

ECG App

Instruction for Use

Please read this Instructions for Use carefully to use it properly.



Samsung Electronics Co., Ltd.

129, Samsung-ro, Yeongtong-gu, Suwon-si,

Gyeonggi-do, 16677, Korea www.samsung.com



eIFU indicator



2024-12 (v 5.0)

--

Intended Purpose

The Samsung ECG App is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy watch and phone.

The ECG App is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG), similar to a Lead I ECG for adults 22 years and older. Classifiable traces are labeled by the app as either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification. In addition to the existing on-demand ECG function, the app also provide Irregular Heart Rhythm Notification (IHRN) feature which analyzes pulse rate data, on the background, to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification suggesting the user record an ECG to analyze the heart rhythm. The IHRN feature 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 acquire pulse rate data when the user is still and analyze the data when determined sufficient toward surfacing a notification.

The ECG App is not intended to replace traditional methods of diagnosis or treatment. The app is not intended for users with other known arrhythmias and users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG rhythm-classification results displayed by the ECG App are for informational purposes only.

About these Instructions for Use

Symbols used

Symbol	Name	Description
	Manufacturer	Indicates the medical device manufacturer.
	Medical Device	Indicates this is a medical device.
	Consult electronic instructions for use	Indicates the need for the user to consult the instructions for use. Indicates the instructions for use is provided in electronic form.
	Reference Number	Indicates the manufacturer's catalogue number so that the medical device can be identified. It's used to identify the versions within one product name on the label of the product.
	Caution	Indicates content which you must follow to avoid any problem or inaccurate measurement resulting from misuse of this app.
	Caution	Indicates content which you must follow to avoid any problem or inaccurate measurement resulting from misuse of this app.
	Average heart rate	Indicates an average heart rate during ECG measurement.

Accessing these Instructions for Use

These Instructions for Use are available electronically within the Samsung Health Monitor application and on the Samsung Health Monitor page of the Samsung website (www.samsung.com/apps/samsung-health-monitor/).

For a printed copy of these Instructions for Use, you can download them from the Samsung website and print them, or contact the official Samsung support center in your country.

Contraindications

DO NOT use the ECG App if you have an implanted pacemaker, implanted cardiac defibrillator, or other implanted electronic device.

DO NOT use the ECG App if you have a known arrhythmia other than atrial fibrillation.

The ECG App is not intended for use by people younger than 22 years old.

Cautions



The ECG App cannot diagnose cardiac conditions or look for signs of a heart attack. If you think you're having a heart attack, which can include these symptoms:

- Shortness of breath
- Chest pain or pressure
- Fainting

Call emergency services immediately.

The ECG App is not meant to replace traditional methods of diagnosis or treatment by a qualified healthcare professional. If you think you're having a medical emergency, contact your local emergency services immediately.

DO NOT use the ECG App to diagnose cardiac conditions. Seek medical attention if you're experiencing concerning symptoms.

DO NOT change your medications or dosage without first consulting your doctor.

The ECG App is NOT constantly looking for atrial fibrillation when the Irregular Heart Rhythm Notification feature is on. This means that Galaxy Watch may not detect all instances of atrial fibrillation and people with atrial fibrillation may not get a notification.

DO NOT take ECG measurements during any physical activity.

DO NOT take ECG measurements when the Galaxy Watch is close to strong electromagnetic fields (for example, magnetic resonance imaging (MRI) or X-Ray equipment, electromagnetic anti-theft systems, and metal detectors).

For security reasons, always pair the Galaxy phone and Galaxy watch via Bluetooth in a private (home-based) setting. It is NOT recommended that pairing be done in a public space.

DO NOT take ECG measurements during a medical procedure (for example, surgery or external defibrillation procedures).

DO NOT take ECG measurements when the Galaxy Watch is outside of the following conditions:

- Temperature: 54 °F – 104 °F/12 °C – 40 °C
- Humidity: 30% – 90% relative humidity

Your Galaxy Watch must have a minimum of 10 MB of storage for the Irregular Heart Rhythm Notification feature to monitor your heart rhythm. If the watch has less than 10 MB of storage, the feature will stop monitoring and try again when enough storage is available.

Before recording an ECG, make sure your fingertip is uncovered and doesn't have any bruises, scars, or cuts.

Various things can prevent the watch from detecting atrial fibrillation. Make sure the skin under the watch sensor is clean and has no bruises, tattoos, scars, or cuts.

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

Various things can impair the watch's ability to detect atrial fibrillation. These include a dirty or damaged watch sensor, skin that's too dry or cold, a dark tattoo on the wrist, a hairy wrist, and user movement while the watch is trying to measure.

ECG and rhythm-classification results displayed by the ECG App are for **informational purposes only**. DO NOT take clinical action based on the ECG App measurements without first consulting with a qualified healthcare professional.

In the event of a serious incident that has occurred in relation to this app, immediately report to the manufacturer (Samsung Electronics) and the Competent Authority of the country where you reside.

Getting started

The ECG App is compatible with following watch models and watch/phone OS versions.

App	Watch models	Watch OS	Phone OS
ECG App v 1.3	Galaxy Watch 4 or higher	Wear OS 4.0 or higher	Android 12 or higher

To set up the ECG App:

1. Update your Galaxy Watch with the latest Galaxy Wearable software.
2. Select the Samsung Health Monitor app on your Galaxy Watch. Then, install a Samsung Health Monitor app on your phone. The app is available from the Galaxy Store.
3. Open Samsung Health Monitor on your phone and follow the on-screen instructions.
4. After you've set up the ECG App in Samsung Health Monitor, you can take an ECG on your Galaxy Watch.

To turn on the irregular heart rhythm notification feature:

- First, record an ECG that isn't poor quality.
- Tap Get started on the ECG App launcher screen.
- Follow the on-screen instructions.

Recording an ECG

1. Open Samsung Health Monitor on your Galaxy Watch.
2. Select ECG.
3. Make sure the Galaxy Watch is snug on your wrist.
4. Place your forearm comfortably on a flat surface and then rest a fingertip of the opposite hand lightly on the Galaxy Watch's home button for 30 seconds. Remain still and don't talk while the Galaxy Watch takes the measurement.

Note: Pressing the home button during recording will stop the recording.

Reviewing your ECG results

Your ECG reports are saved to the Samsung Health Monitor app on your phone for your reference. The ECG rhythm-classification results produced by the ECG App are for informational purposes only.

When you record an ECG, you may get any of the six following results:

- **Sinus rhythm**—This result means that during the recording the heart was beating in a regular rhythm with a heart rate of 50–99 beats per minute (BPM).
 - **Caution:** A Sinus Rhythm result does not guarantee that you are not experiencing an arrhythmia or other health condition. If you are not feeling well, contact your doctor.
- **Atrial fibrillation (AFib)**—This result means that during the recording the heart was beating in an irregular rhythm with a heart rate of 50–99 BPM. If you get this result, contact your doctor for guidance.
- **High heart rate**—High heart rate means your heart rhythm was normal, but your heart rate was between 100 and 150 beats per minute. If you keep getting this result and your resting heart rate isn't normally this high, contact your doctor.
- **Atrial fibrillation with high heart rate**—Atrial fibrillation with high heart rate means the heart rhythm was atrial fibrillation with a heart rate between 100 and 150 beats per minute. If you get a result of atrial fibrillation with high heart rate, contact your doctor as soon as possible. A high heart rate can weaken the heart muscle and reduce its ability to beat properly.
- **Inconclusive**—Your watch recorded a good-quality ECG, but the recording can't be classified for one or both of these reasons:
 - Your heart rate was lower than 50 or higher than 150 beats per minute.
 - You had an irregular heart rhythm other than atrial fibrillation.
- **Poor recording**— This result means the ECG app couldn't analyze the data. A poor recording usually happens because your body moved during recording or the Galaxy Watch didn't have enough skin contact with your wrist or finger. If you get this result, try again.
 - If you keep getting this result, learn about things you can try to get a better recording. In the phone app, go to More options > Help > Troubleshooting

Note: Because the occurrence of asymptomatic atrial fibrillation is not constant and can fluctuate daily, periodic reevaluation is necessary. (Source: 2021 Korean Heart Rhythm Society Guidelines for Screening and Management of Subclinical Atrial Fibrillation)

Note: A low heart rate can be normal, such as in well-trained athletes. It can also be caused by certain medications or conditions associated with abnormal electrical activity within the heart.

Note: A high heart rate can be normal, such as during exercise or emotional stress. It can also be a response to dehydration, fever, infection, or other conditions including atrial fibrillation or another arrhythmia.

Note: Heart rhythm and heart rate are both important and you can have an irregular heart rhythm with a normal heart rate. If you keep getting this result or have concerning symptoms, contact your doctor.

Note: A normal resting heart rate is generally 60-100 bpm (beats per minute).

Receiving an irregular heart rhythm notification

When the Irregular Heart Rhythm Notification feature(IHRN) is on, the Galaxy Watch uses its optical sensor to periodically check your heart rhythm when you're still. It checks for an irregular heart rhythm that may indicate atrial fibrillation. If it detects possible atrial fibrillation, it will take additional readings. You'll receive a notification if the watch detects instances of possible atrial fibrillation for one hour.

Note: If the watch is in silent mode when it detects an irregular heart rhythm, it won't send an irregular heart rhythm notification until after silent mode is turned off.

If you receive an irregular heart rhythm notification:

1. Take an ECG as soon as possible so you have a more accurate record of your heart rhythm.
2. Use the ECG result to decide whether you should contact your doctor. Always seek medical attention if you have concerning symptoms, regardless of your ECG result.

Safety and Performance

Clinical validations of the ECG App with the Irregular Heart Rhythm Notification (IHRN) feature tested the ECG application and IHRN feature in separate clinical trials.

The ECG App version 1.3 was validated in a multi-center study with 1,013 subjects (46.1% female, 53.9% male) who were 22 years old or older. The study enrolled 446 subjects diagnosed with AFib, 536 subjects without AFib, and 31 subjects diagnosed with another type of irregular rhythm. These enrolled subjects contributed to 453 AFib recordings (heart rate 50 to 150 BPM) and 691 Sinus rhythm recordings (heart rate 50 to 150 BPM) for the primary endpoint analysis.

The ECG App version 1.3 accurately classified 435 out of the 453 AFib recordings with a sensitivity of 96.0% and classified 682 out of the 691 Sinus rhythm recordings with a specificity of 98.7%. The ECG App version 1.3 also produced visually interpretable waveforms in 98.7% of the cases. Furthermore, the key intervals (RR, PR, QRS) and R-wave amplitude of the waveforms were accurately measured when compared against the standard Lead 1 ECG.

The Irregular Heart Rhythm Notification (IHRN) feature was validated in a large, multi-center study comprising 810 subjects (51.6% female, 48.4% male) who were 22 years old or older and who had not been previously diagnosed with permanent AFib. Study subjects simultaneously wore a Samsung Galaxy Watch with the IHRN capability and an ECG reference patch for up to 10 days.

The IHRN feature showed a sensitivity of 68.0% by correctly notifying 102 out of 150 participants who had a continuous AFib episode of 1 hour or longer as shown on the reference ECG patch. The IHRN feature also demonstrated a specificity of 98.8% by correctly not notifying 652 out of 660 participants who did not have a concordant AFib episode. The performance of the ECG App with the Irregular Heart Rhythm Notification feature is safe and effective in detecting and notifying the user of potential episodes of atrial fibrillation.

Trouble Shooting

Problem	Solution
I can't activate the ECG App of Samsung Health Monitor on my phone	Make sure that the ECG App is approved for use in your country. Make sure you have an active cellular connection when you activate the Samsung Health Monitor app.
I can't find the ECG App on my Galaxy Watch.	Check that your Galaxy Watch is compatible with the ECG app. The ECG app also needs a Galaxy phone running Android 12 or later. Check https://www.samsung.com/sec/apps/samsung-health-monitor for compatible watch models and country/region where service is available. If your Galaxy Watch is compatible, upgrade your Galaxy Wearable software to the latest Maintenance Release (MR) and install the Samsung Health Monitor App on the phone.

I can't record my ECG.	Dry or cool skin, not enough skin contact, a dark tattoo or excess hair on the wrist, pressing the home button, or user movement can cause the ECG App to shut down, to not start recording, or to stop recording. Go to More options > How to use in Samsung Health Monitor on your phone. If you still can't get a successful recording, it might be that the watch can't detect a strong enough signal to record your ECG.
I don't have enough storage available on my watch.	Your Galaxy Watch needs at least 10 MB of available storage to monitor for atrial fibrillation and to record an ECG. You'll need to free up storage on your watch to continue using this feature. You can clear space by uninstalling apps from your watch in the Galaxy Wearable app on your phone or by deleting files and uninstalling apps directly on your watch.
I don't see my ECG results in the Samsung Health Monitor phone app.	Make sure your Galaxy Watch is paired via Bluetooth with the Galaxy phone, using the Galaxy Wearable application. If you still don't see your results, try syncing the data by tapping 'Sync data' in More options. (e.g.: More options > Settings > Accessories)
I'm repeatedly getting a Poor recording result.	The Galaxy Watch uses an optical sensor to collect signals through the skin. A Poor recording result may be due to "noise" in the signal caused by dirt on the sensors, lack of moisture, a tattoo or other skin pigmentation, a scar, insufficient skin contact, or user movement during the ECG measurement. • Clean the back of the watch, the wrist the watch is in contact with, and the fingertip you're using for the measurement. • Make sure the Galaxy Watch is snug on your wrist, rest your forearms comfortably on a table, and then take the ECG. • Try wearing the watch on your wrist slightly away from your wrist bone, toward your elbow, to create better skin contact. Low peripheral blood flow or other condition may prevent the watch from getting a strong enough signal to analyze.
I'm repeatedly getting an Inconclusive result.	If you think you're having a medical emergency, contact your local emergency services immediately. • An Inconclusive result may be from a heart rate that is lower than 50 or higher than 150 BPM, or that is not atrial fibrillation or sinus rhythm. • A high heart rate can be normal, such as during exercise or emotional stress. It can also be a response to dehydration, fever, infection, or other conditions including atrial fibrillation or another arrhythmia. Stay still for 5–10 minutes, then take an ECG again. • An inconclusive result could be because the heart rhythm was atrial fibrillation but the heart rate was lower than 50 bpm or higher than 150 bpm. If you get an Inconclusive result repeatedly, contact your doctor.

I keep getting irregular heart rhythm notifications.	Make sure you take an ECG as soon as possible after getting a notification and go by the ECG result. An ECG is a more accurate record of your heart rhythm. If you get a sinus-rhythm result (no signs of atrial fibrillation), but you're feeling unwell, contact your doctor.
My ECG waveform appears upside down.	An inverted waveform could be due to the incorrect wrist selection. If you updated to the WearOS version that introduced support for wrist orientation, the update reset the wrist selection to left. If you normally wear your watch on the right wrist, you'll need to set the wrist orientation manually. Go to More options > Settings > Accessories > Wrist selection to see which wrist is selected and how to change it, if needed.