

Instructions for Use: ECG Global 2.0

ENGLISH (EN-AU) : ECG Global 2.0

ECG app

Instructions for Use



Apple Inc.
One Apple Park Way
Cupertino, CA 95014

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

E-mail: 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

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

BRAZIL COUNTRY-SPECIFIC INFORMATION:

ANVISA Nº: 80117580880

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

E-mail: brazilvigilance@ul.com

COLOMBIA COUNTRY-SPECIFIC INFORMATION:

PRODUCTO: Software de Electrografía y aplicación de ECG para software de análisis de fotopletismografía

IMPORTADOR:

IMPOMED S.A.S

Calle 1 SUR NO. 77A-21

Interior 201 Medellin Colombia

REGISTRO SANITARIO NO.: INVIMA 2020DM-0021828

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

ميدوگار للأجهزة الطبية المحدودة

شارع هاسادنا 8، ص.ب. 2566

رעננה 4365104

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

AMAR Certificate Number: 21080016

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 ECG app: 8682450178021

PERU COUNTRY-SPECIFIC INFORMATION:

Registro Sanitario N0 :DB5982E

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 Terasak Lima, Bangsar Baru,

59100 Bangsar, Kuala Lumpur

Device Licence:

Apple ECG app

GB7992021-54025

INDIA COUNTRY-SPECIFIC INFORMATION:

Voluntary Registration Number: Apple-USA/I/MD/002975

IMPORTER:

Asia Actual India (OPC) Pvt. Ltd.

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

Gurgaon, Haryana, India

REPUBLIC OF KOREA COUNTRY-SPECIFIC INFORMATION:

본 앱은 "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 20-177 호

명칭 (제품명, 품목명, 모델명): 심전도 앱, 심전계, ECG App

소프트웨어 버전: 2.X

출시연월: 2022년 01월

포장단위: 1ea

사용목적 :

모바일플랫폼(Apple Watch)에 장착된 심전도(ECG)센서를 이용하여 측정된 단일유도(Lead I) 유사심전도 신호로부터 심방세동 또는 정상박동 존재 여부를 판정함으로써, 심전도 신호를 생성, 기록, 저장, 전송 및 표시하는 의료용 어플리케이션.

INDONESIA COUNTRY-SPECIFIC INFORMATION:

Product Licence Number: KEMENKES RI AKL 20502121822

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: DM000322299, DM000322300
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: 64-2-2-2-0004085
IMPORTER:
บริษัท เอเชีย แอคซัวล (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: 220002519/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 ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (Afib), sinus rhythm and high heart rate (no Afib detected with heart rate 100-150 bpm) on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.

The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating Afib from sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment.

The ECG app is not intended for use by people under 22 years old.

INTENDED PURPOSE (EU REGION)

The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (Afib), sinus rhythm and high heart rate (no Afib detected with heart rate 100-150 bpm) on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.

The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating Afib from sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment.

The ECG app is not intended for use by people under 22 years old.

Target Population and Intended Users

The ECG app 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)

The intended use of the ECG app is to allow the user to take a single lead ECG that is then classified as sinus rhythm or atrial fibrillation (Afib) on a classifiable waveform. The ECG and rhythm classification may be used by users with or without known Afib as data that may be shared with a qualified healthcare professional. The ECG app is intended to be used by laypeople aged 22 years and over.

RUSSIA COUNTRY-SPECIFIC INFORMATION

The ECG app is not considered a medical device per ROSZDRAVNADZOR (Russian Health Authority).

The ECG app is a software-only mobile application intended for use with the Apple Watch to create, record, store, transfer and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (Afib), sinus rhythm and high heart rate (no Afib detected with heart rate 100-150 bpm) on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.

The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. To receive appropriate healthcare advice please visit a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating Afib from sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment.

The ECG app is not intended for use by people under 22 years old.

USING THE ECG APP

App Set-Up/On-boarding

- The ECG app is compatible with Apple Watch Series 4 or later (excluding Apple Watch SE). For regional availability and additional device compatibility information, please visit <https://support.apple.com/HT208955>
- Update Apple Watch and iPhone to latest OS.
- Open the Health app on your iPhone and select "Browse".
- Navigate to "Heart", then select "Electrocardiogram (ECG)".
- Follow the onscreen instructions.
- You may exit on-boarding at any time by tapping "Cancel".

Recording an ECG

- Make sure your Apple Watch is snug on the wrist you selected in Settings > General > Orientation.
 - Open the ECG app on your Apple Watch.
 - Rest your arms on a table or in your lap, and hold your finger on the Digital Crown. You do not need to press the crown during the session.
 - The recording takes 30 seconds.
-

ECG Analysis

- After a successful reading, you will receive one of the following classifications on your ECG app:
 - Sinus Rhythm: A sinus rhythm result means the heart is beating in a uniform pattern between 50–99 BPM.
 - High Heart Rate - No Atrial Fibrillation Detected: A high heart rate result means that the heart is beating between 100–150 bpm and does not show signs of Atrial Fibrillation.
 - Atrial Fibrillation: An AF result means the heart is beating in an irregular pattern between 50–99 BPM.
 - Atrial Fibrillation - High Heart Rate: An Afib High Heart Rate result means that the heart is beating in an irregular pattern between 100–150 bpm.
 - Poor Recording: A poor recording result means that the recording could not be classified because of too much artefact or noise in the waveform. This can happen for many reasons such as excess movement during a recording, or wearing your Apple Watch too loosely. Certain physiological conditions may prevent a small percentage of users from creating enough signal to produce a good recording.
 - Low or High Heart Rate: the ECG app cannot check recordings with a heart rate below 50 bpm or above 150 bpm.
- After an ECG recording is complete, the ECG data is analysed to determine if it is at least 25 seconds long and, if so, if either Sinus Rhythm, high heart rate no Afib detected, Afib is present or if an Inconclusive result is warranted.
- The ECG recording result on the ECG app provides a detailed display of the result. A detailed explanation will also be provided in the Health app on your iPhone.
- Presence of Afib in your ECG results may represent only potential findings. If you are experiencing any symptoms or have concerns, contact your doctor. If you believe you are experiencing a medical emergency, contact emergency services.
- Inconclusive ECG results may mean that there may have been too much artifact or noise to acquire a good signal, or you may have an arrhythmia other than Afib, which the app cannot classify. A small percentage of people may have certain physiological conditions preventing the user from creating enough signal to produce a good recording. You can learn more about Inconclusive ECG results during on-boarding, by accessing educational information in the ECG area of the Health app on your iPhone, or by tapping the “i” icon on the ECG app for more information.
- If you receive an Inconclusive result due to a poor recording, you might try to re-record your ECG. A small percentage of people may have certain physiological conditions preventing the user from creating enough signal to produce a good recording. You can review how to take an ECG during onboarding or by tapping on “How to Take an ECG” in the ECG area of the Health app on your iPhone.
- A heart rate can be low because of certain medications or if electrical signals are not properly conducted through the heart. Training to be an elite athlete can also lead to a low heart rate.

- A heart rate can be high because of exercise, stress, nervousness, alcohol dehydration, infection, Afib, or other arrhythmia.
- All ECGs are synced to the Health app on your iPhone. You may use the Health app to share your ECG with a clinician.

Deleting and Restoring ECG app on Apple Watch

- Delete ECG app on the Apple Watch
 - On your Apple Watch, go to the Home Screen
 - If you are in Grid View, touch and hold the app lightly until it jiggles
 - Tap on the app, then tap the “x” icon
 - If you are in List View, swipe left on the app and tap the Trash icon
 - Tap Delete
 - Press Digital Crown to finish
 - Restore ECG app on the Apple Watch
 - Go to the App Store on your Apple Watch
 - Search for ECG app
 - Tap  to restore the app
-

SAFETY AND PERFORMANCE

The ECG app’s ability to accurately classify an ECG recording into AF and sinus rhythm was extensively tested in a clinical trial of approximately 546 subjects. Rhythm classification of a 12-lead ECG by a cardiologist was compared to the rhythm classification of a simultaneously collected ECG from the ECG 2.0 app. The ECG app demonstrated 98.5% sensitivity in classifying AF (HR 50–150 bpm) and 99.3% specificity in classifying sinus rhythm (HR 50–150 bpm) in classifiable recordings.

The morphology of the waveform was also tested in this clinical trial by visual assessment of the PQRST wave and R wave amplitude in comparison to a reference. The ECG 2.0 app produced a visually acceptable PQRST waveform with a pass rating of 100% compared to the reference waveform. Additionally, the total pass rating for R-wave amplitude assessment was 97.2% compared to the reference.

TROUBLESHOOTING

If you experience difficulties in operating your ECG app, refer to the troubleshooting guide below.

Problem: I cannot get the ECG app to take a reading.

Solution:

- Ensure that you have completed all of the on-boarding steps in the Health app on your iPhone.
- Make sure your wrist and your Apple Watch are clean and dry. Water and sweat can cause a poor recording.
- Ensure that your Apple Watch, arms, and hands remain still during recordings.

Problem: I have a lot of artefact, noise, or interference in my recording.

Solution:

- Rest your arms on a table or in your lap while you take a recording. Try to relax and not move too much.
- Make sure your Apple Watch isn't loose on your wrist. The band should be snug and the back of your Apple Watch needs to be touching your wrist.
- Move away from any electronics that are plugged into a power point to avoid electrical interference.

Problem: The ECG waveforms appear upside down.

Solution:

- The watch orientation may be set to the wrong wrist. On your iPhone, go to the Watch app. Tap My Watch > General > Watch Orientation.

All data recorded during an ECG app session is saved to Health app on your iPhone. If you choose to, you can share that information by creating a PDF.

New ECG data cannot be recorded once your Apple Watch's storage is full. If you are not able to take a recording due to storage space issues, 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".

CAUTIONS:

The ECG app cannot check for signs of a heart attack. If you believe you're having a medical emergency, call emergency services.

DO NOT take recordings when Apple Watch is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).

DO NOT take recordings during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

DO NOT take recordings when Apple Watch is outside of the operational temperature range (0 °C - 35 °C) indicated in the Apple Watch user manual and humidity range of 20% to 95% relative humidity.

DO NOT use to diagnose heart-related conditions.

DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT take a recording during physical activity.

DO NOT change your medication without talking to your doctor.

Not intended for use by individuals under the age of 22 years.

You should talk to your doctor if your heart rate is under 50 or over 150 at rest and this is an unexpected result.

Interpretations made by this app are potential findings, not a complete diagnosis of cardiac conditions. The user is not intended to interpret or take clinical action based on the app output without consultation of a qualified healthcare professional.

The waveform generated by the ECG app is meant to supplement rhythm classification for the purposes of discriminating Afib from normal sinus rhythm and tachycardia (high heart rate) and not intended to replace traditional methods of diagnosis or treatment.

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.

CAUTION: Apple does not guarantee that you are not experiencing an arrhythmia or other health conditions when the ECG app labels an ECG as Sinus Rhythm or Tachycardia (high heart rate). You should notify your doctor if you detect possible changes in your health.

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; 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

099-23781 Revision Q, October 2022
