

Aeroneb[®] Solo System

Micropump Nebulizer

Instruction Manual



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Instruction Manual

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Table of contents

Introduction	1
System description	2
Warnings	5
Electromagnetic susceptibility	7
Symbols	9
Controls and indicators	11
Warranty	13
Life of Product	13
Assembly and Installation	14
Recharging the Battery	21
Installation for use with a ventilator	21
Installation for use with a mask	25
Installation for use with a mouthpiece	26
Adding medication	27
Nebulization	28
Functional test	30
Cleaning of Pro-X Control Module	32
Troubleshooting	33
Order numbers	36
Specifications	38
Physical	38
Environmental	38
Performance	39
Power	39
Appendix 1 EMC tables	41

List of Figures

Figure 1: Aeroneb® Solo System.....	2
Figure 2: Aeroneb® Pro-X controls and indicators.....	11
Figure 3: Connecting nebulizer unit to T-piece.....	14
Figure 4: Connecting control module and nebulizer unit.....	15
Figure 5: Connecting the Aeroneb® Pro-X AC/DC adapter...	15
Figure 6: Connecting tubing and syringe to the Aeroneb® Solo for continuous nebulization.....	18
Figure 7: Connecting to an adult breathing circuit.....	22
Figure 8: Connecting to a pediatric breathing circuit.....	22
Figure 9: Connecting to a neonate breathing circuit.....	22
Figure 10: Alternative neonatal breathing circuit using neonate T-piece.....	23
Figure 11: Control module and universal mounting bracket (Vertical).....	24
Figure 12: Control module and universal mounting bracket (Horizontal).....	24
Figure 13: Equipment mount adapter.....	24
Figure 14: Connecting to a mask.....	25
Figure 15: Connecting to a mouthpiece.....	26
Figure 16: Filling the nebulizer unit with a pre-filled ampoule...	27
Figure 17: Starting and stopping nebulization.....	29

List of Tables

Table 1: Aeroneb® Solo system symbols.....	9
Table 2: Aeroneb® Pro-X controls and indicators.....	12
Table 3: Aeroneb® Pro-X troubleshooting.....	33
Table 4: Aeroneb® Solo Parts List.....	36

Introduction

The Aeroneb® Solo System is an iteration of the Aeroneb® Professional Nebulizer System. The indications for use of the Aeroneb® Professional Nebulizer System are given below. The Aeroneb® Solo System, which consists of the Aeroneb® Solo nebulizer and the Aeroneb® Pro-X controller, is a nebulizer system designed for use with mechanically ventilated patients to aerosolize physician-prescribed medications for inhalation which are approved for use with a general purpose nebulizer. The Aeroneb® Solo nebulizer is for single patient use only and the Aeroneb® Pro-X controller is for re-use.

The Aeroneb® Solo System is suitable for use with neonate, pediatric and adult patients as described in this manual. It is for intermittent and continuous nebulization that incorporates Aerogen's OnQ™ Aerosol Generator.

The Aeroneb® Solo nebulizer 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 Aeroneb® Pro-X control module 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 Aeroneb® Professional Nebulizer 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 Aeroneb® Professional Nebulizer System is suitable for use in adult, pediatric and neonate patients as described in the Instruction Manual.

System description

The Aeroneb® Solo System (Figure 1) includes the following components: nebulizer unit (aerosol generator and plug), T-piece (adult)*, Aeroneb® Pro-X control module, control cable, AC/DC adapter and mounting brackets. (Pediatric & neonate adapters and continuous nebulization tube set are sold separately).

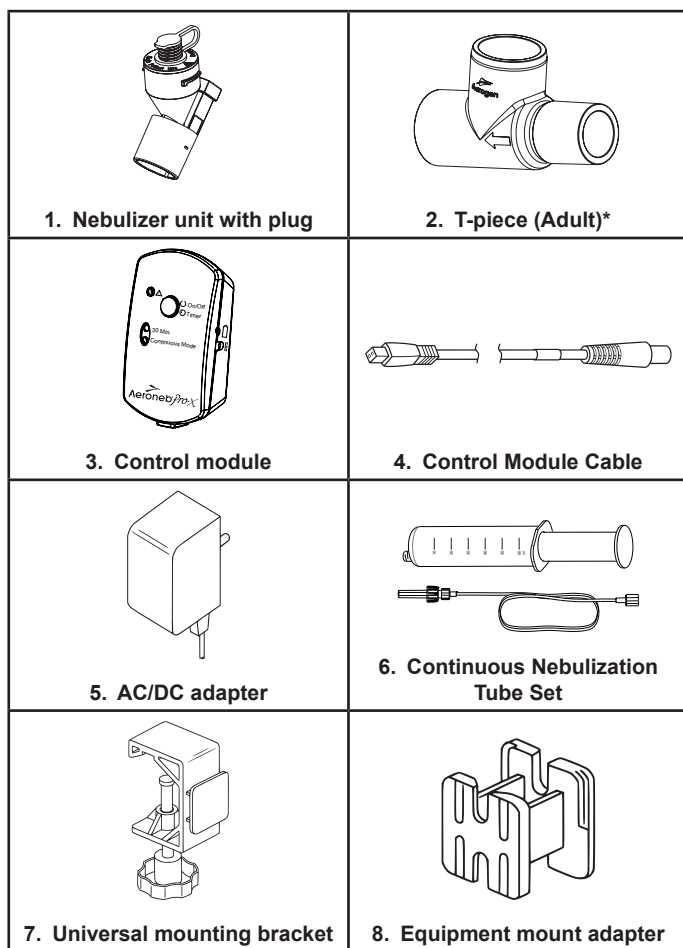


Figure 1: Aeroneb® Solo System

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1. The nebulizer unit holds up to 6mL of liquid medication. The nebulizer unit is clear to allow visual monitoring of medication levels and aerosolization. When the nebulizer unit is connected into the ventilator circuit, the silicone plug can be opened and closed in between doses without causing loss of circuit pressure.

Within the nebulizer unit is an OnQ™ 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 unit into the breathing circuit. The T-piece connections are standard male and female 22mm conical ports and connect to standard patient breathing circuits. Aerogen recommends that the Aeroneb® Solo nebulizer be used in conjunction with a relevant disposable T-piece supplied by Aerogen.
- 3,4,5. The *control module* can operate from the AC/DC adapter or the internal rechargeable battery. The control module includes an on/off power button and sockets for the *control module cable* and the AC/DC adapter. The control module also includes indicators for nebulization cycle selection (30 minutes or continuous), battery charge status and fault conditions.
6. The Aeroneb® Solo can be operated continuously by attaching the continuous nebulization tube set accessory. The continuous nebulization tube set is designed for use with a syringe pump for continuous drug dosing.

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7. A *universal mounting bracket* clamps the control module to standard IV poles and medical rail systems.
 8. An *equipment mount adapter* mounts the control module on standard equipment mounts.

Warnings

Read and study all instructions before using the Aeroneb® Solo system. Only medical personnel should operate the device.

Perform functional test prior to use to ensure correct operation (see page 30).

This is a single patient use device not to be used on more than one patient to prevent cross infection.

Do not use beyond defined life (see page 13).

During use observe for correct functioning of the nebulizer.

The nebulizer unit and T-piece, as packaged, are not sterile.

Do not autoclave the Aeroneb® Solo nebulizer.

The continuous mode can only be operated from the mains supply and cannot be operated by battery power.

To ensure correct and safe connection between the nebulizer and the medication reservoir, trace the medication tube from the nebulizer back to the medication reservoir to make sure the medication tube is connected to the correct source.

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

Do not wrap the nebulizer cable tightly around any of the system components.

Do not place the control module 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.

Only use physician-prescribed solutions that are approved for use with a general purpose nebulizer.

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

Warnings

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

Do not use the Aeroneb Solo in conjunction with the administration of volatile anaesthetics as this may have an adverse effect on the Aeroneb Solo nebuliser or T-piece plastics.

Do not use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air under high pressure.

To avoid the risk of fire, do not use in the presence of flammable substances.

To avoid damage to the nebulizer:

- **Do not apply undue pressure to the domed aperture plate in the center of the nebulizer.**
- **Do not push out the OnQ™ Aerosol Generator.**
- **Do not use a syringe with a needle to add medication.**
- **Do not use abrasive or sharp tools to clean the nebulizer unit.**

Do not use the Aeroneb® Solo nebulizer with the reusable connectors available with the Aeroneb® Pro nebulizer. Aerogen recommend use of the relevant disposable T-pieces and adapters provided by Aerogen with the Aeroneb® Solo nebulizer.

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 Aerogen product sales representative.

Do not immerse or autoclave the control module or AC/DC adapter.

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 unit or the control module.

Warnings

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

The Aeroneb® Pro-X control module 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.

Follow local laws and recycling plans regarding disposal or recycling of components, batteries and packaging.

The Aeroneb® Solo nebulizer is designed for use in continuous mode only when used with the Aeroneb® Pro –X controller.

Do Not use the Aeroneb® Pro Nebulizer in continuous mode.

Caution: Federal law restricts this device to sale by or on the order of a physician

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 Aeroneb® Solo AC/DC adapter (AG-AP1040-XX) has no connection to earth ground because the necessary level of protection is achieved through the use of double insulation.

Warnings

- Only use the Aeroneb® Solo nebulizer with components specified in the Instructions for Use. Use of the Aeroneb® Solo nebulizer with components other than those specified in the Instructions for Use may result in increased emissions or decreased immunity of the Aeroneb® Solo nebulizer system.
- Do not use the Aeroneb® Solo 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 Aeroneb® Solo needs special precautions regarding electromagnetic compatibility (“EMC”) and must be installed and put into service according to the EMC information provided in the Instructions for Use.
- Portable and mobile radio frequency (“RF”) communication devices can disrupt medical electrical equipment.

Refer to Appendix 1 for EMC Tables as per IEC/EN 60601-1-2

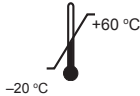
Symbols

The following symbols apply to Aeroneb® Solo nebulizer and Aeroneb® Pro-X controller. These symbols appear on the back of the control module and on the packaging:

Table 1: Aeroneb® Solo System Symbols

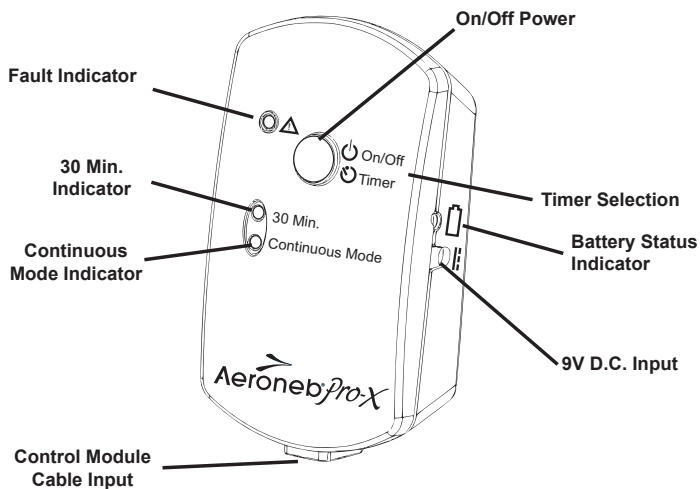
Symbol	Meaning
AP-YYXXXX	Serial number, where YY is the year of manufacture and XXXX is the serial number
	Attention, consult accompanying documents
 IPX1	Degree of protection against dripping water
	Class II equipment per IEC/EN 60601-1
	Type BF equipment per IEC/EN 60601-1
	On/Off power button (standby)
	30 minute operating mode
	Continuous operating mode (International)
	Control Module Input – DC voltage
	Control Module Output – AC voltage
	Does not contain natural rubber latex
	Output
	Battery status indicator
	Fragile, handle with care

Table 1: Aeroneb® Solo System Symbols

Symbol	Meaning
	Transient storage temperature limitations –20 °C to +60 °C.
	Keep dry.
Rx Only	Federal (US) law restricts this device to sale by or on the order of a physician.
	Classified by TUV with respect to electric shock, fire and mechanical hazards.
	This device complies with the requirements of the Medical Devices Directive (93/42/EEC).
	Non-Sterile
	Consult Instructions for Use
	Use by (YYYY-MM)
	Manufacturer
	Batch Code
	Serial Number
	Catalogue Number
	Single Patient Use, Do not reuse

Controls and indicators

North American Controller



International Controller

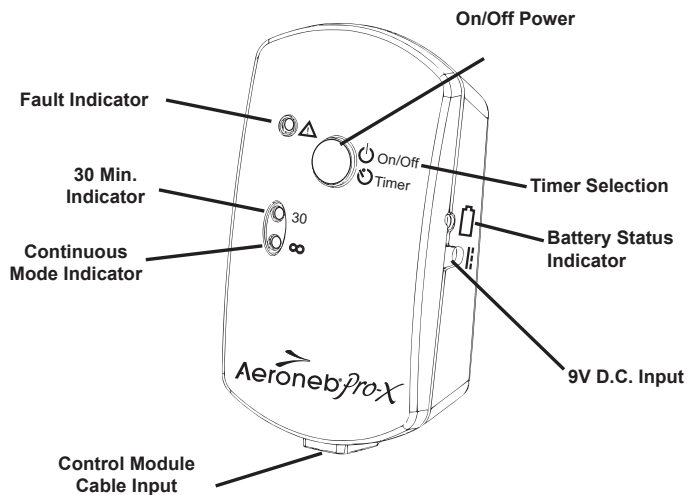


Figure 2: Aeroneb® Pro-X controls and indicators

Table 2: Aeroneb® Pro-X controls and indicators

Control/indicator	Function
<i>30 Min. indicator</i>	Green (steadily lit) = 30 minute nebulization cycle on Green (flashing) = Low battery power Nebulizer unit automatically powers off after 30 minutes have elapsed
<i>Continuous indicator</i>	Green (steadily lit) = Continuous nebulization cycle on Nebulizer unit does not power off automatically
<i>Fault indicator</i>	Amber (steadily lit) = Aeroneb® Solo Nebulizer disconnected from Aeroneb® Pro-X controller. Amber (flashing) = Aeroneb® Pro-X drive voltage error
<i>On/Off power button</i>	Pressing and immediately releasing selects the 30 minute nebulization cycle Pressing and holding for at least three seconds selects the continuous nebulization cycle Pressing during nebulization turns off power to the nebulizer
<i>Battery status indicator</i>	Green = Battery fully charged Amber = Battery charging No light = Battery in operation

Warranty

Aerogen warrants that the Aeroneb® Solo nebulizer shall be free from defects of workmanship and materials for a period of the defined life of the nebulizer when used in accordance with this instruction manual.

The Aeroneb® Pro-X Control Module and AC/DC Adapter are warranted against defects in manufacturing for a period of two years from the date of purchase. All warranties are based on typical usage, detailed below.

Life of Product

As with all active electronic components, the Aeroneb® Solo nebulizer unit has a defined life. In the case of Aeroneb® Solo, the life of the nebulizer unit has been validated for intermittent use for a maximum of 28 days based upon a typical usage profile of 4 treatments per day.

For continuous use the life of the Aeroneb® Solo nebulizer unit and the continuous nebulization tube set have been validated for use for a maximum of 7 days.

The user should note that use in excess of these periods is not validated by Aerogen.

Assembly and Installation

Intermittent Nebulization

Perform a functional test of the Aeroneb® Solo before use as described in the Functional Test section of this manual (See page 30).

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

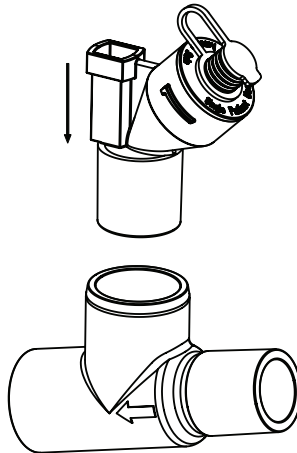


Figure 3: Connecting nebulizer unit to T-piece

2. Insert the nebulizer and the T-piece into the breathing circuit with the arrow on the T-piece pointing in the direction of the air-flow within the circuit.
3. Connect the Aeroneb® Pro-X control module to the Aeroneb® Solo nebulizer unit using the nebulizer cable as shown in Figure 4.

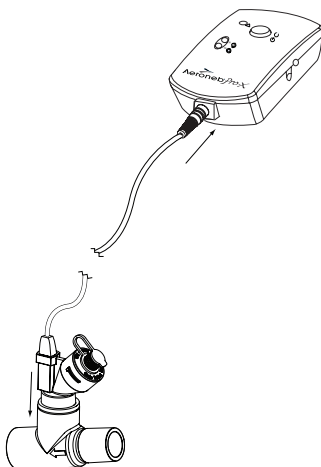


Figure 4: Connecting control module and nebulizer unit

4. Connect the Aeroneb® Pro-X AC/DC adapter to the Aeroneb® Pro-X controller as shown in Figure 5.

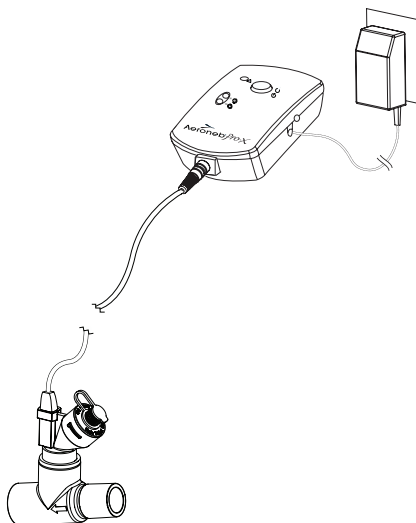


Figure 5: Connecting the Aeroneb® Pro-X AC/DC adapter

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5. To operate on AC power (the primary mode of operation), insert the AC/DC adapter cable into the control module and plug the adapter into an AC power source.
 6. Aeroneb® Pro-X 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 control module will automatically switch to battery operation.

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

Note: To ensure uninterrupted operation of Aeroneb® Solo, secure both the AC/DC adapter cable and the control module 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.

Note: The continuous mode can only be operated from AC power supply. The AC/DC adapter is the means of isolating the Aeroneb® Solo system from the main power supply.

Continuous Nebulization Tube Set

Tubing: AG-AS3075 and Syringe: AG-AS3085

The Aerogen Continuous Nebulization Tube Set is an accessory specific to the Aeroneb® Solo nebulizer which enables safe continuous infusion of liquid medication for aerosolization

Instructions as per Figure 6.

NOTE: Place the syringe cap (1) on the syringe (2) after it is filled with medication.

1. Ensure the Aeroneb® Solo nebulizer unit (3) is firmly fitted into the Aeroneb® Solo T-piece (4) in the breathing circuit.
2. Remove the syringe cap (1) from the medication-filled syringe.
3. Attach the syringe end of the tubing (5) onto the syringe (2).
4. Prime the tubing (6) until the medication reaches end of tubing (Point A). **NOTE:** The tubing priming volume is maximum 3.65 mL.
5. Unplug the tethered cap (7) from the Aeroneb® Solo nebulizer (3), but do not remove it from the nebulizer.
6. Screw the nebulizer end of the tubing (8) onto the top of the nebulizer.
7. Insert the syringe filled with medication into the syringe infusion pump (pump not shown in Figure 6).
8. Turn on the continuous mode option on the Aeroneb® Pro-X control module (refer to Aeroneb® Solo System instruction manual) and turn on the infusion pump (refer to pump manual or manufacturer for guidance).

-
9. Observe nebulizer for proper operation. During continuous nebulization, the nebulizer is on continuously and the medication is nebulized on a drop by drop basis. Nebulization should be visible with regular intermittent pauses. Medication level in the nebulizer reservoir should not rise during use.

NOTE: The manufacturer's recommended input rate of medication into the Aeroneb® Solo nebulizer during continuous nebulization is 0.2mL per minute or 12mL per hour. This is based on the manufacturers specification for the lowest acceptable nebulizer flow rate. For directions on determining flow rates, refer to the Optional Flow Rate Calculation method in the Functional Test section, page 30.

CAUTION: It is important to ensure that the maximum flow rate through the tube set into the nebulizer must not exceed the output rate of the nebulizer.

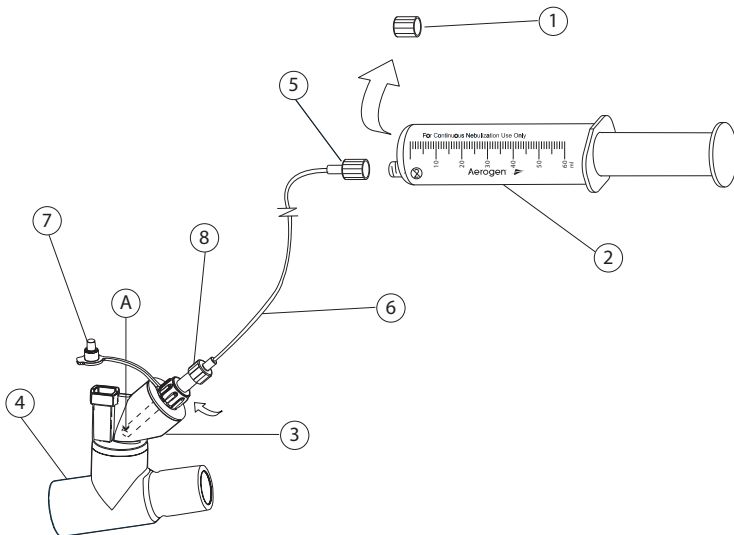


Figure 6: Connecting tubing and syringe to the Aeroneb® Solo for continuous nebulization

Warnings

Read and study all instructions before using the Continuous Nebulization Tube Set system. Only appropriately trained medical personnel should operate the Aeroneb® Solo and the Continuous Nebulization Tube Set device.

The device is for single patient use only and is not to be used on more than one patient to prevent cross infection.

Do not use if there are any signs of cracks, damage or foreign matter.

Do not attempt to connect the system to any nebulizer other than the Aeroneb® Solo.

Do not attempt to connect the tubing or syringe to any non-respiratory apparatus.

The Aeroneb® Solo system is intended to be used with physician-prescribed solutions for inhalation that are approved for use with a general purpose nebulizer.

Check for leaks from the system prior to and during use.

The device is non sterile.

The graduations on the syringe are for indication use only.

Store at room temperature and use product within labelled shelf life.

Cautions

Refer to Figure 6.

The recommended syringe pump software setting with the Aerogen syringe is typically the “BD Plastipak” setting. This must be validated locally before use. Refer to pump manual or manufacturer for guidance. These pumps may also be used in accordance with local hospital or ward policies.

Ensure that the tethered silicone plug (7) is attached to the Aeroneb® Solo (3) when connecting tube set.

Ensure that the tubing (6) is safely orientated to prevent a trip hazard.

Rising level of medication in the reservoir may occur if the Aeroneb Solo nebulizer is turned off while the feed system is still on or the nebulizer is not in its recommended orientation.

The level of the medication in the reservoir of the Aeroneb Solo nebulizer should be periodically monitored to ensure that the fill rate of medication does not exceed the output rate of the nebulizer. A rising level of medication in the reservoir indicates that the fill rate is exceeding the output rate of the nebulizer.

Do not clean or sterilize the device.

Replace the tube set and syringe when changing the type of medication.

Recharging the Battery

To recharge the battery, connect the AC/DC adapter to the control module and connect to AC power source. The battery status indicator is amber while charging and green when fully charged. Allow a minimum of eight hours for the internal battery to fully recharge.

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

Installation for use with a ventilator

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

For **pediatric breathing circuits**, connect the nebulizer unit with pediatric T-piece into the inspiratory limb of the breathing circuit before the patient Y (Figure 8).

For **neonatal breathing circuits**, connect the nebulizer unit with the pediatric T-piece and the neonate adapters approximately 30 cm (12 in.) back from the patient Y (Figure 9), or neonatal set-up as shown in (Figure 10).

WARNING:

- Condensate can collect and occlude ventilator circuits. Always position ventilator circuits so that fluid condensate drains away from the patient.
- Always connect a bacteria filter to the expiratory inlet of the ventilator. Otherwise the function of the expiratory channel may be degraded.

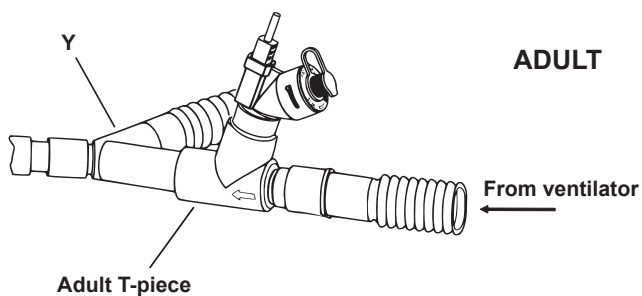


Figure 7: Connecting to an adult breathing circuit

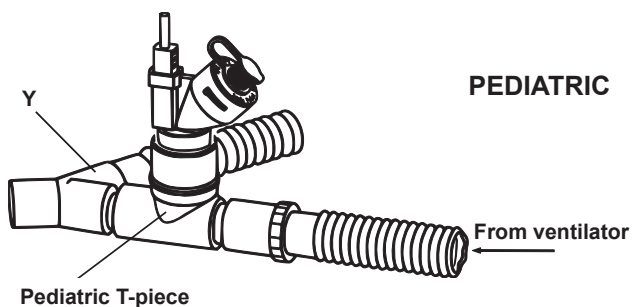


Figure 8: Connecting to a pediatric breathing circuit

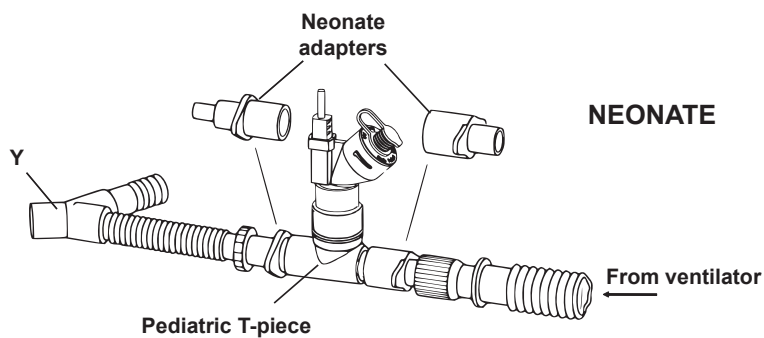


Figure 9: Connecting to a neonate breathing circuit

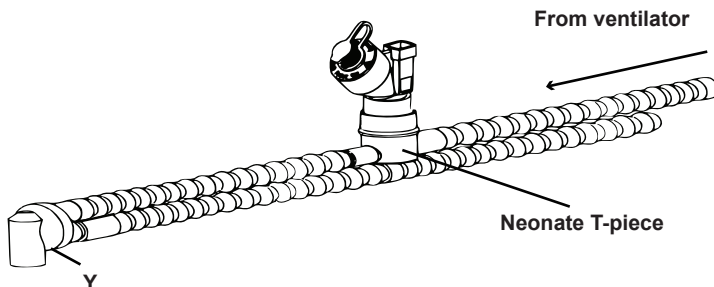


Figure 10: Alternative neonatal breathing circuit using neonate T-piece

2. Always perform a leak test of the breathing circuit after inserting or removing the nebulizer unit. Follow ventilator manufacturer instructions for performing a leak test.
3. Use the universal mounting bracket to attach the control module to an IV pole or bed rail in either a vertical or horizontal orientation (Figure 11 and Figure 12). Do not over-tighten knob.
4. Where a standard equipment mount is available, use the equipment mount adapter to support the control module (Figure 13).

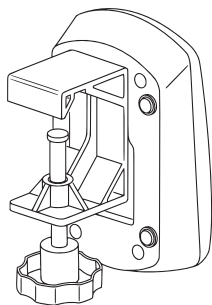


Figure 11: Control module and universal mounting bracket (Vertical)

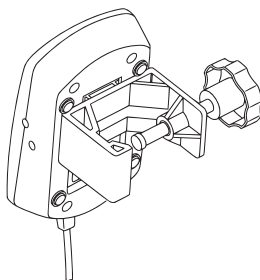


Figure 12: Control module and universal mounting bracket (Horizontal)

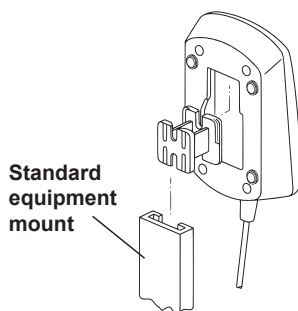


Figure 13: Equipment mount adapter

Installation for use with a mask

Mask kits, which include a vented elbow and mask elbow, are available separately (see Order Numbers section). Contact your Aeroneb® Solo nebulizer system sales representative for ordering information.

1. When using a mask, connect the vented elbow, mask elbow and mask to the nebulizer unit by firmly pushing the parts together.
2. Rotate the vented elbow to suit the position of the patient (Figure 14).

CAUTION: To ensure proper nebulization, maintain the nebulizer in a vertical orientation (Figure 14).

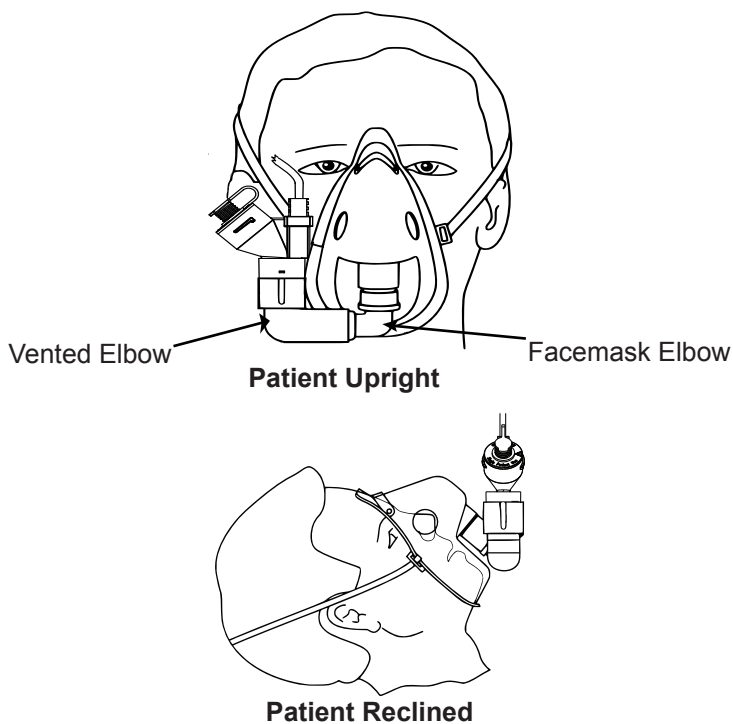


Figure 14: Connecting to a mask

Installation for use with a mouthpiece

Aeroneb® Solo works with any standard ISO 22mm nebulizer mouthpiece inserted into the adult T-piece.

When using a mouthpiece, connect the nebulizer unit to the T-piece as shown in Figure 3 in this manual, and then connect the T-piece to the mouthpiece by pushing the parts firmly together (Figure 15).

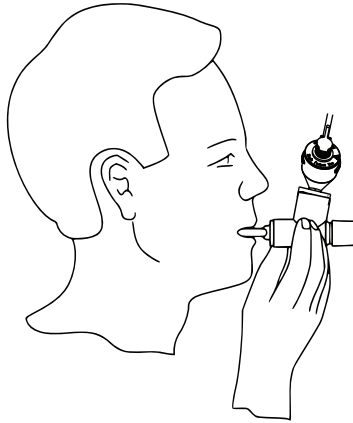


Figure 15: Connecting to a mouthpiece

Caution: To ensure proper nebulization, maintain the nebulizer in a vertical orientation (Figure 15).

Adding medication

1. Open the plug on the nebulizer unit.
2. Use a pre-filled ampoule or syringe to add medication into the filler port of the nebulizer (Figure 16).
3. Close the plug.

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

The maximum capacity of the nebulizer unit is 6 mL.

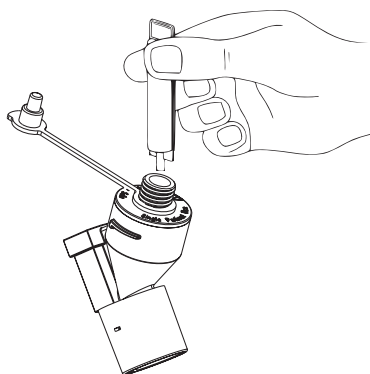


Figure 16: Filling the nebulizer unit with a pre-filled ampoule

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

Nebulization

For intermittent doses less than or equal to 6mL.

1. To start a 30 minute nebulization cycle, add the medication and press and release the blue on/off power button (Figure 17). The green *30 Min.* indicator LED illuminates to indicate that the 30 minute nebulization cycle is in progress.

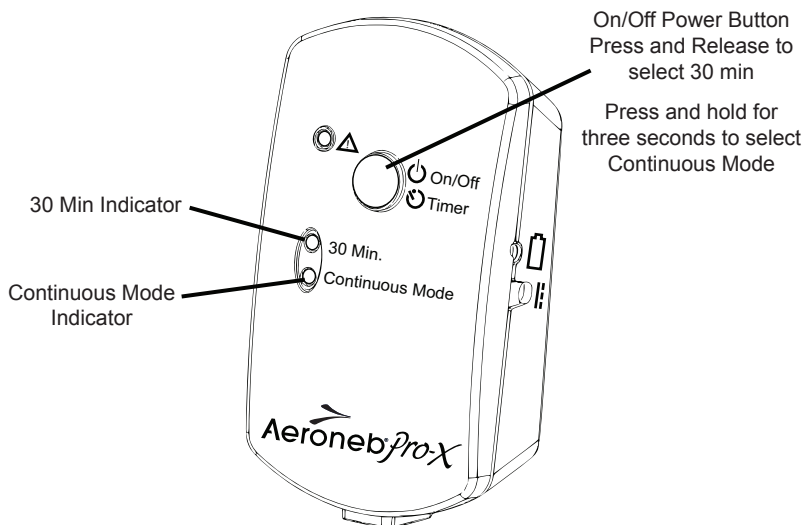
For continuous doses:

WARNING: To ensure correct and safe connection between the nebulizer and the medication reservoir, trace the medication tube from the nebulizer back to the medication reservoir to make sure the medication tube is connected to the correct source.

2. To start a continuous nebulization cycle, connect the continuous nebulization tube set to the nebulizer. Insert the syringe into the syringe pump and set the appropriate flow rate. On the control module press and hold the blue On/Off power button for at least three seconds. The green continuous 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.

Caution: When delivering a continuous dose select the continuous cycle. This will only operate on mains power.

North American Controller



International Controller

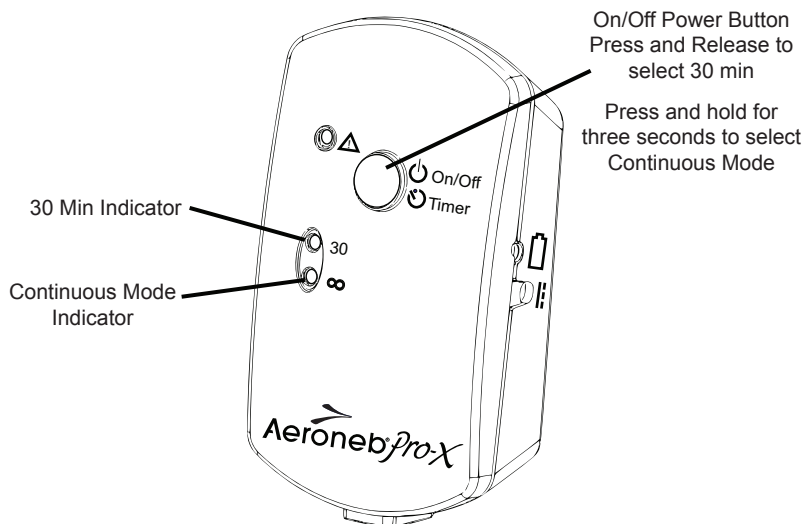


Figure 17: Starting and stopping nebulization

Functional test

Perform a functional test of the Aeroneb® Solo System prior to first 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 1-6 mL of normal saline (0.9%) into the nebulizer unit.
3. Connect the nebulizer unit to the control module using the control module cable. Connect the control module to the AC/DC adapter 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 *30 Min.* indicator LED illuminates and that aerosol is visible.
5. 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 *Continuous* indicator LED illuminates and that aerosol is visible.
6. Disconnect the control module from the AC/DC adapter and verify that nebulization continues and that the battery status indicator turns off.
7. Turn the System off and verify that the *30 Min.* and *Continuous* indicators are off.

Optional Nebulizer Flow Rate Calculation

(Refer to page 18)

Flow rates may vary between individual Aeroneb® Solo nebulizers. The minimum flow rate for all Aeroneb® Solo nebulizers is 0.2 mL per minute. In order to calculate the flow rate of an individual Aeroneb® Solo nebulizer, follow these steps:

1. Transfer 0.5 mL of normal saline (0.9%) or intended drug into the Aeroneb® Solo medication cup.
2. Turn on the nebulizer.
3. Using a stop-watch, measure the length of time it takes from the start of nebulization until all the saline/drug has been nebulized.
4. Calculate the flow rate using the following equations:

$$\text{Flow rate in mL/min} = \left(\frac{\text{Volume of normal saline or drug}}{\text{Nebulization time in seconds}} \right) \times 60$$

$$\text{Flow rate in mL/h} = \left(\left(\frac{\text{Volume of normal saline or drug}}{\text{Nebulization time in seconds}} \right) \times 60 \right) \times 60$$

Cleaning of Pro-X Control Module

Cleaning of control module, control module cable, AC/DC adapter and mounting brackets:

1. Wipe clean with a clean cloth dampened with mild detergent and water.
2. Check for exposed wiring, damaged connectors, or other defects and replace control module if any are visible.
3. Visually inspect for damage and replace the control module if any damage is observed.

CAUTIONS

Do not autoclave.

Do not use abrasive or sharp tools.

Do not spray liquid directly onto the control module.

Do not immerse control module in liquid.

Troubleshooting

If these suggestions do not correct the problem, discontinue use of any device that appears to be damaged or is not operating properly and contact your local Aeroneb® product sales representative.

Table 3: Aeroneb® Pro-X troubleshooting

If this happens:	It could mean:	Try this:
The 30 <i>Min.</i> indicator flashes during nebulization.	Battery power is low.	Recharge battery (see <i>Recharging the battery</i>).
Battery will not recharge. Control module is connected to the AC/DC adapter and the battery charging LED is illuminated green and the 30 <i>Min.</i> indicator light is flashing.	It may be time to replace the battery.	Contact your local Aerogen product sales representative.
Battery will not retain initial charge.	Rechargeable battery may need to be replaced.	Contact your local Aerogen product sales representative.

Table 3: Aeroneb® Pro-X troubleshooting

If this happens:	It could mean:	Try this:
The <i>30 Min.</i> or <i>Continuous</i> . LED illuminates, but aerosol is not visible.	No medication in nebulizer unit.	Refill medication through filler cap in the nebulizer unit (see <i>Adding medication during nebulization</i>).
	It may be time to replace the nebulizer unit.	See <i>Warranty and Life of Product</i> . Refer to Aeroneb® Solo parts list.
<i>30 Min.</i> or <i>Continuous</i> . indicator does not light when on/off power button is pressed.	There is no power to the System.	Verify that AC/DC adapter is securely attached to control module.
	Rechargeable battery is depleted.	Recharge battery (see <i>Recharging the battery</i>).
The fault indicator LED illuminates.	The control module cable is incorrectly connected to the nebulizer, or electronics are malfunctioning.	Verify that control module cable is correctly connected to both the nebulizer unit and the control module.

Table 3: Aeroneb® Pro-X troubleshooting

If this happens:	It could mean:	Try this:
Medication is left in the nebulizer unit after nebulization cycle.	Nebulizer was not turned on or connected to power.	Ensure that nebulizer is connected to power and turned on.
	Rechargeable battery is depleted.	Recharge battery (see <i>Recharging the battery</i>).
	A 30 minute cycle was selected when connected to the continuous feed system.	Run a continuous cycle.
	It may be time to replace the nebulizer unit.	See Warranty and <i>End of Life</i> . Refer to Aeroneb® Solo parts list.
Flashing amber LED	It may mean that it is time to replace controller	Contact your local Aerogen Product sales representative

Note: The rechargeable battery in the control module should only be replaced by Aerogen authorized personnel: contact your Aeroneb® product sales representative.

Order numbers

Table 4 lists the Aeroneb® Solo system order numbers (see Figure 1 for pictures).

Table 4: Aeroneb® Solo Parts List

Description	Order number
Aeroneb® Solo Starter Kit • Aeroneb® Solo nebulizer (x 2) • Adult T-piece with silicone plug (x 2) • Aeroneb® Pro-X Control module • Universal Mounting Bracket • AC/DC Adapter • Instruction Manual	AG-AS3000-XX*
Aeroneb® Solo Convenience Kit - Pack of 5 • Aeroneb® Solo nebulizers • Adult T-pieces with silicone plugs	AG-AS3300
Aeroneb® Solo Convenience Kit - Pack of 10 • Aeroneb® Solo nebulizers • Adult T-pieces with silicone plugs	AG-AS3350
Aeroneb® Solo Nebulizers - Pack of 5	AG-AS3100
Aeroneb® Solo Nebulizers - Pack of 10	AG-AS3200
Disposable Adult T-piece - Pack of 10 • 22M - 22F - 22 M	AG-AS3010
Disposable Pediatric T-piece - Pack of 10 • 15M - 22F - 15M	AG-AS3020
Disposable Pediatric T-piece & Neonate Adapter Kit - Pack of 10 • T-Piece: 15M - 22F - 15M • Adapters: 15M - 10M/ 7.5M 15F - 10M/ 7.5F	AG-AS3025

Table 4: Aeroneb® Solo Parts List

Description	Order number
Disposable Neonate T-piece - Pack of 10 • 12M - 22F - 12F (Fits Fisher & Paykel Neonate Circuit)	AG-AS3035
Disposable Neonate T-piece - Pack of 10 • 10M - 22F - 10F	AG-AS3036
T-piece Silicone Plug For use with: • AG-AS3010, AG-AS3020, AG-AS3025 & AG-AS3036	AG-AS3450
Disposable Mask Kit (US) - Pack of 5 • 22M - 17M/18.5M • 22F - 22F (vented)	AG-AS1065
Disposable Mask Kit (International) - Pack of 5 • 22F - 22M/15F • 22F - 22F (vented)	AG-AS1075
Disposable Vented Elbow - Pack of 5 • 22F - 22F (vented)	AG-AS1055
Continuous Nebulization Tubset Tubing - Pack of 5	AG-AS3075
Continuous Nebulization Tubset Syringe - Pack of 5	AG-AS3085
AC/DC Adapter	AG-AP1040-XX*
Aeroneb® Pro-X Control Module	AG-PX1050-XX*
Control Module Cable	AG-AP1085
Universal Mounting Bracket	AG-AP1060
Equipment Mount Adapter	AG-AP1070
Aeroneb® Solo Starter Kit Instruction Manual	AG-AS3050-XX*

*Consult your local representative for the order code extension specific to your country and for pricing information.

Specifications

Physical

- Nebulizer unit dimensions:** 67 mm H x 48 mm W x 25 mm D
(2.6 in. H x 1.88 in. W x 1.1 in. D)
- Control module dimensions:** 33 mm H x 75 mm W x 131 mm D
(1.3 in. H x 2.9 in. W x 5.2 in. D).
- Control module cable length:** 1.8 m (5.9 ft.) long
- AC/DC adapter cable length:** 2.1 m (6.7 ft.) long
- Nebulizer unit weight:** 13.5 g (0.5 oz) nebulizer unit and plug
- Control module weight:** 230 g (8.1 oz.), including battery and cable
- Nebulizer unit capacity:** Maximum 6 mL

Environmental

Operating:

Maintains specified performance at circuit pressures up to 90 cm H₂O and temperatures from 5 °C (41 °F) up to 45 °C (113 °F).

Atmospheric pressure: 450 to 1100 mbars

Humidity: 15 to 95% relative humidity

Noise level: < 35 dB measured at 0.3 m distance

Storage and transport:

Transient temperature range: -20 to +60°C (-4 to +140°F)

Atmospheric pressure: 450 to 1100 mbars

Humidity: 15 to 95% relative humidity

Performance

Flow rate: > 0.2 mL/min (Average ~ 0.38 mL/min)

Particle size:

Average Mass Median Aerodynamic Diameter (MMAD): 3.4 μm

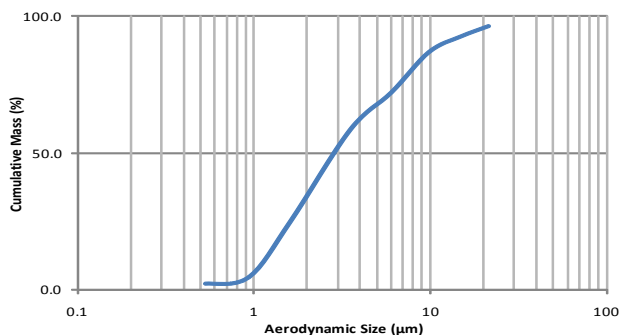
As per EN 13544-1:

- Aerosol Output rate: 0.30 mL/min
- Aerosol Output: 1.02 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:



Power

Power source: Friwo (AG-AP1040-JP) AC/DC adapter (input 100 to 240 VAC 50 – 60 Hz, output 9 V) or internal rechargeable battery (4.8 V nominal output).

Power consumption: < 8 Watts (charging), 2.0 Watts (nebulizing).

Patient isolation: control module circuitry provides 4 kilovolt (kV) patient isolation and complies with IEC/EN 60601-1.

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Appendix 1

EMC tables:

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The Aeroneb Solo nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aeroneb Solo nebulizer system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Aeroneb Solo 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.
RF Emissions CISPR 11	Class B	The Aeroneb Solo 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.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Recommended separation distances between portable and mobile RF communication equipment and the Aeroneb Solo

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	m		
	150 kHz to 80 MHz $d = [1.17] \sqrt{P}$	80 MHz to 800 MHz $d = [1.17] \sqrt{P}$	800 MHz to 2.5 GHz $d = [2.33] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30

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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Aeroneb Solo nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aeroneb Solo nebulizer system should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC/EN 60601 Test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_t$ ($>95\%$ dip in U_t) for 0.5 cycle $40\% U_t$ (60% dip in U_t) for 5 cycles $70\% U_t$ (30% dip in U_t) for 25 cycles $<5\% U_t$ ($>95\%$ dip in U_t) for 5 sec	$<5\% U_t$ ($>95\%$ dip in U_t) for 0.5 cycle $40\% U_t$ (60% dip in U_t) for 5 cycles $70\% U_t$ (30% dip in U_t) for 25 cycles $<5\% U_t$ ($>95\%$ dip in U_t) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Aeroneb Solo nebulizer system requires continued operation during power mains interruption, it is recommended that the Aeroneb Solo nebulizer system be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_t is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Aeroneb Solo nebulizer system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aeroneb Solo nebulizer system should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[3]V	Portable and mobile RF communications equipment should be used no closer to any part of the Aeroneb Solo nebulizer system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [1.17] \sqrt{P}$ $d = [1.17] \sqrt{P} \dots 80\text{MHz to } 800\text{MHz}$ $d = [2.33] \sqrt{P} \dots 800\text{MHz to } 2.5\text{GHz}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	[3]V	

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 Aeronéb Solo nebulizer system is used exceeds the applicable RF compliance level above, the Aeronéb Solo 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 Aeronéb Solo nebulizer system.

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

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Part No.: AG-AS3050-EN
Manufacturing no.: 30-354

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