F&P **my820 System**

Humidification System

Respiratory humidification
for patients in the home

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Fisher&Paykel HEALTHCARE

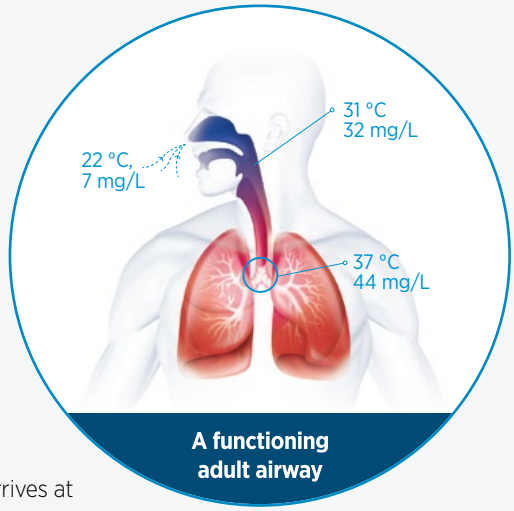
F&P my820 System

The F&P my820 System provides heated humidification for adult and pediatric (> 5 kg) home-based patients receiving invasive or noninvasive ventilation (NIV) therapies.

There are many benefits to using heated humidification in the home, which include maintaining secretion clearance, and supporting patient comfort and tolerance to NIV.

The F&P Simplus™ mask is intended to be used for patients requiring CPAP or Bi-Level Ventilator treatment. Always follow the directions for use.

An overview of a healthy adult airway



A functioning adult airway

The respiratory system is a highly balanced mechanism reliant on humidity.[1]

When we breathe in, air travels down the respiratory tract drawing heat and moisture from mucus in the airway. In a healthy airway, the air reaches a temperature of 37 °C and is saturated with 44 mg/L of water vapor when it arrives at the cartilage at the bottom of the trachea, known as the carina.[2,3]

The airway mucosa needs to retain a balance of heat and moisture to maintain a fully functioning mucociliary transport system. This system traps contaminants in mucus and moves them up and out of the airway using tiny hair-like structures called cilia. This process plays an important role in efficient gas exchange by maintaining clear and open airways with effective mucus clearance[1] while reducing the risk of airway blockages and compromised lung function.[1]

Insufficient respiratory humidification can result in diminished cilia activity, a decrease in cilia beat frequency, and may also result in permanent cellular damage.[1,4]

Heated humidification can increase comfort and tolerance to NIV

Factors such as gas leaks, high flow rates and unidirectional flows which can occur during delivery of noninvasive ventilation can dry the mucosa found in the nose and mouth,[5–7] disrupting the mucociliary transport system.

Upper airway dryness, and in turn discomfort, is often reported when respiratory gases do not contain adequate levels of heat and humidity during noninvasive respiratory support. Discomfort can impact a patient's ability to comply with the required therapy, which may affect patient outcomes.

Heated humidification provides warmth and moisture to inspired gases, reducing the burden on the airway mucosa. Heated humidification may make NIV therapy more comfortable and improve patient tolerance.[8]

Heated humidification assists secretion clearance

Bypassing the upper airway, such as with a tracheostomy tube, impedes the airway's humidifying surfaces and filtering mechanisms while compromising the body's protective cough, gag and sneeze reflexes.[1]

When mucociliary transport is inadequate, mucus can become a risk factor rather than a defence mechanism. Therefore, humidification and as-needed suctioning are the foundations of secretion management in mechanically ventilated patients.[9]

Failure to heat and humidify inspired gases for patients with bypassed airways can increase the risk of complications such as drying of the airway, airway obstruction, bronchoconstriction, and increased risk of artificial airway tube occlusion.[4]

Continuous airway inflammation, and the retention of mucus are also seen in patients with chronic respiratory diseases. These patients commonly have clinical care provided in a homecare setting where the use of humidification can improve secretion clearance.[10,11]

It is widely accepted and mandated by clinical guidelines that inspired gases be heated and humidified for any patient receiving invasive ventilatory support.[8]

F&P my820 System

Features and benefits

1

Heated breathing tubes to minimize condensation
The inspiratory breathing tubes in the F&P my820 System are heated and can be used by a single patient for up to 14 days.

2

No separate probes or adapters
The built-in Heater-wire Adapter features an ambient temperature sensor which provides environmental feedback to the humidifier base to ensure the appropriate humidity levels are delivered to the patient.

3

500 mL chamber capacity
The MR325 manual-fill chamber can be used on a single patient for up to 14 days.

4

Four humidity settings
Four user-selectable temperature and humidity settings support various therapies and levels of comfort.

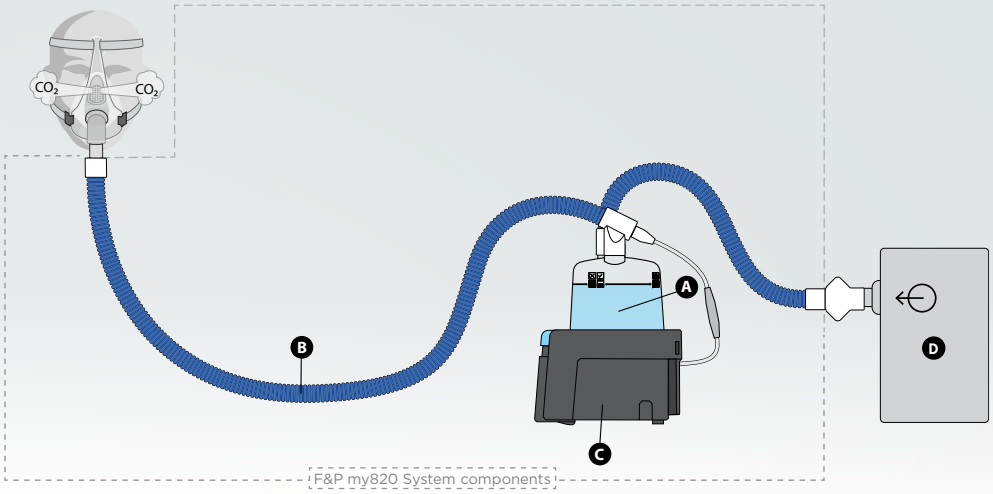
5

Simple alarms

CHECK WATER | AUDIO ALARM PAUSED | CAUTION | CHECK HEATER WIRE

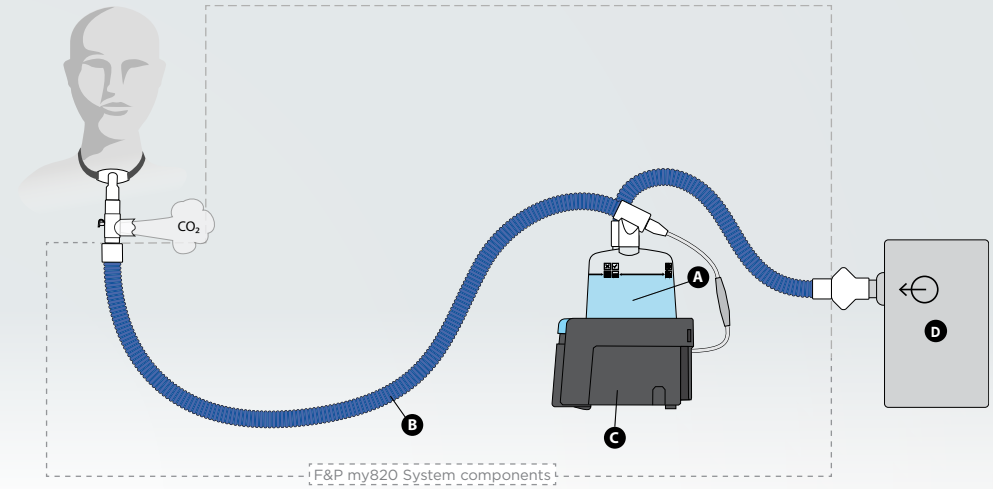
The F&P my820 System has an intuitive alarm system, which includes the ability to detect when the chamber is out of water.

F&P my820 System setups



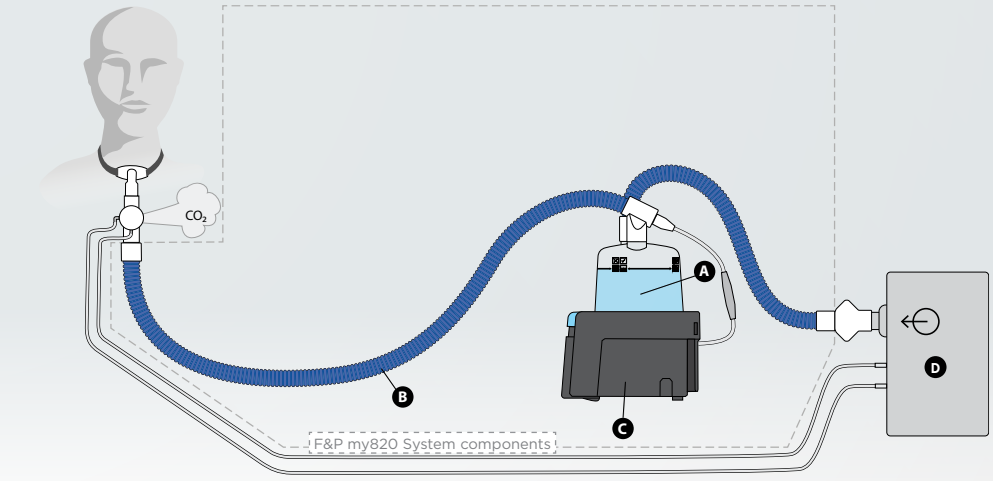
Single-limb vented-mask setup

- **A** Humidification chamber
- **B** Breathing tubes
- **C** Humidifier base
- **D** Ventilator or other flow source



Single-limb tracheostomy setup (passive port)

- **A** Humidification chamber
- **B** Breathing tubes
- **C** Humidifier base
- **D** Ventilator or other flow source



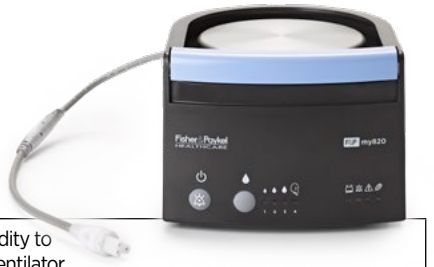
Single-limb tracheostomy setup (active exhalation valve)

- **A** Humidification chamber
- **B** Breathing tubes
- **C** Humidifier base
- **D** Ventilator or other flow source

Always follow the directions for use

Tracheostomy setups may also be used with an appropriate mask. Not all products are available in all markets. Not all accessories shown are included in F&P my820 System breathing sets.

F&P my820 System



F&P my820 – Respiratory Humidifier Base

Specifications

Intended Use	The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow. This system is intended for both non invasive and invasive therapies, the addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways. This system is designed for adult and pediatric (excluding neonate) use in long term care facilities and homes, under the prescription of qualified medical professionals.
Clinical Procedures	Invasive ventilation, noninvasive ventilation, humidified high flow
Use	Multi-use
Service life	7 years (when used in accordance with the User Instructions)
Dimensions	98 x 135 x 154 mm (3.9 x 5.3 x 6.1 inches) with no humidification chamber fitted
Weight	1.7 kg (3.75 lbs) with no chamber fitted
Mounting fixture	30 x 5 mm mounting tongue
Materials	Aluminium, Steel, Copper, Nichrome, Brass, Tin, Gold, Mica, Silicon, Ceramic, Fibreglass, Polycarbonate, Polyphenylene Sulfide, PVC, Polypropylene, Thermoplastic Elastomer, Teflon

Performance | Specifications

	Setting 1	Setting 2	Setting 3	Setting 4
Patient End Temperature Range	26–34 °C	29–37 °C	32–40 °C	35–43 °C
Humidity Performance*	≥ 12 mg/L			≥ 33 mg/L
Flow Range (BTPS)	5–70 L/min			5–40 L/min
Ambient Temperature Range	18–26 °C (64.4–78.8 °F)			
Ambient Relative Humidity	15–90%			
Ambient Pressure	700–1060 hPa			

(including 1 °C temperature measurement uncertainty and 1 mg/L humidity measurement uncertainty)
*Humidity performance (except in the event of a humidifier alarm, power failure or electromagnetic disturbance)

Electrical | Specifications

Supply Voltage my820AXX* my820JXX*	 230 V 115 V
Rated Power	200 VA
Supply Frequency	50/60 Hz
Heater-wire Adapter Voltage	22 V
Heater-wire Adapter Power	35 W max.

*XX represents the country code

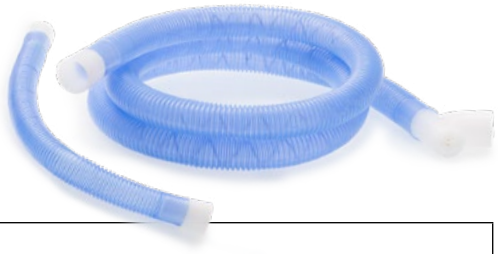
Alarms | Specifications

Alarm Sound Pressure Level	> 45 dBA @1 m
Audio Alarm Signal	Triple beep
Alarm Indicators	Check Water, Caution, Check Heater Wire, Audio Alarm Paused
Auditory Alarm Pause	120 sec

Regulatory | Specifications

Classification	Class II, Class IIb (EU)		
Standard Compliance	ISO 80601-2-74:2017 IEC 60601-1:2005 + A1:2012	IEC 60601-1-2:2014 + A1:2020 IEC 60601-1-11:2015	IEC 60601-1-8:2006 + A1:2012
Country of Origin	New Zealand		

F&P my820 System



820A10 – F&P 820 Circuit Heated Single Limb 22 mm

Specifications

Intended Use	The F&P 820 series breathing tubes are an accessory to the F&P 820 System and are compatible with F&P 820 series humidifiers. The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow. This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways. This system is designed for adult and pediatric (excluding neonate) use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.
Duration of Use	Up to 14 days
Use	Single patient
Shelf Life	3 years

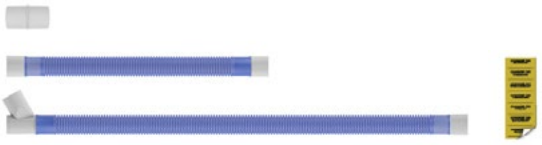
Technical | Specifications

Interface Connections	ISO 5356-1 Conical Connectors (22 mm Male)
Breathing Tube Length	1.57 m (5' 2")
Breathing Tube Minimum Internal Diameter	20 mm
Flowrate range (BTPS) Invasive (Setting 4) Noninvasive (Settings 1-3)	 5–40 L/min 5–70 L/min
Compliance @ 60 cmH_2O (820A10 and MR325 Breathing Set)	1.20 ± 0.10 mL/cmH_2O (including 0.04 mL/cmH_2O measurement uncertainty)
Resistance to Flow (820A10 and MR325 Breathing Set) Inspiratory @ 15 L/min Inspiratory @ 30 L/min	 0.25 ± 0.03 cmH_2O (including 0.02 cmH_2O measurement uncertainty) 0.73 ± 0.06 cmH_2O (including 0.02 cmH_2O measurement uncertainty)
Maximum Operating Pressure	8 kPa
Gas Leakage @ 60 cmH_2O	<40 mL/min

Operating Conditions | Specifications

Ambient Temperature	18–26 °C (64.4–78.8 °F)
Ambient Relative Humidity	15–90%
Pressure	700–1060 hPa

Components and Composition | Specifications

Pack Components • Heated Inspiratory Tube 22 mm • Dryline 0.5 m • Change-out label • 22M-22M Single-use Adapter • Kitting Bag	
Tubing Materials	HDPE, Polyethylene, Polypropylene, Denatured Alcohol
Heater Wire Materials	Copper, Polyester, Polypropylene, Brass

Regulatory | Specifications

Classification	Class II, Class IIa (EU)
Country of Origin	New Zealand

F&P my820 System

MR325 – F&P 820 Chamber Manual Fill 500 mL

Specifications

Intended Use	The MR325 humidification chamber is an accessory to the F&P 820 System and is compatible with F&P 820 series humidifiers. The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow. This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways. This system is designed for adult and pediatric (excluding neonate) use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.
Use	Single patient
Duration of Use	14 days
Shelf Life	3 years
Interface Connections	ISO 5356-1 Conical Connectors (22 mm Male)
Maximum water volume	500 mL
Flowrate range (BTPS) Invasive (Setting 4) Noninvasive (Settings 1–3)	 5–40 L/min 5–70 L/min
Compliance (@ 60 cmH_2O when full) 820A10 and MR325 Breathing Set	 1.20 ± 0.1 mL/cmH_2O (including 0.04 mL/cmH_2O measurement uncertainty)
Resistance to Flow (820A10 and MR325 Breathing Set) Inspiratory limb @ 15 L/min Inspiratory limb @ 30 L/min	 0.25 ± 0.03 cmH_2O (Including 0.02 cmH_2O measurement uncertainty) 0.25 ± 0.06 cmH_2O (Including 0.02 cmH_2O measurement uncertainty)
Maximum Operating Pressure	8 kPa
Gas Leakage @ 60 cmH_2O	<40 mL/min (inspiratory or expiratory circuit)
Chamber Materials	ABS, Santoprene, aluminum, polyethylene

Operating Conditions | Specifications

Ambient Temperature	18–26 °C (64.4–78.8 °F)
Ambient Relative Humidity	15–90%
Pressure	700–1060 hPa

Regulatory | Specifications

Classification	Class II, Class IIa (EU)
Country of Origin	New Zealand

References

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