

Garmin ECG App

Instructions for Use

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Users must read instructions before use

U.S. Instructions for Use**1. INDICATIONS FOR USE**

The Garmin ECG app is a software-only, mobile medical application intended for use with compatible Garmin smartwatches to create, record, store, transfer, and display a single-channel electrocardiograph similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm (SR) 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 normal SR, and it 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.

2. GENERAL WARNINGS AND PRECAUTIONS

**Please observe the following WARNINGS.
Failure to heed these warnings could cause harm.**

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

The ECG app CANNOT detect blood clots, stroke, or other heart conditions, including high blood pressure, congestive heart failure, high cholesterol, and other arrhythmias.

DO NOT change your medication or dosage without first talking to your doctor. ECG app results may not be accurate for people taking certain medications or substances that affect heart rate or blood flow.

DO NOT use in place of any treatment prescribed by your doctor.

DO NOT use for clinical diagnosis of heart-related conditions. ECG app results are NOT a diagnosis.

ECG app results are for **informational purposes only** and are potential findings. DO NOT interpret or take clinical action based on ECG app results without first consulting a qualified healthcare professional.

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

DO NOT use the ECG app if you have a known arrhythmia other than AFib.

DO NOT use for continuous, real-time, or self-monitoring of heart rhythm.

A sinus rhythm result only applies to that ECG recording and DOES NOT mean your heart always beats normally. A sinus rhythm result DOES NOT guarantee you are not experiencing an arrhythmia or other health conditions. You should notify your doctor if you detect possible changes in your health.

Even if you have been diagnosed with AFib, your heart may not always beat irregularly. Detecting AFib can be difficult, even in a doctor's office.

This product has NOT been tested on individuals who are pregnant.



Please follow the PRECAUTIONS listed below.

The ECG app may not be able to provide accurate results if you do not follow these precautions.

DO NOT use the ECG app during physical activity.

DO NOT use the ECG app if you are younger than 22 years old.

DO NOT use the ECG app when you are in close vicinity to strong electromagnetic fields (examples: electromagnetic anti-theft systems, metal detectors).

DO NOT use the ECG app during medical procedures, including magnetic resonance imaging (MRI).

DO NOT use the ECG app when your Garmin watch is outside of the operational temperature range or humidity range indicated in the user manual for that device.

DO NOT use the ECG app while you or the Garmin watch is submerged in water.

Wear your Garmin watch as instructed. The ECG app can only be used on compatible Garmin smartwatches. For information on which Garmin products are compatible with the ECG app, go to [garmin.com/ECG](https://www.garmin.com/ECG).

Make sure your thumb and index finger used to record an ECG are uncovered and free of any bruises, scars, or cuts.

Certain physiological conditions can prevent some people from having a strong enough signal for the ECG app to detect and analyze.

For security reasons, Garmin recommends you maintain control of your Garmin watch and smartphone at all times to prevent unauthorized access to your health data. Garmin also recommends you enable the device lock feature of your Garmin watch. You should enable PIN, password, or fingerprint functionality on your smartphone following the manufacturer's instructions to further prevent unauthorized access. Do not use your smartphone or Garmin watch on

unsecured Wi-Fi® networks. You should also secure your Garmin Connect™ account using a strong password and complete setup of multi-factor authentication.

3. ECG APP SETUP

The ECG app can only be used on a compatible Garmin watch that has been set up with your Garmin Connect account. The ECG app requires a Venu® 2 Plus (firmware version 11.21 or later) and use of the Garmin Connect app (version 4.62 or later) to complete ECG app setup. Garmin Connect is available from the app store on your smartphone. The ECG app is only available in select regions. For region availability and general support for the ECG app, go to garmin.com/ECG.

To use the ECG app on your Garmin watch, you must first complete the setup in the Garmin Connect app.

1. Open the Garmin Connect app on your smartphone.
2. Select the device image at the top of the screen.
Note: If you have more than one device paired with the Garmin Connect app, select the ☰ or ⋮ menu, select **Garmin Devices**, and then select the device.
3. Select **Finish Setup > Set Up ECG App**.
4. Follow the on-screen instructions.
5. After the setup is complete, you can record an ECG using the ECG app on your Garmin watch.

4. RECORDING AN ECG ON YOUR GARMIN WATCH

Follow these instructions to record an ECG on your Garmin watch.

1. Wear the watch just above your wrist bones toward your elbow on the wrist you selected during setup.
Note: The watch should be snug but comfortable.
2. Open the ECG app on your watch and follow the on-screen instructions.
3. Sit comfortably, rest your arm and wrist on a table, and keep still.
4. Place your thumb and index finger on the metal ring around the watch face to start a recording.
5. Keep your fingers in place and remain still for the entire 30-second recording.
6. After the recording is complete, you can view the ECG app result on your watch. Please see below for more information about results you might see.

5. VIEWING YOUR ECG RECORDING IN THE GARMIN CONNECT APP (OPTIONAL)

If you chose to upload your health and fitness data during setup, then you can view your ECG recordings in the Garmin Connect app on your smartphone.

1. From the Garmin Connect app, select the ☰ or ⋮ menu.
2. Select **Health Stats > ECG**.
3. Choose the ECG recording to view more information.

6. HOW IT WORKS

The ECG app uses sensors on your compatible Garmin watch to record the electrical signals that control how your heart beats. This recording is known as an electrocardiogram, or ECG. The ECG app analyzes the recording to get your heart rate and detect signs of an irregular heart rhythm called AFib. AFib rhythms occur when the upper and lower chambers of your heart are not beating in sync.

7. RESULTS YOU MIGHT SEE

After you complete an ECG recording, you will see one of the following results in the ECG app.

Sinus Rhythm

A sinus rhythm result means your heartbeat pattern appears normal. It indicates that the upper and lower chambers of your heart are beating in sync.

Note: A sinus rhythm result only applies to that specific recording and DOES NOT mean your heart always beats normally.

Atrial Fibrillation (AFib)

An AFib rhythm result means your heartbeat pattern appears irregular. AFib is an irregular heart rhythm caused by your heart's upper and lower chambers not beating in sync. You should speak with your doctor if you receive an unexpected AFib rhythm result.

Left untreated, AFib can lead to serious health consequences. The irregular heart rhythm causes improper blood flow in the heart, which can lead to stroke, heart failure, and/or other medical problems.

AFib can be temporary or persistent, but it is a manageable condition when treated by a doctor and with medication. Many people with AFib live healthy lives. Sometimes people with AFib do not have symptoms. However, others may experience one or more of these common symptoms:

- Rapid heartbeat (pounding, fluttering)
- Skipped heartbeat
- Fatigue
- Shortness of breath
- Chest tightness or pain
- Fainting
- Dizziness

Heart Rate Too High or Too Low

If your heart rate is over 120 beats per minute (bpm) or under 50 bpm, the ECG app cannot check for AFib heart rhythms. In these cases, the result will be inconclusive, and your heart rhythm will not be classified. If you get this result repeatedly or you do not feel well, then you should speak with your doctor.

A heart rate below 50 bpm can be caused by taking some medications or by certain heart conditions. Some people with high fitness levels may also have a heart rate below 50 bpm.

A heart rate above 120 bpm is common while exercising and for a short time afterward. It can also be caused by high stress levels, an infection, dehydration, alcohol use, and certain heart conditions, including AFib.

Inconclusive

An inconclusive result means your heart rhythm could not be classified. This could happen for several reasons, such as moving too much or poor skin contact during the ECG recording. Try resting both your arm and wrist on a table and make sure the watch is snug on your wrist. If you get this result repeatedly or if you do not feel well, then you should speak with your doctor.

Here are some steps to help improve your recording:

- Rest your arm and wrist on a table and keep still during the recording.
- Make sure the Garmin watch is snug on your wrist. The back of the watch must be touching your arm.
- Only place your thumb and index finger on the metal ring around the watch face and keep them in place for the full recording.
- Make sure you are wearing the watch on the wrist you chose during setup.
- Make sure both your wrist and the watch are clean and dry.
- Stay clear of other electronics to avoid interference.

Other factors that can cause an inconclusive result:

- A heart rate between 100 and 120 bpm, and the rhythm was not AFib.
- A pacemaker or other implanted cardioverter device (ICD).
- Other heart conditions that the ECG app cannot recognize.
- Not enough electrical signal in the recording.

8. SAFETY AND PERFORMANCE

The ECG app's ability to accurately detect AFib and sinus rhythms in an ECG recording was validated in a clinical study involving approximately 590 subjects. ECG app rhythm classifications were compared to 12-Lead ECG rhythm classifications performed by board-certified cardiologists. The ECG app was able to correctly identify AFib 99.5% of the time and correctly identify SR 100% of the time in the recordings that could be classified.

During this study, the ECG app determined 11.5% of recordings were inconclusive, including those which were deemed of too poor quality for analysis. When including these inconclusive recordings, the probability that the ECG app would return an AFib result for a subject in AFib was 86.5%, and 91.1% for a SR result for subjects in sinus rhythm. Real-world performance may have a higher rate of inconclusive and poor recording results.

Accuracy of the ECG app PDF reports was assessed by comparing to a simultaneously recorded standard Lead I ECG. Key characteristics of the ECG waveforms such as PR and RR intervals, QRS duration, location, and amplitude, and P wave presence and amplitude were compared and found to be statistically equivalent within an acceptable margin of error. Comparison of the board-certified cardiologists' rhythm classifications of simultaneously recorded 12-Lead ECG and ECG app recordings had 96% agreement. No adverse events were observed during the clinical study.

9. TROUBLESHOOTING

If you experience problems using the ECG app, refer to this troubleshooting guide.

Problem: I can't activate the ECG app on my compatible Garmin watch.

Solution:

- Make sure the ECG app is available for your Garmin watch. Go to garmin.com/ECG.
- Make sure the ECG app is approved for use in your country. Go to garmin.com/ECG.
- Make sure you have location permissions enabled for the Garmin Connect app on your smartphone. Refer to the manufacturer's instructions to enable location permissions.
- Review and complete the setup in the Garmin Connect app on your smartphone (see ECG App Setup - Section 3 above).

Problem: I can't find the ECG app on my Garmin watch.

Solution:

- Make sure the ECG app is available for your Garmin watch. Go to garmin.com/ECG.
- Make sure the ECG app is approved for use in your country. Go to garmin.com/ECG.
- Review and complete the setup in the Garmin Connect app on your smartphone (see ECG App Setup - Section 3 above).
- The ECG app can be found in the Apps and Activities menu on your Garmin watch. For help finding this menu, please refer to how to **Start an Activity** in your Garmin watch user manual.

Problem: I can't get the ECG app to create a recording.

Solution:

- Review and complete the setup in the Garmin Connect app on your smartphone (see ECG App Setup - Section 3 above).
- Water and sweat can cause a poor recording. Clean and dry your wrist and your Garmin watch.
- Dry skin, cold skin, a hairy wrist, wearing the watch on your wrist bones, or too much movement can prevent the ECG app from recording your ECG.
 - Use moisturizing lotion on your hands and wrist.
 - Remove the watch and rub your wrist gently to warm the skin. Put the watch back on and try again.
 - Wear the watch just above your wrist bones toward your elbow.
 - Remain still during the recording.

Problem: I get the Inconclusive (Poor Quality) result, or I see a lot of noise or interference in my recording.

Solution:

- Sit comfortably, relax, and try to remain still.
- Rest your arm and wrist on a table while you take a recording.
- Check the fit of the Garmin watch on your wrist. The band should be snug. The back of your Garmin watch must be touching your wrist. Wear the watch just above your wrist bones toward your elbow.
- Use your thumb and index finger on the metal ring around the watch face.
- Move away from any electronics that are plugged into a power source to avoid electrical interference.
- Water and sweat can cause a poor recording. Clean and dry your wrist and your Garmin watch.

Problem: The ECG waveforms appear upside down.

Solution:

- You may not be wearing the watch on the wrist you selected while setting up your Garmin watch. You can either wear the watch on your other arm or change your user profile wrist selection. To change your wrist selection, please refer to **Setting Up Your User Profile** in your Garmin watch user manual and select **Wrist**.

Problem: I can't find my ECG recordings in the Garmin Connect app.

Solution:

- If you chose to upload your health and fitness data during setup, you can view your ECG recordings in the Garmin Connect app on your smartphone and manually share them by creating a PDF.
- From the Garmin Connect app, select the ☰ or ⋮ menu.
- Select **Health Stats > ECG**.

Problem: My Garmin watch storage is full.

Solution:

- If your Garmin watch storage is full, you will not be able to take new ECG recordings. To make room for new ECG recordings, free up space on your Garmin watch by deleting unwanted apps, music, or podcasts.

10. EQUIPMENT SYMBOLS



Manufacturer



Users must read instructions before use

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