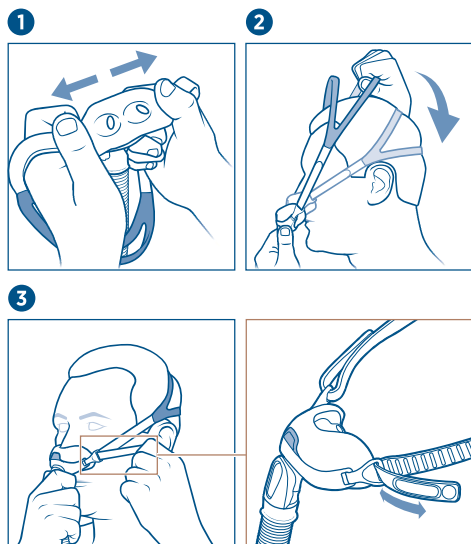


## FITTING YOUR MASK



**F&P Brevida™**

## NASAL PILLOWS MASK

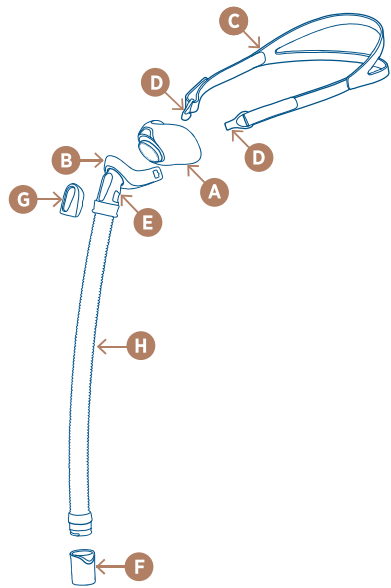
### Use and Care Guide



**F&P Brevida™**

**Thank you for choosing  
your F&P Brevida.**

This nasal pillows mask has been designed to make it easier for you to fit CPAP therapy into your life. This is your mask Use and Care Guide. Please read this entire guide before you first use your mask. Following the steps in this guide, and referring to the images and diagrams will assist you with assembly, fitting and daily use of your F&P Brevida nasal pillows mask.



Rx only      CE 0123

## LANGUAGES

| PAGE | LANGUAGE                    |
|------|-----------------------------|
| 1    | English                     |
| 13   | Français (French)           |
| 25   | Español (Spanish)           |
| 37   | Bahasa Melayu (Malaysian)   |
| 49   | ไทย (Thai)                  |
| 61   | 简体中文版 (Simplified Chinese)  |
| 73   | 繁體中文版 (Traditional Chinese) |
| 85   | 한국어 (Korean)                |
| 97   | 日本語 (Japanese)              |

|                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer</b>                                                                                                                                                                                                                               | <b>Hong Kong</b>                                                                                                                                                                                                                  |
| Fisher & Paykel Healthcare Ltd,<br>15 Maurice Paykel Place,<br>East Tamaki, Auckland 2013<br>PO Box 14 346 Panmure,<br>Auckland 1741,<br>New Zealand<br>Tel: +64 9 574 0100<br>Fax: +64 9 574 0158<br>Email: <a href="mailto:info@fphcare.co.nz">info@fphcare.co.nz</a><br>Web: <a href="http://www.fphcare.com">www.fphcare.com</a> | Tel: +852 216 0032<br>Fax: +852 216 0085                                                                                                                                                                                          |
| <b>India</b>                                                                                                                                                                                                                                                                                                                         | Tel: +91 80 2309 6400                                                                                                                                                                                                             |
| <b>Ireland</b>                                                                                                                                                                                                                                                                                                                       | Tel: 1800 409 011<br>Fax: +44 1628 626 146                                                                                                                                                                                        |
| <b>Italy</b>                                                                                                                                                                                                                                                                                                                         | Tel: +39 06 7839 2939<br>Fax: +39 06 7814 7709                                                                                                                                                                                    |
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| <b>Norway</b>                                                                                                                                                                                                                                                                                                                        | Tel: +47 21 60 13 53<br>Fax: +47 22 99 60 10                                                                                                                                                                                      |
| <b>Russia</b>                                                                                                                                                                                                                                                                                                                        | Tel. and Fax: +7 495 782 21 50                                                                                                                                                                                                    |
| <b>Spain</b>                                                                                                                                                                                                                                                                                                                         | Tel: +34 902 013 346<br>Fax: +34 902 013 379                                                                                                                                                                                      |
| <b>Sweden</b>                                                                                                                                                                                                                                                                                                                        | Tel: +46 8 564 76 680<br>Fax: +46 8 36 63 10                                                                                                                                                                                      |
| <b>Switzerland</b>                                                                                                                                                                                                                                                                                                                   | Tel: 0800 83 47 63<br>Fax: 0800 83 47 54                                                                                                                                                                                          |
| <b>Taiwan</b>                                                                                                                                                                                                                                                                                                                        | Tel: +886 2 8751 1739<br>Fax: +886 2 8751 5625                                                                                                                                                                                    |
| <b>Turkey</b>                                                                                                                                                                                                                                                                                                                        | İthalatçı Firma: Fisher Paykel<br>Sağlık Ürünleri Ticaret Limited Şirketi,<br>İletişim Bilgileri: Oztim Mahallesi 1249,<br>Cadde No:5, Yenimahalle,<br>Ankara, Türkiye 06374,<br>Tel: +90 312 354 34 12<br>Fax: +90 312 354 31 01 |
| <b>UK</b>                                                                                                                                                                                                                                                                                                                            | Fisher & Paykel Healthcare Ltd,<br>Unit 16, Cordwallis Park, Clivemont Road,<br>Maidenhead, Berkshire SL6 7BU, UK<br>Tel: 0800 132 169<br>Fax: +44 1628 626 146                                                                   |
| <b>USA/Canada</b>                                                                                                                                                                                                                                                                                                                    | Tel: 1800 446 3908<br>or<br>+1 949 453 4000<br>Fax: +1 949 453 4001                                                                                                                                                               |

## INTENDED USE

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The F&P Brevida Nasal Pillows Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Brevida Nasal Pillows Mask is intended for single patient adult ( $\geq 66$  lbs (30 kg)) use in the home and for multiple patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

## OPERATING INSTRUCTIONS

---

- The operating pressure range of your mask is 4 to 25 cmH<sub>2</sub>O.
- The operating temperature range of your mask is 5 to 40 °C (41 to 104 °F).
- Before using your mask each time, you should:
  - i. Inspect it for damage or deterioration. If there is any visible deterioration (cracking, tears, etc), do not use your mask and seek replacement part(s) from your healthcare provider.
  - ii. Inspect the exhaust holes on the Elbow **E**. Ensure air is flowing through these holes and do not use if blocked.
  - iii. Make sure path of air in mask is free from objects that may prevent breathing.

**NOTE: Failure to follow the operating instructions above may compromise the performance and safety of the mask.**

## i MASK PARTS

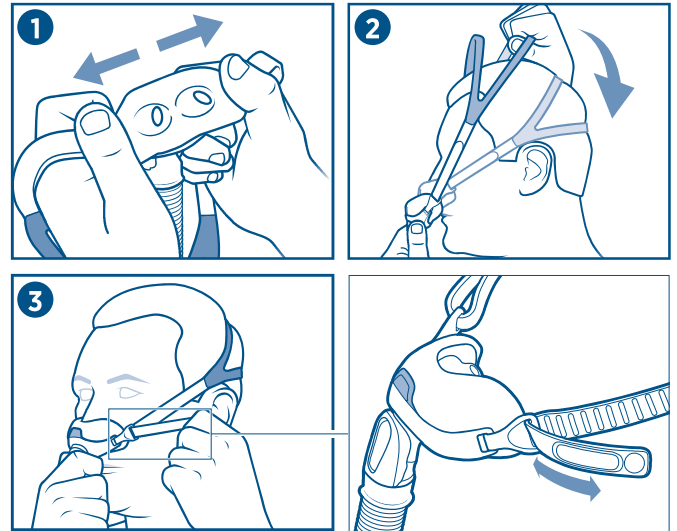
Refer to the mask diagram on the inside cover of this guide.

- |                         |                    |
|-------------------------|--------------------|
| <b>A</b> Silicone Seal  | <b>E</b> Elbow     |
| <b>B</b> Mask Frame     | <b>F</b> Swivel    |
| <b>C</b> Headgear       | <b>G</b> Diffuser  |
| <b>D</b> Headgear Clips | <b>H</b> Mask Tube |

**Note:** The Elbow **E** and Mask Tube **H** are not intended to be removed from the mask by the home user. If removed unintentionally, refer to technical information page for assembly.

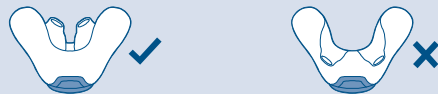
## ii FITTING YOUR MASK

1. Remove all packaging before using your mask.
2. Hold the Silicone Seal **A** away from your nose, use your fingers to carefully spread open the soft side wings of your Silicone Seal **A** and then guide the two openings into your nostrils.
3. Hold the Mask Frame **B** in position with one hand and pull the Headgear **C** over your head with the other hand, positioning the straps above the ears as per the fitting images.
4. Gently tighten or loosen the Headgear straps on the sides of the Headgear **C** until you achieve a comfortable seal.



### Useful fitting tips:

- If you are experiencing any leaks after fitting your mask, you may need to lift the Silicone Seal **A** off your nose and reposition it again so that the two openings on the Silicone Seal **A** fit securely into your nostrils.
- Ensure the mask headgear straps are not fastened too tight.
- Ensure the two silicone openings are not inverted into the Seal **A** and can be placed into each nostril.





### DISASSEMBLY FOR CLEANING

1. Unhook the Headgear Clips **D** from the Mask Frame **B**.
2. Remove the Silicone Seal **A** from the Mask Frame **B**.
3. Unclip the Diffuser **G** from the Elbow **E**.
4. Remove the Swivel **F** from the Mask Tube **H**.



### CLEANING YOUR MASK AT HOME

#### Wash your mask (excluding the Headgear **C** and Diffuser **G**) after each use:

1. Hand-wash your mask in soap dissolved in lukewarm water. Do not soak for more than 10 minutes.
2. Rinse thoroughly with fresh water, ensuring that all soap residue has been removed.
3. Inspect all parts to ensure they are visually clean. If necessary, repeat the cleaning steps until all parts are visually clean.
4. Leave all parts to dry out of direct sunlight before reassembling.

#### Wash your Headgear **C** and Diffuser cover **G** after 7 days of use:

1. Hand-wash your Headgear **C** in soap dissolved in lukewarm water. Do not soak your Headgear for more than 10 minutes.
2. Gently hand wash the Diffuser **G** in soap dissolved in lukewarm water, avoid scrubbing the material. Do not soak for more than 10 minutes.
3. Rinse thoroughly with fresh water, ensuring that all soap residue has been removed.
4. Inspect all parts to ensure they are visually clean. If necessary, repeat the cleaning steps until all parts are visually clean.
5. Leave all parts to dry out of direct sunlight before reassembling.



#### Cleaning Cautions:

- Do not clean your mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.
- Do not clean your mask in a dishwasher.
- Do not store your mask in direct sunlight.

**The above actions may deteriorate or damage the mask and shorten its life. If there is any visible deterioration do not use your mask and seek replacement part(s).**

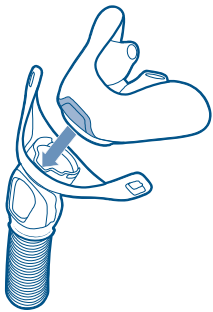
## V MASK ASSEMBLY

1. Push the Silicone Seal **A** onto the Mask Frame **B** in the orientation shown in the below image until a confirmation click is heard.
2. Attach the Headgear Clips **D** on the Headgear **C** to the Mask Frame **B**.
3. Attach the Diffuser **G** to the Elbow **E**.
4. Push the Swivel **F** onto the Mask tube.

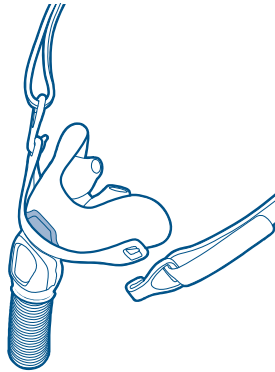
### Mask Assembly Tip:

- Check the Swivel **F** is not stuck in the CPAP tube.

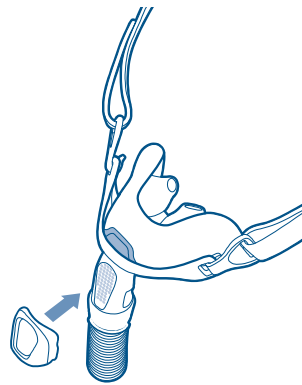
1



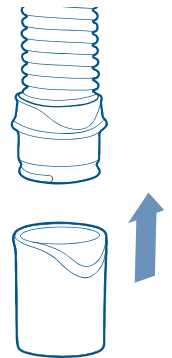
2



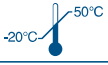
3



4



## SYMBOL DEFINITIONS

|                                                                                          |                                                  |
|------------------------------------------------------------------------------------------|--------------------------------------------------|
|         | Catalogue number                                 |
|         | Manufacturer                                     |
|         | Authorized European Representative               |
|         | Batch code                                       |
|          | Temperature limitation                           |
|         | Date of manufacture                              |
|        | Consult instructions for use                     |
|       | Caution                                          |
|  0123 | Conforms with medical device directive 93/42/EEC |
| <b>Rx only</b>                                                                           | Prescription only                                |
|       | Extra small to small seal                        |
|       | Medium to large seal                             |

## OXYGEN/PRESSURE PORT CONNECTOR

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available (REF 900HC452). Please contact your healthcare provider.

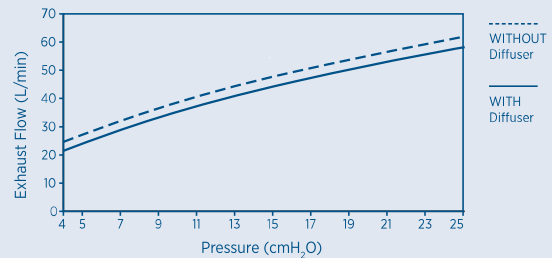
## TECHNICAL SPECIFICATIONS

## F&amp;P BREVIDA EXHAUST FLOW

The F&P Brevida Nasal Pillows Mask has a unique Diffuser that is designed to diffuse air that is expelled from the mask. This reduces the draft. The Diffuser does not significantly change the amount of air flowing from the mask, therefore the mask can be used with or without the Diffuser.

| Pressure (cmH <sub>2</sub> O) | 4  | 5  | 7  | 9  | 11 | 13 | 15 | 17 | 19 | 21 | 23 | 25 |
|-------------------------------|----|----|----|----|----|----|----|----|----|----|----|----|
| Flow with Diffuser (L/min)    | 21 | 24 | 29 | 33 | 37 | 41 | 44 | 47 | 50 | 53 | 56 | 58 |
| Flow without Diffuser (L/min) | 25 | 27 | 32 | 37 | 41 | 44 | 48 | 51 | 54 | 56 | 59 | 62 |

Due to manufacturing variations, the exhaust flow rates may vary from the nominal values shown above.



## RESISTANCE TO FLOW

Pressure drop through XS-S mask with Diffuser @ 50 L/min: 1.7cmH<sub>2</sub>O ± 10%  
 Pressure drop through M-L mask with Diffuser @ 50 L/min: 1.0cmH<sub>2</sub>O ± 10%  
 Pressure drop through XS-S mask with Diffuser @ 100 L/min: 6.3cmH<sub>2</sub>O ± 11%  
 Pressure drop through M-L mask with Diffuser @ 100 L/min: 3.8cmH<sub>2</sub>O ± 11%

## MASK DEAD SPACE

XS-S: 29 cc

M-L: 33 cc

## SOUND

The sound power level of mask with Diffuser is 25.4 dBA, with uncertainty 2.5 dBA.  
 The sound pressure level of the mask with Diffuser is 17.5 dBA, with uncertainty 2.5 dBA.  
 The sound power level of mask without Diffuser is 30.6 dBA, with uncertainty 2.5 dBA.  
 The sound pressure level of the mask without Diffuser is 22.6 dBA, with uncertainty 2.5 dBA.

The F&P Brevida Nasal Pillows Mask and accessories are not made with natural rubber latex.

For single patient reuse, the mask should be replaced no later than 12 months after the date of first use. If any visible deterioration of a mask system component is apparent (for example cracking, discoloration, or seal tears), the component should be discarded and replaced.

MULTI-PATIENT CLEANING INSTRUCTIONS

For the USA only, BREISA, BREIMA and BREISMA are single patient use only, therefore multi-patient cleaning instructions do not apply.

Your F&P Brevida Nasal Pillows Mask is provided patient-ready.

To reuse between patients please follow the guidelines below or see the Fisher & Paykel Healthcare website: [www.fphcare.com/disinfection](http://www.fphcare.com/disinfection)

If you do not have Internet access, please contact your Fisher & Paykel Healthcare representative.

HEADGEAR (C AND D)

1. Hand-wash the Headgear (C and D) in soap dissolved in lukewarm water. Air-dry out of direct sunlight.

DIFFUSER (G)

2. The Diffuser (G) is for single patient use. Replace between patients.

ALL OTHER PARTS

3. Soak all reprocessable parts of the mask in a solution of mildly alkali, anionic detergent e.g. Alconox according to the manufacturer's instructions (at 1% concentration and 50°C for 10mins), ensuring that no air bubbles are present on the device surface. Using a soft non-metallic brush (e.g. medium-hard toothbrush)", vigorously brush the mask parts until visibly clean but not for less than 10 seconds. Pay close attention to crevices and cannulations, such as the join between the silicone seal and plastic housing and the socket between the elbow and frame, and elbow and tube. Rinse by submerging in 5 litres of demineralised water and agitating for at least 10 seconds. Repeat rinse.  
*\*An additional thin bottle brush is required to access the inside of the Brevida Nasal Pillows Mask tube.*

| 4. HIGH-LEVEL THERMAL DISINFECTION                                     | HIGH-LEVEL CHEMICAL DISINFECTION                                                                                                                                                                                | STERILIZATION                                                                                                                  |
|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Pasteurize at 75 °C for 30 mins, 80 °C for 10 mins or 90 °C for 1 min. | CIDEX OPA/METRICIDE OPA PLUS/RAPICIDE OPA/28: Immerse at 20 °C (68 °F) for 12 minutes then rinse thoroughly according to the manufacturer's rinsing instructions.<br>(Replace seal. Replace tube if discolours) | Utilize a STERRAD NX, 100S or 100NX Sterilization System according to the manufacturer's instructions, using the pouch method. |

Before each use, inspect the mask for deterioration. If any visible deterioration of a mask component is apparent, the mask component discarded and replaced. Some discolouration may occur after reprocessing and is acceptable.

To ensure traceability, mask components belonging to an individual mask must be reassembled back into the same mask after cleaning.

The F&P Brevida Nasal Pillows Mask has been validated to withstand 20 cycles of the above parameters. Failure to properly clean this device may result in inadequate disinfection. Fisher & Paykel Healthcare does not recommend any deviations from the recommended method of reprocessing.

ADVANCED DISASSEMBLY/ASSEMBLY

Please refer to the diagrams at the back of this guide.

- To disassemble Mask Tube (H) from Elbow (E):**  
Pull the rigid connection on the Mask Tube (H) down from the bottom of the Elbow (E) until it disconnects.
- To assemble Mask Tube (H) onto Elbow (E):**  
Push the rigid connection on the Mask Tube (H) onto from the bottom of the Elbow (E) until it clicks into position.
- To disassemble Elbow (E) from Mask Frame (B):**
  - Hold the Mask Frame (B) securely with one hand and position the Elbow (E) in its upright orientation.
  - Pull the bottom of the Elbow (E) upward from the Mask Frame (B) until it dislodges completely.
- To assemble Elbow (E) onto Mask Frame (B):**
  - Hold the Mask Frame (B) securely with one hand and position the top surface of the Elbow (E) ball inside the top edge of the Mask Frame (B) socket.
  - Apply downward pressure on the Elbow (E) until the bottom surface of the Elbow (E) enters the socket.
  - Ensure the Elbow (E) can rotate freely once inserted.

**禁忌症**

尚不明确

**警告**

- 本鼻罩仅应临床医生或呼吸治疗师推荐且经认可的 CPAP 或 Bi-Level 呼吸机配套使用。只有在 CPAP 或 Bi-Level 呼吸机已打开且正常工作的情况下才能使用本鼻罩。切勿堵塞鼻罩的排气孔。
- **警告说明：**CPAP 或 Bi-Level 呼吸机需配合特殊的鼻罩使用，即带有排气孔以确保气流持续排出。
  - i. 打开呼吸机（已连接鼻罩）：当 CPAP 或 Bi-Level 呼吸机开启并正常工作时，CPAP 或 Bi-Level 呼吸机中的新鲜空气会将呼出气体通过鼻罩的排气孔吹出。
  - ii. 关闭呼吸机（已连接鼻罩）：当 CPAP 或 Bi-Level 呼吸机关闭后，就没有足够的新鲜空气通过鼻罩，呼出的气体会被重复吸入。在特定环境下重复吸入呼出气体数分钟即可造成窒息。
- 过低的 CPAP 或双水平 Bi-Level 压力使通过通气口的气流压力无法将管路内的呼出气体完全排出，这可能会发生呼出气体的重复吸入。
- 如果出现下列情况，请停止使用，并咨询您的医疗服务提供者或医生：
  - i. 鼻罩不适或者有刺激感
  - ii. 过敏反应
- 如果呕吐或感觉恶心，请勿使用鼻罩。
- 使用氧气：使用 CPAP 或 Bi-Level 呼吸机时，如果机器不能正常工作，必须关闭氧气气源。如果 CPAP 或 Bi-Level 呼吸机内积聚氧气，会有发生火灾的危险。您在经鼻罩吸氧时，不可以吸烟，也不能靠近吸烟的人。
- 只能使用费雪派克 F&P Brevida 扩散器备件。
- 每次使用前确保扩散器已彻底干燥。
- 为保持良好的卫生，请始终遵循清洁说明，使用温和的肥皂水进行清洁。某些清洁产品可能会对鼻罩及其部件和功能造成损伤；如果冲洗不够彻底，残留的有害蒸气可能被患者吸入体内。

**注意事项**

- 本鼻罩仅适用于本指南所描述的用途。
- 如果鼻罩系统的组件有任何明显可见的老化（例如，破裂、脱色、开裂等），则应丢弃该组件并进行更换。

**注意事项**

由于鼻垫式鼻罩的弹性和柔软性，鼻罩佩戴不当会导致其压到鼻子下方的皮肤上，从而堵塞鼻罩通气孔，并使 CPAP 效果降低。

**保修声明**

费雪派克医疗保健公司 (Fisher & Paykel Healthcare) 保证：自终端用户购买之日起 90 天内，按照使用说明使用鼻罩（不含泡沫和材料扩散器），不会出现工艺和材料缺陷，且能够按照费雪派克医疗保健公司 (Fisher & Paykel Healthcare) 正式出版的产品规范中所述的那样正常工作。本保修受以下系列的限制和例外的制约：[www.fphcare.com/sleep-apnea/masks/warranty-mask/](http://www.fphcare.com/sleep-apnea/masks/warranty-mask/)

**处置**

本鼻罩不含任何有害物质，可以当作一般垃圾处置。

**设计用途**

F&P Brevida 鼻枕式面罩提供给被医生诊断需要连续气道正压或双期正压治疗的患者个人使用。F&P Brevida 鼻枕式面罩可由单个成年患者 (≥30 kg (66 lbs)) 在自己家中使用，也可由多位成年患者在医院或其他医疗环境下使用。多位成年患者间使用时需对面罩进行适当消毒。

**操作说明**

- 面罩的操作压力范围是 4 至 25 cmH<sub>2</sub>O。
- 面罩的操作温度范围是 5 至 40 °C ( 41 至 104 °F )。
- 每次使用面罩前，您应：
  - i. 检查面罩是否损坏或老化。若有任何外观损坏（裂纹、撕裂等），请勿使用该面罩并让您的医疗保健提供者提供更换零件。
  - ii. 检查弯头  上的排气孔。确保空气能够通过这些孔，如有堵塞，请勿使用。
  - iii. 确保面罩的空气路径无阻碍呼吸的异物。

**注意：不遵照上述操作说明可能有损面罩的安全及效能。**

## i 面罩零件

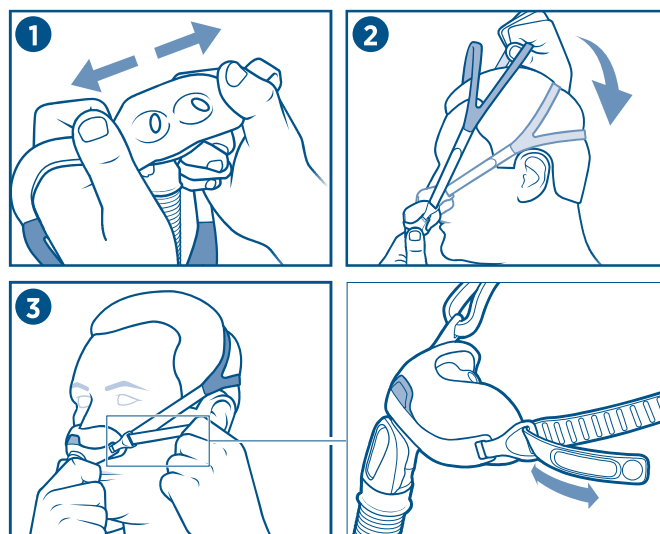
請參考本指南內頁的面罩圖表。

- |                |               |
|----------------|---------------|
| <b>A</b> 矽膠密封圈 | <b>E</b> 彎頭   |
| <b>B</b> 面罩框架  | <b>F</b> 旋轉接頭 |
| <b>C</b> 頭套    | <b>G</b> 擴散器  |
| <b>D</b> 頭套帶扣  | <b>H</b> 面罩管  |

**注意：**在家使用面罩者不得從面罩上取下彎頭 **E** 和面罩管 **H**。若不小心取下，請參考技術資訊頁面進行組合。

## ii 佩戴面罩

1. 使用面罩前，請移除所有包裝。
2. 將面罩的矽膠密封圈 **A** 拿離您的鼻子，用手指小心張開矽膠密封圈 **A** 的兩側軟翼，然後引導兩個開口插入到您的鼻孔內。
3. 用一隻手將面罩框架 **B** 放在適當的位置，另一隻手將頭套 **C** 拉過頭部，按照佩戴圖將固定帶置於耳朵上方。
4. 輕輕拉緊或放鬆頭套 **C** 側面的頭套帶，直到取得舒適的貼合。



### 有用的佩戴訣竅：

- 若面罩佩戴好後發生洩漏，應將矽膠密封圈 **A** 拿離您的鼻子，然後重新放置，使矽膠密封圈 **A** 上的兩個開口穩固地貼在您的鼻孔上。
- 確保面罩頭套帶沒有綁束太緊。
- 確保兩個矽膠開口未凹入密封圈 **A** 且可以分別放入鼻孔。



### iii 拆卸與清潔

1. 從面罩框架 **B** 上解開頭套帶扣 **D**。
2. 從面罩框架 **B** 上拆下矽膠密封圈 **A**。
3. 從彎頭 **E** 上鬆開擴散器 **G**。
4. 從面罩管 **H** 上拆下旋轉接頭 **F**。

### iv 在家中清潔面罩

每次使用後應清洗面罩（頭套 **C** 和擴散器 **G** 除外）：

1. 將面罩放在溫肥皂水中用手清洗。浸泡的時間不要超過 10 分鐘。
2. 用清水徹底沖洗，確保無殘留的肥皂水。
3. 檢查所有部件，確保其目視為清潔。如有需要，重複清潔步驟，直到所有部件目視為清潔。
4. 在重新組合前，避開陽光直射，將所有零件風乾。

使用 7 天後應清洗頭套 **C** 和擴散器封蓋 **G**：

1. 將頭套 **C** 放在溫肥皂水中用手清洗。頭套浸泡的時間不要超過 10 分鐘。
2. 在溫肥皂水中用手輕輕清洗擴散器 **G**，避免擦洗材料。浸泡的時間不要超過 10 分鐘。
3. 用清水徹底沖洗，確保無殘留的肥皂水。
4. 檢查所有部件，確保其目視為清潔。如有需要，重複清潔步驟，直到所有部件目視為清潔。
5. 在重新組合前，避開陽光直射，將所有零件風乾。

#### ⚠ 清潔注意事項：

- 不要用含酒精、殺菌劑、防腐劑、漂白劑、氯或保濕劑的產品清潔面罩。
- 不要把面罩放在洗碗機中清潔。
- 不要將面罩存放在有陽光直射的地方。

上述行動會使面罩老化或損壞，縮短其使用壽命。若有任何外觀損壞，請勿使用面罩並設法更換零件。

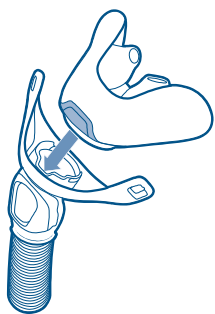
## V 面罩的組合

1. 將矽膠密封圈 **A** 以下圖所示方向推入到面罩框架 **B** 上，直到聽見「卡嗒」一聲，確認安裝到位。
2. 將頭套 **C** 上的頭套帶扣 **D** 連接到面罩框架 **B**。
3. 將擴散器 **G** 連接到彎頭 **E**。
4. 將旋轉接頭 **F** 推入面罩管。

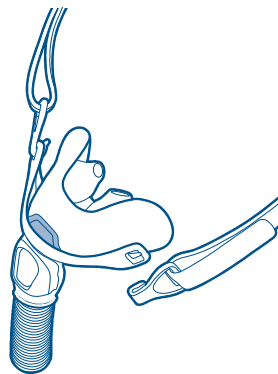
### 面罩組合訣竅：

- 確認旋轉接頭 **F** 未插入連續氣道正壓管路。

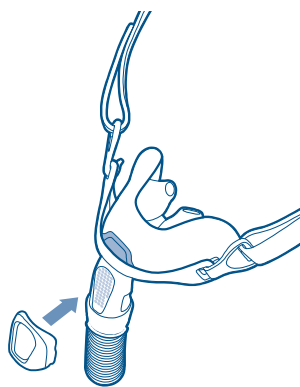
1



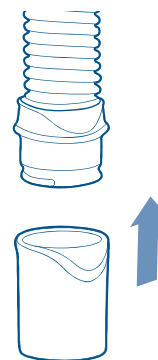
2



3



4



## 符號定義

|                |                    |
|----------------|--------------------|
|                | 目錄編號               |
|                | 製造商                |
|                | 授權歐盟代表             |
|                | 批次代碼               |
|                | 溫度限制               |
|                | 製造日期               |
|                | 參閱使用說明             |
|                | 注意事項               |
|                | 符合醫療裝置指令 93/42/EEC |
| <b>Rx only</b> | 僅限處方使用             |
|                | 極小號至小號密封圈          |
|                | 中號至大號密封圈           |

## 氧氣/壓力埠口連接頭

如需測量壓力和/或加入額外的氧氣，可使用氧氣/壓力埠口連接頭（零件編號 900HC452）。請聯絡您的醫療保健提供者。

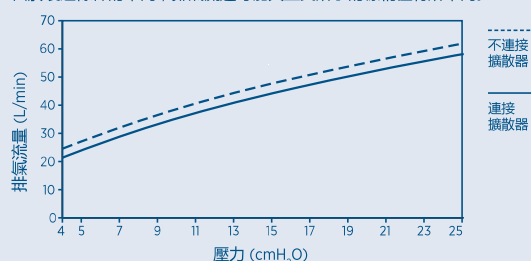
## 技術規格

## F&amp;P BREVIDA 排氣流量

F&P Brevida 鼻枕式面罩有一種獨特的擴散器，該擴散器用於擴散由面罩排出的空氣。此設置可減緩氣流。擴散器並不會明顯改變從面罩排出的呼氣流量，因此面罩在有或沒有擴散器的情況下都可以使用。

| 壓力 (cmH <sub>2</sub> O) | 4  | 5  | 7  | 9  | 11 | 13 | 15 | 17 | 19 | 21 | 23 | 25 |
|-------------------------|----|----|----|----|----|----|----|----|----|----|----|----|
| 連接擴散器時的流量 (L/min)       | 21 | 24 | 29 | 33 | 37 | 41 | 44 | 47 | 50 | 53 | 56 | 58 |
| 不連接擴散器時的流量 (L/min)      | 25 | 27 | 32 | 37 | 41 | 44 | 48 | 51 | 54 | 56 | 59 | 62 |

由於製造條件的不同，排氣流速可能與上文所示的標稱值有所不同。



## 氣流阻力

在 50 L/min 的流量下，連接擴散器時流經 XS-S 面罩的壓降為：1.7 cmH<sub>2</sub>O ± 10%  
 在 50 L/min 的流量下，連接擴散器時流經 M-L 面罩的壓降為：1.0 cmH<sub>2</sub>O ± 10%  
 在 100 L/min 的流量下，連接擴散器時流經 XS-S 面罩的壓降為：6.3 cmH<sub>2</sub>O ± 11%  
 在 100 L/min 的流量下，連接擴散器時流經 M-L 面罩的壓降為：3.8 cmH<sub>2</sub>O ± 11%

## 面罩死腔

XS-S：29 cc

M-L：33 cc

## 聲音

連接擴散器時面罩的聲音功率位準為 25.4 dBA，正負誤差為 2.5 dBA。  
 連接擴散器時面罩的音壓位準為 17.5 dBA，正負誤差為 2.5 dBA。  
 不連接擴散器時面罩的聲音功率位準為 30.6 dBA，正負誤差為 2.5 dBA。  
 不連接擴散器時面罩的音壓位準為 22.6 dBA，正負誤差為 2.5 dBA。

F&P Brevida 鼻枕式面罩及其配件不是由天然乳膠所製成。

對於重複使用的單一患者，應在從第一天使用時起不超過 12 個月內更換面罩。若發現面罩組件有任何明顯的老化（例如，裂紋、褪色或密封圈撕裂），應該將面罩組件丟棄並更換。

### 多個病患使用清潔說明

您的 F&P Brevida 鼻枕式面罩買來即可使用。

若在不同患者間重複使用，請遵照下列指示或參見 Fisher & Paykel Healthcare 網站：  
www.fphcare.com/disinfection

如果您無法連線至網際網路，請聯絡 Fisher & Paykel Healthcare 代表洽詢。

#### 頭套 (C 和 D)

1. 將頭套 (C 和 D) 放在溫肥皂水中用手清洗。自然風乾，避免陽光直射。

#### 擴散器 (G)

2. 擴散器 (G) 僅供單一患者使用。不同患者間使用時應予以更換。

#### 所有其他零件

3. 按照製造商的說明，將面罩所有可再處理的零件浸泡在溫和的鹼性陰離子清潔劑中，例如 Alconox (濃度 1%，溫度 50 °C，持續 10 分鐘)，確保裝置表面不存在氣泡。使用柔軟的非金屬刷 (例如中等硬度的牙刷) \*大力刷洗面罩組件直至其明顯清潔為止，但時間不得低於 10 秒鐘。請注意有無裂縫和穿刺 (例如，矽膠密封圈與塑料外殼之間的連接處以及彎頭與框架、彎頭與管之間的凹槽)。浸入 5 公升去礦物質水並攪拌至少 10 秒鐘。重複沖洗。  
\*需要額外的細瓶刷才能刷洗到 Brevida 鼻枕式面罩的管內部。

| 4. 高標準高溫消毒                                                          | 高標準化學消毒                                                                                                                          | 滅菌                                                             |
|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| 在 75 °C 下加熱殺菌 30 分鐘、<br>在 80 °C 下加熱殺菌 10 分鐘或<br>在 90 °C 下加熱殺菌 1 分鐘。 | CIDEX OPA/METRICIDE OPA<br>PLUS/RAPICIDE OPA/28：在<br>20 °C (68 °F) 下浸泡 12 分鐘，<br>然後根據製造商的沖洗指示徹<br>底地沖洗。<br>(更換密封圈。如果褪色，<br>則更換管) | 依據製造商的指示，<br>使用消毒袋的方法，<br>使用 STERRAD NX、<br>100S 或 100NX 滅菌系統。 |

在每次使用前，檢查面罩是否劣化。若發現面罩組件有任何明顯的老化，應該將面罩組件丟棄並更換。  
在清潔消毒後會出現褪色的現象，並無影響。

為確保可追溯性，必須在清潔後將屬於各個面罩的面罩組件重新組裝回相同的面罩中。

F&P Brevida 鼻枕式面罩已通過驗證可承受以上參數之 20 次消毒循環。本裝置若清洗不當將導致消毒不徹底。Fisher & Paykel Healthcare 不建議對所推薦的再處理方法進行任何改動。

### 高階拆卸/組合

請參考本指南背面的圖表。

1. **要從彎頭 (E) 上卸下面罩管 (H)：**  
將面罩管 (H) 上的剛性連接體從彎頭 (E) 的底部向下拉，直至脫離。
2. **要將面罩管 (H) 組合到彎頭 (E) 上：**  
將面罩管 (H) 上的堅硬的連接體從彎頭 (E) 的底部推入，直至其卡入到位。
3. **從面罩框架 (B) 上卸下彎頭 (E)：**
  - 用一隻手將面罩框架 (B) 持穩，然後將彎頭 (E) 置於其豎直方向。
  - 將彎頭 (E) 的底部從面罩框架 (B) 向上拉，直至其完全移出。
4. **要將彎頭 (E) 組合到面罩框架 (B) 上：**
  - 用一隻手將面罩框架 (B) 持穩，然後將球窩式彎頭 (E) 的上表面置於面罩框架 (B) 插座的頂邊緣內。
  - 下壓彎頭 (E)，直至彎頭 (E) 的下表面進入插座。
  - 確保彎頭 (E) 在插入後可自由旋轉。