

User Guide

English



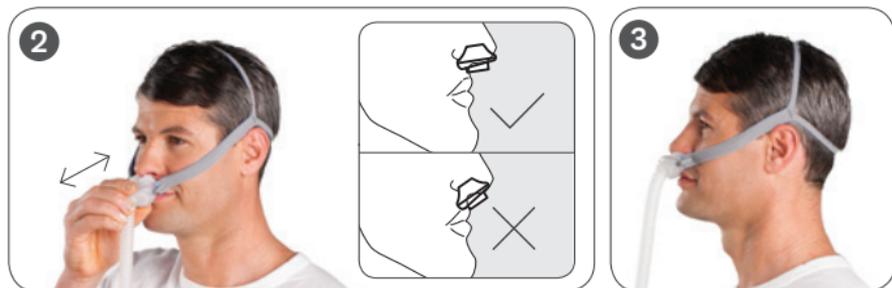
ResMed



AirFit™ P10

Nasal Pillows System

Fitting / Mise en place / Colocación / Colocação



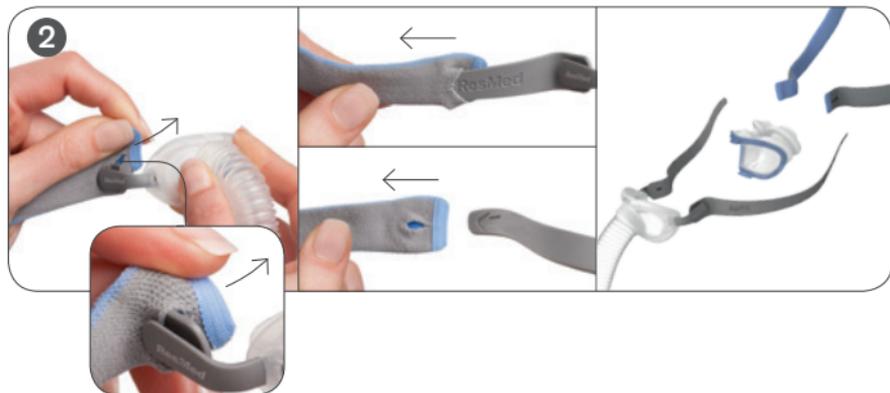
Adjustment / Ajustement / Ajuste / Ajuste



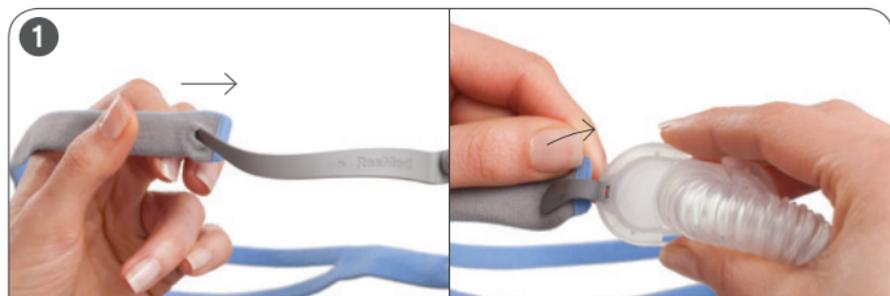
Removal / Retrait / Remoción / Remoção



Disassembly / Démontage / Desmontaje / Desmontagem



Reassembly / Remontage / Montaje / Remontagem



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 (> 66 lb (30 kg)) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

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.
- Remove all packaging before using the mask.

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 on www.resmed.com on the **Products** page under **Service & Support**. If you do not have internet access, please contact your ResMed representative.

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 strap and stretching it around the back of your head. The top strap 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 achieve a comfortable fit, adjust the split straps by spreading them apart to loosen or draw them closer together to tighten.

Removal

To take off your mask system, pull the mask and headgear by the split-strap, 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. Remove the headgear from the stabilizers by holding the fabric end of each strap and pulling out to reveal the buttonhole, then sliding over the node and off the end of each stabilizer. Your mask is now disassembled.

Reassembly

1. With the gray side facing out, insert each end of the headgear strap over the stabilizers through the buttonholes. Secure in place by wrapping each strap end up and around the nodes. Holding the split straps, pull the headgear from the stabilizer to ensure it is tightly secure around the nodes. Ensure the headgear strap 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.

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 86°F/30°C) water using mild soap.
- To optimize 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. Dry the vent by gently wiping with a cloth.

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

Weekly:

- Handwash the headgear in warm (approximately 86°F/30°C) water using mild soap. It may be washed without being disassembled. Rinse well and allow it to air dry out of direct sunlight.

Reprocessing the mask between patients

Only Sleep Lab Mask (SLM) variants of the mask are intended for multi-patient re-use. When using between patients, these masks must be reprocessed according to cleaning and disinfection instructions available on ResMed.com/downloads/masks.

Troubleshooting

Problem/possible cause

Solution

Pillows won't seal properly, mask is uncomfortable or causes red marks

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.

Wash headgear to help it return to its original form. Follow the washing instructions.

Adjust the headgear split straps.

Problem/possible cause

Vent is blocked or dirty/discolored.

Vent is wet.

Solution

If the vent requires cleaning, use a soft bristle brush. The vent may discolor over time and this is not a safety concern. Follow the cleaning instructions in this guide to maintain performance and safety of the mask.

Ensure the vent is dry after cleaning and in the case of excess condensation.

Mask too noisy

System is assembled incorrectly.

Disassemble the mask, then reassemble according to the instructions.

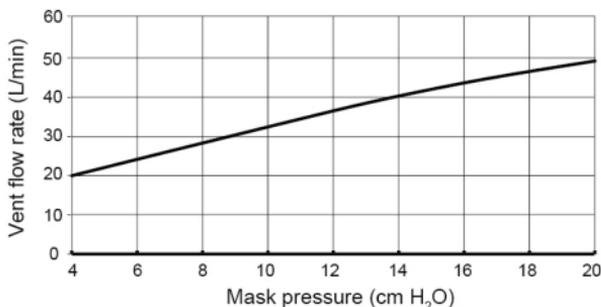
System is leaking air.

Refit or reposition your mask. Adjust your headgear. Check your mask is assembled correctly.

Technical specifications

Pressure-flow curve

The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations, the vent flow rate may vary.



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

Dead space information

Physical dead space is the empty volume of the mask to the end of the swivel. Using the large pillows it is 123 mL.

Therapy pressure

4 to 20 cm H₂O

Resistance	Drop in pressure measured (nominal) at 50 L/min: 0.4 cm H ₂ O at 100 L/min: 1.4 cm H ₂ O
Environmental conditions	Operating temperature: +41°F to 104°F (+5°C to +40°C) Operating humidity: 15% to 95% non-condensing Storage and transport temperature: -4°F to 140°F (-20°C to +60°C) Storage and transport humidity: up to 95% relative humidity non-condensing
Gross dimensions	Large: 23.23" (H) x 5.87" (W) x 1.18" (D) (590 mm (H) x 149 mm (W) x 30 mm (D)) Mask frame system (no headgear)
Mask setting options	For S9: Select 'Pillows' For other devices: Select 'SWIFT' (if available), otherwise select 'MIRAGE' as the mask option.

Notes:

- *The mask system does not contain PVC, DEHP or phthalates.*
- *This product is not made with natural rubber latex.*
- *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 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:



Catalog number



Batch code



Humidity limitation



Temperature limitation



Fragile, handle with care



Not made with natural rubber latex



Manufacturer



European Authorized Representative



Keep away from rain



This way up



Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device



Caution, consult accompanying documents



Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician)



Polypropylene recyclable

Limited warranty

ResMed Ltd (hereafter 'ResMed') warrants that your ResMed mask system (including mask frame, cushion, headgear and tubing) shall be free from defects in material and workmanship from the date of purchase for the period of 90 days or in the case of disposable masks the maximum use period. This warranty is only available to the initial consumer. It is not transferable. If the product fails under conditions of normal use, ResMed will repair or replace, at its option, the defective product or any of its components. This limited warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by ResMed to perform such repairs; and c) any damage or contamination due to cigarette, pipe, cigar or other smoke. Warranty is void on product sold, or resold, outside the region of original purchase.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

ResMed shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, 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 region to region. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

Mask components / Composants du masque / Piezas de la mascarilla / Componentes da máscara

A Headgear / Harnais / Arnés / Arnês

- | | |
|---|--|
| 1 | Split-strap headgear / Harnais avec sangle à lanière double / Arnés con correa dividida / Arnês com correia dividida |
| 2 | Buttonhole / Boutonnière / Ojal / Botoeira |
| 3 | Fabric end / Extrémité en tissu / Extremo de tela / Extremidade de tecido |

B Pillows / Coussins / Almohadillas / Almofadas

- | | |
|---|--|
| 4 | Nasal pillows / Masque narinaire / Almohadillas nasales / Almofadas nasais |
|---|--|

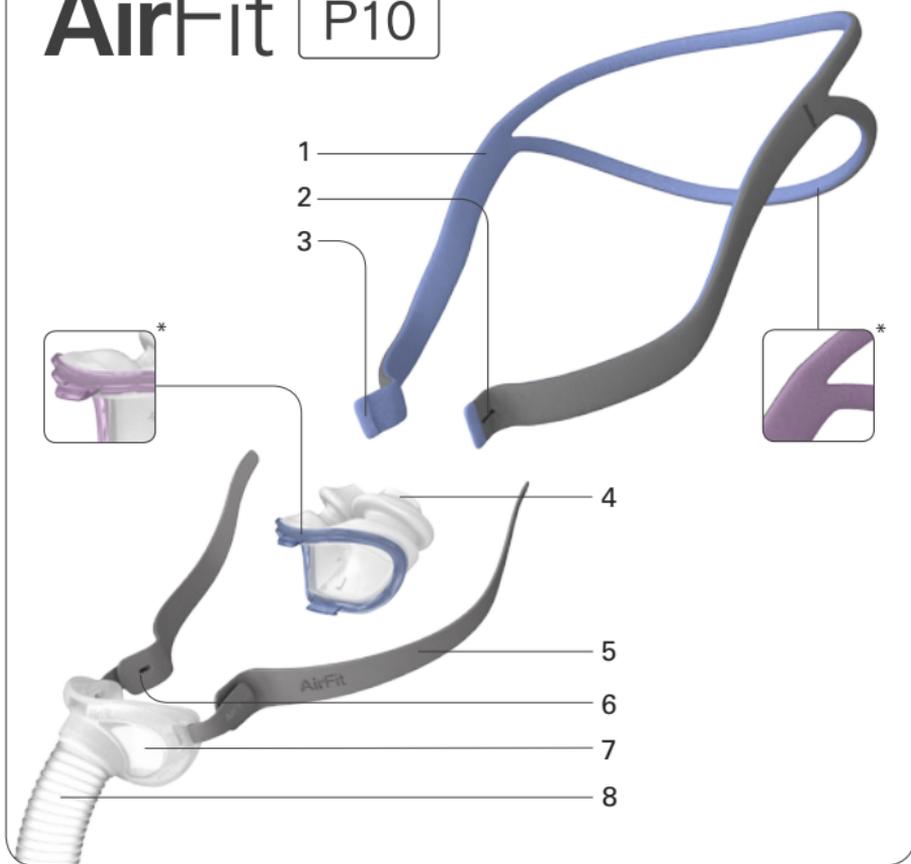
C Frame / Entourage rigide / Armazón / Armação

- | | |
|---|---|
| 5 | Stabilizer / Stabilisateur / Estabilizador / Estabilizador |
| 6 | Node / Nœud / Saliente / Ressalto |
| 7 | Vent / Orifice de ventilation / Ventilación / Respiradouro |
| 8 | Mask tubing / Circuit du masque / Tubo de la mascarilla / Tubo da máscara |

B+C Pillows system (frame system) / Coussins (support complet) / Sistema de almohadillas (Sistema de armazón) / Sistema de almofadas (sistema da armação)

A+B+C Complete system / Système complet / Sistema completo / Sistema completo

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ResMed

Global leaders in sleep and respiratory medicine

www.resmed.com



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Manufacturer: ResMed Ltd 1 Elizabeth Macarthur Drive, Bella Vista NSW 2153 Australia.

See www.resmed.com for other ResMed locations worldwide.

For patent information, see www.resmed.com/ip. AirFit is a trademark of ResMed Ltd. © 2018 ResMed Ltd.