

excite^{OSA}®

Instructions for Use

**IMPORTANT SAFEGUARDS:
READ ALL INSTRUCTIONS BEFORE USE**

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Important safeguards

READ ALL INSTRUCTIONS BEFORE USE.

(for latest User Guide, please refer to <https://exciteosa.com>)

CAUTION:

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

WARNINGS

To avoid the risk of electrocution, burns, fire or physical injury:

- The device is only to be used **while awake**. It should not be used while sleeping.
- Only the supplied products should be used together. Do not use attachments other than those recommended by the manufacturer.
- Discontinue use if the product appears damaged in any way.
- Never attach the mouthpiece directly to a charging source other than the control unit provided.
- This device should only be charged using the USB cable provided.
- Do not operate in close proximity (e.g. 3.4 feet) to a shortwave or microwave unit as other electromagnetic equipment may produce instability in the stimulator output.
- Always keep the control unit away from water.
- Unplug the control unit immediately if it falls into water.
- Never use a damaged USB cable to charge the control unit.
- Recharge the battery using only the USB power cord with a UL-certified USB wall charger (not provided).
- This product contains no user serviceable parts. Refer to “Warranty” and “Troubleshooting” if appliance no longer works as expected.
- The device is only to be used as specified in this document.

READ ALL INSTRUCTIONS BEFORE USE.

WARNINGS

To avoid the risk of physical injury:

- Do not use this device if you are under the age of 18
- eXcite^{OSA®} should be kept away from children and pets (choking hazard and electrical hazard).
- eXcite^{OSA} to be used in a home or healthcare environment (or equivalent).
- The eXcite^{OSA} durable control unit can be re-purposed for use by multiple successive patients.
- eXcite^{OSA}'s disposable mouthpiece is for single patient use.
- Do not use eXcite^{OSA} when driving a vehicle or operating machinery and other equipment.
- When charging the device, keep away from all liquids.
- No modification of this device is allowed. Do not try to alter, trim or change any components of the device.
- The silicone on the mouthpiece must be intact before use. If there is any breach of the silicone (including electrodes) - **DO NOT USE THE MOUTHPIECE.**

Intended use

eXcite^{OSA} is intended for the reduction of snoring and mild obstructive sleep apnea by strengthening tongue muscles via electrical muscle stimulation.

INDICATIONS FOR USE

eXcite^{OSA} is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce mild obstructive sleep apnea (AHI < 15) and snoring for patients that are 18 years or older.

ADDITIONAL CLINICIAN AND PATIENT INSTRUCTIONS FOR USE

- Patients should have a comprehensive dental examination prior to using this device to rule out cavities and intraoral metallic jewelry/piercings.
- Patients should maintain regular follow-up visits with a dentist and sleep health professional.
- Patients should follow up with their sleep health clinician for a repeat Home Sleep Apnea Test after three months of therapy.

CLINICAL SUMMARY

- eXcite^{OSA} was used by 65 mild OSA patients, 20 minutes per day for 6 weeks, and 78% of group (51 patients) achieved an average reduction of 52% in AHI.
- eXcite^{OSA} was used by 115 snoring patients, 20 minutes per day for 6 weeks, and 90% of the group achieved an average reduction of 46% of time spent snoring.

READ ALL INSTRUCTIONS BEFORE USE.

CONTRAINDICATIONS

Do not use eXcite^{OSA} if you:

- are pregnant or may be pregnant.
- have a pacemaker or implanted electrodes.
- have dental jewelry in the mouth.
- are suffering from mouth ulcers.
- have or are suspected of having an AHI ≥ 15 as determined by evaluation by a Sleep Health Professional with a sleep study.

Safety and effectiveness in the above conditions have not been established.

PRECAUTIONS

Consult your doctor/dentist if you:

- 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.

Adverse Reactions:

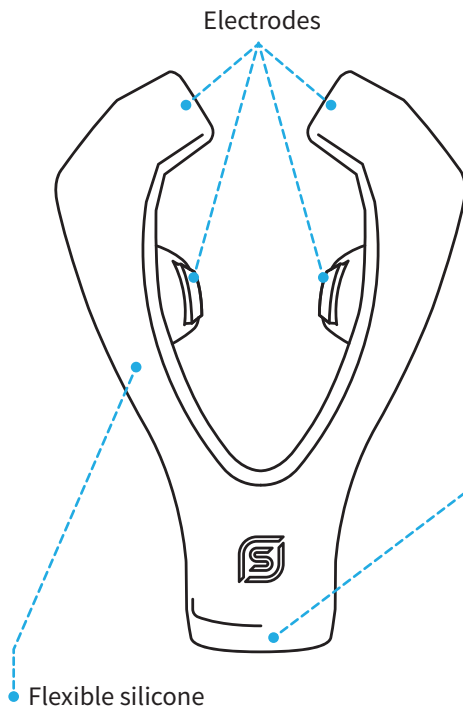
- accumulation of saliva.
- tingling sensation on tongue.
- tooth sensitivity.

What's in the box?

eXcite^{OSA} package includes:

1

Mouthpiece (top view)



If your device is received in packaging that is:

- 1) damaged
- 2) unintentionally opened before use
- 3) packaging is exposed to environmental conditions outside of those specified please do not use the device and contact Signifier Medical Technologies.

Cleaning cap (please retain)



USB-C type connector

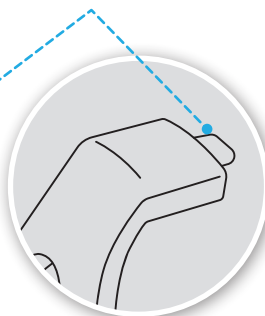


Fig.1

2

Control unit (with Bluetooth)

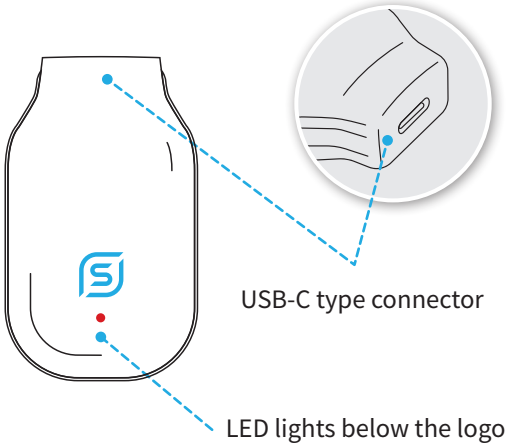


Fig.2

3

Extender cable

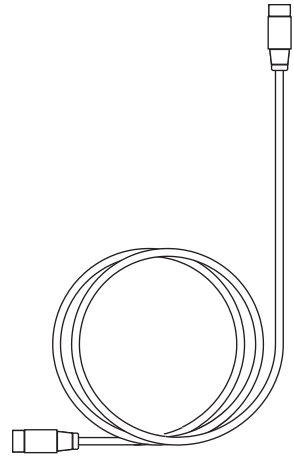


Fig.3

4

eXcite^{OSA} USB charging cable (15 cm cable connect to UL-Certified USB wall charger (not provided) with 5 VDC, Min 0.5 AMP output)

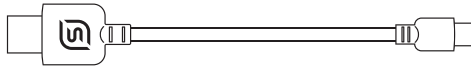


Fig.4

Note: Only use the eXcite^{OSA} USB charging cable provided. Using another cable could damage the device and void your warranty.

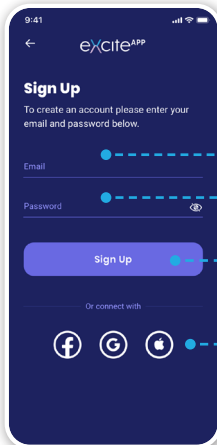
Systems requirements

The eXcite^{OSA} device can be controlled by the smartphone application. This app can be downloaded from the App store (Apple iOS) or Play Store (Google Android)

The mobile app software can be used on iPhone 11, iPhone 11 Pro & iPhone 11 Pro Max and above, with iOS 15.0 and higher. The mobile app software can also be used with Android devices with Bluetooth support and Android 10.0 and above. eXcite^{OSA} uses Bluetooth Smart; mobile devices used must be compatible with Bluetooth Smart.

eXcite^{OSA} smartphone application

eXcite^{OSA} device can be controlled by eXcite^{OSA} Smartphone application. Smartphone application can be downloaded from App Store (Apple iOS) or Play Store (Google Android).



LOG IN & SIGN UP

The log in & sign up section allows you to authenticate or create an account.

SIGN UP

- Enter the e-mail you want to register with
- Enter a secure password (minimum 6 characters)
- If you are already registered you can log in here
- You can sign up with one of these services
(this will require authentication on the appropriate external service)

iPhone, iTunes, and iOS are registered trademarks of Apple, Inc.
Bluetooth is a registered trademark of Bluetooth SIG, Inc.

9:41

Profile setup

The information below helps us deliver more accurate results.

Mandatory

First Name
Daniel

Last Name
Murray

Country
USA

Optional

Phone Number
(123) 456-7890

Birth Gender
☒ Male
 ☐ Female

Date of birth

Ethnicity

Height Weight

PROFILE SET UP

Enter your full name

Enter your country of residence

Select your gender

Select your date of birth

Enter your ethnicity, height and weight*

** This data allows for better eXcite^{OSA} therapy options. Your data is secure with us. You can check our privacy policy, on our website <https://exciteosa.com/privacy-policy>, for further details.*

Select whether you already have an eXcite^{OSA} device or not.

If you choose yes, additional setup is required.


9:41

Not Now

Don't have a device yet?

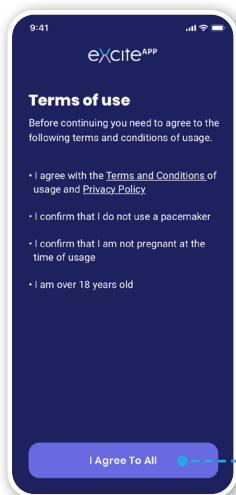
Get your eXcite^{OSA} device now

And start treating your mild OSA and snoring.



Buy Now

I own a device



POLICY

There are a number of terms you have to agree to in order to use the eXcite^{OSA} device with the mobile app.

First, make sure you read the Terms and Conditions page, and agree with them.

Next, please confirm that you do not use a pacemaker and that you are not pregnant. **It is very important that none of these apply to you as the eXcite^{OSA} device can interfere with your pacemaker or with your baby's development.**

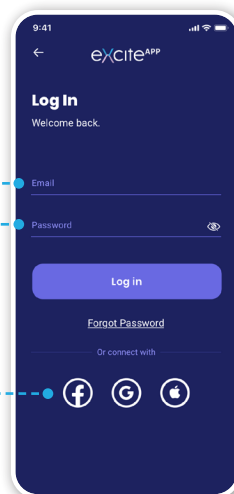
Also, you must be 18 years of age or older.

LOG IN

Enter your registered e-mail and password

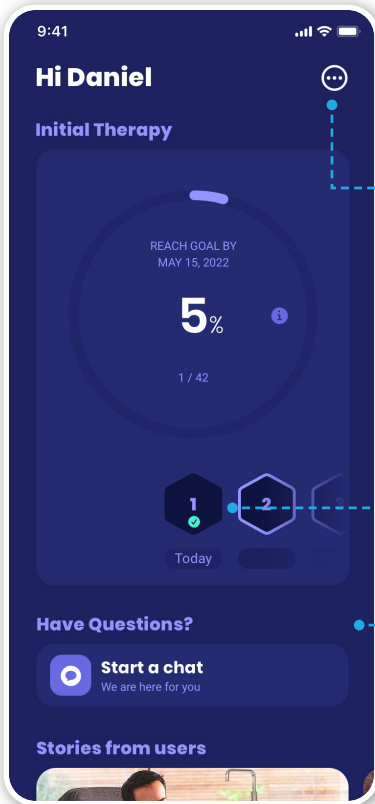
If you forgot your password, tap here. You will receive an e-mail with further instructions.

You can log in with one of these services
(this will require authentication on the appropriate external service)



THE DASHBOARD

The dashboard is the main screen of the app where all the features are available from.



Settings

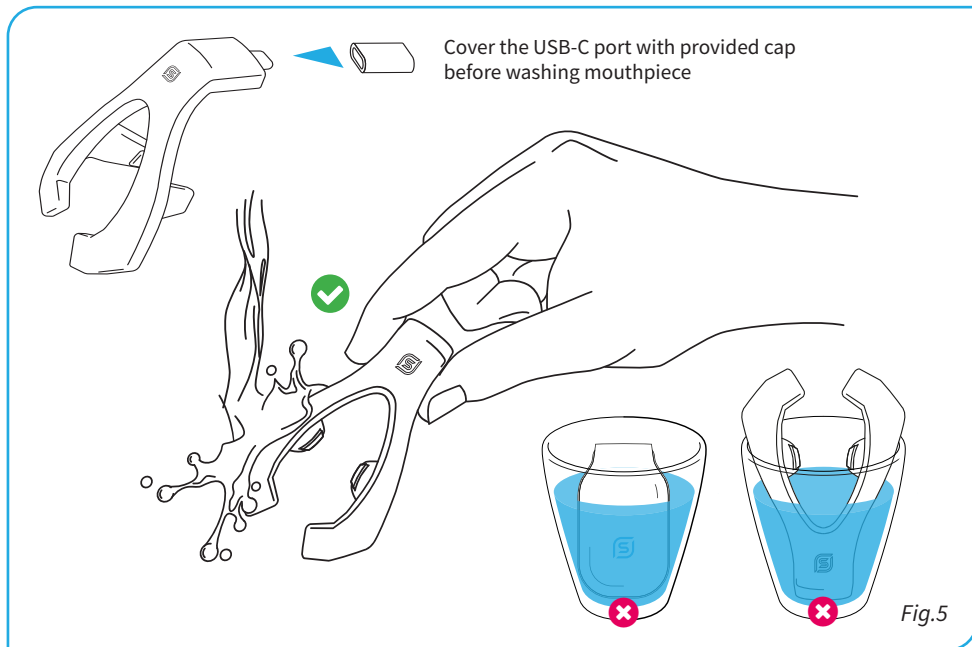
eXcite^{OSA} therapy

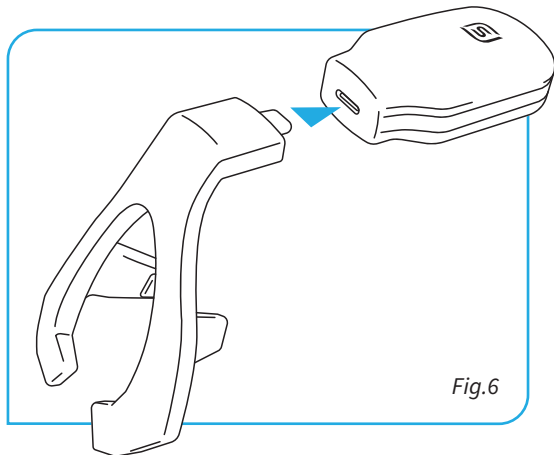
Educational content

Using your eXcite^{OSA} with a smartphone application

Before starting your therapy be sure to: check the silicone on the mouthpiece is not cracked or broken before use. If there is any evidence of damage to the silicone - **DO NOT USE THE MOUTHPIECE.**

Before use, wash the mouthpiece with cold and running tap water as shown in Fig 5. Avoid water reaching the USB port. Dry with clean towel.

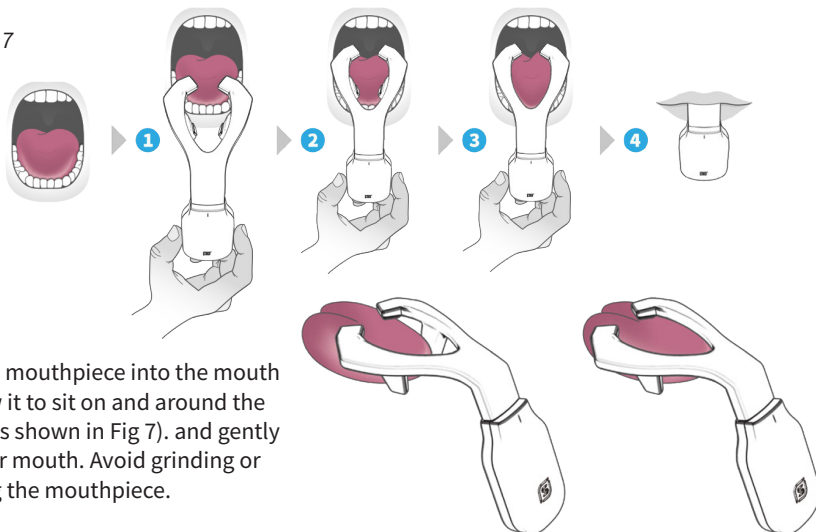




To start using eXcite^{OSA}, connect the mouthpiece to the control unit as shown on Fig 6.

Fig.6

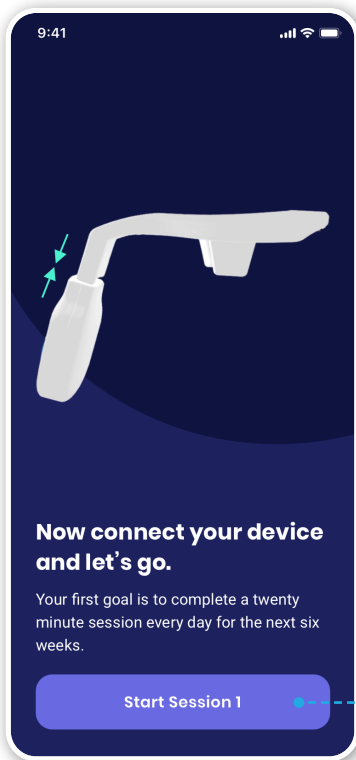
Figure 7



Insert the mouthpiece into the mouth and allow it to sit on and around the tongue (as shown in Fig 7), and gently close your mouth. Avoid grinding or clenching the mouthpiece.

eXcite^{APP}

The eXcite^{OSA} smartphone application is where you can start your eXcite^{OSA} therapy or add your device.



In order for the eXcite^{OSA} device to work, you need to allow Bluetooth connection.

For iOS 13 or above you need to manually allow Bluetooth permission.

Before starting your therapy be sure to check your device for cracks or broken parts, connect the control unit to the mouthpiece, and insert the mouthpiece into the mouth.

Add an eXcite^{OSA} device
(make sure that the device is nearby)

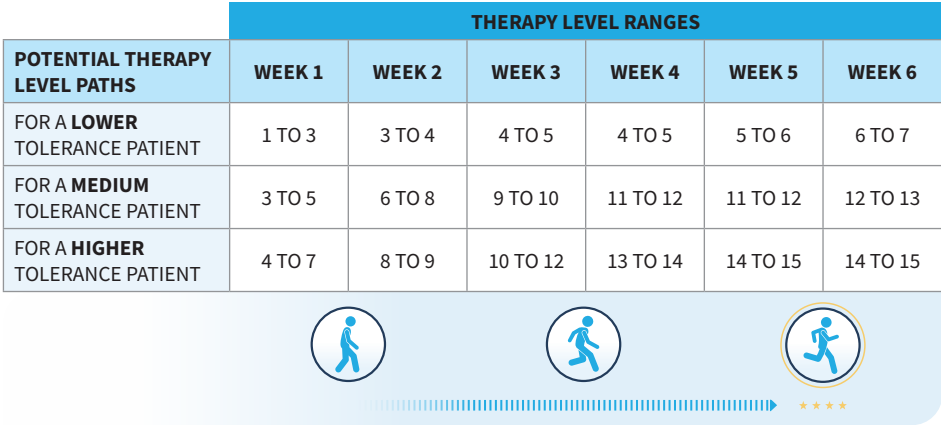
Recommended therapy level

The patient is recommended to set the device to the highest possible therapy level that is still comfortable to them. This will ensure the best possible outcome. Tolerance levels are likely to increase each week, and patients are encouraged to continue to raise levels accordingly. Levels that feel painful or uncomfortable will not speed up outcome or improve results.

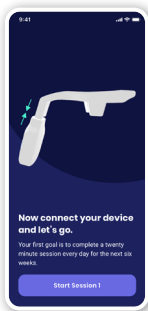
Each 20 minute session is broken up into four 5-minute intervals. Each interval will prompt the device to give off a different frequency. The frequencies will not exceed 20 Hz.

Therapy level guide

Therapy levels can be changed using the therapy intensity bar on the app.



Please note that these are approximations. Every patient is likely to have a different tolerance level. This example chart should serve as a suggestion that can be used to help guide patients.



CONNECT

In order to start the therapy, you need to pair your phone with the control unit. Follow the instructions on the eXcite^{APP} screen to connect and make sure the control unit is close to your phone.

You should see a blue flashing light to connect via Bluetooth to the phone.

Controlling your therapy level

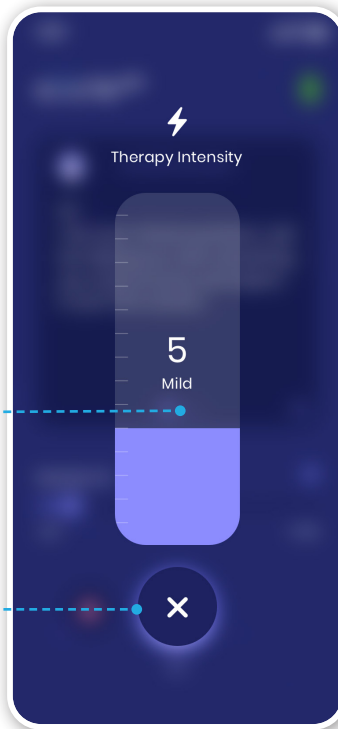
To change your therapy level, simply slide the level setting from the bottom of the bar on your screen.

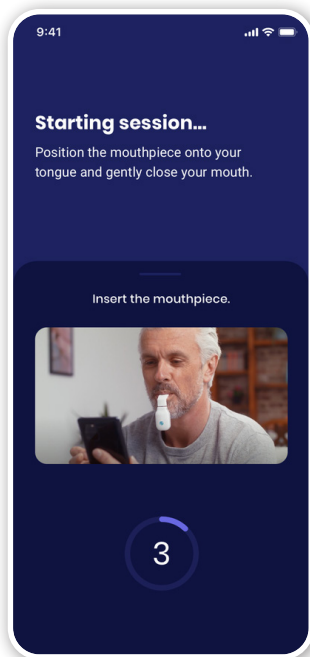
It is important to set the device to the highest possible therapy level that still feels comfortable for you. This will ensure the best possible outcome.

If therapy becomes painful or uncomfortable, simply remove the mouthpiece or lower the therapy level.

Please follow the advice from the prescribing clinician on recommended starting therapy level.

Stops the therapy



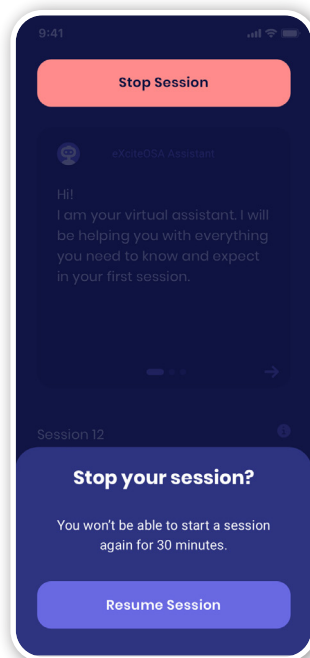


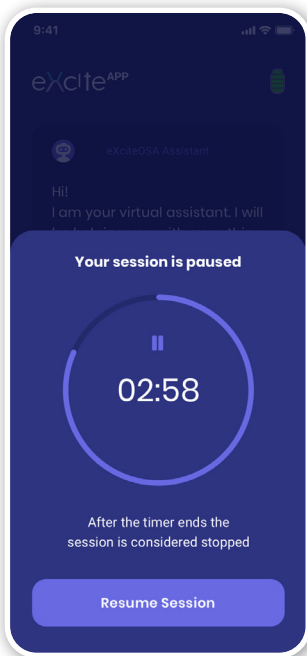
COUNTDOWN

After pairing your eXcite^{OSA} device with your mobile phone, your therapy will start with a countdown from 3 to 1 before initiating the actual therapy.

Therapy can be stopped at any time but due to safety reasons it can only be restarted after 30 minutes after the device has been stopped or the therapy has ended. Keep this in mind when stopping the therapy.

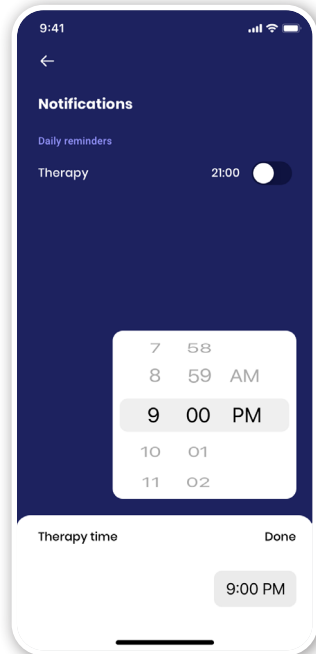
STOP THERAPY





PAUSE THERAPY

Therapy can be paused at any time. It can be paused only for 3 minutes. After the 3 minutes have passed the therapy is considered stopped and can only be restarted after 30 minutes.



SET A REMINDER

You can set a reminder at a specific time each day, so that you don't miss your therapy.

END OF THERAPY SESSION

Therapy can be paused at any time for up to 3 minutes. After the 3 minutes have passed the therapy is considered stopped and can only be restarted after 30 minutes.

Frequency of usage

It is recommended you use eXcite^{OSA} 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 mild OSA or snoring. Once the desired results are achieved, it is recommended to have a once a week regular maintenance regime. eXcite^{OSA} can be used long term. This is comparable to maintaining your physical fitness by undertaking regular exercise.

You are recommended to replace the Mouthpiece after **three months** of first use, which includes the maintenance period.

Charging the control unit

Before using the device for the first time, you must charge the battery for at least 2 hours. The Control Unit LED will flash blue and yellow if there is inadequate charge to run a full 20 minute therapy session. When the Control Unit (Fig 8) blinks blue and yellow, recharge the Control Unit. To charge the Control Unit, use the USB Cable provided and connect the Control Unit connector into a USB power adapter. During charging, the eXcite^{OSA} will blink blue. When fully charged, the eXcite^{OSA} will become continuous blue.

If your control unit flashes red and yellow during charge, this means moisture has been detected within the USB-C connector. Disconnect the control unit from the charger or mouthpiece, let it dry for a minimum of 4 hours and try again. If the issue persists, contact our support team.

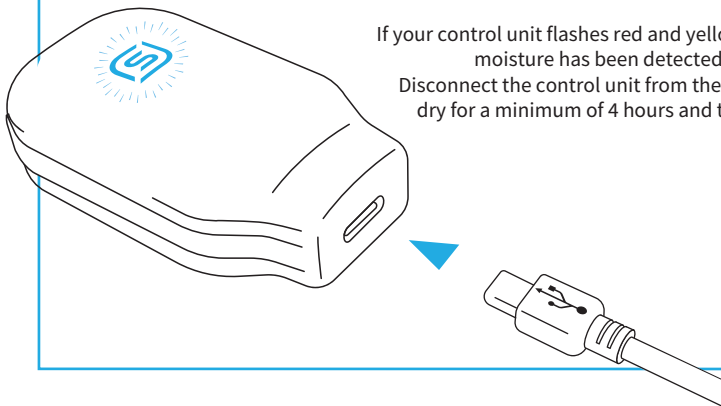


Fig.8

Storing & traveling with your eXcite^{OSA}

MOUTHPIECE

Once the mouthpiece has been washed in tap water and dried, it can be stored in its storage stand. The mouthpiece is packaged in a removable stand which can be used for storage or act as a regular stand the mouthpiece.

CONTROL UNIT

The control unit must be kept dry throughout its use and storage. After use, store in a dry environment or the storage box. If you plan to travel with your eXcite^{OSA}, place each unit in its original packaging to protect during transportation.

Washing

MOUTHPIECE

The mouthpiece should be washed before and after each use. Before cleaning, remember to place the cleaning cap over the mouthpiece connector. Use running tap water to wash the mouthpiece. Dry with a clean towel and store in a dry place. **DO NOT** wash with alcohol based cleaning solutions.

CONTROL UNIT

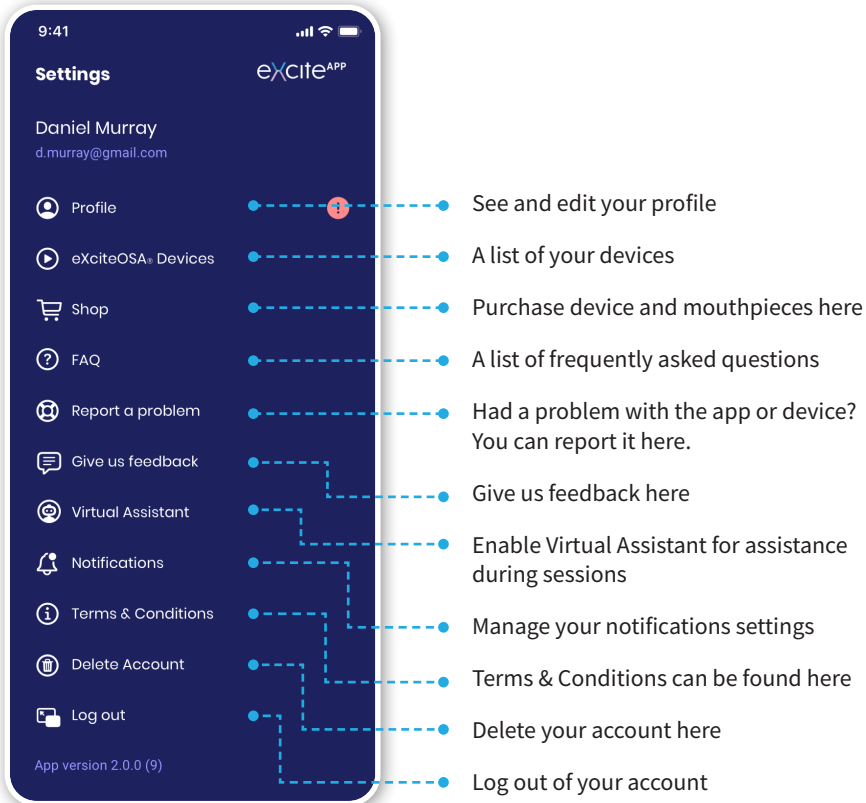
Wipe the control unit surface with a damp cloth or antiseptic wipe once a week. **DO NOT** immerse the control unit in water or cleaning solutions. Always store the control unit in a dry place.

Software Updates

The app will notify you of any necessary software updates. Please follow the instruction on the app.

Settings

Manage all of your settings from a single place.



SEE/EDIT PROFILE

Change any of the data already provided and then tap 'Save', to save your changes.

FAQ

Check the Frequented Asked Questions for further information.

REPORT A PROBLEM

Did anything go wrong with the app or the device? Describe the problem and let us know. We'll try to solve it and take the appropriate measures.

NOTIFICATIONS

Change the time of your notifications. Enable or disable them, so that you can have a smoother experience.

Frequently asked questions

How does the eXcite^{OSA} device work?

The eXciteOSA device will deliver small electric pulses through the mouthpiece to your tongue, this will stimulate the tongue and improve its muscle function. The improved function of the tongue muscle will help in keeping the upper airway open during your sleep and reduce the vibration of the throat region.

What should I expect from eXcite^{OSA} therapy?

- Each session includes four, 5-minute stimulation therapy phases.
- Some patients experience a slight accumulation of saliva during their first few uses.

How should the mouthpiece fit in my mouth?

Two tabs of the mouthpiece should sit comfortably above and below the tongue. The mouthpiece is designed such that when you gently close your mouth, it will naturally sit around your tongue and won't move during your therapy session. Please do not bite down on the mouthpiece as this may cause damage to the device.

When should I wear the eXcite^{OSA} device?

The device can be used at any point during the day. Some users prefer to use the device right before sleep because this helps them be more consistent. We recommend using the device during a time of day that will allow you to build a steady habit out of your therapy.

At what level should I start and what is the optimum level for my 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.

Please reference the therapy level guide on page 16 for recommended levels of intensity.

Increasing the intensity beyond a comfortable level is not advised, you should increase therapy intensity gradually to the maximum tolerated intensity.

How soon do I see the result with eXcite^{OSA}?

You should notice an improvement in your snoring within 6 weeks. This is dependent upon adherence to the recommended therapy program of one 20-minute session daily. Although you may see improvement within 6 weeks, we recommend you finish the 6-week therapy period to ensure you gain the optimal improvement possible.

What does a flashing red & yellow LED mean?

If your Control Unit flashes red and yellow during charge or during mouthpiece connection, this means moisture has been detected within the Control Unit USB-C connector. Disconnect the control unit, let it dry for a minimum of 4 hours and try again. If the issue persists, contact our support team at support@signifiermedical.com.

What does a solid yellow LED mean?

A solid yellow LED indicates a system error. Disconnect the control unit until the yellow LED turns off. Attempt connection again, if the solid yellow LED persists, contact our support team for assistance at support@signifiermedical.com.

Do I need to use the extender cable?

You can use the extender cable if you are experiencing excess salivation and moisture is entering your control unit. This extender cable will help prevent moisture entering your control unit.

The extender cable can be used as an intermediate connection between the Control Unit and Mouthpiece during therapy.

What if I don't replace my mouthpiece after 90 days from first use?

The mouthpiece will deactivate and will not function. Be sure to order a replacement mouthpiece well in advance of 90 days so that your therapy schedule is not interrupted.

Troubleshooting

The control unit powers up but the mouthpiece does not work:

- Check the control unit has adequate power to run a 20 minutes therapy session
- Check there is no fluid ingress within the USB connector
- Check there is no damage to the mini USB connector
- Check there is no damage to the mouthpiece
- If the above steps have been implemented, then contact the eXcite^{OSA} Help/Support team by emailing support@signifiermedical.com or calling +1 844 MildOSA

Cybersecurity

Bluetooth Security

Just like Wi-Fi connections, Bluetooth can put your personal data at risk if you are not careful in public places. While it is better to use the eXcite^{OSA} mobile app in a private environment, here are some steps you may wish to take when using Bluetooth within (10 m/30 ft) of strangers:

- Turn Bluetooth off when not in use. If you keep Bluetooth active, a hacker may be able to discover what other devices you connected to before, spoof one of those devices, and gain access to your device.
- Use Bluetooth in “hidden” mode rather than “discoverable” mode. This prevents other unknown devices from finding your Bluetooth connection.

Passwords

Weak passwords or password shortcuts can leave your personal data less secure. The following best practices may help keep your personal information safer:

Don't use the same password for multiple accounts, especially for the most sensitive ones, such as bank accounts, credit cards, legal or tax records and files containing medical information. Otherwise, someone with access to one of your accounts may end up with access to many others.

Don't use passwords that can be easily guessed, such as common words and birthdays of family members. Instead, use a combination of letters, numbers and symbols. The longer and stronger the password, the safer your information.

The eXcite^{OSA} mobile app software seeks to enforce password strength by using the following requirements: Minimum password length of 8 characters, using at least one

uppercase and lowercase character, at least one numeric character and at least one special character. This is the same password standard used for Windows 10 security.

Malware

- Never jailbreak your iPhone or root an Android device, because you leave it open to the malware it was designed to be protected against.
- Always install the latest iOS updates for increased security. Android's open-source system and delayed update roll out make it more susceptible to malware, which is why Android users should always use an anti-virus from the Google Play Store as an added layer of protection.
- Only purchase and download apps from the Apple App Store, which has historically been a very secure platform for purchasing approved apps from vetted developers. Android users should always use the Google Play Store rather than other third-party app shops.
- Avoid suspicious links, phishing and robocalls. Be suspicious of questionable downloads in an email from a friend, robocalls urging prompt action on a past-due account, or any automated process asking you to update/verify your account or other personal information.
- Don't fall prey to tricky pop-ups such as a virus warning asking you to scan for viruses or malware immediately. The links below describing how to avoid such scams and remove fake security alerts on your iPhone or Android.

iPhone: (<https://www.iphonelife.com/content/iphone-virus-warnings-how-to-get-rid-fake-security-alerts-your-iphone>)

Android: (<https://malwaretips.com/blogs/remove-fake-google-security-warning>).

eXcite^{OSA} system, 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.

eXcite^{OSA} system, transport and storage requirements

Temperature -13°F to +158°F (-25°C to +70°C)

Humidity up to 90%

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.

DISPOSAL

This product contains a rechargeable battery and should not be disposed in general waste, as this could be damaging to the environment. Dispose or recycle this product in accordance with local laws or regulations that apply.

FAULTS & REPAIRS

eXcite^{OSA} should be used in accordance with this Instructions for Use and with the accessories that come with the device. The device does not come with any parts that will require servicing. Do not try to repair, alter or change the components of the three individual units of the eXcite^{OSA}, as this will invalidate your warranty. If the mouthpiece or control unit is not functional due to wear and tear, it will not be covered by the warranty. The mouthpiece must be replaced after 90 days of first use.

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 a period of 90 days for the mouthpiece and 1 year (control unit only) from the date of purchase. For valid warranty claims, the user may return after authorization, the eXcite^{OSA} directly to the local eXcite^{OSA} contact or Signifier Medical Technologies LLC. eXcite^{OSA} warranty does not include any misuse or abuse such as dropping or immersing the control unit in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will void the warranty. This warranty does not apply to “wear and tear” that would occur with usage.

CUSTOMER SERVICE

Please email support@signifiermedical.com or call +1 844 MildOSA for any warranty returns, general assistance in setting up or using the device, or to report any issues or complaints. Your invoice of purchase should state the name and the contact details of your local Signifier Medical Technologies contact. For assistance in setting up, using or maintaining the unit, or to report unexpected operation or events please contact Signifier Medical Technologies customer service.

If you have an absence of clinical benefit following completion of 42 therapy sessions within an 8-week period, please contact your doctor or Signifier Medical Technologies.

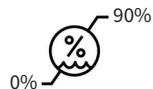
Symbols used



Refer to instructions manual



Storage Temperature Limits



Humidity Limits



Catalog number



Serial number



Keep dry



Country & date
of manufacture



Manufacturer



Type BF applied part



WEE directive



USB C

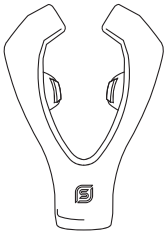


Federal Communications
Commission



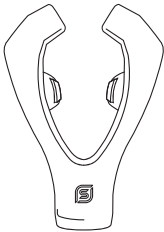
Medical Device

Specifications



	Control Unit	Mouthpiece
Color	White and Blue	White and Grey
Packaging	eXcite ^{OSA} is packed in a protective box package	
Power source	Rechargeable 100mAh LiPo cell	N/A
Max output voltage	30.8 V Output varies with impedance	
Max output current	70mA Output varies with impedance	
Output signal	<p>100 uS for each of the two biphasic output pulses of opposite polarity, resulting in a balance d.c. component.</p> <p>Pulse repetition frequency up to 20 Hz</p> <p>The Control Unit is designed to attempt to output 40 mA at the highest setting (setting 15), and proportionally for other intensity settings. However, it is limited by the maximum available voltage of 30.8 V. The resulting output is then impedance R dependent, so the output is 40 mA * intensity / 15, but thresholded to 30.8 V / R.</p> <p>This is valid for any potential tongue impedance.</p>	
Operating temperature	From +41°F to +104°F (+5°C to +40°C)	
Storage temperature	-13°F to +158°F (-25°C to +70°C)	

Specifications



	Control Unit	Mouthpiece
Atmospheric Pressure Range	10.15 psi to 15.37 psi (70 kPa to 106 kPa)	
Humidity	Relative Humidity 15% to 90%	Relative Humidity up to 100%
Degree of Protection	Control Unit (IP44) (IP 44 - Protection protected against objects > 1 ml and splashing water, IP42 - Protection protected against objects > 1 ml and dripping water) IP 64 - Mouthpiece (Protection against dust and splashing water) IP67 - Mouthpiece (Protection against dust and temporary immersion in water) IP 22 - Extender cable (protected against touch and objects > 12mm and water spray < 15 degrees from vertical)	
Mode of operation	ON/OFF	

Radio Frequency Information	Control Unit
Frequency Band Of Reception	2.4 GHz to 2.48 GHz
The Bandwidth of The Receiving Section in Those Bands	2 MHz
Effective Radiated Power	up to 3.5 dBm

IEC 60601-1-2:2014 (EDITION 4) /
BS EN 60601-1-2:2015+A1:2021 (Home healthcare environment)

Standard	Category		
CISPR 11 / EN 55011	Emissions	Radiated Emissions (30 - 1000 MHz)	Class B
CISPR 11 / EN 55011	Emissions	Conducted Emissions	N/A
IEC/EN 61000-3-2	Emissions	Harmonic Current Emissions	N/A
IEC/EN 61000-3-3	Emissions	Voltage Fluctuations and Flicker	N/A
RTCA/DO160G	Emissions	Radiated Emissions (100 MHz - 6 GHz)	Section 21 Category M
ANSI C63.4, FCC CRF 15.209 / ICES-003	Emissions	Radiated Emissions (30 MHz - 12.5 GHz)	Class B
IEC/EN 61000-4-2	Immunity	Electrostatic Discharge Immunity	Air: 2,4,8,15kV. Contact: 8kV
IEC/EN 61000-4-3	Immunity	Radiated RF Immunity	10 V/m: 80 MHz to 2.7 GHz. 3 V/m: 2.7 GHz to 6 GHz
IEC/EN 61000-4-3 / IEC/EN 61000-4-39	Immunity	Immunity to Proximity fields from RF wireless communications equipment	<div>385 MHz 27 V/m</div> <div>450 MHz 28 V/m</div> <div>710, 745, 780 MHz 9 V/m</div> <div>810, 870, 930 MHz 28 V/m</div> <div>1720, 1845, 1970, 2450 MHz 28 V/m</div> <div>5240, 5500, 5785 MHz 9 V/m</div>
IEC/EN 61000-4-4	Immunity	Electrical Fast Transients Immunity	N/A
IEC/EN 61000-4-5	Immunity	Voltage Surge Immunity	N/A
IEC/EN 61000-4-6	Immunity	Conducted RF Immunity	N/A
IEC/EN 61000-4-8	Immunity	Power Frequency Magnetic Field Immunity	N/A
IEC/EN 61000-4-11	Immunity	Voltage Dips and Short Interruptions Immunity	<div>100 % reduction for Half Cycle</div> <div>30 % reduction for 25/30 Cycles</div> <div>100 % reduction for 1 Cycle</div> <div>>95 % reduction for 250/300 Cycles</div>

WARNING:

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the eXcite^{OSA} System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- eXcite^{OSA} is not specified for use only in a shielded location.
- eXcite^{OSA} is not considered a large ME equipment.
- eXcite^{OSA} does not claim compatibility with HF SURGICAL EQUIPMENT and is not intended for use with HF surgery.

If the eXcite^{OSA} system is exposed to EM disturbance, there should not be any loss or degradation to performance. However, the performance should be monitored for the accuracy of waveform.

Declarations

FOR THE USA

FCC warning statement:

This device complies with Part 15 of the FCC Rules.

- Operation is subject to the following two conditions:
 1. This device may not cause harmful interference, and
 2. This device must accept any interference received, including interference that may cause undesired operation.
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

FOR CANADA

"This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:

1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device."

Please see Section 8.4 of RSS-Gen Issue 4 for further information.

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This product is Manufactured by Signifier Medical Technologies
in compliance with Medical Device Standards and Quality Standards: ISO 13485:2016



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MEDICAL TECHNOLOGIES

Instructions for Use - North America

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