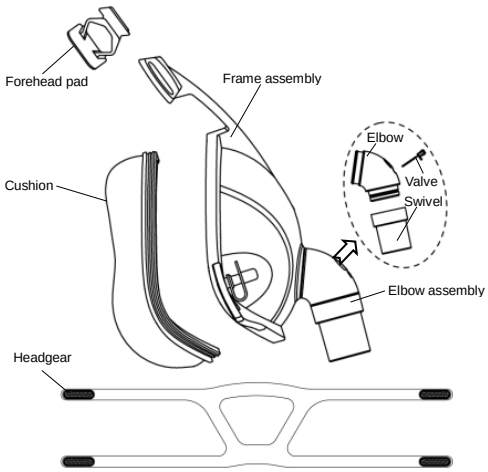
F2 Single-Patient Vented Full Face Mask

User Manual

Components of the Mask



Components of the Mask

F2 Single-Patient Vented Full Face Mask

Thank you for choosing F2 Single-Patient Vented Full Face Mask. The mask is designed to minimize contact with your face, thus ensuring that you feel comfortable during therapy. This user manual provides you with the information you need for the correct use of your mask.
The F2 Single-Patient Vented Full Face Mask is Not made with natural rubber latex.

Intended Use

The F2 Single-Patient Vented Full Face Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The F2 Single-Patient Vented Full Face Mask is:

- To be used by adult patients (> 66 lb / 30 kg) for whom positive airway pressure therapy has been prescribed.
- Intended for single-patient reuse.

CAUTION: In the US, Federal law restricts this device to sale by or on the order of a physician.

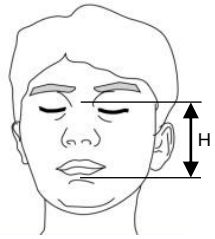
Before Using the Mask

⚠ WARNINGS

- The vent holes must be kept clear.
- Explanation of Warning: CPAP systems are intended for use with special masks with connectors which have vent holes that allow a continuous flow of air out of the mask. When the CPAP machine is on and operating properly, the fresh air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, the fresh air supplied through the mask is insufficient, and exhaled air will be re-inhaled. Rebreathing of exhaled air for more than several minutes may, in some circumstances, lead to suffocation. This warning applies to most models of CPAP systems.
- At low CPAP pressures, the flow through the exhaled port may be inadequate to clear all exhaled gas from the tube. Some rebreathing may occur.
- To minimize the risk of vomiting during sleep, the patient should avoid eating or drinking three hours before using the mask. This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Do not use the mask without the valve in place.
- This mask should not be used on patients who are uncooperative, unresponsive, or unable to remove the mask.
- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the PAP Device is not in operation, so that unused oxygen does not accumulate in the PAP Device enclosure and create a fire hazard.
- At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate.
- The technical specifications of the mask are provided for your clinician to check if it is compatible with the PAP Device. If it is used beyond technical specifications or used with incompatible devices, the seal and comfort of the mask may not be effective, and optimum therapy may not be achieved. Leak or variation in the rate of leak, may affect the function of the PAP device.
- Stop using the Mask and consult your physician or sleep therapist, if you have ANY adverse reaction to the use of the mask.
- Refer to your PAP Device manual for details on settings and operational information.
- Remove all packaging before using the mask.
- Images shown here are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.

Getting the Right Cushion Size

- The following drawing describes the different features of face and the length of the face (H) you need to measure.
- The masks are available in three different sizes.
- Choose the appropriate size according to the table below.



H (inch)	Size
3.15 ≤ H ≤ 3.54	S
3.54 < H ≤ 3.94	M
3.94 < H ≤ 4.53	L

Getting the Right Cushion Size

Fitting the Mask

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

1

Pass the upper straps of the headgear through the installation holes of the mask and secure them. Fold the lower straps to make loops and fasten.

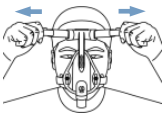
2

Place the mask on the face and extend the upper part of the headgear to the back of the head. Please confirm that the name on the back of the headgear faces outward when the headgear is worn.

3

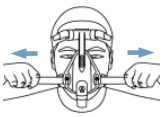
Bring the lower straps forward beneath the ears and insert them into the fixed hooks on the lower part of the mask frame.

4



Stretch the upper straps of the headgear as shown in the figure to secure the mask.

5



Repeat the process for the lower headgear as shown in the figure to secure the mask.

6

Power on the device and start ventilation. Connect the respiratory hose to the swivel of the mask. Adjust the mask to ensure a tight seal.

Disassembling the Mask

Notes:

- *The elbow assembly cannot be disassembled from the frame assembly.*
- *The elbow assembly cannot be disassembled.*
- *The valve cannot be disassembled. Or it may cause damage, and its installation would be difficult.*

1

Remove the upper straps of the headgear out of the holes in the mask frame.

2

Remove the cushion from the installation groove in the mask frame.

3

Remove the forehead pad from the installation groove in the mask frame.

Cleaning the Mask

Notes:

- *The mask and headgear can only be cleaned by washing by hand.*
- *The elbow, the swivel and the valve cannot be disassembled for washing.*

⚠ CAUTIONS

- 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.
- Exposing any part of the system or tubing to direct sunlight or heat may cause deterioration.
- If any visible deterioration of a component is apparent (cracking, crazing, tears, etc.), the component should be discarded and replaced.

Daily / After Each Use

- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear) by gently rubbing in warm water (approx. 86°F / 30°C) using mild, unscented liquid dish detergent for up to 10 minutes.
- Use a soft bristle brush to clean the vent.
- Rinse all components well with drinking quality water and allow them to air dry out of direct sunlight.
- When all components are dry, reassemble the mask according to the reassembly instructions.

Weekly

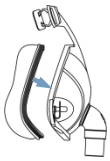
Hand wash the headgear and all components in warm (approx. 86°F / 30°C), mild, unscented liquid dish detergent for up to 10 minutes. Rinse the components well with drinking quality water and allow them to air dry out of direct sunlight before reassembling.

Reassembling the Mask

1

Install the forehead pad into the upper-half installation groove of the mask frame.

2



Install the cushion into the lower-half installation groove of the mask frame and ensure the cushion fits well into the groove.

3

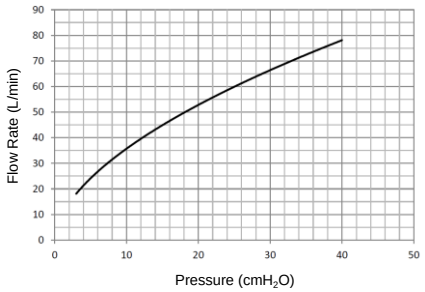
Install the upper-half headgear onto the upper-half installation holes of the mask frame.

Technical Specifications

Problem	Possible Reason	Possible Solution
Mask won't seal properly or is uncomfortable.	Mask may have been fitted incorrectly.	Carefully follow instructions in "Fitting the Mask" section. Make sure the headgear is not over-tightened.
	Mask size is wrong.	Consult your clinician.
Mask leaks around the face.	The cushion is misplaced on the cushion frame.	Check insertion of the cushion and reinsert correctly according to the instructions in "Reassembling the Mask" section.
Mask is too noisy.	Mask size is wrong.	Consult your clinician.
	Vents are blocked or partially blocked.	Clean the vents according to the instructions in "Cleaning the Mask" section.

Technical Specifications

Pressure–Flow Curve



Pressure (cmH_2O)	3	12	22	31	40
Flow Rate (L/min)	18	40	56	67	78

Dead Space Information	Dead space is the empty volume of the mask up to the swivel. The dead space of the mask varies with cushion size but is less than 218 mL.
Therapy Pressure	3 to 40 cmH_2O
Resistance	Drop in Pressure measured (average for 3 sizes) at 50 L/min: 0.15 cmH_2O at 100 L/min: 0.5 cmH_2O
Inspiratory and Expiratory Resistance	The inspiratory resistance of the mask (in combination with the valve) is 1.8 cmH_2O at 50 L/min. The expiratory resistance of the mask (in combination with the valve) is 2.0 cmH_2O at 50 L/min.
The Valve open-to-atmosphere pressure	1.0 cmH_2O
The Valve closed-to-atmosphere pressure	1.2 cmH_2O
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 28 dBA, with an uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 20 dBA, with an uncertainty of 3 dBA.
Environmental Conditions	Operating temperature: +5°C ~ +40°C (41°F ~ 104°F) Operating humidity: 10% ~ 93% relative humidity non-condensing Storage and transport temperature: -20°C ~ +55°C (-4°F ~ 131°F) Storage and transport humidity: 10% ~ 93% relative humidity non-condensing

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.

Disposal

The mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

Symbols

System and Packaging


Caution, consult accompanying documents.
Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device.

Batch code

Temperature limit

Humidity limitation

Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician)


Manufacturer


Date of Manufacture

Made in China


Use-by date

Unique device identifier

Limited Warranty

The expected service life of F2 Single-Patient Vented Full Face Mask is one year.