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F&P Lady Zest™ Q Nasal Mask

Patient Instructions for Use

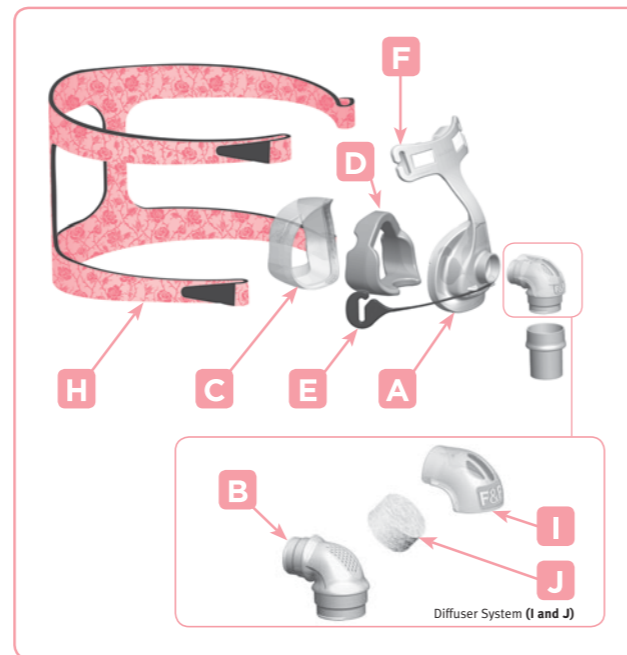
The F&P Lady Zest Q Petite Nasal Mask is intended to be used by individuals greater than 66 lbs (30 kg) who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The F&P Lady Zest Q Petite Nasal Mask is intended for Single Patient Use in the home and Multiple Patient Use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

The F&P Lady Zest Q 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 Lady Zest Q 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.

Assembling Your Mask

Your F&P Lady Zest Q Nasal Mask is fully assembled and ready to use. However, when you need to clean your mask follow these instructions for reassembly:

- Place the Foam Cushion (D) into the Silicone Seal (C) in the orientation shown in the diagram.
- Starting with the slot at the apex of the Silicone Seal, assemble onto Mask Base (A). Push firmly together.
- Lay the Stretchgear™ Headgear (H) flat, with the label side down. Position the assembled mask over the Headgear and attach the four straps into the corresponding slots in the Forehead Rest (F) and the Glider™ Strap (E). This can be done without undoing the VELCRO® brand tabs*, by sliding the Headgear into the slots.
*VELCRO® is a registered trade mark of Velcro Industries B.V.
- To assemble the Diffuser System, place the Diffuser (J) in Cover (I), then attach to the Elbow (B). Attach Elbow (B) to Mask Base (A).



Fitting Your Mask

- Remove the plastic cover from the Silicone Seal.
- Holding your mask in one hand, spread the Stretchgear™ Headgear (H) with your free hand, just enough to fit comfortably over your head.
- Lightly hold the mask against your face, covering the nose, then slowly pull the Headgear over your head.
- Attach the Headgear to the Glider™ Strap (E).
- Pull the lower straps as low as possible down the back of your neck. Gently tighten straps to remove slack. Connect to CPAP/Bi-Level machine set at prescribed pressure.
 - If necessary, tighten the lower straps to eliminate any leaks (avoid over-tightening the straps).
 - When you need to remove your mask, unhook the Stretchgear™ Headgear from the Glider™ Strap.



FITTING TIPS

- Forehead pads should rest gently on the forehead without top straps being pulled too tightly.
- If there are any leaks after gently tightening the top and lower straps, pull the mask slightly out from the face while straps are still attached. This will allow the Silicone Seal to inflate with air. Put the mask back onto the face.

Cleaning Your Mask

To ensure continuing safety and comfort for your F&P Lady Zest Q Nasal Mask:

- Before first use:**
Hand-wash the Stretchgear™ Headgear (H) in soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight.
- Before each use:**
Inspect the mask for deterioration. Do not use if damaged.
- After each use:**
 - Disassemble the Silicone Seal (C), Foam Cushion (D), Elbow (B) and the Headgear (H) from the Mask Base (A).
 - Wash the Silicone Seal and Mask Base in soap dissolved in lukewarm water. Do not soak for longer than 10 minutes.
 - Rinse thoroughly with fresh water, ensuring that all soap residue is removed.
 - Wipe the Foam Cushion with a damp cloth. (Do not immerse the Foam Cushion in water.)
 - Leave all parts to dry out of direct sun light before reassembling.
 - The Diffuser (J) should not be washed or rinsed. Simply replace it with a new Diffuser (J) 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 Lady Zest Q Nasal Mask may be used with, or without, the Diffuser System (I and J).
- Every 7 days:**
Hand-wash the Stretchgear™ Headgear (H) in soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight.

CAUTIONS

- Do not soak the mask for longer than 10 minutes.
- Do not wash the mask in the dishwasher.
- Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.
- 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 Lady Zest Q Nasal Mask weakens or cracks, discontinue use and seek replacement immediately.

Operating Instructions

- The operating pressure range of the mask is 4-25 cmH₂O.
- The operating temperature range of the mask is 5-40 °C (40-104 °F).
- Before using the mask each time:
 - Inspect it for damage. If there is any visible deterioration (cracking, tears, etc) do not use and seek replacement part(s).
 - Ensure Elbow (B) has exhaust holes and do not use if blocked.
 - 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.

Warnings

- Only use F&P Lady Zest Q Diffuser spare parts.
- Ensure only one fabric Diffuser (J) is used in the Diffuser System (I and J).
- 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.

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/Bi-Level machine is turned on and functioning properly, new air from the CPAP/Bi-Level machine flushes the exhaled air out through the exhaust holes. However, when the CPAP/Bi-Level machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. Re-breathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.
- At low CPAP/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 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.
- Use with Stroke Patients: One study has shown poor compliance with CPAP therapy in stroke patients. Careful evaluation of the patient's capabilities for CPAP therapy should be exercised.
- If re-using the F&P Lady Zest Q Nasal Mask between patients, refer to the Multi-Patient Cleaning Instructions for the F&P Lady Zest Q Nasal Mask.
- If oxygen is used with CPAP/Bi-Level machine, the oxygen flow must be turned off when the CPAP/Bi-Level machine is not operating. Oxygen accumulated in the CPAP/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 for its intended use only as directed in this booklet.
- US Federal Law restricts this device to sale by, or on order of, a physician.

For additional information contact your local homecare provider

Warranty and Disposal

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 <http://www.fphcare.com/osa/productWarranty.asp>

DISPOSAL

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

Oxygen/Pressure Port Connector

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port connector is available (REF 900HC452).

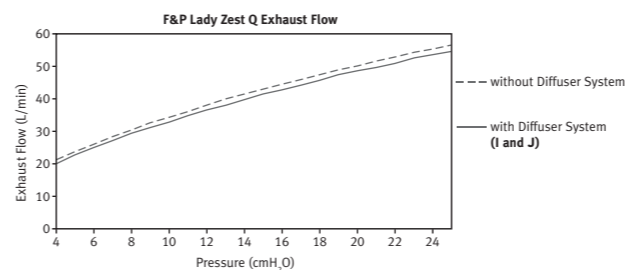
www.fphcare.com/en/osa/mask-resources.html

Technical Specifications

EXHAUST FLOW

Nasal masks for CPAP and Bi-Level have exhaust holes to expel the air that you exhale from the mask. The F&P Lady Zest Q Nasal Mask has a unique Diffuser system that is designed to diffuse the 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 (I and J).

Pressure (cmH ₂ O)	4	5	7	9	11	13	15	17	19	21	23	25
Flow with Diffuser System (I and J) (L/min)	20	23	27	31	35	38	41	44	47	50	52	54
Flow without Diffuser System (L/min)	21	24	28	33	36	40	43	46	49	52	54	56



RESISTANCE TO FLOW

Pressure drop through mask with Diffuser System (I and J) @ 50 L/min 0.3 ± 0.1 cmH₂O
Pressure drop through mask with Diffuser System (I and J) @ 100 L/min 1.1 ± 0.1 cmH₂O
Pressure drop through mask without Diffuser System @ 50 L/min 0.3 ± 0.1 cmH₂O
Pressure drop through mask without Diffuser System @ 100 L/min 1.1 ± 0.1 cmH₂O

MASK DEAD SPACE

F&P Lady Zest Q Petite = 40 cc

F&P Lady Zest Q = 60 cc

SOUND

The Sound Power Level of the mask with Diffuser System (I and J) is 23 dBA, with uncertainty 2.5 dBA.
The Sound Pressure Level of the mask with Diffuser System (I and J) is 15 dBA, with uncertainty 2.5 dBA.

The Sound Power Level of the mask without Diffuser System is 28 dBA, with uncertainty 2.5 dBA.
The Sound Pressure Level of the mask without Diffuser System is 20 dBA, with uncertainty 2.5 dBA.

Multi-Patient Cleaning Instructions

Your F&P Lady Zest Q Nasal Mask is provided patient-ready. To reuse between patients please follow the guidelines on the following website:
www.fphcare.com/en/osa/mask-resources.html

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

The F&P Lady Zest Q Nasal Mask and accessories are Latex free.
Many people find CPAP/Bi-Level therapy causes dryness of the nose and throat. Heated humidification can substantially reduce these symptoms.



This product is covered by or for use under one or more of the following patents or patent applications in the corresponding countries listed below.

USA: US6615834, US6789541, US6701926, US6951218, US7017576, US7308895
Australia: AU784321, AU785331, AU2002302002, AU2003281188, AU2004294873, AU2005228827, AU2009202852
Europe: EP1163924 (GB, IT, ES), EP1905475, EP1306098, EP1289590, EP1521613, EP1720593, EP1737524, EP2145645

