

excite^{OSA}®

Instructions for Use

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

Contents

Important safeguards	3
Intended use.....	5
Contraindications.....	6
What's in the box?	7
Remote control instructions	10
Display screen guide	16
Systems requirement / eXcite ^{OSA} smartphone application	19
Using your eXcite ^{OSA} with a smartphone application	19
eXcite ^{APP}	23
Washing	23
Recommended therapy level.....	24
Frequency of usage	30
Charging the control unit.....	30
Storing & traveling with your eXcite ^{OSA}	30
Software updates	31
Settings.....	32
Frequently asked questions.....	34
Troubleshooting.....	36
Remote control error codes	37
Cybersecurity.....	39
eXcite ^{OSA} system, operational requirements	41
eXcite ^{OSA} system, transport and storage requirements	41
Symbols used	43
Specifications	44
Declarations.....	48

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.
- The Control Unit 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 and remote control 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 control unit 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.
- eXcite^{OSA} 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).
- Do not use eXcite^{OSA} when driving a vehicle or operating machinery and other equipment.
- No modification of this device is allowed. Do not try to alter, trim or change any components of the device.
- eXcite^{OSA's} disposable mouthpiece is for single patient use
- Your eXcite^{OSA} device should not be shared or used by other individuals.
- The eXcite^{OSA} durable control unit can be re-purposed by Signifier Medical Technologies for use by multiple successive patients.
- When charging the device, keep away from all liquids.
- The eXcite^{OSA} durable control unit can be re-purposed for use by multiple successive patients.
- 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:

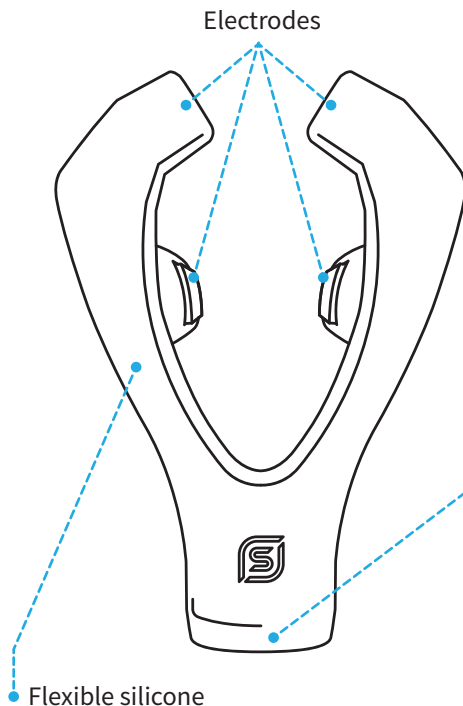
- accumulation of saliva.
- tingling sensation on tongue.
- tooth sensitivity.

What's in the box?

eXcite^{OSA} package includes:

1

Mouthpiece (top view)



If your device packaging is received in the following conditions, please do not use the device and contact Signifier Medical Technologies:

- 1) damaged
- 2) unintentionally opened before use
- 3) exposed to environmental conditions outside of those specified.

Cleaning cap (please retain)



USB-C type connector

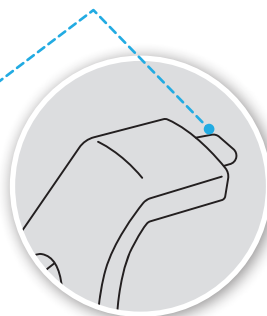


Fig. 1

2

Control unit (with Bluetooth)

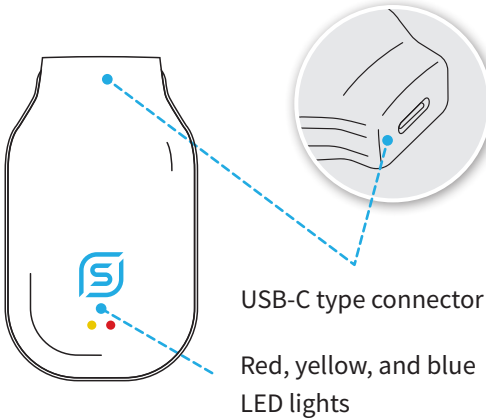


Fig. 2

3

Extender cable
(recommended use)

If you salivate, connect the extender cable between the control unit and mouthpiece to prevent moisture from entering the USB port. If the lights flash yellow and red, let the unit dry for several hours.

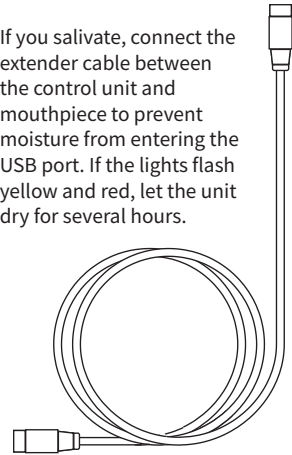


Fig. 3

4

eXcite^{OSA} USB charging cable (1 m cable connect to UL-Certified USB wall charger (not provided) with 5 VDC, Min 0.5 AMP output)

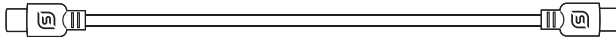


Fig. 4

Note: Only use the eXcite^{OSA} USB charging cable provided, and only with the control unit (not the remote control). Using another cable, or using the cable with the remote control, could damage the device and void your warranty.

Remote control (if included in your box)

Reference pages 16-17 for display screen guide

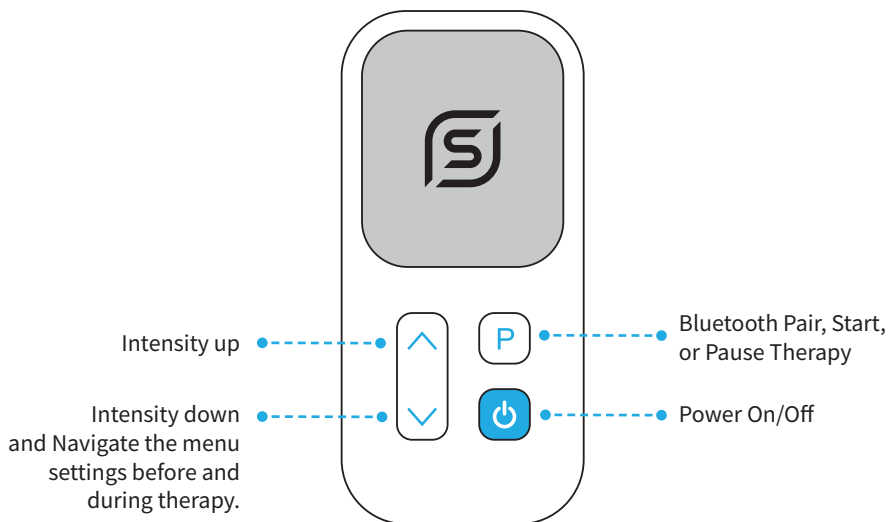
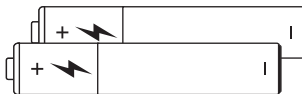


Fig. 5



2 AAA batteries

Fig. 6

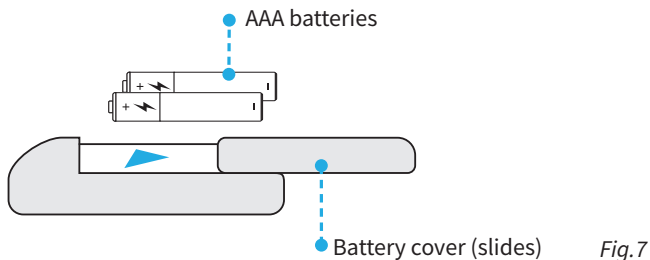
Remote control instructions

(if your box included a remote control)

BEFORE FIRST USE

Check all the components are intact, undamaged, and available as described in the What's in the box section.

1. Charge the control unit fully for 2 hours before first use. The flashing blue light will become continuous when the control unit is fully charged.
2. Open the battery compartment cover on the underside of the remote control.
3. Install two new AAA size alkaline batteries with the positive (+) and negative (-) terminals properly aligned with the corresponding symbols in the battery compartment. Only replace batteries before or after a therapy session. Never replace batteries during a therapy session as this will cause an error and will stop therapy.



4. Close the battery compartment cover.
5. You will need to Bluetooth pair your control unit with the remote control before starting
 - Connect the mouthpiece to the fully charged control unit. Reference Fig. 11 on page 13.
 - Press and hold the Power button  for 3 seconds to power on/off the remote control. Once the remote control is turned on, the Signifier logo  will appear.

6. The remote control display will show one or more control units Fig. 8. Bluetooth identity can be located as the characters following the “BT ID:” on the packaging.
7. Once the correct control unit is highlighted, press the  button on the remote control to request pairing with the selected control unit. Reference Fig. 5.
8. When the control unit is ready to pair with Bluetooth, a blue LED will blink once every 3 seconds. On successful Bluetooth pairing, the blue LED on the control unit will begin to blink once every 5 seconds and the remote will display the Bluetooth paired status as shown in Fig. 9. If Bluetooth pairing is not successful, an error display will appear on the remote. If a BT ID cannot be found, please refer to the troubleshooting section on page 36.



Fig. 8



Fig. 9

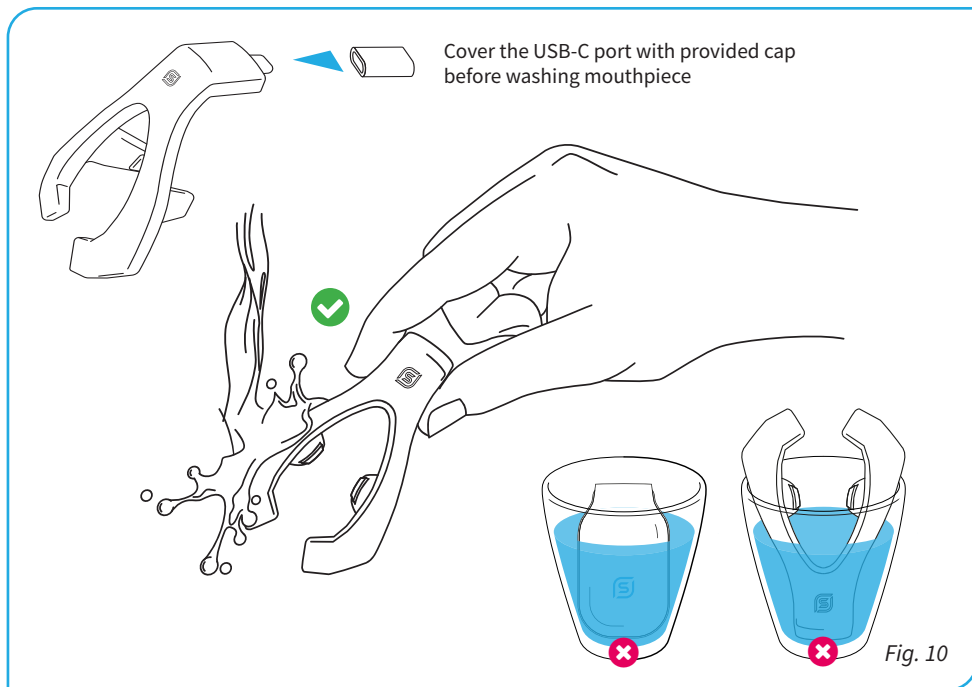
NOTE: Replace both batteries with new ones when the symbol  is displayed on the remote control.

CAUTION

- Install each battery with the positive (+) and negative (-) terminals properly aligned with the corresponding symbols in the battery compartment. See Fig. 7.
- Improper installation of the batteries may cause battery leakage.
- Do not mix new and used batteries. It may cause damage to the remote or shorten the battery life.
- Use alkaline batteries only.
- Do not use rechargeable batteries with this remote.
- Remove the batteries from the battery compartment, when the remote is not to be used. Storing the remote with the batteries installed may result in battery fluid leaking from the batteries, causing damage to the remote.
- Remote control temperature can exceed +105.8°F (+41°C).

USING eXcite^{OSA} WITH A REMOTE CONTROL

1. 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.**
2. Wash the mouthpiece only with cold and running potable tap water as shown in Fig. 10. Avoid water entering the USB port by using the provided USB-C rubber cap. Dry with clean towel. (Follow instruction on washing)



3. Connect the control unit and mouth piece as shown in Fig. 11.
4. Ensure your control unit is fully charged or holds enough charge for a complete 20 minute therapy. The battery status of the control unit can only be checked after pairing with the remote control. The battery status of the remote control and control unit can be found on the remote control display screen (see battery status display screen on pg. 15). The battery symbol  will flash next to the control unit and/or the remote control if it is deemed too low to complete a therapy. The control unit battery status can be checked on the paired remote control display. The battery image outline will flash if control unit battery is low Fig. 12.

The Signifier logo  LED on the control unit will flash yellow and blue if there is inadequate charge to run a full 20 minute therapy session.

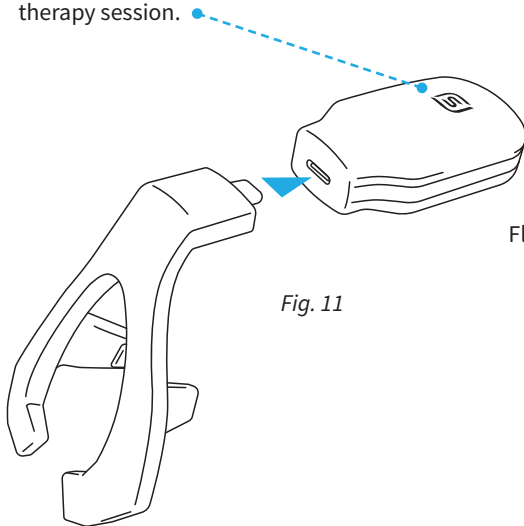


Fig. 11

Flashing outline



Fig. 12

5. Insert the mouthpiece into the mouth and allow it to sit around the tongue as shown in

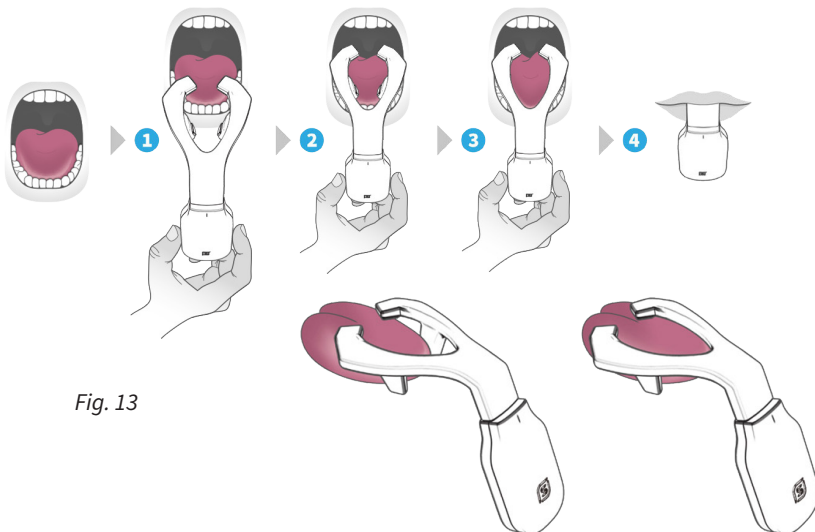


Fig. 13

Fig. 13 and gently close your mouth. Avoid grinding or clenching the mouthpiece.

6. Power on the remote control by holding the power button for 3 seconds. If you have already connected the remote control and control unit in a previous session, the remote control will pair automatically with the control unit as shown in Fig. 9. If this is your first time connecting the remote control and control unit, follow the instructions on page 10.
7. To start therapy, when presented the start button display as shown in Fig. 14, press the **P** button to initiate therapy. A 3 second countdown will begin before therapy starts. Therapy will start at the lowest intensity (intensity 1).



Fig. 14

8. The therapy duration is 20 minutes, a timer will be displayed on remote control to indicate the time remaining for completion of therapy session .
9. To adjust the intensity of the therapy, on the remote press the ▲ to increase intensity, press ▼ to decrease intensity. The intensity level will be shown in the at the top of Fig. 15.

Keep increasing the intensity until you feel the contraction of the tongue. For optimal results, increase the intensity to stimulation that is comfortable. See page 26 for recommended therapy levels of intensity.

Use the ▼ button to reduce the intensity if the stimulation becomes uncomfortable, or remove mouthpiece from mouth. Lock the intensity when you feel comfortable. To turn on/off the intensity lock, hold the P button for at least 2 seconds and the lock icon will appear. Hold for another 2 seconds to unlock.

10. The therapy changes frequencies at 5 minute intervals. If you feel any discomfort or lack of stimulation, then the intensity can be reduced or increased accordingly using the ▲ and ▼ buttons.



Fig. 15

11. Pause therapy - press  button to pause. See Fig. 15.
Resume therapy - press  button again to resume.

Note: If the therapy is paused for more than 3 minutes, the session will be terminated.

Stop therapy - within the pause menu, press the ▼ to change to the stop button display. Once at the stop button display, press  button to confirm. See Fig. 16.



Fig. 16

12. The stimulation will stop automatically when the therapy session has finished.
13. At the end of the therapy session, remove the mouthpiece from your mouth and disconnect the control unit.
14. To power down the remote control, press the power button  for three seconds.
15. Store the control unit and remote control in a dry place. Wash the mouthpiece as shown in Fig. 10.

Display Screen Guide and Troubleshooting

For instructions on how to use your remote control, please see pages 10-15. For additional display screen troubleshooting, please see pages 37-38.

Bluetooth Connection



Bluetooth scan, no devices were found. See page 10 for pairing instructions. See page 37 for troubleshooting instructions.



Bluetooth scanning for devices.



Remote to mobile app connect.*



After a Bluetooth scan, a device was found. The 7 character sequence is your BT ID for your control unit.



Bluetooth connection was successful.

Battery Status



Battery Status. The lightning bolt symbol indicates the device is currently charging.



Battery is at 50% charge. Each bar represents 25% of charge.



Battery is critically low and needs to be charged. Therapy cannot be started if the Control Unit or Remote has a critically low battery level.

Mouthpiece Notifications



Mouthpiece ID check was successful.



The mouthpiece expires after 90 days from first usage. This screen indicates the number of days and hours left until mouthpiece expiration.

Therapy Functions and Notifications



When at this screen, press **[P]** to initiate therapy.



Pressing the **[P]** button during therapy will pause the therapy for 3 minutes. A Pause icon will appear and a three minute countdown will begin.



Number of therapy sessions completed.



Therapy is in session and the intensity level is locked in.



To stop therapy, press the **[P]** button to first pause the therapy, then scroll down to the Stop icon and press the **[P]** button again to confirm.

* To update the remote firmware and synchronize your therapy data with your mobile app account, scroll down to this display in the main menu and press **[P]** to initiate pairing with the mobile app. This feature is in development, and subject to change.

Reminders



This is a reminder to book an appointment with your healthcare provider.



This is a reminder to update the remote firmware and synchronize your therapy with your mobile app. See instructions below.*

Error Codes



Control unit general error. See error troubleshooting instructions on pages 36-38.



Control unit hazard error. See page 38 for troubleshooting instructions.



Remote control general error. See page 37 for troubleshooting instructions.



Mouthpiece general error. See page 38 for troubleshooting instructions.

Therapy Timeouts



Therapy can only be completed once per day. The screen will display a countdown until the next session is allowed. If therapy is paused for more than 3 minutes, manually stopped, or if an error is detected, a 30-minute timeout will occur.

For clinician use only



USB connection failed. Unplug the USB and plug it back in to try again.



USB connection successful.



USB data transfer do not touch.



USB data transfer complete.

**REFERENCE PAGE 37-38
FOR REMOTE CONTROL
ERROR CODES.**

Note: The remote control operates exclusively on AAA batteries and cannot be used for therapy when connected via USB. Therapy functionality will be disabled upon detection of a USB connection to the remote.

Frequency of use

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.

eXcite^{OSA} can be used long term. This is comparable to maintaining your physical fitness by undertaking regular exercise.

You must replace the mouthpiece **three months** after first use.

Storing and travelling with your eXcite^{OSA}

MOUTHPIECE

Once the mouthpiece has been washed in potable running 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 regular stand for the mouthpiece.

CONTROL UNIT

The control unit and the remote control 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 transport.

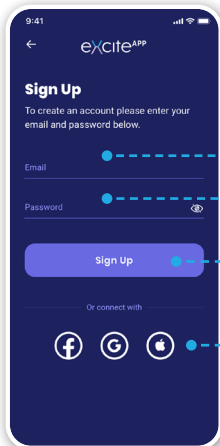
Systems requirements

The eXcite^{OSA} device can be controlled by the smartphone application or by a remote control (if included). The app can be downloaded from the App store (Apple iOS) or Play Store (Google Android). For using eXcite^{OSA} with the remote control, refer to page 12.

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 Low Energy (BLE); mobile devices used must be compatible with BLE.

eXcite^{OSA} smartphone application (eXcite^{APP})

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*

* 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?

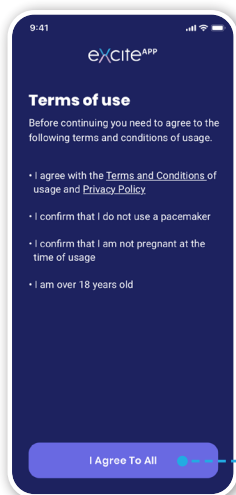
Get your eXciteOSA device now

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.**

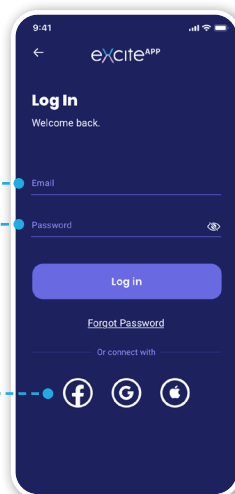
Also, you must be 18 years of age or older.

LOG IN

Enter your registered e-mail and password

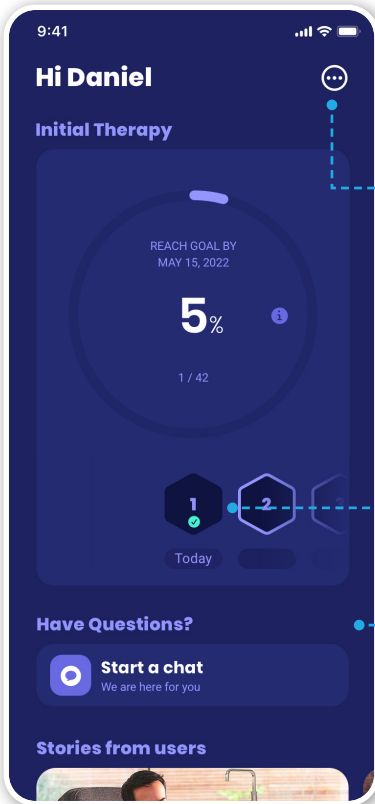
If you forgot your password, tap here. You will receive an e-mail with further instructions.

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.



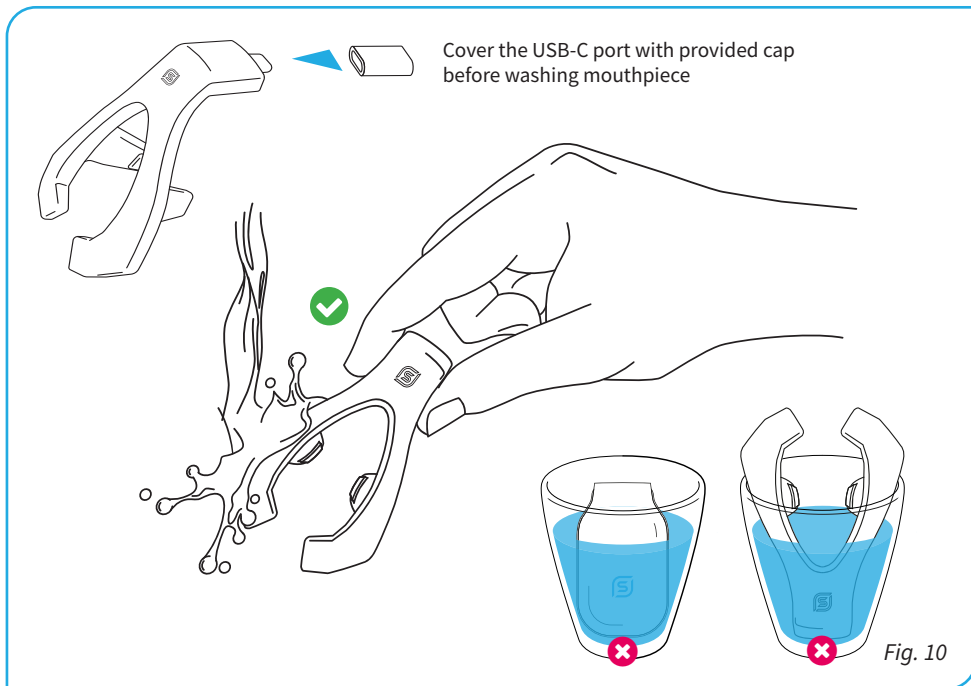
Settings

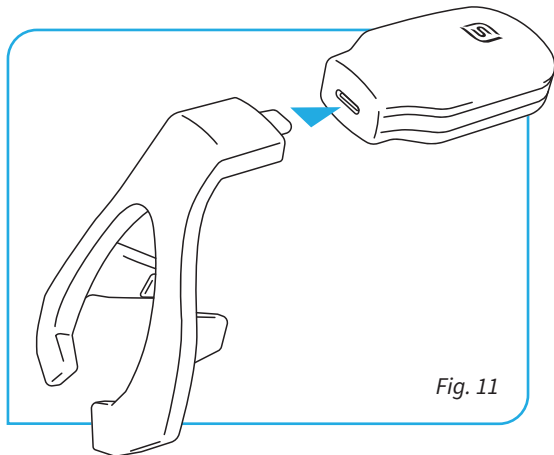
eXcite^{OSA} therapy

Educational content

Using your eXcite^{OSA} with a smartphone application

1. 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.**
2. Wash the mouthpiece only with cold and running potable tap water as shown in Fig. 10. Avoid water entering the USB port by using the provided USB-C rubber cap. Dry with clean towel. (Follow instruction on washing)

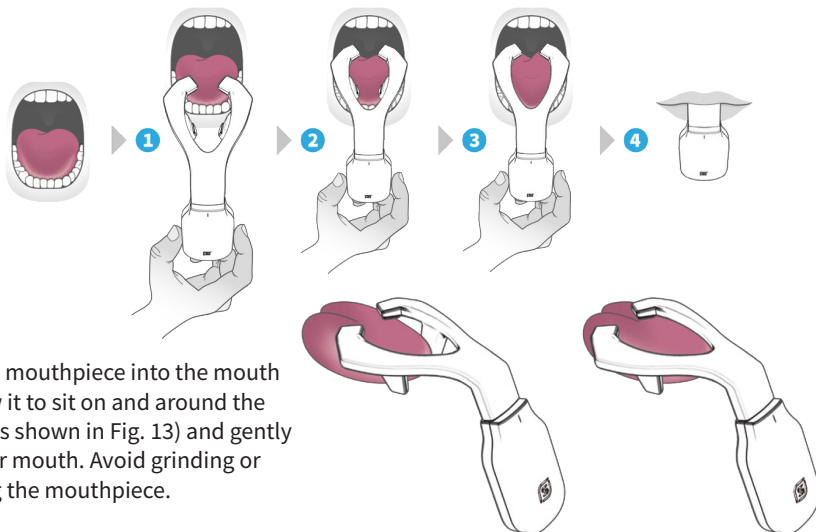




To start using eXcite^{OSA}, connect the mouthpiece to the control unit as shown on Fig. 11.

Fig. 11

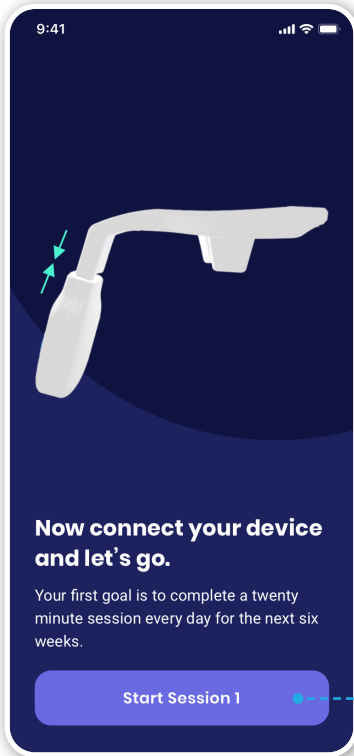
Fig. 13



Insert the mouthpiece into the mouth and allow it to sit on and around the tongue (as shown in Fig. 13) 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.



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

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.

Connect

In order to start the treatment, you need to pair your phone with the control unit. Please make sure that the control unit is close to your phone.

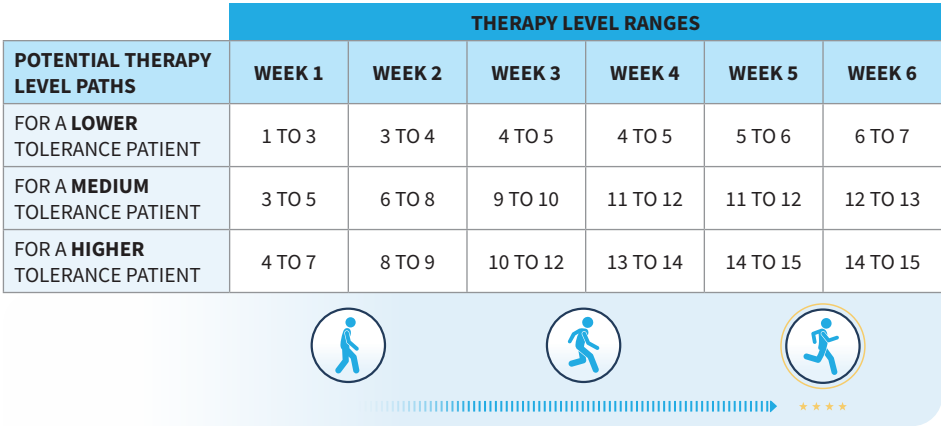
Recommended therapy level

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.

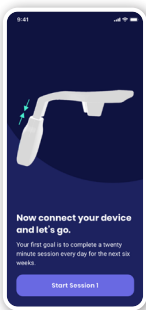
Each 20 minute session is broken up into four 5-minute intervals. Each interval will prompt the device to give off a different frequency. The frequencies will not exceed 20 Hz.

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

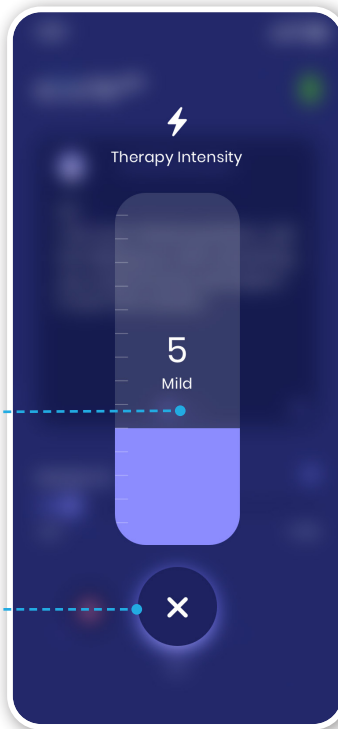
To change your therapy level, simply slide the level setting from the bottom of the bar on your screen.

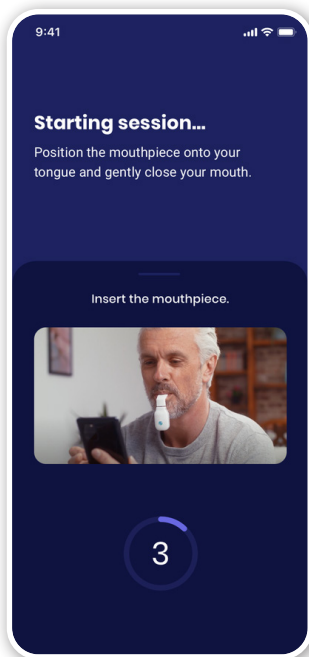
It is important to set the device to the highest possible therapy level that still feels comfortable for you. This will ensure the best possible outcome.

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



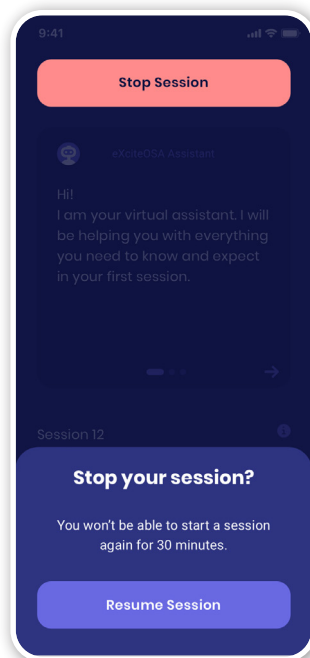


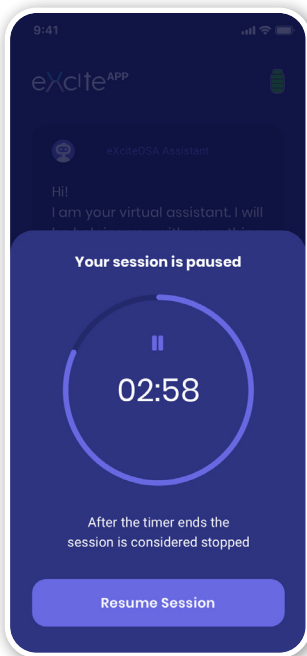
COUNTDOWN

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.

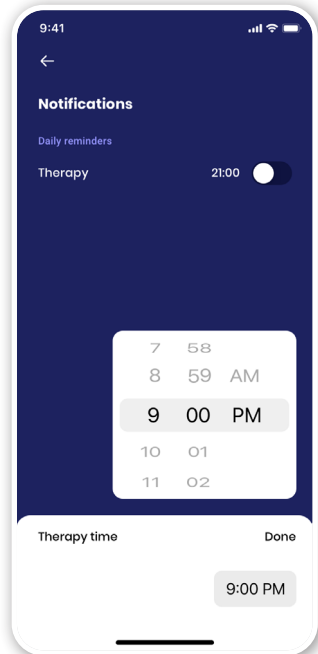
STOP THERAPY





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.

Mouthpiece: You must replace the mouthpiece every 90 days.

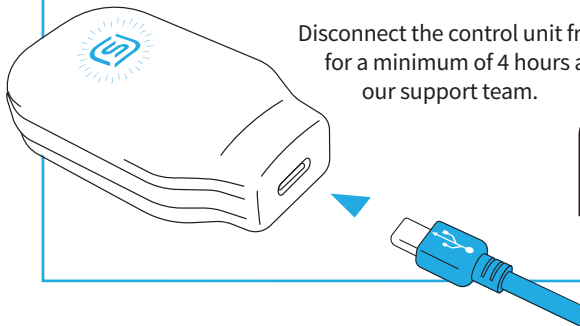
Control Unit and Remote: It is recommended to replace the control unit and remote every 3 years.

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. 11) 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.

Moisture Control: 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.



Note: Only use the USB cable provided. Using another cable could damage the device and void your warranty.

Fig. 17

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 AND REMOTE CONTROL

The control unit and remote control 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.

REMOTE CONTROL (IF INCLUDED IN THE BOX)

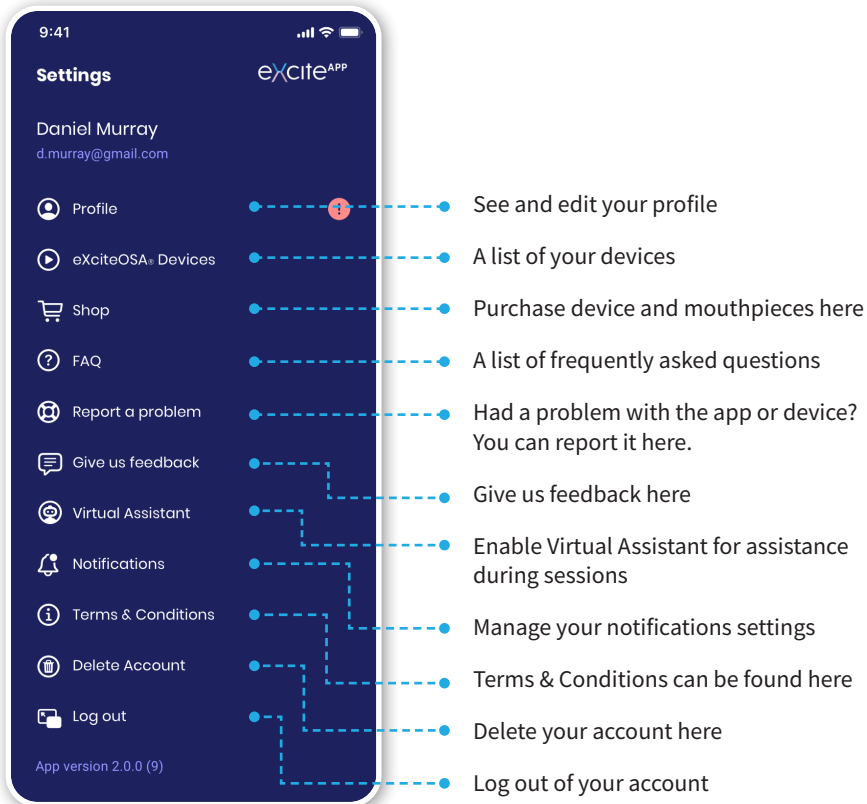
Wipe the remote control surface with damp cloth or antiseptic wipe once a week. **DO NOT** immerse the remote control in water or cleaning solutions. To avoid fluid ingress into the remote control, always store the remote control in a dry place.

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.

9:41

← Save

Profile

Mandatory

First Name
Daniel

Last Name
Murray

Country
USA

Optional

Phone Number
(22) 456-7890

Birth Gender
☒ Male ☐ Female

Date of birth

Ethnicity

Height Weight

FAQ

Check the Frequented Asked Questions for further information.

9:41

← Save

FAQ

Why do I snore? ▾

Is snoring dangerous? ▾

Do I have sleep apnea? ▾

How can I reduce my snoring? ▾

What should I expect in a eXciteOSA box? ▾

How does eXciteOSA device work? ▾

What time of the day should I use the eXciteOSA device? ▾

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.

9:41

←

Report a problem

I

Has an injury occurred?
☐ Yes ☐ No

Submit Report

Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M
123 space Go

NOTIFICATIONS

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

9:41

←

Notifications

Daily reminders

Therapy 21:00 ☒

7 58
8 59 AM
9 00 PM
10 01
11 02

Therapy time Done

9:00 PM

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 26 for recommended levels of intensity.

It is important to note that therapy levels outside of your comfort zone will not improve outcome or speed up results.

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

You should notice an improvement 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 4 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 on the control unit 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 4 hours and try again. If the issue persists, contact our support team at support@signifiermedical.com.

What does a solid yellow LED on the control unit 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.

Can I use the remote control and the mobile app to control therapy?

No. We recommend using the mobile app. If you start therapy with one method (mobile app or remote control), and decide to start using the other method, contact Signifier Medical Technologies for further instructions.

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
- Ensure the phone/app is within 6.8 feet (2 meters) of the control unit
- Check there is no fluid ingress within the USB connector
- Check there is no visible damage to the USB-C 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

The remote control does not connect to the control unit:

- Check and replace the remote control battery
- Ensure the remote control is within 2 meters (6.8 feet) of the control unit
- Ensure the control unit is fully charged
- Check there is no fluid ingress within the USB connector
- Check there is no visible damage to the control unit or remote control
- If the above steps have been implemented and the remote control still presents an error display with a code, record that error code and send it to the eXcite^{OSA} Help/Support team by emailing support@signifiermedical.com or calling +1 844 MildOSA

Remote Control error codes

The eXcite^{OSA} is designed to operate safely at all times, our product will operate in a safe mode if it encounters an error code. Contact Signifier Medical Technologies’s Help Support team at support@signifiermedical.com in the event of persistent error codes.

Icon	Functionality	Comment
No paired icon:  R210	Bluetooth	Pairing: No device found to pair. Follow pairing instructions on page 10.
User presented with General Error Icon and a number 11x or 22x Controller:  C111, C112, C114, C116 Remote:  R211, R212		Here is a list of things that can be done may help fix the issues: 1. Ensure there are no battery low warnings and replace batteries if required. 2. Ensure the controller is within 3.4 feet (1 meter) of remote, wait 10 seconds, re-power the remote and attempt to pair. 3. Connect the control unit to the charger, have the control unit within 3.4 feet (1 meter) of remote, turn off remote, wait 10 seconds re-power and attempt to pair. 4. If the above troubleshooting does not fix the error, then please contact Signifier Medical Technologies directly.

Icon	Functionality	Comment
 R264, R265, R266	USB Connection	Clinician related: R264 - There is a connection error. Make sure USB cable is secure and do not disconnect. R265 - The USB cable connection was initiated, but the user did not start the firmware update or data synchronization process. Patient related: R266 - User is trying to start therapy with the USB cable connected. Therapy can not be completed with the USB cable connected. Disconnect the cable to start therapy.
 M411, M412	Mouthpiece	411 - Mouthpiece has expired past the 90 day replacement period. 412 - Mouthpiece was disconnected from the Control Unit during a therapy session.
	Battery	1. Connect the control unit to a USB-C charging adapter using the provided USB cable. 2. Ensure the control unit is within 3.2 feet (1 meter) of remote. 3. Turn on remote and wait 10 seconds. 4. Re-power and attempt to pair. Note: The remote control is powered by AAA batteries.
User presented with Hazard Icon and a number  C121, C122, C123, C124, C131, C133, C141, C142, M413	Hazard Device Error	Do not use the control unit and contact Signifier Medical Technologies directly.
C112, C125, C126, C132, C162, C162, C163, C171, C172, C173, C174 R221, R231, R241, R242, R243, R261, R262, R263, R264, R265	Device Error	If you see these codes, contact Signifier Medical Technologies directly.

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 upper-case and lower-case 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 OS 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, control unit, or remote control 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 and remote control 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 or remote control 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.

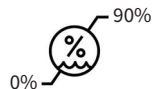
Symbols used



Refer to instructions for use



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



Consult electronic
instructions for use



Medical Device

Specifications



	Control Unit	Mouthpiece	Remote Control (if your box included a Remote Control)
Color	White and Blue	White and Grey	White and Blue
Packaging	eXcite ^{OSA} is packed in a protective box package		
Power source	Rechargeable 100mAh LiPo cell	N/A	Non-rechargeable AAA alkaline batteries
Max output voltage	30.8 V Output varies with impedance	N/A	N/A
Max output current	70mA Output varies with impedance	N/A	N/A
Output signal	100 uS biphasic output pulse, with a total period of 200 uS. Pulse repetition frequency up to 20 Hz. 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. *This is valid for any potential tongue impedance.		
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)		
Atmospheric Pressure Range	10.15 psi to 15.37 psi (70 kPa to 106 kPa)		
Humidity	Relative Humidity 15% to 90%		
Degree of Protection	IP44 - Control Unit (Protection against objects > 1 ml and splashing water) IP64 - Mouthpiece connected to Control Unit (Protection against dust and splashing water) IP67 - Mouthpiece (Protection against dust and temporary immersion in water) IP22 - Extender cable (Protection against touch and objects > 12mm and water spray < 15 degrees from vertical)		
Mode of operation	ON/OFF		

Control Unit Specifications

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) / EN 60601-1-2:2015+A1:2021 (Home healthcare environment)

Standard	Category		Emissions Class / Immunity Test Level
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
FCC 47CFR Part 15 Subpart C	Emissions	Radiated Emissions (100 MHz - 6 GHz)	Class B
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	385 MHz 27 V/m 450 MHz 28 V/m 710, 745, 780 MHz 9 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970, 2450 MHz 28 V/m 5240, 5500, 5785 MHz 9 V/m
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	100 % reduction for Half Cycle 30 % reduction for 25/30 Cycles 100 % reduction for 1 Cycle >95 % reduction for 250/300 Cycles
IEC/EN 61000-4-39	Immunity	Immunity to Proximity Magnetic Fields	Frequency Range of 9 kHz to 13,56 MHz

Remote Control Specifications

Radio Frequency Information	Remote Control
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	Not exceeding -45 dBm

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

Standard	Category		Emissions Class / Immunity Test Level
CISPR 11/EN 55011	Emissions	Radiated Emissions (30 - 1000 MHz)	Class B
CISPR 11/EN 55011	Emissions	Conducted Emissions	CISPR 11
IEC/EN 61000-3-2	Emissions	Harmonic Current Emissions	N/A
IEC/EN 61000-3-3	Emissions	Voltage Fluctuations and Flicker	N/A
FCC 47CFR Part 15 Subpart C	Emissions	Radiated Emissions (100 MHz - 6 GHz)	Class B
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	385 MHz 27 V/m 450 MHz 28 V/m 710, 745, 780 MHz 9 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970, 2450 MHz 28 V/m 5240, 5500, 5785 MHz 9 V/m
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	150 kHz - 80 MHz
IEC/EN 61000-4-8	Immunity	Power Frequency Magnetic Field Immunity	30 A/m: 50/60 Hz
IEC/EN 61000-4-11	Immunity	Voltage Dips and Short Interruptions Immunity	N/A
IEC/EN 61000-4-39	Immunity	Immunity to Proximity Magnetic Fields	8 A/m (30 kHz 65 A/m (134.2 kHz) 7.5 A/m (13.56 MHz)

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.

REMOTE CONTROL

- The USB port is for clinician use only and therapy is disabled when connected.
- Any computer connected with the USB cable must meet CE and UL standards.
- The USB cable used to connect the remote control to the computer shall be shielded and less than 1 meter in length.

THE ESSENTIAL PERFORMANCE OF eXcite^{OSA}

- The waveform parameters shall remain at the selected intensity.
- Loss of Bluetooth connectivity mid-cycle shall put the device in a safe (idle) state. No unintended start of stimulation shall occur when in an idle state.

Each 5 minute segment shall not deviate in duration by more than 10 seconds. The total time of operation shall not deviate by more than 10 seconds.

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

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.

Signifier Medical Technologies LLC

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



Signifier
MEDICAL TECHNOLOGIES

Instructions for Use - North America

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