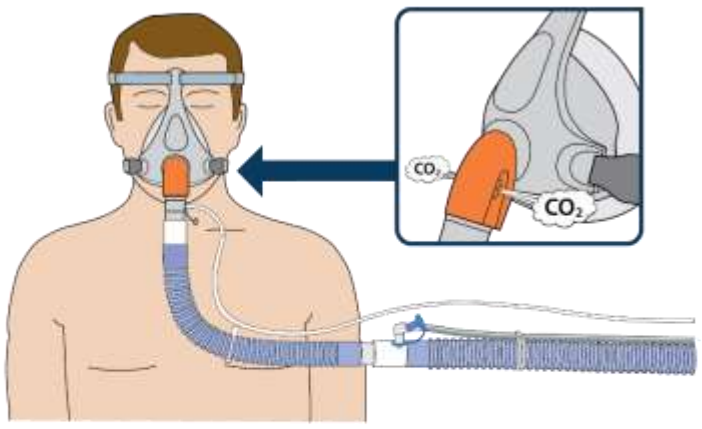
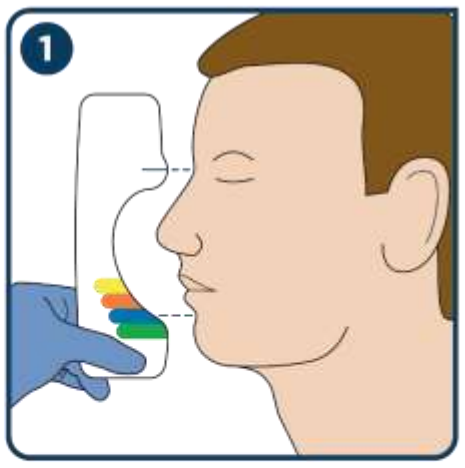
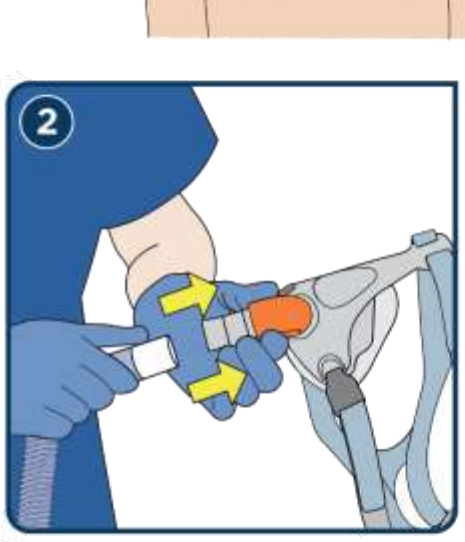
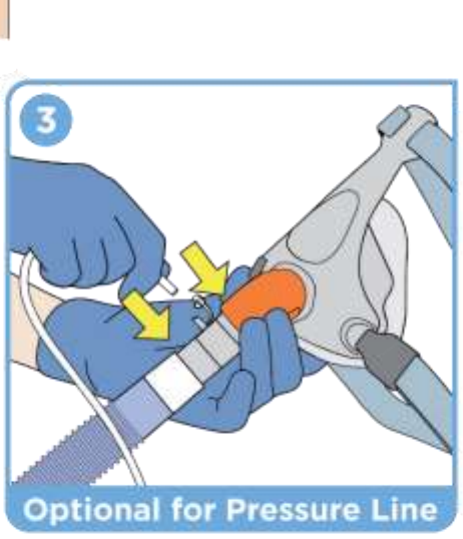
RT047 XS/S/M/L

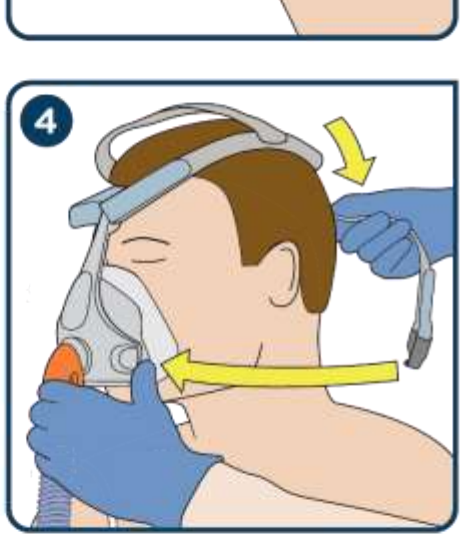
Vented Hospital Full Face Mask Anti-Asphyxiation Valve Version

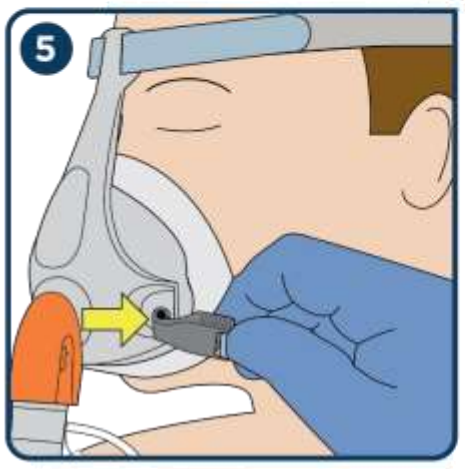


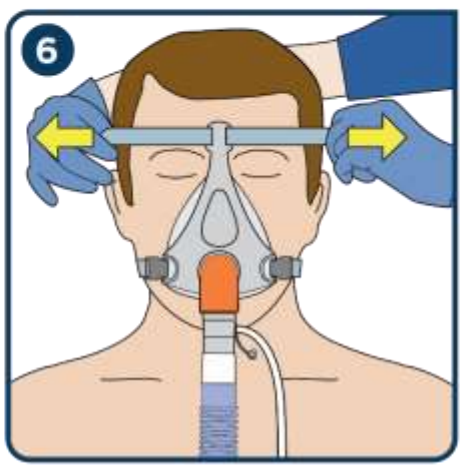


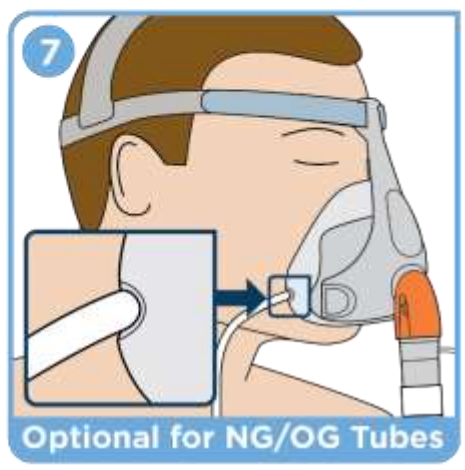


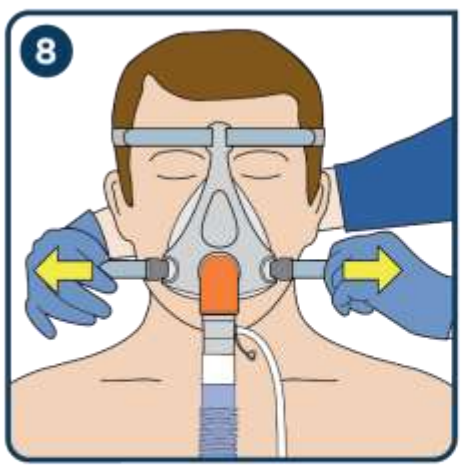


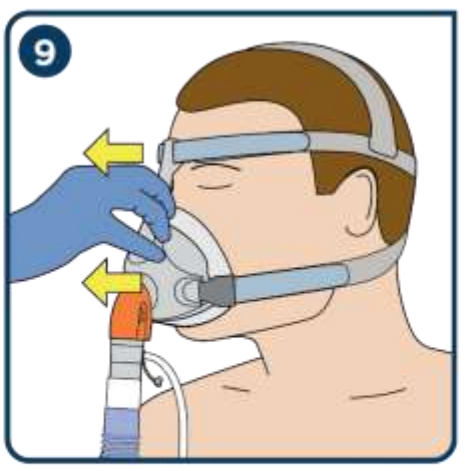












Single Use 14 Rx only CE 0123

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English (en)
Vented Hospital Full Face Mask Anti-Asphyxiation Valve Version

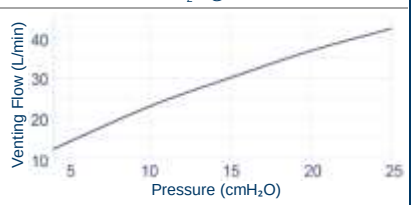
Intended Use
The Fisher & Paykel Healthcare single patient use masks are intended for use as an accessory to ventilators to enable non-invasive positive pressure ventilation (NPPV) therapy (CPAP or bi-level) to be delivered to spontaneously breathing adult patients (>30 kg) with respiratory insufficiency or respiratory failure who have been prescribed NPPV. The masks are to be fitted and therapy maintained by trained medical practitioners in a hospital/institutional environment with patient monitoring in place.

Technical Specifications

Operating Pressure Range:	4 – 25 cmH_2O
Interface Connections:	ISO 5356-1 Conical Connectors
Mask Dead Space:	< 325 cm^3
Anti-Asphyxiation Valve flap open to atmospheric pressure:	0.24 cmH_2O
Anti-Asphyxiation Valve flap closed to atmospheric pressure:	0.80 cmH_2O
Resistance to flow through mask:	0.26 cmH_2O @ 50 L/min, 0.63 cmH_2O @ 100 L/min

Pressure-flow curve for venting:

The venting flow rate may vary due to manufacturing variations.



- This product is intended for use for a maximum of 14 days.
- For use with pressurised gases provided by an external flow source or ventilator.
- For use with Ventilators/Devices delivering NIV therapy using a single limb circuit.
- Can be used with a heated pass over humidifier to deliver humidified gases to the patient.
- When humidifying gases, use as part of Fisher & Paykel Healthcare non-invasive humidification system.
- This product was not made with natural rubber latex.
- Dispose of mask according to hospital protocol.

Label – Mask Symbols

(XS) = Extra Small (S) = Small (M) = Medium (L) = Large

= Full Face = Vented

Before Use
- Ensure you have read and understood the instructions completely.
- Remove all packaging prior to use.
- Do not use if package is damaged.
- Inspect the mask for damage. Discard the mask if any parts are broken or if the seal is torn.
- Ensure that the correct mask is being used for the therapy device. Refer to setup guide on the other side.
- Verify that the mask is the correct size for the patient.
- Verify operation of the anti-asphyxiation valve before use.
- Verify that the therapy device (i.e. ventilator or flow source) including all alarms and safety systems are functioning correctly and that it is supplying the correct pressure(s).
- Clean the patient's face and then inspect for signs of redness, irritation or discomfort. Do not use if signs are present.
- Ensure adequate patient monitoring is in place.

Warnings
- **Do not block or try to seal the venting holes.**
- Verify that the therapy device, including alarms and safety systems, are functioning correctly prior to use.
- This device is fitted with an anti-asphyxiation valve and is not for use with dual limb ventilation systems. With no system flow the external openings in the valve should allow room air to entrain into the mask. With system flow the flap should close the external openings and allow system air to flow into the mask.
- **Do not block anti-asphyxiation valve vents.**
- Replace the mask if the anti-asphyxiation valve does not operate or becomes fouled with secretions.
- The mask must only be worn when the therapy is being delivered.
- The mask must be fitted and therapy established by an appropriately trained medical practitioner or care provider.
- This mask may only be used in a hospital or clinical setting where the patient is adequately monitored by trained medical staff. Failure to monitor the patient may result in loss of therapy, serious injury or death.
- This mask is for single patient use. **Do not reuse**. Reuse may result in transmission of infectious substances, interruption to treatment, serious harm or death. Do not soak, wash, sterilise, or re-use this product. Avoid contact with chemicals, cleaning agents, or hand sanitizers.
- At low CPAP or EPAP pressures the flow through the venting holes may be too low to clear all exhaled gas from the mask. Some rebreathing may occur.
- Facial hair, missing teeth/dentures and facial structure irregularities may compromise mask seal.
- 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
- Do not overtighten any of the headgear straps, overtightening may cause patient discomfort and/or leaks.
- Ensure the mask frame does not directly contact the forehead. If the mask frame touches the forehead the straps are overtightened.
- The RollFit™ Seal is designed to roll back and forth on the bridge of the nose to accommodate a range of face shapes. If the RollFit™ Seal is fully compressed, mask performance may be impaired.
- If the patient experiences skin redness, irritation or discomfort discontinue use and contact a physician.

Contraindications
Should not be used on patients who:
- Have cardiac or respiratory arrest, or severe hemodynamic instability.
- Are unconscious, unable to breathe spontaneously, uncooperative, unresponsive or unable to remove the mask.
- Have an upper airway obstruction, or an inability to clear secretions (impaired cough or swallow reflexes, excessive reflux, epistaxis, hiatal hernia).
- Have copious secretions, at risk of nausea/vomiting, or at high risk of aspiration of emesis.
- Have had head or facial surgery, trauma or burns.
- Have severe upper gastro-intestinal bleeding, or barotrauma (un-drained pneumothorax).

If symptoms of these conditions occur discontinue treatment immediately.

Fitting Instructions
1. Size the patient by aligning the blue line of the sizing guide between the eyes at eye level. The correct mask size is measured just below the lower lip on the chin.
2. Connect the mask to the flow source. Ensure the flow source is turned on.
3. If using a flow source that requires pressure feedback, connect the pressure line to the pressure port on the mask. Otherwise, ensure the pressure port is capped.
4. Undo the lower clip(s) and slide the loose headgear over the patient's head.
5. Connect the headgear clip(s) onto the mask frame.
6. Adjust the upper headgear straps. If the mask frame touches the forehead this indicates that the straps are overtightened.
7. If the patient has an orogastric or nasogastric tube, ensure the tube is placed under the integrated TubeFit zone, to achieve a good seal around the tube.
8. Adjust the lower straps of the headgear.
9. Gently pull the mask forward, allowing the seal to inflate so it can adjust to the patient's face to minimise leak.

Note: Readjust headgear/mask as required to achieve a good seal. Remember to gently pull the mask forward to inflate the seal.

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