

**TytoHome™**

**Important Safety Information**

## **IMPORTANT SAFETY INFORMATION**

Please read, view, understand and follow all safety information contained in this document and the user manual prior to using the TytoHome™ unit. For complete instructions, please refer to the User Manual, which is available through the TytoApp either through the About screen before login, or through the Menu icon at the top-right corner after login.

You should retain these printed instructions for future reference.

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

### **Intended use for Tyto Otoscope**

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

### **Intended use for Tyto Stethoscope**

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 to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis.

### **Intended use for Tyto Exam Camera**

The Tyto Camera is an electronic camera that enables capturing and transmission of video and still images of throat (with/without tongue depressor) and skin, whereby a clinician at one location on an IP network can view images and videos of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations.

### **Intended use for Tyto Thermometer**

The Tyto Thermometer is a non-contact clinical infrared thermometer intended for intermittent determination of human body temperature from the center of the forehead on people of all ages. The Tyto Thermometer is intended for use by both adult lay users and clinicians. It can be used both at home and in clinic environments. **In Canada:** Not recommended for children aged 2 years and under.

**Contraindications:** None known.

**Unpacking** - View the Instruction Video on unpacking available on the Tyto App.

Make sure that all parts of the TytoHome™ Device were properly shipped.

## General Safety Messages

### **Warnings:**

- 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 any 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.
  - Do not use device during defibrillator use.
  - Do not use the device on an open wound or on infected skin.
  - 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.
- Other equipment could interfere with the Tyto Device, even if the other equipment complies with CISPR emission requirements.
- If the Tyto Device does not respond due to EM phenomena, 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 and restart.
- 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.

- 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 Tyto Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

#### **Cautions:**

- 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, the splash screen does not appear, or if 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** option in the menu will erase all device settings and data, and will restore the device to its initial as-new state.
- Examinations cannot be performed while the device is charging.
- Use only the charging cable provided with the device. If the device doesn't 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:**

- If for any reason you cannot perform the connection between the device and the TytoApp, 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 TytoApp 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 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).

A medical diagnosis should only be provided by a physician.

Contact with solvents can cause severe deterioration of the plastic parts and malfunctioning of the instrument and accessories.

If the device image quality is poor, please contact TytoCare Support.

The Tyto Device consists of high-quality precision parts. Do not drop the instrument. Protect it from severe impact and shock.

Never insert a sharp object into the scanner area or any other open surface of the device.

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

The device has been designed for practical use, but is not a substitute for a visit to the doctor/clinician.

If for any reason you cannot perform the connection between the device and the TytoCare App, contact TytoCare Support.

The device connection screen in the TytoApp should only be used to connect to another device or to disconnect from an existing device.

## Tyto Otoscope

### **Note:**


- Do not use disposables that have cracks or contain sharp edges.
- Discard the disposable ear speculum after use.

### **Warning:**

- When starting an ear exam, it is important to select the correct ear (left or right), and to correctly identify the side that you are recording. Mixing between sides could mislead the diagnosing clinician.


- Be careful NOT TO TOUCH THE EARDRUM. If the canal is blocked or obstructed by wax / cerumen, stop the examination and pull back the Tyto Otoscope.
- Stop once you get a view of the eardrum. Do not push the Tyto Otoscope any further! You can use the yellow dotted circle as a guide to know when you are too close to the eardrum. During an online visit, update the clinician when you see the eardrum.
- Do NOT let the tip of the Tyto Otoscope get too close to the eardrum. It must NOT touch the eardrum.
- When performing an online exam while the clinician experiences poor network conditions, the TytoApp might stop displaying the video. In case of self-examination, it is important to tap **ACTIVATE VIDEO** to resume the Otoscope video playback.

## Tyto Stethoscope


 **Note:** Who can use the Tyto Stethoscope:

- Adults aged 18-65.
- Persons comfortable using mobile apps.
- Persons able to manage their own healthcare.
- If you wear eyeglasses, contacts or hearing aids,

please use them while using the Tyto Stethoscope.

 **Warning:** Wheezing and respiratory issues can progress quickly and be fatal. The Tyto Stethoscope is not intended for self-diagnosis, and results should be referred to a professional. The local emergency number should be called in the event of any respiratory event that causes concern.

The device has been designed for practical use, but is not a substitute for a visit to the doctor.

 **Note:** Interpreting stethoscope recordings / auscultations requires professional training and self-diagnoses is not recommended.


Sending Recordings: Stethoscope recordings of the heart and lung may contain information that can be used to diagnose and monitor severity of diseases, like asthma or bronchiolitis.


Please check TytoApp instructions how to send recordings to your physician or another party.

## Tyto Exam Camera

When performing a Throat exam, if the tongue depressor disconnects from the tongue depressor holder, for example by the patient biting the tongue depressor, gently pull the tongue depressor out of mouth, or wait until the patient releases the tongue depressor.

## Tyto Thermometer

 **Note:** The Tyto Thermometer is a non-contact forehead thermometer. The reading displayed is equivalent to oral thermometer temperature.

 **Note:** When prompted, **aim the thermometer at an inner wall, at about the height of the patient** and tap **Start Calibration** to start the calibration process and measure the room temperature.

### **Caution:**

For the most accurate results, the Tyto Thermometer and patient should remain in the same environment and at room temperature for 30 minutes before performing the measurement.

Please follow the general safety precautions when using on children.

Remove any sweat prior to measuring with a dry cloth.

Avoid any cooling or warming cloths on the forehead for at least 30 minutes prior to measurement.

Before taking a measurement, remove dirt or hair from the forehead area. Wait 10 minutes after cleaning the forehead area before taking measurement.

Keep the measurement sensor clean. Avoid directly touching the sensor.

### **Note:**

The Tyto Thermometer has been clinically tested and proven to be safe and accurate when used in accordance with the user guide. Please note that using the thermometer not in accordance with the operation, storage and cleaning instructions may lead to inaccurate temperature measurement.

The temperature measurement must be taken on dry skin. Perspiration on the skin can adversely affect the results.

Temperature elevation may signal a serious illness, especially in neonates and infants, or in adults who are old, frail, or have a weakened immune system. Please seek professional advice immediately when there is a temperature elevation and if you are taking temperature on:

- Neonates and infants under 3 months (consult your physician immediately if the temperature exceeds 37.4°C [99.4°F]).
- Patients over 60 years of age (fever may be blunted or absent in older patients).
- Patients having diabetes mellitus or a weakened immune system (such as HIV positive, cancer chemotherapy, chronic steroid treatment, splenectomy).





- Patients who are bedridden (such as nursing home patient, stroke, chronic illness, recovering from surgery).
- A transplant patient (such as liver, heart, lung, kidney).


Do not allow children to take their temperatures unattended.


Even in the absence of fever, please consult your clinician if you see symptoms such as unexplained irritability, vomiting, diarrhea, dehydration, changes in appetite or activity, seizure, muscle pain, shivering, stiff neck, pain when urinating, etc.


Even in the absence of fever, those who exhibit a normal temperature may still need to receive medical attention. People who are on antibiotics, analgesics, or antipyretics should not be assessed solely on temperature readings to determine the severity of their illness.


 **Note:** It is important to know each individual's normal temperature when they are well. This is the only way to accurately diagnose a fever. Take multiple readings when healthy to determine normal temperature.


 **Note:** A child's normal temperature can be as high as 37.7°C (99.9°F) or as low as 36.1°C (97.0°F).

 **Note:** This thermometer reads 0.5°C (0.9°F) lower than a rectal digital measurement.

 **Note:** Always hold the thermometer and the forehead steady when taking a reading. Do not move the thermometer until you hear the final beep. Do not take a measurement while or immediately after nursing a baby.

 **Note:** Patients should not drink, eat, or be physically active before/while taking the measurement. Remove hats and wait 10 minutes before taking a temperature measurement.

 **Note:** Always take the temperature exactly as directed. Temperature results may vary if positioned in the wrong location.


 **Note:** In the following situations, it is recommended that three temperature readings be taken in the same location and the highest one taken as the reading:

- Children under three years of age with a compromised immune system and for whom the presence or absence of fever is critical.
- When users are learning how to use the thermometer for the first time until they familiarized themselves with the instrument and obtains consistent readings.

## Cleaning and Disinfection Instructions Before Use

The Tyto Device should be low level disinfected in between uses. Make sure that the Tyto Device is turned off and thoroughly wipe the device's exterior with 70% isopropyl alcohol wipes or with pads impregnated with 70% ethyl alcohol. Allow the Tyto Device to air dry for at least two minutes before taking a measurement.


Make sure the tongue depressor holder and blade are disinfected before each use, using wipes or cloth moistened with 70% isopropyl alcohol or with pads impregnated with 70% ethyl alcohol. Thoroughly wipe the tongue depressor holder and blade and allow it to air dry for at least two minutes. Don't reuse the tongue depressor if you notice signs of material degradation such as scratches.

 **Note:** As the Tyto Stethoscope is placed directly on the skin, please use wipes or cloth moistened with 70% isopropyl alcohol or pads impregnated with 70% ethyl alcohol to disinfect the Tyto Stethoscope membrane (black surface touching the skin) before each use.

Thoroughly wipe the Tyto Stethoscope membrane and allow it to air dry for at least two minutes.

Use a Q-tip swab dipped in 70% isopropyl/ethyl alcohol on narrow and less accessible surfaces, such as the otoscope lens or the tongue depressor. Make sure the

lens, located at the front of the camera, is clean.

 **Caution:** Never use abrasive disinfecting agents, and never soak the device in water or other disinfecting liquids.

The instructions provided above have been validated by TytoCare Ltd. as being capable of preparing the device and adaptors for reuse.

## After Use

### Storage instructions

- If you are not using the device for an extended period, charge the device at least every 3 months.
- Store the device and the components in a clean and safe location.
- Do not store the device in a wet, humid or dusty location.
- Do not store the device outside the above-mentioned storage conditions.
- Do not store the device if it is directly exposed to the sunlight.

### User Responsibility

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 of the TytoHome device by anyone other than TytoCare or persons or entities designated by TytoCare.

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

- TytoHome™ has been used according to its intended use and according to this guide and guides accessible through the TytoApp.
- All fittings, extensions, readjustments, changes, or repairs have been carried out by a TytoCare authorized representative.

### **Electrical Safety and Electromagnetic Compatibility**

The device complies with the requirements of IEC/EN 60601-1 for general requirements for safety of medical electrical equipment, and with IEC/EN 60601-1-11 requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

The device complies with IEC 60601-1-2 Class B applies to the basic safety and essential performance of medical electrical equipment and Medical Electrical systems in the presence of electromagnetic disturbances and to E electromagnetic disturbances emitted by medical electrical equipment and medical electrical systems. The device complies with wireless standard IEEE 802.11 g/n (2.4GHz).

TytoCare reserves the right to change or improve its products and accompanying technical literature without specific notice of changes or improvements. No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photo reproductive, recording or otherwise without the express prior written permission of TytoCare.

## **Warranty**

### **TytoHome™ device One (1) Year Limited Warranty**

TytoCare warrants the TytoHome™ branded product, which includes the TytoCare 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 ONE (1) YEAR from the date of original purchase ("Warranty Period"). TytoCare's published guidelines include information contained in the user guide, the instructions available on the Tyto App, and in the Product's technical specifications.

TytoCare does not warrant that the operation of the TytoHome™ 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.

For any warranty question please contact TytoCare Support.

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 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
2. This device must accept any interference received, including interference that may cause undesired operation.

FCC Caution: changes / modifications not approved by the responsible party could void the user's authority to operate the devices.

FCC ID: 2AHKN-K160401

This device complies with Radio Equipment Directive 2014/53/EU (RED).

## Explanation of Symbols

	BF Applied part
	Must read User Manual before use
	Manufacturer Address
	Product Serial Number
	Product Model Number
	WEEE – Properly dispose of Electronic Waste
	Storage temperature limits
	Storage humidity limitations
	Keep device dry
	Do not re-use
	Caution
 (01)07290016672008 (21)TC11735C0356	Unique Device Identifier

## Technical Specification

### Tyto Device

Dimensions: 3.11 x 2.87 x 1.85 inch (79 x 73 x 47mm)

Weight: 0.33 lbs. (0.15kg)

Display: 2.4" LCD touch screen

Battery: Li-ion, built-in, rechargeable

Audio output port: Standard 3.5mm headphone connector

Power Input: Proprietary plug, 5Vdc, 2A

### Tyto Camera

Maximum sensor resolution: 5 MP

Maximum video resolution: 640x480 (VGA)

### Tyto Stethoscope

Frequency range: 20 - 3,500Hz

Heart rate range: 30 - 250 BPM

Dimensions: 1.57 x 1.53 inch (40 x 39 mm)

### Tyto Otoscope

Image resolution: 640x480 (VGA)

Tip diameter: 0.16 inch (4.2mm)

Disposable speculum: Adult - 0.16inch (4mm); Child - 0.12 inch (3mm)

### Tongue Depressor

Depressor blade length: Adult (L8): 3.15inch (80mm); Child (L6): 2.36inch (60mm)

### Tyto Thermometer

Temperature range: 94.0° - 108.0°F (34.4° - 42.2°C)

Laboratory Accuracy: 0.2°C (0.4°F) accuracy for 36°C - 39°C (96.8°F - 102.2°F) range.

0.3°C (0.5°F) accuracy outside the above range.

Complies with ASTM E1965-98&ISO 80601-2-56

### Wireless Network

Wireless comm. standard IEEE 802.11N (recommended)\ G

Frequency band: 2.4GHz only (5GHz band not supported)

Security protocols: WPA, WPA2 (WEP not supported)

Encryption protocols: TKIP, AES

Connection speed (relevant mainly for online)

Recommended: download: 20 Mbps\  
Upload: 5 Mbps. Minimum: download: 5 Mbps\  
Upload: 2 Mbps

### Software

Tyto App Operating System: iOS Last two versions, Android 5.0 and above.

Clinician Web App Supported web browser: Google Chrome only  
For online: microphone, webcam and headphones are required

### Operating Conditions

Temperature: 41 - 104 °F / 5 - 40 °C

For Tyto Thermometer: 60.8 - 104 °F / 16 - 40 °C

Humidity: 15 - 70% (non-condensing)

### Storage Conditions

Temperature: -4 - 140 °F / -20 - 60 °C

Humidity: 15 - 70% (non-condensing)

Atmospheric Pressure: 700hPa to 1060hPa

## Manufacturer Information



TytoCare Ltd.  
14 Beni Gaon Street,  
Netanya, Israel 4250803  
Tel: +972-72-221-0750  
Fax: +972-72-221-0752  
Email: [info@tytocare.com](mailto:info@tytocare.com)  
Website: [www.tytocare.com](http://www.tytocare.com)



For any questions, please call us at

**+972-72-221-0750**

**[support@tytocare.com](mailto:support@tytocare.com)**

[www.tytocare.com](http://www.tytocare.com)