

American Health Gate

SMART BREATHING NEBULIZER AHG-900

INSTRUCTION MANUAL

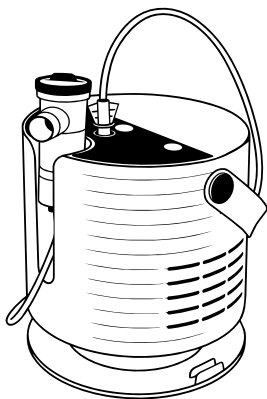


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INTRODUCTION

Thank you for choosing the AHG-900 Smart Breathing Nebulizer. The AHG-900 is a compact piston compressor nebulizing system designed to convert prescribed liquid medicine into an aerosol for inhalation.

Use the device only as described in this manual and only with medication prescribed or recommended for nebulization by a qualified healthcare professional. Correct assembly, cleaning, storage and maintenance are essential for safe and reliable performance.

Cautions: Prescription device

Federal law restricts this device to sale by or on the order of a physician. Use this device only as prescribed.

1.1 Intended purpose

The AHG-900 is a compressor-driven nebulizing system intended to convert prescribed liquid medicines into an aerosol for inhalation into the lower respiratory tract.

1.2 Indications

The AHG-900 is intended to provide a source of compressed air for medical purposes for use with a pneumatic nebulizer to produce medicated aerosol particles for respiratory therapy. It is intended for adult and pediatric patients when nebulized medication has been prescribed by a physician.

Regulatory control note: the final released U.S. IFU must remain identical to the cleared Indications for Use statement in the applicable 510(k)..

1.3 Patient population

Adults and children for whom nebulized medication therapy has been prescribed. Children must be supervised by an adult at all times.

1.4 Intended users

Patients, adult caregivers and healthcare professionals who can understand these Instructions for Use and the medication instructions provided by the prescriber.

1.5 Intended use environment

Home healthcare environments and professional healthcare facilities. The device is intended for indoor use on a flat, stable, dry surface.

1.6 Clinical benefit

The AHG-900 enables prescribed liquid medication to be converted into an inhalable aerosol for delivery to the respiratory tract. The therapeutic benefit depends on the prescribed medicine, the patient's condition and correct use of the device.

SAFETY INFORMATION

The following signal words are used throughout this manual:

Warning: indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ Cautions: indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

Notice: indicates a situation that could result in damage to the device or other property.

Note: provides additional information to help you use the device correctly.

2.1 Contraindications and residual risks

The AHG-900 has no device-specific contraindications when used for its intended purpose. However, do not use aerosol therapy for a patient in whom such therapy has been contraindicated by a physician. The medicine being nebulized may have its own contraindications, warnings and side effects; always read the medicine instructions and follow the prescriber's directions.

- Cross-infection may occur if patient-contact parts are shared or are not cleaned and disinfected as instructed.
- Aerosol escaping toward the eyes may cause irritation; some medicines may aggravate glaucoma.
- Medication residue may irritate facial skin; wash the face after treatment with a mask.
- Coughing or throat irritation may occur. Stop treatment and contact a physician if breathing becomes worse during or shortly after treatment.

2.2 Electrical and fire safety

Warning: Electric shock

Keep the compressor, power cord and plug dry. Never immerse them in water. Do not use the device while bathing or showering, and do not touch the power plug with wet hands.

- Do not use the device if the power cord or plug is damaged, if the device has been dropped, if it has been immersed in water, or if it does not work correctly.
- Do not overload power outlets. Connect the power cord directly to an appropriate wall outlet.
- Do not use the device where flammable gas, vapors, aerosol spray products or an oxygen-enriched atmosphere are present.
- Do not cover the compressor with a blanket, towel or other object during operation. Keep all air openings unobstructed.
- No modification of this equipment is allowed. Do not open the compressor housing; there are no user-serviceable parts inside.
- The mains plug is the means of isolating the device from the power supply. Position the device so the plug remains readily accessible.

2.3 Children and vulnerable users

Warning: Children and infants

The air tube and power cord may present a strangulation hazard, and small parts may present a choking hazard. Use on children only under direct, continuous adult supervision. Store the device, accessories and packaging out of reach of unsupervised children.

2.4 Medication precautions

- Use only medicines in aqueous solution or suspension that have been prescribed for nebulization.
- Never nebulize essential oils, oil-based preparations, alcohol-based preparations or liquids not intended for inhalation.
- Do not exceed the prescribed dose, frequency or duration of therapy.
- The nebulizer cup fill volume is 2 mL minimum and 8 mL maximum. Do not fill below the MIN line or above the MAX line.
- Suspensions and viscous solutions may change particle-size distribution, MMAD, aerosol output and treatment time.

2.5 Electromagnetic compatibility precautions

- Keep portable RF communications equipment, including mobile phones and their antennas/cables, at least 30 cm (12 in) from any part of the AHG-900.
- Avoid using this equipment adjacent to or stacked with other equipment. If such use is necessary, verify normal operation.
- Use only cables and accessories specified or supplied by the manufacturer.

Main components and controls:

1. Mouthpiece
2. Nebulizer / medication cup
3. Adult face mask
4. Air tube
5. Pediatric face mask
6. Accessory-storage cover and lock
7. Carrying handle
8. Power socket
9. Light button
10. Power / Start / Pause button
11. Timer button
12. Air outlet
13. Air filter cover
14. Ventilation openings
15. Breathing-light ring
16. Timer indicators

The final artwork should place the callout key next to the production-device illustration and label all referenced figures clearly.

PACKAGE CONTENTS

- AHG-900 compressor
- Nebulizer cup assembly
- Mouthpiece
- Adult silicone mask
- Pediatric silicone mask
- Air tube
- Power cord
- Air filter
- Instructions for Use

Inspect all components before first use. Do not use a damaged component.

5.1 POWER / START / PAUSE BUTTON

Short-press the center button to wake and power on the device. A 2-second startup phase begins and the timer indicators illuminate. A short press during this startup phase cancels startup and returns the device to standby.

During treatment, short-press the center button to pause. The compressor stops, the timer freezes and the breathing light changes to steady low brightness. Short-press again to resume.

Press and hold the center button for approximately 2 seconds to power off at any time.

5.2 LIGHT BUTTON

Each short press cycles through the available light modes:

OFF → WHITE → BLUE → YELLOW → GREEN → LAVENDER → PINK → OFF

The selected light color is stored and becomes the default for the next startup.

5.3 TIMER BUTTON

Each short press increases treatment time in 5-minute increments:

5 → 10 → 15 → 20 → 25 → 5 MINUTES

The corresponding timer indicators show the selected duration. If no duration is changed, the device starts with the default 5-minute treatment time.

5.4 AUTOMATIC COMPLETION AND STANDBY

When the countdown reaches zero, nebulization stops automatically and the device returns to standby. If the device remains inactive in standby for approximately 5 minutes, it powers down automatically.

PREPARING FOR TREATMENT

17. Wash and dry your hands.
18. Place the AHG-900 on a flat, stable, dry surface where the controls can be reached easily.
19. Make sure the device is switched off and unplugged.
20. Open the accessory-storage cover and remove the required nebulizer components.
21. Check that the air filter is installed and clean.
22. Check that the air tube is dry, undamaged and free of kinks.
23. Open the medication cup and add 2-8 mL of prescribed medicine. Do not exceed the MAX line.
24. Close the medication cup securely.
25. Attach the mouthpiece or the appropriate face mask.
26. Connect one end of the air tube to the nebulizer and the other end to the compressor air outlet. Push both ends on firmly.

27. With the power button off, connect the supplied power cord to the device and then plug it into the appropriate mains outlet.
28. Sit comfortably in an upright position and keep the nebulizer cup upright.
29. Short-press the center Power button. Wait for the 2-second startup indication.
30. Use the Timer button to select 5, 10, 15, 20 or 25 minutes as prescribed.
31. Select the desired light color, or switch the light off.
32. Confirm that a visible aerosol mist is produced.
33. Begin treatment using the mouthpiece or face mask as described below.
34. To pause, short-press the center button. Short-press again to resume.
35. When treatment is complete, press and hold the center button for approximately 2 seconds if the device has not already stopped automatically.
36. Unplug the power cord from the wall outlet.
37. Disconnect and clean the nebulizer components as described in Section 10.

7.1 MOUTHPIECE TREATMENT

Place the mouthpiece between your teeth and close your lips around it. Keep the nebulizer upright. Breathe slowly and deeply through your mouth as instructed by your healthcare professional, then exhale normally.

7.2 FACE-MASK TREATMENT

Place the mask over the nose and mouth and adjust it for a close, comfortable fit. Breathe normally. Avoid directing aerosol toward the eyes. After treatment, wash the face with water to remove medicine residue.

THERMAL PROTECTION AND DUTY CYCLE

The AHG-900 is rated for intermittent operation: a maximum of 30 minutes ON followed by at least 30 minutes OFF.

The compressor has a thermal protector that automatically stops the motor before overheating.

38. Switch the device off.
39. Unplug it from the mains outlet.
40. Check that the air openings are not blocked.
41. Allow the compressor to cool for at least 30 minutes.
42. Restart only after the unit has cooled.

If thermal protection operates repeatedly during normal use, discontinue use and contact an authorized service provider.

AFTER EACH TREATMENT

43. Switch off and unplug the device.
44. Disconnect the air tube from the nebulizer.
45. Disassemble the nebulizer cup.
46. Discard remaining medicine according to the medicine instructions and local requirements.
47. Clean the reusable parts immediately.
48. Allow all parts to air-dry completely before reassembly or storage.

Warning: Cross-contamination

The nebulizer cup, mouthpiece and masks are reusable by a single patient only. Never share them between patients.

10.1 Compressor

Remove the air tube and unplug the device. Wipe the exterior with a soft cloth lightly moistened with water or mild detergent. Dry immediately with a clean, soft cloth. Do not immerse the compressor and do not use abrasive cleaners or solvents.

10.2 After every treatment

49. Disassemble the nebulizer cup.
50. Rinse the nebulizer cup, mouthpiece and masks (but not the air tube) under warm potable running water.
51. Wash them in warm water with a small amount of mild dishwashing detergent.
52. Rinse thoroughly with clean potable water.
53. Shake off excess water and place the parts on a clean, lint-free cloth.
54. Allow all parts to air-dry completely before reassembly.

10.3 Daily disinfection

Once each day, after the final treatment, disinfect the nebulizer cup, mouthpiece and silicone masks by boiling them in clean water for 5 minutes. Use enough water to keep the parts fully immersed and prevent contact with the bottom of an empty pan.

Remove carefully, allow to cool, shake off excess water and air-dry completely on a clean, lint-free cloth.

Notice: Do not disinfect the air tube

Do not boil, autoclave, microwave or immerse the air tube. If condensation is present, disconnect the nebulizer and run the compressor with the tube attached until the inside of the tube is dry.

Do not use bleach, abrasive cleaners, strong solvents, a dishwasher, microwave or autoclave on any part unless specifically authorized by the manufacturer.

AIR FILTER

Do not operate the compressor without an air filter.

Replace the filter every 30 days or sooner if it becomes gray, discolored, wet or visibly contaminated.

55. Switch off and unplug the device.
56. Remove the air-filter cover.
57. Remove and discard the used filter.
58. Insert a new genuine AHG-900 compatible air filter.
59. Reinstall the filter cover securely.

Do not wash the filter. Do not substitute cotton, foam or filters intended for another device.

MAINTENANCE, REPLACEMENT INTERVALS AND SERVICE LIFE

ITEM	CARE	REPLACEMENT INTERVAL
Compressor exterior	Wipe clean	After each day of use / as needed
Nebulizer cup	Clean after each use; disinfect daily	Replace every 6 months or sooner if damaged
Mouthpiece	Clean after each use; disinfect daily	Replace every 6 months or sooner if damaged
Adult / pediatric mask	Clean after each use; disinfect daily	Replace every 6 months or sooner if damaged
Air tube	Inspect and dry as needed	Replace every 12 months or sooner if cracked/contaminated
Air tube	Inspect	Replace every 30 days or sooner if discolored
Power cord	Inspect	Before each use

Expected service life of the compressor: 5 years when used and maintained according to these Instructions for Use.

There are no user-serviceable parts inside the compressor. Repairs must be performed only by the manufacturer or an authorized service center.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	WHAT TO DO
Device does not switch on	Not plugged in; wall outlet not powered; thermal protector active	Check connections and outlet. If recently used, switch off, unplug and cool for 30 minutes.
No mist	No medicine; incorrect assembly; tube disconnected; nebulizer blocked	Add medicine, reassemble, reconnect tube and clean nebulizer.
Weak mist	Filter dirty; tube kinked; nebulizer partly blocked; cup tilted	Replace filter, straighten tube, clean nebulizer, keep cup upright.
Device stops during treatment	Timer completed or thermal protector activated	Check timer. If overheated, unplug and cool for 30 minutes.
Unusual noise or vibration	Unstable surface or blocked air openings	Move to a flat surface and clear openings.
Water droplets in air tube	Condensation	Detach nebulizer and run compressor with tube attached until dry.
Filter is gray/discolored	Filter due for replacement	Replace with a new AHG-900 filter.
Smoke, burning smell, unusual heat	Possible internal fault	Disconnect immediately and stop using the device. Contact service.

TECHNICAL SPECIFICATIONS

PARAMETER	SPECIFICATION
Model	AHG-900
Rated supply	120 V~ 60 Hz
Power consumption	200 VA
Compressor flow	>= 8 L/min
Medicine container capacity	2-8 mL
Particle size range	0.5-6 μ m
MMAD	< 5 μ m
Average nebulization rate	>= 0.2 mL/min
Residual volume	<= 1 mL
Sound pressure level	< 63 dB(A)
Maximum compressor pressure	>= 206 kPa (>= 30 psi)
Nebulizer operating pressure	55-90 kPa (8-13 psi)
Operating temperature	10-40 °C (50-104 °F)
Operating humidity	15-90% RH
Operating atmospheric pressure	700-1060 hPa (70-106 kPa)
Storage temperature	-25 to 55 °C (-13 to 131 °F)
Storage humidity	10-95% RH, non-condensing
Storage atmospheric pressure	700-1060 hPa (70-106 kPa)
Dimensions (L x W x H)	198 × 185 × 202 mm (7.8 × 7.3 × 8.0 in)
Weight	1.83 kg (4.0 lb)
Ingress protection	IP21
Electrical protection	Class II
Applied part	Type BF
Mode of operation	Intermittent: 30 min ON / 30 min OFF
Expected service life	5 years

AEROSOL PERFORMANCE

Aerosol performance is determined according to the manufacturer's validated ISO 27427 test method. Performance can vary with the medicine formulation, fill volume, temperature and operating conditions.

PARAMETER	SPECIFICATION
Particle size range	0.5-6 μm
MMAD	< 5 μm
Average nebulization rate	$\geq$ 0.2 mL/min
Residual volume	$\leq$ 1 mL
Test fill volume	2-8 mL, according to validated test protocol
Test solution	0.9% sodium chloride solution
Measurement method	Validated aerosol-performance method per ISO 27427

Suspensions and higher-viscosity medicines may produce different aerosol output, output rate and particle-size distribution.

STORAGE AND TRANSPORT

Store the device and accessories in a clean, dry place within the storage limits stated in Section 14. Keep away from direct sunlight, excessive heat, freezing conditions outside the specified range, moisture, corrosive chemicals and excessive dust.

If the device has been stored near the temperature limits, allow it to return to room temperature before use. Protect the compressor from shock and impact during transport.

ACCESSORIES AND REPLACEMENT PARTS

DESCRIPTION	ORDER REFERENCE
Complete nebulizer kit	AHG-900-NEB
Nebulizer cup	AHG-900-CUP
Mouthpiece	AHG-900-MP
Adult mask	AHG-900-AM
Pediatric mask	AHG-900-PM
Air tube	AHG-900-TUBE
Air filter, pack of 5	AHG-900-FLT
Power cord	AHG-900-PC-US

Use only the accessories listed above or accessories specifically approved by the manufacturer for the AHG-900.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The AHG-900 complies with the applicable requirements of IEC 60601-1-2 for medical electrical equipment. Use the device according to the EMC information below.

Warning: Portable RF equipment

Portable RF communications equipment, including peripherals such as antenna cables and external antennas, should be used no closer than 30 cm (12 in) to any part of the AHG-900, including cables specified by the manufacturer. Otherwise, degradation of performance could result.

Warning: Adjacent or stacked use

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, verify that both devices operate normally.

Warning: Accessories and cables

Use of accessories and cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity.

Essential performance: delivery of compressed-air output sufficient to generate the specified nebulized aerosol. If electromagnetic disturbance causes the compressor to stop or aerosol output to fall, switch the device off, move it away from the interference source and restart the treatment.

ELECTROMAGNETIC COMPATIBILITY (EMC)

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
RF emissions - CISPR 11	Group 1	The AHG-900 uses RF energy only for internal functions.
RF emissions - CISPR 11	Class B	Suitable for domestic and professional healthcare environments.
Harmonic emissions - IEC 61000-3-2	Class A	Complies.
Voltage fluctuations/-flicker - IEC 61000-3-3	Complies	Complies.

Immunity test levels and RF wireless communications proximity-field values must be maintained in the controlled EMC annex from the current AHG-900 IEC 60601-1-2 verification report. The obsolete Edition 3 separation-distance table is not used.

SYMBOLS USED ON THE DEVICE AND LABELING

SYMBOL	EXPLANATION
	Identifies the medical-device manufacturer.
	Indicates the date the device was manufactured.
REF	Catalogue/model number.
SN	Serial number.
LOT	Lot/batch number.
MD	Not used as an EU-specific regulatory symbol on the U.S. labeling.
	Read the Instructions for Use before operating the device.
	Indicates information requiring attention for safe use.
	Patient-contact applied part classification.
	Double-insulated electrical equipment.
IP21	Protected against access to hazardous parts by fingers and against vertically falling water drops.
	Permitted storage/transport temperature range.
	Permitted humidity range.
	Permitted pressure range.
	Protect from moisture.
Rx ONLY	Federal prescription-device restriction.

DISPOSAL

Dispose of the AHG-900 in accordance with applicable federal, state and local electronic-waste requirements. Do not treat EU WEEE labeling as a U.S. regulatory requirement.

Dispose of used accessories according to applicable local healthcare or household-waste requirements. Dispose of unused or expired medication through appropriate pharmacy or local pharmaceutical-waste channels.

SERVICE, SUPPORT AND WARRANTY

There are no user-serviceable parts inside the compressor. If a fault persists after troubleshooting, contact an authorized service provider.

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Warranty:

Lifetime International Warranty, subject to the applicable AHG warranty terms and exclusions supplied with the product. Consumable accessories and damage resulting from misuse, unauthorized modification or use of non-approved parts are excluded to the extent permitted by law.

APPLICABLE STANDARDS AND REGULATORY FRAMEWORK

- 21 CFR Part 801 - Labeling
- 21 CFR Part 830 - Unique Device Identification
- 21 CFR Part 820 - Quality Management System Regulation (QMSR), effective February 2, 2026
- IEC 60601-1 - Medical electrical equipment - General requirements for basic safety and essential performance
- IEC 60601-1-2 - Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 - Requirements for medical electrical equipment used in the home healthcare environment
- ISO 15223-1 - Symbols to be used with information to be supplied by the manufacturer
- ISO 27427 - Nebulizing systems and components



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