

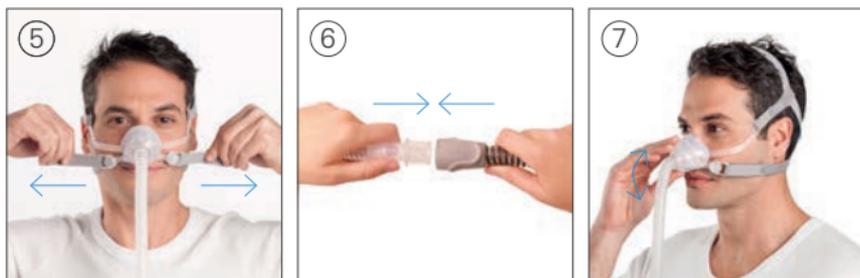
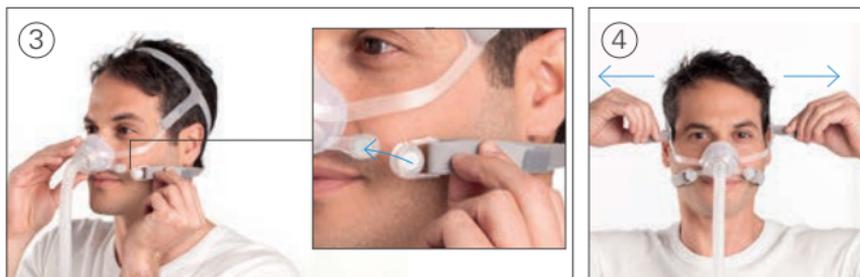
ResMed

AirFit™ N10

Nasal Mask



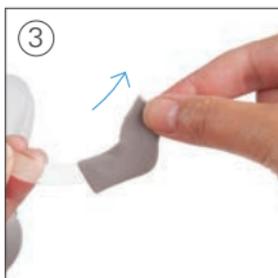
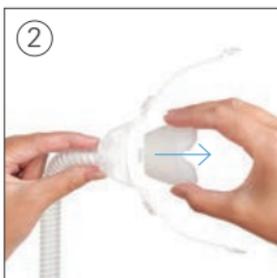
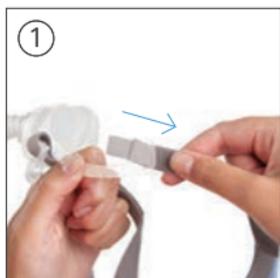
User guide
English



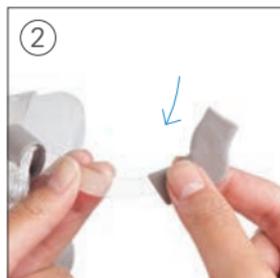
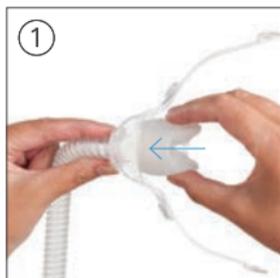
Removal / Retrait / Remoción / Remoção



Disassembly / Démontage / Desmontaje / Desmontagem



Reassembly / Remontage / Montaje / Remontagem



AirFit™ N10

Nasal Mask

Thank you for choosing the AirFit N10. This document provides the user instructions for the AirFit N10 and AirFit N10 for Her masks referred to collectively as AirFit N10 throughout this manual. AirFit N10 has blue headgear while AirFit N10 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 N10 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 N10 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.

WARNING

Magnets used in this mask are within ICNIRP guidelines for general public use. Some active medical implants—such as a pacemaker or defibrillator—may be affected by localized magnetic fields. The magnetic clips in this mask should be kept at least 2 in. (50 mm) away from any active medical implant.

Contraindications

Use of the AirFit N10 may be contraindicated in some patients with the following pre-existing conditions:

- a metallic hemostatic clip implanted in your head to repair an aneurysm
- metallic splinters in one or both eyes following a penetrating eye injury.

GENERAL WARNINGS

- The vent holes 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.

Fitting

1. With the gray side of the headgear facing outward and with both lower headgear straps released, align the bottom of the cushion opening with the bottom of your nose.
2. Place the mask over your nose. Hold the mask against your face and pull the headgear over your head.

Headgear check:

- ✓ Ensure the label on the headgear faces outwards when the headgear is put on.
3. Bring the lower straps below your ears. Attach the magnet clip to the outside of the frame.

4. Undo the fastening tabs on the upper headgear straps. Adjust the straps evenly until the mask sits comfortably just under the nose. Reattach the fastening tabs to the upper headgear straps.
5. Undo the fastening tabs on the lower headgear straps. Adjust the straps evenly until the mask is stable. Reattach the fastening tabs.
6. Connect the free end of the short tube assembly to the device air tubing. Turn on your device so that it is blowing air.
7. Adjust the cushion and headgear until the mask sits comfortably on your nose and is not creased or twisted.

Notes:

- The upper straps are the key adjustments for seal and comfort. Ensure they are not overtightened.
- The lower straps are used to keep the cushion in the right position. They do not need to be tightened much for the mask to fit comfortably.

Removing your mask

1. Remove one or both magnets from the frame by twisting the lower headgear strap and clip away.
2. Pull the mask away from your face and back over your head.

Disassembly

1. Undo the fastening tabs on the upper headgear straps. Pull the straps out of the frame.
2. Squeeze and pull the cushion away from the frame.
3. If the soft sleeves are fitted, remove them by pulling them off of the frame.

Reassembly

1. Attach the cushion to the frame by inserting the top and bottom clips into the correct slots on the frame.
2. To fit the optional soft sleeves, pull them over the upper arms of the frame.
3. With the ResMed logo facing out, thread the top headgear straps into the frame slots from the inside out. Fold the strap over to secure.
4. To reattach the magnet clips to the headgear, thread the lower headgear straps into the slots with the clips facing down. Fold the strap over to secure.

Cleaning your mask in your home

Your mask and headgear should only be handwashed by gently rubbing in warm (approximately 86°F/30°C) water using mild soap. All components should be rinsed well with drinking quality water and allowed to air dry out of direct sunlight.

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.

Daily/After each use:

- To optimize the mask seal, facial oils should be removed from the cushion after use.
- Handwash the separated mask components (excluding headgear and soft sleeves).
- If the vent or swivel requires cleaning, use a soft bristle brush.

Weekly:

- Handwash the headgear and soft sleeves. The headgear may be washed without being disassembled.

Reprocessing the mask between patients

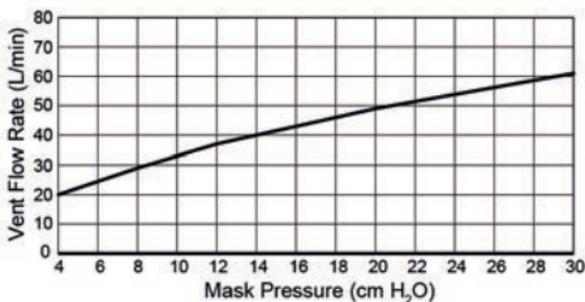
This mask should be reprocessed when used between patients. Cleaning, disinfection and sterilization instructions are available from the ResMed website, www.resmed.com/masks/sterilization/americas. If you do not have internet access, please contact your ResMed representative.

Troubleshooting

| Problem/possible cause | Solution |
|--|---|
| Mask is too noisy. | |
| Vent is blocked or partially blocked. | If the vent requires cleaning, use a soft bristle brush. |
| Mask is incorrectly assembled. | Disassemble the mask, then reassemble according to the instructions. |
| Mask is leaking. | Refit or reposition your mask. Readjust the headgear straps to bring the mask closer to the face and improve your seal. Check that your mask is assembled correctly. |
| Mask leaks around face. | |
| Mask is not positioned correctly. | Check that the ResMed logo is facing downward on the bottom of the cushion along the bottom of your nose. |
| Mask may have been fitted incorrectly. | Pull the mask away from your face and reposition, ensuring that the lower corners of the mask fully enclose your nose. If necessary, readjust the headgear straps to keep the mask in the right place. |
| Cushion membrane is creased or folded. | Remove and refit your mask according to the fitting instructions. Ensure you position the cushion correctly over your nose before pulling the headgear over your head. Do not slide the mask down your face during fitting as this may lead to folding or curling of the cushion. |
| Mask is not tightened correctly. | Ensure that the headgear straps are not overtightened or too loose. You may find that this mask does not need to be tightened as much as other nasal masks. Check that the headgear is not twisted. |
| Mask may be the wrong size. | Talk to your clinician. |
| Mask does not fit properly. | |
| Mask is incorrectly assembled. | Disassemble the mask, then reassemble according to the instructions. |
| Mask may be the wrong size. | Talk to your clinician. |
| Cushion may be dirty. | Clean cushion according to the instructions. |

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 |
| 11 | 35 |
| 12 | 37 |
| 16 | 43 |
| 17 | 44 |
| 20 | 49 |
| 22.5 | 53 |
| 24 | 54 |
| 30 | 61 |

| | |
|-------------------------------|---|
| Dead space information | Physical dead space is the empty volume of the mask to the end of the swivel. Using the wide cushions it is 104 mL. |
|-------------------------------|---|

| | |
|-------------------------|-----------------------------|
| Therapy pressure | 4 to 30 cm H ₂ O |
|-------------------------|-----------------------------|

| | |
|-------------------|--|
| Resistance | Drop in pressure measured (nominal) at 50 L/min: 0.4 cm H ₂ O at 100 L/min: 1.2 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% non-condensing |
|---------------------------------|---|

| | |
|-------------------------|--|
| Gross dimensions | 19.0" (H) x 6.10" (W) x 4.33" (D) (483 mm (H) x 155 mm (W) x 110 mm (D)) Mask fully assembled with short tube assembly (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 BPA, 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)

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**

| | AirFit N10 | AirFit N10 for Her |
|--|--------------------------|-----------------------|
| A Headgear / Harnais / Arnés / Arnês | 63260 (Std) | 63261 (S) |
| 1 Upper headgear straps / Sangles supérieures du harnais / Correas superiores del arnés / Correias superiores do arnês | | |
| 2 Lower headgear straps / Sangles inférieures du harnais / Correas inferiores del arnés / Correias inferiores do arnês | | |
| B Cushion / Bulle / Almohadilla / Almofada | 63240 (Std) 63242 (W) | 63241 (S) |
| C Frame / Entourage rigide / Armazón / Armação | 63270 | 63270 |
| 3 Vent / Orifice de ventilation / Ventilación / Respiradouro | | |
| 4 Short tube / Tuyau court / Tubo corto / Tubo curto | | |
| 5 Swivel / Pièce pivotante / Peça giratoria / Peça giratória | | |
| B+C | | |
| Frame system / Entourage complet / Sistema de armazón / Sistema da armação | 63230 (Std) 63232 (W) | 63231 (S) |
| 6 Magnet clips / Clips magnétiques / Broches magnéticos / Presilhas magnéticas | | |
| 7 Soft sleeves / Gainses souples / Fundas blandas / Mangas maleáveis | | |
| A+B+C | | |
| Complete system / Système complet / Sistema completo / Sistema completo | 63200 (Std) 63202 (W) | 63201 (S) |

S: Small / Petit / Pequeño / Pequeno

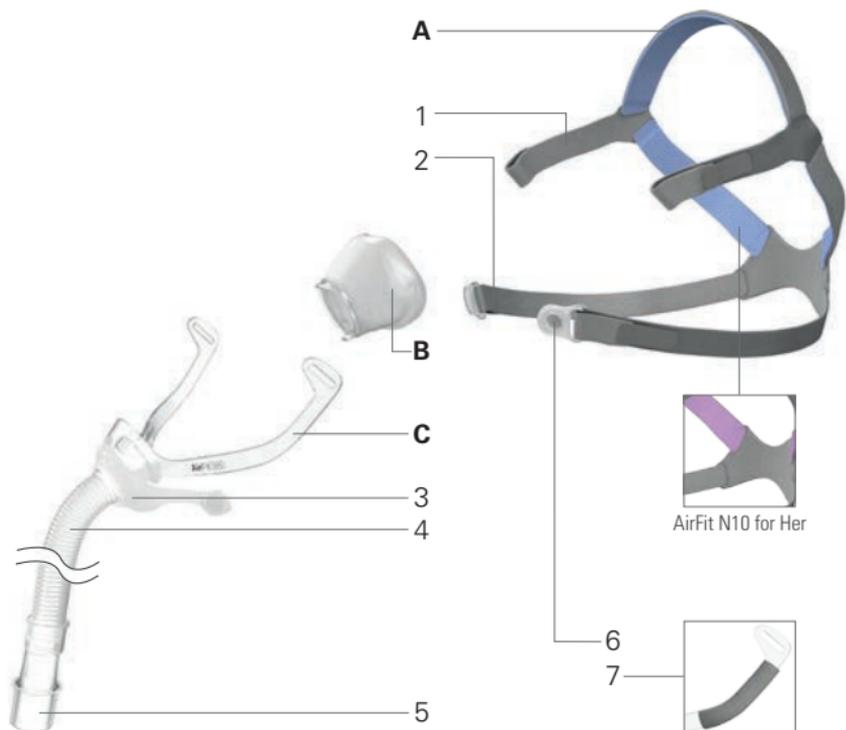
Std: Standard / Standard / Estándar / Padrão

W: Wide / Large / Ancho / Largo



ResMed

AirFit™ N10



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