

Zest™

NASAL MASK

Patient Instructions for Use

English
Français (French)
Español (Spanish)

SHEET A

Zest™ Nasal Mask

Patient Instructions for Use

The Zest™ 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 Zest™ 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 Zest™ Nasal Mask and Zest™ Plus Nasal Mask are intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The Zest™ Nasal Mask and Zest™ Plus Nasal Mask are 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.

Operating Instructions

- The operating pressure range of the mask is 3-25 cmH₂O.
- The operating temperature range of the mask is 5-40 °C (40-104 °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 vent holes. 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.

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.
 - 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/Bi-Level machine is turned on and functioning properly, new air from the CPAP/Bi-Level machine flushes the exhaled air out through the mask exhalation ports. 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 exhalation ports may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Do not block the gas exhaust ports. Before use, always ensure that gas is flowing out the exhaust ports.
- 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 re-using the Zest™ Nasal Mask between patients, refer to the Multi-Patient Cleaning Instructions for the Zest™ Nasal Mask.
- California residents please be advised of the following, pursuant to Proposition 65: This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm. For more information, please visit: www.fphcare.com/prop65.

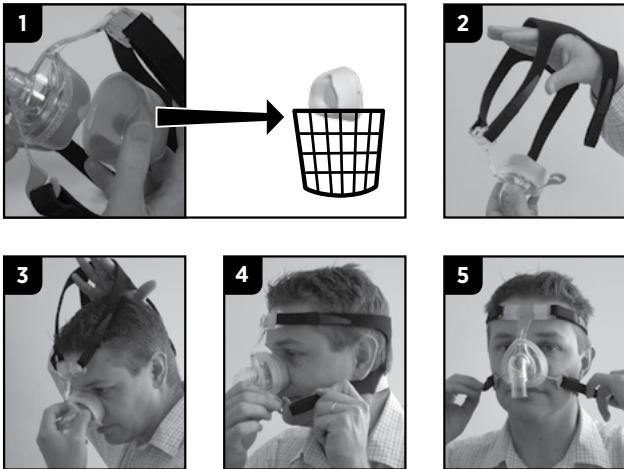
CAUTIONS

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

For additional information contact your local homecare provider

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 Zest™ Nasal Mask:

- Before first use:
 - Hand-wash the Stretchgear™ Headgear (H) in pure 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) and the Headgear (H) from the Mask Base (A).
 - Wash the Silicone Seal and Mask Base in pure 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 sunlight before reassembling.
- Every 7 days:
 - Hand-wash the Stretchgear™ Headgear (H) in pure 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.

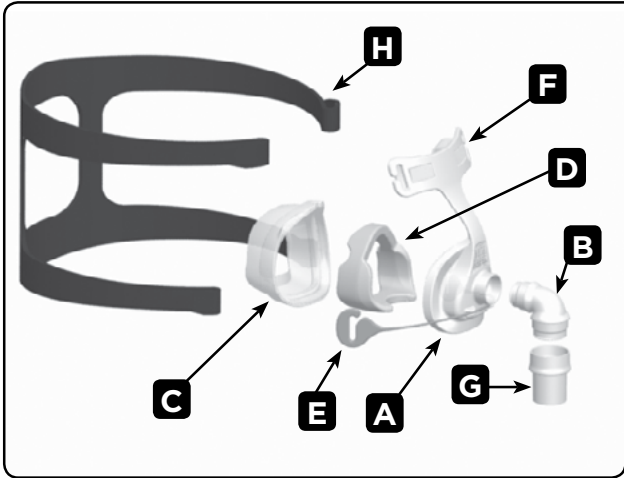
The above actions may deteriorate or damage the mask and shorten its life. If your Zest™ Nasal Mask weakens or cracks, discontinue use and seek replacement immediately.

Assembling Your Mask

Your Zest™ 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 loop 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.



The Zest™ 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.

Warranty and Disposal

WARRANTY STATEMENT

Fisher & Paykel Healthcare warrants that the mask (excluding foams and material dif-fusers), 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 excep-tions set out in detail in <http://www.fphcare.com/osa/productWarranty.asp>

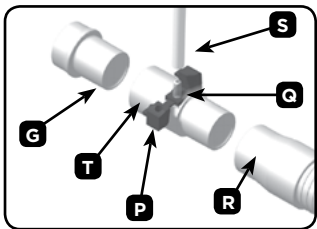
DISPOSAL

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 (Code 900HC452).

- Connect the large end of the Connector (T) to the Swivel (G) on the mask and the small end of the Connector to the main breathing tube (R).
- Open the Port Cap(s) (P) and place the Pressure and/or Oxygen Tube (S) firmly over the Port(s) (Q).
 - (The two ports are identical; either port may be used for oxygen or pressure measure-ment. Only remove the Port Cap from ports that are being used.)
- Note:** At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentra-tion will vary, depending on the pressure settings, patient's breathing pattern, mask selection, and the leak rate.
- Warning:** 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.
 - Explanation of Warning:** When the CPAP/Bi-Level machine is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP/Bi-Level machine enclosure. Oxygen accumulated in the CPAP/ Bi-Level machine enclosure will create a risk of fire.
- Warning:** Do not smoke while using or in the vicinity of someone using oxygen with this mask.
- Warning:** Do not use Polyvinyl Chloride (PVC) pressure and/or oxygen tubing. Use silicone tubing instead.
 - Explanation of Warning:** Contact with PVC can cause premature cracking of ports.

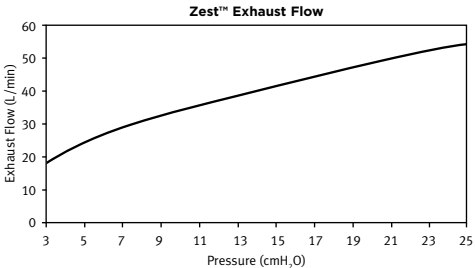


Technical Specifications

EXHAUST FLOW

The Zest™ Nasal Mask has an air exhaust system that vents the expelled CO₂ through a group of fine holes in front of the mask. It is important that these holes are not blocked by any object. This controlled leak ensures exhaled CO₂ is expelled from the mask.

Pressure (cmH ₂ O)	3	5	7	9	11	13	15	17	19	21	23	25
Flow (L/min)	18	24	29	32	35	38	41	45	47	50	52	54



RESISTANCE TO FLOW

Pressure drop through mask @ 50 L/min 0.2 ± 0.1 cmH₂O
Pressure drop through mask @ 100 L/min 0.8 ± 0.1 cmH₂O

MASK DEAD SPACE

Zest™ PETITE = 40 cc Zest™ = 60 cc Zest™ PLUS = 90 cc

SOUND

The Sound Power Level of the mask is 30 dBA, with uncertainty 2.5 dBA.
The Sound Pressure Level of the mask is 23 dBA, with uncertainty 2.5 dBA.

Multi-Patient Cleaning Instructions

For USA only, models 400439A, 400440A and 400441A are single patient use only, therefore multi-patient cleaning instructions do not apply.

Your Zest™ Nasal Mask is provided patient-ready. To re-use between patients please fol-low the guidelines below.

CLEANING / DESOILING

Before disinfection, remove visible soil by disassembling and thoroughly cleaning the mask with a small brush under running potable tap water.

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

HIGH-LEVEL DISINFECTION PARAMETERS

MASK BASE 	Pasteurisation 30 minutes at 70 °C (158 °F), 30 minutes at 75 °C (167 °F), and 10 minutes at 80 °C (176 °F). OR Cidex® OPA 30 minutes at 20 °C (68 °F). OR Hexanox G•R® As per Manufacturers Instructions – but Soak for 30 minutes and not 15 minutes.
SILICONE SEAL 	
ELBOW 	
SWIVEL 	
HEADGEAR 	Hand-wash the Headgear in pure soap dissolved in lukewarm water. Dry out of direct sunlight.
FOAM CUSHION 	Replace with new part.

The Zest™ 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.

ENGLISH

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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.

For patent information, see <https://www.fphcare.com/tp>

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

