

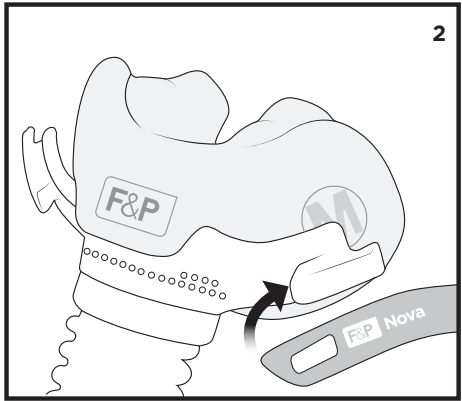
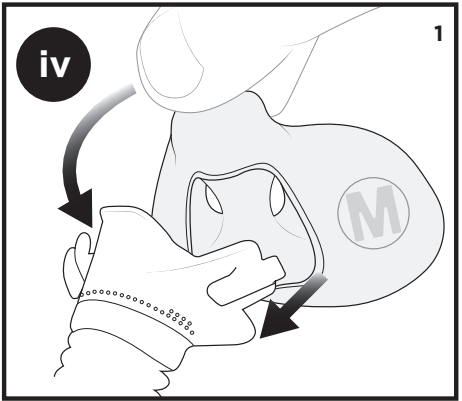
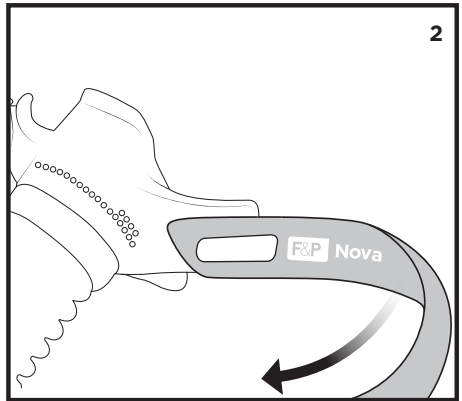
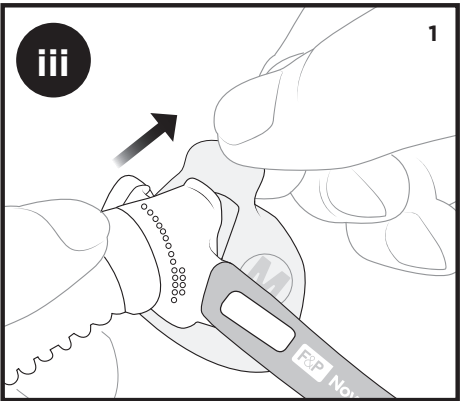
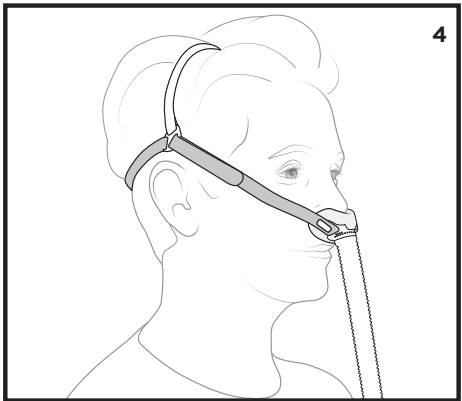
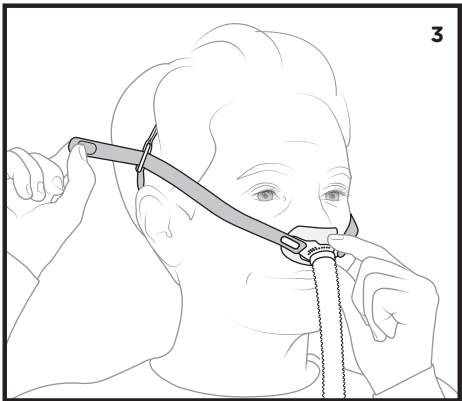
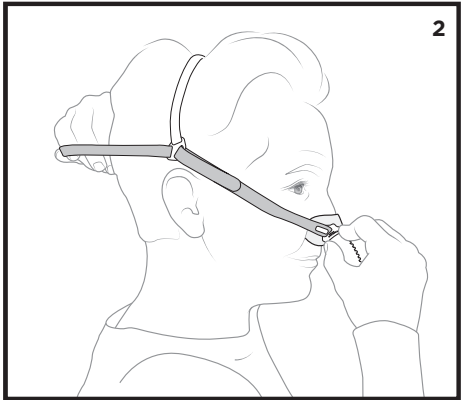
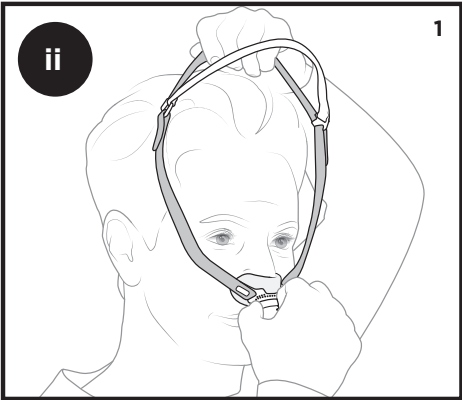
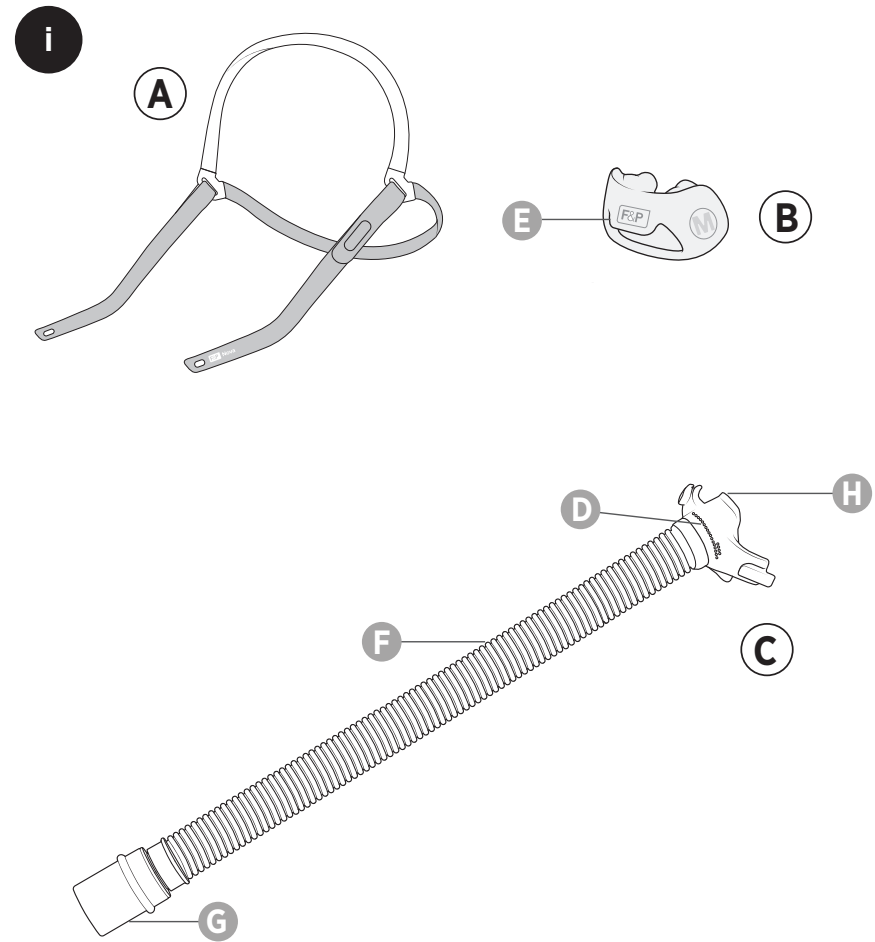


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HEALTHCARE



Indications for use

The F&P Nova Micro™ 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 Micro 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 Micro 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 Micro 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) Frame Assembly (D) Exhaust Holes

(E) Cushion Tab (F) Tube (G) Swivel (H) Frame

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 25 cmH₂O.

- 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 (D). 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.

English

Fitting your mask

Refer to the fitting diagrams in these instructions.

- Position the Cushion (B) in your nose, then pull the Headgear (A) over your head.
- Ensure that the rear straps are spaced apart for stability.
- Gently adjust the side straps until a comfortable fit is achieved.
- Ensure that:
 - The Cushion (B) is securely located into your nostrils.
 - The Cushion Tab (E) is facing upward.
 - The mask name on the side straps is upright.

Useful tips:

- If you are experiencing mask leaks, you may need to lift the cushion 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

Pull the mask away from the nose, lifting up and over the head.

Disassembling your mask

Refer to the disassembly diagrams in these instructions.

- Remove the Cushion (B) by lifting the Cushion Tab (E) and peeling away from the Frame (H).
 - Remove the Headgear (A) by pulling the side strap forward so that the opening stretches over the frame post.
- 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 hooking the bottom corners over the Frame (H) and pulling the Cushion Tab (E) over the frame lip.
- Attach the Headgear (A) by hooking the strap opening over the frame post, then pulling back to secure in place.

Useful tip:

- Take care to correctly orientate the Headgear (A) during assembly. The printed headgear text and the Cushion Tab (E) should both be facing upwards.

Cleaning your mask at home

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

After 7 days of use: Wash the Headgear (A).

- Disassemble for cleaning as described in the 'Disassembling your mask' section.
- 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.

Multi-patient cleaning instructions

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

Your F&P Nova Micro mask is provided patient-ready. To reuse between patients please follow guidelines below or visit www.fphcare.com/ disinfection. If you do not have internet access, please contact your Fisher & Paykel Healthcare representative. When using the mask for single patient use in the home, please refer to your F&P Nova Micro 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 Micro mask, use one of the methods outlined in the table below. Each cycle is limited to one day of use.

	Thermal Disinfection			Chemical Disinfection
	In line with EN ISO 15883, the uncertainty range for disinfection temperature is -0 °C and +5 °C			
	1 min at 90 °C (194 °F)	10 min at 80 °C (176 °F)	30 min at 75 °C (167 °F)	CIDEX ^{®1} OPA, MetriCide ^{™2} OPA Plus or RAPICIDE ^{™3} OPA/28
Cushion (B)*, Frame Assembly (C)	Maximum of 25 cycles			Maximum of 25 cycles
Headgear (A)**	Maximum of 25 cycles			-

*Replace the cushion if it becomes discolored.

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

¹ CIDEX is a trademark of Advanced Sterilization Products, a division of Ethicon Inc., a Johnson & Johnson Company.

² MetriCide is a trademark of Metrex Research LLC.

³ RAPICIDE is a trademark of Medivators Inc.

Validated disinfection procedures

These instructions have been validated as being capable of preparing the masks 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, then peel open the straps on the Headgear **(A)**.

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.

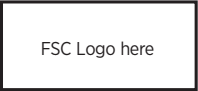
Cleaning the Cushion and Frame Assembly:

- Soak Cushion and Frame Assembly in a solution of mild alkaline anionic detergent according to the manufacturer's instructions (e.g. Alconox^{®4} at 1% concentration and 50 °C) for 10 minutes, 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 10 seconds. An additional narrow bottle brush is required to access the Mask Tube. Pay close attention to crevices, cavities and corners, such as the internal surfaces of the cushion and frame.
- Manually rotate both ends of the tube where it joins the swivel and the frame for at least 10 seconds each, while submerged in the detergent solution.
- Rinse by submerging in 5 liters of fresh demineralized water and agitating for at least 10 seconds.
- Manually rotate both ends of the tube where it joins the swivel and the frame for at least 10 seconds each, while submerged in the demineralized water.
- Repeat the submerged rinse in fresh demineralized water.
- Ensure the Cushion and Frame Assembly are visibly clean before continuing. If not, repeat steps 1-6.

Cleaning the Headgear:

- Soak the Headgear in a solution of mild alkaline anionic detergent according to the manufacturer's instructions (e.g. Alconox at 1% concentration and 50 °C) for 10 minutes, ensuring that no air bubbles are present on the device surface.
- Using a soft non-metallic brush (e.g. medium-hard toothbrush), scrub the headgear until visibly clean but not for less than 30 seconds. Pay close attention to crevices, cavities and corners.
- Rinse 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 Headgear is 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 disinfection.



Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Email: info@fphcare.co.nz Web: www.fphcare.com



Australia (AU) (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 **Brazil (BR)** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China (CN)** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 **France (FR)** **EC REP** Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Email: cs@fphcare.fr **Germany (DE)** Fisher & Paykel Healthcare GmbH, Wiesenstrasse 49, 73614 Schorndorf, Germany Tel: +49 7181 98599 0 **Hong Kong (HK)** Tel: +852 2116 0032 **India (IN)** Tel: +91 80 2309 6400 **Japan (JP)** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea (KR)** Tel: +82 2 6205 6900 **Mexico (MX)** Tel: +52 55 9130 1626 **Poland (PL)** Fisher & Paykel Healthcare Poland Sp. z o.o., Pl. Andersa 7, 61-894 Poznań, Poland Tel: +48 664 846 464 **Russia (RU)** Tel: +7 495 782 21 50 **Switzerland (CH)** **CH REP** Fisher & Paykel Healthcare GmbH, Säntisstrasse 2, 9501 Wil / SG, Switzerland Tel: 0800 83 47 63 **Taiwan (TW)** Tel: +886 2 8751 1739 **Turkey (TR)** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: ÖstİM Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 **UK (GB)** **UK REP** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 **USA (US)/Canada (CA)** Tel: 1800 446 3908 or +1 949 453 4000

Austria (AT) Tel: 0800 29 31 23 **Benelux (BE NL LU)** Tel: +31 40 216 3555 **Denmark (DK)** Tel: +45 70 26 37 70 **Finland (FI)** Tel: +358 9 251 66 123 **Ireland (IE)** Tel: 1800 409 011 **Italy (IT)** Tel: +39 06 7839 2939 **Norway (NO)** Tel: +47 21 60 13 53 **Spain (ES)** Tel: +34 902 013 346 **Sweden (SE)** Tel: +46 8 564 76 680

Disinfection:

Caution: The use of STERRAD^{®5} or Autoclave as a reprocessing method may lead to mask degradation and adverse health effects.

⁵STERRAD is a trademark of Advanced Sterilization Products, a division of Ethicon Inc., a Johnson & Johnson company.

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 A₀ of 600.

Chemical disinfection:

- Immerse completely in an undiluted bath of CIDEX OPA, MetriCide OPA Plus or RAPICIDE OPA/28 at 20 °C, ensuring that no air bubbles are present on the device surface.
- Manually rotate the tube where it joins the frame for at least 10 seconds while submerged.
- Leave the mask parts to soak for 12 minutes.
- Repeat steps 2 and 3.
- Rinse thoroughly following the manufacturer’s rinsing instructions. Manually rotate the tube where it joins the frame for at least 10 seconds while rinsing.

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

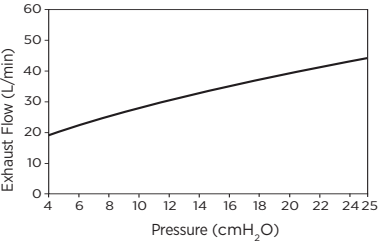
Warning: When using the F&P Nova Micro mask with other 22 mm connector (ISO-5356-1) compatible PAP devices (including F&P Oxygen/Pressure Port Connector REF 900HC452): Refer to the instructions for use for that device as there may be additional warnings that if not followed may result in a range of harms,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

Technical specifications

Exhaust flow information

Pressure (cmH ₂ O)	4	6	8	10	12	14	16	18	20	22	24	25
Flow (L/min)	13	16	19	22	24	27	29	31	33	35	37	38

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



Resistance to flow

Pressure drop through the mask at 50 L/min:

- Small cushion 2.0±0.2 cmH₂O
- Medium cushion 0.9±0.2 cmH₂O
- Large cushion 0.7±0.2 cmH₂O

Pressure drop through the mask at 100 L/min:

- Small cushion 7.9±1.0 cmH₂O
- Medium cushion 3.8±1.0 cmH₂O
- Large cushion 3.1±1.0 cmH₂O

Mask dead space

Small = 14.1 cm³ Medium = 14.2 cm³ Large = 18.2 cm³

Sound

The sound power level of the mask is 21.4 dBA, with uncertainty 2.5 dBA. The sound pressure level of the mask is 13.45 dBA, with uncertainty 2.5 dBA.

Mask materials

The F&P Nova Micro 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 Micro mask, as this may cause an adverse reaction.

Component	Material
Headgear	Nylon (PA)/Spandex/Polypropylene (PP)/Polyurethane foam
Cushion	Silicone
Frame	Nylon (PA)
Tube	Polycarbonate (PC), Polyurethane (PU)
Swivel	Nylon (PA)

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/

Replacement parts

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

Product Code	Description
400NVP111, 400NVP114*	F&P Nova Micro Pillows Spare Cushion - Small
400NVP112, 400NVP115*	F&P Nova Micro Pillows Spare Cushion - Medium
400NVP113, 400NVP116*	F&P Nova Micro Pillows Spare Cushion - Large
400NVP121, 400NVP122*	F&P Nova Micro Pillows Headgear
400NVP131*	F&P Nova Micro Pillows Mask - Mask No Headgear Small
400NVP132*	F&P Nova Micro Pillows Mask - Mask No Headgear Medium
400NVP133*	F&P Nova Micro Pillows Mask - Mask No Headgear Large
400NVP141	F&P Nova Micro Pillows Frame Assembly Spare

*Not available in all countries.

Disposal

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

Intellectual property information

F&P and Nova Micro are trademarks of Fisher & Paykel Healthcare Limited. For patent information, see www.fphcare.com/ip

Symbol definitions

	Catalogue number		Prescription only
	CE Marking		Authorized European Representative
	Unique device identifier		Batch code
	Medical device		Single patient multiple use
	Blue symbol: Follow instructions for use		Consult instructions for use
	Humidity limitation		Storage temperature limitation
	Use by date		Caution/Warning
	Date of manufacture		Manufacturer
	Small cushion size		Medium cushion size
	Large cushion size		Low-Density Polyethylene
	Recycling symbol		Polyethylene Terephthalate, Low-Density Polyethylene
	Importer		Distributor
	Switzerland Authorized Representative		UK Responsible Person