

Full Face Vented Mask



S4354

Full Face Vented Mask

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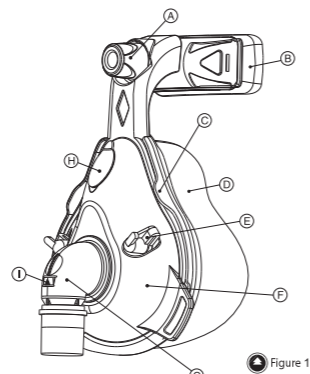


Figure 1

- (A) Forehead Pad Adjustment Nut
- (B) Forehead Pad
- (C) Cushion-To-Faceplate Attachment Tabs X4
- (D) Full Sealing Cushion
- (E) Pick Off Port X2
- (F) Faceplate
- (G) Elbow Swivel
- (H) Exhalation Port
- (I) Valve(Inside Of Clear Elbow)

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INSTRUCTIONS FOR USE

Important safeguards and explanation

Use-by date	Batch code
Non-sterile	Manufacturer
Consult instructions for use	Does not contain natural rubber latex
Does not contain phthalate	Do not use if package is damaged
Warnings	Authorised representative in the European Community

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1. INTENDED USE

The Full Face Mask is an accessory to a non-continuous ventilator (respirator). The mask is for single patient use in the home or in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

2. IMPORTANT NOTE:

An exhalation port is built into the mask so a separate exhalation device is not required.

Warnings:

- This mask is not suitable for providing life support ventilation.
- 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.

Explanation of the Warning:

CPAP systems are intended to be used with special masks with connectors which have vent holes 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 mask exhalation port.

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Do not place the headgear into a dryer.

- Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

5. ACHIEVING THE RIGHT FIT

1. Open the headgear to a large size setting.
2. Hold the mask and place the cushion against the face by first setting the base of the cushion under the lower lip then roll the cushion up the nose, and the Forehead Pad lightly resting on your forehead.

3. Pull the headgear on over your head.

NOTE: Undo one of the lower headgear tabs if necessary.

4. Evenly adjust the upper straps (Figure 3) to a comfortable position by using the tabs on both sides of the headgear. Do not pull the straps tight. The cushion should lightly touch your face and the upper straps



Figure 3

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will rest above your ears.

5. Evenly adjust the lower straps (Figure 4) to a comfortable position by using the tabs on both sides of the headgear. Do not pull the straps tight. The lower straps will rest below your ears, and the headgear will cross at the base of your head (Figure 5).

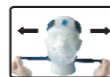


Figure 4

6. Connect the tubing (included with the CPAP or bi-level device) to the tubing swivel.



Figure 5

7. Turn on the airflow.

8. Lie down and breathe normally.

9. Adjust the headgear evenly to reduce leaks or pressure points at the bridge of the nose.

COMFORT TIPS

- The headgear should fit loose and comfortable. If your skin bulges around the mask, loosen the headgear. Over tightening the headgear can hinder the mask's

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However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. This warning applies to most models of CPAP systems.

- 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 enclosure. 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 rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the

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performance and seal.

- Re-seat the mask by pulling the sides of the faceplate directly away from the face then gently set it back into place. This allows the cushion to create a new seal on the face. DO NOT pull the mask by the elbow.

- The height of the forehead pad can be adjusted by turning the forehead pad adjustment nut (component A) to achieve the best comfort and reduce leaks.

6. REMOVING THE MASK

Remove the mask by grabbing the back headgear strap and sliding the entire assembly forward over your head(see Figure 6). If needed, undo the lower headgear straps.



Figure 6

REMOVING THE CUSHION FROM FACEPLATE

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pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of 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 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 a doctor if symptoms persist.)

- At low CPAP or EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.

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NOTE: The mask does not contain natural rubber latex.



3. BEFORE USING THE MASK

- Hand wash the mask.
- Inspect the mask components for any damage or wear, replace if necessary.
- Verify that the air entrainment valve functions correctly.

Valve (attached to the clear Elbow)

The valve consists of an air inlet and a flapper. With the airflow turned off, verify that the elbow with the flapper is lying flat (Figure 2) so that room air can flow in and out through the air inlet.

Next, with the airflow on, the flapper should now cover the air inlet and air from the CPAP or

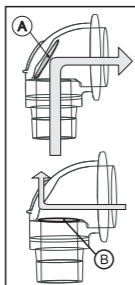


Figure 2
A=Flapper is covering the air inlet
B=Flapper is lying flat

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bi-level device should flow into the mask. If the flapper does not close or does not function properly, replace the mask. Warning: Do not block or try to seal the valve or the exhalation vents.

CARE AND CLEANING INSTRUCTIONS

Hand wash the mask daily or as needed. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

4. CLEANING OF THE MASK

- Hand wash the mask and headgear 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.
- Rinse thoroughly with drinking quality water and air dry. Make sure the mask is dry before use. Lay the headgear flat or line dry.

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- Push the three attachment tabs on each side of the cushion (component C) sideways to disengage it, remove cushion from the faceplate.

7. RE-ATTACH THE HEADGEAR TO THE MASK

- To re-attach the headgear, thread the upper headgear straps into the slots at the top of the mask faceplate. Fold the tabs back to catch the headgear straps.
- Thread the lower headgear straps into the slots at the bottom of the faceplate. Fold the tabs back to catch the headgear straps (Figure 7).



Figure 7

MASK DISPOSAL

Disposes the mask in accordance with local regulations.

NOTE

For optimum mask performance, it is recommended that you replace your mask once every 6 months.

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- 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 any prescription of drug that may cause vomiting.

- When including an additional exhalation device 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 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 a doctor if symptoms persist.)

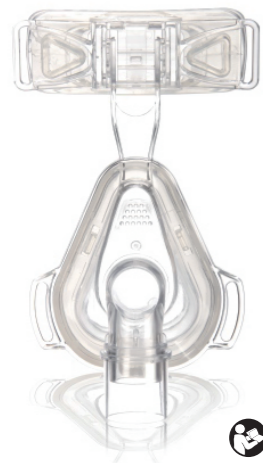
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.

CHOKING HAZARD. The mask contains small parts. Keep out of reach of children.

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Nasal Mask



Nasal Mask

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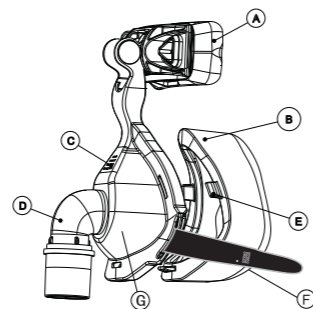


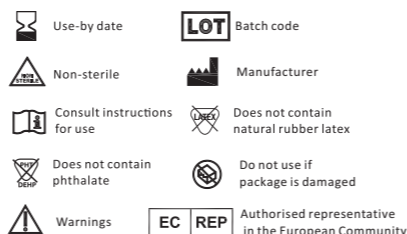
Figure 1

- (A) Forehead Pad
- (B) Sealing Cushion
- (C) Exhalation Port(Do Not Block)
- (D) Elbow Swivel
- (E) Cushion Attachment Tabs
- (F) Headgear Tabs
- (G) Faceplate

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INSTRUCTIONS FOR USE

Important safeguards and explanation



1. INTENDED USE

The Nasal Mask is an accessory to a non-continuous ventilator (respirator). The mask is for single patient use in the home or in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

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2. IMPORTANT NOTE:

An exhalation port is built into the mask so a separate exhalation device is not required.

⚠ Warnings:

- This mask is not suitable for providing life support ventilation.
- 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.

Explanation of the Warning:

CPAP systems are intended to be used with special masks with connectors which have vent holes 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 mask exhalation port.

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However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. This warning applies to most models of CPAP systems.

- 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 enclosure. 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 rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the

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pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of 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 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 a doctor if symptoms persist.)

- At low CPAP or EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.

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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 any prescription of drug that may cause vomiting.

When including an additional exhalation device 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. If any visible deterioration of a system component is apparent (cracking, crazing, tears or cushion damage etc), the component should be discarded and replaced.

- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.

CHOKING HAZARD. The mask contains small parts. Keep out of reach of children.

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NOTE: The mask does not contain natural rubber latex.



3. BEFORE USING THE MASK

- Hand wash the mask.
- Inspect the mask components for any damage or wear, replace if necessary.
- Verify that the air entrainment valve functions correctly.

CARE AND CLEANING INSTRUCTIONS

Hand wash the mask daily or as needed. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

4. CLEANING OF THE MASK

- Hand wash the mask and headgear in warm water with a mild liquid dish washing detergent.
- Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or

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alcohol, or cleaning solutions containing conditioners or moisturizers.

- Rinse thoroughly with drinking quality water and air dry. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into a dryer.

Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

5. ACHIEVING THE RIGHT FIT

- Hold the mask with the sealing cushion over your nose and pull the headgear on over your head. The headgear is preset to a large setting so it can easily go on right out of the package.

- Evenly adjust the upper straps (Figure 2) to a comfortable position by using the tabs on both sides of the headgear. Do not pull the straps tight. The cushion should lightly touch your



Figure 2

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face and the upper strap will rest above your ears.

- Evenly adjust the lower straps(Figure 3) to a comfortable position by using the tabs on both sides of the headgear. Do not pull the straps tight. The lower strap will sit below your ears and the headgear will cross at the base of your head (Figure 4).



Figure 3



Figure 4

- Connect the tubing (included with the CPAP or bi-level device) to the tubing swivel.
- Turn on the airflow.
- Lie down and breathe normally through your nose, keeping your lips closed.
- Adjust the headgear evenly to reduce leaks or pressure points at the bridge of the nose or above the lip.
- Re-seat the mask, if necessary.

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Comfort Tips

- The headgear should fit loose and comfortable. If your skin bulges around the mask, loosen the headgear. Over tightening the headgear can hinder the mask's performance and seal.
- Re-seat the mask by pulling the sides of the faceplate directly away from the face then gently set it back into place. This allows the cushion to create a new seal on the face. DO NOT pull the mask by the elbow.

6. REMOVING THE MASK

Remove the mask by grabbing the back headgear strap and sliding the entire assembly forward over your head. If needed, undo the lower headgear straps.

Removing and Attaching the Cushions :

To Remove:

- Push inward on the three attachment tabs on each side of the sealing cushion until this cushion separates from the mask frame(Component G).

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- Remove the sealing cushion.

7. TO ATTACH:

- Place the sealing cushion on the mask frame.
- Gently and slowly adjust /align the three attachment tabs to the three slots.
- Push tabs into the slots until all three sides click into mask frame(Figure 5).
- Gently pull the sealing cushion to make sure it securely attached/engaged to the frame.



Figure 5

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Disposal of the mask

Disposes the mask in accordance with local regulations.



Figure 6

⚠ Warning:

This nasal CPAP mask is intended for single patient use only. The mask must not be used on more than one person.

Note:

For optimum mask performance, it is recommended that you replace your mask once every 6 months.

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8. Storage Conditions

-4° to +140° F (-20° to +60° c)
15% to 95% RH, non-condensing

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