

fitbit

by Google

Google ECG App Physician's Guide

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Understand the Google ECG app

US*:

The Google ECG app is a software-only mobile medical application intended for use with Google Health 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.

How data is collected

The electrical sensors are on either the metal frame around the face (Google Fitbit Edge, Fitbit Charge 5, Fitbit Charge 6, Fitbit Sense, and Fitbit Sense 2) or crown and on the back of the wrist-worn product (Google Pixel Watch series.) When these sensors are in contact with the

user's skin and the Google ECG app is open, they record the electrical signals from the user's heart for 30 seconds. A proprietary algorithm determines if the reading indicates a normal sinus rhythm or an irregular rhythm suggestive of atrial fibrillation (AFib). The user can take the assessment as many times as they want.

Interpret the results

After completing the ECG reading, the user can download a summary PDF report of their ECG result from the mobile app, which includes the ECG waveform. To open the PDF report, the user should use the latest version of Adobe Acrobat Reader. The possible results shown to the user are:

Normal Sinus Rhythm

The user's heart rhythm appears normal. It doesn't show signs of AFib.

Atrial Fibrillation

The user's heart rhythm shows signs of AFib.

Inconclusive: High heart rate

The user's heart rate was too high to complete the Heart Rhythm Assessment. If the user's heart rate is over 120 bpm, the Google ECG app can't assess the user's heart rhythm.

Inconclusive: Low heart rate

The user's heart rate was too low to complete the Heart Rhythm Assessment. If the user's heart rate is under 50 bpm, the Google ECG app can't assess the user's heart rhythm.

Inconclusive: Didn't get a good reading

The Heart Rhythm Assessment didn't get a good ECG reading. Possible reasons for an inconclusive result include:

- Moving too much during the reading
- Not resting their arms on a table
- Wearing the compatible wrist-worn product too loosely
- Interference with the electrode to skin contact (hair, jewelry, clothing, etc.)
- Wearing the compatible wrist-worn product on the wrist other than the one specified
- Electrical interference from other electronics
- The user has a pacemaker or other implantable cardioverter defibrillator (ICD)
- The user has an arrhythmia or other heart conditions that the Google ECG app isn't designed to detect
- The user is in a small group of people whose electrical signals can't be detected by the Google ECG app

Clinical Study

A clinical study was performed to validate the Google ECG app software algorithm's ability to detect AFib using data derived from a compatible wrist-worn product. The primary objective was to validate the Google ECG app software algorithm's ability to classify cardiac rhythms as AFib or normal sinus rhythm (NSR) from a waveform equivalent to a Lead I ECG. The performance goals for detecting AFib were (lower bound of the confidence interval): 90% with 97.5% confidence for sensitivity, and 92% with 97.5% confidence for specificity. The secondary objective was to confirm the software's ability to produce a waveform clinically equivalent to Lead I of a 12-lead ECG in at least 80% (with 95% confidence) of the paired tracings reviewed both qualitatively and quantitatively.

Subjects with and without a known history of AFib were recruited to participate in the study from nine sites across the United States between November 11th, 2019 and December 20th, 2019. Upon enrollment, a 10-second 12-lead screening ECG was recorded and used to confirm the subject's cohort assignment (AFib or NSR). A subject was considered a screen failure if they had either a known history of AFib and failed to present with AFib or had no known atrial arrhythmias and presented with an atrial arrhythmia. The screening ECG was interpreted by a qualified physician at each site. Subsequently, subjects underwent a simultaneous 30-second 12-lead ECG and Google ECG test. Centralized core lab physicians adjudicated the Google ECG and the 12-lead ECG tracings. Data that was classifiable as SR or AF by both the Google Health software algorithm and physician interpreted 12-lead ECG was used for the primary endpoint sensitivity and specificity calculations. For the secondary endpoint analysis, core lab physicians assessed qualitative and quantitative similarity on a subset of randomly selected data (70 for each the AF and SR cohorts). The proportion of similar tracings between the Google ECG and the 12-lead ECG and the proportion of R-wave amplitudes within 2mm (0.2mV) was calculated.

Four-hundred and seventy-two subjects were enrolled in the study and 440 met eligibility criteria. Thirty subjects failed the screening ECG and were excluded from the study and two subjects were withdrawn. Of the 440 eligible subjects, 265 were placed in the SR cohort and 175 were placed in the AF cohort. Two subjects from each cohort were excluded from analysis due to protocol deviations resulting in 263 subjects from SR cohort and 173 subjects from the AF cohort included in the analysis. No adverse events were reported. The Google ECG Spot Check software algorithm was able to detect AF with the sensitivity and specificity of 98.7% (LCB 95.4%) and 100% (LCB 98.5%), respectively. The Google ECG single-lead waveform was deemed morphologically equivalent to the Lead I of a 12-Lead ECG waveform overall for 95.0% (LCB 90.0%) of AF and SR tracings reviewed qualitatively. The Google ECG R-wave amplitudes were on average 2.4mm (SD 1.4mm) / 0.24mV (SD 0.14mV) larger than the reference 12-Lead R-wave peaks. Although this was slightly greater than the proposed acceptance criterion, clinicians reached the same clinical conclusions from the Google Healthapp ECG waveform as from the 12-lead ECG waveform, indicating that the Google Health app ECG waveform is sufficient for the intended purpose of physician review.

The primary endpoint, sensitivity and specificity, exceeded target performance. The qualitative assessment of secondary endpoint also exceeded target performance. Although the R-wave

amplitude secondary endpoint failed to achieve target performance, this was likely related to placement of the ECG reference device.

User Assistance Information

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

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Equipment Symbols

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