

RESPIRONICS

DreamWear

Nasal Mask with Under the Nose Cushion

Instructions for use - **EN**1 Safety Information

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 (>66 lbs/30 kg) for whom CPAP or bi-level therapy has been prescribed.

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

⊖ Note: Not made with natural rubber latex or DEHP.

Warning: Indicates the possibility of danger to the user or operator.

Caution: Indicates the possibility of damage to the device.

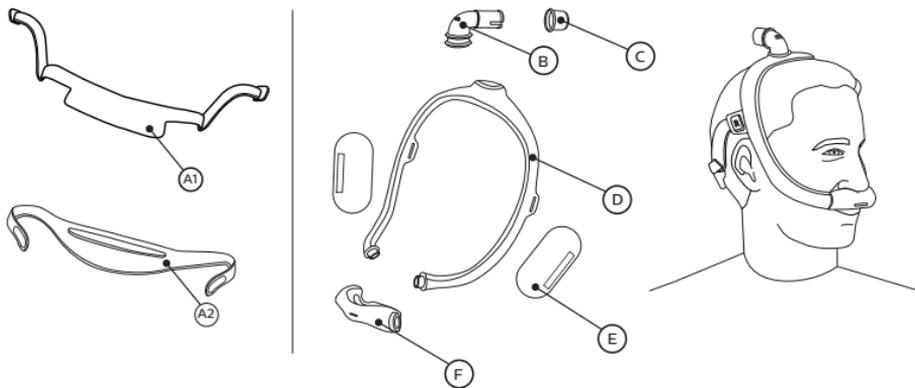
⚠ Warnings

- This mask is not suitable for providing life support ventilation.
- Discontinue use and contact your healthcare professional if any of the following symptoms occur: skin redness, irritation, discomfort, blurred vision, or drying of the eyes.
- Discontinue use and consult your healthcare professional if any of the following symptoms occur: unusual chest discomfort, shortness of breath, severe headache, eye pain or eye infections.
- Discontinue use and consult your healthcare professional if any of the following symptoms occur: tooth, gum, or jaw soreness. Use of a mask may aggravate an existing dental condition.
- 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 symptoms.

- Do not block or seal off the exhalation ports.
- Use of this mask while the system is not on and operating may cause rebreathing of exhaled air. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.

Note: Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the Member State in which the user and/or patient is established.

2 What's in the Package



Headgear

Note: You will receive one of the following headgears with your mask. Throughout these instructions, (A1) and (A2) will both be referred to as "headgear" unless otherwise specified.

- (A1) Headgear with arms
- (A2) Headgear

Other Components

- (B) Elbow with built-in exhalation (do not block)
- (C) Tubing quick release (may remain in the CPAP hose)
- (D) Mask frame (available in small (SM), medium (MED), large (LG))
- (E) Mask frame fabric sleeves (optional)
- (F) Mask cushion (available in multiple sizes) with built-in exhalation (do not block)

3 Before Use

- Hand wash the entire mask before use (see *Mask Care* section).
 - Inspect the entire mask. Discard and replace any damaged or worn parts.
- ⚠ Caution:** Wash your face. Do not use moisturizer or lotion on your hands or face.

4 Achieving the Right Fit

Cushion Sizing

Multiple cushion sizes are available.

- *Tip:** For the best performance, use the smallest cushion that fits your nose.
1. The cushion opening will be directly under your nostrils. The cushion will hug your nose and leak will be minimal.
 2. At no time should your nose be inside the cushion opening. If any part of the cushion overlaps your nose, the cushion is being worn incorrectly. A different size cushion may be needed.

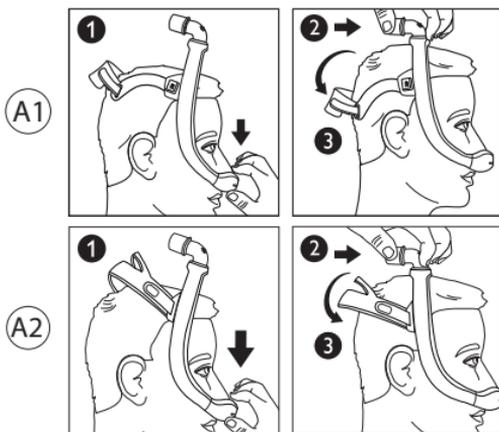
Contact your healthcare provider for additional information.

Philips Respironics DreamStation Mask Type and System One Resistance Control Settings

Using your mask with a Philips Respironics DreamStation or System One device provides optimal comfort. The provider sets this value (X1) on your device.

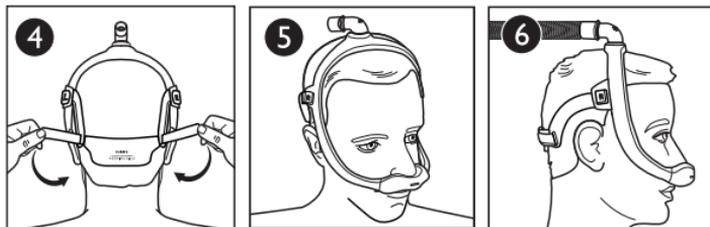
Putting on the Mask

- 1 With the mask assembled (see *Assembly* section), place the cushion under the nose.
- 2 Position the frame on the top of the head.
- * **Tip:** For proper sizing, see *Cushion sizing* and *Mask frame selection* sections.
- 3 Pull the headgear over the back of the head.



Adjusting the Mask

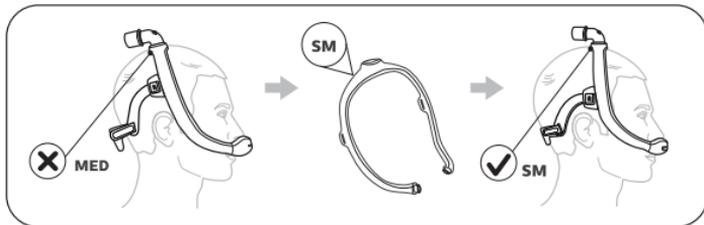
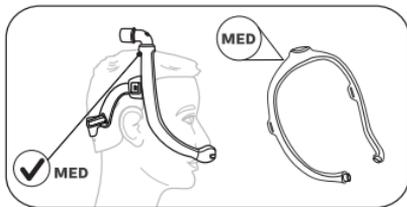
- 4 Peel the headgear tabs away from the fabric. Adjust the strap length. Press the tabs back against the fabric to reattach.
- ≡ **Note:** Do not overtighten the headgear. Signs of overtightening include redness, sores, or bulging skin around the edges of the mask.
- 5 Position the mask until it fits comfortably.
- 6 When finished the elbow should rest at the top of the head.



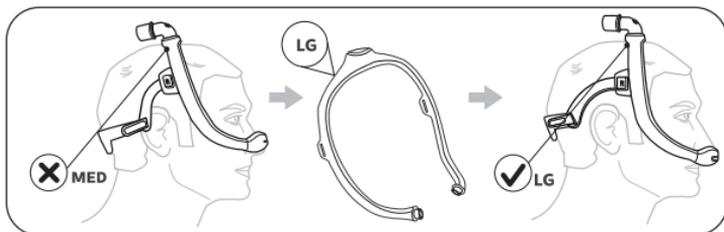
Mask Frame Sizing

- Medium (MED) frame
- Small (SM) frame
- Large (LG) frame

The medium (MED) mask frame will comfortably fit most faces. If the MED frame does not fit your face, contact your healthcare provider to see if a small (SM) or large (LG) mask frame would better suit your needs.



***Tip:** If the mask frame falls backward and is too close to your ears you may need a smaller mask frame.



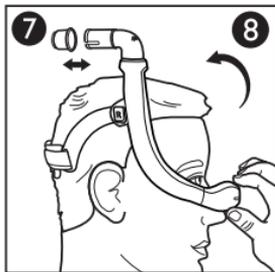
***Tip:** If the mask frame falls forward on the head and is too close to your eyes you may need a larger mask frame.

Using the Mask

1. Connect the CPAP tubing (included with the CPAP device) to the tubing quick release on the elbow.
2. Turn the therapy device on. Lie down. Breathe normally.
3. 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. Pull on the tubing quick release and it will disengage from the elbow and come loose with the tubing. 7



Removing the Mask

To keep your adjustments, remove the mask by grasping the cushion and pulling forward away from the nose. Then pull the cushion and mask up and off of the head. 8

5 Mask Care

Cleaning Instructions

⚠ Cautions:

- Do not place the headgear or the fabric sleeves into a clothes dryer.
- Any deviation from these instructions may impact the performance of the product.
- Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

Daily: Hand wash the mask cushion, frame, elbow, and tubing quick release.

Weekly: Hand wash the headgear and the fabric sleeves.

1. Disassemble the mask (see *Disassembly* section).
 2. Submerge and hand wash the mask in warm water with liquid dishwashing detergent.
- ☹ **Note:** Ensure there are no air pockets present inside the mask parts while submerged.
3. Rinse thoroughly.
 4. Lay the headgear and fabric sleeves flat or line dry. Make sure the entire mask is dry before use.

Dishwashing Instructions

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

⚠ Cautions:

- Use a mild liquid dish washing detergent only to wash the mask.
 - Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
 - Do not use the drying cycle on the dishwasher.
1. Remove the headgear and the fabric sleeves. Do not wash these parts in the dishwasher.
 2. Wash in the top shelf of the dishwasher.
 3. Air dry. Make sure the mask is dry before use.

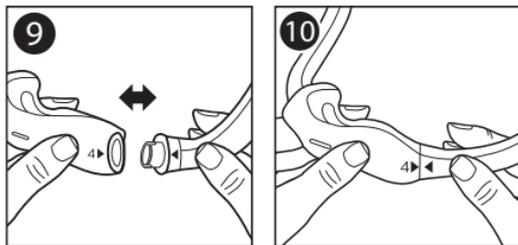
6 Assembly and Disassembly

Assembly

✳ **Tip:** Align the triangles on the cushion and frame for proper assembly.

1. Cushion: Press into the mask frame until the cushion clicks into place. 9 10

⊖ **Note:** The end of the cushion and the opening in the mask frame are 'D' shaped. The cushion end should match the frame.



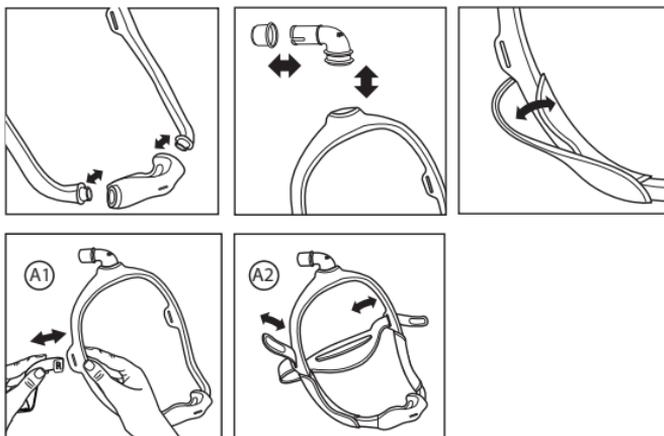
2. Elbow: Insert into the top of the mask frame.
3. Tubing quick release: Push the tubing quick release onto the elbow until it clicks into place.
4. Fabric sleeves: Wrap the sleeves around the mask frame and press the strips together.

⊖ **Note:** The sleeve seams should be on the outside of the frame.

5. Headgear assembly:
- Headgear with arms (A1): Push the headgear clip through the mask frame loop. Connect the second clip to the mask frame loop on the other side. Slide the tabs into the slots on the arms and fold backwards.
- ⊖ **Note:** The headgear arms have “L” and “R” symbols to show which side of your head each arm should go on. Once the mask is on, the symbol should face outward with the “L” on the left side of your head and the “R” on the right side of your head.
- Headgear (A2): Slide the tabs into the slots on the mask frame and fold backwards.
- ⊖ **Note:** The Philips Respironics logo will be on the outside and facing up when correctly assembled.
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Disassembly

- Headgear disassembly:
 - Headgear with arms (A1): Gently pull each headgear clip out of the mask frame loop.
 - Headgear (A2): Undo the headgear tabs and pull through the slots in the mask frame.
- Fabric sleeves: Undo the strips and remove from the mask frame.
- Tubing quick release: Pull the tubing quick release from the elbow.
- Elbow: Pull the elbow from the top of the frame.
- Cushion: Pull the cushion from the mask frame.



7 Health Care Provider & Clinician Information

Useful Life

The useful life of the mask depends on the use conditions and maintenance (cleaning, institutional disinfection, and component replacement) of the device. Inspect the mask parts regularly for damage or wear. Replace components as deemed necessary.

Institutional Disinfection

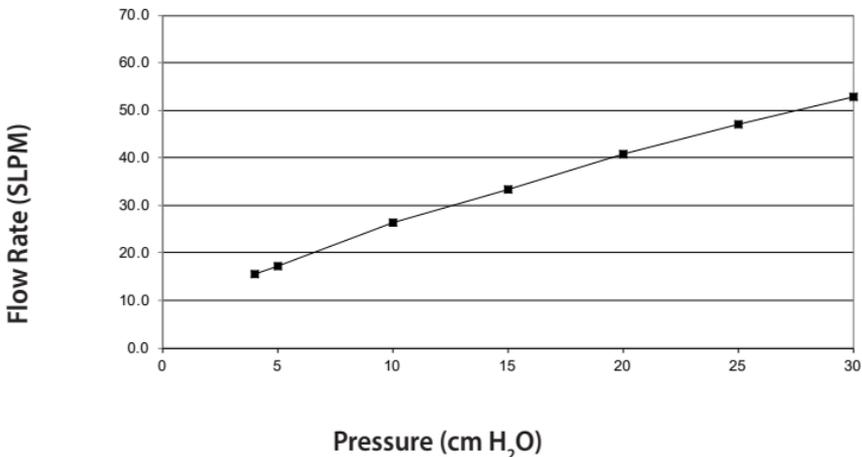
Clean and disinfect the mask daily and between patients when in use in a clinical setting. Refer to the Disinfection Guide for Professional Users to reprocess between patients in a clinical setting. Access the latest version of the Disinfection Guide at www.healthcare.philips.com or by contacting customer service at 1-800-345-6443 (USA or Canada only) or +1-724-387-4000.

Specifications

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.

⚠ Warning: Use outside of these specifications may result in ineffective therapy. The pressure flow curve shown below is an approximation of expected performance. Exact measurements may vary.

Pressure Flow Curve



Resistance

Drop in Pressure (cm H ₂ O)	at 50 SLPM	at 100 SLPM
All cushion sizes	1.1	3.8

Deadspace

87 mL

 **Note:** This value represents largest deadspace of the mask.

Sound Levels

A-weighted Sound Power Level: 25.02 dBA

A-weighted Sound Pressure Level at 1 m: 17.51 dBA

Disposal

Dispose of in accordance with local regulations.

Dispose of the mask and headgear annually.

Storage Conditions

Temperature: -4° F to 140° F (-20° C to 60° C)

Relative Humidity: 15% to 95%

8 Symbols Glossary

Refer to <http://www.symbols.philips.com> for a description of the symbols used on this device and its packaging.

Symbol	Title and Meaning	Symbol	Title and Meaning
	Manufacturer - Indicates the medical device manufacturer		Date of manufacture - Indicates the date when the medical device was manufactured.
	Catalogue number - Indicates the manufacturer's catalogue number so that the medical device can be identified.		Prescription device
	Consult instructions for use		Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation - Indicates the range of humidity to which the medical device can be safely exposed.		Not made with natural rubber latex
	Caution - Indicates the need for the user to consult the instructions for use.		Philips Respironics System One Resistance Control Value - Indicates the therapy device comfort setting.
	Authorized representative in the European Community		Batch code - Indicates the manufacturer's batch code so that the batch or lot can be identified.

9 Limited Warranty

Respironics, Inc., a Philips company, warrants that the system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of ninety (90) days from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace – at its option – the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, water ingress, and other defects not related to material or workmanship. The Respironics, Inc. Service department shall examine any devices returned for service, and Respironics, Inc. reserves the right to charge an evaluation fee for any returned device as to which no problem is found after investigation by Respironics, Inc. Service.

This warranty is non-transferable by unauthorized distributors of Respironics, Inc. products and Respironics, Inc. reserves the right to charge dealers for warranty service of failed product not purchased directly from Respironics, Inc. or authorized distributors.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this 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 warranties – including any warranty of merchantability or fitness for the particular purpose – are limited to two years. Some states do not allow limitations on how long an implied warranty lasts, 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 warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics, Inc. at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550
1-724-387-4000

or
Respironics Deutschland GmbH & Co. KG
Gewerbestr. 17
82211 Herrsching, Germany
+49 8152 93060

Limited Warranty for Australia and New Zealand only

Note: For Australian and New Zealand customers this warranty replaces the warranty contained above.

1. Respironics, Inc., a Philips company (“Philips Respironics”), warrants that the Products shall be free from defects of workmanship and materials and will perform in accordance with the Product specifications. 2. This warranty is valid for a period of 30 days from the

date of purchase from an authorized Philips Respironics dealer. 3. If the Product is found to contain a defect of workmanship or materials or fails to perform in accordance with the Product specifications during the applicable warranty period, Philips Respironics will repair or replace, at its option, the defective material or part. 4. The customer is responsible for returning the product to an authorised Philips Respironics dealer, and collecting the product from the authorised Philips Respironics dealer after repair or replacement, at its own cost. Philips Respironics is responsible only for the freight cost of transporting the product between the authorised Philips Respironics dealer and Philips Respironics. Philips Respironics reserves the right to charge an evaluation and postage fee for any returned Product as to which no problem is found following investigation. 5. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to materials or workmanship. 6. The warranty provided by Philips Respironics herein is not transferrable by the Buyer in the event of any sale or transfer of Products purchased by the Buyer from an authorized Philips Respironics dealer. 7. To the extent permitted by law, where the Buyer has the benefit of an implied guarantee under the Australian Consumer Law, but the Product is not of a kind ordinarily acquired for personal, domestic or household use or consumption Philips Respironics' liability shall be limited, at the option of Philips Respironics, to the replacement or repair of the Product or the supply of an equivalent Product. 8. To exercise your rights under this warranty, contact your local authorised Philips Respironics dealer. A list of all authorised dealers is available at the following link: <http://www.philips.com.au/healthcare>.

Alternatively, you can make a claim under this warranty by contacting Philips Respironics directly at: Philips Electronics Australia Limited, 65 Epping Road, North Ryde NSW 2113, Australia. Tel: 1300 766 488, Email: prcontact@philips.com. 9. The following statement is provided to a Buyer who is a "consumer" under the Australian Consumer Law: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the good repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure. 10. The following statement is provided to a Buyer who is a "consumer" under the Consumer Guarantees Act 1993, New Zealand: Our goods come with guarantees that cannot be excluded under the Consumer Guarantees Act 1993. This guarantee applies in addition to the conditions and guarantees implied by that legislation.

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