

Instructions for Use

Simplicity Nasal Mask

Intended Use

The Simplicity Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

 **Important Note:** An exhalation port is built into the interface so a separate exhalation device is not required.

 **Caution:** U.S. federal law restricts this device to sale by or on the order of a physician.

Symbols



Warnings:

- This mask is not suitable for providing life support ventilation.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. **Do not block or try to seal the exhalation port. Explanation of the Warning:** CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. This warning applies to most models of CPAP systems. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. **Explanation of the Warning:** When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- At low CPAP or EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- Use of a nasal or full face mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.
- If an additional exhalation device is added to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.

Cleaning Instructions

Hand wash the mask before first use and daily. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

1. Hand wash the mask and headgear in warm water with a mild liquid dish washing detergent.

⚠ Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

2. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

For **multi-patient use** in the hospital/institutional environment, use the Mask Cleaning and Disinfection Instructions to reprocess the mask between patients. These instructions can be obtained by visiting www.sleepapnea.com or contacting Customer Service at 1-800-345-6443 (USA or Canada) or 1-724-387-4000.

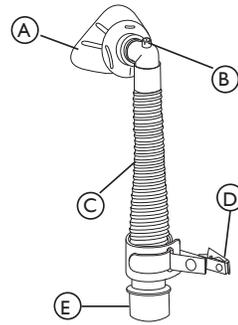


Figure 1

- A= Mask Cushion
- B= Exhalation Port
(Do not block)
- C= 6in. (15.25cm) Tubing
- D= Stability Clip
- E= Tubing Swivel

Connecting the Mask and Headgear

1. A) Unhook the Standard Headgear's tabs and thread them through the slots in the mask (Figure 2). The arrow printed on the back of the headgear should be pointing upward. Fasten the tabs onto the straps for the largest size possible. B) The seams on the mesh of the Softcap Headgear face outward (Figure 3). Unhook the softcap headgear's tabs and thread them through the slots in the mask. Fasten the tabs onto the straps for the largest size possible.
2. Hold the mask in place on the tip of your nose, pressing comfortably against your face, and slide the headgear over your head. Adjust the straps to bring the cushion close to your face (Figure 4).

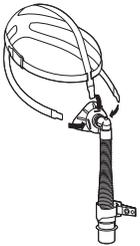


Figure 2

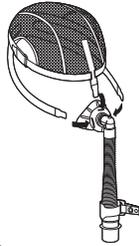


Figure 3

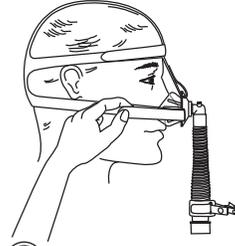


Figure 4

3. Connect the circuit tubing to the tubing swivel. Turn the CPAP or bi-level system on. Optional: Attach the stability clip to the headgear strap (Figure 5).
4. Lie down and breathe normally through your nose, keeping your lips closed. Unhook the straps and gradually tighten them until the mask has minimal leaks and fits comfortably. Adjust the top straps first, making sure that they are above your ears. Adjust the bottom straps, making sure the headgear securely fits the back of your head. Readjust the strap tension if leaks occur as your position changes.

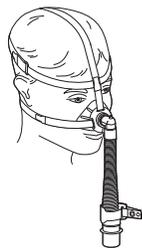


Figure 5

Note: Do not overtighten the straps. Overtightening can cause or worsen leaks.

Note: The tubing can be worn upward (over the head) or downward as desired using either the Standard or the Softcap Headgear.

Removing the Mask and Headgear

Because the entire headgear stretches, you should not need to unfasten the straps to remove the headgear. Simply slide the mask and headgear over your head as you would a cap. If necessary, unfasten either of the bottom straps.

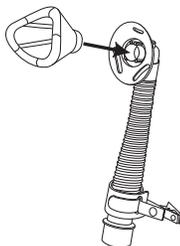


Figure 6

Attaching a New Cushion

Line up the slots on the cushion with the tabs on the exhalation port. Press the cushion firmly into the exhalation port to ensure a thorough seal (Figure 6).

Reorder Numbers

Part #	Description	Part #	Description
1002757	S Simplicity Mask w/ Standard Headgear	1018138	S Simplicity Mask w/ Deluxe Softcap Headgear
1002759	M Simplicity Mask w/ Standard Headgear	1018158	M Simplicity Mask w/ Deluxe Softcap Headgear
1002764	Standard Headgear	1006416	Deluxe Softcap Headgear
1003658	Simplicity Mask Cushion, S, 1 each		
1003657	Simplicity Mask Cushion, S, 5 pack		
1003659	Simplicity Mask Cushion, M, 1 each		
1003656	Simplicity Mask Cushion, M, 5 pack		
1004209	Faceplate Tubing Assembly		

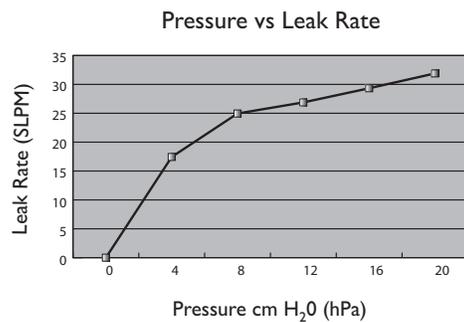
Disposal

Dispose of device in accordance with local regulations.

Specifications

⚠ Warning: The technical specifications of the mask are provided for your healthcare professional to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect device function.

Intentional Leak



Pressure Drop cm H₂O (hPa)

	50 SLPM	100 SLPM
Small	0.6	2.4
Medium	0.8	2.6

Deadspace Volume

Small - 29.9 cc

Medium - 38.5 cc

Storage Conditions

Temperature -20° C to 60° C

RH ≤ 95%, non-condensing

Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA



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