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FLEXIFIT™ 431 NIV FULL FACE MASK INSTRUCTIONS FOR USE

INTENDED USE STATEMENT

The FlexiFit™ 431 NIV Full Face Mask is intended for use on single patient adult use by individuals who have been intubated or non-intubated ventilation assistance.

WARNING: The FlexiFit™ 431 NIV Full Face Mask is to be used only with ventilators that have adequate alarms and safety systems.

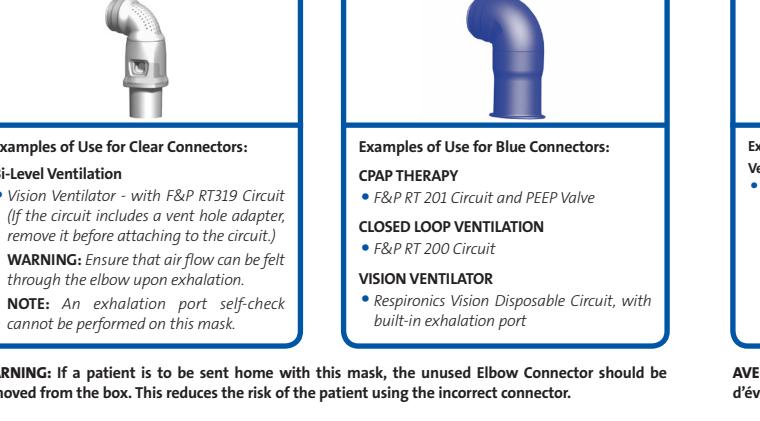
Refer to Warnings and Cautions for description of alarms required.

Ceinture d'aspiration : U.S. Federal Law restricts this device to sale, or by or on behalf of, a physician.

PREPARING YOUR MASK FOR USE

The FlexiFit™ 431 NIV Full Face Mask comes complete with both a Vent and Non-Ventilated Elbow.

It is vital that the correct Elbow connector is used with the appropriate ventilator system as shown in the diagrams below:



WARNING: If a patient is sent home with this mask, the unused Elbow connector should be removed from the box. This reduces the risk of the patient using the incorrect connector.

FITTING YOUR MASK

Refer to the mask assembly diagram.

1) Remove plastic cover from Silicone Seal [C].

2) Attach correct Elbow to the mask. See *Preparing Your Mask For Use**

3) Ensure that the Pressure Port Caps [N] are firmly attached to the mask.

4) Unclip the Headgear [K] from the Glider™ Strap [E] by pulling the Easy-Release Cord [D] down.

Holding your Mask Base [A] in one hand, spread the Headgear with your free hand, just enough to fit comfortably over your head.

5) Lightly hold the most oxygenated face of the bottom of the Silicone Seal under your chin, and spread the Headgear to fit over your head.

6) Rotate the Headgear Clip [H] to the Glider™ Strap [E].

7) Gently adjust any horizontal straps to ensure the bridge of the Silicone Seal remains stable on your nose. Gently tighten lower horizontal straps, ensure the bottom of the Silicone Seal remains fixed under the chin. Ensure that the Glider™ Strap is centered. Gently adjust top crown straps to remove slack.

8) Connect the ventilator to your mask and start breathing normally.

9) Ensure the ventilator settings are correct, in particular for volume-cycled ventilators, make appropriate allowances for mask dead space and leave the tidal volume setting. (Refer to the *TECHNICAL SPECIFICATIONS* section of these instructions for more information.)

If necessary pull the mask slightly away from your face while the straps are still attached and the ventilator is supplying pressure. This allows the Silcone Seal to inflate. Replace the mask on your face to re-inflate.

10) If leaks occur around the upper half of the mask, gently tighten the top horizontal straps. It is not necessary for the forehead cushion to touch your forehead.

11) If leaks occur around the lower half of the mask, gently tighten the lower horizontal straps. (Avoid overtightening the straps.)

12) If no leak persists, change to the alternate size Silicone Seal, which is found in your FlexiFit™ 431 NIV Mask box.

13) When you need to remove your mask, unclip the Headgear from the Glider™ Strap by pulling the Easy-Release Cord towards your nose.

HOME USE CLEANING INSTRUCTIONS

(For High-Level Disinfection, refer to *Multi-Patient Cleaning Instructions*)

To ensure continued safety, efficacy and comfort of your FlexiFit™ 431 NIV Full Face Mask:

BEFORE FIRST USE:

1) Hand wash the mask in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and lay dry out of direct sunlight. It is not necessary to remove the Clip [H] from the Headgear when washing.

BEFORE EACH USE:

1) Ensure that alarms and safety systems on the ventilator are operating correctly.

2) Check that the correct Elbow and tube are used. (See *Preparing Your Mask For Use**)

3) Inspect the mask for deterioration. Do not use if damaged, or if the film is impaired.

AFTER EACH USE:

1) Discard the Silicone Seal [C] (Elbow [B] and Swivel [J]) and the Headgear [K] from the Mask Base [A].

2) Wash the Silicone Seal, Elbow and Mask base in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water.

3) Leave mask to dry, away from direct sunlight before reusing.

EVERY 7 DAYS:

1) Hand wash the Headgear in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and lay dry out of direct sunlight. It is not necessary to remove the Clip [H] from the Headgear when washing.

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, antibacterial agents, antiseptic, bleach, chlorine, or any other harsh chemicals.

• Do not store the mask in direct sunlight.

• The above actions may deteriorate or damage the mask and shorten its life. If your FlexiFit™ 431 NIV Full Face Mask develops or cracks, discontinue use and seek replacement immediately.

REASSEMBLING YOUR MASK

Your FlexiFit™ 431 NIV Full Face Mask is assembled and ready to use. However, after cleaning your mask follow these instructions for reassembly.

1) Place Silicone Seal [C] into Mask Base [A].

2) Attach the correct Elbow and Valve/Swivel [B] or [M] or [L] by following the instructions PREPARING YOUR MASK FOR USE.

3) Attach the Headgear [K] fast with the lather side down.

4) Position the arms correctly on the Headgear and attach the four straps in to the corresponding slots in the Mask Base and the Glider™ Strap [E]. This can be done without undoing the VECLOR® brand ties, by sliding the Headgear off the base.

*VECLOR® is a registered trade mark of Velcro Industries BV.

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 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/bsu/product/Warranty.aspx>

DISPOSAL

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

OXYGEN / PRESSURE PORT CONNECTOR

There are two ports on the base of the mask for taking pressure readings and/or adding additional oxygen.

1) Open the Port Caps [N].

2) Place the Pressure or Oxygen Tube firmly over the port(s).

(The two ports are identical; either port may be used for oxygen or pressure readings, and the look alike port is for a pressure reading only.)

Warning: If oxygen is used with a ventilator, the oxygen flow must be turned off when the ventilator is not operating.

Explanation of Warning: When the ventilator is turned on, the oxygen flow is left open, oxygen delivery through the ventilator may not be available when the ventilator enclosure. Oxygen delivered in the ventilator enclosure will create a risk of fire.

Warning: Do not allow smoking or naked flames 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.

WARNINGS

• This mask should not be used if the patient has impaired laryngeal reflexes, is vomiting, feeling nauseous, or suffering from any other conditions predisposing to aspiration in the event of regurgitation or vomiting.

• This mask is not intended for patients who require a tracheostomy and that may cause vomiting.

• Contact the physician if the patient experiences unusual chest discomfort, shortness of breath, increased respiratory rate, or a severe headache when he/she is receiving ventilation assistance.

• This NIV mask should be used only with Non-Invasive Ventilators recommended by your physician or respiratory therapist. A mask should not be used unless the ventilator is turned on and operating properly, for open loop systems at pressures greater than 3 cm H2O and for closed loop systems at pressures greater than 5 cm H2O.

Explanation of Warning: Non-Invasive Ventilators are intended to be used with NIV masks. When the ventilator is turned on and functioning properly, new air from the ventilator flushes out the exhaled air port or through an expiratory tube. However, when the ventilator is not operating, fresh air will not be passed through the mask, and exhaled air may be re-breathed in the ventilator enclosure. Oxygen delivered in the ventilator enclosure will create a risk of fire.

Warning: Do not allow smoking or naked flames 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.

ADDITIONAL WARNINGS - FOR THE BLUE NON-VENTED SYSTEM

In the event of ventilation failure, use of this mask requires the same level of attention and assistance as a tracheostome.

The FlexiFit™ 431 NIV Full Face Mask is not suitable for use without appropriately qualified supervision and training. It is the responsibility of the healthcare provider to ensure that the user is competent to use the mask.

The NIV mask should be used only with Non-Invasive Ventilators recommended by your physician or respiratory therapist. A mask should not be used unless the ventilator is turned on and operating properly, for open loop systems at pressures greater than 3 cm H2O and for closed loop systems at pressures greater than 5 cm H2O.

Explanation of Warning: Non-Invasive Ventilators are intended to be used with NIV masks. When the ventilator is turned on and functioning properly, new air from the ventilator flushes out the exhaled air port or through an expiratory tube. However, when the ventilator is not operating, fresh air will not be passed through the mask, and exhaled air may be re-breathed in the ventilator enclosure. Oxygen delivered in the ventilator enclosure will create a risk of fire.

Warning: Do not allow smoking or naked flames 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.

CONTRAINDICATIONS

• This mask is contraindicated for patients without a spontaneous respiratory drive.

ADDITIONAL WARNINGS - FOR THE BLUE NON-VENTED SYSTEM

In the event of ventilation failure, use of this mask requires the same level of attention and assistance as a tracheostome.

The FlexiFit™ 431 NIV Full Face Mask is not suitable for use without appropriately qualified supervision and training. It is the responsibility of the healthcare provider to ensure that the user is competent to use the mask.

The NIV mask should be used only with Non-Invasive Ventilators recommended by your physician or respiratory therapist. A mask should not be used unless the ventilator is turned on and operating properly, for open loop systems at pressures greater than 3 cm H2O and for closed loop systems at pressures greater than 5 cm H2O.

Explanation of Warning: Non-Invasive Ventilators are intended to be used with NIV masks. When the ventilator is turned on and functioning properly, new air from the ventilator flushes out the exhaled air port or through an expiratory tube. However, when the ventilator is not operating, fresh air will not be passed through the mask, and exhaled air may be re-breathed in the ventilator enclosure. Oxygen delivered in the ventilator enclosure will create a risk of fire.

Warning: Do not allow smoking or naked flames 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.

CAUTIONS

• This mask is not for use with ventilation, which have a combination of:

- A mask that is unable to compensate for pressure drops, the isolated oxygen concentration will stay constant, the oxygen delivery pattern, mask selection, and the look alike port.

- No expiratory ventilation. If a ventilator with poor leak compensation is used, special attention must be paid to the mask seal.

- As with all mask ventilation systems, significant leak may occur between the mask and the patient's face. The leak may vary depending on such factors as the patient's position and sleep stage. Variation in leak may significantly affect patient ventilation, potentially producing profound hypoxemia and respiratory acidosis. The magnitude of this effect depends on the ventilator's ability to compensate for leak.

- Leak or variation in the leak may cause mis-triggering of the ventilator.

- Use the mask for its intended use only as directed in this booklet.

- Caution: U.S. Federal Law restricts this device to sale by or on behalf of a physician.

CONTRAINDICATIONS

• This mask is contraindicated for patients without a spontaneous respiratory drive.

ADDITIONAL WARNINGS - FOR THE BLUE NON-VENTED SYSTEM

In the event of ventilation failure, use of this mask requires the same level of attention and assistance as a tracheostome.

The FlexiFit™ 431 NIV Full Face Mask is not suitable for use without appropriately qualified supervision and training. It is the responsibility of the healthcare provider to ensure that the user is competent to use the mask.

The NIV mask should be used only with Non-Invasive Ventilators recommended by your physician or respiratory therapist. A mask should not be used unless the ventilator is turned on and operating properly, for open loop systems at pressures greater than 3 cm H2O and for closed loop systems at pressures greater than 5 cm H2O.

Explanation of Warning: Non-Invasive Ventilators are intended to be used with NIV masks. When the ventilator is turned on and functioning properly, new air from the ventilator flushes out the exhaled air port or through an expiratory tube. However, when the ventilator is not operating, fresh air will not be passed through the mask, and exhaled air may be re-breathed in the ventilator enclosure. Oxygen delivered in the ventilator enclosure will create a risk of fire.

Warning: Do not allow smoking or naked flames 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

OPERATING RANGE

Operating pressure is 3-25 cmH₂O for open loop systems, and 5-25 cmH₂O for closed loop systems. Do not use at pressures below 3 cmH₂O on open loop systems, or 5 cmH₂O on closed loop systems.

Operating temperature is 5-50°C (40-120°F).

MASK DEAD SPACE

The leak from the non-vented mask, excluding leak between the face and the mask, is less than 6.0 ml/min at 20 cmH₂O.

VENTED MASK - EXHAUST FLOW

The exhaust vented mask, utilised with systems of delivery of oxygen to the lungs, has an exhaust flow hole to expel the exhaled air from the mask.

It is important that these vents are not blocked by any object. This controlled leak ensures all exhaled

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