



Skynector

Sky Wise Medical Instrument (ShenZhen) Co.,Ltd

Instruction For Use

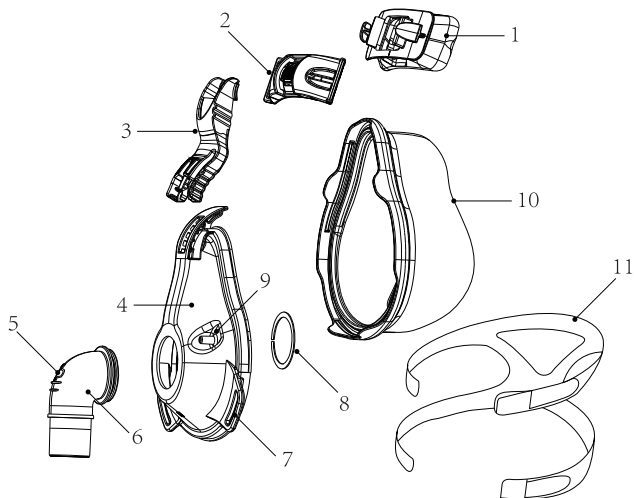
FM-01 Series Full-Face Masks

IFU VERSION:A1

User Guide:

English

Structure Description



Item	Description
1	Forehead Pad
2	Bracket
3	StabilitySelector
4	Faceplate
5	Exhalation Port(Do not block)
6	Elbow
7	Quick Clip
8	Gasket
9	Pick off Port
10	Cushion
11	Headgear

Intended Use:

The reusable Apnea masks with headgear are intended for use as airflow devices for a CPAP or Bi-level system by patients for whom CPAP or Bi-level therapy has been prescribed. The mask covers the nose and mouth, and it is to be for single-patient re-use in the home and multi-patient re-use in the hospital/institutional environment.

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 H₂O (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. 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. The mask is classified as a non-sterile or sterile mask. For the sterile mask, tear the package open and use the mask directly. The mask does not need to be rinsed. The non-sterile mask needs to be washed with drinking quality water before first use.
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 and complies with the ISO 5356 standard. Check whether the outlet of the oxygen machine matches the mask before use.
7. Dispose of mask in accordance with local regulations.

Contraindications:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

Side effects:

Some users may experience skin redness, irritation, or discomfort. Some users may experience unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.

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.

Directions for Use:

1. Make sure the mask is within the expiration date. 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.



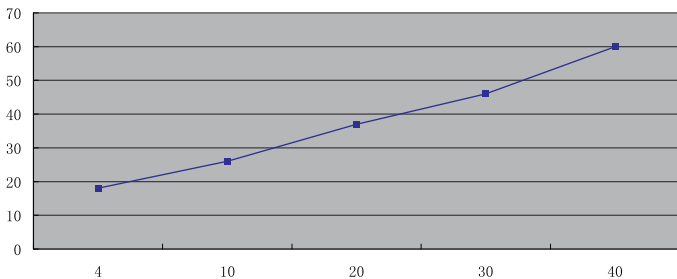
3. Fasten the mask.



Technical parameters:

Pressure vs. Leak rate for apnea mask FM-01

Pressure cm H ₂ O (hPa)	4	10	20	30	40
Exhaust leak rate (SLPM)	18	26	37	46	60



Deadspace Volume

FM-01L < 550ml

FM-01M < 500ml

FM-01S < 400ml

Storage Conditions:

Temperature: $-5^{\circ}\text{C} \sim +50^{\circ}\text{C}$

Relative humidity $\leq 85\%$, corrosive gas free,
well-ventilated.

Rx Only



This product may contain phthalates



Sky Wise Medical Instrument (ShenZhen) Co.,Ltd



Manufactured by:

Sky Wise Medical Instrument (ShenZhen) Co.,Ltd
Address:No. 12 South Ping Xi Road Xinsheng
Community Longgang Street, Longgang District
Shenzhen, Guangdong 518110, China

Made in China

Tel: +86-755-28494330/28491103

Tel: ?Domestic phone number?

Website: <http://www.skynector.com>

Fax: +86-755-28494339

E-mail: sales@skynector.com