User Manual
Nebulizer Accessories Kit

Serial number: REF JLX series
Version: A/4
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CE
2862

Read the instructions carefully before using the device

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1 Description and Intended use

The series of Nebulizer Accessories Kits are composed of air tube, nebulizer and mask and/or mouthpiece, they are easy-to-use and reliable. The devices designed to efficiently convert the medication suspension or high concentration medicine solutions into an aerosol of microscopic droplets, driven by the forces of airflow generated from nebulizer.

We have 15 series of Nebulizer Accessories Kits, which named JLA, JLB, JLC, JLD, JLE, JLF, JLG, JLH, JLI, JLK, JLL, JLM, JLN, JLO and JLQ series, they possess the same nebulizing mechanism, the difference between these series is the shape of the nebulizer. Each of them has 3 different configurations: big mask （adult）, mall mask(child）and mouthpiece, that is, 45 choice in total, you can free choose. There is also no difference in working principle, main functions, structures, performance among all models.

1.1 Intended use/Indication for use

The Nebulizer Accessories Kit is intended to convert the medicine solutions or other liquids into an aerosol of microscopic droplets, which are useful in the treatment of asthma, COPD and other respiratory ailments, it is applicable to match with Homed piston compressor nebulizer for use in hospitals and health care institutions. It is disposable and single-patient-use, and intended for use with pediatric and adult patient.

Shelf life for Nebulizer Accessories Kit: 3 years.

2 Contraindications, 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 device without authorization of the manufacturer.
- Provide close supervision when this device is used by, on or near infants, children or compromised individuals.
- Keep the kits away from the heat source.
- Do not add more than 8ml of medication to the medication cup.
- Do not use the device if the solution temperature greater than 40℃ when used in the max flow rate.
- Do not use the nebulizer parts if the package is damaged.
- Do not store the device out of the environmental conditions in this manual, it will cause material aging or function degeneration.
- The used product should be properly disposed according to the local legislations.
- The device is only used once time for single patient. It should also warn user to not share the nebulizer with other persons.
- Never use a nebulizer with a clogged nozzle. If the nozzle is clogged, no aerosol mist is produced which will affect the effectiveness of the treatment.
- Check the nebulizer of proper assembly. All parts should be seated firmly in place. Use of an improperly assembled nebulizer could prevent adequate delivery of medication.

Precautions

- Make sure air tube, nebulizer and mask/mouthpiece are correctly assembled.
- Inspect the kit each time before using, make sure no parts are damaged or beyond the expired date.
- The nebulizer parts are designed for single use, reusing them among different people may result in cross-contamination.

- User should be trained by the doctor or professional before use.

Contraindications

None.

3 Device information and Content information

Your JLX series Nebulizer Accessories Kits come with the following components:

- Nebulizer
- Air tube
- Big mask (adult type)
- Small mask (pediatric type)
- Mouthpiece

Components of the nebulizer kits

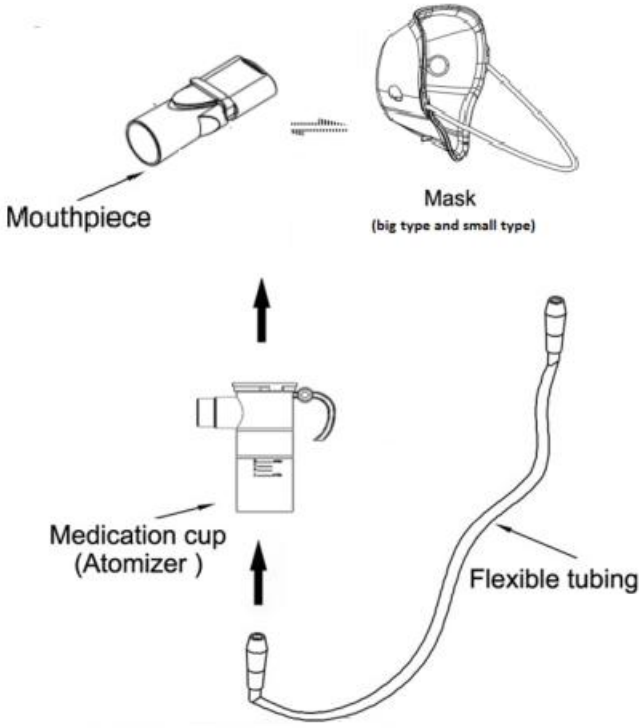
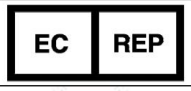


Figure 1-Nebulizer Accessories Kit (take JLA series for example)

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

4 Description of symbols

Symbol	Explanation
	Manufacturer
	Authorized representative in the European Community
	Lot Number
	Serial Number

	Date of Manufacture
	Use-by date
	Waste Electrical and Electronic Equipment (WEEE)
	Consult instructions for use
	The CE conformity marking
	DO NOT REUSE
	Do not use if package is damaged

5 Operating Instructions

Firstly: Ensure the kit is completely intact, please follow instructions below step-by-step, see figure 2:

a) Take the air tube and attach one end to the device's air outlet and the other end to the bottom of the nebulizer.

b) Unscrew the upper sector of the nebulizer by turning it anti-clockwise.

c) Pour the medications to be nebulized into the nebulizer, measuring it by following the scale marked on the side of the nebulizer.

d) Put the upper sector onto the nebulizer, securing it by turning it clockwise

e) Attach either the face mask or the mouthpiece to the upper section of the nebulizer, according to the type of treatment you wish to carry out and the method you choose.

f) Attach the mask on your mouth and nose, or put mouthpiece into your mouth, then breathe normally, until the medications are used up.

Note: The presence of a small amount (about 0.8 ml) of medication in the nebulizer at the end of each treatment is absolutely normal. This amount, called residue volume, cannot be nebulized.

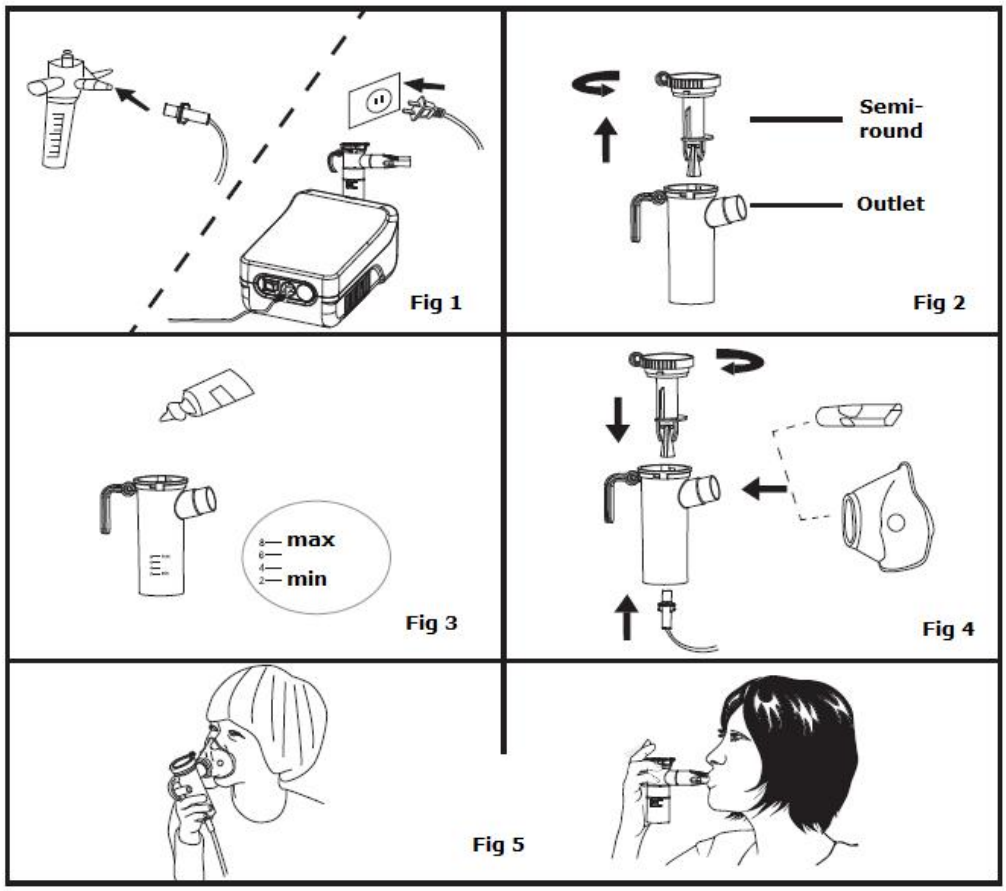


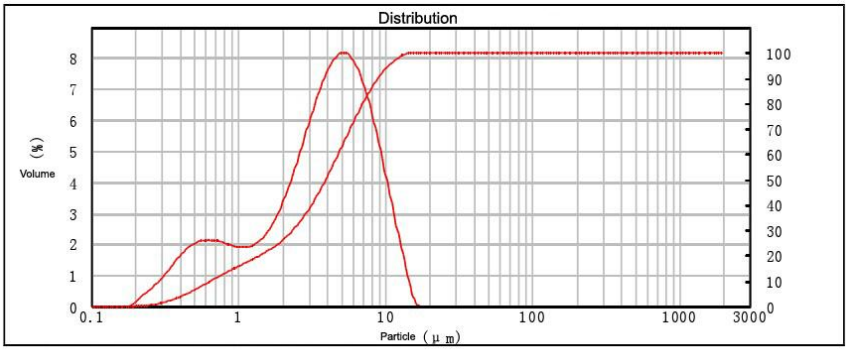
Figure 2: Diagram of using

Confirmation of connection firmness: The Nebulizer Accessories Kit are used in conjunction with air compressor, when the connection is completed according to the above method, apply a 45N tensile force at a point from the end of tubing along the linear axis of the tube, the tube with connector should not be detached from the nebulizer (medication cup) and air compressor, which can show the connection for accessories with nebulizer are fixed.

6 Particle distribution diagram

6.1 Particle distribution diagram

The following table is particle distribution diagram, the test particles are NaCl.



Particle distribution diagram of NaCl

6.2 Particulate distribution data

The basic solvent is albuterol 0.1% (M/V) concentration in 0.9% sodium chloride solution.

1) JLA series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	3.04%	2.35%
	>2 μm and <5 μm	76.44%	76.51%
	<2 μm	20.52%	21.14%
	<1 μm	2.81%	2.82%
MMAD		2.93μm	2.89μm
GSD		1.49	1.50
Respirable fraction (>0.5 μm and <5 μm) (%)		96.69%	97.31%
Aerosol output		85.32%	85.14%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.6%	>88.6%
Residual volume		<0.90ml	<0.90ml

2) JLB series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	14.37%	32.37%
	>2 μm and <5 μm	69.18%	54.05%
	<2 μm	16.45%	13.58%
	<1 μm	2.83%	3.02%
MMAD		3.45μm	4.20μm
GSD		1.58	1.69
Respirable fraction (>0.5 μm and <5 μm) (%)		85.18%	67.08%
Aerosol output		84.52%	85.36%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.4%	>88.4%
Residual volume		<0.91ml	<0.91ml

3) JLC series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	1.19%	10.52%
	>2 μm and <5 μm	64.09%	71.07%
	<2 μm	34.72%	18.41%
	<1 μm	6.91%	3.21%
MMAD		2.48μm	3.26μm
GSD		1.59	1.61
Respirable fraction (>0.5 μm and <5 μm) (%)		97.68%	88.85%
Aerosol output		86.56%	85.72%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.4%	>88.4%
Residual volume		<0.93ml	<0.93ml

4) JLD series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	0.00%	0.49%
	>2 μm and <5 μm	71.68%	23.89%
	<2 μm	28.32%	75.62%

	<1 μm	1.75%	2.88%
MMAD		2.37μm	2.68μm
GSD		1.35	1.45
Respirable fraction (>0.5 μm and <5 μm) (%)		99.08%	99.19%
Aerosol output		84.37%	84.98%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.4%	>88.4%
Residual volume		<0.93ml	<0.93ml

5) JLE series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	7.55%	23.51%
	>2 μm and <5 μm	75.32%	61.93%
	<2 μm	17.13%	14.56%
	<1 μm	2.47%	2.91%
MMAD		3.21μm	3.81μm
GSD		1.53	1.67
Respirable fraction (>0.5 μm and <5 μm) (%)		92.12%	75.92%
Aerosol output		85.35%	83.86%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>89.1%	>89.1%
Residual volume		<0.93ml	<0.93ml

6) JLF series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	31.92%	38.95%
	>2 μm and <5 μm	51.54%	46.53%
	<2 μm	16.54%	14.52%
	<1 μm	4.38%	3.87%
MMAD		4.15μm	4.57μm
GSD		1.83	1.87
Respirable fraction (>0.5 μm and <5 μm) (%)		67.03%	60.11%
Aerosol output		86.12%	85.51%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.7%	>88.7%
Residual volume		<0.88ml	<0.88ml

7) JLG series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	33.18%	31.97%
	>2 μm and <5 μm	52.61%	54.40%
	<2 μm	14.21%	13.63%
	<1 μm	3.29%	2.97%
MMAD		4.23μm	4.18μm
GSD		1.75	1.69
Respirable fraction (>0.5 μm and <5 μm) (%)		66.09%	67.41%
Aerosol output		85.64%	84.39%

Aerosol output rate	≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)	>88.4%	>88.4%
Residual volume	<0.91ml	<0.91ml

8) JLH series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	0.03%	0.15%
	>2 μm and <5 μm	76.12%	77.93%
	<2 μm	23.85%	21.92%
	<1 μm	2.00%	2.00%
MMAD		2.58μm	2.68μm
GSD		1.35	1.41
Respirable fraction (>0.5 μm and <5 μm) (%)		99.82%	99.19%
Aerosol output		84.27%	85.42%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>87.9%	>87.9%
Residual volume		<0.93ml	<0.93ml

9) JLI series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	39.76%	19.56%
	>2 μm and <5 μm	46.46%	65.30%
	<2 μm	13.78%	15.14%
	<1 μm	3.62%	2.84%
MMAD		4.62μm	3.65μm
GSD		1.80	1.61
Respirable fraction (>0.5 μm and <5 μm) (%)		59.61%	79.94%
Aerosol output		83.78%	85.24%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.4%	>88.4%
Residual volume		<0.97ml	<0.97ml

10) JLK series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	20.57%	27.80%
	>2 μm and <5 μm	62.55%	56.41%
	<2 μm	16.88%	15.79%
	<1 μm	3.52%	3.66%
MMAD		3.65μm	3.96μm
GSD		1.69	1.72
Respirable fraction (>0.5 μm and <5 μm) (%)		78.75%	71.42%
Aerosol output		84.34%	85.19%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.1%	>88.1%
Residual volume		<0.93ml	<0.93ml

11) JLL series：

Item	Facemask	Mouthpiece

Percentage of particulate distribution	>5 μm	5.42%	19.99%
	>2 μm and <5 μm	76.27%	65.27%
	<2 μm	18.31%	14.74%
	<1 μm	2.60%	2.71%
MMAD		3.09μm	3.68μm
GSD		1.56	1.63
Respirable fraction (>0.5 μm and <5 μm) (%)		94.27%	79.56%
Aerosol output		82.35%	84.28%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.0%	>88.0%
Residual volume		<0.96ml	<0.96ml

12) JLM series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	21.76%	9.31%
	>2 μm and <5 μm	62.41%	71.77%
	<2 μm	15.83%	18.92%
	<1 μm	3.15%	3.23%
MMAD		3.72μm	3.21μm
GSD		1.65	1.57
Respirable fraction (>0.5 μm and <5 μm) (%)		77.76%	90.18%
Aerosol output		85.34%	83.67%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.6%	>88.6%
Residual volume		<0.96ml	<0.96ml

13) JLN series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	11.89%	25.62%
	>2 μm and <5 μm	71.36%	60.04%
	<2 μm	16.75%	14.34%
	<1 μm	2.75%	2.84%
MMAD		3.36μm	3.90μm
GSD		1.56	1.67
Respirable fraction (>0.5 μm and <5 μm) (%)		87.73%	73.85%
Aerosol output		83.67%	85.25%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.0%	>88.0%
Residual volume		<0.91ml	<0.91ml

14) JLO series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	15.01%	24.43%
	>2 μm and <5 μm	51.42%	59.79%
	<2 μm	33.57%	15.78%
	<1 μm	11.79%	3.32%
MMAD		3.05μm	3.82μm

GSD	2.02	1.67
Respirable fraction (>0.5 μm and <5 μm) (%)	84.62%	74.92%
Aerosol output	85.31%	84.74%
Aerosol output rate	≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)	>88.5%	>88.5%
Residual volume	<0.96ml	<0.96ml

15) JLQ series：

Item		Facemask	Mouthpiece
Percentage of particulate distribution	>5 μm	20.53%	30.99%
	>2 μm and <5 μm	64.15%	53.47%
	<2 μm	15.32%	15.54%
	<1 μm	2.87%	3.71%
MMAD		3.69μm	4.11μm
GSD		1.61	1.76
Respirable fraction (>0.5 μm and <5 μm) (%)		78.96%	68.15%
Aerosol output		84.77%	85.38%
Aerosol output rate		≥0.2ml/min	≥0.2ml/min
Percentage of fill volume emitted (8ml)		>88.6%	>88.6%
Residual volume		<0.92ml	<0.92ml

7 Technical specifications

- Nebulizing rate: ≥0.2ml/min in air flow at 8L/min;
- Medication capability: 8ml;
- Operating Temperature Ranges: Comply with the requirements of piston compressor used;
- Operating Humidity & Air pressure Ranges: 10% to 95% RH, 70 kPa -150 kPa;
- Storage & Transportation Conditions: -20℃-55℃; 10% to 95 % RH; 70 kPa -150 kPa;

8 Warranty and Validity

Validity of Nebulizer Accessories Kit: single use

The legal provisions in this respect apply. The warranty is limited to detective material and workmanship. 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.

Address: 3rd Floor, Block 1, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District, Shenzhen 518109, People's Republic of China
TeL: 0755-29821671/29821673/29821675 Fax: 0755-29821673
Website: www.homedgroup.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175