# eXcite<sup>osa</sup>

# Better sleep or your money back.

Our customer satisfaction commitment. If you are not satisfied with eXciteOSA®, return it for a full refund.

We are confident that with eXciteOSA you will notice an improvement in your mild OSA and snoring, and we'd like to give you the peace of mind to get started.



20 minutes a session

1 time each day

6 weeks

And twice a week thereafter.



# About the Therapy

eXciteOSA improves the function of the tongue and upper airway muscles with stimulation therapy. The goal of this proven method is to build muscle endurance and prevent airway collapse, thereby improving sleep quality.

# Clinically Proven<sup>1</sup>

0% of patients reported a reduction in snoring time

of bed partners reported a reduction of their partners snoring

79% of sleep apnea patients achieved a reduction in sleep apnea measures

#### eXciteOSA user: Marie H



"My experience with eXciteOSA has been great.

It is very easy to use during the day and is not intrusive. Wearing eXciteOSA just a few minutes a day makes a vast difference in how I feel."

#### The eXciteOSA Better Sleep Guarantee:

- Consistent use is critical to success. While we don't expect perfection, we do ask that you complete 70% of your 42 therapies within 8 weeks of receiving your product before receiving your refund.
- This promotion does not include the price of the mouthpiece.

Valid from May 2021 to January 2022.

REFERENCE: 1. Baptista et al. Journal of Clinical Medicine 2021. Kotecha et al. Sleep & Breathing 2021. Our multi-center study included 115 patients with mild OSA (Apnea- Hypopnea Index (AHI) <15 n=65). 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 20 mins, once a day for 6-week period.



For more information, visit our website.



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# THE TECHNOLOGY

eXciteOSA® is an innovative therapy that addresses oral muscle function, unlike traditional therapies.

Daytime stimulation prevents excessive muscle relaxation during sleep, reducing upper airway collapse.

eXciteOSA® is a mild, user-controlled neuromuscular electrical stimulator (NMES). The electrical current has defined frequencies to stimulate and improve muscle function of the tongue.

Results from multiple clinical trials have proven that muscle activity can be improved with electrical stimulation technology. <sup>1,2</sup>

No nighttime wearables are necessary, which results in high adherence with a therapy regime.



- E.Wessoleck et al. Intraoral electrical muscle stimulation in the treatment of snoring. Somnologie (Berl). 2018; 22(Suppl 2): 47–52.
- A.Sama et al. Daytime Intraoral Neuromuscular stimulation with Snoozeal® for treatment of Snoring and Mild Sleep Apnea. CHEST Annual Meeting Notes, 2018.

### HOW THE DEVICE WORKS

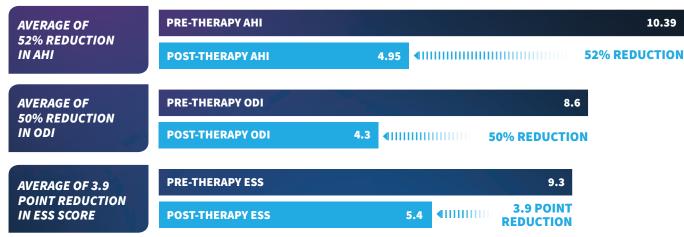
- The eXciteOSA® mouthpiece is attached to the control unit and then placed into the mouth. It is controlled by the app.
- The app activates the electrodes in the mouthpiece via the control unit; electrical pulses stimulate the tongue muscle and improve muscle function.
- The app monitors how often the patient has used the device and supports adherence with the ability to communicate with the patient.



### Objective improvement in mild OSA with the use of eXciteOSA®

AVERAGE % REDUCTION IN AHI, ODI AND ESS IN PATIENTS WITH MILD OSA PRE- AND POST-THERAPY WITH eXciteOSA® 3 p<0.001

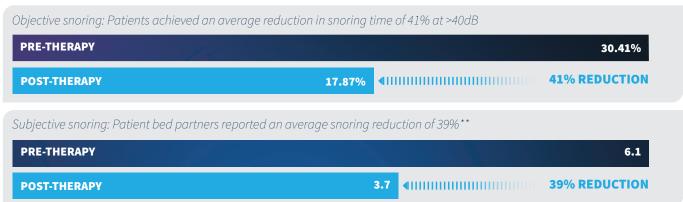
79% of Patients Responded to Therapy\*



<sup>\*</sup>As measured by improvement in AHI

#### Improvement in snoring with the use of eXciteOSA®

AVERAGE % REDUCTION IN SNORING TIME AT >40DB IN PATIENTS PRE- AND POST-THERAPY WITH eXciteOSA® 3 p < 0.001



<sup>3.</sup> eXciteOSA® White Paper (2020). 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 20 mins, once a day for 6-week period. (Internal publication by SMT for educational purposes and submission.)

<sup>\*\*</sup>As measured by VAS

# PATIENT FEEDBACK



# WHAT WAS YOUR EXPERIENCE LIKE USING THE eXciteOSA® DEVICE?

"I found it very easy, very comfortable, and I just felt assured that I was going to have a good night's sleep. After getting a better night's sleep, I felt more refreshed in the morning. For me, it made me feel happier and better in myself."



#### WHAT REAL LIFE IMPROVEMENTS HAVE YOU SEEN?

"I don't feel so tired. This tiny device has made such a massive difference to me. My concentration level has increased; I feel more relaxed, and as if I've got ten times more energy. For the first time in many, many decades, I genuinely look forward to going to sleep."



#### **HOW LONG DID IT TAKE TO SEE RESULTS?**

"In two to three weeks, I noticed really good results: much better restful sleep, no waking up at night. And during the day, obviously, I feel more refreshed, have more energy. No headaches and no complaining because of my snoring at night! This device has made a lot of difference...I am really happy about that."



# WHAT ARE YOUR THOUGHTS ON THE RESULTS YOU EXPERIENCED, AND HOW LONG DID IT TAKE TO SEE THEM?

"It reduced my snoring significantly. Sharing a bed has brought us a lot closer than we were before. I didn't believe snoring was such an awful problem, but I can now see that it affected our relationship. It took a couple of weeks for it to become apparent it was working very well, and by the end of the six weeks it was working extremely well."





1 time each day

6 weeks

week thereafter

eXciteOSA® has been **CLINICALLY PROVEN** to improve the quality of sleep\* by reducing mild obstructive sleep apnea and snoring significantly when used for 20 minutes, 1 time each day for 6 weeks and only twice a





\*As measured by PSQI and ESS Score

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NEW

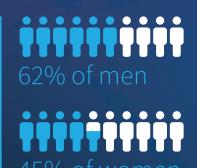
# Mild OSA and Snoring

Quality sleep is vitally important for good health and well-being. It allows the body to rest, to recharge, and to repair itself.

Snoring is the most common cause of sleep deprivation, affecting around 1 in every 3 people, causing excessive tiredness and poor concentration, and having detrimental effects on their partner.

Snoring doesn't just deprive the body of quality sleep; it can also deprive the body of oxygen and is often the first stage of mild OSA, where a person temporarily stops breathing repeatedly during sleep due to a blocked upper airway.

Mild OSA and snoring are caused by the over-relaxation of the muscles in the throat, causing the tongue to fall back in the mouth, partially blocking the upper airway. The snoring sound is generated by the mouth and throat soft tissue vibration.

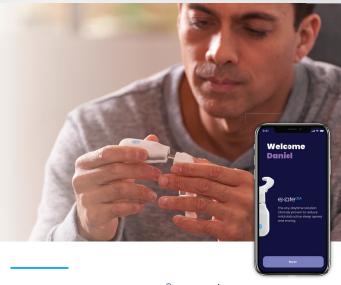


suffer from snoring<sup>3</sup>



This prevents snoring and also increases the intake of oxygen, and

improves the quality of sleep. 1-3



# How exciteOSA® works

- The eXciteOSA® mouthpiece gets positioned onto your tongue.
- The app activates and customizes each therapy session.
- The app tracks your progress and keeps you focused on therapy goals.

# Clinically proven

eXciteOSA® has been clinically proven to improve the quality of sleep by reducing mild OSA and snoring significantly, when used for 20 minutes, 1 time each day for 6 weeks. 1-3 Only two 20-minute sessions are required each week thereafter.







# A convenient daytime therapy for noticeable night-time results

90% of patients reported a reduction in snoring time<sup>3</sup>

89% of bed partners reported a reduction of their partners snoring<sup>3</sup>

79% of sleep apnea patients achieved a reduction in sleep apnea measures³





eXciteOSA® - a winner of iF DESIGN AWARD 2020 for Design Excellence in the "Medical Device" category and a winner of IDEA Design Award 2020



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- 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 Snoozeal® for treatment of Snoring and Mild Sleep Apnea. CHEST Annual Meeting Notes, 2018.
- 3. eXciteOSA® White Paper (2020). 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 20 mins, once a day for 6-week period. (Internal publication by SMT for educational purposes and submission.)

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# Your journey towards better sleep begins today.

Let's get started!



Once you begin therapy, you'll have the ability to manually change your therapy levels during every session. This is what makes this experience so unique to you.

So now it's your time to shine, and we'll be here for you every step of the way. **Here's how it works.** 



# What do the different therapy levels mean?

Therapy level refers to the level of stimulation emitted from the mouthpiece to improve your muscle function and thereby reduce your mild obstructive sleep apnea and snoring. Therapy levels range from 1, being the lightest, to 15, being the strongest.

# What should I expect from therapy?

Each session includes four, 5-minute phases, each designed to train your tongue muscle in a different way.

# How do I change my therapy level?

You are welcome to adjust the level at any time within the eXciteOSA® app. Simply slide your therapy level setting at the bottom of your screen during your session.

To the right is a snapshot of what you will see in the dashboard of your app when you are in the middle of a therapy session. As you can see, this patient has changed their therapy level from 4, to 7, to 10.







# Do the therapy levels change on their own?

The therapy level will remain the same as long as it is not manually changed. You may, however, notice a change in the stimulation pulse rate every five minutes.

# How can I ensure the most effective therapy?

It is important to set the device to the highest possible therapy level that still feels comfortable for you. This will ensure the best possible outcome.

Remember that this journey will be unique to you; your therapy level threshold might be 5 or 13. While it is not required to reach the maximum end of the scale, it is recommended to keep the therapy level at or above 4 to ensure effectiveness.





# Your journey towards better sleep begins today.



# What will my therapy level journey look like?

Below, you can see two therapy level paths taken by Anna, who has mild OSA, and Daniel, who is a snorer. Throughout therapy, they made sure to set their sessions at a comfortable, yet challenging level. By doing so, they both achieved the same desired outcome – improved sleep quality – even though their therapy level journey looked numerically different.

Let's say Anna & Daniel are training for a race. Even though they run at different paces, they both challenge themselves to train a little bit harder during every session. This will allow them both to reach their unique race-day goals.





Much like their endurance training, Anna & Daniel will also try to push themselves to increase the therapy level of their eXciteOSA® therapy every week. By stepping out of their comfort zone and exploring higher therapy levels, they will be one step closer to achieving improved sleep quality.



We are excited to be accompanying you on your journey towards a better quality of sleep!

If you have any further questions, email us at info@signifiermedical.com or call +1 844 MildOSA

Need to download the app? Scan here. »





Signifier Medical Technologies LLC 175 Highland Avenue Needham, MA 02494 USA +1 844 MildOSA | info@signifiermedical.com www.exciteOSA.com **Our testing:** We followed the ISO 10993 series of standards and FDA guidance for evaluating the biocompatibility of our mouthpiece. This was to ensure that we are effectively managing biological risk to our patients. The standard test duration for a non-implantable device with continuous surface contact with the mucosal membrane is 28 days. We passed all tests in the ISO protocol with safe levels of extractables, leachables, toxicity, and carcinogenicity.

**Safe-use period:** When the FDA considered our biocompatibility test results, they concluded that our mouthpiece could have a maximum safe-use lifetime of 90 days. As a MedTech company producing a class 2 medical device, we need to have some use-by date on our device. We've accepted the FDA 90-day period as that standard for our safe-use period.

**Functional-use period:** In real-world tests greater than 90 days, we observe mouthpiece surface discoloration and degraded functional performance in some scenarios. This is not surprising as the oral cavity is a hostile place for a device with delicate electronics. Further, the oral cavity chemistry will vary from patient to patient. To ensure that every patient has a consistent therapy experience, we believe that 90 days is also a reasonable functional-use period.

**Financial impact to patient:** We want to be sensitive to the financial burden that a 90-day consumable places on our patients. To minimize this burden, we established a pricing approach to make the mouthpieces as affordable as possible. A replacement mouthpiece is only one-tenth the price of the initial device. We acknowledge this will be a financial burden for some patients, but we need to place the health of our patients and optimal therapy delivery ahead of any financial consideration.

**90-day guarantee:** We are confident that our mouthpiece will function safely and as intended for 90 days. Beyond this period, the safety and functional performance of the mouthpiece is not guaranteed and places our patients at undue risk.