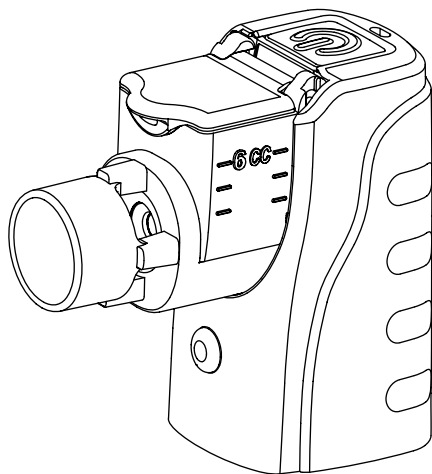


POCKET AIR®

Portable Nebulizer



Instruction Manual

MBPN002 / MB0500300/ MB05006

CE
1639

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General information

Thank you for choosing our Portable Nebulizers. Pocket Air is a handheld device designed to aerosolize medication for respiratory treatment. Three models of Pocket Air available are listed below.

Portable Nebulizer Model No. MB0500300

This model can be operated with two AA batteries or NiMH rechargeable batteries (optional, not included).

Portable Nebulizer Model No. MBPN002 / MB05006

This model can be operated with power adapter or with batteries (or rechargeable batteries). Pocket Air does not charge rechargeable batteries, rechargeable batteries should be charged separately.

Please read the instructions carefully and completely. Failure to comply with instructions for use may result in damage to the device. Instructions for use are also available on the internet in both English and Chinese. Simply visit: www.pocketair.com.tw



 **POCKET AIR®**

Intended Use

Intended purpose	This device is to aerosolize the medication or saline solution and transmit the mist particle into user's oral cavity and respiratory tract.
Intended user	This device is designed for patients of all ages except for patients who are unconscious, not breathing spontaneously or have pulmonary edema. Babies and children must be supervised by an adult during treatment.
Recommended operation environment	This device is intended for use in medical facility, such as hospital, clinic and doctor's office, and in general household. Temperature range: 10°C to 40°C Humidity: 30 to 85 % RH
Precautions for use	Warnings and cautions described in the manual should be observed.

Safety Precautions



READ ALL WARNINGS AND INSTRUCTIONS BEFORE YOU USE THIS DEVICE.

As with any medical device, this product may become unusable due to an electrical outage, battery depletion, or mechanical impaction. We recommend that you have spare batteries and a backup device available to you.

When you use electrical products, always follow basic safety precautions. As with any electrical device, take particular care around children.



WARNINGS

- Only use this device with medications prescribed by your doctor.
- The nebulizer is only intended for respiratory therapy, and any other application of this device is improper and dangerous. The manufacturer is not liable for any damage caused by improper or incorrect use.
- Do not share your nebulizer with others. This product (included medication cup, mask, mouthpiece) must only be used by a single patient.
- Clean and disinfect nebulizer according to instruction manual. Do not keep product and accessories in a damp environment. Contamination and residual moisture encourage the growth of bacterial and increase the risk of infection.
- Adult supervision is required when this device is used by children and individuals who require special assistance.
- For safety reasons, always disconnect the power adapter from the socket under the following circumstances:
 - if a malfunction occurs during operation
 - before cleaning the device
 - immediately after use
- The product must not be operated and the power adapter must be unplugged from the socket immediately if the power adapter is damaged, or if a fault is suspected.
- Be sure the device has been properly cleaned before use to avoid possible contamination.
- Do not handle the power adapter with wet hands.
- Do not pull the power adapter out of the socket by the cable.
- Do not swallow small parts of nebulizer.



CAUTIONS

- Do not attempt to clean the mesh with any foreign objects, it may damage the mesh.
- Avoid dropping the device otherwise it may not function normally.
- Keep the device away from direct sunlight, excessive heat or cold to avoid damaging the batteries.
- Do not attempt to open, repair or modify this device.
- Do not wash the main unit, adapter or USB cable with water. If you spill liquid on the main unit or adapter, wipe it off immediately.
- Do not start the nebulizer without filling in the medication.
- Follow local laws and recycling plans regarding disposal or recycling of components, batteries and packaging.
- Do not attempt to pull or separate the bottom cover and the connective band.
(Available on Model no. MB05006)

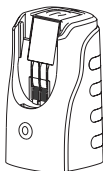
Explanation of Symbols

Symbol	Meaning
	Warning / Caution / Note
	Class II equipment per IEC 60601-1
	Type BF equipment per IEC 60601-1
IP22	Protected against foreign objects equal to or greater than 12.5mm in diameter and against drops of water falling at up to 15° from vertical
	Consult instructions for use
	ON / OFF Button
	DC Power source (Direct Current)
	Operating temperature limits : 10°C to 40°C
	Storage and delivery temperature limits : -20°C to 70°C
	Operating humidity limits: 30 to 85% R.H.
	Storage and delivery humidity limits: 20 to 75% R.H.
	Manufacturer
	Date of manufacture
	Serial number
	Batch code
	Disposal of Electrical & Electronic Equipment (WEEE): Do not treat this product as household waste.
	This device complies with the requirements of the Medical Devices Directive (93/42/EEC)
	Authorized representative in the European Community

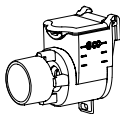
Package Contents

Check before use

The following items are contained in the package. Please check all parts for visible damage. Replace any damaged parts before you use this device. In the case of missing parts, malfunction or damage, please contact the store where you purchased from or the nearest dealer.



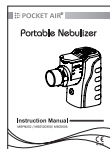
1. Main unit



2. Medication cup



3. Mask



4. Instruction Manual

Optional Parts and Accessories

Main Unit

MBPN00200 / MB0500300 / MB0500600



Medication Cup

MBPN00201 / MB0500601



Mask (Adult)

MBPN00203



(Single patient use)

Mask (Child)

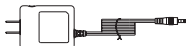
MBPN00204



(Single patient use)

Power Adapter

MBPN00205



(Available on MBPN002, MB05006)

Mouthpiece

MBPN00207



(Single patient use)

USB Cable

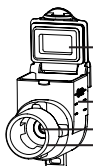
MBPN00208



(Available on MBPN002, MB05006)

- To order replacement parts or accessories, please contact your local supplier.
- Identify the model No. with mark from the medication cup.
- Allow the device to cool down or warm up to operating temperature before turning on the power.

System Overview

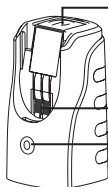


Medication Cup Cap

Medication Cup

Mesh

Mouthpiece (Connector)



Main Unit

ON / OFF Button 

Press ON/OFF Button to turn on the power.

Electrode

Medication Cup Release Button
(Power Indicator)

Press Release Button to remove the medication cup.

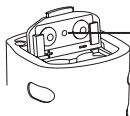


Light Indications

Green light on : Ongoing operation

Orange light on/ flash : Low power / Malfunction

No light : Malfunction

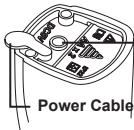


Battery Cover

Bottom View



(Model no.
MB0500300)

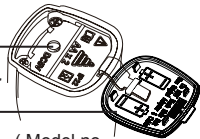


(Model no.
MBPN002)

Power Cable Jack

Bottom cover

Power Cable Jack Cover



(Model no.
MB050006)

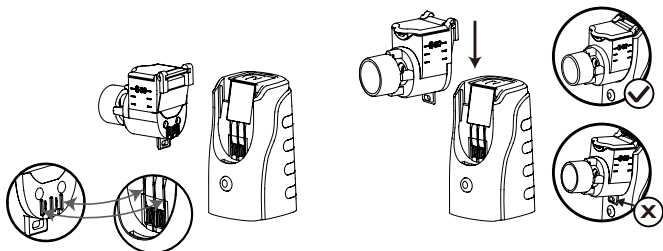
How to set up the Medication cup



Clean all parts of your portable nebulizer before use, after each use and after extended storage.

1. Set up the medication cup

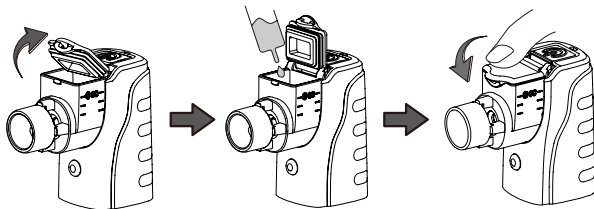
- Align the buckle on the back of the medication cup with the trenches on the main unit and insert the medication cup. Check to ensure that the buckle is aligned and inserted correctly.



2. Adding medication

Make sure that the indicator light is off before adding the medication.

- Open the medication cup cap.
- Add the quantity of medication prescribed by your doctor.
DO NOT EXCEED THE LIMIT (Max. 6ml).
- Close the medication cup cap properly.

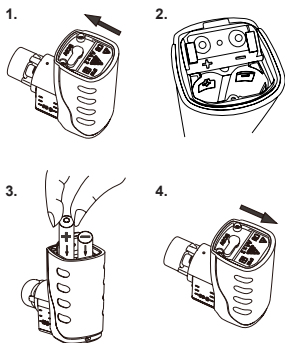


Connecting to power supply

(Applicable to MBPN002, MB0500300)

Installing batteries

This device can be operated with two AA alkaline batteries or two AA nickel-metal-hydride (NiMH) rechargeable batteries. (Secondary lithium batteries shall comply with the requirements of IEC 62133.)



- Turn the unit upside down.
- Press and push the battery cover in the direction of the arrow.
- Insert two AA alkaline/NiMH rechargeable batteries. Make sure that the batteries are aligned to match the polarity symbols on the battery compartment.
- Push the battery cover in the direction of the arrow until it locks in place.



1. Do NOT insert a battery with the positive(+) and negative(-) poles reversed.
2. Do NOT use old and new batteries together or mix and use different brand of batteries together.

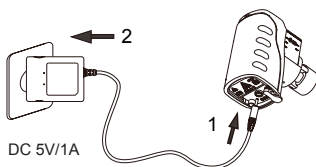
Battery life and battery replacement

1. Nebulizer can be operated with alkaline batteries or nickel-metal-hydride (NiMH) rechargeable batteries.
2. When the power indicator turns orange (means low power), please replace both batteries with new one.
3. Battery life depends on the capacity and condition of the batteries.

Using adapter



1. Only use an external adapter that is in compliance with the requirements of IEC60601-1:2005. Please choose DC 5V/1A adapter, and the connection jack should be 9.5mm in length, with an outer diameter of 3.5mm, interior diameter of 1.35mm, and positive polarity.
2. The adapter does not charge batteries. Please remove the batteries before using the adapter.
3. As with all electronic devices, it is recommended to keep the product unplugged when not in use.
4. Adapter is only available on model No. MBPN002.

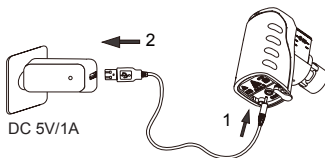


- Insert the jack connector of the power adapter into the adapter jack on the main unit.
 - Plug the adapter into a standard power socket.
- *The power adapter is an optional accessory and the appearance might be different.

Using USB cable



1. The connection jack should be 9.5mm in length, with an outer diameter of 3.5mm, interior diameter of 1.35mm, and positive polarity.
2. The USB cable does not charge batteries. Please remove the batteries before using the USB cable.
3. As with all electronic devices, it is recommended to keep the product unplugged when not in use.
4. USB cable is only available on model No. MBPN002.



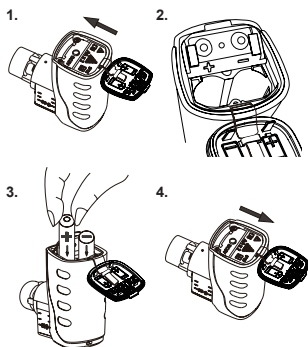
- Insert the jack connector of the USB cable into the cable jack on the main unit.
 - Plug the USB cable into a standard charger.
- *The standard charger is an optional accessory and the appearance might be different.

Connecting to power supply

(Applicable to MB0500600)

Installing batteries

This device can operate on two AA alkaline batteries or two AA nickel-metal-hydride (NiMH) rechargeable batteries. (Secondary lithium batteries shall comply with the requirements of IEC 62133.)



- Turn the unit upside down.
- Open the bottom cover.
- Press and push the battery cover in the direction of the arrow.
- Insert two AA alkaline/NiMH rechargeable batteries. Make sure that the batteries are aligned to match the polarity symbols on the battery compartment.
- Push the battery cover in the direction of the arrow until it locks in place.
- Close and push down the bottom cover.



1. Do NOT insert a battery with the positive(+) and negative(-) poles reversed.
2. Do NOT use old and new batteries together or mix and use different brands of batteries together.
3. Do NOT pull the bottom cover too hard.

Battery life and battery replacement

1. Nebulizer can be operated with alkaline batteries or nickel-metal-hydride (NiMH) rechargeable batteries.
2. When the power indicator turns orange (means low power), please replace both batteries with new one.
3. Battery life depends on the capacity and condition of the batteries.

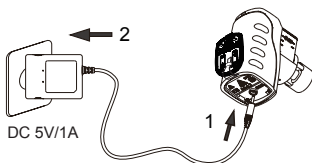
Using adapter



Do not pull or shake the bottom cover during operation.



1. Only use an external adapter that is in compliance with the requirements of IEC60601-1:2005. Please choose DC 5V/1A adapter, and the connection jack should be 9.5mm in length, with an outer diameter of 3.5mm, interior diameter of 1.35mm, and positive polarity.
2. The adapter does not charge batteries. Please remove the batteries before using the adapter.
3. As with all electronic devices, it is recommended to keep the product unplugged when not in use.



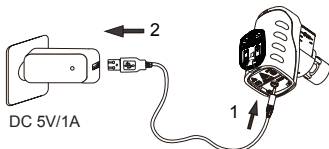
- Open the bottom cover.
- Insert the jack connector of the power adapter into the adapter jack on the main unit.
- Plug the adapter into a standard power socket.

*The power adapter is an optional accessory and the appearance might be different.

Using USB cable



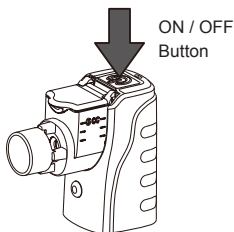
1. The connection jack should be 9.5mm in length, with an outer diameter of 3.5mm, interior diameter of 1.35mm, and positive polarity.
2. The USB cable does not charge batteries. Please remove the batteries before using the USB cable.
3. As with all electronic devices, it is recommended to keep the product unplugged when not in use.



- Open the bottom cover.
- Insert the jack connector of the USB cable into the cable jack on the main unit.
- Plug the USB cable into a standard charger.

*The standard charger is an optional accessory and the appearance might be different.

How to inhale properly



1. Performing the inhalation

- Press ON/OFF button on the top to start nebulization (light Indicator turns green).
- Place the mouthpiece between your teeth, with your lips firmly sealed around the mouthpiece.
- * Accessories such as additional mouthpiece and mask could help to provide a more comfortable inhalation treatment.
- * If mask is used, gently press the mask against the face so that it fits snugly over the mouth and nose.
- Breathe in and out slowly through your mouth until aerosol formation stops.

2. End of inhalation

- Press ON/OFF button to turn it off.
- Press Release Button to remove the medication cup.
- Remove the batteries from the main unit.
- Make sure the bottom cover is closed completely. (Only available on MB05006)



1. Tilt the device slightly until the solution is almost exhausted to make sure that the residual solution contacting the mesh is nebulized completely.
2. High viscosity solution may result in poor nebulization or clogging of the mesh. In this case, turn off the power and remove the accumulated solution on the mesh with gauze or lint free towel.

Cleaning and Disinfection



Device should be cleaned and disinfected after every application to prevent the growth of microorganisms, which increases the risk of infection.

After every use:

Clean the **nebulizer** after each inhalation.

1. Remove the residual solutions in the medication cup.
2. Pour some distilled water into the medication cup.
3. Turn on the device to nebulize the distilled water for 1 to 2 minutes to clean the mesh.
4. Remove batteries or disconnect the adapter from the main unit.
5. Remove the medication cup from the main unit.
6. Wash and rinse the medication cup with distilled water.
7. Shake off excess water and allow parts to be fully air dried on a clean, dry towel.
8. Use gauze or clean towel to wipe off stains on the main unit if necessary.
9. Make sure that all cleaned parts are completely dry before you store or use them next time.



1. Keep the battery compartment dry all the time.
2. Do NOT poke the mesh with finger, cotton swab or any object.
3. Do NOT clean parts in a dishwasher.
4. Do NOT use microwave to dry any parts.

Clean the **mask and mouthpiece** with neutral detergent before first use and after each use.

1. Hand wash the mask and the mouthpiece in warm (30°C) water using neutral detergent and gently rub it for at least 30 seconds.
2. Rinse well with distilled water.
3. Allow them to air dry and keep away from direct sunlight.



Daily disinfections

1. Disinfection by boiled water

- It is important to disinfect the medication cup twice a week (disinfection once every 3 to 4 days).
- Rinse the medication cup with distilled water.
- Use a saucepan to boil distilled water. Wait for the distilled water to boil.
- Turn off the heat source.
- Carefully immerse the medication cup in the boiled water for a maximum of ten (10) minutes.
- Carefully remove the medication cup from the boiled water and shake off excess water.
- Allow parts to fully air dry on a clean, dry towel, and out of reach of children.
- Make sure that all parts are clean and dry before storage or use.

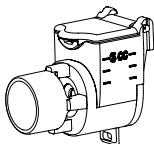
2. Disinfection by alcohol

- It is important to disinfect the medication cup twice a week (disinfection once every 3 to 4 days).
- Rinse the medication cup with distilled water.
- Immerse the medication cup in 75% ethyl alcohol for one (1) minute.
- Rinse the medication cup with distilled water again, shake off excess water and allow parts to be fully air dry on a clean dry towel.
- Make sure that all parts are clean and dry before storage or use.



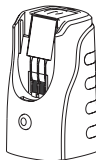
1. Do NOT boil the medication cup directly.
2. Alcohol is highly flammable. Do Not use alcohol within the vicinity of open fire or smoke.

The following item can be disinfected by boiled water or alcohol.

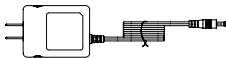


• Medication cup

Parts below CANNOT be disinfected by boiled water or alcohol.



• Main unit



• Power adapter



• USB cable



Do NOT rinse or immerse the main unit, power adapter or USB cable in any liquid.



Storage

Store the device and medication cup in a dry and clean environment.



1. Do NOT leave residual liquid in the medication cup.
2. Remove the batteries if the device will not be in use for a prolonged period. Failure to do so may result in damage due to battery leakage.
3. Do NOT leave the device under direct sunlight, or in high humidity, extreme heat or cold environment.
4. Keep this device away from fire, high electromagnetic fields and out of reach of children.

Troubleshooting

If you have difficulty operating Pocket Air, check the following points:

Problem	Possible Cause	Action
Low atomization	Low battery power	Insert new batteries or connect the power adapter
	Faulty connection due to stains on the electrodes	Use rubbing alcohol to clean the electrodes
	The mesh holes are clogged	Refer to Cleaning and Disinfection procedure to clean the medication cup
	The mesh is damaged	Replace the medication cup
Light indicator does not turn on, no atomization	The batteries are inserted in the wrong direction	Follow (+) and (-) mark on the battery cover to re-insert the batteries in correct direction
	Batteries are dead	Insert new batteries or connect the power adapter
	Faulty connection between the adapter and the main unit	Check and reconnect the adapter to the main unit
No atomization when power switch and indicator are on	The mesh holes are clogged	Refer to Cleaning and Disinfection procedure to clean the medication cup
	The mesh is damaged	Replace the medication cup
Power indicator shows constant orange light	Low battery power	Insert new batteries or connect the power adapter
Power indicator shows flashing orange light	Faulty connection between the electrodes and the main unit	Use rubbing alcohol to clean the electrodes and reinstall the medication cup
	The mesh is damaged	Replace the medication cup
	The medication cup is not installed properly	Refer to How to Set up the medication cup procedure to reinstall the medication cup
The bottom cover separates from the main unit	The connective band disconnects from the bottom cover	Insert the connective band into the fixing hoop of the bottom cover
	The connective band is broken	Please contact the nearest dealer or the store where you purchased the device
	The connective band disconnects from the main unit	



1. If the device does not nebulize normally after taking the above-mentioned procedure, please contact the nearest dealer or the store where you purchased the device.
2. Never operate this device if any of the parts are not working properly or have been damaged.
3. It is recommended to replace the medication cup after 1 year of use, and the device after 2 years of use.
4. Replace the mask and mouthpiece after one week of use, or whenever the accessories are damaged.

Specifications (MBPN002/ MB0500300)

Product	Portable Nebulizer
Model	MBPN002/ MB0500300
Method of operation	Active Vibrating Mesh Technology
Power supply	AA Alkaline Battery x 2 AA NiMH rechargeable Battery x 2 Power Adapter*
Power consumption	< 1.5W**(MBPN00201) / ≤ 2.4W**(MB0500601)
Vibrating frequency	Approx. 117 kHz +/- 15%
Nebulization rate	≥ 0.25 ml/min
Particle size	MMAD < 5μm**
Capacity of medication cup	Approx. 6 ml
Dimension	Approx. L78 X W41 X H73 mm
Weight	Approx. 74g (Excluding batteries)
Operating temperature and humidity	10 ~40°C, 30 ~ 85 % RH, 800~1060hPa
Storage and delivery condition	-20 ~ 70°C, 20 ~ 75 % RH, 800~1060hPa



* The optional power adapter and USB cable are available on Model MBPN002, MB05006, and it should be in compliance with the requirements of IEC60601-1:2005. Contact the nearest dealer for further information.

Secondary lithium batteries should be in compliance with the requirements of IEC 62133.

** Tested with physiological saline, and under normal temperature of 23°C.

Specifications (MB05006)

Product	Portable Nebulizer
Model	MB05006
Method of operation	Active Vibrating Mesh Technology
Power supply	AA Alkaline Battery x 2 AA NiMH rechargeable Battery x 2 Power Adapter*
Power consumption	$< 1.5W^{**}(\text{MBPN00201}) / \leq 2.4W^{**}(\text{MB0500601})$
Vibrating frequency	Approx. 117 kHz +/- 15%
Nebulization rate	$\geq 0.25 \text{ ml/min}$
Particle size	MMAD $< 5\mu\text{m}^{**}$
Capacity of medication cup	Approx. 6 ml
Dimension	Approx. L81 X W44 X H77 mm
Weight	Approx. 84g (Excluding batteries)
Operating temperature and humidity	10 ~40°C, 30 ~ 85 % RH, 800~1060hPa
Storage and delivery condition	-20 ~ 70°C, 20 ~ 75 % RH, 800~1060hPa



* The optional power adapter and USB cable are available on Model MBPN002, MB05006, and it should be in compliance with the requirements of IEC60601-1:2005. Contact the nearest dealer for further information.

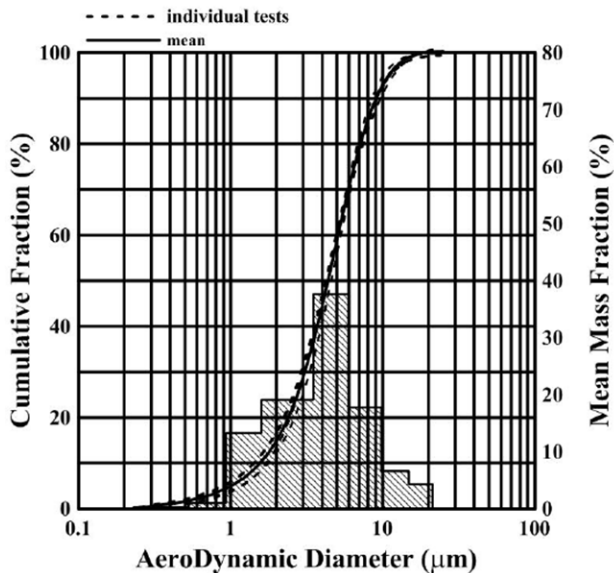
Secondary lithium batteries should be in compliance with the requirements of IEC 62133.

** Tested with physiological saline, and under normal temperature of 23°C.

Technical Data

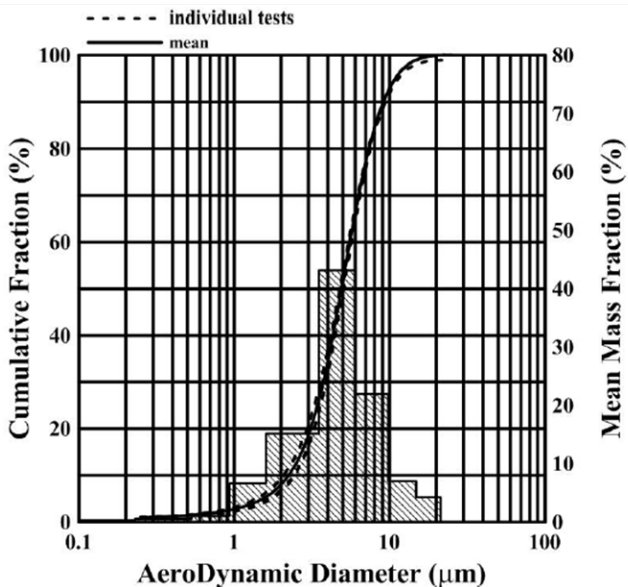
According to the Standard EN 13544-1:2007+A1:2009 "Respiratory therapy equipments - Part 1: Nebulizing systems and their components", Annex CC.3 using multistage cascade impactor to measure particle size.

Model	MBPN00201
Particle Size	MMAD < 5 μ m (MMAD = Mass Median Aerodynamic Diameter)
Medication Cup Capacity	6 ml max.
Noise	Less than 50dB (Around 1 meter)



Technical Data

Model	MB0500601
Particle Size	MMAD < 5 μ m (MMAD = Mass Median Aerodynamic Diameter)
Medication Cup Capacity	6 ml max.
Noise	Less than 50dB (Around 1 meter)



Technical Data

In order to regulate the requirements for EMC with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. The nebulizer MBPN002, MB0500300 conforms to the EN60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, do not use the nebulizer close to the strong electrical or electromagnetic fields. This may result in incorrect operation and create a potentially unsafe situation.

Guidance and manufacturer's declaration - of MBPN002, MB0500300.

Guidance and manufacturer's declaration-electromagnetic emissions		
The <u>MBPN002, MB0500300</u> is intended for use in the electromagnetic environment specified below.		
The customer or the user of the <u>MBPN002, MB0500300</u> should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>MBPN002, MB0500300</u> 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	The <u>MBPN002, MB0500300</u> 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.

Technical Data

Guidance and manufacturer's declaration-electromagnetic immunity

The MBPN002, MB0500300 is intended for use in the electromagnetic environment specified below.

The customer or the user of the MBPN002, MB0500300 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 kV air	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 commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV line(s) to line(s) + 2kV line(s) to earth	+ 1kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations 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 cycles 70% UT(30% dip in UT) for 25 cycles <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 cycles 70% UT(30% dip in UT) for 25 cycles <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 of the <u>MBPN002, MB0500300</u> requires continued operation during power mains interruptions, it is recommended that the <u>MBPN002, MB0500300</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The <u>MBPN002, MB0500300</u> 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.			

Technical Data

Guidance and manufacturer's declaration-electromagnetic immunity

The MBPN002_MB0500300 is intended for use in the electromagnetic environment specified below.

The customer or the user of the MBPN002_MB0500300 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MBPN002_MB0500300 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 to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 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).
Radiated RF IEC 61000-4-3	20 V/m 80MHz to 2,5 GHz	20 V/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 ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 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 MBPN002_MB0500300 is used exceeds the applicable RF compliance level above, the MBPN002_MB0500300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MBPN002_MB0500300.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Technical Data

Recommended separation distance between portable and mobile RF communications equipment and the MBPN002, MB0500300

The MBPN002, MB0500300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MBPN002, MB0500300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MBPN002, MB0500300 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 $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 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 distance d in metres (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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Technical Data

In order to regulate the requirements for EMC with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. The nebulizer MB05006 conforms to the EN60601-1-2:2014 standard for both immunity and emissions.

Nevertheless, do not use the nebulizer close to the strong electrical or electromagnetic fields. This may result in incorrect operation and create a potentially unsafe situation.

Guidance and manufacturer's declaration - of MB05006.

Manufacturer's declaration-electromagnetic emissions		
The <u>MB05006</u> is intended for use in the electromagnetic environment (for home healthcare) specified below.		
The customer or the user of the <u>MB05006</u> should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance (for home healthcare environment)
RF emissions CISPR 11	Group 1	The <u>MB05006</u> 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	The <u>MB05006</u> 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.

Technical Data

Manufacturer's declaration-electromagnetic immunity

The MB05006 is intended for use in the electromagnetic environment (for home healthcare) specified below.

The customer or the user of the MB05006 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home 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 MB05006 requires continued operation during power mains interruptions, it is recommended that the MB05006 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 MB05006 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

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

Technical Data

Manufacturer's declaration-electromagnetic immunity

The **MB05006** is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the **MB05006** should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home 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	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the MB05006 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 to 800 MHz $d = 2,3 \sqrt{P}$ 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).
Radiated RF IEC 61000-4-3	80 % AM at 1 kHz e) 10 V/m 80 MHz – 2,7 GHz b) 80 % AM at 1 kHz c)	80 % AM at 1 kHz e) 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	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. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 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 **MB05006** is used exceeds the applicable RF compliance level above, the **MB05006** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **MB05006**.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Technical Data

Manufacturer's declaration-electromagnetic immunity							
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
The MB05006 is intended for use in the electromagnetic environment (for home healthcare) specified below.							
The customer or the user of the MB05006 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	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0,3	28	28
870							
930							
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9	9
5500							
5785							
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.							

Technical Data

Recommended separation distance between portable and mobile RF communications equipment and the MB05006

The MB05006 is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the MB05006 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MB05006 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 $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



WEEE (Directive on Wasted Electrical and Electronic Equipment)

This marking shown on the product 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 equipment for safe recycling.



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