

VEGA TECHNOLOGIES INC.

INSTRUCTION MANUAL

Medical Nebulizer Kits

**Model: A, A01, A02, A03, A04, A05, A06, A07, A08, A09,
A10, A11, A12, A13, A14, A15, A17, A18, A19**

File Number: MDR-MNK-SPC001

Version/Revision No: 1.0

Date: November 01, 2022



(Read this instruction manual carefully before use)

Contents

1. Introduction	3
2. Safety precaution	9
3. Information for operation.....	10
4. Cleaning and maintenance	11
5. Service information	12
6. Disposal	12
7. Specifications table	13
8. Symbols and description	15
9. Contact information	16

1. Introduction

Thank you for purchasing the Medical Nebulizer Kits. It is intended to cooperate with compressor nebulizer to aerosolize physician-prescribed solutions for inhalation.

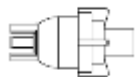

We encourage you to thoroughly read this guidebook to learn about the features of this product. Any use of this product other than its intended use should always be avoided.






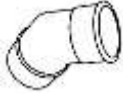
1.1 General description

Intended use	The Medical Nebulizer Kits are intended to cooperate with compressor nebulizer to aerosolize physician-prescribed solutions for inhalation.
Intended User	Professional and lay person (under the guidance of professional)
Intended patients	Adult, children, infant with respiratory disorder such as asthma, Bronchiectasis, Bronchiolitis, COPD, Cystic Fibrosis, tracheostomy, other Obstructive or Interstitial lung diseases, Post lung transplant, Pulmonary Hypertension, Respiratory Infection.
Indications	Cystic Fibrosis, chronic obstructive lung disease, pneumonia, respiratory tract disease, respiratory tract infection.
Contraindications	<ol style="list-style-type: none">1. This product should not be used on patients, who are unconscious or are not breathing spontaneously.2. Pregnant or breastfeeding women.3. Patient is allergic to aerosolized drugs.4. Patient with asthma.

	<p>5. Pentamidine powder and suspension.</p> <p>6. Anesthetics agent.</p>
Clinical benefit	Convey drug droplet for inhalation.
Intended Environment	This device is intended for use in a medical facility, such as hospital, clinic and doctor office, and in a room of general household.
Precautions for use	Warnings and cautions described in the instruction manual should be observed
Solutions used for nebulization	<p>β2 agonists: Salbutamol/Albuterol Sulfate;</p> <p>Antimuscarinics: Ipratropium Bromide;</p> <p>Corticosteroids: Budesonide, Fluticasone;</p> <p>Combination drug: Ipratropium Bromide and Albuterol Sulfate;</p> <p>Mucoactive Drugs: Normal saline, Hypertonic saline, Dornase alpha /Dnase;</p> <p>Antibiotics: Colistimethate Sodium.</p>

1.2 Product identification

		Model
Nebulizer Bottle		CNK-M03
Air Tube		CNK-S01

Mouthpiece		CNK-M06
Nosepiece		CUK-M04
Adult Mask		CUK-M01
Child Mask		CUK-M02
Infant Mask		CNK-M14
Connector		CUK-S01

Model	Consist of
A	Includes: Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Nose piece (model: CUK-M04) , Mouth piece (model: CNK-M06) , Child mask (model: CUK-M02) , Adult mask (model: CUK-M01) , Infant mask (model: CNK-M14) , Connector (model: CUK-S01)
A01	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Mouth piece (model: CNK-M06) , Nose piece (model: CUK-M04) , Adult mask (model: CUK-M01) , Child mask (model: CUK-M02)
A02	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Mouth piece (model: CNK-M06) , Nose piece (model: CUK-M04) ,

	Adult mask (model: CUK-M01) , Infant mask (model: CNK-M14)
A03	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Mouth piece (model: CNK-M06) , Adult mask (model: CUK-M01) , Child mask (model: CUK-M02)
A04	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Mouth piece (model: CNK-M06) , Adult mask (model: CUK-M01)
A05	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Mouth piece (model: CNK-M06) , Child mask (model: CUK-M02)
A06	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Adult mask (model: CUK-M01)
A07	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Child mask (model: CUK-M02)
A08	Includes : Nebulizer bottle (model : CNK-M03) , Mouth piece (model: CNK-M06) , Nose piece (model: CUK-M04)
A09	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01) , Mouth piece (model: CNK-M06)
A10	Includes : Nebulizer bottle (model : CNK-M03) , Air tube (model: CNK-S01)
A11	Includes : Adult mask (model: CUK-M01) , Child mask (model: CUK-M02)
A12	Includes : Nebulizer bottle (model : CNK-M03)
A13	Includes : Child mask (model: CUK-M02)
A14	Includes: Adult mask (model: CUK-M01)
A15	Includes: Nose piece (model: CUK-M04)

A17	Includes: Air tube (model: CNK-S01)
A18	Includes: Mouth piece (model: CNK-M06)
A19	Includes: Infant mask (model: CNK-M14)

1.3 Description of other device intended to be used in combination

Model	CN-01W	CN-01WA	CN-01WB	CN-01WC	CN-01WD
photograph					
Model	CN-01WG	CN-01WH	CN-01WI	CN-01WK	CN-02WL
photograph					
Model	CN-02WP	CN-02WW	CN-02WZ	CN-02WR	CN-02WU
photograph					
Model	CN-02WX	CN-02WM	CN-02WK	CN-02WG	CN-01WJ
photograph					
Model	CN-02MX	CN-01WE	CN-01MI	CN-02WA	CN-02WC
photograph					

Model	CN-02WD	CN-02WJ	CN-02MB	CN-02MD	CN-02MH
photograph					
Model	CN-02MJ	CN-02MK	CN-02MN	CN-02MO	CN-02MU
photograph					
Model	CN-02MY	CN-12WA	CN-02WB	CN-02MC	CN-02MR
photograph					
Model	CN-12MA	CN-12ME	CN-01MD	CN-01MF	CN-02WV
photograph					
Model	CN-02MF	CN-02MI	CN-02MT	CN-02WN	CN-02ME
photograph					
Model	CN-02MG	CN-02MV	CN-02WE	CN-02WF	CN-02WH
photograph					

Model	CN-02WI	CN-02WO	CN-02WS	CN-02WY	CN-01MN
photograph					

2. Safety precaution

Read all the information in the instruction manual and any other literature included in the box before using the device.



Warning:

Indicates a potentially hazardous situation which if not avoided, could result in serious injury.

(Usage)

- 1) For type, dose, and regime of medication, follow the instructions of your doctor or respiratory therapist.
- 2) The long air tube of this product may cause strangulation of the user if use in wrong way.
- 3) Do not use accessories, detachable parts and materials not described in the instructions for use.
- 4) Do not use in an oxygen rich environment.
- 5) Do not interconnect this device with other equipment not described in the instructions for use.
- 6) If you feel anything unusual during use, please stop using the device immediately and consult your doctor.
- 7) Do not use only water in the Nebulizer Bottle for inhaling purposes.
- 8) Keep the device out of the reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.

- 9) Do not use the device while sleeping or sleepy.
- 10) Store the device in a clean location, make sure that the device is clean before use.
- 11) Do not store the Air Tube while there is moisture or medication remaining inside it.
- 12) Do not use the device where it may be exposed to flammable gas.
- 13) Always dispose of any remaining medication after use and only use fresh medication each time.
- 14) Do not leave the device unattended with infants or person who cannot express their consent.
- 15) Do not reuse on more than one patient.

General safety precautions:

- 1) Inspect the device and parts before using them each time, and check that there are not problems. In particular, be sure to check the following:
 - The Nebulizer Bottle and Air Tube are not damaged.
- 2) Operate the device only as intended. Do not use the device for any other purpose.

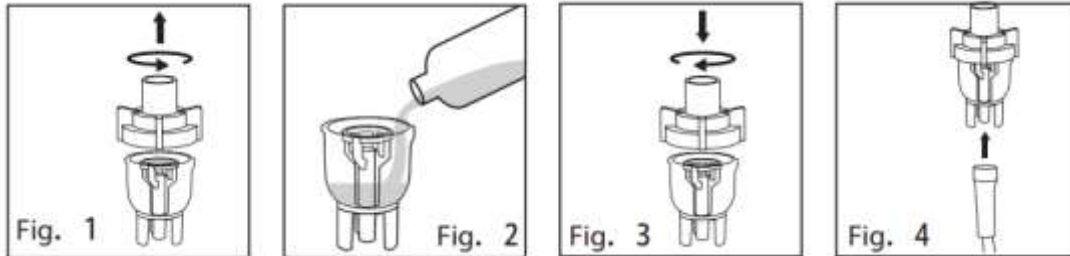
3. Information for operation

3.1 Installation and operation procedure

Important: Prior to initial operation, the device should be thoroughly cleaned referring to the “Cleaning and Maintenance” in the manual.

- 1) Gently twist the top cover of the Nebulizer Bottle counter-clockwise to disassemble the Nebulizer Bottle.(Fig.1)
- 2) Fill the cup base of the Nebulizer Bottle with the medication prescribed by your physician.(Fig.2)

- 3) Gently twist the top cover clockwise to re-assemble the Nebulizer Bottle. Be sure the two sections fit well.(Fig.3)
- 4) Attach one end of Air Tube to the cup base of the Nebulizer Bottle.(Fig.4)



- 5) Attach the other end of Air Tube to the tube connector located on the front of the Compressor Nebulizer.
- 6) Attach one of inhalation device per your choice to the top cover of Nebulizer Bottle, but Infant Mask need to add Connector between mask and Nebulizer Bottle.

Remark: Inhalation device is Mouthpiece, Nosepiece, Adult Mask, Child Mask, Infant Mask.

- 7) Power on Compressor Nebulizer to begin your prescribed treatment.

4. Cleaning and maintenance

Cleaning:

It is recommended to clean the Medical Nebulizer Kits after each use unless there are other instructions by your doctor.

- 1) Rinse the device with pure water;
- 2) Wipe dry the device with clean towel;
- 3) Ensure the device without residual water, then store it in a clean location.

5. Service information

Any abuse, operation other than the intended use of this product as outlined in the manual, negligence, accident, or repairs by someone other than a VEGA' s Authorized Service Professional, shall immediately void this warranty.

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. Disposal

The device and combination devices may come into contact with infectious material and be contaminated during their lifetime. For this reason, the device and its combination devices should be decontaminated before disposal or transportation.

Dispose of the device properly at the end of its service life. According to the European Regulation (EU) 2017/745 the device should not be disposed of with unsorted domestic waste. Look for a careful separation of materials. Consider the country-specific laws and regulations that apply to the disposal of the device. The proper disposal of the device prevents environmental and human damage.


















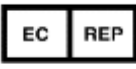




Outside the EU, the appropriate national regulations for disposal must be observed.

7. Specifications table

Device name	Medical Nebulizer Kits
Consist of	Nosepiece: CUK-M04 Mouthpiece: CNK-M06 Child Mask: CUK-M02 Adult Mask: CUK-M01 Nebulizer Bottle: CNK-M03

	Air Tube: CNK-S01 Infant Mask: CNK-M14 Connector: CUK-S01	
Type of nebulizer	Compressor nebulizer	
Physical property	Refer to MSDS report of raw material in Attachment 3 of folder 01 Device description and specification including variants and accessories	
Chemical property	Refer to MSDS report of raw material in Attachment 3 of folder 01 Device description and specification including variants and accessories	
Performance	MMAD: 5 um	
Recommended fill volume	2 to 5 ml	
Nebulization rate	≥0. 20 ml/min. (0.9% salt water solution)	
Applied part	Type BF Mouthpiece Nosepiece Adult/child/ Infant mask	
Device Lifetime	300 times use	
Device shelf-life	One year	
Operating environment	Ambient temperature	5°C ~ 40°C (41°F ~ 104°F)
	Relative humidity	15% ~ 90%
	Atmospheric pressure	70KPa ~ 106KPa
Storage environment	Ambient temperature	-25°C ~ 70°C (-13°F ~ 158°F)
	Relative humidity	0% ~ 90%
	Atmospheric pressure	70KPa ~ 106KPa

8. Symbols and description

	Refer to instruction manual/booklet		Manufacturer
	Batch code		Date of manufacture
	Serial number		Use-by date
	Type BF applied part		Caution
	Keep away from sunlight		Temperature limitation
	Humidity limitation		Non-sterile
	Single patient multiple use		Keep away from rain
	This device complies with the requirements of Regulation (EU) 745/2017		Quantity
	This way up		Authorized representative
	Fragile; handle with care		Atmospheric pressure limitation
	The symbol indicating separate collection for EEE		Medical Device

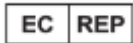
9. Contact information

Vega Technologies Inc.

No.505, Shengping Mid.Road, Yangwu, Dalang Town, 523789
Dongguan City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA



Website: www.vegamedical.com



MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany



Made by:

刘佳

Approved by:

张宗隆