URiGHT NEB Cube
Compressor Nebulizer

311-7013200-008
Version 1.0
2019/03

OPERATION INSTRUCTIONS

TaiDoc Technology Corporation
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EC REP **MedNet GmbH**
Borkstraße 10, 48163 Münster,
Germany

REF TD-7013 ⚠ CE 0123

Dear URiGHT NEB Cube Owner:

Thank you for purchasing the URiGHT NEB Cube Compressor Nebulizer. This instruction provides important information to help you use the set properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the place of purchase or call the Customer Care Line.

INTENDED USE

The compressor nebulizer is designed to provide a compressed air source to deliver physician prescribed inhalation medications. It is intended for use with all ages at home or in clinical settings.

Owner's portion — WARRANTY CERTIFICATE — YEAR WARRANTY

Name of product: _____

Name of owner: _____

Address: _____

Tel No: (Mobile) _____ (H) _____ (O) _____

Email: _____ Age: _____ Gender: ☐ M ☐ F

Date of Purchase: ☐☐ / ☐☐ / ☐☐ (day / month / year)

Serial No.: _____

Dealer's Stamp:

*NOTE: Please produce this card together with the purchase receipt for warranty service.

Dealer's portion — WARRANTY REGISTRATION CARD

Name of product: _____

Name of owner: _____

Address: _____

Tel No: (Mobile) _____ (H) _____ (O) _____

Email: _____ Age: _____ Gender: ☐ M ☐ F

Date of Purchase: ☐☐ / ☐☐ / ☐☐ (day / month / year)

Serial No.: _____

Dealer's Stamp:

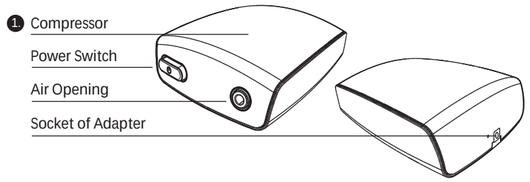
*IMPORTANT: To qualify for the warranty, please fill in this card and mail to us within 14 days from the date of purchase.

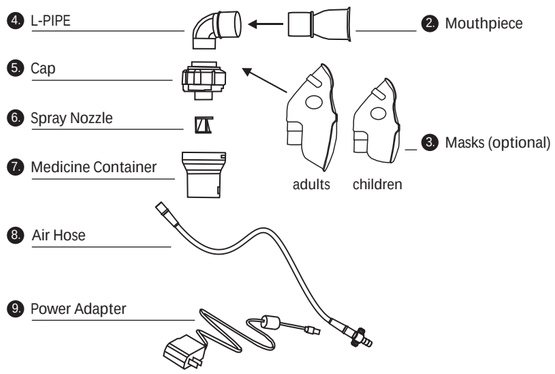
FEATURES

- No warming of medicine, thus preventing damage to the structure of the medication
- Low power consumption
- Small nebulization particle size – 1~3 microns
- Convenient design – compact and lightweight, ideal for travelling
- Short treatment time – with high nebulization rate

ITEMS SUPPLIED AND DESCRIPTIONS OF PARTS

Before you start to use the URiGHT NEB Cube, please check if the following items are included in the package.





NOTE

- For reasons of hygiene, please use the mouthpiece for one specific individual only and do not exchange them. The mouthpiece must be replaced after each use.
- Use only the parts listed above; use of other parts may constitute a hazard.
- The adapter is optional and may not come with the kit. It is recommend to use the power adapter that provides 12 Watts of continuous output power. The operating voltage is 100 to 240 VAC, 50 to 60 Hz.

SAFETY PRECAUTIONS

- Use the equipment only for its intended use as described in this instruction. Do not use attachments not recommended by the manufacturer.
- Use the equipment with medications only under the instruction of your physician.
- Do not use the equipment if it has any damaged parts, or it has fallen into water.
- To use the equipment for the first time, or after storing it for an extended period, be sure to clean all necessary parts as described in the cleaning instructions.
- Do not use while bathing.
- The unit should not be left unattended while plugged in or turned on.
- Keep the unit out of reach of small unsupervised children. The small parts detached from the device may result children choking from inhaling or swallowing.
- The accessible materials used in the device will not cause the potential allergic reactions to skin.
- Do not try to modify the device to prevent any dangers.
- Do not place the device in liquid, nor put it where it could fall into liquid. If the device becomes wet, unplug the device before touching it.
- Do not use the device if it is not working properly, or if it has suffered any damage.
- Do not subject the nebulizer or the mesh cap to any impacts and do not drop them.
- After a period of no use, and after every use, please clean the compressor unit.
- Do not expose the nebulizer to direct sunlight, high temperatures or humidity.
- Always contact the manufacturer or the manufacturer's representative to report unexpected operation or event. Do not try to fix it by yourself.
- Do no expose the device to strong electrostatic fields or strong magnetic fields to avoid affecting the measurement accuracy.
- Used in close proximity to others, EMC must be tested and verified.
- When in use, you should stay away from electromagnetic radiation, such as the mobile in use.

ABOUT INHALATION THERAPY

The device is ideally suitable for inhalation at home or when travelling. It guarantees highly effective, fast-acting inhalation treatment for patients of children and adults.

Carry out inhalation in a quiet and relaxed state, and inhale slowly and deeply, so that the medication can penetrate to the fine, deep bronchial tubes. Exhale normally.

OPERATING INSTRUCTIONS

Important Information Before Use

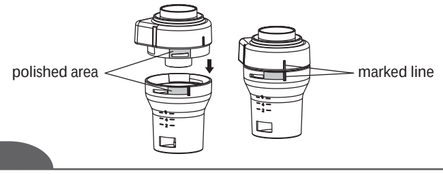
- Ensure that all parts are clean and dry.
- Before starting treatment, talk to your physician about the duration, dosage and frequency of use of the nebulizer.
- The device is designed for an intermittent use: 30 minutes ON / 30 minutes OFF.
- Do not remove the medication container cover from the unit during nebulization.

Unit Assembly and Use

1. Correctly position the spray nozzle inside the medicine container.

2. Slowly pour the prescribed medication into the medicine container. The maximum capacity of the container is 6 ml. Please note that the medication must not exceed this maximum level marking (6 ml).

3. Correctly fit well the polished area on cap and medicine container respectively by slightly closing and turning in clockwise direction. Make sure that both are closed well until the lines marked on cap and medicine container are in alignment. Connect the mouthpiece / mask and L-PIPE, and then attach to the top of the cap.



NOTE

The mouthpiece is to be used for oral inhalation only.

4. The nebulizer can be connected to the compressor by using the air hose with connector.

5. Plug the power adapter into the wall outlet; plug the power cord of the adapter into the socket on the side of the compressor.

6. Press the power switch to turn on the device. Begin treatment according to your physician's instructions.

7. Inhale and exhale naturally. Be sure to stop when the medication is exhausted.

NOTE

when you have completed use, press the power switch to turn the device off before you disconnect the air hose. Unplug the adaptor, remove the inhalation accessory used and proceed with cleaning operations as described in the "Cleaning and Maintenance" section.

Instructions on Mouthpiece and Mask

How to use the mouthpiece

1. Insert the mouthpiece into the L-PIPE.

2. Close your lips around the mouthpiece and start treatment as recommended by your doctor.

How to use the mask

1. Insert the mask into the cap.

2. Place the mask onto your face and start treatment as recommended by your doctor.

CLEANING AND MAINTENANCE

Please clean your device after each use according to the instructions below.

Before Cleaning

Make sure that the nebulizer is turned off before disassembly.

Cleaning of Nebulizer Accessories

1. After you have disconnected the air hose, remove the mouthpiece / mask (optional), L-PIPE, cap, spray nozzle and medicine container.

2. Discard any remaining medications.

3. Wash mouthpiece / mask (optional), L-PIPE, cap, spray nozzle and medicine container with running water or soak in warm water for 15 minutes.

4. Gently wipe off excess water with a clean dry cloth and allow to air dry on a clean paper towel.

Cleaning of Compressor

1. Use alcohol cotton swabs to wipe the outer casing of the compressor.

2. Let it air dry on a clean paper towel.

NOTE

- The above-named accessories can be regarded as consumable items; please replace with new ones if they are dirty and obstructed. To prevent cross-contaminations, do not share the accessories with others.
- Only can use the aerosol nebulizer kit manufactured by TaiDoc for appropriate assembly. Do not use accessories which are not supplied or recommended by the manufacturer. Other cables and accessories may negatively affect EMC performance.

Maintenance for Storage

1. Always handle your nebulizer with care.
2. Disconnect the power plug from the wall outlet when not in use.
3. Keep your nebulizer out of children's reach.
4. If you store your nebulizer, do not bend the air hose.
5. If you store your nebulizer, try to keep it in the following environmental ranges:
   a) Temperature: -25°C to 70°C (-13°F to 158°F),
   b) Relative humidity: 10% to 95%
6. If possible, store your nebulizer in a well-ventilated room.

Disposal

The used unit should be treated as contaminated that may carry a risk of infection during nebulization. Dispose of the device, components, used batteries, and optional accessories according to your local regulations.

TROUBLESHOOTING

Symptom	Probable Cause	Solution
The device does not work or the device nebulizes weakly.	The plug is improperly inserted into the device.	Re-plug again and make sure that the plug is properly inserted into the device.
	The switch is off.	Turn the switch on.
	Air hose is bent.	Remove any bend or kink in the air hose.
	The spray nozzle does not place in its position.	Place the spray nozzle in its correct position.
	No medicine is left.	Add the appropriate amount of medicine prescribed by your physician to the medicine container.
The device is on but does not nebulize.	The medicine container and cap does not assemble well.	Re-assemble the medicine container and cap and twist them well.
	The texture of medicine may be thick.	Slightly shake the medicine well and then nebulization will be produced.

SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
	Consult instructions for use		Type BF applied part
EC REP	Authorized representative in the European Community		Manufacturer
⚠	Caution	SN	Serial number
	Temperature limitation	IP21	Resistant to liquid ingress
CE 0123	CE mark		Humidity limitation
RoHS	RoHS Compliance	REF	Catalogue number
	This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with local regulations for separate collection of spent batteries.		

SPECIFICATIONS

Model No.: URiGHT NEB Cube

Dimension & Weight: 125 x 115 x 46 mm; 220 g

Power Source: DC 12 V power adapter

AC adapter (optional)

-Input: 100~240V, AC

-Output: 12V, 1A, DC

Power Consumption: 12 W

Compressor Pressure Range: 14 to 18 psi

Operating Pressure Range: 5 to 8 psi

Maximum Flow Rate: ≧4 LPM(l/min)

Operating conditions:

5°C to 40°C (40°F to 104°F), 15% to 93% relative humidity, 700 hPa to 1060 hPa

Storage conditions:

-25°C to 70°C (-13°F to 158°F), 10% to 95% relative humidity

IP Classification: IP21

Mode of Operation: 30 mins on/ 30 mins off

Nebulization Rate: ≧0.35 ml/min

Medication Capacity: 6 ml

MMAD: Approximately 3 microns

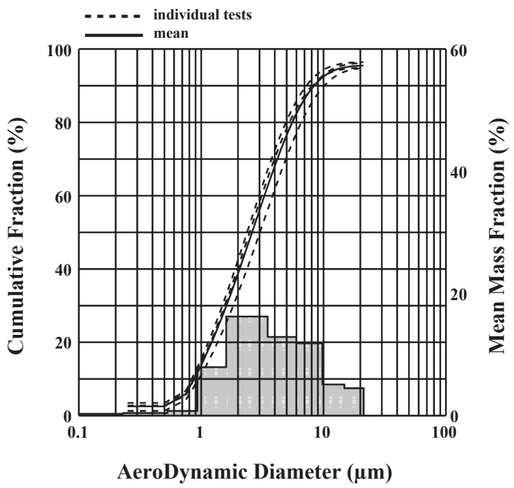
Aerosol output: 1.80 ± 0.02 (ml)*

Aerosol output rate: 0.21 ± 0.02 (ml/min)**

*: Continue the treatment until the medication cup is empty or the mist stops.

**: The treatment time for aerosl output rate is 1 min.

Plot of cumulative size distribution of results



NOTE

- Please contact your dealer for assistance with any other difficulties.
- Performance may vary with medication such as suspensions or high viscosity. See medication supplier's data sheet for further details.
- Performance information provided by the manufacturer in accordance with the standard EN 13544-1:2007 may not apply to drugs supplied in suspension or high viscosity form. Please consult the drug supplier for more information.

Reference to Standards:

- Electric Safety Standards EN 60601-1
- Electromagnetic Compatibility according to EN 60601-1-2
- Particle Size according to EN 13544-1, clause 6.8.2

The device is a class IIa medical device according to Medical Device Directive 93/42/EEC.

Manufacturer's declaration-electromagnetic emissions

The URiGHT NEB Cube is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the URiGHT NEB Cube should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The URiGHT NEB Cube 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	The URiGHT NEB Cube is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity

The URiGHT NEB Cube is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the URiGHT NEB Cube should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact: ±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s) + 0.5kV, +1kV,+ 2kV line(s) to earth	+ 0.5kV, +1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T: 0,5 cycle 0 % U_T: 1 cycle 70 % U_T: 25/30 cycles Voltage interruptions: 0 % U_T: 250/300 cycle	Voltage dips: 0 % U_T: 0,5 cycle 0 % U_T: 1 cycle 70 % U_T: 25/30 cycles Voltage interruptions: 0 % U_T: 250/300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the URiGHT NEB Cube requires continued operation during power mains interruptions, it is recommended that the URiGHT NEB Cube be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The URiGHT NEB Cube power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity

The URiGHT NEB Cube is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the URiGHT NEB Cube should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** URiGHT NEB Cube including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1,2 √P d = 1,2 √P 80MHz to 800 MHz d = 2,3 √P 800MHz to 2,7 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). Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

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.

Recommended separation distance between portable and mobile RF communications equipment and the URiGHT NEB Cube

The URiGHT NEB Cube is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the URiGHT NEB Cube can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the URiGHT NEB Cube 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√P	80 MHz to 800 MHz d =1,2√P	800 MHz to 2,7 GHz d =2,3√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.

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The URiGHT NEB Cube is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the URiGHT NEB Cube should assure that it is used in such an environment.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	Immunity test LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
1 720 1 845 1 970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) 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.

TERMS & CONDITIONS OF WARRANTY

1. We warrant this product to be free of defects in workmanship and materials within the said warranty period on the warranty certificate.
2. During the warranty period, if this product is found to be defective, you may bring it, together with the purchase receipt and Warranty Certificate, on a carry-in basis to our office during normal business hours for warranty service. We will then repair or replace defective parts or exchanging the whole product as we may choose, at no charge to the original owner. After such repair, replacement or exchange, the product will be warranted for up to the remainder of the warranty period.
3. This warranty is valid only if the Warranty Certificate and Warranty Registration Card are duly completed with date of purchase, serial number and dealer's stamp, and if the Warranty Registration Card is sent to our office not later than 14 days from the date of purchase.
4. This warranty is void if this product has been repaired or serviced by unauthorized person. This warranty does not cover defects caused by misuse, abuse, accident, tampering, lack of reasonable care, fire or any other acts beyond human control.
5. Except as stated in the above paragraphs, we disclaim all other warranties, implied or expressed, including the warranties of merchantability or fitness for a particular purpose with respect to the use of this product. We shall not be liable for any direct, consequential or incidental damages arising out of the use or inability to use this product.

PLEASE AFFIX STAMP

DEALER'S INFORMATION