

FORMA™ FULL FACE MASK INSTRUCTIONS

THE FORMA™ FULL FACE MASK IS INTENDED FOR SINGLE PATIENT ADULT USE BY INDIVIDUALS WHO HAVE BEEN DIAGNOSED BY A PHYSICIAN AS REQUIRING CPAP OR Bi-LEVEL VENTILATOR TREATMENT IN THE HOME, HOSPITAL OR OTHER CLINICAL SETTING.



FITTING YOUR MASK

Refer to the mask assembly diagram.

1. Remove plastic cover from Silicone Seal.
2. Unclip the Headgear (K) from the Glider™ Strap (E) by pulling the Easy-Release Cord (I) towards your nose. Holding your Mask Base (A) in one hand, spread the Headgear with your free hand, just enough to fit comfortably over your head.
3. Lightly hold the mask against your face, with the bottom of the Silicone Seal under your chin, and spread the Headgear over your head with your free hand.
4. Reattach the Headgear Clip (H) to the Glider™ Strap.
5. Gently adjust the top horizontal straps, then the lower horizontal straps, then the top crown straps. Ensure the top of the Silicone Seal remains stable on the bridge of the nose, and the bottom remains fixed under the chin. Ensure that the Glider™ Strap is centered.
6. Connect the CPAP/Bi-Level machine hose running at the prescribed pressure to the mask.

FITTING TIPS

- If necessary, pull the mask slightly away from your face while the straps are still attached. This allows the Silicone Seal to inflate. Put the mask back on your face.
- If leaks occur around the upper half of the mask, gently tighten the top horizontal straps.
- If leaks occur around the lower half of the mask, gently tighten the lower horizontal straps. (Avoid over-tightening the straps.)
- When you need to remove your mask unclip the Headgear from the Glider™ Strap by pulling the Easy-Release Cord towards your nose.

CLEANING YOUR MASK AT HOME

To ensure continuing safety and comfort for your Forma™ Full Face Mask:

- **BEFORE FIRST USE:**
 1. Hand-wash the Headgear in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight. It is not necessary to remove the Clip (H) from the Headgear when washing.
- **BEFORE EACH USE:**
 1. Inspect the mask for deterioration. Do not use if damaged.
 2. Inspect the Non-Rebreathing Valve (J). Ensure the silicone flaps are down when the CPAP/Bi-Level machine is turned off.
- **AFTER EACH USE:**
 1. Disassemble the Silicone Seal (C), Foam Cushion (D), Elbow (B), Non-Rebreathing Valve (J), and the Headgear (K) from the Mask Base (A).
 2. Wash the Silicone Seal, Elbow, Valve and Mask Base in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water.
 3. Wipe the Foam Cushion (D) with a damp cloth (do not immerse the Foam Cushion in water).
 4. Before reassembling, leave all parts to dry away from direct sunlight.
- **EVERY 7 DAYS:**
 1. Hand-wash the Headgear in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to air dry out of direct sunlight. It is not necessary to remove the Clip (H) from the Headgear when washing.
- **CAUTION:**
 - Do not soak for longer than 10 minutes.
 - Do not wash the mask in the dishwasher.
 - Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.
 - Do not store the mask in direct sunlight.
- **The above actions may deteriorate or damage the mask and shorten its life. If your Forma™ Full Face Mask weakens or cracks, discontinue use and seek replacement immediately.**

ASSEMBLING YOUR MASK

Your Forma™ Full Face Mask is fully assembled and ready to use. However, when you need to clean your mask, follow these instructions for reassembly:

1. Place Silicone Seal (C) face down on a flat surface. With the thick side of the Foam Cushion (D) facing down, place onto Silicone Seal.
2. Place Silicone Seal (C) and Foam Cushion (D) into the Mask Base (A).
3. Push the Non-Rebreathing Valve (J) onto the Elbow (B), and attach to Mask Base.
4. Lay the Headgear (K) flat with the label side down. Position the assembled mask over the Headgear and attach the four straps into the corresponding slots in the Mask Base and the Glider™ Strap (E). This can be done without undoing the Velcro® Tabs by sliding the Headgear into the slots.

OXYGEN/PRESSURE PORT CONNECTOR

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available (Code 900HC452).

1. Connect the large end of the Connector (T) to the Non-Rebreathing Valve (J) on the mask and the small end of the Connector to the Breathing Tube (R).
 2. Open the Port Cap(s) (P) and place the Pressure and/or Oxygen Tube (S) firmly over the Port(s) (Q).
- (The two ports are identical; either port may be used for oxygen or pressure measurement. Only remove the Port Cap from ports that are being used.)
- Note: At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient's breathing pattern, mask selection, and the leak rate.
 - Warning: If oxygen is used with CPAP/Bi-Level machine, the oxygen flow must be turned off when the CPAP/Bi-Level machine is not operating.
 - Explanation of Warning: When the CPAP/Bi-Level device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP/Bi-Level machine enclosure. Oxygen accumulated in the CPAP/Bi-Level machine enclosure will create a risk of fire.
 - Warning: Do not smoke while using or in the vicinity of someone using oxygen with this mask.
 - Warning: Do not use Polyvinyl Chloride (PVC) Pressure and/or Oxygen tubing. Use silicone tubing instead.
 - Explanation of Warning: Contact with PVC can cause premature cracking of ports.

WARNINGS

- This mask should be used only with CPAP or Bi-Level equipment recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP or Bi-Level machine is turned on and operating properly. The exhalation port(s) associated with the mask should never be blocked.
- Explanation of Warning: CPAP and Bi-Level machines are intended to be used with special masks which have exhalation ports to allow continuous flow of air out of the mask. When the CPAP or Bi-Level machine is turned on and functioning properly, new air from the CPAP or Bi-Level machine flushes the exhaled air out through the exhalation port(s). However, when the CPAP or Bi-Level machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. Re-breathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.
- At low CPAP/Bi-Level pressures, the flow through the exhalation ports may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
- Valve activation/deactivation pressure is 2 cm H₂O.
- Do not use the mask without the Non-Rebreathing Valve in place. This valve ensures CO₂ re-breathing is kept to a minimum in the event of power failure.
- Do not use the mask if vomiting or feeling nauseous.
- Discontinue using the mask if there is an allergic reaction to any part of the mask. Consult your physician if this occurs.
- If reusing the Forma™ Full Face Mask between different patients, refer to the Multi-Patient Cleaning Instructions for the Forma™ Full Face Mask.
- Replace the Non-Rebreathing Valve every 12 months.
- Do not use the Forma™ Full Face Mask Elbow on other Fisher & Paykel Healthcare masks.
- Use the Forma™ Full Face Mask only with the Headgear provided.

CAUTION

- Use the mask for its intended use only as directed in this booklet.
- US Federal Law restricts this device to sale by, or on order of a physician.

CONTRAINDICATIONS

- This mask should not be used by anyone incapable of removing the mask unaided, without continuous supervision.

The Forma™ Full Face Mask and accessories are Latex free.

Many people find CPAP therapy causes dryness of the nose and throat.

Heated humidification can substantially reduce these symptoms.

Contact your supplier and ask about ThermoSmart®.

US Patent Numbers 6615834 / 6789541 / 6701926 / 6951218

Other Patents Pending

TECHNICAL SPECIFICATIONS

EXHAUST FLOW

The Forma™ Full Face Mask has exhalation ports to expel the air that you exhale from the mask.

It is important that these exhalation ports are not blocked by any object. This controlled leak ensures all exhaled CO₂ is expelled from the mask.

PRESSURE (cmH ₂ O)	3	5	7	9	11	13	15	17	19	21	23	25
EXHAUST FLOW (L/MIN)	18	23	26	29	30	32	35	37	40	45	48	49

Exhaust Flow at each pressure is ± 15%

RESISTANCE TO FLOW

Pressure drop through mask @ 50 l/min 0.4 ± 0.1 cmH₂O

MASK DEAD SPACE

108 cc

OPERATING CONDITIONS

- Operating pressure is 3-25 cmH₂O
- Operating temperature range is 40-120°F (5-50°C)

SPECIFICATIONS TECHNIQUES

DEBIT DE FUITE EXPIRAIRE

Le masque Facial Forma™ possède une fuite expiratoire pour évacuer l'air expiré hors du masque.

Il est important que cette fuite expiratoire ne soit pas obstruée. Cette fuite calibrée assure que l'intégralité du CO₂ expiré soit évacuée du masque.

PRESIÓN (cmH ₂ O)	3	5	7	9	11	13	15	17	19	21	23	25
DÉBIT DE FUITE (L/MIN)	18	23	26	29	30	32	35	37	40	45	48	49

Le débit d'évacuation à chaque pression est de ± 15%

RÉSISTANCE AU DÉBIT

Chute de pression du masque à 50 l/min 0.4 ± 0.1 cmH₂O

ESPACE MORT

108 cc

CONDITIONS D'UTILISATION

- Plage de pression d'utilisation de 3 à 25 cmH₂O
- Plage de température d'utilisation de 40 à 120°F (5 à 50°C)

FORMA™ INSTRUCCIONES DE USO MASCARILLA ORONASAL

LA MÁSCARA FULL FACE FORMA™ ESTÁ INDICADA PARA UN ÚNICO PACIENTE ADULTO A QUIEN EL MÉDICO LE HA PRESCRITO UN TRATAMIENTO DE VENTILACIÓN Bi-LEVEL O CPAP DOMICILIARIO, EN EL CASO DE QUE NO SE PUEDE INSTALAR MÉDICA.

COMO COLOCAR SU MÁSCARA

Diríjase al diagrama para ensamblar la máscara.

1. Retire la cubierta plástica del sellado de silicona.
2. Desabroche el arnés (K) del Glider™ (E) tirando del cordón de desenganche rápido (I) hacia su nariz. Sujetando la Base de la máscara (A) con una mano, colocar el arnés con la otra mano para que se ajuste de manera cómoda a su cabeza.
3. Sostener suavemente la máscara contra el rostro con la parte inferior de la Vaina de silicona (C) bocabajo y colocar el arnés en la cabeza con la mano libre.
4. Abrochar el broche del cordón (H) al broche de la máscara.
5. Ajustar suavemente la cinta horizontal superior, luego la cinta horizontal inferior. Asegúrese de que la vaina de silicona esté bien colocada en el puente de la nariz y la parte inferior esté correctamente ajustada al mentón. Verifique que el broche de la máscara esté centrado.
6. Conectar el equipo de CPAP/Bi-Level a la máscara, con la presión prescrita. Liberar el cordón hacia delante o hacia abajo.

CLAVES DE COLOCACIÓN

- Si es necesario, tire de la máscara ligeramente mientras las cintas están aún colocadas. Esto permite que se infle la vaina de silicona. Volver a poner la máscara en la cara.
- Si las fugas persisten en la mitad superior de la máscara, apretar suavemente las cintas horizontales superiores.
- Si las fugas persisten en la parte inferior de la máscara, apretar suavemente las cintas inferiores horizontales. (No apretar demasiado las cintas.)
- Cuando necesite retirar la máscara desabroche el Arnés del Glider™, tirando del cordón de desenganche rápido hacia su nariz.

COMO LIMPIAR SU MÁSCARA

Para mantener continuamente, seguridad y comodidad con su máscara Forma™ Full Face:

- **ANTES DEL PRIMER USO:**
 1. Lavar a la mano el Arnés con jabón puro disuelto en agua templada. Evitar dejar en remojo más de 10 minutos, después actuar con agua limpia y dejar secar fuera del alcance de la luz del sol. Al lavar, no es necesario desprendre la Hebilla (H) del arnés.
- **ANTES DE CADA USO:**
 1. Inspeccionar la máscara para verificar si ha sufrido deterioro. No utilizar la máscara si estuviera dañada.
 2. Revisar la Válvula de No Re-Inhalación (I). Asegurarse de que las tapas de silicona estén abajo cuando se desconecte el aparato de CPAP/Bi-Level.
- **DESPUÉS DE CADA USO:**
 1. Desmontar la Vaina de silicona (C), el codo (B), la válvula de no re-inhalación (I) y el Arnés (K) de la base de la máscara (A).
 2. Lavar la Vaina de silicona, Codo, Válvula y Base de la Máscara con jabón puro disuelto en agua templada. Evitar dejar en remojo más de 10 minutos, después aclarar con agua limpia.
 3. Limpiar el Codo (B) con un paño húmedo (no sumergir el Codo en agua).
 4. Dejar secar todas las partes, evitando la luz del sol directa, antes de armalar nuevamente.
- **CADA 7 DÍAS:**
 1. Lavar a la mano el Arnés con jabón puro disuelto en agua templada. Evitar dejar en remojo más de 10 minutos, después aclarar con agua limpia y dejar secar fuera del alcance de la luz directa del sol. Al lavar, no es necesario desprendre la Hebilla (H) del arnés.
- **PRECAUCIÓN:**
 - Evitar dejar en remojo más de 10 minutos.
 - No lavar la máscara en el lavavajillas.
 - No limpiar la máscara con productos que contengan: alcohol, cloro, agentes antibacteriales, antisépticos, cloruro, o humectantes.
 - No guardar la máscara en lugares con luz directa del sol.

Lo mencionado anteriormente puede deteriorar o dañar la máscara y disminuir su vida útil. En caso de que su máscara Forma™ Full Face se debilite o rompa, deje de usarla y reemplácela de inmediato.

COMO ARMAR SU MÁSCARA

Su máscara Forma™ Full Face está completamente armada y lista para ser usada. Cuando necesite limpiar su máscara, siga las instrucciones de armado:

1. Colocar la Vaina de silicona (C) boca abajo sobre una superficie plana. Con la parte delgada del Codo (B) boca abajo, coloque la Vaina de silicona.
2. Colocar la Vaina de silicona (C) y el Codo (B) en la base de la máscara (A).
3. Empujar la Válvula de no re-inhalación (I) hacia el Codo (B) y unirlo a la base de la máscara.</li