User Manual

Piston compressor Nebulizer

Serial number: REFJLN-S0XA Version: A/0

Issued date: 2014-10 -12

1 Description and Intended use

Dear Client,

First of all we wish to thank you for choosing our products and congratulate you on your choice of JLN-S0xA series piston compressor nebulizers, which are easy-to-use and extremely reliable. They are a kind of compact medical devices designed to efficiently convert the medication suspension or high concentration medicine solutions into an aerosol of microscopic droplets and deliver them into the bronchus and lungs. It is intended for use in the treatment of asthma, COPD and other respiratory diseases for which an aerosolized medication is required during therapy. The device is for pediatric and adult population, and wildly used in hospitals and health care institutions.

The user manual is suitable for models of JLN-S01A, JLN-S02A, JLN-S03A, JLN-S04 A, JLN-S05A, JLN-S06A, which have the same intended use and technical specifications, only the shape of enclosures are different.

2 Warnings and Precautions

Warnings

- For type, dose and regime of medication follow the instructions of your physician or licensed healthcare practitioner.
- Do not modify this equipment without authorization of the manufacturer.
- Do not cover the compressor with a blanket, towel, or any other type of cover during use, which could result in the compressor overheating or malfunctioning.
- Do not use the device in anesthetic breathing systems or lung ventilator breathing systems.
- The device is not compatible with the use of oxygen and oxygen mixtures, and is not compatible between oxygen and administrated drugs.
- Do not use the device where it may be exposed to flammable gas or vapors.
- Provide close supervision when this device is used by, on or near infants, children or compromised individuals.
- Keep the device out of the reach of unsupervised infants, children and physiological disable people.
- Do not insert any object into the compressor.
- Do not block the air filter cover.
- Do not add more than 8ml of medication to the medication cup.
- Do not operate the device if the motor is at temperature greater than 120℃.
- Do not use the device if the solution temperature greater than 40℃ when used in the max flow rate.
- Do not dismantle or attempt to repair the device or components.
- Use only HOMED authorized parts and accessories, parts and accessories which are not approved for use with the device may damage the unit.
- Do not immerse the main unit in water or other liquid.
- Do not use the device for transposable use with solutions.
- Do not leave the cleaning solution in the medication cup, rinse the nebulizer parts with clean water and dry it after disinfecting.
- Do not use the nebulizer parts if the package is broken at first use, change another one.

- Do not use the device continuously for longer than 45minutes.

Precautions

- Make sure Flexible tubing, Atomizer and mask/mouthpiece are correctly assembled, the air filter is properly installed.
- Always unplug the power cord from the electrical outlet before cleaning the device.
- Always unplug the power cord from the electrical outlet after using the device.
- Always dispose of any remaining medication in the medication cup after each use, and use fresh medication each time you use the device.
- Clean, disinfect the device according to the method demonstrated in this manual after each use.
- Inspect the main unit and the nebulizer parts each time before using, make sure no parts are damaged.
- The nebulizer parts are designed for single use, reusing them among different people may result in cross-contamination.

3 Device information and Content information

Your JLN-S0xA series nebulizer comes with the following components:

- Main Unit (Compressor)
- Two nebulizer cups (one standard one and one COPD cup)
- Flexible tubing
- Adult mask
- Child mask
- Mouthpiece
- User Manual
- Five Air Filters
- One power adaptor

Main Unit and Component

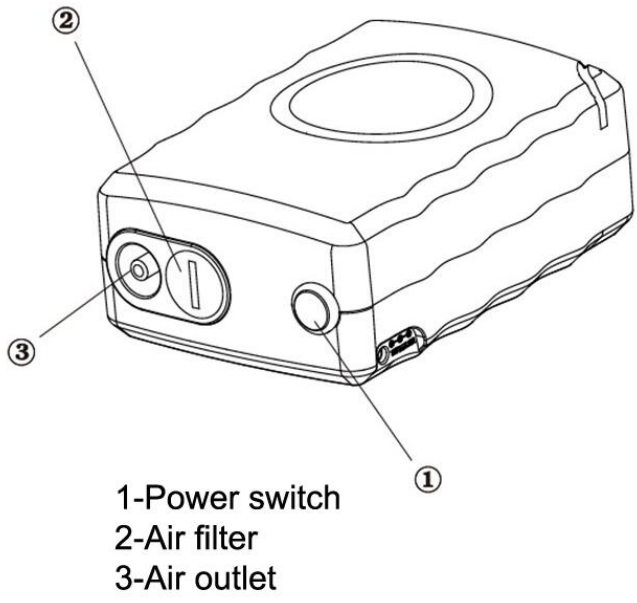


Figure 1-Main Unit

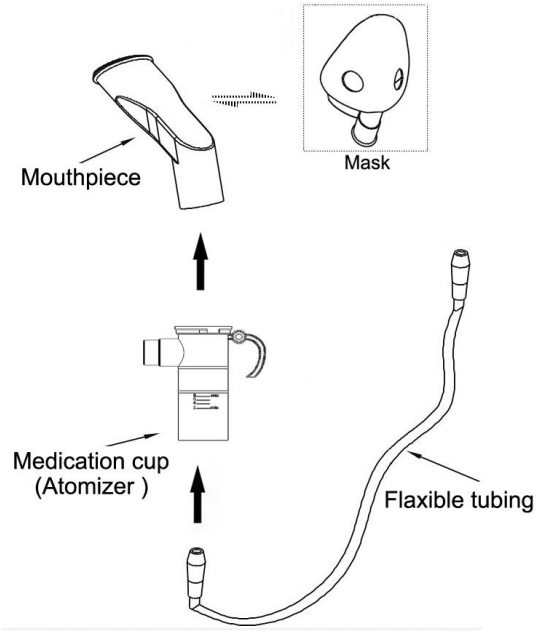


Figure 2-Component (nebulizer parts)

Statement: The parts in table above are required for correct function and that they have to be in compliance with

this European Standard.

Handling

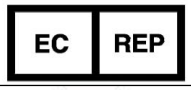
The shipping container has been designed to assure protection of this device, if the device is to be reshipped by common carrier, it should be packed in the same carton.

Information of power adaptor

Input: AC100-240V 50/60HZ, 1.0A max

Output: 12V, 1.25A

4 Description of symbols

Symbol	Explanation
	Manufacturer
	Authorised representative in the European Community
	Lot Number
	Serial Number
	Date of Manufacture
	Caution,
	Waste Electrical and Electronic Equipment (WEEE)
	The CE conformity marking
	Refer to the instructions
	Type B applied part
	Class II equipment

5 Operating Instructions

Firstly: Ensure the device and all the accessories are completely clean, please follow instructions below step-by-step:

- Place the device on a level and secure surface (ex. a table top) with easy access to an electrical socket.
- Unwind the power supply cord by cutting the plastic tie that holds it folded.
- Take the flexible tubing and attach one end to the device's air outlet and the other end to the bottom of the atomizer.
- Unscrew the upper section of the atomizer by turning it anti-clockwise.
- Put the medication to be nebulised into the atomizer, measuring it according to the scale marked on the side of the atomizer.

- Replace the upper section of the atomizer, securing it by turning it clockwise.
- According to the type of treatment you wish to carry out and the method you choose, attach either the face mask or the mouthpiece to the upper section of the atomizer.

Secondly: Your device is now ready for use to carry out aerosol therapy treatment.

- Plug your device into a socket of the correct voltage.
- Press the switch of the device to position 1.
- Start the treatment and carry on for as long as you can still see the “mist” produced by the nebulisation of the medication performed by the device.

Note: The presence of a small amount (about 0.4 ml) of medication in the atomizer at the end of each treatment is absolutely normal. This amount, called residue volume, cannot be nebulised.

Thirdly: at the end of each treatment:

- Turn off the device by pressing its switch to position 0.
- Unplug the device from the power socket.
- Wind up the power supply cord and place it sideways inside the appropriate panel (exactly as it was before use).
- Detach the face mask (or mouthpiece) from the atomizer.
- Detach the flexible tubing from both the atomizer and the device's air outlet.
- Wipe the face mask (or mouthpiece) and the atomizer clean according to the instructions in the following paragraph.

To ensure maximum efficiency and life-span of your device

While your nebulizer does not need any special care, you should:

- Avoid knocking it or dropping it;
- Store it in a suitable place, away from excessive heat, direct sunlight, damp and dust;
- Clean it with a slightly damp cloth and/or mild detergent (do not use benzine, thinners or similar substances), and dry it carefully and thoroughly;
- Never soak the device in water;
- After each treatment, it is advisable to clean the used accessories in the correct way.
- All you need to do is unscrew the upper section of the atomizer and wash it thoroughly in running water; the same should be done to whatever was attached to the chamber (adult face mask or mouthpiece). Should you wish to disinfect these accessories, you may use a cold solution as advised by your doctor.

Note: Each time clean/disinfect the nebulizer parts, please reassemble them according to the order in Figure 2.

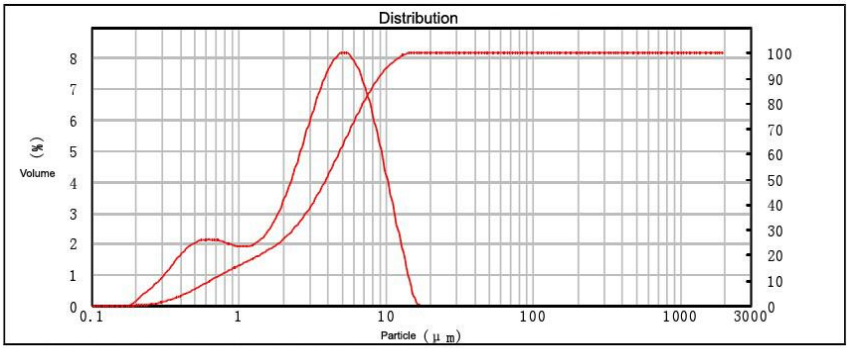
Note: The compressor motor has a thermal protector which will shut off the unit before the unit is overheated. When the thermal protector shuts the unit off, please:

- Switch off the unit.
- Unplug the unit from the electrical outlet.
- Wait 30 minutes for the motor to cool down before another treatment. Make sure the air openings are not obstructed.
- When treatment is finished, shut off the unit and unplug it from the electrical outlet.

Statement: Performance information provided by the manufacturer in accordance with this European Standard may not apply to drugs supplied in suspension or high viscosity form. In such cases, information should be sought from the drug supplier.

6 Particle distribution diagram

The following table is particle distribution diagram, the test particles are respective NaCl, Muscle Protein, Gentamicin and Dexamethasone.



Particle distribution diagram of NaCl,

7 Cleaning and Disinfection

Cleaning

- All the accessoies is for single use and need not cleaning.
- Rinsing (after each treatment)
- Disconnect the air tube, nebulizer, mouthpiece and mask.
- Gently twist the nebulizer to open it.
- Rinse the nebulizer, mouthpiece and mask with water.
- Dry them with clean soft towel or let it air dry.
- Reassemble the nebulizer when completely dry and put these parts in a dry, sealed container.

Disinfections

Please follow the following steps to disinfect your nebulizer unless otherwise specified by your physician. It is suggested that the unit is disinfected after the last treatment.

1, Use one part white vinegar with three parts distilled water. Make sure mixed solution is enough to submerge the nebulizer, mouthpiece and mask.
2, Disconnect the flexible tubing, atomizer, mouthpiece or mask.
3, Remove the baffle carefully.
4, Wash nebulizer, mouthpiece and mask in warm water and a mild detergent. Then rinse them in hot tap water.
5, Submerge these parts in the vinegar and distilled water solution for thirty minutes.
6, Remove the parts and discard the solution, rinse the parts with hot tap water.
7, Hand dry or air dry in a clean environment using a soft, clean, lint-free cloth.
8, Assemble the nebulizer and keep it in a clean, dry bag.

Cleaning the compressor

- Wipe daily with a damp cloth.
- Do not use any powdered cleaners or soap pads, which may damage the finish.

Filter change

We strongly suggest that you change the air filter every 15/20 treatments, or when the filter appears grey in color. Change the filter, you will need to:

- Take off the cover of the compartment which houses the air filter;
- Remove the old filter and insert a new one;
- Replace the cover.
- Do not use cotton or any other materials. Do not wash or clean the filter. Use only filters provided by HOMED and don't operate without a filter.

8 Technical specifications

- The maximum A-weighted sound pressure level: less than 55dBA
- Motor: Compact piston compressor BD80 CX
- Power supply: AC 100-240V 50/60Hz
- Working pressure: Without tube and atomizer: 70 Kpa -100 Kpa/0.7-1bar; with tube and atomizer: at least 0.19Mpa
- Air flow: 8.0 l/min
- Air filter included
- Maximum nebulizing rate: ≥0.15ml/min
- Operating Temperature Range: 50℉ to 104℉ (10℃ to 40℃)
- Operating Humidity Range: 10 to 95% RH
- Storage Temperature Range: -40℃ to 70℃
- Storage Humidity Range: 10 to 95 % RH
-Transportation conditions: -40℃-70℃, 10%-95％RH
- Dimension: 95 x 135 x 55 mm
- Weight: 425 g
- Waterproof degree: IPX0
- Degree of safety in the presence of flammable anesthetics or oxygen: No AP/APG (Not suitable for use in the presence of flammable anesthetice or oxygen)

9 EMC information

This medical device manufactured by HOMED conforms to this EN60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

Note: Do not use mobile (cellular) telephones and other devices which generate strong electrical or electromagnetic fields, near the medical device.

This may result in incorrect operation of the unit and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter. See the table 9.1 to table 9.4 in the following:

Table 9.1 Electromagnetic emissions

JLN-S0xA series piston compressor nebulizers are intended for use in the electromagnetic environment specified below; The customer or the user should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	JLN-S0xA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	

Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 9.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
JLN-S0xA is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 9.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
JLN-S0xA is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of JLN-S0xA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which JLN-S0xA is used exceeds the applicable RF compliance level above, JLN-S0xA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating JLN-S0xA

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 9.4 Electromagnetic Immunity

JLN-S0xA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and JLN-S0xA as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10 Troubleshooting

Problem	Probable cause	Solution
Excessive noise with the device	No filter	Reload a filter
The device doer not operate	Power off	Power on
	Not clean the cup last time	Clean the cup
	Tube bends	Unbend the tube
	Filter blocks	Replace a new filter
	No medication liquid	Add the appropriate medication liquid into the cup
	Inhalation top or baffle does not screw well	Screw it well
Excessive water drops attached inside the tubing wall	Too much medication liquid loaded	Remove some liquid by tool, until the liquid line down to the 8ml scale mark.

11 Warranty and Validity

Validity of Main Unit: Two years

Validity of Nebulizer parts: single use

The legal provisions in this respect apply. The warranty is limited to detective material and workmanship. Batteries and cable are not covered by the warranty, damage through misuse or modification is not covered. The warranty is only valid if the product has neither been opened nor subjected to violence or willful damage and it is return with the original receipt. Contact your dealer if you have any complaints. For further information contact the customers service (TeL: +86 0755 29821671/29821673/29821675, E-mail: sales-oe@systems.citizen.co.jp). In the event of warranty claims being deemed to be justified, the customer concerned will be supplied with a replacement product. The customer is only entitled to receive a comparable replacement product.

Caution: Instructions for a correct disposal of the product

Disposal requirement: Comply with WEEE directive, it must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

Shenzhen Homed Medical Device Co,.Ltd

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