Clinicians Implementation Guide for Consumer Sleep Apnea Risk Assessment Devices

A resource guide developed by the American Academy of Sleep Medicine Emerging Technology Committee:

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Overview and objectives

Consumer technologies capable of detecting sleep related breathing disturbances have expanded quickly, creating new challenges for clinicians. In 2024, the U.S. Food and Drug Administration (FDA) introduced a new category, over-the-counter devices to assess risk of sleep apnea (OTC-ARSA) devices, allowing certain applications to notify consumers of possible sleep apnea risk, while still prohibiting diagnosis or clinical decision making based on these results. Additionally, the FDA guidance for general wellness devices was updated in 2026 to clarify that other consumer devices may report physiologic metrics for wellness purposes but cannot reference or screen for medical conditions without regulatory oversight. As more patients present with device-generated sleep notifications, clinicians need a clear, practical framework to interpret these results, understand device limitations, and integrate consumer data responsibly into clinical care.

Objectives

This guide will help clinicians:

Describe	Describe the current regulatory landscape governing OTC-ARSA devices and general wellness technologies.
Differentiate	Differentiate the capabilities, limitations, and appropriate uses of FDA cleared vs. non cleared consumer sleep-related breathing devices.
Apply	Apply structured clinical algorithms to interpret device notifications and integrate them into clinical triage.
Identify	Identify patient populations in whom device results may be unreliable or contraindicated.
Promote	Promote safe and clinically responsible workflows for incorporating consumer sleep apnea screening technologies into practice.

FDA oversight of consumer devices

Consumer devices often use the same underlying technology as clinical devices when collecting physiologic variables. For example, both consumer and clinical pulse oximeters use photoplethysmography (PPG) to determine pulse rate and oxygen saturation. However, the performance of these may vary, and additional predictive algorithms may be used to report derived metrics. These metrics and how they are presented to the end user are potentially under FDA oversight if indicated for medical use.

Consumer devices with FDA clearance: OTC-ARSA

Prior to the development of these new technologies, the U.S. Preventive Services Task Force (USPSTF) recommendations from November 2022 concluded that evidence was insufficient to recommend screening in the general population. However, in February 2024, the FDA granted De Novo classification for a new device type, over-the-counter devices to assess risk of sleep apnea (OTC-ARSA). Per the FDA, this type of device is intended to provide notification of the risk of sleep apnea in users who have not previously been diagnosed with sleep apnea. It is not intended to provide a standalone diagnosis, replace traditional methods of diagnosis (polysomnography or home sleep apnea tests), assist clinicians in diagnosing sleep disorders, or be used as an apnea monitor. So far, devices in this category have been software-only, mobile medical applications that operate with compatible hardware (smartphone paired with smartwatch).

Consumer devices without FDA clearance: General Wellness Devices

It is important to understand that not all consumer devices require FDA oversight to report sleep-related breathing metrics to the user. In January 2026, the FDA updated guidance on how consumer devices are evaluated under the General Wellness: Policy for Low Risk Devices.[1] Under this guidance, FDA oversight is not needed if the device only claims to promote general wellness and does not report clinical markers intended to monitor or treat diseases, such as the apnea-hypopnea index (AHI). Devices cannot reference, screen for, or diagnose clinical conditions, report diagnostic thresholds, inform medical management, or inform the user to seek specific clinical action without oversight. However, non-invasively obtained physiologic parameters may be reported as solely for wellness uses, with several relevant listed examples including blood pressure, oxygen saturation, and heart rate variability. So long as the device presents low risk to the user, it would be considered acceptable to report device-specific respiratory event indices or even alerts to seek further medical attention.

Clinical Algorithm

The following algorithm will help clinicians determine if further diagnostic testing is appropriate for patients presenting with results from a consumer device.

A. Initial Clinical Triage

- [ ] The clinician must first determine the patient's baseline risk by assessing **symptoms** (e.g., excessive daytime sleepiness, habitual loud snoring, witnessed apnea, gasping or choking) and **comorbidities** (e.g., obesity, heart failure, atrial fibrillation, stroke, or hypertension).

B. Result Interpretation and Action

Non-FDA cleared General Wellness Devices should be viewed with higher clinical scrutiny; use results only to prompt a more detailed clinical evaluation.

For devices with OTC-ARSA clearance, there are four primary patient scenarios to guide the next steps:

1. **Positive Notification + Symptomatic/Comorbidities:**

- [ ] These patients are at **high risk**. The clinician should proceed with a comprehensive clinical evaluation and diagnostic testing, such as polysomnography (PSG) or a home sleep apnea test (HSAT), following standard AASM guidelines.

2. **Positive Notification + Asymptomatic/No Comorbidities:**

- [ ] While this could be a **false positive**, the notification indicates **elevated risk**. Clinicians should conduct a clinical evaluation, discuss the results, and determine if confirmatory testing is appropriate based on the patient's individual profile.

3. **Negative Notification + Symptomatic/Comorbidities:**

- [ ] Clinicians must be wary of **false negatives**. If clinical suspicion for obstructive sleep apnea (OSA) remains high despite the device's results, the patient should still proceed with further diagnostic testing.

4. **Negative Notification + Asymptomatic/No Comorbidities:**

- [ ] Generally, these patients require no further evaluation at this time.

C. Critical Considerations for the Clinician

1. Not a Diagnosis:

These over-the-counter devices to assess risk of sleep apnea (OTC-ARSA) are for risk assessment only and are not cleared by the FDA for diagnosis or for use as an apnea monitor.

2. Excluded Populations:

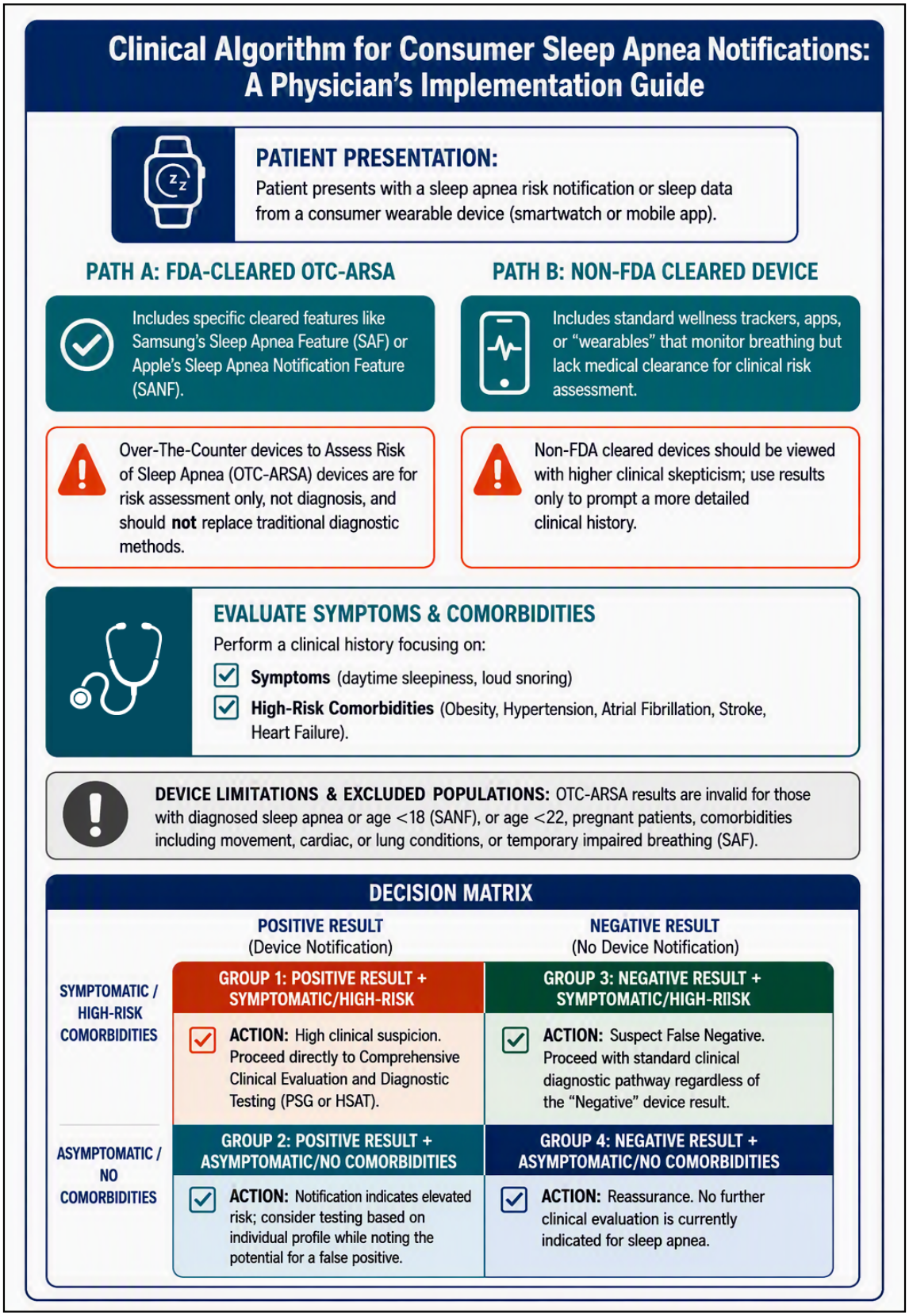
Current devices are only valid for individuals without a history of OSA, with exclusions varying by device manufacturer:

- ☐ **Samsung Sleep Apnea Feature (SAF)[2] exclusions:** Age under 22 years old, pregnant women, or those with existing conditions including:
  - Movement related conditions (Parkinson's disease, tremors, periodic limb movement)
  - Cardiac conditions (congestive heart failure, atrial fibrillation)
  - Lung conditions (chronic obstructive pulmonary disease [COPD], chronic bronchitis, emphysema, pulmonary fibrosis)
  - Temporary symptoms of impaired breathing from any condition such as flu, allergies, or asthma.
- ☐ **Apple's Sleep Apnea Notification Feature (SANF)[3]** exclusions: Age under 18 years old.

3. Device Differences:

- ☐ **Samsung (SAF)[2]:** Provides a binary result ("detect signs" or "didn't detect") after **two nights** of on-demand testing
- ☐ **Apple (SANF)[3]:** Passively analyzes data over **30-day periods** and only notifies the user if elevated disturbances are found in at least 50% of recordings (with a minimum of 10 nights of data)

Clinical Algorithm



References

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