Fitbit Irregular Rhythm Notifications 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 irregularly.

C

Consumer wrist-worn product

Consumer 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).

P

Photoplethysmography (PPG)

Photoplethysmography (PPG) is a light-based technology used to detect the rate of your blood flow.

Pulse rate

Fitbit smartwatches and trackers have optical sensors that can detect the pulse of blood that goes to your wrist with every heartbeat. The pulse rate is used to estimate heart rate (see above) and to look for irregularities in beat-to-beat measurements.

Indications for Use

US*:

The Fitbit Irregular Rhythm Notifications is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provide a notification to the user.

The Fitbit Irregular Rhythm Notifications is intended for over-the-counter (OTC) use. It is not intended to provide a notification on every episode of irregular rhythm suggestive of AFib and the absence of a notification is not intended to indicate no disease process is present; rather the Fitbit Irregular Rhythm Notifications is intended to opportunistically surface a notification of possible AFib when sufficient data are available for analysis.

These data are only captured when the user is still. Along with the user's risk factors, the Fitbit Irregular Rhythm Notifications can be used to supplement the decision for AFib screening. The Fitbit Irregular Rhythm Notifications is not intended to replace traditional methods of diagnosis or treatment.

The Fitbit Irregular Rhythm Notifications has not been tested for and is not intended for use in people under 22 years of age. It is also not intended for use in individuals previously diagnosed with AFib.

Non-US**:

The Fitbit Irregular Rhythm Notifications software is intended as a pre-screening technology for atrial fibrillation. The software is not recommended for users with known atrial fibrillation, and is intended for home use by lay people aged 22 years and over.

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

*** Non-US Indications for Use apply to the following countries: Austria, Australia, Belgium, Canada, Chile, Czech Republic, France, Germany, Iceland, Ireland, Italy,*

Liechtenstein, Luxembourg, Malta, Mauritius, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, South Africa, Spain, Sweden, Switzerland, the United Kingdom, and Vietnam.

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. See fitbit.com/irregular-rhythm for additional details.

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

Intended Purpose (EU)

To analyze pulse rate data gathered from photoplethysmography (PPG) sensors to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provide a notification to the user.

Product Description

The Fitbit Irregular Rhythm Notifications feature is used to track and analyze pulse rhythm data for irregularities in beat-to-beat measurements, which can be indicative of AFib. Heart-rhythm data are temporarily stored on your consumer wrist-worn product until the data sync to your account. If signs of AFib are found in the data, you'll receive a notification on your phone to view details of the findings in the Fitbit app. The data are not analyzed in real-time and are not intended for diagnostic purposes.

The feature can be found in the Irregular rhythm notifications tile within the Health assessments section of the You tab in the Fitbit app. This tile is also used for onboarding, displaying past results, and other non-medical device data.

Intended Clinical Benefit

The primary benefit of the Fitbit Irregular Rhythm Notifications is to analyze pulse rate data to identify episodes of irregular heart rhythms consistent with atrial fibrillation and to provide a notification to the user.

Cautions

The feature has not been tested for and is not intended for use in people under 22 years of age. The feature is not intended for use for people with a history or diagnosis of atrial fibrillation.

General Warnings and Precautions

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

DO NOT use this product in place 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 receive a notification and have not been diagnosed with AFib by a physician, you should talk to your doctor. Erroneous false negative or false positive results due to the device or user error may occur. If you don't get a notification, it's possible to still have AFib. Fitbit is not always looking for AFib. We can't notify you for all instances of irregular heart rhythm that may be AFib. For more information on the performance of Fitbit Irregular Rhythm Notifications, see "Clinical Study" on page 16.

This feature has not been tested on people with a cardiac pacemaker or implantable cardioverter-defibrillator. If you have one of these devices, please consult with a doctor before using this feature.

DO NOT use for clinical diagnosis of AFib.

DO NOT use for continuous, real-time 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 is **NOT** intended for use in a clinical setting.

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

Wear your consumer wrist-worn product as instructed. For more information, see help.fitbit.com.

- Wear your device slightly higher on your wrist.
- Make sure your device is in contact with your skin.
- Your device should be snug but not constricting.

A number of factors can affect the accuracy of the pulse rate data used to look for signs of AFib, including body motion, wrist or finger movements, wrist tattoos, and decreased blood flow to the wrist.

NOTE: Fitbit Irregular Rhythm Notifications can only be used on compatible consumer wrist-worn products that have been paired to your account. For more information on consumer wrist-worn products compatible with Fitbit Irregular Rhythm Notifications, see "Operating Instructions" on page 12.

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 help.fitbit.com. If available on your consumer wrist-worn product, we recommend that you enable device lock. For more information, see help.fitbit.com.

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.

Expectations

How Fitbit Irregular Rhythm Notifications work

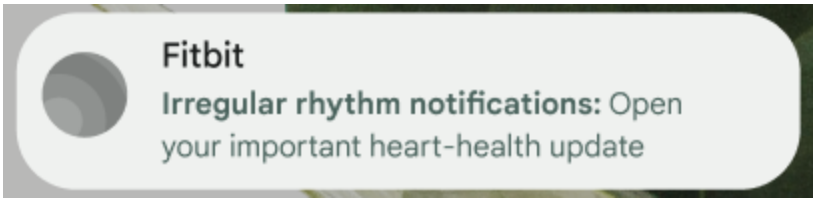
The Fitbit Irregular Rhythm Notifications feature collects heart rhythm and motion data to check for signs of AFib. When you turn on the feature, your heart rhythm data is collected in the background while you are still or sleeping, and analyzed for AFib. After your consumer wrist-worn product collects enough analyzable heart rhythm data, we look at your beat-to-beat measurements to check for irregularities. Beat-to-beat measurements indicate how quickly one heart beat comes after the other. It's typically measured in milliseconds (ms) and converted into beats per minute (bpm). Normally, these measurements are relatively predictable and smooth. Big increases or decreases (over 10 bpm) in a short period of time may be considered irregular.

Notifications you might see

Fitbit doesn't analyze your data in real-time. If you receive a notification, it means we saw signs of an irregular rhythm that may be AFib in multiple readings. You can receive up to 1 notification each day.

Phone notification

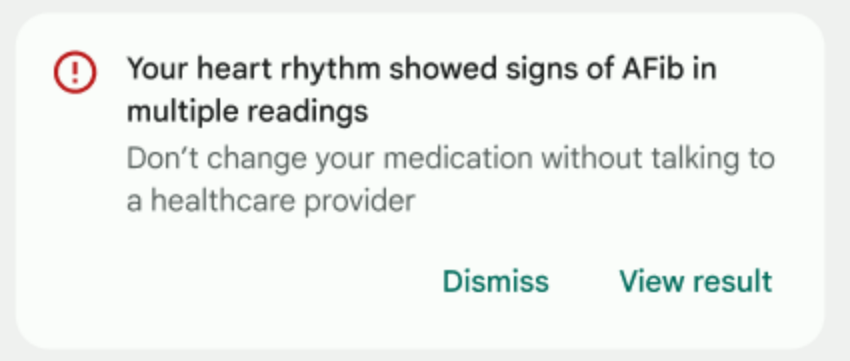
If you allow notifications from the Fitbit app on your phone, you see a notification on your phone:



Tap the notification to open the Fitbit app.

Fitbit app notification

When you open the Fitbit app, you see a notification at the top of the Today tab:



Tap **View result** to see the readings where we saw signs of an irregular heart rhythm.

Operating Instructions

Compatible devices and System Requirements

Irregular Rhythm Notifications are available on:

- Fitbit Charge 3 running firmware version 1.88.11 or higher
- Fitbit Charge 4 running firmware version 44.1.100.43 or higher
- Fitbit Charge 5 running firmware version 1.149.11 or higher
- Fitbit Inspire 2 running firmware version 44.1.124.34 or higher
- Fitbit Inspire 3 running firmware version 63.200001.179.13 or higher
- Fitbit Luxe running firmware version 1.151.16 or 1.146.4 or higher
- Fitbit Sense running firmware version 44.128.6.12 or higher
- Fitbit Sense 2 running firmware version 60.20001.169.126 or higher
- Fitbit Versa 2 running firmware version 35.72.1.9 or higher
- Fitbit Versa 3 running firmware version 36.128.6.12 or higher
- Fitbit Versa 4 running firmware version 61.20001.169.337 or higher
- Fitbit Versa Lite Edition running firmware version 38.72.1.9 or higher

If an incompatible device is paired after the user has consented to the feature, the algorithm will not analyze data from an incompatible device.

For information on device compatibility with the Fitbit app, see fitbit.com/global/us/technology/compatible-devices.

Note that the Fitbit Irregular Rhythm Notifications is only available in select locations at this time. Additional devices & countries will be added as regulatory clearance is obtained. See fitbit.com/irregular-rhythm for additional details.

Turn on irregular rhythm notifications

Irregular rhythm notifications appear in the Fitbit app and as a notification on your phone.

1. From the You tab in the Fitbit app on your phone, find the Irregular rhythm notifications tile in the Health assessments section. Tap **Set up**.
2. Follow the on-screen instructions to set up irregular rhythm notifications.

View irregular rhythm details and history

1. From the You tab in the Fitbit app on your phone, find the Irregular rhythm notifications tile in the Health assessments section. Tap **View history**. If Fitbit detects signs of any irregular heart rhythms that might be AFib, you see a list of notifications and when they occurred.
2. Tap a notification for detailed information. A list of irregular rhythm readings appears, marked with the time when the reading occurred, and the minimum and maximum heart rate during that time period. Swipe up to see the summary at the bottom of the page, which lists the date and time of the first irregular rhythm reading, last irregular rhythm reading, and when the data was recorded in the Fitbit app.
3. Tap an irregular rhythm reading for additional information. A list of your beat-to-beat measurements appears. Each heartbeat has a bpm value and a timestamp of when it occurred. The summary at the top displays the minimum and maximum bpm value recorded.

Delete irregular rhythm notifications

To delete a single irregular rhythm notification:

1. From the You tab in the Fitbit app on your phone, find the Irregular rhythm notifications tile in the Health assessments section. Tap **View history**.
2. Tap the notification you want to delete.
3. Tap the menu icon ⋮ > **Delete result** > **Delete**.

For instructions on how to delete all irregular rhythm notifications within a date range, see help.fitbit.com.

Export irregular rhythm notification data

For instructions on how to export your Fitbit data, see help.fitbit.com.

Turn off irregular rhythm notifications

For instructions on how to turn off irregular rhythm notifications, see help.fitbit.com.

Troubleshooting

Data collection

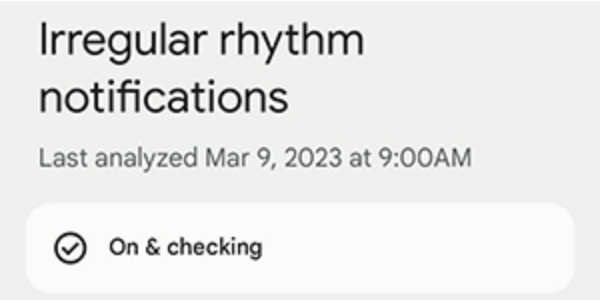
Fitbit can only analyze your heart rhythm data for AFib when you're still. Wear your consumer wrist-worn product often, especially to sleep, and sync your data often to help look for signs of AFib more often. We only send a notification if we see signs of an irregular rhythm in multiple readings, which means you might not receive irregular rhythm notifications if we're not able to collect enough data each day.

To troubleshoot heart-rate tracking, see help.fitbit.com.

Data analysis

Fitbit doesn't analyze your data in real-time. Keep the Fitbit app running in the background to make sure your compatible watch or tracker can regularly sync. To check when your heart rhythm data was last analyzed:

From the You tab in the Fitbit app on your phone, find the Irregular rhythm notifications tile in the Health assessments section. Tap **View history**.The time and date when your data was last analyzed appears below your history of notifications.



If your data hasn't been analyzed in several days, see help.fitbit.com.

Note that data is stored on your consumer wrist-worn product for 7 days. If you haven't synced with the Fitbit app in over 7 days, older data might be deleted and won't be analyzed.

Receiving notifications

If your phone doesn’t receive push notifications from the Fitbit app:

- Turn on notifications for the Fitbit app in your phone's settings. For instructions, see support.google.com for Android phones or support.apple.com for iPhones.
- Check that the Fitbit app on your phone is updated. For instructions, see help.fitbit.com.

Clinical Study

A clinical study was performed to validate the Fitbit Irregular Rhythm Notifications (IRN) software algorithm's ability to detect atrial fibrillation (AFib) using data collected from consumer wrist-worn products. The Fitbit Validation of Software for Assessment of Atrial Fibrillation From PPG Data Acquired by a Wearable Smartwatch Study (NCT04380415) included 455,699 subjects. There were 4,728 subjects who received an irregular rhythm notification and were invited to receive and wear an electrocardiogram (ECG) patch. Of those, 1,057 wore and returned a 7-day ECG patch monitor with usable data. The prevalence of AFib based on the 7-day ECG patch monitoring results was 32.2% (340/1057).

The Fitbit Irregular Rhythm Notifications software algorithm detected signs of AFib in 225 subjects while they were wearing an ECG patch after an initial IRN notification. Of those, 98.2% (221/225) showed AFib detections from the Fitbit Irregular Rhythm Notifications software algorithm and the ECG patch at approximately the same time. No serious 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 [https://www.cdc.gov/], American Heart Association [https://www.heart.org/], 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 [https://www.cdc.gov/], American Heart Association [https://www.heart.org/], 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 [https://www.cdc.gov/], American Heart Association [https://www.heart.org/], or by visiting the website of the European Society of Cardiology [https://www.escardio.org/].

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.

If you live in the European Economic Area, the United Kingdom or Switzerland, these Terms are an agreement between you and Fitbit International Limited, an Irish company with its registered office at 76 Lower Baggot Street, Dublin 2, Ireland. If you reside elsewhere, these Terms are an agreement between you and Fitbit LLC, 199 Fremont Street, 14th Floor, San Francisco, CA 94105 U.S.A. When the Terms 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: FB604 version 1.0-1.0-1.0 or higher.

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Medical Device

For customer support, visit help.fitbit.com.

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