Instruction Manual

Product name: Nebulizer Accessory kit

Model: NAK-SJ-001，NAK-SJ-002

1. Explanation of Symbols

Symbols	Meaning	Symbols	Meaning
	Consult instructions for use		Authorized Representative in the European Union
	Manufacturer		Caution
	Complies with the European Medical Device Regulation (2017/745. Notified Body is SGS.		DATE OF MANUFACTURE
	Use-by date		Non-sterile
	Importer		Waste products should be recycled according to local regulations
	Keep dry		Batch Code
	Medical device		Unique device identifier

2. Product introduction

2.1 Models and Components

The device includes 2 models, and the differences of the 2 models include components and material:

Models	Component and Material
NAK-SJ-001	Nebulizer cup (PP+SAN), Air tube (PVC), Child mask (PVC), Adult mask (PVC), Mouthpiece (PP) + Nosepiece (PP)
NAK-SJ-002	Nebulizer cup (PP+PP), Air tube (PVC), Child mask (PVC), Adult mask (PVC), Mouthpiece (PP) + Nosepiece (PP)

2.2 Intended use

The device is used to atomize the drug using airflow generated by the compressed gas and delivers it to the respiratory tract for inhalation therapy of the respiratory atomized drug. It is

intended for use at home or medical institute.

2.3 Indications:

The nebulizer kit is suitable for the delivery of aerosol medications delivery that meet hospital and subacute requirements.

2.4 Target population

a) Age: 2years old to adult.

b) Health: Patients who need inhalation therapy.

2.5 Intended users

a) Legally certified medical experts, such as doctor, nurse and therapist, or healthcare personnel or patient under the guidance of qualified medical experts.

b) The user should also be capable of understanding general operation of compressor nebulizer and the content of the instruction manual.

2.6 Contraindication

No.

2.7 Side effects

The product has no known side effects.

2.8 Clinical benefits:

Medicine aerosol delivery

2.9 Combined equipment

This device is usually used with an Air Compressor which meet the requirements of EN 13544-2-2002+A1-2009 for connection interface size. The gas flow rate of the Air Compressing Nebulizer should be⩾5 L/min, and the pressure range should be 60kPa~130kPa.

3. Method of use

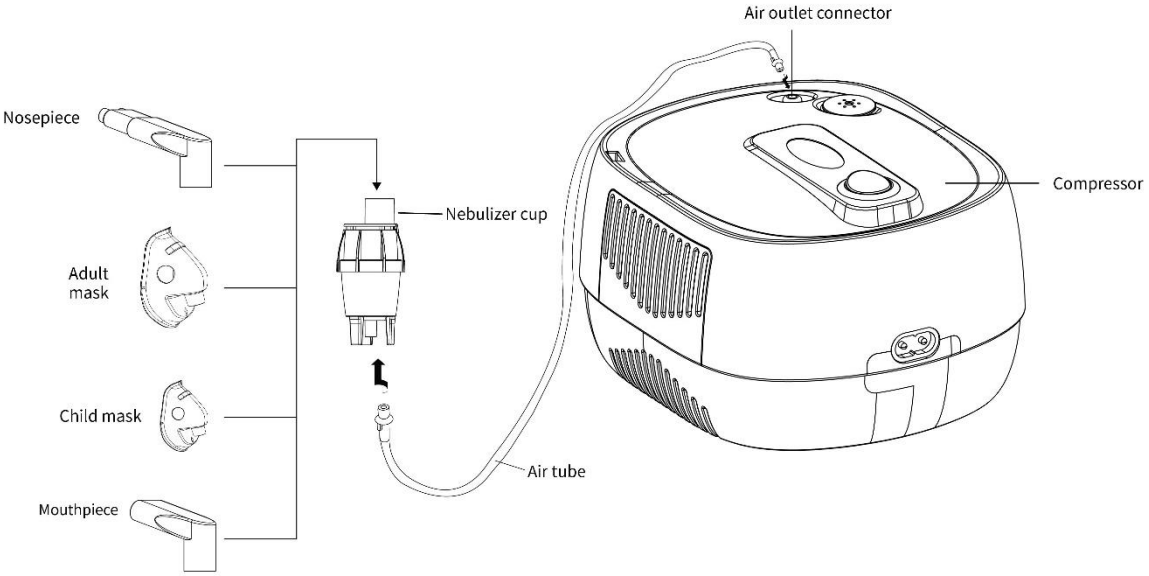
Caution

Check all product assemblies and accessories before use. Replace any damaged, deformed or badly faded parts. The nebulizer cup must be changed if it gets clogged. The damaged components and / or the wrong assembling may impair the nebulizer kits function, thereby weakening the quality effect.

For safety reasons, the device can only be used by single patient. The nebulizer kits is only suitable for approved drugs that can be used for inhalation therapy. Pay attention to any restrictions in the instructions on the use of the relevant drugs.

1) Filling the nebulize medication into the nebulizer cup;
2) Connect one end of the air tube with the air source, and connect the other end with the air inlet of the nebulizer cup (Compressor output max pressure ≥200KPa, Free flow≥10 l/min; outlet connector outside diameter: Ø 6.5~7.0mm，length size≥12mm) ;

3) The mask (or mouthpiece/nosepiece) is installed at the outlet on the top of the nebulizer cup;
4) Put on the mask (or mouthpiece/nosepiece) to open the compressor switch and start treatment.
The assembly diagram is as follows:



4. Others

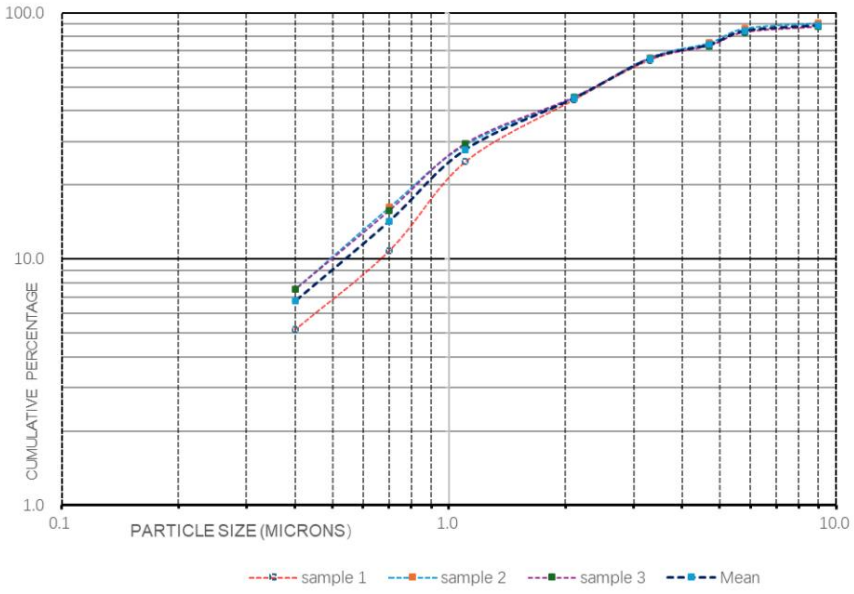
4.1 Technical data

Model / Data	NAK-SJ-001	NAK-SJ-002
Diameter distribution of particles produced by nebulizer:	The proportion of particles with diameters of ≤ 5μm is more than 76.95%.	The proportion of particles with diameters of ≤ 5μm is more than 77.97%.
Aerosol Output Rate:	0.096mg/min (5ml, Albuterol 0.1%(M/) concentration in 0.9 % sodium).	0.089mg/min (5ml, Albuterol 0.1%(M/) concentration in 0.9 % sodium).
Aerosol Output	1.345 ml (5ml Albuterol 0.1%(M/V) concentration in 0.9 % sodium M/V)	1.553 ml (5ml Albuterol 0.1%(M/V) concentration in 0.9 % sodium M/V)
Appropriate Medication Quantities	2ml minimum -6ml maximum	2ml minimum -6ml maximum
Particle size distribution	*MMAD * approximately 2.4μm	*MMAD * approximately 2.5μm
Geometric standard deviation	2.778	2.767
Operation conditions	+5℃ to + 40℃，30% R.H. to 85% R.H.	

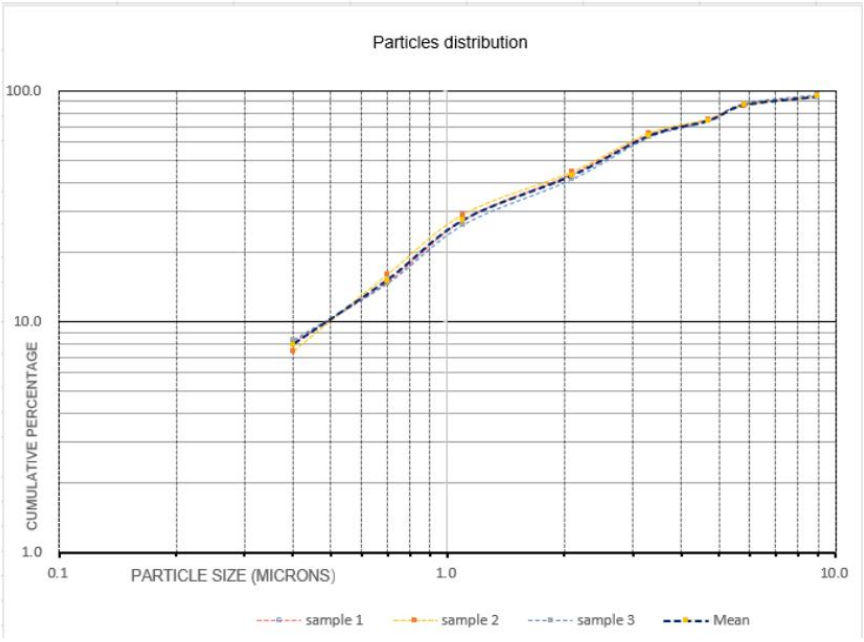
Storage conditions	-20℃~60℃,10%R.H.~93%R.H
Shelf life	3years

4.2 Nebulizer the particle size distribution curve as well

Result of cascade impactor measurements for particle size



NAK-SJ-001 MMAD = Mass Median Aerodynamic Diameter



NAK-SJ-002 MMAD = Mass Median Aerodynamic Diameter

The tests were carried out according to ISO 27427:2023 by Shenzhen bi-rich medical device co, Ltd. at the SGS-CSTC Standards Technical Services Co., Ltd. According to ISO 27427:2023 testing.

5. Important safety instructions

1)Should be used under the guidance of a doctor.
2)The injection volume of nebulizer medication liquid shall not exceed the maximum scale range marked on the nebulizer cup.
3)Follow the doctor's advice when using inhaled medicine.
4)The nebulizer cup should be kept upright as far as possible, and the tilt range should not exceed 30°.
5)Children or people without self-conscious ability should not use it without adult supervision.
6)This product shall not be used in respiratory anesthesia system or ventilator system.
7)Narcotic drugs or mixtures thereof shall not be used for nebulization.
8)Do not use suspension or high concentration of liquid medicine and follow the doctor's advice in special cases.
9)Avoid using it in dark, damp or dusty environments.
10)Avoid contact with infants or mental patients.

6. Maintenance methods, storage and transportation conditions

1)The product should be stored in a room with humidity less than 80%, no pollution, no corrosive gas and good ventilation.
2)During transportation, it should prevent impact, violent vibration, moisture and excessive compression. It can be transported by ordinary means of transportation. During transportation, it should prevent impact, violent vibration, moisture and excessive compression.

7. Cleaning and Disinfecting

1)Thoroughly clean all components to remove medication residuals and possible impurities after each treatment.
2)Before and after each treatment need to cleaning, one or twice a week,the nebulizer kit should be disinfected.
TO CLEAN: Cleaning the nebulizer parts with dish detergent and water. Disassemble mouthpiece, nebulizer cup or mask and wash this item in water with dish-washing detergent Rinse these items thoroughly to remove the detergent.

 The nebulizer cup, mask and tube must not be boiled.

3)TO DISINFECT: Disinfect with the following options:
Soak in 70% isopropyl alcohol for 5 min.
Soak in 3% hydrogen peroxider for 30 min.
4)Rinse with sterile water.
5)Air-dry thoroughly prior to storage.

8. Warning:

-During inhalation therapy，children, and anyone in need must be taken care of by adults. This is the only way to ensure safe and effective treatment. Individuals who belong to this group often

underestimate the risks associated with it (such as choking on power cords or connecting tubes), thereby bringing risk of injury.

-The product contains small parts. Small parts can clog up the respiratory tract and cause choking risk. Therefore, make sure young children are kept out of contact with compressors, nebulizer cups, and accessories.

-The nebulizer kit is only suitable for self-breathing and conscious patients. This is the only way to ensure effective treatment and avoid choking risk.

- 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.

-This product should not be used by patients, who are unconscious or are not breathing spontaneously.

-Use with caution if you are allergic to polyvinyl chloride or polypropylene.

9. Contact information

For all product information and for any defects of product, please contact us:

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