

F&P Nova Nasal

Instructions for Use

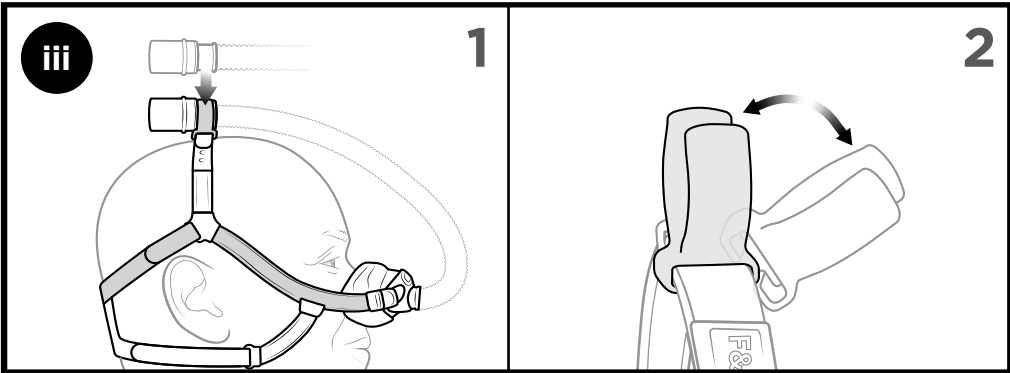
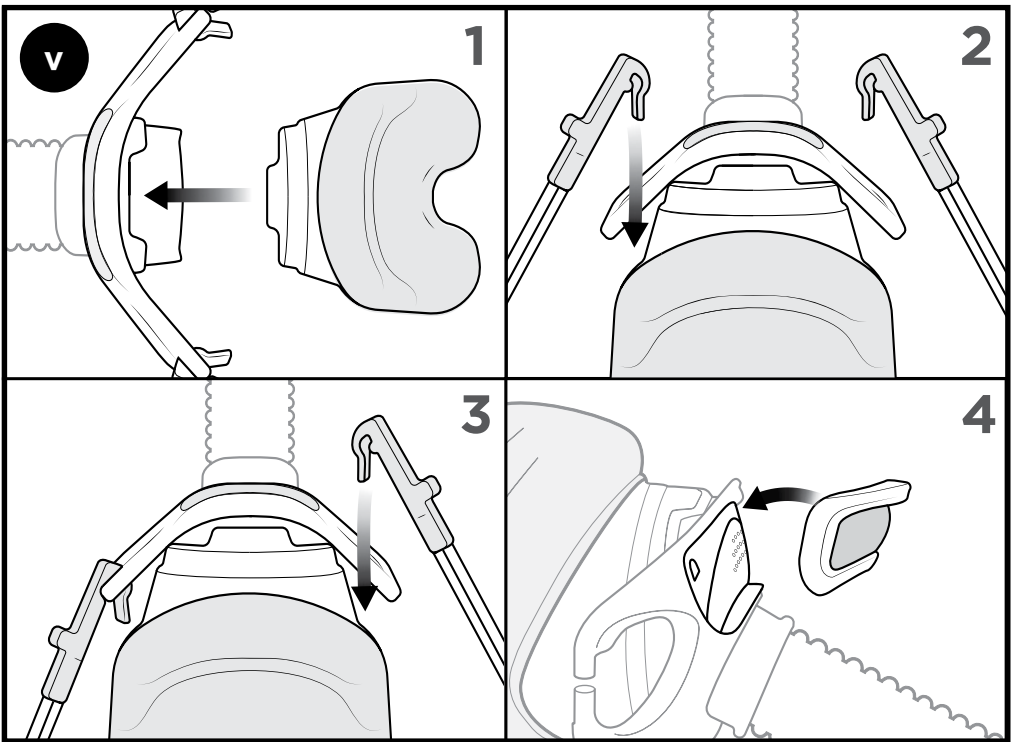
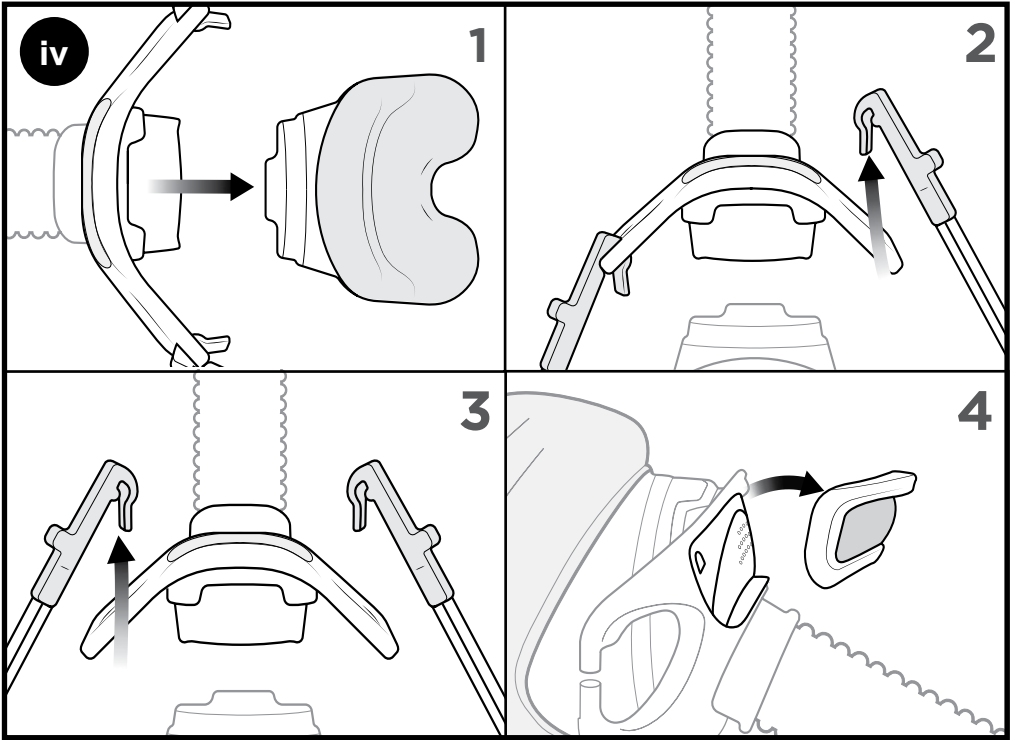
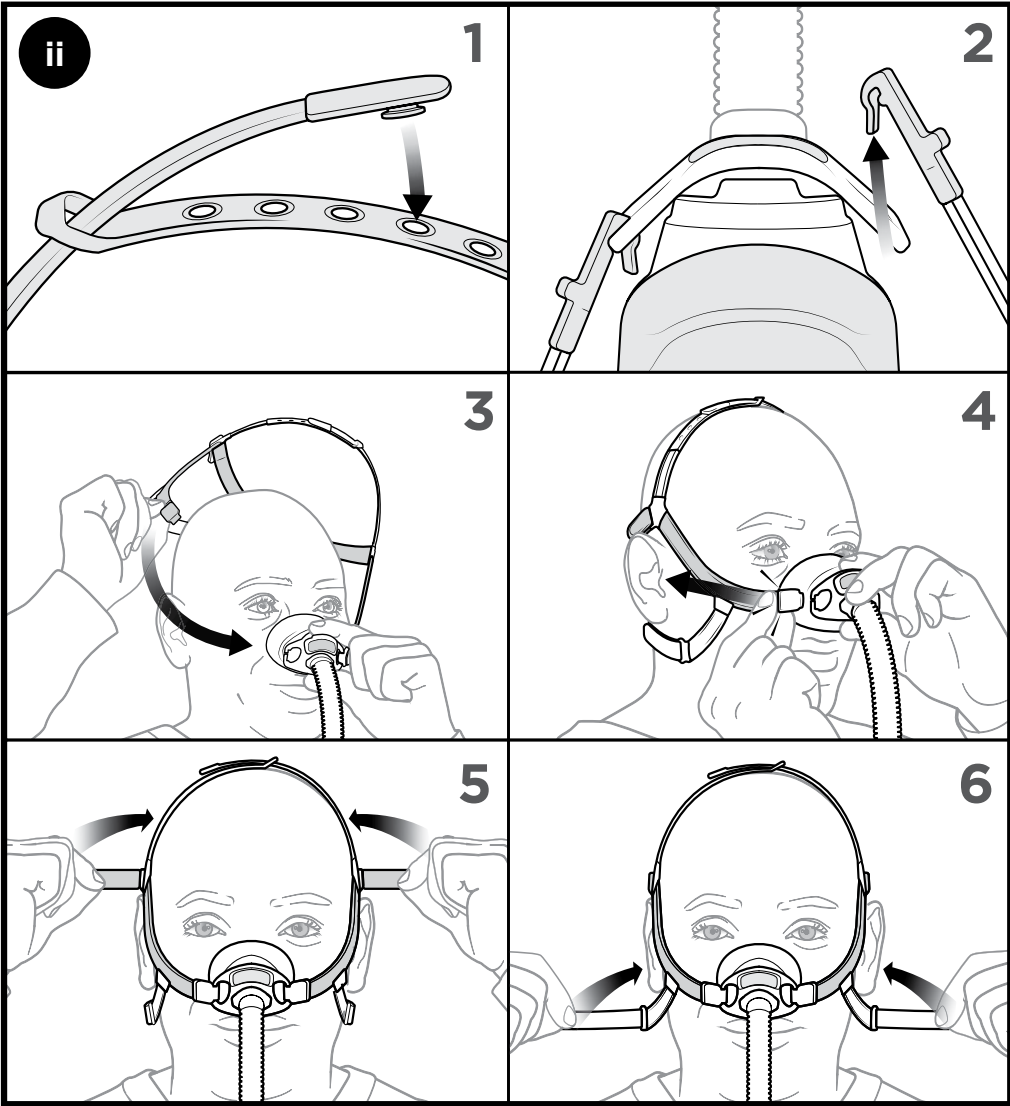
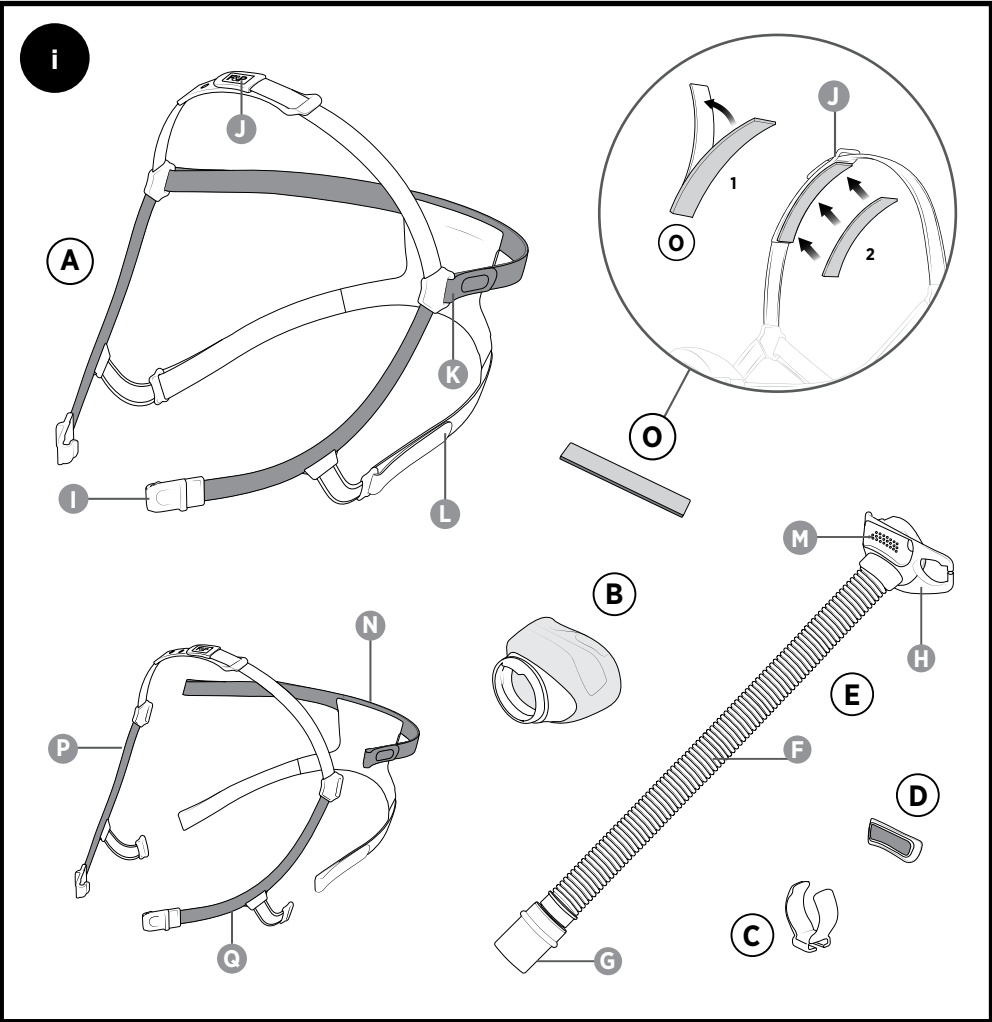
Nasal Mask

SL A

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## Indications for use

The F&P Nova™ Nasal mask is intended to be used by adults weighing ≥ 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The Nova Nasal 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.

## Contraindications

None.

## General warnings and cautions

Any serious incident must be reported to the competent authority and your Fisher & Paykel Healthcare representative.

**Warning:** Do not use the mask unless the PAP device is turned on and operating properly as this may result in excessive carbon dioxide inhalation.

**Warning:** This mask is not suitable for life support ventilation as this may result in death.

**Warning:** Do not administer drugs or medications into the device or breathing tube, with the exception of supplemental oxygen, as it may impact the efficacy of the medicine.

**Warning:** Do not use the mask outside of the indications for use as this may result in a range of harms, some of which are severe.

**Caution:** Therapy may be compromised if your airway is congested. Use of a different mask may be recommended in this situation. Consult your healthcare provider.

**Caution:** Discontinue use and consult your healthcare provider or physician if you are experiencing:

- Discomfort or irritation near your eyes as this may result in an eye injury.
- Excessive leaks between the cushion and your face as this may result in compromised therapy.
- An adverse reaction after using the mask, including an allergic reaction.

## Possible side effects

While using the F&P Nova Nasal mask, you may experience:

- Difficulty sleeping.
- Facial irritation (pressure sores, skin redness, skin dryness and/or abrasion).
- Oral pain (toothache and/or gum soreness).
- Dental deformation (tooth movement and/or misalignment).
- Claustrophobia and/or anxiety.
- Eye dryness, swelling and/or redness.

If you experience any of the above side effects, including any not listed in these instructions, discontinue using the F&P Nova Nasal mask and consult your physician immediately. Any other serious incidents must be reported to the competent authority and your Fisher & Paykel Healthcare representative.

## Mask parts and features

Refer to the mask diagram in these instructions.

**(A)** Headgear **(B)** Cushion **(C)** Tube Clip **(D)** Diffuser **(E)** Frame Assembly **(F)** Tube **(G)** Swivel **(H)** Frame **(I)** Headgear Clips **(J)** Top Strap **(K)** Upper Straps **(L)** Lower Straps **(M)** Exhaust Holes **(N)** Back Panel **(O)** Headgear Pad **(P)** Right Sidearm **(Q)** Left Sidearm

## Operating instructions

Please refer to the Warnings and Cautions within these instructions. Failure to follow the operating instructions may compromise the performance and safety of the mask. Only use your mask according to the indications for use as directed in these instructions.

### Conditions of use

The operating pressure range of your mask is 4 to 30 cmH<sub>2</sub>O.

**Warning:** Only use the mask within the specified pressure range. Use outside of this range may result in excessive carbon dioxide inhalation or excessive leak which may result in an eye injury.

**Warning:** Your mask should only be used with approved PAP equipment recommended by your physician or respiratory therapist. Using the mask with any other medical device could decrease the safety or alter the performance of the mask.

The operating temperature range of your mask is 5 to 40 °C (41 to 104 °F).

Store your mask dry in clean conditions. The storage temperature of your mask is -20 to 50 °C (-4 to 122 °F).

**Caution:** Do not store your mask in direct sunlight as this may compromise the function of the mask.

The expiry date is printed on the label of the plastic bag. Do not use your mask after its expiry date. For single patient use in the home, replace the mask no later than 12 months after the date of first use.

### Before use

Before using your mask the first time, remove all packaging.

Before using your mask each time:

**Warning:** Make sure the air path through the mask is free from blockages that may prevent or restrict airflow as this may result in excessive carbon dioxide inhalation.

**Warning:** Inspect the Exhaust Holes **(M)**. Ensure air is flowing through the exhaust and do not use if blocked as this may result in excessive carbon dioxide inhalation.

**Caution:** Inspect it for damage or deterioration. If there is any visible deterioration (cracking, tears, etc.), do not use the mask and seek replacement part(s) from your healthcare provider as using the mask may result in lacerations or compromised therapy.

**Caution:** Inspect the mask for soiling and dust and, if present, follow the cleaning instructions to remove the soiling or dust, as this may result in a range of harms, some of which are severe.

## Fitting your mask

Refer to the fitting diagrams in these instructions.

- Connect the Top Strap **(J)** to one of the holes in the Headgear **(A)**.
- Unhook one of the Headgear Clips **(I)** from the Frame **(H)**.
- Place the Cushion **(B)** on your nose and swing the unhooked Headgear Clip **(I)** around your head.
- Connect the Headgear Clip **(I)** to the Frame **(H)** once the Headgear **(A)** is positioned on your head. You should hear the Headgear Clip **(I)** click into place.
- Gently adjust the Upper Straps **(K)**.
- Gently adjust the Lower Straps **(L)**.

**Useful tips:**

- The Headgear **(A)** should not touch your ears. Adjust the Top Strap **(J)** if required. You may need to take off the mask to do this.
- If you are experiencing mask leaks, you may need to lift the Cushion **(B)** off your face and reposition it.
- For a comfortable fit, the mask should be worn as loose as possible, without excessive leak.

**Warning:** Do not overtighten the mask as this may result in facial deformation.

**Caution:** Failure to follow fitting instructions or using the incorrect mask size may result in pressure sores or excessive leak causing eye injury.

### Taking off your mask

- Unhook one of the Headgear Clips **(I)** from the Frame **(H)**.
- Unwrap the Headgear **(A)** from your head. The Upper Straps **(K)**, Lower Straps **(L)** and the Top Strap **(J)** do not need to be loosened.

## Disassembling your mask

Refer to the disassembly diagrams in these instructions.

- Remove the Cushion **(B)** by pulling it away from the Frame **(H)**.
- Remove the Headgear **(A)** by pushing one of the Headgear Clips **(I)** forward until it disconnects from the Frame **(H)**.
- Remove the other Headgear Clip **(I)** by repeating step 2.
- To remove the Diffuser **(D)**, use your finger to rotate it off the Frame **(H)**.

**Caution:** The Frame **(H)**, Tube **(F)** and Swivel **(G)** components are permanently connected together and are not intended to be disassembled. Attempting to disassemble these components may compromise the function of the mask.

## Assembling your mask

Refer to the assembly diagrams in these instructions.

- Attach the Cushion **(B)** by pushing it onto the Frame **(H)**. You should hear a click when connected properly.
- Attach the Headgear **(A)** by aligning both Headgear Clips **(I)** to the Frame **(H)** and pulling back until you hear a click.
- Attach the other Headgear Clip **(I)** by repeating step 2.
- If you need to reattach the Diffuser **(D)**, align it with the recess in the Frame **(H)** and push to connect.

## Using optional Tube Clip

Refer to the Tube Clip diagrams in these instructions.

- Find the Tube Clip **(C)** on the Top Strap **(J)**. The Tube **(F)** can be fitted by pushing it into the Tube Clip **(C)** or removed by pulling it out. If you have fitted the Tube **(F)** to the Tube Clip **(C)**, the Tube **(F)** should now sit on the top of your head.
- The Tube Clip **(C)** can be removed by rotating and unhooking it from the Top Strap **(J)**. To attach the Tube Clip **(C)**, hook and rotate it back onto the Top Strap **(J)**.

**Useful tips:**

- Take care to correctly orient the Headgear **(A)** during assembly. The printed text on the Headgear **(A)** should be facing upwards and the Diffuser **(D)** should be above the Tube **(F)**.
- There are features on the Headgear Clips **(I)** to prevent incorrect assembly to the Frame **(H)**.
- The Tube Clip **(C)** will not fit in the usual position if you have adjusted the Top Strap **(J)** to the largest setting. The Tube Clip **(C)** will have to be fitted on the fabric part of the Top Strap **(J)** on the opposite side.

## Using optional Headgear Pad

Refer to the Headgear Pad diagrams in these instructions.

- The Headgear Pad **(O)** is a single-time setup item and cannot be removed once it has been applied. To use the Headgear Pad **(O)**, remove the backing layer from the Headgear Pad **(O)** to expose the sticky adhesive layer.
- Align the adhesive side of the Headgear Pad **(O)** and press down firmly to secure it to the Right Sidearm **(P)**.

### Cleaning your mask at home

**After each use:** Wash the Cushion **(B)** and Frame Assembly **(E)**.

**After 7 days use:** Wash the Headgear **(A)**, Tube Clip **(C)** and Diffuser **(D)**.

- Disassemble for cleaning as described in the 'Disassembling your mask' section. It is only necessary to disassemble the Diffuser **(D)** for the weekly wash.
- Hand-wash the mask parts in soap dissolved in lukewarm water. Do not soak for more than 10 minutes.
- Rinse thoroughly in fresh water. Ensure that all soap residue has been removed.
- Inspect all parts to ensure they are visibly clean. If necessary, repeat the cleaning steps until all parts are visibly clean.
- Leave all parts to dry out of direct sunlight before reassembling.

**Warning:** Do not share your mask with another person when using it at home as it may result in the transfer of biological agents such as viruses or bacteria.

**Caution:** Only clean the mask with cleaning products specified in the cleaning instructions of this guide, as any other products may result in an adverse reaction if cleaning residue is left behind.

**Caution:** Do not clean the mask with products containing alcohol, antiseptic, bleach, chlorine or moisturizer as these may compromise the function of the mask.

**Caution:** Do not clean the mask in a dishwasher, as this may compromise the function of the mask.

**Caution:** Failure to fully disassemble the mask prior to cleaning may compromise the effectiveness of cleaning and may result in a range of harms, some of which are severe.

## Advanced Assembly/Disassembly

- To disassemble the Back Panel **(N)** from the Right Sidearm **(P)** and Left Sidearm **(Q)**: Undo the tabs of the Upper Straps **(K)** and Lower Straps **(L)** and slide each end of the Back Panel **(N)** out through the opening.
- To assemble the Back Panel **(N)** with the Right Sidearm **(P)** and Left Sidearm **(Q)**: Lay the Back Panel **(N)** flat and guide each end of the Back Panel **(N)** through the openings. The "F&P Nova" label on the Back Panel **(N)** should be facing outward.
- To disassemble the Top Strap **(J)**: Undo the Top Strap **(J)** button and pull the end of the Top Strap **(J)** firmly out through the opening.
- To assemble the Top Strap **(J)**: Guide the end of the Top Strap **(J)** through the opening. Connect the Top Strap **(J)** button to one of the holes.

## Multi-patient cleaning instructions

These instructions are intended for multi-patient use of the F&P Nova Nasal mask in a hospital, or other clinical setting, where proper disinfection of the device must occur between patients.

Your F&P Nova Nasal 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. When using the mask for single patient use in the home, please refer to your F&P Nova Nasal Instructions for Use under 'Cleaning your mask at home'.

**Warning:** Deviations from the recommended methods of reprocessing may result in inadequate disinfection/sterilization and adverse health effects.

**Warning:** Frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents, or exceeding the number of processing cycles can have an adverse effect on the mask and consequently the safety or the quality of the therapy.

**Caution:** Only clean the mask with cleaning products specified in the cleaning instructions of this guide, as any other products may result in an adverse reaction if cleaning residue is left behind.

**Caution:** Do not clean the mask with products containing alcohol, antiseptic, bleach, chlorine or moisturizer as these may compromise the function of the mask.

**Caution:** Do not clean the mask in a dishwasher, as this may compromise the function of the mask.

### Overview of reprocessing methods

To disinfect the F&P Nova Nasal mask, use one of the methods outlined in the table below. Each cycle is limited to one day of use.

	Thermal Disinfection In line with EN ISO 15883, the uncertainty range for disinfection temperature is -0 °C and +5 °C			Chemical Disinfection
	1 min at 90 °C (194 °F)	10 min at 80 °C (176 °F)	30 min at 75 °C (167 °F)	CIDEX™1 OPA
<b>Cushion (B)*, Frame Assembly (E)</b>	Maximum of 25 cycles			Maximum of 25 cycles
<b>Headgear (A)**, Tube Clip (C)**</b>	The Headgear <b>(A)</b> and Tube Clip <b>(C)</b> are not required to be disinfected, thorough cleaning between patients is sufficient. Follow 'Cleaning the Headgear and Tube Clip' instructions for a maximum of 25 cycles.			
<b>Diffuser (D)</b>	The Diffuser <b>(D)</b> is not intended for reuse between patients. If used, replace Diffuser <b>(D)</b> between patients.			
<b>Headgear Pad (O)</b>	The Headgear Pad <b>(O)</b> is not intended for reuse between patients and is not removable. If used, replace Headgear <b>(A)</b> between patients.			

\*Replace the cushion if it becomes stained or discolored.

\*\*If contaminated with blood, please replace the contaminated component between patients.

<sup>1</sup>CIDEX is a trademark of ASP Global Manufacturing GmbH.

### Validated disinfection procedures

These instructions have been validated as being capable of preparing the mask for reuse.

Fisher & Paykel Healthcare does not recommend any deviations from the recommended method of reprocessing.

**Point of Use (optional):** Any gross soiling on the mask may be removed by wiping or rinsing with potable water.

**Disassembly:** Disassemble the mask according to the 'Disassembling your mask' instructions provided and these additional steps:

- Remove the Back Panel **(N)** from the Headgear **(A)**.
- Remove the Tube Clip **(C)** from the Top Strap **(J)**.
- Disconnect the Top Strap **(J)**.

**Caution:** Failure to fully disassemble the mask may compromise the effectiveness of cleaning and the subsequent disinfection steps which may result in a range of harms, some of which are severe.

**Cleaning:** Masks should always be properly cleaned before further reprocessing.

**Warning:** Failure to properly clean this device according to these instructions or the use of an automated cleaning method may result in ineffective disinfection/sterilization and adverse health effects.

### Cleaning the Cushion and Frame Assembly:

- Soak Cushion and Frame Assembly in a 1% concentration solution of Alconox™<sup>12</sup> (or equivalent mild alkaline anionic detergent) for 5 minutes at 50 °C, ensuring that no air bubbles are present on the device surface. (Alconox is a trademark of Alconox, Inc.)
- Using a soft non-metallic brush (e.g. medium-hard toothbrush), vigorously brush the mask parts until visibly clean but not for less than 30 seconds. An additional narrow bottle brush is required to access the Mask Tube. Brush the components while submerged and out of

the solution. Pay close attention to crevices, cavities and corners, such as the join between the silicone cushion, plastic surrounds and the internal surfaces of the frame.

- Vigorously brush the joint between the frame and tube alternating between the inside and outside surfaces for at least 30 seconds.
- Manually rotate the swivel for at least 10 seconds, while submerged in the detergent solution.
- Repeat steps 1 to 4 (total soaking time of 10 minutes).
- Rinse by submerging in 5 liters of fresh demineralized water and agitating for at least 10 seconds. Repeat rinse.
- Manually rotate the swivel for at least 10 seconds, while submerged in the demineralized water.
- Ensure the mask is visibly clean before continuing. If not, repeat steps 1-7.

### Cleaning the Headgear and Tube Clip

- Soak the Headgear and Tube Clip Assembly in a 1% concentration solution of Alconox (or equivalent mild alkaline anionic detergent) for 10 minutes at 50 °C, ensuring that no air bubbles are present on the device surface.
- Using a soft non-metallic brush, (e.g. medium-hard toothbrush), scrub the parts until visibly clean but not for less than 30 seconds. Pay close attention to crevices, cavities and corners.
- Rinse the parts under running water for at least 30 seconds, intermittently wringing the fabric.
- Submerge in 5 liters of demineralized water while agitating and squeezing for at least 30 seconds.
- Repeat submerged rinse in fresh demineralized water. Ensure that all detergent residue is removed by repeating submerged rinse as many times as necessary.
- Ensure the parts are visibly clean before continuing. If not, repeat steps 1–5.

**Drying:** Make sure mask components are thoroughly dry before continuing by leaving them to air dry out of direct sunlight. Failure to do this may result in ineffective chemical disinfection.

### Disinfection:

**Caution:** The use of STERRAD™<sup>3</sup> or Autoclave as a reprocessing method may lead to mask degradation and adverse health effects.

<sup>3</sup>STERRAD is a trademark of ASP Global Manufacturing GmbH.

**Thermal disinfection:** Run a disinfection cycle in a legally marketed automatic washer-disinfector using one of the time/temperature combinations shown in the reprocessing table. These time/temperature combinations are consistent with EN ISO 15883 and are equivalent in terms of known thermal inactivation kinetics of vegetative microorganisms, meeting an A<sub>0</sub> of 600.

**Chemical disinfection:** Immerse completely in an undiluted bath of CIDEX OPA at 20 °C for 12 minutes, ensuring that no air bubbles are present on the device surface. Rinse thoroughly following the manufacturer's rinsing instructions.

**Drying:** Allow all components to air dry out of direct sunlight.

**Inspection:** Before each use, inspect the mask for deterioration. If any visible deterioration of a mask component is apparent, the mask component should be discarded and replaced.

**Reassembly:** Reassemble the mask according to the 'Assembling your mask' instructions provided in these instructions. To ensure traceability, mask components belonging to an individual mask must be reassembled back into the same mask after cleaning, excluding the components requiring replacement as marked in the reprocessing table.

**Storage:** Ensure the mask is completely dry before storing. Store in clean conditions out of direct sunlight. Storage temperature: -20 °C to 50 °C (-4 °F to 122 °F).

## Oxygen/pressure port connector

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

**Warning:** Mask use with supplemental oxygen will create a risk of fire. Do not smoke, or be in the vicinity of someone smoking, or any other ignition source while using supplemental oxygen with your mask. This may result in ignition of the oxygen, leading to serious burns or death.

## Use with other PAP devices

**Warning:** When using the F&P Nova Nasal mask with other 22 mm connector (ISO-5356-1) compatible PAP devices (including F&P Oxygen/Pressure Port Connector REF 900HC452): Refer to the instructions for use for that device as there may be additional warnings that if not followed may result in a range of harms, some of which are severe.

## Technical specifications

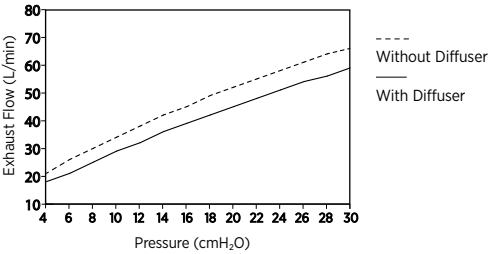
### The F&P Nova Nasal mask exhaust flow

The F&P Nova Nasal mask has a unique Diffuser System that is designed to diffuse air which is expelled from the mask. This reduces 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.

### Exhaust flow information

Pressure (cmH <sub>2</sub> O)	4	6	8	10	12	14	16	18	20	22	24	26	28	30
Flow with Diffuser (L/min)	18	21	25	29	32	36	39	42	45	48	51	54	56	59
Flow without Diffuser (L/min)	21	26	30	34	38	42	45	49	52	55	58	61	64	66

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



### Resistance to flow

Pressure drop through the mask with Diffuser at 50 L/min:

0.3±0.1 cmH<sub>2</sub>O.

Pressure drop through the mask without Diffuser at 50 L/min:

0.3±0.1 cmH<sub>2</sub>O.

Pressure drop through the mask with Diffuser at 100 L/min:

1.5±0.3 cmH<sub>2</sub>O.

Pressure drop through the mask without Diffuser at 100 L/min:

1.5±0.3 cmH<sub>2</sub>O.

### Mask dead space

Small = 68.6 cm<sup>3</sup> Medium = 75.0 cm<sup>3</sup> Large = 86.8 cm<sup>3</sup>

### Sound

The sound power level of the mask with Diffuser is 25.5 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 the mask without Diffuser is 30.0 dBA, with uncertainty 2.5 dBA.

The sound pressure level of the mask without Diffuser is 22.0 dBA, with uncertainty 2.5 dBA.

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

## Mask materials

The F&P Nova Nasal mask and accessories are pyrogen free and not made with natural rubber latex or DEHP.

**Caution:** If you are allergic or intolerant to any of the following materials, consult your physician before using the F&P Nova Nasal mask, as this may cause an adverse reaction.

Component	Material
Headgear	Acetal (POM), Nylon (PA), Polyether Block Amide (PEBA), Polyurethane (PU)
Cushion	Silicone, Polycarbonate (PC)
Frame	Polycarbonate (PC)
Diffuser	Polycarbonate (PC), Polyethylene Terephthalate (PET)
Tube Clip	Acetal (POM)
Tube	Polycarbonate (PC), Polyurethane (PU)
Swivel	Nylon (PA)
Headgear Pad	Acrylic (PMMA), Polyethylene (PE)

## Replacement parts

The following parts are available for replacement. Please contact your healthcare provider for more information.

Product Code	Description
400NVN11, 400NVN114*	F&P Nova Nasal Spare Cushion - Small
400NVN112, 400NVN115*	F&P Nova Nasal Spare Cushion - Medium
400NVN113, 400NVN116*	F&P Nova Nasal Spare Cushion - Large
400NVN121, 400NVN125*	F&P Nova Nasal Headgear – Standard
400NVN122, 400NVN126*	F&P Nova Nasal Headgear – Large
400NVN123	F&P Nova Nasal Back Panel – Standard
400NVN124	F&P Nova Nasal Back Panel – Large
400NVN131*	F&P Nova Nasal Mask - Mask No Headgear Small
400NVN132*	F&P Nova Nasal Mask - Mask No Headgear Medium
400NVN133*	F&P Nova Nasal Mask - Mask No Headgear Large
400NVN141	F&P Nova Nasal Frame Assembly Spare
400NVN151	F&P Nova Nasal Diffuser Spare
400NVN161	F&P Nova Nasal Tube Clip Spare
400NVN162	F&P Nova Nasal Headgear Pad Spare

\*Not available in all countries.

## Disposal

The F&P Nova Nasal mask does not contain any hazardous materials and may be disposed of with general waste or following hospital procedure.

## Intellectual property information

F&P