

# DreamWear Silicone Pillows Mask

## User Manual

### 1 Using the Product Safely

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#### Intended Use

The DreamWear Silicone Pillows Mask is intended for use as an interface for performing CPAP or bi-level therapy. This mask is used on a single patient in the home or on multiple patients in hospitals and healthcare facilities. The mask is used on patients (weight exceeding 30 kg) for whom CPAP or bi-level therapy is prescribed.

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#### Note:

- This mask does not contain natural rubber latex or DEHP (di(2-ethylhexyl) phthalate).

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**Warning:** Warnings indicate a hazard to the patient or the operator of the device.

**Caution:** Cautions indicate possible damage to the mask.

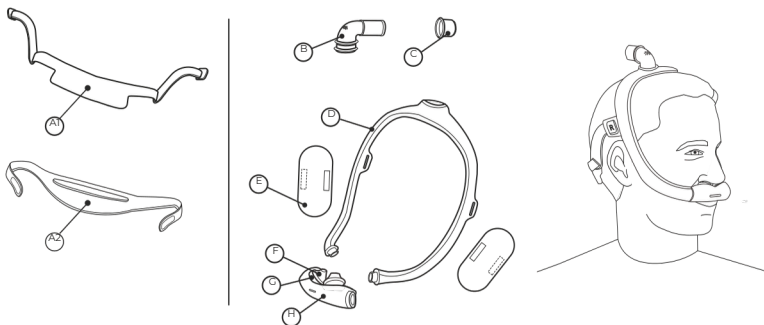
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#### Warnings

- This mask is not suitable for patients who are using an assist ventilator device for life support.
- If this mask is used when the CPAP or bi-level device is not operating, exhaled air may be re-breathed. If the patient re-inhales exhaled breath for more than a few minutes, suffocation may occur.
- If any of the following symptoms occurs, stop using the mask and consult a physician: skin redness, irritation, discomfort, blurred vision, dry eyes, eye pain, or eye infection.
- Abnormal chest discomfort, shortness of breath, or severe headache.

- Pain in teeth, gums, or jaw. If preexisting symptoms involving the teeth become worse, consult a physician.
- Do not overtighten the headgear strap. Watch for signs of overtightening, such as bulging, redness, or sores of the skin around the edges of the mask. Loosen the headgear strap to alleviate these symptoms.
- Do not block or seal off the exhalation ports.

## 2 Package Contents



### Headgear

(A1) Headgear with arms (included)

(A2) Headgear (optional)

Note: The (A2) headgear is optional. Contact your health care provider for more information. Unless specifically indicated in this Instruction Manual, the term “headgear” refers to both (A1) and (A2).

### Other Components

(B) Elbow with exhalation port (do not block)

(C) Quick swivel (may be used attached to CPAP breathing circuit)

(D) Mask frame (may be selected from small (SM), medium (MED), and large (LG))

(E) Fabric frame cover (optional)

(F) Pillows cushion tip

- Ⓒ Pillows cushion base (do not insert into nostrils)
- Ⓗ Pillows cushion platform (available in multiple sizes) with built-in exhalation port (do not block exhalation port)

## 3 Before Use

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- Hand wash the entire mask before use. (See the “Mask Handling” section.)
  - Inspect the mask. Discard and replace any parts which are damaged or worn.
- ⚠ Caution: Wash your face. Do not apply moisturizer or lotion on your hands or face.

## 4 Correct Mask Wearing

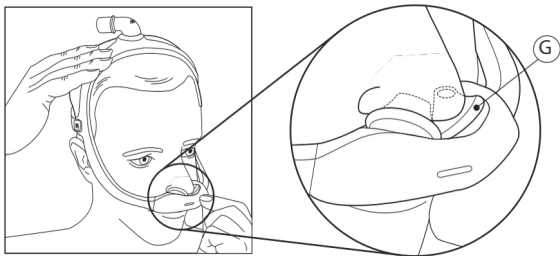
### Cushion Size Selection

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Multiple cushion sizes are available.

1. Place the pillows cushion tips into your nostrils.
2. Choose the cushion so the pillows cushion bases sit comfortably under your nose without any gaps. (See G in the figure below.)

Note: Do not push the pillows cushion bases into your nostrils.



- Ⓒ Pillows cushions base

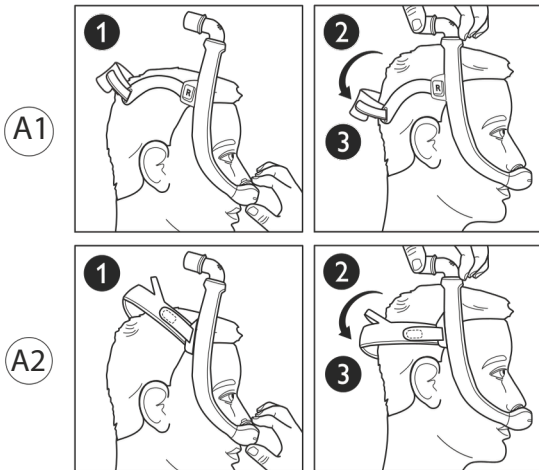
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## Putting On the Mask

- 1 As shown in the figure below, with the mask assembled (see “ Assembly” section), place the cushion under your nose and insert the pillows cushion tips into your nostrils.
- 2 Position the frame on the top of your head.

Tip: For proper sizing, see the “Cushion Size Selection” and “ MaskFrame Size Selection” sections.

- 3 Pull the headgear over the back of your head.



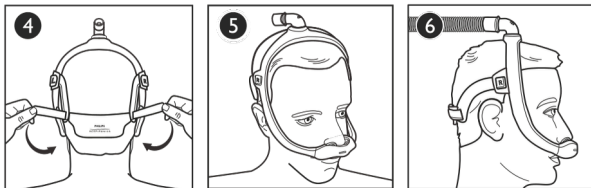
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## Adjusting the Mask

- 4 Peel the headgear tabs away from the fabric. Adjust the length of the straps. Press the tabs against the fabric to reattach.

Note: Do not overtighten the headgear. It may be overtightened if redness or sores around the edges of the mask are seen or if the mask is biting into your cheeks.

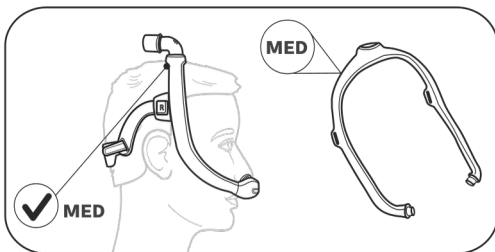
- 5 Position the mask so that it fits comfortably.
- 6 When the mask is worn correctly, the elbow should rest on the top of your head.



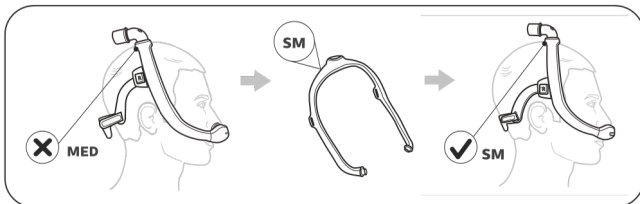
## Mask Frame Size Selection

The mask frame is available in small (SM), medium (MED), or large (LG).

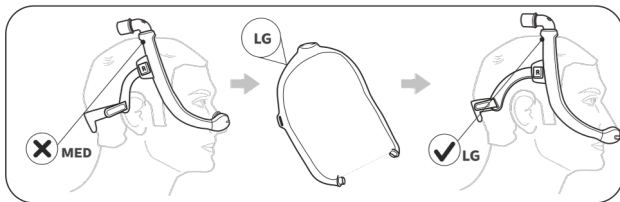
The MED mask frame will comfortably fit most people. If the MED frame is not the right size for your face, contact your healthcare provider to try a SM or LG mask frame.



Tip: If the mask frame falls backward and is too close to your ears as shown in the figure below, you may need a smaller mask frame.



Tip: If the mask frame falls forward on your head and is too close to your eyes as shown in the figure below, you may need a larger mask frame.



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## Using the Mask

1. Connect the CPAP tube (included with the CPAP device) to the tubing quick release on the elbow.
2. Turn on the therapy device power supply, lie down, and breathe normally.
3. Assume different sleeping positions and try them until you are comfortable. Some air leakage is normal, but if you notice excessive air leakage, make adjustments.

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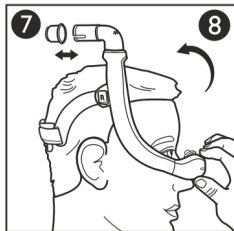
## Quick Swivel

The elbow is equipped with a tubing quick swivel. Pull on the tubing quick swivel, and it will disengage from the elbow and the breathing circuit will loosen. 7

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## Mask Removal

To keep your strap-length adjustments intact when removing the mask, remove it by grasping the cushion and pulling it forward, away from your nose. Then pull the cushion and mask up and off your head. 8



# 5 Mask Handling

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## Cleaning Instructions

### Caution:

- Any use that deviates 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.
- Do not use unapproved cleaners (ozone or UV-based products, etc.) that are not listed in the Cleaning section.
- Do not use a clothes dryer for the fabric frame cover.

Hand wash the mask cushion, frame, elbow, and quick swivel daily. Wash the headgear and frame cover by hand once a week or as needed.

1. Disassemble the mask (see the “Disassembly” section).
2. Inspect the mask for damage or wear (cracks, fissures, tears, damage resulting in gel exposure, etc.). Discard and replace parts as necessary.
3. Submerge and hand wash the mask in lukewarm water (27-32° C) with liquid dishwashing detergent.

Note: Ensure no air is present inside the mask parts while they are submerged.

4. Rinse thoroughly.
5. Lay the headgear and fabric frame cover flat or line dry it. Confirm that the entire mask is dry before using it.

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## Dishwasher Instructions

### Caution:

- Use only a mild liquid dishwashing detergent when washing the mask.
- Do not use the heated drying cycle on the dishwasher.
- Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

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

1. Remove the headgear and the fabric frame cover. Do not wash these in the dishwasher.


2. Disassemble the mask (see the “Disassembly” section).
3. Wash in the top rack of the dishwasher.
4. Air dry. Make sure the mask is dry before use.

## 6 Assembly and Disassembly

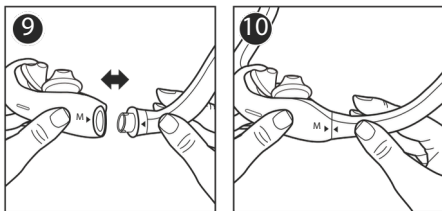
### Assembly

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1. Align the triangles on the cushion and mask frame. Press the cushion into

the mask frame until it clicks into place. 


Note: The end of the cushion and the opening in the mask frame are “D” shaped. Align the edge of the cushion with the frame.



2. Insert the elbow into the top of the mask frame.
3. Press the quick swivel onto the elbow until it clicks into place.
4. Wrap the fabric frame cover around the mask frame and press the edge bonding surfaces together.

Note: The bonding surfaces should be on the outside of the frame.

5. Headgear assembly:

- Headgear with arms 
  - a. Push the end of the right headgear arm (marked with an “R”) through the right mask frame loop. Similarly, push the end of the left headgear arm (marked with an “L”) through the left mask frame loop.
  - b. Slide the fabric tabs into the slots on the arms and fold backwards.

Note: When wearing the mask, the letters must face outward with the “L” on the left side of your face and the “R” on the right side.

- 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.

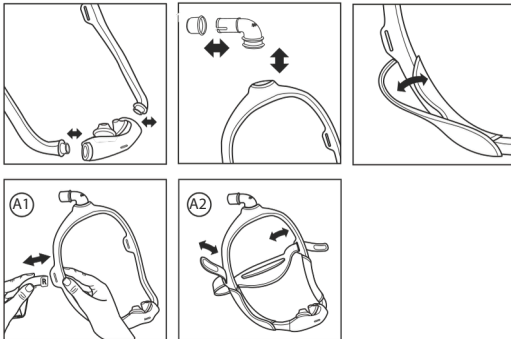
## Disassembly

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### 1. Headgear disassembly:

- Headgear with arms A1: Gently pull each headgear arm out of the mask frame loop.
- Headgear A2: Release the headgear tabs and pull through the slots in the mask frame.

2. Release the strips on the fabric frame cover and remove from the mask frame.
3. Release the quick swivel from the elbow.
4. Release the elbow from the top of the frame.
5. Release the cushion from the mask frame.



## 7 Information for Healthcare Workers and Clinical Physicians

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Note: This section is for health care providers and clinicians.

### MRI Safety Information



The DreamWear Silicone Pillows Mask is MR- incompatible.  
Do not use this mask in an MRI examination room (Zone IV).

## Service life/Number of uses

The useful life of the mask depends on the use conditions and maintenance of the device (cleaning, disinfection method in a hospital or healthcare facility, and part replacement). Inspect the mask regularly to confirm that there is no damage or wear to the parts of the mask. Replace the parts if it is judged necessary.

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## Use in Multiple Patients

For instructions on cleaning and disinfection of the mask when used on patients in a hospital or healthcare institution or for instructions on cleaning and disinfection when used on multiple patients in a hospital or healthcare facility, see the Disinfection Guide for Hospitals and Healthcare Institutions. If you have any questions, please contact a medical institution or Philips Japan.

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## Philips Respironics DreamStation Mask Type and System One Resistance Control Settings

Using the mask with a Philips Respironics DreamStation or System One device provides optimal comfort. The health care provider sets the values below on the device.

Cushion size	Setting
S	X2
M, L	X1

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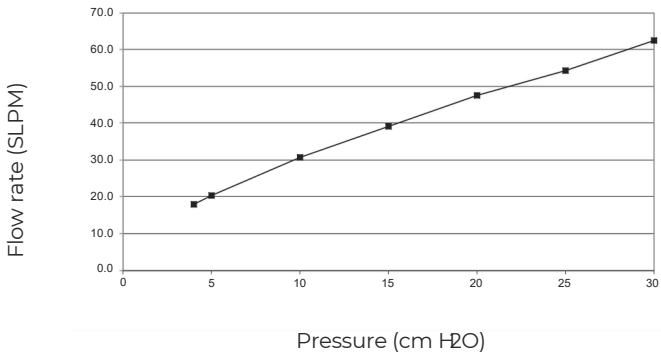
## Specifications

The technical specifications of the masks are described in such a way that healthcare workers can determine if the masks are compatible with the CPAP or BiPAP device.

**Warning:** Use outside of these specifications may result in an inability to obtain optimal therapeutic effects. The pressure flow curve shown below is an approximation of the anticipated performance. The actual measurement value may differ.

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## Pressure Flow Curve



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## Resistance

Pressure drop (cmH <sub>2</sub> O) All cushion sizes	50 SLPM	100 SLPM
	1.2	4.3

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## Dead Space

84ml

Note: This value represents largest deadspace of the mask.

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## Noise Level

Declared dual-number noise emission values (in accordance with ISO 4871)

Noise level at 1 m: 19 dB (A), including 2 dB margin of error

Noise power level: 27 dB (A), including 2 dB margin of error

Values determined according to noise test code given in ISO 17510, using the basic standards ISO 3744 and ISO 4871.

Note: The total of the measured noise emission level plus margin of error indicates the upper boundary of the range of possible measured values.

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## Device Disposal

Dispose of the mask and headgear annually.

Dispose of this device in accordance with local collection and recycling regulations.

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




## Storage Conditions





Temperature: -20° C to 60° C

Relative Humidity: 15% to 95%

## 8 Symbols Glossary

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Symbol	Description	Symbol	Description
	Caution, consult the accompanying documents.		Not Made with Natural Rubber Latex - Indicates that this mask is not made with natural rubber latex.
	Unique Device Identifier - Indicates the Unique Device Identifier information.		Batch Code - Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Humidity Range - Indicates the range of humidity to which the medical device can be safely exposed.		Temperature Range - Indicates the temperature limits to which the medical device can be safely exposed.
	Catalogue Number - Indicates the manufacturer's catalogue number so that the medical device can be identified.	X1 X2	Philips Respironics System One Resistance Control Value - Indicates the therapy device comfort settings.
	Manufacturer - Indicates the medical device manufacturer.		Medical Device - Indicates that the item is a medical device.

Symbol	Description	Symbol	Description
	Electronic Instructions for Use - Indicates that relevant information for use of the product is available in electronic form.		Date of Manufacture - Indicates the date when the medical device was manufactured. Country of Manufacture - Indicates the country of manufacture of the product. Note: On the label, "CC" is replaced by the 2-letter country code.
	Packaging Unit - Indicates the number of pieces in the package.		
	MR unsafe.		

## 9 Warranty

Customers who purchase the DreamWear Silicone Pillows Mask ("Product") directly from Philips Japan, Ltd., or an authorized dealer are provided with a non-transferable limited warranty.

**Warranty Details:** Philips Japan, Ltd. warrants each new Product will be free from defects in materials and workmanship and will perform in accordance with the Product specifications under normal and proper use and maintenance

in accordance with applicable instructions, subject to the exclusions below.

**Warranty Period:** The warranty period for the Product is 90 days from whichever

comes first, the date of shipment to the purchaser or the date on which the purchaser sets this up for the end user. The warranty period for accessories including but not limited to chin straps, replacement parts and disposable products is 90 days from when they are shipped to the initial purchaser.

**Products Not Covered by the Warranty:** This warranty does not apply to any software included with the Product as the software warranty is included in the software license. This warranty does not cover damage or injury to the Product,

personal property, or persons caused by accident, misuse, abuse, natural disaster, water ingress, repair or alteration by anyone other than Philips Japan, Ltd., or an

authorized service center, failure to operate in accordance with the operation manual and instructions, lack of reasonable care, the discontinuance of a network

(e.g. 3G, 3G+, etc.) by a carrier (e.g. ATT, Verizon, etc.) or other defects not


Support from Philips Japan, Ltd.: If a Product fails to conform to the warranties set forth in this manual during the applicable warranty period, Philips Japan, Ltd. will repair or replace the Product or refund the purchase price, at the sole discretion of Philips Japan, Ltd. Philips Japan, Ltd. may use new or remanufactured assemblies, components, and parts in repair and new or recertified refurbished devices for replacement. The remaining period of the original warranty is applied to a Product or component which is repaired or replaced based on this warranty.

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Specific legal rights have been granted to the customer in this warranty, but other rights that differ depending on the country may also be granted. If you have any questions, please contact a medical institution or Philips Japan.



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