



fitbit

by Google

Breathing Emergency Detection

Version C

V920-000329-00
July 1, 2026

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Glossary

This section will be completed in conjunction with an FDA submission.

- **Apnea (or Sleep Apnea):** A medical condition where breathing repeatedly stops and starts during sleep leading to low blood oxygen levels
- **Breathing Emergency:** A sudden and persistent reduction in the oxygen saturation of the blood (low blood oxygen), which generally requires urgent emergency intervention. This can happen due to various reasons including, but not limited to, drug toxicity accidents, alcohol toxicity accidents, respiratory or circulatory failure, or poisoning
- **Breathing Emergency Detection:** A software-only medical application intended to be used with compatible consumer wrist-worn products to identify unanticipated breathing emergency events during a low motion state and prompt a call to emergency medical services and optionally notify emergency contacts. .
- **Dorsal aspect of the wrist:** The top or back side of your wrist where the watch rests and the sensors make contact with your skin.
- **Hypoxia:** A medical term for a state in which there is not enough oxygen reaching the tissues in the body.
- **OTC (Over-the-counter):** The intended use classification for the Google Breathing Emergency Detection feature.
- **PPG (Photoplethysmography):** The optical sensors on the back of the watch used to detect changes in the oxygen saturation in the blood.
- **Sickle cell disease:** An inherited blood disorder that affects the shape of red blood cells and their ability to carry oxygen. This condition can interfere with the optical sensors, which is why the feature is not intended for use by individuals with this disease.
- **SpO2:** It stands for Saturation of Peripheral Oxygen. It is a measure of the percentage of hemoglobin in your blood that is carrying oxygen compared to the total amount of hemoglobin

Indications for Use

Breathing Emergency Detection is a software-only medical application that is intended to be used with compatible consumer wrist-worn products with verified and qualified inputs. Breathing Emergency Detection identifies potential breathing emergencies that manifest physiologically as impaired oxygenation (i.e., normoxia → hypoxia) during a low motion state and provides audio, visual, and haptic alerts to the user. If the user remains unresponsive to these alerts, Breathing Emergency Detection can prompt a call to emergency services and optionally contact emergency contacts through the user's connected compatible hardware, such as a smartphone or smartwatch.

Breathing Emergency Detection is intended for over-the-counter (OTC) use. It is not intended to provide a notification on every impaired oxygenation event; the absence of an alert is not intended to indicate that no such event has occurred: rather the feature is intended to opportunistically surface an alert when sufficient data are available for analysis.

The feature is not intended to replace traditional methods of diagnosis, treatment, or monitoring. The feature has not been tested for and is not intended for use in people under 18 years of age.

Product Description

Breathing Emergency Detection is a feature on Google Pixel Watch that places a call to emergency services on your behalf if a breathing emergency is detected, even if you're unconscious. If a potential breathing emergency is detected, your watch vibrates and checks in to see if you need help. If you don't dismiss the notification, your watch also sounds an audio alert after 30 seconds. If you still don't respond, your watch will attempt to call emergency services, share your location, and optionally alert your emergency contacts.

Algorithm Development

The Breathing Emergency Detection algorithm identifies potential breathing emergency events. The algorithm includes a machine learning component that consists of a neural network, which analyzes data from photoplethysmography (PPG) sensors. The algorithm was developed on a dataset consisting of tens of thousands of hours of free-living data across hundreds of participants who experienced no breathing emergency events and dozens of participants who experienced simulated breathing emergency events induced in a hypoxia lab. The datasets used for model development were split at the participant level into training and testing sets. The Breathing Emergency Detection algorithm was trained on the training set and evaluated on the test set. When algorithm development was complete, the algorithm was locked and

implemented on a watch. The datasets used for development included data from diverse participants with varied demographics, including age, sex, and skin tone.

Intended Clinical Benefit

The primary benefit of Breathing Emergency Detection is to identify unanticipated impaired oxygenation events during a low motion state and attempt to prompt the placement of a call to emergency services and/or optionally, contact pre-specified emergency contacts through the user's connected compatible hardware, such as a smartphone or smartwatch.

The aspects clinical benefits include:

- Inform clinical management in so far as it relates to whether emergency services are called or not
- May enable access to medical care

Cautions

Breathing Emergency Detection software has not been tested for:

- Not intended for individuals under 18 years of age.
- Not intended for individuals who are pregnant.
- Not intended for individuals with chronically low oxygen saturation levels below 93% SpO₂.
- Not intended for individuals with sickle cell disease, chronic obstructive pulmonary disease (COPD) and heart failure.
- Not intended for individuals with decreased blood flow to the wrist.
- Not intended for individuals with a tattoo on the dorsal aspect of the wrist that interferes with watch functionality.
- Not a replacement for medical supervision or monitoring.
- Not intended to detect all impaired oxygenation events.
- Not intended to detect impaired oxygenation events during sleep sessions longer than 30 minutes.
- Not intended to detect impaired oxygenation events at elevations of approximately 2,500 meters (8,200 feet) or higher.
- Not intended to detect impaired oxygenation due to carbon monoxide.
- Not for self-diagnosis nor treatment.
- Not intended for use in hospital or ambulance environments.
- Not designed to detect apnea. Do not use Breathing Emergency Detection as an apnea monitor.

- Alerts may be less specific when other medical conditions are present (e.g., severe sleep apnea, obesity).

General Warnings and Precautions

This feature **DOES NOT** replace any real-time and/or continuous oxygen or SpO2 monitoring devices prescribed by healthcare professionals.

This feature may not always be able to detect a breathing emergency. It **CANNOT** predict or determine a cause for breathing emergencies.

It will not detect emergencies after you've been asleep for 30 minutes.

Breathing Emergency Detection uses your smartwatch's photoplethysmography, barometer, and motion sensors to detect breathing emergencies, even when the app is not in use. You may receive a check-in when there is a potential breathing emergency, which can happen as a result of normal day-to-day activities.

You must set up Breathing Emergency 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, determine when to perform security updates, and locate the product's security support lifecycle.

You can manage your health data and privacy settings through your Google account.

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 Breathing Emergency Detection works

When your heart beats, your heart pushes blood throughout your body. Breathing Emergency Detection uses optical PPG sensors on the back of your watch to detect changes in the oxygen saturation in the blood. The watch also uses additional sensors to ensure it can detect changes in your oxygen saturation accurately. These sensors are the accelerometer sensor, which identifies when you're in a low motion state, and the barometer, which identifies when you're at a low elevation. When your watch detects it's on your wrist and has a high quality signal, but your oxygen saturation drops suddenly and remains low, you may receive a check-in. If you don't respond to this check-in, your watch attempts to prompt a call to emergency services and a designated contact. It will not detect emergencies after you've been asleep for 30 minutes.

How Breathing Emergency Detection avoids false alerts

If your watch detects a sudden drop in your blood oxygen saturation and stays low, 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 make sure that the watch sensors have high quality signals
3. Passively checking that the watch is at low elevation and in a low motion state

Furthermore, if you have either 2 false emergency calls or 3 days with false haptics notifications in a rolling 30 day window, this feature will be turned off to not overburden you and the emergency medical services and we'll let you know.

These checks are meant to avoid false alerts.

Compatible devices and system requirements

Breathing Emergency Detection is available on:

- Google Pixel Watch 4 or higher

Update Google Pixel and Pixel Watch to Android and WearOS.

Make sure your Pixel Watch is paired to your Pixel Phone.

Watch: Wear OS (7.0+)

Phone: Android (12.0+)

Operating Instructions

Turn on Breathing Emergency Detection

If you didn't set up Breathing Emergency 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 mobile app.
2. Tap **Safety and Emergency > Breathing Emergency Detection**.
3. Tap "Breathing Emergency Detection" to start the Breathing Emergency Detection Onboarding flow and follow the on-screen instructions to turn on the feature. You will see the "You've turned on Breathing Emergency Detection" page which serves as a confirmation that you've successfully turned the feature ON. After you turn on Breathing Emergency Detection, your watch detects potential breathing emergency events whenever you're wearing your watch.

Receive Breathing Emergency Detection check-ins

Check-in notification



If a sudden drop in oxygen saturation and low motion state is detected, your Pixel Watch vibrates and displays a full screen check-in, asking you to confirm you're okay. This phase lasts for 30 seconds.

You can dismiss the notification by moving your wrist or tapping the **Show details** button. If you dismiss the notification, emergency services won't be called.

Breathing Emergency Notification



If you don't respond to the check-in, your watch starts a 30 seconds 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 play an audio alert. Tap the X icon to cancel the countdown and stop your watch from calling emergency services. This countdown remains for 30 seconds before progressing to the next phase.

Calling emergency services



If the countdown expires and you don't respond to the countdown, your watch will try to connect to emergency services. When your watch connects to the emergency services number, it plays an automated message that tells responders that your watch detected a potential breathing emergency 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.

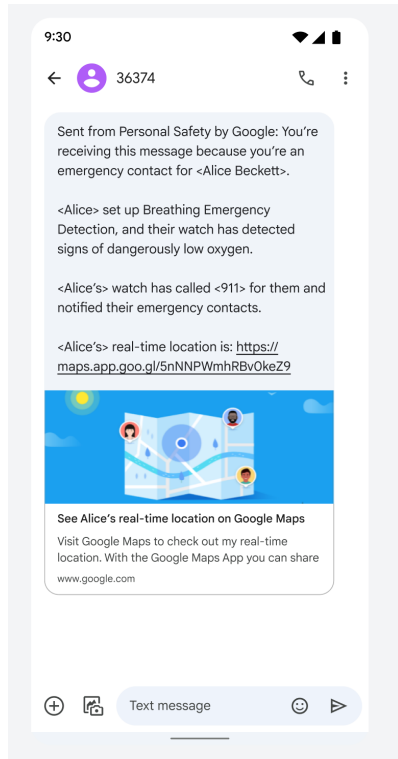
Open call with emergency services (optional)



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.

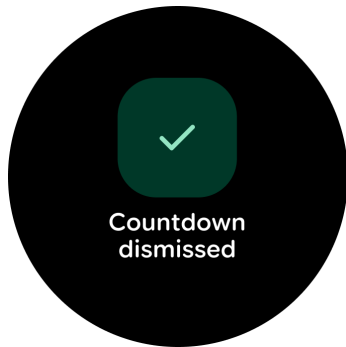
Emergency Contacts Notification (Optional)

If you have set up emergency contacts, Breathing Emergency Detection will also send them a notification to the provided phone number with the message and your location.



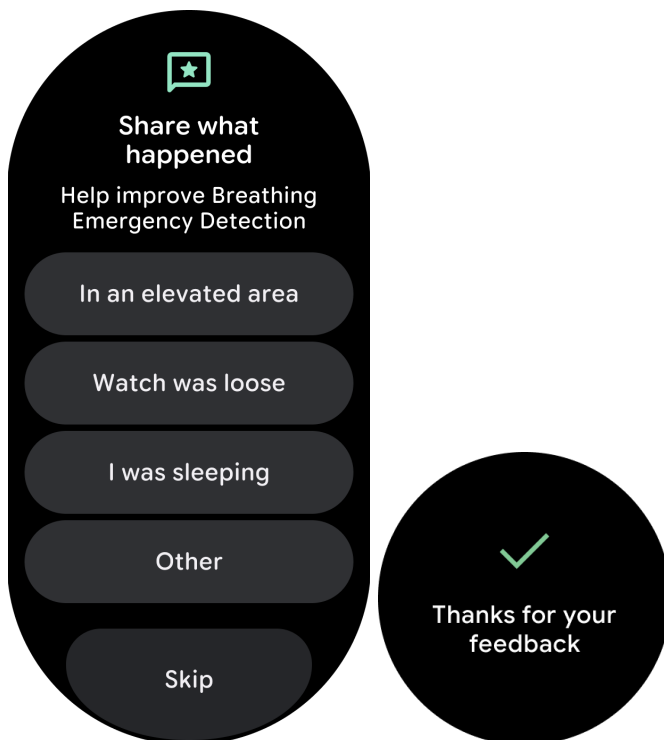
Deescalation

If you dismiss the check-in or countdown, you get an acknowledgement and an opportunity to provide feedback.



Provide feedback on notification

If you cancel a check-in or countdown, you're invited to provide more information so that we can improve the feature.



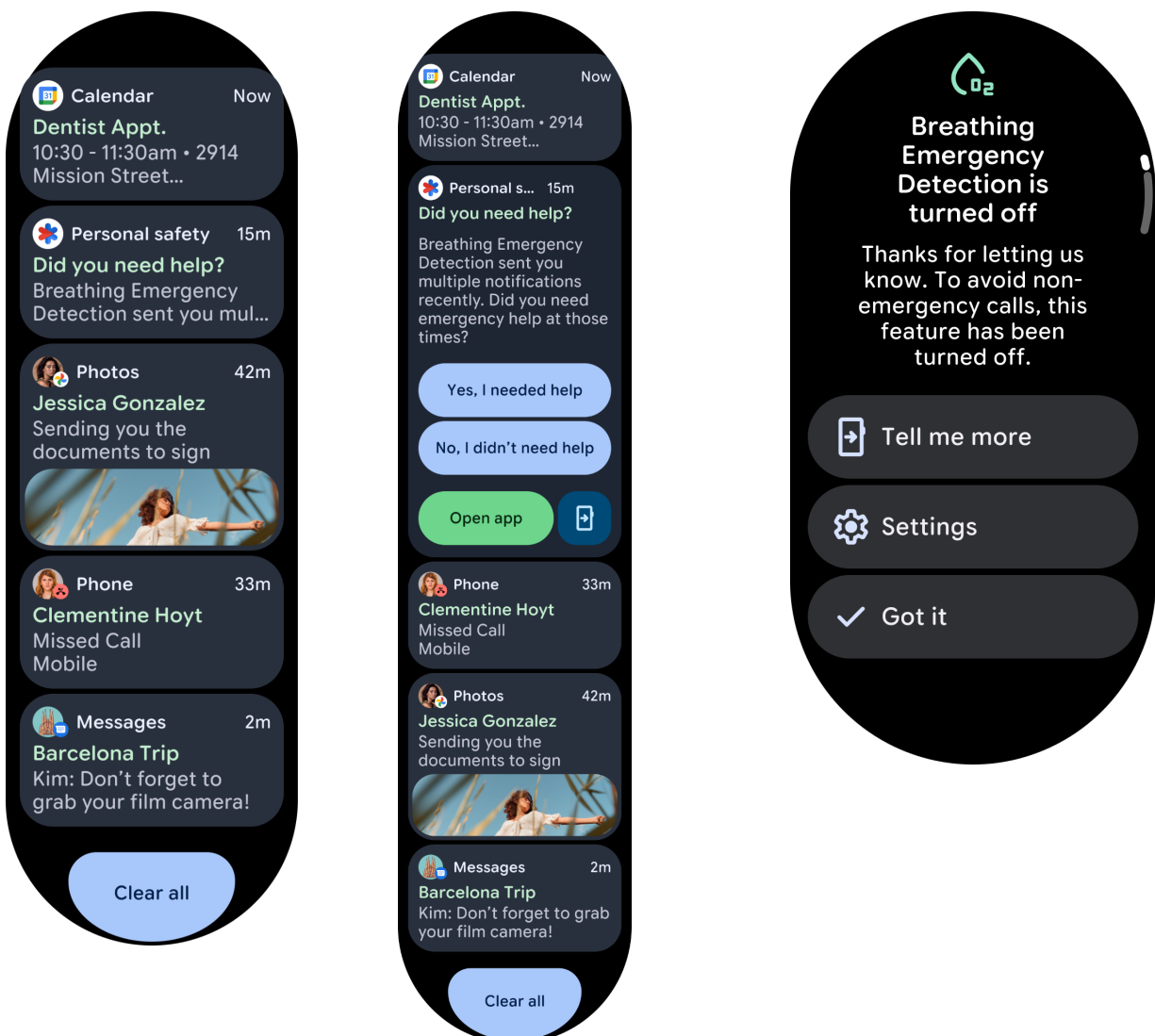
Turn off Breathing Emergency Detection

Turn off Breathing Emergency Detection in the Google Pixel Watch app:

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

Auto Turn Off

If you experience multiple false alerts either 2 false emergency calls or 3 days with false haptics notifications in a rolling 30 day window, this feature will be turned off to not overburden you and the emergency medical services and you will be notified if the feature is auto turned 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) if your blood oxygen saturation temporarily goes down suddenly and remains low. This sometimes occurs if you suddenly go from low to high elevation or have another cause of low blood oxygen.

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 loose wear.

Tap **Dismiss countdown** or **X** when you receive a check-in (or dismiss the subsequent alert), and then provide feedback on the most likely cause.

Clinical Studies

The Breathing Emergency Detection feature was validated in clinical studies. The studies aimed to evaluate the feature's ability to detect potential breathing emergencies and initiate a call.

A total of 36 participants completed Study 1, and 160 participants completed Study 2. The participants in both studies included a diverse population, including adults of diverse age, skin tone and sex. The results from Study 1 showed a sensitivity of 86.3% (95% confidence interval: 76.5%, 94.4%) and Study 2 showed a day-level specificity of 99.8% (95% confidence interval: 99.6%, 99.9%), corresponding to an average of 0.66 calls per person-year. There were 6 calls from 5 participants across 9.09 person-years; the participants with calls were characterized by elevated BMI. No adverse events were related to the Breathing Emergency Detection feature. Demographic characteristics of the participants are summarized in the tables below.

Study 1 demographics	Participants (n=36)
Age	
18-34	21 (58.3%)
35-50	15 (41.7%)
Sex	
Male	17 (47.2%)
Female	19 (52.8%)
Monk skin tone	
1-3	12 (33.3%)
4-7	14 (38.9%)
8-10	10 (27.8%)

Study 2 demographics	Participants (n=160)
Age	
18-21	11 (6.9%)
22-39	35 (21.9%)
40-60	66 (41.3%)
>60	48 (30.0%)
Sex	
Male	69 (43.1%)
Female	91 (56.9%)
Monk skin tone	
1-3	67 (41.9%)
4-7	52 (32.5%)
8-10	41 (25.6%)

Disease and Self-care Information

What is a breathing emergency?

Breathing emergencies can cause a reduction in the oxygen saturation of the blood. When someone experiences a breathing emergency suddenly and their oxygen saturation remains low, it means blood has less oxygen than normal, which deprives organs and tissues of oxygen. This is a potential emergency that may result in loss of consciousness. Sudden and persistent breathing emergencies generally require urgent emergency intervention.

What causes a breathing emergency?

Breathing emergencies can occur from a variety of causes including, but not limited to, drug toxicity accidents, alcohol toxicity accidents, respiratory or circulatory failure, or poisoning.

Terms of Service

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When the Terms mention “Google,” “Fitbit,” “we,” “us,” or “our,” they refer to the party to your agreement that provides you with the Fitbit Service.

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Additional information regarding these Terms may be obtained by visiting the Google Terms of Service or [Fitbit Terms of Service](#).

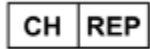
User Assistance Information



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Equipment Symbols



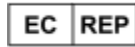
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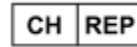
Read
Instructions
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