

# Portable Nebulizer



# **Instruction Manual**

MBPN002 / MB0500300/ MB05006



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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
- 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 batteriés.
- 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		
$\triangle$	Warning / Caution / Note		
	Class II equipment per IEC 60601-1		
<b>†</b>	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		
[ji	Consult instructions for use		
<b>(b)</b>	ON / OFF Button		
===	DC Power source (Direct Current)		
10°C \$\int 40°C	Operating temperature limits : 10°C to 40°C		
-20°C	Storage and delivery temperature limits : -20°C to 70°C		
30%	Operating humidity limits: 30 to 85% R.H.		
20%_575%	Storage and delivery humidity limits: 20 to 75% R.H.		
	Manufacturer		
	Date of manufacture		
SN	Serial number		
LOT	Batch code		
Z	Disposal of Electrical & Electronic Equipment (WEEE): Do not treat this product as household waste.		
<b>C</b> €	This device compiles with the requirements of the Medical Devices Directive (93/42/EEC)		
EC REP	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.









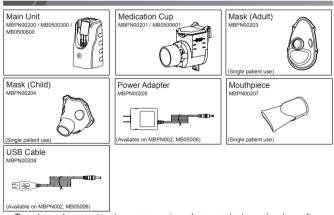
1. Main unit

2. Medication cup

3. Mask

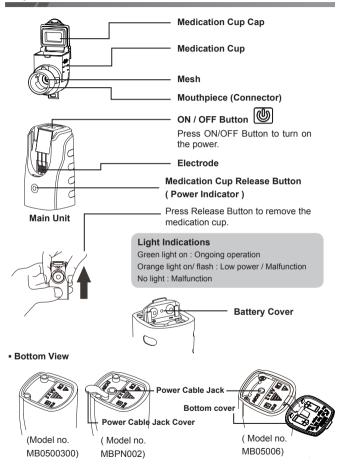
4. Instruction Manual

# **Optional Parts and Accessories**



- 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



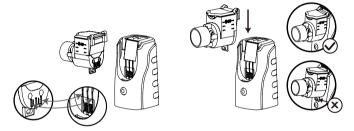
# How to set up the Medication cup

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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.



- 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.

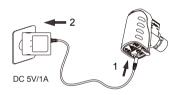
#### Battery life and battery replacement

- Nebulizer can be operated with alkaline batteries or nickel-metal-hydride (NiMH) rechargeable batteries.
- 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



- 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. ○─€─○
- The adapter does not charge batteries. Please remove the batteries before using the adapter.
- 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.

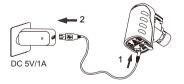


- Insert the jack connector of the power adapter into the adapter jack on the main unit.
- Plug the adapter into a standard power socket.
- \*The power adapter is an optional accessory and the appearance might be different.

### 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. ○─€—↔
- The USB cable does not charge batteries. Please remove the batteries before using the USB cable.
- 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

- Nebulizer can be operated with alkaline batteries or nickel-metal-hydride (NiMH) rechargeable batteries.
- 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.

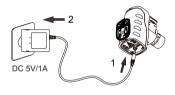
### Using adapter



Do not pull or shake the bottom cover during operation.



- 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. (→ (♣) (♣)
- The adapter does not charge batteries. Please remove the batteries before using the adapter.
- As with all electronic devices, it is recommended to keep the product unplugged when not in use.

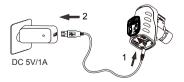


- -Open the bottom cover.
- Insert the jack connector of the power adapter into the adapter jack on the main unit.
- -Plug the adapter into a standard power socket.
- \*The power adapter is an optional accessory and the appearance might be different.

### 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.
- 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.
- 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

- Remove the residual solutions in the medication cup.
- 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.
- Remove batteries or disconnect the adapter from the main unit.
- Remove the medication cup from the main unit.
- Wash and rinse the medication cup with distilled water.
- Shake off excess water and allow parts to be fully air dried on a clean, dry towel.
   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.
- Rinse well with distilled water.
- Allow them to air dry and keep away from direct sunlight.

### Daily disinfections

It is important to disinfect the medication cup on a daily basis.

#### 1. Disinfection by boiled water

- 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

- 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.





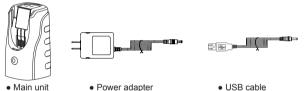
- 1. Do NOT boil the medication cup directly.
- 2. Alcohol is highly flammable. Do Not use alcohol within the vicinity of open fire or smoke.

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



Medication cup

#### Parts below CANNOT be disinfected by boiled water or alcohol.



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



- 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.
- 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 1year of use, and the device after 2 years of use.
- 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 < 5um**	
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.

<sup>\*\*</sup> Tested with physiological saline, and under normal temperature of 23°C.

# Specifications (MB05006)

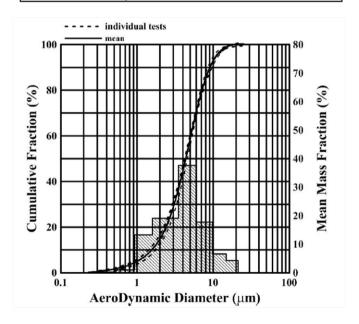
Product	Portable Nebulizer	
Model	MB05006	
Method of operation	Active Vibrating Mesh Technology	
Power supply	AA Alkaline Battery x 2 AA NiMH rechargeable Battery x 2 Power Adapter*	
Power consumption	< 1.5W**(MBPN00201) / ≤ 2.4W**(MB0500601)	
Vibrating frequency	Approx. 117 kHz +/- 15%	
Nebulization rate	≧ 0.25 ml/min	
Particle size	MMAD < 5um**	
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	



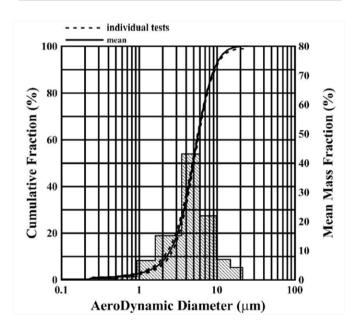
- \* The optional power adapter and USB cable are available on Model MBPN002, \* The optional power adapter and GOS casts at Statements of IEC60601-MB05006, and it should be in compliance with the requirements of IEC60601-1:2005. Contact the nearest dealer for further information.
  - Secondary lithium batteries should be in compliance with the requirements of IEC 62133.
  - \*\* Tested with physiological saline, and under normal temperature of 23°C.

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 < 5um (MMAD = Mass Median Aerodynamic Diameter)	
Medication Cup Capacity	6 ml max.	
Noise	Less than 50dB (Around 1 meter)	



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



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 <u>MBPN002</u>, <u>MB0500300</u> 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  $\underline{\text{MBPN002}}, \underline{\text{MB0500300}}$  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 MBPN002, MB0500300 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 Harmonic emissions IEC 61000-3-2	Class B Class A	The MBPN002, MB0500300 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.
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

#### Guidance and manufacturer's declaration-electromagnetic immunity

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.

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 MBPN002, MB0500300 requires continued operation during power mains interruptions, it is recommended that the MBPN002, MB0500300 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 MBPN002. MB0500300 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.

#### 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 is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the MBPN002_MB0503000 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
Conducted RF	3 Vrms	3 Vrms	d = 1,2 √ P 80MHz to 800 MHz
IEC 61000-4-6	150 KHz to 80 MHz		d = 2,3 √ P 800MHz to 2,5 GHz
Radiated RF	20 V/m	20 V/m	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).
IEC 61000-4-3	80MHz to 2,5 GHz	20 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range*.
			Interference may occur in the vicinity of equipment marked with the following symbol:
			$((\omega))$

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 stalions for radio (cellulariccordiess) 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 MBEPNOZ\_MBS050030 is used exceeds the applicable RF compliance level above, the MBEPNOZ\_MBS050030 should be observed to verify normal operation. If shormal performance is observed, additional measures my be necessary, such as re-orienting or relocating the MBEPNOZ\_MBS050300.

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

# 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.

associating to the maximum curput power of the communications equipment.				
Rated maximum output	Separation distance according to frequency of transmitter			
·	m			
power of transmitter W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz	
vv	d =1,2 √ P	d =1,2 √ P	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 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.

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 <u>MB05006</u> 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 <u>MB05006</u>.

#### 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 MB05006 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 MB05006 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply netwo		
Harmonic emissions IEC 61000-3-2	Class A	that supplies buildings used for domestic purposes.		
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance			

#### 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; 1,5 cycle 0 % U T; 1 cycle 70 % U T; 25/30 cycles  Voltage interruptions: 0 % U T; 250/300 cycle	Voltage dips: 0 % U τ; 0,5 cycle 0 % U τ; 1 cycle 70 % U τ; 1 cycle 70 % U τ; 25/30 cycles Voltage interruptions: 0 % U τ; 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.

#### 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)		
			Portable and mobile RF communications equipment should be used no closer to any part of the MB0500b including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.		
			Recommended separation distance:		
Conducted RF	3 Vrms:	3 Vrms:	d = 1,2 √P		
IEC 61000-4-6	0,15 MHz - 80 MHz	0,15 MHz - 80 MHz	d = 1,2 √P 80MHz to 800 MHz		
	6 Vrms:	6 Vrms:	d = 2,3 √P 800MHz to 2,7 GHz		
	in ISM and amateur	in ISM and amateur			
	radio bands between 0,15 MHz and 80 MHz	radio bands between 0,15 MHz and 80 MHz	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)	80 % AM at 1 kHz e) 10 V/m 80 MHz – 2.7 GHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>		
	80 MHz – 2,7 GHz b) 80 % AM at 1 kHz c)	80 % AM at 1 kHz	Interference may occur in the vicinity of equipment marked with the following symbol:		
			(((\dot))		

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.

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

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

The <u>MB05006</u> 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 <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	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 <sup>c)</sup> ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710							
745	704-787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
780							
810		GSM 800/900, TETRA 800, iDEN 820, CDMA 850.	Pulse modulation b) 18 Hz	2	0,3	28	28
870	800-960						
930		LTE Band 5					
1720		GSM 1800; CDMA 1900;					
1845	1700-1990	GSM 1900; DECT;	Pulse modulation b) 217 Hz	2	0,3	28	28
1970		LTE Band 1, 3, 4, 25; UMTS					
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							
5500	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
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.

# 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	Separation distance according to frequency of transmitter m			
power of transmitter W	150 kHz to 80 MHz d =1.2 √ P	80 MHz to 800 MHz d =1.2 √ P	800 MHz to 2,5 GHz d =2,3 √ 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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HT11-17014-01

# Warranty card

Product Name	Portable Nebulizer
Model Number	
Serial Number	
Purchase Date	
Dealer	

- Please get a shop stamp from your dealer, put the purchase date on this card, and keep this card with you. Presentation of this card is required when a warranty service is requested. (No new card will be issued to you if this card is lost.)
- 2. Microbase guarantees that the main unit of Pocket Air, if used according to the instructions, will be free from defects in material and workmanship caused by the manufacturing process for the warranty period of 2 years. Any other replacement parts or accessories are not covered hereby. You will void this warranty if you disassemble the main unit of this Portable Nebulizer.
- The warranty period of the medication cup will be 12 months, starting from the purchase date. The warranty does not apply to ( what's NOT covered):
  - I. Mesh clogging.
  - II . Any failure to follow our written instructions for the product.
  - III . Damage or defect due to willful neglect or negligence by anyone other than us.
- 4. During the warranty period, Microbase will repair or replace the device if a defect is discovered. If it is replaced, the replacement device may either be the same model or a model that is at least comparably equipped. Replacement or repair of the device shall not serve as the basis for a new warranty. All replaced old devices or parts shall become the property of Microbase. Further claims are excluded. This disclaimer of warranty shall be ineffective in the event of injury to life, limb or health, in cases of wrongdoing and gross negligence, product liability and if substantive obligations under the warranty agreement are violated. Any expenses of non-maintenance work (including but not limited to, the back and forth shipping cost or expenses arising from your specific request) will be borne by you.
- 5. The warranty shall be cancelled if:
  - -the device has been operated or used improperly with respect to the descriptions in the instructions for use
    - -damage is present that is attributable to the effects of water, fire, lightning, etc.
  - -the damage was caused by transporting the device incorrectly or a falling impact
  - -the device has been misused or not cared for correctly
  - -repairs, adaptations or modifications have been made to the device by persons not authorized by Microbase
- For any service requested without this warranty card, beyond the warranty period, or not covered by this warranty, a service fee will be charged.
- In the event that replacement parts or warranty service is needed, please contact the nearest dealer or the store where you purchased this device.

