



fitbit

by Google

Fitbit Body Temperature Software
Instructions for Use

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Glossary

B

Body temperature

Value of the temperature of the human body, measured in degrees

Body Temperature Software

Body Temperature Software provides users of compatible smartphone platforms with intermittent determination of human body temperature

C

Compatible devices

Compatible devices include qualified Pixel platforms

D

Device

Body Temperature Software – Software as a Medical Device (SaMD)

H

Hypothermic temperature

An involuntary drop in body temperature below a certain level, which may be hazardous to health for most individuals (source: <https://www.ncbi.nlm.nih.gov/books/NBK545239/>)

I

Infrared (IR) sensor

Sensor that supports multiple functions on the smartphone platform including measurement of the infrared energy emitted by the body

O

Over-the-counter (OTC)

Over-the-counter product that can be accessed without a prescription from a healthcare professional

S

Smartphone

Pixel 8 Pro, Pixel 9 Pro, or Pixel 9 Pro XL hardware

Indications for Use

Body Temperature Software is a software-only mobile medical application intended for over-the-counter (OTC) use with compatible mobile computing platforms that includes a general purpose infrared sensor for the intermittent determination of human body temperature on people of all ages.

Product Description

Body Temperature Software is a mobile medical application that runs on qualified mobile computing platforms such as a Google Pixel smartphone. When you open the app and follow the on-screen instructions, you can use your smartphone to take body temperature measurements.

All objects emit infrared radiation; the hotter an object is, the more infrared radiation energy it emits. Qualified Pixel platforms have an infrared (IR) sensor, located on the back of the smartphone below the camera flash. To take a body temperature reading, you must swipe the IR sensor across your forehead, as instructed in the app. When you swipe the IR sensor across your forehead, it senses the IR being emitted from your skin and converts it into a body temperature measurement that is then shown in the app. Syncing the Body Temperature Software data with the Fitbit app allows users to track body temperature over time, as well as access educational resources related to body temperature.

Body temperature data is stored on the smartphone for 7 days on qualified Pixel platforms and can be sent securely to the Fitbit app.

Intended Clinical Benefit

The primary benefit of Body Temperature Software is to provide a measurement of body temperature using a non-contact infrared sensor on a qualified mobile computing platform.

Cautions

The feature has not been tested for and is not intended to be used to measure the body temperature of a premature baby (defined as less than 37 weeks of gestation at birth).

Use of Body Temperature Software is not intended to diagnose or monitor a serious medical condition or disease and is not a substitute for a consultation with a healthcare professional. Don't interpret or take clinical action based on the device output without consulting a qualified healthcare professional.

General Warnings and Precautions

This device **CANNOT** detect illnesses.

This device **DOES NOT** replace the advice of your healthcare provider.

This device should only be operated by persons over 18 years of age.

WARNING: If you are concerned about your health, or if you feel unwell, consult your healthcare provider.

WARNING: The device provides accurate measurements when the movements of the smartphone are performed properly. Follow all instructions when taking a measurement.

To take an accurate reading, follow the instructions carefully and make sure the sensors are not obstructed.

This device is **NOT** intended for measuring or interpreting temperatures below the specified ranges. If there is concern for an individual with a measured temperature below the specified ranges, contact a healthcare provider.

This device is **NOT** intended for diagnostic purposes.

DO NOT use this device to measure the body temperature of a premature baby (defined as less than 37 weeks of gestation at birth).

DO NOT measure body temperature immediately after physical exercise or after exposure to either warm or cold conditions for extended periods of time as this could lead to inaccurate results.

Only take measurements on dry, intact skin. Facially applied products (e.g., makeup, lotion, sunscreen, face paint) may lead to inaccurate results

DO NOT use this device to measure body temperature when exposed to the following conditions:

- Excessive motion (e.g., operating machinery, walking), and/or
- Direct sun or near radiant heat sources (e.g., heaters).

DO NOT use this device to measure the body temperature when the external environmental temperature is outside of the 59.0°F - 95.0°F (15.0°C - 35.0°C) range.

DO NOT use this device to measure body temperature if you suspect hypothermia.

DO NOT use this device if your hair or any accessory (e.g., hats, scarves, sunglasses, etc.) covers or obstructs your forehead or temple. Follow the onboarding instructions to remove these obstructions prior to and during a measurement sweep.

DO NOT use this device to measure body temperature when the smartphone is visibly damaged, or has sensors or ports obstructed. Reference smartphone manufacturer instructions for maintenance and repair. Maintenance or repairs not performed in accordance with your phone's manufacturer instructions for maintenance and repair may damage the sensors (enclosed in the back casing) or ports and may impact the accuracy of temperature readings.

WARNING: Certain smartphone cases may obstruct the sensors utilized to obtain a temperature measurement. If using a smartphone case, ensure the smartphone case does not obstruct any sensors and does not interfere with the use of the device.

For security purposes, it's recommended that you maintain control and possession of your mobile device to prevent unauthorized access to your health data. Refer to the manufacturer's instructions for your mobile device to enable passcode functionality to deter unauthorized access.

If you feel like this product is in violation of any laws, or is threatening to an individual, report it to the manufacturer and your local health authority. This is a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Expectations

After you successfully complete a body temperature measurement, you will see a numeric body temperature value (in units °F/°C) with tenth of a degree resolution in the app.

The confirmation screen indicates the app recorded an accurate temperature measurement.

You can see and interpret your results using the Temperature guide in the app, which provides the following information:

| Age range | Below range | Normal | Elevated | High |
|-------------|---------------------------------------|--|---|--|
| 0*-3 months | Below 97.7°F (36.5°C) ¹ | 97.7°F-100.3°F (36.5°C-37.9°C) ² | N/A | 100.4°F (38.0°C) or higher ^{2,4} |
| 3-36 months | Below 96.8°F (36.0°C) ³ | 96.8°F-100.3°F (36.0°C-37.9°C) ² | 100.4°F-102.1°F (38.0°C-38.9°C) ² | 102.2°F (39.0°C) or higher ^{2,4} |
| 3+ years | Below 96.8°F (36.0°C) ³ | 96.8°F-100.3°F (36.0°C-37.9°C) ^{3,4} | 100.4°F-103.0°F (38.0°C-39.4°C) ⁴ | 103.1°F (39.5°C) or higher ⁴ |

Notes:

- Results outside temperature ranges but within 94.1°F-109.4°F (34.5°C-43.0°C) will display as below range.
- Significant increase or decrease in temperature may signal a serious illness. Consult a healthcare provider if there are any concerns about an individual's health.
- 0* months is defined as birth at 37 weeks of gestation or greater.

Operating Instructions

Compatible devices and system requirements

The Body Temperature Software feature in the Thermometer app is compatible with the following smartphone platforms:

- Pixel 8 Pro
- Pixel 9 Pro
- Pixel 9 Pro XL

The Body temperature feature in the Thermometer app works only with qualified Pixel platforms. If the smartphone does not have a compatible sensor and has not been qualified, users will not

¹ World Health Organization (WHO), Thermal Control of the Newborn: a Practical Guide. Hypothermia in Infants. 1994, World Health Organization: Geneva, Switzerland. p. 3. [\[WHO\]](#)

² Baraff LJ, Bass JW, Fleisher GR, Klein JO, McCracken GH, Jr, Powell KR, et al. Practice guideline for the management of infants and children 0 to 36 months of age with fever without source. Agency for Health Care Policy and Research. Ann Emerg Med. 1993 Jul;22(7):1198–1210.doi: 10.1016/S0196-0644(05)80991-6. [\[DOI\]](#)[\[PubMed\]](#)

³ Levy MM, Fink MP, Marshall JC, Abraham E, Angus D, Cook D, Cohen J, Opal SM, Vincent JL, Ramsay G; SCCM/ESICM/ACCP/ATS/SIS. 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. Crit Care Med. 2003 Apr;31(4):1250-6. [\[Crit Care Med\]](#)

⁴ See “Herzog L, Phillips SG. Addressing concerns about fever. Clin Pediatr (Phila) 2011 May; 50(5):383-90.”

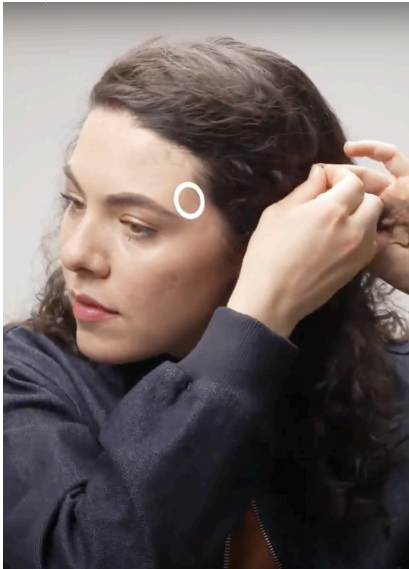
see the Body temperature feature in the Thermometer app. The Body temperature feature in the Thermometer app requires Android 14 operating system release or higher.

Note that the Body temperature feature in the Thermometer app is only available for users in Austria, Belgium, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Kingdom of the Netherlands, Latvia, Lithuania, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland, and the United States at this time. Additional devices and countries will be added as regulatory authorization is obtained.

For more information, see the [related help article](#).

Take a body temperature measurement

1. Open the Thermometer app on your smartphone and tap **Body temperature**.
2. Follow the on-screen instructions to set up the correct permissions and settings to take body temperature measurements.
3. Before you take a temperature reading, remove any accessories that cover your forehead or temple. For example, remove glasses and pull hair away from temples.



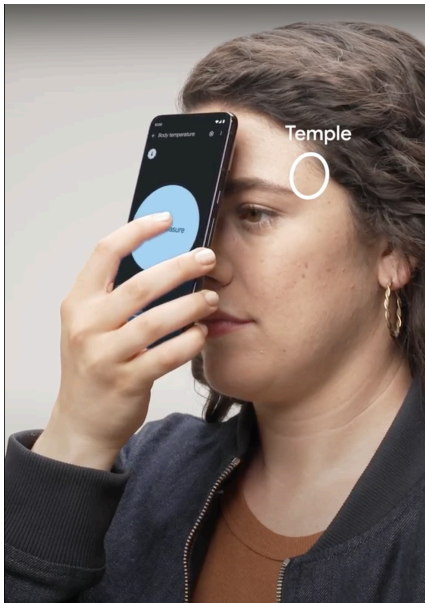
4. Point the camera bar (located below the camera flash) on the smartphone over the center of your forehead. The smartphone will vibrate when in range.

Note: Keep the camera bar as close to your head as possible without touching your

forehead.



5. After the smartphone is in position, tap the **Tap to measure** button in the center of the screen.



6. Start scanning the smartphone across your temple within 4 seconds time. Ensure that you cross over the temple. The app stops recording after 4 seconds.



7. View your temperature.
8. If you want to save the measurement, tap **Save**.


Review recent results

1. Open the Thermometer app on your smartphone and tap **Recent results**.
2. View all measurements from the past 7 days.


Delete results

1. To delete a measurement immediately after a scan, tap **Reset**.
2. To delete previous measurements:
 - a. Open the Thermometer app on your smartphone and tap **Recent results**.
 - b. Find the measurement you want to delete and swipe left, then tap the trash can icon.
3. To delete all measurements:
 - a. Open the Thermometer app on your smartphone and tap **Recent results**.
 - b. Tap the trash can icon.


Change temperature units

1. Open the Thermometer app on your smartphone and tap **Body temperature**.
2. Tap the **Settings** icon .
3. Under Unit, tap **Celsius - °C** or **Fahrenheit - °F**.

Adjust settings and view app version

1. Open the Thermometer app on your smartphone and tap **Body temperature**.
2. Tap the **Settings** icon .
3. Turn on or turn off Voice assist.
4. Turn on or turn off Temperature guide.
5. View the app version.

Interpret results

1. Open the Thermometer app on your smartphone and tap **Body temperature**.
2. Tap the **Settings** icon .
3. Turn on the Temperature guide.
4. Review the Temperature guide information to understand your results. See the table in [Expectations](#) for a guide to your temperature measurement

Troubleshooting

Sensor out of range

Move the temperature sensor as close as possible to the skin without touching during the measurement.

Ensure the forehead is clean, dry and not blocked during measurement.

Forehead temperature out of range

If you're coming from an outdoor environment which may be cold or too warm, stay in a room at typical room temperatures for at least 10 minutes before taking a measurement.

Measurement error

Unable to start measurement or Measurement failed

Try the following tips:

- Keep the back of the phone with the camera bar centered to your forehead, as close as possible to the skin without touching.
- Move the camera bar from the center of the forehead and cross one of your temples.
- Move the camera bar across the temple within 4 seconds when measuring.
- Measure indoors or out of direct sunlight.
- Make sure your skin is clean and sweat-free before measuring.
- Make sure the sensor window is clean, dirt-free and dry. Follow the Pixel platform instructions for cleaning.
- Make sure hair, hats, and all other head coverings are out of the way, and that glasses are not obstructing the temple. Ensure that the person's body temperature or temperature at the forehead has not been increased or decreased by wearing excessive clothing or head covers (for example hat, headbands, bandanas), or by using facial cleansing products (for example cosmetic wipes).
- Make sure the device and person are in the room for a minimum of 10 minutes prior to use to allow them to adjust to the environment.

Temperature sensor is too warm or too cool

Try the following tips:

- Remove your device from direct sunlight or other hot locations.
- Let your device warm or cool at room temperature before attempting to take another measurement.

Temperature sensor unavailable

Contact [Customer Support](#) for more information.

Clinical Study

Body Temperature Software was validated in a clinical study of 145 subjects from 3 clinical sites. Participants were racially and ethnically diverse, and included infants, young children, older children, and adults.

The Body Temperature Software algorithm was able to accurately measure body temperature reference temperature range of 96.9°F - 104.0°F (36.1°C - 40.0°C) to within $\pm 0.5^\circ\text{F}$ ($\pm 0.3^\circ\text{C}$) when compared with the FDA-cleared temporal artery thermometer.

No adverse events were observed during the clinical study.

Device Performance

| Specifications: | |
|--|---|
| Human body temperature Measurement Range (Min/Max) | 94.1°F-109.4°F (34.5°C-43.0°C) |
| Laboratory Accuracy (Max) | ±0.5°F (±0.3°C) |
| Measurement Site | Temporal Artery |
| Reference Body Site | Rectal |
| Display Modes | Displayed temperature is the temperature of the temporal artery plus a mathematical adjustment to approximate rectal temperature. |
| Operating Ambient Ranges: | |
| Temperature | 59.0°F-95.0°F (15.0°C-35.0°C) |
| Display Resolution | 0.1°F/0.1°C |
| Temperature Scales | Degrees °F/°C |

Disease and Self-care Information

Why is body temperature important?

Part of your brain called the hypothalamus continually adjusts your body temperature to maintain an optimal environment for your body functions. The body's thermoregulatory system helps to ensure that the body's cells are able to function properly, aids in regulating metabolism, and maintains the body's fluids.

Several factors can affect body temperature. For example, exercise, stress, and illness can cause the body's temperature to rise. In some cases, a high body temperature can be dangerous; heat stroke, for example, can be fatal.

If you are concerned about your body temperature, you should talk to your healthcare provider. Your healthcare provider can help you to determine if your temperature is normal and can also give you advice on how to manage your temperature.

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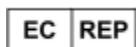
You must accept these Terms to create a Fitbit account and to access or use the Fitbit Service. If you do not have an account, you accept these Terms by using any part of the Fitbit Service. If you do not accept these terms, do not create an account, or use the Fitbit Service.

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Equipment Symbols



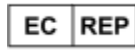
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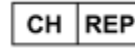
Read
Instructions
for Use



Manufacturer



European
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Representative



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Representative



Medical
Device

For customer support, visit support.google.com/fitbit.

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