
Sleep Apnea Feature

Instructions for Use



Samsung Electronics Co., Ltd.

129, Samsung-ro,

Yeongtong-gu,

Suwon-si, Gyeonggi-do,

16677,

Republic of Korea

www.samsung.com



Samsung electronics GmbH

Am Kronberger Hang 6, 65824

Schwalbach am Taunus,

Germany



2460



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

eIFU indicator



v 1.0

2024-04 (v 1.0)

Intended Purpose

The Sleep apnea feature is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone.

This feature is intended to detect signs of moderate-to-severe obstructive sleep apnea in the form of significant breathing disruptions over a two-night monitoring period, for adult users 22 years or older. This feature is intended for on-demand use.

This feature is not intended for users who have previously been diagnosed with sleep apnea. Users should not use this feature to replace traditional methods of diagnosis and treatment by a qualified clinician. The data provided by this feature are also not intended to assist clinicians in diagnosing sleep disorders.

About these Instructions for Use

This section contains information on the symbols used in this document and in the Sleep apnea feature, as well as how to access these instructions for use.

Symbols used

Symbol	Name	Description
	Manufacturer	Indicates the name and address of the manufacturer.
	Read the Instructions for Use	Indicates that the user must carefully read the Instructions for Use before using Samsung Health Monitor.
	Authorised representative	Indicates information of authorised representative for EU.
	Reference number	Indicates the version of the product so that the medical device can be identified
	Caution	Indicates information you must follow to use Samsung Health Monitor safely and effectively and to avoid inaccurate results.

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 ([Samsung.com](https://www.samsung.com)).

For a print 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.

Customer support

If you have questions about the Sleep apnea feature, contact Samsung customer support at healthmonitor@email.support.samsung.com.

Cautions

	DON'T use this Sleep apnea feature if you've already been diagnosed with sleep apnea.
	DON'T use this Sleep apnea feature if you've been diagnosed with any of these conditions: • Movement related conditions: Parkinson's, Tremor, Periodic Leg Movement During Sleep (PLMS) • Cardiac conditions: Congestive Heart Failure (CHF), atrial fibrillation • Lung conditions: Chronic Obstructive Pulmonary Disease (COPD), chronic bronchitis, emphysema, pulmonary fibrosis.
	DON'T use this Sleep apnea feature if you're under 22 years old.
	You shouldn't use this Sleep apnea feature if you're pregnant or have temporary symptoms of impaired breathing from flu, allergies, asthma, or any other condition, because your results may be inaccurate.
	DON'T change the dose or schedule of any medications based on results from this feature. Always talk to your doctor first.
	Your Galaxy Watch can't catch every case of obstructive sleep apnea. The watch only checks for signs of moderate to severe obstructive sleep apnea and can't detect central sleep apnea.
	Your Galaxy Watch is not approved by a regulatory body as a pulse oximeter.
	The Sleep apnea feature is only a pre-diagnosis tool. It isn't meant to replace diagnosis or treatment by a qualified healthcare professional. If you aren't feeling well, contact your doctor, even if the watch doesn't detect signs of sleep apnea.
	For security reasons, always pair the Galaxy phone and Galaxy Watch via Bluetooth in a private (home-based) setting. It's NOT recommended that you pair your devices in a public space.

Using the Sleep apnea feature

Getting started

The Sleep apnea feature is compatible with the following watch models and watch/phone OS versions.

Watch Model	Watch OS	Phone OS
Galaxy Watch4 or higher	Wear OS 5.0 or higher	Android 9 Pie or higher

For regional availability, see the Samsung Health Monitor page on the Samsung website ([Samsung.com](https://www.samsung.com)).

- Make sure your Galaxy Watch has the latest maintenance release (MR) and that the latest version of Samsung Health Monitor is installed on the watch and phone. If you haven't installed Samsung Health Monitor on your Galaxy phone, install it first and follow the on-screen instructions to set it up. Samsung Health Monitor is available from the Galaxy Store.
- To set up the Sleep apnea feature, open Samsung Health Monitor on the phone, tap the Sleep apnea tab, and follow the on-screen instructions.

Turning on the feature

Note: Make sure your Galaxy Watch is charged to at least 30% before you go to sleep.

1. On your Galaxy Watch or phone, open Samsung Health Monitor and tap Sleep apnea.
2. Tap the Sleep apnea feature switch.
3. Wear your watch snugly to sleep on 2 nights within 10 days of turning on the feature. Approximately 4 hours of sleep is required each night for the watch to get enough data for a result.

Receiving a notification

When the Sleep apnea feature is on, the Galaxy Watch will use its PPG-based SpO2 sensor and actigraphy to look for breathing disruptions based on how many relative decreases in blood oxygen you have while you're asleep. Breathing disruptions can indicate sleep apnea. After two successful nights of measuring at least 4 hours of sleep each, the watch will let you know whether it detected signs of moderate to severe obstructive sleep apnea. The result is saved in Samsung Health Monitor on your phone.

Note: It can take up to 90 minutes to analyze a night's sleep data.

If the watch detected signs of moderate-to-severe obstructive sleep apnea:

- Your Galaxy Watch detected enough breathing disruptions to indicate moderate-to-severe obstructive sleep apnea.
- Contact your doctor for an evaluation.
- DON'T change the dose or schedule of any medications based on results from this feature.
- DON'T use the Sleep apnea feature again before talking to your doctor. It won't provide a more accurate result.

If the watch didn't detect signs of moderate-to-severe obstructive sleep apnea:

- Your Galaxy Watch didn't detect enough breathing disruptions to indicate moderate-to-severe obstructive sleep apnea.
- Your Galaxy Watch can't catch every case of obstructive sleep apnea.
- If you aren't feeling well, contact your doctor.
- This feature isn't a tracking or monitoring tool. Wait at least 30 days before using the feature again unless you experience a significant change in your health or lifestyle.

Safety and Performance

The Sleep apnea feature was validated in a large, multi-center study comprising 470 subjects who were 22 years old or older. Study subjects underwent a 2-night polysomnography (PSG) study while simultaneously wearing a Samsung Galaxy Watch with the Sleep apnea feature capability.

The Sleep apnea feature showed a sensitivity of 82.67% by correctly identifying 167 out of 202 participants who exhibited moderate-to-severe obstructive sleep apnea (OSA) on both nights of the PSG study. The Sleep apnea feature also demonstrated a specificity of 87.69% by correctly identifying 235 out of 268 participants who did not exhibit moderate-to-severe OSA on both nights of the PSG study. Furthermore, the Sleep apnea feature demonstrated that it agreed with the PSG study on 84.15% of the analyzable nights.

Therefore, the Sleep apnea feature is safe and effective in identifying users with signs of moderate-to-severe obstructive sleep apnea.

Troubleshooting

If you have problems using the Sleep apnea feature, see below for possible solutions.

Problem	Solution
Can't activate Sleep apnea feature on phone	Make sure that the Sleep apnea feature is approved for use in your country. Make sure you have an active cellular connection when you activate the Samsung Health Monitor app.
Can't find Sleep apnea feature on watch	Check that your Galaxy Watch is compatible with the Sleep apnea feature. See the information on the Samsung Health Monitor page of the Samsung website (Samsung.com). If your watch is compatible, make sure to update it to the latest versions of the watch software and the Samsung Health Monitor app. To update the watch software, in Galaxy Wearable, go to Watch settings > Watch software update > Download and install.
Don't see my sleep apnea result in the phone app	Make sure your Galaxy Watch is paired via Bluetooth with your Galaxy phone, using the Galaxy Wearable app. If you still don't see the result, swipe down from the top of the screen to manually sync the data.
Not enough available watch storage	You need at least 10MB of available storage on your watch to check for the likelihood of sleep apnea. You can free up space by deleting apps or content from your watch.
Not getting enough data for a result	In some cases, your watch might not be able to get enough blood-oxygen data to provide a result. Reasons you might not get a result: You weren't asleep for long enough. At least 4 hours of sleep is needed.

-
- | | |
|--|--|
| | <ul style="list-style-type: none">• You moved in your sleep in ways that your watch detected as wakefulness, so it didn't detect 4 hours of sleep.• Your watch was too close to your wrist bone.• You wore your watch while taking a nap during the day.• Skin pigmentation or low peripheral blood flow might prevent the optical sensor on your watch from getting a strong enough signal to analyze. |
|--|--|

Things you can try:

- Make sure your skin is clean and dry.
- Clean the sensor on the back of your watch.
- Wear your watch snugly so it won't move around while you sleep.
- Wear the watch farther away from your wrist.
- If you have dense hair, a tattoo, or a scar on your wrist, try to reposition the watch to avoid those areas.