



# NASAL PILLOWS MASK

## Patient Instructions for Use

**English** (French) (Español) (German) (Nederlands) (Dutch) (Italiano) (Italian) (Português) (Portuguese) (Svenska) (Swedish) (Suomi) (Finnish) (Norsk) (Norwegian) (Dansk) (Danish) (Türkçe) (Turkish) (Ελληνικά) (Greek) (繁體中文) (Simplified Chinese) (简体中文) (Traditional Chinese) (繁體中文) (Korean) (日本語)

REORDER CODE: HC482

NET WT/POUNDS (G) 200 250 300 350 400 450 500 550 600 650 700 750 800 850 900 950 1000

**1. Mask Parts**

A. Mask Frame	E. Ball Flow	I. Back Strap
B. Silicone Pillows	F. Head Strap	J. Side Strap
C. Mask Strap	G. Embossed Seal	K. No-Block
D. Lateral Adjusting Strap	H. Top Strap	L. Top Strap

**2. Fitting Your Mask**

- Remove Back Strap from Silicone Pillows (B).
- Hold the Mask Frame (A) with one hand and the Head Strap (H) with the other hand. Push the Silicone Pillows (B) into your nostrils until the Head Strap (H) is snug against your forehead.
- Adjust the Side Strap (D) so that the Top Strap (H) is directly above each ear.
- Adjust the Back Strap (L) so that the Top Strap (H) is at the headgear just behind the top of the head.
- Connect the mask to the CPAP/BiPAP machine set at the prescribed pressure.

**3. FITTING TIPS**

- If masks occur, repositioning the Silicone Pillows (B) in your nostrils to get a better seal. You may need to reposition the Silicone Pillows (B) more than once.
- If masks still occur you may need a different size Mask. (See Sizes and Measurements.)
- The Headgear (L) can be fixed in three positions or left free. Use Mask Assembly Items 4 and 5.

**4. Disassembly for Cleaning**

- Remove Silicone Pillows (B) from the Mask Frame (A).
- Remove Headgear Assembly from the Mask Frame (A). This is done by slipping the Mask Frame (A) over the headgear straps. Do not remove the headgear straps.
- Remove the Ball Flow (E) from the Mask Frame (A).
- Remove the Head Strap (F) from the Mask Frame (A).
- Remove the Mask Strap (C) from the Mask Frame (A).



**Clean Your Mask at Home**

- Wash Mask Frame (A), Silicone Pillows (B), Headgear Assembly (E, F, G) and Male Straps (C) in soap solution in lukewarm water. Do not use hot water and do not use bleach.
- Rinse thoroughly with fresh water, ensuring that all soap residue is removed.
- Leave all parts to dry in a shaded area before reassembly.

**Weekly:**

- Hand-wash the Headgear Assembly in pure soap dissolved in lukewarm water.
- Rinse thoroughly with fresh water, ensuring that all soap residue is removed.
- Air dry of direct sunlight before reassembly.

**CAUTIONS**

- Do not use the mask in direct sunlight.
- Do not wash the mask in detergent.
- Labels on the mask are made of plastic and may contain latex, natural rubber, adhesive, latex, chlorine or irritants.

**Note: Follow the following cleaning instructions which compromise the performance and safety of the mask and shorten its life.**

- Do not use alcohol, acetone, bleach, or other harsh chemicals to clean the mask.
- Do not use the mask if the mask is damaged or if the mask is not properly assembled.
- Do not use the mask if the mask is contaminated with any substance that could irritate the skin or the respiratory tract.

**Mask Assembly**

- Push the Mask Frame (A) into the Female Seal (G).
- Push the Ball Flow (E) into the socket on the Mask Frame (A).
- Push the Head Strap (F) into the socket on the Mask Frame (A).
- Push the Headgear Assembly (E, F, G) onto the Mask Frame (A).
- Push the Mask Strap (C) into the socket on the Mask Frame (A).
- Push the Side Straps (D) onto the Mask Frame (A).

**Warranty and Disposal**

Fisher & Paykel Healthcare warrants that the mask (including bands and material diffusers), headgear and accessories are free from defects in materials and workmanship under normal use and wear. This warranty does not cover damage to the mask caused by misuse, accident, or other causes. This warranty is void if the mask is used for purposes other than those intended. For more information, please contact your local Fisher & Paykel Healthcare representative.

**DISPOSAL**

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

**TECHNICAL SPECIFICATIONS**

**DESIGN FLOW**

The Opus 360 Nasal Pillows Mask has an exhaust system that provides the expiratory CO<sub>2</sub> through a group of holes in the front of the mask. This controlled back pressure maintains exhaled CO<sub>2</sub> is recycled from the mask.

Pressure (cmH <sub>2</sub> O)	4	5	7	9	11	13	15	17	19	21	23	25
Flow (l/min)	19	21	23	25	28	32	34	37	40	42	45	49

**RESISTANCE TO FLOW**

Pressure drop through mask at 50 l/min @ 9.0 cmH<sub>2</sub>O

Pressure drop through mask at 100 l/min @ 9.0 cmH<sub>2</sub>O

**MASK DEAD SPACE**

Pressure (cmH <sub>2</sub> O)	4	5	7	9	11	13	15	17	19	21	23	25
Flow (l/min)	19	21	23	25	28	32	34	37	40	42	45	49

**SOUND**

The Sound Pressure Level of the mask is 31 dBA, with uncertainty ± 2.5 dBA. The Sound Pressure Level of the mask is 26 dBA, with uncertainty ± 2.5 dBA.

**Oxygen/Pressure Port Connector**

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available (REF 900K432).

**Opus 360 Nasal Pillows Mask Multi-Patient Cleaning Instructions**

Your Opus 360 Nasal Pillows Mask is provided assembled and ready for patient use. To reuse between patients please follow the guidelines below:

**CLEANING & DISINFECTION**

Disassemble all components from the Mask Frame as described in the instructions. Wash the Mask Frame and Male Straps. Clean all surfaces of the mask and control according to the instructions. Use a soft brush to clean the mask. Ensure all visible soil is removed. Rinse thoroughly under running potable water to remove detergent.

**How to properly clean this device may result in inadequate disinfection.**

Thermal	Chemical	Cide®/OPA	Sterant® 1005
Mask parts hot to touch	Follow manufacturer's instructions for disinfection.	Follow manufacturer's instructions for disinfection.	Follow manufacturer's instructions for disinfection.
Flashable Silicone Mask Assembly	30 minutes at 75°C (167°F)	30 minutes at 75°C (167°F)	30 minutes at 75°C (167°F)

**Headgear**

Wash with warm water and leave to dry.

**Mask Frame**

Wash with warm water and leave to dry.

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**Headgear**

Wash with warm water and leave to dry.

**Masque Nasal Direct Opus 360**  
Modèle d'emploi

Le masque nasal direct Opus 360 est destiné à l'utilisation par des personnes qui ont été diagnostiquées comme ayant besoin d'une PEP ou d'une thérapie par ventilation à pression positive continue. Le masque nasal direct Opus 360 est une utilisation intentionnelle par patient adulte à domicile ou en clinique avec un réglage de pression positive continue. Le masque nasal direct Opus 360 est une utilisation intentionnelle par patient adulte à domicile ou en clinique avec un réglage de pression positive continue. Le masque nasal direct Opus 360 est une utilisation intentionnelle par patient adulte à domicile ou en clinique avec un réglage de pression positive continue.

**Operating Instructions**

- The operating pressure range of the mask is 3 to 25 cmH<sub>2</sub>O.
- The operating temperature range of the mask is 14°C (57°F) to 40°C (104°F).
- Before use, inspect the mask for damage.
- Inspect the flow sensor. If there is any visible deterioration (cracking, tears or discoloration) or any loose or missing parts, do not use the mask.
- Inspect the vent holes. Do not use if blocked.
- Inspect the headgear straps. Do not use if damaged.
- Inspect the mask for any visible damage.

**Note: Follow the following operating instructions which compromise the performance and safety of the mask.**

- Do not use alcohol, acetone, bleach, or other harsh chemicals to clean the mask.
- Do not use the mask if the mask is damaged or if the mask is not properly assembled.
- Do not use the mask if the mask is contaminated with any substance that could irritate the skin or the respiratory tract.

**Warnings & Cautions**

- 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. Do not use the mask associated with any mask should never be disconnected from the CPAP or Bi-Level machine.
- Explanation of Warning: CPAP or Bi-Level machines are intended to be used with special masks that have characteristics that allow continuous flow of air into the mask. When the CPAP or Bi-Level machine is turned on and functioning properly, air will flow into the mask through the headgear straps. Do not use the mask if the headgear straps are damaged or if the headgear straps are not properly adjusted. Do not use the mask if the headgear straps are damaged or if the headgear straps are not properly adjusted.

**Avvertimenti e precauzioni**

- Questo apparecchio deve essere utilizzato solo con apparecchi CPAP o Bi-Level raccomandati dal medico. Il dispositivo deve essere utilizzato solo se il dispositivo CPAP o Bi-Level è acceso e funzionante correttamente. Non scollegare mai il dispositivo dal dispositivo CPAP o Bi-Level. Non utilizzare mai il dispositivo se il dispositivo CPAP o Bi-Level non è acceso e funzionante correttamente.
- Spiegazione dell'avvertimento: I dispositivi CPAP o Bi-Level sono progettati per funzionare con maschere speciali che consentono un flusso continuo di aria nella maschera. Quando il dispositivo CPAP o Bi-Level è acceso e funzionante correttamente, l'aria fluisce nella maschera attraverso le cinghie. Non utilizzare la maschera se le cinghie sono danneggiate o se le cinghie non sono correttamente regolate.

**Avvertimenti e precauzioni**

- Este máscara debe ser usada únicamente con el equipamiento CPAP o Bi-Level recomendado por el médico. El dispositivo debe ser utilizado solo si el dispositivo CPAP o Bi-Level está encendido y funcionando correctamente. Nunca desconecte el dispositivo del dispositivo CPAP o Bi-Level. Nunca utilice el dispositivo si el dispositivo CPAP o Bi-Level no está encendido y funcionando correctamente.
- Explicación de la advertencia: Los dispositivos CPAP o Bi-Level están diseñados para funcionar con mascarillas especiales que permiten un flujo continuo de aire hacia la máscara. Cuando el dispositivo CPAP o Bi-Level está encendido y funcionando correctamente, el aire fluye hacia la máscara a través de las correas. No utilice la máscara si las correas están dañadas o si las correas no están correctamente ajustadas.

**Pieces du masque**

A. Structure du masque	E. Embout à rotule	I. Sangle arrière
B. Embout nasal	F. Ceinture	J. Sangle latérale
C. Embout latéral	G. Embout femelle	K. No-Block
D. Sangle réglable	H. Ceinture	L. Sangle supérieure

**1. Mise en place du masque**

- Enlever la sangle arrière (I) de la structure du masque (A).
- Tenir le cadre du masque (A) d'une main et la sangle supérieure (L) de l'autre main. Pousser les embouts nasaux (B) dans vos narines jusqu'à ce que la sangle supérieure (L) soit serrée contre votre front.
- Ajuster la sangle latérale (J) de sorte que la sangle supérieure (L) se trouve juste au-dessus de chaque oreille.
- Ajuster l'embout nasal (B) de sorte que la sangle supérieure (L) soit serrée contre votre front.
- Ajuster la sangle arrière (I) de sorte que la sangle supérieure (L) soit serrée contre votre front.

**2. Cómo colocar la máscara**

- Retirar la correa posterior (I) de la estructura de la máscara (A).
- Mantener el marco de la máscara (A) con una mano y la correa superior (L) con la otra. Empujar los almohadillos nasales (B) dentro de sus fosas nasales hasta que la correa superior (L) quede ajustada contra su frente.
- Ajustar la correa lateral (J) de modo que la correa superior (L) quede justo encima de cada oído.
- Ajustar el embudo nasal (B) de modo que la correa superior (L) quede ajustada contra su frente.
- Ajustar la correa posterior (I) de modo que la correa superior (L) quede ajustada contra su frente.

**3. Anpassen der Maske**

- Entfernen Sie das Rückband (I) von der Maskenstruktur (A).
- Halten Sie den Maskenrahmen (A) mit einer Hand und das obere Band (L) mit der anderen Hand. Drücken Sie die Nasenpolster (B) in Ihre Nasenlöcher, bis das obere Band (L) gegen Ihre Stirn drückt.
- Stellen Sie das Seitenband (J) so ein, dass das obere Band (L) genau über dem Kopf liegt.
- Stellen Sie das Nasenpolster (B) so ein, dass das obere Band (L) gegen Ihre Stirn drückt.
- Stellen Sie das Rückband (I) so ein, dass das obere Band (L) gegen Ihre Stirn drückt.

**4. Limpieza de la máscara en casa**

- Lavar la máscara (A) y los almohadillos de silicona (B) con agua tibia y jabón.
- Enjuagar la máscara (A) y los almohadillos de silicona (B) con agua tibia y jabón.
- Dejar la máscara (A) y los almohadillos de silicona (B) para secarse a temperatura ambiente.

**CAUTIONS**

- Do not use the mask in direct sunlight.
- Do not wash the mask in detergent.
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**Note: Follow the following cleaning instructions which compromise the performance and safety of the mask and shorten its life.**

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**Mask Assembly**

- Push the Mask Frame (A) into the Female Seal (G).
- Push the Ball Flow (E) into the socket on the Mask Frame (A).
- Push the Head Strap (F) into the socket on the Mask Frame (A).
- Push the Headgear Assembly (E, F, G) onto the Mask Frame (A).
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**TECHNICAL SPECIFICATIONS**

**DESIGN FLOW**

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**RESISTANCE TO FLOW**

Pressure drop through mask at 50 l/min @ 9.0 cmH<sub>2</sub>O

Pressure drop through mask at 100 l/min @ 9.0 cmH<sub>2</sub>O

**MASK DEAD SPACE**

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**SOUND**

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**Oxygen/Pressure Port Connector**

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**CLEANING & DISINFECTION**

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Flashable Silicone Mask Assembly	30 minutes at 75°C (167°F)	30 minutes at 75°C (167°F)	30 minutes at 75°C (167°F)

**Headgear**

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