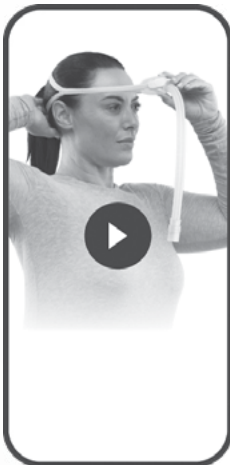


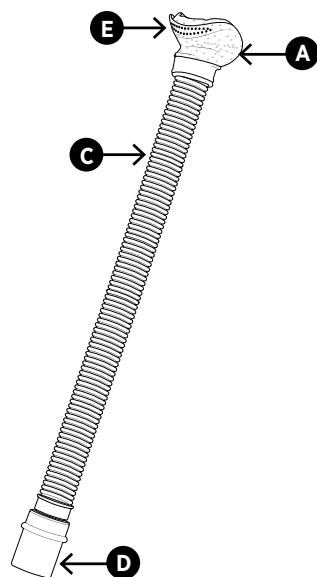
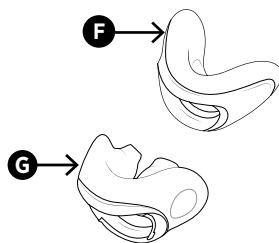
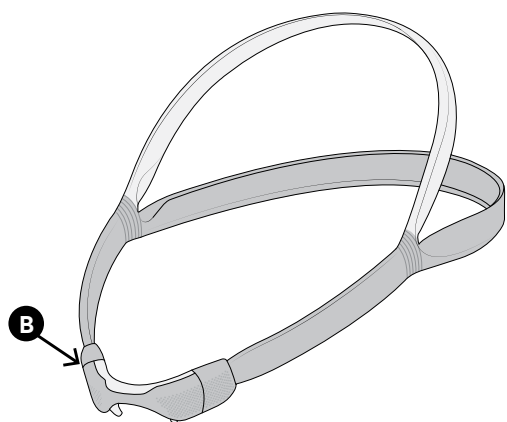
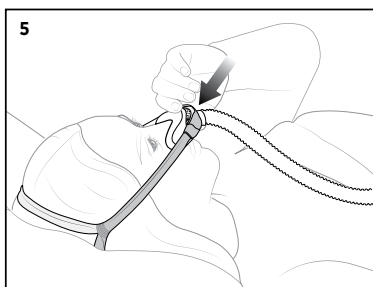
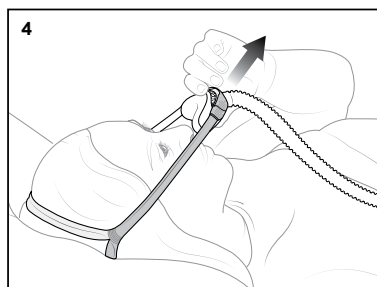
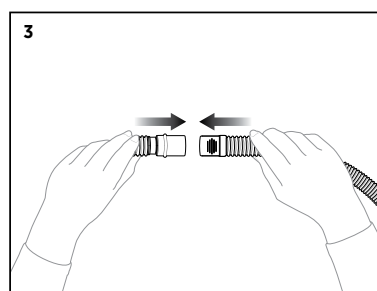
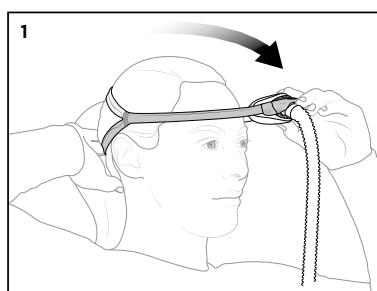
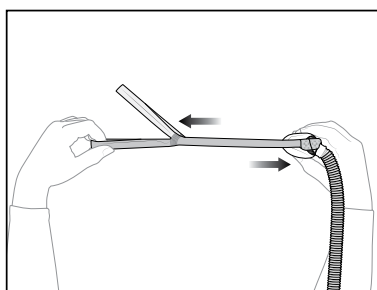
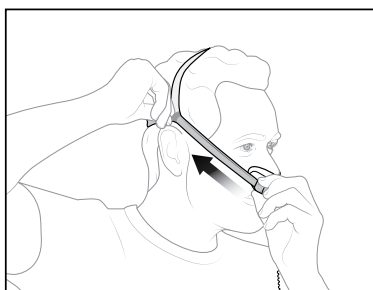
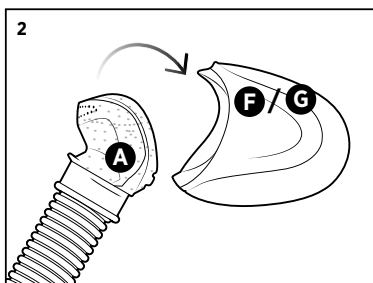
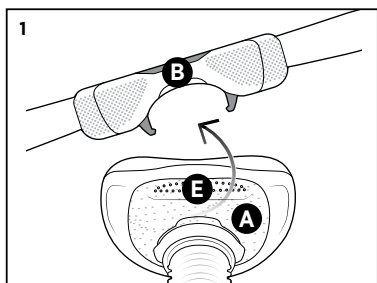
Instructions for Use



F&P myMask App*



* Not available in all countries

i**ii****iii****iv****v**

F&P Solo mask
Instructions for Use

English

Indications for use

The F&P Solo mask is intended to be used by adults weighing ≥ 66lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The F&P Solo mask is intended for single-patient use in the home and for multiple patient uses in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

Contraindications
None.

General warnings & cautions

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

- Warning: Do not use the mask without supervision on patients who are unable to remove the mask themselves as this may result in excessive carbon dioxide inhalation if vomiting occurs.
- Warning: Do not use the mask if feeling nauseous or vomiting as this may result in excessive carbon dioxide inhalation if vomiting occurs.
- 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 intended purpose 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 seal 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 Solo 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 Solo 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 & features

Refer to the mask diagram on the front panel of these instructions.

- (A) Frame (B) Headgear (C) Tube (D) Swivel (E) Exhaust Holes (F) Nasal Cushion (G) Pillows Cushion

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 for its Intended Purpose as directed in these instructions.

Conditions of use

The operating pressure range of your mask is 4 to 20 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.
- Caution: Replace your mask/components after any of the following occur as failure to do so may compromise the function of the mask.
 - After the expiry date printed on the external label on the mask packaging.
 - Mask excluding Headgear: 12 months from date of first use of the Frame (A), Tube (C), Swivel (D) or Cushion (F or G) Headgear: 6 months from date of first use of the Headgear (B).
 - After the components have been through their maximum reprocessing cycle limit (multi-patient only).

Caution: When storing or traveling with your mask ensure it is stored in such a way to avoid bending or twisting as this may compromise the function of the mask.

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 (E). Ensure air is flowing through the exhaust and do not use if blocked as this may result in excessive carbon dioxide inhalation.
- Caution: Inspect the mask 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

Remove all packaging before using the mask.

Refer to the fitting images inside the front cover of these instructions.

- Anchor the grey strap behind your head and pull forward to stretch the Headgear (B) over your head.
- Position the Cushion (F or G) under your nose and orange strap on the top of your head.
- Connect the Swivel (D) to the PAP device breathing tube. Turn on the PAP device.
- Pull the Cushion (F or G) away from the nose to loosen the Headgear (B).
- Push the Cushion (F or G) into the nose to tighten Headgear (B).

Useful tips:

- Adjustment tip: The Headgear (B) can be adjusted by lengthening and shortening the side straps.
- The Cushion (F or G) should seal and feel comfortable under your nose.
- Your nose should never be inside the Nasal Cushion (F) opening.
- If you are experiencing any leaks try repositioning the Cushion (F or G) under your nose.

- 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.

Disassembling your mask

- Unclip the front of the Headgear (B) from the Frame (A) located in front of the Exhaust Holes (E).
- Pull the Cushion (F or G) from the Frame (A).
- Caution: Do not attempt to remove the swivel as this may compromise the function of the mask.
- Caution: Do not attempt to remove the tube from the frame as this may compromise the function of the mask.

Assembling your mask

- Push the Cushion (F or G) on to the Frame (A).
- Push the Headgear (B) down on to the Frame (A) in front of the Exhaust Holes (E).

Cleaning your mask at home

Mask excluding Headgear: After each use, wash the Frame (A), Tube (C), Swivel (D) and Cushion (F or G).

Headgear: After 7 days use, wash the Headgear (B) thoroughly to minimize any dirt and oil build up to maintain longevity and function.

- Disassemble for cleaning as described in the 'Disassembling your mask' section above.
- Hand-wash the mask parts in soap dissolved in lukewarm water. Do not soak for more than 10 minutes. Do not extend headgear while wet.
- Rinse thoroughly in fresh water. Ensure that all soap residue has been removed.
- Inspect all parts to ensure they are visually clean. If necessary, repeat the cleaning steps until all parts are visually 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 guidelines of these instructions, as any other products may result in an adverse reaction if cleaning residue is left behind.

Caution: Failure to follow the cleaning instructions may compromise the function of the mask.

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 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 Solo mask in the hospital, or other clinical settings, where proper disinfection of the device must occur between patients.

Your F&P Solo mask is provided patient-ready. To reuse between patients please follow the guidelines below or visit <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 Solo Instructions for Use under 'Cleaning Your Mask at Home'.

Warning: Deviations from the recommended methods of reprocessing may result in inadequate disinfection 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 guidelines provided in these instructions, 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 Solo 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
Mask Components	1 min at 90 °C (194 °F)	10 mins at 80 °C (176 °F)	30 mins at 75 °C (167 °F)	CIDEX [®] OPA, MetriCide ^{™2} OPA Plus or RAPICIDE ^{™3} OPA/28
Frame (A), Tube (C), Swivel (D), Nasal Cushion (F)*, Pillows Cushion (G)*	-	Maximum 25 Cycles	Maximum 25 Cycles	Maximum 10 Cycles
Headgear (B)	Replace these parts with new parts between patients			

* Replace cushion if it discolors.

¹ CIDEX is a trademark of Advanced Sterilization Products Global Manufacturing GmbH.

² MetriCide is a trademark of Metrex Sterilization LLC.

³ RAPICIDE is a trademark of Medivators Inc.

Validated disinfection procedures

The guidelines provided in these instructions have been validated as being capable of preparing the masks for re-use. Fisher & Paykel Healthcare does not recommend any deviations from the recommended method of reprocessing.

Point of Use: Remove any gross soiling on the mask by wiping or rinsing in potable water.

Disassembly: Disassemble the mask according to the Disassembling your Mask guidelines provided in these instructions.

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 and adverse health effects.

1. Soak all reprocessable parts in a solution of mild alkaline anionic detergent according to the manufacturer's instructions (e.g. Alconox[™] at 1% concentration and 50 °C) for 5 minutes, ensuring that no air bubbles are present on the device surface. (*Alconox is a trademark of Alconox, Inc.)
2. 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 and plastic surrounds and the internal surfaces of the frame.
3. Vigorously brush the joint between the frame and tube alternating between the inside and outside surfaces for at least 30 seconds.
4. Manually rotate the swivel for at least 10 seconds, while submerged in the detergent solution.
5. Repeat steps 1 to 4 (total soaking time of 10 minutes).
6. Rinse by submerging in 5 liters of fresh demineralised water and agitating for at least 10 seconds. Repeat rinse.
7. Manually rotate the swivel for at least 10 seconds, while submerged in the demineralised water.
8. Ensure the mask is visibly clean before continuing. If not, repeat steps 1-7.
9. 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.

Disinfection:

⚠ Caution: The use of STERRAD* or Autoclave as a reprocessing method may lead to mask degradation and adverse health effects.

*STERRAD is a trademark of Advanced Sterilization Products 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 table above. 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:

1. 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.
2. Leave the mask parts to soak for 12 minutes.
3. 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 guidelines 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 components requiring replacement as marked in the table above.

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.

⚠ 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 Solo mask with other 22 mm connector (ISO-5356-1) compatible PAP devices (including an F&P Oxygen/Pressure Port Connector REF 900HC452): Refer to the Instructions for Use for that device as there may be additional warnings and cautions that if not followed may result in a range of harms, some of which are severe.

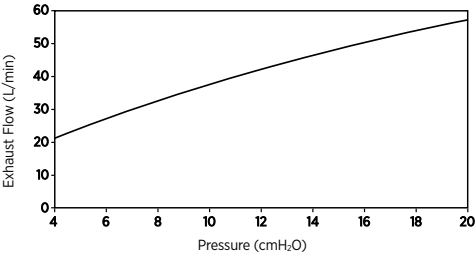
Technical specifications

Exhaust flow information

The F&P Solo 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 exhaled CO₂ is expelled from the mask.

Pressure (cmH₂O)	4	6	8	10	12	14	16	18	20
Flow (L/min)	15	20	25	29	34	38	42	46	49

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



Resistance to flow

Pressure drop through the nasal mask at 50 L/min: 0.8 ± 0.5 cmH₂O.
Pressure drop through the nasal mask at 100 L/min: 2.9 ± 1.0 cmH₂O.
Pressure drop through the pillows mask at 50 L/min: 1.6 ± 1.1 cmH₂O.
Pressure drop through the pillows mask at 100 L/min: 6.0 ± 3.1 cmH₂O.

Mask dead space

Nasal: Small = 29.6 cm³ Medium = 26.8 cm³ Large = 31.1 cm³
Wide = 36.9 cm³
Pillows: Small = 25.8 cm³ Medium = 27.7 cm³ Large = 30.5 cm³

Sound

The sound power level of the mask is 31.5 dBA, with uncertainty ± 2.5 dBA.
The sound pressure level of the mask is 23.6 dBA, with uncertainty ± 2.5 dBA.

Mask materials

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

Component	Material
Cushion	Polycarbonate (PC)/Silicone
Frame	Nylon
Headgear	Polyether Block Amide (PEBA)/Nylon/Silicone/Polycarbonate (PC)/Carbon Reinforced Nylon
Tube	Polycarbonate (PC)/Polyurethane
Swivel	Nylon

Replacement parts

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

Product Code	Description
400SLN111, 400SLN115*	Solo Nasal Cushion Small Spare
400SLN112, 400SLN116*	Solo Nasal Cushion Medium Spare
400SLN113, 400SLN117*	Solo Nasal Cushion Large Spare
400SLN114, 400SLN118*	Solo Nasal Cushion Wide Spare
400SLP111, 400SLP114*	Solo Pillows Cushion Small Spare
400SLP112, 400SLP115*	Solo Pillows Cushion Medium Spare
400SLP113, 400SLP116*	Solo Pillows Cushion Large Spare
400SLN131*	Solo Nasal Mask No H/G Small
400SLN132*	Solo Nasal Mask No H/G Medium
400SLN133*	Solo Nasal Mask No H/G Large
400SLN134*	Solo Nasal Mask No H/G Wide
400SLP131*	Solo Pillows Mask No H/G Small
400SLP132*	Solo Pillows Mask No H/G Medium
400SLP133*	Solo Pillows Mask No H/G Large
400SL121, 400SL122*	Solo Headgear Spare
400SL141	Solo Tube, Frame & Swivel

*Not available in all countries.

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

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

Intellectual property information

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

Symbol definitions

 Single patient multiple use	 Date of manufacture	 Recycling symbol	 Manufacturer	 Catalogue number	 Batch code
 Authorized European Representative	 Storage temperature limitation	 Caution/Warning	 Humidity limitation	 Medical device	 Use by date
 Prescription only	 Unique device indicator	 Consult instructions for use	 Follow instructions for use	 Small cushion size	 Medium cushion size
 Large cushion size	 Wide cushion size	 Importer	 Distributor	 Authorised representative for Switzerland	 UK Responsible Person

Rx only



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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: c.s@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: Ostim 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

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