# Instructions for Use : AFIB

# ENGLISH (EN) : AFIB

Atrial Fibrillation History Feature

Instructions for Use

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**INDICATIONS FOR USE**

The Atrial Fibrillation (AFib) History Feature (AFH) is an over-the-counter (“OTC”) software-only mobile medical application intended for users 22 years of age and over who have a diagnosis of AFib. The AFib History feature opportunistically analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of AFib and provides the user with a retrospective estimate of AFib burden (a measure of the amount of time spent in AFib during past Apple Watch wear).

Maintaining a healthy weight, reducing alcohol consumption, and getting better sleep may have a positive impact on AFib management.

The AFib History Feature is intended for use with compatible Apple Watches and the Health app on iPhone.

**INTENDED PURPOSE (EU REGION)**

The Atrial Fibrillation (AFib) History Feature is an over-the-counter (“OTC”) software-only mobile medical application intended for users 22 years of age and over who have a diagnosis of atrial fibrillation (AFib). The feature opportunistically analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of AFib and provides the user with a retrospective estimate of AFib burden (a measure of the amount of time spent in AFib during past Apple Watch wear).

The feature also tracks and trends estimated AFib burden over time, and includes lifestyle data visualizations to enable users to understand the impact of certain aspects of their lifestyle on their AFib. It is not intended to provide individual irregular rhythm notifications or to replace traditional methods of diagnosis, treatment, or monitoring of AFib.

The feature is intended for use with the Apple Watch and the Health app on iPhone.

Target Population and Intended Users

The AFib History Feature is intended for users who are 22 years and over. The feature is also intended for users that have been diagnosed with atrial fibrillation. Users who are interested in learning more about their cardiovascular health may choose to activate the feature upon successful completion of an onboarding process.

**ABOUT AFIB HISTORY FEATURE**

The AFib History Feature (AFH) measures the frequency of irregular pulse rhythms to provide an estimate for AFib burden. AFib burden can be defined as the percentage of time a person's heart is in AFib during a specified monitoring time period. The AFib History Feature on Apple Watch will allow you to track and assess how your lifestyle impacts your AFib burden.

Knowing about AFib burden is important because it can help you understand how various lifestyle changes, such as reducing your alcohol consumption, improving the quality of your sleep, and maintaining a healthy weight, could have a positive impact on how often you are in (frequency of) AFib.

The AFib History Feature uses PPG pulse rhythm data from compatible Apple Watches. Apple Watch uses green LED lights paired with light-sensitive photodiodes to detect relative changes in the amount of blood flowing through a user's wrist at any given moment. When the heart beats it sends a pressure wave down the vasculature, causing a momentary increase in blood volume when it passes by the sensor. By monitoring these changes in blood flow, the sensor detects individual pulses when they reach the periphery and thereby measure beat-to-beat intervals. In certain portions of the user interface, heart rhythm is used interchangeably with pulse.

**USING THE AFIB HISTORY FEATURE**

**Set-Up/On-boarding**

- The AFib History Feature is compatible with Apple Watch Series 4, Series 5, Series 6, Series 7, and SE and iPhone 8 or later. For regional availability and additional device compatibility information, please visit https://support.apple.com/HT212214.
- Update Apple Watch and iPhone to the latest versions of watchOS and iOS.
- Open the Health app on your iPhone and select "Browse".
- Navigate to "Heart" then select "AFib History".
- Follow the onscreen instructions.
- You may exit on-boarding at any time by tapping "Cancel".

**USING THE AFIB HISTORY FEATURE**

- Once the AFib History Feature is turned on, it will begin collecting pulse rhythm data to generate an AFib burden estimate. AFib burden estimates appear as a percentage in notifications and in the Health app and represents the proportion of time your heart was beating in atrial fibrillation relative to Watch wear over the previous week (7 days). A lower percentage means your heart was in AFib less often, a higher percentage means more often.
- AFib History only measures atrial fibrillation and does not measure other atrial arrhythmias, such as atrial flutter or atrial tachycardia.
- The AFib History Feature attempts to generate a burden estimate every 7 days. AFib burden estimates are published in the Health app on iPhone in AFib History. As time passes, you can track and trend your AFib burden by viewing your data over various time scales.
- If insufficient data is collected over the past 7 days, the AFib History Feature will not provide a AFib burden estimate. Instead, you will receive a notification indicating there is no data for the week.
- The AFib History Feature incorporates lifestyle data collected by Apple Watch or saved to HealthKit, including alcohol consumption, sleep, and more. You can view lifestyle data alongside AFib burden data to help understand the impact of your lifestyle on your AFib. To learn more about the relationship between AFib and lifestyle choices, tap the info icon next to each lifestyle factor data type.
- After using the AFib History Feature for 6 weeks, the feature will attempt to generate AFib History highlights. AFib History highlights display the percentage of time spent in AFib on days of the week over the past 6 weeks (Mondays, Tuesdays, Wednesdays, etc.) and 4-hour segments of the day over the past 6 weeks (12 AM-4 AM, 4 AM-8 AM, 8 AM-12 PM, etc.). Highlights can help you better understand more specific patterns relating to your AFib.

All data collected and analyzed by the AFib History Feature is saved to the Health app on your iPhone. If you choose to, you can share that information by exporting your health data in the Health app.

New data cannot be collected once your Apple Watch’s storage is full. You can free up space by deleting unwanted apps, music or podcasts. You can check your storage usage by navigating to the Apple Watch app on your iPhone, tapping “My Watch”, tapping “General”, and then tapping “Storage”.

**SAFETY AND PERFORMANCE**

The performance of the AFib History Feature was extensively tested in a clinical study of 413 participants ages 22 and older with a mix of AFib diagnoses (paroxysmal & permanent). Enrolled subjects wore an Apple Watch and a reference electrocardiogram (ECG) patch concurrently for up to 13 days. Study demographic characteristics are summarized in the table below:

**AFib History Feature Clinical Study Subject Demographics**

| | N=413 |
|---|---|
| **Age Group** | |

| | |
|---|---|
| <55 | 59 (14.3%) |
| >=55 to <65 | 99 (24.0%) |
| >=65 | 255 (61.7%) |
| **Sex** | |
| Male | 219 (53.0%) |
| Female | 194 (47.0%) |
| **Ethnicity** | |
| Hispanic or Latino | 19 (4.6%) |
| Non-Hispanic or Latino | 394 (95.4%) |
| **Race** | |
| White | 371 (89.8%) |
| Black or African American | 31 (7.5%) |
| Other | 11 (2.7%) |

The objective of the study was to assess the accuracy of the weekly AFib burden estimate generated by the feature compared to a weekly AFib burden reference measurement. To do so, Apple employed a Bland-Altman Limits of Agreement (LoA) approach. A LoA approach is a way of assessing agreement accuracy between two measurement methods.

Of the 413 enrolled subjects, 280 contributed data to the primary endpoint analysis to determine if the level of agreement between the reference ECG AFib burden and the feature's AFib burden estimate was acceptable. Based on the results of the study, the lower and upper Bland-Altman limits (i.e., two standard deviations from the mean difference) were -11.4% and 12.8%, respectively.

The average difference between the feature's weekly burden estimate and reference weekly burden was 0.67%. 92.9% (260/280) of subjects had paired weekly AFib burden differences within ±5%; 95.7% (268/280) of subjects' weekly AFib burden estimates were within +/- 10%.

The AFib History Feature and the Irregular rhythm Notification Feature (IRNF 2.0) use the same classification algorithm that leverages machine learning techniques to differentiate between AFib and non-AFib rhythms. To support use in the AFib History Feature's indicated use population, those with a diagnosis of AF, the algorithm was adjusted to prioritize sensitivity.

The table below outlines classification algorithm performance for IRNF 2.0 and the AFib History Feature in the clinical validation study.

**Clinical Validation Study Performance**

| | Sensitivity | Specificity |
|---|---|---|

| | | |
|---|---|---|
| AFib History Feature | 92.6% | 98.8% |
| IRNF 2.0 | 85.5% | 99.6% |

These results demonstrate that the AFib History Feature is effective in generating accurate AFib burden estimates. During the course of the study, 8 serious adverse events were reported. None of the events were found to be related to study procedures or to the feature.

**CAUTIONS**

**The AFib History Feature cannot detect heart attacks. If you ever experience chest pain, pressure, tightness, or what you think is a heart attack, call emergency services.**

**The AFib History Feature is not intended to be used to aid in medical management of AFib (i.e. it is not intended to help change your medications or for your doctor to adjust your treatment). The AFib History Feature is intended to help you understand the relationship between your AFib burden and lifestyle over time. Do not change your medication or AFib management plan without talking to your doctor first.**

**The AFib History Feature is not continuously looking for AFib and should not be relied on as a continuous monitor. This means the feature cannot detect all instances of AFib and may not always produce AFib burden estimates. You should notify your physician if you experience any changes to your health.**

**The AFib History Feature is not designed to detect atrial arrhythmias that produce regular patterns. Atrial fibrillation is irregular, but if you have a history of significant atrial arrhythmias that are regular in pattern, such as atrial flutter or atrial tachycardia, this feature may not be for you.**

**Apple developed the AFib History feature to maintain high sensitivity to irregular rhythms. As such, it is possible that users with a history of non-AF irregular heart rhythms will have higher than expected AF burden estimate.**

Apple Watch may be unable to collect data when Apple Watch is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).

A number of factors can impact the ability of the feature to measure your pulse and collect data to generate an AFib burden estimate. These include factors like motion, hand and finger movements, environmental factors such as ambient temperature, dark tattoos on the wrist, and the amount of blood flow to your skin (which can be reduced by cold temperatures).

DO NOT wear your Apple Watch during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

Not intended for use by individuals under age 22.

For best results, charge your Apple Watch regularly and make sure it fits snugly on top of your wrist. The heart rate sensor should stay close to your skin.

SECURITY: Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your iPhone and a passcode (personal identification number [PIN]) to your Apple Watch to add a layer of security. It is important to secure the iPhone since you will be storing personal health information. Users will also receive additional iOS and watchOS update notifications on their iPhone and Apple Watch, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes. See “iOS and watchOS Security Guide” which describes Apple’s security practices and is available to all of our users. For the iOS and watchOs Security Guide please visit https://support.apple.com/guide/security/welcome/web.

**EQUIPMENT SYMBOLS**

| | |
|---|---|
|  | Manufacturer |
|  | Consult instructions for use |
|  | European Authorized Representative |
|  | Medical Device |

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