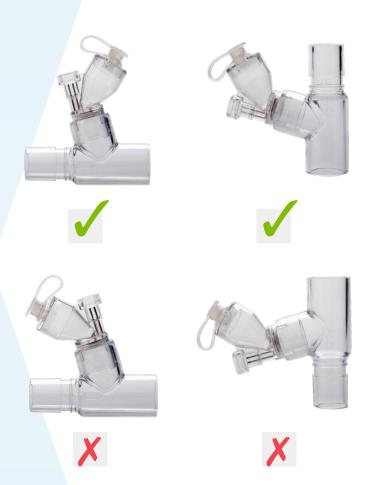




for approved set up, patient populations and environment of use.

Optimal orientation of the Aerogen® Solo

The Aerogen Solo is a gravity-fed device. Always ensure the proper orientation of the Aerogen Solo within the application.



Continuum of care



OVERVIEW

Aerogen technology overview

Aerogen's intended use for Hospital is:

- For on and off ventilation or other positive pressure breathing assistance
- Intermittent and continuous nebulisation
- Physician prescribed medication approved for inhalation with a general purpose nebuliser
- Suitable for Neonate*, Paediatric
 (29 days or older) and Adult patients



Aerogen Solo

- Non-sterile, Single patient use
- Intermittent use up to 28 days, based on 4 treatments per day

Does not:

· Require oxygen/additional air flow



Aerogen Ultra

- Non-sterile, Single patient use
- Is an accessory specific to the Aerogen Solo
- Does not require oxygen to operate*
- Facilitates intermittent and continuous nebulisation to adults and paediatric patients via either mouthpiece or mask
- Can be used for 20 intermittent use treatments (at a rate of four 3 mL doses per day over 5 days) or a maximum 3 hours of continuous use







Aerogen Pro-X Controller

Powers the Aerogen Solo and has 2 power sources:

- AC/DC power
- Battery (up to 45 minutes when fully charged)

2 x operation modes:

- 30 minute mode
- Continuous mode (only with AC/DC mode)
- Is re-usable
- Is portable, when powered by the battery

In the case of AC/DC power failure the Aerogen Pro-X Controller will automatically switch to battery operation



Aerogen USB Controller

Powers the Aerogen Solo through:

- USB ports on Medical electrical equipment**
- Aerogen USB AC/DC Adapter

2 x operation modes:

- 30 minute mode
- 6 hour mode (only with AC/DC mode)
- Is re-usable
- Is portable, must be plugged in at all times to function



Continuous Nebuliser Tube Set

- Enables safe and continuous infusion of liquid medication for aerosolisation***
- Is an accessory specific to the Aerogen Solo
- Can be used for a maximum of 7 days



Aerogen AC/DC Adapter

Connects the power source to the Aerogen Controllers



Aerogen Pro-X Controller Cable

Connects the Aerogen Solo to the Aerogen Pro-X Controller



Aerogen T-piece

Connects the Aerogen Solo to the ventilation circuit, various sizes available



Aerogen Universal Mounting bracket

Secures the Aerogen Pro-X/ USB Controller to an IV Pole or bed rail



^{**} not approved in the USA

 $^{^{\}ast\ast\ast}$ may not be approved in all markets, please refer to your local IFU for directions

SET-UP

Product checklist

Before you start please make sure you have the following items:





Aerogen Pro-X **Controller Cable**



Aerogen Pro-X Controller



Aerogen T-piece



Aerogen AC/DC **Adapter**



Aerogen USB Controller



Aerogen Instruction **Manuals**

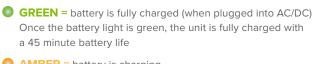
Aerogen Pro-X Controller set-up



The Aerogen Pro-X Controller powers the Aerogen Solo

- 1. Connect the Aerogen AC/DC Cable to the Aerogen Pro-X Controller and plug into mains electrical supplies
- 2. The Battery status indicator shows that the unit is receiving power
- 3. Allow a minimum of 4 hours to fully recharge the battery

The battery status indicator shows that the unit is receiving power



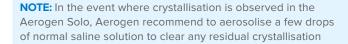
AMBER = battery is charging

Aerogen recommend that the Aerogen Pro-X Controller is always plugged in to ensure it is charged in the event the unit becomes unplugged or the patient needs to be transferred

Connecting and filling the Aerogen Solo



- 1. Plug the Aerogen Pro-X Controller Cable into the base of the Aerogen Pro-X Controller firmly and attach the other end to the Aerogen Solo
- 2. Open the plug on the Aerogen Solo
- 3. Use a pre-filled ampoule or syringe to add medication into the Aerogen Solo. Close the plug. To avoid damage to the core, do not use a syringe with a needle



Power mode selection



30 minute mode

- FROM OFF Press the On/Off button for 1 second
 - 30 minute mode light illuminates
- · Automatically switches Off after 30 minutes

Continuous mode

- FROM OFF Press the On/Off button for 3 seconds
- Continuous mode light illuminates
- Does not automatically switch Off
- Only operates in continuous when connected to Aerogen Pro-X Controller AC/DC power
- Continuous mode will continue if there is an interruption to power for less than 10 seconds. If longer, the Aerogen Pro-X Controller will revert to 30 minute mode

Verification

The Aerogen Solo is now in operation; check that aerosol is being produced

Error and 30 minute/continuous indicator lights



Error indicator lights

- Constant AMBER = disconnection
- The Aerogen Solo is disconnected from the Aerogen Pro-X Controller Cable, and/or
- The Aerogen Pro-X Controller Cable is disconnected from the Aerogen Pro-X Controller. If this occurs, check the Aerogen Controller Cable connection between the Aerogen Pro-X Controller and the Aerogen Solo



- If this occurs, check the Aerogen Pro-X Controller AC/DC connection
- If the unit is old, the battery may need to be replaced contact your supplier

30 minute/continuous indicator lights

- Constant GREEN = Aerogen Pro-X Controller is on and selected timing mode is operating
- Flashing GREEN = the unit is low on power. If this occurs, plug the unit into the Aerogen Pro-X Controller AC/DC Adapter

Mounting the Aerogen Pro-X Controller



Aerogen Pro-X

Use the Aerogen Universal Mounting Bracket to attach the Aerogen Pro-X Controller to a pole or bed rail in either vertical or horizontal orientation

Serial number



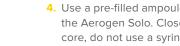
Year of manufacture is the first two numbers in the serial number on the back of the Aerogen Pro-X Controller

Aerogen USB Controller set-up



The Aerogen USB Controller powers the Aerogen Solo:

- 1. The Aerogen USB Controller is powered from the Aerogen AC/DC Adapter
- 2. Connect the Aerogen Solo to the end of the Aerogen USB Controller Cable
- 3. Open the plug on the Aerogen Solo



4. Use a pre-filled ampoule or syringe to add medication into the Aerogen Solo. Close the plug. To avoid damage to the core, do not use a syringe with a needle

NOTE: In the event where crystalisation is observed in the Aerogen Solo, Aerogen recommend to aerosolise a few drops of normal saline solution to clear any residual crystalisation

Power mode selection



30 minute mode

- FROM OFF Press the On/Off button for 1 second
- 30 minute mode light illuminates
- · Automatically switches Off after 30 minutes

6 hour mode

- FROM OFF Press the On/Off button for 3 seconds
- 6 hour mode light illuminates
- Automatically switches Off after 6 hours

Verification

The Aerogen Solo is now in operation; check that aerosol is being produced

Set-up configurations



For full product set-up configurations please consult the DFU or the individual Quick Reference Guides.

TROUBLESHOOTING

Hospital user guide

Troubleshooting Aerogen Pro-X Controller

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

30 minute/continuous indicators

If this happens	It could mean	Try this
Does not light when On/Off power button is pressed	There is no power to the system	Verify that the Aerogen AC/DC Adapter is securely attached to the Aerogen Pro-X Controller
	Rechargeable battery is depleted	Recharge battery
The 30 minute indicator light flashes during nebulisation	Battery power is low	Recharge battery
Light illuminates, but aerosol is not visible	No medication in Aerogen Solo	Refill medication in the Aerogen Solo
	It may be time to replace the Aerogen Solo	See Warranty and Life of Product

Battery or fault light

If this happens	It could mean	Try this
The error indicator light illuminates	The Aerogen Controller Cable is incorrectly connected to the Aerogen Solo, or electronics are malfunctioning	Verify that the Aerogen Controller Cable is correctly connected to both the Aerogen Solo and the Aerogen Pro-X Controller
Flashing amber light	It may be time to replace the Aerogen Pro-X Controller	
Battery will not recharge. Aerogen Pro-X Controller is connected to the Aerogen AC/DC Adapter, the battery charging light is illuminated green and the 30 minute. indicator light is flashing	It may be time to replace the battery	Contact your local Aerogen sales representative
Battery will not retain initial charge	Rechargeable battery may need to be replaced	

Left over medication

If this happens	It could mean	Try this
Medication is left in the Aerogen Solo after nebulisation cycle	Aerogen Solo was not turned on or connected to the power	Ensure that the Aerogen Solo is connected to the power and turned on
	Rechargeable battery is depleted	Recharge battery
	A 30 minute mode was selected when connected to the continuous feed system	Run a continuous cycle
	It may be time to replace the Aerogen Solo	See Warranty and Life of Product

NOTE: The rechargeable battery in the Aerogen Pro-X Controller should only be replaced by Aerogen authorised personnel: contact your Aerogen sales representative.

Hospital user guide

TROUBLESHOOTING

Troubleshooting Aerogen USB Controller

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

30 minute/6 hour indicators

If this happens	It could mean	Try this
Light is green, but aerosol is not visible	No medication in the Aerogen Solo	Refill medication
	Aerogen Solo is used beyond life of product	See Warranty and Life of Product
Does not light when On/Off power button is pressed	There is no power to the system	Verify Aerogen USB Controller is securely attached to a functioning power source
		Verify green power indicator light on AC/DC is on (if using Aerogen USB Controller AC/DC Adapter)
		Verify that the Battery is charged (if using Aerogen USB Controller Battery). If LED indicator light is red, connect the charging cable
Lights amber	The Aerogen USB Controller Cable is incorrectly connected	Verify the Aerogen USB Controller Cable is correctly connected to the Aerogen Solo
	Aerogen Solo is used beyond life of product	See Warranty and Life of Product
Flash amber alternatively twice	Internal error condition	See Warranty and Life of Product

Left over medication/longer than expected treatment time

If this happens	It could mean	Try this
Medication is left in the Aerogen Solo after nebulisation cycle	Aerogen Solo was not turned on or connected to power	Ensure that the Aerogen Solo is connected to power and turned on
	Aerosol was not generated	Verify aerosol is visible
	It may be time to replace the Aerogen Solo	See Warranty and Life of Product
Longer than expected treatment time e.g. 6mL of Normal Saline (0.9%) should take no longer than 30 minutes to nebulise	Aerogen Solo is used beyond life of product	See Warranty and Life of Product

Cleaning

Cleaning instructions for:

- ✓ Aerogen Pro-X Controller
- ✓ Aerogen USB Controller
- ✓ Aerogen Controller Cable
- Aerogen AC/DC Power Cable
- ✓ Aerogen Universal Mounting Bracket
- 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 the Aerogen Controllers if any are visible
- 3. Visually inspect for damage and replace the Aerogen Controllers if any damage is observed

Warning:

- Do not immerse or autoclave the Aerogen Pro-X/USB Controller, Aerogen Pro-X Controller Cable or Aerogen AC/DC Adapter
- Do not use abrasive or sharp tools
- Do not spray liquid directly onto the Aerogen Controllers
- Do not wrap the Aerogen Controller Cable tightly around any of the system components

Distributed By



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Notes

CLEANING

SET-UP TROUBLESHOOTING

OVERVIEW

Notes

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