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Introduction

The Aerogen® Pro System is a portable medical device for multiple patient use that is intended to aerosolize physician-prescribed medications for inhalation that are approved for use with a general purpose nebulizer. This device can be used by patients on and off mechanical ventilation or other positive pressure breathing assistance.

Aerogen® Pro is intended for hospital use only. It is suitable for use by pediatric and adult patients as described in this manual. It incorporates the Aerogen Vibronic® aerosol generator.

Aerogen® Pro is designed to operate in-line with standard ventilator circuits and mechanical ventilators. It operates without changing patient ventilator parameters and can be refilled without interrupting ventilation.

The controller operates from the AC/DC adapter and can be operated on its internal rechargeable battery for up to 45 minutes when fully charged. The product operates without compressed gas, making it suitable for portable applications.

Indications for Use

The Aerogen® Pro System is a portable medical device for multiple patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance. The Aerogen® Pro System is suitable for use in adult and pediatric patients.
Aerogen Pro System

The Aerogen Pro System includes the following components:

1. Nebulizer with Filler Cap
2. T-Piece (Adult) with Plug
3. Aerogen Pro Controller
4. Controller Cable
5. AC/DC Adapter
6. Universal Mounting Bracket & Equipment Mount Adapter

Note: Device names previously referencing ‘Aeroneb’ are now referencing ‘Aerogen’. Visit www.aerogen.com for full parts list.
1. The nebulizer holds up to 10 mL of liquid medication. The nebulizer is translucent to allow visual monitoring of medication levels and aerosolization. When the nebulizer is connected into the breathing circuit, the filler cap can be opened or removed from the nebulizer without causing loss of circuit pressure.

Within the nebulizer is the Aerogen Vibronic® aerosol generator, which consists of a domed aperture plate with precision-formed holes that control the size of the aerosol droplets and a vibrational element that creates micro-pumping action to aerosolize medication. Gravity brings the medication in contact with the aerosol generator; the liquid is then drawn through the aperture plate and converted into an aerosol.

2. The T-piece securely connects the nebulizer into the breathing circuit and can be easily removed for cleaning. The T-piece connections are standard male and female 22 mm ISO conical ports and connect to standard patient breathing circuits.

3, 4, 5.

The controller can operate from the AC/DC Adapter or the internal rechargeable battery. The controller includes an On/Off power button and sockets for the controller cable and the AC/DC Adapter. The controller also includes indicators for nebulization cycle selection (15 or 30 minutes), battery charge status and fault conditions.

6. A Universal Mounting Bracket clamps the controller to standard IV poles and medical rail systems.

7. An Equipment Mount Adapter mounts the controller on Standard Equipment Mounts.

**Note:** Pediatric T-piece, Mask Adapter Kits, Elbow Connectors and Mouthpiece are sold separately.
System Warnings

Read and study all instructions before using the Aerogen Pro System and accessories. Only trained medical personnel should operate the device.

During use observe for correct functioning of the nebulizer by regularly verifying aerosol is visible and no flashing indicator lights.

Do not use a filter or heat-moisture exchanger (HME) between the nebulizer and patient airway.

Do not attach a continuous supply of medication to the nebulizer; the device operates in 15 or 30 minute cycles.

Clean, sterilize, assemble and perform a functional test (page 19) according to the instructions in this manual before first use and between patients.

Do not place the controller in an incubator during use.

To avoid exhaled medication affecting the ventilator, follow ventilator manufacturer’s recommendations for use of a bacterial filter in the expiratory limb of a breathing circuit.

To ensure optimum drug administration, consult the drug manufacturer’s instructions regarding suitability for nebulization.

Do not use in the presence of flammable substances or a flammable anaesthetic mixture combined with air or with oxygen or nitrous oxide.

To avoid the risk of fire do not use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air under high pressure.

Do not modify this equipment without the authorization of the manufacturer.

 Disconnect the nebulizer from controller before cleaning.
Inspect all parts before use, and do not use if any parts are missing, cracked or damaged. In case of missing parts, malfunction or damage, contact your sales representative.

Do not immerse or autoclave the controller or AC/DC adapter.

Disassemble all parts before autoclaving.

Use only with components specified by Aerogen.

Do not use or store outside of specified environmental conditions.

To avoid mechanical or electrical damage, do not drop the nebulizer or the controller.

Do not use in the presence of devices generating high electromagnetic fields such as magnetic resonance imaging (MRI) equipment.

The Aerogen Pro controller contains a nickel metal hydride (NiMH) rechargeable battery, which should be disposed of in accordance with local governing restrictions at the end of its useful life.

To avoid damage to the nebulizer:

- Prior to use, autoclave according to specified directions and temperature given in the Cleaning, Disinfection and Sterilization section of this Instruction Manual only. Any deviation from directions given in this Instruction Manual may cause damage to the nebulizer and render it inoperable.

- Do not apply undue pressure to the domed aperture plate in the center of the nebulizer.

- Do not push out the Aerogen Vibronic® aerosol generator.

- Do not use a syringe with a needle to add medication.

- Do not use abrasive or sharp tools to clean the nebulizer.
Aerogen Pro Controller

On/Off Power
- 15 Min. - Press & Release
- 30 Min. - Press & hold for 3 Sec.

Error Indicator

30 Minute Mode Indicator light

15 Minute Mode Indicator light

Battery Status Indicator

9V DC Input

Controller Cable Input

Figure 2. Aerogen Pro Controls & Indicators
### Table 1. Aerogen Pro Controls & Indicators

<table>
<thead>
<tr>
<th>Control / Indicator</th>
<th>Function</th>
</tr>
</thead>
</table>
| **15 Min. Indicator** | • Green (steadily lit) = 15 Minute nebulization cycle on  
                          • Green (flashing) = Low battery power  
                          • Nebulizer automatically powers off after 15 minutes have elapsed |
| **30 Min. Indicator** | • Green (steadily lit) = 30 Minute nebulization cycle on  
                          • Green (flashing) = Low battery power  
                          • Nebulizer automatically powers off after 30 minutes have elapsed |
| **Error Indicator**   | • Amber = Faulty electrical connection |
| **On/Off Power Button** | • To operate in 15 Minute Mode, press and immediately release the On/Off button  
                            • To operate in 30 Minute Mode, press and hold the On/Off button for at least 3 seconds from off  
                            • Pressing during nebulization turns off power to the nebulizer |
| **Battery Status Indicator** | • Green = Battery fully charged  
                               • Amber = Battery charging  
                               • No light = Battery in operation |

### Recharging the Battery

To recharge the battery, connect the AC/DC Adapter to the controller and connect to AC power source. The battery status indicator is amber while charging and green when fully charged.

If the controller is placed in long-term storage, it is recommended that the battery be recharged every 3 months.

Allow a minimum of four hours for the internal battery to fully recharge.
Assembly & Installation

Aerogen Pro System Set-Up

Clean and sterilize the nebulizer and T-piece(s) as described in the Cleaning, Disinfection and Sterilization section of this manual.

**Note:** The nebulizer and T-piece, as packaged, are not sterile.

1. Perform a functional test of Aerogen Pro before use and between patients as described in the Functional Test section of this manual (see page 19).

2. Insert the filler cap into the opening on the nebulizer.

3. Connect the nebulizer to the T-piece by pushing the nebulizer firmly onto the T-piece (Figure 3).

![Figure 3. Connecting nebulizer to T-piece](image-url)
4 Connect the Aerogen Pro controller and the nebulizer together using the controller cable (Figure 4).

![Figure 4. Connecting controller and nebulizer](image)

5 To operate on AC power (the primary mode of operation), connect the Aerogen Pro AC/DC adapter to the Aerogen Pro controller and plug the adapter into an AC power source (Figure 5).

![Figure 5. Connecting the AC/DC Adapter](image)
The Aerogen Pro can be battery-operated for portable applications. The rechargeable battery can power the System for up to 45 minutes when fully charged. In the case of AC power failure the controller will automatically switch to battery operation.

**Note:** Allow a minimum of four hours for the internal battery to fully recharge.

**Note:** To ensure uninterrupted operation of the Aerogen Pro, secure both the AC/DC adapter cable and the controller cable so they cannot become disconnected during treatment. If clips are available on patient circuits, run the cables through the eyes of the clips. If clips are not available, ensure that all cables are routed safely.
Installation for use with a Ventilator
Connection to a Breathing Circuit

1. For adult breathing circuits, connect the nebulizer with adult T-piece into the inspiratory limb of the breathing circuit before the patient Y (Figure 6).

![Figure 6. Connecting the Aerogen Pro to an adult breathing circuit](image)

**Note:** Figure 6 shows adult configuration only

For pediatric breathing circuits, connect the nebulizer with the pediatric T-piece into the inspiratory limb of the breathing circuit before the patient Y (Figure 7).

![Figure 7. Connecting to a 12 mm I.D. pediatric breathing circuit](image)
Figure 8. Alternative pediatric breathing circuit using 12 mm Male/12 mm Female T-piece

Alternatively connect the nebulizer with the pediatric T-piece and the adapters approximately 30 cm (12 in.) back from the patient Y (Figure 7). Alternatively connect the nebulizer with the 22F/10F/10M T-piece 30 cm (12 in.) back from the patient Y (Figure 8).

2. Always perform a leak test of the breathing circuit after inserting or removing the nebulizer. Follow ventilator manufacturer instructions for performing a leak test.

3. Use the universal mounting bracket to attach the controller to an IV pole or bed rail in either a vertical or horizontal orientation (Figure 9). Do not over-tighten knob.

Where a standard equipment mount is available, use the equipment mount adapter to support the controller (Figure 9).
Warnings

- Always maintain the nebulizer in a vertical orientation (with the filler cap uppermost) while in the patient circuit (Figures 6, 7, & 8). This orientation prevents condensate from blocking the nebulizer and ensures proper nebulization. Always visually inspect the nebulizer prior to placing in the ventilator circuit to assure that no secretions are blocking the Aerogen Vibronic® aerosol generator.
- When removing the nebulizer from the patient circuit always replace the T-piece plug to maintain circuit pressure.
- Always connect a bacteria filter to the expiratory inlet of the ventilator. Otherwise the function of the expiratory channel may be degraded.
- Do not use a filter or heat-moisture exchanger (HME) between the nebulizer and patient airway.
Adding Medication

- Open the filler cap tab on the nebulizer.
- Use a pre-filled ampoule or syringe to add medication into the filler port of the nebulizer (Figure 10).
- Close the filler cap tab.

**Warning:** To avoid damage to the nebulizer, do not use a syringe with a needle.

The maximum capacity of the nebulizer is 10 mL. Do not fill the nebulizer beyond the maximum fill indication point (Figure 10). The underside of the filler cap represents maximum fill indication point.

**Figure 10.** Filling the nebulizer with a pre-filled ampoule

**Note:** Medication can be added in this manner during nebulization. This does not interrupt nebulization or ventilation.
Nebulization

For doses less than or equal to 3 mL.

1. To start a 15 Minute nebulization cycle, add the medication and press and release the blue On/Off power button (Figure 2). The green 15 Min. indicator lights to indicate that the 15 Minute nebulization cycle is in progress.

For doses greater than 3 mL.

2. To start a 30 Minute nebulization cycle, add the medication and press and hold the blue On/Off power button for at least three seconds. The green 30 Min. indicator lights to indicate that the 30 Minute nebulization cycle is in progress.

3. To stop the nebulizer at any time, press the On/Off power button. The indicator turns off to indicate that nebulization has stopped.

Note: When delivering a dose greater than 3 mL, select the 30 Minute cycle.
Installation for use Off-Ventilator

Use with a Face Mask

Mask kits, which include a vented elbow and mask elbow, are available separately (visit www.aerogen.com for full parts list). Contact your sales representative for ordering information.

1. When using a mask, connect the vented elbow, mask elbow and mask to the nebulizer by firmly pushing the parts together.

2. Rotate the vented elbow to suit the position of the patient (Figure 11).

![Figure 11. Connecting to a mask](image)

**Warning:** To ensure correct nebulization, maintain the nebulizer in a vertical orientation (Figure 11).

Use with a Mouthpiece

The Aerogen Pro works with any standard ISO 22 mm nebulizer mouthpiece inserted into the adult T-piece.

![Figure 12. Connecting to a mouthpiece](image)
When using a mouthpiece, connect the nebulizer to the T-piece as shown in Figure 3 and then connect the T-piece to the mouthpiece by pushing the parts firmly together (Figure 12).

**Warning:** To ensure correct nebulization, maintain the nebulizer in a vertical orientation (Figure 12).
Functional Test

Perform a functional test of the Aerogen Pro System prior to first use, after each sterilization before each patient use or at any time to verify proper operation. Follow these steps:

1. Visually inspect each part of the system for cracks or damage and replace if any defects are visible.

2. Pour 1-5 mL of normal saline (0.9%) into the nebulizer.

3. Connect the nebulizer to the controller using the controller cable. Connect the AC/DC Adapter to the controller and plug the AC/DC Adapter into an AC power source.

4. Press and release the blue On/Off power button and verify that the green 15 Min. indicator light illuminates and that aerosol is visible.

5. Disconnect the nebulizer from the controller. Verify that the amber Error Indicator lights. Reconnect the nebulizer to the controller.

6. Press the On/Off power button again to turn the system off. Press and hold the button for at least three seconds. Verify that the green 30 Min. indicator light illuminates and that aerosol is visible.

7. Disconnect the controller from the AC/DC Adapter and verify that nebulization continues and that the battery status indicator turns off.

8. Turn the system off and verify that the 15 Min. and 30 Min. indicators are off.

Cleaning, Disinfection and Sterilization

This section describes how to clean, disinfect, sterilize and inspect Aerogen Pro System components. It is important that Aerogen Pro device components are cleaned and sterilized prior to first patient use. The components are:

- Aerogen Pro (including filler cap)
- T-piece (including T-piece plug) for adult and pediatric
- Aerogen Pro Controller*
- Controller Cable* and AC/DC Adapter*
- Mounting Bracket*

* Components not to be autoclaved.

**Warning:** Always clean, sterilize and disinfect in accordance with current hospital protocols.

To avoid damage to the nebulizer:

- Autoclave according to specified directions and temperature given in the Cleaning, Disinfection and Sterilization section of this Instruction Manual only. Any deviation from directions given in this Instruction Manual may cause damage to the nebulizer and render it inoperable.
- Do not apply undue pressure to the domed aperture plate in the center of the nebulizer.
- Do not push out the Aerogen Vibronic® aerosol generator.
Manual Cleaning

Cleaning nebulizer, T-pieces and Adapters

1. Ensure there is no medication remaining in the device.
2. Remove nebulizer from T-piece. Remove filler cap from nebulizer.
3. Clean all parts with warm water and mild liquid detergent.
4. Rinse parts with sterile water.
5. Shake excess water from parts and allow parts to fully air dry.

**Warning:** Do not use abrasive or sharp tools to clean the nebulizer.

Disinfection

Aerogen Pro nebulizer, T-pieces and Adapters with disinfection agents.

1. Follow steps 1 through 3 in Manual Cleaning section.
2. Completely immerse parts in appropriate disinfecting agent in accordance with current hospital protocols and disinfectant agent manufacturer guidelines.

**Note:** Aerogen approves the following disinfection solutions for use with its Aerogen Pro nebulization system regarding material compatibility. With respect to microbiological effectiveness, please ask the manufacturer. Refer to the product labeling for specific instructions regarding activation, safe use and disposal of these solutions.

- Isopropyl (70%)
- CIDEX®
- NU-CIDEX®
- CIDEX® OPA
- Hexanios G+R

**Warning:** The use of any other means of cleaning, disinfection or sterilization has not been qualified and is likely to reduce the life of your nebulizer and will invalidate your warranty.
Automated Washing Cycle

The Aerogen Pro nebulizer system has been qualified for the following automated washing cycles.

Automated Cycle One

**Detergent:** Liquid alkaline cleaner (diluted as per manufacturers instruction).

**Water Quality:** Mains water.

**Method:**

1. Load the components in the automated washer.
2. Pre-rinse the components for 3 minutes.
3. Clean the components with liquid alkaline cleaner at 55 °C (131 °F) for 10 minutes.
4. Rinse for 1 minute.
5. Rinse using thermal disinfection cycle at 93 °C (199.4 °F) for 10 minutes.

Automated Cycle Two

**Detergent:** The following cycle was validated without the use of a detergent.

**Water Quality:** Mains water.

**Method:**

6. Load the components in the automated washer.
7. Wash components for 10 minutes at 91 °C (195.8 °F).
8. Drain the machine for 40 seconds.
9. Rinse at 90 °C (194 °F) for 1 minute.
10. Drain the machine for 40 seconds.
11. Rinse at 90 °C (194 °F) for 1 minute.
12. Drain the machine for 40 seconds.
13. Dry at 90 °C (194 °F) for 15 minutes.
Sterilization of the Aerogen Pro Nebulizer

Sterilization of Aerogen Pro Nebulizer, T-Pieces & Adapters

1. Disconnect the nebulizer from the controller, and then remove the nebulizer and adapters from the ventilator circuit, mask or mouthpiece.

2. Disassemble the nebulizer and adapters into individual components.

3. Remove the filler cap from the nebulizer.

4. Clean all parts with warm water and mild liquid detergent in accordance with current hospital protocols. Rinse thoroughly and air dry.

5. Check for cracks or damage and replace if any defects are visible.

6. Place the disassembled components into appropriate sterilization wrapping.

**Warning:** Do not reassemble parts prior to autoclaving.

**Sterilize Components**

Steam sterilization can be performed using the following three methods:

1. Autoclave wrapped parts using steam sterilization pre-vacuum cycle, a minimum of 134 °C (270 °F - 275 °F) for 3.5 minutes with drying cycle (134 °C wrapped cycle).

2. Autoclave wrapped parts using steam sterilization pre-vacuum cycle, a minimum of 121 °C (250 °F) for 20 minutes with drying cycle (121 °C wrapped cycle).

3. Autoclave wrapped parts using steam sterilization pre-vacuum cycle, a minimum of 134 °C (270 °F - 275 °F) for 20 minutes with drying cycle.

**Note:** Sterilization using the long autoclave cycle (No. 3 above) may cause some areas of the nebulizer to become discolored. This is not indicative of the performance of the nebulizer.

To sterilize with hydrogen peroxide gas plasma, place wrapped parts in a STERRAD® System and use the long cycle.
**Warning:** Users should refer to the product labeling for the STERRAD® 100S Sterilization System for specific instructions regarding its correct operation.

Prior to next use:

1. Check for cracks or damage and replace if any defects are visible.
2. Perform a functional test as described in this manual.
Cleaning the Aerogen Pro Controller

Cleaning of controller, controller cable & AC/DC adapter

1. Wipe clean with an alcohol based disinfectant wipe or a quaternary ammonium compound based disinfectant wipe.

2. Check for exposed wiring, damaged connectors, or other defects and replace if any are visible.

3. Visually inspect for damage and replace the controller if any damage is observed.

Warnings

• Do not autoclave.
• Do not use abrasive or sharp tools.
• Do not spray liquid directly onto the controller.
• Do not immerse controller in liquid.

Note: The Aerogen Pro nebulizer contains active electronic components. Aerogen has validated the methods of cleaning, disinfection and sterilization above. The use of any other means of cleaning, disinfection or sterilization has not been validated and is likely to reduce the life of your nebulizer and will invalidate your warranty.

Cleaning of mounting brackets

Wipe clean with a damp cloth and mild liquid detergent. Do not use abrasive or sharp tools.
Troubleshooting

If these suggestions do not correct the problem, discontinue use of any device and contact your local Aerogen sales representative.

### Table 2. Aerogen Pro Troubleshooting

<table>
<thead>
<tr>
<th>If this happens:</th>
<th>It could mean:</th>
<th>Try this:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The 15 Min. or 30 Min. indicator flashes during nebulization.</td>
<td>Battery power is low.</td>
<td>Recharge battery (see Recharging the Battery).</td>
</tr>
<tr>
<td>Battery will not recharge. Constant green light showing on the battery status indicator and flashing green light on either the 15 Min. or 30 Min. indicator light, when the controller is connected to the AC/DC Adapter.</td>
<td>It may be time to replace the battery.</td>
<td>Contact your local Aerogen sales representative.</td>
</tr>
<tr>
<td>Battery will not retain initial charge.</td>
<td>Rechargeable battery may need to be replaced.</td>
<td>Contact your local Aerogen sales representative.</td>
</tr>
<tr>
<td>The 15 Min. or 30 Min. light illuminates, but aerosol is not visible.</td>
<td>No medication in nebulizer.</td>
<td>Refill medication through filler cap in the nebulizer (see page 15).</td>
</tr>
<tr>
<td></td>
<td>Nebulizer has not been cleaned properly.</td>
<td>Clean nebulizer (see page 20)</td>
</tr>
<tr>
<td></td>
<td>It may be time to replace the nebulizer.</td>
<td>See Warranty and Life of Product. Refer to Aerogen Pro parts list by visiting <a href="http://www.aerogen.com">www.aerogen.com</a>.</td>
</tr>
<tr>
<td>15 Min. or 30 Min. indicator does not light when On/Off power button is pressed.</td>
<td>There is no power to the system.</td>
<td>Verify that AC/DC adapter is securely attached to controller.</td>
</tr>
<tr>
<td></td>
<td>Rechargeable battery is depleted.</td>
<td>Recharge battery (see Recharging the Battery).</td>
</tr>
<tr>
<td>The fault indicator light illuminates.</td>
<td>The controller cable is incorrectly connected to the nebulizer, or electronics are malfunctioning.</td>
<td>Verify that controller cable is correctly connected to both the nebulizer and the controller.</td>
</tr>
</tbody>
</table>
### Table 2. Aerogen Pro Troubleshooting (Continued)

<table>
<thead>
<tr>
<th>If this happens:</th>
<th>It could mean:</th>
<th>Try this:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Longer than expected treatment time. e.g. 3 mL of Normal Saline (0.9%) should take no longer than 15 minutes to nebulize.</td>
<td>Rechargeable battery is depleted.</td>
<td>Recharge battery (see Recharging the Battery).</td>
</tr>
<tr>
<td></td>
<td>Nebulizer has not been properly cleaned.</td>
<td>Clean nebulizer (see page 20).</td>
</tr>
<tr>
<td></td>
<td>It may be time to replace the nebulizer.</td>
<td>See Warranty and Life of Product. Refer to Aerogen Pro parts list by visiting <a href="http://www.aerogen.com">www.aerogen.com</a>.</td>
</tr>
<tr>
<td>Medication is left in the nebulizer after nebulization cycle.</td>
<td>Nebulizer was not turned on or connected to power.</td>
<td>Ensure that nebulizer is connected to power and turned on.</td>
</tr>
<tr>
<td></td>
<td>Rechargeable battery is depleted.</td>
<td>Recharge battery (see Recharging the Battery).</td>
</tr>
<tr>
<td></td>
<td>Nebulizer has not been properly cleaned.</td>
<td>Clean nebulizer (see page 20).</td>
</tr>
<tr>
<td></td>
<td>A 15 Minute cycle was selected and a volume greater than 3 mL was added to the nebulizer.</td>
<td>Run an additional 15 Minute cycle. When delivering a dose greater than 3 mL select the 30 Minute cycle.</td>
</tr>
<tr>
<td></td>
<td>It may be time to replace the nebulizer.</td>
<td>See Warranty and Life of Product. Refer to Aerogen Pro parts list by visiting <a href="http://www.aerogen.com">www.aerogen.com</a>.</td>
</tr>
</tbody>
</table>

**Note:** The rechargeable battery in the Aerogen Pro controller should only be replaced by Aerogen authorized personnel: contact your Aerogen sales representative.
Warranty

The Aerogen Pro nebulizer is warranted for one year from date of purchase against defects in manufacturing. The Aerogen Pro controller and AC/DC Adapter are warranted for a period of two years from the date of purchase against defects in manufacturing. All warranties are based on typical usage.

Life of Product

As with all active electronic components, the Aerogen Pro nebulizer has a defined life. In the case of Aerogen Pro controller, the life of the controller unit has been validated for use for 1460 doses. This is based on a typical product usage profile over a two year period, including four treatments per day, 50% of the time.

The life of the Aerogen Pro nebulizer and components have been validated for use for 730 doses and 26 autoclave treatments based on a typical one year usage profile of four treatments per day and one sterilization per week, where the device is assumed to be in service for 50% of the time. The user should note that any use in excess of this may result in reduced life of the product.
## Specifications

### Table 3. Physical Specifications of the Aerogen Pro System

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nebulizer Dimensions</td>
<td>45 mm H x 50 mm W x 50 mm D</td>
</tr>
<tr>
<td></td>
<td>1.8” H x 2.0” W x 2.0” D</td>
</tr>
<tr>
<td>Aerogen Pro Controller Dimensions</td>
<td>33 mm H x 75 mm W x 131 mm D</td>
</tr>
<tr>
<td></td>
<td>1.3” H x 2.9” W x 5.2” D</td>
</tr>
<tr>
<td>Controller Cable Length</td>
<td>1.8 m (5.9 ft.)</td>
</tr>
<tr>
<td>AC/DC Adapter Cable Length</td>
<td>2.1 m (6.7 ft.)</td>
</tr>
<tr>
<td>Nebulizer Weight</td>
<td>25 g (0.9 oz) nebulizer and filler cap</td>
</tr>
<tr>
<td>Aerogen Pro Controller Weight</td>
<td>230 g (8.1 oz.), including battery and cable</td>
</tr>
<tr>
<td>Nebulizer Capacity</td>
<td>Maximum 10 mL</td>
</tr>
</tbody>
</table>

### Table 4. Environmental Specifications of the Aerogen Pro System

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating</td>
<td>Maintains specified performance at circuit pressures up to 90 cm H₂O and temperatures from 5 °C (41°F) up to 45 °C (113°F).</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>450 to 1100 hPa</td>
</tr>
<tr>
<td>Humidity</td>
<td>15% to 95% relative humidity</td>
</tr>
<tr>
<td>Noise Level</td>
<td>&lt; 35 dB measured at 0.3 m distance</td>
</tr>
<tr>
<td>Storage &amp; Transport</td>
<td></td>
</tr>
<tr>
<td>Transient Temperature Range</td>
<td>-20 to +60°C (-4 to +140°F)</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>450 to 1100 hPa</td>
</tr>
<tr>
<td>Humidity</td>
<td>15 to 95% relative humidity</td>
</tr>
</tbody>
</table>

### Table 5. Power Specifications of the Aerogen Pro System

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Source</td>
<td>Can operate from AC/DC Adapter (input 100 to 240 VAC 50 – 60 Hz, output 9 V) or internal rechargeable battery (4.8 V nominal output). Note: The Aerogen Pro controller is approved for use with Aerogen AC/DC adapter AG-AP1040-US (Manufacturer Reference: FRIWO FW7660/09)</td>
</tr>
<tr>
<td>Power Consumption</td>
<td>&lt; 6.5 Watts (charging), 2.0 Watts (nebulising).</td>
</tr>
<tr>
<td>Patient Isolation</td>
<td>Controller circuitry provides 4 kilovolt (kV) patient isolation and complies with IEC/EN 60601-1.</td>
</tr>
</tbody>
</table>
Performance

Table 6. Performance Specifications of the Aerogen Pro

<table>
<thead>
<tr>
<th>Flow Rate</th>
<th>&gt; 0.2 mL/min (Average ~ 0.4 mL/min)</th>
</tr>
</thead>
</table>
| Particle Size | As measured with the Andersen Cascade Impactor:  
Specification Range: 1-5 μm  
Average Tested: 3.1 μm  
As per EN 13544-1, with a starting dose of 2 mL:  
Aerosol Output rate: 0.24 mL/min  
Aerosol Output: 1.08 mL emitted of 2.0 mL dose  
Residual Volume: <0.1 mL for 3 mL dose |

Performance may vary depending upon the type of drug and nebulizer used. For additional information contact Aerogen or drug supplier.

The temperature of the medication will not rise more than 10°C (18°F) above ambient during normal use.

Representative particle size distribution for Albuterol as per EN 13544-1 is shown below.
# Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>YYXXXXX</td>
<td>Serial number designation, where YY is the year of manufacture and XXXXX is the serial number</td>
<td>![Temperature Symbol]</td>
<td>Transient storage temperature limitations -20 ºC to +60 ºC</td>
</tr>
<tr>
<td>![Caution Symbol]</td>
<td>Caution Attention: Consult accompanying documents</td>
<td>QTY</td>
<td>Quantity (Number of units contained in package)</td>
</tr>
<tr>
<td>![IPX1 Symbol]</td>
<td>Degree of protection against dripping water</td>
<td>![Certified Symbol]</td>
<td>Certified by TUV with respect to electric shock, fire and mechanical hazards</td>
</tr>
<tr>
<td>![Class II Symbol]</td>
<td>Class II equipment per IEC/EN 60601-1</td>
<td>![Controller Input Symbol]</td>
<td>Controller Input - DC voltage</td>
</tr>
<tr>
<td>![Type BF Symbol]</td>
<td>Type BF equipment per IEC/EN 60601-1</td>
<td>![Controller Output Symbol]</td>
<td>Controller Output – AC voltage</td>
</tr>
<tr>
<td>![On/Off Symbol]</td>
<td>On/Off power button (standby)</td>
<td>![Output Symbol]</td>
<td>Output</td>
</tr>
<tr>
<td>![Timer Symbol]</td>
<td>Timer selection (to select the 15 Minute or 30 Minute nebulization cycles)</td>
<td>![Battery Symbol]</td>
<td>Battery status indicator</td>
</tr>
<tr>
<td><strong>Rx Only</strong></td>
<td>Federal (US) Law restricts this device to sale by or on the order of a physician.</td>
<td>![Rx Only Symbol]</td>
<td>Refer to instruction manual/booklet</td>
</tr>
</tbody>
</table>
Appendix 1

Electromagnetic Susceptibility

This device meets the requirements of the Electromagnetic Compatibility (EMC), pursuant to the Collateral Standard, IEC/EN 60601-1-2, which addresses EMC in North America, Europe and other global communities. This includes immunity to radio frequency electric fields and electrostatic discharge, in addition to the other applicable requirements of the standard. Compliance with EMC standards does not mean a device has total immunity; certain devices (cellular phones, pagers, etc.) can interrupt operation if they are used near medical equipment. Follow institutional protocol regarding the use and location of devices that could interfere with medical equipment operation.

Note: This device is classified as Class II Type BF medical electrical equipment and the device complies with specified safety levels for electrical isolation and leakage current. The Aerogen Pro AC/DC Adapter (AG-AP1040-US) has no connection to earth ground because the necessary level of protection is achieved through the use of double insulation.

Warnings

- Only use the Aerogen Pro nebulizer with components specified in the Instruction Manual. Use of the Aerogen Pro nebulizer with components other than those specified in the Instruction Manual may result in increased emissions or decreased immunity of the Aerogen Pro nebulizer system.
- Do not use the Aerogen Pro adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in this configuration.
- The Aerogen Pro needs special precautions regarding electromagnetic compatibility (“EMC”) and must be installed and put into service according to the EMC information provided in the Instruction Manual.
• Portable and mobile radio frequency ("RF") communication devices can disrupt medical electrical equipment.
## Appendix 1: EMC Tables

The following tables are provided in accordance with IEC/ EN 60601-1-2

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The Aerogen Pro nebulizer 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.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class B</td>
<td>The Aerogen Pro nebulizer system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC/EN 61000-3-2</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC/EN 61000-3-3</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>
## Recommended separation distances between portable and mobile RF communication equipment and the Aerogen Pro nebulizer system that is not life supporting

This Aerogen Pro nebulizer system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Aerogen Pro nebulizer system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aerogen Pro nebulizer system as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.70</td>
</tr>
<tr>
<td>100</td>
<td>11.70</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

**Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
This Aerogen Pro nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen Pro nebulizer system should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC/EN 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC/EN 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast Transient/burst IEC/EN 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC/EN 61000-4-5</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11</td>
<td>&lt;5 % Ut (&gt;95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles &lt;5 % Ut (&gt;95 % dip in Ut) for 5 sec</td>
<td>&lt;5 % Ut (&gt;95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles &lt;5 % Ut (&gt;95 % dip in Ut) for 5 sec</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Aerogen Pro nebulizer system requires continued operation during power mains interruption, it is recommended that the Aerogen Pro nebulizer system be powered from an uninterruptible power supply or battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) Magnetic field IEC/EN 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Note: Ut is the A.C. mains voltage prior to application of the test level.
This Aerogen Pro nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen Pro nebulizer system should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC/EN 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>[3]V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Aerogen Pro nebulizer system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>[3]V</td>
<td>Recommended Separation Distance $d = [1.17] \sqrt{P}$ $d = [1.17] \sqrt{P}$... 80MHz to 800MHz $d = [2.33] \sqrt{P}$... 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

**Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Aerogen Pro nebulizer system is used exceeds the applicable RF compliance level above, the Aerogen Pro nebulizer system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Aerogen Pro nebulizer system.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m
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