F&P 820 System

F&P my820 Respiratory Humidifier

USER INSTRUCTIONS

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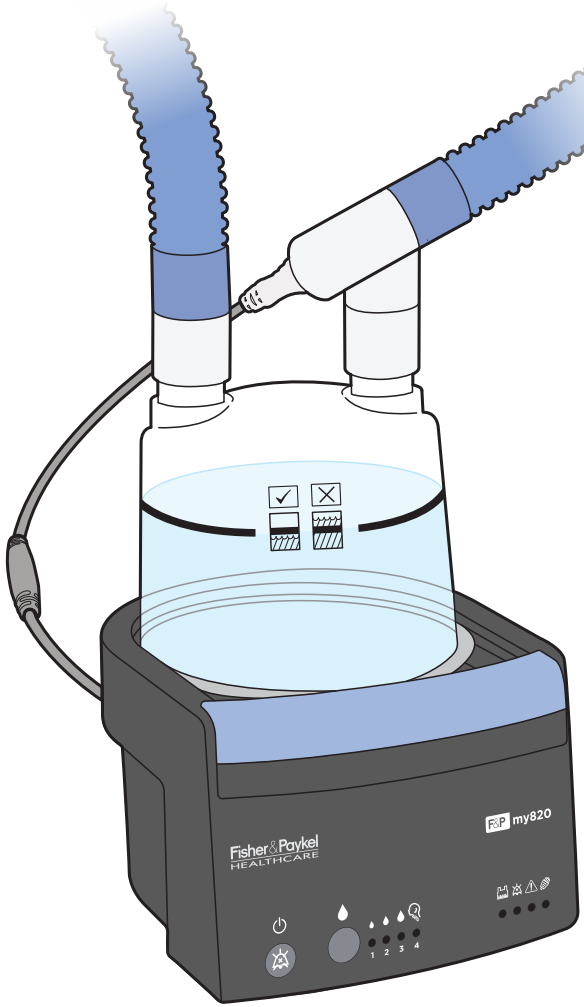


BEFORE YOU START

Before using the F&P 820 System, please carefully read the safety and set-up instructions outlined in this document and all documents that come with F&P 820 system components.

If the device or its accessories are not operating in accordance with this document, please contact your healthcare provider or local Fisher & Paykel Healthcare representative.

Keep this document in a safe place so you can refer to it later if you need to.

CONTENTS

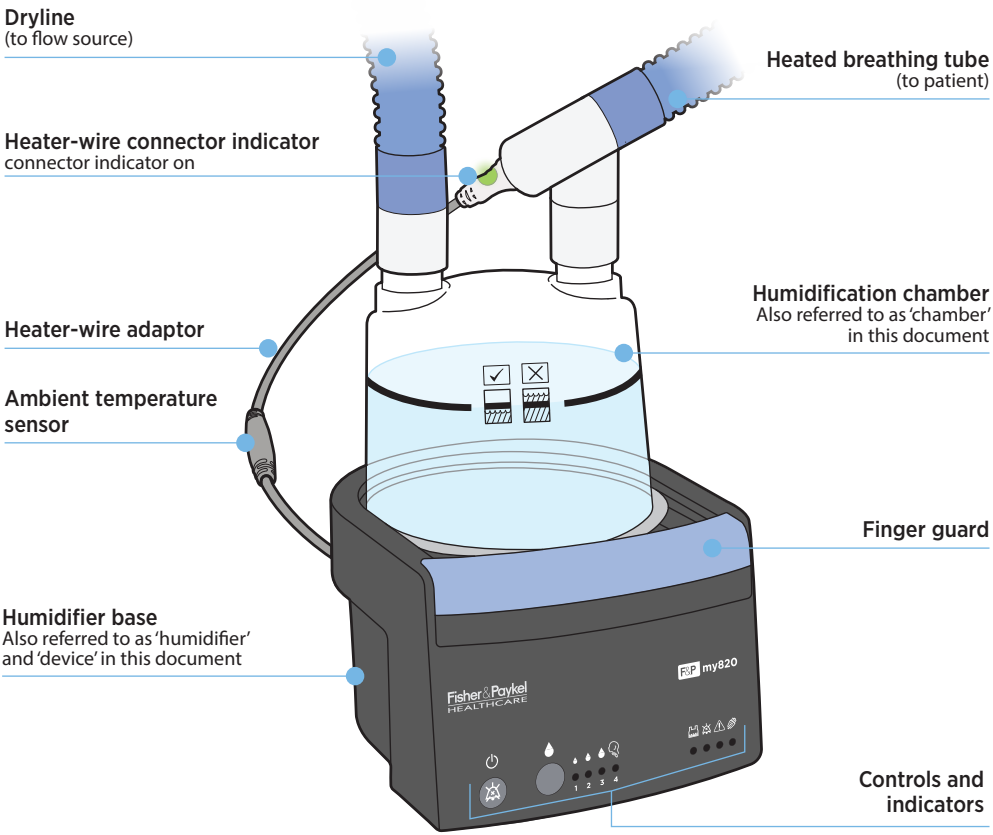
INTENDED USE (INDICATIONS FOR USE)

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 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 long term care facilities and homes, under the prescription of qualified medical professionals.

SYSTEM OVERVIEW

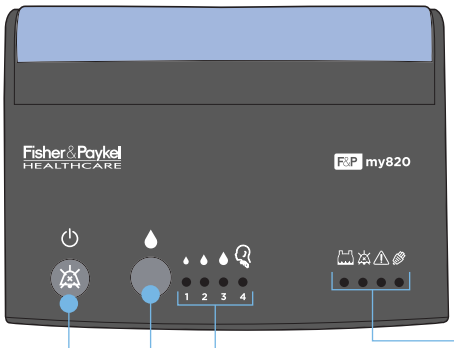


SYSTEM OVERVIEW *(continued)*

OPERATING PRINCIPLE

The F&P 820 System provides heat and humidity to the respiratory gases by passing the gas through a humidification chamber and heated breathing tube.

CONTROLS AND INDICATORS



Check-water
Indicates the chamber may require refilling

Audio alarm paused
Indicates the audio alarm has been paused

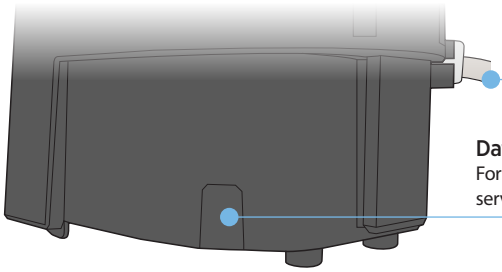
Caution
Indicates a humidifier fault

Check heater-wire
Indicates a breathing tube problem, see 'Alarm description' for details

Setting indicators
Indicates the selected temperature (humidity) setting

Setting button
Selects the desired temperature (humidity) setting

Standby button
Turns the humidifier on or off and pauses the audio alarm



Power cord

Data port
For Fisher & Paykel Healthcare production and service personnel use only

Caution: Do not remove data port cover during normal use. Removing the data port cover could cause the device to be vulnerable to malicious actions, or unintentional misuse, potentially increasing risk of patient harm.

WARNINGS

- Remove any ignition sources, such as cigarettes, an open flame or materials that ignite easily at high-oxygen concentrations, from the vicinity of the humidifier and its accessories. Failure to comply may result in serious harm.
- The operation of high frequency surgical apparatus, or shortwave or microwave equipment in the vicinity of the humidifier may adversely affect its performance. The humidifier should be removed from the vicinity of such equipment.
- Operation of the humidifier outside of the recommended operating conditions (as stated in these user instructions) may impair the performance of the humidifier or compromise safety, including potentially causing patient harm.
- This humidifier is only designed and verified for use with accessories approved by Fisher & Paykel Healthcare. Unauthorized accessories used with the humidifier may impair the performance of the humidifier, or compromise safety (including potentially causing serious patient harm).
- Use of this humidifier adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this humidifier and the other equipment should be observed to verify that they are operating normally.
- Portable radio frequency (RF) communications equipment (including peripherals, such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the humidifier, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- Do not attempt to service the humidifier as it is not intended to be serviced. Failure to comply may impair the performance of the humidifier or result in serious harm.
- Do not modify the humidifier or its accessories in any way. Failure to comply voids the user's authority to operate the device and may impair performance or result in serious harm.
- Do not touch the electrical connections and the patient simultaneously. Failure to comply may result in harm.
- The prescribing physician or responsible organization is accountable for the compatibility of the flow source, patient interface and other devices used in combination with the F&P 820 System to administer clinical therapy to a patient. This includes ensuring there is an appropriate expiratory gas pathway to avoid the build up of CO_2 that could lead to hypercapnia, and that there is appropriate pressure control or relief to avoid pressure that could lead to barotrauma.

NOTES

- Please refer queries relating to setup, troubleshooting, service, repair and unexpected operation of the humidifier or accessories to your healthcare provider or local Fisher & Paykel Healthcare representative.
- If a serious incident has occurred while using this device, please inform your local Fisher & Paykel Healthcare representative and the Competent Authority in your country.

HUMIDIFIER INSTALLATION

The humidifier shall be installed on a flat, stable surface or mounted to an appropriate medical equipment stand, mount or medical equipment rail with an approved mounting bracket.

Position the humidifier so the power cord connection to the power supply is easily accessible and can be easily disconnected.

If the humidification system has been stored outside of the specified operating ambient temperature range, the system must be left for 24 hours within the specified operating temperature range before use.

Plug the power cord into mains power.

WARNINGS

- Before use, visually inspect the power cord for damage. Do not use the humidifier if there is visible damage to the power cord. Failure to comply may result in serious harm.
- Install the humidifier away from heat sources, such as direct sunlight, radiant heaters, fireplaces, ovens and kettles, and cooling sources, such as dehumidifiers, fans, air conditioners and ventilators. Failure to comply may impair the performance of the humidifier or result in serious harm.
- Place the humidifier on a flat, level surface to ensure that the chamber is level and the vent holes on the base of the humidifier are not blocked. Failure to comply may impair performance or result in serious harm.
- Always place the chamber lower than the patient end of the breathing tube. This setup allows condensate to drain away from the patient and towards the water chamber. Failure to comply may result in serious harm.
- If required, to isolate the humidifier from the mains, disconnect the power cord from the mains power supply.
- Do not use the humidifier in combination with electrical extension leads, power strips or other power adaptors.
- In the home-use environment, if applicable, consideration should be given to the possible hazards that could arise from children, pests and pets.

HUMIDIFICATION CHAMBER (MR325), SETTING UP AND USE

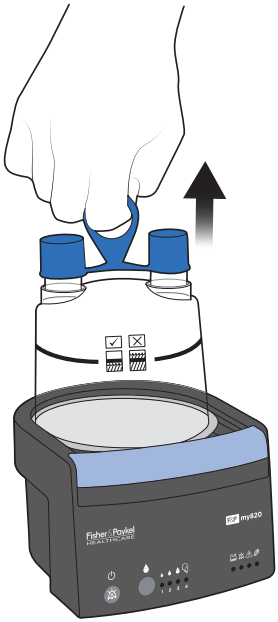
WARNINGS

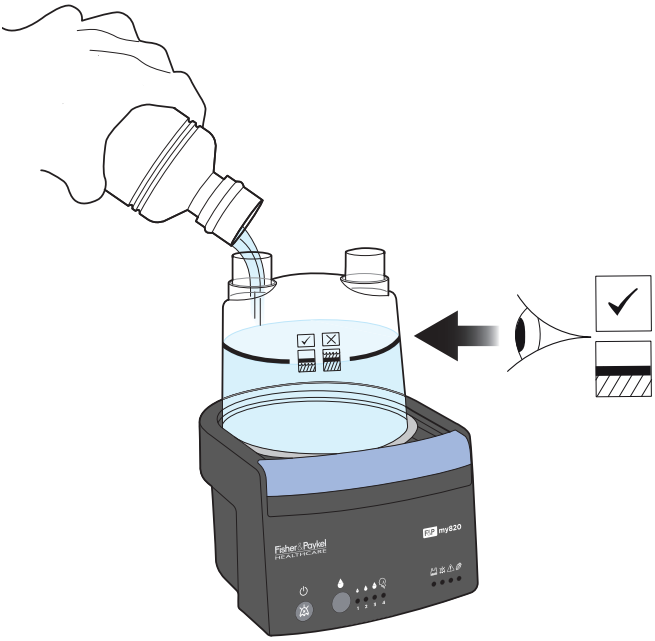
- Before setting up or use, visually inspect the chamber for damage (e.g. cracks or deformation), soilage, blockage or contamination. Replace the chamber if damaged, soiled, blocked or contaminated. Failure to comply may impair performance or result in serious harm.
- The surface temperature of the heater plate may exceed 80 °C. To avoid skin burn:
    - do not touch the hot surface of the heater plate or chamber base
    - ensure the chamber is fully inserted and securely guarded by the finger guard.
- Use only USP Sterile Water to fill the chamber to the marked fill level. Failure to comply may impair performance.
- Do not add substances to the water in the chamber (e.g. aromatic-based substances, scented oils or nebulizer drugs), as this may have adverse effects.

CAUTION

- Do not fill the chamber past the marked-fill level.

HUMIDIFICATION CHAMBER (MR325), SETTING UP AND USE *(continued)*





BREATHING TUBES, SETTING UP

WARNINGS

- Before setting up or use, visually inspect the breathing tubes and any attached accessories for damage (cracks, stretching or deformation), soilage, blockage, or contamination. Replace the breathing tubes if damaged, soiled, blocked, or contaminated. Failure to comply may impair performance or result in serious harm.
- Ensure that the breathing tubes are correctly connected to facilitate sufficient delivery of respiratory gases to the patient. Failure to comply may impair performance or result in serious harm.
- To avoid strangulation or tripping, ensure the breathing tubes and power cord are positioned in a tidy manner away from the floor and patient, so they will not get entangled or wrapped around the limbs or neck.
- Be aware of the layout of the breathing tubes during set up. Avoid stretching, deforming, or kinking (i.e. sharp bends) the breathing tubes.

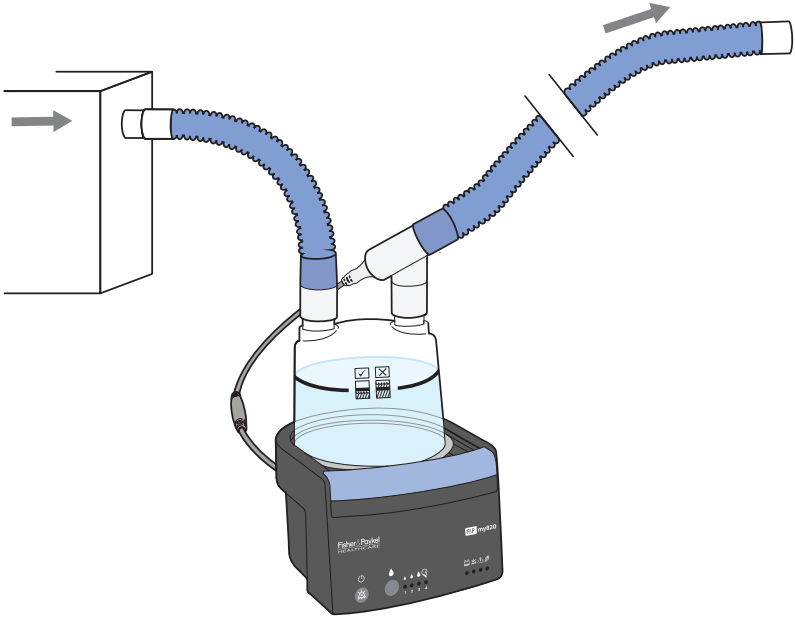
CAUTION

- Do not cover breathing tubes (e.g. with a blanket). Failure to comply may impair performance or injure the patient.

NOTE

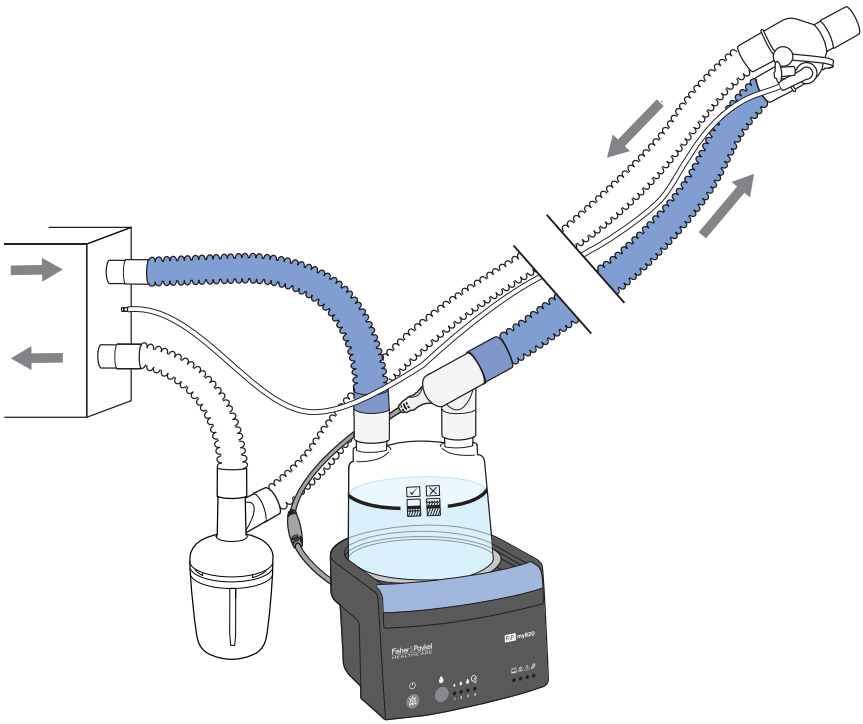
- Breathing tube may be kitted with accessories. The accessories may or may not be necessary depending on the specific use scenario.

Single Limb (820A10)



BREATHING TUBES, SETTING UP *(continued)*

Dual Limb (820A21)



Ensure the following:

- The dry line is connected between the flow source and a chamber outlet.
- The heater-wire connector end of the heated breathing tube is attached to the other chamber outlet.

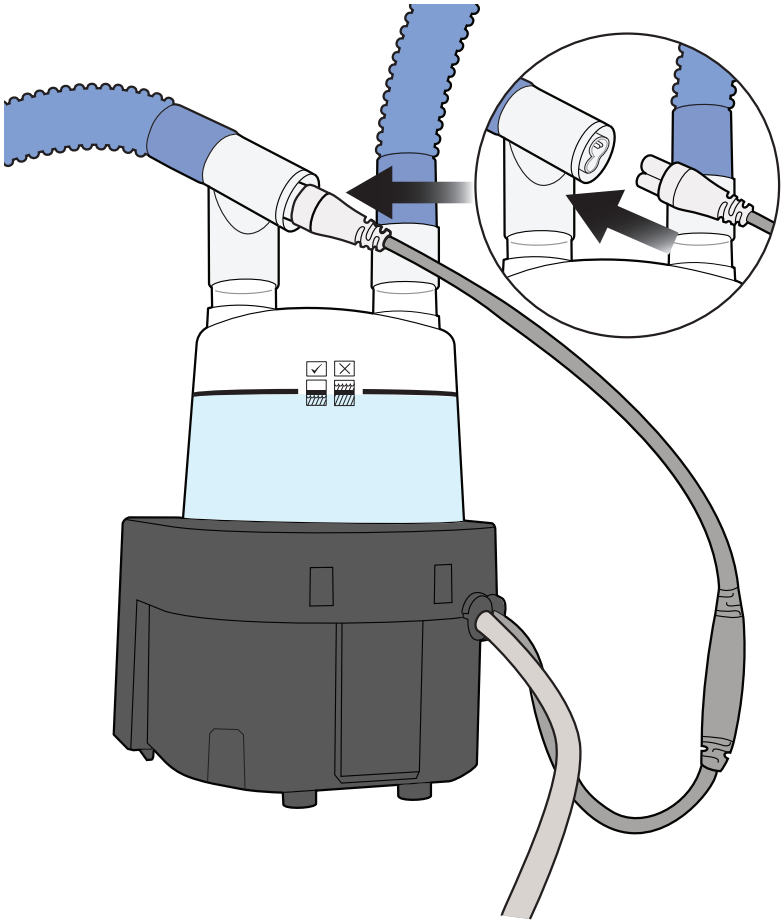
Either tube may be connected to either chamber outlet.

HEATER-WIRE CONNECTOR

Ensure that the heater-wire connector is connected to the breathing tube before use.
Do not touch the exposed electrical connections of the heater-wire connector and the patient simultaneously.

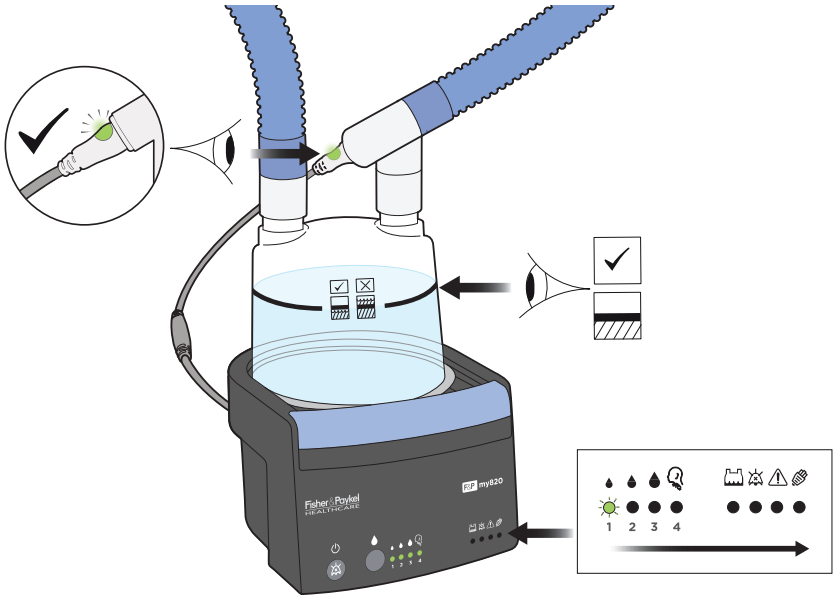
CAUTION

- Position the ambient temperature sensor to not touch the hot surface of the humidifier or chamber during use. Failure to comply may impair performance or compromise safety.



HUMIDIFIER OPERATION

Warning: Before operating the humidifier, ensure that the flow source is connected, turned on and set within the flow settings stated in these user instructions. Failure to comply may result in serious harm.



POWER ON and START-UP CHECKS

Caution: The operator must perform a start-up check **EACH TIME** the humidifier is used to ensure the humidifier's speaker and light indicators are working.

Power on

Turn on the humidifier by pressing the standby button and performing the start-up check. If required, the start-up check can be repeated by turning the humidifier off and on.

Start-up checks

To perform the start-up check, turn on the humidifier and **LISTEN FOR A BEEP AND THEN CONFIRM ALL 8 LIGHT INDICATORS ARE WORKING** as they illuminate from left to right.

The humidifier will then enter the warm-up stage.

Check that the heater-wire connector indicator illuminates to confirm that connection to the heated breathing tube has been successful.

Do not use the humidifier if:

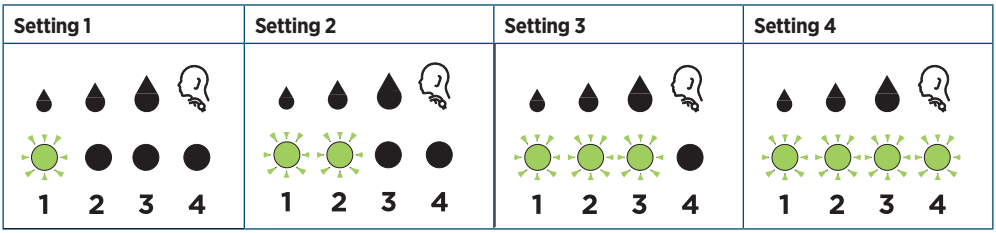
- the beep is not heard during the start-up check
- any light indicators do not illuminate during the start-up check.

If you experience either of these issues, contact your Fisher & Paykel Healthcare representative.

HUMIDIFIER OPERATION *(continued)*

CHANGE HUMIDITY SETTING

Briefly press the setting button to change the humidity (temperature) setting. The selected setting is indicated by the number of illuminated setting indicators, as shown below.



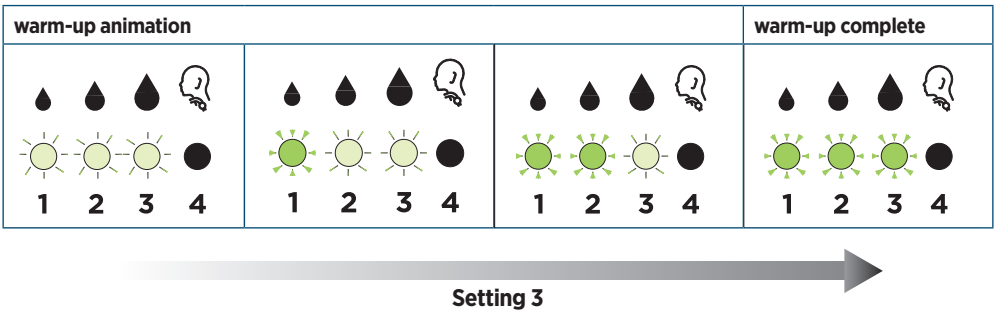
Refer to the 'Performance Parameters' in the Technical Specifications section for details on humidity and temperature outputs for each setting.

Caution: To avoid patient harm, ensure setting 4 is selected for a therapy mode requiring a humidity output of > 33 mg/L.

WARM-UP TIME

The F&P 820 System requires some time to reach the selected humidity setting, referred to as warm-up time. During this time, the setting indicators will display a fading animation.

The setting indicators will become solidly lit as the humidifier reaches the humidity (temperature) targets of the setting selected.



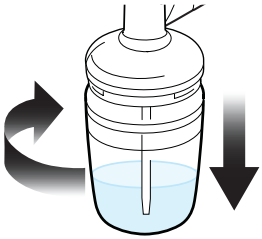
Once the warm-up phase is complete, the F&P 820 System will be delivering target humidity of the selected setting. The humidifier may re-enter the warm-up phase when the chamber is refilled, or if the humidity target is increased by changing the setting.

HUMIDIFIER OPERATION *(continued)*

PAUSE AUDIO ALARM

When present, the audio alarm can be silenced by briefly pressing the standby button. Alarm pause can be deactivated by briefly pressing the standby button again. Otherwise, it will automatically deactivate after 120 seconds.

MANAGE CONDENSATE



Monitor the breathing tubes for condensate hourly to prevent excessive build-up of mobile condensate.

Warning: If excessive build-up of mobile condensate is identified in the inspiratory breathing tube, drain the excess condensate back into the chamber as required by lifting the inspiratory breathing tube, taking care not to let condensate travel towards the patient. Failure to comply may impair performance or result in serious harm.

Caution: For a dual limb breathing tube setup with water trap, check the water trap hourly. Empty the water trap if the water level is at, or close to, the maximum fill level line.

HUMIDIFIER OPERATION *(continued)*

REFILL CHAMBER (CHECK-WATER ALARM)

Caution: Check the water level in the humidification chamber periodically and when a check-water alarm occurs. Failure to comply may impair performance or compromise safety. Water consumption varies with flow and humidity setting. Refill as required.

SHUT DOWN

Press and hold the Standby button for two seconds to turn the humidifier off.

REPROCESSING

Warning: Only clean and disinfect the device as per the instructions outlined in this section. Failure to comply may impair performance or result in serious harm.

Efficacy and safety of cleaning and/or disinfection procedures not outlined in these instructions remain the responsibility of the responsible organization.

CLEANING

Initial treatment at the point of use	If required, wipe with a clean, non-abrasive cloth to remove significant amounts of soiling.
Preparation before cleaning	• Ensure the device is powered off and unplugged from the power supply. • Remove the breathing tube or tubes and unplug the heater wire connector. • Remove the chamber from the device. • Check that the data-port cover is in place.
Automated Cleaning	Not applicable.
Manual Cleaning	**Equipment** • Clean, non-abrasive cloth • Mild detergent **Contraindications/cautions** • Do not submerge the device in liquid of any kind. • Do not spray liquid directly onto the device. **Manual cleaning instructions** 1. Mix the cleaning solution at a temperature of 55–60 °C, according to the detergent manufacturer's recommended concentration. 2. Dampen a clean cloth with the warm detergent solution. 3. Wipe all the device surfaces thoroughly for at least one minute or longer if required for the device to be visibly clean. **Rinse** 4. Dampen a clean cloth with tap water. 5. Wipe all surfaces of the device thoroughly. **Dry** 6. Wipe the surfaces of the devices with a dry cloth. 7. Allow to air dry until completely dry.
Frequency of cleaning	Follow the responsible organization's guidelines.

REPROCESSING *(continued)*

DISINFECTION

Automated Disinfection	Not applicable.
Manual Disinfection	Disinfection should be performed only after cleaning steps are complete. **Equipment** • Clean, non-abrasive cloth. • Lysol®* disinfecting wipes. **Contraindications/cautions** • Do not use bleach on the device surfaces. • Do not submerge the device in liquid of any kind. • Do not spray liquid directly onto the device. **Disinfection instructions** 1. Wipe the cleaned and dry device with Lysol® disinfecting wipes until the surfaces of the device are visibly wet. 2. Allow to stand for four minutes; if the device surfaces become dry within that time, use another wipe to apply more disinfectant so that they remain wet for at least four minutes. **Rinse** 3. Dampen a clean cloth with tap water. 4. Wipe the device thoroughly with the damp cloth. **Dry** 5. Wipe the device surfaces using a clean dry cloth until it is visibly dry. 6. Allow to air dry until completely dry.
Frequency of disinfection	Follow the responsible organization's guidelines.

*Lysol is a trademark of Reckitt Benckiser LLC.

GENERAL

Sterilization	The device does not require sterilization.
Maintenance, inspection and testing	After completing cleaning and disinfection, turn the device on and check that: • all indicators light up • audio beep is heard • all buttons can be pushed.
Storage	The device should be cleaned before storage and cleaned and disinfected before use after storage.
Transportation	Follow the responsible organization's guidelines.
Packaging	Follow the responsible organization's guidelines.

MAINTENANCE

The humidifier and its accessories do not require preventative maintenance. Please refer queries relating to humidifier maintenance to your local Fisher & Paykel Healthcare representative.

DISPOSAL

At the end of service life, dispose of the humidifier as per responsible organization's or local authorities' guidelines. For disposal of accessories, refer to their respective instructions for use.

TROUBLESHOOTING

For any alarms, refer to Alarm Description and Resolution section on page 21. If the alarm persists or for any other faults and queries related to troubleshooting, please refer to your Fisher & Paykel Healthcare representative.

TECHNICAL INFORMATION

PERFORMANCE PARAMETERS

	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
(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)*

OPERATING CONDITIONS

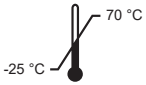
Ambient Temperature	18–26 °C (64–79 °F)
Ambient Relative Humidity	15–90%
Pressure	700–1060 hPa

INLET GAS TEMPERATURE AND HUMIDITY

Temperature	Minimum Inlet Gas Temperature: Current Ambient Temperature Maximum Inlet Gas Temperature: Current Ambient Temperature + 10 °C
Humidity	≤ 20 mg/L

TECHNICAL INFORMATION *(continued)*

TRANSPORT AND STORAGE CONDITIONS



Transport and storage temperature limitation

Transport and storage humidity limitation

PRODUCT SPECIFICATIONS

Dimensions (Humidifier)	98 mm x 135 mm x 154 mm (3.9" x 5.3" x 6.1")
Weight (Humidifier)	1.7 kg (3.7 lb)
Supply Frequency	50/60 Hz
Rated Supply Voltage	my820AXX 230 V my820JXX 115 V XX represents the country code
Permissible Supply Voltage Fluctuation	+/- 10%
Rated Power	200 VA
Heater-wire Adaptor Voltage	22 V
Heater-wire Adaptor Power	35 W max.
Alarm Sound Pressure Level	> 45 dBA @ 1 m
Data Port	The data port is only intended to be used by Fisher & Paykel Healthcare production and service personnel to read device faults, warning logs, usage times and equipment data.
Maximum Delivered Gas Temperature	43 °C
Maximum Surface Temperature of the Breathing Tube (Applied Part)	44 °C
Warm-up Time	< 60 minutes
Humidifier Expected Service Life	7 years
Designed to Conform to the Requirements of	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 ISO 80601-2-74:2017
General	The patient is an intended operator.

TECHNICAL INFORMATION *(continued)*

ELECTROMAGNETIC COMPATIBILITY

The F&P 820 System complies with the electromagnetic compatibility requirements of IEC 60601-1-2:2014 + A1:2020. Users should install and use the device according to the electromagnetic compatibility information in this user instruction.

The F&P 820 System is intended for use in the electromagnetic environment specified below. The customer or the user of the F&P 820 System should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The F&P 820 System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The F&P 820 System is suitable for use in the professional healthcare facility environment and home healthcare environment, except for near active high-frequency surgical equipment and the RF shielded room of a Medical Electrical System for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.

CLASSIFICATIONS

Electrical Classification	Class II, continuous
Humidifier Classification (ISO 80601-2-74)	Category 1 (Setting 4) Category 2 (Settings 1 to 3)
IP Classification	IP21 Protected from ingress by fingers or similar objects and protected from dripping liquid
Degree of Protection Against Electric Shock	Type BF applied part

THIRD-PARTY LICENSES

Certain elements of the software included with the F&P my820 are supplied under the license terms of third parties, including elements of the software that are subject to certain open source software licenses. Where required by the terms of these licenses, Fisher & Paykel Healthcare Limited provides notices regarding such software elements on its website.

Please visit www.fphcare.com/820/third-party-licensing/ to view these notices. Note that the notices that apply may be updated as the software included in the F&P my820 is updated.

TECHNICAL INFORMATION *(continued)*

ALARM SIGNALS

F&P my820 humidifier has audio and visual alarms to warn the user about the disruption to therapy.

- Visual alarm – indicator corresponding to the Alarm condition turns on, indicated by a:
    - solid yellow in event of low priority alarm condition
    - flashing yellow in event of medium priority alarm condition.
- Audio alarm – only active in medium-priority alarm condition, indicated by three beeps repeated every five seconds.

All alarms have been designed to be detectable within 1 m of the humidifier. As the F&P my820 humidifier does not include patient monitoring, these alarms are considered technical indicators of humidifier performance.

VERIFY ALARM FUNCTIONALITY

To verify the alarm system's functionality while turning the humidifier on, check that all setting and alarm indicators illuminate during start-up and an audible beep is heard. The operator should be positioned < 1 m from the humidifier during verification.

ALARM DESCRIPTION AND RESOLUTION

The possible alarm conditions, along with priority and required action, are listed in the table below.

It is possible to have multiple alarm conditions occur simultaneously. Under these conditions, the humidifier uses an internal ranking system to display the highest-ranked alarms.

Caution: Monitor the alarms and respond by taking the required action. Failure to take the required action for each alarm condition may impair performance or compromise safety.

TECHNICAL INFORMATION *(continued)*

Indicator	Alarm Condition	Priority	Delay	Required Action
 **Check water**	Alarm indicator will turn solid yellow when the humidification chamber is running out of water.	Low	< 60 min	Fill the humidification chamber with water.
	Alarm indicator will be flashing yellow, and the audio alarm will be activated when the humidification chamber is running out of water.	Medium	< 3 hrs	Fill the humidification chamber with water. Pressing the Standby button will pause the audio alarm for 120 seconds.
 **Caution**	Alarm indicator will turn solid yellow, indicating that the device is operating outside rated operating conditions, and therapy may not be optimal.	Low	< 30 min	Check that the humidifier is being used within the Operating Conditions stated on page 18 of these user instructions.*
	Alarm indicator will be flashing yellow, and the audio alarm will be activated, indicating one or both of the following: a. The humidifier is operating in an ambient temperature of greater than 39 °C or mains power is outside the range expected. b. A hardware fault has been detected.	Medium	< 10 min	Check that the humidifier is being used within the Operating Conditions stated on page 18 of these user instructions.* Pressing the Standby button will pause the audio alarm for 120 seconds.
 **Check heater wire**	Alarm indicator will turn solid yellow, indicating that in the highest humidity setting, the presence of a compatible heater wire is not detected. Or A non-compatible heater wire has been detected.	Low	< 5 sec	Connect heater wire connector to the breathing tube and check that the heater-wire connector indicator turns on.*
 **Audio alarm paused**	Alarm indicator will turn solid yellow, indicating that the audio alarm has been paused.	Not applicable	< 5 sec	No action required.

**If any alarms persist, power off and remove mains power to the humidifier, and contact your local Fisher & Paykel Healthcare representative.*

TECHNICAL INFORMATION *(continued)*

AUDIO SIGNAL SUMMARY

Audio alarm signals	Medium priority alarms	3 beeps (repeating)
Audio information signals	Audio pause	1 beep
	Power on	1 beep
	Setting change	1 beep
	Entering standby	2 beeps

SYMBOL DEFINITIONS

 Follow instructions for use	 Manufacturer and date of manufacture	 Date of manufacture*	 Warning – Hot surface	 Type BF applied part
 Class II equipment	IP21 IP classification	REF Catalogue number	LOT Lot number	SN Serial number
 Transport and storage temperature limitation	 Transport and storage humidity limitation	 Keep dry	 Fragile, handle with care	 This way up
 Recyclable	 Importer	 Distributor	EC REP Authorized representative in the European Community*	 Regulatory compliance mark*
CE 0123 European conformity - TÜV SÜD*	 WEEE (Waste Electrical and Electronic Equipment)*	MD Medical device*		

** Symbol displayed on select models*

CE 0123

MD

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