# Quattro<sup>™</sup> FX Quattro<sup>™</sup> FX for Her

FULL FACE MASK

# **User Guide**

English



Did you know?

Replacing your mask and supplies is one of the most important steps in maintaining effective therapy.



# **Replace when...**

- The cushion is no longer clear and transparent.
- The cushion is cracked, torn or damaged in any way.
- The headgear is stretched and needs to be tightened more than when it was new.



# What to do...

Consult your equipment provider to learn what replacement schedule may be available through your insurance policy.



# Quattro™ FX Quattro™ FX for Her

 $R_{\!X\,\text{Only}}$ 

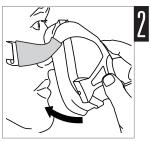
FULL FACE MASK / MASQUE FACIAL / MASCARILLA FACIAL / MÁSCARA FACIAL

# Fitting / Mise en place / Colocación / Colocação e ajuste













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







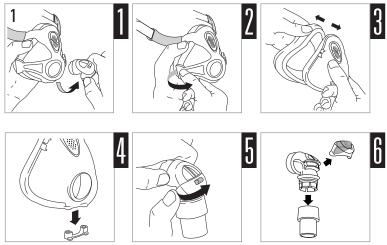
Cushion check / Vérification de la bulle / Revision de la almohadilla / Verificação da almofada

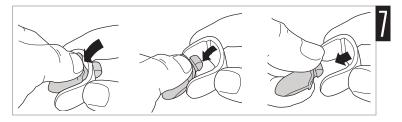






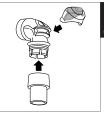
# Disassembly / Démontage / Desmontaje / Desmontagem





# Reassembly / Remontage / Montaje / Remontagem









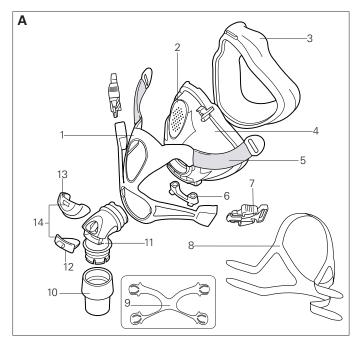


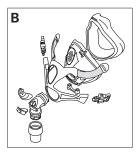






# Quattro FX Quattro FX for Her





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

ltem / Article / Artículo / Item	Description / Description / Descripción / Descrição	Part number / Code produit / Número de pieza / Código do produto	
		Quattro FX	Quattro FX for Her
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)	62506 (S) 62507 (STD)
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)	62501 (S) 62502 (M)
В	Frame system / Support / Sistema del armazón / Sistema da armação	61724 (S) 61725 (M) 61726 (L)	62513 (S) 62514 (M)

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

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

L Large / Large / Grande / Grande

# Quattro<sup>™</sup> FX Quattro<sup>™</sup> FX for Her

#### FULL FACE MASK

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

# Intended use

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

**Note:** 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

- 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.
- 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.
- 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.
- Unfasten the Velcro<sup>®</sup>, 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/Quattro FX for Her 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.
- 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.



 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.

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- 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.

# 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/Quattro FX for Her 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.			

### Problem/possible cause Solution

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/Quattro FX for Her 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.			



- 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. This warning applies to most types of CPAP devices.

# **Technical specifications**

Inspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) closed to atmosphere. Physical dead space is the empty volume of the mask to the end of the swivel. Using the large cushions it is 243 mL.   Inspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) open to atmosphere. Inspiration at 50 L/min 0.7 cm H <sub>2</sub> 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 104°F (+5°C to +40°C) Operating humidity: 15% to 95% non-condensing. Storage and transport. 4°F to 104°F (-20°C to +60°C) Storage and transport. 4°F to 104°F (-20°C to -60°C) Storage and transport. 4°F to 100°F (-20°C to -60°C) Sto	Pressure–flow curve	The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations,	Pressure (cm H <sub>2</sub> O)	Flow (L/min)	
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$\begin{array}{c c c c c c c } \hline & 12 & 41 \\ \hline & 16 & 48 \\ 20 & 54 \\ 24 & 60 \\ 28 & 66 \\ \hline & 30 & 69 \\ \hline \\ $			8	32	
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Image: Constraint of the second system is a second system in the second system is the second syst			16	48	
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informationof the swivel. Using the large cushions it is 243 mL.Therapy pressure4 to 30 cm H2OResistance 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 H2OInspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) closed to atmosphere.Inspiration at 50 L/min 0.1 cm H2OInspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) open to atmosphere.Inspiration at 50 L/min 0.7 cm H2OEnvironmental conditionsOperating 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: -4°F to 140°F(-20°C to +60°C) Storage and transport with elbow assembly – no headgear.Small:4.76" (H) x 6.93" (W) x 5.67" (D) 121mm (H) x 176 mm (W) x 144 mm (D) Large:Large:5.51" (H) x 6.93" (W) x 5.67" (D) 140 mm (H) x 176 mm (W) x 144 mm (D)			30	69	
Resistance with Anti Asphyxia Valve (AAV) closed to atmosphere.Drop in pressure measured (nominal) 					
Anti Asphyxia Valve (AAV) closed to atmosphere.at 50 L/min: 0.1 cm H_2O at 100 L/min: 0.5 cm H_2OInspiratory and expiratory resistance with Anti Asphyxia Valve (AAV) open to atmosphere.Inspiration at 50 L/min Derating temperature: +41°F to 104°F (+5°C to +40°C) Operating temperature: +41°F to 104°F (+5°C to +40°C) Operating temperature: +41°F to 104°F (-20°C to +60°C) Storage and transport: -4°F to 140°F(-20°C to +60°C) Storage and transport: -4°F to 140°F(-20°C to +60°C) Storage and transport humidity: up to 95% non-condensing.Gross dimensionsMask fully assembled with elbow assembly – no headgear. Small: 0.7°f (H) x 6.93° (W) x 5.67° (D) 121mm (H) x 176 mm (W) x 144 mm (D) Large: 0.511° (H) x 6.93° (W) x 5.67° (D) 140 mm (H) x 176 mm (W) x 144 mm (D)	Therapy pressure	4 to 30 cm H <sub>2</sub> O			
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resistance with Anti Asphyxia Valve (AAV) open to atmosphere.Expiration at 50 L/min0.7 cm H₂OEnvironmental 		Inspiration at 50 L/min 0.7 cm H <sub>2</sub> O			
conditionsOperating 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 dimensionsMask fully assembled with elbow assembly – no headgear.Small: $4.76"$ (H) x 6.93" (W) x 5.67" (D) 121mm (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) 130 mm (H) x 176 mm (W) x 144 mm (D)	<b>resistance</b> with Anti Asphyxia Valve (AAV) open to	Expiration at 50 L/min $0.7 \text{ cm H}_2\text{O}$			
Small: 4.76" (H) × 6.93" (W) × 5.67" (D)   121mm (H) × 176 mm (W) × 144 mm (D)   Medium: 5.12" (H) × 6.93" (W) × 5.67" (D)   130 mm (H) × 176 mm (W) × 144 mm (D)   Large: 5.51" (H) × 6.93" (W) × 5.67" (D)   140 mm (H) × 176 mm (W) × 144 mm (D)		Operating humidity: 15% to 95% non-condensing. Storage and transport: -4°F to 140°F( -20°C to +60°C)			
121mm (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)	Gross dimensions	Mask fully assembled with elbow assembly – no headgear.			
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)	Small:				
140 mm (H) x 176 mm (W) x 144 mm (D)	Medium:				
Mask setting Select 'MIR FULL' (if available), otherwise select 'FULL FACE' as	Large:				
options the mask option.	•				

English

#### Notes:

- The mask system does not contain PVC, DEHP or phthalates.
- This product does not contain 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. 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; 🔟 Batch code;

📧 Catalogue number; 📌 Temperature limitation; 🔎 Humidity limitation;

🛇 Does not contain natural rubber latex; 🕍 Manufacturer;

 ${f \Lambda}$  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; 11 This way up; ♥ Fragile, handle with care;



















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