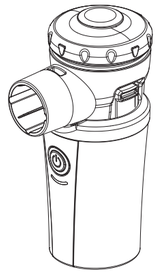
URiGHT NEB Cylinder
Mesh Nebulizer

311-7013200-008
Version 1.0
2019/03



OPERATION INSTRUCTIONS

TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Rd.,
Wugu Dist., 24888 New Taipei City, Taiwan
www.taidoc.com

EC REP **MedNet GmbH**
Borkstraße 10, 48163 Münster,
Germany

REF TD-7001 ⚠ CE 0123

Dear URiGHT NEB Cylinder Owner:

Thank you for purchasing the Mesh Nebulizer. This instruction provides important information to help you use the system 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

This ultrasonic (vibrating mesh) nebulizer system is designed to aerosolize physician-prescribed solution for inhalation by the patient. 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:

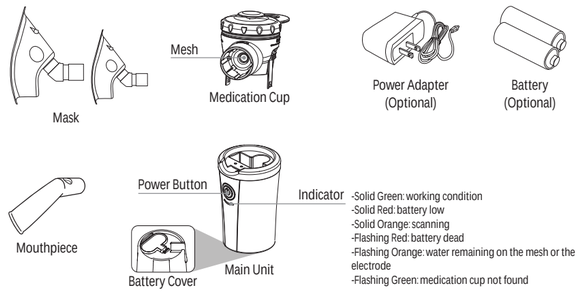
*IMPORTANT: To qualify for the warranty, please fill in this card and mail to us within 14 days from the date of purchase.

FEATURES

- Deliver aerosol automatically.
- Two choices of electricity: battery or AC adapter (optional)
- Small nebulization particle size – Approximately 3 µm
- Convenient design – compact and lightweight, ideal for travelling
- Short treatment time – with high nebulization rate
- Reset function: provide a simple way to calibrate the device

ITEMS SUPPLIED AND DESCRIPTIONS OF PARTS

Check your system to make sure all parts are included and not broken before use.



NOTE

- The mask, power adapter and battery are optional. Please contact local dealer for purchase, or Customer Service for more information.
- The medication cup, mouthpiece, and masks can be regarded as consumable items. Please replace with new ones if they become dirty and obstructed. In consideration of the risk of cross-contamination, do not share the accessories with others.
- Use only the parts and accessories 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.
- For reasons of hygiene, please use the mouthpiece, mask and medication cup for one specific individual only and do not exchange them. The mouthpiece, and the mask 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 recommended 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.
- Do not use the device under conditions of inter-hospital transport. This device is not intended for transport use.
- Use the equipment with medications only under instructions of your physician.
- 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 to any impacts and do not drop them.
- Do not expose the nebulizer to direct sunlight, high temperature or humidity.
- The nebulizer is NOT suitable for use in anaesthetic breathing systems or lung ventilator breathing systems.

ABOUT INHALATION THERAPY

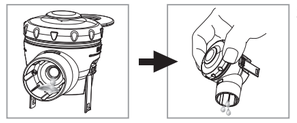
The device is ideally suitable for inhalation at home or when travelling. It guarantees highly effective, fast-acting inhalation treatment for patients of all ages.

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.

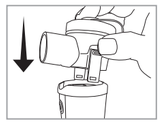
IMPORTANT INFORMATION BEFORE USE

- Ensure that all parts are clean and dry.
- Before starting treatment, talk to your physician about the duration, dosage and frequency of use.
- The device automatically turns off in15 minutes without pressing the ON/OFF button.
- Do not remove the medication cup cover from the unit during nebulization.
- Pour the drinking water (7 to 10 ml) into the medication cup. Do not go beyond the MAX. line. Press the power botton to activate the device and to check if the nebulization is working properly. Discard any remaining water and re-start the operation.
- In operation, the device does not heat up the medication cup. Please follow the recommended volume of medicine capacity.
- 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.

HOW TO USE



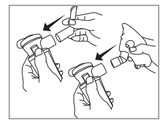
1. Make sure there is no liquids on the aerosol outlet.
The unit might fail to work if there are liquids on the aerosol outlet. Please shake the medication cup back and forth or left to right to remove the liquid. Never use cotton swabs on the mesh or the aerosol outlet.



2. Attach the medication cup to the nebulizer unit firmly.

3. Pour the prescribed medication slowly into the medication cup. Its maximum capacity is 10 ml. Do not exceed the line marked "MAX.".

4. Attach the cap and screw it tight as illustrated.



5. Attach the mask or mouthpiece to the medication cup.

6. Press and release the power button to activate the nebulizer. It will start to deliver prescribed medication continuously for 15 minutes.

7. Now, place the mouthpiece to your mouth and close your lips firmly around it. When using the mask, place it over your nose and mouth.

8. Any time you want to stop the treatment, press the power button again to turn off the unit.

NOTE

- The mouthpiece is designed for oral inhalation only.
- Do not drop medication or liquids on the main unit. If you do, immediately wipe it off.
- Do not touch the unit with wet hands while it is plugged in; do not allow liquids to be sprayed onto the unit. The unit must be operated only when it is completely dry.

Storage

1. Always handle your nebulizer with care.
2. Disconnect the power plug from the wall outlet when not in use. (For AC adapter)
3. 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%
4. If possible, store your nebulizer in a well-ventilated room.

Battery Replacement

Replace the batteries when the indicator is red.

To replace the battery, make sure that the nebulizer is turned off.

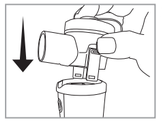
1. Press the buckle on the battery cover and lift up to remove the cover.
2. Remove the used batteries. Insert the new battery according to its polarity as indicated.
3. Close the battery cover by pressing it down firmly until you hear a "click".

NOTE

- When using the AC adapter, the unit does not draw power from the batteries.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Properly dispose of the batteries according to your local environmental regulations.

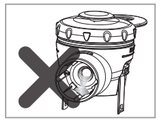
Reset the Vibration Rate

Reset the vibration rate when you encounter weak nebulization or change a new medication cup.



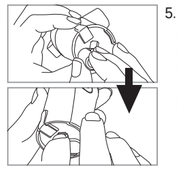
1. Attach the medication cup to the nebulizer unit.

2. Pour the prescribed medication or water **to the line marked "MAX."** for proper vibrating calibration.

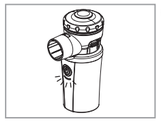


3. Screw the cap tight and carefully examine the mesh. Make sure there is no liquid on the mesh in order to minimize interferences. Remove liquids by shaking the medication cup back and forth.

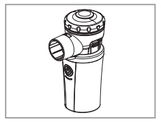
4. Take the batteries out.



5. Still pressing the power button, insert the batteries back and close the battery cover.



6. Release the power button until the orange light is on. Then, the device will shut itself down.



7. Keep the device upright and make sure that the medication cup is not empty.
Press the power button to turn on the device. The indicator first lights orange for a few seconds and then turns to green.
Now the nebulizer is ready for use.

CAUTION

- You must keep the unit upright or the calibration will be failed.
- In case of insufficient power supply, please use new batteries to reset the vibration rate.

Disposal

Dispose of the device, components, used batteries, and optional accessories according to your local regulations.

TROUBLESHOOTING

Symptom	Probable Cause	Solution
Flashing red for 3 times, and then device shuts itself down.	Battery dead.	Replace the batteries immediately.
Flashing green light for 3 times.	The unit fails to detect the medication cup.	Make sure the electrode is clean to ensure its functionality. Wipe the electrode with a lint-free cloth and re-attach the cup to the unit.
Flashing orange light for 3 times.	There are liquids on the aerosol outlet or the electrode is wet.	Gently shake the medication cup to remove liquids. Wipe dry the electrode with a cotton swab if necessary; however, never swab the mesh.
The device fails to work when it is turned on.	No power.	Check the batteries.
		Check connection between the AC adapter and the nebulizer.
The indicator is green but does not nebulize or nebulize weakly.	The medication cup does not assemble well.	Re-assemble the medication cup .
	The medicine is too viscous to work.	This medication should not be used with this nebulizer. Consult with a licensed physician and/or pharmacist to change prescriptions.
	No medicine inside.	Add the appropriate amount of medicine prescribed by your physician.
	The unit fails to detect the medication cup.	Make sure the electrode is clean to ensure its functionality. Wipe the electrode with a lint-free cloth and re-attach the cup to the unit.
	Air obstructed in medication cup.	Gently shake the medication cup to remove the air.
	Liquids found on the aerosol outlet.	Gently shake the medication cup to remove liquids.
	Reset the nebulization rate if the above methods do not work.	Perform the vibration rate resetting procedure as directed in **"Reset the Vibration Rate".**

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	IP22	Resistant to liquid ingress
CE 0123	CE mark		Humidity limitation
	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.	RoHS	RoHS Compliance
		REF	Catalogue number

SPECIFICATIONS

Model No.: URiGHT NEB Cylinder

Dimension & Weight: Est. 74D x 126H (mm), 100 g

Power Source: 1) 2 X AA alkaline batteries
2) AC adapter (optional)
Input: 100~240V, AC
Output: 6V, 1A, DC

Power consumption: ≤1.5W

Nebulization Rate: ≧0.2ml/min[1]

Medication capacity: 10 ml

MMAD: Approximately 3μm

IP classification: IP22

Mode of operation: Automatically turns off in 15 minutes

Aerosol output: 1.99 ± 0.01 (ml) [2]

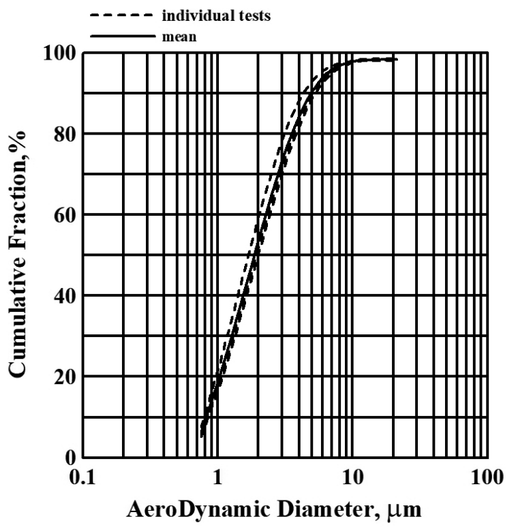
Aerosol output rate: 0.30 ± 0.01 (ml/min) [3]

Operating conditions: 5°C to 40°C (41°F to 104°F), 15% to 93% relative humidity Storage conditions: -25°C to 70°C (-13°F to 158°F), 10% to 95% relative humidity

Atmospheric pressure range: 700 hPa to 1060 hPa

[1] : The Nebulization rate is measured with saline 0.9% solution at 25°C and might vary with medication and ambient conditions.

Plot of cumulative size distribution of results



[2] : Continue the treatment until the medication cup is empty or the mist stops.

[3] : The treatment time for aerosl output rate is 1 min.

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 Cylinder is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the URiGHT NEB Cylinder 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 Cylinder 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 Cylinder 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 Cylinder is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the URiGHT NEB Cylinder 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 Cylinder 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 Cylinder 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 Cylinder is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the URiGHT NEB Cylinder 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 Cylinder 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 Cylinder

The URiGHT NEB Cylinder 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 Cylinder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the URiGHT NEB Cylinder 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 Cylinder is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the URiGHT NEB Cylinder 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