

INSTRUCTIONS FOR USE

18504532 Rev May-09

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Fisher & Paykel
HEALTHCARE

WARNINGS

- This mask should be used only with CPAP or Bi-Level equipment recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP or Bi-Level machine is turned on and operating properly. The exhalation port(s) associated with the mask must be open.
- Explanation of Warning:** CPAP and Bi-Level machines are intended to be used with special masks which have exhalation ports to allow continuous flow of air out of the mask. When the CPAP or Bi-Level machine is turned on and functioning properly, the leaky air from the mask will be exhausted through the exhalation port(s). However, if the mask is not operating enough fresh air will not be provided through the mask and it may be re-breathed. Re-breathing of exhaled air for longer than several minutes can cause suffocation.
- At low pressure levels, the flow through the exhalation ports may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Valve activation/deactivation pressure is 2 cmH₂O.
- Do not use the mask without the Non-Rebreathing valve in place. This valve ensures CO₂ re-breathing is kept to a minimum in the event of power failure.
- Do not use the mask if you are feeling nauseous.
- Discontinue use of the mask if there is an allergic reaction to any part of the mask. Consult your physician if this occurs.
- If you are using the Forma™ Full Face Mask between different patients, refer to the Multi-Patient Cleaning Instructions for the Forma™ Full Face Mask.
- Replace the valve Anti-Rebreathvalve tous les ans.
- Do not use the Non-Rebreathing valve every 12 months.
- Use the Forma™ Full Face Mask only with the Headgear provided.

CAUTION

- The mask must be strictly utilised only in the way described in this manual.
- Les lois fédérales américaines n'autorisent la vente de ces appareils que par prescription médicale ou directement par un médecin.

CONTRAINDICATIONS

- This mask should not be used by anyone incapable of removing the mask unaided, without continuous supervision.

The Forma™ Full Face Mask and accessories are Latex free.
Many people find CPAP therapy causes dryness of the nose and throat.
Heated humidification may substantially reduce these symptoms.
Contact your supplier and ask about ThermoSmart™.

US Patent Numbers 6615834 / 6789541 / 6701926 / 6951218
Other Patents Pending

TECHNICAL SPECIFICATIONS

EXHAUST FLOW									
<i>The Forma™ Full Face Mask has exhalation ports to expel the air that you exhale from the mask.</i>									
<i>It is important that these exhalation ports are not blocked by any object. This controlled leak ensures all exhaled CO₂ is expired from the mask.</i>									
PRESION (cmH ₂ O)	3	5	7	9	11	13	15	17	19
DÉBIT (L/MIN)	18	23	26	30	32	35	37	40	45
RESISTANCE TO FLOW									
<i>Pressure drop through mask @ 50 l/min 0.4 ± 0.1 cmH₂O</i>									
<i>Pressure drop through mask @ 100 l/min 1.4 ± 0.1 cmH₂O</i>									
MASK DEAD SPACE									
108 cc									
INSPIRATORY AND EXPIRATORY RESISTANCE									
<i>The respiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 1.7 cmH₂O</i>									
<i>The expiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 2.9 cmH₂O</i>									
OPERATING CONDITIONS									
<i>• Operating pressure is 3-25 cmH₂O</i>									
<i>• Operating temperature range is 40-120 °F (5-50 °C)</i>									
<i>• Exhaust flow at each pressure is ± 15%</i>									
SOUND									
<i>The Sound Pressure Level of the mask is 29 dBA with an uncertainty of 2.5 dBA.</i>									
<i>The Sound Pressure Level of the mask is 22 dBA with an uncertainty of 2.5 dBA.</i>									
FORMA™ FULL FACE MASK MULTI-PATIENT CLEANING INSTRUCTIONS									
<i>Your Forma™ Full Face Mask is provided patient ready. To re-use between patients please follow the guidelines below.</i>									
CLEANING / DESINFOLING									
<i>• Before de-disinfecting disassemble all components from the Mask-Base. Clean all surfaces of mask and components thoroughly with a mild detergent solution and a soft bristled brush. Ensure all visible soil is removed. Rinse thoroughly under running potable water to remove detergent residue.</i>									
<i>FAILURE TO PROPERLY CLEAN THIS DEVICE MAY RESULT IN INADEQUATE DISINFECTION</i>									
HIGH LEVEL DISINFECTION PARAMETERS									
<i>PARAMÈTRES DE DÉSINFECTION DE HAUT Niveau</i>									
<i>MASK FRAME</i>									
<i>PASTEURISATION</i>									
<i>30 minutes at 70 °C (158 °F), 30 minutes at 75 °C (167 °F) and 10 minutes at 80 °C (176 °F).</i>									
<i>OR</i>									
<i>CIDEX® OPA</i>									
<i>30 minutes at 20 °C (68 °F).</i>									
<i>OR</i>									
<i>HANEXIOS G+R®</i>									
<i>As per Manufacturers Instructions – but Soak for 30 minutes and not 15 minutes.</i>									
<i>HEADGEAR WITH CLIP</i>									
<i>Wash in warm soapy water and leave to dry.</i>									
<i>FOAM CUSHION</i>									
<i>Replace with new part.</i>									
<i>THE FORMA™ FULL FACE MASK HAS BEEN VALIDATED TO WITHSTAND 20 CYCLES OF THE ABOVE PARAMETERS. DO NOT USE IF DAMAGED.</i>									
<i>Disclaimer: It is the user's responsibility to qualify any deviations from the recommended methods of re-processing. Some deviation may occur after re-processing.</i>									
<i>CONTACT YOUR LOCAL HOMECARE PROVIDER FOR ADDITIONAL INFORMATION.</i>									
Pressure (cmH ₂ O)	Flow (L/min)								
5	20								
10	30								
15	40								
20	50								
25	55								



