

Instructions for Use : IRN 1.0

ENGLISH (EN)

Irregular Rhythm Notification Feature

Instructions for Use



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포장단위: 1ea

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Apple Irregular Rhythm Notification Feature (IRNF)

GB7830421-55921

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INDICATIONS FOR USE

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.

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.

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.

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.

INTENDED USE (NON-EU REGION & REPUBLIC OF KOREA)

Intended Use

The Irregular Rhythm Notification Feature (IRNF) is intended to pre-screen and notify the user of the presence of irregular rhythms suggestive of atrial fibrillation (AFib). The feature can be used to supplement a clinician's decision to screen for possible AFib. The feature is intended for over-the-counter (OTC) use.

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.

Indications

The feature is indicated to pre-screen for irregular rhythms suggestive of AFib for anyone aged 22 years and over.

RUSSIA COUNTRY SPECIFIC INFORMATION

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

The Irregular Rhythm Notification Feature is a software-only 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.

In order to receive appropriate healthcare advice please visit a qualified healthcare professional.

USING THE IRREGULAR RHYTHM NOTIFICATION FEATURE

Set-Up/On-boarding

- For region availability and device compatibility for the IRNF, please visit <https://support.apple.com/HT208931>
- Update Apple Watch and iPhone to latest OS.
- Open the Health app on your iPhone and select "Browse".
- Navigate to "Heart", then select "Irregular Rhythm Notifications".
- Follow the onscreen instructions.
- You may exit on-boarding at any time by tapping "Cancel".

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 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 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

In a study of 226 participants aged 22 years or older who had received an AFib notification while wearing Apple Watch and subsequently wore an electrocardiogram (ECG) patch for approximately 1 week, 41.6% (94/226) had AFib detected by ECG patch. During concurrent wear of Apple Watch and an ECG patch, 57/226 participants received an AFib notification. Of those, 78.9% (45/57) showed concordant AFib on the ECG patch and 98.2 % (56/57) showed AFib and other clinically relevant arrhythmias. A total of 370 irregular rhythm notifications with readable ECG patch data was received by the 57 participants. Of those 370 notifications, 322 (87.0%) were assessed to be AFib, 47 (12.7%) were arrhythmias other than AFib, and 1 (0.3%) was sinus rhythm. These results demonstrate that, while in the majority of cases the notification will accurately represent the presence of AFib, in some instances, a notification may indicate the presence of an arrhythmia other than AFib. No serious device adverse effects were observed.

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, 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, make sure your Apple Watch 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 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 the device, 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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