ENGLISH (EN)
Irregular Rhythm Notification Feature

Instructions for Use

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INDICATIONS FOR USE

The Irregular Rhythm Notification Feature (IRNF) is a software-only mobile medical application that is intended to be used with the Apple Watch. The feature analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification to the user. The feature 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 feature 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 feature can be used to supplement the decision for AFib screening. The feature is not intended to replace traditional methods of diagnosis or treatment.

The feature 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.

INTENDED PURPOSE (EU REGION)

The Irregular Rhythm Notification Feature is a software-only mobile medical application that is intended to be used with the Apple Watch. The feature analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification to the user. The feature 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 feature 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 feature can be used to supplement the decision for AFib screening. The feature is not intended to replace traditional methods of diagnosis or treatment.

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Target Population and Intended Users

The IRNF is intended for users who are 22 years and over. There is no specific clinical condition required to use the app. Users who are interested in learning more about their cardiovascular health may choose to activate the feature upon successful completion of an onboarding process.

RUSSIA COUNTRY SPECIFIC INFORMATION

The Irregular Rhythm Notification Feature is not considered a medical device per ROSZDRAVNADZOR (Russian Health Authority).

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USING THE IRREGULAR RHYTHM NOTIFICATION FEATURE

Getting Started

- The Irregular Rhythm Notification Feature is compatible with Apple Watch Series 3 or later. For region availability and device compatibility for the IRNF, please visit: https://support.apple.com/HT208931
- Update Apple Watch and iPhone to latest OS.

Receiving a Notification

- Once the feature is turned on, you will receive a notification if the feature identified a heart rhythm suggestive of AFib and confirmed it on multiple readings.
- If you have not been diagnosed with AFib by a physician, you should discuss the notification with your doctor.

All data collected and analyzed by the Irregular Rhythm Notification Feature is saved to the Health app. If you choose to, you can share that information by exporting your health data.

New data cannot be collected once your Apple Watch's storage is full. You should 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 Irregular Rhythm Notification Feature (IRNF) was extensively tested in a clinical study of 573 participants ages 22 and older with a mix of diagnosed AFib and no known history of AFib. Study demographic characteristics are summarized in the table below:

IRNF 2.0 Clinical Study Subject Demographics

	N=573
Age Group	
<55	123 (21.5%)
>=55 to <65	140 (24.4%)
>=65	310 (54.1%)
Sex	
Male	286 (49.9%)
Female	287 (50.1%)
Ethnicity	
Hispanic or Latino	38 (6.6%)
Non-Hispanic or Latino	535 (93.4%)
Race	
White	502 (87.6%)
Black or African American	57 (9.9%)
Other	14 (2.4%)

Enrolled subjects wore an Apple Watch and a reference electrocardiogram (ECG) patch concurrently for up to 13 days. For those subjects contributing data to the primary endpoint analysis, 32.4% (n=140/432) presented with AFib as identified on the reference ECG patch and were included in determining the device sensitivity. Of those, 124 received an IRNF irregular rhythm notification with concordant AFib on the ECG patch, and the sensitivity was 88.6%. Of the 292 subjects who did not present with AFib on the ECG patch and contributed data to the analysis of device specificity, 290 did not receive a notification. The AF detection specificity was 99.3%. The remaining subjects (n=141/573) either contributed data to only secondary endpoint analyses and/or did not complete the study. These results support the device's effectiveness in detecting AFib.

CAUTIONS

The Irregular Rhythm Notification 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 Irregular Rhythm Notification Feature is not constantly looking for AFib and should not be relied on as a continuous monitor. This means the feature cannot detect all instances of AFib, and people with AFib may not get a notification.

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 detect an irregular rhythm suggestive of AFib. 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).

DO NOT change your medication without talking to your doctor.

Not intended for use by individuals under age 22.

Not intended for use by individuals previously diagnosed with AFib.

Notifications made by this feature are potential findings, not a complete diagnosis of cardiac conditions. All notifications should be reviewed by a medical professional for clinical decision-making.

Apple does not guarantee that you are not experiencing an arrhythmia or other health conditions even in the absence of an irregular rhythm notification. You should notify your physician if you experience any changes to your health.

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 IRNF device should be reported to the

manufacturer (Apple) 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 the iOS compatible devices 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.

For country specific regulatory registration information please visit: https://www.apple.com/legal/ifu/regulatory-registration-info.pdf

EQUIPMENT SYMBOLS

Manufacturer

Consult instructions for use

European Authorized Representative

Medical Device

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