

Intended Use

The TrueBlue 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 TrueBlue Nasal Mask so a separate exhalation port is not required.

ⓘ **Note:** This mask does not contain natural rubber latex or DEHP.

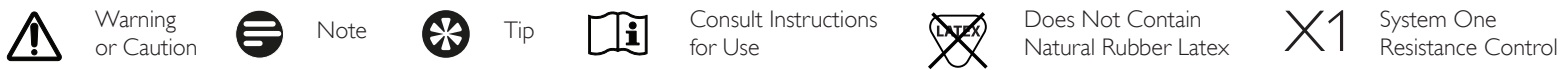
⚠ **Caution**

U.S. Federal law restricts this device to sale by or on the order of a physician.

⚠ **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.
- 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.
- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears, cushion damage resulting in gel exposure, etc). Discard and replace any components as necessary.
- The gel mask is not customizable. Do not attempt to heat.
- 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.

Symbols



Before Use

- Read and understand the instructions completely.
- Hand wash the mask.
- Wash your face.
- Do not apply moisturizer/lotion to your face or hands prior to handling/wearing the mask.

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. To disassemble the mask for cleaning, please refer to the **Removing and Attaching the Mask Cushion** later in this document.

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 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.

⚠ **Warning:** Inspect the mask for damage or wear (cracking, crazing, tears, cushion damage resulting in gel exposure, etc). Discard and replace any components as necessary.

Institutional Disinfection

For **multi-patient use** in the hospital/institutional environment, use the **Disinfection Guide** to reprocess the mask between patients. These instructions can be obtained by visiting us online at www.philips.com/respironics or by contacting Philips Respironics Customer Service at 1-800-345-6443 (USA or Canada) or at 1-724-387-4000.

Philips Respironics System One Resistance Control

The following symbol may appear on your Philips Respironics therapy device (e.g., ← X1). This represents the level of mask resistance compensation. Match the setting to the mask as appropriate.

ⓘ **Important Notes:**

- Verify the System One setting if the mask or mask cushion changes.
 - The System One setting is not compatible with masks requiring a separate/additional exhalation device.
- If your provider has locked the resistance compensation setting, you can view the setting but cannot change it, and the screen will display a lock symbol. If your provider has disabled the resistance compensation, you will not see this setting.

Putting on the Mask

1. Disconnect one headgear clip before putting on the headgear (Figure 2) by turning the clip outward, just like you would turn a key.
2. Before putting on the mask, connect the flexible tubing from your therapy device to the swivel on the mask. Slide the headgear on over your head.
3. Turn on the airflow.
4. Hold the mask cushion over your nose and reconnect the headgear clip after you have the headgear in position (Figure 3).

Achieving the Right Fit

1. Adjust the headgear side straps evenly so the forehead pad is resting comfortably on the forehead (Figure 4). To adjust, peel the headgear tabs away from the headgear straps, evenly adjust straps, then press tabs against the headgear straps to reattach.
2. Adjust the headgear lower straps evenly. To adjust, peel the headgear tabs away from the headgear straps, evenly adjust straps, then press tabs against the headgear straps to reattach. The mask should rest comfortably against your face.
3. Adjust the headgear crown strap, if necessary. If the headgear side straps are resting on your ears, adjust the headgear crown strap to lift the straps slightly off your ears (Figure 5).

ⓘ **Note:** Do not overtighten the headgear crown strap as it may cause the headgear to bunch.

4. Minimal leaks are acceptable. Small adjustments are needed to eliminate excessive leaks. We suggest performing the adjustments in the following order:
 - a) If leaks occur, reseat the mask by pulling the mask faceplate directly away from your face and set it gently back into place (Figure 6). This allows the cushion to create a new seal on the face. Do not pull the mask by the elbow.
 - b) For leaks around the eyes, adjust the side straps.
 - c) For leaks around the top lip, adjust the lower straps (Figure 7).
 - d) Repeat the sequence as necessary.

5. Lay down and assume different sleeping positions while moving your head around. If there are any air leaks, make any final adjustments. Some air leakage is normal.

ⓘ **Note:** The spring should only be slightly compressed when final adjustments have been made. The spring is intended to allow the mask to float and self-adjust to the face. If the mask is overtightened, it can hinder the mask's performance and seal.

ⓘ **Note:** Do not overtighten the headgear.

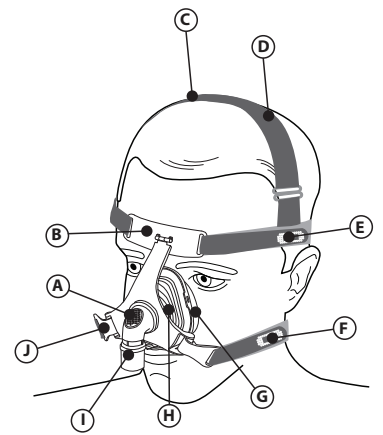


Figure 1
 A = Exhalation Chip (do not block holes or remove chip)
 B = Forehead Support Bracket and Gel Forehead Pad
 C = Headgear Crown Tab
 D = Headgear Crown Strap
 E = Headgear Side Strap
 F = Headgear Lower Strap
 G = Mask Cushion and Flap
 H = Spring
 I = Swivel
 J = Headgear Clip

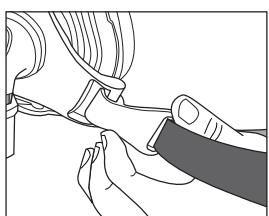


Figure 2

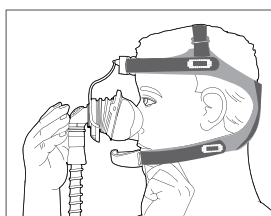


Figure 3

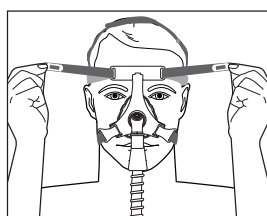


Figure 4

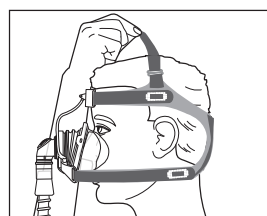


Figure 5

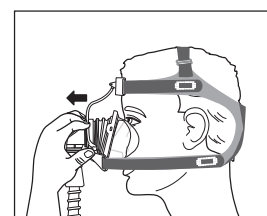


Figure 6

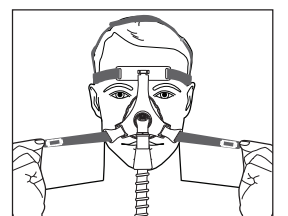


Figure 7

✱ Comfort Tips

- The headgear should fit both loosely and comfortably. If your skin bulges around the mask, loosen the headgear.
- Reseat the mask. Pull the mask by the sides of the faceplate directly away from the face then gently set it back into place.
- For pressure at the bridge of the nose, loosen the side straps.
- For pressure on the top lip, loosen the lower straps.
- If the headgear side straps are lying on your ears, adjust the headgear crown strap to slightly lift the headgear off your ears. The headgear should lay flat against your head. If it is bunching, adjust the headgear crown strap to allow the headgear to flatten.
- To help stabilize the mask, adjust the headgear crown strap. This will help keep the mask from sliding down on the face.

Removing the Mask

Disconnect the lower straps by removing one or both headgear clips.
Slide the headgear over your head. The entire headgear stretches for easy removal.

Removing and Attaching the Mask Cushion

Removing:

1. Pull outward on the three attachment tabs on each side of the mask cushion until this cushion separates from the mask frame (Figure 8).
2. Remove the gel cushion and flap to allow for cleaning.

Attaching:

1. To replace the gel cushion, place the gel cushion inside the flap and press into place.
2. Place the flap and gel cushion over the spring and press down along the sides and bottom of the flap until it clicks into place. If the spring is not correctly seated inside the flap, you may hear a whistling noise when the airflow is applied.

Removing and Attaching the Forehead Pad

1. To remove the gel forehead pad, simply grasp the pad and peel it away from the forehead support bracket (Figure 9).
2. To attach, place the gel forehead pad into the forehead support bracket. Line up the tabs and press the forehead gel cushion into place. The gel pad is correctly in place when the tabs on the forehead bracket are over the white base of the gel pad.

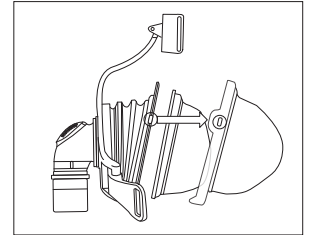


Figure 8

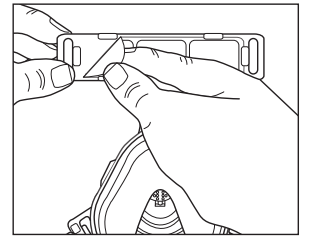
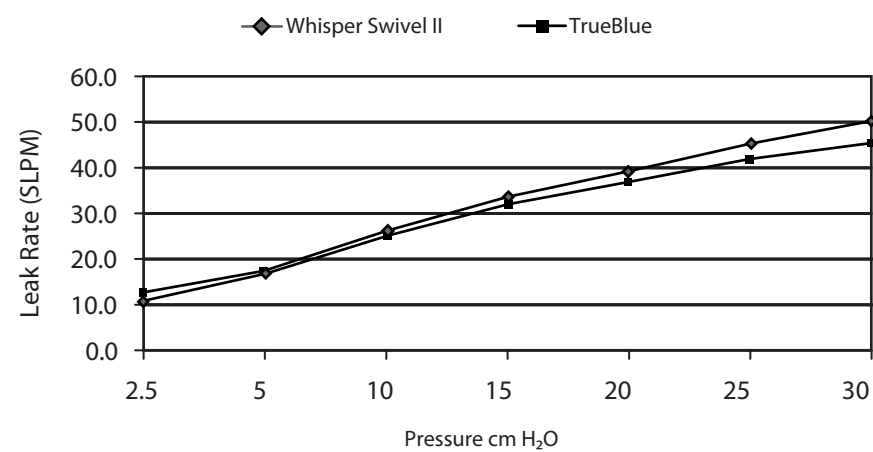


Figure 9

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)

	50 SLPM	100 SLPM
All sizes	0.3	0.9

Deadspace Volume

Petite	88 mL
Small	108 mL
Medium	108 mL
MediumWide	124 mL
Large	122 mL

Disposal

Dispose of in accordance with local regulations.

Storage Conditions

Temperature: -4° to 140° F (-20° to +60° C)
Relative Humidity: 15% to 95% non-condensing

Limited Warranty

Respironics, Inc. warrants that its mask systems (including mask frame and cushion) (the "Product") shall be free from defects of workmanship and materials for a period of ninety (90) days from the date of purchase (the "Warranty Period").

If the Product fails under normal conditions of use during the Warranty Period and the Product is returned to Respironics within the Warranty Period, Respironics will replace the Product. This warranty is non-transferable and only applies to the original owner of the Product. The foregoing replacement remedy will be the sole remedy for breach of the foregoing warranty. This warranty does not cover damage caused by accident, misuse, abuse, negligence, alteration, failure to use or maintain the Product under conditions of normal use and in accordance with the terms of the product literature, and other defects not related to materials or workmanship. This warranty does not apply to any Product that may have been repaired or altered by anyone other than Respironics.

Respironics disclaims all liability for economic loss, loss of profits, overhead, or indirect, consequential, special or incidental damages which may be claimed to arise from any sale or use of the Product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS SPECIFICALLY DISCLAIMED. SOME STATES DO NOT ALLOW DISCLAIMERS OF IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE.

To exercise your rights under this limited warranty, contact your local authorized Respironics, Inc. dealer or Respironics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

Manufactured for:

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