ECG App

v1.2

Instructions for Use

Samsung Electronics Co., Ltd.
129, Samsung-ro,

Yeongtong-gu,
Suwon-si, Gyeonggi-do,
16677,
Republic of Korea

www.samsung.com

MD

Please read this Instruction for Use carefully to use the product properly

eIFU indicator

2024-12 (v 4.1)

Terminology

- Atrial fibrillation (AFib or AF) is an abnormal heart rhythm that occurs when the top chambers of the heart (atria) beat irregularly.
- Electrocardiogram (ECG) is a test that records the electrical activity of the heart.
- Sinus rhythm is the name given to the normal rhythm of the heart.

Symbols used in this application

Symbol	Name	Description
	Caution	Indicates information you must follow to use this app safely and effectively and to avoid inaccurate results.
	Manufacturer	Indicates the name and address of the manufacturer.
 eIFU indicator	Consult electronic Instructions for Use	Indicates that the user must carefully read the Instructions for Use before using the application.
	Medical Device	Indicates that this is a medical device.
	Cautions	Indicate content which you must to follow to avoid any problem or inaccurate measurement resulting from misuse of this app.
	Cautions	Indicate content which you must to follow to avoid any problem or inaccurate measurement resulting from misuse of this app.
	Average heart rate	Indicate 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.

Intended Purpose

The Samsung's 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 with IHRN feature 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.

Contraindications

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

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

DO NOT use the ECG App if you have known arrhythmia other than Atrial Fibrillation.

Cautions

⚠	The ECG App cannot diagnose cardiac conditions or look for signs of a heart attack. Contact your doctor if you're not feeling well or are experiencing physical symptoms such as shortness of breath, chest pain or pressure, and fainting.
⚠	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 if you experience: 1. Shortness of breath 2. Chest pain or pressure 3. Fainting 4. What you think might be a heart attack Contact emergency services immediately.
⚠	DO NOT change your medications or dosage without first consulting your doctor.
⚠	ECG 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.
⚠	The ECG App and Irregular Heart Rhythm Notification feature never look for any forms of arrhythmia other than atrial fibrillation.
⚠	The ECG App and Irregular Heart Rhythm Notification feature never look for other heart-related conditions, including blood pressure, congestive heart failure, high cholesterol, blood clots, or stroke.
⚠	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.
⚠	Make sure that the finger used to record the ECG is uncovered and free of any bruises, scars, or cuts.
⚠	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.
⚠	Certain physiological conditions can prevent some people from having a strong enough signal for the ECG App to detect and analyze.
⚠	In the event of a serious incident that has occured in relation to this app, immediately report to the manufacturer (Samsung Electronics) and the Competent Authority of the country where you reside.

Using the ECG App

Getting started

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

App	Watch models	Watch OS	Phone OS
ECG (v1.1)	Galaxy Watch Active2 and Watch3	Tizen 4.0.0.8 or higher	Android 12 or higher
	Galaxy Watch4 or higher	WearOS 3.0 or higher	
ECG (v1.2) *ECG App with IHRN feature	Galaxy Watch4 or higher	WearOS 4.0 or higher	

To set up the ECG App:

- Update your Galaxy Watch to the latest version software.
- Install the Samsung Health Monitor app on your phone. The app is available from the Galaxy Store.
- Open Samsung Health Monitor on your phone and follow the on-screen instructions.
- After you've set up the ECG App, you can take an ECG using Samsung Health Monitor on your Galaxy Watch.

To turn on the irregular heart rhythm notification feature:

- Set up the ECG App and record an ECG that isn't poor quality.
- Tap Get started on the ECG app launcher screen.
- Follow the on-screen instructions.

Receiving an irregular rhythm notification

When the irregular rhythm notification feature is turned on, the Galaxy Watch uses its optical sensor to periodically check your heart rhythm when you're still. It's checking for an irregular rhythm that may indicate atrial fibrillation. If it detects a rhythm that might indicate atrial fibrillation, it will take additional readings to confirm atrial fibrillation. If the watch detects atrial fibrillation for one hour, you'll receive a notification

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

1. If you receive an irregular heart rhythm notification, 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 if you should contact your doctor.

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 key for 30 seconds. Remain still and don't talk while the Galaxy Watch takes the measurement.
   Note: Pressing the home key 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.

ECG Results you may see

You may get any of the four following results:

Sinus rhythm	This result means that during the recording the heart was beating in a regular rhythm with a heart rate of 50–100 beats per minute (BPM). **Caution**: A sinus rhythm result does not guarantee that you're not experiencing an arrhythmia or other health condition. If you're 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 50–120 BPM. If you get this result, contact your doctor for guidance. **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)
Inconclusive	This result means that the ECG recording could not be classified because the heart rate was either too high or too low, or the rhythm was not atrial fibrillation or sinus rhythm. If you get this result repeatedly, contact your doctor. Any of the following conditions can lead to an Inconclusive result:

	• The heart rate during the recording was less than 50 BPM (low heart rate*) • The heart rate was greater than 100 BPM (high heart rate**) and rhythm was not Atrial Fibrillation • The heart rhythm was not Sinus or Atrial Fibrillation • The heart rhythm was Atrial Fibrillation, and the heart rate was greater than 120 BPM * 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. ** 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.
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.

Safety and Performance

The clinical validation for ECG Monitor App tested its accuracy in detecting sinus rhythm and atrial fibrillation in ECG recordings for 544 subjects. The ECG Monitor App rhythm classifications were compared with rhythm classifications performed by a board-certified cardiologist using a 12-lead ECG. For the classifiable recordings, the ECG Monitor App's on-demand ECG function had a sensitivity of 98.1% in detecting atrial fibrillation and a specificity of 100% in classifying sinus rhythm.

The ECG PDF report was compared against a standard Lead 1 ECG for key intervals (PR, RR), QRS duration and amplitude. No adverse events were reported during this clinical trial.

The ECG Monitor App's Irregular Heart Rhythm Notification (IHRN) feature was separately 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/persistent 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. Additionally, among 1572 tachograms that the algorithm concluded as suggestive of AFib, 1505 were determined as AFib by board-certified cardiologists. The performance of the ECG Monitor App with the Irregular Heart Rhythm Notification feature is safe and effective in detecting and notifying the user of potential episodes of atrial fibrillation.

Troubleshooting

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, install the Samsung Health Monitor App on the phone and upgrade your Galaxy Wearable software to the latest Maintenance Release (MR).
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 in the upper right corner.
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 potentially high or low heart rate or another heart rhythm that’s 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 rate is more than 120 BPM, and the rhythm is atrial fibrillation. 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 Wear OS 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.