



## Nebulizer Kit

### User Manual

**Model:**

A-DA01

**PLEASE NOTE:**

THE MEDICAL DEVICE MUST BE USED ACCORDING TO USER MANUAL.

**CE** 0123

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Table 1: Diagram of nebulizer kit

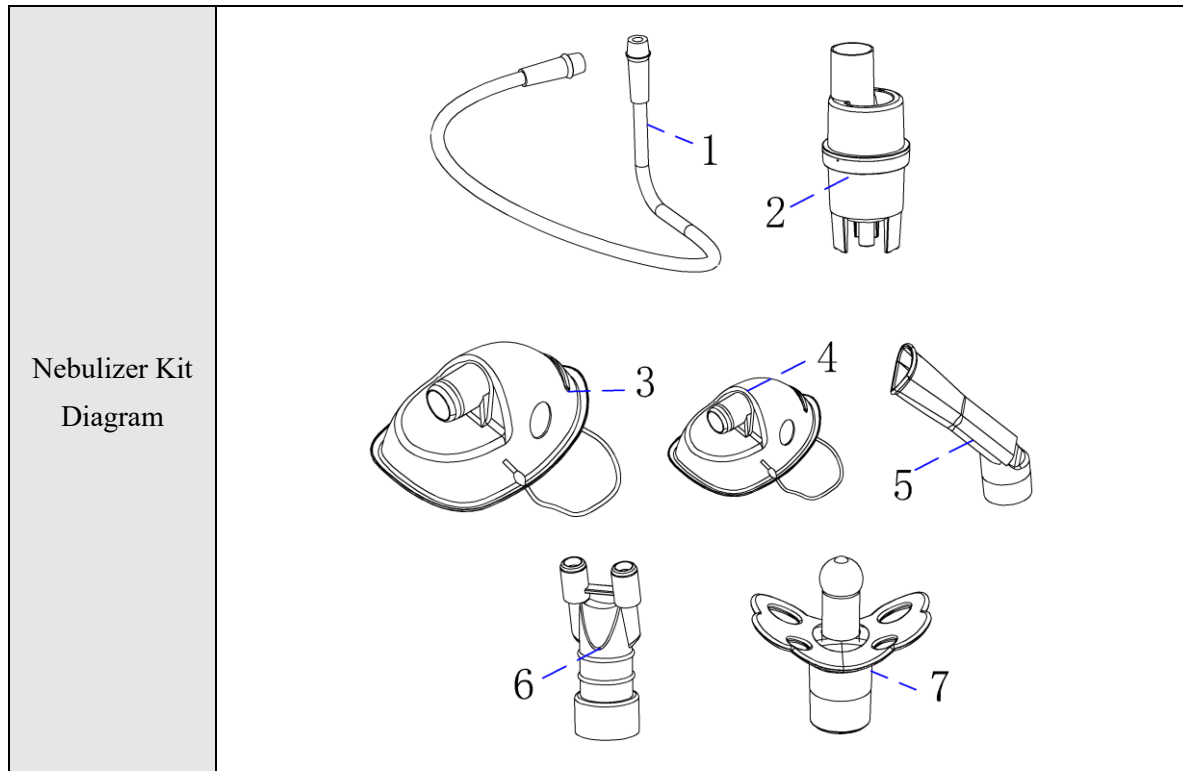


Table 2: Description of the number in the product diagram above

No.	Description	No.	Description	No.	Description
1	Tube	2	Nebulizer	3	Adult mask
4	Child mask	5	Mouthpiece	6	Nasal inhaler
7	Pacifier inhaler component				

**Note:** Model A-DA01 Nebulizer Kit is manufactured by Shenzhen Aeon Technology Co., Ltd.

## 1 Safety

### 1.1 Important Safety Instruction Read before Use

The following basic safety precautions should always be taken.

- (1) Close supervision is necessary when the product is used by, on, or near children, handicapped persons or invalids.
- (2) Use the product only for the intended use described in this manual.
- (3) Do not use the product if it is not working properly, or if it has suffered any damage.

### 1.2 Caution and Warning

- (1) Read all instructions carefully before use. And follow the method specified in the

manual. The following basic precautions are needed when using an electrical product.





- (2) Only use the parts and accessories manufactured by the original manufacturer or meet the requirements of the instructions, otherwise it may increase the emission of the product or reduce the immunity. If the damage is caused by the use of accessories or parts that do not meet the requirements, the warranty will not be given.
- (3) If the product fails, please refer to this manual. If the failure cannot be eliminated, please contact an authorized service center for repair.
- (4) Connect in order, otherwise the nebulizer effect will be affected.
- (5) If the product is damaged or cracked, please do not use it.
- (6) To avoid the risk of suffocation, please keep children away from and touch the packaging. The product should be stored out of children's reach. Children should be supervised by an adult.
- (7) Do not use the product near flammable gas, oxygen, or anesthetic mixture.
- (8) Do not use the product near high-frequency electromagnetic transmitters.
- (9) Do not use the product in the shower or bath.
- (10) Do not store the product under direct sunlight, high temperature or humidity.
- (11) If you have diabetes or other diseases, please consult the corresponding doctor before using the product.
- (12) Be careful with tube, which is prone to strangulation.
- (13) Do not inhale or swallow small parts.
- (14) Prevent children from accidental contact with this device.
- (15) Do not use single-use contactable materials more than once, as this may cause allergic reactions.
- (16) Before starting treatment, please consult your doctor about the duration of use, dosage of medication, frequency of treatment, etc.
- (17) If there are contusions, burns, inflammations, wounds or sensitive parts, please consult the corresponding doctor before using the product.
- (18) In the process of using the product, if you feel unwell, please stop using it immediately and consult the corresponding doctor.
- (19) When using the product, please do not use it close to or stacked with other equipment.
- (20) Please remove all packaging materials before use, and confirm that the parts and accessories of the product are complete.
- (21) If there is no liquid medicine in the nebulizer, do not operate the equipment.
- (22) When using, keep the nebulizer as vertical as possible. A slight swing will not affect the






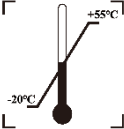

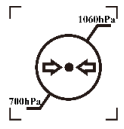



use. Please do not move the unit during use.

- (23) The nebulizer kit connected compressor nebulizer is legally marketed in the EU, works better when used with the compressor nebulizer manufactured by Shenzhen Aeon Technology Co., Ltd.
- (24) The nebulizer kit is disposable, single-patient-use, so that cross-infection or the transmission of harmful substances can be avoided.
- (25) Please consult the corresponding doctor before using any medicinal products or drugs to ensure that they select the appropriate medicinal products for you.
- (26) It is not suitable for viscous medicines, volatile oils and oily medicines, as this may cause damage to the nebulizer.
- (27) Nebulized drugs do not contain bacteriostatic agents and cannot be stored in the nebulizer for a long time, they need to be used immediately after opening. The dosage of each nebulization should be recommended by the doctor, the volume is too large to cause too long nebulization time affecting the compliance of children and other users.
- (28) If your physician prescribes more than one nebulizer at the same time, please pay attention to whether different nebulizers can be mixed.
- (29) Avoid excessive eating 30 min before nebulization treatment, and do not apply oily creams before the use of hormonal drugs.
- (30) Children should be nebulized in a quiet state, the best choice of sitting position, for those who cannot take the sitting position, the head should be elevated and 30° with the chest, and young children can be semi-sitting position.
- (31) Clean the face in time after nebulization to remove the drugs attached to the face. Immediately gargle with water for 3 times or more, and spit out the gargle. For child who cannot gargle, use a cotton swab to wipe the mouth for care.

### 1.3 Definitions and Symbols

Table 3: Symbol and Description

Symbol	Description	Symbol	Description
	Indicates the item is a medical device		Indicates a carry that contains unique device identifier information
	Indicates the manufacturer's serial number so that a specific medical device can be identified		Indicates the date after which the medical device is not to be used

Symbol	Description	Symbol	Description
	Indicates the medical device manufacturer		Indicates the date when the medical device was manufactured
	Indicates a medical device that is intended for one single use only		Follow the instructions for use
	Type BF Equipment	<b>IP22</b>	Anti-dust & Anti-water class
<b>CE</b> <sub>0123</sub>	Notified Body with identification no.	<b>EC REP</b>	Indicates the authorized representative in the European Community/European Union
	Indicates the temperature limits to which the medical device can be safely exposed		Indicates the range of humidity to which the medical device can be safely exposed
	Indicates the range of atmospheric pressure to which the medical device can be safely ex-posed		Upward
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences		Symbol for When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling
<b>Note</b>	The important information you should know.		

## 2 Introduction

The nebulizer kit is a small volume jet nebulizer designed to deliver aerosolized medications for inhalation to the respiratory system, the compressed air is forced into the nebulizer through a nozzle cover, where it accelerates and emerges at a high velocity, creating a vacuum (Venturi effect), in the process the liquid medicine is converted into small droplets called aerosol by impacting upon a rigid baffle, the aerosol may be used for inhalation treatment of a physician's prescription. The excited medicine forms an aerosol that passes through the mouthpiece or mask and can be inhaled by the patient. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a

patient using a Small Volume Nebulizer. Nebulizer kit include Tube, Nebulizer, Adult Mask, Child Mask, Mouthpiece, Nasal Inhaler, Pacifier Inhaler Component. We encourage you to thoroughly read this guidebook to learn about the features of this product. Any use of this product other than its intended use should always be avoided.

## **2.1 Intended Use**

The nebulizer kit is intended to cooperate with compressor to aerosolize physician-prescribed medication for inhalation. It is designed for use with children and adult patients in hospital, clinic, or home environments.

## **2.2 Indications**

Cystic Fibrosis, chronic obstructive lung disease, pneumonia, respiratory tract disease, respiratory tract infection.

## **2.3 Contraindications**

- (1) Do not use for patients who are unconscious or are not breathing spontaneously.
- (2) Do not use for patients with acute pulmonary edema.
- (3) Do not use for patients who have completely lost the ability to spontaneously expectorate.
- (4) Infants, premature neonate and newborns.
- (5) Pregnant or breastfeeding women.
- (6) Patient is allergic to aerosolized drugs.

## **2.4 Intended User**

Professional and lay person (under the guidance of professional)

## **2.5 Intended patients**

Adult, children with respiratory disorder such as Bronchiectasis, Bronchiolitis, COPD, Cystic Fibrosis, tracheostomy, other Obstructive or Interstitial lung diseases, Post lung transplant, Pulmonary Hypertension, Respiratory Infection.

## **2.6 Intended clinical benefit**

Indirect: Used in combination with compressor to aerosolize medications.

# **3 Operating the Nebulizer Kit**

- (1) Observe the buckles at the interface of the upper and lower shells of the nebulizer.

- (2) Rotate the upper shell of the nebulizer counterclockwise, turn the upper shell buckle to the bayonet and gently lift it to separate the upper and lower shells of the nebulizer.
- (3) After confirming that the small vertebrae are correctly placed in the nebulizer, inject the liquid medicine into the nebulizer.
- (4) Align the upper and lower shell positions of the nebulizer, and then rotate the upper shell of the nebulizer clockwise, and screw the upper shell buckle into the hole of the lower shell of the nebulizer.
- (5) Attach one end of the catheter to the bottom of the nebulizer by connecting it to the tube connection and the other end to the bottom of the nebulizer. The tube here can be clamped onto the main unit tube bayonet.
- (6) Connect one end of the tube to the tube connector of the unit, and the other end to the bottom of the nebulizer. The tube here can be clamped to the tube bayonet of the unit.
- (7) Choose Mouthpiece, Mask, Nasal Inhaler or Pacifier Inhaler Component to be used on top of nebulizer.
- (8) Now you can breathe slowly and deeply, if you hold your breath for a short time after inhaling the medicine, you can increase the effect of the treatment.
- (9) During the treatment, keep quiet and relax, do not inhale too fast.
- (10) If you need to stop for a short time, you can take the mask out of your mouth/remove the mask, and put it on your mouth after resting/put on the mask to continue inhaling.
- (11) A single treatment should not take more than 30 minutes.
- (12) If there is a very small amount of medicine left in the nebulizer, press the power button to turn off the machine and stop inhaling.
- (13) End of treatment. Pour out the remaining medicine and don't use it again.
- (14) Dispose of used nebulizer kit in the trash.

## 4 Cleaning

The nebulizer kit is disposable, single-patient-use, discard when finished.

## 5 Troubleshooting

The nebulizer kit should be used by following the operation steps in the manual or using under the guidance of a doctor. Some common problems, faults and troubleshooting methods during the use of the equipment are shown in the following table:

Table 4: Troubleshooting

No.	Problems	Cause Analysis	Elimination method
1	No fog	<ol style="list-style-type: none"> <li>1. The way the device is held is incorrect</li> <li>2. The nebulizer is not installed</li> <li>3. The drug is not suitable</li> </ol>	<ol style="list-style-type: none"> <li>1. Reinstall the nebulizer and its components</li> <li>2. Too little medicine or not suitable for using the device (please consult your doctor for what medicine to use)</li> <li>3. The way the device is held is incorrect</li> <li>4. Please contact authorized repair center or manufacturer</li> </ol>
2	Foggy	<ol style="list-style-type: none"> <li>1. Abrasion of the vertebral body of the nebulizer</li> <li>2. The drug is not suitable</li> </ol>	<ol style="list-style-type: none"> <li>1. Replace the nebulizer</li> <li>2. Too little medicine or not suitable for using the device (please consult your doctor for what medicine to use)</li> <li>3. Please contact an authorized repair center or manufacturer</li> </ol>
3	Which drugs are suitable for nebulization	Consult a doctor	It is recommended to use medication under the guidance of a doctor

Notice: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## 6 Specifications

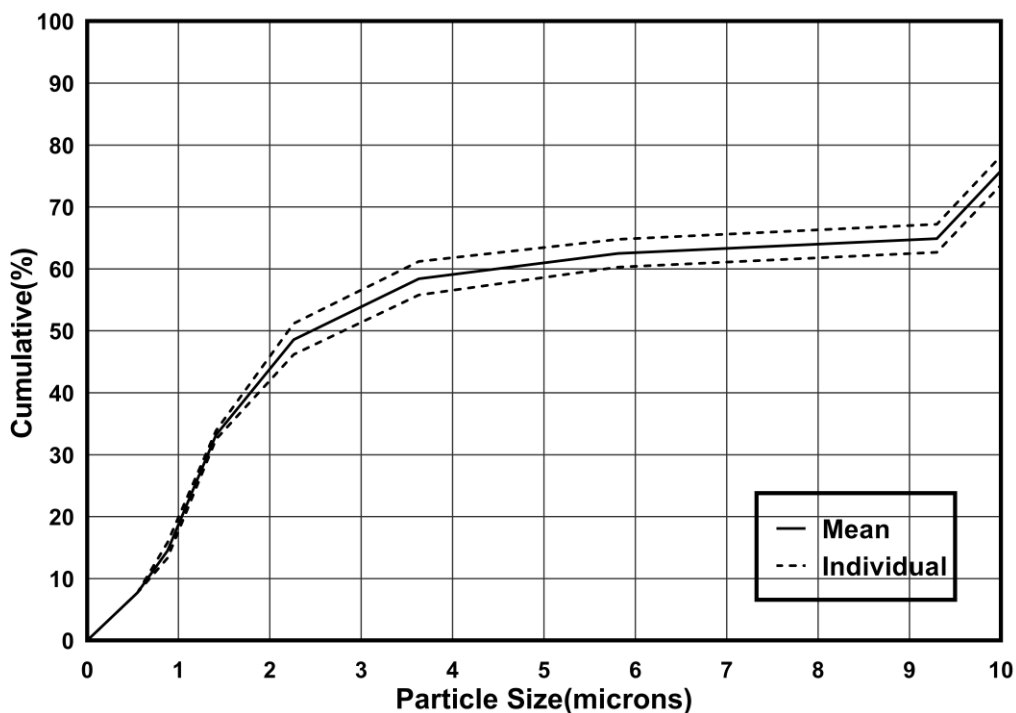
Table 5: Nebulizer kit specification

Maximum fill volume	6mL ± 2mL
Aerosol Output Range and Accuracy	Range: ≥ 3.0 L/min
	Accuracy: ±10% of the value shown
Aerosol Output Rate	0.2 mL/min – 0.4 mL/min
Residual Volume	≤ 0.8mL
Mass median aerodynamic diameter (MMAD)	2.01µm~4.89µm
Maximum Noise	Around 60 dB(A)
Max Temperature of Liquid in The Nebulizer	≤ 40°C

Applied Parts	Adult Mask, Child Mask, Mouthpiece or Nasal Inhaler, Pacifier Inhaler Component as BF type Applied Parts
Service Life	Disposable, single-patient-use.
Shelf Life	2 years
Operating Environment	Temperature: +5°C to +40°C (+41°F to +104°F)
	Humidity: 25% to 93% RH (non-condensing)
	Air Pressure: 700hPa-1060hPa
Transport and Storage Environment	Temperature: -20°C to +55°C (-4°F to +131°F)
	Humidity: 25% to 93% RH (non-condensing)
	Air Pressure: 700hPa-1060hPa
Set	Standard set: Tube, Nebulizer, Adult Mask, Child Mask, Mouthpiece
	Optional set: Nasal Inhaler, Pacifier Inhaler Component

Particle Characterization per Cascade Impactor using Albuterol Sulfate for particle size:

**Cumulative% particle mass of Albuterol Sulfate**



AEON nebulizer kit independently measured by Piper Medical, Inc, California, according to ISO 27427 Annex C and D, using albuterol sulfate, ipratropium bromide, and cromolyn sodium. It may vary with the type of medication.

Notes:

- Subject to technical modification without prior notice.
- The AEON compressor nebulizer is produced under the strict quality system of Shenzhen Aeon technology Co., Ltd., China.
- The device may not work if the temperature and voltage conditions are different to those defined in the specifications.
- The AEON nebulizer kit fulfils the provisions of the European Standard ISO 27427: Anaesthetic and respiratory equipment - Nebulizing systems and components.
- Performance may vary with drugs such as suspensions or high viscosity. See drug supplier's data sheet for further details.
- Please contact your dealer for assistance with any other difficulties.

## 7 Compatible devices used in combination

Device name	Model	Specification	Manufacturer
Compressor Nebulizer	A500LWD01 A500LWDC01	Aerosol Output Range and Accuracy: Range: ≥ 3.0 L/min, accuracy: ±10% of the value shown; Aerosol Output Rate: 0.2 mL/min – 0.4 mL/min	Shenzhen Aeon Technology Co., Ltd.
	A500LWD02 A500LWDC02	Aerosol Output Range and Accuracy: Range: ≥ 3.0 L/min, accuracy: ±10% of the value shown; Aerosol Output Rate: 0.2 mL/min – 0.4 mL/min	
	A500LWD04 A500LWDC04	Aerosol Output Range and Accuracy: Range: ≥ 3.0 L/min, accuracy: ±10% of the value shown; Aerosol Output Rate: 0.2 mL/min – 0.4 mL/min	
	A500LWD05 A500LWDC05	Aerosol Output Range and Accuracy: Range: ≥ 3.0 L/min, accuracy: ±10% of the value shown; Aerosol Output Rate: 0.2 mL/min – 0.4 mL/min	

## 8 Warranty

Before open the package, please check to ensure all components are complete. This nebulizer

kit is for single use only. The warranty period of the nebulizer kit is 6 months from the date of sale (see the package for manufacturing date). We will not provide free warranty service for the failure caused by the user's reasons as follows:

- Any damage caused by improper use, failure to operate in accordance with the requirements or transfer of the nebulizer kit to other users.
- Failure caused by dropping during use or handling.
- Failure to operate in accordance with the correct instructions in the user manual.

Repair service beyond warranty will be charged accordingly. After-sale service unit: Shenzhen Aeon Technology Co., Ltd.

## 9 WEEE explanation

Adhere to the applicable regulations when disposing of Nebulizer Kit. This device must not be disposed of together with domestic waste. The nebulizer kit should be processed according to the local law and regulations at the stage of its life expectancy.

