

# AirFit™ P10

## Nasal Pillows System

Thank you for choosing the AirFit P10. This document provides the user instructions for the AirFit P10 and AirFit P10 for Her masks referred to collectively as AirFit P10 throughout this manual. AirFit P10 has blue headgear while AirFit P10 for Her has pink headgear.

## Using this guide

Please read the entire guide before use. When following instructions, refer to the images at the front and back of the guide.

## Intended use

The AirFit P10 channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device.

The AirFit P10 is:

- to be used by patients (>30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment.

## Clinical benefits

The clinical benefit of vented masks is the provision of effective therapy delivery from a therapy device to the patient.

## Intended patient population/medical conditions

Obstructive pulmonary diseases (eg, Chronic Obstructive Pulmonary Disease), restrictive pulmonary diseases (eg, diseases of the lung parenchyma, diseases of the chest wall, neuromuscular diseases), central respiratory regulation diseases, obstructive sleep apnoea (OSA) and obesity hypoventilation syndrome (OHS).

## GENERAL WARNINGS

- The mask must be used under qualified supervision for users who are unable to remove the mask by themselves. The mask may not be suitable for those predisposed to aspiration.
- The vent must be kept clear.
- The mask should only be used with CPAP or bilevel devices recommended by a physician or respiratory therapist.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air. Explanation: CPAP and bilevel devices are intended to be used with special masks (or 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 mask vent holes. However, when the device is not operating, insufficient fresh air will be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP or bilevel devices.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the CPAP or bilevel device is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well ventilated rooms.
- At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate. This warning applies to most types of CPAP or bilevel devices. The technical specifications of the mask are provided for your clinician to check that they are compatible with the CPAP or bilevel device. If used outside specification or if used with incompatible devices, the seal and comfort of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect the CPAP or bilevel device function.
- Discontinue using this mask if you have ANY adverse reaction to the use of the mask, and consult your physician or sleep therapist.

- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.
- As with all masks, some rebreathing may occur at low CPAP pressures.
- Refer to your CPAP or bilevel device manual for details on settings and operational information.
- The mask is not intended to be used simultaneously with nebulizer medications that are in the air path of the mask/tube.
- Remove all packaging before using the mask.

**Note:** For any serious incidents that occur in relation to this device, these should be reported to ResMed and the competent authority in your country.

## Using your mask

When using your mask with ResMed CPAP or bilevel devices that have mask setting options, refer to the Technical specifications section in this user guide for mask selection options.

For a full list of compatible devices for this mask, see the Mask/Device Compatibility List at [ResMed.com/downloads/masks](https://www.resmed.com/downloads/masks).

### Notes:

- This mask is not compatible for use with ResMed AutoSet CS™ 2 and VPAP™ Adapt SV devices.
- SmartStart may not operate effectively when using this mask with some CPAP or bilevel devices that have this feature.
- If you experience nasal dryness or irritation, using a humidifier is recommended.

## Fitting

1. Hold the pillows away from your nose ensuring that the pillow size (eg, M) with the left (L) and right (R) indicators are correctly facing towards you then guide the nasal pillows into your nostrils (L into your left nostril, R into your right nostril). Pull the headgear over your head by holding the bottom band and stretching it around the back of your head. The top band should sit comfortably on top of your head.

**Tip!** There are raised logos on top of the frame so you can feel the correct way up when fitting in the dark.

2. Move the mask away from your face then place it back to get a comfortable fit. Ensure the nasal pillows fit securely into your nostrils with both pillows positioned upright.
3. Finally, connect the end of the mask tubing into your device air tubing. Your mask is now fitted and ready to use. When the device is running, a light breeze should be felt through the vent. To inspect the vent place a finger close but not over the entire vent area.

## Adjustment

To fix any mask leaks, adjust the headgear by pulling the headgear through the buckle. Adjust only enough for a comfortable seal and do not overtighten. You may need to adjust the headgear as it stretches over time.

## Removal

To take off your mask system, pull the mask and headgear by the split-band, up and over your head.

## Disassembly

1. Holding the top of the mask tubing, squeeze and pull the pillows away from the mask frame.
2. Unhook the headgear from the stabiliser by pulling on the end cap to reveal the buttonhole.
3. Slide the headgear off the end of the stabiliser.

## Reassembly

1. With the grey side facing out, insert each end of the headgear band over the stabilisers through the buttonholes. Secure in place by wrapping each band end up and around the nodes. Holding the split bands, pull the headgear from the stabiliser to ensure it is tightly secure around the nodes. Ensure the headgear band is not twisted.
2. Attach the pillows to the mask frame by inserting the top and bottom clips into the correct slots (shorter clip into top slot, longer clip into bottom slot) on the mask frame. Your mask is now reassembled.
3. Ensure the inner walls of the nasal pillows are not compressed or collapsed. If they are, squeeze each nasal pillow so they return to the correct shape.

## Cleaning your mask at home

Your mask and headgear should only be gently handwashed. The mask vent may discolour over time due to dust. Follow the cleaning instructions in this guide to maintain performance and safety of the mask.

### **WARNING**

Always follow cleaning instructions and use mild soap. Some cleaning products may damage the mask, its parts and their function, or leave harmful residual vapours that could be inhaled if not rinsed thoroughly.

### **CAUTION**

- If any visible deterioration of a system component is apparent (cracking, crazing, tears etc), the component should be discarded and replaced.
- Avoid connecting flexible PVC products (eg, PVC tubing) directly to any part of the mask. Flexible PVC contains elements that can be detrimental to the materials of the mask, and may cause the components to crack or break.
- When fitting the mask, do not overtighten the headgear as this may lead to skin redness or sores around the mask cushion.
- Do not iron the headgear as the material is heat sensitive and will be damaged.

#### Daily/After each use:

- Disassemble the pillows from the frame according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear), by gently rubbing in warm (approximately 30°C) water using mild soap.
- To optimise the mask seal, facial oils should be removed from the pillows after use.
- Use a soft bristle brush to clean the vent.
- Inspect each component and, if required, repeat washing until visually clean.
- Rinse all components well with drinking quality water and allow to air dry out of direct sunlight.

- When all components including the vent are dry, reassemble according to the reassembly instructions.

### Weekly:

- Soak the headgear in warm water with a mild liquid detergent.
- Hand wash the headgear with a soft bristle brush.
- Thoroughly rinse the headgear under running water.
- Leave the headgear to air dry out of direct sunlight.

## Reprocessing the mask between patients

Reprocess this mask when using between patients. Reprocessing instructions are available on [ResMed.com/downloads/masks](https://www.resmed.com/downloads/masks).

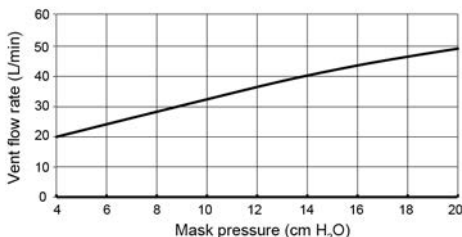
## Troubleshooting

Problem/possible cause	Solution
<b>Pillows won't seal properly, mask is uncomfortable or causes red marks</b>	
Pillows may have been fitted incorrectly, adjusted incorrectly or the headgear is fitted incorrectly.	Check that the nasal pillows with the left (L) and right (R) indicators are inserted correctly (L into your left nostril, R into your right nostril). Carefully follow the fitting instructions. Readjust the headgear to ensure it is fitted comfortably.
Inner wall position of one or both pillows is incorrect.	Squeeze pillow sides to release inner wall. The correct position is shown in the reassembly instructions.
Pillows are the wrong size.	Talk to your clinician.
Pillows may be dirty.	Clean pillows according to the instructions.
Headgear is too loose.	Adjust the headgear by pulling the headgear through the buckle. Adjust only enough for a comfortable seal and do not overtighten. You may need to adjust the headgear as it stretches over time.
Vent is blocked or dirty/discharged.	If the vent requires cleaning, use a soft bristle brush. The vent may discolour over time and this is not a safety concern. Follow the cleaning instructions in this guide to maintain performance and safety of the mask.
Vent is wet.	Ensure the vent is dry after cleaning and in the case of excess condensation.

Problem/possible cause	Solution
<b>Mask too noisy</b>	
System is assembled incorrectly.	Disassemble the mask, then reassemble according to the instructions.
System is leaking air.	Refit or reposition your mask. Adjust your headgear. Check your mask is assembled correctly.

## Technical specifications

<b>Pressure-flow curve</b>	The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations, the vent flow rate may vary.
----------------------------	---



Pressure (cm H <sub>2</sub> O)	Flow (L/min)
4	20
8	29
12	37
16	43
20	49

<b>Dead space information</b>	Physical dead space is the empty volume of the mask to the end of the swivel. Using the large cushions it is 123 mL.
<b>Therapy pressure</b>	4 to 20 cm H <sub>2</sub> O
<b>Resistance</b>	Drop in pressure measured (nominal) at 50 L/min: 0.4 cm H <sub>2</sub> O at 100 L/min: 1.4 cm H <sub>2</sub> O
<b>Sound</b>	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 21 dBA, with uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 13 dBA, with uncertainty of 3 dBA.
<b>Environmental conditions</b>	Operating temperature: +5°C to +40°C Operating humidity: 15% to 95% non-condensing Storage and transport temperature: -20°C to +60°C Storage and transport humidity: up to 95% relative humidity non-condensing

<b>Gross dimensions</b>	590 mm (H) x 149 mm (W) x 30 mm (D) Mask fully assembled with short tube assembly (no headgear)
<b>Mask setting options</b>	<b>For S9:</b> Select 'Pillows' <b>For other devices:</b> Select 'SWIFT' (if available), otherwise select 'MIRAGE' as the mask option.

**Note:** The manufacturer reserves the right to change these specifications without notice.

## Storage









Ensure that the mask is thoroughly clean and dry before storing it for any length of time. Store the mask in a dry place out of direct sunlight.

## Disposal

This mask and packaging does not contain any hazardous substances and may be disposed of with your normal household refuse.

## Symbols

The following symbols may appear on your product or packaging:

	Nasal Pillows mask		Polypropylene recyclable
	Size - Extra small		Size - Small
	Size - Medium		Size - Large
	Importer		Medical device

**LATEX?** Not made with natural rubber latex

See symbols glossary at [ResMed.com/symbols](https://www.resmed.com/symbols).

## Consumer warranty

ResMed acknowledges all consumer rights granted under the EU Directive 1999/44/EC and the respective national laws within the EU for products sold within the European Union.