Samsung Health Monitor Application (Blood Pressure App)

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



eIFU indicator

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1. About these Instructions for Use

1.1 Symbols

Symbols used in 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 Instruction for Use carefully to use the product properly before use.

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.
	Pulse rate	Indicate current heart rate (Pulse rate) during blood pressure 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 Blood Pressure App (BP App) is a software-only, mobile medical application intended for use with a compatible Samsung Galaxy Watch and Phone to create, record, store and display blood pressure information. The BP App determines the systolic and diastolic blood pressure, as well as pulse rate, and

provides values and history charts following calibration with an upper-arm, cuff-based blood pressure monitor. These data are only captured when the user is at rest.

The BP App is intended for **over-the-counter (OTC)** use by adults 22 years and older. It may not provide accurate results for pregnant women. This information can be used as an indication for trends in blood pressure between regular checks by a healthcare professional. The user is not intended to interpret or take clinical action based on the device output without consultation with a qualified healthcare professional and validation with a standard measurement method. The BP App is not intended to replace traditional methods for diagnosis or treatment of hypertension.

3. Contraindications

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

DO NOT use the BP App if you are pregnant.

DO NOT use the BP App if you have any of the following:

- Arrhythmia
- Prior heart failure or heart attack
- Peripheral vascular disease or compromised circulation
- Valvular disease (diseases concerning the aortic valve)
- Cardiomyopathy
- Other known cardiovascular disease
- End-stage Renal Disease (ESRD)
- Diabetes
- Neurological disorder (for example, tremors)
- Clotting disorder or you are taking prescribed blood thinners
- Tattoo(s) on the wrist where you will wear the Galaxy Watch

4. Cautions

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

	The BP App cannot diagnose hypertension, other conditions, or check for signs of a heart attack. The BP 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 BP App measurements without first consulting with a qualified healthcare professional.
	DO NOT use the BP App to diagnose hypertension, heart-related, or other medical conditions.
	DO NOT use a Galaxy Watch for Blood Pressure measurements if the Galaxy Watch has been calibrated for use by another person.
	DO NOT take Blood Pressure measurements during any physical activity.
	DO NOT take Blood Pressure 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 Blood Pressure measurements during a medical procedure (for example, surgery or external defibrillation procedures).
	DO NOT take Blood Pressure measurements when the Galaxy Watch is outside of the following operating conditions: • Temperature: 54 °F - 104 °F / 12 °C - 40 °C • Humidity: 30% – 90% relative humidity
	The BP App's range for blood-pressure readings is as follows: • Calibration Range - Systolic: 80–170 mmHg, Diastolic: 50–110 mmHg • Measurement Range - Systolic: 70–180 mmHg, Diastolic: 40–120 mm Hg

5. Getting Started

The Blood Pressure App (“BP App”) consists of the Galaxy phone app (BP-Android) and the Galaxy Watch app (BP-Tizen/Wear OS). The app can be accessed via the Samsung Health Monitor application. The BP App requires a Galaxy Watch Active2 or Galaxy Watch 3 with Tizen version 4.0.0.8 or later, or Galaxy Watch 4 or later model with Wear OS 3.0 that is paired with a Samsung Galaxy phone running Android 12 or later.

Before you can use the BP App, you must do the following:

1. Set-up the BP App in Samsung Health Monitor on your Galaxy Watch
2. Install the Samsung Health Monitor application on your Galaxy phone
3. Calibrate your Galaxy Watch with an upper-arm, cuff-based blood pressure monitor

5.1 Setting Up the BP App

Before you can start measuring your blood pressure using the BP App, you must set up your BP App profile and calibrate your Galaxy Watch.

1. Ensure that your Galaxy Watch is paired via Bluetooth with the Galaxy phone that you will use for your blood pressure measurements.
2. If the Samsung Health Monitor application is installed on your Galaxy Watch, open the Samsung Health Monitor app and select the Blood Pressure and follow the onscreen set-up instructions.

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

► To set up the BP App Profile on Your Galaxy Phone

1. Download the Samsung Health Monitor App from the Google Play Store or the Galaxy Store.
2. Complete and confirm the profile set-up and agree to the terms of use and privacy policy.
3. Select the Blood Pressure option and calibrate your Galaxy Watch.

5.1.1 Calibrating Your Galaxy Watch



To ensure more accurate measurements, be sure to calibrate your Galaxy Watch with an upper-arm, cuff-based blood pressure monitor. Before you start the calibration, read the instructions that accompany the blood pressure monitor and make sure you know how to use it.

Note 1: You use the upper-arm, cuff-based blood pressure monitor only to calibrate your Galaxy Watch. After you calibrate your Galaxy Watch, you do not need to use the cuff-based blood pressure monitor when you use the BP App on your Galaxy Watch to take your blood pressure.

Note 2: Calibration on the Galaxy Watch customizes the BP App specifically—and only—for the person wearing the paired Galaxy Watch during calibration.

To ensure more accurate calibration, do the following:

- 30 minutes before doing the calibration, do not have any alcohol or caffeine, and do not smoke, exercise, or bathe.
- Make sure your arm and wrist are dry and free of excessive perspiration or skin lotion.
- Do the calibration indoors in a quiet place.
- Put a comfortable chair next to a table.
- Sit in the chair with your back well-supported, your legs uncrossed, and your feet flat on the ground.
- Let your hands and forearms rest on the table.
- Rest in this position for at least 5 minutes before starting the calibration.
- When you start the calibration, stay still and do not move your arm or talk while the cuff-based blood pressure monitor performs the measurement.
- During the measurement, breathe normally. Do not try to deepen or slow down your breath.

To calibrate your Galaxy Watch:

1. Place the blood pressure cuff on an upper arm.
2. Wear the Samsung Galaxy Watch on the wrist of ***the other*** arm. Make sure the Galaxy Watch strap is snug around your wrist, but not too tight.
3. Place your Galaxy phone on the table, within easy reach.
4. On your Galaxy phone, open the Samsung Health Monitor app and press the Blood Pressure and follow the onscreen instructions to do the following:
    1. Start the blood pressure measurement on the cuff-based blood pressure monitor.
    2. Measurement on the Galaxy Watch will begin automatically.
    3. Enter the cuff-based blood pressure monitor reading in the phone BP App.
    4. Repeat Steps a.-c. two more times (for a total of three measurements) to finish the Galaxy Watch calibration.

Note: Make sure that you finish all measurements required for calibration within 30 minutes of completing the first calibration measurement. To keep your Galaxy Watch properly calibrated, you must calibrate it every 28 days, as directed by the BP App. You may also calibrate your Galaxy Watch any time before then by selecting **Recalibrate** from the menu on the Blood Pressure History screen.

5.2 Measuring Your Blood Pressure Using Your Galaxy Watch

After you have calibrated your Galaxy Watch with the upper-arm, cuff-based blood pressure monitor, you are ready to use the BP App on your Galaxy Watch to measure your blood pressure. You will not need to use the cuff-based monitor again until the next calibration in 28 days.

Note: After you calibrate your Galaxy Watch, you do not need to use the cuff-based monitor when you use the BP App on your Galaxy Watch to take your blood pressure.

To ensure a more accurate BP measurement, do the following:

- Wear your Galaxy Watch on the same wrist as during the calibration and make sure the Galaxy Watch strap is snug around your wrist, but not too tight.
- 30 minutes before doing the measurement, do not have any alcohol or caffeine, and do not smoke, exercise, or bathe.
- Make sure your arm and wrist are dry and free of excessive perspiration or skin lotion.
- Do the measurement indoors in a quiet place.
- Put a comfortable chair next to a table.
- Sit in the chair with your back well-supported, your legs uncrossed, and your feet flat on the ground.
- Let your hands and forearms rest on the table.

- Rest in this position for at least 5 minutes before starting the measurement.
- When you start the measurement, stay still and do not move your arm or talk while the Galaxy Watch takes the measurement.
- During the measurement, breathe normally. Do not try to deepen or slow down your breath.

► To measure your blood pressure

1. Press the **Measure** button on the Galaxy Watch.
2. If the measurement is successful, BP measurements including systolic and diastolic readings appear on the Galaxy Watch face. See “Reviewing Your Blood Pressure Measurements” below.
   If the measurement is unsuccessful (for example, because you moved or because the signal was not strong enough), the Galaxy Watch displays an error message.

6. Reviewing Your Blood Pressure Measurements

You can review your blood pressure measurements on your Galaxy Watch and on your Galaxy phone.

6.1 On Your Galaxy Watch

After the BP App on the Galaxy Watch successfully measures your blood pressure, the Galaxy Watch displays the following results:

- Systolic blood pressure (BP)
- Diastolic blood pressure (BP)
- Pulse Rate (heart rate)



CAUTION

Do not change your medications or dosage based on the numbers provided by the BP App. Always talk to your doctor first.

6.2 On Your Galaxy Phone

When a Bluetooth connection is established between your Galaxy Watch and the Galaxy phone you used to calibrate the Galaxy Watch, your measurement results are synced to the Samsung Health Monitor App on the Galaxy phone. You can share this information with your doctor for review or consultation.

► To view your blood pressure measurements on your phone

Open the Samsung Health Monitor App and select the Blood Pressure Card to see the history chart

Note: How many results you can store on your Galaxy phone depends on the amount of storage memory your Galaxy phone has.

7. Safety and Performance

The Samsung BP App was validated to measure blood pressure 30 minutes after calibration in a clinical trial of 85 subjects against reference blood pressure cuff measurements taken by two medical professionals, with a performance of

- mean systolic BP error of -0.11 mmHg (standard deviation of 7.46 mmHg) and
- mean diastolic error of -0.28 mmHg (standard deviation of 5.85 mmHg).

These studies were done following a modified ISO 81060-2 blood pressure standard protocol with proper representation of gender, arm circumference, skin pigmentation, and blood pressure ranges. The Samsung BP App measurements demonstrated performance sufficient for the device's intended use of non-diagnostic BP measurements with which the user is not intended to interpret or take clinical action on without consultation with a qualified healthcare professional and validation with a standard measurement method.

Specifications: Accuracy: Mean difference ± Standard deviation < 5 ± 8 mmHg (based on auscultatory calibration), and Mean difference ± Standard deviation < 6 ± 10 mmHg (based on cuff blood pressure monitor calibration) up to 28 days.

Note: Based on a study conducted at one clinical study facility between July 2019 and October 2019. The clinical site was responsible for determining the accuracy of blood pressure measurement. Patient age under 22 was excluded from this study.

8. Troubleshooting

If you have problems using your BP App, check the list below for possible solutions.

Problem: I cannot find the BP App on my Galaxy Watch.

Solution:

- Check that your Galaxy Watch is compatible with the BP App. The BP 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 it to the latest Maintenance Release (MR) using the Galaxy Wearable application. A successful MR upgrade should load the BP App on the Galaxy Watch.

Problem: I can't enable Samsung Health Monitor on my phone.

Solution:

- Make sure that your phone was purchased in a country where the BP App has received regulatory approval.
- Make sure that you install and activate Samsung Health Monitor (by creating a profile and accepting the Terms of Use and Privacy Policy) in a country where the BP App has received regulatory approval.
- Make sure you have an active cellular connection when you install and activate the BP App of Samsung Health Monitor.

Problem: I don’t see an option to measure my blood pressure.

Solution:

- Make sure that you set up your profile on the paired phone Samsung Health Monitor App. See “To set up the BP App Profile on Your Galaxy Phone” in “5.1 Setting Up the BP App”.
- Make sure that you successfully have calibrated the Galaxy Watch with an upper-arm, cuff-based BP monitor. See “5.1.1 Calibrating your Galaxy Watch”.
- If you have calibrated your Galaxy Watch, make sure that the calibration is up to date. The Galaxy Watch must be recalibrated every 28 days. Check the BP App screen on either the Galaxy Watch or Galaxy phone to see the calibration status.

Problem: I cannot get a successful blood pressure reading.

Solution:

- Make sure the Galaxy Watch is worn snugly on your wrist (not loose or too tight). The bottom surface of the Galaxy Watch should touch the skin but should not be uncomfortable.
- Make sure you sit still and relaxed, with both feet flat on the ground, during the blood pressure measurement.
- Make sure you do not move your arm or talk during the blood pressure measurement.
- Rest the arm with the Galaxy Watch on a table while you take the measurement.
- Make sure your arm and wrist are dry and free of excessive perspiration or skin lotion.
- If your hands and arms are cold, remove the GalaxyWatch and rub the wrist gently to warm up the skin. Put the Galaxy Watch back on and try again to take a measurement.
- The BP App uses optical signals collected from a sensor on the Galaxy Watch and needs a good-quality signal in order to calculate blood pressure. The quality of the signal can be affected by various factors, such as the watch sensor's cleanness or the measured area's optical properties.

Problem: I am getting an abnormally high or low BP reading.

Solution:

- If you have unusual symptoms or think you are having a medical emergency, contact your doctor or local emergency services immediately.
- If you do not think you are having a medical emergency, take at least two more blood pressure measurements and follow the guidance below before you take the measurements:
    - Do not have caffeine or alcohol 30 minutes before you start themeasurement.
    - Do not smoke, exercise, or bathe 30 minutes before you start the measurement.
    - Rest quietly for at least 5 minutes before you start the measurement.
    - Make sure you are not experiencing excessive stress or anxiety during the measurement.
- If you are still getting abnormal readings, contact your doctor or local emergency services immediately for guidance.

Problem: I cannot sync my BP data from the Galaxy Watch to the Galaxy phone Blood pressure card.

Solution:

- Make sure your Galaxy Watch is paired, using Bluetooth, with the Galaxy phone via the Galaxy Wearable application.
- Make sure you are using the same Galaxy phone that you used to set up your profile and calibrate the Galaxy Watch.
- Make sure you have at least 100 MBs of storage available on the Galaxy phone.