

Instructions for Use

Intended Use - The Image 3 Disposable Full Face Mask is intended to provide an interface for adult patients when used with Respironics CPAP and bi-level systems. The mask covers the nose and mouth and is designed to be worn with the Respironics Disposable 3-Strap Headgear. Before using this mask, verify device pressure(s).

Caution: US Federal law restricts this device to sale by or on the order of a physician.

Warnings

- This mask is not suitable for providing life support ventilation.
- A minimum pressure of 3.0 cm H₂O at the mask (CPAP or EPAP) is required.
- This mask requires a separate exhalation device.
- Contact the physician if the patient experiences unusual chest discomfort, shortness of breath, stomach distention, belching, or severe headache when he awakens or when he is receiving positive airway pressure.
- To minimize the risk of vomiting during sleep, the patient should avoid eating or drinking for three hours before using the mask. This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- If the patient has respiratory insufficiency, he should wear this mask ONLY when therapy is being delivered.
- If the patient experiences skin irritation, consult the physician.

Notes

- Verify that the mask and headgear are the correct size.
- Dispose of this mask in accordance with local regulations.
- If a nasogastric (NG) tube or similar device is in place, use the optional NG tube sealing pad. Position the pad so that its flat surface is against the patient's face and the C-shaped opening surrounds the tube.

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 uncooperative, obtunded, unresponsive, or unable to remove the mask.

Before Each Use

- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.
- Wash the patient's face, and clean the mask.
- Check the entrainment valve. With the CPAP or bi-level system turned off, verify that the entrainment valve flapper is positioned so that room air can flow through the large opening in the valve. Turn on the system; the flapper should close, and system air should flow into the mask. If the flapper does not close or does not function properly, replace the mask. Do not block the opening on the entrainment valve or the openings on the exhalation device. Ensure that the valve is not blocked with secretions and that the flapper is dry.

Using the Mask

- Step 1.** Hold the mask lightly against the patient's face and slide the headgear over his head.
- Step 2.** Connect the patient circuit (exhalation device and flexible tubing) to the entrainment valve.
- Step 3.** Turn on the CPAP or bi-level system. Instruct the patient to lie down, and breathe normally.
- Step 4.** Adjust the middle and lower side straps by pulling each strap until the mask has minimal leaks and fits comfortably on the patient's face. DO NOT overtighten the straps. Overtightening can cause or worsen leaks.

NOTE: The disposable 3-strap headgear has two sets of adjustable hook tabs. For larger sized heads, use the outer tabs. For smaller sized heads, use the inner tabs. The extra tabs can be removed with scissors.

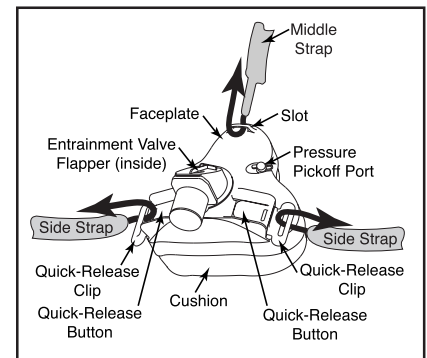
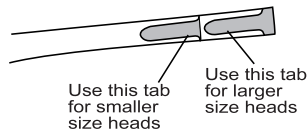


Figure 1

Removing the Mask

To quickly remove the mask, press the Quick Release Buttons located on the mask.

Reconnecting the Headgear and Mask

- Step 1.** Slide the headgear quick-release clips into the faceplate until they lock.
- Step 2.** Insert the two lower straps through the appropriate quick-release clip. Fold back and press the hook tab on each strap until the strap is secure.
- Step 3.** Insert the middle strap (from the top of the headgear) through the slot on the top of the mask faceplate. Fold back and press the hook tab until the strap is secure.
- Step 4.** Adjust the top strap if necessary.

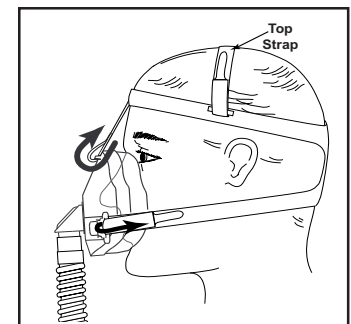


Figure 2

RESPIRONICS®
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Murrysville, Pennsylvania
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Reorder Numbers

1004878	Small, with Headgear
1004849	Medium, with Headgear
452040	NG Tube Sealing Pad (10/pack)
1004870	Headgear Quick-Release Clip Kit
1004877	Disposable 3-Strap Headgear