Sleep Apnoea Notification Feature

Instructions for Use

Apple Inc.
One Apple Park Way
Cupertino, CA 95014, USA
www.apple.com

EC REP
Apple Distribution International
Hollyhill Industrial Estate,
Hollyhill, Cork,
Ireland
Contact: medicalcompliance@group.apple.com

CE 0123

INDICATIONS FOR USE

The Sleep Apnoea Notification Feature (SANF) is a software-only mobile medical application that analyses Apple Watch sensor data to identify patterns of breathing disturbances suggestive of moderate-to-severe sleep apnoea, and provides a notification to the user. This feature is intended for over-the-counter (OTC) use by adults aged 18 and over who have not previously received a sleep apnoea diagnosis, and is not intended to diagnose, treat or aid in the management of sleep apnoea. The absence of a notification is not intended to indicate the absence of sleep apnoea.

(EU)

INTENDED PURPOSE

The Sleep Apnoea Notification Feature (SANF) is a software-only mobile medical application that analyses Apple Watch sensor data to identify patterns of breathing disturbances suggestive of moderate-to-severe sleep apnoea, and provides a notification to the user. This feature is intended for over-the-counter (OTC) use by adults aged 18 and over who have not previously received a sleep apnoea diagnosis, and is not intended to diagnose, treat or aid in the management of sleep apnoea. The absence of a notification is not intended to indicate the absence of sleep apnoea.

Target Population and Intended Users

The Sleep Apnoea Notification Feature is indicated for adults aged 18 and older who have not previously received a sleep apnoea diagnosis.

PRECAUTIONS AND WARNINGS

Not all people with sleep apnoea will receive a notification. The absence of a notification is not intended to indicate the absence of sleep apnoea. If you believe you have sleep apnoea, you should talk to a doctor.

Not intended for use by individuals under 18 or individuals previously diagnosed with sleep apnoea.

Notifications made by this feature are potential findings, not a diagnosis of sleep apnoea. Any notifications should be reviewed by a medical professional for clinical decision-making.

DO NOT change your treatment without talking to your doctor.

For best results, charge your Apple Watch sufficiently to track your sleep and make sure it fits snugly on top of your wrist.

If your Apple Watch reboots during a sleep session, data for the night may not be collected.

Apple Watch may be unable to collect data if the accelerometer in your Apple Watch is non-functional.

A variety of factors, such as sleeping position, alcohol intake, upper respiratory illnesses and even some medications, can lead to increased Breathing Disturbances on a night-to-night basis.

Breathing Disturbances yields an event estimate that is an event rate (per hour). Breathing Disturbances numbers should not be used as a one-to-one comparison to Apnoea-Hypopnoea Index (AHI).

CUSTOMER SUPPORT

This information and other labelling, including the user instructional brochure, are available on the internet at: [**https://www.apple.com/legal/ifu**]. You may also call Apple Support through the Contact Apple Support option in the About Sleep Apnoea Notification Feature screen, or write to **medicalcompliance@group.apple.com** or One Apple Park Way, Cupertino, CA 95014, USA to request a paper copy of this information and other labelling.

As a user, you should report any serious incident that has occurred in relation to the device to the manufacturer and competent authority (health authority) in your EU Member State.

SECURITY

Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your iOS compatible devices and a passcode (personal identification number [PIN]) to your Apple Watch to add a layer of security. It is important to secure the iOS compatible devices since you will be storing personal health information. Users will also receive additional iOS and watchOS update notifications on the device, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes. See "iOS and watchOS Security Guide", which describes Apple's security practices and is available to all our users. For the iOS and watchOS Security Guide, please visit https://support.apple.com/guide/security/welcome/web.

In the event that you suspect or would like to report any security issues with your device, please visit Apple's support web page, which describes how to get help with your security issues (https://support.apple.com/111756).

USING THE SLEEP APNOEA NOTIFICATION FEATURE

Setup/Onboarding

- For region availability and device compatibility information, please visit https://support.apple.com/120031
- Update iPhone and Apple Watch to latest iOS and watchOS.
- Make sure your Apple Watch is paired to your iPhone.
    - For more information on pairing your Apple Watch to your iPhone, please visit https://support.apple.com/HT204505.
- Make sure Sleep Tracking is enabled.
    - For more information on Sleep Tracking, please visit https://support.apple.com/HT211685.
    - **NOTE:** The Sleep Apnoea Notification Feature operates in sequential 30-day windows and requires at least 10 days of Breathing Disturbance data in order to output a possible sleep apnoea notification. It is recommended you wear your Apple Watch to sleep consistently during each 30-day window.

- Enter the Sleep Apnoea Notification Feature's onboarding screen using your iPhone in one of the following ways:
    - Open Health → Browse → Respiratory → Breathing Disturbances → Set Up Notifications
    - Open Health → Browse → Sleep → Sleep Apnoea Notifications → Set Up Notifications
    - **NOTE:** You can only onboard to the Sleep Apnoea Notifications from your iPhone.
- Follow the onscreen instructions.
- You may exit onboarding at any time by tapping Cancel.

Receiving a Notification

- The Sleep Apnoea Notifications Feature operates on sequential 30-day windows starting on the day of onboarding. Notifications can only be sent after a 30-day window has been completed, with at least 10 nights of Breathing Disturbances data.
- If you receive a notification, you should discuss the notification with your doctor at your next appointment.

About Breathing Disturbances

- Once the Sleep Apnoea Notifications Feature is turned on, it will begin collecting nightly Breathing Disturbances data.
- After successful collection of Breathing Disturbances data, your data will fall under one of the following classifications in the Health app:
    - Elevated means the Apple Watch identified an elevated number of Breathing Disturbances per hour while you were asleep.
    - Not Elevated means the Apple Watch did not identify an elevated number of Breathing Disturbances while you were asleep.
    - No Data means the Apple Watch was unable to compute Breathing Disturbances. This could be because you did not wear your watch to bed, it was unable to measure your breathing, there was excessive motion during sleep or the watch rebooted during the sleep session.

- You will receive a notification if the Feature identifies "Elevated" status for more than 50% of the minimum required number of days within the 30-day window. These Breathing Disturbance patterns are suggestive of moderate to severe sleep apnoea.

All Breathing Disturbances data collected and analysed by the Sleep Apnoea Notification Feature is saved to the Health app. If you choose to, you can share that information by exporting your health data in the Health app.

New data cannot be collected once your Apple Watch storage is full. If necessary, you can free up space by deleting unwanted apps, music or podcasts.

SAFETY AND PERFORMANCE

The Sleep Apnoea Notification Feature (SANF) was validated in a clinical study with 1,499 participants aged 18 years or older. Subjects wore Apple Watch to sleep for up to 30 nights and underwent a minimum of 2 nights of Home Sleep Apnoea Testing (HSAT) in a home-use setting. The HSAT results were used as the reference measurement for the participants' sleep apnoea classification and to determine the performance of the SANF. For sleep apnoea notifications, the device sensitivity and specificity were calculated using the classification of apnoea determined by HSAT (i.e. AHI ≥ 15). For Breathing Disturbances, accuracy was calculated based on a comparison of paired (Breathing Disturbances, AHI) data obtained from the device and HSAT, respectively. The study enrolled subjects across the spectrum of sleep apnoea severity classifications, with a broad distribution across each of the following AHI categories using the "4%" hypopnoea scoring rule: 0 to <5 (Normal), 5 to <15 (Mild), 15 to <30 (Moderate) and ≥30 (Severe). Subjects were also enrolled based on a broad range of demographic factors including age, sex, BMI, and racial and ethnic subgroup targets representative of the intended patient population.

The clinical study determined that:

- For sleep apnoea notifications, the device met all predetermined acceptance criteria and reported a sensitivity of 66.3% (95% CI: [62.2%, 70.3%]) and specificity of 98.5% (95% CI: [98.0%, 99.0%]).

- For Breathing Disturbances, out of the total of 1,305 subjects who had at least one paired (Breathing Disturbance, AHI) data value, 1,193 (91.4%; 95% CI: [89.8%, 92.9%]) had Breathing Disturbance measurements within the pre-specified performance zone.

- Observed performance of the device exceeded pre-specified endpoints across all demographic subgroups (age, sex, BMI, race, ethnicity).

The study was conducted with no protocol deviations that would have impacted the results. Finally, no serious device-related adverse events were reported in the study.

Overall, the clinical study provides reasonable assurance of safety and effectiveness for the SANF.

CLINICAL BENEFIT (EU)

The Sleep Apnoea Notification Feature's intended clinical benefits include identifying patterns of breathing disturbances suggestive of moderate-to-severe sleep apnoea and providing a notification to the user.

TROUBLESHOOTING

If you experience difficulties in operating your SANF, refer to the troubleshooting guide below.

Problem: I am not able to turn on the SANF.

Solution:

- Make sure you follow the onscreen instructions to fully complete onboarding to the SANF.
- SANF is intended for adults 18 years or older.
- SANF is not intended for people who have a previous diagnosis of sleep apnoea.
- Ensure that Sleep Session is enabled.

Problem: I think I have sleep apnoea but I am not getting any notifications.

Solution:

- Ensure you completed all the onboarding steps to enable SANF.
- Ensure that Sleep Tracking is enabled.
- Ensure you wear your watch to sleep for at least 10 nights within the 30-day window. You will not receive any notification from SANF until your 30-day window has been completed. Your 30-day window begins on the day of the first analysis.
- Ensure you log at least 4 hours of sleep per night. Minimum of 4 hours of data is required to constitute 1 sleep session.
- Not all people with sleep apnoea will receive a notification. The absence of a notification is not intended to indicate the absence of sleep apnoea. If you believe you have sleep apnoea, you should talk to your doctor.

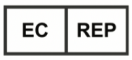
TECHNICAL SPECIFICATION

Device Requirement	iPhone 11 or later Apple Watch Series 9 or later, Ultra 2, excluding Apple Watch SE

EQUIPMENT SYMBOLS

 Manufacturer

 Read instructions before use



European Authorised Representative



Medical Device

B099-42741 Revision E, July 2024