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| Product Name | eXciteOSA® |
| Manufactured By | Signifier Medical Technologies |
| Packaging Includes | <p>Mouthpiece</p> <p>1 Control Unit with Bluetooth, Includes USB-C type connector</p> <p>1 USB Cable for Control Unit Charging (15cm cable connects to UL certified USB wall charger (not provided) with 5 VDC, minimum 0.5amp output)</p> <p>1 Quick Start Guide</p> |
| Country of Manufacturing | EU |
| Part Number | 13010 |
| UPC Code | 060627480048 |
| System Requirements | <p>The mobile app software can be used on iPhone 5S, iPhone 6/6 Plus, iPhone 6s/6s Plus, iPhone 7/ 7 Plus, iPhone 8/8 Plus, iPhone X, with iOS 11.0 and higher.</p> <p>The mobile app software can also be used with Android devices with BLE support (Bluetooth 4.0) and Android 7.0 and above. eXciteOSA® uses Bluetooth Smart; mobile devices used must be compatible with Bluetooth Smart.</p> |
| Description | eXciteOSA® is the world's first clinically proven daytime therapy for mild obstructive sleep apnea and snoring. Worn for 20 minutes, 1 time each day for 6 weeks, eXciteOSA® is focused on solving the root cause of mild OSA and snoring – the loss of muscle function of the tongue. |
| How eXciteOSA® Works | <ol style="list-style-type: none"> 1. Download the eXciteOSA® app for iOS or Android directly on your phone or tablet. 2. Attach the eXciteOSA® mouthpiece to the control unit and then place into the mouth. 3. The eXciteOSA® app activates the electrodes in the mouthpiece via the control unit; tiny electrical pulses stimulate the tongue muscle and improve muscle function. 4. The eXciteOSA® app monitors patient use of the device. |
| Intended Use | eXciteOSA® is intended for the reduction of snoring and mild obstructive sleep apnea by strengthening tongue muscles via electrical muscle stimulation. |
| Frequency of Use | It is recommended you use eXciteOSA® once daily for a continuous 20 minutes. It can take up to 6 weeks of daily therapy before you will gain the desired improvement in your snoring and mild OSA. Once the desired results are achieved, it is recommended to have a twice-a-week regular maintenance regime. eXciteOSA® can be used long term. This is comparable to maintaining your physical fitness by undertaking regular exercise. You must replace the Mouthpiece after 90 calendar days of first use, this includes the maintenance period. |
| Operational Requirements | Temperature +41°F to +104°F (+5°C to +40°C); Humidity 15% to 90%; Atmospheric Pressure 10.15 psi to 15.37 psi (70 kPa to 106 kPa). Operational life is 3 years. |
| Transport and Storage Requirements | <p>Temperature -13°F to +158°F (-25°C to +70°C); Humidity up to 90%</p> <p>Atmospheric Pressure 10.15 psi to 15.37 psi (70 kPa to 106 kPa). When the device is exposed to extreme temperatures, please wait at least 60 minutes before attempting to use the device.</p> |
| Warranty | 3 months for the eXciteOSA® Mouthpiece and 1 year for the eXciteOSA® Control Unit from the date of purchase |
| Prescription Information | Prescription required by licensed physician to purchase this item |
| Reimbursement | Currently, not reimbursable under Medicare, Medicaid or Commercial Insurance. |
| Product Website | www.exciteosa.com |