

FORMA™ NIV FULL FACE MASK INSTRUCTIONS FOR USE

INTENDED USE STATEMENT
 The Forma™ NIV Full Face Mask is intended to be used by individuals who have been prescribed Non-Invasive Ventilation treatment or diagnosed by a physician as requiring CPAP or Bi-Level Ventilation treatment. The Forma™ NIV Full Face Mask is **NOT** to be used for Sleep Apnea treatment in the home and Multiple Patient Adult Use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

WARNING: The Forma™ NIV Full Face Mask is to be used only with ventilator that has adequate alarms and safety systems. Refer to Warnings and Cautions for description of alarms required. **Cautions:** US Federal Law restricts this device to sale by or on order of a physician.

PREPARING YOUR MASK FOR USE
 The Forma™ NIV Full Face Mask comes complete with both a Ventured and Non-Ventured Elbow. It is vital that the correct Elbow Connector is used with the appropriate ventilator system as shown in the diagrams below:

<p>For systems requiring a VENTED MASK</p> <p>Examples of Use for Clear Connectors:</p> <ul style="list-style-type: none"> • Bi-Level Ventilation • Visson Ventilator - with F&P RT39 Circuit (If the circuit includes a vent hole adjust/remove before attaching to the circuit.) • WARNING: Ensure that air flow can be felt through the elbow upon exhalation. • NOTE: An exhalation port will not work unless it can be performed on this mask. 	<p>For systems requiring a NON-VENTED MASK</p> <p>Examples of Use for Blue Connectors:</p> <ul style="list-style-type: none"> • CPAP THERAPY • F&P RT 201 Circuit and PEEP Valve • CLOSED LOOP VENTILATION • F&P RT 200 Circuit • VISION VENTILATOR • Hexanios G+R® • Hexanios G+R® with built-in exhalation port
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WARNING: If a patient is to be sent home with this mask, the unused Elbow Connector should be removed from the box. This reduces the risk of the patient using the incorrect connector.

FITTING YOUR MASK
 Refer to the mask assembly diagram.

- Remove plastic cover from Silicone Seal (C)
- Attach correct Elbow Connector to the mask. (See "Preparing Your Mask For Use.")
- Ensure that the Pressure Port Cap (N) is on or off.
- Unclip the Headgear (B) from the Mask - Step (B) by pulling the Easy-Release Cord (I) and holding your Mask Base (A) in one hand, spread the Headgear with your free hand, just enough to fit comfortably over your head.
- 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.
- Reattach the Headgear Clip (B) to the Mask - Step (B)
- Adjust top horizontal straps to ensure the bridge of the Silicone Seal remains stable on your nose. Gently tighten lower horizontal straps under the bottom of the Silicone Seal remains fixed under the chin. Ensure that the Mask - Step (B) is centered. Gently adjust top crown straps to move mask.
- Connect the ventilator hose to your mask and start breathing normally.
- Ensure the ventilator settings are correct. In particular for volume-cycled ventilators, make appropriate allowance for mask dead space and leak for the "tidal volume" setting. (Refer to the TECHNICAL SPECIFICATIONS section of these instructions for more information.)

FITTING TIPS

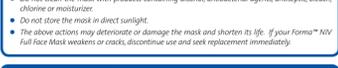
- If necessary, pull the mask slightly away from your face while the straps are still attached and the ventilator is supplying pressure. This allows the mask to self-adjust. Adjust the mask on your face to improve the seal.
- If leaks occur around the upper half of the mask, gently tighten the top horizontal straps.
- If leaks occur around the lower half of the mask, gently tighten the lower horizontal straps. (Do not over-tighten the straps)
- When you need to remove your mask, unclip the Headgear from the Mask - Step (B) by pulling the Easy-Release Cord towards your nose.

HOME USE CLEANING INSTRUCTIONS
 (For High-Level Disinfection, refer to Multi-Patient Cleaning Instructions)
 Use to ensure continuing safety, efficacy and comfort of your Forma™ NIV Full Face Mask.

- BEFORE FIRST USE:**
- Hand wash the headgear (B) 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 (B) from the Headgear when washing.
- BEFORE EACH USE:**
- Ensure that alarms and safety systems on the ventilator are operating correctly.
 - Check that the correct Elbow and Swivel are used. (See "Preparing Your Mask For Use.")
 - Inspect the mask for deterioration. Do not use if damaged, or if the flow is impeded.
- AFTER EACH USE:**
1. Disassemble the Silicone Seal (C), Foam Cushion (D), Elbow (B) and Non-Rebreathing Valve (A) and the Headgear (B) 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. Leave all parts to dry away from direct sunlight before reassembling.
- EVERY 7 DAYS:**
- 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 (B) from the Headgear when washing.

CAUTIONS:

- Do not soak the mask for longer than 10 minutes.
- Do not wash the mask in the dishwasher.
- Do not clean the mask with products containing alcohol, antibacterial agents, antiseptic, bleach, chlorine or moisturizer.
- Do not store the mask in direct sunlight.
- The silicone alarms may deteriorate or damage the mask and shorten its life. If your Forma™ NIV Full Face Mask swivels or cracks, discontinue use and seek replacement immediately.



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

- Place Silicone Seal (C) on a flat surface. With the thick side of the Foam Cushion (D) facing down, place the Silicone Seal (C) on top.
- Place Silicone Seal (C) and Foam Cushion (D) into the Mask Base (A)
- Attach the correct Elbow and Swivel/Valve (B with or without U) by following the instructions "PREPARING YOUR MASK FOR USE"
- Lay the Headgear (B) 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 Mask - Step (B). This can be done without undoing the Velcro® tabs by sliding the Headgear into the slots.

WARRANTY AND DISPOSAL

WARRANTY STATEMENT
 Fisher & Paykel Healthcare warrants that the mask (excluding foam and material (A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z)), when used in accordance with the instructions for use, will perform in accordance with the specifications set out in the user manual. This warranty is subject to the limitations and exceptions set out in detail in the <http://www.fisher.com/usa/product/Warranty.asp>

DISPOSAL
 This device does not contain any hazardous substances and may be disposed of with general waste.

OXYGEN/PRESSURE PORT CONNECTOR
 There are two ports on the base of the mask for taking pressure readings and/or adding additional oxygen.

- Open the Port Cap(s) (M)
 - Place the Pressure and/or Oxygen Tube firmly over the port(s).
- (The two ports are identical; either port may be used for oxygen or pressure measurement. Only remove the Port Cap(s) from ports that are being used.)**
- Note: A leak from the base 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 the ventilator, the oxygen flow must be turned off when the ventilator is not operating.
 - **Explanation of Warning:** When the ventilator is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the ventilator enclosure. Oxygen accumulated in the ventilator tubing will create a risk of fire.
 - **Warning:** Do not allow smoking or naked flames 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 not be used if the patient has impaired laryngeal reflexes, is vomiting, feeling nauseous, or suffering from any other conditions predisposing to aspiration in the event of regurgitation or vomiting.
- This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Contact the physician if the patient experiences unusual chest discomfort, shortness of breath, stomach distention, belching, or a severe headache when he/she is receiving ventilatory support.
- This mask should be used only with Non-Invasive Ventilators recommended by your physician or respiratory therapist. A mask should not be used unless the ventilator is turned on and operating properly for open loop systems at pressures greater than 5 cmH₂O and for closed loop systems at pressures greater than 5 cmH₂O.
- **Explanation of Warning:** Non-Invasive Ventilators are intended to be used with NIV masks. When the ventilator is turned on and functioning properly, non-invasive ventilation (NIV) is established. If the mask is not properly sealed, the mask will leak and the patient will not receive the intended level of ventilation. The level of ventilation will be reduced. In the event of a leak, the level of ventilation will be reduced. In the event of a leak, the level of ventilation will be reduced. In the event of a leak, the level of ventilation will be reduced.
- 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™ NIV Full Face Mask between different patients, refer to the Multi-Patient Cleaning Instructions for the Forma™ NIV Full Face Mask.
- Replace the Non-Rebreathing Valve every 12 months.
- Do not use the Forma™ NIV Full Face Mask Elbow on other Fisher & Paykel Healthcare masks.
- Use the Forma™ NIV Full Face Mask only with the Headgear provided.
- This mask should not be used by anyone incapable of removing the mask unaided, without continuous supervision.
- This mask should not be used for patients without a spontaneous respiratory drive.

CAUTIONS

- 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.

The Forma™ NIV Full Face Mask and accessories are **Letzte-Fix**. Many patients find CPAP therapy causes dryness of the nose and throat. Heated humidification can substantially reduce these symptoms. Contact your supplier and ask about Thermomist™.

US Patent Numbers: 6,899,441 / 6,709,266 / 6,693,218
 Other Patents Pending

TECHNICAL SPECIFICATIONS

OPERATING RANGE	Operating pressure range is 3.25 cmH ₂ O for open loop systems, and 5.25 cmH ₂ O for closed loop systems. Do not use at pressures below 3 cmH ₂ O on open loop systems, and 5 cmH ₂ O on closed loop systems. Operating temperature range is 5-40 °C (40-104 °F)
MASK DEAD SPACE	192 cc
NON-VENTED MASK LEAK	The leak from the non-vented mask, excluding leak between the face and the mask, is less than 6.0 l/min at 20 cmH ₂ O
VENTED MASK - EXHAUST FLOW	The clear vented elbow, which is used only with open loop ventilation systems, has exhaust flow holes to expel the air that you breathe from the mask. It is important that these vents are not blocked by any object. This controlled leak ensures all exhaled CO ₂ is expelled from the mask.
EXHAUST FLOW (l/min)	24 28 33 36 38 39 42 44 48 50 53 25 25
ESKAUST FLOW (l/min)	24 28 33 36 38 39 42 44 48 50 53 25 25
VALVE ACTIVATION/DEACTIVATION PRESSURE	Value closed to atmospheric pressure of 0.49 cmH ₂ O
RESISTANCE TO FLOW	Pressure drop through mask @ 50 l/min is 0.25 cmH ₂ O Pressure drop through mask @ 100 l/min is 1.25 cmH ₂ O
INSPIRATORY AND EXPIRATORY RESISTANCE	The inspiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 17 cmH ₂ O The expiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 2.6 cmH ₂ O
SOUND	The Sound Pressure Level of the mask is 28.3 dBA with uncertainty 2.5 dBA The Sound Pressure Level of the mask is 21.7 dBA with uncertainty 2.5 dBA

FORMA™ NIV FULL FACE MASK MULTI-PATIENT CLEANING INSTRUCTIONS

Your Forma™ NIV Full Face Mask is provided patient ready to re-use between patients please follow the guidelines below:

CLEANING / DESOLING

- Before disinfecting, disassemble all components from the Mask Base. Clean all surfaces of mask and components thoroughly with a mild detergent solution and a soft bristled brush. Rinse all visible soil removed. Rinse thoroughly under running potable water to remove detergent solution.

HIGH LEVEL DISINFECTION PARAMETERS

MASK FRAME	PASTEURISATION	DESINFECTION À CHAUD
	30 minutes at 70 °C (158 °F), 10 minutes at 75 °C (167 °F) and 10 minutes at 80 °C (176 °F)	30 minutes à 70 °C (158 °F), 10 minutes à 75 °C (167 °F) et 10 minutes à 80 °C (176 °F)
SILICONE SEAL	OR	OU
	Cidex® OPA 30 minutes à 20 °C (68 °F)	Cidex® OPA 30 minutes à 20 °C (68 °F)
ELBOW	OR	OU
	Hexanios G+R® As per Manufacturers instructions - but Soak for 30 minutes and 15 minutes.	Hexanios G+R® As per Manufacturers instructions - but Soak for 30 minutes and 15 minutes.
NON-REBREATHING VALVE		
HEADGEAR WITH CLIP		
	Wash in warm soapy water and leave to dry.	Nettoyer à l'eau savonneuse et laisser sécher.
FOAM CUSHION		
	Replace with new part.	Remplacer par une neuve.

THE FORMA™ NIV FULL FACE MASK HAS BEEN VALIDATED TO WITHSTAND 20 CYCLES OF THE ABOVE PARAMETERS. DO NOT USE IF DAMAGED.

Disclaimers: It is the user's responsibility to qualify any deviations from the recommended methods of re-use/re-use. Some disinfection may occur after re-use.

CONTACT YOUR LOCAL HOME CARE PROVIDER FOR ADDITIONAL INFORMATION.

MODE D'EMPLOI DU MASQUE FACIAL FORMA™ NIV

DOMAINE D'APPLICATION:
 Le masque facial Forma™ NIV est destiné à l'utilisation par des personnes à qui une thérapie par ventilation non invasive a été prescrite ou qui ont été diagnostiqués comme ayant besoin d'une PPC ou d'une ventilation NIV. Le masque facial Forma™ NIV n'est pas à utiliser pour le traitement de l'apnée du sommeil à domicile, en milieu hospitalier ou tout autre environnement clinique dans lequel il est possible de désinfecter correctement.

AVERTISSEMENT: Le masque facial Forma™ NIV est utilisé exclusivement avec des ventilateurs possédant un système d'alarme et de sécurité adéquats. Consulter les précautions et les avertissements pour la description des alarmes requises. **Attention:** La loi fédérale américaine impose la vente de ce produit par un médecin ou sur sa prescription.

PRÉPARER VOTRE MASQUE
 Le masque facial Forma™ NIV est livré complet, avec un raccord coudé à fût et un autre bûche. Il est primordial d'employer le coudé approprié au système de ventilation utilisé.

<p>Pour les systèmes nécessitant un MASQUE AVEC FUITE EXPIRATOIRE</p> <p>Exemples d'utilisation de raccords transparents:</p> <ul style="list-style-type: none"> • CPAP THERAPY • F&P RT 201 Circuit and PEEP Valve • CLOSED LOOP VENTILATION • F&P RT 200 Circuit • VISION VENTILATOR • Hexanios G+R® • Hexanios G+R® with built-in exhalation port 	<p>Pour les systèmes nécessitant un MASQUE SANS FUITE EXPIRATOIRE</p> <p>Exemples d'utilisation de Raccords Bleus:</p> <ul style="list-style-type: none"> • TREATMENT PUMP • Circuit F&P RT 201 et valve de PEEP • VENTILATION avec un CIRCUIT BI-BRANCHE • Circuit F&P RT 200 • VENTILATOR VISION • Hexanios G+R® • Hexanios G+R® avec port d'exhalation intégré
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AVERTISSEMENT: Si un patient utilise un masque à domicile, retirez le coudé non utilisé de la boîte afin d'éviter toute utilisation incorrecte.

MISE EN PLACE DU MASQUE
 Veuillez vous référer au schéma de mise en place.

- Retirer la protection de la jupe (E)
- Attacher le coudé adéquat au masque. (Voir "Préparer votre masque.")
- S'assurer que les capuchons des prises de pression (N) soient fermement fixés.
- Détacher le harnais (O) de la glissière (B) en tirant sur la sangle à détachement rapide (I) vers le bas. Tenir la jupe (E) d'une main et déplier le harnais de l'autre main jusqu'à ce qu'il soit placé sur la tête confortablement.
- Appliquer délicatement le masque sur le visage, en plaçant le bas de la jupe sous le menton et étirer le harnais sur la tête avec la main libre.
- Accrocher de manière sûre la sangle du harnais (O) à la glissière.
- Ajuster délicatement les sangles supérieures horizontales pour que les points de la jupe s'adaptent correctement sur le nez. Serrer légèrement la mentonnière horizontale en tissant que le bas de la jupe soit en contact permanent avec le dessous du menton. S'assurer que la jupe "Glissière" soit centrée. Retirer le mou en tirant doucement sur les sangles supérieures.
- Connecter le circuit ventilatoire au masque et respirer normalement.
- S'assurer que les paramètres de ventilation soient corrects. Lorsque l'état de ventilation fonctionne, prendre en compte le volume mort et la fuite au masque pour le réglage de "volume courant". (Voir le chapitre sur les CARACTÉRISTIQUES TECHNIQUES de ce guide pour de plus amples informations.)

ASTUCES DE MISE EN PLACE

- Si nécessaire, décoller légèrement le masque du visage sans détacher les sangles et laisser le ventilateur sous pression, ce qui permet à la jupe de se remplir d'air. Répéter le masque sur le visage pour améliorer l'étanchéité.
- Si une fuite se produit dans la moitié supérieure du masque, serrez doucement les sangles supérieures horizontales.
- Si une fuite se produit dans la moitié inférieure du masque, serrez légèrement les sangles inférieures horizontales. (Pas trop fort.)
- Pour retirer le masque, détachez le harnais de la glissière en tirant la sangle vers le bas ou vers l'avant.

INSTRUCTIONS DE NETTOYAGE À DOMICILE
 (Pour une désinfection de haut niveau, consultez le guide d'entretien pour utilisation multi-patient (reconditionnement).)
 Utilisez une solution stérilisante et conforme aux normes de l'utilisation de votre masque facial Forma™ NIV.

- AVANT LA PREMIÈRE UTILISATION:**
- Nettoyer la jupe en silicone (E) et le harnais (O) dans l'eau savonneuse tiède. Ne pas immerger plus de 10 minutes, puis rincer à l'eau claire et laisser sécher à l'air libre, à l'abri de la lumière du soleil. Il n'est pas nécessaire de retirer le Clip (B) du harnais lors du nettoyage.
- AVANT CHAQUE UTILISATION:**
1. Vérifier que les alarmes et systèmes de sécurité du ventilateur fonctionnent correctement.
 2. Vérifier que le coudé et la rotule adéquate soient utilisés. (Voir "Préparer votre masque.")
 3. Vérifier l'état du masque et s'assurer qu'il n'est pas endommagé ou si le débit est réduit.
- APRÈS CHAQUE UTILISATION:**
1. Détacher la jupe en silicone (E), la mousse (D), le coudé (B), et la valve anti-réinhalação (A), et le harnais (O) de la jupe (E).
 2. Nettoyer la jupe en silicone (E), la valve et la coupe du masque dans l'eau savonneuse tiède. Ne pas immerger plus de 10 minutes, puis rincer à l'eau claire.
 3. Nettoyer la Mousse (D) avec un chiffon (NE PAS IMMERGER la mousse).
 4. Avant le remontage, laisser sécher tous les éléments, à l'abri du soleil.
- CHAQUE SEMAINE:**
- Nettoyer la mousse à l'eau savonneuse tiède. Ne pas immerger plus de 10 minutes, puis rincer à l'eau claire et laisser sécher à l'air libre, à l'abri de la lumière du soleil. Il n'est pas nécessaire de retirer le Clip (B) du harnais lors du nettoyage.

PRÉCAUTIONS:

- Ne pas immerger le masque plus de 10 minutes.
- Ne pas lever le masque ou le dévisser.
- Ne pas nettoyer le masque avec des produits contenant de l'alcool, du chlore, des agents antiseptiques ou des agents blanchissants.
- Ne pas placer le masque en plein soleil.
- Si le masque facial Forma™ NIV est placé dans les conditions précitées, cela pourra endommager et/ou décolorer le tissu en tissu tricoté.

DECLARATION DE GARANTIE
 Fisher & Paykel Healthcare garantit que les masques Fisher & Paykel Healthcare (B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z), lorsqu'ils sont utilisés conformément aux instructions d'emploi, fonctionneront conformément aux spécifications techniques indiquées dans le manuel de l'utilisateur. Cette garantie est soumise aux limitations et exceptions énumérées en détail au site web <http://www.fisher.com/usa/product/Warranty.asp>

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 Fisher & Paykel Healthcare garantiza que los mascaros Fisher & Paykel Healthcare (B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z), cuando se utilizan de acuerdo con las instrucciones de uso, cumplirán con las especificaciones técnicas indicadas en el manual del usuario. Esta garantía está sujeta a las limitaciones y excepciones enumeradas en detalle en el sitio web <http://www.fisher.com/usa/product/Warranty.asp>

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