

RESMED

Quattro™ FX

FULL FACE MASK

User Guide

English



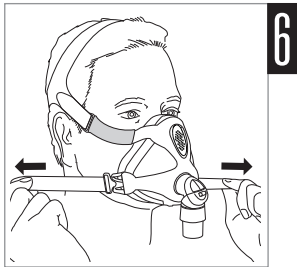
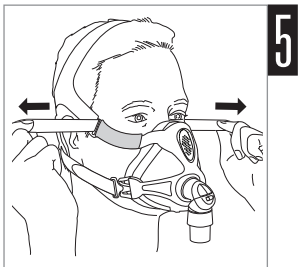
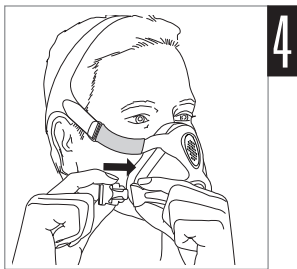
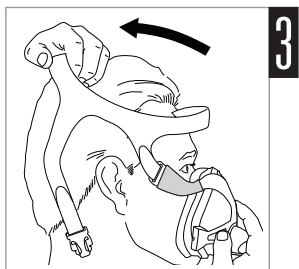
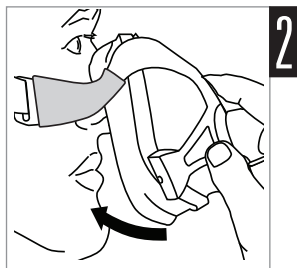
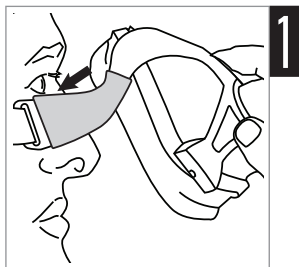
RESMED

Quattro™ FX

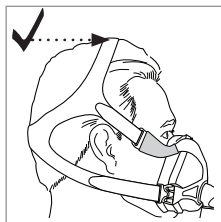
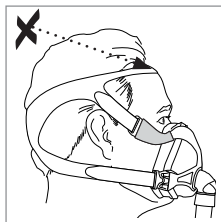
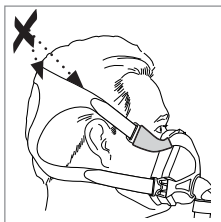
FULL FACE MASK / MASQUE FACIAL /
MASCARILLA FACIAL / MÁSCARA FACIAL

Rx Only

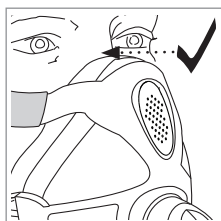
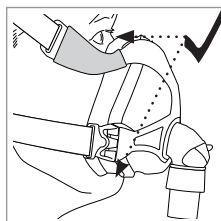
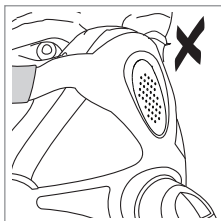
Fitting / Mise en place / Colocación / Colocação e ajuste



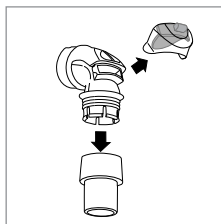
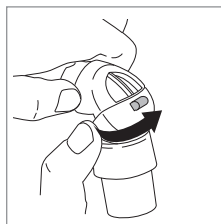
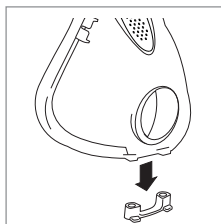
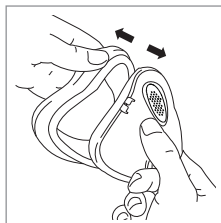
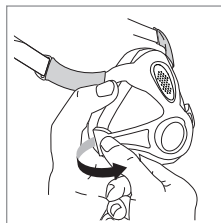
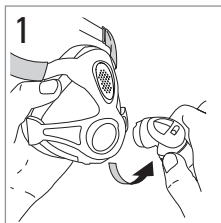
**Headgear position / Position du harnais /
Posición del arnés / Posição do arnês**

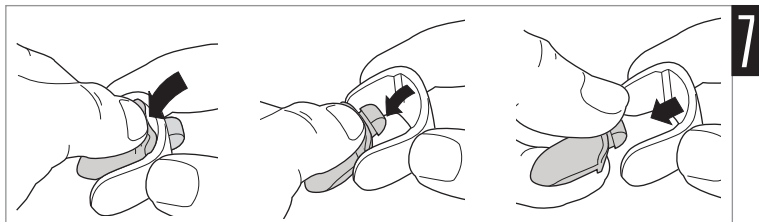


**Cushion check / Vérification de la bulle /
Revision de la almohadilla / Verificação da almofada**

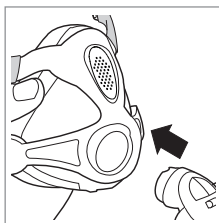
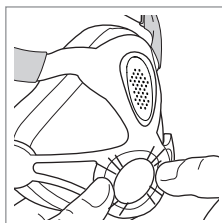
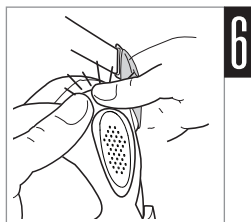
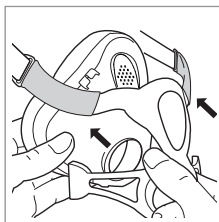
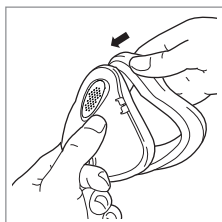
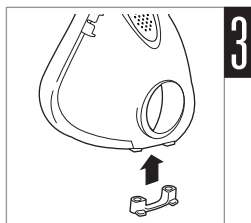
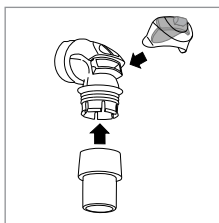
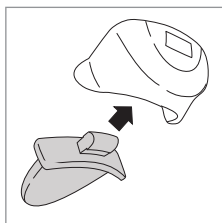


Disassembly / Démontage / Desmontaje / Desmontagem

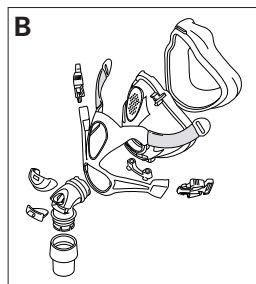
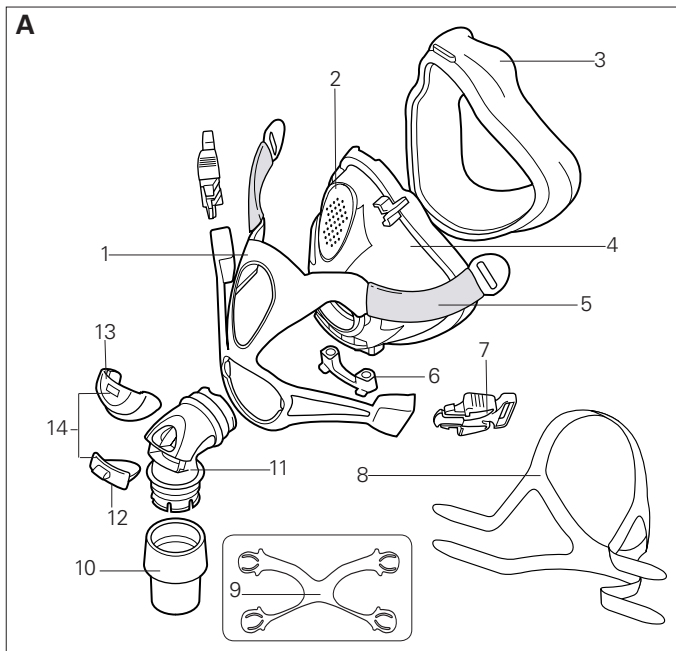




Reassembly / Remontage / Montaje / Remontagem



Quattro FX



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

| Item / Article / Artículo / Item | Description / Description / Descripción / Descrição | Part number / Code produit / Número de pieza / Código do produto |
|---|---|--|
| 1 | Spring frame / Entourage flexible / Armazón elástico / Armação flexível | — |
| 2 | Vent / Orifice de ventilation / Ventilación / Respiradouro | — |
| 3 | Cushion / Bulle / Almohadilla / Almofada | 61721 (S) 61722 (M) 61723 (L) |
| 4 | Frame / Entourage rigide / Armazón / Armação | — |
| 5 | Soft sleeves / Sangles souples / Fundas blandas / Luvas maleáveis | — |
| 6 | Ports cap / Bouchon d'entrées / Tapón de los puertos / Tampa das portas | — |
| 7 | Headgear clip / Clip d'attache du harnais / Broche del arnés / Presilha do arnês | — |
| 8 | Headgear / Harnais / Arnés / Arnês | 61734 (S) 61733 (M) 61738 (L) |
| 9 | Spring frame support / Support de l'entourage flexible / Soporte del armazón elástico / Suporte da armação flexível | — |
| 10 | Swivel / Pièce pivotante / Pieza giratoria / Peça giratória | — |
| 11 | Elbow / Coude / Codo / Cotovelo | — |
| 12 | Valve / Valve / Válvula / Válvula | — |
| 13 | Valve clip / Clip de la valve / Broche de la válvula / Presilha da válvula | — |
| 14 | Valve & clip / Valve et clip / Válvula y broche / Válvula e presilha | — |
| A | Complete system / Système complet / Sistema completo / Sistema completo | 61700 (S) 61701 (M) 61702 (L) |

| | | |
|---|--|-------------------------------------|
| B | Frame system / Support / Sistema del armazón / Sistema da armação | 61724 (S) 61725 (M) 61726 (L) |
|---|--|-------------------------------------|

S Small / Small / Pequeño/a / Pequeno(a)

M Medium / Medium / Mediano/a / Médio(a)

L Large / Large / Grande / Grande

Quattro™ FX

FULL FACE MASK

Thank you for choosing the Quattro FX. Please read the entire manual before use.

Intended use

The Quattro FX channels airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device.

The Quattro FX is:

- to be used by adult 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

- 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 valve should be replaced if it is damaged, distorted or torn.
- The vent holes must be kept clear.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air.
- 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.
- Remove all packaging before using the mask.
- Ensure the soft sleeves are fitted at all times during use.

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:

- *SmartStop may not operate effectively when using this mask with some CPAP or bilevel devices that have this feature.*
- *If you experience airway dryness or irritation, using a humidifier is recommended.*

Fitting

Prior to fitting your mask, remove the spring frame support from the rear of your mask and retain for future use. The Fitting illustrations section in this guide show the sequence for obtaining the best fit and comfort in using your mask.

Fitting steps

1. With both lower headgear clips released, position your mask at an angle against your face, ensuring that the top of the cushion contacts your nasal bridge first.
2. Keeping the upper position of the mask in place, swing the lower half of the mask down against your face so that it rests halfway between your bottom lip and chin.
3. Hold the mask firmly against your face and pull the headgear over your head.
4. Bringing the lower straps below your ears, clip the headgear into the lower part of the spring frame.
5. Unfasten the Velcro®, pull the upper headgear straps evenly until they are comfortable and firm, and reattach the Velcro.
6. Repeat step 5 with the lower headgear straps.

Headgear and cushion check

- Ensure your headgear is positioned correctly. Refer to the Headgear check illustrations in this user guide.
- The Quattro FX cushion is designed to sit mid-bridge. Refer to the Cushion check illustrations for correct positioning.

Removing your mask

To remove your mask, disconnect the lower headgear clips and pull the mask and headgear up over your head.

Disassembly

Before disassembling your mask, detach the air tubing and unclip the lower headgear clips from the spring frame. Refer to the disassembly illustrations in this guide.

Disassembly steps

1. Remove the elbow assembly from the mask.
2. Gently pull the spring frame away from the frame. Remove the soft sleeves from the spring frame.
3. Gently separate the cushion from the frame.
4. Remove the ports cap.
- 5-6. Remove the valve clip and detach the swivel from the elbow.
7. Peel the valve away from the valve clip. Do not pull on the membrane to remove the valve.

Reassembly

Refer to the reassembly illustrations in this guide.

Reassembly steps

1. Insert the valve into the clip.
2. Push the valve clip onto the elbow and insert the swivel into the end of the elbow.
3. Replace the ports cap.
4. Fit the cushion into the channel of the frame. Fit the top section first, then work your way around, pushing the cushion into the frame. Ensure that the cushion is not twisted or distorted around the frame.
5. Replace the soft sleeves onto the spring frame and align the spring frame with the frame.
6. Starting at the top, gently push and click the spring frame into the frame.
7. Gently push and click each side of the lower spring frame into the frame.
8. Replace the elbow into the mask assembly.

Cleaning your mask in the home

Your mask and headgear should only be gently handwashed.

Daily/After each use:

- Disassemble the mask components 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 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. It may be washed without being disassembled.
- Handwash the soft sleeves.

**WARNING**

- Do not use aromatic-based solutions or scented oils (eg, eucalyptus or essential oils), bleach, alcohol or products that smell strongly (eg, citrus) to clean any of the mask components. Residual vapours from these solutions can be inhaled if not rinsed thoroughly. They may also damage the mask, causing cracks.

**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.

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. The Quattro FX cushion is designed to sit mid-bridge.

Headgear is touching top of ears.

Remove and refit your mask according to the instructions. Check that the top and bottom headgear straps are correctly positioned. Ensure that the Velcro tab is correctly aligned with headgear material and not cutting into top of ear.

Cushion is riding up the face during use.

Check headgear positions against the instructions. Headgear should not be worn too far back on your head. Headgear may be the wrong size. If the problem persists, talk to your clinician.

Spring frame is sitting too close to the eyes.

Your mask could be the wrong size. Talk to your clinician to have your face size checked against the fitting template.

Mask is too noisy

Ports cap or elbow incorrectly inserted.

Remove the ports cap and 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.

Turn off the CPAP or bilevel device and remove mask. Refit your mask according to the instructions. Ensure you position the cushion correctly on your face before pulling headgear over your head. Do not slide mask down your face during fitting as this may lead to folding or curling of the cushion.

Cushion incorrectly inserted into frame.

Remove cushion from frame and reinsert starting at the top. Line up raised section on cushion with recess in top of frame. Ensure the alignment markers at bottom corners of the cushion line up with the indent features on frame. Ensure cushion membrane looks even before refitting. If the problem persists, talk to your clinician.

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. The Quattro FX cushion is designed to sit mid-bridge.

Spring frame incorrectly fitted to frame.

Remove the spring frame from the frame, then reassemble according to the instructions.



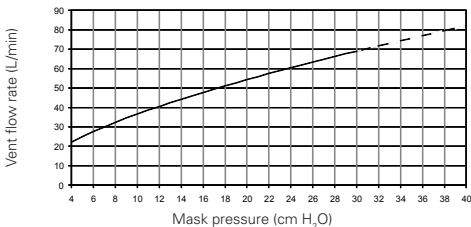
WARNING

- 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.
- 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.

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 | 22 |
| 8 | 32 |
| 12 | 41 |
| 16 | 48 |
| 20 | 54 |
| 24 | 60 |
| 28 | 66 |
| 30 | 69 |

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 243 mL.

Therapy pressure

4 to 30 cm H₂O

Resistance with Anti Asphyxia Valve (AAV) closed to atmosphere.

Drop in pressure measured (nominal)
at 50 L/min: 0.1 cm H₂O
at 100 L/min: 0.5 cm H₂O

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

| | |
|-------------------------|-------------------------|
| Inspiration at 50 L/min | 0.7 cm H ₂ O |
| Expiration at 50 L/min | 0.7 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: -4°F to 140°F (-20°C to +60°C)
Storage and transport humidity: up to 95% non-condensing.

Gross dimensions

Mask fully assembled with elbow assembly – no headgear.

| | |
|---------|---|
| Small: | 4.76" (H) x 6.93" (W) x 5.67" (D) 121 mm (H) x 176 mm (W) x 144 mm (D) |
| Medium: | 5.12" (H) x 6.93" (W) x 5.67" (D) 130 mm (H) x 176 mm (W) x 144 mm (D) |
| Large: | 5.51" (H) x 6.93" (W) x 5.67" (D) 140 mm (H) x 176 mm (W) x 144 mm (D) |

Mask setting options

Select 'MIR FULL' (if available), otherwise select 'FULL FACE' as the mask option.

Notes:

- The mask system does not contain latex, PVC or DEHP materials.
- 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. To ensure optimum care of your mask, fit the spring frame support when traveling.

Disposal

This mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

Symbols

 Caution, consult accompanying documents;  Lot number;  Part number;  Temperature limitation;  Humidity limitation;  Does not contain latex;  Manufacturer;  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;  Keep away from rain;  This way up;  Fragile, handle with care;  Rx 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.



Manufacturer:

ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia

Distributed by:

ResMed Corp 9001 Spectrum Center Boulevard San Diego CA 92123 USA

ResMed (UK) Ltd 96 Milton Park Abingdon Oxfordshire OX14 4RY UK

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

Protected by patents: AU 777033, AU 785376, EP 1187649, EP 1314445, EP 1582230, EP 1640034, HK 1057714, JP 4354664, NZ 538699, US 6439230, US 6581594, US 6823865, US 7159587, US 7669599. Other patents pending.

Design registrations pending.

Quattro is a trademark of ResMed Ltd.

© 2010 ResMed Ltd.



618168/1 2010-08

QUATTRO FX

USER

AMER - ENG



618168