The Aerogen® Ultra is an accessory specific to the Aerogen® Solo nebulizer. It facilitates intermittent and continuous nebulization and optional supply of supplemental oxygen to pediatric (29 days or older) and adult patients in hospital use environments via mouthpiece or aerosol face mask. If supplemental oxygen is used, for pediatric patients under 18 years of age, a maximum flow rate of 2 LPM should be used.

**Note:** The mouthpiece should not be used for children under 5 years of age.

The Aerogen Ultra is a single patient use device with a validated defined life of:
- In intermittent use for a maximum of 20 treatments; which is based upon a typical usage profile of four 3 ml doses per day over 5 days, with an average treatment time of 9 minutes.
- Or
- In continuous use, for a maximum of 3 hours.

The Aerogen Ultra can be used in conjunction with the Aerogen Solo Continuous Nebulization Tube Set. See Aerogen Solo System Instruction Manual.

Optimal aerosol delivery is achieved with valved mouthpiece or valved face mask (as supplied) with low/no oxygen flow.

**Instructions for Use - Refer to Figures on Page 1**

Inspect for device integrity and correct valve placement prior to use.

1. Insert Aerogen Solo nebulizer firmly into Aerogen Ultra in orientation shown.
2. If supplemental oxygen is required, firmly attach oxygen tubing to Aerogen Ultra.
   
   **Note:** Oxygen flow rate should be set between 1-6 LPM for adult and a maximum of 2 LPM for pediatric patients less than 18 years of age.
3. If an aerosol face mask is required, remove mouthpiece and attach the aerosol face mask to Aerogen Ultra.
   
   **Note:** When using an aerosol face mask, a minimum oxygen flow of 1 LPM is required.
4. Add prescribed medication to nebulizer as instructed in Aerogen Solo System Instruction Manual.
5. Connect cable to Aerogen Solo.
   
   **Note:** Refer to Aerogen Solo System Instruction Manual for intermittent and continuous nebulization set-up and operation instructions.
6. Power on and observe Aerogen Ultra to confirm aerosol is visible.
7. Introduce Aerogen Ultra to patient and observe aerosol flow to ensure correct operation.
8. Remove excess rainout from the Aerogen Ultra periodically (hourly with continuous nebulization).
   
   To ensure optimum performance of the Aerogen Ultra, remove any residue by rinsing through with sterile water, shake off excess and allow to air dry.

**Warnings**

**Performance**

Do not use with a closed face mask or a standard oxygen mask.

When using with an aerosol face mask, always use supplemental oxygen flow of 1-6 LPM for adult and a maximum of 2 LPM for pediatric patients less than 18 years of age.

Performance of the Aerogen Ultra may vary depending upon the type of drug and Aerogen Ultra configuration used.

Do not exceed recommended oxygen flow for system.

Visually check Aerogen Ultra post-rinsing to ensure that valves have not become dislodged.

**General**

To be used by trained personnel only.

Use only with recommended components.

Ensure tubing is safely orientated to prevent strangulation hazard.

Ensure oxygen connection port or tubing is not occluded.

Do not use the Aerogen Ultra without a mouthpiece or face mask.

Do not autoclave any component of the kit.

Do not cover Aerogen Ultra valves during use.
Aerogen Ultra Kits

AG-AS7000-US: Aerogen Ultra (10 pack): Aerogen Ultra, oxygen tubing

Rx Only

Manufacturer
Aerogen Ltd.
Galway Business Park,
Dangan, Galway,
Ireland.