Google ECG App Instructions for Use

Version C

129-0517-01
October 27, 2026

Table of Contents

Glossary **3**
Indications for Use **4**
Product Description **5**
Cautions **5**
Expectations **5**
How the Google ECG app works 5
General Warnings and Precautions **6**
Operating Instructions **7**
Install the Google ECG app 7
Take the assessment 8
Cancel the assessment 9
See your results 9
Delete your results 10
Delete and Restore the Google ECG app 10
Troubleshooting **10**
Inconclusive: High heart rate 10
Inconclusive: Low heart rate 11
Inconclusive: Didn’t get a good reading 11
Clinical Study **12**
Disease and Self-care Information **12**
What is atrial fibrillation? 12
Signs that you may have atrial fibrillation 13
Lifestyle and other factors 13
Potential treatment options 13
Information for Physicians **14**
Terms of Service **14**
User Assistance Information **15**

Glossary

Atrial fibrillation (AFib)

Atrial fibrillation (AFib) is a type of irregular heart rhythm, caused when the upper chambers of the heart beat out of rhythm.

Electrocardiogram (ECG)

An electrocardiogram (ECG) is a test that measures the electrical activity of your heart.

Compatible wrist-worn product

For the Google ECG App, compatible-wrist worn products include Fitbit smartwatches, Fitbit trackers, and Google -affiliated wrist-worn products such as the Google Pixel Watch Series.

Google Pixel Watch series

A collective term to refer to Google Pixel Watch, Google Pixel Watch 2, Google Pixel Watch 3, Google Pixel Watch 4, and Google Pixel Watch 5.

Heart rate

Your heart rate is the number of times your heart contracts (beats) in a minute. It's often expressed as beats per minute (bpm).

Normal sinus rhythm

A normal sinus rhythm is a normal heart rhythm.

Indications for Use

US*:

The Google ECG app is a software-only mobile medical application intended for use with Fitbit wrist-wearable products to create, record, store, transfer, and display a single-channel electrocardiogram (ECG) qualitatively similar to a Lead I ECG. The Google ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The AFib detection function is not recommended for people with other known arrhythmias.

The Google ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the app is intended for informational use only. Don't interpret or take clinical action based on the device output without consulting a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm. It's not intended to replace traditional methods of diagnosis or treatment. The Google ECG app is not intended for use by people under 22 years old.

Non-US (EU/EEA/UK):**

The Google ECG app is intended to allow the user to record a waveform similar to a single-lead ECG that is then classified as sinus rhythm or atrial fibrillation (AFib) on a classifiable waveform. The ECG and rhythm classification is not recommended for users with other known arrhythmias. Google ECG app is intended for home use by lay people aged 22 years and over.

**US Indications for Use applies to the United States, India, and the following US territories: American Samoa, Puerto Rico, Guam, US Virgin Islands*

***Non-US Indications for Use applies to the following countries:*
EU countries where the Google ECG app is available: Germany, Ireland, Spain, France, Netherlands, Sweden, Italy, Belgium, Poland, Austria, Czech Republic, Portugal, Romania, and Luxembourg.

Non-EU countries including: United Kingdom, Switzerland, Canada, New Zealand, South Africa, Norway, Chile, Hong Kong, Singapore, and Australia.

This user manual is available on support.google.com in the local languages for the countries listed above.

Additional countries will be added as regulatory clearance is obtained.

Certain compatible wrist-worn products may not be available in all regions listed above.

Product Description

The Google ECG software-only medical application is used to create and record an ECG, similar to a single-lead ECG, when you open the Google ECG app and follow the instructions on your compatible wrist-worn product. The Google ECG app is qualitatively similar to a Lead I ECG in that it can be used to discriminate between AFib and normal sinus rhythm; it is not intended for diagnostic purposes. The app is a spot check that analyzes the recording and presents the results. The ECG data can be used for non-clinical applications, such as providing an estimate of your heart rate. The ECG recording is temporarily stored in the ECG app on your compatible wrist-worn product until the data syncs to your account; you're then able to view your results in the Google Health app.

Cautions

The feature has not been tested for and is not intended for use in people under 22 years of age, or those who have a pacemaker, internal defibrillator, or other cardiac device.

Expectations

How the Google ECG app works

The rhythm your heart makes can be detected using the electrical sensors on your compatible wrist-worn product. This data is analyzed for signs of AFib, an irregular heart rhythm.

The electrical sensors are on the back of the compatible wrist-worn product and on either the metal frame around the face (Fitbit Charge 5, Fitbit Charge 6, Fitbit Sense, and Fitbit Sense 2) or crown (Google Pixel Watch series). When these sensors are in contact with your skin and the Google ECG app is open, they record the electrical signals from your heart.

Normally, the heart's upper and lower chambers work together. When the heart is in AFib, the upper chambers contract irregularly, increasing the risk of heart attack, blood clots, stroke, and other heart conditions.

With AFib, the heart may not always beat irregularly, making it hard to detect. While this assessment can't diagnose AFib, you can use it right from your wrist. Your results can help you have a better conversation with your doctor.

Results you might see

Normal Sinus Rhythm

Your heart rhythm appears normal. It doesn't show signs of AFib, an irregular heart rhythm.

Atrial Fibrillation

Your heart rhythm shows signs of AFib, an irregular heart rhythm. AFib can have serious health effects. You should contact your doctor.

Inconclusive

If your heart rate is over 120 bpm or under 50 bpm, the ECG app can't assess your heart rhythm.

There are many possible reasons for getting an inconclusive result, but common causes are moving too much during the assessment, not resting your hands on a table, or other arrhythmia.

For more information, see Troubleshooting.

General Warnings and Precautions

DO NOT change your medication without first speaking to your doctor. The results of the Google ECG app may not be accurate in people who take medication or substances that affect heart rate or blood flow.

DO NOT use this product in lieu of treatment prescribed by your doctor. Palpitations and shortness of breath can be symptoms of AFib, but some people don't have any symptoms. AFib is treatable, so the earlier you detect it, the sooner you and your doctor can do something about it.

If you have any symptoms related to AFib or have concerns, talk to your doctor. Erroneous false negative or false positive results due to the device or user error may occur. A person with a false negative result could delay seeking medical care and have prolonged symptoms of AFib. A person with a false positive result could have unnecessary additional testing or make inappropriate behavioral or physical changes. For more information on the accuracy of the Google ECG app, see Clinical Study.

DO NOT use for clinical diagnosis of AFib.

DO NOT use for continuous, real-time or self-monitoring of heart rhythm.

This product **CANNOT** detect heart attack, blood clots, stroke, or other heart conditions.

The assessment carried out by this product is **NOT** a diagnosis.

This product has **NOT** been tested on individuals who are pregnant.

This product is **NOT** intended for use in a clinical setting.

DO NOT interpret or take clinical action solely based on the assessment result without consultation of a qualified healthcare professional.

DO NOT take an ECG reading when your compatible wrist-worn product is outside the operational temperature or humidity range indicated in the user manual or safety guide for that device.

DO NOT use this feature to create an electrocardiogram when the compatible wrist-worn product is visibly damaged or has sensors or ports obstructed. Reference device manufacturer instructions for maintenance and repair. Maintenance or repairs performed not in accordance with your compatible wrist-worn product's manufacturer instructions for maintenance and repair may damage the sensors or ports and may impact the accuracy of an ECG record.

DO NOT take a reading while submerged in water.

With AFib, your heart may not always beat irregularly, making it challenging to detect even in the doctor's office.

Wear your compatible wrist-worn product as instructed. **NOTE**: The Googlet ECG app can only be used on compatible wrist-worn products that have been paired to your account. For more information on compatible wrist-worn products compatible with the Google ECG app, see What is the Google ECG app? Third party accessories have not been validated with the Google ECG app and should not be used. For more information on how to wear Google wrist-worn products and accessories, see How to wear Pixel Watch and adjust band size. For compatible wrist-worn products and accessories, see How do I wear my Fitbit device?

For security purposes, it's recommended that you maintain control and possession of your compatible consumer wrist-worn product and mobile devices 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. Additionally, secure your Fitbit account with a strong password. For more information, see How do I change or reset my Fitbit password? If available on your consumer wrist-worn product, we recommend that you enable device lock. For more information, see How do I use the device lock on my Fitbit device?

If you feel like this product is in violation of any laws, or is threatening to an individual, please 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.

Operating Instructions

Install the Google ECG app

If the Google ECG app isn't already installed on your compatible wrist-worn product, download it. The Google ECG App can only be used on compatible wrist-worn products that have been paired to your account.

Google Fitbit Edge, Fitbit Charge 6, Fitbit Charge 5, Fitbit Sense 2, and Fitbit Sense

1. Open the Google Health app .
2. Tap Connections > your device.
3. Tap **Apps.**
4. In the list of apps, tap **ECG** > **Install**.

Google Pixel Watch series

1. On your watch or phone, open the Play Store app . Search for the GoogleECG app. If you use the Play Store on your phone, make sure your device is set to your watch.
2. Tap the **Google ECG** app > **Install**.
3. Open the Google ECG app on your watch. If you haven't set up the Google Health app on your phone, you're prompted to do so. Follow the instructions to install and log in to the Google Health app on your phone.

Take the assessment

Before you take your first reading:

1. Open the Google Health app , tap the Health tab .
2. Under "Health checks", tap **ECG** > **Get Started** and follow the instructions. After you complete the Heart Rhythm Assessment introduction, you can take an ECG reading.

To take an ECG reading:

1. Wear your compatible wrist-worn product snugly, but with enough room for comfort. It should sit a finger's width above your wrist bone. The back of the compatible wrist-worn

product should rest securely against your skin. For more information, see How do I wear my Fitbit device?

2. Sit down and open the ECG app on your compatible wrist-worn product. When you start an ECG reading, if Do Not Disturb (DND) mode is off, we automatically turn on DND in order to ensure you receive a reading. You can turn it back off after the ECG is complete.
3. Follow the instructions on your compatible wrist-worn product to start the assessment.
4. Put your finger(s) on your compatible wrist-worn product as shown on the screen. Sit still while the test is in progress with your feet on the floor and forearms and wrists resting on a solid surface in front of you. Remain calm and relaxed, breathing regularly. Continue to hold the contact point(s) until the countdown is complete. Avoid touching other parts of the compatible wrist-worn product or your wrist.
5. When your results appear, swipe up to see the full report. Google Pixel Watch series must be connected to LTE or Wi-Fi to sync ECG data to the Google Health app.

Cancel the assessment

To cancel the assessment, press the button on Fitbit Sense 2 and Fitbit Sense, press the crown on Google Pixel Watch series, or swipe right on Fitbit Charge 6 and Fitbit Charge 5. A result is only provided after completing the 30-second ECG reading and data analysis. If you cancel the assessment prior to completion, a result won't be available.

See your results

After you complete the Heart Rhythm Assessment you'll get one of the following results:

- **Normal sinus rhythm:** Your heart rhythm appears normal. Tap **Learn more** for more information, or tap **Done** to exit the assessment.
- **Atrial fibrillation:** Your heart rhythm shows signs of AFib. You should contact your doctor. Tap **Learn more** for more information or tap **Done** to exit the assessment.
- **Inconclusive:** The ECG app couldn't get a good reading either because your heart rate was too low, too high, or there wasn't a good enough signal. Tap **Retake** to try again, or tap **Done** to exit the assessment. For more information on why you might receive this result, refer to Troubleshooting.

When you open the Google Health app, your results transfer from your compatible wrist-worn product to the Google Health app, and can be viewed on your phone or tablet. Note that Google Pixel Watch series must be connected to LTE or Wi-Fi to sync your ECG data to the Google Health app. To see your results at a later time, such as during an appointment with your healthcare provider:

1. Open the Google Health app , tap the Health tab . Under “Health checks,” tap **ECG.** Your most recent results are displayed with the date and time that they were taken. For additional results, tap **Show more**.
2. Tap any of the results to view more details. **Note:** If your compatible wrist-worn product wasn’t able to measure your heart rate, the ECG results might show dashes where your average heart rate normally appears. Follow the instructions in Inconclusive: Didn’t get a good reading to retake the assessment.
3. To download the report, tap **Export a PDF for your provider** > **Download PDF** > name and save your report.. You’ll receive a notification when your report is ready. We recommend using the latest version of Adobe Acrobat Reader to open the report.

Delete your results

1. Open the Google Health app , and tap the Health tab . Under “Health checks,” tap **ECG**. Your most recent results are displayed with the date and time that they were taken. For additional results, tap **Show more**.
2. Tap the result you want to delete. Swipe to the bottom of the page, and tap **Delete result**.

Delete and Restore the Google ECG app

To remove the Google ECG app:

Fitbit Charge 6, Fitbit Charge 5, Fitbit Sense 2, and Fitbit Sense

1. Open the Google Health app .
2. Tap Connections > your device.
3. Tap **Apps**.
4. In the list of apps, tap **ECG** app > **Uninstall**.

You can reinstall the app at any time.

Google Pixel Watch series

1. On your watch, open the Play Store app .
2. Tap **My Apps**.
3. In the list of apps installed on your watch, find the **Google ECG** app and tap it.
4. Tap **Uninstall**.

Troubleshooting

There are 3 types of inconclusive results you might receive after taking the assessment:

Inconclusive: High heart rate

If your heart rate is over 120 bpm, the Google ECG app can't assess your heart rhythm. Heart rate can be high for many reasons, such as:

- Recent exercise
- Stress
- Nervousness
- Alcohol
- Dehydration
- Infection
- AFib, or other arrhythmia

Learn more from the American Heart Association or by visiting the website of the European Society of Cardiology [https://www.escardio.org/].

Inconclusive: Low heart rate

If your heart rate is under 50 bpm, the Google ECG app can't assess your heart rhythm. Heart rate can be low for many reasons, such as:

- Taking certain medications such as beta-blockers or calcium channel blockers
- Having excellent aerobic fitness
- Other arrhythmia

Learn more from the American Heart Association or by visiting the website of the European Society of Cardiology [https://www.escardio.org/].

Inconclusive: Didn't get a good reading

There are many possible reasons for getting an inconclusive result, but common causes are:

- Moving too much during the reading
- Not resting your hands on a table
- Wearing your device too loosely
- Uneven or strenuous breathing
- Wearing your device on a wrist other than the one you specified

- Being near electronics since this can interfere with the reading

If the Google ECG app couldn't get a good reading, try the following troubleshooting tips:

- Make sure you're sitting down and relaxed.
- Rest your arms on a table while you take the assessment and avoid moving.
- Check that your compatible wrist-worn product is on the wrist you selected when you started the assessment.
- Keep your finger(s) on your compatible wrist-worn product for the duration of the assessment. Avoid touching other parts of the compatible wrist-worn product or your other wrist.
- Check the fit of your compatible wrist-worn product. It should feel comfortably secure, not too loose or too tight. Wear it a finger's width above your wrist bone. The back of the compatible wrist-worn product should rest securely against your skin. For more information, see How do I wear my Fitbit device?
- Ensure there is no interference with the electrode to skin contact (hair, jewelry, clothing, etc.)
- If you recently put on your compatible wrist-worn product, the electrodes might need to warm to your skin temperature. The electrodes are located on the side of the watch face for compatible wrist-worn products and on the bottom of the device for Google Pixel Watch series. Try retaking the assessment at a later time.
- Avoid taking the assessment after recent exercise because heavy breathing and elevated heart rate after exercise can make it challenging to obtain a good reading.
- Move away from other electronics to prevent interference.
- If you have dry skin, a small amount of lotion applied to your finger(s) and wrist can help the electrodes get a good reading.
- Make sure your compatible wrist-worn product and wrist are clean and dry. Water or sweat can interfere with the reading. If you recently washed your hands, went swimming, showered, or perspired, clean and dry your compatible wrist-worn product. See fitbit.com/productcare for wear and care instructions.
- If your Google Pixel Watch comes into contact with liquid, gently shake the device with moderate force to help expel any trapped liquid from the sensor area.

Retake the assessment to try again. If you get an inconclusive result repeatedly, or you're not feeling well, talk to your healthcare provider.

For troubleshooting syncing, see Why won't my Fitbit device sync? For troubleshooting heart-rate tracking, see What factors can affect my heart-rate reading on my Fitbit device?

Clinical Study

A clinical study was performed to validate the Google ECG software algorithm's ability to classify cardiac rhythms as atrial fibrillation (AFib) and sinus rhythm (SR) from a waveform similar to a Lead I ECG, and confirm the software's ability to produce a waveform similar to Lead I of a 12-lead ECG.

472 subjects, with and without a known diagnosis of AFib, were recruited and enrolled to participate across 9 US sites. Eligible subjects underwent a 10-second screening using a 12-lead ECG. Subjects with a known history of AFib were screened for AFib by a single qualified physician and assigned to the AFib cohort. Subjects without a known history of AFib were screened for SR and assigned to the SR cohort.

Subsequently, 440 subjects underwent a simultaneous 30-second 12-lead ECG and Google ECG App test. The Google ECG App software algorithm was able to correctly identify people with AFib 98.7% of the time and correctly identify people with SR 100% of the time.

When compared qualitatively, i.e. when the waveforms from the 12-lead ECG and Google ECG App were visually compared to classify AFib and SR, the Google ECG App's single lead waveform was deemed similar to the Lead I of a 12-Lead ECG waveform overall for 95.0% of the time.

When compared quantitatively, i.e. when the R-wave amplitudes were compared between the 12-lead ECG and Google ECG App, the Google ECG R-wave amplitudes were on average 2.4mm larger than the reference 12-lead R-wave peaks. This is due to the placement of the 12-lead ECG on the torso of the subject as opposed to their wrist during the clinical study.

No adverse events were observed during the clinical study.

Disease and Self-care Information

What is atrial fibrillation?

Atrial fibrillation (AFib) is a type of irregular heart rhythm of the upper chambers of the heart (the atria). Normally, the upper chambers contract regularly to move blood into the lower chambers. With AFib, the upper chambers contract irregularly, causing some blood to move slowly in the upper chambers. This slow-moving blood can clot, which raises the risk for stroke and heart-related issues.

Signs that you may have atrial fibrillation

Some people with AFib don't have any symptoms, but others may experience:

- Irregular heartbeat
- Heart palpitations
- Lightheadedness
- Extreme fatigue
- Shortness of breath
- Chest pain

Learn more from the CDC or by visiting the website of the European Society of Cardiology [https://www.escardio.org/].

Lifestyle and other factors

Risk factors for AFib include:

- Advanced age
- High blood pressure
- Obesity
- European ancestry
- Diabetes
- Heart failure
- Ischemic heart disease
- Hyperthyroidism
- Chronic kidney disease
- Heavy alcohol use
- Enlargement of the chambers on the left side of the heart

Learn more from the CDC or by visiting the website of the European Society of Cardiology [https://www.escardio.org/].

Potential treatment options

Consult your healthcare provider before making major lifestyle changes or changes to your medication. Potential treatment options include:

- Medication
- Surgery
- Lifestyle changes

Learn more from the CDC or by visiting the website of the European Society of Cardiology [https://www.escardio.org/].

Information for Physicians

A physician's guide is available. Visit support.google.com/googlehealth or call (877) 623-4997.

Terms of Service

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Additional information regarding these Terms may be obtained by visiting the Google Terms of Service or Fitbit Terms of Service.

User Assistance Information

This document is for SKU: FB 603, version 2.0 or higher.

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