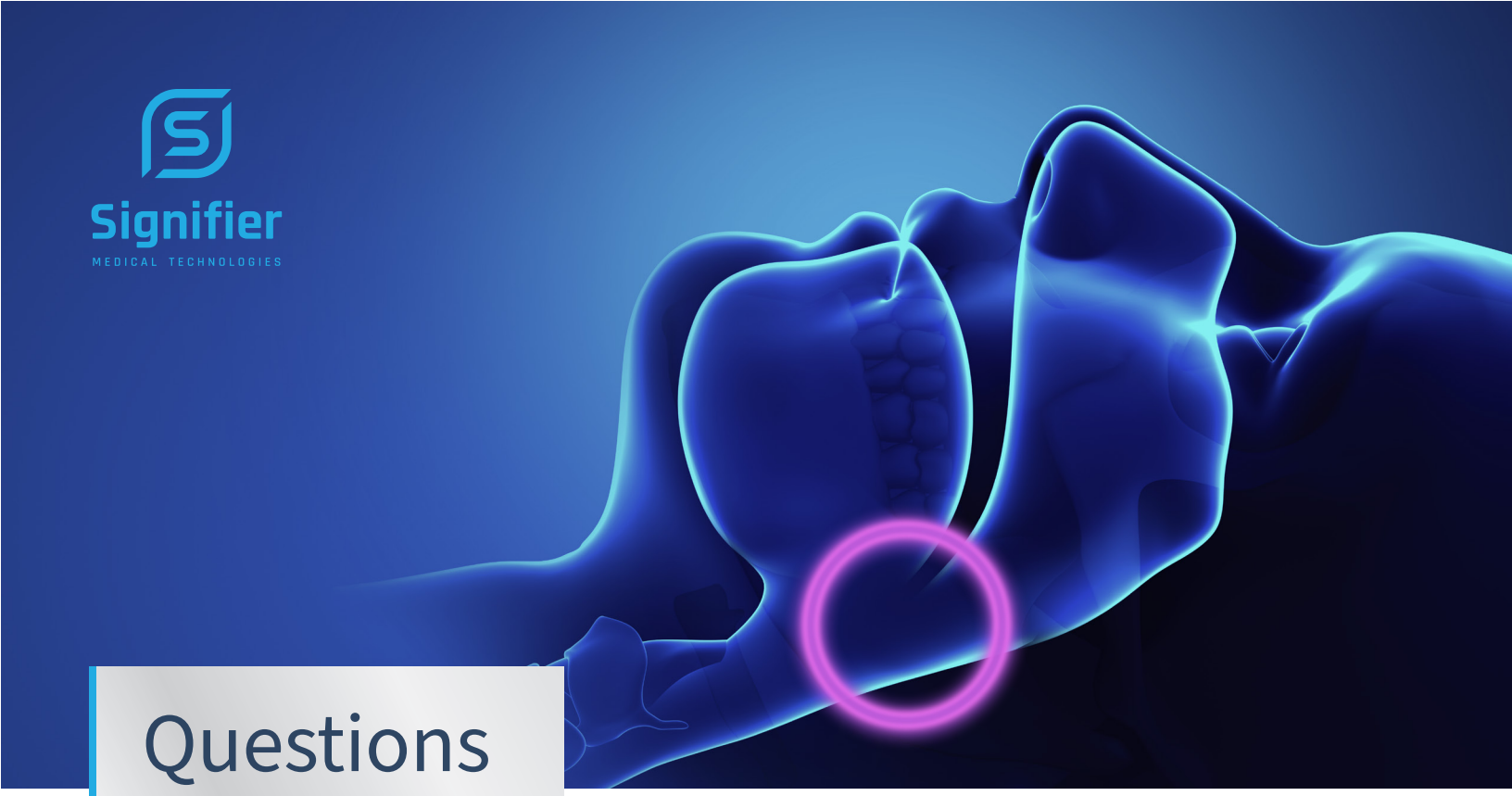
Signifier
MEDICAL TECHNOLOGIES



Questions & Answers

What are the indications for eXciteOSA®?

eXciteOSA® is indicated for the reduction of mild obstructive sleep apnea (AHI <15) and/or snoring for patients that are 18 years or older.

How is eXciteOSA® different from other therapies?

eXciteOSA® is the first, daytime therapy for sleep-disordered breathing that uses an entirely novel and original method to train the airway against collapsing during sleep. Unlike traditional therapies, which are mechanical or pneumatic airway splints to be used during sleep, the device works by improving tongue endurance and responsiveness preventing collapse during sleep. Clinically significant results have been observed, when used for 20 minutes, once a day for 6 weeks.[1-3]

How does eXciteOSA® work?

eXciteOSA® works by using non-invasive intraoral neuromuscular electrical stimulation (NMES) - a tiny electrical current, to stimulate and improve muscle function in the mouth and tongue. The improved responsiveness of these muscles prevents the tongue from collapsing, maintaining airway patency. This reduces obstructive events, its associated desaturations, and improves the quality of sleep.[1-3]

How is eXciteOSA® worn?

The mouthpiece is connected to the control unit through the USB connector and port. The mouthpiece is then placed into the mouth above and below the tongue. Two flanges of the mouthpiece and associated electrodes sit comfortably above and two below – like a glove.

The mouthpiece is designed such that when it is being used, it gently encloses the tongue, without the need for fixation during the therapy period.

How effective is eXciteOSA® in clinical studies?

The non-invasive intraoral neuromuscular stimulation technology has been extensively tested with premier clinical institutions in the UK, Europe, and the USA, some of which have included over one hundred subjects.

The clinical data shows clinically relevant and statistically significant changes in objective and subjective measures (AHI, ODI, objective snoring sound, VAS, ESS, and PSQI).[3]

This data has been presented at the American Thoracic Society 2020 Virtual Conference, and Sleep 2020 Virtual Conference.[4-7]

Please contact your regional representative for the latest clinical evidence and white paper.

Q&As continued on the next page

What should my patient expect during and after therapy?

During the therapy, your patient may experience tongue muscle contractions, which at higher intensities can be perceived to be stronger. Increasing the intensity beyond a comfortable level will not improve the outcome or speed up the results.

Please remind patients to set the intensity that provides maximum comfortable tongue contraction.

How would I describe the therapy to my patient?

The therapy is similar to endurance training, like a long-distance track athlete. The purpose is not to add more muscle like a bodybuilder, but rather to improve muscle function and endurance in order to reduce airway collapse during sleep.

How soon can patients see a result?

Our data suggests that most users noticed an improvement within four weeks of therapy. Nevertheless, we recommend adherence to the full 6-week therapy period to maximize outcomes.

If a person stops using eXciteOSA®, will OSA or snoring return?

Our studies show that after our recommended 20 minutes per day for 6 weeks of treatment, the patient may sustain the results post-therapy for 3 to 6 months. We would recommend some form of maintenance (1-2 treatments per week) to provide a more sustained effect.

Is eXciteOSA® advised for somebody who is already using Continuous Positive Airway Pressure (CPAP)?

eXciteOSA® is indicated for the reduction of mild sleep apnea (AHI <15) and/or snoring for patients that are 18 years or older. Under the controlled supervision of a physician, it may be possible to use eXciteOSA® to support CPAP therapy.

Is there a best time of day to recommend the therapy?

There is no specific time of day that has correlated with a better outcome.

We recommend everyone to assess their lifestyle for whichever time best suits them for optimal adherence and compliance to reach the recommended 6-week treatment goal. Routine and consistency are our only recommendations.

Is it as effective with high BMI patients?

Patients with a higher BMI are known to have excessive fat content around the tongue and neck, and additional factors contributing to their OSA. Our clinical studies used a maximum BMI of 35 as a cut off and these results did not demonstrate a correlation between clinical outcomes and BMI. Based on our clinical data to date, there is no reason not to recommend eXciteOSA® to patients with a higher BMI level.

Are there any side-effects?

To date, no serious adverse events have been reported and there are no long-term effects that would preclude you from eXciteOSA to a patient.

In the clinical trials, some patients reported transient side effects of excessive salivation (12), tongue discomfort (11), tooth discomfort (7), tingling (7), metallic taste (3), or mouth tightness (1).[3]

All symptoms were transient and experienced only during active stimulation, with no patient having ongoing effects after finishing the 20-minute therapy. Notably, the prevalence of the symptoms reduced dramatically through the therapy period.

Are there any side-effects for patients with dental implants?

In a subgroup of 50 patients, dental examinations were performed pre and post 6-week therapy by professional dentists. No adverse effects were found in patients with dental fillings or with implants, or nor a detrimental effect on dental hygiene.

What are the contraindications?

eXciteOSA® is contraindicated if the patient is pregnant or may be pregnant, or if they have a pacemaker or implanted electrodes. The patient is advised not to use eXciteOSA® if they are suffering from mouth ulceration or have undergone recent dental work, and if they have dental braces or jewelry in the mouth.

Always refer to the packaging and information booklet which contains all safety information.

Where do I find more information?

More information is available from the website (www.exciteosa.com), or please contact a Signifier Medical Technologies representative at info@signifiermedical.com.

Healthcare professional specific queries can be directed to HCP@signifiermedical.com.

References

1. E.Wessoleck et al. Intraoral electrical muscle stimulation in the treatment of snoring. Somnologie (Berl). 2018; 22(Suppl 2): 47–52.
2. A.Sama et al. Daytime Intraoral Neurostimulation with eXciteOSA® for treatment of Snoring and Mild Sleep Apnea. CHEST Annual Meeting Notes, 2018
3. Clinical study of 115 patients with snoring or mild OSA (Apnea- Hypopnea Index (AHI) <15 n=65) completed the trial. Objective snoring and respiratory parameters were recorded with 2 consecutive WatchPat night sleep studies before and after the use of the device. An intra-oral tongue stimulator device was used for 20mins, once a day for 6-week period.
4. B. Kotecha et al. A Novel Daytime Intra-Oral Neuromuscular Stimulation Therapy in Simple Snorers: Objective Improvement in Snoring . Sleep 43(Supplement_1):A245-A245 ·
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7. B. Kotecha et al. Daytime Intra-Oral Neuromuscular Stimulation Therapy on Patients with Mild Obstructive Sleep Apnoea. American Journal of Respiratory and Critical Care Medicine 2020;201:A2444