



TytoPro

Tyto Basal Thermometer

User Guide

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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 Basal Thermometer is an electronic thermometer that enables measuring basal body temperature (BBT) as an aid in ovulation prediction to aid in conception (not to be used for contraception).

In addition, the Tyto Basal Thermometer enables storage and transmitting the temperature measurement to a clinician 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 Basal Thermometer is indicated for use by both adult lay users and clinicians. It can be used both at home and in clinic environments.

Product Overview

The **Tyto Basal Thermometer™** is a user-friendly, electronic thermometer that measures basal body temperature.

The Tyto Basal Thermometer connects to the Tyto App on your mobile device (iPhone, iPad or iPad Mini) to facilitate the process of communicating data with clinicians. Recorded results may be forwarded for review by a clinician in a different location, who should interpret the variations in basal body temperature to aid in ovulation prediction.

The Tyto Basal 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). Full responsibility for the conformance of this product to the standard is assumed by TytoCare Inc.

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	0.4°F (0.2°C) accuracy for 100.4°F - 105.8°F (38°C - 41°C) range 0.3°C (0.5°F) accuracy outside the above range. Complies with ASTM E1965-98 (2009)
Resolution	0.01°F (0.01°C)

Before the Exam

 **Warning:** The Tyto Basal Thermometer should not to be used for contraception

 **Note:** The Tyto Basal 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.

For cleaning please follow the cleaning instructions described in [Section - Cleaning Instructions](#) of the General Operation User Guide.

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

For best accuracy, the Tyto device and patient should remain in the same environment and room temperature for 30 minutes before performing the measurement.


What is Basal Body Temperature

Basal body temperature is the lowest normal body temperature of a person immediately upon awakening in the morning. To obtain an accurate basal temperature, you must take your temperature when you first awake in the morning. For best results, this waking temperature

should be taken at the same time each morning. Since any activity may tend to raise your temperature, do not get out of bed until you have taken your basal temperature. Postpone going to the bathroom, eating, smoking or drinking until after taking your basal temperature. Hot drinks, smoking and exercise cause higher readings. Using an electric blanket or heating pad can affect your basal temperature. If you use one, it should be kept at the same setting each night throughout the time you are taking your basal temperature.

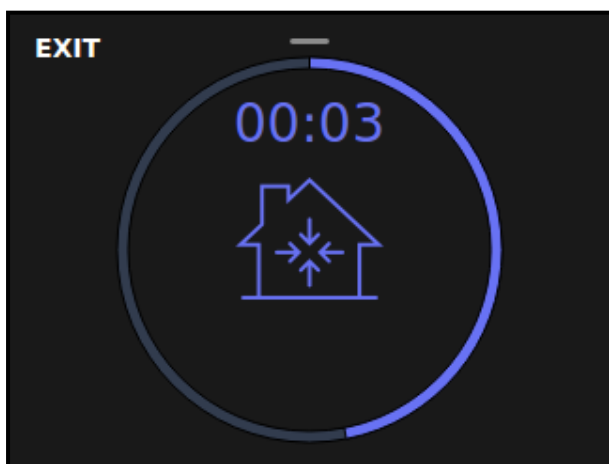
The use of charting basal temperature will indicate the slight body changes taking place during the menstrual cycle (the interval between the beginning of one period and the onset of the next period). A pattern of temperature fluctuation in the monthly cycle will develop and be noticed. The slight increase in basal temperature indicates ovulation or fertility by which a pattern of activity to achieve conception.

Although, the generally accepted “normal” temperature of a healthy person is 98.6°F (37.0°C), the basal body temperature in the first part of a cycle is usually in a range between 96.5°F (35.8°C) and 98.0°F (36.7°C). In approximately the last two weeks of the cycle, the basal temperature is typically 0.5°F (0.3°C) higher.

 **Note:** The shift from the lower to the higher temperature occurs at around the time of ovulation. Since ovulation (the release of an egg (ovum) from the ovary) ordinarily happens only once during each menstrual cycle, charting basal temperature can be helpful in determining if and when ovulation occurs. If intercourse takes place at or near this time, during the interval of the transition between low and high temperature level, conception can take place.


Manual Calibration

The Tyto Basal Thermometer also measures the room temperature to accurately measure your basal body temperature. The Tyto Basal Thermometer features a self-calibration mechanism, activated automatically when turned on. Sometimes the device may require a manual calibration, to verify the room’s ambient temperature to achieve the highest accuracy. In such cases, you’ll be prompted by the Tyto device to run a short one-step calibration process.

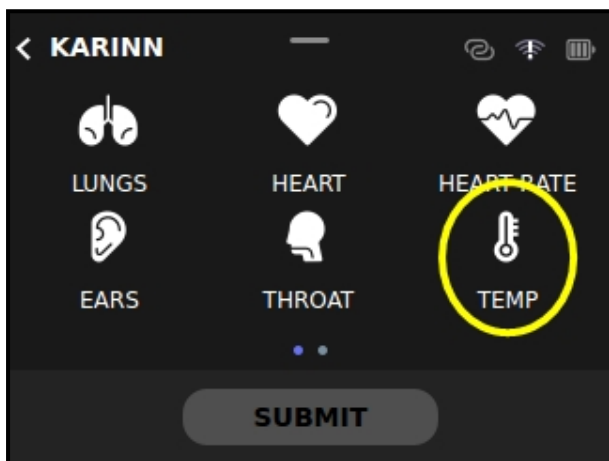


When prompted, you’ll need to aim the thermometer towards the plastic tray or towards an inner wall, with some distance, and then press Start to start the calibration process, and measure the room temperature.

Guided Exam


 **Note:** Refer to the TytoPro™ General Operation User Guide (Document number: 760-00046) for preliminary instructions on logging in to the system and viewing the Exam menu.

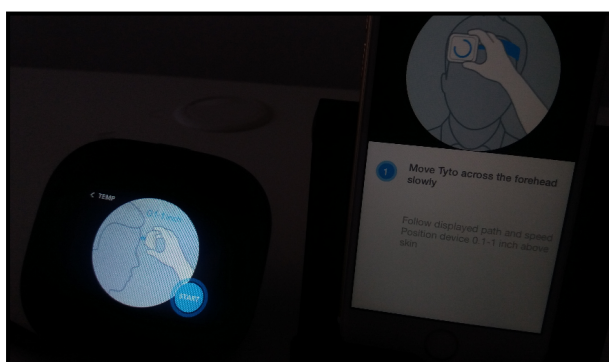
Select the TEMP Exam



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

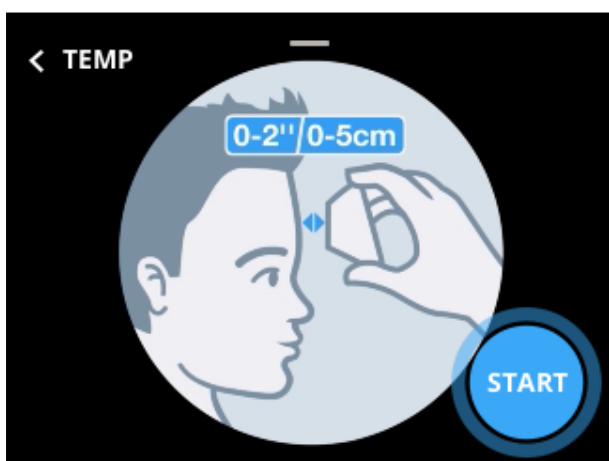
 **Note:** When measuring Basal Body Temperature, measure the temperature immediately after rising in the morning, before any physical activity, while lying down on the back. It's important to measure at the same time every morning for accurate tracking of temperature.




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

Position the Device

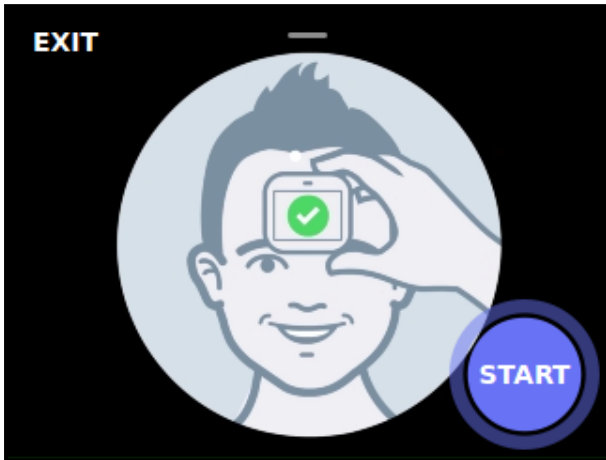
When you are ready to begin taking the temperature, aim the Tyto Basal Thermometer at the center of the forehead, just between and above the eyebrows, with a distance of no more than 2 inches (5 cm).



Place The Tyto Basal Thermometer close to the skin, not exceeding 2 inches (5 cm) from forehead.

 **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

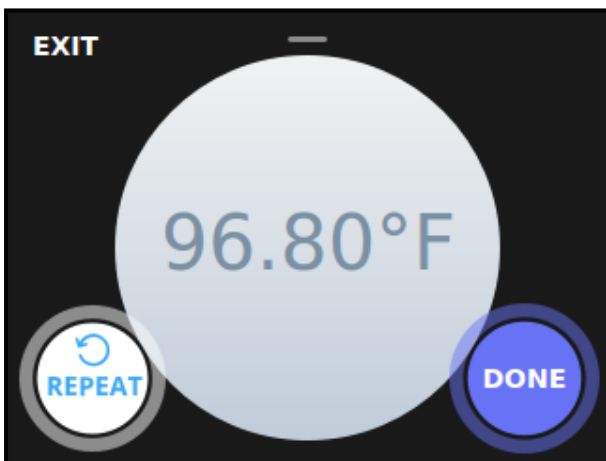


1. Tap **START** when you are ready to begin the exam.
2. Hold Tyto steady on the forehead during one timing circle (3 seconds), until you hear a beep.

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

Temperature Display

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



Tap **Repeat** (in picture here Add) 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 basal body temperature, and was adjusted to be the same as when taken orally.

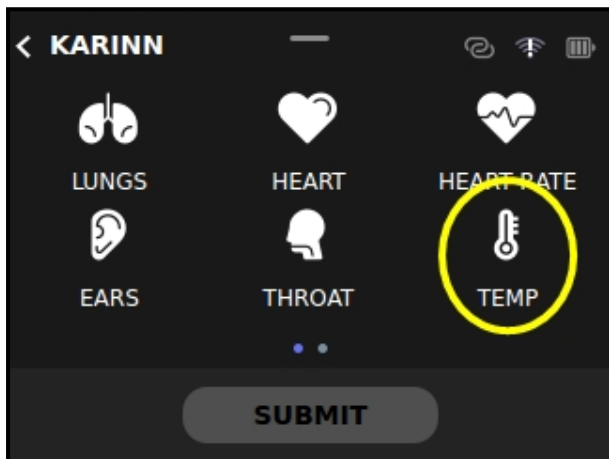


Note: The temperature units can be displayed either in Fahrenheit or Celsius units. To change the temperature units, open the menu on the app (through the upper-left icon on the Choose Patient screen) and choose Settings. Select the desired units displayed under the Temperature units. To apply the change,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

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




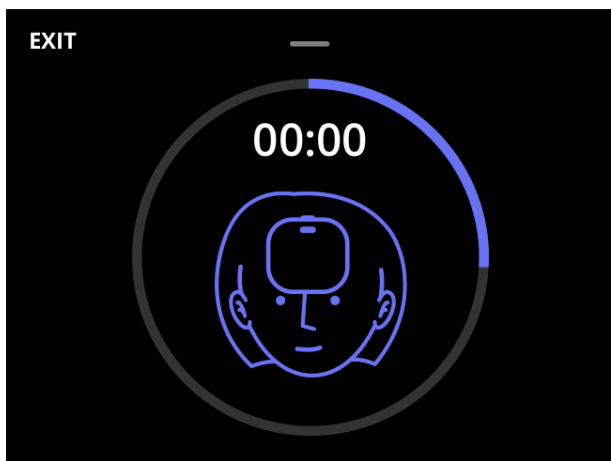
Tap the **TEMP** (temperature) exam from the **Device** screen. The measurement will start immediately.

Take Temperature Reading from the Forehead

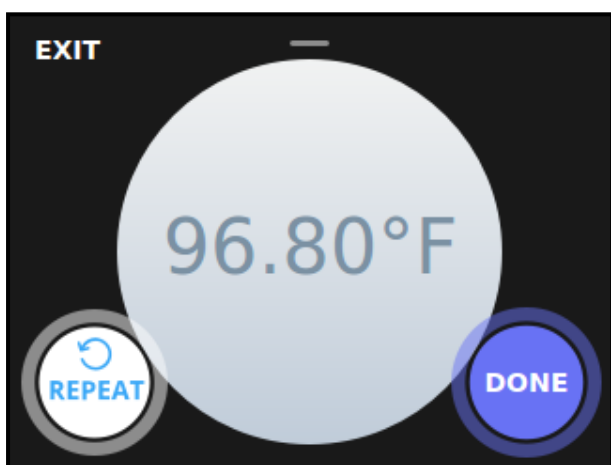
 **Note:** Make sure the forehead is exposed, without hair interfering. The patient should be in a relaxed state. Remove any excess perspiration from the patient's forehead.





 **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 Basal 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 Basal 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 basal 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.