Samsung Health Monitor Application (ECG App)

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Please read these Instructions for Use carefully to use the product properly.

eIFU indicator

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Australian Sponsor

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1. About these Instructions for Use

1.1 Symbols

Symbols used in the these Instructions for Use

Symbol	Name	Description
⚠	Cautions	Indicate content that you must follow to avoid any problem or inaccurate measurement resulting from misuse of the Samsung Health Monitor application.
🏭	Manufacturer	Indicate manufacturer of the Samsung Health Monitor.
📖	Consult Instructions for Use	Indicate that user shall read Instructions for Use carefully to use the product properly before use
EC REP	Authorised representative	Indicate information of authorised representative for EU.

Symbols used in the Samsung Health Monitor

The symbols used in the Samsung Health Monitor can be changed.

Symbol	Name	Description
⚠	Cautions	Indicate content that you must follow to avoid any problem or inaccurate measurement resulting from misuse of the Samsung Health Monitor application
🚫	Cautions	Indicate content that you must follow to avoid any problem or inaccurate measurement resulting from misuse of the Samsung Health Monitor application
❤	Average heart rate	Indicate an average heart rate during ECG measurement.

1.2 Instructions for Use provided in Electronic form

The Instructions for Use of the Samsung Health Monitor are provided in electronic form and are available in the Samsung Health Monitor application and on its web site within samsung.com.

If you need Instructions for Use in paper form, you can request it by calling at the Official Samsung Support center in your country.

2. Intended Purpose

The Samsung ECG Application is an **over-the-counter (OTC)** software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. The 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; it 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 and rhythm classification may be used by users with or without known AFib as data that may be shared with a qualified healthcare professional.

3. 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.

4. Cautions

Please follow the Cautions listed below. If you do not follow them, the ECG App may not be able to record accurate measurements.

⚠	The ECG App cannot diagnose cardiac conditions or look for signs of a heart attack.
⚠	The ECG App is not meant to replace traditional methods of diagnosis or treatment by a qualified healthcare professional. If you think you are having a medical emergency, contact your local emergency services immediately.
⚠	DO NOT change your medications or dosage without first consulting your doctor.
⚠	DO NOT interpret or take clinical action based on the ECG App measurements without first consulting with a qualified healthcare professional.

⚠️	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 ºF – 104 ºF/12 ºC – 40 ºC • Humidity: 30% – 90% relative humidity
⚠️	Make sure that the finger used to record the ECG is 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.

5. Getting Started

The ECG app consists of Galaxy phone app (ECG-Android) and Galaxy Watch app (ECG-Tizen). The app can be accessed via Samsung Health Monitor application. The ECG App requires a Galaxy Active2 with Tizen version 4.0.0.8 or later, or a later Watch model than the Galaxy Active2 that is paired with a Galaxy phone running Android Nougat or later.

1. Make sure that your Galaxy Watch is paired with your Galaxy phone using Bluetooth.
2. If the ECG App is installed on your Galaxy phone, open the Samsung Health Monitor app and follow the onscreen instructions to set up your profile.

If the ECG App is not installed on your Galaxy phone, install the Samsung Health Monitor App from the Galaxy store and then install the latest update of the Galaxy Wearable software. After installing the update, open the Samsung Health Monitor application and follow the onscreen set-up instructions.

6. Recording an ECG Using Your Galaxy Watch

1. Open the Samsung Health Monitor application on your Galaxy Watch.
2. Make sure the Galaxy Watch is snug on your wrist.
3. Rest your forearms comfortably on a table and then rest a fingertip of the opposite hand *lightly* on the Galaxy Watch's Home key for 30 seconds. Remain still and do not talk while the Galaxy Watch takes the measurement. When the recording process has finished, the ECG results will appear on

your watch. Note: **Don't Press** the Home key during recording; pressing the Home key during recording will stop the recording.
4. Scroll up and down to see your ECG result. If you are experiencing symptoms, tap **Add,** and on the **Symptoms** screen, scroll through the list and tap each symptom you are experiencing. Then tap **Save** to add the symptoms to your ECG report and to return to the **Results** screen.
5. Tap **Done** to go back to the **Start** screen. You can review your ECG report in the ECG app on your phone. (Note that syncing requires that the watch and phone are paired using Bluetooth.)

7. Reviewing Your ECG Reports on Your Galaxy Phone

After you take an ECG, the ECG data is synced to the paired Galaxy phone where a PDF report is created.

1. Open the Samsung Health Monitor app on your Galaxy phone.
2. Tap the thumbnail to see your latest ECG report, or tap **View history** to see all the available reports.

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).
  - o **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 50–120 BPM. If you get this result, contact your doctor for guidance.
- **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.
  - o *Conditions that lead to an Inconclusive result:*
    - ▪ The heart rate during the recording was less than 50 BPM (low heart rate*), *or*
    - ▪ the heart rate was greater than 100 BPM (high heart rate**) and rhythm was not Atrial Fibrillation, *or*
    - ▪ the heart rhythm was not Sinus or Atrial Fibrillation, *or*
    - ▪ 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 other arrhythmia.

- **Poor Recording**—This result means the ECG App was not able to analyze the data. A poor recording usually happens because your body moved during recording or the Galaxy Watch did not have enough skin contact with your wrist or finger. If you get this result repeatedly, refer to "Recording an ECG Using Your Galaxy Watch," above

8. Safety and Performance

The clinical validation for ECG App tested its accuracy in detecting Sinus Rhythm and Atrial Fibrillation in ECG recordings for 544 subjects. The ECG App rhythm classifications were compared with rhythm classifications performed by a board-certified cardiologists using a 12-lead ECG. The ECG App had a

sensitivity of 98.1% in detecting AFib and specificity of 100% in classifying sinus rhythm for all classifiable recordings.

During clinical trials, 16.8% of ECG recordings were either inconclusive or poor recording. If all of these recordings are included, the sensitivity of the ECG App is 87.1% and specificity to detect sinus rhythm is 82.5%. Real-world performance may have more inconclusive and poor recordings.

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.

* Note: Based on a study conducted at one clinical study facility between September 2019 and April 2020. The clinical site was responsible for determining the accuracy of irregular rhythm measurement. Patient age under 22 was excluded from this study

9. Troubleshooting

If you have problems using your ECG App, check below table for possible solutions.

Problem	Solution
I can't activate the ECG feature 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 cannot find the ECG App on my Galaxy Watch.	Check that your Galaxy Watch is compatible with the ECG App. The ECG App requires a Galaxy Active2 with Tizen version 4.0.0.8 or later, or a later Watch model than the Galaxy Active2 that is paired with a Galaxy phone running Android Nougat or later. 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 cannot record my ECG.	Dry or cool skin, not enough skin contact, hairy wrist, pressing the Home key or user movement can cause the ECG app to shut down, to not start recording, or to stop recording. Before taking an ECG: - Put some moisturizing lotion on your hands and wrist. - If your hands and arms are cold, remove the Galaxy Watch and rub the wrist gently to warm up the skin. Put the Galaxy Watch back on and try again to record an ECG. - Try wearing the watch on your wrist slightly away from your wrist bone toward your elbow to create better skin contact. During the recording process make sure - Your forearms are resting on a table. - Your fingertip fully covers the Home key.

	• You do not move your arms or talk. • You do not press the Home key. • Your finger is resting *lightly* on the Home key for the 30 seconds it takes to do the recording. If the ECG App continues to shut down as soon as you open it, it may be a software issue. Restart the Galaxy Watch and try again. If you still cannot get a successful recording, it might be because the watch may not be able to detect a strong enough signal to record your ECG.
I don't see my ECG results in the Samsung Health Monitor 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 to sync the data by tapping **Sync** in the upper right corner.
I am repeatedly getting a Poor Recording result.	A Poor Recording result may be due to "noise" in the signal caused by dirt on the sensors, lack of moisture, insufficient skin contact, or user movement during the ECG measurement. • Clean the back of the Watch, the wrist the Watch is contacting 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. • Certain physiological conditions can prevent some people from having a strong enough signal for the ECG App to detect and analyze.
I am repeatedly getting an Inconclusive result.	If you think you are having a medical emergency, contact your emergency services immediately. • An Inconclusive result may be from a potentially high or low heart rate or another heart rhythm that is not AFib 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 other arrhythmia. Stay still for 5–10 minutes and try taking the 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 Inconclusive result repeatedly, contact your doctor.
My ECG waveform appears upside down.	An inverted waveform could be due to the wrong wrist selection. Please check your wrist setting and select the wrist that the ECG is recorded from.
Wrist orientation is reset to left	The wrist orientation is reset to the default setting (left) with Wear OS update. Please check your wrist setting and select the wrist that the ECG is recorded from.