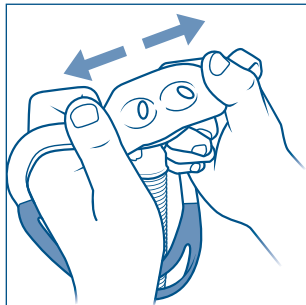
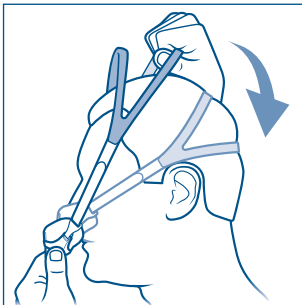


FITTING YOUR MASK

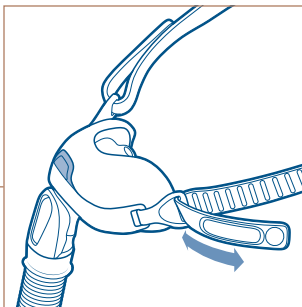
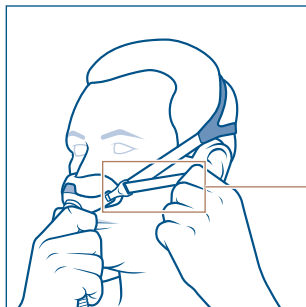
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2



3



F&P Brevida™

NASAL PILLOWS MASK

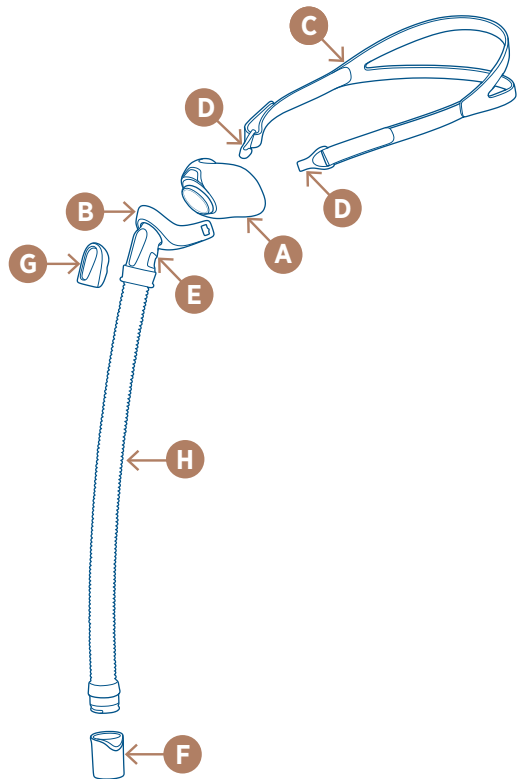
Use and Care Guide



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)
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73	繁體中文版 (Traditional Chinese)
85	한국어 (Korean)
97	日本語 (Japanese)

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INTENDED USE

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 (≥ 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 cmH₂O.
- 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

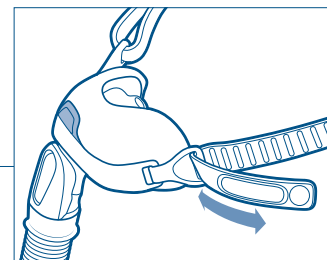
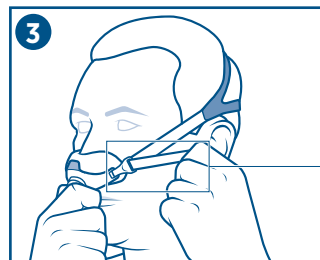
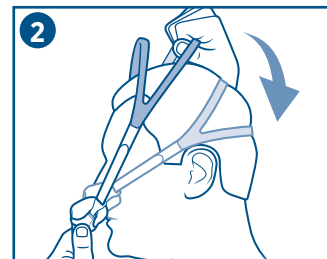
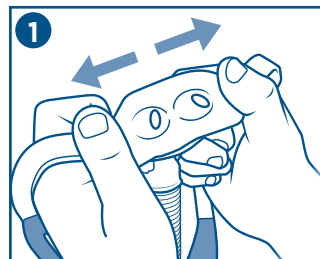
Refer to the mask diagram on the inside cover of this guide.

- | | |
|-------------------------|--------------------|
| A Silicone Seal | E Elbow |
| B Mask Frame | F Swivel |
| C Headgear | G Diffuser |
| D Headgear Clips | H 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.

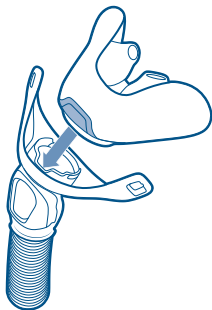
The above actions may deteriorate or damage the mask and shorten its life. If there is any visible deterioration do not use your mask and seek replacement part(s).

V

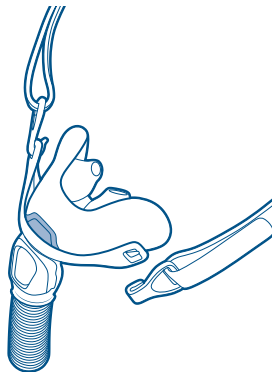
MASK ASSEMBLY

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.

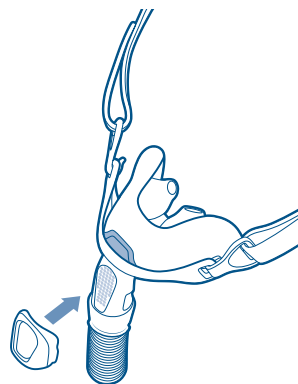
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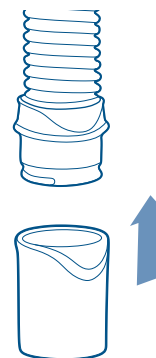
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**Mask Assembly Tip:**

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

SYMBOL DEFINITIONS



Catalogue number



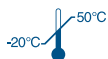
Manufacturer



Authorized European Representative



Batch code



Temperature limitation



Date of manufacture



Consult instructions for use



Caution



Conforms with medical device directive 93/42/EEC

Rx only

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.

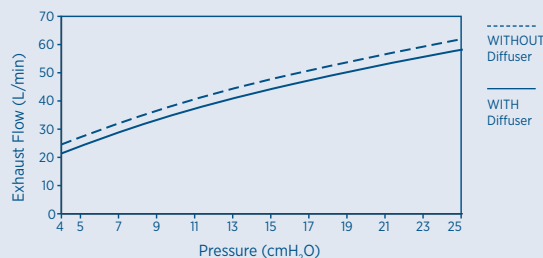
TECHNICAL SPECIFICATIONS

F&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 ₂ 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: 1.7cmH₂O ± 10%
 Pressure drop through M-L mask with Diffuser @ 50 L/min: 1.0cmH₂O ± 10%
 Pressure drop through XS-S mask with Diffuser @ 100 L/min: 6.3cmH₂O ± 11%
 Pressure drop through M-L mask with Diffuser @ 100 L/min: 3.8cmH₂O ± 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

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. (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.

- 1 **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.
- 2 **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.
- 3 **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.
- 4 **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.

CONTRAINDICATION

None known.



WARNINGS

- Your mask should only be used with approved CPAP or Bi-Level equipment recommended by your physician or respiratory therapist. Your mask should not be used unless the CPAP or Bi-Level machine is turned on and operating properly. The exhaust holes 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 exhaust holes to allow continuous flow of air out of the mask.
 - i. Device switched on (with mask connected): 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 mask's exhaust holes.
 - ii. Device switched off (with mask connected): When the CPAP or Bi-Level machine is turned off, not enough fresh air will be provided through the mask, and exhaled air may be re-breathed. Re-breathing of exhaled air for longer than several minutes can lead to suffocation in some circumstances.
- At low CPAP or Bi-Level pressures the flow through the exhaust holes may be inadequate to clear all exhaled gas from the tubing. Some re-breathing of exhaled air may occur.
- Discontinue use and consult your healthcare provider or physician if the following occurs:
 - i. Mask discomfort or irritation
 - ii. Allergic reaction
- Do not use if vomiting or feeling nauseous.
- Mask use with oxygen: With your CPAP or Bi-Level machine, the oxygen flow must be turned off when the CPAP or Bi-Level machine is not operating. Oxygen accumulated in your CPAP or Bi-Level machine enclosure will create a risk of fire. You should not smoke or be in the vicinity of someone smoking while using oxygen with your mask.
- Only use F&P Brevida Diffuser spare parts.
- Ensure the diffuser is completely dry before each use.
- As part of good hygiene, always follow cleaning instructions and use mild soap. Some cleaning products may damage the mask, its parts and their function, or leave harmful residual vapors that could be inhaled if not rinsed thoroughly.
- California residents please be advised of the following, pursuant to Proposition 65: This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm. For more information, please visit www.fphcare.com/prop65



CAUTIONS

- Use your mask only for its intended use as directed in this guide.
- If any visible deterioration of a system component is apparent (cracking, discoloration, tears etc.), the component should be discarded and replaced.

PRECAUTION

Due to the flexibility and softness of the nasal pillows, positioning of the pillows incorrectly could lead to compression of the pillows against the skin below the nose, thus blocking the holes of the pillows and leading to a reduction in CPAP efficacy.

WARRANTY STATEMENT

Fisher & Paykel Healthcare warrants that the mask (excluding foams and material diffusers), when used in accordance with its instructions for use, shall be free from defects in workmanship and materials and will perform in accordance with Fisher & Paykel Healthcare's official published product specifications for a period of 90 days from the date of purchase by the end user. This warranty is subject to the limitations and exceptions set out in detail in www.fphcare.com/sleep-apnea/masks/warranty-mask/

DISPOSAL

Your mask does not contain any hazardous material and may be disposed of with general waste.

PATENT INFORMATION

For patent information, see <https://www.fphcare.com/ip>

DOMAINE D'UTILISATION

Le masque nasal à coussins d'air F&P Brevida est destiné aux personnes dont le diagnostic médical nécessite un traitement par PPC ou par ventilation à deux niveaux de pression (VNPD). Le masque nasal à coussins d'air F&P Brevida est conçu pour une utilisation à domicile pour un patient adulte unique (≥ 30 kg (66 lbs)) ou pour une utilisation multiple sur des patients adultes en milieu hospitalier ou dans tout autre environnement clinique où il est possible de le désinfecter correctement entre chaque patient.

MODE D'EMPLOI

- La pression de fonctionnement du masque est comprise entre 4 et 25 cmH₂O.
- La température de fonctionnement du masque est comprise entre 5 et 40 °C (41 et 104 °F).
- Avant toute utilisation du masque, vous devez :
 - i. Rechercher tout signe de dommage ou de détérioration. S'il existe une quelconque détérioration visible (fissures, déchirures, etc.), ne pas utiliser le masque et se procurer une ou des pièce(s) de rechange auprès de son prestataire de soins.
 - ii. Inspecter les orifices de sortie sur le coude **E**. Vérifier le passage de l'air au travers de ces orifices et ne pas utiliser le masque en cas d'obstruction.
 - iii. Vérifier que le trajet de l'air dans le masque est exempt d'objets susceptibles d'empêcher la respiration.

REMARQUE : si ce mode d'emploi n'est pas respecté, les performances et la sécurité du masque peuvent en être compromises.