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R e d i s c o v e r S l e e p

SomnuSeal masks' line operation guide

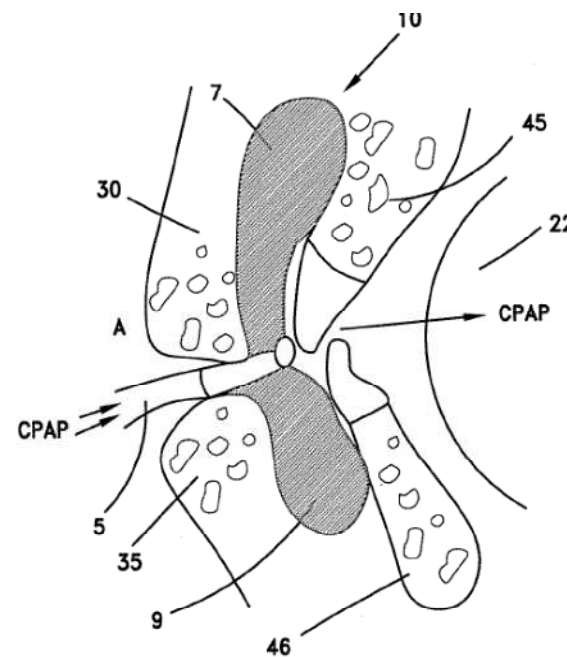
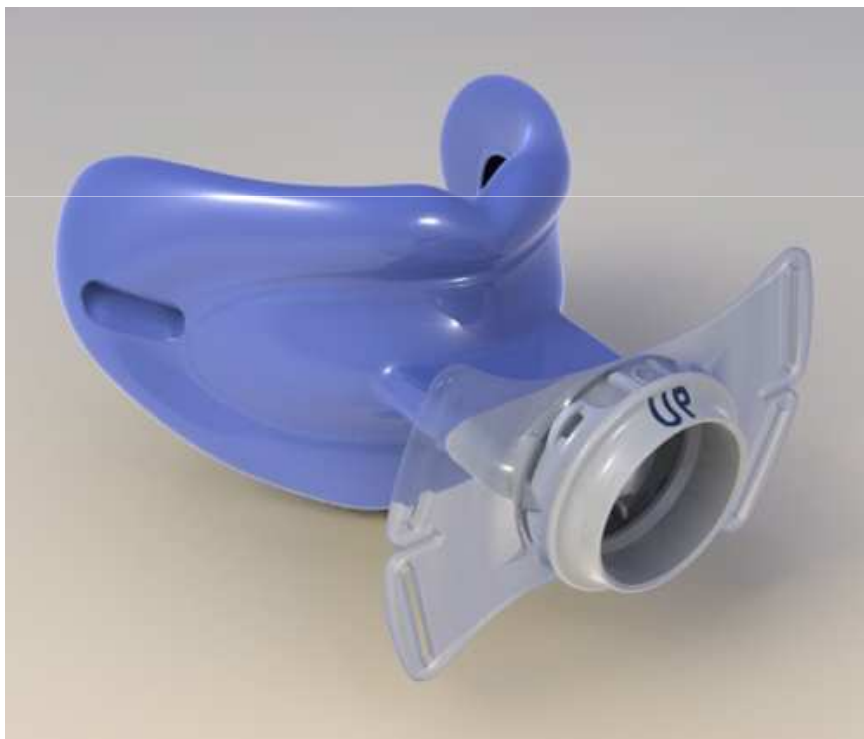
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The SomnuSeal CPAP mask

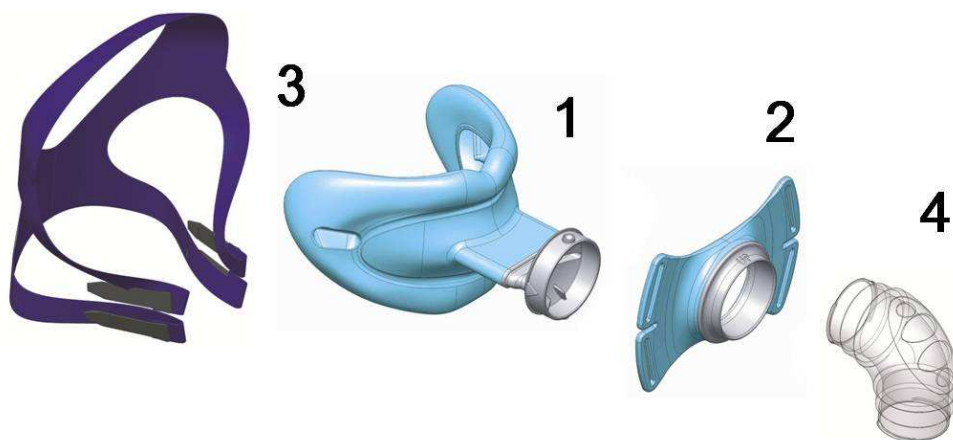




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The SomnuSeal





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The SomnuSeal masks' line

- SomnuSeal 1 – standard size (suits most patients)
- SomnuSeal 2 – large size
- Characteristics:
 - Self adaptable to every user
 - Maintains its position in the oral cavity
 - Uses phenomenon of oral habituation
 - Does not contact sensitive oral structures
 - Non-obtrusive to external facial structures
 - None of the typical side effects created by other traditional masks
 - Require less air pressure to achieve the same therapeutic results as traditional masks (contribute to compliance)



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Clinical trials results – 51 patients

	<u>Second clinical trial</u>	<u>First clinical trial</u>
	31 non compliant patients Complete line – 2 masks sizes Duration: 1 month	10 compliant and partially compliant patients 10 non compliant patients 1 mask size Duration: up to 14 nights
Patients that became fully compliant	From non compliant population: 26%	From compliant and partially compliant population: 90% From non compliant population: 20%
Patients that became partially compliant	From non compliant population: 13%	From compliant and partially compliant population: 10% From non compliant population: 40%



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Awards

**DMD is the winner
of the Frost &
Sullivan 2010**

**Product
Differentiation
Innovation Award
for Sleep Apnea**





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Important issues for compliance

It is **crucial** to limit the upper air pressure - from the outset. The SomnuSeal requires less air pressure than comparable masks in every trial that we have performed. A reduced upper air pressure is crucial for compliance in the SomnuSeal mask. Therefore we suggest that you begin each trial with a patient that uses a SomnuSeal mask with an **upper limit of 6 cmH₂O** and **lower limit of 4 cmH₂O** (unless he requires less air pressure in the diagnosis of the OSA - in which case we suggest you use the prescribed air pressure as the upper limit). **We recommend to call the patient after 2-3 days of use**, if the patient complains about the air pressure level, we suggest you lower the upper limit of air pressure to 5 cmH₂O.



Additional issues for compliance

- Since the SomnuSeal is an intra oral mask, we suggest that the humidifier will be set initially to the highest humidification level.
After 2-3 days, if the patient complains about the high humidification level, we suggest to lower it a little.
- Salivation is reduced during the habituation period. We suggest that the mask is applied in a lying position



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Instructions For Use (1)

Dear Customer,

The multi-use SomnuSeal™ Oral Mask allows a single patient at home or multiple patients at a clinic (hospital, sleeping lab, etc.) to undergo Positive Air Pressure (PAP) treatment, provided that a physician has prescribed PAP treatment.

The SomnuSeal™ is used to create the Positive Air Pressure required to treat sleep apnea by comfortably transferring air directly into the mouth in order to keep the patient's airways open.

Users can continue using their existing PAP machine since the SomnuSeal™ can be connected to any CPAP, Bi-level and Auto PAP machine, as well as to any other PAP machine used to treat sleep apnea.

It is recommended that users replace the SomnuSeal™ every three (3) months of continuous nightly use.

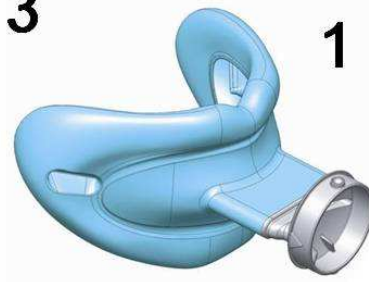


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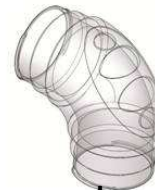
3



1



2



4

IFU 2

The intra-oral parts of the SomnuSeal™ mask are made of medical grade silicone.

The SomnuSeal™ has four main parts:

1) main Body, 2) Strap Connector 3) Straps and 4) SomnuSeal Air Vent (tube).

The strap connector (2) connects the body of the mask (1) to both the straps (3) and the SomnuSeal air vent (4), which in turn connects (at the other side) to the PAP machine's tube.

The mask is offered in two sizes depending on mouth size – Standard (the most commonly used size) and Large



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IFU 3

Do NOT use the SomnuSeal™ if:

1. You have a known sensitivity to silicone.
2. You are incapable of removing the mask unaided.
3. PAP treatment was not prescribed to you by a physician.
4. The PAP machine is not working properly.
5. The SomnuSeal air vent is blocked.
6. The mask provokes your gag reflex.



IFU 4

1. **Always** use a humidifier when using the SomnuSeal™.
2. Always activate the PAP machine before placing the mask in your mouth.
3. Always breathe through your mouth.
4. Never connect the SomnuSeal™ directly to the PAP machine's tube. The SomnuSeal air vent must be always positioned between them.
5. Never insert the mask into your mouth any further in than the teeth.



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IFU 5

If you are new to using the SomnuSeal™

The SomnuSeal masks require less air pressure than traditional masks for the same very good therapeutic result. Therefore the recommended initial Auto PAP/Bi-level air pressure setting:

lowest boundary air pressure: 4 cm H₂O, highest boundary air pressure 6 cm H₂O.

In Continuous Positive Air Pressure (CPAP) mode, set the air pressure level to 60% of the original prescribed air pressure level (aimed at traditional masks), not less than 5 cm H₂O and not more than 6 cm H₂O – it is recommended to consult a sleep professional for the desired change in air pressure.



IFU 6

- Humidifier: begin with highest humidification level.
- There are two sizes of the SomnuSeal. If your mouth is small-medium, please use the standard size (SomnuSeal 1), otherwise, please use the large size (SomnuSeal 2). You may try both sizes to find the best fit for you.
- Set the air flow parameters for your PAP machine as recommended by a sleep technician or other sleep professional.

Very important: lower maximal air pressure. If possible choose mask setting type to: oral, intra oral or full face mask.



IFU 7

- At first, activate the humidifier at its highest level. After a few nights you may gradually change humidification levels to best suit your needs.
- You may adjust the Straps as needed until the mask is comfortably positioned (centered to the lips).
- You may experience more salivation when you start using the SomnuSeal but the amount will decrease when you get used to it. You may also see more salivation when you sit up. Salivation will decrease drastically when you lie down.



IFU 8

Before going to sleep

- Make sure the humidifier is full of water and turn it on five minutes before you start using the SomnuSeal™.
- Activate the PAP machine after making sure its tube is properly connected.
- Connect the SomnuSeal Air Vent to the PAP machine's tube.
- Connect the Strap Connector to the main Body of the mask by pushing the Connector towards the main Body and turning it until you hear a soft click. Make sure that the "up" marking on the strap connector is placed upwards.
- **NOTE:** There is only one correct way to connect the two pieces - the protruding triangle on the mask's Body must align with the socket in the Strap Connector.



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IFU 9

Attach the Strap Connector to the SomnuSeal Air Vent, (by now the SomnuSeal air vent should already be connected to the PAP machine's tube) by pushing the SomnuSeal Air Vent towards the Strap Connector and turning it.

Lie down where you intend to sleep and place the Body of the mask in your mouth between your teeth and lips (in front of the teeth).

NOTE: The arrow pointing up, which you can see on the inner part of the mask, indicates the mask's top part. Also make sure that the "up" marking on the strap connector is also placed upwards. Make sure they are positioned correctly before you insert the mask into your mouth.





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IFU 10

The mask will easily adjust itself to your mouth structure. Simply move it slightly left and right with your lips or with a hand holding the mask.





IFU 11

Place the straps as shown in the following figures. It is recommended that the part that should encompass the nape will be moved first. Fasten the straps lightly until the main Body of the mask is centered to your lips and no part of the straps pulls more tightly than the others.

If air leaks from your lips during use, you **should** tighten the straps more.





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IFU 12

- Please note that in low air pressures, the straps are used to stabilize the mask in contrast to traditional masks that use the straps to create a seal and therefore are tightened forcefully.

- Now you are ready for sleep.



IFU 13

On waking up

1. Remove the Straps from your head and the Body of the mask from your mouth.
2. Turn the PAP machine and humidifier off .
3. Detach the Strap Connector and the Straps from the main Body of the mask.
4. Detach the SomnuSeal Air Vent from the Strap Connector.
5. Thoroughly clean the main Body of the mask according to the instructions in the Maintenance section of this document.
6. The Strap Connector and Straps do not need to be cleaned every day and should not get wet while you are cleaning the main Body of the mask.



IFU 14

SomnuSeal Maintenance

- Store the mask and its accessories in a cool dry place (tolerance: 5-50 Celsius = 40-120 Fahrenheit).
- Do not expose the mask to direct sunlight for a prolonged period of time.
- Replace the SomnuSeal™ after three (3) months of continuous nightly use.
- Replace and discard the mask sooner if it shows any mechanical deterioration such as deformation and/or color change.



IFU 15

For home users:

- Detach the Strap Connector (with the Straps and the SomnuSeal Air Vent attached to it) from the main Body of the mask.

Detach the SomnuSeal Air Vent from the strap connector.

- Thoroughly wash the main Body of the mask and the SomnuSeal air vent with antiseptic soap or antiseptic mouthwash. Make sure you also clean the inner part of the main Body and the SomnuSeal Air Vent. Please refrain from using sharp objects or finger nails during the cleaning process.

Rinse with lukewarm water and place to dry out of direct sunlight.

Every 7 days:

- Hands wash the straps with antiseptic soap dissolved in lukewarm water and place to dry out of direct sunlight.



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IFU 16

For institutional users:

Detach the Strap Connector (with the Straps and the SomnuSeal Air Vent attached to it) from the main Body of the mask.

Detach the SomnuSeal Air Vent from the strap connector.

Immerse the main Body of the mask and the SomnuSeal air vent completely, filling all lumens and eliminating air pockets, in a CIDEX OPA Solution for a minimum of 12 minutes at 20°C or higher.

After removing the Body of the mask and the SomnuSeal air vent from the CIDEX OPA Solution, thoroughly rinse it by immersing it completely in a large volume (e.g., 8 liters) of water.

Keep the mask's Body and the SomnuSeal air vent completely immersed for at least one (1) minute.

Manually flush all lumens with large volumes of rinse water (at least 100ml).



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IFU 17

Remove the Body of the mask and the SomnuSeal air vent and discard the rinse water.

Repeat the procedure two (2) more times, for a total of three (3) rinses, with large volumes of fresh water.

Hand wash the straps with antiseptic soap dissolved in lukewarm water and place to dry out of direct sunlight.



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Good luck!

Eran Lavi

info@discovermedical.com