

TytoPro

General Operation

User Guide

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Important Notice

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Important

This User Guide is subject to periodic review, update and revision.

The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than TytoCare Ltd. (TytoCare).

The safety, reliability, and performance of this device can only be assured under the following conditions:

- The device has been used for its indicated use and according to the operating instructions in this User Manual.
- All fittings, extensions, readjustments, changes, or repairs have been carried out by a TytoCare authorized representative.

This product is protected by the following US patent applications: US 8,953,837 and US-2013-0338447 and other pending US patents.

The device complies with requirements of IEC/EN 60601-1 for general requirements for safety of medical electrical equipment. The device has IEC 60601-1-2 Class B compliance applies to the basic safety and essential performance of medical electrical equipment and Medical Electrical systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by medical electrical equipment and medical electrical systems.

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**PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM.**

This first part of the user manual includes all the instructions which are general and common to all TytoPro devices. The user manual continues in the followings documents, according to the specific TytoPro device that you are using:

- **Tyto Otoscope** – Document 760-00044
- **Tyto Exam Camera** – Document 760-00045
- **Tyto Basal Thermometer** – Document 760-00046
- **Tyto Stethoscope** – Document 760-00047


PLEASE READ THE ABOVE 4 DOCUMENTS AFTER READING THIS DOCUMENT AND BEFORE OPERATING THE SYSTEM.

General Safety Messages


⚠️ Warnings: A warning indicates precautions to avoid the possibility of personal injury or death.

- If the device packaging, the device itself or any of its accessories are damaged or not intact – do not use the device.
- Do not immerse the device or any of its accessories in water or in any other liquid. Do not use a wet device. If the device becomes wet, wipe off all moisture and allow at least 48 hours to dry before operating.
- The system contains no user-serviceable components. Do not disassemble, service or repair this product or any of its parts.
- Disposal of this device should be performed in accordance with local regulations.
- If device is not working as expected, discontinue use. Refer servicing to qualified service personnel.
- Use the equipment only for the purpose described, as explained in this user manual.
- Do not use accessories which are not supplied or recommended by the manufacturer.
- Do not remove the covers of the device components.
- Only perform maintenance procedures specifically described in this user manual.
- Do not use device during defibrillator use.
- Do not use the device on an open wound or on infected skin.
- **Keep these instructions for use.**

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

- Connect only authorized accessories to the device.
- If the LCD screen is broken or cracked, or the image quality is poor, please contact TytoCare Support.
- If the LCD screen is dirty, clean the screen with a dry cloth or towel.
- If the device does not turn on or initialize properly, or the Splash screen does not appear as shown , or it cannot be turned off, contact TytoCare Support.
- If the audible speaker does not sound briefly or the LED does not turn on during system initialization, contact TytoCare Support.
- If the LED does not turn on during Throat, Skin or Ears exam, contact TytoCare Support
- If you see static artifacts on videos or images, or if the image quality is insufficient, contact TytoCare Support

- The Restore to Factory Defaults action from the menu will erase all device settings and data and will restore the device to its initial as-new state.
- Use 70% Isopropyl alcohol moisture wipes for cleaning of the device if in contact with skin.
- Contact with solvents can cause severe deterioration of the plastic parts and malfunctioning of the instrument and accessories.
- Examinations cannot be done while the device is charging.
- Use only the charging cable provided with the device. If the device does not charge, contact TytoCare Support. To charge the device, plug the charging cable into the USB port on your computer or a UL-certified USB wall charger
- Use only a secured Wi-Fi network such as WPA2 wireless encryption.
- If data or instructions are not displayed on the mobile device during an examination, view the device screen.

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

- If for any reason you cannot perform the connection between the device and the TytoCare App, contact TytoCare Support.
- When performing a measurement, a date and time stamp is automatically included with the recording. If you do not see the date and time of the recording, contact TytoCare Support.
- The device connection screen in the TytoCare App should only be used to connect to another device or to disconnect from an existing device.
- Operating conditions: 5° to 40° Celsius (41° to 104° Fahrenheit) / 15% to 70% humidity (non-condensing).

For Tyto Basal Thermometer: 16° – 40° Celsius (60.8° - 104° Fahrenheit)

Storage conditions: -20° to 60° Celsius / -4° to 140° Fahrenheit / 15% to 70% humidity (non-condensing).

- When charging, the activity LED will be orange, and when charging is complete, it will turn green.
- The device complies with wireless standard IEEE 802.11 g/n (2.4GHz).

Repair Policy

When under warranty, repair and service must be performed by TytoCare. When the TytoCare warranty is expired, repairs may be made by TytoCare or authorized representatives, on a parts and labor basis.

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.

Warranty

TytoPro™ device Two (2) Years Limited Warranty.

TytoCare warrants the TytoPro™ branded product, which includes the base unit, its software and ancillary parts (the “Product”), to be free from defects in materials and workmanship when used normally in accordance with TytoCare’s published guidelines for a period of TWO (2) YEARS from the date of original purchase (“Warranty Period”). Warranty for battery is for one (1) year. TytoCare’s published guidelines include information contained in this User Manual, the instructions available on the Tyto APP, and in the Product’s technical specifications.

TytoCare does not warrant that the operation of the TytoPro™ will be uninterrupted or error-free. If the Product is determined by TytoCare to be defective during the Warranty Period, TytoCare shall, at its option, repair or replace the Product free of charge to the original purchaser. In the event TytoCare cannot repair or replace a product determined to be defective during the Warranty Period, TytoCare will refund the amount of the original purchase price upon receipt of proof of purchase. To receive warranty repair or replacement, a warranty claim must be made during the Warranty Period and within ten (10) days following the discovery of the defect. In addition, the Product must be returned to TytoCare in accordance with the instructions provided at the time the claim is made. Warranty claims must be submitted in writing as follows:

TytoCare Inc. 215 W 40th Street, 9th Floor, New York, NY 10018

This warranty is subject to the following limitations:

- This warranty is valid only if the sticker at the bottom of the Product is present indicating the serial number and manufacturing details.
- TytoCare is not responsible for damage arising from failure to follow instructions relating to the use of the Product.
- The user shall be responsible for proper maintenance and handling of the Product.
- No warranty is extended if the Product has been altered or modified in any way.
- No warranty is extended to any Product that has been misused or damaged.
- This warranty is extended only to the original purchaser of the Product.
- This warranty does not include problems or product malfunctions caused by the user’s acts (or failure to act), the acts of others, or events beyond TytoCare’s reasonable control.

NO OTHER WARRANTY

This limited warranty is the only warranty made by TytoCare for the Product. TytoCare MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT AND EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND TytoCare DOES NOT REPRESENT THAT THE PRODUCT WILL MEET THE PURCHASER'S OR USER'S REQUIREMENTS.

TytoCare's sole liability under this warranty will be, at its option, to either repair or replace the defective Product or to refund or credit the purchase price to the original purchaser. IN NO EVENT SHALL TytoCare BE LIABLE FOR ANY DAMAGES, INCLUDING BUT NOT LIMITED TO, ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES, OR DAMAGES FOR ECONOMIC LOSSES, LOST PROFITS, BUSINESS INTERRUPTION, OR LOST INFORMATION, ARISING OUT OF YOUR USE OF THE PRODUCT, EVEN IF TytoCare HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, WHETHER ARISING OUT OF WARRANTY OR CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER TORT. THE USER AGREES THAT UNDER NO CIRCUMSTANCES WILL TytoCare's LIABILITY RELATING TO THIS PRODUCT EXCEED THE PURCHASE PRICE PAID FOR THE PRODUCT.

FCC Radio frequency interference statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

TytoCare is not responsible for any radio or communication interference caused by using other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Product Overview

The **Tyto Device** is a user-friendly electronic device that allows you to perform examinations, and to optionally transmit the sound, video or image data to a medical professional in another location.

Tyto Device is used with additional add-on units to perform the following types of examinations:

- Lungs
- Heart
- Heart Rate
- Ears
- Throat
- Basal Body Temperature
- Skin
- General audio auscultation

Tyto Device connects to the TytoApp on your mobile device (iPhone, iPad, iPad mini or iPod touch) to facilitate the process of communicating examination data and performing an online visit with the clinician.

This device is designed for use by a healthcare professional in a clinical or home environment. It can be used in a number of scenarios:

- By an individual clinician/healthcare professional at his clinic
- By a clinician/healthcare professional, who forwards exam data to another healthcare professional for later analysis
- By a clinician/healthcare professional, who collaborates online with another healthcare professional during or after the exams.

Intended Use

Refer to the relevant user manual for the intended use of Tyto Stethoscope (760-00058), Tyto Exam Camera (760-00045), Tyto Otoscope (760-00044) and Tyto Basal Thermometer (760-00046).

Contraindications

None known.

What's in the Box



1. Tyto Device	Includes an LCD touch screen, main processing unit, rechargeable battery, camera, illumination, sensors and connector which is used to mount the add-on devices (see Section - Exams and Add-Ons User Guides), and which is held when taking an exam.
2. Stethoscope	Add-on for heart and lungs auscultations and measurement of heart rate
3. Otoscope	Add-on for ears exam
4. Tongue Depressor	Optional tool for throat exam, including a re-usable holder and blades. There are 2 sizes for the blades: <ul style="list-style-type: none"> • 10 adult tongue depressor blades • 10 child tongue depressor blades
5. Tray	Holder for device and add-ons. To be used during examinations

6. Disposables (not shown)

- 10 adult disposable ear specula
- 10 child disposable ear specula

7. Carrying Case

Stores and keeps the entire TytoPro™ product, including Tyto device, add-ons, disposables. Note there is a designated place on the case top to be used as a mobile stand, to hold an iPhone during examination and online virtual visit

8. Charging Cable

Used to charge Tyto device, using the USB port on your computer or a UL-certified USB wall charger



Charging outlet

Note: The device comes pre-charged. If it does not power on, connect the charging cable to Tyto to charge it. Remove the rubber band and connect the charging cable into the charging outlet.

Note: Be sure to connect the charging cable into the charging outlet (see picture), not into the headphones outlet, which is nearby and larger.

Note: You cannot perform exams during the charging process. It is recommended to fully charge the battery before use.

Note: When the device is charging, an orange LED indicator will display. When fully charged, the LED indicator will change to green.

Note: Store the device charged, and to re-charge it once every 3 months. Storing the device when battery is drained may shorten the battery life.


How the System works

The components of the TytoCare system work together to help you communicate with clinicians:





Download the Tyto App

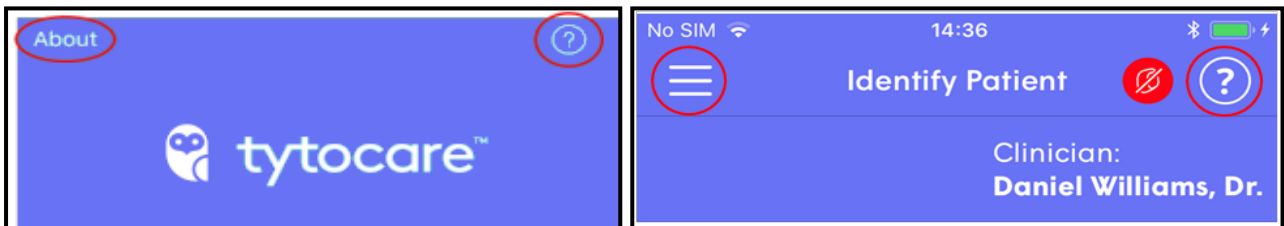
Downloading Tyto App

Open the App Store on your Apple device. Search for “**TytoCare**”  and download the free App by clicking “**Get**”.

The TytoCare App allows you to perform exams, share the recorded exams with clinicians, perform online virtual visits with live video conference with the clinician, and obtain exam results from clinicians. After downloading and installing the TytoCare App on your device, you can run it from the Apps Menu.

Help Menu

The user manual may be reached at any time, either before login through the About link, at the top-left corner of the login screen, or after login, through the menu,  accessed through the top-left corner icon. The tutorial videos may be reached at any time by pressing the help icon  on the App.



First Time Setup

What do I need to start working with the Device

- A Wi-Fi network, secured by a known password, that I can connect to, or a Personal Hotspot on my mobile device.
- Tyto device, fully charged.
- Tyto App, installed on any of the following iOS mobile devices: iPhone 5S and up, iPad Air and up, iPad mini 2 and up, iPod touch 6 and up.
- The carrying case, or any mobile stand, to hold the mobile device during work.
- Internet access via the Wi-Fi network.
- For best performance, the following connection speed is recommended: Download 20 Mbps \ Upload 5 Mbps.
- At minimum, the following connection speed is required: Download 2 Mbps \ Upload 2 Mbps.



Note: in case the iOS mobile device supports Hotspot with a stable LTE connection, it can be used instead of a Wi-Fi router.

Pairing the device and Tyto App

In order to start using the Tyto device, you must perform a short pairing process between the device and user mobile app. This pairing enables the communication between the two devices, over the Wi-Fi network or Hotspot. This process is done once per device. If you change your Wi-Fi password, change your Wi-Fi router or perform any other change to your wireless network, you will need to pair the device again.

Before pairing, please make sure that your iPhone/iPad is connected to your Wi-Fi network, which should have internet connection, and you know its password.



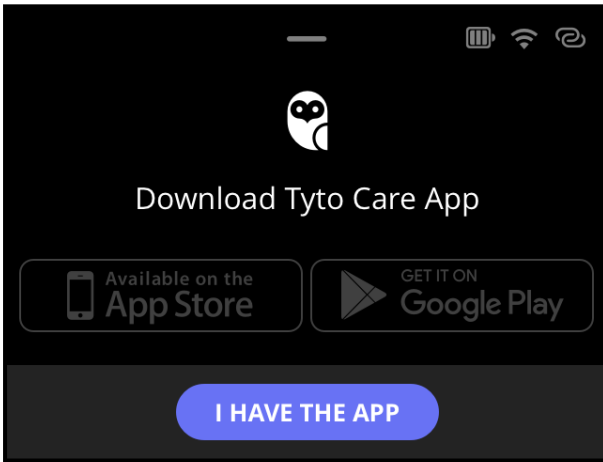
Note: If your Wi-Fi network is not secured by a password, you will not be able to pair the device and app.

1. If you are not logged in to the system, log in as described in Section [User login](#).




2. **Turn ON the device** by pressing the button on the top edge of the device.

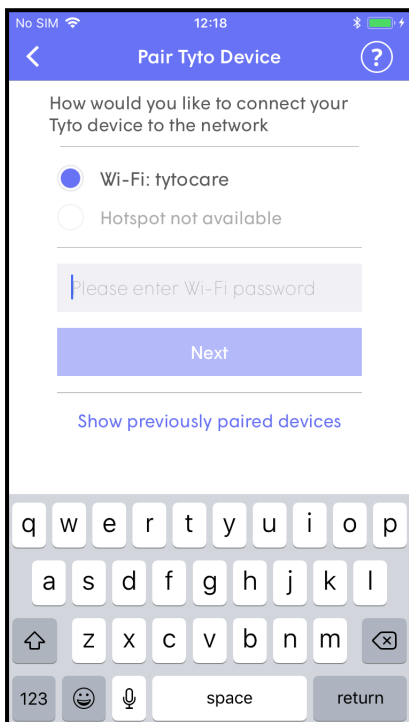
The screen displayed on the device will prompt you to download the TytoCare App onto your iPhone/iPad:



3. Tap **"I HAVE THE APP"**, and continue below.

Pairing Procedure

 **Note:** The pairing procedure should start automatically, upon login or after the registration process, with the following Device Pairing screen:



- If you see this screen, continue in Section [Pairing Procedure on First-Time Use](#) below.
- If you do not see this screen, continue in Section [Manual Pairing Procedure](#) below.

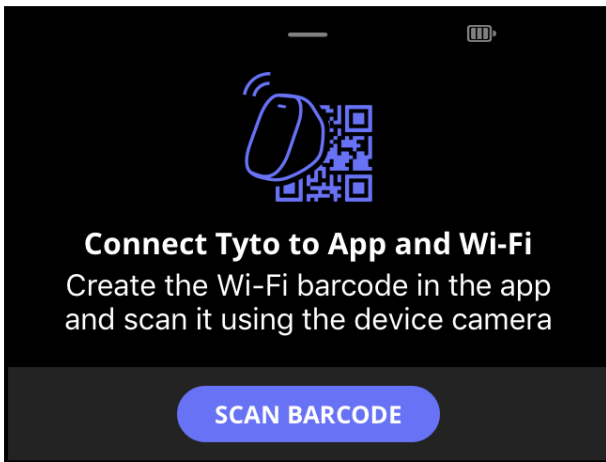
Pairing Procedure on First-Time Use

Using Wi-Fi

1. Enter your Wi-Fi password and tap **Next** on the App **Device Pairing** screen. This creates a QR code on the iPhone screen:

<p>Enter Wi-Fi password and tap "Next"</p>	<p>QR code created on the iPhone</p>

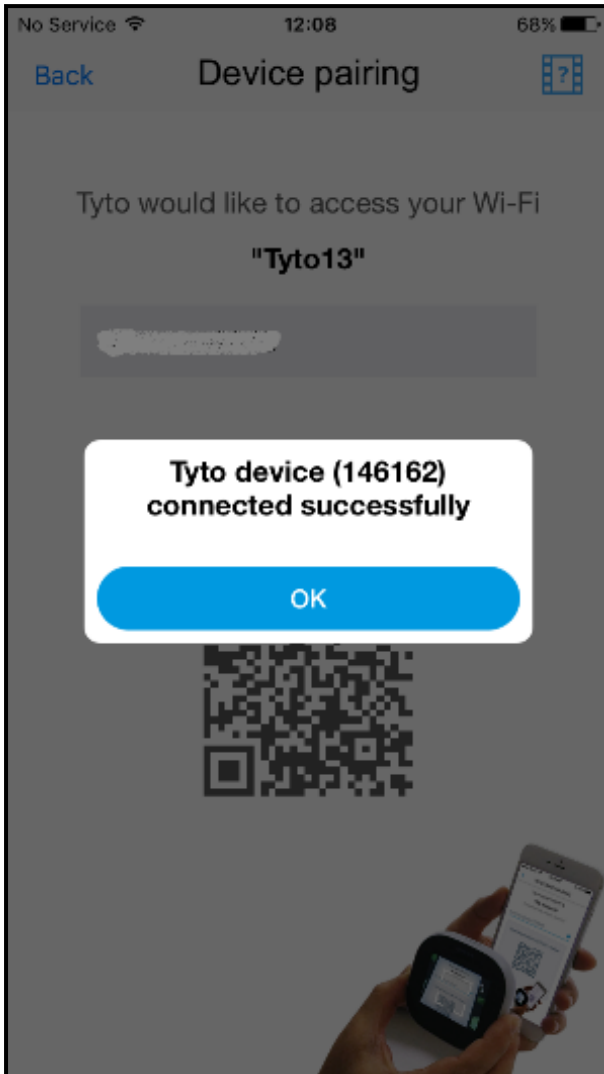
2. You now want to use the **device camera** to read the QR code from the iPhone/iPad screen. Follow the four steps labeled **A-D** as shown below:



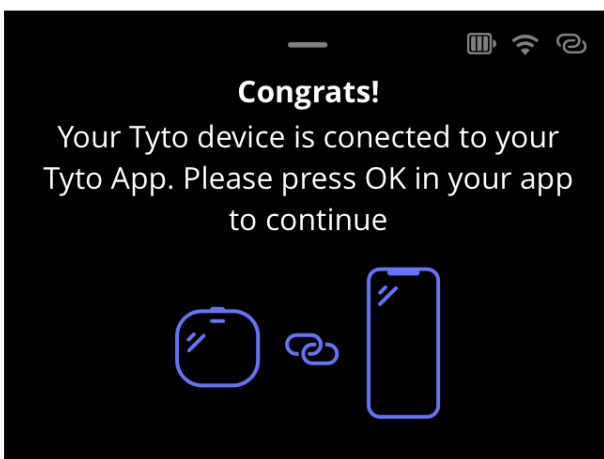
- a. Tap **SCAN BARCODE** on Device. The device camera is activated.




- b. Position the cross-hairs over the QR code displayed in the App. When identified, wait until pairing process is finished.



c. Success confirmation in App – tap **OK**.

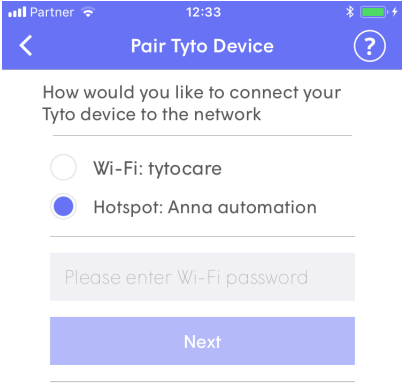


d. Confirmation in Device.

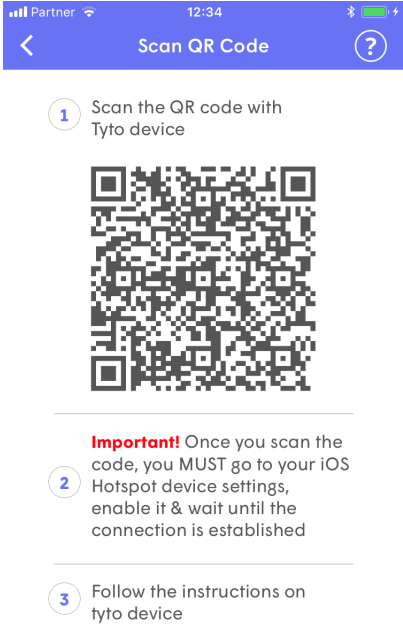
 **Note:** If an error occurs, make sure the Wi-Fi password is correct, and retry the pairing process. If error persists, see [Section - Frequently Asked Questions and Troubleshooting Tips](#)

Using the mobile Hotspot

1. Select Hotspot, enter your hotspot password and tap **Next** on the App Device Pairing screen. This creates a QR code on the iPhone screen:

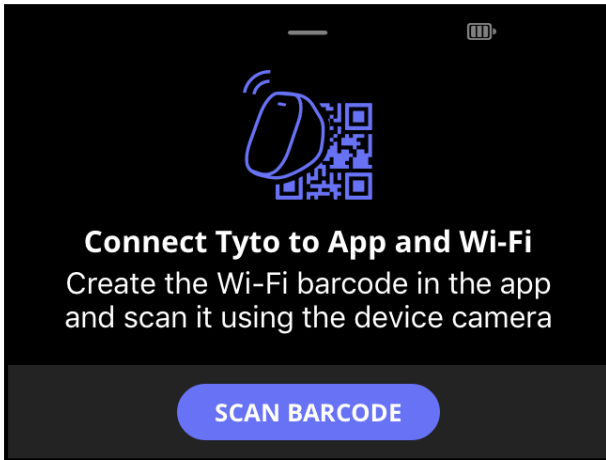


Enter Wi-Fi password and tap “Next”



QR code created on the iPhone

2. You now want to use the device camera to read the QR code from the iPhone/iPad screen. Follow the four steps labeled A-D as shown below:



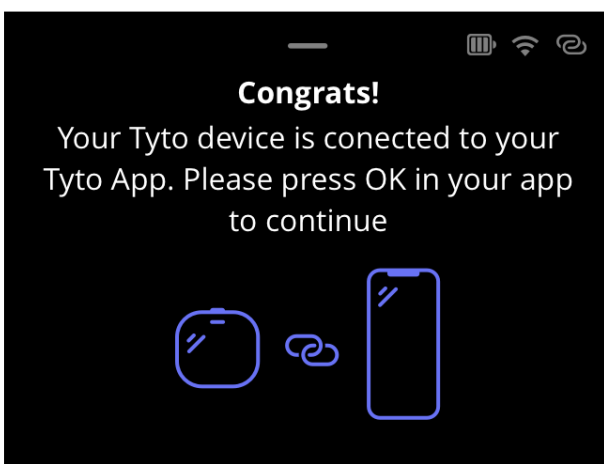
- a. Tap **SCAN BARCODE** on Device. The device camera is activated.




- b. Position the cross-hairs over the QR code displayed in the App. Notice the Device directs you to open the settings




- c. Open the iOS **“Personal Hotspot”** settings, and enable the Hotspot.



- d. Wait for the Device confirmation, and switch back to the Tyto App.



 **Note:** If an error occurs, make sure the Hotspot password is correct, and retry the pairing process. If error persists, see [Section - Frequently Asked Questions and Troubleshooting Tips](#).

Device Pairing Indications



 **Note:** The connectivity status of the device to the TytoCare App is indicated in the upper right corner of the device screen as well as on the Tyto app.


Device connected to the App

Indications on the device:

	
<p>Device connected to the App</p>	<p>Device not connected to the App</p>

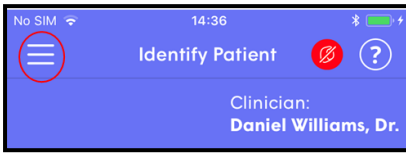
Indications on the Tyto App:


	
<p>Device is paired</p>	<p>Device is disconnected</p>

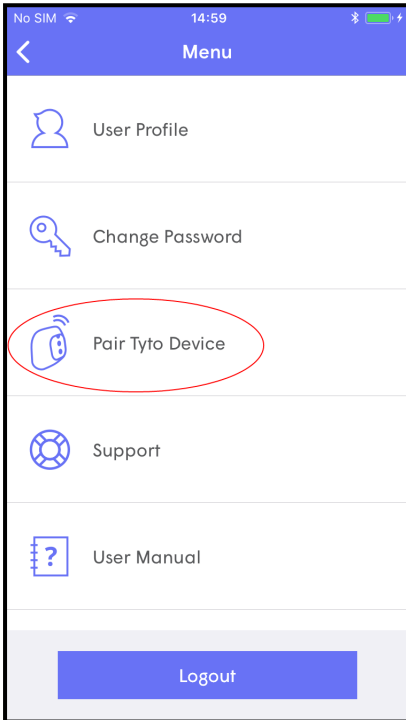
 **Note:** Following connection, the Tyto device will check online if software update is available. In case a new version is available, you'll be asked to download and install the new version. Please follow the instructions on the device's screen. The version upgrade process may take several minutes, depending on network speed. Please charge the device during the upgrade.

Manual Pairing Procedure

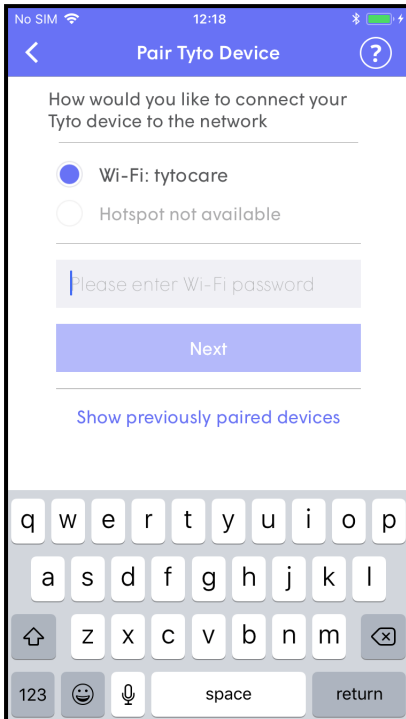
Follow these steps to perform the manual pairing process.



1. Tap **Menu** , located at the top-left corner of the App.

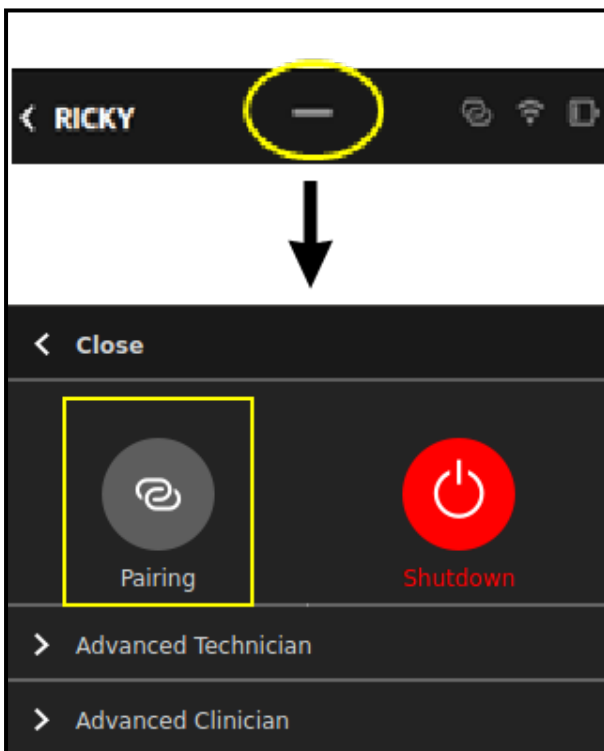


2. Tap **Pair Tyto Device**.

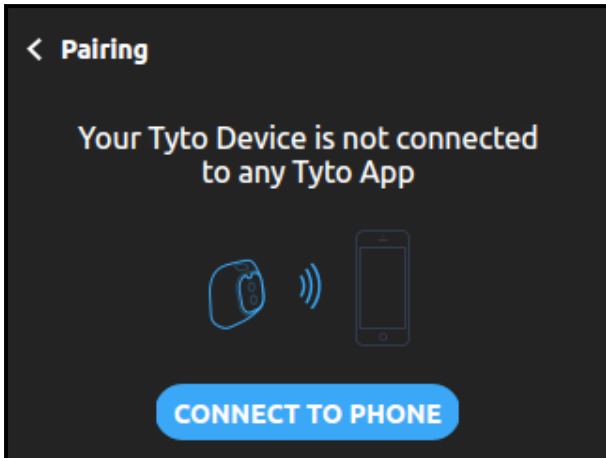


3. Follow the App instructions in Section [Pairing Procedure on First-Time Use](#)

4. When QR Code is displayed. Scan QR Code with device.



5.
 - A. Swipe down on the short line on the top of the device.
 - B. Tap **Pairing**.




6. Tap **CONNECT TO PHONE**, and then **SCAN BARCODE**.




7. Use the device camera to scan the QR code: Position the cross-hairs over the QR code displayed in the App



8. Success message will pop-up. Tap **OK** to continue.

 **Note:** Online visits, using only the video call, can also be started without having the Tyto device connected and also without connected to a Wi-Fi network by using 4G/LTE cellular connection. Please note that in such cases, where the Tyto device is not connected, and you're connected to a Wi-Fi network, you'll not be able to use the Tyto device.

 **Note:** In case the pairing is not successful, also after few scanning trials, and after restarting the device and app, then you can always use your smartphone's hotspot. A hotspot is essentially a Wi-Fi network provided by a smartphone, that can be used by the Tyto device.

Important: the hotspot must be provided by a smartphone, which is different than the one running the Tyto app. You can't use the hotspot on the iPhone/iPad you're using for the Tyto app.

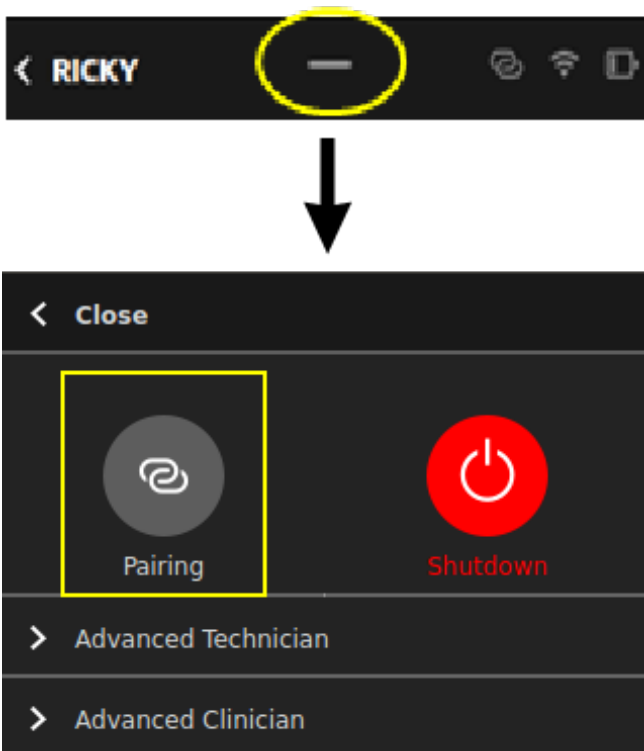
Please note that using a hotspot can also be helpful in cases where the clinician experience poor video or sound quality during the online visit, using your home or clinic Wi-Fi network.

Device Options Menu

The Device Options menu is always available if you require these facilities:

- Pair the device and the iPhone
- Shut down the device

You can access the device options menu by swiping down on the short line on the top of the device screen:



Pairing

Click **Pairing** on the menu to perform the Pairing procedure, as explained in item 7 in Section [Manual Pairing Procedure](#)

Pairing External Connected Devices

In case you have received an additional medical device with the Tyto Device, like an Omron Blood Pressure Monitor, you can use it as the source of external device.

You will be prompted to pair with the medical device upon first time use and before reading the exam, in case you have not previously paired.

Omron EVOLV – Blood Pressure Monitor

To start the pairing process, follow the instructions:

1. Start pairing from one of the below:
 - a. First time use dialog.
 - b. Open Settings and choose to pair with external Omron BPM.
2. Click the Pairing button on the Omron EVOLV device for **3 seconds** (marked in yellow below).



3. Approve the pairing request on your mobile device.

Shutdown

Click **Shutdown** to turn off the device.





Note: If you experience difficulty in shutting down the system, or if you experience a software crash, or if the device does not respond, you can force a shutdown. Press and hold the physical button on the top of the device for ten seconds to force the system to shut down.


Starting a visit

Cleaning instructions before use

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 alcohol wipes. Use the Q-tip swab, dipped in 70% alcohol, on narrow and less accessible surfaces, such as the otoscope lens, or the tongue depressor holder. Make sure the lens, located at the front of the camera, is clean.

 **Caution:** Do not immerse or soak the device in any solution or liquid.

 **Caution:** Do not use steam, heat, or gas sterilization on the device.

 **Caution:** Keep the device away from extreme heat, cold, solvents and oils.

A visit includes all the recorded exams for a single patient. Before starting a new visit, it is recommended to first identify the patient you are about to examine. Then, you can perform and record the needed exams.

When finished, you should tap "**Save Visit**" in the device to end and keep the visit, and then select how you would like to share it with a clinician – either by an online visit, featuring a video conference, or offline as an exam-and-forward visit.

In addition, if you wish to start the examination immediately, without identifying the patient in advance, you may choose the "Start Unidentified Visit" option, available through the device.

Please note that in any case, if you wish to save or share a visit with a clinician, you'll have to identify the patient at the end of the visit.

Note on Tyto Device Battery Saving Modes

Tyto device features a power consumption efficiency mechanism, which switches the Tyto device into sleep mode or shuts it down automatically when not in use, to save battery usage.

Tyto device triggers the following actions to save battery usage:

- **Exit Exam** - When Tyto device is not in use for one minute, while performing an exam, it will exit the exam automatically, and return to the Exam Selection screen.
- **Sleep Mode** - When Tyto device is not in use for one minute, and not performing an exam, it will enter sleep mode automatically.

During Sleep mode, the device's screen will be turned off. This mode is indicated by a blinking green light on the device. To exit sleep mode, press the physical button on top of the device.

-
- **Power Off** - When the Tyto device is in sleep mode for three minutes, without being re-stored to active mode, it will automatically turn itself off to save battery. When the device is turned on again, it will revert to its previous state automatically.



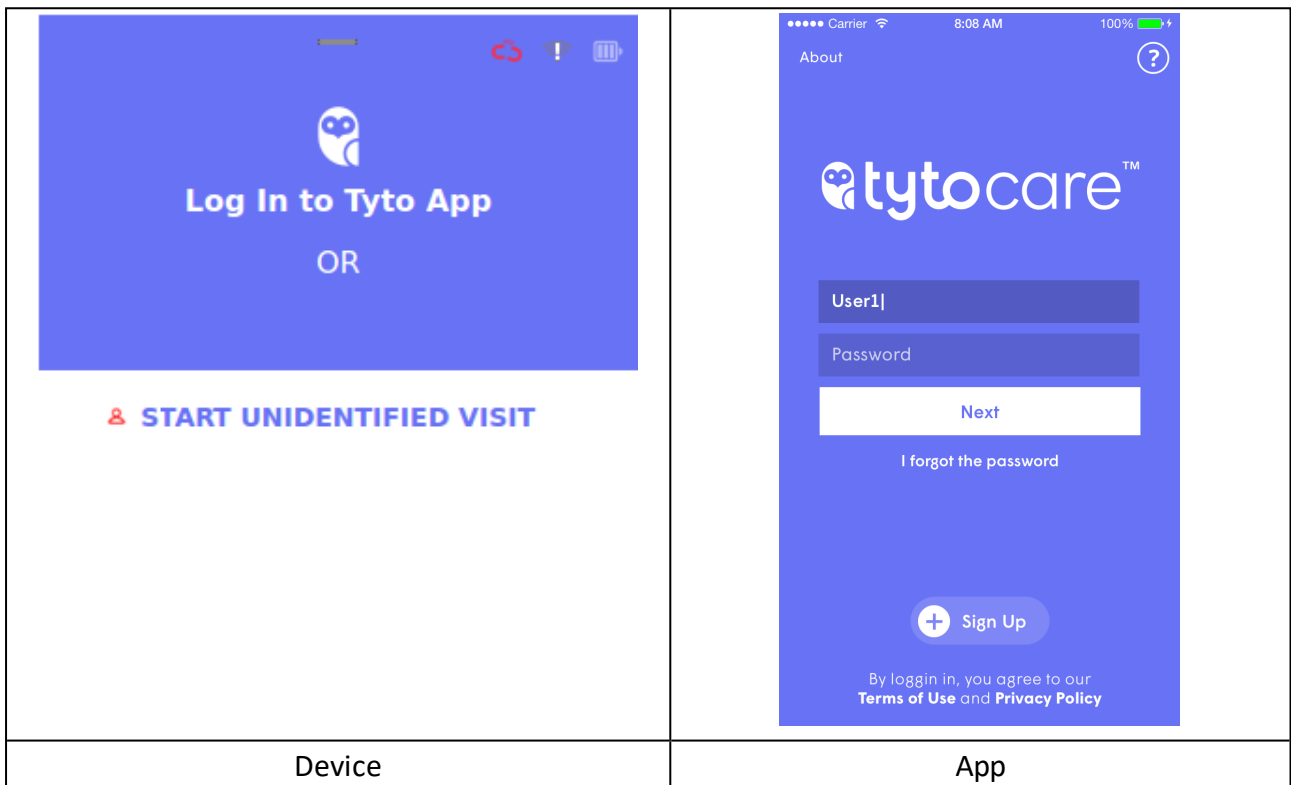
Note: “Not in use” means both the device’s screen has not been touched and it was not physically moved during the above period.

Performing an Identified Visit

An identified visit is one where the patient is identified at the beginning of the visit. This is the standard and recommended procedure. If you do not wish to identify the patient in advance, see Section [Performing an Unidentified Visit](#).

User login


After turning on the device and the App, the following screens appear:



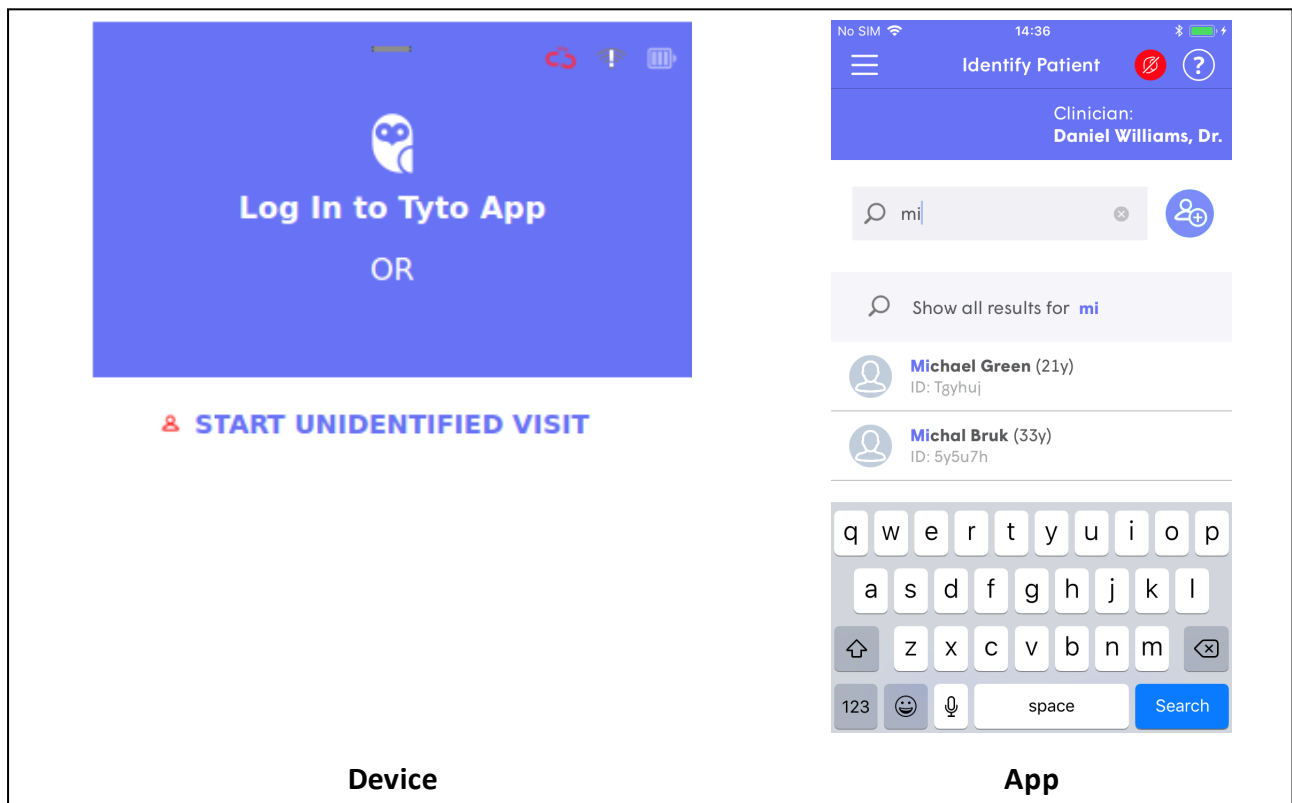
Please login using your **User name** and **Password** on the App. If you don't have your username and password, please contact your system administrator.


Identify patient

When identifying the patient:

- Type the patient name, first name and/or last name or patient ID.
- After typing the first two letters, the system will try automatically to match the relevant patients. You may continue typing the complete name or ID, or select the patient from the list.
- Tap the correct patient, or tap **Add New Patient**  if the patient was not found and you wish to add a new patient.
- When the correct patient is selected and highlighted, tap **Select Patient** to start the visit.

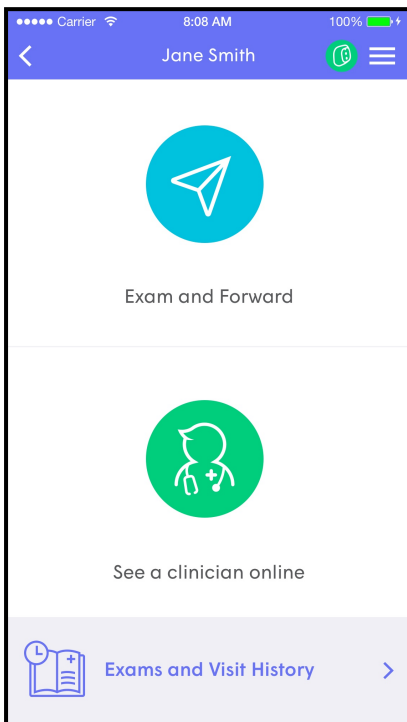
The Identify Patient screen appears in the Tyto app as follows:



 **Note:** After the patient is identified, their name will appear on the upper blue line in the Tyto app, which allows you to always know which patient is currently being examined.

Choose Type of Visit

The next screen on the App asks how you would like to perform the visit:



Exam-and-forward (offline) exam: Perform the examinations now independently, with the option later to send the exam results to another clinician or have an online visit using the examination data you have already collected.

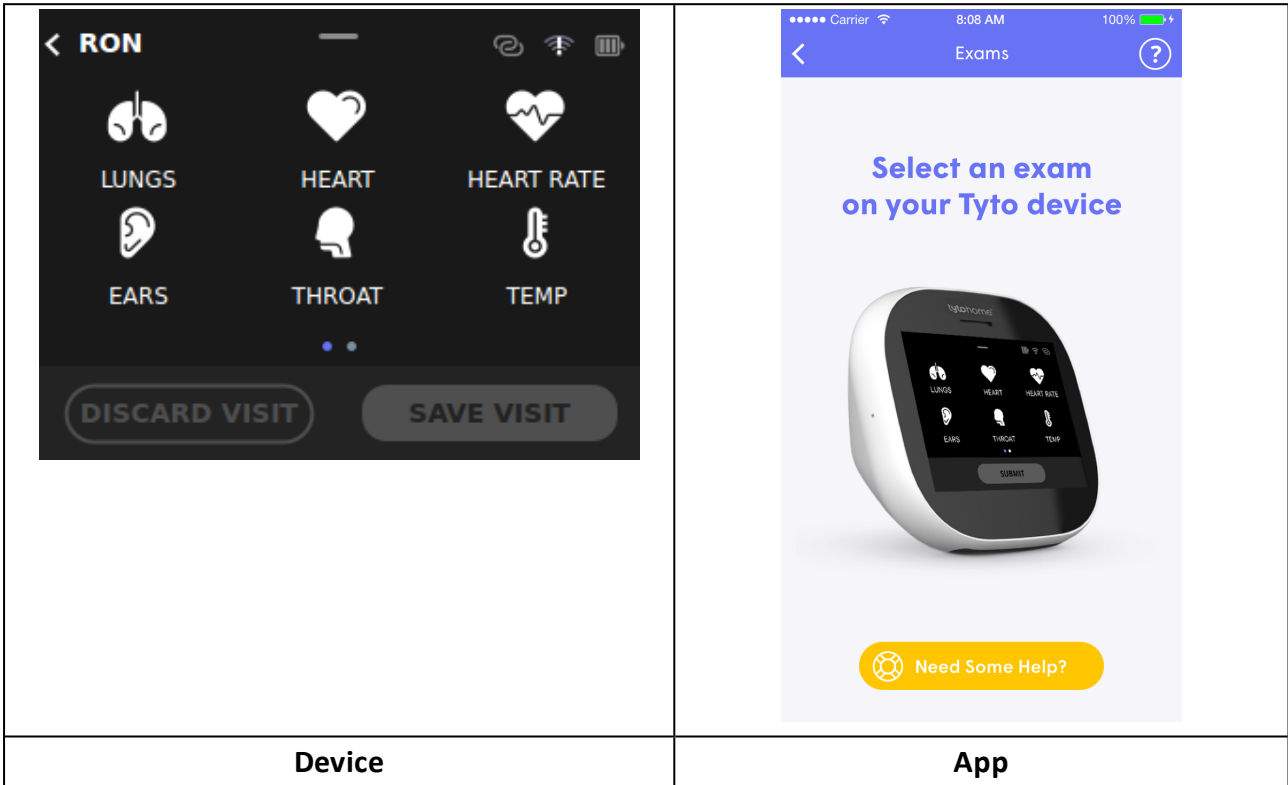
See a clinician online: Initiate an online video conference now with a clinician, before performing examinations.

The clinician will remotely control your device, and request that you perform exams under his guidance. For more details, see Section [Online Visit](#).

Inbox: This option displays the clinician’s notes of previous visits, as well as status of examinations yet to be sent to a clinician. For more details, see Section [Inbox](#).

Start Visit and Select Exams

After the patient is identified, and the **Exam-and-forward** option is selected, you can start performing the exams. The examinations are performed and managed using the device. Tap on the device screen to choose which type of exam to perform.



Note that in the identified visit workflow, the upper left corner of the device has the name of the patient (**RON** in this example).

Please note additional exams (Skin and Audio – not displayed here) are available in the second screen in the device. Swipe to the left, using your finger, to access the second exams selection screen.

⚠ Warning: Always make sure the correct patient is identified before starting a new visit.

Perform Exams

User Role Performing Unguided and Guided 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 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.

Unguided exams are intended for healthcare professionals, who have medical knowledge and experience in performing a physical exam, namely are proficient in heart and lungs auscultation, and in performing ears and throat exams. Unguided exams provide a streamlined approach allowing more flexible recording and faster operation, with minimal instructions for use.

Information in this Tyto Device User Guide is **identical** for Guided and Unguided users, as the difference between those two methods affects only the process of performing the exams themselves. The Add-Ons User Guides provide two sets of instructions, for both Guided and Unguided users.

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.

The exact instructions for each type of exam are described in the separate Add-On User Guides (Stethoscope, Otoscope, Exam Camera or Basal Thermometer). Refer to the appropriate User Guide for detailed instructions for performing the exam.

Exams and Add-Ons User Guides

Exam	Add-On	Reference
Ears	Tyto Otoscope	Tyto Otoscope User Guide (#760-00044)
Throat and Skin	Tyto Exam Camera (built-in)	Tyto Exam Camera User Guide (#760-00045)
Temperature	Tyto Basal Thermometer (built-in)	Tyto Basal Thermometer User Guide (#760-00046)
Heart, Lungs, Heart Rate, Audio	Tyto Stethoscope	Tyto Stethoscope User Guide (#760-00058)

Reviewing Recorded Exams

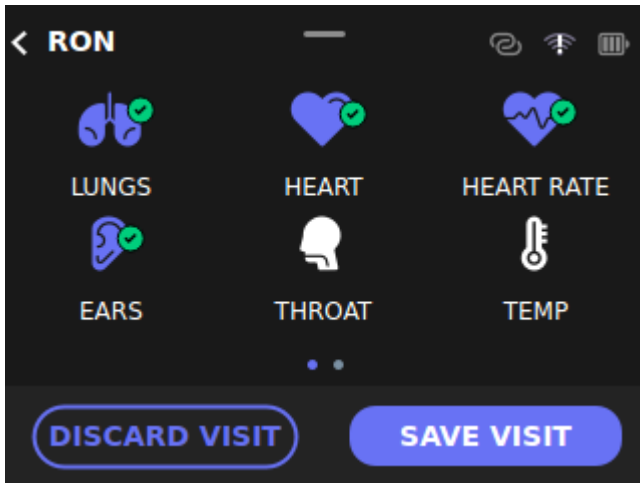
When an exam is recorded, it is marked in purple and with a green check mark on the device, and is listed on the App. You may re-do the purple marked exam by tapping it again. The existing recorded exam will be kept.

<p>The device screen displays a grid of six exam categories: LUNGS, HEART, HEART RATE, EARS, THROAT, and TEMP. Each category has a purple icon with a green checkmark, indicating it has been recorded. At the bottom, there are two buttons: 'DISCARD VISIT' and 'SAVE VISIT'.</p>	<p>The app screen shows a list of recorded exams. The top bar is purple and says 'Exams'. Below it is a button '+ Add external exam or data'. The list includes: 'General Exam', 'Heart Rate' (88 bpm), 'Heart', 'Temperature' (36.7 °C), 'Skin', and 'Lungs'. Each item has a right-pointing arrow. At the bottom, there is a purple button 'Finish Exam'.</p>
<p>Device screen, showing exams performed</p>	<p>App screen, showing list of recorded exams</p>


In the App, each recorded exam will be displayed as a separate line, allowing you to review the recorded exam (play sound, view video etc.). You may also delete the exam if desired. See Section [Review and Edit Exams](#) for more details.


Completing the Visit

When you finish examining the patient and you wish to complete the visit, you have two options, using the two buttons at the bottom of the device's screen:



1. **DISCARD VISIT** – Tap this option in case you don't see a need to keep the recorded exams for sharing with a clinician or any future use, and you wish to delete them. A confirmation pop-up message will ensure that you didn't press this option by mistake.

 **Caution:** discarding a visit is an irreversible action and all recorded exams will be deleted!

 **Note:** The Save and Discard visit buttons will become enabled after you perform at least one exam.

2. **SAVE VISIT** – After you click **Save visit**, you have a choice of several final actions, shown below. Note that if you are working in Unidentified Mode, you are also prompted at this point in the App to identify the patient.

Adding External Exams or Data

After you tap to save the visit in the device, you will then be able to review the recordings captured during the visit. In addition, you now have an option to add to the visit measurements or vitals from external medical devices, or relevant medical information. The added exams or data will be sent to the clinician, together with the Tyto exams.

If you wish to add such exams, tap “**Add External Exams or Data**”, displayed on top of the Tyto exams.

Then, tap the type of measurement you would like to add.

The following measurements (vitals) can be added:

- Blood Pressure – Enter the systolic and diastolic values, as displayed on the Blood Pressure monitor you have used.
- Blood Saturation (SpO2) – Enter the blood saturation level, as measured by the Pulse Oximeter you have used.
- Weight – Enter the patient’s weight, as measured by the weight scale you have used.
- Blood Glucose – Enter the patient’s glucose level, as measured by the glucometer you have used.
- Other – In case you would like to add additional measurement, not mentioned above. use this option, and take a picture of the medical device you have used.

After you entered the measurement result, and verified it is correct, tap **Done**.

To allow the clinician to see the type of medical device you have used (brand, model etc), and to accompany the result you typed in, please take a picture of the external medical device you have used.

Tap **Add a picture**, and then you can either tap **Take Picture** to take a picture of the screen of the medical device now, using your iPhone/iPad’s camera, or tap **Photo Library** in case you’ve already took that image, and you want to upload it from your camera roll.

When choosing **Take Picture**, aim the iPhone/iPad’s camera towards the screen of the medical device. Make sure the measurement result is seen clearly, without reflections. When ready, tap the blue dot to capture the image. If you wish to switch to the front camera, tap the switch camera icon, located at the upper-right corner.

When choosing **Photo Library**, tap the relevant picture from your camera roll.

In case the measurement result is not seen clearly, tap **Retake a picture** to capture again the medical device’s screen. In addition, you can delete the captured image using the **Delete** icon, located at the bottom-right corner of the image.

If you wish to provide the clinician with a comment concerning the measurement result, for example, if you’ve just eaten or took some medicine before the measurement, then tap **Add a comment** to elaborate on the result.

You can also include Lab Results and Medical Documents as part of the Tyto Visit you’re sending to the clinician.

Such medical documents could be a summary of your medical history, previous admissions or your doctor’s notes from your last appointment to the clinic.

Tap **Add External Exams or Data**, and then either **Lab Results** or **Medical Documents**. Then, take a picture of those documents using the iPhone/iPad’s camera, as described above under **Add a picture**.

Using Connected External Devices

When selecting an external exam of the type supported by your connected external device, you will be prompted to start the relevant exam.

Omron EVOLV – Blood Pressure Monitor

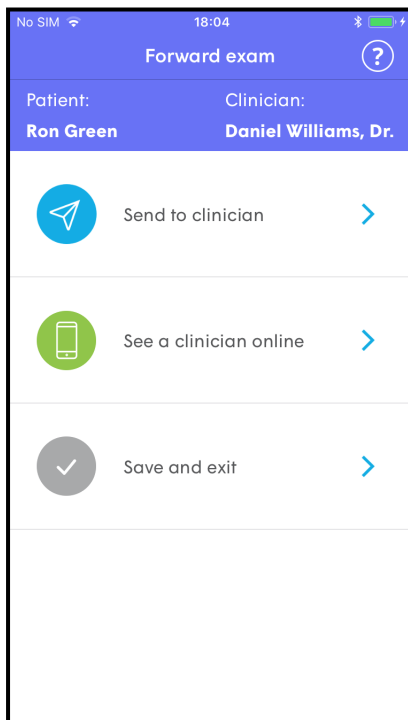
1. Select the Blood Pressure exam.
2. Make sure your mobile device’s Bluetooth is enabled.
3. Perform the Blood Pressure exam with the Omron EVOLV device.
4. Wait a few seconds after a successful reading.
5. Look at the results on the App, and approve if they are identical to your expectations.

Note: If you prefer, you can skip the connected reading and enter the results manually

Note: The reading shows the time of day in which the measurement was performed.

Once finished reviewing the recorded exams, and optionally adding external exams or data, click **Finish Exam** to upload the recordings, and continue to the next step.


Please note this upload process might take some time, depending on the number of exams done and your internet connection speed.



Send the recorded exams for this visit to a clinician for their review (“exam and forward”). You’ll be then asked to choose the clinician who will review the recorded exams.

Request an **online video conference** with a clinician. The recorded exams will be shared with the clinician before the online visit begins, to allow review before seeing the patient. See Section [Online Visit](#) for further instructions.

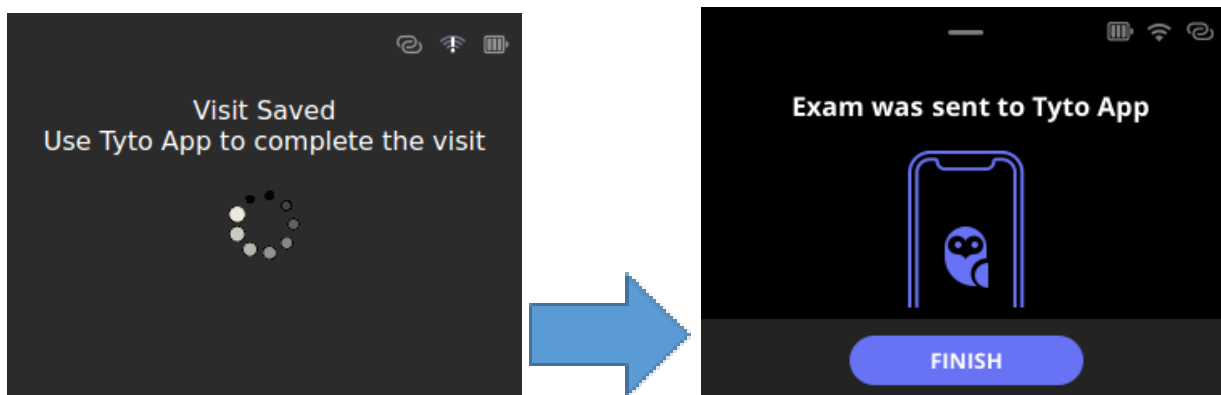
Save and exit this visit without sending it to anyone. The recorded exams will be saved for future use, such as having complete exams history for the patient, e.g. to allow comparison over time of a clinical condition, or to allow consultations between clinicians using the Clinician web application.

 **Note:** In case there is an error connecting to the server and uploading the saved exams, make sure you have an internet connection, and choose one of the above options again. If this error persists, please contact TytoCare Support.

 **Note:** TytoCare doesn't verify the reliability of the External Exams or Data.

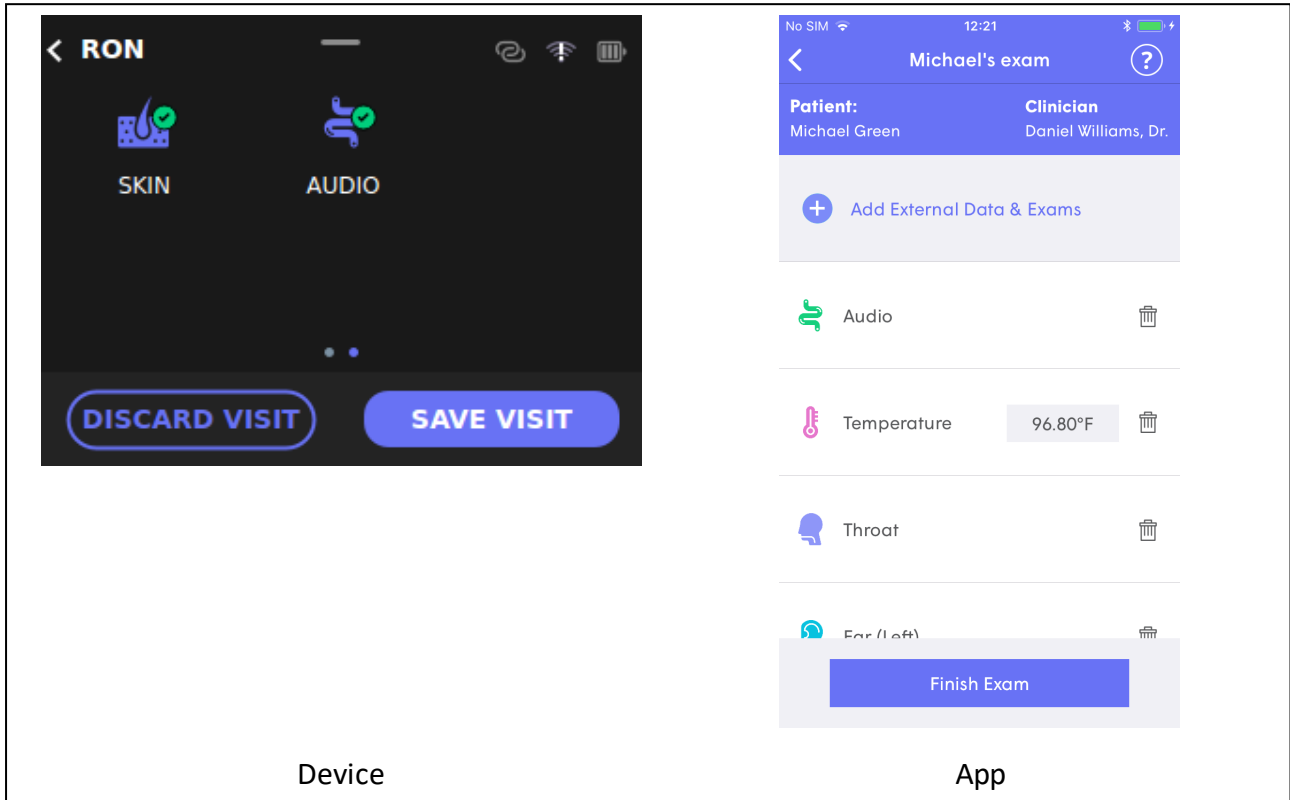
Confirmation screen after Save visit

After you press Save visit, the recordings will be sent to the Tyto App. Once completed, a message is displayed on the device confirming the visit was sent to the Tyto App.



Review and Edit Exams

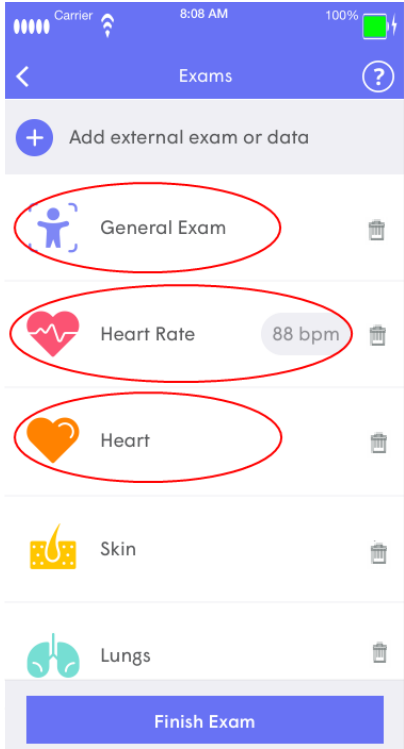
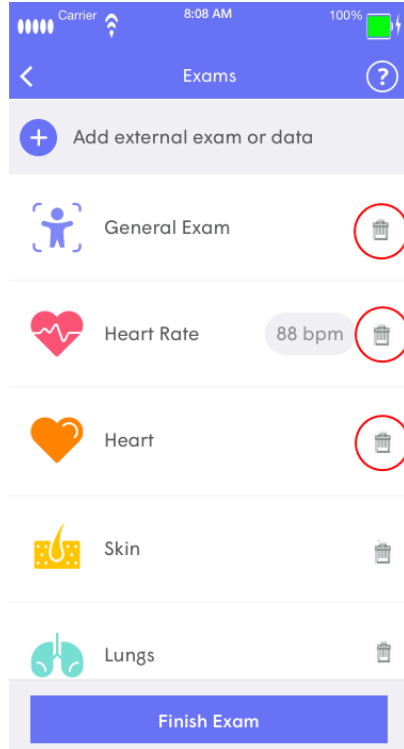
After you have completed an exam, the App will display a list of all exams performed during the visit:



You can now perform several actions in the App:

- Listen to the recorded Heart or lungs auscultation
- View an ears or throat exam’s video, or discard (delete) an exam – See Section [View or delete an exam’s video](#).
- View and Tag a skin exam’s pictures – See the Tyto Exam Camera User Guide.

View or delete an exam's video

To view an exam's video, tap on the exam in the list of exams displayed by the App:	To delete an exam, tap the Delete icon next to the exam:
 <p>The screenshot shows the 'Exams' screen with a list of exam types: General Exam, Heart Rate (88 bpm), Heart, Skin, and Lungs. A 'Finish Exam' button is at the bottom. Red circles highlight the 'General Exam', 'Heart Rate', and 'Heart' entries.</p>	 <p>The screenshot shows the same 'Exams' screen. Red circles highlight the delete icons (trash can) located to the right of the 'General Exam', 'Heart Rate', and 'Heart' entries.</p>

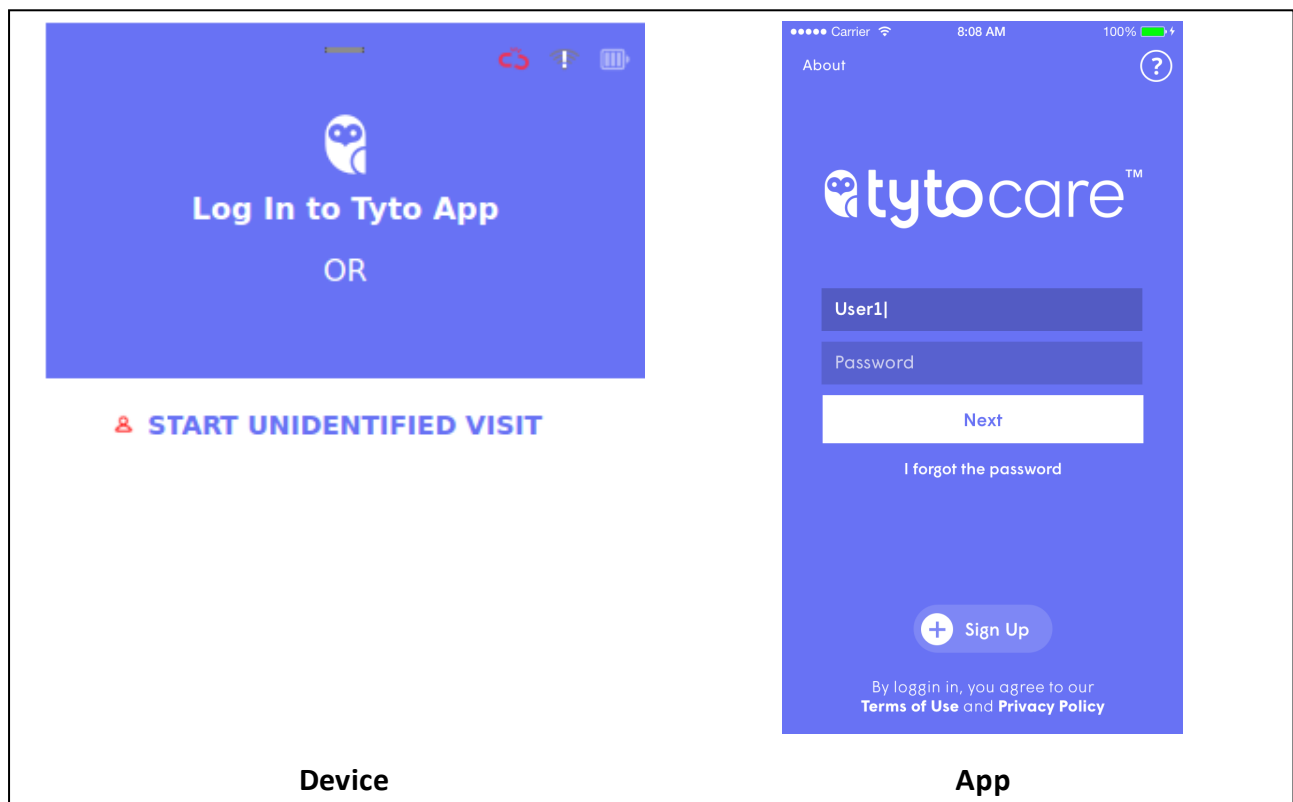
Performing an Unidentified Visit

An unidentified visit allows you to perform an exam without identifying the patient in advance.

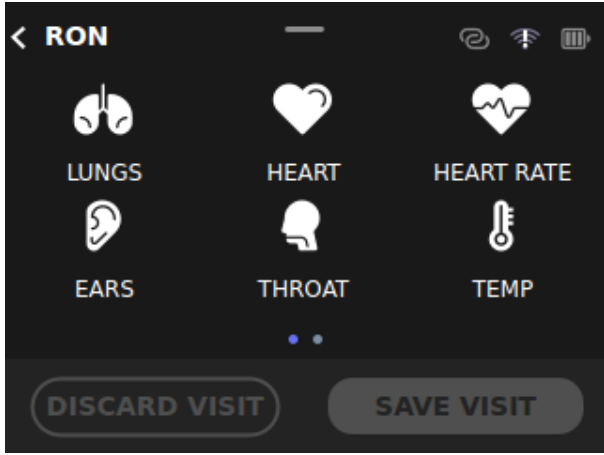
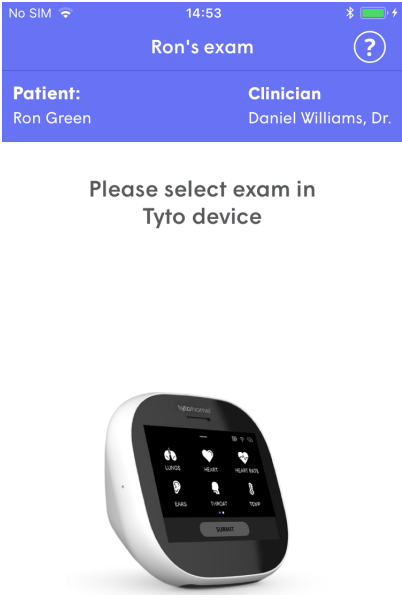
Note: When performing exams for an unidentified visit, you may work with the device only – the App is not mandatory in that case.

User Login (Optional) and Start Unidentified Visit

After turning on the device and the App, the following screens display:



1. The user app login is optional when performing an unidentified visit. If you wish to log in, enter your **User name** and **Password** on the App. It is recommended to login to the app to have the videos displayed during exams or be able to review recorded exams.
2. Tap **START UNIDENTIFIED VISIT** displayed on the white bottom line of the device. Note that you may start an unidentified visit also after you've logged in to the app.

	
<p>Device</p>	<p>App</p>

Note that in the unidentified visit workflow, the upper left corner of the device has a red icon.

Performing Exams

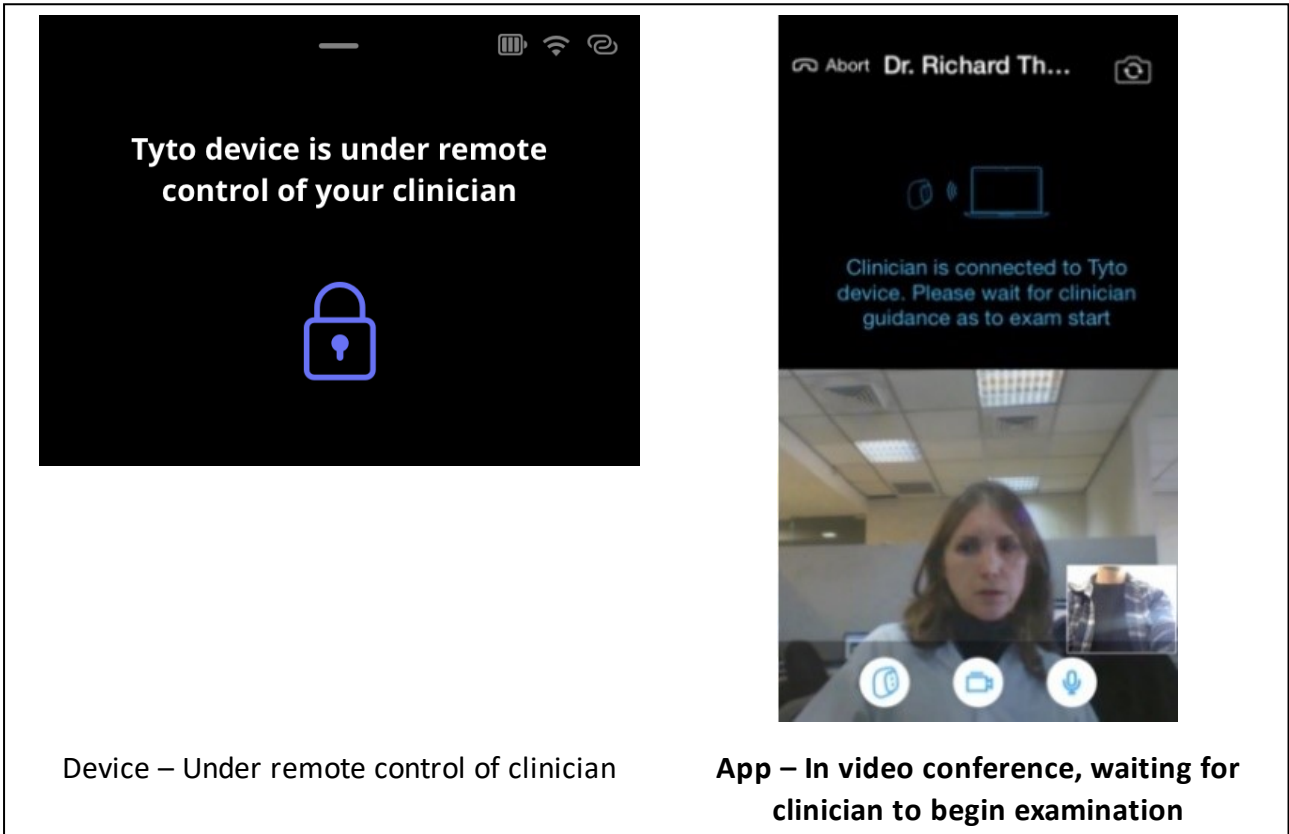
Performing Exams in unidentified mode is identical to the identified mode. Refer to Section [Perform Exams](#) for detailed instructions for performing the examinations. Please note when you press the Save Visit button on the device, you'll be prompted to identify the patient in the app.

Receive Confirmation and Wait for Clinician

After you receive the confirmation message, “Waiting for clinician”, please wait for the clinician to respond. This may take some time depending on clinician availability.

Clinician Accepts Your Online Visit Request

Once the clinician accepts your visit request, you are prompted by the Tyto App to accept the video conference. Click “Join” to initiate the video conference and activate your iPhone camera.



Device – Under remote control of clinician

App – In video conference, waiting for clinician to begin examination

Now you’re connected with the clinician, who will remotely control your device and will guide you through the exam process. A yellow outline on the device screen indicates that the device is under remote control.

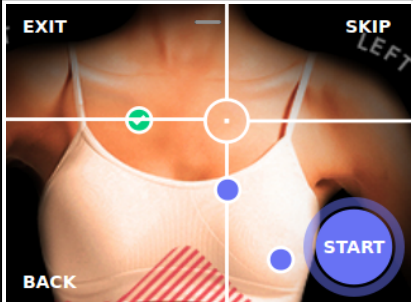
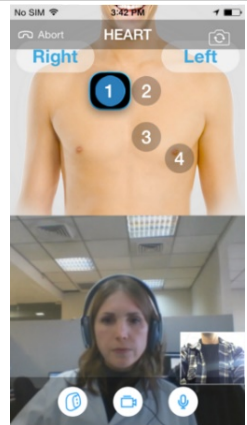
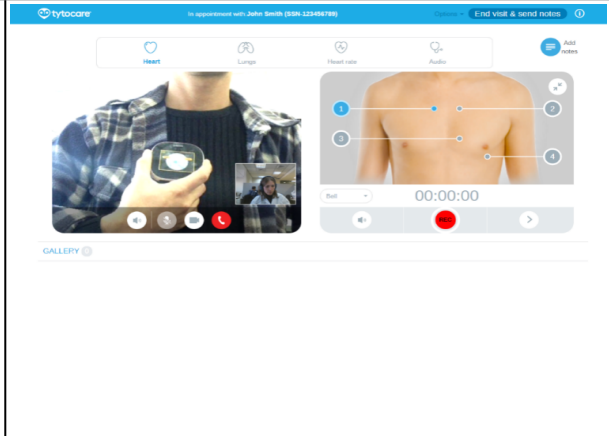
Using the Phone Stand



To operate the device during a video conference, place the iPhone on the designated location on the upper side of the carrying case. Make sure you position the iPhone camera so the clinician can see where you are placing the device on your body.

Clinician Begins Exam

Once the clinician selects the relevant exams, these will automatically appear on your device and Tyto App screens. See the example below, of a heart exam performed during an online visit with a clinician.

		
<p>Example of Device display during an online heart examination</p>	<p>Example of Tyto App display during an online heart examination</p>	<p>This is what the clinician sees during the examination</p>

Follow the clinician instructions and the indications on the device screen regarding proper placement of the device on the body.

Using a Connected External Medical Device

When requested by the clinician, you can use an external connected device, provided with the Tyto Device, to send the clinician additional exams

Omron EVOLV – Blood Pressure Monitor and Weight

Perform the blood pressure exam or the Omron weight and approve the result when prompted on the app screen.

If not yet paired, you might be prompted to approve the pairing.

Performing the Exam with Poor Network Conditions

When the online visit is performed with poor network conditions, the clinician might decide to disable the video streams, except for the video from the Tyto Device to the Clinician.

You will be able to continue communicating with the clinician by voice.

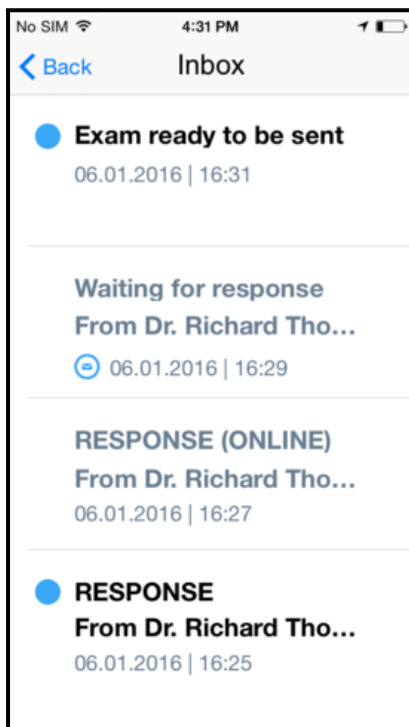
In case you need to watch the Device video in the App, you can enable the Device video on the App by clicking the **“ACTIVATE VIDEO”** button.

Completing the Online Visit

After the visit is completed by the clinician, you will receive a summary notes of the visit automatically, which will be available through the Clinician’s notes. In addition, a notification will be sent to you when the clinician's notes are ready for your review.

Inbox

The Inbox screen shows the status and clinician’s notes for all of your examinations.




Exam ready to be sent means that an exam was performed and was not sent to a clinician yet.

Waiting for response means that an exam was sent to a clinician, but there is no response yet.

RESPONSE (ONLINE) means that you have performed an online exam and received the clinician’s response.






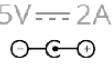












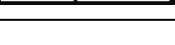
RESPONSE means that you have sent an Exam-and-forward exam for clinician review and have received the clinician’s response.

User Settings

For various functionalities which are not related to the visit, tap **Settings Menu**  .

System Labels and Symbols

Explanation of Symbols

	BF Applied part
	Type B Applied part
	Water proof in IP22 level
	Must read User Manual before use
	UDI barcode contains Serial Number and Part Number
	Input Voltage level
	Manufacturing Address
	Product Serial Number
	Product Model Number
	FCC approval
	Do not dispose
	Storage temperature limits
	Storage humidity limitations
	Keep device dry
	Package is recyclable
	Non-Sterile
	Do not re-use
	Caution
	EU Authorized Representative

Technical Specifications

Tyto Device	
Dimensions	3.35 x 2.87 x 1.85 inch (85 x 73 x 47mm)
Weight	0.33 lbs. (0.15kg)
Display	2.4" LCD touch screen
Battery	Li-ion, built-in, rechargeable
Typical battery life	Up to 400 cycles of charge/discharge
Audio output port	Standard 3.5mm headphone connector
Power input	Proprietary plug, 5Vdc, 2.0A
Tyto Camera	
Max Sensor Resolution	5 MP
Max Video Resolution	640x480 (VGA)
Illumination	LED, Embedded
Tyto Stethoscope	
frequency range	20 - 3,500Hz
Heart rate range	30 - 250 BPM,
Audio output	3.5mm standard headphone connector
Dimensions	1.57 x 1.53 inch (40 x 39 mm)
Weight	0.13 lbs. (0.06kg)
Tyto Otoscope	
Image resolution	640x480 (VGA)
Tip diameter	0.16 inch (4.2mm)
Disposable speculum	Adult – 0.16inch (4mm); Child – 0.12 inch (3mm)
Weight	0.044 lbs. (0.02kg)
Tyto Tongue Depressor	
Blade length	Adult (L8): 3.15 inch (80mm); Child (L6): 2.36 inch (60mm)
Weight	0.024 lbs. (0.011kg)
Tyto Basal Thermometer	
Temperature range	34.4° – 42.2°C (94.0° – 108.0°F)
Laboratory Accuracy	0.2°C (0.4°F) accuracy for 36° - 39°C (96.8° – 102.2°F) range 0.3°C (0.5°F) accuracy outside the above range. Complies with ASTM E1965-98 (2009)
Resolution	0.1°C (0.1°F)

Wireless Network	
Wireless comm. standard	IEEE 802.11 N (recommended) \ G
Frequency band	2.4 GHz only *
Security protocols	WPA, WPA2 **
Encryption protocols	TKIP, AES
Connection speed (relevant mainly for online)	Recommended: download: 15 Mbps \ Upload: 3 Mbps Minimum: download: 5 Mbps \ Upload: 2 Mbps
Software	
TytoCare App	Operating System: <ul style="list-style-type: none"> ▪ iOS 10 and up Apple models: iPhone 5S and up, iPad Air and up, iPad mini 3 and up, iPod touch 6 and up
Clinician Web App	Supported web browser: Google Chrome only For online visit: Microphone, webcam and high-quality headphones are required.
Operating Conditions	
Temperature	5° – 40°C (41° - 104°F) For Tyto Basal Thermometer: 16° – 40°C (60.8° - 104°F)
Humidity	15 - 70% (non-condensing)
Storage Conditions	
Temperature	-20° – 60°C (-4° - 140°F)
Humidity	15 - 70% (non-condensing)
Atmospheric pressure	700hPa to 1060hPa

* 5GHz band is not supported

** Not supported:

- WPA-Enterprise using a RADIUS authentication server (802.1x)
- HTTP proxy server authentication
- WEP

Wi-Fi password is mandatory.

Appendix A. Forgot Password

If **I forgot the password** is tapped in the login screen of the TytoCare App, the user will need to enter the email address they used during the registration process and tap **SEND**. An email with the reset password will be sent to the email address.

To update the password, fill in the old password, then the new password, then a repetition of the new password, and tap **SAVE**.

Appendix B. Wireless Network Requirements

The following Wi-Fi network specifications are supported by the Tyto device.

1. IEEE 802.11 N standard is recommended for optimal performance.
 - a. G standard is also supported.
2. 2.4 GHz band only.
 - a. Please note that 5GHz / AC standard is not supported.
3. WPA-PSK and WPA2-PSK security standards.
 - a. Both TKIP and AES encryption protocols are supported.
 - b. WEP encryption is not supported.
 - c. Please note that a Wi-Fi network password is mandatory to use the TytoCare device and app.
4. WPA-Enterprise using a RADIUS authentication server (802.1x) is not supported.
5. AP (access point) isolation (also known as “Client Isolation”, “Guest Mode” or “Inter client connection”) should be disabled in the router configuration.
 - a. Please note that this configuration is usually disabled in home use networks.
6. Web connection proxy, which requires accepting network terms and conditions, is not supported.

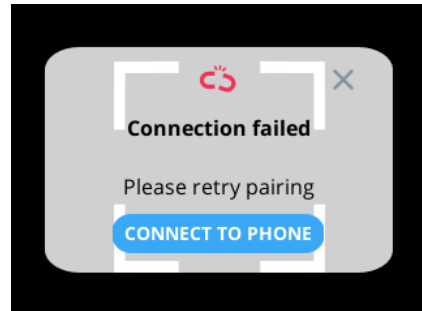
Appendix C. Frequently Asked Questions and Troubleshooting Tips

Why can't I pair/connect the device and my Phone/Tablet running the Tyto App?

You may see one of these screens while attempting to connect the iPhone to the device:



Waiting for connection



Cannot connect

In order to establish a connection between the device and Tyto App, a Wi-Fi connection is required. Make sure that your Wi-Fi network is working properly and that your iPhone is connected to it. Make sure that the Wi-Fi network password that you have is the right one (try it on your iPhone). Make sure your Wi-Fi network meets the router requirements described in Appendix B. Try not to be located too far away from the Wi-Fi router. Then retry the pairing process by generating the QR code in the Tyto App and scanning it with the device. If the problem persists after several attempts, contact TytoCare Service.

Why doesn't my device turn ON?

It might not be charged. Connect the charging cable to the Device and to the USB charger. Let it charge for at least several hours. You should see an orange LED near the Base Unit LCD indicating that the Base Unit is charging. After charging, when the LED indicator is green, disconnect from the charging cable and turn the base unit on. If the problem persists, contact TytoCare Service.

Why can't I login into the Tyto App?

Try checking your user login details (username/password). Make sure you have internet connection on your iPhone. Also, try "killing" the app, i.e. double-click the main round circle button of the iPhone/iPad and swipe up the Tyto App. If this does not work, go through the "Forgot Password" flow in Appendix A, which will generate a new password. If the problem persists, contact TytoCare Service.

Why can't I get a good signal when performing an exam?

Try to eliminate external noise when doing the exam. Also, do not move the device on the body when recording a measurement and make sure the device is in full contact with the patient's body. Make sure the device is placed firmly on the patient's body and if possible place it directly on the patient's skin. If the problem persists, contact TytoCare Service.

Why is the Tyto App not allowing me to START the exam?

During an exam, the Tyto App is **not** used to conduct the exam. The device is used to perform the exam.

The picture on the Tyto App is a fixed representation of the device screen and is for informational purposes only.

My Tyto device is stuck. I see a TytoCare blue screen. What can I do?

Force shut down of the device by pressing down the upper physical button of the device continuously for 10 seconds.

Why my Tyto device is not charging?

There are two similar ports on the bottom side of the device, one is for charging (smaller) and the other is to connect headphones (larger). Ensure the charging cable is being inserted into the correct port and the orange LED is lit.

The image seen on the video exams (Ears, Throat or Skin) is not sharp / blurry. What can I do?

One reason could be the camera lens is dirty or wax is adhered to the otoscope lens:

For the Ears exam, clean the lens at the tip of the otoscope thoroughly, using 70% isopropyl alcohol wipes or cotton swabs (q-tips) dipped in 70% isopropyl alcohol.

For the Throat and Skin exams, clean the camera lens at the front of the device, using 70% isopropyl alcohol wipes.

Another reason could be the image is not focused. During the throat or skin exams, touch the device screen, at the area of interest, to apply auto-focus. In the skin exam, make sure the camera is not too close to the skin.

Appendix D. Electromagnetic Compatibility (EMC) Information

Table 1. Declaration – Electromagnetic Emissions



Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class B	The TytoCare Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	<p>The TytoCare Device is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</p> <p> Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the TytoCare Device or shielding the location.</p>
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

Table 2. Declaration – Electromagnetic Immunity

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<p>NOTE UT is the AC mains voltage prior to application of the test level.</p>			

Table 2. Declaration – Electromagnetic Immunity (continued)

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Tyto Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	<p>10V/m</p> <p>3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz</p> <p>10V/m from 80MHz to 2.7GHz</p>	<p>10V/m</p> <p>3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz</p> <p>10V/m from 80MHz to 2.7GHz</p>	$d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>D Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Recommended separation distances between portable and mobile RF communications equipment and the Tyto Device				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}] \sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}] \sqrt{P}$
0, 01	0.12	0.2	0.4	1
0, 1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠ Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.


⚠ Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TytoCare Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 3. Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28

Table 3. Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (continued)

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5500							
5785							
<p> Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the TytoCare Device may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.</p> <p>a) For some services, only the uplink frequencies are included.</p> <p>b) The carrier shall be modulated using a 50 % duty cycle square wave signal.</p> <p>c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p>							