

An apnea event is counted when respiration amplitude drops to under 12% of the average for more than 10 seconds. A hypopnea event is counted if respiration amplitude drops to less than 50%, but more than 12%, of the average for more than 10 seconds. Respiratory events (apneas and hypopneas) are counted for the duration of the study. These values were selected for maximum correlation with polysomnographic results.

After a study is complete, the apnea and hypopnea counts are used to calculate the final test score, which is readable on the display half an hour after the study has ended.

The SleepStrip's intended use is for screening purposes only. It should be used on patients who are considered high risk for SAS and require additional information for diagnosis. If the indication of the SleepStrip is positive, together with additional indications and risk factors such as obesity, hypertension, heavy snoring, and/or a family history of SAS, patients can then be referred for further evaluation.

US and international patents apply

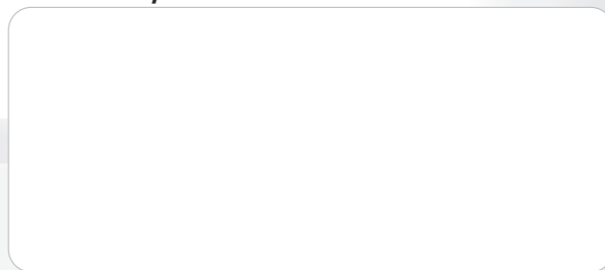
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SleepStrip®
Disposable Sleep Apnea Screener

Instructions for the Professional

Please visit our web site at
www.slp-med.com
for more information and updates

Overview

The Sleep Strip is a novel low-cost device designed to help physicians screen patients for sleep apnea syndrome (SAS) reliably and conveniently. To fully exploit the advantages this innovative device offers, it is helpful to know and understand its inner workings and technology.

A “one-channel sleep lab”

The SleepStrip is, in fact, a “one-channel sleep lab” comprising signal detection, acquisition, analysis and display in one easy-to-use disposable package. The flow signals are derived from three thermistors (respiration airflow temperature sensors) similar to those used in standard sleep-lab sensors. These sensors are located under the three blue dots on the nose and mouth prongs. The signal is processed ten times each second by SleepStrip's internal microprocessor (CPU). The CPU tracks the signal continuously, calculating average amplitude of normal respiration cycles, peak-to-peak amplitude for each consecutive breath cycle, and other parameters of the respiration pattern.

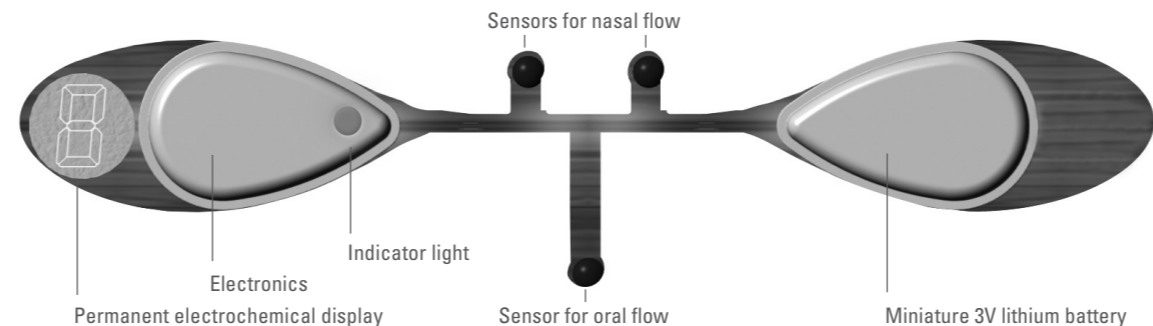
Patient setup

Instruct the patient to read through the instructions and follow them closely before using SleepStrip. The SleepStrip should be applied at bedtime. The device is activated by first rubbing the display area with the alcohol prep pad provided, and then firmly attaching the green sticker on the display area as described in the instructions to the patient.

A small red light will turn on (located on the left side underneath the oval-shaped white cover) thus indicating proper placement of the sticker. The SleepStrip is then affixed on the face under the nose. Within a few seconds, the red light turns off and then will blink each time the patient exhales. During this time the SleepStrip “learns” the normal respiration pattern of the patient, assuming he or she is still awake. Instruct the patient to apply the SleepStrip on his face immediately after activation.

Approximately 20 minutes after activation, the blinking stops, and the device switches to study mode and begins counting respiratory events. This delay is designed to allow to patient to fall asleep before the study begins.

In the morning, approximately three minutes after the patient wakes up and removes the SleepStrip from his or her face, or automatically eight and a half hours after activation time (while the SleepStrip is still on the face), the red light will turn on again to mark the end of the study. The display will be readable half an hour later, and the green sticker must not be removed until then.



Reading the SleepStrip display

The display consists of a single digit, which appears in black against the bright silver color of the background.

The final score represents five possible test outcomes based on sleep apnea severity level:

- No apnea**
comparable to a sleep lab AHI of less than 15
- Mild**
comparable to a sleep lab AHI between 15 and 24
- Moderate**
comparable to a sleep lab AHI between 25 and 39
- Severe**
comparable to a sleep lab AHI of more than 40
- Error**
Error in measurement

Peel the green sticker off the SleepStrip to read the display as soon as possible after the study, **but not less than half an hour after the study has terminated**. Once the green sticker is removed the display is readable indefinitely.

Read number (0, 1, 2, or 3) to establish test outcome (as shown below). An E on the display indicates the SleepStrip was removed less than four hours after commencing the sleep study (not including the first 20 minutes set-up time), which is not sufficient for accurate outcome. The study must be repeated.

If necessary, place the orange Strip Reader card over the display area to make reading easier.

The display is permanent and the SleepStrip can be kept as the hard copy record of the test.

If no number or letter can be seen on the display, a technical malfunction is suspected. The study must be repeated, but the SleepStrip will be replaced under warranty.

⚠ Precautions and miscellaneous

- Touching the display with your fingers may cause the red light to turn on momentarily. This is not a problem, and the device can still be used.
- The patient must leave the green sticker in place in the morning.
- The SleepStrip should be stored in a cool dry place until it is ready to be used. The laminated bag should not be opened unnecessarily.
- Review with the patient the correct way to fold the nose sensors forward, so they do not enter the nostrils.
- Make sure the patient knows to remove the sensor in the morning, but to leave the green sticker in place.
- If the SleepStrip's red light does not flash with respiration when it is activated, advise the patient to try and reposition it on the face, so that the sensors are in the airflows from the nostrils and mouth.
- Patients who are suffering from a cold, congested nose or any other respiratory tract illness should not use the SleepStrip.
- Should the patient develop anything more than a mild skin rash or reaction at the site of attachment, instruct him or her to consult a dermatologist.