



ResMed

AirFit™ F10

Full face mask



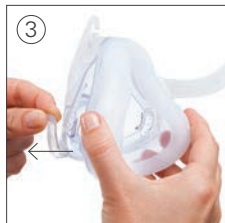
User Guide
English



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Disassembly / Démontage / Desmontaje / Desmontagem



Reassembly / Remontage / Montaje / Remontagem



AirFit™ F10

Full face mask

Thank you for choosing the AirFit F10. This document provides the user instructions for the AirFit F10 and AirFit F10 for Her masks referred to collectively as AirFit F10 throughout this manual. AirFit F10 has blue headgear while AirFit F10 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 F10 is a noninvasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The AirFit F10 is:

- to be used by patients (weighing >66 lb (30 kg)) for whom positive airway pressure therapy has been prescribed
- intended for single-patient reuse in the home environment and multipatient reuse 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 elbow and valve assembly have specific safety functions. The mask should not be worn if the valve is damaged as it will not be able to perform its safety function. The elbow should be replaced if the valve is damaged, distorted or torn.
- 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 holes. When the device is turned off, the mask valve opens to atmosphere allowing fresh air to be breathed. However, a higher level of exhaled air may be rebreathed when the device is off. This applies to most full face masks for use with CPAP and 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.

Use a standard conical connector if pressure readings and/or supplemental oxygen are required.

Fitting

1. Remove the elbow from the mask by pressing the side buttons and pulling the elbow away.
2. With both lower headgear straps released, hold the mask against your face and pull the headgear over your head. Ensure that the label on the back of the headgear faces outwards when the headgear is put on.
3. Undo the fastening tabs on the upper headgear straps. Pull the straps evenly until the mask is stable and positioned as shown in the illustrations. Reattach the fastening tabs.
4. Bring the lower straps below your ears and loop the headgear into the lower hooks on the frame.
5. Undo the fastening tabs on the lower headgear straps. Pull the straps evenly until the mask sits firmly on the chin and reattach the fastening tabs.
6. Connect the air tubing from your device to the elbow. Attach the elbow to the mask by pressing the side buttons and pushing the elbow into the mask. Turn on your device so that it is blowing air.
7. Undo the fastening tabs on the upper headgear straps. Readjust the straps evenly only enough that a seal is achieved and reattach the fastening tabs. Overtightening may cause leaks.
8. Your mask and headgear should be positioned as shown.

Removing your mask

1. Disconnect one or both of the lower headgear straps from the hook.
2. Pull the mask away from your face and back over your head.

Disassembly

1. Unhook the upper headgear straps from the frame. There is no need to undo the fastening tabs.
2. Remove the elbow from the mask by pressing the side buttons and pulling the elbow away. Remove the elbow from the air tubing.
3. While holding the bottom of the hook, pull the corner of the frame slightly away from the side of the mask.
4. Remove the frame from the rest of the mask.
5. If the soft sleeves are fitted, remove them by pulling them off of the frame.

Reassembly

1. Press the top of the frame onto the rest of the mask, ensuring it clicks into place.
2. Press the bottom corners of the frame onto the rest of the mask, ensuring they click into place.
3. To fit the optional soft sleeves, pull them over the upper arms of the frame.
4. Attach the top headgear straps to the frame by looping through each of the upper headgear hooks. Ensure that the ResMed logo on the headgear is facing outward and right side up.
5. Attach the elbow to the air tubing. Attach the elbow and air tubing to the mask by pressing the side buttons and pushing the elbow into the mask. Pull on the elbow to check that it sits securely in the mask.

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, discoloration, tears etc.), the component should be discarded and replaced.

Daily/After each use:

- Disassemble the mask components according to the disassembly instructions.
- Handwash the separated mask components (excluding headgear and soft sleeves).
- To optimize the mask seal, facial oils should be removed from the cushion 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 are dry, reassemble according to the reassembly instructions.

Weekly:

- Handwash the headgear and soft sleeves.

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.

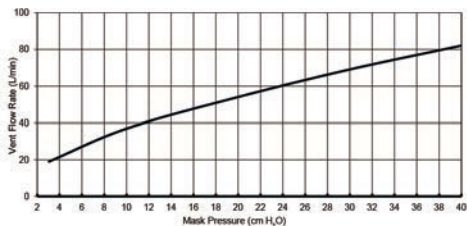
Troubleshooting

| Problem/possible cause | Solution |
|--|---|
| Mask is uncomfortable Headgear straps are too tight. | The cushion membrane is designed to inflate against your face to provide a comfortable seal with low headgear tension. Adjust straps evenly. Ensure that the headgear straps are not too tight and that the cushion is not crushed or creased. |
| Mask could be the wrong size. | Talk to your clinician to have your face size checked against fitting template. Note that sizing across different masks is not always the same. |
| Mask is too noisy Elbow incorrectly installed. | Remove the elbow from your mask, then reassemble according to the instructions. |
| Vent is blocked or partially blocked. | Clean with a soft bristle brush until the vent is clear. |
| Mask leaks around the face. Cushion membrane is creased or folded. | Refit your mask according to the instructions. Ensure that you position the cushion correctly on your face before pulling 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 could be the wrong size. | Talk to your clinician to have your face size checked against fitting template. Note that sizing across different masks is not always the same. |
| Frame incorrectly fitted. | Remove the rest of the mask from the frame, then reassemble 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) |
|--------------------------------|--------------|
| 3 | 19 |
| 4 | 22 |
| 8 | 32 |
| 10 | 37 |
| 12 | 41 |
| 16 | 48 |
| 20 | 54 |
| 24 | 60 |
| 28 | 66 |
| 30 | 69 |
| 32 | 72 |
| 36 | 77 |
| 40 | 82 |

Dead space information

Physical dead space is the empty volume of the mask to the end of the swivel. Using the large cushions it is <222 mL.

Therapy pressure

3 to 40 cm H₂O

Resistance with Anti Asphyxia Valve (AAV) closed to atmosphere

Drop in pressure measured (nominal)
 at 50 L/min: 0.2 cm H₂O
 at 100 L/min: 0.9 cm H₂O

Inspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) open to atmosphere

| | |
|-------------------------|-------------------------|
| Inspiration at 50 L/min | 0.6 cm H ₂ O |
| Expiration at 50 L/min | 1.0 cm H ₂ O |

Anti Asphyxia Valve (AAV) open-to-atmosphere pressure

≤1.6 cm H₂O

Anti Asphyxia Valve (AAV) closed-to-atmosphere pressure

≤1.8 cm H₂O

| | |
|---------------------------------|---|
| 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 | Extra Small: 4.61" (H) x 5.59" (W) x 5.67" (D) (117 mm (H) x 142 mm (W) x 144 mm (D)) Small: 4.69" (H) x 5.59" (W) x 5.67" (D) (119 mm (H) x 142 mm (W) x 144 mm (D)) Medium: 5.39" (H) x 5.75" (W) x 5.59" (D) (137 mm (H) x 146 mm (W) x 142 mm (D)) Large: 5.51" (H) x 5.75" (W) x 5.59" (D) (140 mm (H) x 146 mm (W) x 142 mm (D)) Mask fully assembled with elbow assembly (no headgear) |
| Mask setting options | For S9: Select 'Full Face' For other devices: Select 'MIR FULL' (if available), otherwise select 'FULL FACE' 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) | | |

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

| | | AirFit F10 | AirFit F10 for Her |
|----------|--|---------------------------------------|--------------------------------------|
| A | Elbow / Coude / Codo / Cotovelo | — | — |
| 1 | Valve / Valve / Válvula / Válvula | | |
| 2 | Side buttons / Boutons latéraux / Botones laterales / Botões laterais | | |
| B | Frame / Entourage rigide / Armazón / Armação | 63137 (XS/S) 63138 (M/L) | 63137 (XS/S) 63138 (M/L) |
| 3 | Lower headgear hooks / Crochets inférieurs du harnais / Ganchos inferiores del arnés / Ganchos inferiores do arnês | | |
| 4 | Upper headgear hooks / Crochets supérieurs du harnais / Ganchos superiores del arnés / Ganchos superiores do arnês | | |
| C | Cushion / Bulle / Almohadilla / Almofada | 62737 (S) 62738 (M) 62739 (L) | 62736 (XS) 62737 (S) 62738 (M) |
| 5 | Vent / Orifice de ventilation / Ventilación / Respiradouro | | |
| D | Headgear / Harnais / Arnés / Arnês | 63165 (S) 63164 (Std) 63166 (L) | 63167 |
| 6 | Lower headgear straps / Sangles inférieures du harnais / Correas inferiores del arnés / Correias inferiores do arnês | | |
| 7 | Upper headgear straps / Sangles supérieures du harnais / Correas superiores del arnés / Correias superiores do arnês | | |

| | | AirFit F10 | AirFit F10 for Her |
|----------------|---|-------------------------------------|--------------------------------------|
| A+B+C | | | |
| | Frame system / Entourage complet / Sistema de armazón / Sistema da armação | 63161 (S) 63162 (M) 63163 (L) | 63160 (XS) 63161 (S) 63162 (M) |
| 8 | Soft sleeves / Gainses souples / Fundas blandas / Mangas maleáveis | | |
| A+B+C+D | | | |
| | Complete system / Système complet / Sistema completo / Sistema completo | 63101 (S) 63102 (M) 63103 (L) | 63139 (XS) 63140 (S) 63141 (M) |

XS: Extra Small / Très Petit / Extra Pequeña / Extra Pequena

S: Small / Petit / Pequeña / Pequena

M: Medium / Médium / Mediana / Médio

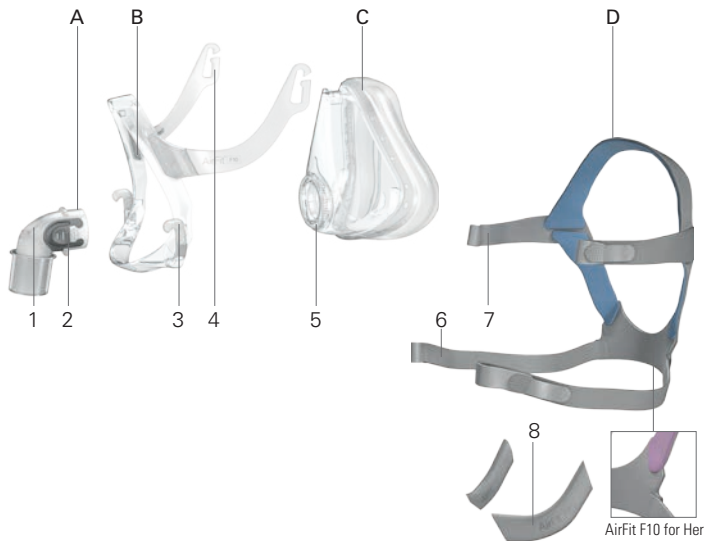
L: Large / Large / Grande / Grande

Std: Standard / Standard / Estándar / Padrão



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