



# FULL FACE MASK

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## Use and Care Guide





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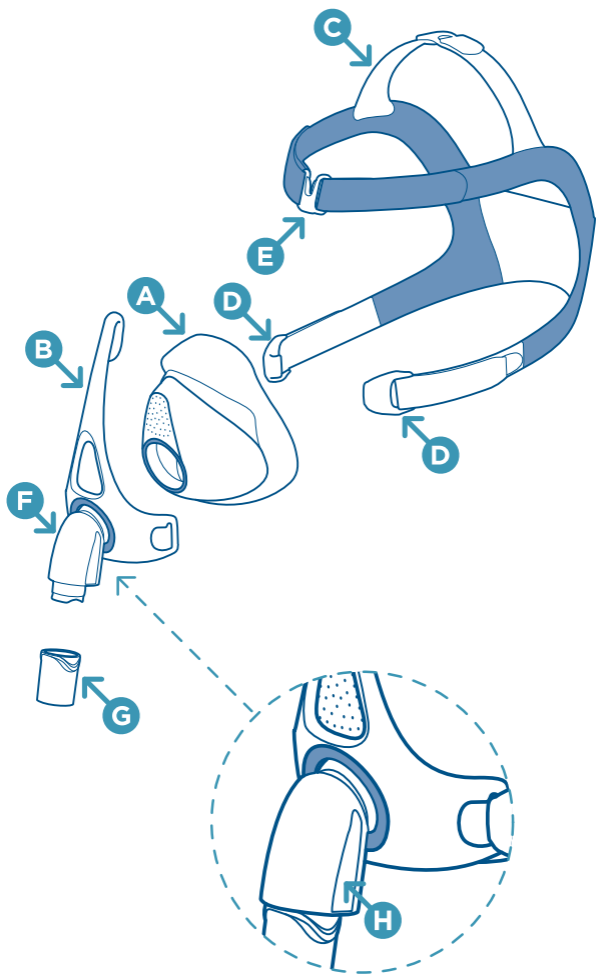
**Thank you for choosing  
your F&P Vitera.**

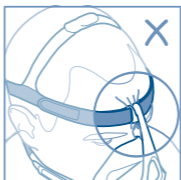
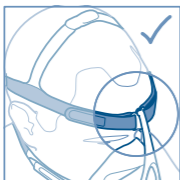
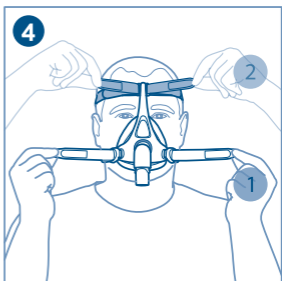
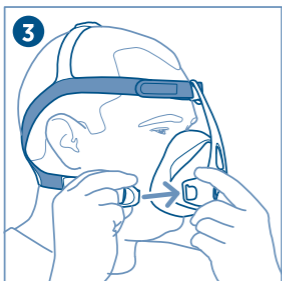
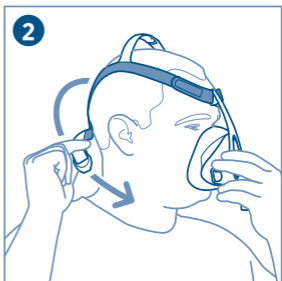
**This Full Face mask has been designed to make it easier for you to fit CPAP therapy into your life. This is your mask Use and Care Guide. Please read this entire guide before you first use your mask. Following the steps in this guide, and referring to the images and diagrams will assist you with assembly,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

# LANGUAGES

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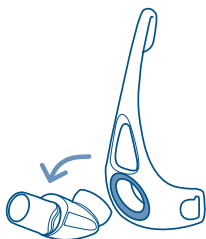
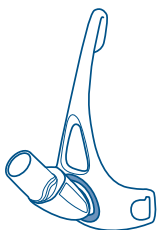
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or +1 949 453 4000  
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Rx only  0123

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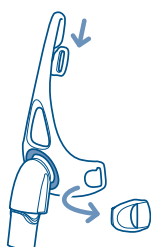
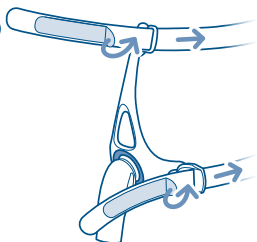
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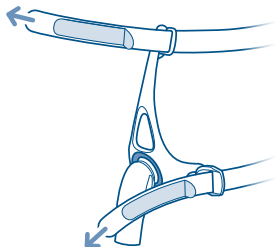
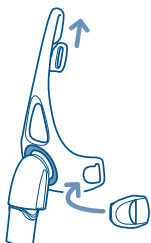
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## INTENDED USE

The F&P Vitera Full Face mask is intended to be used by adults weighing  $\geq 66$ lbs (30kgs) who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Vitera Full Face mask is intended for single patient use in the home and for multiple patient 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 30 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 Seal **A**. 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.
  - iv. Ensure Elbow Side Vents **H** are not blocked.

**Note:** Please refer to the Warnings and Cautions  within this guide. 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 front cover of this guide.

- |                         |                           |
|-------------------------|---------------------------|
| <b>A</b> Seal           | <b>E</b> Forehead Clip    |
| <b>B</b> Frame          | <b>F</b> Elbow            |
| <b>C</b> Headgear       | <b>G</b> Swivel           |
| <b>D</b> Headgear Clips | <b>H</b> Elbow Side Vents |

**Note:** The Elbow **F** is permanently attached to the Frame **B**. It is 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

### Remove all packaging before using your mask.

Refer to the fitting images on the inside front cover of this guide.

1. Hold the front of the mask with one hand and the Headgear **C** with the other. Ensure that one Headgear Clip **D** is unhooked from the Frame **B**.
2. Place the Seal **A** onto your face and guide the Headgear **C** over your head.
3. Hook the unattached Headgear Clip **D** onto the Frame **B**.
4. Gently tighten the Headgear straps of the Headgear **C** starting with the bottom straps, followed by loosely fitting the blue forehead straps.

### Caution

To avoid the risk of suffocation, ensure the headgear is not overtightened. The mask, when fitted correctly, should be able to be pulled away from the mouth without adjusting the headgear straps or disconnecting the Headgear Clips **D**.

### Useful Tips:

- If you are experiencing mask leaks, you may need to lift the Seal **A** off your face and reposition it.
- Ensure the Headgear straps are not fastened too tightly.
- The blue forehead straps should rest horizontally just above the ears. If required, the crown strap can be adjusted to achieve this.
- For easy mask removal, rotate Headgear Clip **D** downward to unhook Headgear **C**.

## iii DISASSEMBLY FOR CLEANING

1. Unhook the Headgear Clips **D** from the Frame **B**.
2. Slide the Forehead Clip **E** downwards towards the Seal **A**.
3. Remove the Seal **A** from the Frame **B**.
4. Remove the Swivel **G** from the Elbow **F**.

## iv CLEANING YOUR MASK AT HOME

### Wash your mask (excluding the Headgear **C**) 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 in 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** after 7 days use:

1. Hand-wash your Headgear **C** in soap dissolved in lukewarm water. Do not soak for more than 10 minutes.
2. Rinse thoroughly in 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.

### Cleaning Cautions:

- It is not necessary to remove the Headgear Clips **D** or the Forehead Clip **E** when cleaning the Headgear **C**.
- Do not remove the Elbow **F** from the Frame **B**. It is not intended to be detachable by the home user.
- Do not pull on or attempt to remove the Silicone Flap from the Elbow **F**, or attempt to disassemble the Elbow **F**. It is not intended to be disassembled.
- 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.
- Do not iron the Headgear **C**.

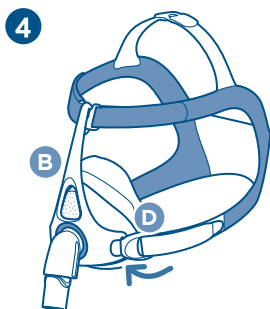
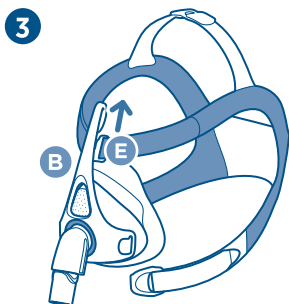
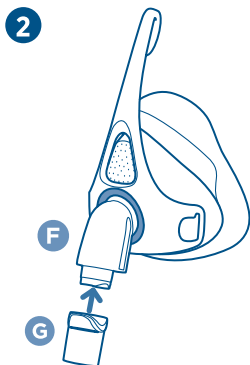
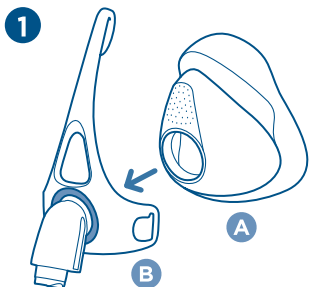
**The above actions may deteriorate or damage the mask and shorten its life. If there is any visible deterioration do not use your mask and seek replacement part(s).**

## V MASK ASSEMBLY

1. Push the Seal **A** firmly into place on the Frame **B**.
2. Push the Swivel **G** onto the Elbow **F**.
3. Slide the Forehead Clip **E** onto the top of the Frame **B**.
4. Hook the Headgear Clips **D** onto the Frame **B**.

### Mask Assembly Tip:

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



## SYMBOL DEFINITIONS

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Catalogue number

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Manufacturer

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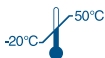
Authorized European Representative

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Batch code

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Temperature limitation

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Date of manufacture

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Consult instructions for use

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Caution

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Conforms with medical device directive 93/42/EEC

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**Rx only**

Prescription only

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Small headgear size

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Medium-Large headgear size

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Small seal size

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Medium seal size

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Large seal size

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Date of shelf life expiry

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**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.

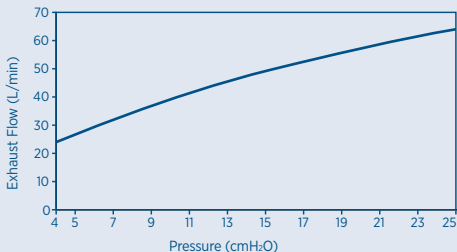
**TECHNICAL SPECIFICATIONS**

The F&P Vitera Full Face mask has exhaust holes to expel the air that you exhale from the mask. It is important that these exhaust holes are not blocked by any object. This controlled leak ensures all exhaled CO<sub>2</sub> is expelled from the mask.

**F&P VITERA EXHAUST FLOW INFORMATION**

Pressure (cmH <sub>2</sub> O)	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Flow (L/min)	24	28	32	36	40	43	47	50	53	55	58	60	62	64

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

**RESISTANCE TO FLOW**

Pressure drop through mask at 50 L/min: 0.24±0.15 cmH<sub>2</sub>O

Pressure drop through mask at 100 L/min: 0.47±0.15 cmH<sub>2</sub>O

**INSPIRATORY AND EXPIRATORY RESISTANCE**

Inspiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 1.05±0.15 cmH<sub>2</sub>O

Expiratory resistance of the mask (in combination with the Non-Rebreathing Valve) is 0.80±0.15 cmH<sub>2</sub>O

The opening to atmosphere pressure of the Non-Rebreathing Valve is <0.56 cmH<sub>2</sub>O

The closing to atmosphere pressure of the Non-Rebreathing Valve is <2.16 cmH<sub>2</sub>O

**MASK DEAD SPACE**

Small = 246 cc

Medium = 271 cc

Large = 322 cc

**SOUND**

The sound power level of mask is 29.8 dBA, with uncertainty 2.5 dBA

The sound pressure level of the mask is 21.8 dBA, with uncertainty 2.5 dBA

**ADDITIONAL INFORMATION**

The F&P Vitera Full Face mask and accessories are not made with natural rubber latex or DEHP.

For single patient reuse, the mask should be replaced no later than 12 months after the date of first use.

Store dry mask in clean conditions out of direct sunlight. Storage temperature: -20 to 50°C (-4 to 122°F)

**MULTIPATIENT REPROCESSING INSTRUCTIONS**

**Your F&P Vitera Full Face mask is provided patient-ready.**

To reuse between patients please follow the guidelines below or visit [www.fphcare.com/disinfection](http://www.fphcare.com/disinfection).

If you do not have internet access, please contact your F&P Healthcare representative.

At point of use, remove any gross soiling on the mask by wiping or rinsing in potable water.

## MANUAL CLEANING

Disassemble the mask according to the Disassembly for Cleaning instructions **(iii)** and the advanced instructions below. Soak all reprocessible 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, cavities and corners. Rinse by submerging in 5 litres of demineralised water and agitating for at least 10 seconds. Repeat rinse. Ensure mask components are air-dried thoroughly before continuing.

## HIGH-LEVEL DISINFECTION/STERILIZATION

To disinfect the F&P Vitera Full Face mask use one of the methods outlined in the table below:

	Thermal Soak in a water bath or run a disinfection cycle in an automatic washer-disinfector using the time/temperature combinations below.	Cidex OPA	Sterilization
Seal	75°C (167°F) – 30 min 80°C (176°F) – 10 min 90°C (194°F) – 1 min	–	–
Frame		–	–
Swivel		–	–
Headgear*/Headgear Clips*/ Forehead Clip*	–	–	–
Elbow*	–	–	–

\* Please replace these components between patients.

Air dry the mask out of direct sunlight. Before each use, inspect the mask for deterioration. If any visible deterioration of a mask component is apparent, it should be discarded and replaced immediately.

Reassemble the mask according to the Mask Assembly instructions **(v)** and the advanced instructions below. To ensure traceability, mask components belonging to an individual mask must be reassembled back into the same mask after cleaning, excluding components requiring replacement as marked in the table above.

The F&P Vitera Full Face mask has been validated to withstand 20 cycles of the above parameters.

## CAUTIONS

Failure to properly clean this device, or deviations from the recommended methods of reprocessing, may affect the function/lifetime of the device or result in inadequate disinfection and adverse health effects.

## ADVANCED ASSEMBLY/DISASSEMBLY

Please refer to the diagrams on the inside back cover of this guide.

- 1 To disassemble the Elbow from the Frame:**
  - Position the Elbow so it is facing upward.
  - Pull the Elbow downward, away from Frame, until Elbow pops out.
- 2 To assemble Elbow back into Frame:**
  - Position the Elbow so it is facing upward.
  - Push the Elbow at an angle and rotate into the Frame until the Elbow pops in.
- 3 To disassemble Headgear Clips and Forehead Clip from the Headgear:**
  - Lie the flexed tabs flat against the Headgear strap and glide them through the Headgear Clip and Forehead Clip opening.
  - Unhook the Headgear Clips from Frame and slide the Forehead Clip down from the Frame.
- 4 To assemble Headgear Clips and Forehead Clip with the Headgear:**
  - Hook the Headgear Clips back onto the Frame and slide the Forehead Clip up onto the top of the Frame.
  - Thread the bottom straps of the Headgear through the Headgear Clip opening.
  - Thread the blue forehead straps of the Headgear through the Forehead Clip opening.

**⚠ WARNINGS**

- This mask is not suitable for life support ventilation.
- This mask must be used under qualified supervision for users whom are unable to remove the mask themselves.
- 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. To avoid having an adverse effect on the safety and quality of the therapy, the exhaust holes on 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. Discomfort or irritation in or near the eyes.
  - ii. Excessive leaks between mask Seal and face.
  - iii. Gum, jaw or mouth soreness/ discomfort or an aggravation of an existing dental condition occurs.
  - iv. Allergic reaction.
  - v. Mask discomfort or irritation.
- Do not use if vomiting or feeling nauseous.
- Do not block Elbow side vents.
- 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.
- 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 vapours 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](http://www.fphcare.com/prop65)

**⚠ CAUTIONS**

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

**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/](http://www.fphcare.com/sleep-apnea/masks/warranty-mask/)

**CONTRAINDICATION**

None known.

**DISPOSAL**

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

**PATENT INFORMATION**

For patent information, see [www.fphcare.com/ip](http://www.fphcare.com/ip)