

Snoozeal User Guide



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

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IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE USE. (for latest User Guide, please refer to <https://snoozeal.com/product/>)

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 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.
- This product contains no user serviceable parts. Refer to “Warranty” and “Trouble Shooting” if appliance no longer works as expected.
- The device is only to be used as specified in this document.

IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE USE.

WARNINGS

To avoid the risk of physical injury:

- This device should not be used by persons:
 - children (under 18 years of age)
- Snoozeal should be kept away from children and pets (choking hazard and electrical hazard).
- Snoozeal to be used in home healthcare environment (or equivalent).
- Snoozeal is a single person device and should not be shared or used by other individuals.
- Do not use Snoozeal 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 silicon on the Mouthpiece must be intact before use. If there is any breach of the silicon (including electrodes) - **DO NOT USE THE MOUTHPIECE.**

IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE USE.

CONTRAINDICATIONS

Do not Use Snoozeal if:

- you are pregnant or maybe pregnant
- you have a pace maker or implanted electrodes
- you have temporary or permanent implants, dental braces or jewellery in your mouth.
- you are suffering from mouth ulceration
- having or suspecting of having obstructive sleep apnoea with AHI greater than 15.

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.
- you experience pain, numbness or bleeding after using this product.
- you have any medical concerns.

This device should not be used:

- while asleep (device 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.

Adverse Reactions:

- excessive salivation
- tingling sensation on tongue

WHAT'S IN THE BOX

SNOOZEAL PACKAGE INCLUDES:

1. MOUTHPIECE (TOP VIEW)

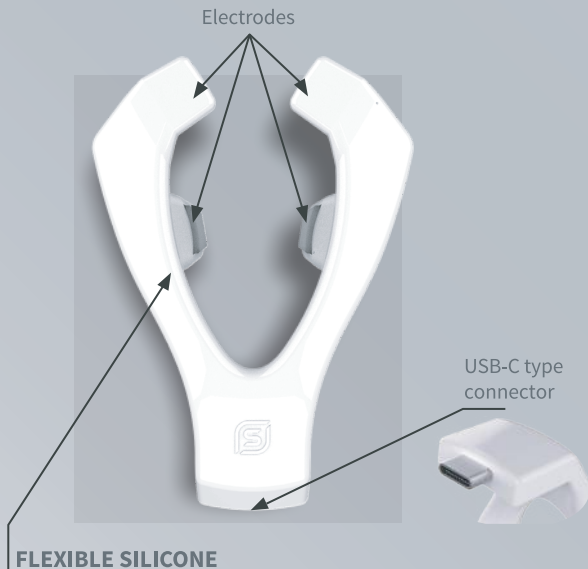


Fig 1.

2. CONTROL UNIT (WITH BLUETOOTH)

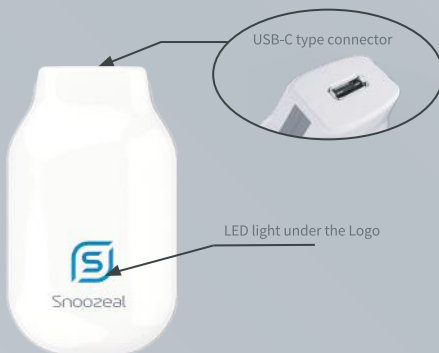


Fig 2.

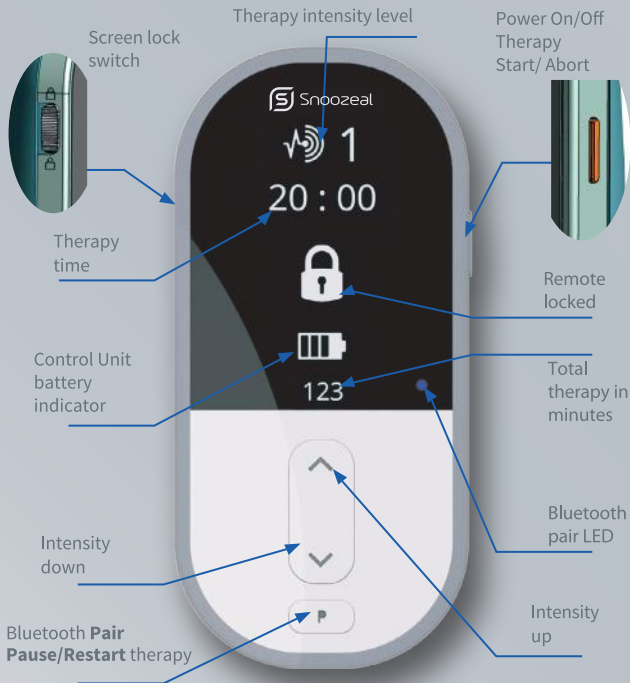
3. USB CABLE (15 CM CABLE, CONNECT TO APPROPRIATELY APPROVED ADAPTER WITH 5 VDC, MIN 0.5AMP OUTPUT)



Fig 3.

4. REMOTE CONTROL (IF INCLUDED IN YOUR BOX)

If Remote Control is included in your box, please refer to Appendix A (page 37) for additional instructions.



FCC ID:2AVCE5060627480031

Fig 4.

INTENDED USE

Snoozeal is intended for the reduction of snoring and obstructive sleep apnoea by strengthening tongue muscles via electrical muscle stimulation.

INDICATIONS FOR USE:

Snoozeal is indicated for use to reduce snoring and mild sleep apnoea (AHI ≤ 15) for patients that are 18 years or older.

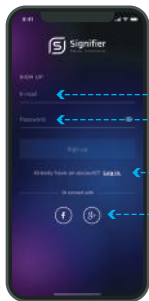
Snoozeal device can be controlled by Snoozeal Smartphone application or by a Remote Control (if one is included in your box).

Smartphone application can be downloaded from App Store (Apple iOS) or Play Store (Google Android). For using Snoozeal with the Remote Control, refer to Appendix A on page 37.



SNOOZEAL PHONE APPLICATION: 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 login here
- You can sign up with one of these services (this will require authentication on the appropriate external service)

PROFILE SETUP

Enter your full name

Enter your country of residence

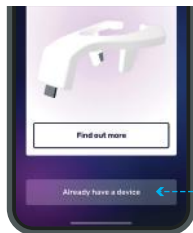
Select your gender

Select your date of birth

Enter your ethnicity, height and weight*

* This data helps us give you more accurate sleep tracking results and better Snoozeal treatment options.

* Your data is always safe with us. You can check our privacy policy for further details.



Select whether you already have a Snoozeal device or not.

If you choose yes, additional setup is required.

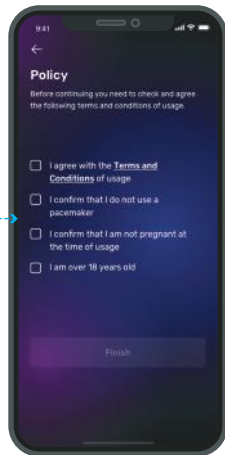
Policy (only for using the app with a Snoozeal device)

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

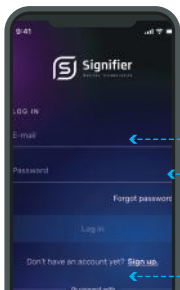
First, make sure you read the Terms and Conditions page, and agree with them.

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 Snoozeal device can interfere with your pacemaker or with your baby's development.**

Also, you have to be a legal adult.



LOG IN



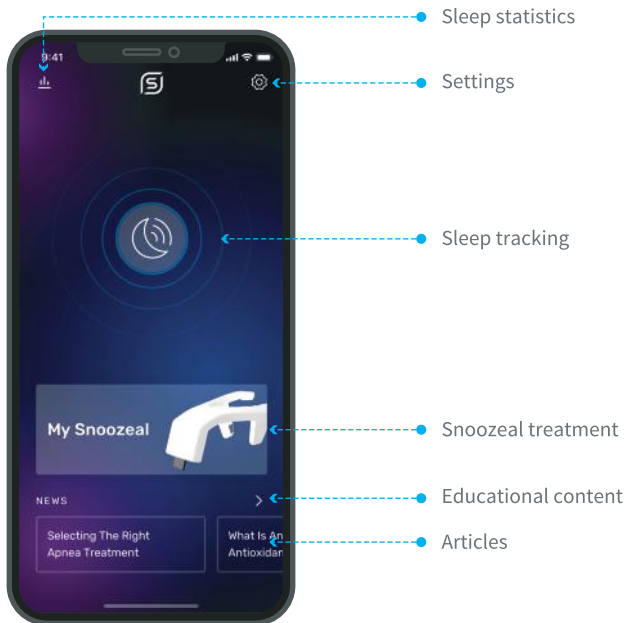
Enter your registered e-mail and password

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)

DASHBOARD

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



USING YOUR SNOOZEAL WITH A SMARTPHONE APPLICATION

Before starting your treatment be sure to: check the silicon 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.**

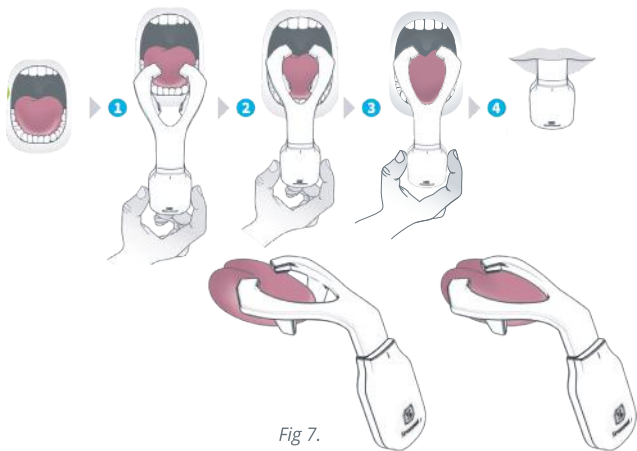
Before use, wash the Mouthpiece with cold and running potable tap water as shown in *Fig 5*. Avoid water reaching the USB port. Dry with clean towel.

To start using Snoozeal, connect the Mouthpiece with the Control Unit as shown on *Fig 6*.





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



MY SNOOZEAL PHONE APPLICATION

My Snoozeal is the place where you can start your Snoozeal treatment or add your device.



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

In order for the Snoozeal device to work, you need to allow Bluetooth connection.

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

Before starting your treatment be sure to: check your device for cracks or broken parts, connect the controller to the mouthpiece, insert the mouthpiece into the mouth.

Add a Snoozeal device
(make sure that the device is nearby)

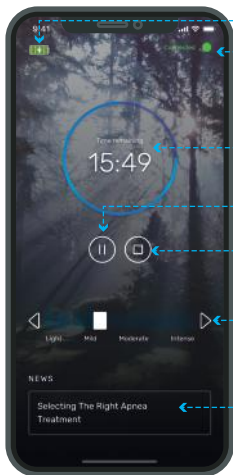


CONNECT



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.

REMOTE CONTROL



Indicates the device battery status

Indicates if the device is connected to the phone.

Indicates the remaining time of the treatment

Pauses the treatment

Stops the treatment

Treatment intensity controller (you can choose between 15 levels; please wait a couple of seconds before the new setting takes effect)

Reading mode/Newsletter

COUNTDOWN

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



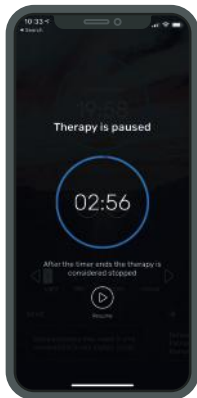
STOP TREATMENT

Treatment 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 treatment has ended. Keep this in mind when stopping the treatment.



PAUSE TREATMENT

Treatment can be paused at any time. It can be paused only for 3 minutes. After the 3 minutes have passed the treatment 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 treatment.



END OF THERAPY SESSION

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

FREQUENCY OF USAGE

It is recommended you use Snoozeal once daily for a continuous 20 minutes. It can take up to 6 weeks of daily therapy before you will gain the desired improvement in your snoring. Once the desired results are achieved, it is recommended to have a once a week regular maintenance regime. Snoozeal can be used long term. This is comparable to maintaining your physical fitness by undertaking regular exercise. You are recommended to replace the Mouthpiece after **three months** of first use.

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 Snoozeal logo will blink. When fully charged, the Snoozeal logo will become continuous blue.



Fig 8.

STORING & TRAVELLING WITH YOUR SNOOZEAL

MOUTHPIECE

Once the Mouthpiece has been washed in clean 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 regular stand for the Mouthpiece.

CONTROL UNIT

The Control Unit and the Remote 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 Snoozeal, 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 (*Fig 5*). 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 your box included a Remote Control)

Wipe the Remote Control Unit 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 Control Unit, always store the Remote Control in a dry place.

SOFTWARE UPDATES

The app will notify you of the need to download any software updates. Please follow the instruction on the app.

SLEEP TRACKING

The sleep tracking feature allows the user to record his sleep and get advanced details about his sleeping patterns and snoring habits.

In order for the sleep tracking to work, you need to allow access to Microphone.

FACTORS

Before you start recording, you can choose a few factors that apply to you as these may influence the quality of your sleep.



SLEEP TRACKING

Once sleep tracking starts you don't have to do anything more. Simply place your phone close to your head.

Swipe to stop
the recording



SLEEP TRACKING STATISTICS

After the sleep tracking stops, you will have the ability to see statistics regarding your snoring activity during your sleep.



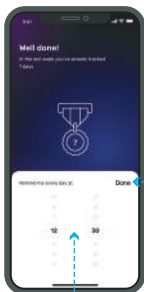
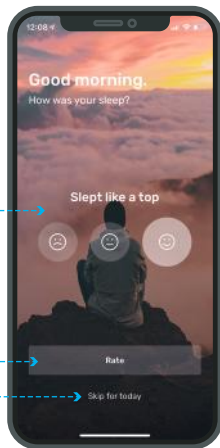
RATE YOUR SLEEP

Giving a subjective rating to your sleep helps you track your sleep quality in the long run. And, eventually, point out connections between factors, snoring levels and perceived sleep quality.

Choose your mood

Confirm your choice

If you don't want to track your mood, you can skip this step



Set up reminder

Select time

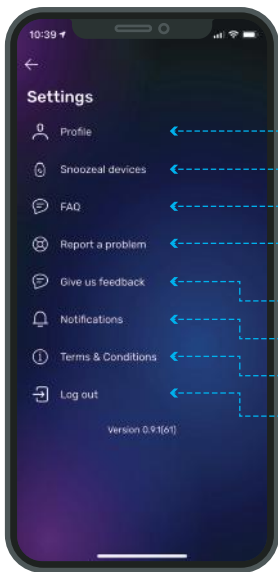
Tap 'Done'

SET UP REMINDER

In order to see a better overview of your sleep patterns over time, it is important to track your sleep in a regularly. Therefore you can set up a daily reminder, at the time of you choice.

SETTINGS

Manage all of your settings from a single place.



See and edit your profile

A list of your devices

A list of frequently asked questions

Had a problem with the app or device?
You can report it here.

Feedback make us improve the product

Manage your notifications settings

All legal matters can be found here

Log out of your account

SEE/EDIT PROFILE

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



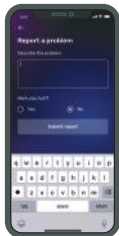
FAQ

Check the Frequented Asked Questions to see answers for your problems.



REPORT A PROBLEM

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



NOTIFICATIONS

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



FREQUENTLY ASKED QUESTIONS

Why do I snore?

Snoring is caused by vibration of the structures of the throat during sleep. When you sleep, the muscles of the throat relax and partially collapse. The narrowest parts of the throat can then create turbulence of the air flowing through your throat which makes the snoring sound

You're more likely to snore if you:

- are overweight
- smoke
- drink too much alcohol
- sleep on your back

Is snoring dangerous?

It has been shown that Snoring affects sleep quality of the snorer and partner. It is important to note that snoring may just be the tip of the iceberg. Although snoring per say does not damage your health, Snoring can be a clue to a more serious condition called obstructive sleep apnoea (intermittent complete blockage of breathing during sleep).

FREQUENTLY ASKED QUESTIONS

Do I have sleep apnoea?

Sleep apnoea is a serious health condition associated with health problems like high blood pressure and increased risks of heart attack, stroke, or death. It is often associated with day time sleepiness and your partner may notice you breath hold or stop breathing in the night.

If you have these symptoms or are concerned you may have the condition, please refer to your doctor.

How does Snoozeal device work?

The Snoozeal device will deliver small electric currents through the Mouthpiece to your tongue, this will stimulate the tongue muscle and improve its tone. The improved tone of the tongue muscle will help in keeping the breathing passage open during your sleep and reduce the vibration of the throat region.

How soon do I see the result with Snoozeal?

You should notice an improvement in your snoring within 4 weeks. This is dependent upon adherence to the recommended therapy programme 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.

FREQUENTLY ASKED QUESTIONS

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

The intensity always starts at level 1; it is recommended that you increase the intensity to a level that is comfortable for you for each therapy session. The therapy changes frequencies at 5 minute intervals. At these intervals the stimulation will automatically drop in intensity for comfort. If you feel any discomfort or lack of stimulation, then the intensity can be reduced or increased accordingly.

Over the duration of the recommended therapy programme you will notice that your tolerance levels will increase, and you can go up in intensity comfortably. It is important to avoid increasing the intensity to beyond comfortable level, as higher intensity will not lead to additional improvement.

What should I expect during and after my treatment?

During the therapy you should experience a tingling sensation on the tongue and tongue muscle contractions. As the intensity is increased the muscle contraction will get stronger. Please remember to set the intensity at a level that is comfortable for you. Increasing the intensity beyond comfortable level will not improve the outcome of the therapy session. It may become an uncomfortable sensation.

What time of the day should I use the Snoozeal device?

The Snoozeal can be used anytime during the day, but it is recommended to be used before you go to sleep at night

TROUBLE SHOOTING

1. 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 Remote Control 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 damage to the mini USB connector
- Check there is no damage to the Mouthpiece
- If the above steps have been implemented, then contact the Snoozeal's Help/Support team

2. 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 damage to the Control Unit or Remote Control
- If the above steps have been implemented, then contact the Snoozeal's Help/Support team

SNOOZEAL SYSTEM, OPERATIONAL REQUIREMENTS

Temperature + +50°F to +104°F (+10°C to +40°C)

Humidity 20% to 85%

Atmospheric Pressure 10.15 psi to 15.37 psi (70 kPa to 106 kPa)

Operational life is 3 years.

SNOOZEAL SYSTEM, TRANSPORT AND STORAGE REQUIREMENTS

23 °F to + 140°F (-5°C to +60°C)

Up to 85%

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

Please return the products to your supplier for disposal. The Control Unit contains a rechargeable battery and should not be disposed in general waste.

FAULTS & REPAIRS

Snoozeal should be used in accordance with the User Guide above and with the approved accessories and contains no user serviceable parts. Do not try to repair, alter or change the components of the three individual units of the Snoozeal, as this will invalidate your warranty. If the Mouthpiece, Remote Control or Control Unit is not functional due to wear and tear, it will not be covered by the warranty. The Mouthpiece is recommended to be replaced after 3 months of first use.

WARRANTY

Signifier Medical Technologies Ltd. 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 and Remote Control only) from the date of purchase. For valid warranty claims, the user may return after authorization, the Signifier Medical Technologies directly to the local Snoozeal contact or Signifier Medical Technologies Ltd.. Snoozeal warranty does not include any misuse or abuse such as dropping or immersing the Control Unit and 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 contact your local Signifier Medical Technologies contact for any warranty returns. 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



Catalogue number



Serial number



Manufacturer



Date of manufacture



Storage Temperature Limits



Keep dry



Non Sterile



Type BF applied part



WEEE directive

SPECIFICATIONS

	Control Unit		Mouthpiece	Remote Control (if your box included a Remote Control)
Color	White and Blue		White and Grey	White, Grey and Black
Packaging	Snoozeal is packed in a protective box package			
Power source	Rechargeable 90mAh LiPo cell			Non-rechargeable AAA Alkaline batteries
Max output voltage	32.4 V Output varies with impedance (see Table A on page 49)			
Max output current	70mA Output varies with impedance (see Table A on page 49)			
Output signal	100us/phase (Bi-Phasic output) Up to 20 Hz			
Operating temperature	From +50°F to +104°F (+10°C to +40°C)			
Transport and Storage temperature	23°F to +140°F (-5°C to +60°C)			
Atmospheric Pressure Range	10.15 psi to 15.37 psi (70 kPa to 106 kPa)			
Humidity	Relative Humidity for Control Unit and Remote Control 20% to 85% Relative Humidity for Mouthpiece up to 100%			
Degree of Protection	Control Unit (IP44 when connected to mouthpiece) – and Remote Control (IP42) (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	Remote
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	
		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

WARNING:

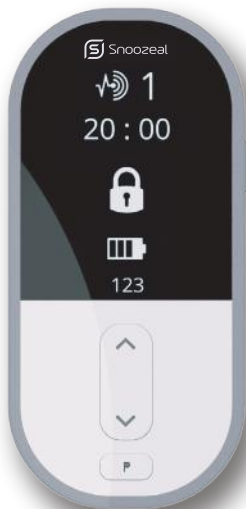
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables 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 Snoozeal System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

IF the Snoozeal 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.

APPENDIX A

REMOTE CONTROL INSTRUCTIONS

(if your box included a Remote Control)



INTENDED USE

INDICATIONS FOR USE: Snoozeal is indicated for use to reduce snoring and mild sleep apnoea (AHI ≤ 15) for patients that are 18 years or older.

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. Ensure new AAA batteries are placed within the battery compartment in the Remote Control.
3. You will need to Bluetooth pair your Control Unit with the Remote Control before starting.
 - Connect the Mouthpiece to the fully charged Control Unit.
 - Press the Power on/off button on Remote Control.
 - Press the  and  arrow on the Remote Control simultaneously for three seconds.
 - The blue LED on the Remote Control and the Snoozeal logo on the Control Unit will start to blink, to indicate Bluetooth pairing process.
4. The Remote Control display will show one or more Control Units (*Fig 9*). (Bluetooth identity can be located as the characters following the "BT ID:" on the packaging)
5. Once the correct Control Unit is highlighted, press the 'P' button on the remote to request pairing with the selected Control Unit.
6. On successful Bluetooth pairing, the blue LED on the remote and Control Unit will blink once every 5 seconds and the remote will display the Bluetooth paired status (*Fig 10*). If the Bluetooth pairing status is not shown on the remote, then please refer to the troubleshooting section below.



Fig 9.



Fig 10.

USING YOUR SNOOZEAL WITH A REMOTE CONTROL

Note: for directions on using the mobile application, iOS and Android, please refer to the App User Guide.

1. Check the silicon 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.**
2. Wash the Mouthpiece only with cold and running potable tap water as shown in Fig 12.
Avoid water reaching the USB port. Dry with clean towel.
(Follow instruction on washing)
3. Connect the Control Unit and Mouthpiece as shown in Fig 13.
4. Ensure your Control Unit is fully charged or holds enough charge for a complete 20 minute therapy. The Control Unit battery status can be checked on the paired Remote Control display (Fig 4). The battery image outline will flash if control unit battery is low (Fig 11).

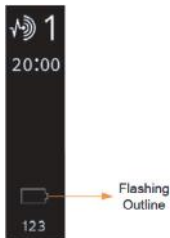


Fig 11.

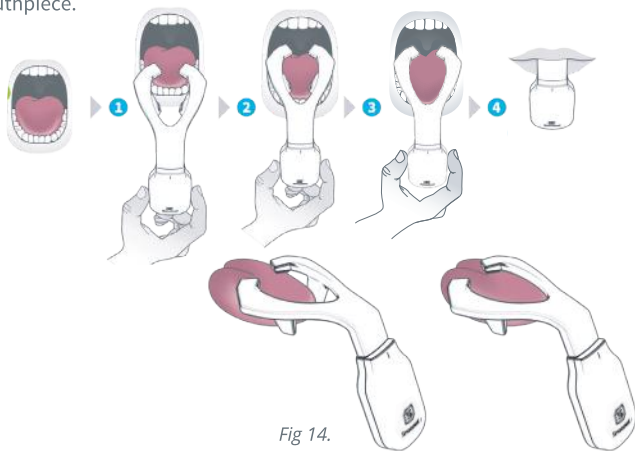
The Control Unit LED will Flash red and blue if there is inadequate charge to run a full 20 minute therapy session.

Fig 12.





5. Insert the Mouthpiece into the mouth and allow it to sit around the tongue as shown in Fig 14. and gently close your mouth. Avoid grinding or clenching the Mouthpiece.



USING YOUR SNOOZEAL

6. Power on the Remote Control through the Power on/off button, the remote will pair automatically with Control Unit as shown in *Fig 15*. (If Bluetooth pairing has been completed - see "Before first use" page 38).
7. To start therapy, press the Power on/off button, the therapy will start at the lowest intensity (intensity 1).
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.



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.

Use the ▼ button to reduce the intensity if the stimulation becomes uncomfortable, or remove Mouthpiece from mouth.

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

11. Pause therapy - Press P button to pause.
Restart therapy - Press P button again to restart.
If the therapy is paused for more than 3 minutes, it will terminate session.
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 on/off button for three seconds.
15. Store the Control Unit and Remote Control in a dry place. Wash the Mouthpiece (*Follow instruction on washing*).

FREQUENCY OF USAGE

It is recommended you use Snoozeal once daily for a continuous 20 minutes.

It can take up to 6 weeks of daily therapy before you will gain the desired improvement in your snoring.

Once the desired results are achieved, it is recommended to have a once a week regular maintenance regime.

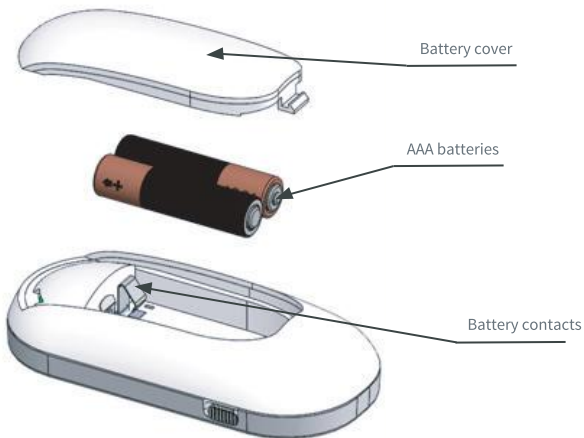
Snoozeal can be used long term. This is comparable to maintaining your physical fitness by undertaking regular exercise.

You are recommended to replace the Mouthpiece **three months** after first use.

REPLACING BATTERIES ON THE REMOTE

REMOTE CONTROL

1. Replace both batteries with new ones when the symbol  is displayed on the Remote Control.
2. Open the battery compartment cover on the underside of the remote.
3. Install two new AAA size alkaline batteries with the positive (+) and negative (-) terminals properly aligned with the corresponding symbols in the battery compartment (do not replace batteries during a therapy session).
4. Close the battery compartment cover.





Caution

- Install each battery with the positive (+) and negative (-) terminals properly aligned with the corresponding symbols in the battery compartment.
- 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).

STORING & TRAVELLING WITH YOUR SNOOZEAL

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 removal stand which can be used for storage or regular stand for the Mouthpiece.

CONTROL UNIT

The Control Unit and the Remote 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 Snoozeal, place each unit in its original packaging to protect during transportation.

ERROR CODES

The Snoozeal 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 in the event of persistent error codes.

Icon	Functionality	Comment
No paired icon: 	Bluetooth	Pairing: No device found to pair. Use Pairing instruction in this IFU
User presented with General Error Icon and a number 11x or 22x: ERR 123 Controller: 111 112 113 114 115 116 Remote: 211 212 213 214		Here is a list of things that can be done that will help to fix the issues: 1 Ensure there are no battery low warnings and replace batteries if required 2 Ensure the controller in within 1 metre of the remote, power off remote, wait 10 secs, repower the remote and attempt to pair 3 Connect the controller to the charger, have controller within 3.4 feet (1 meter) of remote, turn off remote, wait 10 sec, repower and attempt to pair IF the above trouble shooting does not fix the error, then please contact Signifier Medical Technologies directly.

Icon	Functionality	Comment
142 152	Battery	1. Connect the controller to the charger 2. Ensure controller is within 3.4 feet (1 meter) of remote 3. Turn on remote and wait for 10 seconds 4. Repower and attempt to pair
161 221	Firmware Upgrade	1. Do not connect the controller to the charger 2. Have controller within 3.4 feet (1 meter) of mobile app device 3. Turn off remote and wait 10 sec 4. Repower and re-pair to the app and start the upgrade again 5. IF the above trouble shooting does not fix the error, then please contact Signifier Medical Technologies
User presented with Hazard Icon and a number :  121 122 131 141 251	Usage	Do not use the product and contact Signifier Medical Technologies
User presented with General Error Icon and three digit number not stated above	Other fail-safe errors	Any code not mentioned above and with a General Error Icon contact Signifier Medical Technologies for advice

DECLARATIONS

FOR USA

FCC warning statement:

This device complies with Part 15 of the FCC Rules.

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

FOR CANADA

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

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

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

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This product is Manufactured by Signifier Medical Technologies

in compliance with Medical Device Standards and

Quality Standards: ISO 13485:2016

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	0.3	0.6	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



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