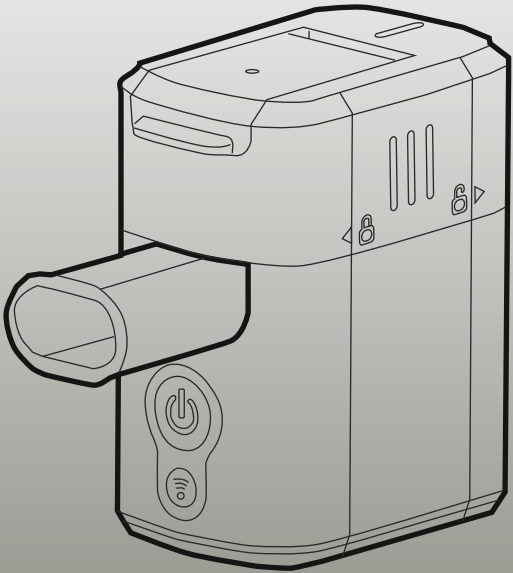


Vibrating Mesh Nebulizer system

Instruction for Use

PY-010



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Dear Customer

This Instructions for Use contains important information you must know about the nebulizer. Please read it thoroughly before use. Please follow this Instructions for Use carefully to ensure optimal nebulizer performance.

INTENDED USE

■ Indications

The PY-010 is a vibrating mesh nebulizer system designed to aerosolize approved liquid medications for inhalation. The PY-010 is intended for use in the home environment or in a hospital/clinic setting, as defined by the prescribed medication and your physician.

■ Operating condition

Temperature range of + 10°C to + 40°C

Humidity range of 30% RH to 80% RH, non-condensing

Atmospheric pressure 700 hPa to 1060 hPa

■ Storage and transport conditions

Temperature range of MIN -25°C MAX +70°C

Humidity range of MAX 85% RH

■ Expected service life

Main Body : 1 years from date of purchase

Top Cover : 3 months of first use

AN IMPORTANT SAFETY INSTRUCTIONS

READ THIS BEFORE USING

When using an electronic appliance, basic precautions should always be followed, including the following.

WARNING:

- Adult supervision is necessary when the device is used by, on, or near children or physically challenged individuals or individuals with learning difficulties.
- Do not operate under the blanket or pillow. Excessive heating can occur and cause fire, electric shock, or injury to persons.
- Use the device only for its intended use purpose as described in this Instructions for Use. Only use accessories provided with the device and recommended by the manufacturer.
- Do not use cotton swab to swab the mesh, or poke it with any sharp objects. This could damage the mesh and prevent the device from operating properly.
- Discard the remaining medication after each usage. Do not carry or store the medication in the device.
- Be sure to follow the doctor's instructions for the type, dose, and regimen of the medication
- Do not submerge the Main Body in water or other liquid cleaning agents
- Place the power adapter of the device at proper position so as to easily plug-in or plug-out from the power supply. Device should remain upright and stable after plugging in the power adapter.
- If the device is accidentally dropped into a liquid, immediately disconnect the AC adapter from the wall outlet, prior to removing the device from the liquid.
- Do not drop or apply strong shock to the device.
- If the device has been stored at the extremes of the storage temperature (40°C). The device should not be used for more than 10 minutes during this scenario.

NOTICE FOR SAFETY OPERATION

To ensure safety, kindly take following precautions:

1.Before use

- Use your device in the correct manners as outlined in this manual.
- The treatment using device should be taken only according to the directions given by a physician or designate personnel.
- If the abnormal performance is observed, please discontinue the use and consult your study coordinator.
- Do not add liquid over the indicated line marked on medication cup.
- Do not disassemble or make any modification on this appliance.
- The applied part is mouthpiece.
- The patient is an intended operator.

- If the medication cup is not functioning well, please perform the cleaning instructions. If the problem persists, please replace it before using.
- Do not add liquid over the indicated line marked on medication cup.
- Do not disassemble or make any modification on this appliance.

2.When using

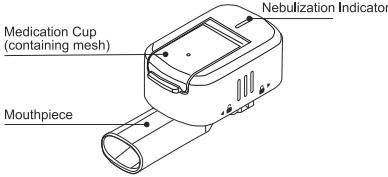
- Children or disabled patients should be assisted by adults or medical personnel when using device.
- Do not use device when medication cup is empty.
- Place the device on a flat surface for keeping device position upright and steady during operation to ensure has good contact with mesh and avoid spillage.
- Add the medication gently into the medication cup to avoid introducing air bubbles into the medication. Only use the medication and fill volume provided by your study coordinator or healthcare provider.
- The maximum fill volume is 1.0 ml. Do not fill medication above this level.
- Attach the Top Cover per procedures presented in INSTALLATION section. It will click into place.
- If you are using the power adapter to power the device, plug the cable into the socket on the Main Body and plug the adapter into the wall outlet.
- Press the Power Button on the Main Body to switch the device on. The Power Button Indicator will illuminate. Check the battery level as presented in Component Function Description section for Power Button Indicator.
- This product has a built-in timer which turns off automatically in 20 minutes. If it cannot turn off automatically, discontinue using and consult your study coordinator
- Against servicing and maintenance while the me equipment is in use.
- The adapter plug is served to disconnect the device, do not position the device to make it difficult to disconnect the adapter plug.

3.After using

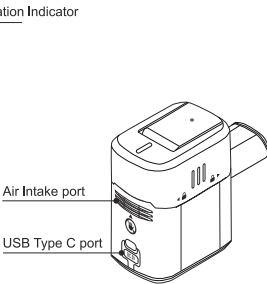
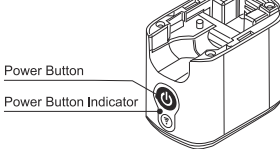
- Do not store device in direct sunlight or outside the suggested storage temperature & humidity.
- Keep device out of reach of children.
- The equipment can be used immediately after being moved from the lowest storage temperature of -25°C to room temperature of 20°C.
- The equipment can be used immediately after being moved from the maximum storage temperature of 70°C to room temperature of 20°C.

NAME OF COMPONENT

Top Cover



Mouthpiece



Component Function Description

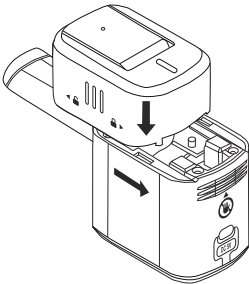
Component	Description
Top Cove	Equipped with flow rate sensor for measuring patients breathing flow rate
Medication Cup	Container for inhalation solution to be aerosolized
Mesh	Generates aerosol
Nebulization Indicator	User interface on the Top Cover. - Constant blue : Treatment (nebulization) in progress when the inspiratory flow rate reaches the trigger threshold - Flash red: There is no medication in the medication cup, treatment is finished. Device will switch off automatically.
Mouthpiece	Patient interface to administer aerosolized inhalation solution
Main Body	Main circuit board and battery containment
Power Button	Press to switch device on and off

Power Button Indicator	User interface on the Main Body; includes power on/off push button with the power and indicates low battery (green: normal; orange : medium power; red: low battery) - Constant green: Ready for treatment (full battery) - Constant orange: The battery at 25% charge remaining - Constant red: The battery is low. Charge as soon as possible. - Flash orange: The battery is charging in standby mode. - Flash green: The battery is charging in operating mode - Flash red: There is no medication in the medication cup, treatment is finished. Device will switch off automatically.
Air Intake Port	The entrance that guides airflow. Do not block the port on the back to avoid affecting the device function.
USB Type C Port	Support using USB Type-C plug to charge the battery
Power Source	Lithium – ion rechargeable battery and AC power adaptor Input: 100 – 240 VAC, 50/60 Hz; Output: 5V DC, 1.5A AC/DC adaptor Model and manufacturer: UMB305-0512, Unifive Technology Co., Ltd.

INSTALLATION

Assemble the Top Cover

Vertically align the arrow icon of the Top Cover and the Main Body. Attach and slide the Top Cover into Main Body in the direction of engraved lock icon until it clicks



Remove the Top Cover

Slide the Top Cover in the direction of the engraved unlock icon, removing it from the Main Body.

HOW TO USE

- Check the device and accessories are clean, dry and not damaged prior to use.
- Place the PY-010 device on a flat surface. Open the medication cup cover and add the medication gently into the cup. And close the cup cover firmly, it will click into place. Only use the medication and fill volume provided by your clinical trial coordinator or healthcare provider.
- Power on the PY-010 device by briefly pressing and releasing the power button. The Power Button Indicator shows constant green light indicating the device is ready to use.
- Hold the device in your hand while keeping the device level. Ensure that your fingers are not blocking the exhalation port on the back of the Main Body. Place the Mouthpiece between your teeth with your lips sealed around it.
- Before the first breath in, exhale fully through the Mouthpiece.
- Begin to inhale slowly. When your breath reaches the correct flow rate, the Nebulization Indicator light will show constant bluet and start to nebulize the medication.
- Continue breathing in and out through your mouth slowly. At the end of your treatment, both Power Button Indicator and Nebulization Indicator change to red and flash five times, your dose is completed and the device will automatically power off.

If you need to take a rest, remove the Mouthpiece from your mouth. To continue your treatment, pick up the PY-010 and start breathing through the Mouthpiece. If you do not start the treatment again within 10 minutes, the PY-010 will automatically switch off. If the PY-010 shuts off, you cannot restart your treatment. You must take it apart, empty the medication chamber and clean it following the cleaning instructions.

⚠ **NOTICES WHEN USE:**

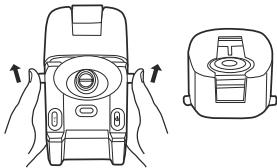
- When the Power Button is pressed. The Power Button Indicator turns GREEN and the build-in timer shall start countdown to 20 minutes then automatically power off.
- When the Power Button Indicator turns ORANGE indicates that batteries are weak, RED indicates the batteries are exhausted and need to be charged immediately.
- If treatment is finished (no medicine inside the Medication Cup), Power Button Indicator will turn RED and flash three times before the appliance turns off automatically.

CLEAN AND MAINTAINANCE NOTICE

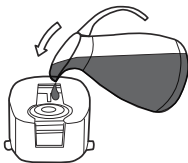
The steps of cleaning and maintenance.

After each use, please follow below procedures to clean and maintain.

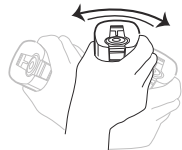
1. Push the Release Lever back with both hands, the white Top Cover will pop up, and then remove the Top Cover from the Main Body.



2. Open the transparent lid of the Medication Cup and rinse the Medication Cup inside with tap water.



3. Let the Mouthpiece under tap water, and rinse Mouthpiece inside with running tap water for about 30 seconds, and then shake the Top Cover slightly to remove the excess water.



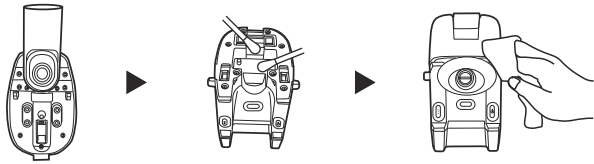
4. Add the boiling water into the Medication Cup, fill it up and cover the transparent lid of the Medication Cup. (The capacity of the Medication Cup is small, please be careful to avoid scalded, you may add boiling water with a dropper or a syringe)



5. Assemble the Top Cover to the Main Body and keep press the Power Button for 5 seconds and then start the cleaning mode. At this time, the PY-009 will start spraying for 1 minute and then stop automatically.



6. After the spraying stops, push the Release Lever back with both hands, the white Top Cover will pop up. Remove the Top Cover from the Main Body and pour out the remaining water in the Medication Cup.
7. Let the Mouthpiece under tap water, and rinse Mouthpiece inside with running tap water for about 30 seconds again.
8. After rinsing, shake the Medication Cup slightly to remove excess water, and use a clean cloth or tissue paper to completely dry the whole Top Cover, including the inside of the Medication Cup and the Mouthpiece.



Warning

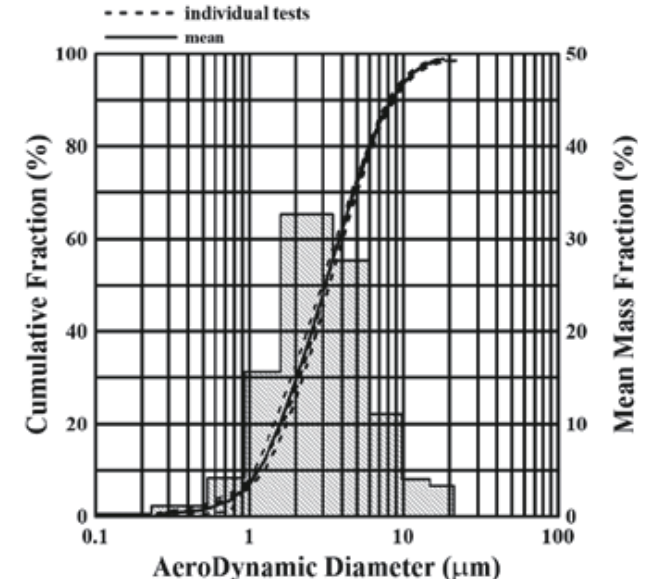
1. Do not autoclave the top cover or main body.
2. Do not put any part of the device in a microwave, microwave steam sterilizer, dishwasher or conventional oven.
3. Do not immerse the main body in liquid.
4. Never poke or clean the mesh with any sharp objects as this will damage the mesh.
5. Disconnect device from power supply prior to cleaning.
6. Clean medication cup thoroughly, otherwise the mesh will be clogged.

TROUBLE SHOOTING

Problems	Solutions
Cannot nebulize or not enough mist output.	Check the Top Cover is installing properly or not. If not, please remove it from the Main Body and slide it back again.
The Power Button Indicator turns constant red during nebulization	Battery has insufficient charge, follow NOTICES WHEN USE instructions. If the problem persists, contact your study coordinator or healthcare provider.
The Power Button Indicator and Nebulization Indicator flash red five times	Check the medication cup is filled with appropriate amount of medication.

SPECIFICATION

Parameter	Description
Power Consumption	1.3-1.7 W
Principle of operation	High-speed vibration to turn liquid into fine mist
Dimension/Weight	87.25 x 40.0 x 74.0mm (L x W x H), 125g (battery excluded)
Case color	White (main body and top cover), transparent (medication cup)
Power Source	Lithium –ion rechargeable battery and AC power adaptor Input: 100 – 240 VAC, 50/60 Hz; Output: 5V DC, 1.5A
	Microprocessor circuitry including O.P. amplifier, analog-to digital converter and PWM (Pulse Width Modulation)
User interface	Power Button Indicator : Constant green : Ready for treatment (full battery) Constant orange : The battery at 25%? charge remaining Constant red : The battery is low. Charge as soon as possible. Flash orange : The battery is charging in standby mode. Flash green : The battery is charging in operating mode Flash red : There is no medication in the chamber, treatment is finished. Nebulization Indicator: Constant blue : Treatment (nebulization) in progress Flash red : There is no medication in the chamber, treatment is finished.
Reaction time	1 second
Output rate	0.15 – 0.25 mL/min
Particle size	< 5 µm (MMAD)
Operating conditions	10°C – 40°C; 30 – 80% RH
Storage conditions	-25°C – 70°C; ≤85% RH
Product shelf life	Main unit: 1 years Top cover: 3 months
Battery operation life	At least 40 minutes of continuous operation



Particle size

The method of measuring particle size is according to EN 13544-1:2007 Annex CC

- Particle size: 3.14 µm ± 0.15
- Nebulization rate: 0.15 ml/min ~ 0.25 ml/min
- Aerosol output: 1.28 ± 0.16 ml (1ml, 2.5%(M/V). NaF)
- Aerosol output rate: 0.46 ± 0.06 ml/min (1ml, 2.5%(M/V). NaF)

SYMBOLS DESCRIPTION

Symbol	Meaning	Symbol	Meaning
	WEEE symbol, this indicates that it should not be disposed of, with other household wastes at the end of its working life.		Protection against solid foreign object of 12.5 mmØ and greater and protection against vertically falling water drops when enclosure tilted up to 15°
	Warning		Controller Input – DC voltage
	Batch Symbol		Serial number Symbol
	On/Off power button		Refer to instruction manual/booklet
	Reference number		Manufacturer

Electromagnetic compatibility

Many electronic devices are used in our near environment. Your nebulizer is susceptible to electromagnetic interference from these electronic devices. These interferences may cause incorrect functioning of the nebulizer and can generate unsafe situations.

In order to prevent such unsafe situations, your nebulizer is designed and tested according to EN60601-1-2 standards. These standards define the levels of immunity to a device from electromagnetic interference as well as maximum levels of electromagnetic emissions from the medical device. The electromagnetic emissions of your nebulizer are extremely low, however, special precautions should be observed:

- It is recommended that you do not place the device on top of or close to other devices (such as mobile phone). Should you notice any interference with other electrical devices, keep the device away from those electronic devices.

PY-010 PORTABLE NEBULIZER WARRANTY CARD

The manufacturer warrants to the original retail purchaser that nebulizer will be free from defects in materials and workmanship for 1 year from the date of the original purchase. During the period, we shall, at no charge, repair or replace a unit found to be defective with an equivalent or current version of the original warranty expiration or ninety (90) days after shipment of the repaired or replacement system, whichever period is longer. This warranty is limited to replacement due to defects in parts or workmanship. Failure of the device due to damage by accident, abuse, or use not in accordance with the instructions is not covered by this warranty.

Manufacturer	Local distributor	Dealer(Stamp)
Pu Yuan Biotech Co., LTD. 4F., 4F.-1, No.51, Ln. 35, Jihu Rd., Neihu Dist., Taipei City 11492, Taiwan (R.O.C.) TEL: + 886-2-2627-0630 / FAX: + 886-2-2627-0636		
Name: _____		
Address: _____		
Telephone Number: _____		
E-mail Address: _____		
Nebulizer Serial Number: _____		
Date of Purchase: _____		
Purchased Form(Dealer Name): _____		

From: _____	Stamp: _____

To: _____	_____
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FEDERAL COMMUNICATIONS COMMISSION

INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC RF Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

Pu Yuan Biotech Co., Ltd.
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