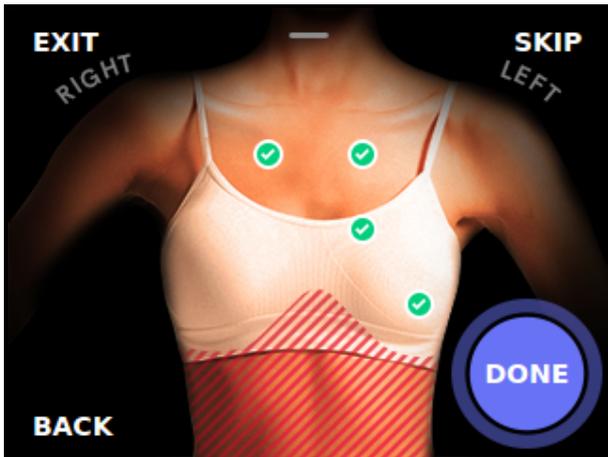


**Poor signal quality**

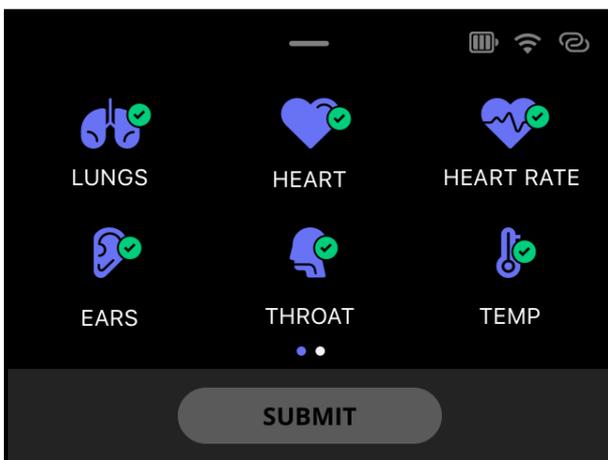


**Good signal quality**

## 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 (all 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, please refer to the General Operation User Guide, beginning in [Section - Recorded Exams](#) , for further instructions.