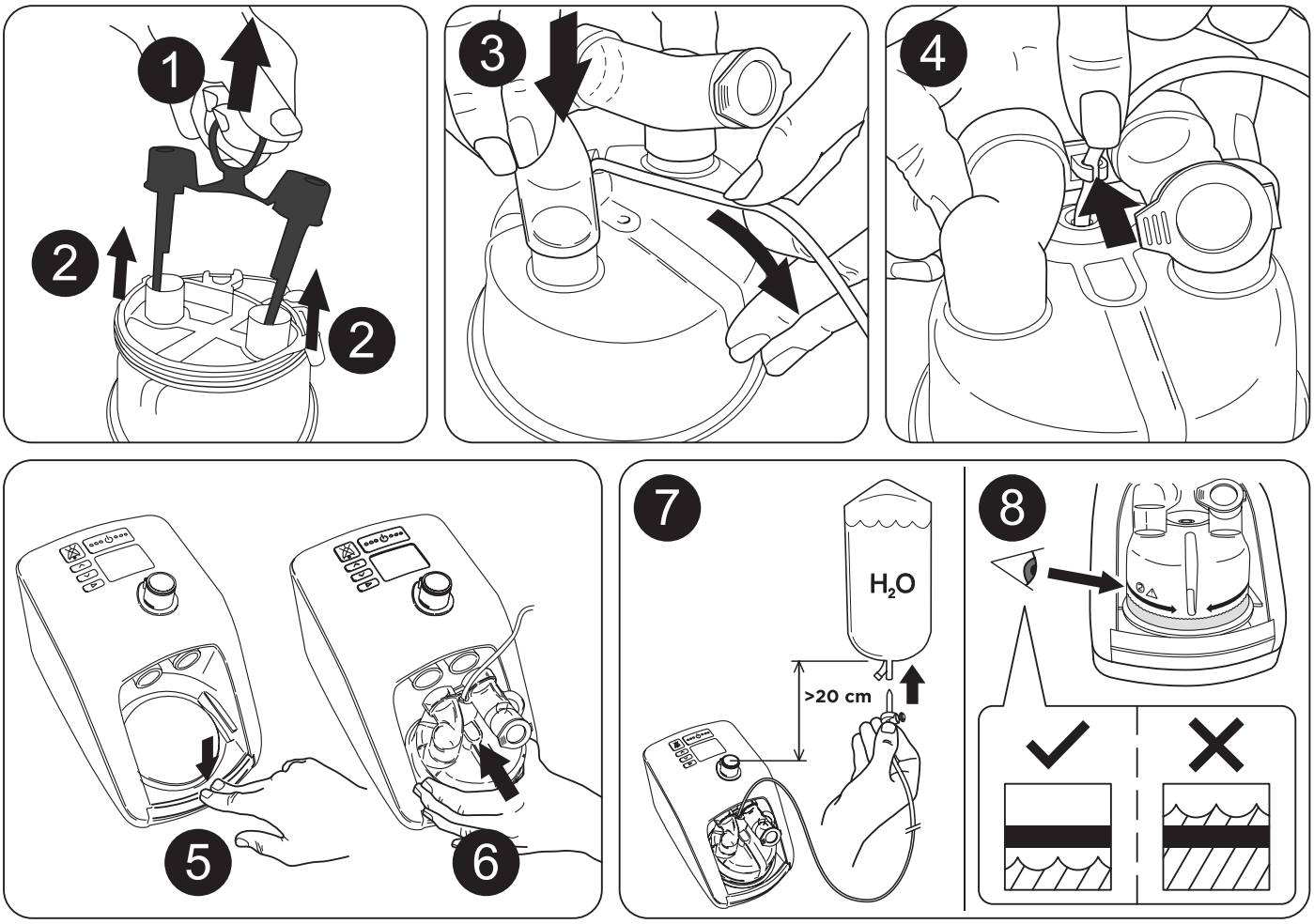
F&P AIRVO™2 Tube and Chamber Kit

(with nebulizer adapter) 900PT563



Single Use Rx only

For patent information, see www.fphcare.com/ip

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Airvo™ Tube and Chamber Kit with nebulizer adapter - 900PT563

(en)

Indications for use - Airvo nebulizer adapter:

When used with a nebulizer:
The nebulizer adapter is a medical device accessory for single-patient use to facilitate aerosolization of Albuterol sulfate for inhalation to adult patients receiving high-flow humidified breathing gases via tracheostomy patient interface. Intended for use by healthcare professionals in hospitals or long-term care facilities.

When used without a nebulizer:
For use in hospitals and long-term care facilities, for the delivery of humidified respiratory gases to patients via nasal, tracheostomy and mask interfaces.

System Specifications:
Circuit Length: 1.8 m (6 ft) + interface.

Use WITHOUT a nebulizer

- If never used with a nebulizer, the 900PT563 kit must be disposed of after a maximum of 14 days' use.
- Do not soak, wash or sterilize.

Setup:
- Airvo 2 humidifier ("Airvo") on a flat surface.
- For use at flows from 2 to 60 L/min depending on the patient interface.
- OPT316/OPT318/OPT942/OPT944/OPT946/OPT1042/OPT1044/OPT1046 nasal interfaces OR OPT970 tracheostomy interface OR OPT980 mask adapter interface

WARNING: Use of a non-approved accessory could impair performance or compromise safety.

Steps 1 - 7:
Assemble and connect water chamber.

Step 8:
Ensure water level is rising but not going over the maximum water level.


Incorrect water level
Replace MR290 chamber


Correct water level in the MR290 chamber

Use USP sterile/distilled water for inhalation, or equivalent.

Step 9:
Connect breathing tube to Airvo.

Step 10:
Make sure blue connector is fully located into place.

Step 11:
Connect breathing tube to patient interface once the system has warmed up. Position breathing tube below patient interface so that condensate flows away from the patient.

Step 12:
Connect breathing tube clip to patient clothing or bedding. Note: connecting to patient clothing may not be suitable for all patient groups.

Step 13:
In the absence of a nebulizer, make sure the nebulizer port plug is firmly in place.
- WARNING: Loss of therapy may occur if the nebulizer port plug is not in place.

Use WITH a nebulizer

- If used with a nebulizer at any time, the 900PT563 kit must be disposed of after a maximum of 7 days' use, whether nebulization is continuous or intermittent during this time.
- Do not soak, wash or sterilize.

CAUTION: Using the kit with a nebulizer for longer than 7 days may cause damage to the kit, particularly the water chamber, and eventually the Airvo itself.

Setup:

WARNING: Nasal delivery of nebulized drugs for lung deposition is not approved by FDA.

WARNING: Use of a non-approved accessory could impair performance or compromise safety.
- Airvo 2 humidifier ("Airvo") on a flat surface.
- For use at flows from 10 to 30 L/min using the OPT970 patient interface.
- OPT970 tracheostomy interface
- Aerogen Solo nebulizer

Compatible medications:
- **This kit is compatible with the following medications only:**
  - **Albuterol sulfate**
- Refer to drug manufacturers' instructions for correct usage and restrictions.
- WARNING: Do not nebulize the following medications, as they are incompatible with Airvo and its consumables and may cause patient harm:
  - Alcohol-based medications
  - Significantly acidic or basic medications eg. epoprostenol (Flolan)
  - Saline

Step 14 (Nebulizer use):
- Follow Steps 1-13.
- Remove the nebulizer port plug from the nebulizer port and connect the nebulizer in its place.
  CAUTIONS:
  - Refer to the nebulizer manufacturer's instructions for setup and usage information.
  - Do not add oxygen or other gases through the nebulizer port or use a flow-generating nebulizer (eg. jet nebulizer) as this will cause discrepancies in humidity, flow and oxygen outputs.
  - Ensure the Airvo is switched on with humidified gas flowing before the nebulizer is used.
  - The medication delivery efficiency decreases as the Airvo flow increases. Ensure that the patient receives adequate flow at all times when adjusting flow during nebulization. Titrate medication delivery as required.
  - Nebulized medications can form residue and cause cosmetic discoloration of the breathing tube and chamber during normal operation.
  - Nebulization may cause increased levels of condensate in the breathing tube and chamber.
  - Avoid skin contact with condensate as it may contain nebulized medication.

Performance:

Albuterol sulphate (1 mg/mL, 2.5 mL)	10 L/min	20 L/min	30 L/min
Total delivered dose (µg)*	1362.9 - 2087.7	548.6 - 1938	383.3 - 1461.8
Total respirable dose (µg, 1-5µm)*	1035.9 - 1550.3	470.7 - 1428.2	387.9 - 837.3
Respirable fraction (%)	63 - 87.1	59.3 - 93.8	31.3 - 100
Coarse particle dose (µg, >4.7µm)*	206.6 - 528.2	0 - 507.8	0 - 531.9
Coarse particle fraction (>4.7µm)	14.9 - 27.6	4.7 - 32.4	0 - 47.2
Fine particle dose (µg, <4.7µm)*	1111.3 - 1604.5	519 - 1500.8	448.5 - 987.4
Fine particle fraction (<4.7µm)	72.4 - 85.1	67.6 - 95.4	52.8 - 100
Mass-Median Aerosol Diameter (MMAD) (µm)*	2.67 - 2.94	2.41 - 3.05	2.08 - 3.00
Geometric Standard Deviation (GSD) (µm)*	1.56 - 2.30	1.18 - 2.58	0.1 - 4.91

*** 95% confidence intervals**

Testing carried out with one Aerogen Solo nebulizer, three sets of Airvo 2, 900PT563 kit and OPT970 interface and three tests per set. Cascade impactor testing conducted at 15 L/min using NGI.

WARNINGS:
- For single patient use only. Reuse may result in transmission of infectious substances. Attempting to reprocess will result in degradation of materials and render the product defective.
- Using the breathing tube for longer than the specified time can result in serious injury, including infection.
- Do not use the auto-fill MR290 chamber if it has been dropped or been allowed to run dry as this could lead to the chamber over-filling.
- Do not use the MR290 chamber if the water level rises above the maximum water level line as this may lead to water entering the patient's airway.
- Never operate the unit if the breathing tube has been damaged with holes, tears or kinks.
- Do not block the flow of air through the unit and breathing tube.
- California residents please be advised of the following, pursuant to Proposition 65: This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm. For more information, please visit: www.fphcare.com/prop65

To avoid burns:
- Do not allow the breathing tube to remain in direct contact with skin for prolonged periods of time.
- Do not use in the presence of a naked flame, to avoid fires.
- Do not add heat to any part of the breathing tube e.g. covering with a blanket, or heating it in an incubator or overhead heater for a neonate, as this could result in serious injury.

Cautions:
- Avoid product contact with chemicals, cleaning agents, or hand sanitizers.
- Use only USP sterile/distilled water for inhalation, or equivalent.
- Nebulized medications may be emitted into the surrounding area.
- Condensate containing nebulized medication may be present after use. Wear appropriate personal protective equipment such as gloves.

To prevent condensation:
- Use in a room warmer than 18 °C (64 °F).
- Remove/minimize the impact of anything that may cool the heated breathing tube, e.g. a fan, air conditioning, open window.

To manage excessive condensation:
- Place the Airvo below patient head height.
- Drain condensate back into the water chamber. At higher target flow settings it may be necessary to first reduce the target flow setting to 30 L/min, to ensure that the condensate drains safely and effectively.
- Disconnect the patient interface from the heated breathing tube.
- Lift the patient end of the heated breathing tube, allowing the condensate to run into the water chamber.