

# FLEXIFIT™ 431 FULL FACE MASK INSTRUCTIONS

THE FLEXIFIT™ 431 FULL FACE MASK IS INTENDED FOR MULTIPLE PATIENT OR SINGLE PATIENT ADULT USE BY INDIVIDUALS WHO HAVE BEEN DIAGNOSED BY A PHYSICIAN AS REQUIRING CPAP OR BI-LEVEL VENTILATOR TREATMENT IN THE HOME, HOSPITAL OR OTHER CLINICAL SETTING.

## FITTING YOUR MASK

Refer to the mask assembly diagram.

1. Remove plastic cover from Silicone Seal (C).
2. Unclip the Headgear (K) from the Glider™ Strap (E) by pulling the Release Cord (I) down. Holding your Mask Base (A) in one hand, spread the Headgear with your free hand, just enough to fit comfortably over your head.
3. Lightly hold the mask against your face, with the bottom of the Silicone Seal under your chin, and spread the Headgear over your head with your free hand.
4. Reattach the Headgear Clip (H) to the Glider™ Strap.
5. Gently adjust the top horizontal straps, then the lower horizontal straps, then the top crown straps. Ensure the top of the Silicone Seal remains stable on the bridge of the nose, and the bottom remains fixed under the chin. Ensure that the Glider™ Strap is centered.
6. Connect the CPAP/Bi-Level machine hose running at the prescribed pressure to the mask.

## FITTING TIPS

- If necessary, pull the mask slightly away from your face while the straps are still attached. This allows the Silicone Seal to inflate. Put the mask back on your face.
- 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 if it does not.
- If leaks occur around the lower half of the mask, gently tighten the lower horizontal straps. (Avoid over tightening the straps.)
- If leaks persist, change to the alternate size Silicone Seal, which is found in your FlexiFit™ 431 Mask box.
- When you need to remove your mask, unclip the Headgear from the Glider™ Strap by pulling the Release Cord forward or down.

## CLEANING YOUR MASK AT HOME

To ensure continuing safety and comfort for your FlexiFit™ 431 Mask:

### BEFORE FIRST USE:

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 allow to dry out of direct sunlight. It is not necessary to remove the Clip (H) from the Headgear when washing.

### BEFORE EACH USE:

1. Inspect the mask for deterioration. Do not use if damaged.
2. Inspect the Non-Rebreathing Valve (J). Ensure the silicone flaps are down when the CPAP/Bi-Level machine is turned off.

### AFTER EACH USE:

1. Disassemble the Silicone Seal (C), Elbow (B), Non-Rebreathing Valve (J), and the Headgear (K) from the Mask Base (A).
2. Wash the Silicone Seal, Elbow, Valve 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 all parts to dry, away from direct sunlight before reassembling.

### 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 allow to 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, 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 FlexiFit™ 431 Full Face Mask weakens or cracks, discontinue use and seek replacement immediately.

## ASSEMBLING YOUR MASK

Your FlexiFit™ 431 Full Face Mask is fully assembled and ready to use. However, when you need to clean your mask follow these instructions for reassembly:

1. Place Silicone Seal (C) into Mask Base (A).
2. Push the Non-Rebreathing Valve (J) onto the Elbow (B), and attach to Mask Base.
3. Lay the Headgear (K) flat, with the label side down. Position the assembled mask over 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 Velcro® Tabs by sliding the Headgear into the slots.

## OXYGEN/PRESSURE PORT CONNECTOR

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available (Code 900HC452).

1. Connect the large end of the Connector (T) to the Non-Rebreathing Valve (J) on the mask and the small end of the Connector to the Breathing Tube (R).
2. 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 measurement. Only remove the Port Cap from ports that are being used.)

- **Note:** At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient's breathing pattern, mask selection, and the leak rate.

- **Warning:** If oxygen is used with this 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 device 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.

## WARNINGS

- This CPAP mask should be used only with CPAP/Bi-Level systems recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP/Bi-Level machine is turned on and operating properly. The exhaust flow holes associated with the mask should never be blocked.

**Explanation of Warning:** CPAP/Bi-Level machines are intended to be used with special masks which have exhaust flow holes 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 attached mask exhaust flow holes. 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 rebreathed. Rebreathing 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 exhaust flow holes may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Do not use the mask without the Non-Rebreathing Valve in place. This valve ensures CO<sub>2</sub> re-breathing is kept to a minimum in the event of power failure.
- Do not use the mask if vomiting or feeling nauseous.
- 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 FlexiFit™ 431 Mask between different patients, refer to the Multi-Patient Cleaning Instructions for the FlexiFit™ 431 Full Face Mask.
- Replace the Non-Rebreathing Valve every 12 months.
- Do not use the FlexiFit™ 431 Elbow on other Fisher & Paykel Healthcare masks.
- Use the FlexiFit™ 431 Full Face Mask only with the Headgear provided.

### CAUTIONS

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

### CONTRAINDICATIONS

- This mask should also not be used by anyone incapable of removing the mask unaided, in the case of vomiting and aspiration, without continuous supervision.

The FlexiFit™ 431 Full Face 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.

Contact your supplier and ask about ThermoSmart™ Technology.

US Patent Number 6 615 834

Other Patents Pending

## TECHNICAL SPECIFICATIONS

### EXHAUST FLOW INFORMATION

The FlexiFit™ 431 Full Face Mask has exhaust flow holes to expel the air that you exhale from the mask.

It is important that these vents are not blocked by any object. This controlled leak ensures all exhaled CO<sub>2</sub> is expelled from the mask.

PRESSURE (cmH <sub>2</sub> O)	3	5	7	9	11	13	15	17	19	21	23	25
EXHAUST FLOW (L/MIN)	24	28	32	35	37	40	43	44	46	48	50	51

### RESISTANCE TO FLOW

Pressure drop through mask @ 60 l/min 0.25 cm H<sub>2</sub>O

Pressure drop through mask @ 100 l/min 0.48 cm H<sub>2</sub>O

### MASK DEAD SPACE

192cc

### OPERATING CONDITIONS

- Operating pressure range is 3-25 cm H<sub>2</sub>O
- Operating temperature range is 40-120°F (5-50°C)

## FLEXIFIT™ 431 FULL FACE MASK MULTI-PATIENT CLEANING INSTRUCTIONS

Your FlexiFit™ 431 Full Face Mask is provided patient-ready. To reuse between patients please follow the guidelines below.

## CLEANING / DESOILING

- Before disinfecting, disassemble all components from the Mask Base (the Glider™ Strap and Glider Cover do not detach from the Mask Base). Clean all surfaces of mask and components thoroughly with a mild detergent solution and a soft-bristled brush. Ensure all visible soil is removed. Rinse thoroughly under running potable water to remove detergent solution.

FAILURE TO PROPERLY CLEAN THIS DEVICE MAY RESULT IN INADEQUATE DISINFECTION.

## HIGH-LEVEL DISINFECTION PARAMETERS

### MASK BASE



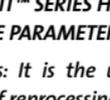
### SILICONE SEAL



### ELBOW



### NON-REBREATHING VALVE



### THERMAL DISINFECTION

Soak parts in hot-water bath for:  
30 minutes at 70°C (158°F)  
or  
30 minutes at 75°C (167°F)

### OR

### CIDEX® OPA

Follow manufacturer's instructions for high-level disinfection. Immerse for 3 HOURS at 20°C (68°F). Rinse thoroughly in potable water.

### OR

### AUTOCLAVING

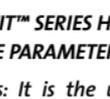
Gravity displacement-type autoclave. Components should be enclosed in a sterilization peel pouch for 30 minutes exposure at 121°C (250°F).

### OR

### STERRAD® 100S

Follow manufacturer's instructions for STERRAD® 100S sterilization system.

### HEADGEAR WITH CLIP



Wash in warm soapy water and leave to dry.

THE FLEXIFIT™ SERIES HC431 FULL FACE MASK HAS BEEN VALIDATED TO WITHSTAND 20 CYCLES OF THE ABOVE PARAMETERS. DO NOT USE IF BADLY DAMAGED.

Disclaimers: It is the user's responsibility to qualify any deviations from the recommended methods of reprocessing. Some discoloration may occur after re-processing.

CONTACT YOUR LOCAL HOMECARE PROVIDER FOR ADDITIONAL INFORMATION.