MedeScan NE-M01L

Ultrasonic Nebuliser

Medescan is a product of:
TLC Diagnostics Pty Ltd
www.medescan.com.au
info@medescan.com.au
1300 736 330

Statements

- Thank you for purchasing the Medescan Ultrasonic Nebuliser.
- To ensure correct usage, please read the User Manual carefully before use.
- Please keep the User Manual in a safe location for future reference.
- Medescan takes no responsibilities and will not warranty any damage caused by inappropriate use, maintenance, or storage.

1 - Precautions

Please read the user manual carefully to ensure safe usage.

⚠Warnings

- Please follow doctors' advice regarding your medication, dosage and usage.
- Please follow the operating instructions specified in the user manual to avoid unit failure.
- The accessories of device are designed for single person use. Do not reuse the accessory to avoid cross infection.
- For the First time using the Medescan Ultrasonic Nebuliser or if the medication cup is unused for a long time, the medication cup and mask must be cleaned and disinfected.
- After disinfecting the accessories, please ensure thorough rinsing with fresh water to inhaling residual disinfectant.
- Do not use the device to inhale water.
- Do not use the device at ambient temperature above 40℃. It may cause nasal mucosa injury or device failure.
- Do not rinse or soak the main unit in water. Do not store the device in humid environment, otherwise it may cause device failure.
- Please do clean the device after use and dry it immediately after cleaning.
- Please keep the device out of the reach of children.
- Do not use the device near flammable or explosive gas or anesthetic mixture.
- Possible suffocation danger if power cord wraps on child's neck.
- If the device does not auto-shutoff when the medication is totally nebulised, please immediately press the ON/OFF button to turn it off. Refer to Chapter 6 for Troubleshooting.
- Clean medication cup after each use.
- Recommended maximum liquid carrying capacity is 10ml, minimum capacity is 2ml.
- Do not use this product near high-frequency electromagnetic transmitters and other high-frequency electronic products.
- Keep the device upright during use.
- Avoid high impact on the device body and accessories.
- Do not touch the ultrasonic mesh diaphragm with sharp objects as it can void the warranty.
- The face mask is made of plasticizer-free PVC material.
- Do not use suspended or high-concentration medicinal solutions. Please consult your doctor for specific types of nebulization medication and follow doctor's recommendations and use.
- Charge the device if low power appears.
- If the device will not be used for a long time, please charge it periodically.
- Children must use the device under direct adult supervision
- Do not store or carry the device with medication in the medication cup.
- Disposal of waste main units and accessories shall follow the local government regulations.
- This product cannot be used in respiratory anesthesia systems and ventilator systems.

2 - General

2.1 Function and application

The nebulizer can atomize medication into a mist of microscopic droplets, which can be easily inhaled into respiratory system along with breathing, achieving therapeutic effect for respiratory diseases such as acute inflammation of the upper respiratory tract, acute and chronic tracheitis, bronchitis and swelling and pain in throat, etc. The device has two nebulization modes.

Application: inhalation treatment of atomized medication via respiratory system

2.2 Features

Power supply: DC 5V or (3.7V rechargeable lithium battery)
Input power: <5 VA
Nebulization rate in level I: ≥ 0.25mL/min
Nebulization rate in level II: ≥ 0.15mL/min
Noise: ≤50 dB
Equivalent volume particle diameter distribution: the volume distribution ratio of small, atomized particles (diameter<5 μm) is no less than 60 %
Type of protection against electric shock: Class Ⅱ equipment, internally powered equipment
Degree of protection against electric shock: type BF applied part
Waterproof Rating: IP22
Note: Please purchase suitable power adapter (input: AC 100-240V, 50Hz-60Hz, output: DC 5V, 1.0A).

2.3 Operational environment

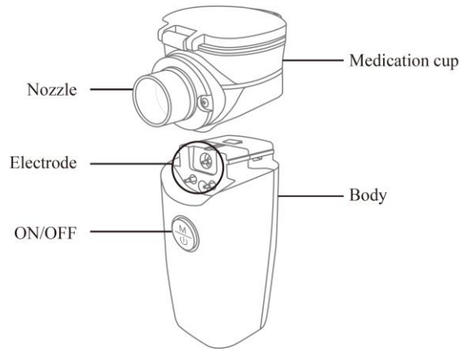
Temperature: 5 ℃~40 ℃
Humidity: 15 %~90 %
Atmospheric pressure: 700 hPa~1060 hPa

Attention: This product is not suitable for use in strong electromagnetic interference environments (such as various medium/high frequency therapeutic instruments, transformers, large electrical cabinets, radio and television transmission towers, other radio frequency transmitting equipment, and other electrical appliances or medical equipment may generate interference.).

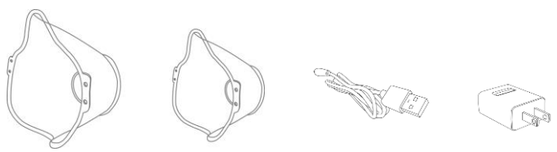
3 Product Composition

Structure: The nebulizer consists of a body, a medication cup, mask, power cord and adapter (optional).

Main unit:



Accessories:



Adult mask　Child mask　USB Cable　Adapter (optional)

Chapter 4 How to use

4.1 Assembly

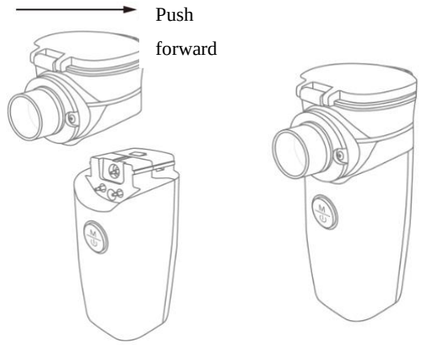
1. Remove all packages

Attention: When using for the first time, please clean and disinfect the device before use.

2. Assembly of main unit

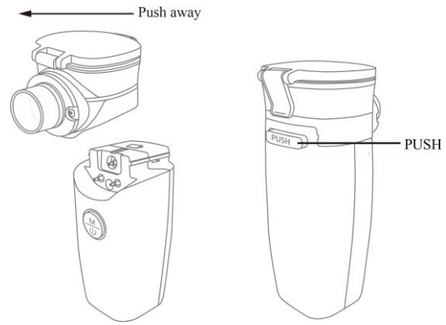
(1) Install medication cup to the device body.

Attention: When installing medication cup to the device body, be sure to install to proper position, and you can hear a click sound.



(2) Remove medication cup from device body. Press and hold the "PUSH" button on the body, and push medication cup away from the device body.

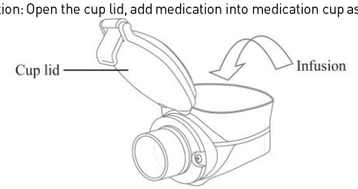
Attention: In order to avoid device damage, please press the "PUSH" button first when removing medication cup.



4.2 Operations for treatment use

Preparations before use:

1. Remove medication cup, clean and disinfect it before use.
2. Add medication: Open the cup lid, add medication into medication cup as shown below:



Attention:

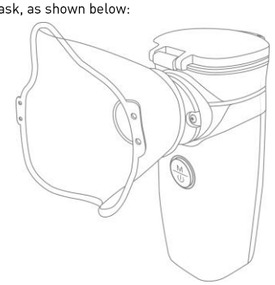
(1) Before using any pharmaceutical products or medicines, please consult your doctor or pharmacist to ensure that you are using the product correctly.

(2) Do not use the medication of high concentrations, high viscosity, oily medicines, suspended or volatile liquid medicine.

(3) It is recommended not to exceed the maximum capacity of medication cup. If medication cup is filled with medication, be sure to close the cup lid to prevent leakage.

3. Close the cup lid.

4. Install medication cup to device body.
5. Assemble the mask, as shown below:



Operation method:

1. Startup: press ON/OFF button to turn on the device, 1 second later, the indicator lights up in green, and the device starts atomizing.

2. Mode switch: The device has two working modes: level I and level II. Level I is the high nebulization rate mode, level II is the low nebulization rate mode. User could change the working mode by short pressing ON/OFF button.

3. Inhalation: Hold the device in hand, put on the mask, slowly inhale the medication mist.

Attention:

If medication cup is not filled with any medication, the device will automatically switch off. Before turning off, the indicator light flickers orange as a prompt.

After pressing the ON/OFF button, the device will go through a short start up period (within 2s), then start atomizing.

When the medication is going to run out, it is recommended to slightly tilt the device towards to user (the side with button should be closer to user), so that the remaining solution could contact the nebulizing diaphragm for atomization.

Due to the difference of characteristics of medicinal solutions, the device may not shutdown automatically when the medication is used up. The user may need to turn off the device manually to protect the nebulizing diaphragm from damage.

During use, please hold the device steady and do not shake it.

There is an air hole on the lid of medication cup, do not cover it to ensure normal atomization.

Duration of each dosing should be no more than 20 minutes, if you have any discomfort during use, please stop the treatment and consult your doctor or pharmacist.

4. Turn off the power: If you need to shut the device down during use, please press the ON/OFF button, after 1 second, the indicator light goes out and the device turns off.

Attention:

In order to prevent the device from accidentally switching on when it is carried in a bag, the product is designed to perform power on and off operations after a long press of the button for 1 second.

At the end of treatment, it is normal that a little medication left in medication cup after automatically shut off.

4.3 Use and Charging of lithium battery

Battery operation:

(1) The indicator lights up in orange when battery is low, prompting user to charge the device.

(2) During normal operation, the battery can continuously work for 1 hour after being fully charged.

Charging:

(1) Insert the power adapter plug into the power interface on the device.

(2) Plug the adapter into a power socket.

When charging, the indicator lights up in blue, and it goes off automatically after charging is completed.

Attention:

Specification of power adapter: input: AC100-240V 50-60Hz, output: DC5V, 1.0A.

Please unplug the power adapter after use, avoid connecting with the power for a long time.

When the device is left unused for a long time, it should be charged every six months, which could greatly extend the battery life. The battery is not replaceable.

5 Maintenance, Transport and Storage

5.1 Cleaning

Clean and disinfect the device after each use. If the device is not regularly cleaned it may affect the effective performance and medicine delivery.

1. Remove medication cup and accessory from the device body.
2. Open the cup lid and discard residual medication.
3. Add 75% ethanol solution in medication cup, cover the cup lid, then leave it for at least 10mins. Gently shake it for better disinfection.
4. Immerse the accessories to be disinfected into a container with ethanol solution and close the container. Use 75% ethanol solution soaking for 10mins or longer.
5. Discard the disinfectant in medication cup, take accessories out from the disinfectant; clean the medication cup and accessories with clear water repeatedly.
6. Fill medication cup with clear water, assemble it to the device body, let the device work 10mins to clean the nebulizing diaphragm.
7. After cleaning, use new medical gauze to wipe away the water, and fully dry.
8. Use 75% medicinal alcohol to wipe the surface of device body, then air-dry or wipe-dry with a clean, soft cloth.
9. After all steps above, store the device body, medication cup and accessories in a dry, clean place.

Attention:

Do not disinfect medication cup and accessories in boiling water. Do not put them in a microwave oven for drying.

The parts disinfected with disinfectant must be fully cleaned and any residual disinfectant removed.

5.2 Medication cup replacement

The nebulizing diaphragm is a kind of consumable. Generally, the service life of nebulizing diaphragm is six months (if it is used 3 times a day, 20 mins each time.). Its service life depends on the use method, medication, and the degree of cleaning. If no atomizing or little atomizing appears when device working, please replace medication cup in time. (If you need to purchase medication cup, please contact Medescan 1300 736 330.)

5.3 Transport and storage

Environment of transport and storage:

Temperature: -40 ℃~+55 ℃

Relative humidity: 5 %~96 %

Atmospheric pressure: 500 hPa ~ 1060 hPa

Requirement of transport and storage:

✧ No corrosive gas and well-ventilated room.

✧ Keep the device out of the reach of children.

✧ Do not store the device in places such as direct sunlight, high temperature, humid, or dusty environment.

✧ Avoid excessive vibration or shocks.

5.4 Pollution-free disposal and recycle

Please dispose of in accordance with relevant local laws and regulations.

Chapter 6 Troubleshooting

Problems	Reason analysis	Solutions
The device doesn't startup.	Low battery.	Please charge the device.
No atomizing or little atomizing appears when device working.	Medication cup is not well installed.	Check the installation of medication cup and reinstall it.
	No medication in medication cup	Trickle medication into medication cup, remember do not exceed its maximum capacity.
	Non-suitable medication	Consult a doctor if the medication is suitable for the device.
	The nebulizing diaphragm is dirty	Clean medication cup.
	The medication cup may need replacement	Contact Medescan 1300 736 330 to purchase a new medication cup
There is water around the nozzle of nebulizer.	Due to temperature differences, the temperature of medication cup surface is relatively low, medication mist in contact with the nozzle then condenses into water droplets.	Remove medication cup, pour the water out.
After startup, power indicator lights about 1s, then immediately goes out.	Medication cup is not well installed.	Re-install medication cup once again.
	Medication cup is not loaded with any medication	Put the medication into medication cup as instructed by your doctor or pharmacist.
After startup, power indicator lights up, but immediately goes out, or it does not work normally.	Battery is dead.	Please charge the device.
Nebulizer doesn't automatically shut off when medication is used up.	Medication may generate bubbles in medication cup	Press ON/OFF button to turn off the device and clear up the bubbles.
	Medication may be attached on the nebulizing sheet	Press ON/OFF button to turn off the device, and clean medication cup.
	The electrodes contacting with the medication cup may be dirty	Press ON/OFF button to turn off the device and clean the electrodes.
The working hour is too short after the device is charged.	Battery is not fully charged.	Please charge the device.
	Battery is damaged.	Please contact local customer service team 1300 736 330.
If the device still not working properly after troubleshooting, please contact our customer service team on 1300 736 330.		

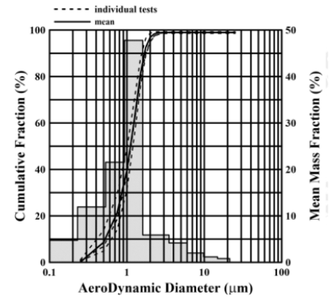
Chapter 7 Symbols

Symbol	Meaning
IP22	The level of waterproof and dustproof rating is IP22.
	Class Ⅱ equipment
	Type BF applied part
	Keep dry
	Fragile, handle with care
	This way up
	Humidity limitation: 5 %~96 %
	Temperature limitation: -40 ℃~+55 ℃
	Atmospheric limitation: 500 hPa ~ 1060 hPa
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
	ON/OFF button and Nebulization rate switch button
	Refer to instruction manual/booklet Note: On ME equipment "follow instructions for use"
SN	Serial number
	Manufacturer
	WEEE (2002/96/EC)
	Date of manufacture

1. Device body 1pc
2. User manual 1pc
3. Medication cup 1pc
4. Accessories 1set (adult mask, child mask)
5. Power cord 1pc

Appendix Ⅰ

Curve chart of equivalent volume particle diameter distribution:



the median particle diameter (D 0.50) is1~4 μm. Error margin within ±25 %

Appendix II EMC Guidance and Manufacturer Declaration

Warning:

- This device should not be used when close to or stacked with other equipment, if necessary, please observe and verify that device can operate normally in this configuration.
- The use of ACCESSORIES and cables other than those specified and supplied by manufacturer should not be used.

The device complies with the emission and immunity requirement specified in YY0505-2012.

Table 1: Electromagnetic emission

Guidance and manufacture's declaration-electromagnetic emission		
The device is tended for use in the electromagnetic environment specified below. The purchaser or the user of the device should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device 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 device 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 emission IEC 61000-3-3	Applicable	

Table 2: Electromagnetic immunity 1

Guidance and manufacture's declaration-electromagnetic immunity			
The device is intended for use in the environment specified below. Buyer or operator should assure that it is used in such environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floor is 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 ± 1 kV for I/O line	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV lines to lines ±2 kV lines to earth	±1 kV lines to lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage vatiations on power supply input lines IEC 61000-4-11	<5%UT(>95%dip in UT) for 0.5 cycle 40% UT(60%dip in UT) for 5 cycle 70%UT(30%dip in UT) for 25 cycle <5%UT(>95%dip in UT) for 5 sec	<5%UT(>95%dip in UT) for 0.5 cycle 40% UT(60%dip in UT) for 5 cycle 70%UT(30%dip in UT) for 25 cycle <5%UT(>95%dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 3: Electromagnetic immunity 2

Guidance and manufacture's declaration-electromagnetic immunity			
The device is intended for use in the environment specified below. Buyer or operator should assure that it is used in such environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC61000-4-3	3 V (effective value) 150kHz ~ 80MHz	3 V (effective value)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz-800MHz $d=2.3\sqrt{P}$ 800MHz-2.5GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3 V/m 80 MHz~2.5 GHz	3 V/m	
NOTE 1: At 80MHz 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.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device or system is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as adjusting the direction or location of the device. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4: Recommended safety distance

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated power of transmitter(W)	Separation distance according to power of transmitter (m)		
	150 k Hz – 80 MHz $d=1.2\sqrt{P}$	80 MHz – 800 MHz $d=1.2\sqrt{P}$	800 MHz – 2.5 GHz $d=2.3\sqrt{P}$
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 distanced 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 80MHz and 800MHz, 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.			