

SleepStrip[®] FAQ

Can the SleepStrip be Re-used?

No, the SleepStrip is a single-patient use, disposable item. After the study ends, the result is permanently etched on the display and can't be erased.

Why did you design the SleepStrip as a disposable device?

Making the SleepStrip disposable allowed us to make it far less expensive and much simpler to operate than any reusable system. Other advantages:

- a. No need to invest in expensive sleep equipment
- b. No need for maintenance, insurance, or replacement parts
- c. No need to recharge batteries, operate a PC, or any other handling
- d. No need to operate a facility for delivering the device to the patient and bringing it back
- e. Ability to test as many patients as required every night
- f. Broad range of time as to when the patient uses the device, performs the test, or returns the results.

What is the SleepStrip's shelf life?

The SleepStrip's shelf life is two years from date of manufacture. The expiration date is clearly marked on the box.

What is the advantage of thermistors versus pressure sensors for flow sensing?

Although the trend is moving toward pressure sensing, the vast majority of labs and systems still rely on thermistors and will probably continue to do so.

In general, pressure cannula is more sensitive than thermistors, specifically regarding mild hypopnea events, which demonstrate changes in the shape of the trace, rather than a decrease in its amplitude.

Pressure sensing records a large number of false events which are very easy to misinterpret, due to the very complex waveforms it generates. There is also a major problem of mouth breathing, confusing the pressure sensor located on the nose.

To compensate for the thermistors' lower sensitivity to hypopnea, we've designed a relatively high flow threshold in the SleepStrip algorithm, resulting in good overall sensitivity at a slightly lowered specificity (more false positives) - which is an acceptable specification for a screening tool.

Comparing SleepStrip readings to pressure cannula readings will indeed show a lower RDI, but the difference will be almost exclusively very mild hyponeas and other minor breathing irregularities which have little clinical significance.

Can I use SleepStrip under a CPAP mask?

In principle the SleepStrip should work under a CPAP mask, but it has not been tested or validated this way. There may be an issue of mask leaks, if the mask seal falls on the white covers. Therefore, we can't recommend or support such use. If you want to experiment with this application, you should make sure the mask seal is good.

What is the green sticker on the SleepStrip?

The green sticker carries a layer of hydrogel material, which serves two purposes: (1) At the beginning of the study the gel closes an electrical circuit to activate the device (like an on/off button). (2) At the end of the study, the gel is used as a chemical component to etch the result on the display. This is why we specifically ask to wait 45 minutes before removing the green sticker from the display after the study ends. This is the time it takes to etch the result onto the display.

Why do you require a physician's prescription to get a SleepStrip?

Sleep apnea is a medical disorder and, as such, should be diagnosed and treated by a physician. There are many parameters involved in determining the existence and severity of the disorder, so we recommend that a qualified physician make the final diagnosis, based on SleepStrip and questionnaire results and a physical evaluation of the patient.

How long does the result last on the SleepStrip display?

The result is permanent. It is etched on to the display 45 minutes after the study ends. Due to the possibility of corrosion, however, we recommend not waiting more than three months before returning the SleepStrip to the physician. After the green sticker is removed, the display is readable for at least five years.

How sensitive is the SleepStrip to sleep apnea?

Any reading other than 0 is considered positive for sleep apnea. Numerous clinical studies demonstrated good sensitivity (over 80%) for mild cases of sleep apnea (AHI<25), very good sensitivity (over 93%) for moderate cases of sleep apnea (AHI<40), and excellent sensitivity for severe cases (AHI>40). However, it is always important to consider the patient's clinical history together with the SleepStrip indication to decide on the course of action.

Why did my SleepStrip show an E at the end of the study?

The "E" on the display indicates an invalid study.

This is usually caused by the patient removing the SleepStrip before the minimum study time has elapsed (less than 4.5 hours on the face), which may occur without the patient even being aware. Loss of flow signal may also result in an "E" reading. This can happen if the patient slept with his face buried in the pillow or had his hand directly on the sensors.

Can I stop the study and continue some other night?

The study may be canceled if you remove the SleepStrip from the face and remove the green sticker from the device **within the first 20 minutes of the study**. The Strip and sticker should be carefully stored, so they do not stick to anything. They can then be used again the following night.

I have sleep apnea and use CPAP, but when I tested myself the result was 0. Where is my apnea?

There is a “residual effect” from prolonged use of CPAP, meaning that apnea is greatly alleviated for one or two nights after your CPAP is not used. Therefore, if you use CPAP and your physician instructs you to use SleepStrip, do not use CPAP for at least two nights prior to using SleepStrip.

Why should I fold the nose prongs forward?

In order for the heat-sensitive elements to sense the warm air exhaled from the nostrils and mouth, they must not touch anything. It is best to align the mouth sensor in front of the center of the mouth, and then align the nose sensors directly under each nostril and straight out. The nasal sensors should not go into the nose.

For further information or a presentation:

Contact for Medline Sales Representative
1-800-MEDLINE (633.5463)