



eVolution[®] 3e Ventilators

“A new paradigm in blower-based ventilators,
delivering ICU ventilator care anywhere, anytime.”

- Comprehensive Graphics and Trending
- High Performance PSOL and Active Exhalation
- Servo Controlled for Precise Breath Delivery
- Adult through Neonate (2ml Tidal Volume)
- Invasive and Noninvasive
- Feedback-Controlled NCPAP and NCPAP+
- Easy to Use Touch Screen User Interface
- Capnography Ready
- High Flow Oxygen
- Optional: High Performance Internal Gas Source Technology
- HEPA Filter (standard on Turbine model)
- HL7 Compatibility and Virtual Report





PRVC

Volume targeted ventilation includes three important capabilities; Pressure Regulated Volume Control (PRVC), Volume Support (VS) and AUTO Control. The primary advantage of all three capabilities lies with their ability to adapt breathing support in response to the patient's dynamic respiratory drive.

In PRVC, the clinician determines the inspiratory time and tidal volume. The ventilator performs a series of test breaths to determine lung compliance and the necessary pressure required to deliver the targeted volume. Pressures are then adjusted breath by breath in response to volume discrepancies. Patients can breathe freely above the set tidal volume within an automatic or clinician defined volume limit and the active exhalation valve allows patients to splint or cough during ventilation.

Volume Support (VS) is a spontaneous mode in which the clinician determines the appropriate tidal volume and the ventilator responds by adjusting the Pressure Support level to achieve the target value. Volume Support (VS) is a good means of supporting patients with variable drive in a non-fatiguing state.

Our AUTO Control takes apnea ventilation to a new level by creating a seamless bridge between CMV modalities and spontaneous breathing without the annoying alarms! eVent Medical's sophisticated software and algorithms allow the ventilator to switch between a control mode of ventilation and a spontaneous mode when certain parameters are met by the patient's breathing pattern.

Noninvasive Ventilation

When it comes to ease of use and versatility, nothing can compare to eVent Medical's ventilators. Regardless of where you are in the ED, ICU or on a Transport, rest assured that all of your bases are covered.

Take its standard NIV function, an option on most other ventilators. NIV allows you to use any non-vented patient interface, and can be connected via a standard, dual-limb ventilator circuit. The ventilator's simplified alarm structure in NIV eliminates nuisance alarms for all patients across the continuum of care. With an operator interface that can be configured by the user to display up to 2 waveforms or loops and a programmable apnea backup system, your patients have never had such complete and reliable ventilatory support!

Volumetric Capnography (VCO₂)

Capnography has become an important tool to evaluate the adequacy of ventilation. Volumetric capnography has emerged as the preferred method to access both the quality and quantity of ventilation. The eVent Medical Ventilator provides continuous feedback regarding ventilation and perfusion, proper assessment of arterial CO₂, dead space and minute ventilation measurements which permits a proper assessment of alveolar ventilation and physiological dead space (Vd/Vt) measurement which permits the assessment of total dead space to tidal volume ventilation in support of the weaning process.



SPAP - Spontaneous Positive Airway Pressure

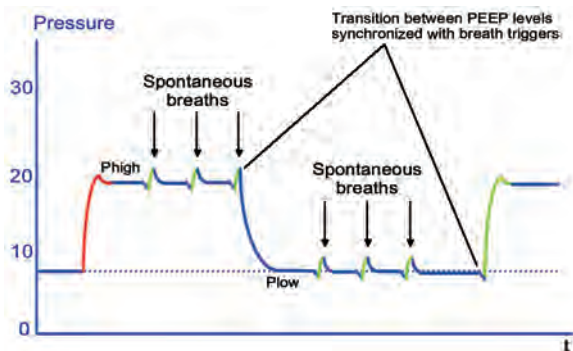
Regardless of your ventilation strategy (Volume or Pressure), the eVolution 3e ventilators provides modalities that afford your patient the ultimate in control and synchrony.

SPAP is a pressure-based breathing mode that allows patients to breathe spontaneously at two user-selected levels of PEEP. The user sets the high and low PEEP (Phigh and Plow) and independent levels of pressure support (if desired) at each PEEP level (Psup high, Psup low).

The user also selects how much time the patient breaths at each PEEP level. Setting selections can be based on I:E ratio or time including:

- Cycle + time at high pressure (Phigh)
- Cycle + ratio of time high to time low (Thigh and Tlow)
- Time only at high and low pressures (Phigh and Plow)

At each PEEP level, the ventilator delivers a spontaneous breath when the patient triggers a breath (based on the trigger setting). These breaths can be pressure supported or not. Transitions between high and low PEEP levels are synchronized with the patient's spontaneous efforts such that Time high may be slightly lengthened to allow patients to finish the inspiration before dropping to the low pressure level. The time at low pressure is preferentially maintained when I:E settings are inverted.



Lung Model and Weaning Target Tool

Our alveolar inspired Lung Model allows clinicians to visualize lung mechanics and optimally monitor the patients condition.

Since each patient is unique, the Weaning Target Tool allows the clinician to customize patient weaning goals and monitor real time progress. Further, target parameters can be configured according to institutional weaning protocols.



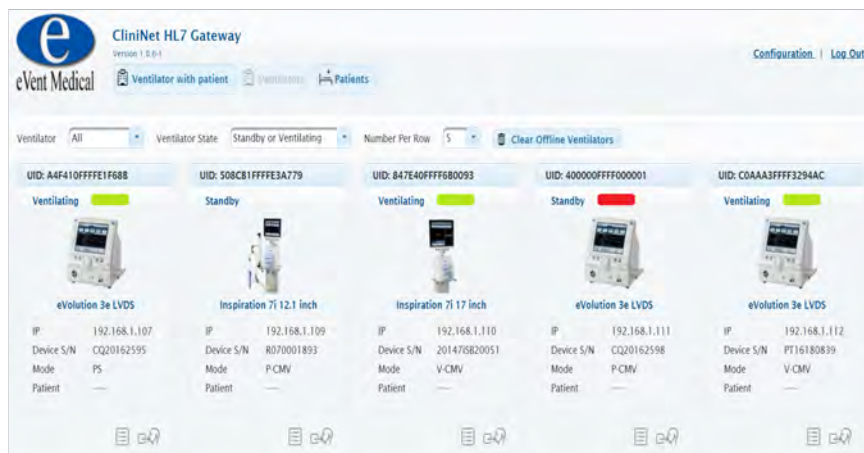
CliniNet® Virtual Report™ Viewing System and HL7 Protocol Compatibility

Highlights

The unique CliniNet® interface and CliniNet Virtual Report viewing system bring centralized, real-time data and patient management to the entire care team. The intuitive user interface provides access to your ventilators, allowing clinicians to view up to eight ventilators simultaneously on each computer monitor. Your ventilators then have the ability to communicate in real time—via wireless or Ethernet all settings, monitored data, alarms, trends and graphics as well as the ventilators configuration and location. In fact all the data that can be seen on the ventilator at the bedside can be seen in real-time from any computer with access to the network the ventilator is connected to and can now be seen in real-time via eVent Medical's data encrypted multilevel password protected Virtual Report Remote Monitoring platform.

Features

- Remote ventilator viewing
- Real time viewing of multiple ventilators and patient data
- Intranet and Internet connections
- Three levels of user access with password protection
- Facility defined level of security and encryption
- Easy system integration and easy to use



Interface

Our friendly graphic user-interface design has been optimized to help reduce the number of operational failures.⁴ The eVolution 3e ventilators graphic user-interface makes navigation and parameter changes intuitive. Its colour coded parameters and settings highlight changes and makes viewing simple. This translates into less time spent making ventilator changes, and more time to treat your patient.



Alarm Log

- 1000 event log with time and date stamp
- Filter by time, event type, and settings changes
- Event log window provides a detailed view of an individual event

Graphics and Trending

- One, two or three waveforms viewable on main screen
- Loops, waveforms or trending adjustable scale from 6 seconds up to 72 hours
- Colour graphics allow for easy analysis of spontaneous and mechanical breaths
- Freeze function on all graphs, loops and waveforms

Ideal Body Weight (IBW)

- Automatic IBW calculator based on patient height and gender
- IBW calculator provides a quick and safe start to ventilation
- Prepopulated ventilator parameter settings based on IBW

Modes

- A complete array of ventilation modes – Controlled, Synchronized or Spontaneous
- A complete array of ventilator breath types – Pressure (P), Volume (V), Pressure Support (PS), Volume Support (VS), Spontaneous Positive Airway Pressure (SPAP), or Pressure Regulated Volume Compensated (PRVC),
- Tidal volume ranging from 2ml (Neonatal Software Option) or 20 ml (standard), to 3 L permits ventilation of neonate to adult patients

Auto Control

- Auto Control - automatically transitioning from full ventilatory support by the ventilator to full ventilatory control by the patient.
- Allows for a very easy, automatic and seamless transition between mandatory or spontaneous support in either pressure or volume modes.
- Auto Control assists in weaning the patient from mechanical ventilation.

Non-Invasive Ventilation (NIV)

- The eVolution 3e provides multi dimensional ventilation through NIV available in all modes
- Large leak compensation, fitting masks and increasing patient comfort made easier
- An increasing body of evidence suggests that NIV can effectively reduce the number of ventilator days improving outcomes and decreasing risk.⁵

High Flow Oxygen

- Hi FlowO₂ allows the clinician to improve gas exchange
- Seamless humidified therapy can help decrease work of breathing for chronic patients.⁶

Paramagnetic O₂ Sensor (Optional)

- Non-depleting Paramagnetic cell.
- Accuracy with full range of oxygen measurements.

Lung Model

- Standard feature for eVolution ventilators.
- Continuously monitors and graphically displays the real time compliance and resistance of the patient, suggesting a diagnostic category. Also displays the value of driving pressure and plateau pressure for mandatory breaths in addition to average tidal volume per kg IBW and RSBI for spontaneous breaths.

Weaning Target Tool

- Standard feature within the Lung Model.
- WTT has six different adjustable parameters for patients that are weaning.
- Parameters can be configurable according to weaning protocols.

eVolution® 3e Ventilators

In keeping with previous studies¹ the below in-house test results confirm the high performance of our eVolution 3e ventilators in terms of triggering and pressurization to be as good or better than a marketing leading compressed-gas and blower-based ventilator. Thus, demonstrating that our eVolution 3e ventilators has been designed to exceed ventilator design standards and performance criteria.

The eVolution 3e ventilators system combines ease of use, reliability and high performance with advance lung protective strategies making them the ideal ventilator of choice for ICU critical care environments. The Comprehensive graphic user interface provides an intuitive approach to analyzing patient-ventilator waveforms to improve patient synchrony and reduce work of breathing (WOB) which may lead to improved patient outcomes and shortened ICU stay.^{2,3}

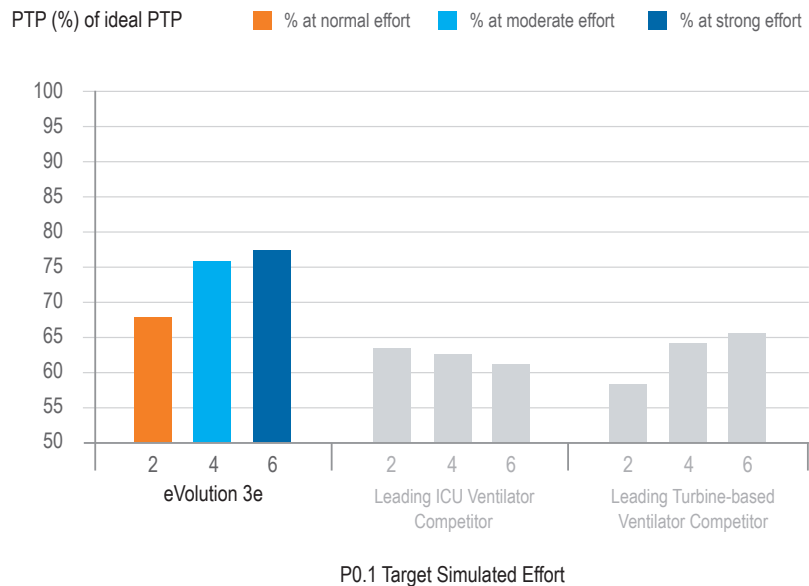


Performance

Pressure–Time Product Percent of Ideal PTP

Pressure–time product expressed as a percentage of the ideal pressure time curve for each ventilator. Higher PTP values indicate better pressurization.

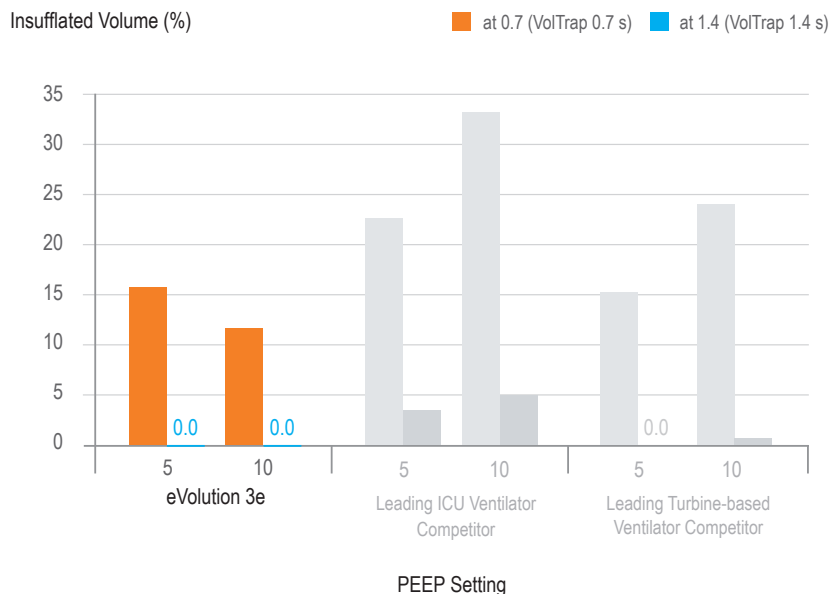
Values in this graph represent the mean averages for the samples measured at three simulated inspiratory effort intensities (normal, moderate, and strong), four levels of pressure-support (5, 10, 15, and 20 cmH₂O), and two levels of positive end expiratory pressure (1 and 5 cmH₂O).



Trapped Volume

Comparison of the amount of exhaled volume remaining in the lung after 0.7 sec (VolTrap 0.7) and 1.4 sec (VolTrap 1.4) after the end of inspiration at two different PEEP levels and a tidal volume of 500 ml and an inspiratory time of 1 second.

Values in this graph are expressed as the percentage of delivered volume and represent the mean averages for the samples measured at the two PEEP levels for each ventilator. Lower values indicate less imposed expiratory resistance.



Highlights

The eVolution[®] 3e Ventilators are a new paradigm in ventilator design.

Dual PSOL valves ensure the precise flow, volume and pressure delivery for your sickest patients—true ICU ventilator care—while the innovative turbine design means you can deliver this ICU equivalent care wherever and whenever you need it.

The ventilator can receive O₂ input from either a high or low pressure gas source, giving the eVolution precision and versatility throughout the continuum of ventilator care.

A full suite of modes gives the clinician the flexibility to choose the mode that best suits the patient's needs.

Each eVolution Turbine ventilator comes standard with a HEPA filter for the air inlet. This provides HEPA filtration to reduce potential contaminants which could be delivered to patient from room air.



Our eVolution 3e ICU ventilators are available in a high pressure external gas source model or with an internal turbine flow generator.

1. Amaud W. Thille. Et al, Intensive Care Med (2009) 35:1368-1376 A bench study of intensive-care unit ventilators: new versus old and turbine-based versus compressed gas-based ventilators
2. Using Ventilator Graphics to Identify Patient-Ventilator Asynchrony, Jon O Nielsestuen, PhD, RRT, FAARC et al, Respiratory Care, Feb/2005 VOL 50 NO 2
3. Using ventilator waveforms to optimize patient-ventilator interaction, Jin Xiong Lian BSN, RN, Critical Care Nursing Sept/ 2010, VOL 5, NO 2
4. Uzawa, Y. Et al. Evaluation of the User Interface simplicity in the Modern Generation of Mechanical Ventilators. Resp Care 2008;53(3):329-337
5. Keenan SP. Et al; Canadian Critical Care Trials Group/Canadian Critical Care Society Noninvasive Ventilation Guidelines Group. Clinical practice guidelines for the use of noninvasive positive-pressure ventilation and noninvasive continuous positive airway pressure in the acute care setting. CMAJ. 2011 Feb 22;183(3):E195-214
6. Gotera C et al. Clinical evidence on high flow oxygen therapy and active humidification in adults. Rev Port Pneumol. 2013; 19(5):217-227.

Specifications subject to change.

ML0166 Rev N, Int'l Version

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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) cmH₂O
- Flow triggering 0.1 - 25 lpm

Additional Settings

- Respiratory rate 1 - 120 bpm
- Tidal volume 20 - 3000 ml
- PEEP / CPAP 0 - 50 cmH₂O
- Pcontrol 1 - 100 cmH₂O
- Psupport 0 - 100 cmH₂O
- 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
- EtCO₂ Part Number: EVM400182
- Hi FlowO₂ 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)
- EtCO₂ Graphics Display
- PaCO₂ 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 ₂	- 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 ₂ Graphics	EtCO ₂
- Flow Volume Loop	- PCO ₂ Volume Loop	- PetCO ₂ - Vd / Vt
- Pressure Volume Loop	- FCO ₂ Volume Loop	- VCO ₂ / min - Valv
- Flow + Time	- PCO ₂ + Time	- VtiCO ₂ - Valv / min
- Pressure + Time	- FCO ₂ + Time	- FetCO ₂ - PeCO ₂
- Volume + Time	- VteCO ₂ + Time	- Vd ana - FeCO ₂
		- 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 O₂ Capability*
- Paramagnetic O₂ Sensor (Optional)

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



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.

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.

Contents

AIRVO™ 2 System	A - 1
------------------------------	-------

F&P 850™ System

Humidifier & accessories.....	B - 2
Humidification chambers.....	B - 3
Adult nasal high flow breathing circuits.....	B - 4
Adult nasal high flow interfaces & accessories.....	B - 4
Adult noninvasive ventilation breathing circuits.....	B - 5
Adult face masks & accessories.....	B - 6
Adult invasive ventilation breathing circuits.....	B - 7
Adult invasive ventilation interfaces & accessories.....	B - 8
Infant nasal high flow breathing circuits.....	B - 9
Infant nasal high flow interfaces & accessories.....	B - 9
Infant CPAP therapy breathing circuits & gas supply.....	B - 11
Infant CPAP therapy interfaces & accessories.....	B - 12
Infant invasive ventilation breathing circuits.....	B - 15
Infant invasive ventilation interfaces & accessories.....	B - 15
Infant resuscitator & accessories.....	B - 16
Infant resuscitation circuits & kits.....	B - 17
Infant resuscitation interfaces & accessories.....	B - 19

F&P 810™ System

Humidifier & accessories.....	C - 2
Evatherm™ breathing circuits.....	C - 2

General humidifier brackets & hardware

Humidifier brackets & hardware.....	D - 1
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F&P Reusable Tubing Systems

Humidifier accessories for reusable systems.....	E - 1
Reusable humidification chambers.....	E - 1
Reusable breathing circuit kits.....	E - 1
Adult reusable breathing circuit (900MR784) spare parts.....	E - 2
Infant reusable breathing circuit (900MR782) spare parts.....	E - 3

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 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













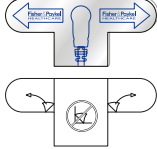
The MR850 (F&P 850 System) Heated Humidifier is part of a complete system designed to deliver optimally humidified gas (37°C and 44 mg/L).

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.








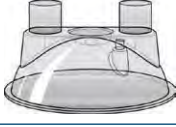

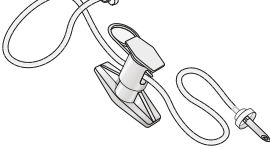
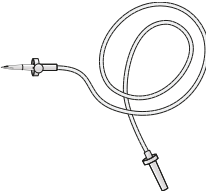
The F&P 850 System incorporating the MR850 Heated Humidifier can be used for the full range of Fisher & Paykel Healthcare therapies across the F&P Respiratory Care Continuum™, including invasive and noninvasive ventilation and Optiflow™ therapies.



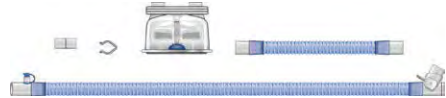
Humidifier & accessories

Product Code	Description	Quantity	
MR850XXX	MR850 respiratory heated humidifier (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	




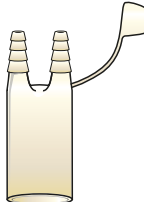
Adult nasal high flow breathing circuits

Product Code	Description	Quantity	
RT202	Adult inspiratory heated breathing circuit with autotimed chamber	10 pack	

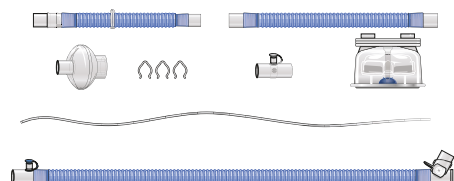
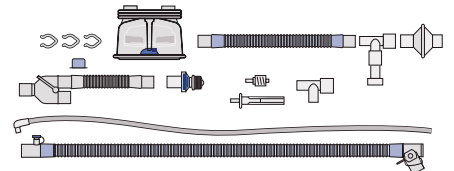

Adult nasal high flow interfaces & accessories

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	




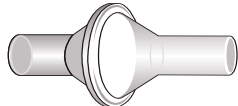
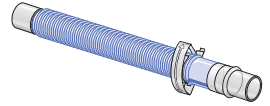
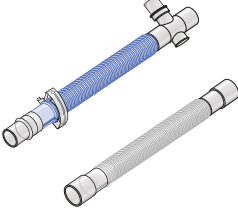
Adult noninvasive ventilation breathing circuits

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	

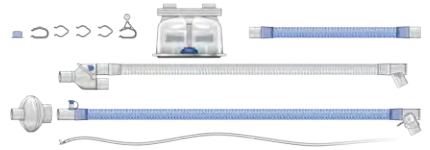

Adult face masks & accessories

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	

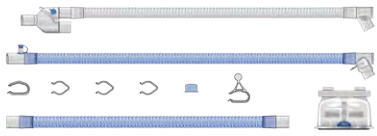
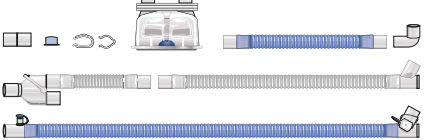
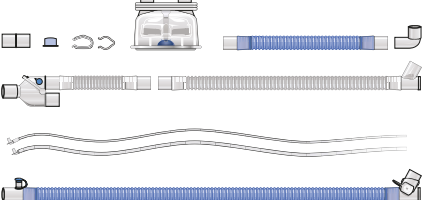
Adult face masks & accessories

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	

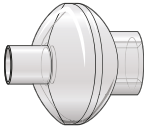
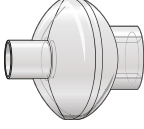

Adult invasive ventilation breathing circuits

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 Adult Evaqua™ 2 dual heated breathing circuit with autofeed chamber & filter	10 pack	

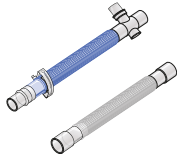
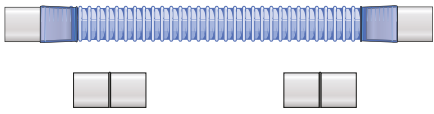
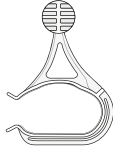


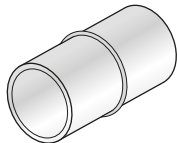
Adult invasive ventilation breathing circuits

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	

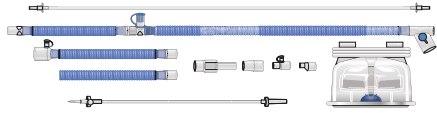

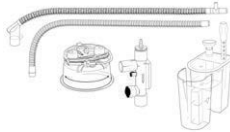
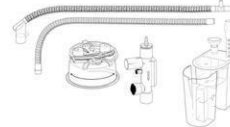
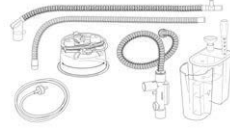

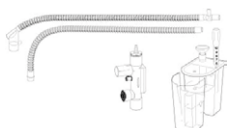
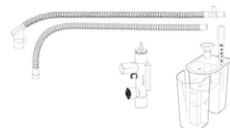



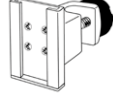
Infant nasal high flow interfaces & accessories

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	

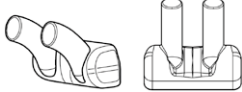
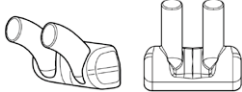
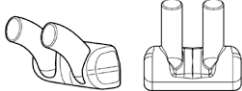
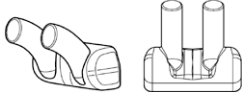









Infant CPAP therapy breathing circuits & gas supply

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	










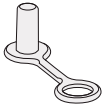
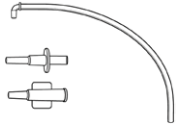
Infant CPAP therapy interfaces & accessories

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	

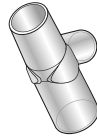





Infant invasive ventilation breathing circuits

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	



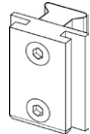
Infant invasive ventilation interfaces & accessories

Product Code	Description	Quantity	
RT010	Inline nebulizer adaptor kit	20 pack	

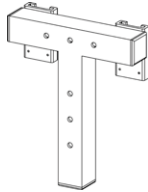
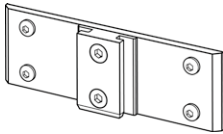
Infant invasive ventilation interfaces & accessories

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	

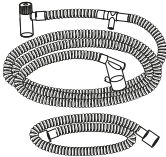
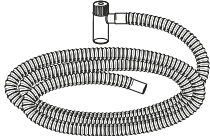
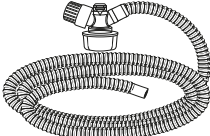
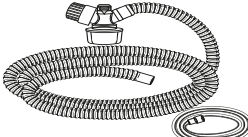
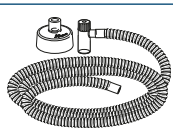
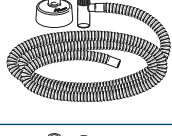
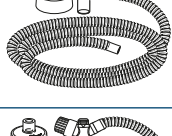

Infant resuscitator & accessories

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

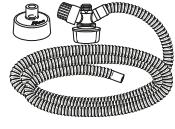
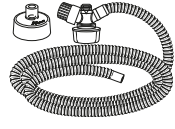
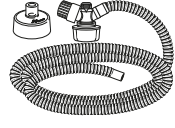
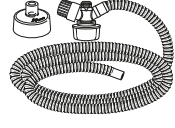
Infant resuscitator & accessories

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










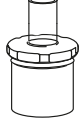
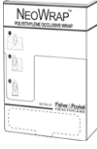
Infant resuscitation circuits & kits

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) 10 pack (NC100-10) 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.

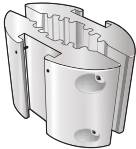
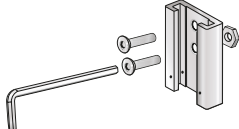
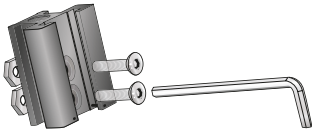

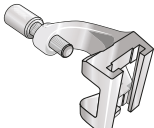

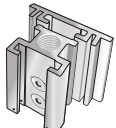
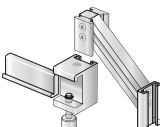

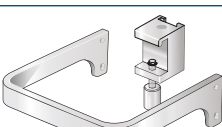
Humidifier & accessories

Product Code	Description	Quantity	
MR810XXX	MR810 respiratory heated humidifier (XXX indicates regional plug variation)	1 each	



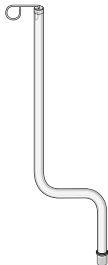


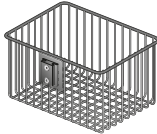
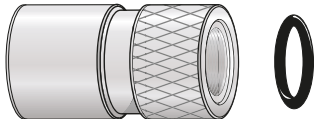
Evatherm™ breathing circuits

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	

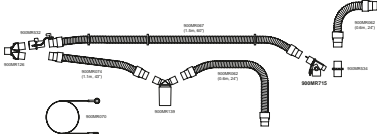
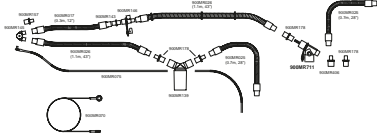
Humidifier accessories for reusable systems

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

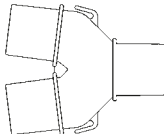
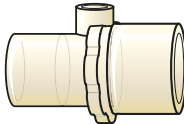
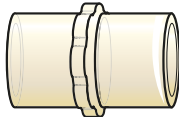
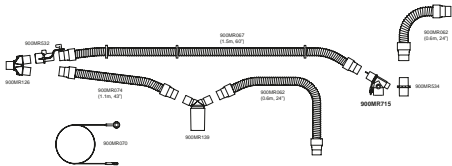




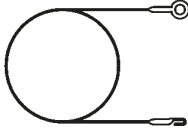
Reusable humidification chambers

Product Code	Description	Quantity	
MR370	Adult humidification chamber	1 each	
MR340X	Infant/Neonatal humidification chamber "X" indicates regional variation	1 each	

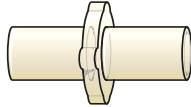
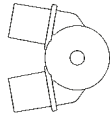
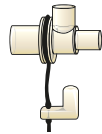
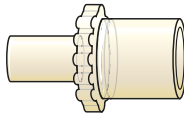
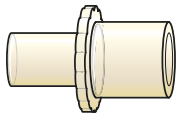

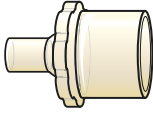



Reusable breathing circuit kits

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	


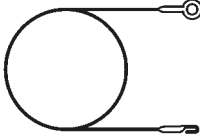

Adult reusable breathing circuit (900MR784) spare parts

Product Code	Description	Quantity	
900MR126	Adult Y-piece	1 each 50 pack (900MR126L) 100 pack (900MR126C)	
900MR532	Temperature probe housing 22 mm Female - 22 mm Male/15 mm Female	1 each 50 pack (900MR532L) 100 pack (900MR532C)	
900MR534	Tube joint 22 mm Male/15 mm Female	1 each 50 pack (900MR534L) 100 pack (900MR534C)	
900MR715	Reusable adult 1.5 m inspiratory heaterwire with cloverleaf plug	1 each	
900MR139	Autoclavable water trap	1 each 50 pack (900MR139L) 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 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 50 pack (900MR139L) 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	

Index

900IW130X.....	B - 16	900PT421.....	A - 3
900MR012.....	D - 2	900PT422.....	A - 3
900MR017.....	E - 3	900PT426.....	A - 3
900MR025.....	E - 3	900PT427.....	A - 3
900MR026.....	E - 4	900PT501.....	A - 2
900MR030.....	D - 1	900PT531.....	A - 2
900MR062.....	E - 2	900PT600.....	A - 3
900MR067.....	E - 2	900PT601.....	A - 3
900MR070.....	E - 2	900PT602.....	A - 3
900MR070.....	E - 4	900PT603.....	A - 3
900MR074.....	E - 2	900PT913.....	A - 3
900MR075.....	E - 4	900RD008.....	B - 19
900MR086.....	D - 1	900RD009.....	B - 19
900MR087.....	D - 1	900RD010.....	B - 17
900MR088.....	D - 1	900RD014-10.....	B - 17
900MR126.....	E - 2	900RD015-10.....	B - 17
900MR139.....	E - 2	900RD016-10.....	B - 17
900MR139.....	E - 3	900RD101.....	B - 19
900MR143.....	E - 3	900RD110.....	B - 17
900MR145.....	E - 3	900RD301.....	B - 16
900MR146.....	E - 3	900RD302.....	B - 17
900MR148.....	B - 19	BC115-05.....	B - 10
900MR157.....	E - 3	BC115-05.....	B - 14
900MR170.....	D - 1	BC151-10.....	B - 11
900MR178.....	E - 3	BC153-10.....	B - 11
900MR190.....	B - 3	BC161-10.....	B - 11
900MR191X.....	B - 3	BC163-10.....	B - 11
900MR208.....	B - 2	BC171-10.....	B - 11
900MR290.....	D - 2	BC173-10.....	B - 11
900MR291.....	D - 2	BC190-05.....	B - 12
900MR292.....	D - 2	BC191-05.....	B - 12
900MR293.....	D - 2	BC192-05.....	B - 12
900MR301.....	D - 1	BC300-05.....	B - 13
900MR302.....	D - 1	BC303-05.....	B - 13
900MR303.....	D - 1	BC306-05.....	B - 13
900MR304.....	D - 1	BC309-05.....	B - 13
900MR305.....	D - 1	BC325-05.....	B - 13
900MR306.....	D - 2	BC328-05.....	B - 14
900MR406.....	E - 3	BC331-05.....	B - 14
900MR532.....	E - 2	BC351-10.....	B - 14
900MR534.....	E - 2	BC353-10.....	B - 14
900MR599.....	D - 2	BC355-10.....	B - 14
900MR711.....	E - 3	BC357-10.....	B - 14
900MR715.....	E - 2	BC400-10.....	B - 14
900MR782.....	E - 1	BC402-05.....	B - 10
900MR784.....	E - 1	BC402-05.....	B - 14
900MR805.....	B - 2	BC410-10.....	B - 14
900MR806.....	B - 2	BC420-10.....	B - 14
900MR810.....	C - 2	BC501-01.....	B - 11
900MR810E.....	C - 2	BC506-01.....	B - 11
900MR817.....	B - 2	BC507-01.....	B - 11
900MR858.....	E - 1	BC510-01.....	B - 11
900MR859.....	E - 1	BC800-10.....	B - 13
900MR860.....	B - 2	BC801-10.....	B - 13
900MR861.....	B - 2	BC802-10.....	B - 13
900MR863.....	B - 2	BC803-10.....	B - 13
900MR868.....	B - 2	BC2425-20.....	B - 10
900MR869.....	B - 2	BC2435-20.....	B - 10
900MR870.....	B - 2	BC2745-20.....	B - 10
900MR961.....	B - 5	BC2755-20.....	B - 10
900PT405.....	A - 3	BC3020-10.....	B - 12
900PT411.....	A - 3	BC3520-10.....	B - 12
		BC3780-20.....	B - 10

Index

BC4030-10.....	B - 12	RD1340-10.....	B - 18
BC4540-10.....	B - 12	RD1350-10.....	B - 18
BC5040-10.....	B - 12	RD1360-10.....	B - 18
BC5050-10.....	B - 12	RD1370-10.....	B - 18
BC5550-10.....	B - 12	RT010.....	B - 15
BC5560-10.....	B - 13	RT013.....	A - 2
BC6060-10.....	B - 13	RT016.....	B - 7
BC6070-10.....	B - 13	RT019.....	B - 8
BC6570-10.....	B - 13	RT020.....	B - 8
MR210.....	B - 3	RT021.....	B - 8
MR210X.....	B - 3	RT022.....	B - 7
MR225.....	B - 3	RT023.....	B - 7
MR225X.....	B - 3	RT023.....	B - 9
MR250.....	B - 3	RT024.....	B - 9
MR250X.....	B - 3	RT028.....	B - 9
MR290HFV.....	B - 3	RT030.....	B - 16
MR290V.....	B - 3	RT032.....	B - 9
MR290VX.....	B - 3	RT040.....	B - 6
MR340X.....	E - 1	RT040L.....	B - 6
MR370.....	E - 1	RT040M.....	B - 6
MR810XXX.....	C - 2	RT040S.....	B - 6
MR850XXX.....	B - 2	RT041L.....	B - 6
NC100.....	B - 19	RT041M.....	B - 6
OPT010.....	B - 10	RT041S.....	B - 6
OPT012.....	B - 10	RT042.....	B - 6
OPT014.....	B - 10	RT042L.....	B - 6
OPT016.....	B - 10	RT043L.....	B - 7
OPT312.....	B - 9	RT043M.....	B - 7
OPT314.....	B - 10	RT043S.....	B - 7
OPT316.....	A - 2	RT061.....	B - 16
OPT316.....	B - 10	RT062.....	B - 16
OPT318.....	A - 2	RT063.....	B - 16
OPT318.....	B - 10	RT064.....	B - 16
OPT542.....	B - 4	RT065.....	B - 16
OPT544.....	B - 4	RT200.....	B - 8
OPT546.....	B - 5	RT201.....	B - 5
OPT570.....	B - 5	RT202.....	B - 4
OPT842.....	A - 2	RT204.....	B - 8
OPT842.....	B - 4	RT224.....	B - 11
OPT844.....	A - 2	RT225.....	B - 15
OPT844.....	B - 4	RT226.....	B - 15
OPT846.....	A - 2	RT227.....	B - 15
OPT846.....	B - 4	RT228.....	B - 15
OPT870.....	A - 2	RT265.....	B - 15
OPT870.....	B - 5	RT266.....	B - 15
OPT942.....	A - 2	RT267.....	B - 15
OPT942.....	B - 4	RT268.....	B - 15
OPT944.....	A - 2	RT280.....	B - 8
OPT944.....	B - 4	RT301.....	B - 5
OPT946.....	A - 2	RT319.....	B - 5
OPT946.....	B - 4	RT324.....	B - 11
PT101XX.....	A - 2	RT330.....	B - 9
RD020-01.....	B - 19	RT380.....	B - 7
RD050-01.....	B - 17	RT385.....	B - 7
RD803-10.....	B - 19	RT913.....	B - 9
RD804-10.....	B - 19	RT914.....	B - 9
RD805-10.....	B - 19		
RD806-10.....	B - 19		
RD807-10.....	B - 19		
RD900XXX.....	B - 16		
RD1300-10.....	B - 17		
RD1301-10.....	B - 17		
RD1330-10.....	B - 17		

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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

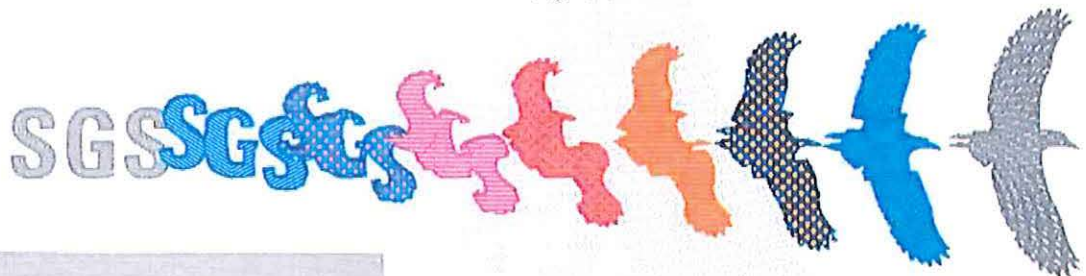
Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 1



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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

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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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**

-/-

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT

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) 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) 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）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

認證契約

認證は 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)に同意したものとす。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認證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) 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

HC SGS 13485 2016 0118

Page 1 of 1



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Certificate

No. Q5 010815 0037 Rev. 00

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

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). See also notes overleaf.

Report No.: JAQ235033136

Valid from: 2018-11-14
Valid until: 2021-11-13

Date, 2018-11-14

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT