



TytoPro

Tyto Thermometer

User Guide

August 2019

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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
Website: www.tytocare.com





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General Safety Messages/Product Overview

General Safety Messages

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

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

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

Disclaimer

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

Intended Use / Indications for Use

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

Product Overview

The **Tyto Thermometer™** is a user-friendly, non-contact, electronic, infrared thermometer that measures body temperature.

The Tyto Thermometer connects to the Tyto App on your mobile device (iPhone, iPad or iPad Mini) to facilitate the process of storing the recorded data and communicating data with clinicians. Recorded results may be forwarded for review by a clinician in a different location.

The Tyto Thermometer is designed for a clinical or home environment, for use in several scenarios:

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

This infrared thermometer meets requirements established in ASTM Standard (E1965-98) and ISO 80601-2-56 standards. Full responsibility for the conformance of this product to the standard is assumed by TytoCare Ltd.


Technical Specifications

Operating Environment: (Ambient) Temperature and Humidity	60.8 - 104°F (16 - 40°C) 15-70% (non-condensing)
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
Resolution	0.1°F (0.1°C)

Before the Exam

 **Warning:**

- Use the equipment only for the purpose described, as explained in this user manual.
- Use of this thermometer is not intended as a substitute for consultation with your physician.
- Only perform maintenance procedures specifically described in this user manual.

 **Note:** The Tyto Thermometer has been clinically tested and proven to be safe and accurate when used in accordance to the operation instruction manual. Please note that using the thermometer not according to the operation, storage and cleaning instructions may lead to inaccurate temperature measurement.

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

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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).

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Do not allow children to take their temperatures unattended.

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Please consult your doctor 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.

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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.

⚠ 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.
- Do not use the device on an open wound or on infected skin.
- Do not take temperature measurements over scar tissue, open sores or abrasions.
- 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.
- This thermometer 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 thermometer.
- Keep the measurement sensor clean. Avoid directly touching the sensor.

User Role: Performing Guided and Unguided Exams

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

Guided exams are intended for any person who is not a healthcare professional, and 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 are experienced in measuring temperature. Unguided exams provide a streamlined approach allowing more flexible recording and faster operation, with minimal instructions for use.

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

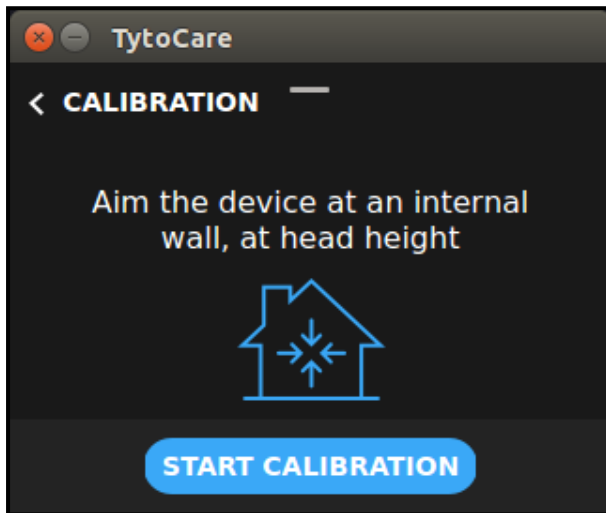
Contact the System Administrator of your TytoCare system to determine whether your user is defined as Guided or Unguided, or in case you wish to change your user role.

The measurement has to be taken on dry skin. Sweaty skin could impact the results.

Operation Environment

Tyto Thermometer should be operated only in room temperatures of 60.8 - 104°F / 16 - 40°C, and humidity of 15 - 70% (non-condensing)

Manual Calibration




When prompted, you'll need to aim the thermometer towards an inner wall, at about the height of the patient and press "Start Calibration" to start the calibration process, and measure the room temperature.

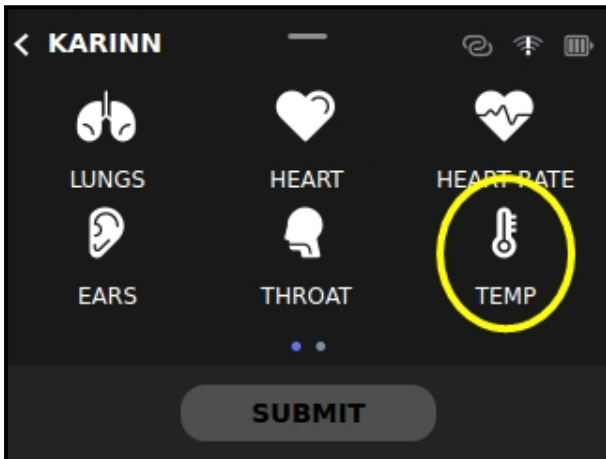
Bear in mind, the Tyto Thermometer measures the room temperature to accurately measure your body temperature, therefore you are required to be in the same room for 30 minutes before the exam. The Thermometer features a

self-calibration mechanism, activated automatically when turned on - so usually manual calibration will not be needed.

Guided Exam


 **Note:** Refer to the TytoPro™ General Operation User Guide (Document number: 760-00263) for preliminary instructions on logging in to the system and viewing the Exam menu.

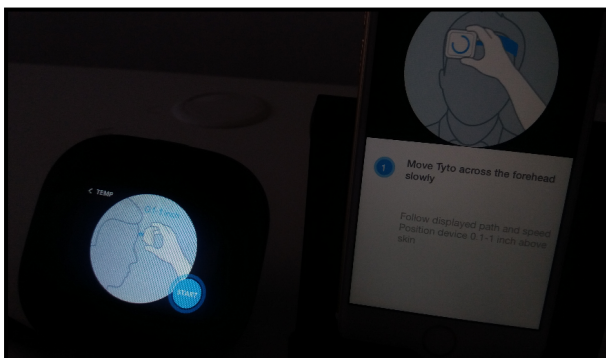
Select the TEMP Exam



Tap the **TEMP** (temperature) exam from the **Device** screen, and click **SUBMIT**.

Video Tutorial and Animation


The first time you do the exam, a video tutorial will display. It is always available by clicking the  (question mark) on the top-right of the TytoCare App screen.



Every time you perform a temperature exam, a short animation displays to remind you of the key points needed to perform a successful exam.

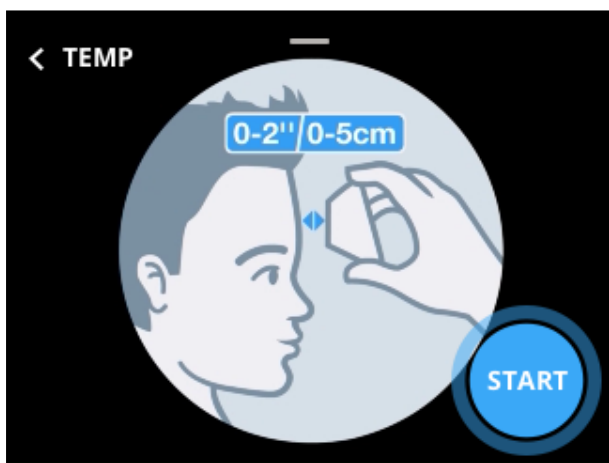
Before You Start How to Conduct the Exam



 **Note:** The Infrared temperature sensor is located at the front of the device:


Position the Device

When you are ready to begin taking the temperature, aim the Tyto Thermometer at the center of the forehead, just between and above the eyebrows, with a distance of no more than 2 inches (5 cm).

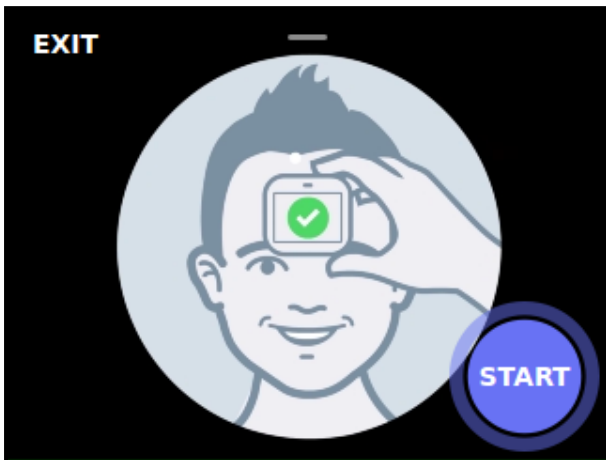


Place device close to the skin, not exceeding 2 inches (5 cm) from forehead.

For most accurate results, avoid touch with the skin.

 **Note:** Make sure the forehead is exposed, without hair interfering and not sweat on forehead. Also, the patient should be in a relaxed state. Remove any excess perspiration from the patient's forehead.

Perform the Exam

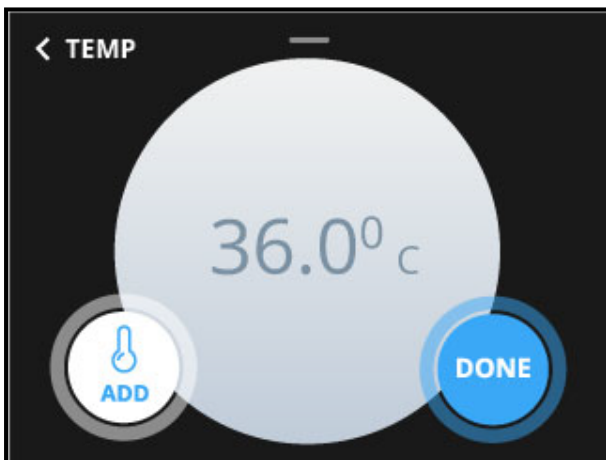


1. Tap **START** when you are ready to begin the exam.
2. Hold Tyto steady on the forehead during one timing circle (3 seconds), until you hear a beep.

Figure 1-1. Device screen showing correct location on forehead and Start button

Temperature Display


The Tyto Thermometer and the Tyto App show the measured temperature value:





Tap **Repeat** to measure the temperature again, or **DONE** when you have finished measuring the temperature.


Figure 1-2. Measured temperature


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


 **Note:** The temperature displayed reflects the body temperature, and was adjusted to be the same as when taken orally.


 **Note:** The temperature units can be displayed either in Fahrenheit or Celsius units. To change the temperature units, open the menu on the app (through the upper-left icon on the Choose Patient screen) and choose Settings. Select the desired units displayed under the Temperature units. To apply the change, you'll need to log out and log in again.


 **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). Be sure to note this unit 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. Don't 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 measurement.

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

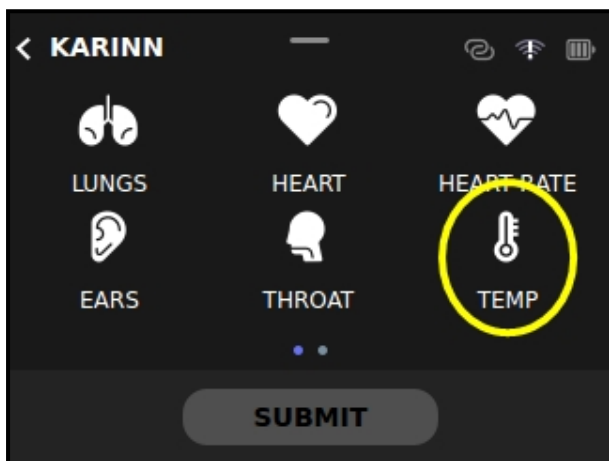
 **Note:** In the following situations it is recommended that three temperatures in the same location be taken and the highest one taken as the reading:

- 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 obtain consistent readings.

Unguided Exam


 **Note:** Refer to the TytoPro™ General Operation User Guide for instructions to log in to the system and view the Exam menu.

Select the TEMP Exam




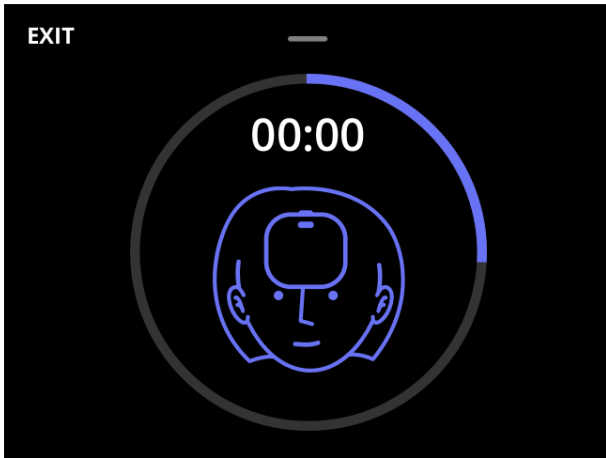
Tap the **TEMP** (temperature) exam from the **Device** screen. The measurement will start immediately.

Take Temperature Reading from the Forehead

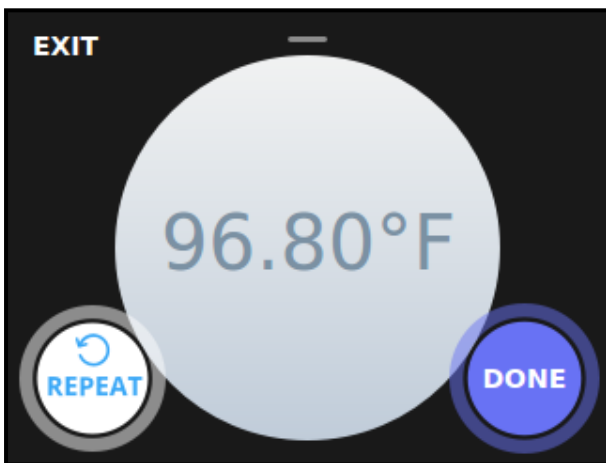
 **Note:** Make sure the forehead is exposed, without hair interfering. The patient should be in a relaxed state. Remove any excess perspiration from the patient's forehead.





 **Note:** The infrared temperature sensor is located at the front of the device:




1. Immediately upon tapping **TEMP**, place the Thermometer on the patient's forehead.
2. Aim The Tyto Thermometer at the center of the forehead, just between and above the eyebrows, with a distance of no more than 2 inches (5 cm).
3. A timer will display on the Tyto Thermometer and the Tyto App.



4. During the six-second timer period, hold the thermometer over the center of the forehead. Keep the thermometer close to the skin, no more than 2 inches (5 cm) from the skin of the forehead. After 3 seconds, you'll hear a beep and the temperature will display.
5. When you have finished taking the temperature, tap  (**DONE**).

 **Note:** The temperature displayed reflects the body temperature, and was adjusted to be the same as when taken orally.

 **Note:** The temperature units can be displayed either in Fahrenheit or Celsius units. To change the temperature units, open the menu on the app (through the upper-left icon on the Choose Patient screen) and choose Settings. Select the desired units displayed under the Temperature units. To apply the change, you'll need to log out and log in again.

Please refer to [Section - After the Exam](#) in the General Operation User Guide for further instructions on how to complete the exam and send it to a clinician.