

Instructions for Use: IRN 1.0

ENGLISH (EN-GB)

Irregular Rhythm Notification Feature

Instructions for Use



Apple Inc.
One Apple Park Way
Cupertino, CA 95014, USA

www.apple.com



Apple Distribution International
Hollyhill Industrial Estate,
Hollyhill, Cork,
Ireland

Contact: medicalcompliance@group.apple.com



UKRAINE COUNTRY-SPECIFIC INFORMATION:

ТОВ «ДЖЕРЕЛО-УКРАЇНА»

01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27

email: uarep@jerelo.eu

тел. +38 (044) 360 30 11



UA-TR.120

SWITZERLAND COUNTRY-SPECIFIC INFORMATION:

CH-REP:

QUNIQUE GmbH
Bahnhofweg 17
5610 Wohlen
Switzerland

TURKEY COUNTRY-SPECIFIC INFORMATION:

Apple Teknoloji ve Satış Limited Şirketi
Büyükdere Caddesi
Levent 199 Kat:22-23

34394 Şişli
İstanbul

Türkiye

Product Tracking Number for Irregular Rhythm Notification feature: 8682450178007

BRAZIL COUNTRY-SPECIFIC INFORMATION:

ANVISA N^o: 80117580881

RESPONSÁVEL TÉCNICO: Luiz Levy Cruz Martins – CRF-SP: 42415

IMPORTADOR:

Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda.

Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200

CNPJ: 04.967.408/0001-98

Email: brazilvigilance@ul.com

COLOMBIA COUNTRY-SPECIFIC INFORMATION:

PRODUCTO: Función de notificación de ritmo irregular (IRNF por sus siglas en ingles)

IMPORTADOR:

IMPOMED S.A.S

Calle 1 SUR NO. 77A-21

Interior 201 Medellin Colombia

REGISTRO SANITARIO NO.: INVIMA 2020DM-0021835

ISRAEL COUNTRY-SPECIFIC INFORMATION:

AMAR REGISTRATION HOLDER:

Medogar Medical Equipment Ltd.

Hasadna St. 8 P.O.B 2586 Ra'annana 4365104 ISRAEL

Office Tel: +972-9-7401457 Fax: +972-9-7401459

מדוגר מכשור רפואי בע"מ

הסדנא 8 ת.ד. 2566 רעננה 4365104

טל: 09-7401457

פקס: 09-7401459

מידוגר للأجهزة الطبية المحدودة

شارع هاسادنا 8، ص.ب. 2566

رעננה 4365104

www.medogar.co.il info@medogar.co.il

AMAR Certificate Number: 21080017

REPUBLIC OF KOREA COUNTRY-SPECIFIC INFORMATION:

본 기능은 "의료기기" 임.

수입업자: 이머고코리아 (유)

06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층 제조원: Apple Inc.

(본사) One Apple Park Way, Cupertino, CA 95014, USA

(공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA

허가번호: 수허 20-176 호

명칭 (제품명, 품목명, 모델명): 불규칙한 박동 알림 기능, 심전계, Irregular Rhythm Notification Feature (IRNF)

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포장단위: 1ea

AUSTRALIA COUNTRY-SPECIFIC INFORMATION:

Sponsor Details:

Apple Pty Ltd

Level 3, 20 Martin Place

Sydney, NSW, 2000

Australia

<https://www.apple.com/au/>

TEL: 1-300-321-456

PERU COUNTRY-SPECIFIC INFORMATION:

Registro Sanitario N⁰ :DB6240E

IMPORTADOR:

Drogería Emergo Peru S.R.L.

Calle Las Orquídeas Nro. 585, Int. 1301,

San Isidro, Lima, Perú

RUC: 205 52 75 65 34

MALAYSIA COUNTRY-SPECIFIC INFORMATION:

Authorised Representative:

Nyprax Business Solutions

37 Jalan Terasek Lima, Bangsar Baru,

59100 Bangsar, Kuala Lumpur

Device Licence:

Apple Irregular Rhythm Notification Feature (IRNF)

GB7830421-55921

INDIA COUNTRY-SPECIFIC INFORMATION:

Import Licence Number: IMP/MD/2022/000754

IMPORTER:

Asia Actual India (OPC) Pvt. Ltd.

523A, Tower A, Spaze I-Tech Park, Sector 49,

Gurgaon, Haryana, India

INDONESIA COUNTRY-SPECIFIC INFORMATION:

Product Licence Number: KEMENKES RI AKL 20502121725

REGISTRANT:

PT. ASIA ACTUAL INDONESIA, DKI Jakarta

Gandaria 8 Office Tower, Unit 6J. Jl. Sultan Iskandar Muda

Jakarta Selatan 12240 – Indonesia

+62 (021) 2930-3747

MOLDOVA COUNTRY-SPECIFIC INFORMATION:

Registration Number: DM000322301, DM000322302

AUTHORISED REPRESENTATIVE:

JERELO S.R.L.

MD-2024, str. Pietrăriei, nr 19A, of. 3.

mun. Chişinău, Republica Moldova

+37378538295

THAILAND COUNTRY-SPECIFIC INFORMATION:

Medical Device Licence Number: 64-2-2-2-0002928

IMPORTER:

บริษัท เอเชีย แอคซวล (ประเทศไทย) จำกัด

8 อาคารทีวัน ห้องเลขที่ 15-102 ชั้น 15 ซอยสุขุมวิท 40 ถนนสุขุมวิท

แขวงพระโขนง เขตคลองเตย กรุงเทพฯ 10110

โทร. 02-821-5998

VIETNAM COUNTRY-SPECIFIC INFORMATION:

MA Import Licence Number: 220002520/PCBB-HCM

LICENCE HOLDER:

Asia Actual Vietnam Co., LTD.

45/90 Binh Tien

Ward 07, District 6

Ho Chi Minh City

INDICATIONS FOR USE

The Irregular Rhythm Notification Feature is a software-only mobile medical application that is intended to be used with Apple Watch. The feature analyses pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AF) 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 of every episode of irregular rhythm suggestive of AF and the absence of a notification is not intended to indicate no disease process is present; rather, the feature is intended to opportunistically display a notification of possible AF when sufficient data is available for analysis. This data is only captured when the user is still. Along with the user's risk factors, the feature can be used to supplement the decision for AF 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 AF.

INTENDED PURPOSE (EU REGION)

The Irregular Rhythm Notification Feature is a software-only mobile medical application that is intended to be used with Apple Watch. The feature analyses pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AF) 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 of every episode of irregular rhythm suggestive of AF and the absence of a notification is not intended to indicate no disease process is present; rather, the feature is intended to opportunistically display a notification of possible AF when sufficient data is available for analysis. This data is only captured when the user is still. Along with the user's risk factors, the feature can be used to supplement the decision for AF 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 AF.

Target Population and Intended Users

The IRNF is intended for users who are 22 years old 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 (AF). The feature can be used to supplement a clinician's decision to screen for possible AF. 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 AF.

Indications

The feature is indicated to pre-screen for irregular rhythms suggestive of AF 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 Apple Watch. The feature analyses pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AF) 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 of every episode of irregular rhythm suggestive of AF and the absence of a notification is not intended to indicate no disease process is present; rather, the feature is intended to opportunistically display a notification of possible AF when sufficient data is available for analysis. This data is only captured when the user is still. Along with the user's risk factors, the feature can be used to supplement the decision for AF 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 AF.

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

USING THE IRREGULAR RHYTHM NOTIFICATION FEATURE

Setup/Onboarding

- 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 onboarding 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 AF and confirmed it on multiple readings.

- If you have not been diagnosed with AF by a medical practitioner, you should discuss the notification with your doctor.

All data collected and analysed 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 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, then tapping Storage.

SAFETY AND PERFORMANCE

In a study of 226 participants aged 22 years or older who had received an AF notification while wearing Apple Watch and subsequently wore an electrocardiogram (ECG) patch for approximately 1 week, 41.6% (94/226) had AF detected by an ECG patch. During concurrent wear of Apple Watch and an ECG patch, 57/226 participants received an AF notification. Of those, 78.9% (45/57) showed concordant AF on the ECG patch and 98.2 % (56/57) showed AF and other clinically relevant arrhythmias. A total of 370 irregular rhythm notifications with readable ECG patch data were received by the 57 participants. Of those 370 notifications, 322 (87.0%) were assessed to be AF, 47 (12.7%) were arrhythmias other than AF 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 AF, in some instances, a notification may indicate the presence of an arrhythmia other than AF. 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 AF and should not be relied on as a continuous monitor. This means the feature cannot detect all instances of AF, and people with AF may not get a notification.

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

A number of factors can impact the ability of the feature to measure your pulse and detect an irregular rhythm suggestive of AF. 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 the age of 22.

Not intended for use by individuals previously diagnosed with AF.

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 doctor 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 your iPhone since you will be storing personal health information on it. 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 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

099-12479 Revision AD, February 2023
