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. This mask does not contain natural rubber latex or DEHP.

Caution

US 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.
• 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.
• If you are using the device, the oxygen flow must be turned off when the device is not in operation. 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.
• Do not place the headgear into the dryer.
• 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.

Caution

Do not block or try to seal the exhalation port. Explanation of the Warning:

Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. By allowing 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.

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” in this document.

1. Hand wash the mask and headgear in warm water with a mild liquid dish washing detergent. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.

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

2. Rinse thoroughly with water and air dry out of direct sunlight. Make sure the mask is dry before use.

Consult Instructions for Use

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

Hand wash the mask after every use. Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

Institutional Disinfection

For multi-patient use in the hospital/institutional environment, use the Disinfection Guide to reprocess the masks 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.

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 supplier 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.

Put-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 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. This allows the mask to 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.

Minimal leaks are acceptable. Small adjustments are needed to eliminate excessive leaks. We suggest performing the adjustments in the following order:

4. Overtightened, it can hinder the mask’s performance and seal.

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.
5. Over tightening can overstated.

b) Do not pull the mask by the elbow.

2. If leaks occur, adjust the side straps.

3. Do not pull the mask by the elbow.

c) For leaks around the top lip, adjust the lower straps (Figure 7).

4. 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 gel mask is not customizable. Do not attempt to heat. The gel mask is not customizable.

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.

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.

Warning: Do not apply moisturizer/lotion to your face or hands prior to handling/wearing the mask.

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

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

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

Hand wash the mask. 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” in this document.

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.

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

Hand wash before first use and daily. The headgear should be hand washed weekly, or as needed.
Comfort Tips

- The headgear should fit both loosely and comfortably. If your skin bulges around the mask, loosen the headgear.
- 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.

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 the hairflow 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.

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

![Intentional Leak graph]

Pressure Drop (cm H₂O)

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<th>Pressure cm H₂O</th>
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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: -4º to 140º F (-20º to +60º 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 not 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.

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