

CPAP/BIPAP Masks EaseFit FMI-NV User Manual

Please read it carefully before using this product



Intended Use

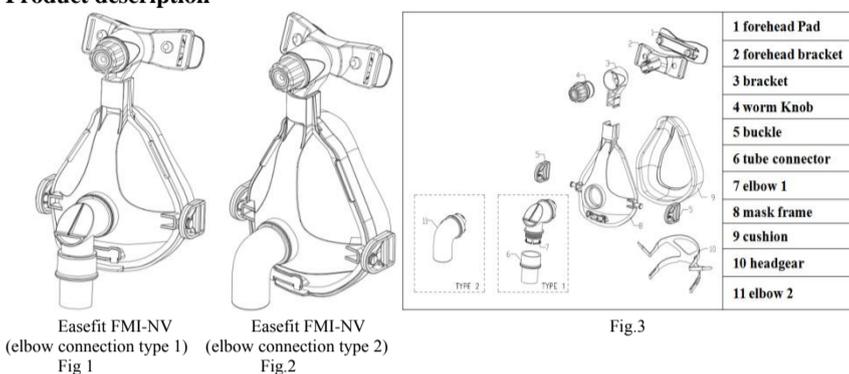
The Easefit FMI-NV (Full Face Mask I Non-Vented) is intended to provide an interface to patients, which is applied to the CPAP or bi-level systems with active-exhaust-valve. The mask is for single patient use in the home/hospital/institutional environment. The mask is to be used on patient (>30kg) for whom CPAP or bi-level therapy has been prescribed.

Contraindications

The mask may not be suitable for use on patients with the following conditions:

- Unconsciousness.
- Patient unable to remove mask.
- Open wounds that are prone to infection.
- Hemodynamic or cardiorespiratory instability.
- Facial or nasopharyngeal deformity, beard, or other inability to fit mask and seal properly.
- Excessive reflux, Gastrointestinal bleeding or other secretions
- Impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions.
- Upper airway obstruction or facial trauma.
- Barotrauma.
- Recent facial, esophageal or gastric surgery.
- Patients under medication with a drug that may cause vomiting.
- Patients requiring immediate intubation.

Product description



Elbow connection type:

- elbow connection type 1(male connector): the components 6&7 are intended to be used together, the component 6 is of 22mm outer diameter (tube connector).
- elbow connection type 2(female connector): the component 11 is intended to be used independently, the component 11 is of 22mm inner diameter.

Warnings

- The mask is not suitable for providing life support ventilation.
- The mask is designed for use with CPAP or bi-level systems with active-exhaust-valve 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 active-exhaust-valve. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have active-exhaust-valve to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached active-exhaust-valve. However, when the CPAP machine is not operation, enough fresh air will not be provided through the mask ,and exhaled air may be rebreathed .This warning applies to most models of CPAP system .
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Explanation of the warning: when the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosed. Oxygen accumulated in the device enclosure will create a risk of fire.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- At a fixed flow rated of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure setting, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types CPAP and bi-level machines.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- The patient's physician should be contacted if the patient experience the flowing 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.)
- At low CPAP or EPAP pressure, the flow through the active-exhaust-valve may be inadequate to clear all exhaled gas from the tubing .some rebreathing may occur.
- This mask should not be used for patients who are uncooperative, obtunded, unresponsive, or unable to remove the mask.
- This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.
- If an additional exhalation device is added to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.
- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tear, etc).Discard and replace any components as necessary.
- Use of a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.
- The Mask does not contain natural rubber latex or DEHP.

List of Symbols

The symbols on the device as follows:

Symbol	Definition	Symbol	Definition
	Serial number of the product		Information of manufacture
	Date of the product		CE Mark
	Follow instructions for use		Caution or Warning
	The authorized EU-representative		

Wearing the mask

- ① Remove packaging.
- ② Check if there any damage or abrasion.
- ③ Fasten the part of broader headgear with the forehead bracket, Narrow fasten the buckle.
- ④ Put the mask on the face in good position.
- ⑤ Trap the headgear on head. Make the headgear upper and under the ear, Trap the headgear buckle into the rod of mask frame.
- ⑥ Adjust the headgear by elastic, make sure comfortable.
- ⑦ Rotate Worm knob to adjust the bracket of the mask, make comfortable enough.

Remove the mask

Push the buckle in the direction far away from face until to hear " Pop" sound, The mask can be removed from the frame.

Note:

- ① If the height of the mask does not fit your face, bracket can be removed from the mask frame after reassembly it into another position, the mask will change the height.,(see Fig.4& Fig.5)
- ② If the leakage situation can't be solved, other size cushion of mask is required.
- ③ Do not remove the headgear directly not by removing the buckle.



Fig.4

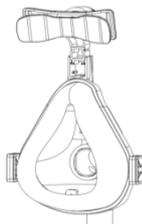
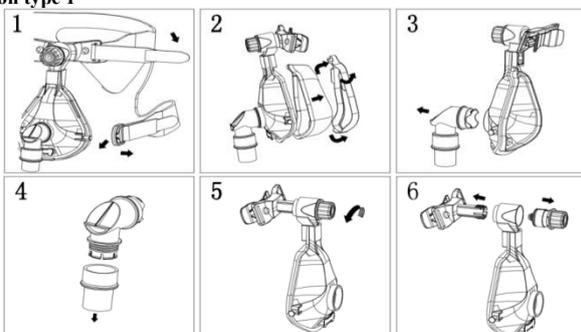


Fig.5

Disassemble the mask

elbow connection type 1



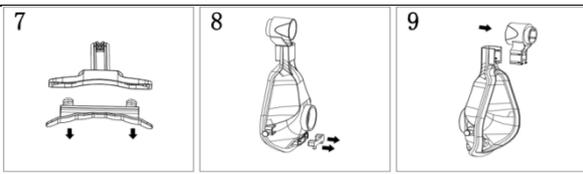


Fig.6

elbow connection type 2

Reference to the above Fig 6 to disassemble the mask (elbow connection type 2), but only to skip the step 4.

Assemble the mask

elbow connection type 1

Note:

When the worm knob assembly, the first forehead bracket snaps into the bracket, while forehead bracket slipped away bracket position, then the worm knob insert bracket, make ensure that the worm knob and bracket substantially flat state under the control clockwise rotation of the worm knob until the worm knob snaps into the bracket. (See Fig. 8)

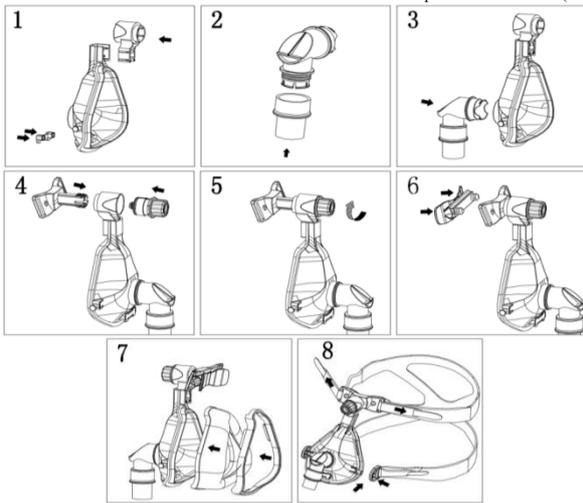


Fig.7

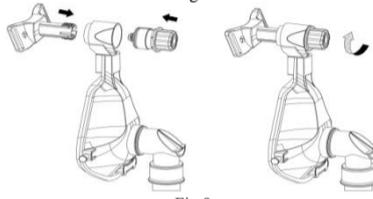


Fig.8

elbow connection type 2

Reference to the above Fig 7 to assemble the mask (elbow connection type 2), but only to skip the step 2.

Technical specifications

Tube connector

Both 22mm conical male (elbow connection type 1) and 22mm conical female (elbow connection type 2) are available (in compliance with ISO 5356-1). It's used to connect an external ventilator tube.

Dead space information

Physical dead space is the empty volume of the mask to the end of the elbow. The dead space of the mask varies according to cushion sizes but is less than 320ml.

Pressure range: 4-30cmH2O

Environmental conditions

Operating temperature: + 5 °C to + 40 °C; Operating humidity, 15-95% relative humidity, non-condensing. Storage and transport temperature: -20 °C to + 60 °C; Storage and transport humidity: not exceeding 95% RH, non-condensing .

External dimensions

S: 175.9mm (height) × 110mm (width) × 112.4mm (thickness)

M: 183.9mm (height) × 118mm (width) × 114.4mm (thickness)

L: 194.9mm (height) × 122mm (width) × 114.4mm (thickness)

The above external dimensions are for reference only. Goods in kind prevail!

Cleaning instructions

Cleaning the mask should be carried out before the first use and should be cleaned daily. Headgear should be cleaned once a week, or if necessary, cleaned.

- with warm soapy water to clean the mask and headgear, and avoid soaking over 10 minutes, To clean up the vent with a soft brush.
- Mask all parts of drinking water in addition to applications outside of the headgear rinse, and dry naturally in a dark place. Before each use, make sure the mask is dry.
- Headgear after cleaning rinses with water and placed in a place, away from direct sunlight to dry naturally.
- Mask and breathing circuit cannot be exposed to direct sunlight place, this will accelerate the aging of the product.
- Mask before use, check for damage or wear (cracking, crazing, tears, etc), when necessary, discard and replace the parts.

Note: Mask need to be asked for a daily cleaning when used.

Expired products

In consideration of the time limit for the component and medical equipment safety, the service life for the mask shall not exceed 2 years after the production date. The expired products should be handled following local laws. It is dangerous to use these expired products.

Trouble shooting

problem	possible cause	solution
Mask wearer uncomfortable	headband strap is too tight	even adjust the headgear, that forehead bracket "fixed" mask, should be secured at the forehead
	wearing tight	Loosen knob worm
mask too noisy	cushion buckle is not inserted correctly	Remove cushion from frame and then re-upholstered trap snaps on the frame.
		If the buckle is fixed properly installed, the problem still exists, please consult your doctor.
Mask leaks around the face	mask not positioned correctly will cushion	gently pulled away from the face, making it swell again, follow the instructions to put the mask back in place.
	air leakage around the nose	tighten the worm knob
	air leakage around the top of the lip	loosen worm knob and / or tightening headgear
worm knob is not smooth	forehead bracket slide to the stroke limit position	in the opposite direction of rotation of the worm knob
	worm knobs and forehead bracket is installed incorrectly	direction toward the worm knob push forehead bracket, the worm support bracket and rotate the knob from the forehead from the forehead bracket, follow the instructions to reassemble

Storage

Ensure that the mask is thoroughly clean and dry before storing it for any length time. Store the mask in a dry place out of direct sunlight.

Disposal

This mask does not contain any hazardous substances, according to the general household refuse discarded.

Packing list

mask ×1, headgear ×1, user manual ×1.

Warranty

It is warranty that the mask, including Frame, Cushion, Forehead pad, Headgear shall be free from defects in material and workmanship for a period of ninety (90) days from the date of purchase by the initial consumer.

To exercise the rights under this warranty, contact the local authorized dealers.

Manufacturer

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 www.csbeyond.com

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