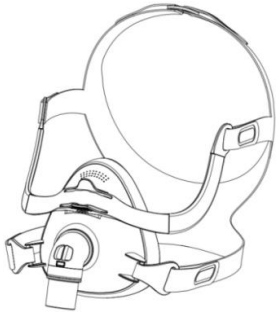


Breathing Mask (Model: AF-02)

LuvOn F2 Full Face Mask User manual



Thank you for choosing LuvOn F2 full face mask, please read this manual before use.

Intended use

The breathing mask is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a continuous positive airway pressure (CPAP) or bilevel system. The breathing mask is to be used by adult patients (weighing >30 kg) for single-patient reuse in the home environment or single-use in the hospital/institutional environment.

Contraindications

Do not use the mask for those with facial trauma, facial deformity or allergy to the mask material.

Clinical benefits

The clinical benefit of breathing mask is the provision of effective therapy delivery from a therapy device to the patient.

⚠ CAUTION:

- In the US, Federal law restricts the sale of this device to sale by or on the order of a physician.
- For any serious incidents that occur in relation to this device, these should be reported to our company and the competent authority in your country.

⚠ WARNINGS:

- The mask should only be used with CPAP or bilevel devices that are already on the market and meet ISO 80601-2-70 standard. The technical specifications of the mask are provided for your healthcare professional to determine if it is compatible with your therapy device. If the mask is used in combination with other medical devices not intended to be combined with the mask, this can decrease the safety or alter the performance of the mask.
- The mask must be used under qualified supervision for users who are unable to remove the mask by themselves.
- The vent holes should be kept clear.
- The mask should not be used unless the device is turned on and blowing air. Explanation: When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. However, when the device is not operating, insufficient fresh air will be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP or bilevel devices.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the CPAP or bilevel device is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well ventilated rooms.
- Discontinue using this mask if you have any adverse reaction to the use of the mask, and consult your physician or sleep therapist.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.
- As with all masks, some rebreathing may occur at low CPAP pressures.
- Refer to your CPAP or bilevel device manual for details on settings and operational information.
- Remove all packaging before using the mask. Please store the mask away from light after use.
- The mask cannot be used for life support.

Mask components

The mask consists of parts such as cushion, bracket arm assembly, elbow assembly, swivel, headgear assembly and standard conical connector. The product includes large, medium and small three sizes.

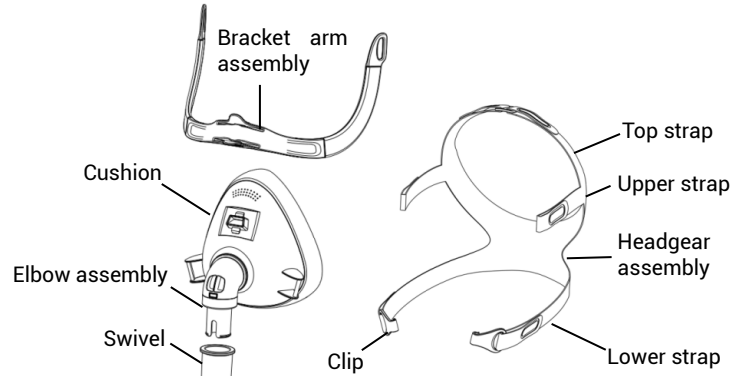


Figure of AF-02 mask components

Before using your mask

- Use the fitting template to assist in selecting the right size mask.
- Inspect the mask for damage (cracking, crazing, tears, etc) that may affect the performance of the mask, please replace the mask.
- If the mask has stubborn stains or becomes severely yellowed that may affect the performance of the mask, please replace the mask.

Fitting the mask

- Use a standard conical connector if pressure readings and / or supplemental oxygen are required.



1. Remove the clips of lower straps on either side of the mask, hold the mask against your face and pull the headgear over your head.



2. Attach the clips of lower straps to the lower shafts of the mask frame.



3. According to the degree of tightness, adjust the positions of the magic hooks of top straps.



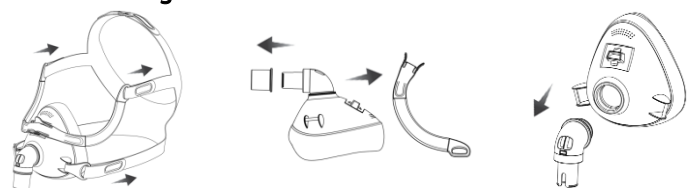
4. According to the degree of tightness, adjust the positions of the magic hooks of the upper and lower straps and connect the tube to the swivel of the mask.

- Turn on your device so that it is blowing air, adjust the mask only enough for a comfortable seal.

Removing the Mask

Release one of the lower headgear clips away from the mask frame and pull the mask away from your face and back over your head.

Disassembling the Mask



1. Unclip the clips of the lower straps and unhook the upper straps.

2. Disassemble the bracket arm assembly from the cushion and disassemble the swivel from the elbow assembly.

3. Disassemble the elbow assembly from the cushion.

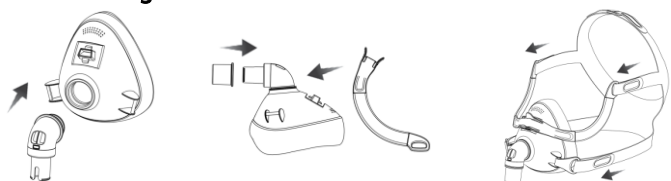
Cleaning the Mask (Manual in your home)

- Soaking the components in a solution of Alconox (or other mild liquid detergent) by diluting with drinking quality water at 1% at 30±5°C for 10 minutes. Whilst immersed in the solution, clean each component of the mask with a soft bristle brush for one minute. Pay particular attention to all crevices and cavities.
- Soaking the components of mask in clean water (drinking quality water) twice, rinse the components twice (five litres per mask each time).
- Allow the mask components to air dry, out of direct sunlight.
- Handwash the mask components (except for the headgear) daily/after each use, and handwash the headgear weekly.

CAUTION:

- The mask is designed to be used repeatedly by a single patient, eliminating the need for disinfection and sterilization.
- Do not use solutions containing bleach, chlorine, alcohol, aromatics, moisturizers, antibacterial agents, or scented oils to clean any part of the system or air tubing. These solutions may cause damage and reduce the life of the product. Please clean the mask with clean water (drinking quality water).
- If cleaning is not done in accordance with the instructions (or increase the frequency of cleaning). May result in poor product performance or reduced product life. If any components of the mask are damaged, please replace it in time.
- Air dry, avoid direct sunlight which ages the products. After cleaning the mask, place the mask into its original packaging.

Reassembling the Mask



1. Reassemble the swivel to the elbow assembly to the cushion.

2. Reassemble the bracket arm assembly to the cushion and reassemble swivel to the elbow assembly.

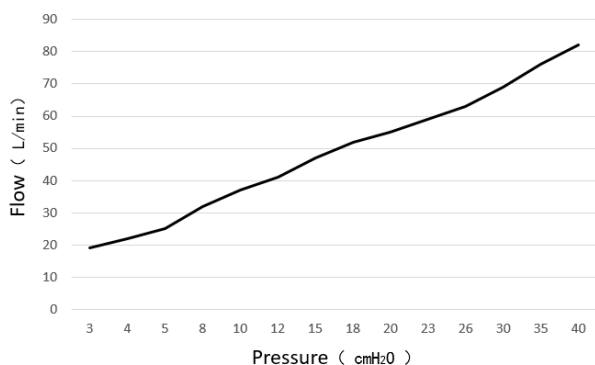
3. Reattach the upper straps and the clips of the lower straps to the mask.

Use in the hospital/institutional environment

- This mask is for single-use by patient in the hospital/institutional environment. The general use cycle is 14 days. Cleaning, disinfection and sterilization are not required. Please do not disassemble the mask.
- If it is seriously polluted (e.g. sputum, vomitus) or damaged, please replace the mask with a new one.

Technical specifications

Pressure-flow curve



Pressure (cmH ₂ O)	3	4	5	8	10	12	15	18	20	23	26	30	35	40
Flow (L/min)	19	22	25	32	37	41	47	52	55	59	63	69	76	82

Therapy pressure	3 to 40 cmH ₂ O
Dead space	L=275ml, M=240ml, S=202ml
Resistance (Anti Asphyxia Valve closed to atmosphere)	at 50 L/min: ≤0.8 cm H ₂ O at 100 L/min: ≤1.5 cm H ₂ O
Anti Asphyxia Valve open to atmosphere pressure	≤2 cmH ₂ O
Anti Asphyxia Valve closed to atmosphere pressure	≤2 cmH ₂ O
Inspiratory and expiratory resistance with Anti Asphyxia Valve open to atmosphere	Inspiration at 50 L/min: ≤2cmH ₂ O Expiration at 50 L/min: ≤2cmH ₂ O

Sound

Declared Dual-Number noise emission values in accordance with ISO 4871. The A-weighted sound power level of the mask is less than 38 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is less than 30 dBA.

Environmental conditions

Operating temperature: 5°C to 40°C (41°F to 104°F)

Operating humidity: 10% to 90% non-condensing

Storage and transport temperature: -20°C to 60°C (-4°F to 140°F)

Storage and transport humidity: 10% to 90% non-condensing

Troubleshooting

Problem/possible cause	Solution
Mask is too noisy. Mask vents are blocked.	Clean vents
Mask leaks around the face. Cushion is torn or distorted. Mask is incorrectly positioned or adjusted.	Replace cushion and refit your mask according to the instructions
Mask leaks around the nose. The tightness of the top and upper straps is inappropriate.	Adjust the tightness of the top and upper straps according to the instruction.
Mask leaks around the lip. The tightness of the lower straps is inappropriate.	Adjust the tightness of the lower straps according to the instruction.

Symbols

	Consult instructions for use		Caution
	Use-by date		Batch code
	Date of manufacture		Single patient multiple use
	Temperature limit		Humidity Limitation
	Do not re-use		Medical device
	Not made with natural rubber Latex		Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician)
	Unique device identifier		Non-sterile

Note: This product is not made with natural rubber latex, PVC or phthalates such as DEHP, DBP.

Storage

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

Replacement cycle (Home environment)

- Cushion assembly: 1 month
- Headgear assembly and soft sleeve: 3 months
- Mask: 6 months

Note: Overuse of the mask will degrade the performance of the mask and affect the therapeutic effect.

Replacement cycle (Hospital/institutional environment)

- Mask: 14 days

Note: Overuse of the mask will degrade the performance of the mask and affect the therapeutic effect.

Disposal

This mask does not contain any hazardous substances and may be disposed of medical waste or in accordance with local environmental regulations.

Limited Warranty

Heyer Care warrants that your mask and components will be free from defects in material and workmanship from the date of purchase for 90 days. If the product fails under conditions of normal use, we will repair or replace the defective product or any of its components.

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