fitbit by Google

Loss of Pulse Detection

Version D

129-1389-01
February 10, 2025

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Glossary

C

Cardiac arrest
Cardiac arrest is a sudden loss of heart function, breathing, and consciousness. It occurs when the heart's electrical system malfunctions, causing the heart to stop beating effectively.

Cardiomyopathy
Cardiomyopathy refers to a group of diseases that affect the heart muscle, making it harder for the heart to pump blood effectively.

Coronary artery disease
Coronary artery disease is a condition where the blood vessels that supply the heart muscle with oxygen and nutrients become narrowed or blocked.

L

Loss of pulse
Loss of pulse is the absence of a detectable pulse. It is a potential emergency that may result in loss of consciousness. It may require urgent emergency intervention.

P

Pulse
Your pulse is the rhythmic push of blood through your arteries. It can be detected by Google Pixel Watch using optical sensors that detect the pulse of blood that goes to your wrist with every heartbeat.

S

Syncope
Syncope is a temporary loss of consciousness usually related to insufficient blood flow to the brain. It's often referred to as fainting.

Indications for Use

Loss of Pulse Detection is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse data to identify loss of pulse events and provide audio, visual, and haptic alerts to the user.

If the user remains unresponsive to these alerts, Loss of Pulse Detection will attempt to prompt a call to emergency services through the user's connected compatible hardware, such as a smartphone or smartwatch.

Loss of Pulse Detection is intended for over-the-counter (OTC) use. It is not intended to provide a notification on every loss of pulse event and the absence of an alert is not intended to indicate that no such event has occurred; rather the Loss of Pulse Detection is intended to opportunistically surface an alert of possible loss of pulsatility when sufficient data are available for analysis.

These data are only captured when the user is still. Loss of Pulse Detection is not intended to replace traditional methods of diagnosis, treatment, or monitoring.

Loss of Pulse Detection has not been tested for and is not intended for use in people under 22 years of age. It is also not intended for use in individuals previously diagnosed with a high risk for sudden cardiac death such as those with coronary artery disease, cardiomyopathy and/or unexplained syncope/fainting.

Product Description

Loss of Pulse Detection is a feature on Google Pixel Watch 3 that prompts calls to emergency services on your behalf if a pulse isn't detected, even if you're unconscious. After you set up Loss of Pulse Detection, your watch detects your pulse. If a pulse isn't detected, your watch vibrates and checks in to see if you need help. If you don't move or dismiss the notification and your pulse still isn't detected, your watch also plays a loud sound after around 15 seconds. If you still don't respond, your watch will attempt to call emergency services and share your location.

Algorithm Development

The Loss of Pulse Detection algorithm identifies potential loss of pulse events. The algorithm includes a machine learning component that consists of a convolutional neural network, which analyzes data from photoplethysmography (PPG) and accelerometer sensors. The algorithm was developed on a dataset consisting of over one hundred thousand hours of free-living data across hundreds of participants who experienced no loss of pulse events and 99 participants

who experienced simulated loss of pulse events induced by an arterial occlusion model. The dataset used for model development was split at the participant level into training, validation, and held-out test sets. The Loss of Pulse Detection algorithm was trained on the training split and evaluated on the validation set. When algorithm development was complete, the algorithm was locked and the algorithm was evaluated on the held-out test set. The training, validation, and test splits used for development included data from diverse participants with varied age, sex, BMI, and skin tone.

Intended Clinical Benefit

The primary benefit of Loss of Pulse Detection is to detect loss of pulse events and prompt the placement of a call to emergency services.

Cautions

Loss of Pulse Detection software has not been tested for:

- Individuals who have been prescribed to use, or who have been identified by a healthcare professional as a candidate for, real-time and/or continuous cardiac or pulse monitoring devices.
- Individuals under the age of 22
- Individuals identified by healthcare professionals as high risk for sudden cardiac death such as those with coronary artery disease, cardiomyopathy and/or unexplained syncope/fainting
- Individuals with a tattoo on dorsal aspect of wrist that interferes with function of watch
- Individuals who have chronic pain condition or peripheral nerve condition
- Individuals who have decreased blood flow to the wrist
- Individuals who have been diagnosed with cognitive impairment
- Individuals who have been diagnosed with sickle cell disease
- Individuals who are pregnant

General Warnings and Precautions

This feature **DOES NOT** replace any real-time and/or continuous cardiac or pulse monitoring devices prescribed by healthcare professionals.

This feature may not always be able to detect a loss of pulse. It **CANNOT** predict or determine a cause for a loss of pulse.

Loss of Pulse Detection uses your smartwatch's pulse and motion sensors to detect a pulse, even when the app is not in use. You may receive a check in when there is a poor pulse sensor reading, which can happen as a result of normal day-to-day activities.

You must set up Loss of Pulse Detection when you set up your watch or turn it on in the Google Pixel Watch app and wear your Pixel Watch in order for the feature to be on and running.

Always talk to a healthcare provider about your health concerns. A check-in from this feature **DOES NOT** serve as a diagnosis, indicate the presence or lack of an underlying health issue, or suggest the need for medical care.

Emergency services contact is **NOT** guaranteed. Emergency calls require a mobile network connection and do not guarantee that emergency services will respond. Not all calls may connect.

For security purposes, it's recommended that you maintain control and possession of your mobile devices (phone and smartwatch) to prevent unauthorized access to your health data. Refer to the manufacturer's instructions for your mobile devices to enable passcode functionality to deter unauthorized access.

If you feel like this product is in violation of any laws, or is threatening to an individual, report it to the manufacturer and your local health authority. This is a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Expectations

How Loss of Pulse Detection works

When your heart beats, your capillaries expand and contract based on blood volume changes. Loss of Pulse Detection uses optical heart-rate sensors on the back of your watch to detect your heart rate. The sensor also uses infrared light to determine when the watch is on your wrist to improve the accuracy of your heart-rate data. When your watch detects it's on your wrist, but your pulse can no longer be detected, you receive a check-in. If you don't respond to this check-in, and you continue to have no pulse or movement detected, your watch attempts to call emergency services.If you don't respond to this check-in, and you continue to have no pulse or movement detected, your watch will attempt to call emergency services.

How Loss of Pulse Detection avoids false alerts

If your watch is unable to detect your pulse, it performs a series of checks before it checks in with you or takes any action to call for help. These passive checks happen in the background and will not appear as notifications on your watch face. You likely won't know when they happen.

These background checks include:

1. Passively checking to make sure you are wearing your watch
2. Passively checking to see if you are moving
3. Actively intensifying the strength of the light signal input to the heart-rate sensors to see if the watch can detect a pulse signal

These checks can take up to 20 seconds, and are meant to avoid false alerts.

Compatible devices and system requirements

Loss of Pulse Detection is available on:

- Google Pixel Watch 3 (41mm) and Google Pixel Watch 3 (45mm) running firmware version AW2A.240415.022.A2 or higher

Make sure your Google Pixel Watch is running the latest version of Wear OS and your Google Pixel Phone is running the latest Android version. Your Pixel Watch must also be paired to your Pixel Phone.

- Watch: Wear OS (5.0+)
- Phone: Android (12.0+)

Note that the Loss of Pulse Detection is only available in select locations at this time. Additional devices & countries will be added as regulatory clearance is obtained. For details, refer to What is Loss of Pulse Detection on my Google Pixel Watch?

Operating Instructions

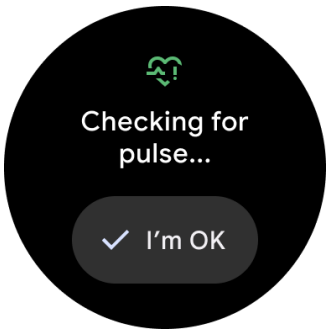
Turn on Loss of Pulse Detection

If you didn't set up Loss of Pulse Detection when you set up your watch, turn it on in the Google Pixel Watch app:

1. On your phone, open the Google Pixel Watch app.
2. Tap **Safety and Emergency** > **Loss of Pulse Detection**.
3. Tap “Loss of Pulse Detection” to start the Loss of Pulse Detection Onboarding flow and Follow the on-screen instructions to turn on the feature. You will see the “You’ve turned on Loss of Pulse Detection” page which serves as a confirmation that you’ve successfully turned the feature ON. After you turn on Loss of Pulse Detection, your watch detects your pulse and a potential loss of pulse whenever you’re wearing your watch.

Receive Loss of Pulse Detection check-ins

Check-in notification

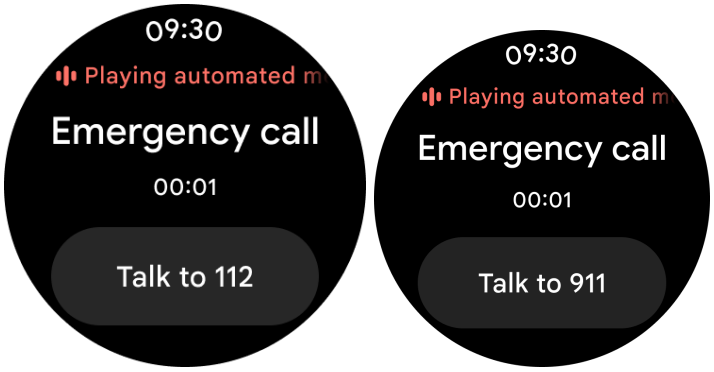


If a pulse isn’t detected, your Pixel Watch vibrates and displays a full screen check-in, asking you to confirm you’re okay. Tap **I’m OK** to dismiss the notification. If your watch detects your pulse or movement, it will automatically dismiss the check-in and emergency services won’t be called. This check-in remains for 15 seconds before progressing to the next phase of the experience.

No pulse detected alert

If the check-in expires and no pulse, movement, or interaction with the clock face is detected, your watch starts a countdown and informs you that it's going to call emergency services if you don't cancel the countdown. During this countdown, your watch continues to vibrate and will begin to play a loud sound. Tap the **X** icon to cancel the countdown and stop your watch from calling emergency services. Moving your wrist will not cancel the countdown at this point. This countdown remains for 20 seconds before progressing to the next phase.

Calling emergency services



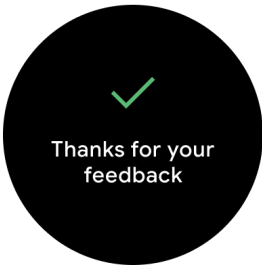
When your watch connects to the emergency services number, it plays an automated message that tells responders that your watch detected a loss of pulse and that you're unresponsive. It also shares your approximate location. This message isn't audible to you or any bystanders. To stop the audio message and speak to emergency services, tap the button at the bottom of the screen.

Open call with emergency services (optional)

If you tap the button to speak with emergency services, you can speak with responders through your watch's microphone and hear them respond through the watch's speaker. The call remains open until you tap the red end call icon.

Provide feedback on false alerts

If you cancel a check-in (or if your watch automatically cancels an alert because it detects movement or a pulse), you're invited to provide more information so that we can improve the feature.



Turn off Loss of Pulse Detection

Turn off Loss of Pulse Detection in the Google Pixel Watch app:

1. On your phone, open the Google Pixel Watch app.
2. Tap **Safety and Emergency > Loss of Pulse Detection**.
3. Tap the slider next to **Use Loss of Pulse Detection**.
4. Confirm that you want to turn the feature OFF and tap "Turn Off"

Troubleshooting

Follow the tips in How to wear Pixel Watch and adjust band size for optimal tracking.

You might receive a check-in (or a false alert) i if you temporarily restrict blood flow to your wrist. This sometimes occurs if you fall asleep in a position that compresses your arm. False

alerts can also occur if you take your watch off and it incorrectly senses that it's still on your wrist.

There are other factors that can impact the quality of the PPG signal and result in a check-in; these include but are not limited to individual variability, motion artifacts, ambient light, and applied pressure to the skin.

Tap I'm OK when you receive a check-in (or dismiss the subsequent alert), and then provide feedback on the most likely cause.

Clinical Studies

The Loss of Pulse Detection feature was validated in a clinical study. The study enrolled 156 participants which included a racially and ethnically diverse population, including adults of diverse sex and age.

The Loss of Pulse Detection (LPD) software, intended for use with wrist-worn devices, was clinically validated in a study. The study aimed to evaluate the software's ability to detect loss of pulse events and initiating an emergency call.

A total of 135 participants were enrolled in one clinical study and 21 participants in another clinical study. The participants included a racially and ethnically diverse population, including adults of diverse sex and age. The results from the clinical validation study showed a sensitivity of 69.3% (95% CI: 64.3%, 74.1%) across 135 users and a sensitivity of 64.5% (95% CI: 55.7% to 74.2%) after adjusting for performance after a simulated collapse. The specificity was analyzed using evaluable data from 131 participants from the first study. It showed a day-level specificity of 99.965% (95% CI 99.980, 99.999). A total of 5 adverse events were reported. No adverse events reported were related to the LPD software. Most adverse events were identified as possible anticipated risks in the study protocol, namely skin irritation from wearing a consumer wrist-worn device. Demographic characteristics of the study population are summarized in the table below.

	Clinical validation study (pulseless and pulsatile)	Clinical validation study (pulseless)
N	135	21
Age		
≤35	16.3% (22)	14.3% (3)
36–59	38.5% (52)	61.9% (13)
60+	45.2% (61)	23.8% (5)
Sex		
Female	60.7% (82)	47.6% (10)
Male	39.3% (53)	52.4% (11)
Monk skin tone		
1–4	40.7% (55)	28.6% (6)
5–6	35.6% (48)	66.7% (14)
7–8	20.7% (28)	4.8% (1)
9–10	3.0% (4)	0.0% (0)
Individual typology angle scale		
1	3.0% (4)	0.0% (0)
2	5.9% (8)	9.5% (2)
3	11.1% (15)	28.6% (6)
4	11.1% (15)	33.3% (7)
5	43.0% (58)	19.0% (4)
6	25.9% (35)	9.5% (2)

The results from the clinical validation study showed a sensitivity of 64.5% across 156 users. The specificity was analyzed using evaluable data from 131 participants from this study. It showed that there was 1 false positive call over 7.75 user-years.

Disease and Self-care Information

What is loss of pulse?

Loss of pulse is the absence of a detectable pulse. When someone experiences loss of pulse, it means blood isn't being circulated effectively, which deprives organs and tissues of oxygen and nutrients. This is a potential emergency that may result in loss of consciousness. Loss of pulse generally requires urgent emergency intervention.

What causes loss of pulse?

Loss of pulse can occur from a variety of causes including, but not limited to, cardiac arrest, respiratory or circulatory failure, overdose, or poisoning.

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