



COMFORTFIT DELUXE FULL FACE MASK

100FDS - SMALL

100FDM - MEDIUM

100FDL - LARGE



LOT



Date of Manufacture:
2010-MM



Use by:
YYYY-MM

Intended Use

The CPAP/Bi-Level Mask is intended to be used for patients who have been prescribed CPAP or Bi-Level therapy and are under the specific direction of a physician. It is used in conjunction with continuous positive airway pressure (CPAP/Bi-Level) devices in home, hospital and Institutional environments.

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

Features

- *One piece molded silicone rubber; small, light and comfortable.
- *Clear mask allows a good view of nasal area.
- *Low dead space results in low CO₂ build up.
- *Dual 360 degree swivels at the mask attachment and at the standard 22mm tubing attachment point.
- *Headgear with Velcro fasteners provide maximum versatility and movement.

Cleaning instructions

- *Detach headgear from mask.
- *Handwash gently with mild soap and warm water, rinse the mask and components thoroughly.
- *Let mask and components air dry before reusing.
- *Replace mask if there are cracks, tears or excessive discoloration.

Caution

The use of bleach, chlorine, alcohol or aromatic-based solutions may cause hardening of the materials of construction and reduce the life of the product.

Contraindications

This mask may not be suitable for patients 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 unresponsive, obtunded, unable to remove the mask, or uncooperative.

Warnings

- *This mask should only be used with CPAP systems recommended by your physician or respiratory therapist.
- *Do not use this mask unless the CPAP or Bi-Level system is turned on and operating properly.
- *Never block the mask's vent holes or exhalation port.

Note: CPAP systems are intended to be used with special masks with vent holes in either the connectors or the mask that allows continuous flow out of the mask. When the CPAP machine is turned on and functions properly, new air from the CPAP machine flushes the exhaled air out through the mask's exhalation port. However, when the CPAP 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.

*If oxygen is used with the CPAP system, the oxygen flow must be turned off when the CPAP machine is not in operation.

Note: When the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP machines enclosure and create a risk of fire.

Note: At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration will vary depending on the pressure setting, patient pattern and leak rate.

*Do not smoke if oxygen is in use.

*Contact a health care professional if chest discomfort, shortness of breath, stomach distention, belching, or severe headache are experienced.

*Avoid eating or drinking three hours before using this mask to minimize the risk of vomiting during sleep.

*Do not use this mask if you are taking drugs that may cause vomiting.

Caution: At low CPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing and some rebreathing may occur.

*Must only be used by persons who have received adequate training and instruction from qualified medical personnel

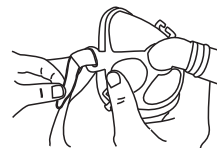
If headgear is included, follow assembling instruction below:

Figure 1



Place headgear with Velcro side down on a flat surface, detach 2 Velcro tapes on A1 & A2.

Figure 4



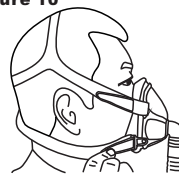
Fasten the Velcro tape.

Figure 7



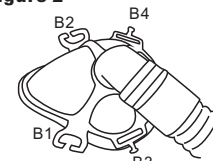
Place the headgear over your head and adjust both upper headgear straps to a comfortable tension.

Figure 10



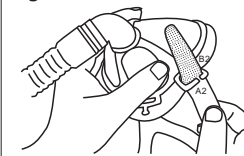
Adjust both lower headgear straps A3 & A4 to a comfortable tension.

Figure 2



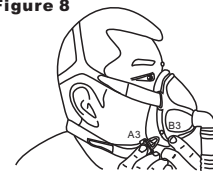
Identify headgear fastening positions on the mask.

Figure 5



Pull the upper headgear strap A2 through the slot B2 on the mask, making sure the Velcro faces outward.

Figure 8



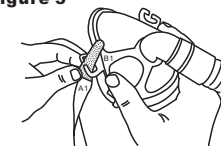
Hook the plastic buckle A3 onto B3 and A4 onto B4 on mask frame.

Figure 11



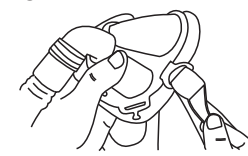
Making sure the overhead strap is in proper position to avoid slipping down.

Figure 3



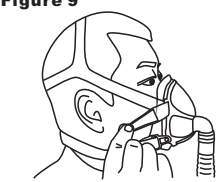
Pull the upper headgear strap A1 through the slot B1 on the mask, making sure the Velcro faces outward.

Figure 6



Fasten the Velcro tape.

Figure 9



Adjust again both upper headgear straps A1 & A2 to a comfortable tension.

*It doesn't need to readjust the length of headgear or unfasten the Velcro tape when cleaning headgear, just simply pull 2 upper head straps away from the slot gaps on mask frame and replace after cleaning.

*To remove the mask and headgear, simply unbuckle both buckles from the mask frame and pull the upper head strap away from the head.

*To reuse the mask and headgear, simply place upper head strap over head and hook up to both buckles.

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