

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
eXciteOSA® smartphone application.....	9
Using your eXciteOSA® with a smartphone application	13
My eXciteOSA® phone application	15
Frequency of usage	20
Charging the Control Unit.....	20
Storing & traveling with your eXciteOSA®	21
Washing	21
Software updates	21
Settings.....	22
Frequently asked questions.....	24
Troubleshooting.....	26
Cybersecurity.....	27
eXciteOSA® system, operational requirements.....	29
eXciteOSA® system, transport and storage requirements	29
Symbols used	31
Specifications.....	32
Declarations.....	35
Table A: Representative output with varying loads.....	37

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 simulator 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
- eXciteOSA® should be kept away from children and pets (choking hazard and electrical hazard).
- eXciteOSA® to be used in a home or healthcare environment (or equivalent).
- eXciteOSA®'s durable controller unit can be repurposed for use by multiple successive patients
- eXciteOSA®'s disposable mouthpiece is for single patient use
- Do not use eXciteOSA® 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

eXciteOSA® is intended for the reduction of snoring and mild obstructive sleep apnea by strengthening tongue muscles via electrical muscle stimulation.

INDICATIONS FOR USE

eXciteOSA® 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, dental implants, metal prosthesis, metal braces, dental appliances, 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

- eXciteOSA® was used by 65 mild OSA patients, 20 minutes per day for 6 weeks, and 79% of group (51 patients) achieved an average reduction of 52% in AHI.
- eXciteOSA® 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 eXciteOSA® if you:

- are pregnant or may be pregnant.
- have a pacemaker or implanted electrodes.
- have temporary or permanent metal implants, dental braces, intraoral metal prosthesis/restorations/appliances or dental jewelry in the mouth.
- 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?

eXciteOSA® package includes:

1

Mouthpiece (Top view)

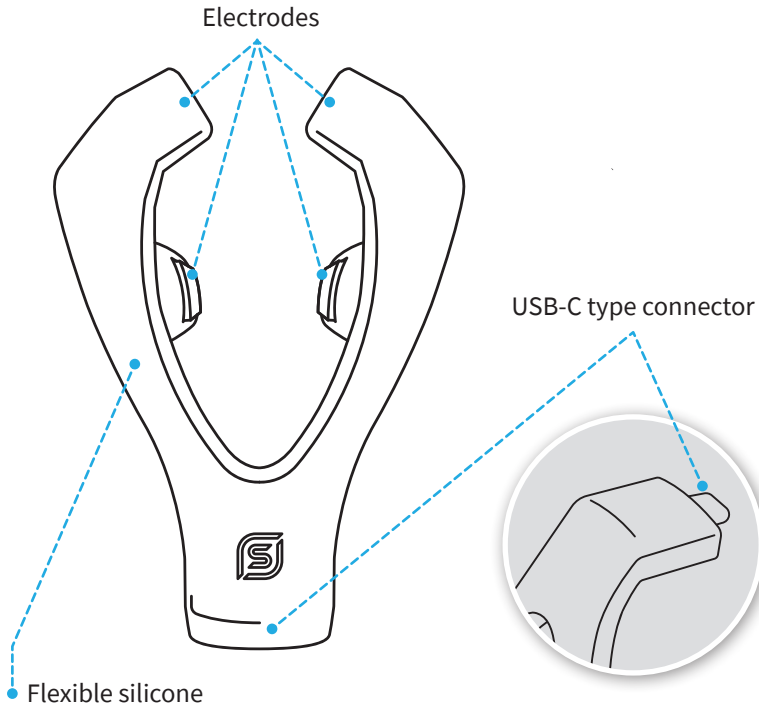


Fig.1

2

Control Unit (With Bluetooth)

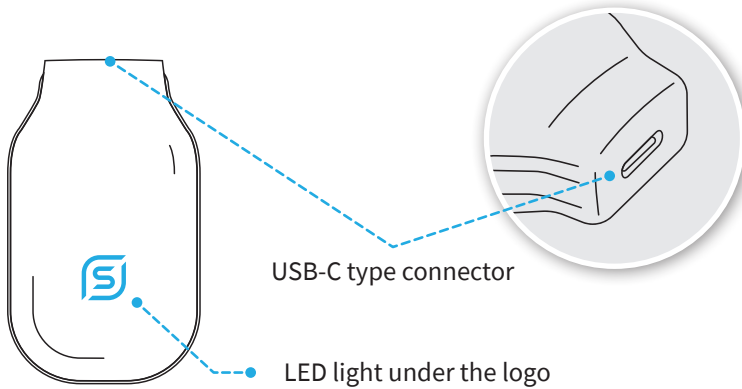


Fig.2

3

USB Cable (15 cm cable connect to UL-Certified USB wall charger (not provided) with 5 VDC, Min 0.5 AMP output)

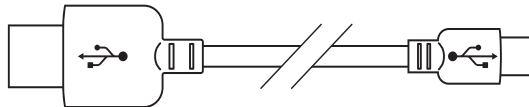


Fig.3

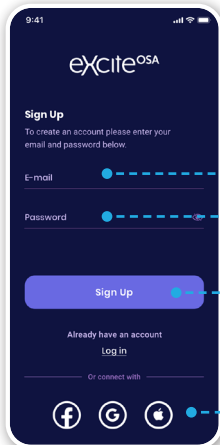
Systems requirements

The eXciteOSA® 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 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. 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.

eXciteOSA® smartphone application

eXciteOSA® device can be controlled by eXciteOSA® Smartphone application. Smartphone application can be downloaded from App Store (Apple iOS) or Play Store (Google Android).



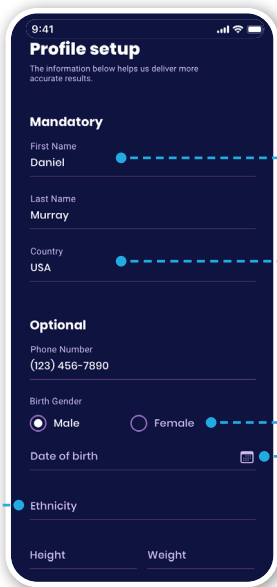
LOG IN & SIGN UP

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.



PROFILE SET UP

Enter your full name

Enter your country of residence

Select your gender

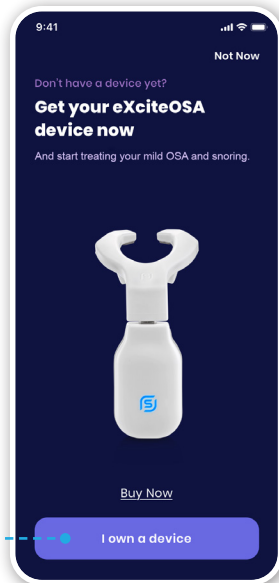
Select your date of birth

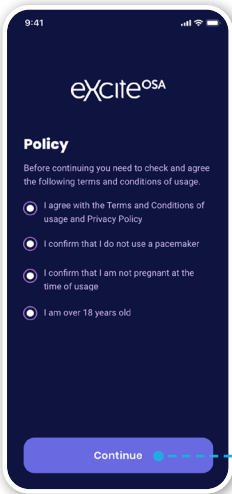
Enter your ethnicity, height and weight*

** This data allows for better eXciteOSA 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 a eXciteOSA® device or not.

If you choose yes, additional setup is required.





POLICY

There are a number of terms you have to agree to in order to use the eXciteOSA® device with the mobile app.

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

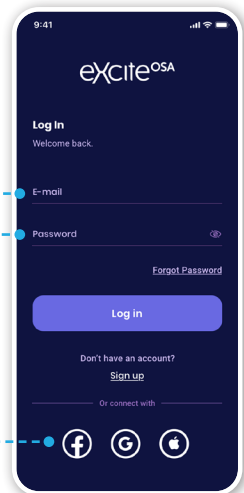
Next, please confirm that you do not use a pacemaker and that you are not pregnant. **It is very important that none of these apply to you as the eXciteOSA® device can interfere with your pacemaker or with your baby's development.**

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

LOG IN

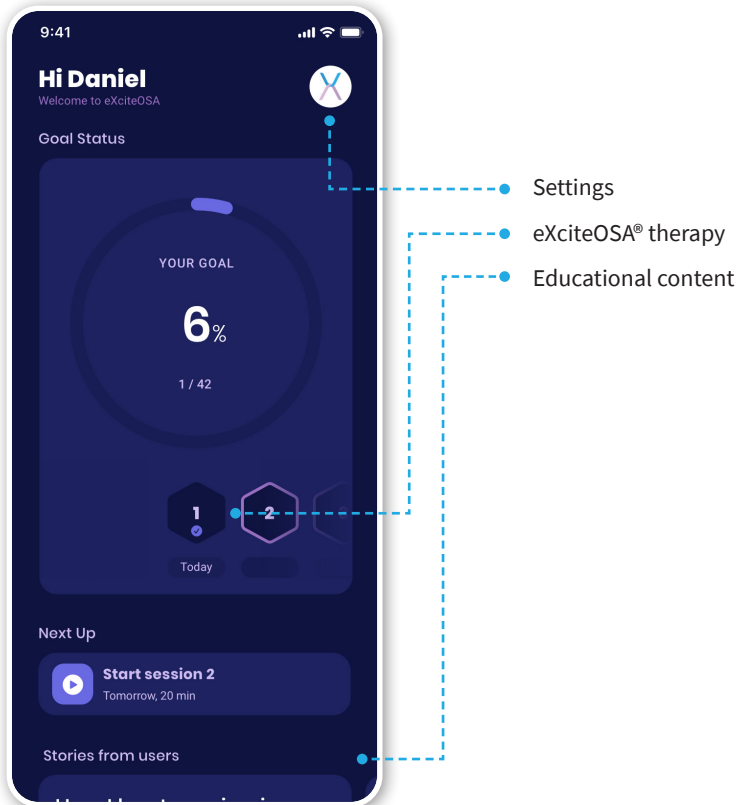
Enter your registered e-mail and password
If you forgot your password, tap here. You will receive an e-mail with further instructions.

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.



Using your eXciteOSA® 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 silicon - **DO NOT USE THE MOUTHPIECE.**

Before use, wash the Mouthpiece with cold and running tap water as shown in Fig 4. Avoid water reaching the USB port. Dry with clean towel.

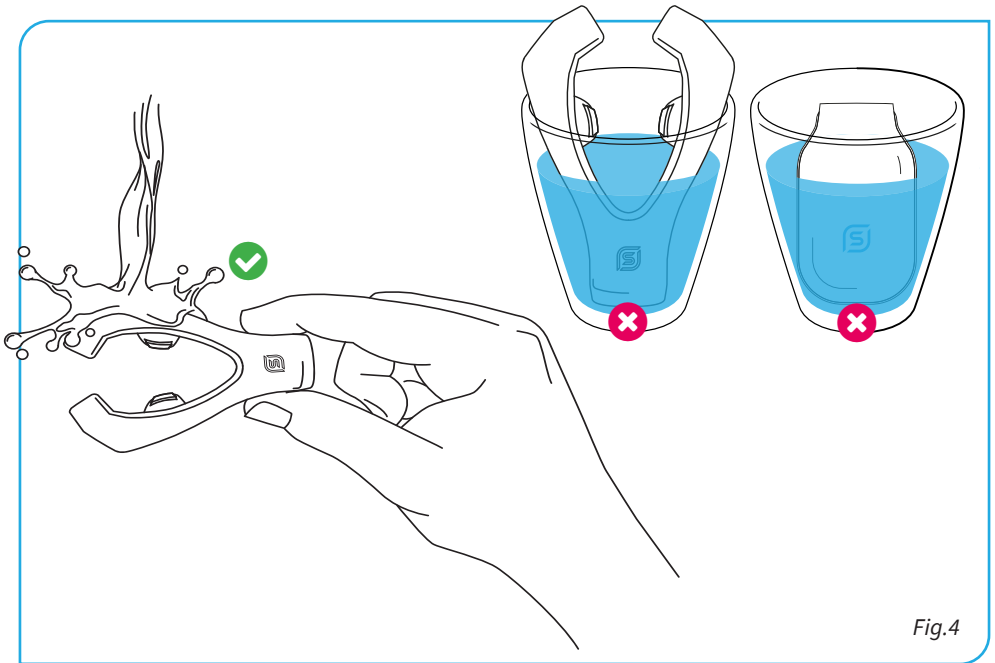
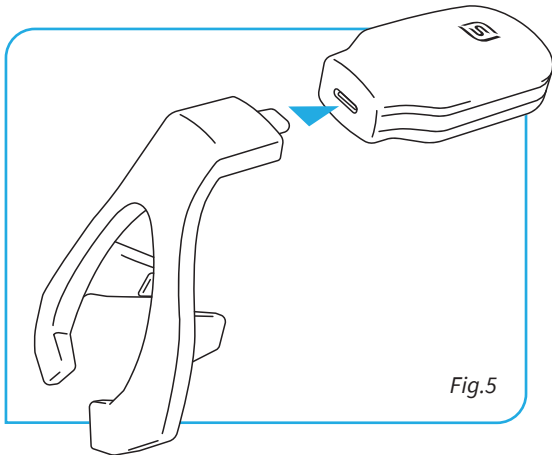


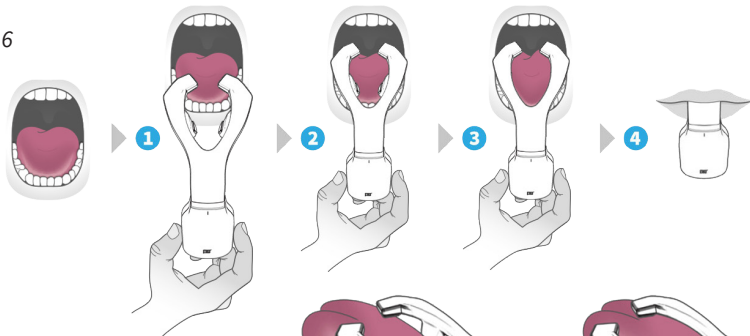
Fig.4



To start using eXciteOSA[®], connect the Mouthpiece with the Control Unit as shown on Fig 5.

Fig.5

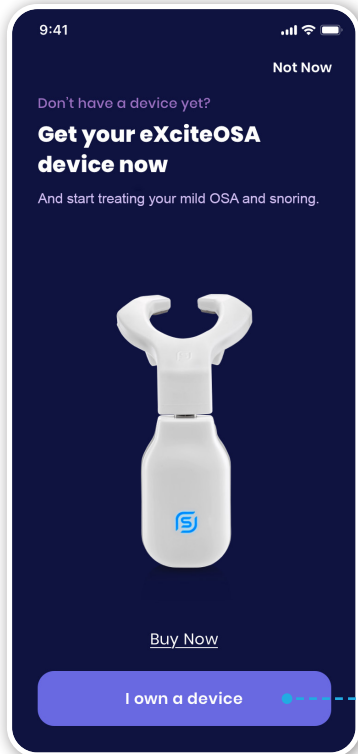
Figure 6



Insert the Mouthpiece into the mouth and allow it to sit around the tongue as shown in Fig 6. and gently close your mouth. Avoid grinding or clenching the Mouthpiece.

My eXciteOSA® phone application

My eXciteOSA® is the place where you can start your eXciteOSA® therapy or add your device.



Add a eXciteOSA® device
(make sure that the device is nearby)

This screen will appear if you haven't already added a device.

In order for the eXciteOSA® 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 controller to the mouthpiece, insert the mouthpiece into the mouth.

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 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 arrow buttons on the app.

	THERAPY LEVEL RANGES					
POTENTIAL THERAPY LEVEL PATHS	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
FOR A LOWER TOLERANCE PATIENT	1 TO 3	3 TO 4	4 TO 5	4 TO 5	5 TO 6	6 TO 7
FOR A MEDIUM TOLERANCE PATIENT	3 TO 5	6 TO 8	9 TO 10	11 TO 12	11 TO 12	12 TO 13
FOR A HIGHER TOLERANCE PATIENT	4 TO 7	8 TO 9	10 TO 12	13 TO 14	14 TO 15	14 TO 15



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 your patient.



CONNECT

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

APPLICATION DURING A THERAPY SESSION

Indicates if the device is connected to the phone

Indicates the device battery status

Indicates the remaining time of the therapy

Pauses the therapy

Stops the therapy

Controlling your therapy level

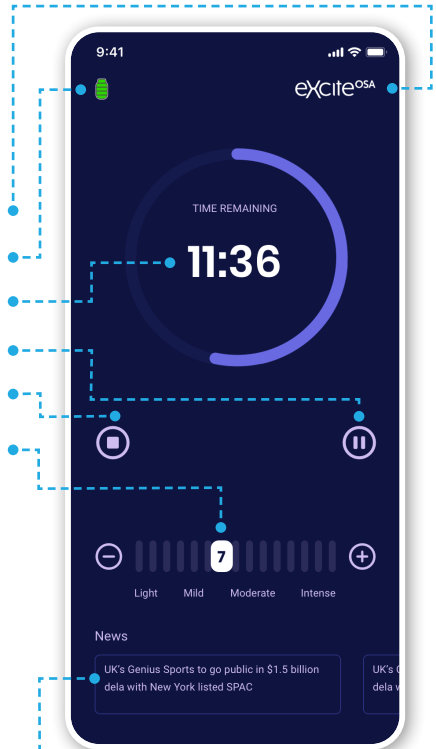
To change your therapy level, simply slide the level setting at the bottom of your screen during your session.

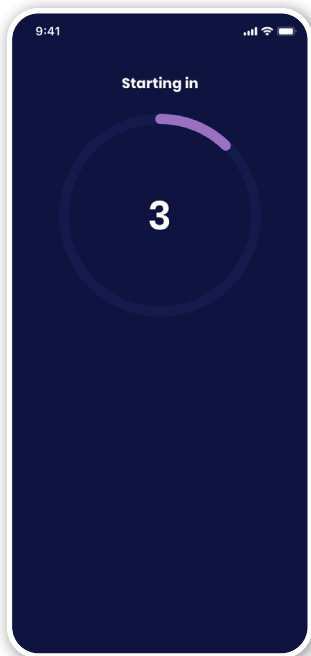
It is important to set the device to the highest possible therapy level that still feels comfortable for you. This will ensure the best possible outcome.

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.

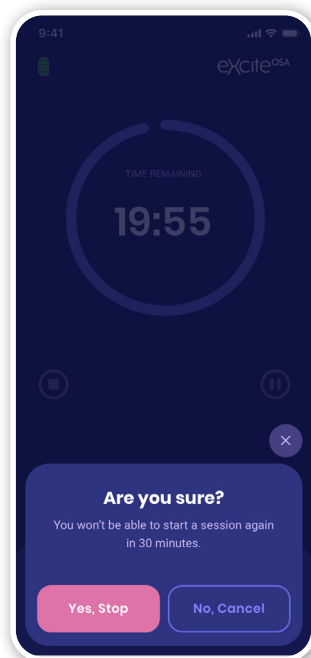
Reading mode/Newsletter





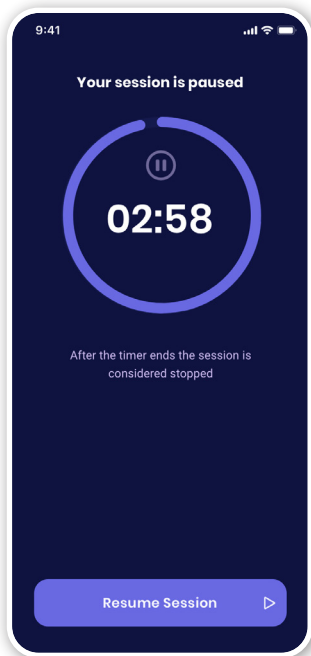
COUNTDOWN

After pairing your eXciteOSA® device with your mobile phone, your therapy will start with a countdown from 3 to 1 before initiating the actual therapy.



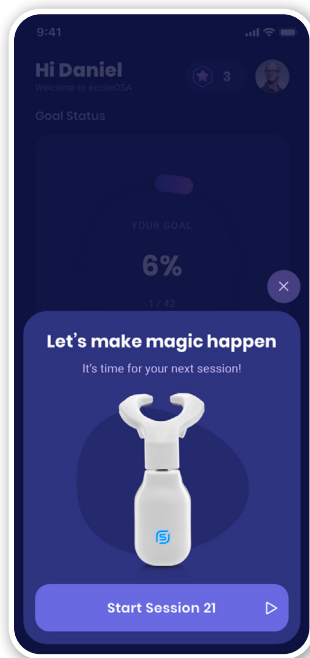
STOP THERAPY

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.



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. 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.

Frequency of usage

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 mild OSA or snoring. After 6 weeks of therapy, only two, 20-minute sessions are required each week thereafter. eXciteOSA® can be used long term. This is comparable to maintaining your physical fitness by undertaking regular exercise.

You must 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 amber if there is inadequate charge to run a full 20 minute therapy session. When Control Unit logo (Fig 8) blinks blue and amber, recharge the Control Unit. To charge the Control Unit, use the USB Cable provided and connect the Control Unit jack into a USB power adapter. During charging, the eXciteOSA® logo will blink. When fully charged, the eXciteOSA® logo will become continuous blue.

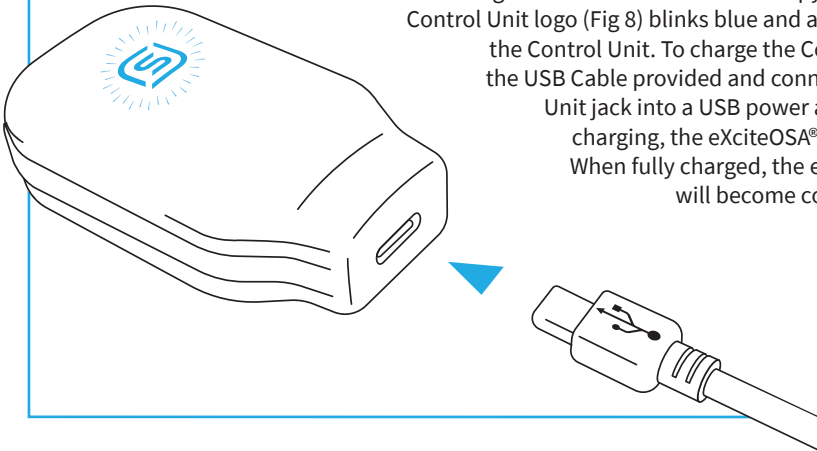


Fig.8

Storing & traveling with your eXciteOSA®

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 removal 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 eXciteOSA®, place each unit in its original packaging to protect during transportation.

Washing

MOUTHPIECE

The Mouthpiece should be washed before and after each use. 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

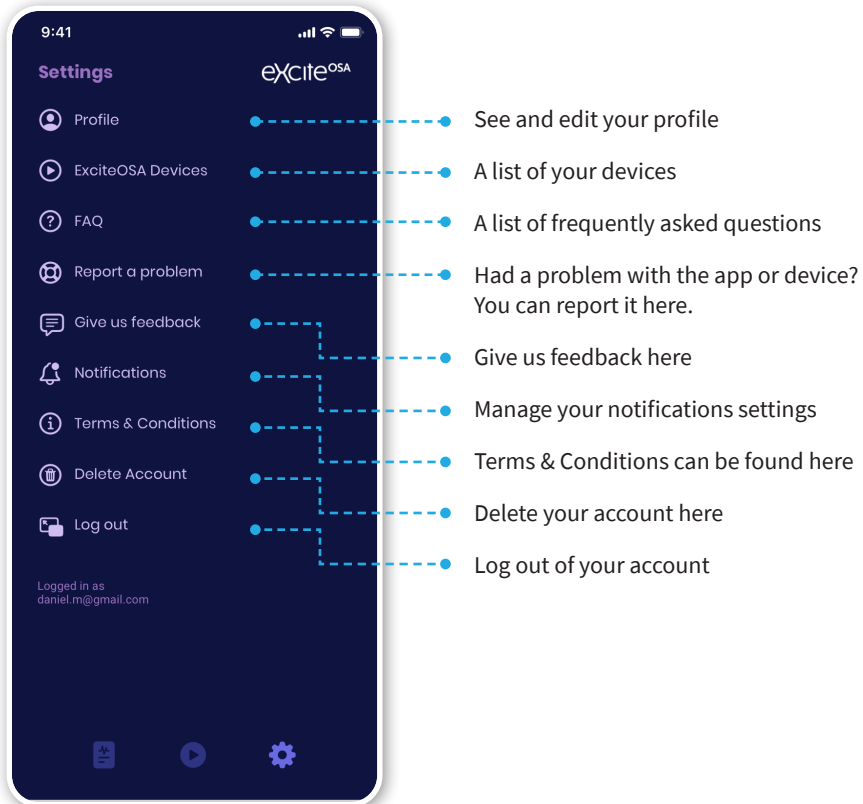
Wipe the Control Unit surface with a damp cloth or antiseptic wipe once a week. **DO NOT** immerse the Control Unit in water or cleaning solutions. Always store the Control Unit in a dry place.

Software Updates

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

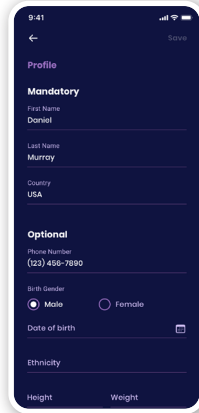
Settings

Manage all of your settings from a single place.



SEE/EDIT PROFILE

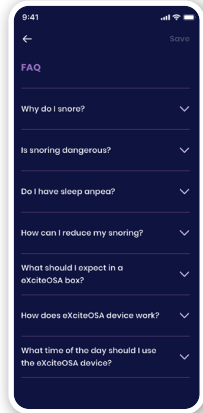
Change any of the data already provided and then tap 'Save', to save your changes.



A screenshot of the 'Profile' page in a mobile app. The page is titled 'Profile' and has a 'Save' button in the top right corner. It is divided into two sections: 'Mandatory' and 'Optional'. Under 'Mandatory', there are fields for 'First Name' (Daniel), 'Last Name' (Murray), and 'Country' (USA). Under 'Optional', there are fields for 'Phone Number' ((223) 456-7890), 'Birth Gender' (with radio buttons for 'Male' and 'Female'), 'Date of birth', 'Ethnicity', 'Height', and 'Weight'.

FAQ

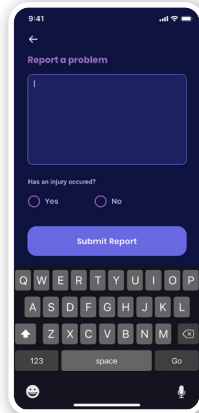
Check the Frequented Asked Questions for further information.



A screenshot of the 'FAQ' page in a mobile app. The page is titled 'FAQ' and has a 'Save' button in the top right corner. It lists several frequently asked questions, each with a downward arrow indicating it can be expanded: '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?', and 'What time of the day should I use the eXciteOSA device?'.

REPORT A PROBLEM

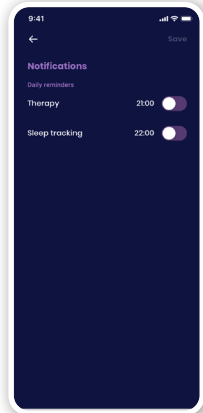
Did anything go wrong with the app or the device? Describe the problem and let us know. We'll try to solve it and take the appropriate measures.



A screenshot of the 'Report a problem' page in a mobile app. The page is titled 'Report a problem' and has a 'Save' button in the top right corner. It features a large text input field for describing the problem. Below the input field, there are radio buttons for 'Yes' and 'No' under the heading 'Has an injury occurred?'. A blue 'Submit Report' button is located below the radio buttons. At the bottom of the screen, a keyboard is visible.

NOTIFICATIONS

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



A screenshot of the 'Notifications' page in a mobile app. The page is titled 'Notifications' and has a 'Save' button in the top right corner. It lists two notification settings: 'Daily reminders' with a time of 21:00 and a toggle switch, and 'Sleep tracking' with a time of 22:00 and a toggle switch.

Frequently asked questions

How does the eXciteOSA® device work?

The eXciteOSA device will deliver small electric currents 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 eXciteOSA® 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 eXciteOSA® 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.

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

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 eXciteOSA®?

You should notice an improvement in your snoring within 4 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.

How long will I use eXciteOSA®?

Therapy sessions are 20 minutes long, are completed 1 time each day, for 6 weeks. A minimum of two 20-minute sessions are required each week thereafter. Failure to complete the therapy sessions following the 6-week period may result in a return of your mild obstructive sleep apnea and/or snoring symptoms. Consistency is key!

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 eXciteOSA®'s 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 eXciteOSA 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 eXciteOSA 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 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>).

eXciteOSA[®] 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.

eXciteOSA[®] system, transport and storage requirements

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

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

eXciteOSA® should be used in accordance with this User Guide 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 eXciteOSA®, 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 3 months 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 3 months 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 eXciteOSA® directly to the local eXciteOSA® contact or Signifier Medical Technologies LLC. eXciteOSA® 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.

Symbols used



Refer to instructions manual



Storage Temperature Limits



Catalogue number



Keep dry



Serial number



Non Sterile



Manufacturer



Type BF applied part



Date of manufacture

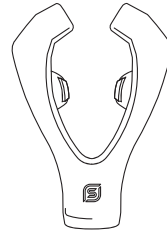


WEE directive



USB C

Specifications



	Control Unit	Mouthpiece
Color	White and Blue	White and Grey
Packaging	eXciteOSA is packed in a protective box package	
Power source	Rechargeable 100mAh LiPo cell	N/A
Max output voltage	32.4 V Output varies with impedance (see Table A on page 37)	
Max output current	70mA Output varies with impedance (see Table A on page 37)	
Output signal	100us/phase (Bi-Phasic output) Up to 20 Hz	
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 20% to 85%	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)	
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) / EN 60601-1-2:2015 (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	<table border="0"> <tr> <td>385 MHz</td> <td>27 V/m</td> </tr> <tr> <td>450 MHz</td> <td>28 V/m</td> </tr> <tr> <td>710, 745, 780 MHz</td> <td>9 V/m</td> </tr> <tr> <td>810, 870, 930 MHz</td> <td>28 V/m</td> </tr> <tr> <td>1720, 1845, 1970, 2450 MHz</td> <td>28 V/m</td> </tr> <tr> <td>5240, 5500, 5785 MHz</td> <td>9 V/m</td> </tr> </table>	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
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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	<table border="0"> <tr> <td>100 % reduction for Half Cycle</td> </tr> <tr> <td>30 % reduction for 25/30 Cycles</td> </tr> <tr> <td>100 % reduction for 1 Cycle</td> </tr> <tr> <td>>95 % reduction for 250/300 Cycles</td> </tr> </table>	100 % reduction for Half Cycle	30 % reduction for 25/30 Cycles	100 % reduction for 1 Cycle	>95 % reduction for 250/300 Cycles								
100 % reduction for Half Cycle															
30 % reduction for 25/30 Cycles															
100 % reduction for 1 Cycle															
>95 % reduction for 250/300 Cycles															

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 eXciteOSA® System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If the eXciteOSA® 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.

Signifier Medical Technologies LLC

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Distributed in the USA by

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

Table A: Representative output with varying loads

Mouthpiece load	900 Ohm		500 Ohm		338 Ohm	
Therapy level	Measured Voltage (V)	Calculated current (mA)	Measured Voltage (V)	Calculated current (mA)	Measured Voltage (V)	Calculated current (mA)
1	2.21	2.46	1.67	3.34	1.34	3.96
2	4.6	5.11	3.46	6.92	2.59	7.66
3	6.7	7.44	5.31	10.62	3.74	11.07
4	8.06	8.96	6.91	13.82	5.6	16.57
5	10.9	12.11	9.1	18.2	6.6	19.53
6	12.6	14	10.7	21.4	7.8	23.08
7	14.7	16.33	12.3	24.6	9.1	26.92
8	17.3	19.22	14.1	28.2	10.4	30.77
9	19.5	21.67	17.9	35.8	11.4	33.73
10	21.4	23.78	20.2	40.4	12.5	36.98
11	23.4	26	21.8	43.6	13.8	40.83
12	25.3	28.11	23.7	47.4	15.2	44.97
13	27.2	30.22	25	50	16.5	48.82
14	28.8	32	26.6	53.2	17.3	51.18
15	29.8	33.11	28.5	57	19.8	58.58



Signifier

MEDICAL TECHNOLOGIES



1282

Instructions for Use North America

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