

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 organization in the world to make a humidifier specifically for use in the treatment of patients with obstructive sleep apnea (OSA).

Today, through an unrivaled 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, which 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 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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Disclaimer: Please note that the information in this catalog (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. Not all products are available in all markets.

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	
PT101US	AIRVO™ 2 humidifier with integrated flow generator	1 each	
OPT942	Optiflow™+ nasal cannula –Small	20 pack	
OPT944	Optiflow™+ nasal cannula –Medium	20 pack	
OPT946	Optiflow™+ nasal cannula –Large	20 pack	
900PT501	Tube and chamber kit	10 pack	
OPT970	Optiflow™+ tracheostomy interface	20 pack	
OPT980	Mask interface adapter	20 pack	
900PT531	Tube and chamber kit for AIRVO™ 2 (Junior)	10 pack	
OPT316	Optiflow™ Junior nasal cannula –Infant (Wigglepads™ replacement = OPT012)	20 pack	
OPT318	Optiflow™ Junior nasal cannula –Pediatric (Wigglepads™ replacement = OPT012)	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




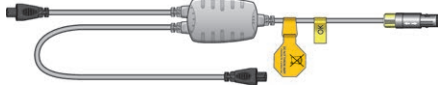






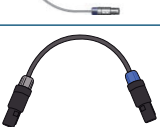
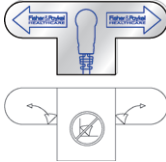
The MR850 (F&P 850 System) heated humidifier is part of a complete system designed to deliver optimally humidified gas (37 °C and 44 mg/L) and control circuit condensate.

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.


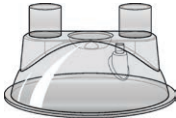
The F&P 850 System, incorporating the MR850 Heated Humidifier, can be used for the full range of Fisher & Paykel Healthcare therapies across the F&P Respiratory Care Continuum™, including invasive and noninvasive ventilation and Optiflow™ nasal high flow therapy.





Humidifier and accessories

Product Code	Description	Quantity	
MR850XXX	MR850™ respiratory heated humidifier (XXX indicates regional plug variation)	1 each	
900MR805	Heater-wire adapter for dual-heated breathing circuits	1 each	
900MR806	Heater-wire adapter for inspiratory heated breathing circuits	1 each	
900MR863	Temperature/Flow probe adapter for use with circuits 0.7 m (28") long	1 each	
900MR868	Temperature/Flow probe adapter for use with circuits 1.1 m (44") long	1 each	
900MR860	Temperature/Flow probe adapter for use with circuits 1.3 m (52") long	1 each	
900MR869	Temperature/Flow probe adapter for use with circuits 1.5 m (60") long	1 each	
900MR861	Temperature/Flow probe adapter for use with circuits 1.8 m (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	
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	



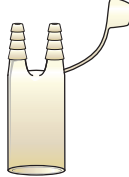
Adult nasal high flow breathing circuits

Product Code	Description	Quantity	
RT202	Adult inspiratory heated breathing circuit with autofeed chamber	10 pack	
RT114	Adult inspiratory heated breathing circuit	10 pack	

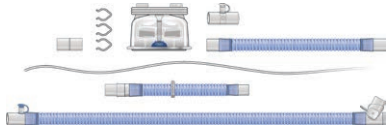
Adult nasal high flow interfaces and accessories

Product Code	Description	Quantity	
OPT942	Optiflow™+ nasal cannula -Small	20 pack	
OPT944	Optiflow™+ nasal cannula -Medium	20 pack	
OPT946	Optiflow™+ nasal cannula -Large	20 pack	




Adult nasal high flow interfaces and accessories

Product Code	Description	Quantity	
OPT970	Optiflow™+ tracheostomy interface	20 pack	
OPT980	Mask interface adapter	20 pack	
900MR961	Dual-flow adapter –22 mm Female	20 pack	












Adult noninvasive ventilation breathing circuits

Product Code	Description	Quantity	
RT219	Adult bi-level/CPAP inspiratory heated breathing circuit with autofeed chamber, pressure line and exhalation port	10 pack	

Adult face masks and 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	

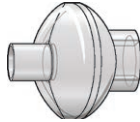
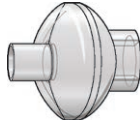





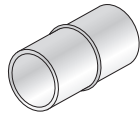
Adult face masks and accessories

Product Code	Description	Quantity	
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	
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	

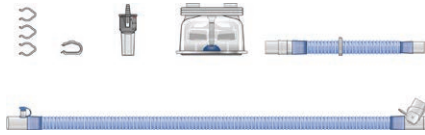
Adult invasive ventilation breathing circuits

Product Code	Description	Quantity	
RT380	Adult Evaqua™ 2 dual heated breathing circuit with autofeed chamber and filter	10 pack	
RT280	Adult Evaqua™ 2 dual heated breathing circuit with autofeed chamber	10 pack	
RT210	Adult dual heated breathing circuit with autofeed chamber	10 pack	
RT211	Adult dual heated breathing circuit with autofeed chamber and pressure lines	10 pack	
RT137	Adult inspiratory heated breathing circuit –2 m expiratory with water trap	10 pack	
RT215	Adult inspiratory heated breathing circuit with autofeed chamber and pressure lines –2 m expiratory with water trap	10 pack	
RT134	Adult unheated dual watertrap breathing circuit with pressure lines –1.8 m expiratory	10 pack	
RT110	Adult dual heated breathing circuit	10 pack	
RT111	Adult dual heated breathing circuit with pressure lines	10 pack	












Adult invasive ventilation interfaces and accessories

Product Code	Description	Quantity	
RT019	Inspiratory/Expiratory filter	20 pack	
RT020	End expiratory filter	20 pack	
RT021	DirectConnect dual swivel catheter mount	20 pack	
RT023	Patient ventilator weaning kit	20 pack	
RT024	Dryline extension kit	20 pack	
RT032	Water trap	20 pack	
RT913	Inspiratory elbow adapter - PB7200	10 pack	
RT914	Inspiratory adapter - PB840	10 pack	








Adult miscellaneous breathing circuits

Product Code	Description	Quantity	
RT408	Adult oxygen therapy inspiratory heated breathing circuit with autofeed chamber, flexible extension and air entrainer	10 pack	




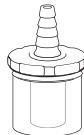
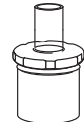
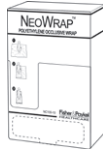
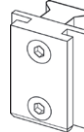
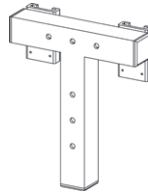
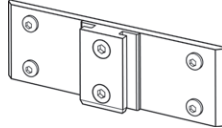
Infant resuscitation circuits and kits

Product Code	Description	Quantity	
900RD110	Infant inspiratory heated resuscitation circuit with T-piece –Humidified	10 pack	
900RD010	Infant T-piece resuscitation circuit with adjustable PEEP valve –	10 pack	
RD1300-10	Infant T-piece resuscitation circuit with adjustable PEEP valve –Ergonomic	10 pack	
900RD014-10	Infant resuscitation kit including T-piece circuit (Classic) and premature mask (S)	10 pack	
900RD015-10	Infant resuscitation kit including T-piece circuit (Classic) and neonatal mask (M)	10 pack	
900RD016-10	Infant resuscitation kit including T-piece circuit (Classic) and infant mask (L)	10 pack	
RD1330-10	Infant resuscitation kit including T-piece circuit (Ergonomic) and micro-premature mask (XS)	10 pack	
RD1340-10	Infant resuscitation kit including T-piece circuit (Ergonomic) and premature mask (S)	10 pack	
RD1350-10	Infant resuscitation kit including T-piece circuit (Ergonomic) and neonatal mask (M)	10 pack	
RD1360-10	Infant resuscitation kit including T-piece circuit (Ergonomic) and infant mask (L)	10 pack	
RD1370-10	Infant resuscitation kit including T-piece circuit (Ergonomic) and pediatric mask (XL)	10 pack	



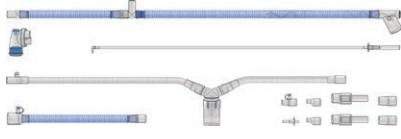
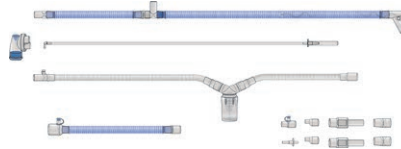
Infant resuscitator and masks

Product Code	Description	Quantity	
RD900AEU	Neopuff™ infant T-piece resuscitator	1 each	
900IW130E	Neopuff™ infant T-piece resuscitator (infant warmer module)	1 each	
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	

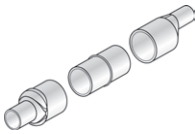



Infant resuscitation accessories

Product Code	Description	Quantity	
RD020-01	Reusable test lung	1 each	
900RD008	Short gas supply line –31 cm (12.2")	10 pack	
900RD009	Long gas supply line –210 cm (82.7")	10 pack	
900RD101	Gas inlet adapter	1 each	
900MR148	Reusable T-piece neonatal circuit adapter –15 male/10 female to 10 male	1 each	
NC100	NeoWrap™ occlusive wrap	2 pack (NC100-SK) 10 pack (NC100-10) 25 pack (NC100-25)	
900RD301	Side-mounting block for Neopuff™	1 each	
900RD302	Wall-mounting bracket for Neopuff™	1 each	
RD050-01	Central-mounting block kit for Neopuff™	1 each	


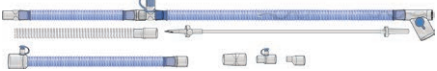

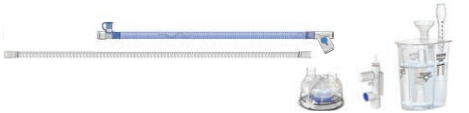

Infant invasive ventilation breathing circuits

Product Code	Description	Quantity	
RT265	Infant Evaqua™ 2 dual heated breathing circuit with autofeed chamber and pressure line (flows > 4 L/min)	10 pack	
RT266	Infant Evaqua™ 2 dual heated breathing circuit with autofeed chamber and pressure line (flows 0.3 to 4 L/min)	10 pack	
RT130	Infant ventilator circuit (0.3 to 4 L/min) single heated	10 pack	
RT131	Infant ventilator circuit (> 4 L/min) single heated	10 pack	

Infant invasive ventilation accessories

Product Code	Description	Quantity	
RT010	Inline nebulizer adapter kit	20 pack	
RT030	Side-stream nebulizer adapter kit	20 pack	
RT061	Adapter kit for Dräger (2)	50 pack	
RT062	Luerlock adapter (2)	50 pack	
RT063	Pressure port adapter (2)	100 pack	
RT064	Adapter kit for oxygen/CPAP (2)	50 pack	
RT065	Adapter kit for Hamilton/EME	10 pack	

Infant CPAP therapy breathing circuits

Product Code	Description	Quantity	
RT324	Infant inspiratory heated breathing circuit with autofeed chamber, pressure line, adapter kit, expiratory extension and water feed extension (flows > 4L/min)	10 pack	
RT132	Infant continuous flow inspiratory heated breathing circuit with pressure line and adapter kit (flows > 4L/min)	10 pack	
BC151-10	Infant Bubble CPAP system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold and 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 and CPAP generator (connects to FPH interface)	10 pack	
BC171-10	Infant Bubble CPAP system including inspiratory heated breathing circuit with autofeed chamber, pressure manifold with dryline, pressure line and CPAP generator (connects to Flow Driver)	10 pack	





Infant CPAP therapy interfaces

Product Code	Description	Quantity	
BC190-05	FlexiTrunk™ nasal tubing universal fitting (50 mm)	5 pack	
BC191-05	FlexiTrunk™ nasal tubing universal fitting (70 mm)	5 pack	
BC192-05	FlexiTrunk™ nasal tubing universal fitting (100 mm)	5 pack	
BC3020-10	Nasal prong (3.0 mm nare diameter/ 2.0 mm septal width)	10 pack	
BC3520-10	Nasal prong (3.5 mm nare diameter/ 2.0 mm septal width)	10 pack	
BC4030-10	Nasal prong (4.0 mm nare diameter/ 3.0 mm septal width)	10 pack	
BC4540-10	Nasal prong (4.5 mm nare diameter/ 4.0 mm septal width)	10 pack	
BC5040-10	Nasal prong (5.0 mm nare diameter/ 4.0 mm septal width)	10 pack	
BC5050-10	Nasal prong (5.0 mm nare diameter/ 5.0 mm septal width)	10 pack	
BC5550-10	Nasal prong (5.5 mm nare diameter/ 5.0 mm septal width)	10 pack	
BC5560-10	Nasal prong (5.5 mm nare diameter/ 6.0 mm septal width)	10 pack	
BC6060-10	Nasal prong (6.0 mm nare diameter/ 6.0 mm septal width)	10 pack	
BC6070-10	Nasal prong (6.0 mm nare diameter/ 7.0 mm septal width)	10 pack	
BC6570-10	Nasal prong (6.5 mm nare diameter/ 7.0 mm septal width)	10 pack	

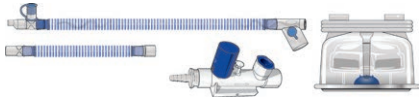

Infant CPAP therapy interfaces

Product Code	Description	Quantity	
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 (17–22 cm)	5 pack	
BC303-05	Infant bonnet (22–25 cm)	5 pack	
BC306-05	Infant bonnet (25–29 cm)	5 pack	
BC309-05	Infant bonnet (29–36 cm)	5 pack	
BC325-05	Infant headgear (29–36 cm)	5 pack	
BC328-05	Infant headgear (35–40 cm)	5 pack	
BC331-05	Infant headgear (40–45 cm)	5 pack	
BC351-10	Chin strap (20–26 cm)	10 pack	
BC353-10	Chin strap (26–32 cm)	10 pack	
BC355-10	Chin strap (32–38 cm)	10 pack	
BC357-10	Chin strap (38–44 cm)	10 pack	






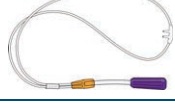
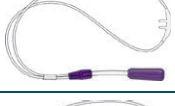
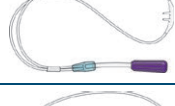

Infant CPAP therapy accessories

Product Code	Description	Quantity	
BC400-10	Gas supply line 2.1 m for blender	10 pack	
BC402-05	Gas supply line kit for dual flow meters	5 pack	
BC501-01	Bird® MicroBlender 2 to 16 L/min DISS	1 each	
BC510-01	Bird® MicroBlender pole-mount bracket	1 each	




Infant nasal high flow breathing circuits

Product Code	Description	Quantity	
RT329	Infant continuous flow circuit (0.3 to 10 L/min) inspiratory heated breathing circuit with autofeed chamber and pressure relief manifold	10 pack	
RT330	Optiflow™ Junior inspiratory heated breathing circuit with autofeed chamber and pressure relief manifold	10 pack	

Infant nasal high flow interfaces

Product Code	Description	Quantity	
OPT312	Optiflow™ Junior nasal cannula –Premature (Wigglepads™ replacement = OPT010)	20 pack	
OPT314	Optiflow™ Junior nasal cannula –Neonatal (Wigglepads™ replacement = OPT012)	20 pack	
OPT316	Optiflow™ Junior nasal cannula –Infant (Wigglepads™ replacement = OPT012)	20 pack	
OPT318	Optiflow™ Junior nasal cannula –Pediatric (Wigglepads™ replacement = OPT012)	20 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	








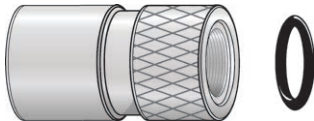
Infant nasal high flow accessories

Product Code	Description	Quantity	
OPT010	Optiflow™ Junior Wigglepads™ replacement –Premature (20 in each pack)	2 pack	
OPT012	Optiflow™ Junior Wigglepads™ replacement –Neonatal/Infant/Pediatric (20 in each pack)	2 pack	
OPT014	Optiflow™ Junior oxygen tubing	10 pack	
OPT016	Optiflow™ Junior adapter kit	10 pack	
BC115-05	Pressure relief manifold 40 cm (Blue) suitable for oxygen therapy delivery to infants using systems such as the FPH RT329 or RT330	5 pack	


Humidifier brackets and hardware

Product Code	Description	Quantity	
900MR030	Mounting bracket -Pole clamp 15 to 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	
900HC032	Free-standing metal tray with humidifier mount. Designed for use in conjunction with a homecare ventilator or flow-generating device	1 each	



Humidifier brackets and hardware

Product Code	Description	Quantity	
900MR011	Waterbag pole -1.25 m (50")	1 each	
900MR012	Waterbag pole -1.0 m (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 to 2.64 m (64 to 104")	1 each	
900MR293	Humidifier stand with waterbag pole -1.65 m (65")	1 each	
900MR306	Humidifier stand basket	1 each	
900MR599	Oxygen flow adapter -22 mm Male to 9/16"	1 each	

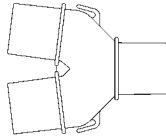
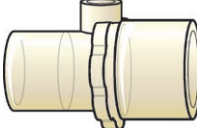
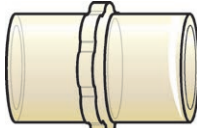




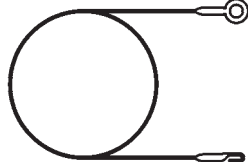
Humidifier accessories for reusable systems

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

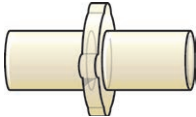
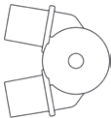

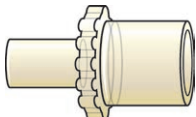
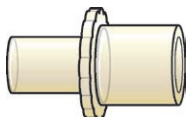

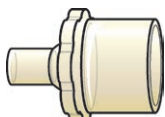



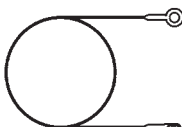
Reusable humidification chambers

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

Adult reusable breathing circuit (900MR784) spare parts

Product Code	Description	Quantity	
900MR126	Adult Y-piece	1 each 100 pack (900MR126C)	
900MR532	Temperature probe housing -22 mm Female to 22 mm Male/15 mm Female	1 each 100 pack (900MR532C)	
900MR534	Tube joint -22 mm Male/15 mm Female	1 each 100 pack (900MR534C)	
900MR139	Autoclavable water trap	1 each 100 pack (900MR139C)	
900MR062	Reusable adult tubing -0.6 m (24")	1 each	
900MR067	Reusable adult tubing -1.5 m (60")	1 each	
900MR074	Reusable adult tubing -1.1 m (44")	1 each	
900MR070	Draw wire -1.5 m (60")	1 each	

Infant reusable breathing circuit (900MR782) spare parts

Product Code	Description	Quantity	
900MR143	Adapter 10 mm Male to 10 mm Male	10 pack	
900MR145	Neonatal Y-piece pressure port	1 each	
900MR146	Temperature probe housing 10 mm Male to 15 mm Male/10 mm Female	1 each 100 pack (900MR146C)	
900MR157	Adapter 10 mm Male to 15 mm Male/11 mm Female (Dräger)	1 each	
900MR178	Adapter 12 mm Male to 15 mm Male	1 each	
900MR139	Autoclavable water trap	1 each 50 pack (900MR139L) 100 pack (900MR139C)	
900MR406	Adapter 22 mm Female to 10 mm Male	1 each	
900MR017	Reusable infant tubing -0.3m (12")	1 each	
900MR025	Reusable neonatal tubing -0.7 m (28")	1 each	
900MR026	Reusable neonatal tubing -1.1m (43")	1 each	
900MR070	Draw wire -1.5m (60")	1 each	

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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

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

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

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

Classification:	IIa
Device Group:	R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose:	-/-

Classification:	IIa
Device Group:	R030101 - VENTILATION MASKS
Intended Purpose:	-/-

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