

# eVolution® 3e Essential

## Features

- Comprehensive Graphics and Trending
- High Performance PSOL and Active Exhalation
- Servo Controlled for Precise Breath Delivery
- Neonatal through Adult
- Invasive and Noninvasive
- HL7 Compatibility and Virtual Report
- Capnography ready
- High Flow Oxygen
- 2ml Tidal Volume
- Weaning Target Tool
- Lung Model
- HEPA Filter (standard on Turbine Model)

High Pressure System Ventilator

Internal Turbine System Ventilator



## eVolution® 3e Essential

## Modes of Ventilation

- Assisted Control Mandatory Ventilation (CMV)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Spontaneous Ventilation (CPAP + PS, CPAP + VS, SPAP)

## Additional Features

- Auto Control
- Apnea Backup Ventilation
- SPAP Philosophy Options: Time, Cycle + Time, Cycle + I:E
- IBW Calculator
- NIV On/Off in all Modes
- Active Exhalation Valve
- Automatic Leak Compensation (up to 60 lpm)
- Work of Breathing Imposed
- Maneuvers: PO.1 and PiMax

## Breath Types

- Volume-controlled (V-CMV; V-SIMV)
- Pressure-controlled (P-CMV; P-SIMV, PS)
- Volume Targeted Pressure-controlled (PRVC-CMV; PRVC-SIMV, VS)
- Dual Level PEEP (SPAP)
- Equivalent to APRV & BiLevel

## Breath Triggering

- Pressure triggering -0.1 to (- 20) cmH<sub>2</sub>O
- Flow triggering 0.1 - 25 lpm

## Additional Settings

- Respiratory rate 1 - 120 bpm
- Tidal volume 20 - 3000 ml
- PEEP / CPAP 0 - 50 cmH<sub>2</sub>O
- Pcontrol 1 - 100 cmH<sub>2</sub>O
- Psupport 0 - 100 cmH<sub>2</sub>O
- Peak flow (mandatory) 1 - 150 lpm
- Peak flow (spontaneous) Up to 200 lpm
- Peak flow (Turbine Output) Up to 300 l/min
- I-Times 0.2 - 10.0 sec
- Oxygen concentration 21 - 100%
- Rise time settings 1 - 20
- Exhalation sensitivity % (of spontaneous peak flow) 1 - 80%
- Base Flow (with leak comp off) 2.5 - 25 lpm
- Plateau (insp pause) 0 - 2.0 sec

## Neonatal Software Option Part Number: EVM400156

- NCPAP+
- Respiratory Rate 1 - 150 bpm
- Tidal volume 2 - 3000 ml
- I-Times 0.1 - 10 sec
- PS Tmax 0.15 - 5.0 sec

## Additional Software Options

- Suction support Part Number: EVM400158
- Automatic tube compensation Part Number: EVM400157
- EtCO<sub>2</sub> Part Number: EVM400182
- Hi FlowO<sub>2</sub> Part Number: EVM400184

## User Initiated Functions

- Manual inspiration • Inspiratory and expiratory
- Alarm silence • breath holds
- 100% oxygen • Standby

## User Configurable Graphic User Interface (GUI) and Functions

- Multiple Easy View Tabs (Main, Settings, Monitoring, Alarms, Configuration)
- Graphics Display (2-Loops and 3-Waveforms)
- Apnea Back-up
  - User-selected breath type and settings
- Smart Nebulizer™
- Smart Sigh™
- Humidification Selection (HME, Humidifier, and None)
- EtCO<sub>2</sub> Graphics Display
- PaCO<sub>2</sub> Time Stamp Entry

## Monitored / Displayed Data

- Delivered oxygen concentrations: 21 - 100%
- Trend Data (1-72 hrs.) (31 trend parameters)
- Monitoring Data (36 monitored parameters):

| Basic                  | Mechanics                      | Weaning                                  |
|------------------------|--------------------------------|------------------------------------------|
| - Respiratory Rate     | - Auto - PEEP                  | - Ve Spont                               |
| - PEEP + Pplateau      | - Pmin                         | - Vte Spont                              |
| - Ppeak & Pmean        | - Cdyn                         | - PO.1 & PiMax                           |
| - Exp Min Vol (Ve)     | - Cstat                        | - RSBI                                   |
| - Vte & Vti            | - Cstat / kg                   | - Rate Spont                             |
| - O <sub>2</sub>       | - Ptrach                       | - Ti / Ttot                              |
| - Te & Ti              | - Ri & Re                      | - Spont % 1h                             |
| - PFi & PFe            | - Rce                          | - Spont % 8h                             |
| - I:E / H:L            | - VT/kg                        | - PO.1 / PiMax                           |
| - Leak                 |                                | - WOBimp                                 |
| Real Time Graphics     | EtCO <sub>2</sub> Graphics     | EtCO <sub>2</sub>                        |
| - Flow Volume Loop     | - PCO <sub>2</sub> Volume Loop | - PetCO <sub>2</sub> - Vd / Vt           |
| - Pressure Volume Loop | - FCO <sub>2</sub> Volume Loop | - VCO <sub>2</sub> / min - Valv          |
| - Flow + Time          | - PCO <sub>2</sub> + Time      | - VtiCO <sub>2</sub> - Valv / min        |
| - Pressure + Time      | - FCO <sub>2</sub> + Time      | - FetCO <sub>2</sub> - PeCO <sub>2</sub> |
| - Volume + Time        | - VteCO <sub>2</sub> + Time    | - Vd ana - FeCO <sub>2</sub>             |
|                        |                                | - Vd alv                                 |

## Prioritized Alarms (High, Medium and Low)

- Auto set alarm feature & 1000 Event log

## Communication Interfaces

- Ethernet and Nurse call

## Physical Data

- AC power: 100 - 240 VAC (47/63Hz)
- Standard internal battery (Lithium-Ion\* & Lead Acid\*\*)
- Battery backup: 2 Hours (HP Model), 4 Hours (Turbine Model)
- Gas supply pressure, 2 to 6 Bar
- Screen: LCD 12.1" / Touch Screen

## HL7 Protocol Compatibility and Optional Remote Viewing System

- CliniNet® Virtual Report™ Software
- CliniNet® HL7 Gateway™

## High Performance Internal Technology

- Integrated high performance turbine technology with included HEPA filter\*
- Low Flow O<sub>2</sub> Capability\*

## Ordering Information

- Model EVL100500-HP, High Pressure System
- Model EVL100500-T, Internal Turbine System
- Model EVL100500-HP-NF, High Pressure System without Exhalation Filter
- Model EVL100500-T-NF, Internal Turbine System without Exhalation Filter

\*Only available on turbine models. \*\*Only available on high pressure models.

Specifications subject to change. eVent Medical recommends using exhalation filters on all systems.

## Adult and Infant Respiratory Care



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## Our Story

At Fisher & Paykel Healthcare, we fully understand the life-changing impact that can result from delivering inspired and world-leading healthcare solutions. After all, we changed the way the world delivers respiratory humidification to critically ill patients in hospital, and were the first organisation in the world to make a humidifier specifically for use in the treatment of patients with obstructive sleep apnea.

Today, through an unrivalled commitment to innovation; to doing the right thing; and doing what is best for the patient, we continue to inspire world-leading healthcare solutions. Our team of self-motivated, empathetic and committed individuals is our strength. It is this team; our originality; the value we place on relationships; our international perspective; and the utmost care for all patients, customers, suppliers, shareholders, as well as the environment, that will ultimately ensure we will be the healthcare company of choice.

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## Our Purpose

Improving care and outcomes through inspired and world-leading healthcare solutions.



# Welcome



**Fisher & Paykel Healthcare is a global leader in design, manufacturing and marketing of medical devices and systems for use in respiratory care and acute care.**

Our products and systems are sold in over 120 countries worldwide. We sell our products through direct sales offices operations in most of our major markets, and a network of distributors that sell to hospitals, healthcare providers and other manufacturers of medical devices.

Fisher & Paykel entered the respiratory care market in 1971 with the development of a unique respiratory humidifier system for use in critical care. We now offer a broad range of products and systems for use in respiratory and acute care and in the treatment of OSA.



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## **F&P 810™ System**

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## **General humidifier brackets & hardware**

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**Disclaimer:** Please note that the information in this catalogue (including the product information and images) is summarized and provided for illustrative purposes only. Please refer to the relevant user instructions for more information and confirm details with your local Fisher & Paykel Healthcare representative prior to placing an order. Information is subject to change without notice.



# AIRVO™ 2 Humidifier

with Integrated Flow Generator



The AIRVO 2 generates high flows of warmed and humidified respiratory gases, delivered to the patient through a variety of nasal, tracheostomy and mask interfaces.

## AIRVO™ 2 System

| Product Code | Description                                                                           | Quantity |                                                                                       |
|--------------|---------------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| PT101XX      | AIRVO™ 2 humidifier with integrated flow generator<br>XX indicates regional variation | 1 each   |    |
| OPT942       | Optiflow™+ nasal cannula for AIRVO™/F&P 850 System - Small                            | 20 pack  |    |
| OPT944       | Optiflow™+ nasal cannula for AIRVO™/F&P 850 System - Medium                           | 20 pack  |    |
| OPT946       | Optiflow™+ nasal cannula for AIRVO™/F&P 850 System - Large                            | 20 pack  |    |
| 900PT501     | Tube and chamber kit for AIRVO™                                                       | 10 pack  |   |
| OPT842       | Optiflow™ nasal cannula for AIRVO™/F&P 850 System - Small                             | 20 pack  |  |
| OPT844       | Optiflow™ nasal cannula for AIRVO™/F&P 850 System - Medium                            | 20 pack  |  |
| OPT846       | Optiflow™ nasal cannula for AIRVO™/F&P 850 System - Large                             | 20 pack  |  |
| OPT870       | Optiflow™ tracheostomy interface for AIRVO™/F&P 850 System                            | 20 pack  |  |
| RT013        | Mask interface adaptor                                                                | 20 pack  |  |
| 900PT531     | Tube and chamber kit for AIRVO™ 2 (Junior)                                            | 10 pack  |  |
| OPT316       | Optiflow™ Junior nasal cannula - Infant                                               | 20 pack  |  |
| OPT318       | Optiflow™ Junior nasal cannula - Pediatric                                            | 20 pack  |  |

## AIRVO™ 2 System

| Product Code | Description                | Quantity |                                                                                       |
|--------------|----------------------------|----------|---------------------------------------------------------------------------------------|
| 900PT422     | Oxygen inlet extension kit | 1 each   |    |
| 900PT600     | Disinfection kit           | 1 each   |    |
| 900PT601     | Disinfection filter        | 2 pack   |    |
| 900PT602     | Cleaning sponge stick      | 20 pack  |    |
| 900PT603     | Clean storage cover        | 20 pack  |    |
| 900PT913     | Air filter                 | 2 pack   |   |
| 900PT405     | Pole mounting tray         | 1 each   |  |
| 900PT411     | UPS mounting kit           | 1 each   |  |
| 900PT421     | Mobile pole stand          | 1 each   |  |
| 900PT426     | Accessories basket         | 1 each   |  |
| 900PT427     | Oxygen cylinder holder     | 1 each   |  |

# F&P 850™ System



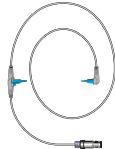
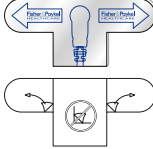
The MR850 (F&P 850 System) Heated Humidifier is part of a complete system designed to deliver optimally humidified gas (37°C and 44 mg/L).

Temperature is measured at both the chamber and at the end of the breathing circuit and a dual feedback system incorporates advanced algorithms designed to achieve optimal humidity levels, while minimizing caregiver attention.

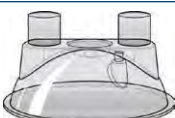
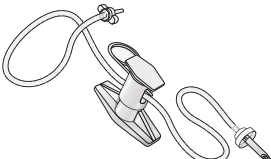
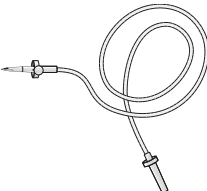
The F&P 850 System incorporating the MR850 Heated Humidifier can be used for the full range of Fisher & Paykel Healthcare therapies across the F&P Respiratory Care Continuum™, including invasive and noninvasive ventilation and Optiflow™ therapies.



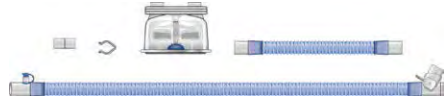
## Humidifier & accessories

| Product Code | Description                                                                    | Quantity |                                                                                       |
|--------------|--------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| MR850XXX     | MR850 respiratory heated humidifier<br>(XXX indicates regional plug variation) | 1 each   |    |
| 900MR817     | MR850 dual heated connection kit                                               | 1 each   |    |
| 900MR805     | Heater wire adaptor for dual-heated breathing circuits                         | 1 each   |    |
| 900MR806     | Heater wire adaptor for inspiratory heated breathing circuits                  | 1 each   |    |
| 900MR863     | Temperature/Flow probe adaptor for use with circuits 0.7 m (28") long          | 1 each   |   |
| 900MR868     | Temperature/Flow probe adaptor for use with circuits 1.1 m (44") long          | 1 each   |  |
| 900MR860     | Temperature/Flow probe adaptor for use with circuits 1.3 m (52") long          | 1 each   |  |
| 900MR869     | Temperature/Flow probe adaptor for use with circuits 1.5m (60") long           | 1 each   |  |
| 900MR861     | Temperature/Flow probe adaptor for use with circuits 1.8m (72") long           | 1 each   |  |
| 900MR870     | MR850 calibration reference probe                                              | 1 each   |  |
| 900MR208     | Reflective shield for temperature probe                                        | 20 pack  |  |

## Humidification chambers

| Product Code | Description                                                          | Quantity |                                                                                       |
|--------------|----------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| MR290V       | Autofeed adult/infant humidification chamber - Vented                | 40 pack  |    |
| MR290VX      | Autofeed adult/infant humidification chamber - Vented                | 10 pack  |    |
| MR290HFV     | Autofeed adult/infant humidification chamber - High frequency vented | 40 pack  |    |
| MR210        | Manual fill adult humidification chamber - Male/Female ports         | 40 pack  |    |
| MR210X       | Manual fill adult humidification chamber - Male/Female ports         | 10 pack  |   |
| MR250        | Manual fill adult humidification chamber - Male/Male ports           | 40 pack  |  |
| MR250X       | Manual fill adult humidification chamber - Male/Male ports           | 10 pack  |  |
| MR225        | Manual fill infant/pediatric humidification chamber                  | 50 pack  |  |
| MR225X       | Manual fill infant/pediatric humidification chamber                  | 10 pack  |  |
| 900MR190     | Chamber water feed set for MR225/MR250                               | 30 pack  |  |
| 900MR191X    | Chamber water feed set extension for MR290                           | 10 pack  |  |

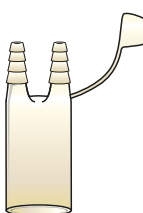
## Adult nasal high flow breathing circuits

| Product Code | Description                                                      | Quantity |                                                                                    |
|--------------|------------------------------------------------------------------|----------|------------------------------------------------------------------------------------|
| RT202        | Adult inspiratory heated breathing circuit with autotest chamber | 10 pack  |  |

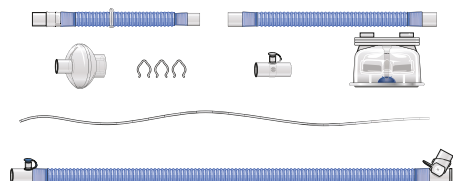
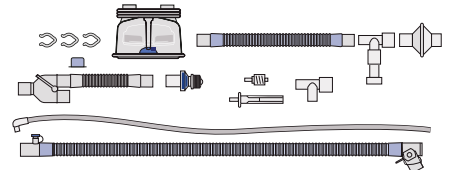
## Adult nasal high flow interfaces & accessories

| Product Code | Description                                                 | Quantity |                                                                                       |
|--------------|-------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| OPT942       | Optiflow™+ nasal cannula for AIRVO™/F&P 850 System - Small  | 20 pack  |    |
| OPT944       | Optiflow™+ nasal cannula for AIRVO™/F&P 850 System - Medium | 20 pack  |   |
| OPT946       | Optiflow™+ nasal cannula for AIRVO™/F&P 850 System - Large  | 20 pack  |  |
| OPT842       | Optiflow™ nasal cannula for AIRVO™/F&P 850 System - Small   | 20 pack  |   |
| OPT844       | Optiflow™ nasal cannula for AIRVO™/F&P 850 System - Medium  | 20 pack  |   |
| OPT846       | Optiflow™ nasal cannula for AIRVO™/F&P 850 System - Large   | 20 pack  |   |
| OPT542       | Optiflow™ nasal cannula for F&P 850 System - Small          | 20 pack  |  |
| OPT544       | Optiflow™ nasal cannula for F&P 850 System - Medium         | 20 pack  |  |

## Adult nasal high flow interfaces & accessories

| Product Code | Description                                                | Quantity |                                                                                     |
|--------------|------------------------------------------------------------|----------|-------------------------------------------------------------------------------------|
| OPT546       | Optiflow™ nasal cannula for F&P 850 System - Large         | 20 pack  |   |
| OPT870       | Optiflow™ tracheostomy interface for AIRVO™/F&P 850 System | 20 pack  |  |
| OPT570       | Optiflow™ tracheostomy interface for F&P 850 System        | 20 pack  |  |
| 900MR961     | Dual flow adaptor - 22 mm Female                           | 20 pack  |  |

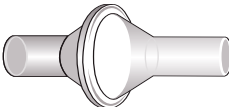
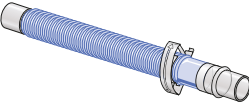
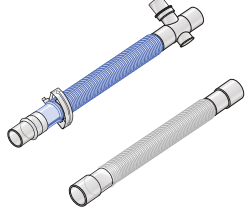
## Adult noninvasive ventilation breathing circuits

| Product Code | Description                                                                                                                              | Quantity |                                                                                      |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------|----------|--------------------------------------------------------------------------------------|
| RT319        | Adult bilevel/CPAP inspiratory heated breathing circuit with autofeed chamber, filter, pressure line & exhalation port                   | 10 pack  |  |
| RT301        | Adult inspiratory heated breathing circuit with autofeed chamber, Y-piece, CPAP extension, adjustable PEEP valve & pressure relief valve | 10 pack  |  |
| RT201        | Adult inspiratory heated breathing circuit with autofeed chamber, Y-piece & CPAP extension                                               | 10 pack  |  |

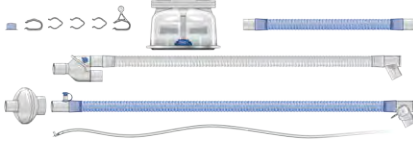
## Adult face masks & accessories

| Product Code | Description                                                                        | Quantity |                                                                                       |
|--------------|------------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| RT040L       | FreeMotion™ vented full face mask with anti-asphyxiation valve - Large             | 10 pack  |    |
| RT040M       | FreeMotion™ vented full face mask with anti-asphyxiation valve - Medium            | 10 pack  |    |
| RT040S       | FreeMotion™ vented full face mask with anti-asphyxiation valve - Small             | 10 pack  |    |
| RT040        | FreeMotion™ vented full face mask without anti-asphyxiation valve (Australia only) | 10 pack  |    |
| RT041L       | FreeMotion™ non-vented full face mask - Large                                      | 10 pack  |   |
| RT041M       | FreeMotion™ non-vented full face mask - Medium                                     | 10 pack  |  |
| RT041S       | FreeMotion™ non-vented full face mask - Small                                      | 10 pack  |  |
| RT042        | FreeMotion™ vented nasal mask                                                      | 10 pack  |  |
| RT042L       | FreeMotion™ vented nasal mask - Large                                              | 10 pack  |  |

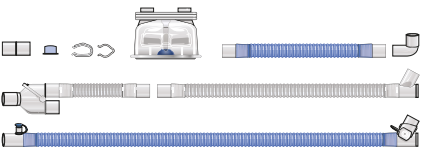
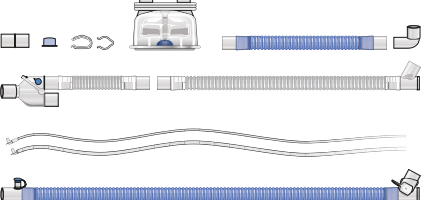
## Adult face masks & accessories

| Product Code | Description                                                                 | Quantity |                                                                                       |
|--------------|-----------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| RT043L       | FreeMotion™ non-vented full face mask with anti-asphyxiation valve - Large  | 10 pack  |    |
| RT043M       | FreeMotion™ non-vented full face mask with anti-asphyxiation valve - Medium | 10 pack  |    |
| RT043S       | FreeMotion™ non-vented full face mask with anti-asphyxiation valve - Small  | 10 pack  |    |
| RT016        | Inspiratory filter                                                          | 20 pack  |    |
| RT022        | Unheated flexible extension                                                 | 20 pack  |   |
| RT023        | Patient ventilator weaning kit                                              | 20 pack  |  |

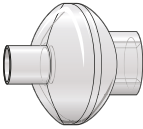
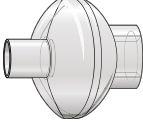
## Adult invasive ventilation breathing circuits

| Product Code | Description                                                                                                                                                  | Quantity |                                                                                      |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|--------------------------------------------------------------------------------------|
| RT385        | Adult Evaqua™ 2 dual heated breathing circuit with autofeed chamber, pressure line & filter                                                                  | 10 pack  |  |
| RT380        | Adult Evaqua™ 2 dual heated breathing circuit with autofeed chamber & filter<br>Adult Evaqua™ 2 dual heated breathing circuit with autofeed chamber & filter | 10 pack  |  |

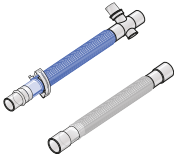
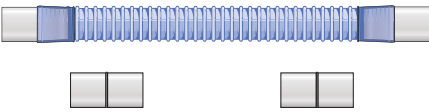
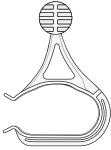
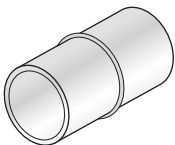
## Adult invasive ventilation breathing circuits

| Product Code | Description                                                                | Quantity |                                                                                     |
|--------------|----------------------------------------------------------------------------|----------|-------------------------------------------------------------------------------------|
| RT280        | Adult Evaqua™ 2 dual heated breathing circuit with autofeed chamber        | 10 pack  |  |
| RT200        | Adult dual heated breathing circuit with autofeed chamber                  | 10 pack  |   |
| RT204        | Adult dual heated breathing circuit with autofeed chamber & pressure lines | 10 pack  |   |

## Adult invasive ventilation interfaces & accessories

| Product Code | Description                               | Quantity |                                                                                       |
|--------------|-------------------------------------------|----------|---------------------------------------------------------------------------------------|
| RT019        | Inspiratory/Expiratory filter             | 20 pack  |   |
| RT020        | Expiratory filter                         | 20 pack  |  |
| RT021        | DirectConnect™ dual swivel catheter mount | 20 pack  |  |

## Adult invasive ventilation interfaces & accessories

| Product Code | Description                        | Quantity |                                                                                       |
|--------------|------------------------------------|----------|---------------------------------------------------------------------------------------|
| RT023        | Patient ventilator weaning kit     | 20 pack  |    |
| RT024        | Dry line extension kit             | 20 pack  |     |
| RT028        | Circuit hanger                     | 20 pack  |    |
| RT032        | Water trap                         | 20 pack  |    |
| RT913        | Inspiratory elbow adaptor - PB7200 | 10 pack  |   |
| RT914        | Inspiratory adaptor - PB840        | 10 pack  |  |

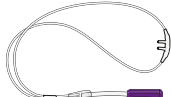
## Infant nasal high flow breathing circuits

| Product Code | Description                                                                                         | Quantity |                                                                                      |
|--------------|-----------------------------------------------------------------------------------------------------|----------|--------------------------------------------------------------------------------------|
| RT330        | Optiflow™ Junior inspiratory heated breathing circuit with autofeed chamber & pressure relief valve | 10 pack  |  |

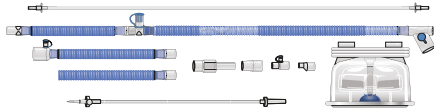
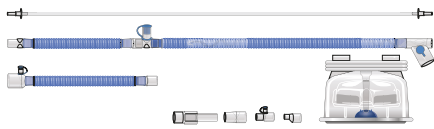
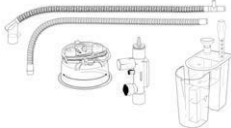
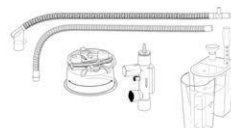
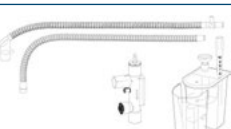
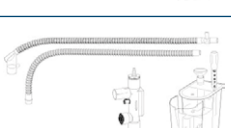
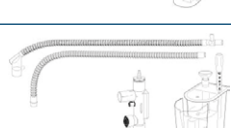
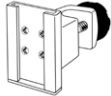
## Infant nasal high flow interfaces & accessories

| Product Code | Description                                | Quantity |                                                                                       |
|--------------|--------------------------------------------|----------|---------------------------------------------------------------------------------------|
| OPT312       | Optiflow™ Junior nasal cannula - Premature | 20 pack  |  |

## Infant nasal high flow interfaces & accessories

| Product Code | Description                                        | Quantity |                                                                                       |
|--------------|----------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| OPT314       | Optiflow™ Junior nasal cannula - Neonatal          | 20 pack  |    |
| OPT316       | Optiflow™ Junior nasal cannula - Infant            | 20 pack  |    |
| OPT318       | Optiflow™ Junior nasal cannula - Pediatric         | 20 pack  |    |
| OPT010       | Optiflow™ Junior Wigglepads™ - Premature (20)      | 2 pack   |    |
| OPT012       | Optiflow™ Junior Wigglepads™ - Infant (20)         | 2 pack   |    |
| OPT014       | Optiflow™ Junior oxygen tubing                     | 10 pack  |   |
| OPT016       | Optiflow™ Junior adaptors kit                      | 10 pack  |  |
| BC402-05     | Gas supply line kit for dual flow meters           | 5 pack   |  |
| BC115-05     | Pressure relief valve                              | 5 pack   |  |
| BC2425-20    | Oxygen therapy nasal cannula - Premature           | 20 pack  |  |
| BC2435-20    | Oxygen therapy nasal cannula - Neonatal            | 20 pack  |  |
| BC2745-20    | Oxygen therapy nasal cannula - Infant              | 20 pack  |  |
| BC2755-20    | Oxygen therapy nasal cannula - Intermediate infant | 20 pack  |  |
| BC3780-20    | Oxygen therapy nasal cannula - Pediatric           | 20 pack  |  |

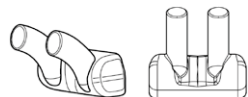
## Infant CPAP therapy breathing circuits & gas supply

| Product Code | Description                                                                                                                                                       | Quantity |                                                                                       |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| RT324        | Infant inspiratory heated breathing circuit with autofeed chamber, pressure line, adaptor kit, expiratory extension & water feed extension (flows > 4L/min)       | 10 pack  |     |
| RT224        | Infant inspiratory heated breathing circuit with autofeed chamber, pressure line & adaptor kit (flows > 4L/min)                                                   | 10 pack  |     |
| BC151-10     | Infant Bubble CPAP™ system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold & CPAP generator (connects to T-bar interface) | 10 pack  |    |
| BC161-10     | Infant Bubble CPAP™ system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold & CPAP generator (connects to F&P interface)   | 10 pack  |    |
| BC171-10     | Infant Bubble CPAP™ system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold & CPAP generator (connects to Flow Driver)     | 10 pack  |    |
| BC153-10     | Infant Bubble CPAP™ system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold & CPAP generator (connects to T-bar interface) | 10 pack  |  |
| BC163-10     | Infant Bubble CPAP™ system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold & CPAP generator (connects to F&P interface)   | 10 pack  |  |
| BC173-10     | Infant Bubble CPAP™ system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold & CPAP generator (connects to Flow Driver)     | 10 pack  |  |
| BC501-01     | Bird® MicroBlender 2-16 L/min DISS                                                                                                                                | 1 each   |  |
| BC506-01     | Blender oxygen/air Bio-Med 2-16 L/min DISS - Green                                                                                                                | 1 each   |  |
| BC507-01     | Blender oxygen/air Bio-Med 2-16 L/min DISS - White                                                                                                                | 1 each   |  |
| BC510-01     | Bird® MicroBlender pole mount bracket                                                                                                                             | 1 each   |  |

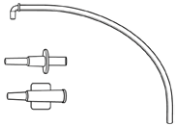
## Infant CPAP therapy interfaces & accessories

| Product Code | Description                                            | Quantity |  |
|--------------|--------------------------------------------------------|----------|--|
| BC190-05     | FlexiTrunk™ nasal tubing universal fitting (50mm)      | 5 pack   |  |
| BC191-05     | FlexiTrunk™ nasal tubing universal fitting (70mm)      | 5 pack   |  |
| BC192-05     | FlexiTrunk™ nasal tubing universal fitting (100mm)     | 5 pack   |  |
| BC3020-10    | Nasal prong (3.0mm nare diameter / 2.0mm septal width) | 10 pack  |  |
| BC3520-10    | Nasal prong (3.5mm nare diameter/ 2.0mm septal width)  | 10 pack  |  |
| BC4030-10    | Nasal prong (4.0mm nare diameter / 3.0mm septal width) | 10 pack  |  |
| BC4540-10    | Nasal prong (4.5mm nare diameter / 4.0mm septal width) | 10 pack  |  |
| BC5040-10    | Nasal prong (5.0mm nare diameter / 4.0mm septal width) | 10 pack  |  |
| BC5050-10    | Nasal prong (5.0mm nare diameter / 5.0mm septal width) | 10 pack  |  |
| BC5550-10    | Nasal prong (5.5mm nare diameter / 5.0mm septal width) | 10 pack  |  |

## Infant CPAP therapy interfaces & accessories

| Product Code | Description                                            | Quantity |                                                                                       |
|--------------|--------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| BC5560-10    | Nasal prong (5.5mm nare diameter / 6.0mm septal width) | 10 pack  |    |
| BC6060-10    | Nasal prong (6.0mm nare diameter / 6.0mm septal width) | 10 pack  |    |
| BC6070-10    | Nasal prong (6.0mm nare diameter / 7.0mm septal width) | 10 pack  |    |
| BC6570-10    | Nasal prong (6.5mm nare diameter / 7.0mm septal width) | 10 pack  |    |
| BC800-10     | Infant nasal mask - Small                              | 10 pack  |    |
| BC801-10     | Infant nasal mask - Medium                             | 10 pack  |    |
| BC802-10     | Infant nasal mask - Large                              | 10 pack  |   |
| BC803-10     | Infant nasal mask - Extra large                        | 10 pack  |  |
| BC300-05     | Infant bonnet (17-22cm)                                | 5 pack   |  |
| BC303-05     | Infant bonnet (22-25cm)                                | 5 pack   |  |
| BC306-05     | Infant bonnet (25-29cm)                                | 5 pack   |  |
| BC309-05     | Infant bonnet (29-36cm)                                | 5 pack   |  |
| BC325-05     | Infant head gear (29-36cm)                             | 5 pack   |  |

## Infant CPAP therapy interfaces & accessories

| Product Code | Description                              | Quantity |                                                                                       |
|--------------|------------------------------------------|----------|---------------------------------------------------------------------------------------|
| BC328-05     | Infant head gear (35-40cm)               | 5 pack   |    |
| BC331-05     | Infant head gear (40-45cm)               | 5 pack   |    |
| BC351-10     | Chin strap (20-26cm)                     | 10 pack  |    |
| BC353-10     | Chin strap (26-32cm)                     | 10 pack  |    |
| BC355-10     | Chin strap (32-38cm)                     | 10 pack  |    |
| BC357-10     | Chin strap (38-44cm)                     | 10 pack  |    |
| BC115-05     | Pressure relief valve                    | 5 pack   |   |
| BC400-10     | Gas supply line 2.1m for blender         | 10 pack  |  |
| BC402-05     | Gas supply line kit for dual flow meters | 5 pack   |  |
| BC410-10     | Temperature port plugs                   | 10 pack  |  |
| BC420-10     | Infant interface pressure luer adaptor   | 10 pack  |  |

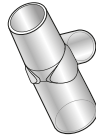
## Infant invasive ventilation breathing circuits

| Product Code | Description                                                                                                             | Quantity |  |
|--------------|-------------------------------------------------------------------------------------------------------------------------|----------|--|
| RT265        | Infant Evaqua™ 2 dual heated breathing circuit with autofeed chamber & pressure line (flows > 4L/min)                   | 10 pack  |  |
| RT266        | Infant Evaqua™ 2 dual heated breathing circuit with autofeed chamber & pressure line (flows 0.3 - 4L/min)               | 10 pack  |  |
| RT267        | Infant Evaqua™ 2 dual heated breathing circuit with autofeed chamber & pressure line (for SLE2000)                      | 10 pack  |  |
| RT268        | Infant Evaqua™ 2 dual heated breathing circuit with autofeed chamber & pressure line (for SLE5000)                      | 10 pack  |  |
| RT225        | Infant inspiratory heated breathing circuit with autofeed chamber & pressure line (flows > 4L/min)                      | 10 pack  |  |
| RT226        | Infant inspiratory heated breathing circuit with autofeed chamber & pressure line (flows 0.3 - 4L/min)                  | 10 pack  |  |
| RT227        | Infant inspiratory heated breathing circuit with autofeed chamber & pressure line (for SLE2000/SLE2000 HFO ventilators) | 10 pack  |  |
| RT228        | Infant inspiratory heated breathing circuit with autofeed chamber & pressure line (for SLE4000/SLE5000 ventilators)     | 10 pack  |  |

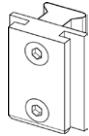
## Infant invasive ventilation interfaces & accessories

| Product Code | Description                  | Quantity |  |
|--------------|------------------------------|----------|--|
| RT010        | Inline nebulizer adaptor kit | 20 pack  |  |

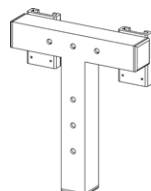
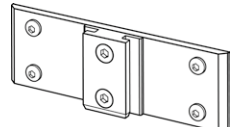
## Infant invasive ventilation interfaces & accessories

| Product Code | Description                       | Quantity |                                                                                       |
|--------------|-----------------------------------|----------|---------------------------------------------------------------------------------------|
| RT030        | Side-stream nebulizer adaptor kit | 20 pack  |    |
| RT061        | Adaptor kit for Dräger (2)        | 50 pack  |    |
| RT062        | Luerlock adaptor (2)              | 50 pack  |    |
| RT063        | Pressure port adaptor (2)         | 100 pack |    |
| RT064        | Adaptor kit for oxygen/CPAP (2)   | 50 pack  |   |
| RT065        | Adaptor kit for Hamilton/EME      | 10 pack  |  |

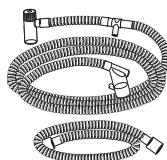
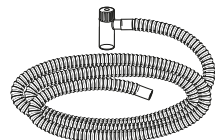
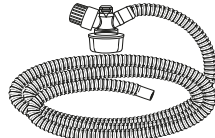
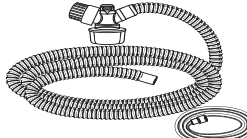
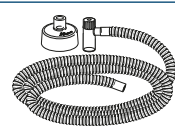
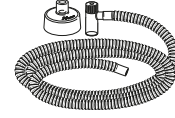
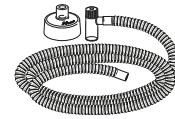
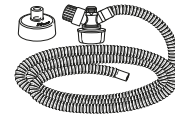
## Infant resuscitator & accessories

| Product Code | Description                                                                                     | Quantity |                                                                                       |
|--------------|-------------------------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| RD900XXX     | Neopuff™ infant T-piece resuscitator<br>(XXX indicates regional plug variation)                 | 1 each   |  |
| 900IW130X    | Neopuff™ infant T-piece resuscitator (infant warmer module)<br>(X indicates language variation) | 1 each   |  |
| 900RD301     | Side mounting block for Neopuff™                                                                | 1 each   |  |

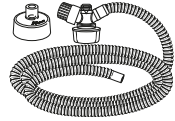
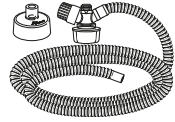
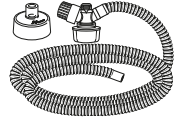
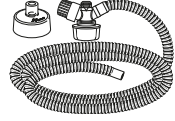
## Infant resuscitator & accessories

| Product Code | Description                             | Quantity |                                                                                     |
|--------------|-----------------------------------------|----------|-------------------------------------------------------------------------------------|
| 900RD302     | Wall mounting bracket for Neopuff™      | 1 each   |  |
| RD050-01     | Central mounting block kit for Neopuff™ | 1 each   |  |

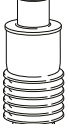
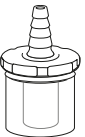
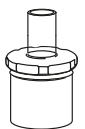
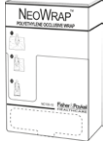
## Infant resuscitation circuits & kits

| Product Code | Description                                                                                   | Quantity |                                                                                       |
|--------------|-----------------------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| 900RD110     | Infant inspiratory heated resuscitation circuit with T-piece                                  | 10 pack  |    |
| 900RD010     | Infant T-piece resuscitation circuit with adjustable PEEP valve - Classic                     | 10 pack  |   |
| RD1300-10    | Infant T-piece resuscitation circuit with adjustable PEEP valve - Ergonomic                   | 10 pack  |  |
| RD1301-10    | Infant T-piece resuscitation circuit with adjustable PEEP valve & gas supply line - Ergonomic | 10 pack  |  |
| 900RD014-10  | Infant resuscitation kit including T-piece circuit (Classic) & premature mask (S)             | 10 pack  |  |
| 900RD015-10  | Infant resuscitation kit including T-piece circuit (Classic) & neonatal mask (M)              | 10 pack  |  |
| 900RD016-10  | Infant resuscitation kit including T-piece circuit (Classic) & infant mask (L)                | 10 pack  |  |
| RD1330-10    | Infant resuscitation kit including T-piece circuit (Ergonomic) & micro-premature mask (XS)    | 10 pack  |  |

## Infant resuscitation circuits & kits

| Product Code | Description                                                                          | Quantity |                                                                                     |
|--------------|--------------------------------------------------------------------------------------|----------|-------------------------------------------------------------------------------------|
| RD1340-10    | Infant resuscitation kit including T-piece circuit (Ergonomic) & premature mask (S)  | 10 pack  |  |
| RD1350-10    | Infant resuscitation kit including T-piece circuit (Ergonomic) & neonatal mask (M)   | 10 pack  |  |
| RD1360-10    | Infant resuscitation kit including T-piece circuit (Ergonomic) & infant mask (L)     | 10 pack  |  |
| RD1370-10    | Infant resuscitation kit including T-piece circuit (Ergonomic) & pediatric mask (XL) | 10 pack  |  |

## Infant resuscitation interfaces & accessories

| Product Code | Description                                                              | Quantity                                                      |                                                                                       |
|--------------|--------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------|
| RD803-10     | Neonatal resuscitation mask - Micro-premature (XS) 35 mm                 | 10 pack                                                       |    |
| RD804-10     | Neonatal resuscitation mask - Premature (S) 42 mm                        | 10 pack                                                       |    |
| RD805-10     | Neonatal resuscitation mask - Neonatal (M) 50 mm                         | 10 pack                                                       |    |
| RD806-10     | Neonatal resuscitation mask - Infant (L) 60 mm                           | 10 pack                                                       |    |
| RD807-10     | Neonatal resuscitation mask - Pediatric (XL) 72 mm                       | 10 pack                                                       |    |
| RD020-01     | Reusable test lung                                                       | 1 each                                                        |    |
| 900RD008     | Short gas supply line - 31cm (12.2")                                     | 10 pack                                                       |   |
| 900RD009     | Long gas supply line - 210cm (82.7")                                     | 10 pack                                                       |  |
| 900RD101     | Gas inlet adaptor                                                        | 1 each                                                        |  |
| 900MR148     | Reusable T-piece neonatal circuit adaptor - 15 Male/10 Female to 10 Male | 1 each                                                        |  |
| NC100        | NeoWrap™ occlusive wrap                                                  | 5 pack (NC100-SK)<br>10 pack (NC100-10)<br>25 pack (NC100-25) |  |

# F&P 810™ System



The F&P MR810 System is designed to deliver airway humidity to match the patient's respiratory and therapy needs. When the MR810 Heated Humidifier is used with the F&P Evatherm™ heated breathing circuit, humidity output performance is enhanced while reducing the unwanted effects of condensate. These benefits are provided with only one probe connection to the circuit, simplifying setup.

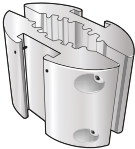
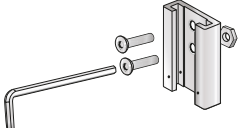
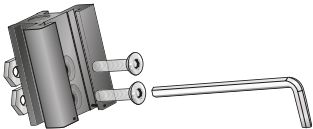
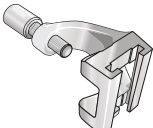
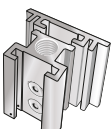
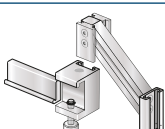
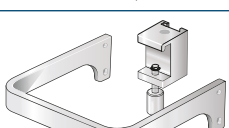
# Humidifier & accessories

| Product Code | Description                                                                    | Quantity |                                                                                     |
|--------------|--------------------------------------------------------------------------------|----------|-------------------------------------------------------------------------------------|
| MR810XXX     | MR810 respiratory heated humidifier<br>(XXX indicates regional plug variation) | 1 each   |  |

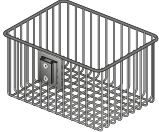
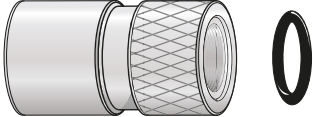
# Evatherm™ breathing circuits

| Product Code | Description                                                                     | Quantity |                                                                                     |
|--------------|---------------------------------------------------------------------------------|----------|-------------------------------------------------------------------------------------|
| 900MR810E    | Adult Evatherm™ inspiratory heated breathing circuit with expiratory water trap | 10 pack  |  |
| 900MR810     | Adult Evatherm™ inspiratory heated breathing circuit                            | 10 pack  |  |

## Humidifier brackets & hardware

| Product Code | Description                            | Quantity |                                                                                       |
|--------------|----------------------------------------|----------|---------------------------------------------------------------------------------------|
| 900MR030     | Mounting bracket - Pole clamp 15-50mm  | 1 each   |    |
| 900MR086     | Mounting bracket - Wall                | 1 each   |    |
| 900MR087     | Mounting bracket - Waterbag pole       | 1 each   |    |
| 900MR088     | Mounting bracket rail - Dräger/Siemens | 1 each   |    |
| 900MR170     | Mounting bracket - C-clamp             | 1 each   |   |
| 900MR301     | Mounting bracket - Bird 44 mm slot     | 1 each   |  |
| 900MR302     | Mounting bracket - Concha conversion   | 1 each   |  |
| 900MR303     | Mounting bracket - Rail                | 1 each   |  |
| 900MR304     | Mounting bracket - PB840               | 1 each   |  |
| 900MR305     | Mounting bracket - Dräger Evita 4      | 1 each   |  |

# Humidifier brackets & hardware

| Product Code | Description                                                           | Quantity |                                                                                       |
|--------------|-----------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| 900MR012     | Waterbag pole - 1.0m (40")                                            | 1 each   |    |
| 900MR290     | Waterbag pole bent - 0.8 m (28") high                                 | 1 each   |    |
| 900MR291     | Waterbag pole bent - 1.08 m (42") high                                | 1 each   |   |
| 900MR292     | Humidifier stand with telescopic waterbag pole - 1.64-2.64m (64-104") | 1 each   |  |
| 900MR293     | Humidifier stand with waterbag pole - 1.65m (65")                     | 1 each   |  |
| 900MR306     | Humidifier stand basket                                               | 1 each   |  |
| 900MR599     | Oxygen flow adaptor - 22 mm Male to 9/16"                             | 1 each   |  |

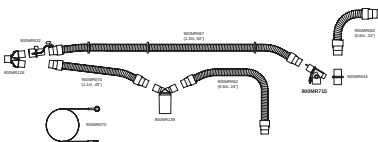
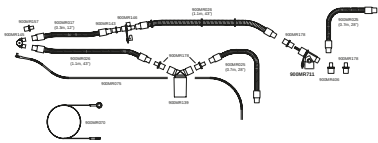
## Humidifier accessories for reusable systems

| Product Code | Description                           | Quantity |                                                                                     |
|--------------|---------------------------------------|----------|-------------------------------------------------------------------------------------|
| 900MR858     | MR850 inspiratory heater wire adaptor | 1 each   |  |
| 900MR859     | MR850 inspiratory heater wire adaptor | 1 each   |  |

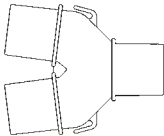
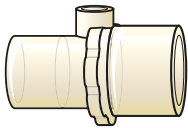
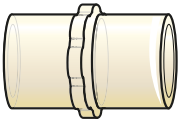
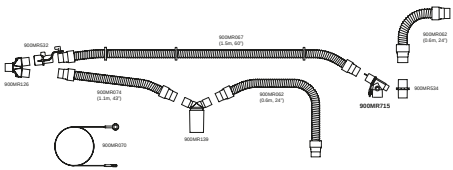
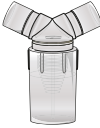
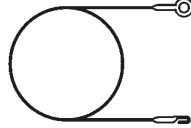
## Reusable humidification chambers

| Product Code | Description                                                                | Quantity |                                                                                      |
|--------------|----------------------------------------------------------------------------|----------|--------------------------------------------------------------------------------------|
| MR370        | Adult humidification chamber                                               | 1 each   |   |
| MR340X       | Infant/Neonatal humidification chamber<br>"X" indicates regional variation | 1 each   |  |

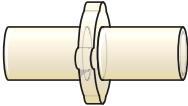
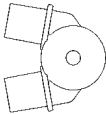
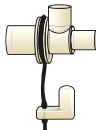
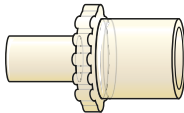
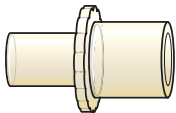
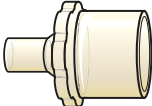
## Reusable breathing circuit kits

| Product Code | Description                                                       | Quantity |                                                                                       |
|--------------|-------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------|
| 900MR784     | Adult reusable breathing circuit kit for F&P 850 & 810 Systems    | 1 each   |  |
| 900MR782     | Neonatal reusable breathing circuit kit for F&P 850 & 810 Systems | 1 each   |  |

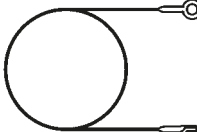
# Adult reusable breathing circuit (900MR784) spare parts

| Product Code | Description                                                      | Quantity                                              |                                                                                              |
|--------------|------------------------------------------------------------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------|
| 900MR126     | Adult Y-piece                                                    | 1 each<br>50 pack (900MR126L)<br>100 pack (900MR126C) |           |
| 900MR532     | Temperature probe housing 22 mm Female - 22 mm Male/15 mm Female | 1 each<br>50 pack (900MR532L)<br>100 pack (900MR532C) |           |
| 900MR534     | Tube joint 22 mm Male/15 mm Female                               | 1 each<br>50 pack (900MR534L)<br>100 pack (900MR534C) |           |
| 900MR715     | Reusable adult 1.5 m inspiratory heaterwire with cloverleaf plug | 1 each                                                |            |
| 900MR139     | Autoclavable water trap                                          | 1 each<br>50 pack (900MR139L)<br>100 pack (900MR139C) |          |
| 900MR062     | Reusable adult tubing - 0.6m (24")                               | 1 each                                                |  |
| 900MR067     | Reusable adult tubing - 1.5m (60")                               | 1 each                                                |  |
| 900MR074     | Reusable adult tubing - 1.1m (44")                               | 1 each                                                |  |
| 900MR070     | Draw wire - 1.5m (60")                                           | 1 each                                                |  |

## Infant reusable breathing circuit (900MR782) spare parts

| Product Code | Description                                                  | Quantity                                              |                                                                                             |
|--------------|--------------------------------------------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------|
| 900MR143     | Adaptor 10 mm Male to 10 mm Male                             | 10 pack                                               |          |
| 900MR145     | Neonatal Y-piece pressure port                               | 1 each                                                |          |
| 900MR146     | Temperature probe housing 10 mm Male-15 mm Male/10 mm Female | 1 each<br>100 pack (900MR146C)                        |          |
| 900MR157     | Adaptor 10 mm Male to 15 mm Male/11 mm Female (Drager)       | 1 each                                                |          |
| 900MR178     | Adaptor 12 mm Male to 15 mm Male                             | 1 each                                                |          |
| 900MR139     | Autoclavable water trap                                      | 1 each<br>50 pack (900MR139L)<br>100 pack (900MR139C) |        |
| 900MR406     | Adaptor 22 mm Female-10 mm Male                              | 1 each                                                |        |
| 900MR711     | Reusable infant heaterwire with cloverleaf plug              | 1 each                                                |        |
| 900MR017     | Reusable infant tubing - 0.3m (12")                          | 1 each                                                |  |
| 900MR025     | Reusable neonatal tubing - 0.7 m (28")                       | 1 each                                                |  |

Infant reusable breathing circuit (900MR782) spare parts

| Product Code | Description                                    | Quantity |                                                                                     |
|--------------|------------------------------------------------|----------|-------------------------------------------------------------------------------------|
| 900MR026     | Reusable neonatal tubing - 1.1m (43")          | 1 each   |  |
| 900MR070     | Draw wire - 1.5m (60")                         | 1 each   |  |
| 900MR075     | Reusable silicon pressure tubing - 1.65m (66") | 1 each   |   |

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EC Certificate Full Quality Assurance System: Certificate US19/819943514



The management system of

## eVent Medical Ltd

60 Empire Drive,  
Lake Forest, CA, 92630, United States

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

**INSPIRATION™ ventilators for continuous respiratory support in an acute and sub-acute institutional healthcare environment,**  
**EVOLUTION™ ventilators for continuous ventilation for patients requiring respiratory support.**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 10 February 2023  
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 05 October 2000  
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MW 201252

Authorised by

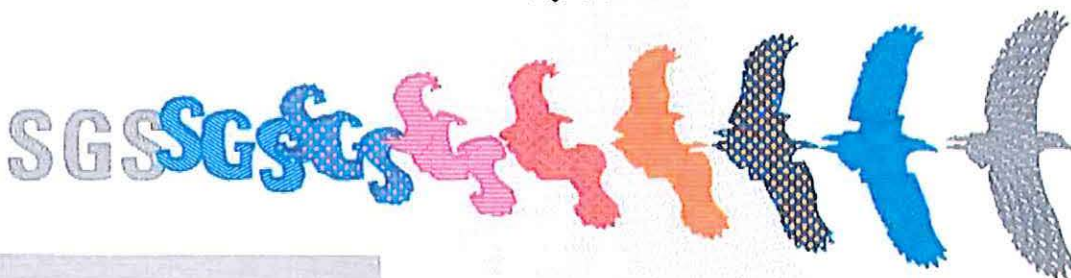
Pieter Weterings  
Certification Manager

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
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LPUD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 010815 0038 Rev. 01**

**Manufacturer:**

**Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place  
East Tamaki, Auckland 2013  
NEW ZEALAND**

**Product Category(ies):** Respiratory Gas Delivery Systems,  
Heated Humidifiers, Continuous Positive Airway  
Pressure Units, Gas Powered Pulmonary Resuscitators,  
Nasal and/or Oral Interfaces for Delivery of  
Respiratory Gases, Patient Monitoring Software for  
Use with Fisher & Paykel Healthcare Medical Devices,  
Insufflation Gas Conditioning Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

**JAQ235040717**

**Valid from:**

**2019-12-12**

**Valid until:**

**2024-05-26**

**Date,**

**2019-12-12**

Christoph Dicks  
Head of Certification/Notified Body



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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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ZLG-BS-244.10.08



Product Service

## EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 010815 0038 Rev. 01**

**Facility(ies):**

**Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place, East Tamaki,  
Auckland 2013, NEW ZEALAND**

-/-

### **Zertifizierungsvertrag**

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an ([www.tuev-sued.de/ps\\_regulations](http://www.tuev-sued.de/ps_regulations)) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

### **Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:**

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

### **Certification contract**

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations ([www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations)) and thus becomes partner in the TÜV SÜD Product Service Certification System.

### **Requirements for the validity of the certificate in principle:**

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

### **认证合约**

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 [www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations)）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

### **维持证书有效性的原则要求：**

- 认证所依据标准的有效性
- 此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
  - 生产场地通过定期的监督

### **認証契約**

認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約([www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations))に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

### **認証書の有効性に関する原則的な要求事項**

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
  - 定期的な工場監査を実施している

### **Contrato de certificação**

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD ([www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations)) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

### **Requisitos para a validade do certificado (em princípio):**

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
  - Auditoria de monitoração realizada regularmente.

Certificate US00/52067

The management system of

## eVent Medical Ltd

60 Empire Drive,  
Lake Forest, CA, 92630, United States

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**  
**EN ISO 13485:2016**

For the following activities

**Design, manufacture, servicing and distribution of INSPIRATION™ LS,  
5i, and 7i ventilators and EVOLUTION™ 3e ventilators.**

This certificate is valid from 10 February 2021 until 10 February 2024  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 10 February 2024

Issue 18. Certified since 05 October 2000

Authorised by



SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

HC SGS 13485 2016 0118

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0005



# Certificate

No. Q5 010815 0037 Rev. 01

**Holder of Certificate:** Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place  
East Tamaki, Auckland 2013  
NEW ZEALAND

**Facility(ies):** Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place, East Tamaki,  
Auckland 2013, NEW ZEALAND

See scope of certificate

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Respiratory Gas Delivery Systems, Heated Humidifiers, Infant Radiant Warmers, Continuous Positive Airway Pressure Units, CPAP Data Transmission Equipment, Gas Powered Pulmonary Resuscitators, Nasal and/or Oral Interfaces for Delivery of Respiratory Gases, Patient Monitoring Software for Use with Fisher & Paykel Healthcare Medical Devices, Insufflation Gas Conditioning Systems

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 010815 0037 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 010815 0037 Rev. 01)

# Certificate

No. Q5 010815 0037 Rev. 01

Report No.: JA1669262  
Valid from: 2021-11-14  
Valid until: 2024-11-13

Date, 2021-11-11



Christoph Dicks  
Head of Certification/Notified Body



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 010815 0039 Rev. 00**

**Manufacturer:**

**Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place  
East Tamaki, Auckland 2013  
NEW ZEALAND**

**SRN Manufacturer:**

**NZ-MF-000002556**

**Authorized  
Representative:**

**Fisher & Paykel Healthcare SAS  
10 Avenue du Québec, Bâtiment F5, BP 512,  
Villebon-Sur-Yvette, 91946 Courtaboeuf CEDEX,  
FRANCE**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 010815 0039 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10 010815 0039 Rev. 00)

**Report No.:**

**JA1613888**

**Valid from:**

**2021-12-06**

**Valid until:**

**2026-12-05**

Christoph Dicks

Head of Certification/Notified Body

**Issue date:** 2021-12-06



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 010815 0039 Rev. 00**

|                          |                                                                                |
|--------------------------|--------------------------------------------------------------------------------|
| <b>Classification:</b>   | <b>IIb</b>                                                                     |
| <b>Device Group:</b>     | <b>R060201 - ACTIVE VENTILATION HUMIDIFICATION SYSTEMS,</b>                    |
| <b>Intended Purpose:</b> | <b>To provide heat and humidity to respiratory gases delivered to patients</b> |

|                          |                                              |
|--------------------------|----------------------------------------------|
| <b>Classification:</b>   | <b>IIa</b>                                   |
| <b>Device Group:</b>     | <b>R020101 - STANDARD BREATHING CIRCUITS</b> |
| <b>Intended Purpose:</b> | <b>-/-</b>                                   |

|                          |                                    |
|--------------------------|------------------------------------|
| <b>Classification:</b>   | <b>IIa</b>                         |
| <b>Device Group:</b>     | <b>R030101 - VENTILATION MASKS</b> |
| <b>Intended Purpose:</b> | <b>-/-</b>                         |

|                                                                                                   |            |
|---------------------------------------------------------------------------------------------------|------------|
| <b>The validity of this certificate depends on conditions and/or is limited to the following:</b> | <b>-/-</b> |
|---------------------------------------------------------------------------------------------------|------------|