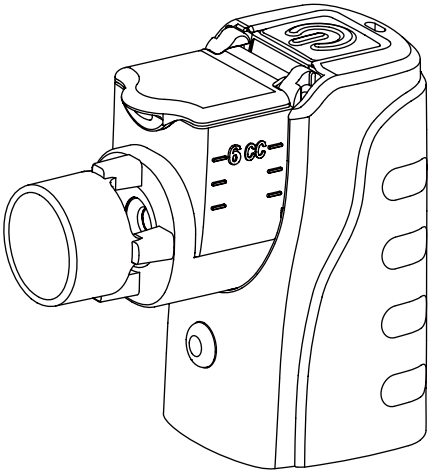
Portable Nebuliser



Instruction Manual

Breath-A-Tech® Portable Nebuliser REF MBPN002

Table of Contents

- General information 1
- Intended Use 2
- Safety Precautions 3
- Explanation of Symbols 4
- Package Contents 5
- Optional Parts and Accessories 5
- System Overview 6
- How to set up the Medication cup 7
- Connecting to power supply 8
- How to inhale properly 10
- Cleaning and Disinfection 11
- Troubleshooting 13
- Specifications 14
- Technical Data 15

General information

Thank you for choosing our Portable Nebulisers. Portable Nebuliser is a handheld device designed to aerosolise medication for respiratory treatment.

Portable Nebuliser Model No. MBPN002
This model can be operated with a USB cable or with batteries (or rechargeable batteries). Portable Nebuliser 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.

Intended Use

Intended purpose	This device is to aerosolise 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. For human use only.
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 nebuliser 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 nebuliser with others. This product (including medication cup and mask) must only be used by a single patient.
- Do not use with any oil based product.
- Clean and disinfect nebuliser according to instruction manual. Do not keep product and accessories in a damp environment. Contamination and residual moisture encourages the growth of bacteria and increases 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 USB cable 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 USB cable must be unplugged from the socket immediately if the USB cable or power adaptor 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 USB cable or power adaptor with wet hands.
- Do not pull the power adaptor out of the socket by the USB cable.
- Do not swallow small parts of nebuliser.

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 or USB cable with water. If you spill liquid on the main unit or USB cable, wipe it off immediately.
- Do not start the nebuliser without filling it with medication.
- Follow local laws and recycling plans regarding disposal or recycling of components, batteries and packaging.

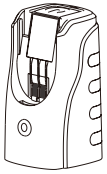
Explanation of Symbols

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
	Refer to instruction manual/booklet
	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
SN	Serial number
LOT	Batch code
	Disposal of Electrical & Electronic Equipment (WEEE): Do not treat this product as household waste.

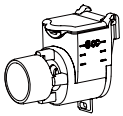
Package Contents

Check before use

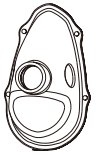
The following items are contained in the package. Please check all parts for visible damage. Replace any damaged parts before you use this device. In the case of missing parts, malfunction or damage, please contact the store where you purchased from or the nearest dealer.



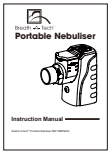
1. Main unit



2. Medication cup



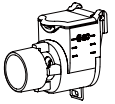
3. Mask (Child and Adult)



4. Instruction Manual

Optional Parts and Accessories

Medication Cup
MBPN00201



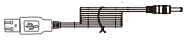
Mask (Adult)
MBPN00203

(Single patient use)

Mask (Child)
MBPN00204

(Single patient use)

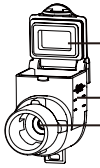
USB Cable
MBPN00208



(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.

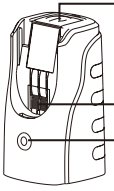
System Overview



Medication Cup Cap

Medication Cup

Mesh



ON / OFF Button

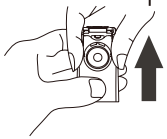
Press ON/OFF Button to turn on the power.

Electrode

Medication Cup Release Button (Power Indicator)

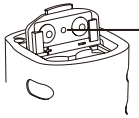
Press Release Button to remove the medication cup.

Main Unit



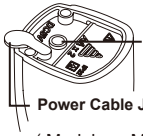
Light Indications

Green light on : Ongoing operation
Orange light on/ flash : Low power / Malfunction
No light : Malfunction



Battery Cover

▪ **Bottom View**



Power Cable Jack

Power Cable Jack Cover

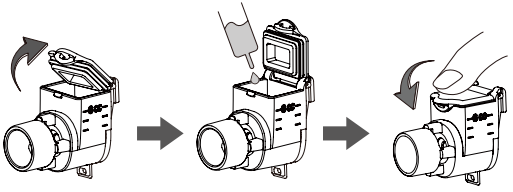
(Model no. MBPN002)

How to set up the Medication cup

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

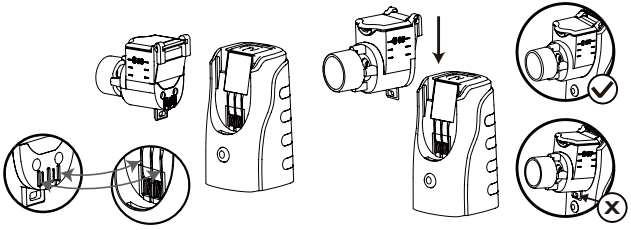
1. Fill Medication

- Fill the medication in accordance with instruction from doctors. The maximum capacity is 6ml.
- Make sure the medication cup lid had closed properly.
- Use a dry lint free cloth to wipe excessive medication or solution before install the medication cup onto the main unit.



2. Install the Medication Cup

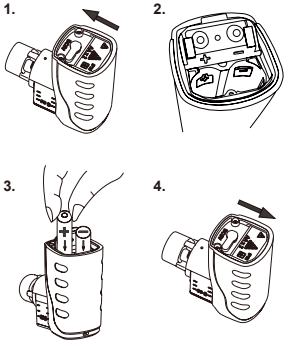
- Align the buckle on the back of the medication cup with the trenches on the main unit and insert the medication cup. Check to ensure that the buckle is aligned and inserted correctly.



Connecting to power supply

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.

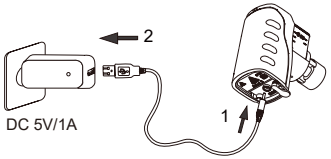
1. Do NOT insert a battery with the positive(+) and negative(-) poles reversed.
2. Do NOT use old and new batteries together or mix and use different brand of batteries together.

Battery life and battery replacement

1. Nebuliser 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 USB cable

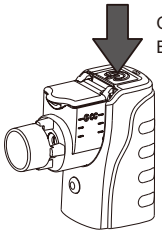
1. **The connection jack should be 9.5mm in length, with an outer diameter of 3.5mm, interior diameter of 1.35mm, and positive polarity.**
2. **The USB cable does not charge batteries. Please remove the batteries before using the USB cable.**
3. **As with all electronic devices, it is recommended to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

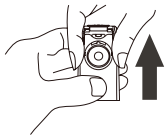


- Insert the jack connector of the USB cable into the cable jack on the main unit.
- Plug the USB cable into a power adaptor.

* Note: Power adaptor is not included with this product. If a power adaptor is to be used, it shall be in compliance with the requirements of IEC 60601-1:2005.

How to inhale properly





1. Performing the inhalation

- Press ON/OFF button on the top to start nebulisation (light Indicator turns green).
- Place the mouthpiece between your teeth, with your lips firmly sealed around the mouthpiece.

* Accessories such as additional 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.

1. **Tilt the device slightly until the solution is almost exhausted to make sure that the residual solution contacting the mesh is nebulised completely.**
2. **High viscosity solution may result in poor nebulisation 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 appropriately after every application to prevent the growth of microorganisms, which increases the risk of infection.

After every use:

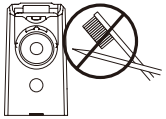
Clean the **nebuliser** after each inhalation.

1. Remove the residual solutions in the medication cup.
2. Pour some distilled water into the medication cup.
3. Turn on the device to nebulise the distilled water for 1 to 2 minutes to clean the mesh.
4. Remove batteries or disconnect the USB cable 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** with neutral detergent before first use and after each use.

1. Hand wash the mask 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.



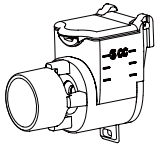
Disinfections

1. Disinfection by boiled water

- It is important to disinfect the medicine 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.

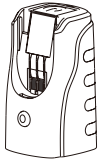
1. Do NOT boil the medication cup directly.

The following item can be disinfected by boiled water



● Medication cup

Parts below CANNOT be disinfected by boiled water



● Main unit

● USB cable

Do NOT rinse or immerse the main unit 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 Portable Nebuliser, check the following points:

Problem	Possible Cause	Action
Low atomisation	Low battery power	Insert new batteries or connect the USB cable
	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 atomisation	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 USB cable
	Faulty connection between the USB cable and the main unit	Check and reconnect the USB cable to the main unit
No atomisation 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 USB cable
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 nebulise 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 from first use, and the device after 2 years from date of manufacture.
4. Replace the mask after one week of use, or whenever the accessories are damaged.

Specifications

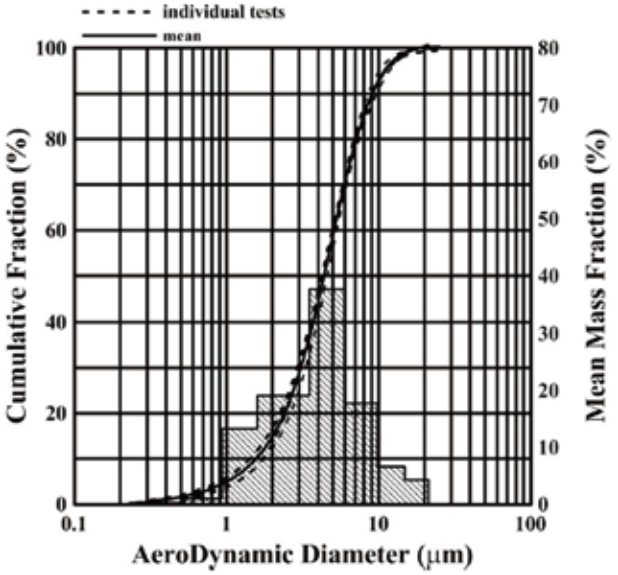
Product	Portable Nebuliser
Model	MBPN002
Method of operation	Active Vibrating Mesh Technology
Power supply	AA Alkaline Battery x 2 AA NiMH rechargeable Battery x 2 USB cable*
Power consumption	< 1.5W**(MBPN00201)
Vibrating frequency	Approx. 117 kHz +/- 15%
Nebulisation rate	≧ 0.25 ml/min
Particle size	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 adaptor and USB cable are available on Model MBPN002, 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: Nebulising systems and their components", Annex CC.3 using multistage cascade impactor to measure particle size.

Model	MBPN002
Particle Size	MMAD < 5um (MMAD = Mass Median Aerodynamic Diameter)
Medication Cup Capacity	6 ml max.
Noise	Less than 50dB (Around 1 metre)



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 nebuliser MBPN002, conforms to the EN60601-1-2:2007 standard for both immunity and emissions.
Nevertheless, do not use the nebuliser 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.

Guidance and manufacturer's declaration-electromagnetic emissions

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

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

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The MBPN002 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 MBPN002 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration-electromagnetic immunity

The MBPN002 is intended for use in the electromagnetic environment specified below.
The customer or the user of the MBPN002 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 requires continued operation during power mains interruptions, it is recommended that the MBPN002 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 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 is intended for use in the electromagnetic environment specified below.
The customer or the user of the MBPN002 should assure that it is used in such and 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 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 is used exceeds the applicable RF compliance level above, the MBPN002 should be observed to verify normal operation. If abnormal performance is observed, additional measures my be necessary, such as re-orienting or relocating the MBPN002.
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			
The MBPN002 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MBPN002 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MBPN002 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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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First Use Card

Portable Nebuliser Medication Cup

Accessory Pack

Product Name	Portable Nebuliser Medication Cup
Model Number	**BAT-NEB-CUP-V3**
Serial Number	
Date First Used	

The portable nebuliser cup has a shelf life of 12 months from date of first use, within a maximum of 2 years from date of manufacturing. You can record the date of first use on this card.

If you have experienced issues with the cup, please send this card and supporting information to Medical Developments International. Please note the instructions for use for this product before making any claim.

MicroBase Technology Corporation
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NEB_WCARD_BATV3_V4

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