Compressor Nebulizer

Instruction Manual

Model No.: BR-CN001

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1.Explanation of Symbols

Symbols	Meaning	Symbols	Meaning
	Follow instructions for use	|	ON
	Type-BF device	○	OFF
	Device class II (electric shock protection class).	IP21	Protection against solid foreign objects and harmful effects due to the ingress of water
SN	Serial number	EC REP	Authorized Representative in the European Union
	Manufacturer		Caution/Warning
CE 1639	Complies with the European Medical Device Regulation (2017/745. Notified Body is SGS.	~	Alternating Current
	Disposal in accordance with Directive 2002/96/EC (WEEE)		Indoor use only
	Upward		Fragile, handle with care
	Keep dry		Pile Limit 6 layers
MD	Medical device	UDI	Unique device identifier

2.Important safety instructions

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

⚠ **Caution:**Indicates a potentially hazardous situation which if not avoided, may result in minor or moderate injury, or physical damage.

⚠ **Caution:**

1).Federal Law restrict this device for sale or use on the order of a physician.

2).Follow the instruction of your physician to operate this unit.

3).This product is a nebulizer for the inhalation of medical aerosols and is suitable for children used solutions. Use only the type and amount of medication prescribed by patient’s doctor.

4).This product is intended for aerosol therapy only. And other use is not recommended.

5). Have not untwist the nebulizer during operation.

⚠ Warning: To Reduce the risk of electrocution.

1).Always unplug the unit immediately after using.

2).Do not use while bathing.

3).Do not place or store the unit where it can fall or be pulled into a tub or sink.

4).Do not place or drop into water or other liquid.

5).Do not reach for a product that has fallen into water .Unplug immediately.

⚠Warning :To Reduce the risk of burns, electrocution, fire or injury

1).Electrical Shock Hazard—do not open the cover.

2).Disconnect the power cord from the electrical outlet before cleaning or servicing.

3).Do not place this equipment near hot, sparking or burning objects.

4).Do not use oil or grease on or near this device.

5).Turn the unit off when it is not in use.

6).Keep the cord away from HEATED or HOT surfaces.

7.)NEVER drop or insert any object into any opening.

8).NEVER block the air openings of the product or place it on a soft surface ,such as a bed or couch, where the air openings may be blocked.

9).Avoid operating in wet or damp locations.

10).Unplug the unit before filling the nebulizer.

11).When using this product near TV, microwave oven ,pulse telephone X ray or other strong electric field, it will be disturbed, suggested to be far away from these device measuring.

⚠Warning: To reduce the risk of infection

1).This Nebulizer kit is intended single patient use.

2).Cleaning of the nebulizer is recommended after each aerosol treatment.disinfecting is recommended once a week. Please follow cleaning and disinfecting instructions in this manual.

3)This unit is not suitable for use in anaesthetic breathing systems

4)This unit is not suitable in suspension or high viscosity form. In such cases information should be sought from the drug supplier

3.Introduction

3.1 Intended use

This product is designed to deliver the prescribed medication solution to treat patient respiratory disorders ,The nebulizer converts the medication solution into an aerosolized mist which is inhaled by the patient through the mouthpiece or mask.

3.2 Patient population

a) Age: 2years old to geriatric

b) Health: Patients with respiratory diseases

c)PATIENT state: Treat patient respiratory disorders, such as asthma, allergies and bronchitis.

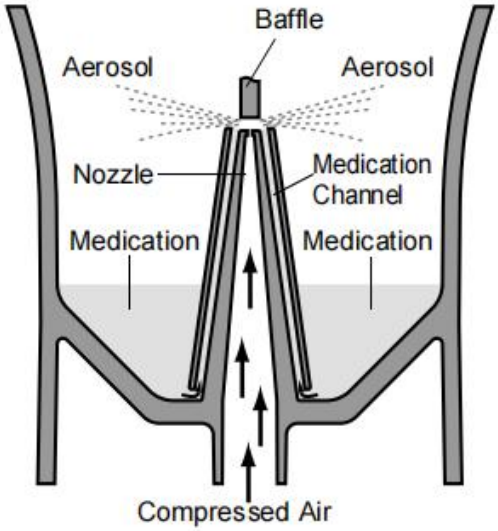
3.3 Intended users

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 instruction manual.

3.4 Operating Principle

The medication that is pumped up through the medication channel is mixed with compressed air which is generated by a compressor pump. The compressed air mixed with medication is tuned into fine particles and sprayed by being impacted to the baffle.



3.5 Contraindication

No

3.6 Side effect

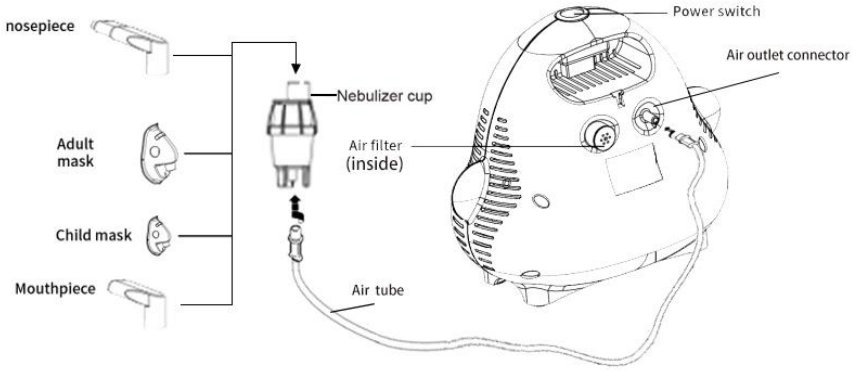
No

4.Specifications

Power supply	230VAC/ 50Hz
Power Consumption	≤ 0.7A
Operating pressure range	9~16 psi
Operating flow range	5~8 lpm
Max.pressure range	≥35 psi (241 kPa)
Nebulizer rate	0.37mL/min （by weight loss）
Particle size MMAD	approximately 3μm

Noise level	≤58 dB(A)　(at 1meter distance)
Maximum fill volume	6mL
Residual　volume	≤0. 5mL
Service life	3 years or 1000 h
Dimensions	Length 155mm × Width 140mm × Height 95mm
Weight	1.2kg
Shelf life of accessories(Medicine cup,mask,mouth piece/nosepiece)	N/A
Type of protection against electric shock	Class II
Degree of protection against electric shock	Type BF device
Mode of operation	Continuous operation
IP Class	IP21
Operating Temperature Range	5℃ to 40℃(41℉ to 104℉)
Operation Humidity Range	15% to 90%RH
Storage Temperature Range	-20℃ to +70℃(-4℉ to 158℉)
Storage Humidity Range	10% to 95%RH
Operating atmospheric pressure range	700～1060 hPa

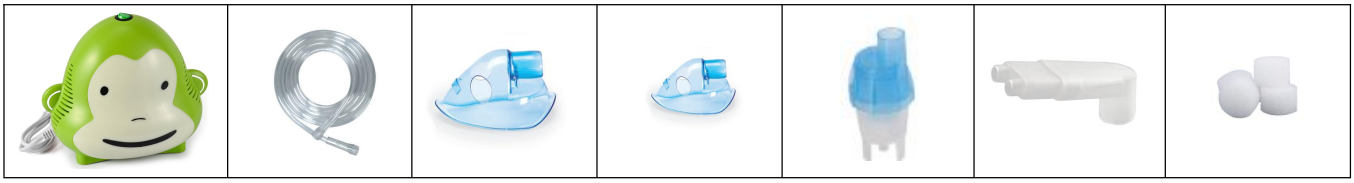
5.Description



The compressor nebulizer connected figure

6.Unit and Accessories

Compressor	Air tube	Adult mask	Child mask	Nebulizer cup	Mouthpiece + Nosepiece	Air filters



7.Operation Instructions

(1) Preparation and Usage of this Device Prior to using the device for the first time, we recommend cleaning it as described in the section “Cleaning and Disinfecting”.

(2) Assemble the nebulizer cup. Ensure that all parts are complete.

(3) Fill the nebulizer with the inhalation solution as per your doctor’s instructions. Ensure that you do not exceed the maximum level.

(4) Connect the nebulizer with the air tube to the compressor’s air outlet ,The mask or mouthpiece assemble with nebulizer cup and plug the power lead into the socket (230V 50 Hz AC).

- The mouthpiece gives you a better drug delivery to the lungs.

- Choose between adult or child face mask and make sure that it encloses the mouth and nose area completely.

(5) To start the treatment, set ON/OFF switch into the ”I” position.

(6) During inhalation, sit upright and relaxed at a table and not in an armchair, in order to avoid compressing your respiratory airways and impairing the treatment effectiveness. Do not lie down while inhaling. Stop inhalation if you feel unwell.

(7) After completing the inhalation period recommended by your doctor, switch the ON/OFF switch to position “O” to turn off the device and unplug it from the socket.

(8) Empty the remaining medication from the nebulizer cup and clean the device as described in the section “Cleaning and Disinfecting”.

⚠ **Caution:**

- The device requires no calibration.
- No modification to the device is permitted

8.Cleaning and Disinfecting

8.1 Cleaning the compressor

Thoroughly clean all components to remove medication residuals and possible impurities after each treatment.

(1) Use a soft and dry cloth with non-abrasive cleaners to clean the compressor.

(2) Make sure that the internal parts of the device are not in contact with liquids and that the power plug is disconnected.

8.2 Cleaning and disinfecting of the accessories

(1) Turn the power off and unplug from the wall outlet .

(2) Remove the air tube from the nebulizer cup and air outlet.

(3)TO CLEAN: Cleaning the nebulizer parts with dish detergent and water. Disassemble mouthpiece, nebulizer cup or mask and wash this items in water with dish-washing detergent Rinse these items thoroughly to remove the detergent .

(4)TO DISINFECT:

Soak in 70% isopropyl alcohol for 5 min.

Soak in 3% hydrogen peroxide for 30 min.

（5）Rinse with sterile water.

（6）Air-dry thoroughly prior to storage

There is no need to clean the air tube. If necessary wipe the surface regularly.

CAUTION:The nebulizer cup must be changed if it gets clogged.
CAUTION:Do not boil Air tube, nebulizer cup and mask (PVC).

9.Maintenance, Care, and Service

Order all spare parts from your dealer or pharmacist.

9.1 Replacement of the nebulizer cup

Replace the nebulizer cup after a long period of inactivity, in cases where it shows deformities, breakage, or when the vaporiser head is obstructed by dry medicine, dust, etc.
We recommend to replace the nebulizer cup after a period between 6 months and 1 year depending on the usage.

⚠**Caution:**

Only use original nebulizer cup!

9.2 Replacement of the air filter

In normal conditions of use, the air filter must be replaced approximately after 200 working hours or after each year. We recommend to periodically check the air filter (10 - 12 treatments) and if the filter shows a grey or brown colour or is wet, replace it.(Extract the filter and replace it with a new one).

⚠ **Caution:**

- Do not try to clean the filter for reusing it.
- The air filter shall not be serviced or maintained while in use with a patient. Only use original filters! Do not use the device without filter!

10.Guarantee

This device is covered by 1 year guarantee from the date of purchase. During this guarantee period, at our discretion, Bi-rich will repair or replace the defective product free of charge.
Opening or altering the device invalidates the guarantee.
The following items are excluded from the guarantee:

- Transport costs and risks of transport.
- Damage caused by incorrect application or non-compliance with the instructions for use.
- Damage caused by accident or misuse.
- Packaging/storage material and instructions for use.
- Regular checks and maintenance.
- Accessories and wearing parts: Nebulizer cup, masks, mouthpiece, nose piece, tube, filters.

Should guarantee service be required, please contact the dealer from where the product was purchased.
Compensation is limited to the value of the product. The guarantee will be granted if the complete product is returned with the original invoice. Repair or replacement within guarantee does not prolong or renew the guarantee period. The legal claims and rights of consumers are not limited by this guarantee.

11. Technical data

Technical data for the Compressor with the Nebulizer cup :

Particle Size: **MMAD * approximately 3μm

Appropriate Medication Quantities: 2ml minimum -6ml maximum

Geometric standard deviation (GSD):2.066

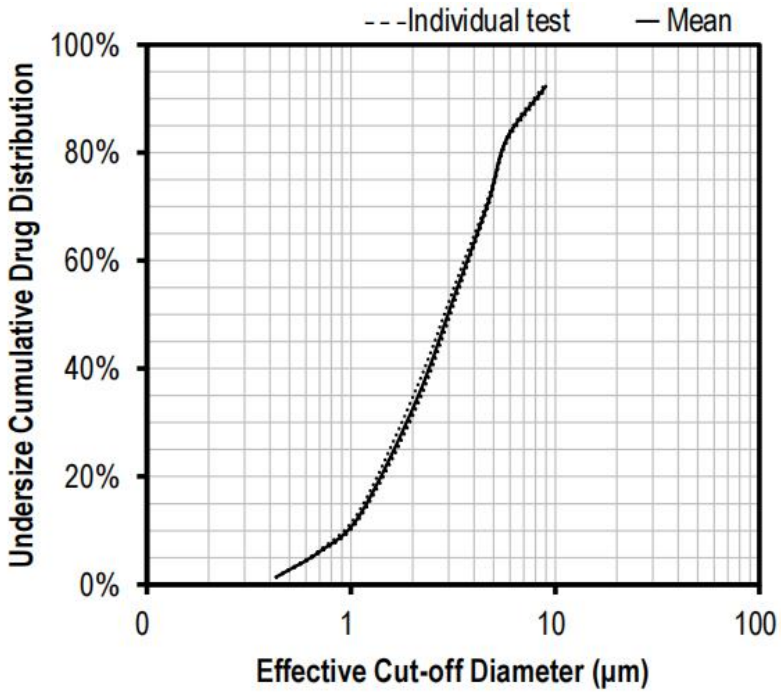
Aerosol Output:1.047 ml (4ml Albuterol 0.1% (M/) concentration in 0.9 % sodium chloride solution)

Aerosol Output Rate:0.075ml/min

Fine particle fraction (%) (< 5 μm) (FPF):83.3

Compressor nebulizer the particle size distribution curve as well:

Result of cascade impactor **measurements for particle size .



MMAD = Mass Median Aerodynamic Diameter
The tests were carried out by Shenzhen bi-rich medical device co,ltd. at MicroBase Technology Corporation，Taiwan.

12.Important information regarding Electro Magnetic Compatibility (EMC)

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BR-CN1001, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B

Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines	± 0.5kV, ± 1 kV line(s) to lines
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RFIEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

13.Malfunctions and Actions to take

Check the following if your unit should fail during operation. You can also refer to the pages of this manual for complete instructions.

Problem	Cause	Remedy
Nothing happens when the power switch is pressed.	Is the AC plug connected correctly to the an electrical outlet and the compressor?	Check that the plug is inserted in an electrical outlet. Unplug then reinsert the plug if necessary.

No nebulisation or low nebulisation rate,when the power is on.	Is there medication in the medication tank?	Add the correct amount of medication to the medication tank.
	Is there too much/little medication in the medication tank?	
	Is the vaporiser head missing and not assembled correctly?	Attach the vaporiser head correctly.
	Is the nebulizer kit assembled correctly?	Assemble the nebulizer kit correctly.
	Is the nozzle blocked?	Make sure that the nozzle is free of blockages.
	Is the nebulizer kit tilted at a sharp angle?	Make sure that the nebulizer kit is not tilted at an angle of more than 45 degrees.
	Is the air tube connected correctly?	Make sure that the air tube is correctly connected to the compressor and nebulizer kit.
	Is the air tube folded or damaged?	Make sure that the air tube does not contain kinks.
	Is the air tube blocked?	Make sure that the air tube is free of blockages.
	Is the air filter dirty?	Replace the air filter with a new one.
The device is abnormally loud.	Is the air filter cover attached correctly?	Attach the air filter cover correctly.
The device is very hot.	Is the compressor covered?	Do not cover the compressor with any type of cover during use.

Note: If the suggested remedy does not solve the problem, do not try to repair the device- no parts of the unit are user serviceable.Return the unit to an authorized retail outlet or distributor.

14. Disposal statement

Correct Disposal of this product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of , with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling .

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

CE 1639

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