

PillowFit Deluxe Nasal Pillow CPAP System



REF 100NP
100NP-NH



CAUTION : Federal (U.S.) Law restricts
this device to sale by or on the order
of a physician.

driveTM

PILLOWFIT DELUXE NASAL PILLOW CPAP MASK

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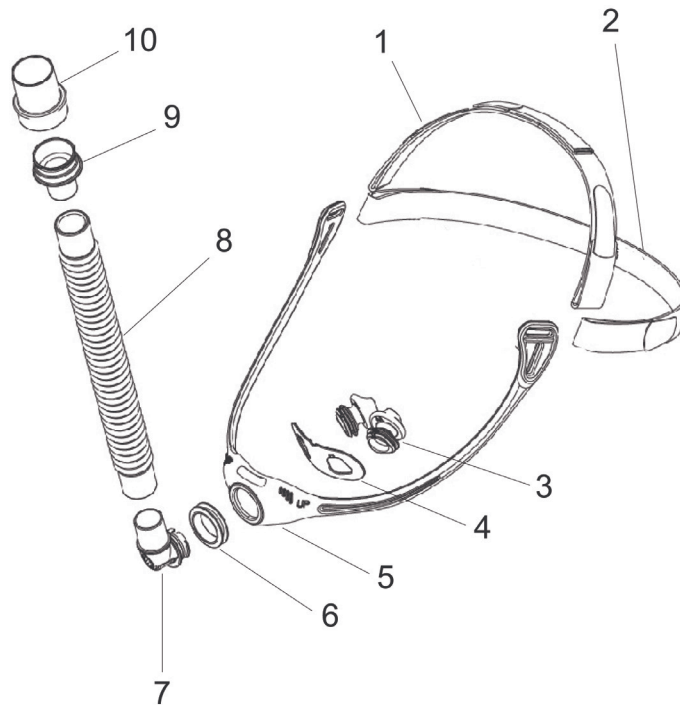
Intended Use

The PillowFit Deluxe nasal pillow mask CPAP system is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level system.

The mask to be used by adult patients (>66lb/ 30kg) for whom positive airway pressure has been prescribed. The mask is for single-patient re-use in the home environment and with proper cleaning multi-patient re-use in the hospital/ institutional environment.

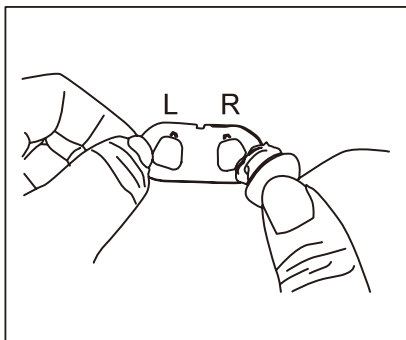


Parts of the Pillow t Deluxe Nasal Pillow CPAP Mask System

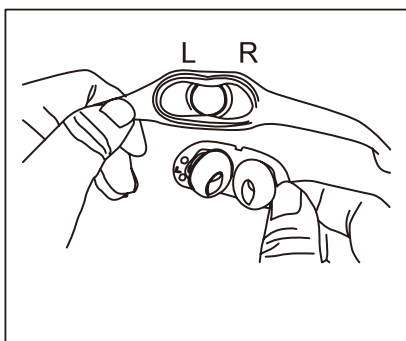


No.	Description
1.	Top headgear
2.	Rear headgear
3.	Pillows(S, M, & L)
4.	Platform
5.	Main frame-silicone
6.	Connector ring
7.	Elbow connector
8.	Silicone tube
9.	Swivel connector
10.	Tubing connector

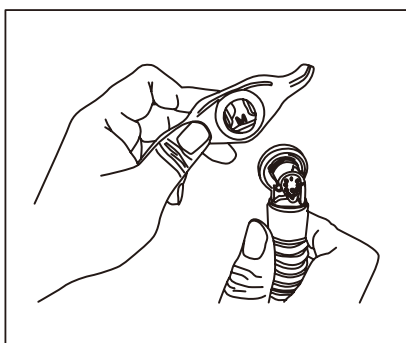
Fitting your Nasal PillowFit Mask



Attach the pillows on the platform. Make sure the tenons are fitted. Your new PillowFit will already have the pillows attached.

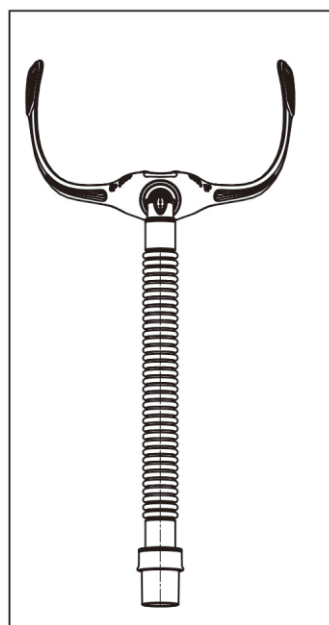


Attach the pillow set into the main frame. Make sure the platform concave is fitted to the main frame protuberance. Match the L and the R on the platform to the L and R on the frame.

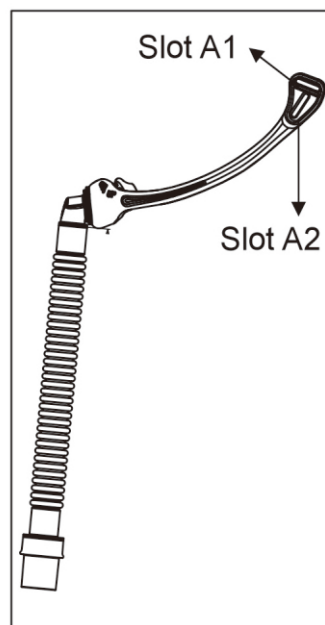


Plug the tube into the main platform.

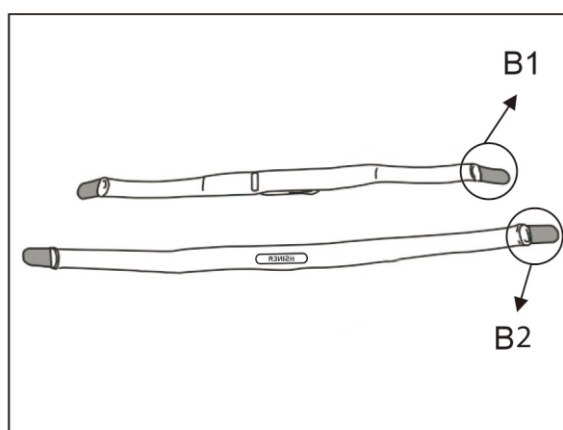
Fitting your PillowFit Deluxe Nasal CPAP System



Front View

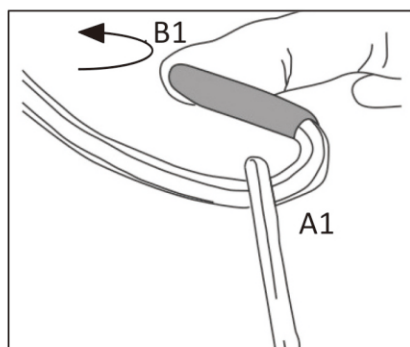


Lateral View

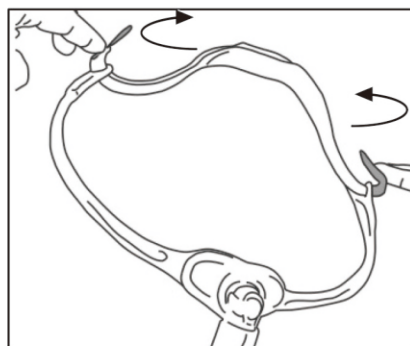


Head Straps

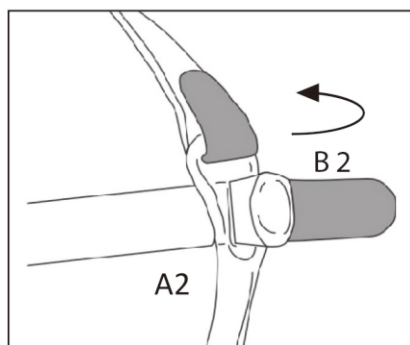
Fitting your PillowFit Deluxe Nasal CPAP System



Insert the head strap B1 into A1 and fasten it.

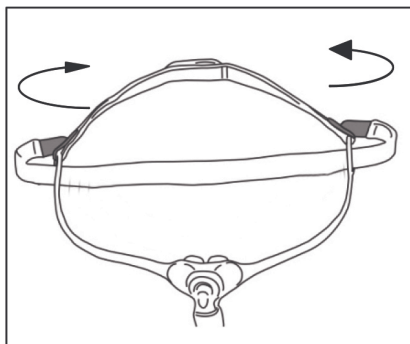


The same with the other side.

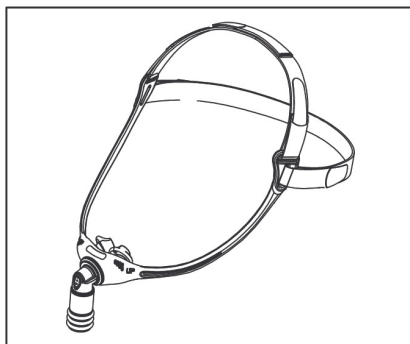


Insert the head strap B2 into A2 and fasten it.

Fitting your PillowFit Deluxe Nasal CPAP System



The same with the other side



Both head straps are now fitted.



Hold the pillows at your nose, and pull the headgear over your head.

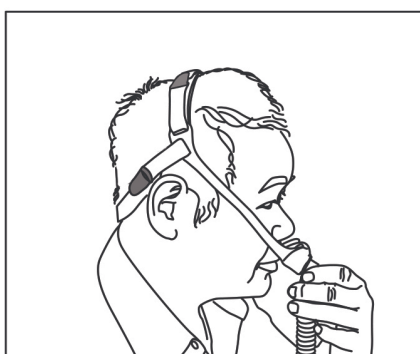
Fitting your PillowFit Deluxe Nasal CPAP System



Adjust top straps
(over tightening
may cause excess
pressure on your
nose).



Adjust each end of
the back strap.

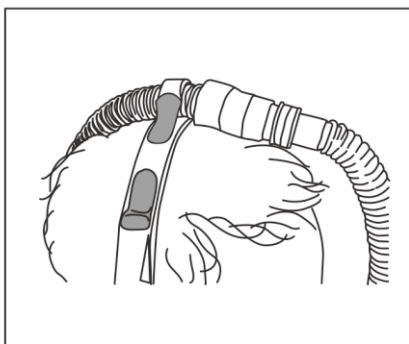


Adjust the angle of
the pillow to ensure
it sits comfortably.

Fitting your PillowFit Deluxe Nasal CPAP System



Now the nasal pillow mask is fitted and ready for use.



Fasten the air tubing through top strap. The tubing can be positioned in the center.



If the pillow mask pulls on your nose, increase length of tube between mask and top strap.

Cleaning the interface:

The cushion, nasal interface, and tubing should be cleaned daily or as needed.

- Hand wash in warm water with a mild liquid dish washing detergent.
Do not use bleach, alcohol, or cleaning solutions containing alcohol.
Do not use cleaners containing conditioners or moisturizers.
- Rinse thoroughly. Pat with a towel and air dry completely before use.
- Inspect all parts for damage or wear; replace if necessary.

Cleaning the Headgear:

Hand wash the headgear weekly or as needed. Lay the headgear flat or line dry.

Disposal:

The nasal pillow mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

**Warnings**

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 device is turned on and functioning properly, new air from the device flushes the exhaled air out through the attached mask exhalation port. However, when the device is not operating enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. At low pressures, the airflow through the exhalation port may not be enough to clear all of the exhaled gas (CO₂) from the mask. You may breathe in some of the air that you have exhaled.

- 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, nasal interface selection, and the leak rate.
- Some users may experience skin redness. If this happens, contact your health care professional.

Replacement Accessories

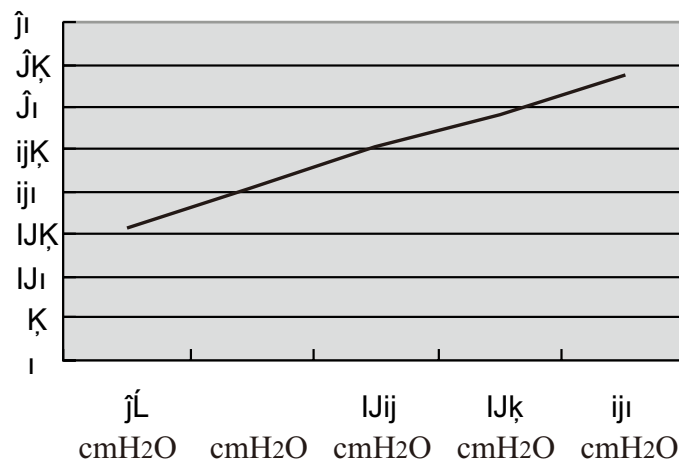
100NP-NH	PillowFit Deluxe Nasal CPAP without Headgear
100NPH	PillowFit Deluxe Replacement Headgear
100NPS-CUSHION	PillowFit Deluxe Small Replacement Cushion
100NPM-CUSHION	PillowFit Deluxe Medium Replacement Cushion
100NPL-CUSHION	PillowFit Deluxe Large Replacement Cushion

Technical Specifications

Pressure-Flow Curve

Note: The mask contains passive venting that meets the requirements for protection against rebreathing as specified in ISO 17510-2. As a result of manufacturing variations, the vent flow rate may vary.

Pressure	4 cmH ₂ O	8 cmH ₂ O	12 cmH ₂ O	16 cmH ₂ O	20 cmH ₂ O
Flow	15.7 LPM	20.4 LPM	25.1 LPM	29.0 LPM	33.7 LPM



Standards

CE designation in accordance with EC directive 93/42/EEC, class Iia. ISO 14971, ISO13485, ISO 10993-1 and ISO 17510-2.

therapy Pressure

4 to 20cmH₂O.

Resistance

Drop in pressure measured at 50L/min: 2.1cmH₂O & 100L/min: 8.0cmH₂O

Sound

27.2 dBA @ 10cmH₂O; 34.6dBA @ 20cmH₂O

Environmental Conditions

Operation temperature: 5°C~50°C
Storage temperature: -20°C~60°C
Storage relative humidity: <85%



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