ENGLISH (EN-AU)
Atrial Fibrillation History Feature

Instructions for Use

INDICATIONS FOR USE

The Atrial Fibrillation (AF) 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 AF. The AF History feature opportunistically analyses pulse rate data to identify episodes of irregular heart rhythms suggestive of AF, and provides the user with a retrospective estimate of AF burden (a measure of the amount of time spent in AF during past Apple Watch wear).

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

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

INTENDED PURPOSE (EU REGION)

The Atrial Fibrillation (AF) 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 (AF). The feature opportunistically analyses pulse rate data to identify episodes of irregular heart rhythms suggestive of AF and provides the user with a retrospective estimate of AF burden (a measure of the amount of time spent in AF during past Apple Watch wear).

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

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

Target Population and Intended Users

The AF 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 AF HISTORY FEATURE

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

Knowing about AF burden is important because it can help you understand the relationship between AF Burden and lifestyle. Some studies have shown that a healthy lifestyle can play an important role in reducing your AF burden over time; maintaining a healthy weight, reducing alcohol consumption and getting better sleep may have a positive impact on AF management.

The AF 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 AF HISTORY FEATURE

Set-Up/On-boarding

- The AFib History Feature is compatible with Apple Watch Series 4 or later 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 "AF History".
- Follow the onscreen instructions.
- You may exit on-boarding at any time by tapping "Cancel".

USING THE AF HISTORY FEATURE

- Once the AF History Feature is turned on, it will begin collecting pulse rhythm data to generate an AF burden estimate. AF 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 AF less often, and a higher percentage means more often. AF History only measures atrial fibrillation and does not measure other atrial arrhythmias, such as atrial flutter or atrial tachycardia.

- The AF History Feature attempts to generate a burden estimate every 7 days. AF burden estimates are published in the Health app in AF History. As time passes, you can track and trend your AF burden by viewing your data over various time scales.

- If insufficient data is collected over the previous 7 days, the AF History Feature will not provide an AF burden estimate. Instead, you will receive a notification indicating there is no data for the week.

- The AF 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 AF burden data to help understand the impact of your lifestyle on your AF. To learn more about the relationship between AF and lifestyle choices, tap the info icon next to each lifestyle factor data type.

- After using the AF History Feature for 6 weeks, the feature will attempt to generate AF History highlights. AF History highlights display the percentage of time spent in AF 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 AF.

All data collected and analysed by the AF 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, then tapping Storage.

SAFETY AND PERFORMANCE

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

AF 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 AF burden estimate generated by the feature compared to a weekly AF burden reference measurement. To do so, Apple employed a Bland-Altman Limits of Agreement (LoA) approach. An 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 AF burden and the feature's AF 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 AF burden differences within ±5%; 95.7% (268/280) of subjects 'weekly AF burden estimates were within +/- 10%.

The AF History Feature and the Irregular Rhythm Notification Feature (IRNF 2.0) use the same classification algorithm that leverages machine-learning techniques to differentiate between AF and non-AF rhythms. To support use in the AF History Feature's indicated use population, those with a diagnosis of AF, the algorithm was adjusted to prioritise sensitivity. The table below outlines classification algorithm performance for IRNF 2.0 and the AF History Feature in the clinical validation study.

Clinical Validation Study Performance

	Sensitivity	Specificity
AF History Feature	92.6%	98.8%
IRNF 2.0	85.5%	99.6%

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

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

The AF 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 AF 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 AF 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 the age of 22 years.

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.

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.

SECURITY: Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your iOS compatible devices and a passcode (personal identification number [PIN]) to your Apple Watch to add a layer of security. It is important to secure your iPhone since you will be storing personal health information on it. 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 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 Authorised Representative

Medical Device

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