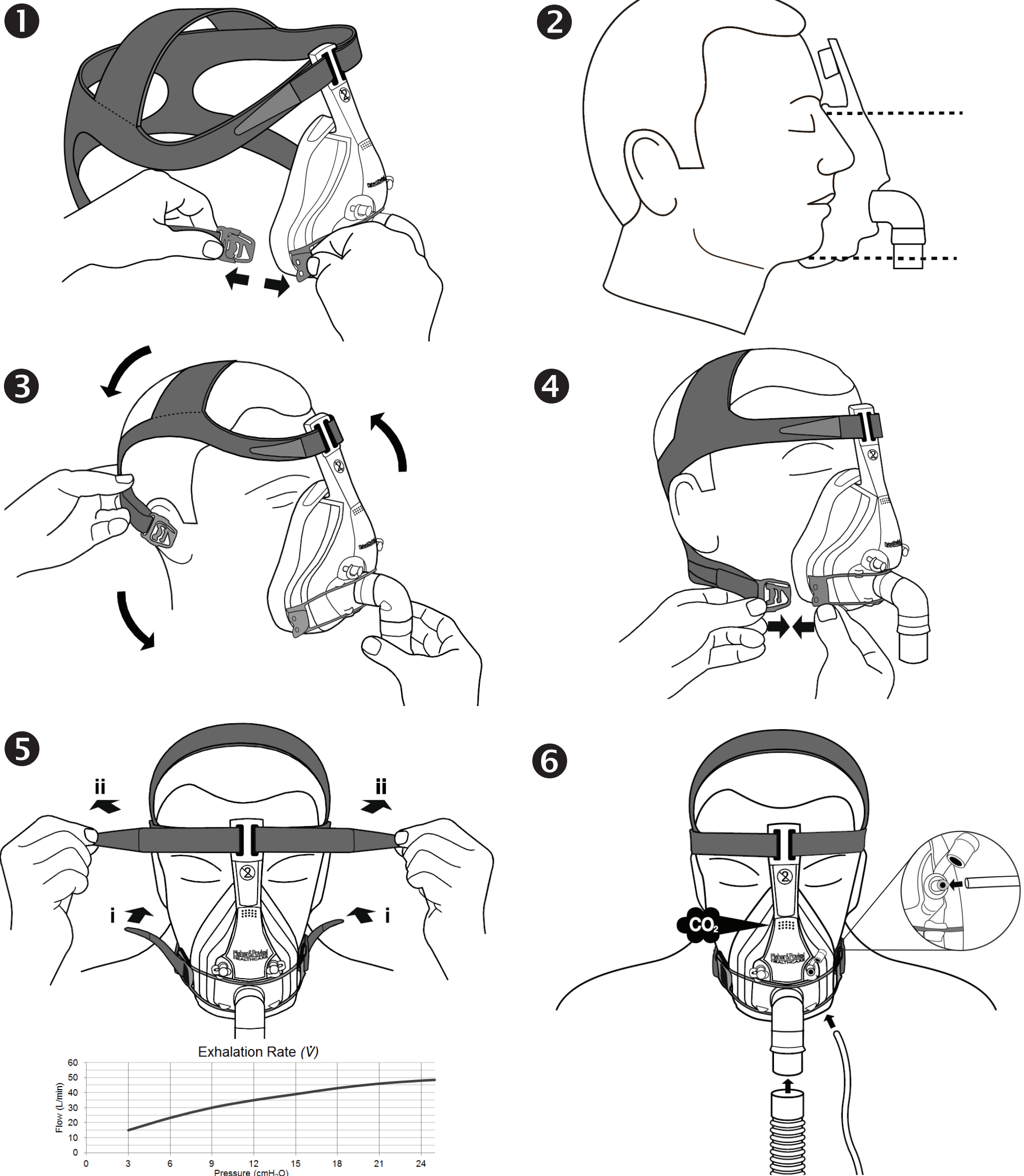


Vented Hospital Full Face Mask



Single use only
Ready for Use

CE 0123 Rx only


Fisher & Paykel
HEALTHCARE

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RT040 Vented Hospital Full Face Mask

Indications for Use:
The Fisher & Paykel Healthcare RT040 Vented hospital full face mask is an oronasal patient interface for use as an accessory to therapy devices providing non-invasive bi-level or continuous positive airway pressure support therapy. The therapy device must have adequate alarms and safety systems for device failure. This mask is for single patient use with spontaneously breathing adult (> 30 kg) patients with respiratory insufficiency or respiratory failure who are suitable for non-invasive positive pressure support therapy in a hospital or clinical setting.

Technical Specification:
Operating pressure range: 3 – 25 cmH₂O
Interface connections: ISO 5356-1 Conical connectors
Compatible with MR850 series non-invasive humidification systems.
Mask dead space <218 cc
This product was not made with natural rubber latex

-  **Warnings**
- Verify that the therapy device, including alarms and safety systems, have been validated prior to use.
 - Only wear mask when therapy is delivered.
 - This mask should only be used on single limb systems, where gas exhalation vents are required.
 - This mask should NOT be used on single limb circuits that have permanently integrated exhalation venting. Exhalation holes are provided in the mask.
 - A minimum pressure of 3 cmH₂O is required.
 - Set MR850 humidifier to non-invasive mode when administering humidity.
 - Remove all packaging before use.

 - 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 does not include an anti-asphyxiation valve that would allow the patient to breath if the ventilator failed.
 - Do not block the gas exhalation vents on the mask.
 - In the case of therapy device failure, the use of this mask requires the same level of attention and assistance as in the use of a tracheal tube.
 - Reuse may result in transmission of infectious substances, interruption to treatment, serious harm or death.
 - Contact the physician if the patient experiences unusual chest discomfort, shortness of breath, stomach distension, belching or severe headache upon waking or when receiving positive airway pressure.
 - To minimise the risk of vomiting during sleep, the patient should avoid eating or drinking for three hours before using the mask.
 - If the patient experiences skin irritations, consult physician.
 - This product is intended for use for a maximum of 7 days. Discard according to hospital protocol.

- Contraindications**
- This mask may not be suitable for persons with the following conditions: Impaired cardiac sphincter function, excessive reflux, impaired cough reflex, and hiatal hernia. It should not be used if the patient is vomiting or feeling nauseous, or if the patient is unconscious, uncooperative, unresponsive or unable to remove the mask.
 - Do not use on patients with hypotension, secondary to hypovolemia. If symptoms of these conditions occur discontinue treatment immediately.