SOMNICS

Sleep well. Wherever you are.

iNAP ® One
Sleep Therapy System

INSTRUCTIONS FOR USE

Model: R07-A

IFU-134 ver.01
Released: Aug. 28, 2023

This user guide contains instructions for using the iNAP® One Sleep Therapy System.
Read all Instructions for Use before using the system.

Table of Contents

1	INTRODUCTION	3
1.1	Description of iNAP One Sleep Therapy System	3
1.2	Indications for Use	3
1.3	Contraindications	4
1.4	iNAP One Sleep Therapy System Components	4
1.4.1	Console	5
1.4.2	Saliva Container	6
1.4.3	Tubing Set	6
1.4.4	ral Interface	7
1.5	iNAP One Sleep Therapy System Console Icons	8
2	BEFORE USING THE INAP ONE SLEEP THERAPY SYSTEM	10
2.1	Important Safety Notes	10
2.1.1	Warnings (Possible Health Risks)	10
2.1.2	Warnings	12
2.1.3	Cautions	14
2.1.4	Precautions	15
3	PREPARING FOR USE INAP ONE SLEEP THERAPY SYSTEM	16
3.1	Check the Battery Status	16
3.2	Charge the System	16
3.3	Installation of DryPad	17
3.4	Connect the Oral Interface	20

3.5	Wearing the Oral Interface	22
3.6	iNAP Muffler	24
4	OPERATING INSTRUCTIONS	25
4.1	Starting the Treatment of the iNAP One Sleep Therapy System	25
4.2	Getting Used to the Treatment of the iNAP One Sleep Therapy System	27
4.3	Stop the Treatment of the iNAP One Sleep Therapy System	28
4.4	Bluetooth and App Setup Procedures	29
5	CLEANING, MAINTENANCE AND STORAGE	30
5.1	Cleaning	30
5.1.1	Disconnect the Tubing Set and the Container	30
5.1.2	Discard the DryPad	30
5.1.3	Clean the Container, the Oral Interface and the Tubing Set	31
5.1.4	Clean the Console	34
5.2	Weekly Cleaning	34
5.3	Maintenance	36
5.4	Disposal	36
6	TROUBLESHOOTING	37
7	SYSTEM SPECIFICATIONS	42
8	GUIDANCE AND MANUFACTURER'S DECLARATION REGARDING ELECTROMAGNETIC COMPATIBILITY	44
9	CLINICAL DATA	57
10	SYMBOL	59
11	LIMITED WARRANTY	61

1 INTRODUCTION

1.1 Description of iNAP One Sleep Therapy System

iNAP One Sleep Therapy System is designed to treat obstructive sleep apnea (OSA) in adults. When using iNAP One Sleep Therapy System during sleep, it provides a pressure gradient within the oral cavity, and the pressure gradient pulls the tongue toward the upper palate and also pulls the soft palate forward. By moving the tongue and the soft palate in a forward direction, the patency of the upper airway near the pharynx is maintained to prevent sleep-disordered breathing. This reduces or eliminates the upper airway obstruction that causes OSA and allows each patient with OSA to enjoy deep, refreshing and uninterrupted sleep.

More importantly, OSA patients will get rest and oxygen that they need to prevent some of the health risks associated with OSA. Furthermore, the iNAP One Sleep Therapy System® is designed to provide quiet and comfortable treatment so that each user can sleep through the night without distraction. The iNAP One Sleep Therapy System continuously detects air pressure within the oral cavity and automatically adjusts the pressure gradient applied to the airway. The pressure in the oral cavity is continuously and stably maintained which prevents respiratory obstructive events that may disturb the user's sleep. In the absence of respiratory events, the user will have a good night’s sleep to maximize his or her quality of life. Clinical studies conducted over a period of 28 days have demonstrated the effectiveness of the iNAP System.

1.2 Indications for Use

The iNAP One Sleep Therapy System is indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults in whom positive airway pressure is not the preferred treatment choice.

1.3 Contraindications

The iNAP One Sleep Therapy System shall not be used by anyone who:

- Has Central Sleep Apnea (CSA)
- Is under the age of 21.

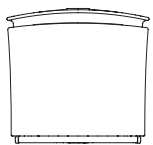
For use only by order of a physician.

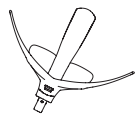
1.4 iNAP One Sleep Therapy System Components

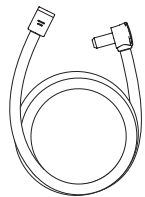
iNAP One Sleep Therapy System is a portable system designed to deliver a pressure gradient to the oral cavity to prevent sleep-disordered breathing.

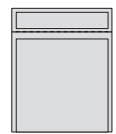
Note Use only the power adapter supplied with the device to charge your iNAP One Sleep Therapy System.
Please check that all item listed are included in the package. Contact local dealer or iNAP Customer Service if any items are missing.

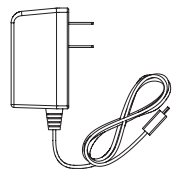
Console

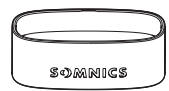

Container


Oral Interface


Tubing Set

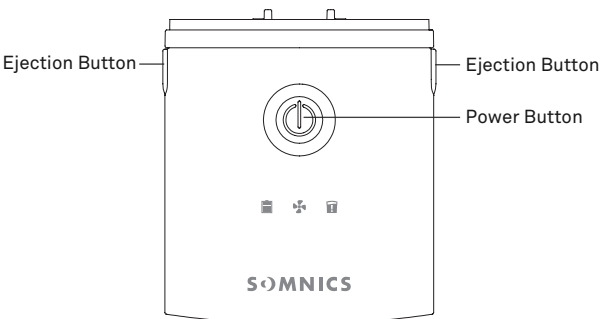

DryPad


Power Adapter

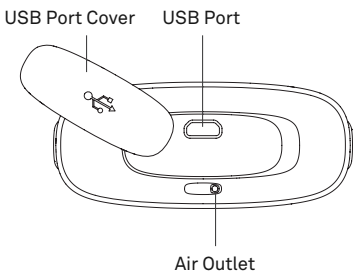


Muffler
(Optional)

1.4.1 Console



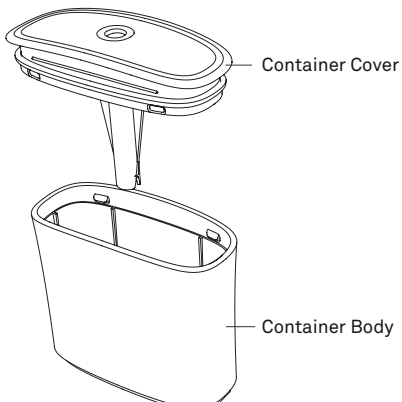
Bottom of Console



⚠ **Caution** Blocking the air outlet of the device while in operation might lead to insufficient negative pressure.

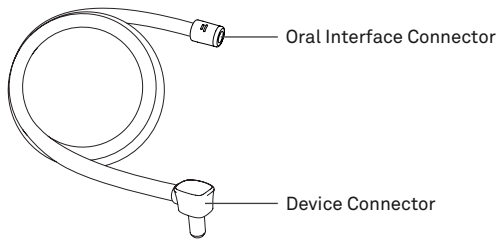
1.4.2 Saliva Container

C07



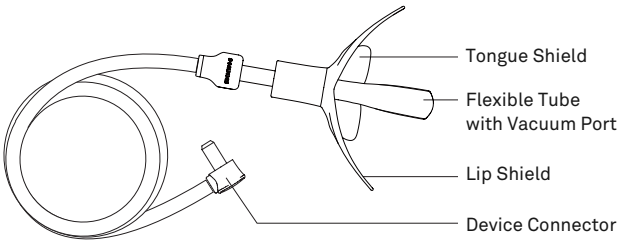
1.4.3 Tubing Set

T01(Only for I07 series)

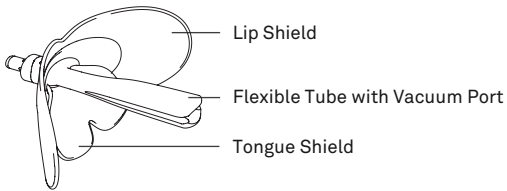


1.4.4 Oral Interface

I02 Series



I07 Series



1.5 iNAP One Sleep Therapy System Console Icons

Icon		Light Status	Status Indicator
Battery Power Status			
		Flash	Low battery. Please charge!
		On	Enough battery
		Flash	Charging
		On	Fully charged (with charging cable plugged in)
Vacuum Status			
		Flash	Pump to target vacuum
		Off	At target vacuum

Container		
	Flash	Incorrect installation
	Off	Properly installed
	On	Container full or excessive suction detected

2 BEFORE USING THE INAP ONE SLEEP THERAPY SYSTEM

2.1 Important Safety Notes

2.1.1 Warning (Possible health risks)

- Use of the iNAP One Sleep Therapy System may cause:
  - Drying of the nose, mouth, or throat
  - Aspiration Pneumonia
  - Infection of teeth/gingiva
  - Oral tissue irritation
  - Hematoma / Bleeding
  - Gingival or dental soreness
  - Blood in mucus
  - Excessive salivation
  - Headache
  - Soft Palate pain
  - Nasal congestion
  - Obstruction of oral breathing
  - Chest tightness
  - Soreness of the wrist
  - Dental discomfort
  - Tooth movement or changes in dental occlusion
  - Pain or soreness to the temporomandibular joint
  - Higher risk in elderly-Dementia, Parkinson's disease and those with movement disorders affecting the tongue
  - Possible Bronchial infections/Upper respiratory infections/Pneumonia due to contamination in the tubing system

- Assessment of effectiveness of the iNAP One Sleep Therapy System should be conducted by your physician to ensure adequate treatment.
- If the oral interface causes prolonged discomfort, remove it and contact your physician.
- The oral interface, tubing set, saliva container, and DryPad are for your use only. **DO NOT** share your oral interface, saliva container and DryPad with others.
- The long term effectiveness and safety of the iNAP One Sleep Therapy System has not been determined. Assessment of effectiveness and safety of long term use of the iNAP One Sleep Therapy System should be conducted by your physician to ensure adequate treatment.

2.1.2 Warnings

- Universal precautions should be observed whenever working with potentially contaminated components or equipment of the iNAP One Sleep Therapy System. When transporting, operating, repairing or disposing of the iNAP One Sleep Therapy System and its accessories, the risk of infectious liquids being aspirated or contamination of the device through incorrect use cannot be eliminated.
- The iNAP One Sleep Therapy System is not computed tomography (CT) or Magnetic resonance imaging (MRI) compatible. **DO NOT** put the console into the scanner range or MRI suite.
- The iNAP One Sleep Therapy System is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- The iNAP One Sleep Therapy System is not suitable for use in areas where there is danger of explosion (e.g., hyperbaric oxygen unit).
- The iNAP One Sleep Therapy System and its accessories are provided nonsterile and should not be used in a sterile field.
- Use only **Authentic Somnics accessories (container, tubing set, oral interface and DryPad).** A different type of the tubing and the oral interface may damage the system. Always follow the instructions enclosed with the accessories.
- This system has been evaluated by biocompatibility testing. In the case of oral tissue discomfort, stop using it immediately and consult with physician.
- **DO NOT** leave long length of tubing around the top of your bed. It could twist around your head or neck to cause suffocation while you sleep. Leave some slack in the tubing when you might turn over or move around.
- Make sure the power adapter and plug are in good condition and the equipment is not damaged.
- Beware of electric shock. Keep the iNAP One Sleep Therapy System away from all sources of liquids and **DO NOT** immerse in

water or other liquids. Always unplug the device before cleaning and make sure it is dry before reconnecting.

- **DO NOT** operate the iNAP One Sleep Therapy System in an area which may cause overheating.
- **DO NOT** cover the iNAP One Sleep Therapy System with any object or material which would cause them to overheat.
- **DO NOT** leave the system on prolonged charge when not in use.
- Please use the power adapter provided by Somnics, Inc., Use of an improper power adapter might cause electric shock or damage the iNAP One Sleep Therapy System.
- Keep the iNAP One Sleep Therapy System away from hot or flammable surfaces, gases or materials.
- iNAP One Sleep Therapy System is not intended for life support.

2.1.3 Cautions

- Physician should consider the medical history and condition of the patient, including but not limited to, history of asthma, sinusitis, nasal obstruction, breathing, or respiratory disorders or other relevant health problems, and refer the patient to the appropriate health care provider before prescribing this system.
- In the event of a power failure or console malfunction, remove the oral interface. The system will not provide effective therapy if the console is not powered on or functioning properly.
- Patients should have documented obstructive sleep apnea.
- Adequacy of nasal patency should be assessed.
- Patients who have obstructed nasal passages, as evidenced by the inability to breathe through the nose with the mouth closed, should not use iNAP One Sleep Therapy System.
- iNAP One Sleep Therapy System effectiveness has not been assessed in patients with nighttime mouth breathing.

2.1.4 Precautions

- Check the system regularly when in use, for pump operation, battery status, interface integrity and type/amount of exudates.
- Keep the iNAP One Sleep Therapy System away from all sources of liquids and **DO NOT** immerse in water or other liquids.
- **DO NOT** expose the system and its accessories to open flames, or other sources of ignition, such as cigarettes, etc.
- **DO NOT** store the system in direct sunlight.
- Make sure the system is clean and dry prior to storage.
- This system is for **SINGLE PERSON USE** only. Use of the oral interface or saliva container for more than one patient may result in cross contamination that may lead to infection.
- If you put the system on the floor, make sure that the area is free from dust and clear of bedding, clothes or other objects that could block the air outlet.
- Make sure the area around the system is dry and clean.
- Please keep small parts and accessories away from children and pets at all time to avoid any risk of the parts been swallowed.
- Contact iNAP Customer Service if there are any questions during setup, use or maintenance.
- **DO NOT** use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps, scented oils, or phenol-based solutions to clean the system. These solutions may create a shock hazard, cause damage and reduce the life of these items.
- Retain the original product literature for future reference.

3 PREPARING FOR USE INAP ONE SLEEP THERAPY SYSTEM

3.1 Check the Battery Status

Press the power button to check the battery status.

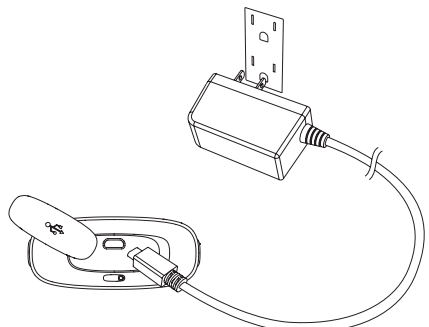
Battery status		Status Indicator	Suggestion
	On	Enough battery	
	Flash	Low battery	Please charge!

3.2 Charge the System

Open the USB port cover and connect the micro USB plug of the power adapter into the port of the console, then plug the power adapter into a standard wall outlet (100-240 Vac).

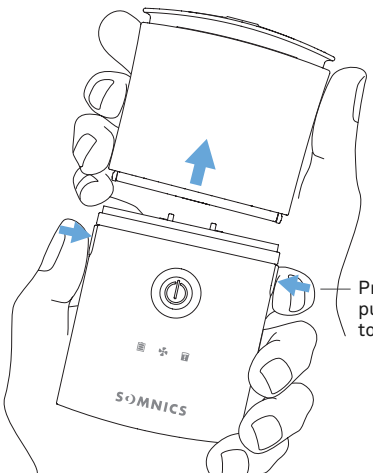
Note A lithium-ion battery embedded in the console is not replaceable. Please charge more than 8 hours for the first time.

⚠ **Caution** **DO NOT** use the system while charging. The device does not work while charging. Use ONLY Authentic Somnics accessory to charge the console.



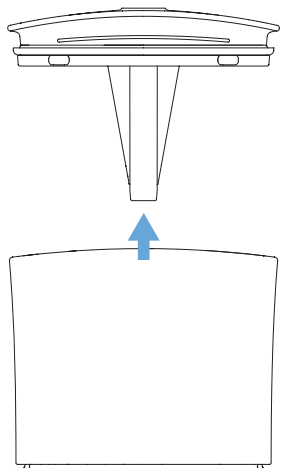
3.3 Installation of DryPad

1. Disconnect the console and the container.

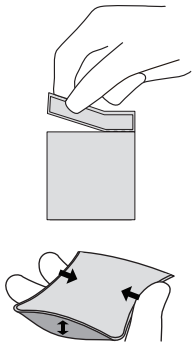


Press the ejection button, then pull the saliva container upward to separate it from console.

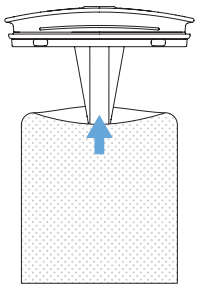
2. Open the Container.



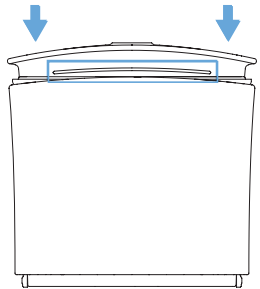
3. Squeeze the sides of DryPad, match the opening of the DryPad with the center tube of the container cover, then place the container cover with the DryPad into the container.



Remove the strip where it is perforated if applicable. Squeeze the sides of DryPad.

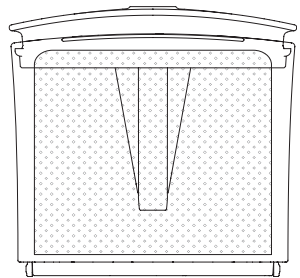


Match the opening of the DryPad with the center tube of the container cover.

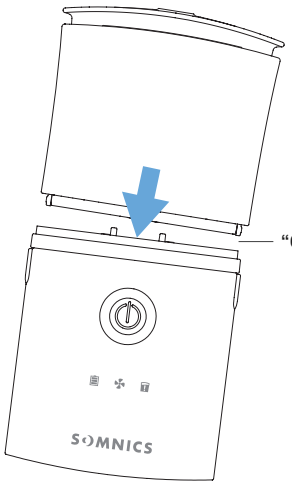


Place the container cover with the DryPad into the container.

4. Ensure that you hear it "click" into place. You will see the gap between the lid and the container less than ¼". Be sure it is a tight fit.

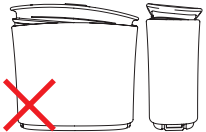


5. Connect the console and container make sure that you hear the click sound.

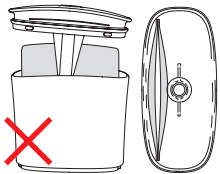


Note If the container icon is flashing, please reconfirm the connection condition of the container and the console.

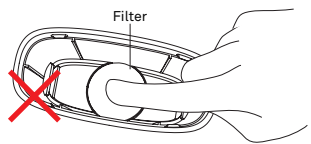
Please refer to Section 1.5



⚠ **Caution** Wrong container cover position



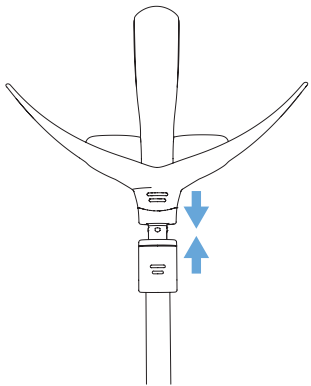
⚠ **Caution** Wrong DryPad position



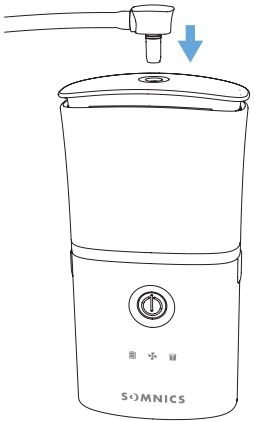
⚠ **Caution** **DO NOT** contact the filter

3.4 Connect the Oral Interface

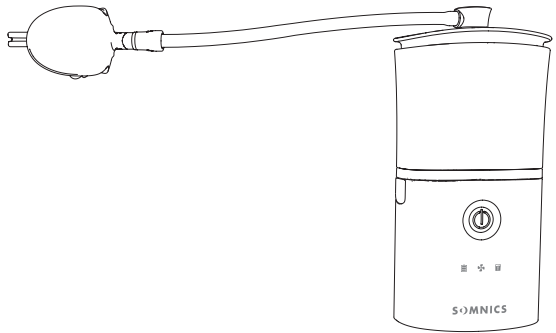
I07 Series



1. Connect the oral interface with the tubing.

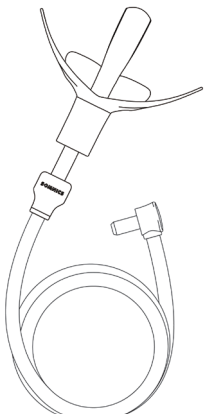


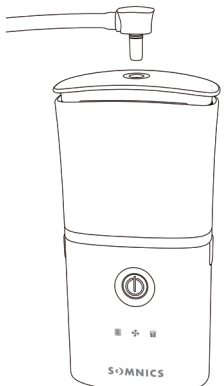
2. Connect the tubing to the console.

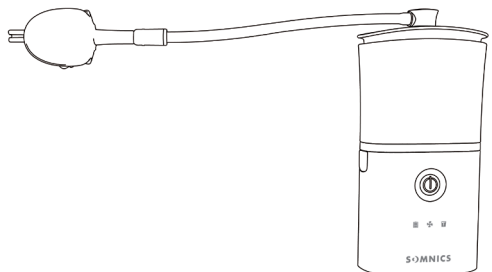


3. Ready to use.

I02 Series





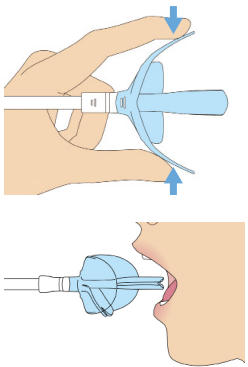


For the adjustable oral interface I02 series, connect its tubing with the container cover.

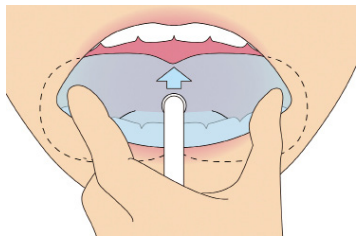
3.5 Wearing the Oral Interface

If you find any possible defect that you think will impact the performance of the system, **DO NOT** use the oral interface. Contact iNAP Customer Service.

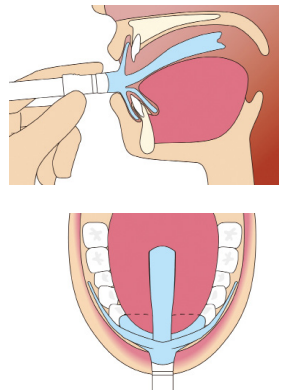
Note Wash the oral interface with warm water before using it the first time.



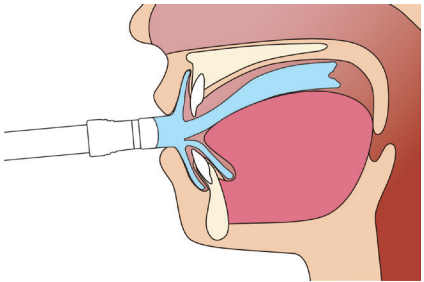
Insert the oral interface in your mouth by squeezing the lip shield appropriately.



Be sure that the lip shield is placed between the front teeth and lips.

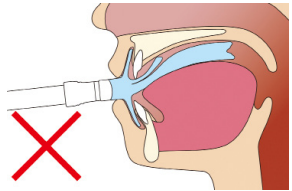


Keep the lip shield and the flexible tube in your mouth, then have the tongue rest on the tongue shield.

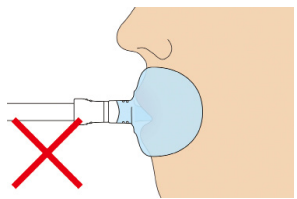


Keeping your lips closed, you are now ready to start using the iNAP One Sleep Therapy System.

Note Please put the oral interface ONLY in your mouth.
Note **DO NOT** chew on or swallow the oral interface.
Note **DO NOT** wear the oral interface while eating or drinking.



⚠ **Caution** **DO NOT** put the tongue shield on the tongue inside your mouth.

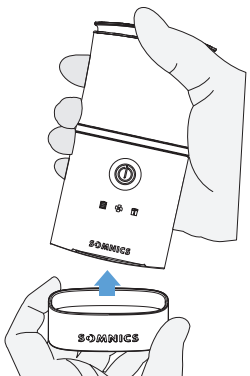


⚠ **Caution** **DO NOT** put lip shield outside the lips.
What's the tongue shield? Please refer to Section 1.4.4

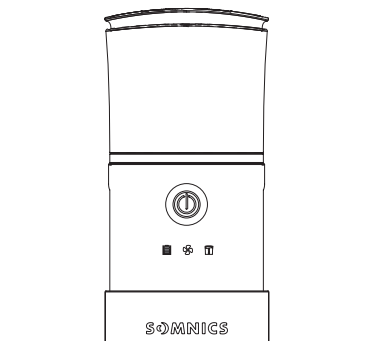
3.6 iNAP Muffler

It is an accessory dedicated to use with iNAP One Sleep Therapy System. Please read this instruction thoroughly before use.

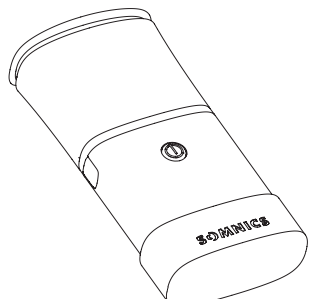
Note For patients experiencing noise from the device during treatment, a muffler can help reduce the device's noise level.



1. Hold the muffler tight and put iNAP Console into the muffler.



2. Make sure the connection between iNAP Console and the muffler is stable.

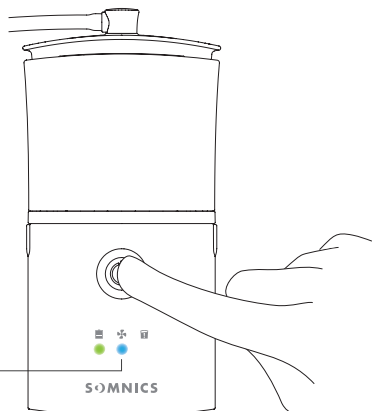


3. Place iNAP Console flat and enjoy the treatment.

4 OPERATING INSTRUCTIONS

4.1 Starting the Treatment of the iNAP One Sleep Therapy System

- Hold the start button until all three lights illuminate, then release. The three icons will flash for a few seconds while warming up, and then the icon of battery power status will turn to solid green when the system is fully powered ON.



When iNAP has reached target pressure, the blue light will turn off.

Note Icons dim after 30 seconds of treatment started. Press the power button again to activate and illuminate the Icons.

Note If the three icons keep flashing, there is a problem with your console. Press and hold the power button for at least 7 seconds to reset it. Turn the console ON again, if the lights keep on flashing, **DO NOT** use the system. Contact iNAP Customer Service.

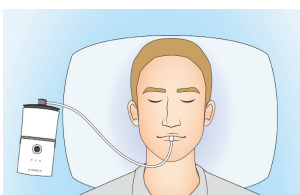
- Wait for the vacuum level on the console to reach the target vacuum.

  Wait for the light of the vacuum icon turns from blue to OFF. If the light keeps flashing, it means the console is in the process of increasing vacuum pressure to its target level. That can take about 10-30 seconds. The vacuum pumping process can occur during a system check during the treatment period of the iNAP One Sleep Therapy System.

  If you have difficulty maintaining the target vacuum pressure during the treatment, please refer to the troubleshooting guide for potential causes and their solutions. If the problem can not be resolved, contact iNAP Customer Service.

  Note If your console is still pumping after 30 seconds, please recheck the installation of tubing and make sure the tubing is properly connected.

- Continue breathing through your nose and lie down to sleep.



Note Make sure the tubing will not get tangled or kinked while you sleep. Leave some slack in the tubing when you might turn over or move around.

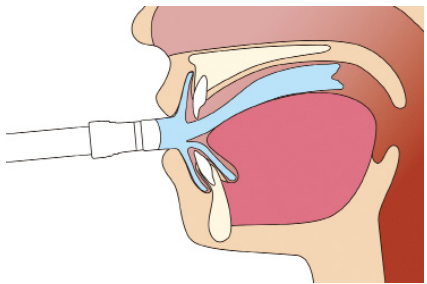
Note **DO NOT** use the system while charging.

4.2 Getting Used to the Treatment of the iNAP One Sleep Therapy System

Anything new, including the iNAP One Sleep Therapy System, takes time to get used to. You may not feel comfortable with the oral interface in your mouth when you first start using the iNAP One Sleep Therapy System.

Here are some tips to help familiarize you with the system more quickly:

- Try to wear the oral interface of iNAP One Sleep Therapy System, while switching the console "On" or "Off." Practice breathing through your nose with the oral interface in your mouth for an hour or so while watching television, reading or performing some other sitting activity.



- Try to put your tongue on the tongue shield and make a sucking motion. The vacuum will be achieved easily and hold your tongue in place.

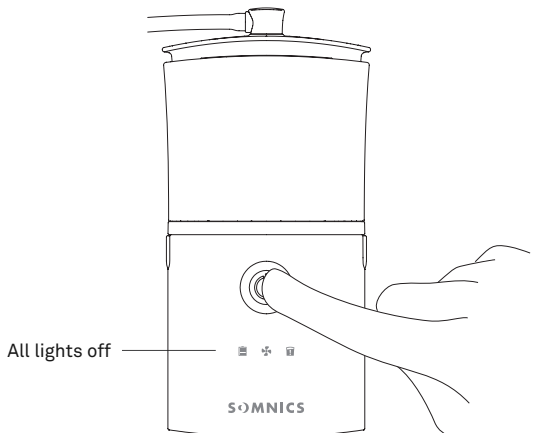
- Try to use the iNAP One Sleep Therapy System during your nap time as well.

- Try to use the iNAP One Sleep Therapy System for about 3-4 hours of sleep each night when you first use the iNAP One Sleep Therapy System.

- Use the iNAP One Sleep Therapy System® for an entire night once you get used to it.

4.3 Stop the Treatment of the iNAP One Sleep Therapy System

Remove the oral interface, then press the power button on the console for 3 seconds to turn off iNAP. The oral interface and the container should be cleaned after each use.



Note In case you need to leave bed during night sleep, press and hold the power button to turn OFF the console. Remove the oral interface and put it into the Oral Interface Box (sold separately) or a clean container such as mug, bowl...etc. Resume the treatment when return.

4.4 Bluetooth and App Setup Procedures

iNAP supports a mobile app for you to track your daily progress. You can adjust the vacuum pressure according to the prescription. You may download the iNAP Lab+ app via Google Play (Android) or App Store (iOS).

1. Click the iNAP Lab+ app icon on the mobile device.
2. Turn on the iNAP One Sleep Therapy System.
3. Click the Scan button on the app. A device list is shown after a few seconds.
4. Match the serial number on the console and tap the corresponding serial number to connect.
5. Follow instructions to complete app setup.
6. Read the usage/treatment data on the app.
7. Manually adjust the device's vacuum pressure and flow level via the app.
8. For detailed information, please refer to the Instructions for Use of the app.

Note Before using the iNAP device, the medical professional treating the OSA must assess how to best use the system,including vacuum setting and oral interface selection for an individual patient. Please refer to the iNAP Lab+ app instruction for more information about app usage.

Note The Bluetooth Low Energy module used in iNAP One Sleep Therapy System is Bluetooth® Smart 4.2 BLE compliant.

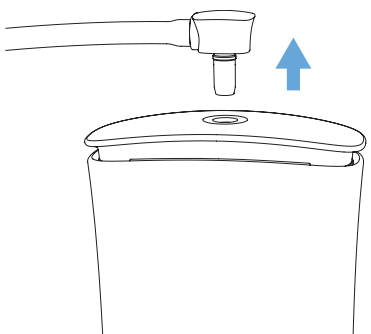
5 CLEANING, MAINTENANCE AND STORAGE

Clean the oral interface, tubing set, and container after each use.

5.1 Cleaning

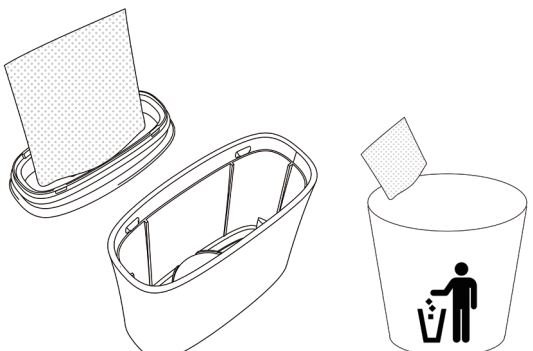
5.1.1 Disconnect the Tubing Set and the Container

Remove the oral interface from your mouth and disconnect the tubing from the container cover.



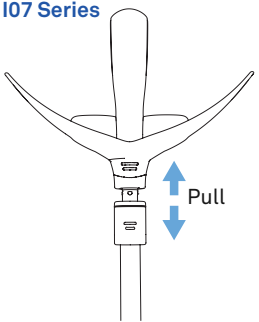
5.1.2 Discard the DryPad

Remove the used DryPad from the container and discard it.

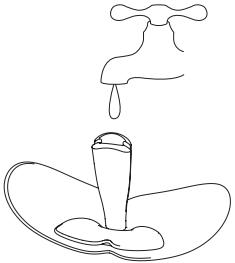


5.1.3 Clean the Container, the Oral Interface and the Tubing Set

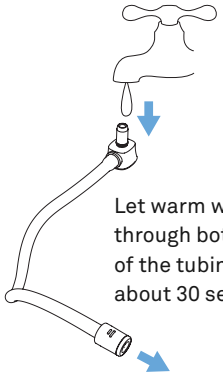
I07 Series



Separate the oral interface from the tubing by gently pulling it apart at the connector ends.

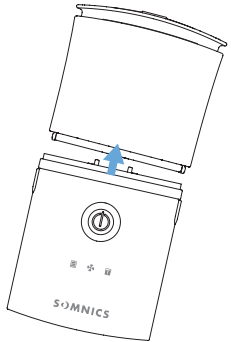


Rinse and gently rub the oral interface with warm water, so it no longer feels slippery.



Let warm water flow through both ends of the tubing for about 30 seconds.

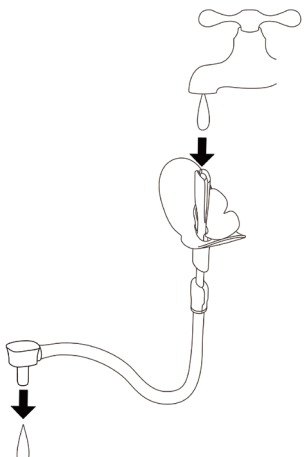
Disconnect the console from the container and rinse the container with cool water.



Note Both the oral interface and tubing set should be cleaned after each use by washing them in warm mild soap or diluted dishwashing detergent water. Any soap residue should be removed from the oral interface and tubing by completely rinsing them in warm water.

Note You can use a soft brush or a sponge to gently scrub the surface of the oral interface.

I02 Series

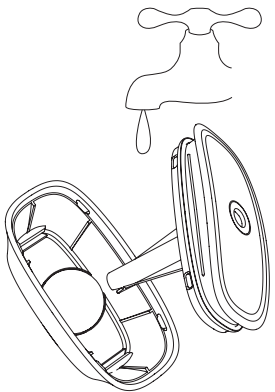


For cleaning of the adjustable oral interface, I02 series, clean the used oral interface and tubing.

Rinse and gently rub the oral interface with cold water.

Let cold water flow through the tubing set for about 30 seconds.

Note You can use a soft brush or a sponge to gently scrub the surface of the oral interface.

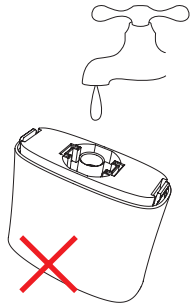


Note If the container body is not wetted by saliva, you can use a soft brush or a sponge to gently scrub the surface of the container.

Note Rinse the container with warm water. **DO NOT** touch or brush the filter inside the container body.

Note Shake off excessive water, wipe dry the exterior surface of saliva container and tubing set with clean cloth.

Note Set all components on a towel to dry. Keep away from direct sunlight.



⚠ **Caution** **DO NOT** wash, poke or brush the filter on the bottom of the container container. It should be completely dry for the next night's use if the filter gets wet.

Note **DO NOT** clean the oral interface in the dishwasher.

Note **DO NOT** clean the oral interface with toothpaste.

5.1.4 Clean the Console

The console does not require cleaning after each use, and it can be wiped when necessary with a damp towel.

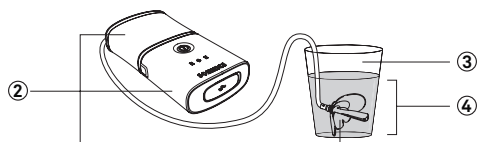
Note Keep the iNAP One Sleep Therapy System away from all sources of liquids and **DO NOT** immerse in water or other liquids.

5.2 Weekly Cleaning

① Clean the oral interface, tubing set, and container daily. Please refer to the recommended daily cleaning steps.
② Connect the oral interface, tubing, container, and the iNAP console.
③ Prepare a cup of appropriate capacity and immerse 150mL of lukewarm drinking water.

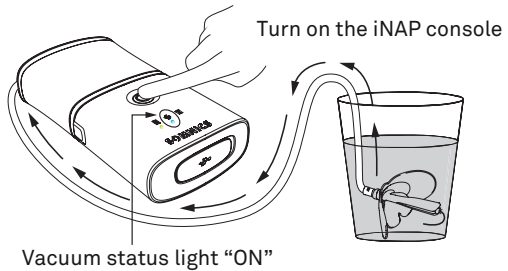
Note **DO NOT** use hot water with a temperature greater than 40 °C/ 104 °F.

④ Place the oral interface inside the cup. The oral interface and its connector must be entirely submerged underwater.
⑤ Soak the oral interface for 15 minutes to clean the oral interface.



Note Please **DO NOT** soak your oral interface, tubing, and saliva container in the cleaning solution overnight. Prolonged immersion might cause damage to the filter.

⑥ Lay down the container and turn on the iNAP console. At this time, the battery power light will be solid green , and the vacuum status light will be flash blue . The negative pressure will draw the water through the tubing and into saliva container.



⑦ When the container is full, the clean saliva container light will be solid orange , and the vacuum status light will become dim , at the point turn off the iNAP console and wait 15 minutes to clean saliva container and tubing.

⑧ Disconnect the console and clean the oral interface, tubing and container by washing them in warm mild soap or diluted dishwashing detergent water. And remove any soap residue from the oral interface and tubing by completely rinsing them in warm water.

⑨ Dry off the oral interface, tubing, and container.

5.3 Maintenance

- Console: iNAP One Sleep Therapy System is designed to provide accurate pressure without the need of additional calibration by the end user. No routine maintenance is required if the system is used in accordance with the user manual.
- Accessory: Clean the oral interface, the tubing set, and the container after each use. Replace the oral interface and the tubing every 3 months; replace the container every 6 months or sooner if necessary. Contact iNAP Customer Service, if you have any questions on how to order or get consumables for the system.

⚠ **Caution** **DO NOT** modify the iNAP One Sleep Therapy System without authorization from the manufacturer.

Note Check the console before use and clean it if necessary. If the console has not been used for a long time, please recharge the battery before use.

Note When traveling, be aware of the voltage differences in different regions. The iNAP One Sleep Therapy System is ONLY compatible with electrical outlets from 100-240Vac (50~60Hz).

5.4 Disposal

At the end of the product life cycle, dispose the iNAP One Sleep Therapy System according to the local regulation of disposal of bio-contaminated electronic devices.

6 TROUBLESHOOTING

Problem	Possible Cause	Light Status	Solution
Cannot feel vacuum in Mouth	Incorrect connection of oral interface and tubing		Re-connect oral interface and tube and make sure hear the “click sound”.
	Incorrect connection of saliva container and tubing		Re-connect container connector and saliva container cover and make sure hear the “click sound”.
	Incorrect installation of the body and cover of saliva container		Close the container cover and body again and make sure the marking line of saliva container cover is at the right position.
	Tube blocked		Make sure water flow can pass through tube; if not, replace with a new tube.
	Oral interface tube with vacuum port blocked		Clean the oral interface, and make sure water flow can pass through vacuum port. If water cannot flow through, replace a new oral interface.

Problem	Possible Cause	Light Status	Solution
Cannot feel vacuum in Mouth	Saliva container cover blocked	In the situation of blockage, Indicators might appear normal.	Clean the hole of saliva container cover or replace a new saliva container.
	Saliva container body blocked		1.Check if the filter in saliva container is blocked. 2.Make sure the connection between console and saliva container is not blocked. 3.If blocked, remove the obstruction, or clean it with a damp swab. Rest for 30 minutes before power on again.
	Saliva container full		1. Remove and replace DryPad. 2. Empty the container.
	Inlet port of console blocked		1.Check if the inlet port on the console is free from obstructions. 2.If blocked, remove the obstruction, or clean it with damp swab. Rest for 30 minutes before power on again. 3.If the problem persists, please contact iNAP Customer Service.

Problem	Possible Cause	Light Status	Solution
Cannot maintain target vacuum	Improper oral interface placement		Make sure the lip shield and flexible tube with vacuum port in your mouth, and put the tongue rest on the tongue shield.
	Damage on oral interface, saliva container or tubing		Check if there is any visible damage on tubing, oral interface or saliva container. Replace the damaged part if found. In the case of no visible damage found, contact Somnics Customer Service for help.
Console does not power ON	Improper saliva container assembly with console		Separate saliva container from the console and assemble again. Make sure a "click" is heard when assembling.
	Low battery		Check battery status by pressing power button. If battery indicator flashes for 2 seconds, recharge the console using adapter comes with the package. **Note**: Use **ONLY** Somnics authentic adapter to charge.

Problem	Possible Cause	Light Status	Solution
Console does not power ON	System reboot required		1.Press and hold the power button for at least 7 seconds to reset the console. 2.Turn on the console again. If the problem persists, please contact Somnics Customer Service for help.
	Charging		Check if the charging plug is still connected to the console. Unplug it and try again. The console turns off with all lights off while unplugging the charger. The device does not work while charging.
Console is not charging	The battery is fully charged		Unplug the USB plug, cover the USB port and try again.
	Use the unqualified power adapter		Use ONLY Somnics authentic adapter to charge.
Oral interface does not fit comfortably	Improper oral interface placement	NA	1.Follow the instructions to place the oral interface in the mouth for proper oral interface placement. 2.If oral interface still does not fit comfortably, contact your physician.

Problem	Possible Cause	Light Status	Solution
Pain, soreness or physically change to your teeth or gum	Oral interface is improperly worn. Prolonged use of oral interface	NA	Stop using the system immediately. Contact your physician.
Console is noisy	The console is close to ears	NA	Place the console farther from the head.
	Vibrations from floor or other surface	NA	1.Make sure console is placed on a level surface. 2.If placed on the floor, move console to a carpet or carpeted or covered surface.

7 SYSTEM SPECIFICATIONS

Product Name	iNAP One Sleep Therapy System
Dimensions (Console and Container)	5.98'' x 3.14'' x 1.41''(152 x 80 x 36mm)
Weight (Console and Container)	0.47 lbs (210g)
Warranty/Life time (Console)	2 years
Battery Run Life	Approximately 4 nights (8 hours per night)
Bluetooth Module	Frequency Range: 2.402 GHz - 2.480 GHz Transmit Power: Class 2 output power (0 dBm typical, +2 dBm maximum)
Power Adapter	Input: 100-240 Vac, 50~60Hz Output: 5.0Vdc, 0~2.0A
Storage/Transport	-20°C ~ 50°C
	15 ~ 93% (non condensing)

Product Name	iNAP One Sleep Therapy System
Operating Range	5°C ~ 40°C
	15 ~ 93% (non condensing)
Operation/Storage Atmospheric pressure:	700hPa ~ 1060hPa
Operating Altitude	Up to 8,858ft (2700m)
Vacuum Setting / Accuracy	-27~-122 cmH2O / ±6.8 cmH2O
Ingress Protection	IP22
Patient Protection	Type BF
Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11

8 GUIDANCE AND MANUFACTURER'S DECLARATION REGARDING ELECTROMAGNETIC COMPATIBILITY

Manufacturer's declaration-electromagnetic emissions

The iNAP One is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the iNAP One should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home healthcare environment)
RF emissions CISPR 11	Group 1	The iNAP One uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The iNAP One is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity			
The iNAP One is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the iNAP One should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact:±8 kV Air±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/ output lines	Not applicable Not applicable	Main power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s) + 0.5kV, +1kV,+ 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare environment.

Manufacturer's declaration-electromagnetic immunity			
The iNAP One is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the iNAP One should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Main power quality should be that of a typical home healthcare environment. If the user of the iNAP One requires continued operation during power interruptions, it is recommended that the iNAP One be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The iNAP One power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity			
The iNAP One is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the iNAP One should assure that is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the iNAP One including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meter (m).

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE3 Testing indicated that use of RFID readers at 870-960 or 2450MHz near the iNAP may interfere with the Bluetooth connection that supports the iNAP mobile app.

⚠ **Caution** Some of these RF emitters (e.g. RFID readers) in the intended environment of use might be concealed and the device can potentially be exposed to fields from these RF emitters without the user's awareness.

Recommended separation distance between portable and mobile RF communications equipment and the iNAP One			
The iNAP One is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the iNAP One can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iNAP One as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EMC Information

The iNAP Sleep Therapy System has been designed to meet EMC standards throughout its service life without additional maintenance. There is always an opportunity to relocate your iNAP Therapy Device within an environment that contains other devices with their own unknown EMC behavior. If you believe your unit is affected by locating it closer to another device, simply separate the devices to remove the condition.

Pressure Accuracy

The iNAP Sleep Therapy System is designed to perform within the negative pressure specified in the user manual. If you suspect the pressure is affected by EMC interference, remove the power and relocate the device to another area. If performance continues to be affected, discontinue use and contact your home care provider.

Manufacturer's declaration-electromagnetic immunity Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
The iNAP One is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the iNAP One should assure that it is used in such an environment.							
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9	9

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28	28
1 720 1 845 1 970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28	28
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28	28

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
5 240 5 500 5 785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9	9

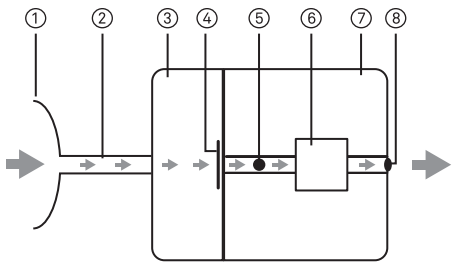
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Maximum single fault steady pressure

Device will shut down in the presence of a single fault if the steady state pressure exceeds -204 cm H2O for more than 30 seconds.

Note: -204 cmH2O = -150mmHg



① Oral Interface
② Tubing
③ Saliva Container
④ Membrane Filter
⑤ Pressure Sensor
⑥ Pump
⑦ Console
⑧ Air Outlet

Pressure Accuracy

Maximum static pressure variation at -27~-122 cmH2O according to ISO 80601-2-70:

Tested with oral interface: ±6.8 cmH2O

Measurement system uncertainties In accordance with ISO 80601-2-70:2015 the measurement uncertainty of the manufacturer's test equipment is:	
For measurement of static pressure	±1 cmH2O
Note: ISO 80601-2-70:2015 stated accuracies and test results provided in this manual for these items already includes the relevant measurement uncertainty from the table above	
Sound	
Declared dual-number noise emission values in accordance with ISO 4871:1996	
Pressure level measured according to ISO 80601-2-70:2015	28 dB(A) with uncertainty of 2dB(A)
Power level measured according to ISO 80601-2-70:2015	36 dB(A) with uncertainty of 2dB(A)
Design Life	
Device, power supply unit:	2 years
Air tubing, connectors	3 months
Saliva container, Muffler	6 months
DryPad	Dispose per use
General	The patient is an intended operator

FCC Compliance Statement (FCC ID: A8TBM70ABCDEFGH)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

9 CLINICAL DATA

There are two pivotal studies for iNAP One.

Clinical Pivotal Trial 1

Data from one clinical study showed a clinical response rate of 75% according to the Sher criteria comparing treatment PSG with baseline values.

Clinical Pivotal Trial 2

Data from a second clinical study showed a 52% response to the treatment (see next page). The duration of this study lasted only 28 days. As OSA is a chronic clinical condition, the short duration may not show the durability of the device in the treatment of OSA.

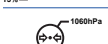
Treatment Reponse Rate of iNAP One in Clinical Pivotal Trial 2

	PE Cohort [*1] Basline PSG Study vs Tx[*3] PSG Study (n=63)	ITT Cohort [*2] Basline PSG Study vs Tx PSG Study (n=130)
Response Rate	52% (33/63)	40% (53/130)
95% CI (Wilson)	40-65 %	33-49 %
P-value *	p = 0.003	p = 0.129*

* The performance goal of clinical success rate = 36%

[*1] PE: Primary Endpoint
[*2] ITT: Intention-to-treat
[*3] Tx: Treatment

10 SYMBOL

	Warning or caution
	Refer to instruction manual
	Product manufacturer
	Type BF, applied part
	Serial number
	Batch number
	Storage/Transport temperature limits
	Storage/Transport humidity limits
	Operation/Storage atmospheric pressure limits

Rx Only	Prescription only medical device
IP22	Protection against ingress of solids larger than 12.5 mm and drip water
	Do not use if package is damaged
	Keep dry
	The symbol of the crossed out wheeled bin indicates that the product (electrical and electronic equipment) should not be placed in municipal waste. Please check local regulations for disposal of electronic products.

11 LIMITED WARRANTY

Somnics, Inc. (“Somnics”) warrants that the iNAP One Sleep Therapy System (the “Product“ or “iNAP One“) shall be free from defects in materials and workmanship and will perform in accordance with the Product specifications set forth in the Product instructions for use, for a specified period below:

- iNAP One Console with Battery - 2 years from date of sale to patient
- iNAP Saliva Container & Muffler – 6 months from date of sale to patient
- Accessories Kit (Oral Interface, Tubing Set) - 3 months from date of sale to patient

Should the Product fail to conform to the above warranty, as customers’ sole remedy (and Somnics’ sole liability), Somnics will repair or replace at its discretion, any nonconforming material or part. Warranty claims on defective Product must be made by the initial customer of record, based on assigned serial number, lot number or warranty registration. In order to obtain warranty service, please contact Somnics Customer Service.

Conditions

- This warranty is only available to the initial consumer.
- It is not transferable.

- This is a limited warranty and does not cover:
  1. Repairs carried out by any service organization that has not been expressly authorized by Somnics to perform such repairs;
  2. Any nonconforming, missing or damage in the serial or lot number;
  3. Any damage caused as a result of improper use, improper operating range, accident, neglect, abuse, modification, water ingress, alteration static interference or unstable power supply of the Product;
  4. Any damage or contamination due to cigarette, pipe, cigar or other smoke

SOMNICS PROVIDES NO OTHER EXPRESS WARRANTIES WITH RESPECT TO THE PRODUCTS. ALL IMPLIED WARRANTIES WITH RESPECT TO THE PRODUCTS (INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) ARE LIMITED IN DURATION TO THE APPLICABLE WARRANTY PERIOD SET FORTH ABOVE (OR, IF LONGER, THE SHORTEST PERIOD ALLOWED BY APPLICABLE LAW).

International Customer Service
TEL: +886-3-5509623
FAX: +886-3-5503633
Email: info@somnics.com

United States Customer Service
TEL: +1-833-766-6427
(+1-833-SOMNICS)
FAX: +1-833-847-2009
Email: contact.us@somnics.com

Manufactured by

SOMNICS
Somnics, Inc.
5F, No.22, Sec.2, Sheng Yi Rd, Hsinchu Science Park,
Zhubei City, Hsinchu County 30261, Taiwan

TEL +886-3-5509623
FAX +886-3-5503633
Email info@somnics.com

iNAP One is protected by one or more of the following patents.
For detail information, see *http://www.somnics.com/en/legal-and-ip.html*
Additional patents may be pending in the EU and elsewhere.

℞ Only