

# eXciteOSA® Product Information

## Product Description for HSA & FSA

### eXciteOSA® Description

eXciteOSA® is a tongue neuromuscular electrical stimulation (NMES) device for Obstructive Sleep Apnea (OSA) with adjustable stimulation manufactured by Signifier Medical Technologies, LLC.

The complete device includes 3 parts:



**1. Mouthpiece** – a universal-sized silicone disposable mouthpiece with 4 electrodes, which must be replaced every 90 days. Single patient use only.



**2. USB-C charging cable** – connects to the control unit via USB connection.

**3. Control unit (with Bluetooth)** – a durable control unit with life expectancy of at least 36 months, which can be cleaned and refurbished for use by multiple successive patients.



### FDA Status

Under FDA's regulations, the eXciteOSA® is a Class II device, with special controls. It received a De Novo classification, DEN200018, on February 5, 2021 and is listed as a neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea under 21 CFR 872.5575.

This is a prescription device that complies with 21 CFR 801.109 and has met all applicable other requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), medical device reporting (21 CFR Part 807), good manufacturing practices (21 CFR Part 820), and as applicable, electronic product radiation control provisions (Sections 31- 542 of the FD&C Act), and general and specific standards according to 21 CFR 1000-1050.

### Product Descriptive Narratives:

- 1. Mouthpiece** – Tongue neuromuscular stimulation mouthpiece for OSA, with 4 electrodes, each
- 2. Control Unit** – Tongue neuromuscular stimulation control unit for OSA, adjustable stimulation, each + monitoring feature/device

### Warranty

Signifier Medical Technologies, LLC provides a warranty to the original purchaser confirming the product will be free from defects in the material, components, and workmanship for the period listed below.

- 1. Mouthpiece** – 3 months.
- 2. Control unit (with Bluetooth)** – 1 year.

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The warranty does not include any misuse, abuse, or tampering with the unit. This warranty does not apply to “wear and tear” that would normally occur with usage.

### Indications for Use

eXciteOSA® is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce snoring and mild OSA (AHI<15) for patients that are 18 years or older.

### Contraindications

Do not use eXciteOSA® if:

- Pregnant or may be pregnant.
- Have a pacemaker or implanted electrodes.
- Have temporary or permanent metal implants dental braces, intraoral metal prosthesis/restorations/appliances or dental jewelry in the mouth.
- Suffering from mouth ulcers.

Have or are suspected of having an AHI  $\geq 15$  as determined by evaluation by a Sleep Health Professional with a sleep study.

### Precaution

Consult a Doctor/Dentist in these situations:

- Have gum disease or have bleeding from your gums or other oral conditions.
- Experience pain, numbness or bleeding after using this product.
- Have any medical concerns.

This device should not be used:

- While asleep (the device should only be used when awake)
- In contact with your head, neck, spine, chest, eyes, ears or any other parts of the body other than inside the mouth as instructed.
- The device has not been tested for MRI compatibility and should not be used in the vicinity of an MRI device.

For more information, visit [eXciteOSA.com](http://eXciteOSA.com)