

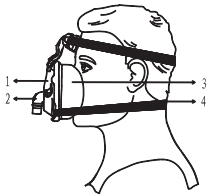
# Instruction For Use

## FM-01 Series Full-Face Masks

IFU VERSION: A0

**Structure Description:** This product is composed of Faceplate, Connector, Cushion, and Headgear.

- 1. Faceplate
- 2. Connector
- 3. Cushion
- 4. Headgear



**Intended Use:** The Full Face mask is a ventilation device of CPAP or Bi-level therapy. It is used by medical care professional for oxygen transmission to patients.

**Warnings:**

- 1. This mask is not suitable for providing life support ventilation.
- 2. This mask is designed for use with CPAP or Bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or Bi-level system is turned on and operating properly. Do not block or try to seal the exhalation port.
- 3. If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- 4. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and Bi-Level machines.
- 5. This product may contain chemicals(phthalates)which may cause adverse reactions for the patients who are pregnant or lactational. Consult the health care professional before use.
- 6. Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your health care professional.
- 7. The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.(Consult an ophthalmologist if symptoms persist).
- 8. A minimum of 3cm H<sub>2</sub>O (hPa) must be maintained when using this mask.
- 9. This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.
- 10. Hand wash mask prior to first use and daily.
- 11. Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition, Consult your physician or dentist if symptoms occur.

**Caution:**

- 1. Do not use if the package is damaged.
- 2. Read and understand the instructions completely.

- 3. Hand wash the mask before first use and daily.
- 4. Wash patient's face before use.
- 5. Check the size of the mask and the headgear.
- 6. The connector of this mask is conical 22mm complied with the ISO 5356 standard. Check whether the outlet of the oxygen machine is matched the mask before use.
- 7. Dispose of in accordance with local regulations.

**Cleaning Instructions:** This product can be repeatedly used after hand wash. The headgear should be cleaned weekly or when needed by hand.

- 1. Hand wash mask in warm water with a mild liquid dish washing detergent.
- Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
- 2. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
- 3. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

**Direction for Use:**

- 1. Make sure the mask is within the validity. Tear the package and take out the mask.
- 2. Cover the mask on the patient's face and fasten with the headgear.
- 3. Connect the oxygen hose to the oxygen supply.

**Wearing Methods:**

- 1. Connect the headgear to the mask. Position the mask over your face, and press the mask cushion gently against your face, pull the headgear over your head.
- 2. Adjust the top and the bottom straps so that the mask is sitting gently on your face.
- 3. Fasten the mask.



**Storage Conditions:**

Temperature : -5 °C----+50 °C.  
Relative humidity ≤85%, corrosive gas free, well-ventilated.

