Fitbit ECG App Instructions for Use

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Glossary

A

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.

E

Electrocardiogram (ECG)

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

F

Fitbit wrist-worn product

Fitbit wrist-worn products include Fitbit smartwatches and Fitbit trackers.

H

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).

N

Normal sinus rhythm

A normal sinus rhythm is a normal heart rhythm.

Indications for Use

US*:

The Fitbit 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 Fitbit 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 Fitbit 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 Fitbit ECG app is not intended for use by people under 22 years old.

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

The Fitbit 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. Fitbit ECG app is intended for home use by lay people aged 22 years and over.

**US Indications for Use applies to the United States 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 Fitbit ECG app is available: Germany, Ireland, Spain, France, Netherlands, Sweden, Italy, Belgium, Poland, Austria, Czech Republic, Portugal, Romania, and Luxembourg. This user manual is available on help.fitbit.com in the local languages for the countries listed above.

Fitbit ECG app is available in the United Kingdom and other non-EU countries include: Switzerland, Canada, New Zealand, India, South Africa, Norway, Chile, and Singapore. This user manual is available on help.fitbit.com in the local languages for the countries listed above.

Additional countries will be added as regulatory clearance is obtained.

Note that this product is not regulated as a medical device in the following countries/regions: Hong Kong

Product Description

The Fitbit ECG software-only medical application is used to create and record an ECG, similar to a single-lead ECG, when you open the Fitbit ECG app, follow the instructions, and place 2 fingers on the electrical sensors. The Fitbit 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 Fitbit wrist-worn product until the data syncs to your account; you're then able to view your results in the Fitbit app on your phone or tablet.

You can find the Fitbit ECG app data in the Heart Rhythm Assessment tile within the Health Assessments section in the Fitbit app. This tile is also used for onboarding, displaying past results, exporting a report, and other non-medical device data.

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 Fitbit ECG app works

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

The electrical sensors are on the back of the Fitbit wrist-worn product and on the metal frame around the face. When these sensors are in contact with your skin and the Fitbit 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 Fitbit 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 arrythmia.

For more information, see "Troubleshooting" on page 12.

General Warnings and Precautions

DO NOT change your medication without first speaking to your doctor. The results of the Fitbit 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 Fitbit ECG app, see "Clinical Study" on page 14.

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 Fitbit wrist-worn product is outside the operational temperature or humidity range indicated in the user manual for that device.

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 Fitbit wrist-worn product as instructed. **NOTE**: The Fitbit ECG app can only be used on compatible Fitbit wrist-worn products that have been paired to your account. For more information on Fitbit wrist-worn products compatible with the Fitbit ECG app, see help.fitbit.com.

For security purposes, it's recommended that you maintain control and possession of your compatible Fitbit 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 help.fitbit.com. If available on your Fitbit wrist-worn product, we recommend that you enable device lock. For more information, see help.fitbit.com.

Operating Instructions

Install the Fitbit ECG app

If the Fitbit ECG app isn't already installed on your Fitbit wrist-worn product, download it from the Fitbit App Gallery. For more information on the availability of the Fitbit ECG app in your region, see fitbit.com/ecg.

The Fitbit ECG App can only be used on compatible Fitbit wrist-worn products that have been paired to your account. The Fitbit ECG App is currently available on Fitbit Sense. Your Fitbit Sense must be running firmware version 5.0 or higher. For more information, see help.fitbit.com.

Take the assessment

Before you take your first reading, review the Heart Rhythm Assessment introduction:

1. Open the Fitbit app on your phone or tablet, and log in to your Fitbit account if you haven't already done so.
2. From the Discover tab in the Fitbit app, tap **Health Assessments & Reports** > **Heart Rhythm Assessment (ECG)** 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 Fitbit wrist-worn product snugly, but with enough room for comfort. It should sit a finger's width above your wrist bone. For more information, see help.fitbit.com.
2. Sit down and open the ECG app on your Fitbit wrist-worn product.
3. Follow the instructions on your Fitbit wrist-worn product to start the assessment.
4. Put your index finger and thumb on the metal corners of your Fitbit wrist-worn product as shown on the screen. Continue to hold the corners until the countdown is complete.
5. When your results appear, swipe up to see the full report.

Cancel the assessment

To cancel the assessment at any time, press the button on your Fitbit wrist-worn product. 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 and the data is analyzed, you see 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: Your heart rate was too low, too high, or the Fitbit ECG app couldn't get a good reading. Tap **Retake** to try again, or tap **Done** to exit the assessment. For more information on why you might receive this result, see "Troubleshooting" on the next page.

When you open the Fitbit app, your results transfer from your Fitbit wrist-worn product to the Fitbit app, and can be viewed on your phone or tablet. To see your results at a later time, such as during an appointment with your healthcare provider:

1. From the Discover tab in the Fitbit app, tap **Health Assessments & Reports** > **Heart Rhythm Assessment**.
2. Tap **View Results** to see a list of all your previous results.
3. Tap any of the previous results to view the details. The results are displayed with the date and time that they were taken on the compatible Fitbit wrist-worn product. Within each result, tap **Export a PDF for your doctor** to download the 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.

See help.fitbit.com for more information on the Heart Rhythm Assessment.

Delete your results

1. From the Discover tab in the Fitbit app, tap **Health Assessments & Reports** > **Heart Rhythm Assessment**.
2. Tap **View Results** to see a list of all your previous results.
3. Tap the results you want to delete.

Delete and Restore the Fitbit ECG app

To remove the Fitbit ECG app:

1. In the Fitbit app on your phone or tablet, tap the Today tab  > your profile picture > your Fitbit wrist-worn product image.
2. Tap **Apps** > your device tab.
3. In the list of apps installed on your watch, find the **Fitbit ECG** app and tap it.
4. Tap **Uninstall**.

You can reinstall the app at any time from the Fitbit App Gallery. For more information on how to delete, install, and manage apps, see help.fitbit.com.

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 Fitbit 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 Fitbit 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 assessment
- Not resting your hands on a table
- Other arrhythmia

If the Fitbit 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 Fitbit wrist-worn product is on the wrist you selected when you started the assessment.
- Keep your index finger and thumb on the metal corners of your Fitbit wrist-worn product for the duration of the assessment.
- Check the fit of your Fitbit wrist-worn product. It should feel comfortably secure, not too loose or too tight. Wear it a finger's width above your wrist bone. For more information, see help.fitbit.com.
- Move away from other electronics to prevent interference.
- Make sure your Fitbit 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 Fitbit wrist-worn product. See fitbit.com/productcare for wear and care instructions.

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 help.fitbit.com. For troubleshooting heart-rate tracking, see help.fitbit.com.

Clinical Study

A clinical study was performed to validate the Fitbit 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 Fitbit ECG App test. The Fitbit 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 Fitbit ECG App were visually compared to classify AFib and SR, the Fitbit 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 Fitbit ECG App, the Fitbit 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. Normally, the heart contracts and empties all blood in the upper chambers. With AFib, the heart contracts irregularly, causing some blood to remain in the upper chambers. The remaining 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 help.fitbit.com or call (877) 623-4997.

Terms of Service

Fitbit designs products and tools that help you achieve your health and fitness goals and empower and inspire you to lead a healthier, more active life. These Terms of Service ("Terms") apply to your access and use of the Fitbit Service. The "Fitbit Service" includes our devices including associated firmware, applications, software, websites, APIs, products, and services.

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mention “Fitbit,” “we,” “us,” or “our,” they refer to the party to your agreement that provides you with the Fitbit Service.

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.

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

User Assistance Information

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

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EC REP Emergo Europe
Prinsessegracht 20
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CE 0123

Equipment Symbols

CE Mark

Read Instructions for Use

Manufacturer

EC REP European Authorised Representative

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