

Instructions for use

Pico Traditional Nasal Mask

Intended Use

This 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.

Notes:

- Exhalation is built into this mask. A separate exhalation device is not required.
- This mask is not made with natural rubber latex or DEHP.

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

Symbols



Warning or Caution



Note



Tip



Not Made with Natural Rubber Latex



System One Resistance Control

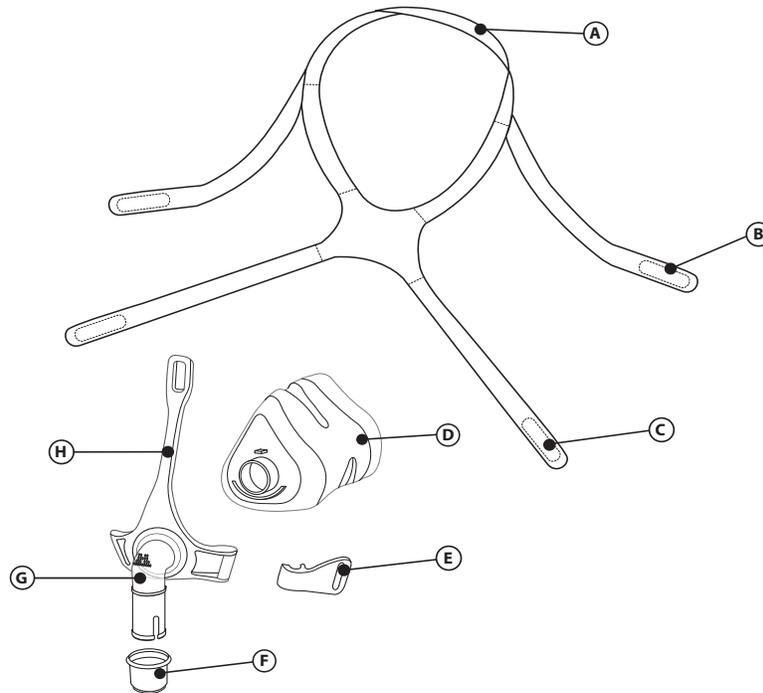
⚠ Warnings

- This mask is not suitable for providing life support ventilation.
- Hand wash prior to use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- Consult a physician or dentist if you encounter tooth, gum, or jaw soreness. Use of a mask may aggravate an existing dental condition.
- Consult a physician if you experience the following symptoms while using the mask or after removing it: Drying of the eyes, eye pain, eye infections, or blurred vision. Consult an ophthalmologist if symptoms persist.
- Do not block or seal off the exhalation ports.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, sores, or bulging skin around the edges of the mask. Loosen the headgear straps to alleviate problems.
- 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.
- 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.

- 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.
- 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.
- Attaching an exhalation device requires therapy pressure level adjustment to compensate for increased leak.

Features



- (A) Headgear crown strap
- (B) Headgear top strap with tabs
- (C) Headgear bottom strap with tabs
- (D) Mask cushion
- (E) Clip
- (F) Tubing quick release
- (G) Elbow with built-in exhalation ports (Do not block)
- (H) Mask frame

Before Use Read and Understand the Instructions Completely.

- Hand wash the entire mask ①.
- Wash your face. Do not use moisturizer/lotion on your hands or face.
- Inspect the mask for damage or wear. Discard and replace any damaged or worn parts.

Cleaning Instructions

Hand wash the entire mask before first use ①. The non-fabric parts should be hand washed daily. The fabric parts should be hand washed weekly.

1. Hand wash in warm water with a liquid dish soap.

⚠Cautions:

- Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
- Do not place the fabric parts into the dryer.
- Any deviation from these instructions may impact the performance of the product.
- Inspect the entire mask for damage or wear (cracking, crazing, tears, damage, etc). Discard and replace any parts as necessary.

2. Rinse thoroughly. Air dry completely before use. Make sure the entire mask is dry before use. Lay the fabric parts flat or line dry.

Dishwashing Instructions

In addition to hand washing, the mask may be cleaned in the dishwasher once a week.

⚠ Caution: Use a liquid dish washing detergent only to wash the mask.

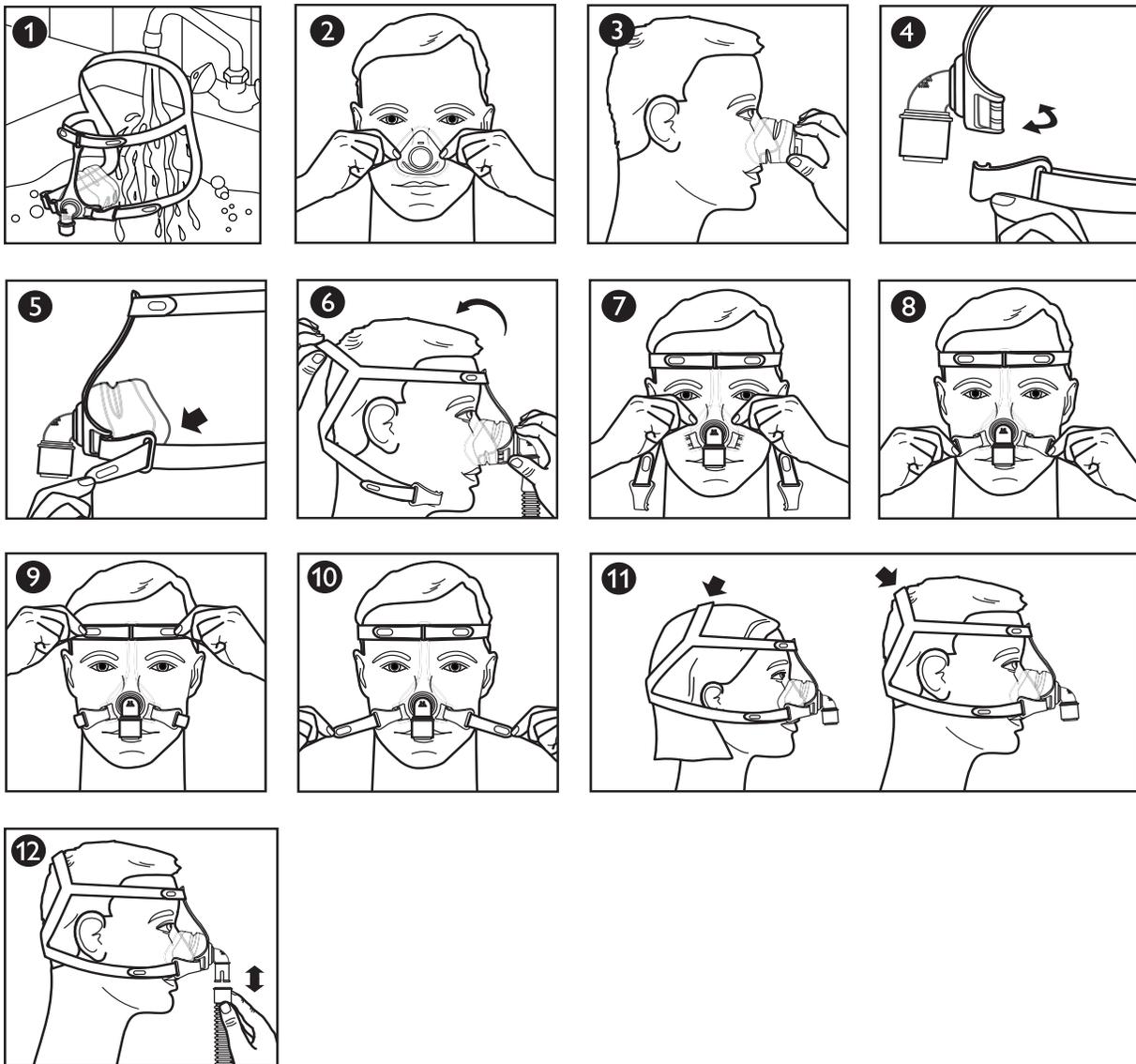
1. Remove the headgear. Do not wash the headgear in the dishwasher.
2. Separate the cushion and the frame and wash in the top shelf of the dishwasher.
3. Air dry. Make sure the mask is dry before use.

⚠ Warning: Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any parts 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 online at www.healthcare.philips.com, or by contacting Philips Respironics Customer Service at 1-800-345-6443 (USA or Canada) or at +1-724-387-4000.

Achieving the Right Fit



Before Putting on the Mask

1. Sizing: The cushion should fit the width of your nose without blocking the nostrils ❷. The top of the cushion may sit between the bridge and tip of your nose ❸.

Putting on the Mask

2. Clip: To disconnect turn like a key ❹.
3. Headgear tab: To undo peel away from the headgear strap ❺.
4. Headgear: Pull the headgear on over your head ❻.
5. Cushion: Place the cushion over your nose ❼.
6. Clip: To connect, press onto the mask frame ❽.
7. Headgear tab: Press tab against the headgear strap to reattach ❾.

Adjusting the Mask

8. Headgear: Adjust the top straps evenly ❿.
9. Headgear: Adjust the bottom straps evenly ⓫.

⊖ Note: Do not overtighten the headgear.

The location of the headgear crown strap may vary depending on head size. Position the strap so the mask sits comfortably ⓬.

Using the mask

10. Connect the flexible tubing (included with CPAP or bi-level device) to the quick release swivel.
11. Turn the therapy device on. Lie down. Breathe normally.
12. Assume different sleeping positions. Move around until comfortable. If there are any excessive air leaks, make final adjustments. Some air leaking is normal.

Tubing Quick Release

The elbow is equipped with a tubing quick release for the CPAP tubing. Pull on the tubing quick release and it will disengage from the elbow and come loose with the tubing ⓭.

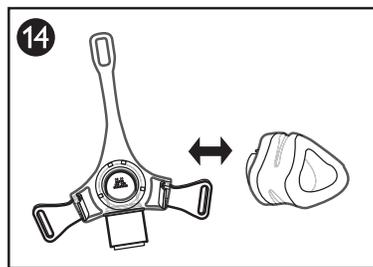
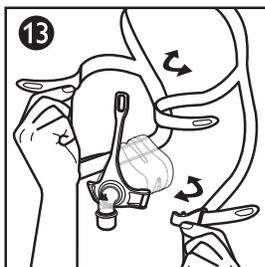
✳ Comfort Tips

- The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If your skin bulges around the mask or if red marks appear on your face, loosen the headgear.
- Re-seat the mask by pulling it directly away from your face and gently setting it back into place.

Removing the Mask

Disconnect a bottom clip or undo a headgear tab. Slide the headgear forward over your head.

Disassembly / Assembly



Removing the Headgear ❿

Peel away the tabs and pull through the slots in the mask frame or clip.

Removing the Cushion ⓫

Pull cushion away from the frame.

Attaching the Cushion 14

1. Align the cushion size (S/M, L, XL) mark on the bottom of the cushion to the bottom edge of the frame.
2. Press cushion onto frame until it clicks into place.

Attaching the Headgear 13

1. With the crown strap upward hold the top straps together.

ⓘ Note: The Philips Respironics logo is on the outside back of the headgear when correctly assembled.

2. Thread the top straps through the top slot in the mask frame.
3. Thread the bottom straps through the bottom slots in the mask frame or clips.
4. Fold the ends back and press the tabs onto the straps.

Philips Respironics System One Resistance Control

This mask when combined with a Philips Respironics System One device, provides optimal resistance compensation. This mask value is X1 and should be set by the provider.

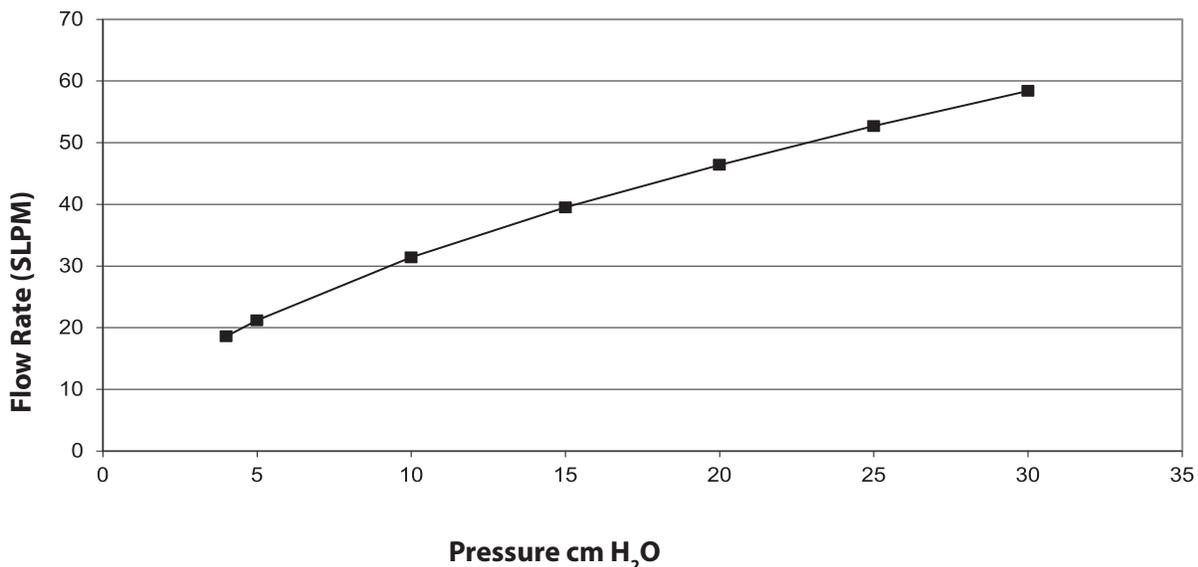
ⓘ Notes:

- Compare the mask to the device. See the device manual if the values do not match.
- System One is not compatible with masks that use a separate exhalation device.

Specifications

⚠ Warning: The technical specifications of the mask are provided for the healthcare professional to determine if it is compatible with the 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.

Pressure Flow Curve



Resistance

Drop in Pressure at

	50 SLPM	100 SLPM
All sizes	0.4	1.4

Deadspace

S/M	60 mL
L	72 mL
XL	80 mL

Sound Levels

A-weighted Sound Power Level 27 dBA
A-weighted Sound Pressure Level at 1 m 19 dBA

Disposal

Dispose of in accordance with local regulations.

Storage Conditions

Temperature: -4° F to 140° F (-20° C 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.



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