ResMed

# AirFit™ F20

Full face mask

User guide

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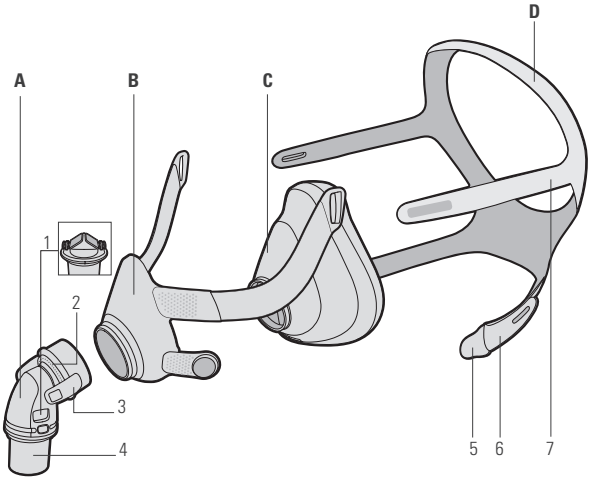
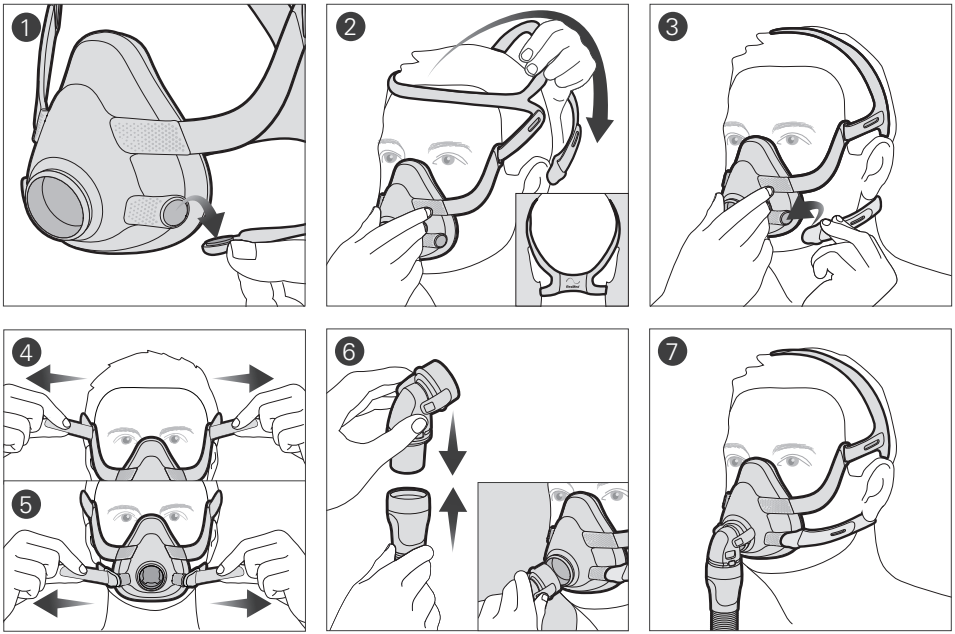
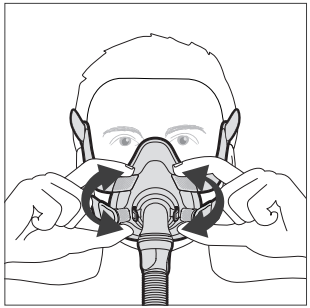
# AirFit™ F20

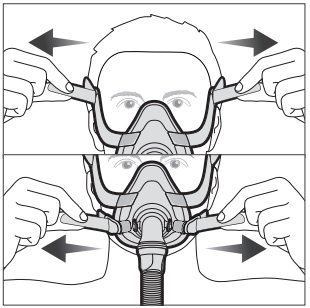



Fitting / Colocación / Colocação / Τοποθέτηση της μάσκας / Maskenin Takılması / Zakładanie / Felhelyezés / Fixarea măştii / Поставяне / Nasazení masky

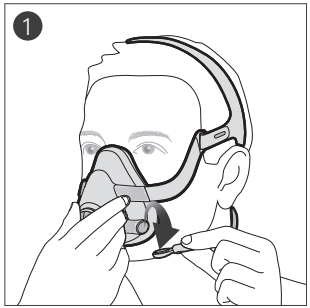


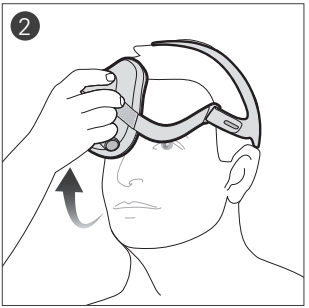
Adjustment / Ajuste / Ajuste / Προσαρμογή / Ayarlama / Regulacja / Beállítás / Ajustare / Регулиране / Úprava masky



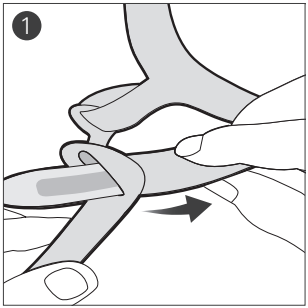


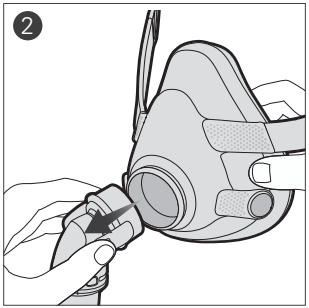
Removal / Retirada / Remoção / Αφαίρεση / Çıkarma / Zdejmowanie / Eltávolítás / Îndepărtare / Сваляне / Sejmutí masky

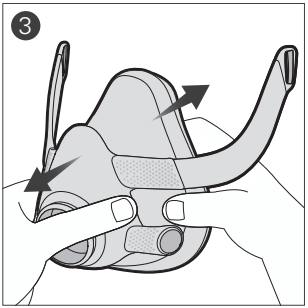


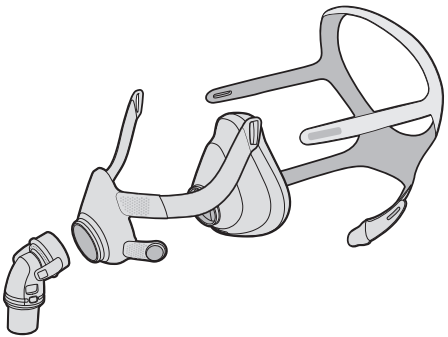



Disassembly / Desmontaje / Desmontagem / Αποσυναρμολόγηση / Sökme / Demontaż / Szétszerelés / Dezasamblare / Разглобяване / Demontáž

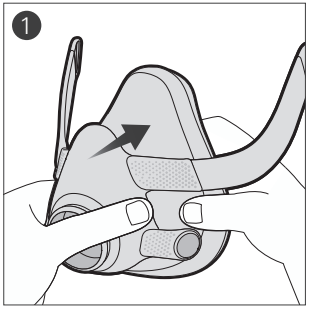


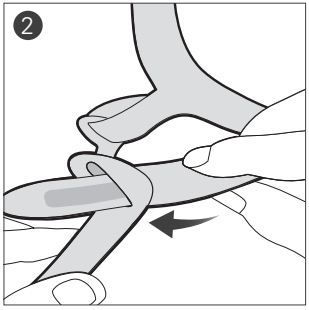



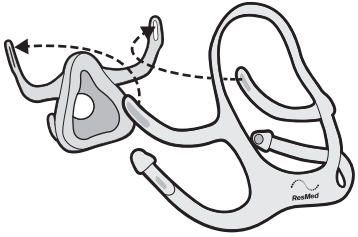



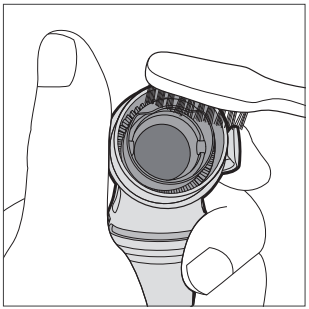
Reassembly / Nuevo montaje / Nova montagem / Επανασυναρμολόγηση / Yeniden montaj / Składanie / Ismételt összeszerelés / Reasamblare / Повторно сглобяване / Opětovné sestavení

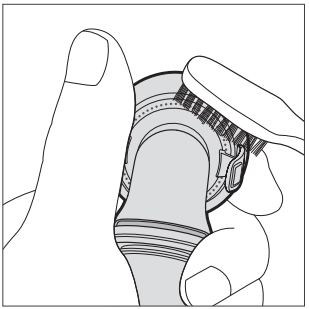



Cleaning the vent / Limpieza de la ventilación / Limpeza do respiradouro / Καθαρισμός ανοίγματος εξαερισμού / Hava deliğini temizleme / Czyszczenie odpowietrznika / A szellőzőnyílás tisztítása / Curățarea orificiului / Почистване на отдушника / Čištění ventilačního otvoru





## ENGLISH

Thank you for choosing the AirFit F20. This document provides the user instructions for the AirFit F20 and AirFit F20 for Her masks referred to collectively as AirFit F20 throughout this manual.

## Using this guide

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

## Intended use

The AirFit F20 is a non-invasive 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 F20 is:

- to be used by patients weighing more than 30 kg for whom positive airway pressure therapy has been prescribed
- intended for single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional environment.

## ⚠ WARNING

Magnets are used in the lower headgear straps and the frame of the AirFit F20. Ensure the headgear and frame is kept at least 50 mm away from any active medical implant (eg, pacemaker or defibrillator) to avoid possible effects from localized magnetic fields. The magnetic field strength is less than 400 mT.

## Contraindications

Use of masks with magnetic components is contraindicated in 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 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 mask must be fitted with the supplied elbow (containing the valve and vent assembly) to ensure safe and functional usage unless otherwise specified. Do not use the mask if the valve or vent assembly is damaged or missing.
- The elbow, valve and vent 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 and valve should be kept clear.
- The mask should only be used with CPAP or bilevel devices recommended by a physician or respiratory therapist.

- Avoid connecting flexible PVC products (eg, PVC tubing) directly to any part of the mask. Flexible PVC contains elements that can be damaging to the materials of the mask, and may cause the components to crack or break.
- 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 venting 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.
- The F20 line of full face CPAP masks are not intended to be used simultaneously with nebulizer medications that are in the air path of the mask/tube.
- 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 the correct setting.
- Follow the instructions provided by your physician or sleep therapist.
- Adjustment tips:
  - With air pressure applied, pull the mask away from your face to allow the cushion to inflate and reposition onto your face.
  - To resolve any leaks at the upper part of the mask, adjust the upper headgear straps. For the lower part, adjust the lower headgear straps.
  - Adjust only enough for a comfortable seal. Do not overtighten as this may cause discomfort.
- For a full list of compatible devices for this mask, see the Mask/Device Compatibility List on www.resmed.com/downloads/masks. 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.

## Cleaning your mask at home

Handwash your mask and headgear by gently rubbing in warm (approximately 30°C) water using mild liquid detergent. Rinse all components well under running water and allow to air dry out of direct sunlight.

## ⚠ WARNING

- As part of good hygiene, always follow cleaning instructions and use a mild liquid detergent. 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.
- Regularly clean your mask and its components to maintain the quality of your mask and to prevent the growth of germs that can adversely affect your health.

## ⚠ CAUTION

Visible criteria for product inspection: 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:

1. Disassemble the mask according to the disassembly instructions.
2. Rinse the frame, elbow and cushion under running water. Clean with a soft brush until dirt is removed.
3. Soak the components in warm water with a mild liquid detergent for up to ten minutes.
4. Shake the components in the water.
5. Brush the moving parts of the elbow and around the vent holes.
6. Brush the areas of the frame where the arms connect, and inside and outside the frame where the elbow connects.
7. Rinse the components under running water.

8. Leave the components to air dry out of direct sunlight. Make sure to squeeze the arms of the frame to ensure that excess water is removed.

### Weekly:

1. Disassemble the mask. The magnets can remain attached to the headgear during cleaning.
2. Handwash the headgear in warm water with mild liquid detergent.
3. Rinse the headgear under running water. Inspect to ensure the headgear is clean and detergent free. Wash and rinse again, if necessary.
4. Squeeze the headgear to remove excess water.
5. Leave the headgear to air dry out of direct sunlight.

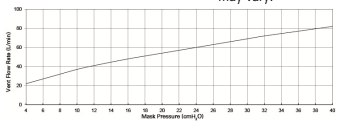
## Reprocessing the mask between patients

Reprocess this mask when using between patients. Cleaning, disinfection and sterilization instructions are available on www.resmed.com/downloads/masks. If you do not have internet access, please contact your ResMed representative.

## 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 $H_2O$) | Flow (L/min) |
|---|---|
| 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 240 mL. |
| **Therapy pressure** | 4 to 40 cm $H_2O$ |
| **Resistance with Anti Asphyxia Valve (AAV) closed to atmosphere** | Drop in pressure measured (nominal)<br>at 50 L/min: 0.2 cm $H_2O$<br>at 100 L/min: 0.8 cm $H_2O$ |

| | | |
|---|---|---|
| Inspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) open to atmosphere | Inspiration at 50 L/min:<br>Expiration at 50 L/min: | 0.5 cm $H_2O$<br>0.6 cm $H_2O$ |
| Anti Asphyxia Valve (AAV) open-to-atmosphere pressure | ≤4 cm $H_2O$ | |
| Anti Asphyxia Valve (AAV) closed-to-atmosphere pressure | ≤4 cm $H_2O$ | |
| Environmental conditions | Operating temperature: 5°C to 40°C<br>Operating humidity: 15% to 95% non-condensing<br>Storage and transport temperature: -20°C to +60°C<br>Storage and transport humidity:<br>up to 95% non-condensing | |
| Sound | DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 31 dBA, with uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 23 dBA, with uncertainty of 3 dBA. | |
| Gross dimensions | Mask fully assembled with elbow assembly (no headgear)<br>154 mm (H) x 159 mm (W) x 147 mm (D) | |

| | |
|---|---|
| International Commission on Non-Ionizing Radiation Protection (ICNIRP) | Magnets used in this mask are within ICNIRP guidelines for general public use. |
| Service life | The service life of the AirFit F20 mask system is dependent on the intensity of usage, maintenance, and environmental conditions to which the mask is used or stored. As this mask system and its components are modular in nature, it is recommended that the user maintain and inspect it on a regular basis, and replace the mask system or any components if deemed necessary or according to the 'visual criteria for product inspection' in the 'Cleaning your mask at home' section of this guide. Refer to the 'Mask components' section of this guide for information of how to order replacement parts. |
| Mask setting options<br>  <br>Device Setting<br>Full Face | For AirSense, AirCurve or S9: Select 'Full Face'.<br>For other devices: Select 'MIR FULL' (if available), otherwise select 'FULL FACE' as the mask option. |

Notes:

- This product is not made with PVC or phthalates such as DEHP, DBP or BBP.
- 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:

| | | | |
|---|---|---|---|
| REF CATALOG NUMBER | Catalog number | LOT BATCH CODE | Batch code |
| 95% 0% HUMIDITY LIMITATION | Humidity limitation | 60°C 140°F -20°C -4°F TEMPERATURE LIMITATION | Temperature limitation |
| FRAGILE, HANDLE WITH CARE | Fragile, handle with care | LATEX NOT MADE WITH NATURAL RUBBER LATEX | Not made with natural rubber latex |
| MANUFACTURER | Manufacturer | EC REP | European Authorized Representative |
| KEEP DRY | Keep away from rain | THIS WAY UP | This way up |
| Full Face Mask | Full face mask | Device Setting Full Face | Device setting - Full Face |

| | | | |
|---|---|---|---|
| S | Size - small | M | Size - medium |
| L | Size - large | | |
| ⚠ | 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 | | |

## 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.