ENGLISH (EN-GB)

ECG App

Instructions for Use

INDICATIONS FOR USE

The ECG app is a software-only mobile medical application intended for use with 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 (AF) or sinus rhythm 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 with a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AF from normal 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 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 (AF) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.

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Target Population and Intended Users

The ECG app 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)

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 (AF) on a classifiable waveform. The ECG and rhythm classification may be used by users with or without known AF 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).

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USING THE ECG APP

App Setup/Onboarding

- For region availability and device compatibility for the ECG app, 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 onboarding at any time by tapping Cancel.

- Once onboarding is complete, you can take an ECG using the ECG app on your Apple Watch.

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 50–100 BPM.
    - Atrial Fibrillation: An AF result means the heart is beating in an irregular pattern between 50–120 BPM.
    - Inconclusive: An inconclusive result means the recording can't be classified. This can happen for many reasons such as not resting your arms on a table during a recording, or your Apple Watch is too loose. Certain physiological conditions may prevent a small percentage of users from creating enough signal to produce a good recording.
    - Low or High Heart Rate: A heart rate under 50 bpm or over 120 bpm affects the ECG app's ability to check for AF and the recording is considered inconclusive.
- 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 or AF 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 on your iPhone.
- Presence of AF 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, you should contact emergency services.

- A result of Sinus Rhythm means your heart rate is between 50 and 100 beats per minute and is beating in a uniform pattern.

- Inconclusive ECG results may mean there may have been too much artefact or noise to acquire a good signal, or you may have an arrhythmia other than AF the app cannot classify, or your heart rate is between 100 and 120 bpm. A small percentage of people may have certain physiological conditions preventing them from creating enough signal to produce a good recording. You can learn more about Inconclusive ECG results during onboarding, by accessing educational information in the ECG area of the Health app, or by tapping the "i" icon on the ECG app for more information.

- 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, AF or other arrhythmia.

- If you receive an Inconclusive result due to a poor recording, you might try to re-record your ECG. You can review how to take an ECG during onboarding or by tapping "How to take an ECG" in the ECG area of the Health app.

- All ECGs are synced to the Health app. You may use the Health app to share your ECG with a clinician.

Deleting and Restoring ECG App on Apple Watch (For iOS 13 and later and watchOS 6 and later)

- Delete ECG app on 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 the app, then tap the "x" icon
    - If you are in List View, swipe left on the app and tap the Bin 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 600 subjects. Rhythm classification of a 12-lead ECG by a cardiologist was compared with the rhythm classification of an ECG collected simultaneously from the ECG app. The ECG app demonstrated 98.3% sensitivity in classifying AF and 99.6% specificity in classifying sinus rhythm in classifiable recordings.

In this clinical trial, 12.2% of recordings were inconclusive and not classifiable as either sinus rhythm or AF. When inconclusive recordings were included in the analysis, the ECG app correctly classified sinus rhythm in 90.5% of subjects with sinus rhythm and AF in 85.2% of subjects with AF. The clinical validation results reflect use in a controlled environment. Real-world use of the ECG app may result in a greater number of strips being deemed inconclusive and not classifiable.

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 with a reference. During this clinical trial, no adverse events were observed.

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 you have completed all the onboarding steps in the Health app on your iPhone.
- Make sure your wrist and Apple Watch are clean and dry. Water and sweat can cause a poor recording.
- Ensure 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 strap 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. If you choose to, you can share that information by creating a PDF.

New ECG data cannot be recorded once your Apple Watch 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 proximity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems or 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.

You should talk to your doctor if your heart rate is under 50 or over 120 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 with a qualified healthcare professional.

The waveform generated by the ECG app is meant to supplement rhythm classification for the purposes of discriminating AF from normal sinus rhythm and is 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.

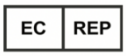
CAUTION: Apple does not guarantee that you are not experiencing an arrhythmia or other health conditions when the ECG app labels an ECG as Sinus Rhythm. You should notify your doctor if you detect possible changes in your health.

SECURITY: Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your 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 iOS-compatible devices since you will be storing personal health information on them. 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

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