Nasal Mask

F&P Eson

Patient Instructions for Use

English
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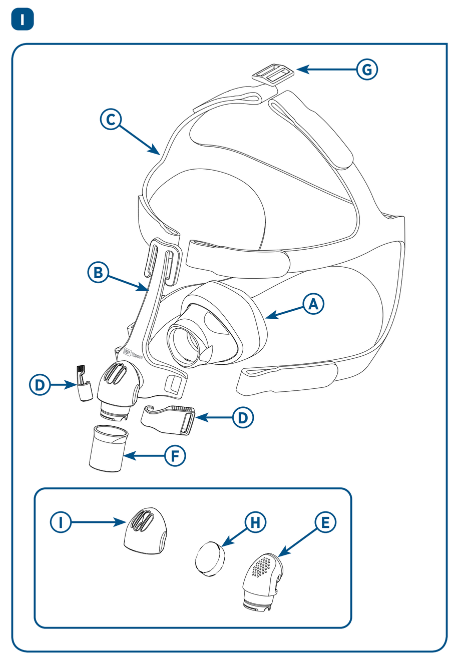
CE 0123

Fisher & Paykel HEALTHCARE

I



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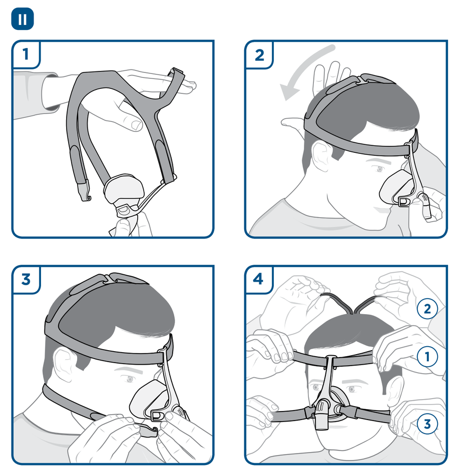

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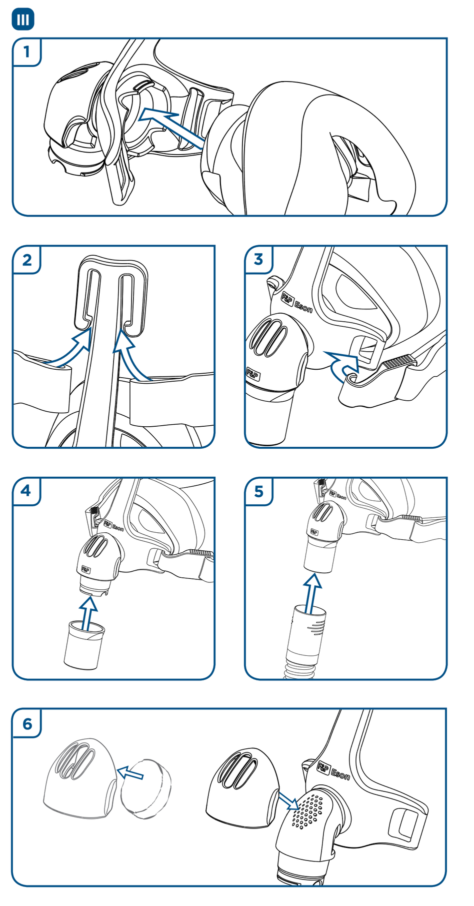

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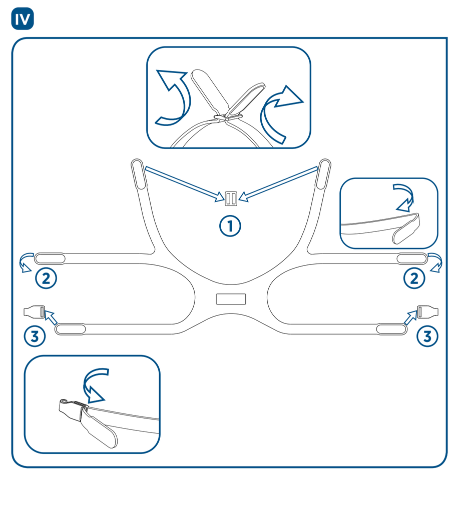


For patent information, see www.fphcare.com/ip

F&P Eson™ Nasal Mask

Patient Instructions for Use

The F&P Eson Nasal Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The F&P Eson Nasal Mask is intended for Single Patient Adult Use in the home and Multiple Patient Adult Use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

Warnings

- Only use F&P Eson Diffuser spare parts.
- Ensure only one fabric Diffuser **(H)** is used in the Diffuser System **(H and I)**.
- This mask should only be used with approved 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 exhaust holes associated with the mask should never be blocked.
- **Explanation of Warning:** CPAP and Bi-Level machines are intended to be used with special masks, which have exhaust holes to allow continuous flow of air out of the mask. When the CPAP or Bi-Level machine is turned on and functioning properly, new air from the CPAP or Bi-Level machine flushes the exhaled air out through the mask's exhaust holes. However, when the CPAP or Bi-Level machine is not operating, not enough fresh air will be provided through the mask, and exhaled air may be re-breathed. Re-breathing of exhaled air for longer than several minutes can lead to suffocation in some circumstances.
- At low CPAP or Bi-Level pressures the flow through the exhaust holes may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Do not block the exhaust holes. Before use, always ensure that the gas is flowing out the exhaust holes.
- Do not use the mask if vomiting or feeling nauseous.
- Discontinue use if discomfort or irritation occurs, and consult your healthcare provider.
- Discontinue using the mask if there is an allergic reaction to any part of the mask. Consult your physician if this occurs.
- If oxygen is used with CPAP or Bi-Level machine, the oxygen flow must be turned off when the CPAP or Bi-Level machine is not operating. Oxygen accumulated in the CPAP or Bi-Level machine enclosure will create a risk of fire.
- Keep ignition sources (e.g. smoking) away from anyone using oxygen with this mask.

CAUTIONS

- Use the mask only for its intended use as directed in this booklet.
- US Federal Law restricts this device to sale by, or on order of, a physician.

Warranty Statement

Fisher & Paykel Healthcare warrants that the mask (excluding foams and material diffusers), when used in accordance with its instructions for use, shall be free from defects in workmanship and materials and will perform in accordance with Fisher & Paykel Healthcare's official published product specifications for a period of 90 days from the date of purchase by the end user. This warranty is subject to the limitations and exceptions set out in detail in www.fphcare.com/osa/mask-solution/mask-warranty.html

DISPOSAL

The device does not contain any hazardous substances and may be disposed of with general waste.

I Mask Parts

A. Silicone Seal	**D**. Headgear Clips	**G**. Buckle
B. Mask Frame	**E**. Elbow	**H**. Diffuser
C. Headgear	**F**. Swivel	**I**. Diffuser Cover

NOTE: The Elbow **(E)** is permanently attached to the Frame **(B)**. It is not intended to be removed.

II Fitting Your Mask

1. Remove all packaging before using your mask.
2. Remove the plastic cover from the Silicone Seal **(A)**.
3. Hold the Frame **(B)** with one hand and the Headgear **(C)** in the other. One of the Headgear Clips **(D)** should be hooked onto the Frame **(B)**.
4. Place the Seal **(A)** on the nose and guide the Headgear **(C)** over your head.
5. Hook the unattached Headgear Clip **(D)** onto the Frame **(B)**.
6. Gently tighten the Headgear Straps in order.

FITTING TIPS

- Do not over-tighten any of the Headgear Straps.
- Forehead Straps should rest horizontally on the forehead, just above the ears.

III Mask Assembly/Disassembly

1. Push the Silicone Seal **(A)** onto the Mask Frame **(B)** in the orientation shown until a confirmation click is heard.
2. Slide the Forehead Loops of the Headgear **(C)** into the slots of the Mask Frame **(B)**. This can be done without undoing the VELCRO® brand tabs.*
**VELCRO® is a registered trademark of Velcro Industries B.V.*
3. Hook the Headgear Clips **(D)** onto the Mask Frame **(B)**.
4. Push the Swivel **(F)** onto the Elbow **(E)**.
5. Attach the assembled mask to the CPAP tube. Ensure that the Swivel **(F)** is removed from the CPAP tube when disassembling.
6. To assemble the Diffuser System, place the Diffuser **(H)** in Cover **(I)**, then attach to the Elbow **(E)**.

IV Headgear Assembly/Disassembly

Lay the Headgear **(C)** flat, with label side facing up.

1. Loop the Crown Straps of the Headgear **(C)** through the Buckle **(G)**.
2. Fold the Forehead Straps of the Headgear **(C)** back on itself.
3. Loop the Bottom Straps of the Headgear **(C)** through the Headgear Clips **(D)**.

Operating Instructions

- The operating pressure range of the mask is 4 to 25 cmH_2O.
- The operating temperature range of the mask is 5 to 40 °C (40 to 104 °F).
- Before using the mask each time:
  i. Inspect it for damage. If there is any visible deterioration (cracking, tears, etc) do not use and seek replacement part(s).
  ii. Inspect the exhaust holes on the Elbow **(E)**. Do not use if blocked.
  iii. Make sure the air path through the mask is clear.

NOTE: Failure to follow the operating instructions above may compromise the performance and safety of the mask.

Disassembly for Cleaning

1. Unhook the Headgear Clips **(D)** from the Mask Frame **(B)**.
2. Slide the Forehead Straps of the Headgear **(C)** downwards from the top of the Mask Frame **(B)**.
3. Remove the Silicone Seal **(A)** from the Mask Frame **(B)**.
4. Remove the Swivel **(F)** from the Elbow **(E)**.

Cleaning Your Mask at Home

After each use:

1. Wash your mask excluding the Headgear Assembly in soap dissolved in lukewarm water. Do not soak for more than 10 minutes.
2. Rinse thoroughly with fresh water, ensuring that all soap residues are removed.
3. Leave all parts to dry out of direct sunlight before reassembling.
4. The Diffuser **(H)** should not be washed or rinsed. Simply replace it with a new Diffuser **(H)** if it becomes noisy or deteriorates. It should last two to three months. Small dots may appear on the Diffuser – these do not affect its performance. The F&P Eson Nasal Mask may be used with, or without, the Diffuser System **(H and I)**.

After 7 days of use:

1. Hand-wash the Headgear Assembly in soap dissolved in lukewarm water. Do not soak for more than 10 minutes.
2. Rinse thoroughly with fresh water, ensuring that all soap residues are removed.
3. Leave all parts to dry out of direct sunlight before reassembling.

CAUTIONS

- Do not remove the Elbow **(E)** from the Mask Frame **(B)**. It is not intended to be detachable.
- Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.
- Do not soak the mask for longer than 10 minutes.
- Do not clean the mask in a dishwasher.
- Do not store the mask in direct sunlight.

The above actions may deteriorate or damage the mask and shorten its life. If your F&P Eson Nasal Mask weakens or cracks, discontinue use and seek replacement immediately.

Oxygen/Pressure Port Connector

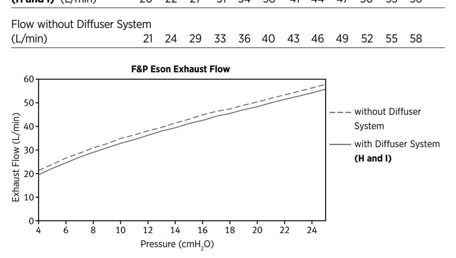
If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available (REF 900HC452). Please contact your healthcare provider.

Technical Specifications

EXHAUST FLOW

The F&P Eson Nasal Mask has a unique Diffuser System that is designed to diffuse air that is expelled from the mask. This reduces the draft. The diffuser does not significantly change the amount of air flowing from the mask, therefore the mask can be used with or without the Diffuser System **(H and I)**.

Pressure (cmH_2O)	4	5	7	9	11	13	15	17	19	21	23	25
Flow with Diffuser System **(H and I)** (L/min)	20	22	27	31	34	38	41	44	47	50	53	56
Flow without Diffuser System (L/min)	21	24	29	33	36	40	43	46	49	52	55	58



RESISTANCE TO FLOW

Pressure drop through mask with Diffuser System **(H and I)** @ 50 L/min: 0.14 ± 0.1 cmH_2O
Pressure drop through mask with Diffuser System **(H and I)** @ 100 L/min: 0.65 ± 0.1 cmH_2O

Pressure drop through mask without Diffuser System @ 50 L/min: 0.15 ± 0.1 cmH_2O
Pressure drop through mask without Diffuser System @ 100 L/min: 0.62 ± 0.1 cmH_2O

MASK DEAD SPACE

Small = 61 cc   Medium = 67 cc   Large = 79 cc

SOUND

The Sound Power Level of the mask with Diffuser System **(H and I)** is 30 dBA, with uncertainty 2.5 dBA.
The Sound Pressure Level of the mask with Diffuser System **(H and I)** is 22 dBA, with uncertainty 2.5 dBA.

The Sound Power Level of the mask without Diffuser System is 32 dBA, with uncertainty 2.5 dBA.
The Sound Pressure Level of the mask without Diffuser System is 24 dBA, with uncertainty 2.5 dBA.

Multi-Patient Cleaning Instructions

For USA only, models 400449, 400450 and 400451 are single patient use only, therefore multi-patient cleaning instructions do not apply.

Your F&P Eson Nasal Mask is provided patient-ready. To reuse between patients please follow the guidelines on the following website: www.fphcare.com/disinfection

If you do not have Internet access, please contact your Fisher & Paykel Healthcare representative or see details below.

Failure to properly clean this device may result in inadequate disinfection.

Headgear (C, D & G)
Hand-wash the Headgear **(C, D & G)** in soap dissolved in lukewarm water. Air dry out of direct sunlight.

Diffuser (H)
The Diffuser **(H)** is for single patient use. Replace between patients.

All other parts:

1. Pre-cleaning: Soak in 1 % Alconox detergent solution at 50 °C for 10 mins, scrub components in solution with soft non-metallic brush, then rinse twice in demineralized water and dry completely by leaving to air dry out of direct sunlight.
2.

High Level Disinfection	OR	Sterilization
Pasteurize at 75 °C for 30 min, 80 °C for 10 min or 90 °C for 1 min.		Follow manufacturer's instructions for either Sterrad 100S, NX or 100NX cycles.

- The F&P Eson Nasal Mask has been validated to withstand 20 cycles of the above parameters.
- Do not use if damaged.
- Disclaimer: It is the user's responsibility to qualify any deviations from the recommended method of reprocessing.
- Contact your local Homecare Provider for additional information.

The F&P Eson Nasal Mask and accessories are not made with natural rubber latex. Many people find CPAP or Bi-Level therapy causes dryness of the nose and throat. Heated humidification can substantially reduce these symptoms.

F&P and Eson are trademarks of Fisher & Paykel Healthcare Limited.

Nasal Mask

F&P Eson

Patient Instructions for Use

Dansk (Danish)

Русский (Russian)

Türkçe (Turkish)

Ελληνικά (Greek)

Slovenščina (Slovene)

简体中文版 (Simplified Chinese)

繁體中文版 (Traditional Chinese)

Português do Brasil (Brazilian Portuguese)

日本語 (Japanese)

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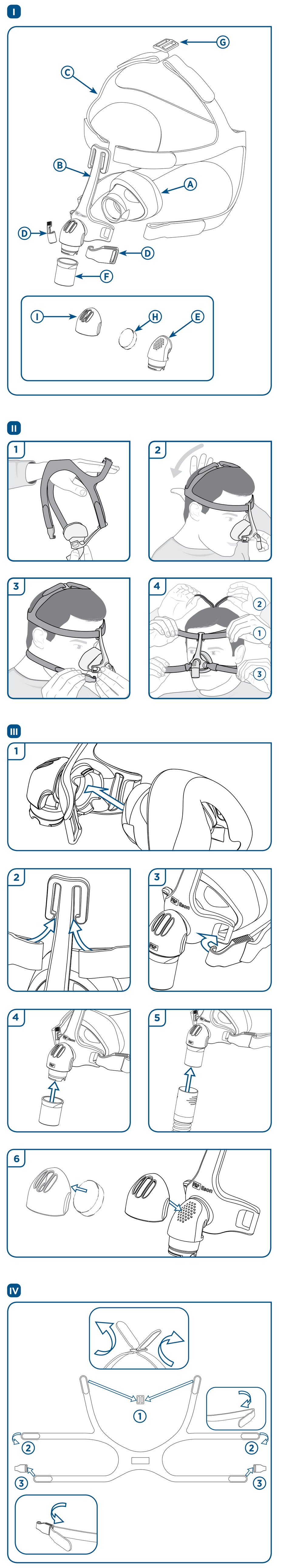

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Comfort

Seal

Easy Use