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ResMed

AirFit™ F30

USER GUIDE

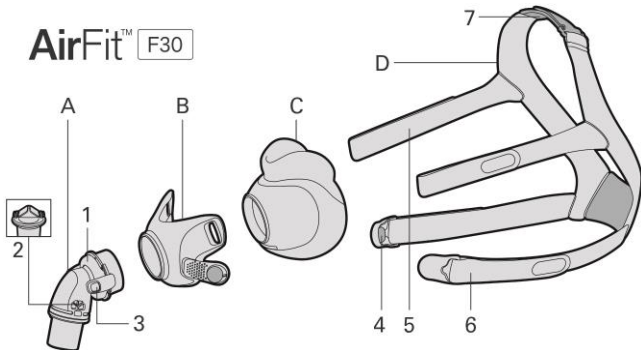


QuietAir



Full face
mask

AirFit™ F30



- | | | | |
|---|---------------------------|---|----------------------|
| A | QuietAir / standard elbow | 3 | Side buttons |
| B | Frame | 4 | Magnetic clips |
| C | Cushion | 5 | Upper headgear strap |
| D | Headgear | 6 | Lower headgear strap |
| 1 | Vent | 7 | Top headgear strap |
| 2 | Anti-Asphyxia Valve | | |

Intended use

The AirFit F30 mask is intended to be used by patients weighing more than 30 kg who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP or bi-level therapy. The mask is intended for single patient re-use in the home and multi-patient re-use in the hospital/institutional environment.

Please read the entire guide before use.

QuietAir elbow

The QuietAir elbow is intended for single patient re-use in the home and hospital/institutional environment.

Contraindications

Use of masks with magnetic components is contraindicated in patients with the following pre-existing conditions:

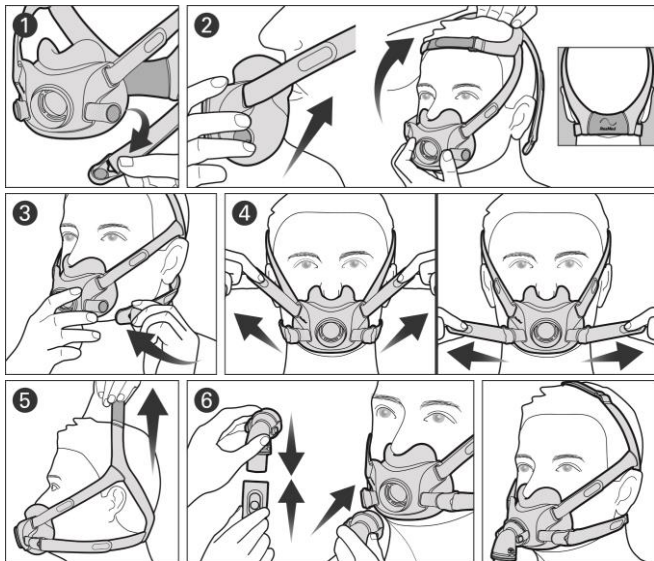
- a metallic hemostatic clip implanted in your head to repair an aneurysm
- metallic splinters in one or both eyes.

Before using your mask

Remove all packaging and inspect each mask component for visible deterioration.

Use the fitting template to assist in selecting the right size cushion and frame.

Fitting your mask



1. Twist and pull both magnetic clips away from the frame.
2. Place the cushion under your nose and ensure it sits comfortably against your face. With the ResMed logo on the headgear facing up, pull the headgear over your head.
3. Bring the lower headgear straps under your ears and attach the magnetic clips to the frame.
4. Undo the fastening tabs on the upper headgear straps and pull evenly. Repeat with the lower headgear straps.
5. If the headgear is too close to the ear, adjust the top headgear strap
6. Connect the device air tubing to the elbow and attach the elbow to the mask, ensuring that it clicks in place.

Adjusting your mask

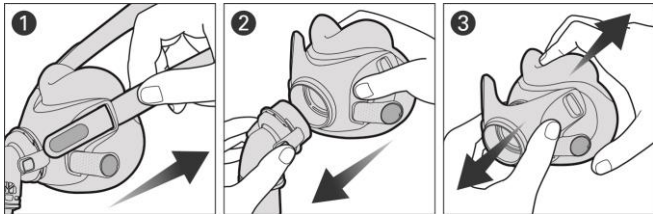
- With the device turned on and blowing air, adjust the position of the cushion for the most comfortable fit under your nose. Ensure that the cushion is not creased and the headgear is not twisted.
- To fix any leaks at the upper or lower part of the mask, adjust the top, upper or lower headgear straps. Adjust only enough for a comfortable seal and do not overtighten.

Removing your mask

1. Twist and pull both magnetic clips away from the frame.
2. Pull the mask away from your face and back over your head.

Disassembling your mask for cleaning

If your mask is connected to a device, disconnect the device air tubing from the mask elbow.



1. Undo the fastening tabs on the upper headgear straps and pull them from the frame. Keep the magnetic clips attached to the lower headgear straps.
2. Squeeze the side buttons on the elbow and detach from the frame.
3. Hold the top and bottom of the cushion and separate from the frame.

Cleaning your mask

After each use: QuietAir elbow, frame, cushion

Weekly: Headgear

1. Soak the components in warm water with a mild liquid detergent. Ensure that there are no air bubbles while soaking.
2. Shake the components vigorously in the water for at least one minute and hand wash with a soft bristle brush. Pay particular attention to all connection areas, elbow vent holes and valves.
3. Thoroughly rinse the components under running water.
4. Squeeze the headgear to remove excess water. Leave the components to air dry out of direct sunlight.

If the mask components are not visibly clean, repeat the cleaning steps.

Reassembling your mask

1. With the ResMed logo facing outwards and up, insert the upper headgear straps into the frame from the inside and fold the fastening tabs over to secure.
2. Hold the top and bottom of the cushion and attach to the frame.
3. Attach the elbow to the frame.

WARNING

- The mask must be used under qualified supervision for patients who are unable to remove the mask by themselves. This mask is not for use on patients with impaired laryngeal reflexes or other conditions predisposing to aspiration in the event of regurgitation or vomiting.
- To avoid affecting the safety and quality of therapy, the mask vents must be kept clear to protect against rebreathing. Regularly inspect the vents to ensure they are kept clean, undamaged and clear of blockages.
- The mask contains specific safety features with the supplied elbow (containing the valve and vent assembly) to ensure safe and functional usage. Do not use the mask if these features are damaged or missing.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air to reduce risk of rebreathing exhaled air.
- Oxygen supports combustion and must only be used in well ventilated rooms. Do not use oxygen while smoking or near an open flame. Oxygen flow must be turned off when the device is not operating.
- 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 bi-level devices.
- The technical specifications of the mask are provided for your clinician or respiratory therapist to check that they are compatible with the CPAP or bi-level 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 bi-level device function.
- Discontinue using the mask if you have ANY adverse reaction 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 F30 line of full face CPAP masks are not intended to be used simultaneously with nebuliser medications that are in the air path of the mask/tube.

WARNING

- Magnets are used in the lower headgear straps and the frame of the mask. 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 localised magnetic fields. The magnetic field strength is less than 400 mT.
- 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.
- Regularly clean your mask to maintain the quality of your mask and to prevent the growth of germs that can adversely affect your health.
- Always follow cleaning instructions. Some cleaning products may damage the mask, its parts and their function, or leave harmful residual vapours.

CAUTION

- Remove all packaging before using the mask.
- When fitting the mask, do not overtighten the headgear as this may lead to skin redness or sores around the mask cushion.
- As with all masks, some rebreathing may occur at low pressures.
- Visual criteria for product inspection: If there is any visible deterioration of a mask component (cracking, crazing, tears etc.), the component should be discarded and replaced.

Technical specifications

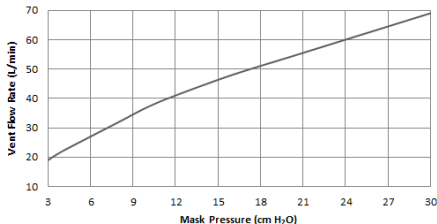
Mask setting options

For AirSense or AirCurve: Select 'Full Face'.

Compatible devices

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).

Pressure-flow curve:



Pressure (cm H ₂ O)	Flow (L/min)
3	19
10	37
20	54
30	69

Therapy pressure: 3 to 30 cm H₂O

Resistance with Anti- Asphyxia Valve closed to atmosphere

Drop in pressure measured (nominal) at 50 L/min: 0.3 cm H₂O

Drop in pressure measured (nominal) at 100 L/min: 0.7 cm H₂O

Inspiratory and expiratory resistance with Anti Asphyxia Valve open to atmosphere

Inspiration at 50 L/min: 0.6 cm H₂O

Expiration at 50 L/min: 0.8 cm H₂O

Anti Asphyxia Valve open-to-atmosphere pressure: ≤3 cm H₂O

Anti Asphyxia Valve closed-to-atmosphere pressure: ≤3 cm H₂O

Sound: Declared dual-number noise emission values in accordance with ISO4871 and ISO3744. The A-weighted sound power level and A-weighted sound pressure level of the mask at a distance of 1 m, with uncertainty of 3 dBA, are shown.

Power level (with QuietAir elbow): 21 dBA

Pressure level (with QuietAir elbow): 14 dBA

Power level (with standard elbow): 31 dBA

Pressure level (with standard elbow): 23 dBA

Environmental conditions

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% non-condensing

Gross dimensions

Mask fully assembled (H x W x D)

110 mm x 116 mm x 102 mm

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 F30 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 'Warning' section of this guide.

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.

Reprocessing the mask between patients

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

Symbols

The following symbols may appear on your product or packaging:



Full face mask



Device setting - Full face



Cushion size - small



Cushion size - medium



Caution, consult accompanying documents



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

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.



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