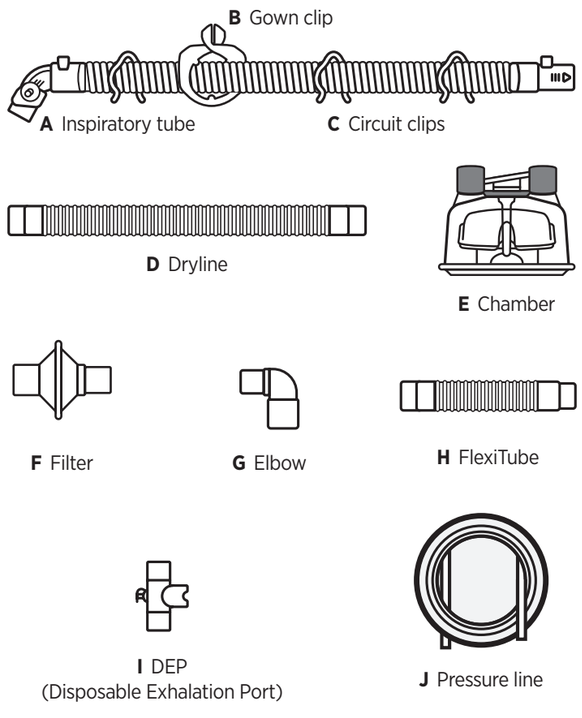
F&P 850

F&P 850 AirSpiral™
Adult NIV and NHF circuit kit

USER INSTRUCTIONS REF 850A61J

Rx only

Kit components



Note: The Elbow (G) is optional and can be used to simplify the connection of the dryline and filter to a ventilator with a side-facing inspiratory gas connection.

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Fisher & Paykel HEALTHCARE

Essential information

F&P 850 AIRSPIRAL ADULT NIV AND NHF CIRCUIT KIT
For the delivery of heated, humidified breathing gases to spontaneously breathing adult patients. This breathing set is suitable for use with Fisher & Paykel Healthcare MR850 Humidifiers in hospital and long-term care environments.

CONTRAINDICATIONS
When using the exhalation port, it should not be used on patients who:
- Are unconscious, are unable to breathe spontaneously, are uncooperative, or are unresponsive.
- Have copious secretions, are at risk of nausea or vomiting, or are at risk of aspiration of vomitus.

If symptoms of these conditions occur, discontinue treatment immediately.

TECHNICAL SPECIFICATIONS
Compatible with Fisher & Paykel Healthcare MR850 Humidifiers. Refer to humidifier user instructions.

INTERFACE CONNECTIONS ISO 5356-1 Conical Connectors

850A61 SET-UPS	COMPONENTS
Breathing Set with FlexiTube and Elbow	A, D, E, F, I, J, H, G
Breathing Set	A, D, E, F, I, J

COMPLIANCE @ 60 cmH$_2$O
Breathing set with FlexiTube and Elbow 1.46 ± 0.13 mL/cmH$_2$O
Breathing set 1.25 ± 0.12 mL/cmH$_2$O
(including 0.06 mL/cmH$_2$O measurement uncertainty)

RESISTANCE TO FLOW @ 30 L/min
Breathing set with FlexiTube and Elbow 1.23 ± 0.13 cmH$_2$O
Breathing set 1.11 ± 0.13 cmH$_2$O
(including 0.03 cmH$_2$O measurement uncertainty)

MAXIMUM OPERATING PRESSURE 80 cmH$_2$O
MINIMUM OPERATING PRESSURE 4 cmH$_2$O
CIRCUIT LENGTH 1.6 m
MINIMUM INTERNAL DIAMETER 17 mm
COMPRESSIBLE VOLUME 1.0 L
GAS LEAKAGE @ 60 cmH$_2$O < 40 mL/min

OVERALL PERFORMANCE AT 20 °C TO 26 °C AMBIENT TEMPERATURE		
	NONINVASIVE MODE	INVASIVE MODE
Humidification Output	> 12 mg/L	> 33 mg/L
Flow Rate	10-120 L/min	10-60 L/min

FILTRATION EFFICIENCY
Viral > 99.99%
Organism ΦX174 Bacteriophage
Bacterial > 99.999%
Organism Bacillus subtilis
Mean particle size 3 µm
NaCl 98.04%

	Incorrect water level, replace MR290 chamber	Rx only	Prescription only
	Correct water level in the MR290 chamber	CE 0123	CE Marking 93/42/EEC
	Consult operating instructions		Date of manufacture
	Type BF applied part		Manufacturer
	Not made with phthalates		Use-by date
	Not made with natural rubber latex		Caution/Consult instructions for use
	Single use	14	14 Days maximum use
LOT	Lot number		Transportation and storage temperature limits
	To Be Disposed		Do not open with blade
	Patient end		Circuit end
MD	Medical Device		Exhaled gas

WARNINGS, CAUTIONS AND NOTES

⚠ WARNINGS
- DO NOT reuse this product. Reuse may result in transmission of infectious substances, interruption to treatment, serious harm or death.
- The use of breathing circuits, chambers, accessories, or combinations which are not approved by Fisher & Paykel Healthcare may result in poor humidification system performance, ventilator malfunction and harm to the patient/user.
- Appropriate patient monitoring (e.g. oxygen saturation) must be used at all times. Failure to monitor the patient (e.g. in the event of an interruption to gas flow) may result in serious harm or death.
- DO NOT touch the heater-plate or chamber base. Surfaces may exceed 85 °C. Failure to comply may result in a skin burn.
- Exhalation port must be used with a non-vented interface on a single limb system. Failure to comply may lead to patient inhaling excess carbon dioxide resulting in hypercapnia.

Failure to comply with the following warnings may impair performance of the device or compromise safety (including potentially cause serious harm):
- DO NOT use beyond 14 days maximum duration of use.
- The F&P Optiflow OPT970 'Tracheostomy Direct Connection' MUST be used when providing high flow therapy via a tracheostomy tube. This is to ensure that there is an open pathway for the patient to exhale.
- DO NOT soak, wash, or sterilize this product. Avoid contact with chemicals, cleaning agents, or hand sanitizers.
- DO NOT use the chamber if the water level rises above the maximum water level line.
- DO NOT use the chamber if the seals are not intact when received, or if it has been dropped.
- When mounting a humidifier adjacent to a patient, ensure that humidifier is always positioned lower than the patient.
- DO NOT operate the chamber at an angle in excess of 10°.
- DO NOT spike the water source until the blue caps have been removed. Should the primary float fail, splashing into the circuit may occur if the chamber is being operated in excess of 80 L/min.
- DO NOT use heated wire breathing circuits without gas flow. If gas flow is interrupted, turn the humidifier off.
- Ensure there is a water supply connected to the chamber and that water is present within the chamber.
- Use USP Sterile Water for Inhalation or equivalent for humidification. DO NOT add other substances to the water.
- The water source must be at least 50 cm higher than the chamber.
- DO NOT fill the chamber with water in excess of 37 °C.
- DO NOT cover circuit with materials such as blankets, towels or bed linen.
- Avoid prolonged contact of heated tubes with patient's skin.
- DO NOT stretch or milk the tubing.
- Change filter every 24 hours, or sooner if noticeable deterioration occurs, following standard hospital procedure.
- When nebulized drugs are used, resistance to flow should be monitored, and the filter replaced following standard hospital procedure.
- DO NOT block or seal the vent holes on the exhalation port.
- Ensure appropriate ventilator or flow source alarms are set before connecting breathing set to patient.
- Before connecting to patient, ensure that flow and pressure testing applicable to the ventilator has been completed.
- Visually inspect breathing sets for damage (e.g. a crushed tube or cracked connector) before use, and replace if damaged.
- Regularly monitor and drain condensate build-up in the circuit.
- Check all connections are tight before use.
- Remove any sources of ignition such as cigarettes or open flames.
- 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
- This product is not intended to be used with an endotracheal tube.

NOTES
- For use under the supervision of trained medical personnel.
- Dispose of product according to Hospital protocol. User may be exposed to breathing tract fluids during disposal.
- The responsible organization is accountable for the compatibility of the humidifier and all of the parts and accessories used to connect to the patient and other equipment before use.
- If a serious incident has occurred while using this device please notify your local Fisher & Paykel Healthcare representative and Competent Authority.
- Refer to the interface's user instruction for detailed instructions for use.

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Australia (AU) (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **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 传真: +86 20 32052132 **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 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany (DE)** Fisher & Paykel Healthcare GmbH, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong (HK)** Tel: +852 2116 0032 Fax: +852 2116 0085 **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 Fax: +82 2 6309 6901 **Mexico (MX)** Tel: + 52 55 9130 1626 **Poland (PO)** Tel: 00800 49 119 77 Fax: 00800 49 119 78 **Russia (RU)** Tel. and Fax: +7 495 782 21 50 **Switzerland (CH)** CH REP Fisher & Paykel Healthcare GmbH, Zweigniederlassung Wil, Säntisstrasse 2, 9501 Wil / SG, Switzerland Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan (TW)** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey (TK)** 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 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA (US)/Canada (CA)** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001
Austria (AT) Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux (BE NL LU)** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Denmark (DK)** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland (FI)** Tel: +358 9 251 66 123 Fax: +46 83 66 310 **Ireland (IRE)**Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy (IT)** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Norway (NO)** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Spain (ES)** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden (SE)** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10

F&P 850

Humidifier Setup

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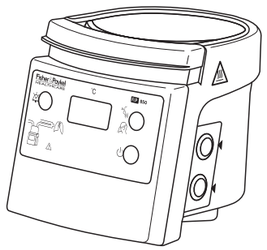
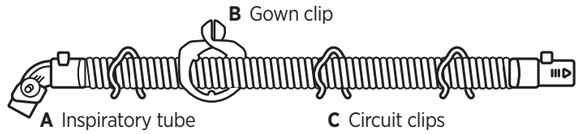
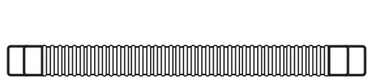


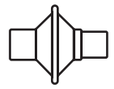
Kit components required for humidifier setup





D Dryline

E Chamber



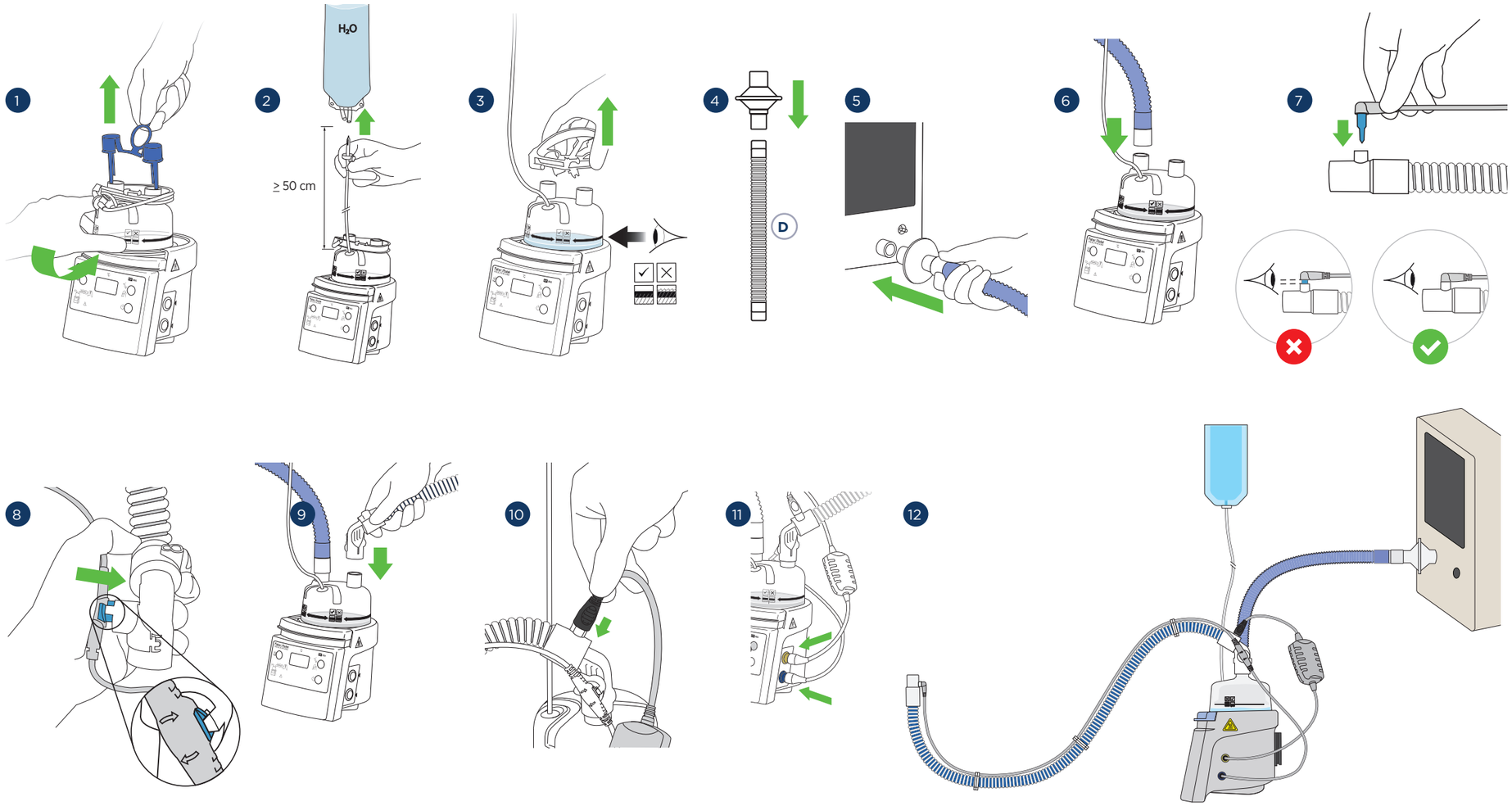
F Filter

Optional

G Elbow

Setup instructions

1. Remove the blue port caps from the chamber. Slide the chamber **(E)** into the MR850 humidifier.
2. Unwind the water feed set. Connect the water bag spike to a water bag. Ensure the water bag is positioned at least 50 centimetres above the chamber.
3. Remove the water feed set winder. Check the chamber **(E)** water level is below the maximum water line.
4. Connect the filter **(F)** to the dryline **(D)**.
5. Connect the filter **(F)** end of the dryline **(D)** to the flow source outlet port,
6. Connect the other end of the dryline **(D)** to the chamber **(E)** port.
7. Insert the patient-end temperature probe into the patient-end probe port on the inspiratory tube **(A)**. Ensure the probe is fully engaged. There should be no blue probe visible outside the probe port.
8. Insert the chamber end of the temperature probe; push the probe until it is engaged with the latch on the connector.
9. Connect the chamber end of the AirSpiral inspiratory limb **(A)** to the other chamber **(E)** port.
10. Plug in the inspiratory heater-wire adapter to the chamber end of the AirSpiral inspiratory limb **(A)**.
11. Insert the temperature probes and heater-wire adapter into the MR850 humidifier.
12. Check that the system configuration is set-up as shown.



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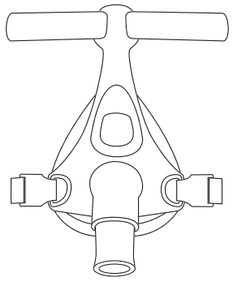
F&P 850

Noninvasive Therapy (NIV)
Non-vented Mask



Before starting:

Non-Vented Mask Requirements:

- Mask must be compatible with humidified gas
- Mask must be compatible with ventilators delivering CPAP or Bi-Level therapy using a single limb circuit
- Mask must have a 22 mm female conical taper connector that conforms to ISO:5356-1

Examples:

- F&P Visairo™: RT075X
- F&P Nivairo™: RT045X

MR850 Humidifier Settings:

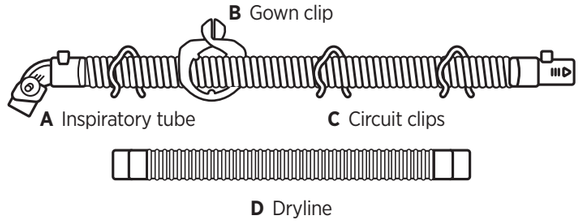
- Mask mode

Ventilator Compatibility:

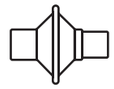
- Ventilator which can provide CPAP or Bi-Level therapy via a single-limb circuit with an exhalation port that is intended to leak.

Ventilator Mode	CPAP or Bi-Level
Allowable Flow Range	10 to 120 LPM (refer to patient interface instructions for additional flow limitations)
Input Gas:	• Dry medical air • Room Air • Oxygen–air blends
Breathing Tube connection	ISO:5356-1 22 mm female conical taper connector
Pressure Tube connection	A pressure monitoring port that can accept an 1/8" (3.2mm) ID pressure line.

Kit components required for humidifier setup



E Chester



F Filter

Optional

G Elbow

Additional components for non-vented mask setup

H FlexiTube

I DEP

J Pressure line

Setup instructions

13. Connect one end of the pressure line **(J)** to the pressure port on the DEP (Disposable Exhalation Port) **(I)**.
14. Connect the other end of the pressure line **(J)** to the pressure-monitoring port on the ventilator.
15. Connect the DEP **(I)** to the patient end of the AirSpiral™ inspiratory limb **(A)**.
16. Connect the opposite end of the DEP **(I)** to the non-vented mask.
    - Do not connect the exhalation port of the DEP **(I)** to the AirSpiral inspiratory limb **(A)** or the mask.
17. Use the gown clip **(B)** to secure the circuit to clothing or bedding.
18. Check that the system configuration is set-up as shown, then turn on the ventilator selecting appropriate modes and settings. Refer to Ventilator Compatibility section shown on the left. Finally, fit the mask to the patient. Please refer to the mask user instructions for proper sizing and fitting.
19. Turn on the MR850 humidifier. Please refer to the MR850 humidifier user instructions.
20. Check that the MR850 humidifier is in Mask mode.

Optional:

21. If the patient finds the humidification too hot, or the mask is pulling on their face, the FlexiTube **(H)** may be added to the set-up. Ensure the Flexi Tube **(H)** is placed between the AirSpiral inspiratory limb **(A)** and the DEP **(I)**.

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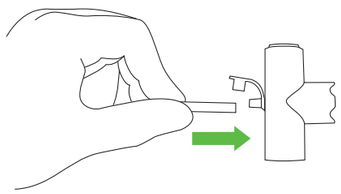

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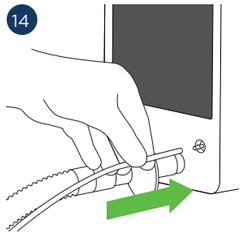

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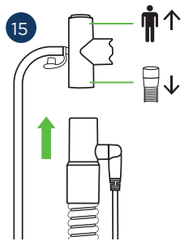

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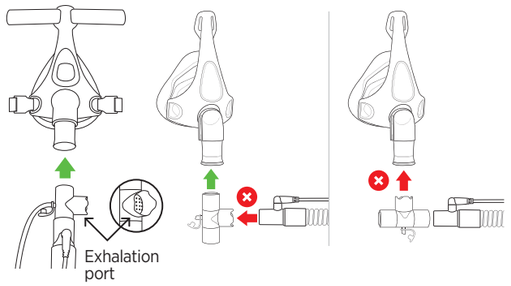

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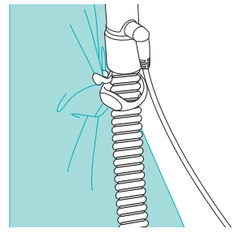

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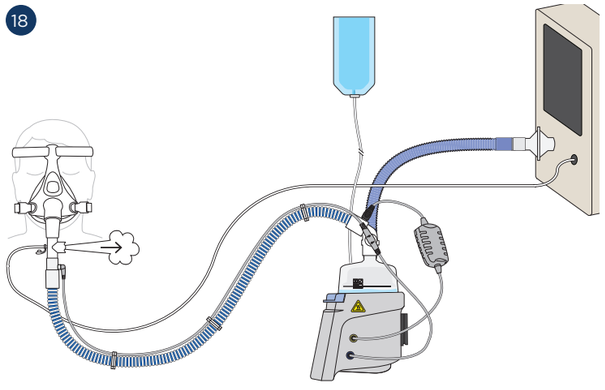

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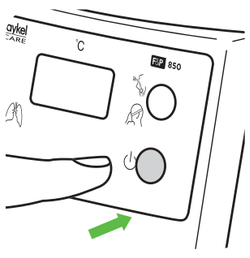

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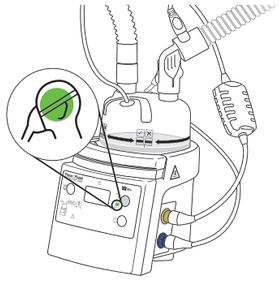

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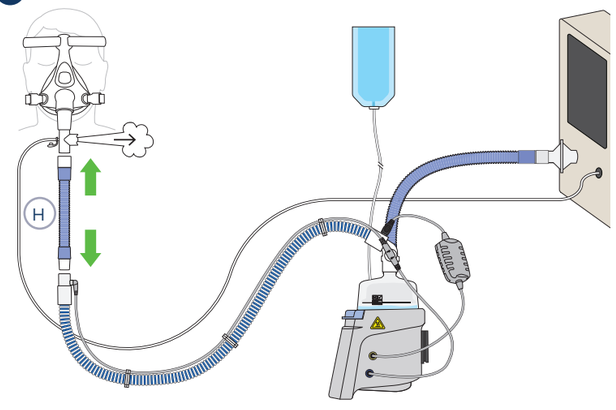
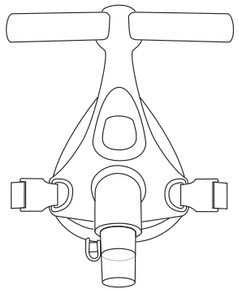


F&P 850

Noninvasive Therapy (NIV)
Vented Mask



Before starting:

Vented Mask Requirements:

- Mask must be compatible with humidified gas
- Mask must be compatible with ventilators delivering CPAP or Bi-Level therapy using a single limb circuit
- Mask must have a 22 mm conical taper connector that conforms to ISO:5356-1

Examples:

- F&P Visairo: RT077X
- F&P Nivairo: RT047X

MR850 Humidifier Settings:

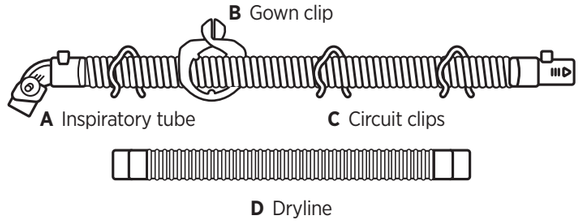
- Mask mode

Ventilator Compatibility:

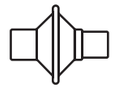
- Ventilator which can provide CPAP or Bi-Level therapy via a single-limb circuit with an exhalation port that is intended to leak.

Ventilator Mode	CPAP or Bi-Level
Allowable Flow Range	10 to 120 LPM (refer to patient interface instructions for additional flow limitations)
Input Gas:	• Dry medical air • Room Air • Oxygen–air blends
Breathing Tube connection	ISO:5356-1 22 mm female conical taper connector
Pressure Tube connection	A pressure monitoring port that can accept an 1/8" (3.2mm) ID pressure line.

Kit components required for humidifier setup



E Chamber



F Filter

Optional

G Elbow

Additional components for vented mask setup

H FlexiTube

J Pressure line

Setup instructions

13. Connect the pressure line **(J)** to the pressure port on the mask.
14. Connect the other end of the pressure line **(J)** to the pressure-monitoring port on the ventilator.
15. Connect the AirSpiral inspiratory limb **(A)** to the vented mask.
16. Use the gown clip **(B)** to secure the circuit to clothing or bedding.
17. Check that the system configuration is set-up as shown, then turn on the flow source, selecting appropriate modes and settings. Refer to ventilator Compatibility section shown on the left. Finally, fit the mask to the patient. Please refer to the mask user instructions for proper sizing and fitting.
18. Turn on the MR850 humidifier. Please refer to the MR850 humidifier user instructions.
19. Check that the MR850 humidifier is in Mask mode.

Optional:

20. If the patient finds the humidification too hot, or the mask is pulling on their face Flexi Tube **(H)** may be added to the set-up. Ensure the Flexi Tube **(H)** is placed between the AirSpiral inspiratory limb **(A)** and the vented mask.

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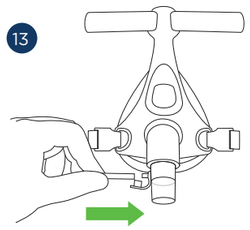

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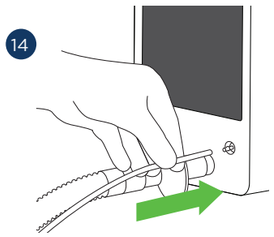

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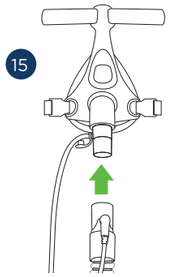

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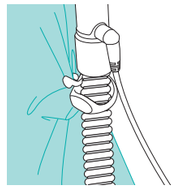

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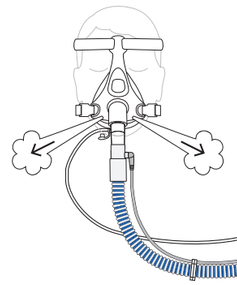

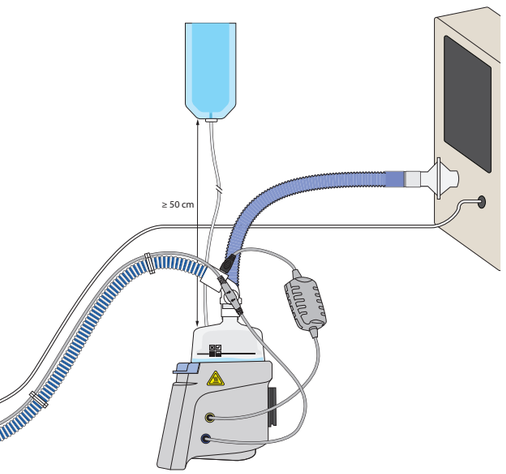

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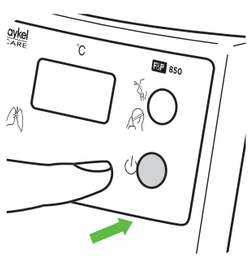

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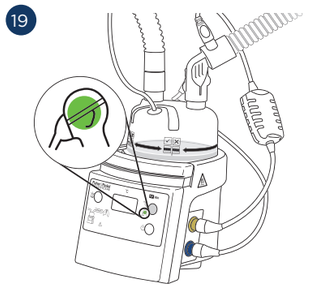

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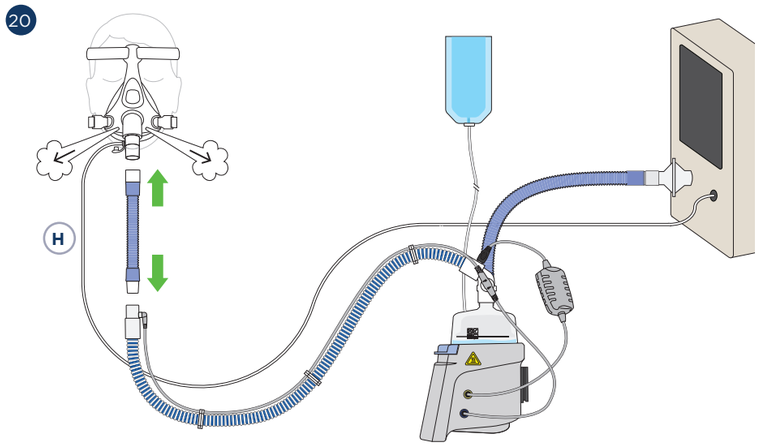
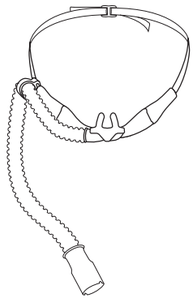


F&P 850

High Flow Therapy (HF)
Nasal Cannula



Before starting:

Nasal Cannula requirements:

- Nasal Cannula must be compatible with humidified gas
- Nasal Cannula must be compatible with flow sources delivering high flow therapy using a single limb circuit
- Nasal Cannula must have a 22 mm male conical taper connector that conforms to ISO:5356-1

Examples:

- F&P Optiflow™ 3S: OPT104X
- F&P Optiflow™ +: OPT94X

MR850 Humidifier Settings:

- Invasive mode

When using nasal high flow interfaces for high flow therapy, Invasive Mode is recommended to provide levels of humidity closer to saturated at body temperature.

Flow Source Compatibility:

Flow Source	• Ventilator with high flow therapy mode • Air-Oxygen Blender • Venturi Blender with Flow Meter.
Flow Source Mode	High Flow
Allowable Flow Range	10 to 60 LPM (refer to patient interface instructions for additional flow limitations)
Input Gas:	• Dry medical air • Room Air • Oxygen–air blends
Breathing Tube connection	ISO:5356-1 22 mm female conical taper connector

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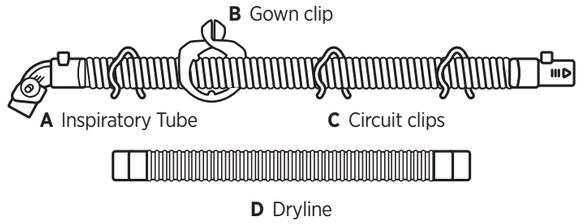
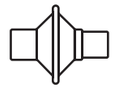
Kit components required for humidifier setup



E Chamber



F Filter

Optional

G Elbow

Setup instructions

13. Fit the nasal cannula to the patient. Please refer to the nasal cannula user instructions for proper sizing and fitting. Then connect the Nasal Cannula directly to the AirSpiral inspiratory limb **(A)**.
14. Use the gown clip **(B)** to secure the circuit to clothing or bedding.
15. Check that the system configuration is set-up as shown, then turn on the flow source selecting appropriate modes and settings. Refer to the Flow Source Compatibility section shown on the left.
16. Turn on the MR850 humidifier. Please refer to the MR850 humidifier user instructions.
17. Check that the MR850 humidifier is in Invasive mode.
18. **Do not** use the FlexiTube **(H)** in the Nasal Cannula setup.

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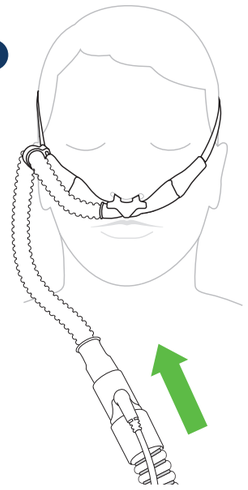

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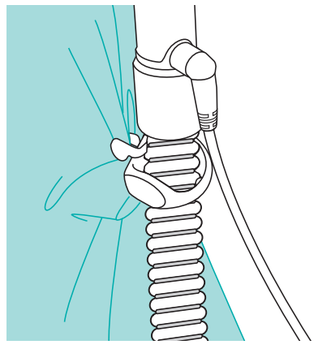

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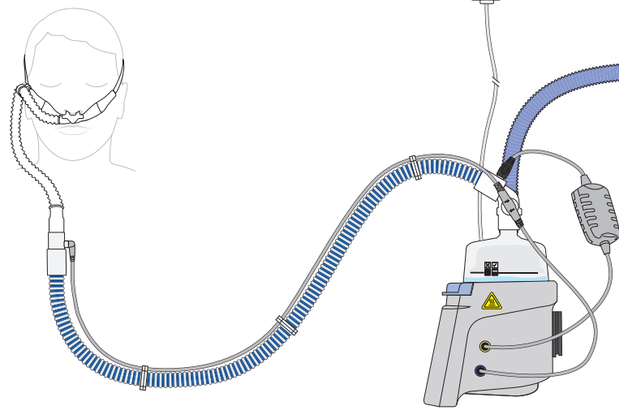

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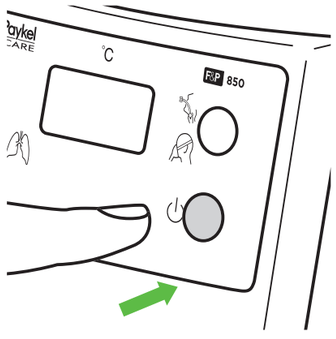

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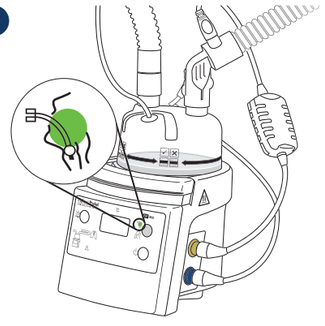

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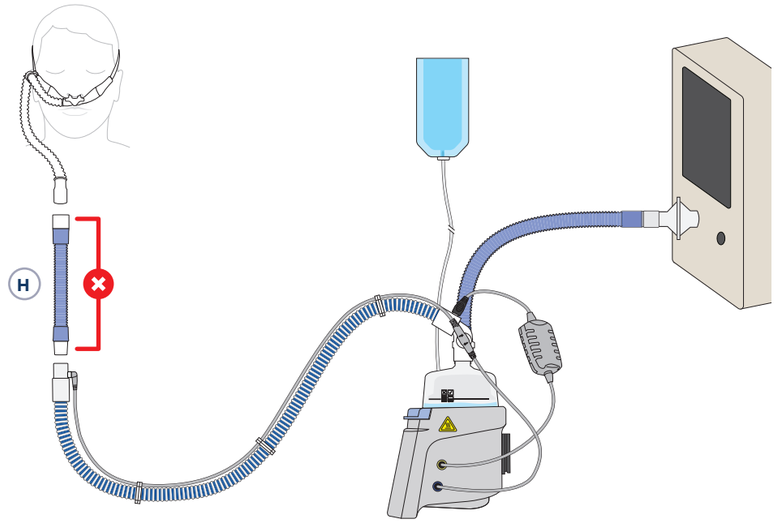
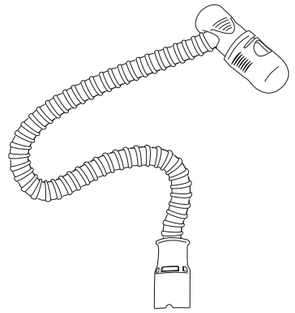


F&P 850

High Flow Therapy (HF)
Tracheostomy Direct Connection



Before starting:

High Flow Therapy via only F&P 'Tracheostomy Direct Connection' Interface:

- F&P Optiflow+: OPT970 (Including built-in exhalation path).

MR850 Humidifier Settings:

- Invasive Mode

Flow Source Compatibility:

Flow Source	• Ventilator with high flow therapy mode • Air-Oxygen blender • Venturi Blender with flow meter.
Flow Source Mode	High Flow
Allowable Flow Range	10 to 60 LPM (refer to patient interface instructions for additional flow limitations)
Input Gas	• Dry medical air • Room Air • Oxygen–air blends
Breathing Tube connection	ISO:5356-1 22 mm female conical taper connector

Tracheostomy Tube Compatibility:

- Single lumen tubes
- Double lumen tubes
- Uncuffed tubes
- Cuffed tubes
- Fenestrated tubes
- Adjustable flange tubes

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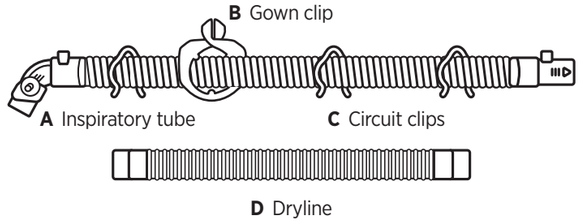
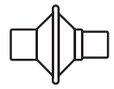
Kit components required for Humidifier setup



E Chamber



F Filter

Optional

G Elbow

Setup instructions

13. Connect the 22mm male conical connector of the tracheostomy direct Connection directly to the AirSpiral inspiratory limb **(A)**.
Warning: The F&P Optiflow OPT970 'Tracheostomy Direct Connection' MUST be used when providing high flow therapy via a tracheostomy tube. This is to ensure that there is an open pathway for the patient to exhale.
14. Use the gown clip **(B)** to secure the circuit to clothing or bedding.
15. Check that the system configuration is set-up as shown, then turn on the flow source selecting appropriate modes and settings. Refer to the Flow Source Compatibility section shown on the left. Finally, fit the Tracheostomy Direct Connection to the patient. Please refer to the Tracheostomy Direct Connection user instructions for proper fitting.
16. Turn on the MR850 humidifier. Please refer to the MR850 humidifier user instructions.
17. Check that the MR850 humidifier is in Invasive Mode.
18. **Do not** use the FlexiTube **(H)** in the tracheostomy direction connection setup.

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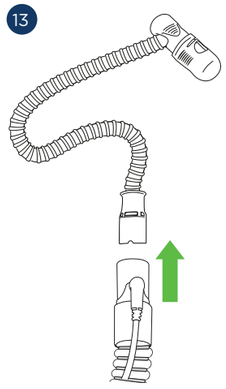

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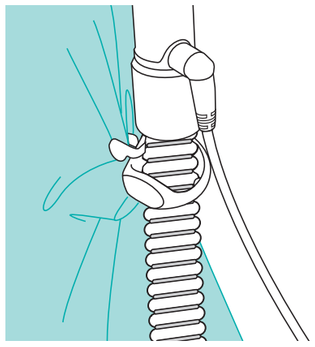

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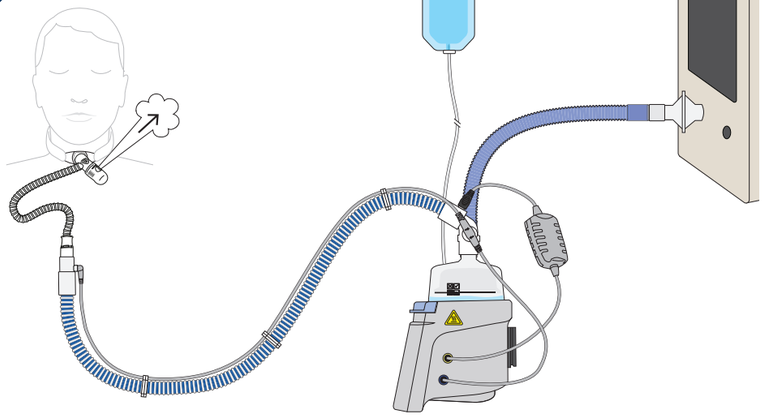

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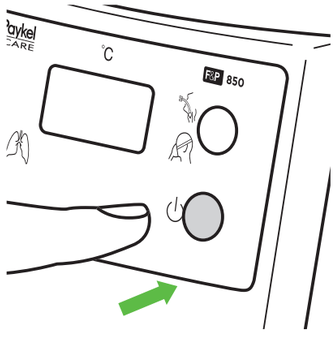

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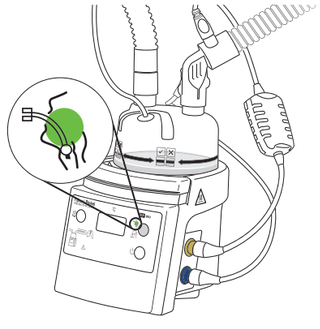

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