BIOS
Diagnostics™/MC

2-in-1 Nebulizer

Instruction Manual
Model: 100NB

Desktop, or handheld use.
Provides a compressed air source to deliver physician prescribed inhalation medication.



1/02/2024

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1. Introduction

Thank you for purchasing the BIOS Diagnostics™ 2-in-1 Nebulizer.
This device is both a desktop and handheld (portable or stationary) aerosol nebulizer, that is electronically powered by an external power adapter. Compressed air, created by the pump within the device, flows into the nebulizer container kit. The air pressure then forces the prescription inhalation medication through the nozzle where it is atomized to an optimal aerosol particle size. This manual is a comprehensive guide designed to help you understand the capabilities and operation of the 100NB 2-in-1 Nebulizer. Before using this device, carefully read this manual for setup, configuration, use, troubleshooting, and maintenance of the device.

1.1 Indications for Use

The BIOS Diagnostics™ 2-in-1 Nebulizer is intended to administer aerosol treatments of prescription medication to adults and children over the age of 2, by using compressed air to operate a nebulizer kit. The device is designed for both homecare and healthcare settings. The nebulizer kit is intended for multiple uses by a single patient.

1.2 Features

Use this product for inhaling prescription medication for respiratory disorders such as asthma, chronic bronchitis, allergies and other respiratory disorders.

- 2-in-1 use: Desktop or Handheld
- Easy to operate
- Nebulizes at an optimal particle size of 2-5 μm
- Use with either the mouthpiece, or masks provided
- Compact and convenient for travel

1.3 General Warnings and Cautions

Important Information Before Use

- **DO NOT** expose the device to extreme temperatures or very high humidity levels.
- **DO NOT** apply heavy weight/pressure on the device. Avoid extreme stress, shock or accidental dropping.
- The nebulizer is made for inhaling prescription medications for respiratory disorders only. **DO NOT** use this device for reasons other than the intended purpose.

- User should not hold their breath while using the device.
- If the user feels unwell at any point during the use of the device, stop the machine, and consult a doctor immediately.
- Always use fresh medication for each session. Dispose of any remaining medication after use.
- Store the device and its parts in a clean location to avoid chance of infection. **DO NOT** use or store the device where it may be exposed to noxious fumes or volatile substances.
- **DO NOT** disassemble or attempt to repair the nebulizer, or its parts. Doing so will void the warranty.
- The device is not suitable for use in an anesthetic breathing system or a ventilator breathing system.
- **DO NOT** use tap or mineral water in the nebulizer for nebulizing purposes.
- During the nebulization, avoid turning off the power unexpectedly. Sudden power cuts may result in not receiving a full dose, treatment interruption, or incomplete treatment.
- **DO NOT** use a damaged nebulizer kit, mouthpiece or facemask.
- The nebulizer and charging cable are not waterproof. **DO NOT** spill or submerge these parts in any liquid. If liquid comes into contact with these parts, immediately unplug the charging cable and wipe off the liquid.
- To avoid medication residue if using masks, wipe down face after session.
- Keep this device out of sunlight.
- The nebulizer may become hot during long periods of operation. This is normal.
- Use only the original nebulizing parts, air filters and air filter cover.
- **DO NOT** add more than 8 ml of medication to the medication tank.
- **DO NOT** carry or leave the nebulizer kit with medication in the tank.
- **DO NOT** use the device if you are overly tired, or drowsy.
- The nebulizer is approved for human use only.
- For genuine replacement parts please contact Thermor Ltd. customer service.

General Warnings

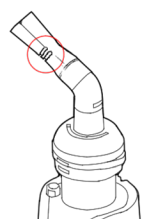
- Always follow instructions from your doctor regarding the type of medication, dosage, frequency, and duration of inhalation time to use.
- Only use medication prescribed or recommended by your doctor or physician.

- **DO NOT** modify this equipment without authorization of the manufacturer. This will void the warranty.
- **DO NOT** use in an environment where it may be exposed to flammable gas.
- If you experience any allergic reactions or other issues during use, stop the device immediately and consult your doctor.

Cautions

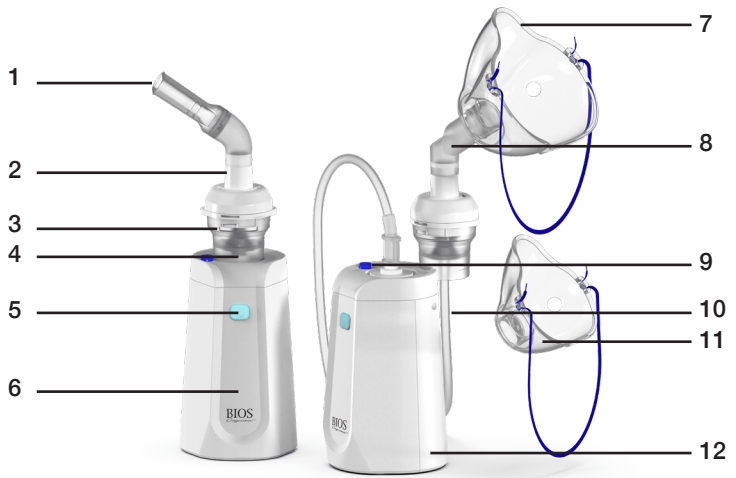
- Keep the device out of reach of unsupervised infants and children. The device may contain small pieces that could pose a choking hazard.
- To avoid potential reactions; avoid nebulizer parts coming into contact with any open wounds.
- Always use the device in an appropriate operating environment. If the device is exposed to extreme temperature/humidity/atmosphere, allow it to sit at room temperature for 2 hours before use.
- This product should not be used on patients who are unconscious or not breathing independently.
- Never use the device near flammable gases, oxygen, or nitrogen oxide.
- **DO NOT** cover the nebulizer with a blanket, towel, or any other type of cover during use. This may cause the device to overheat, and could cause a risk for burns.
- When using this device, there will be some noise and vibration caused by the pump in the nebulizer. There will also be some noise caused by the emission of compressed air from the nebulizer kit. This is normal and does not indicate a malfunction.
- **DO NOT** mix two or more types of prescribed medication. Use only one prescribed medication at a time.
- When using with the mouthpiece, make sure not cover the exhalation port.
- **DO NOT** store the air hose if there is moisture or medication remaining inside. Make sure it is completely dry before storing for next use.
- **DO NOT** use or store the device if the air hose is creased.

Exhalation Port



2. Getting Started

2.1 About the 2-in-1 Nebulizer



1. Mouthpiece
2. Inhalation Top (with adjustable cover)
3. Medication Tank
4. Vaporizer Head
5. Power Key
6. Front Case
7. Adult Mask
8. Mask connector tube
9. Filter Cover (air filter inside)
10. Air Hose
11. Child Mask
12. Bottom Case

2.2 List of Components

- Nebulizer
- USB-C Charging Cable
- Mouthpiece
- Masks (1x Adult/1x Child, with Mask connector tube)
- Air Hose
- Air Filters x5

2.3 Important Information about Inhalation Therapy with the 100NB

The BIOS Diagnostics™ 2-in-1 Nebulizer is not intended to diagnose or replace a diagnosis provided by a physician's advice or inhaler labels. Patients are expected to follow their doctor's advice and inhaler labels.

The 2-in-1 Nebulizer does not act as an MDI medication dose counter and does not include a dose counting function.

***MDI= Metered Dose Inhaler**

Use Restrictions/Contraindications

- The device should not be used on patients, who are unconscious or not breathing independently.
- Check medication package/leaflet for possible contraindications for use with common aerosol therapy systems.

Operating Principle

Prescription inhalation medication that is pumped up through the medication channel is mixed with compressed air generated by a compressor pump. The medication is processed into fine particles and sprayed outwards. Compressed air is then forced along the tube to the nebulizer chamber, where it is converted into a fine mist, which can be inhaled via a mouthpiece or facemask.

The unit can function as a desktop nebulizer where one end of the air hose is connected to the vaporizer head and the other end connected to a mouthpiece or facemask for the administration of medication via the air hose.

The unit can also function as a handheld nebulizer where the vaporizer head is directly connected to a mouthpiece or facemask for the administration of medication.

Intended User(s)

1. Legally certified medical experts, such as doctor, nurses, or therapists.
2. A caregiver or the patient themselves under the guidance of a qualified medical expert for home treatment.

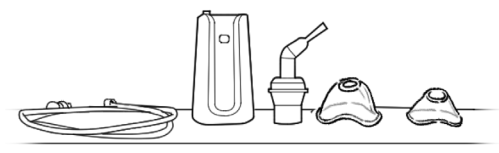
NOTE: The user should be capable of understanding the general operation of the device and the content of this instruction manual.

2.4 Using the Device

1. Inspect the device and parts before using them each time. Check that there are no problems. In particular, be sure to check the following:
    a. That the vaporizer head or air hose are not damaged or blocked.
    b. That the nebulizer operates normally.
    c. That the accessories are good to use.
2. Make sure that the parts that are attachable are secured correctly.
3. Make sure that the air filter is clean and correctly inserted.

2.4.1 General Set Up/Instructions

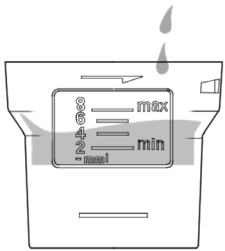
1. Place the 2-in-1 Nebulizer and all of its accessories on a flat, stable surface within reach.



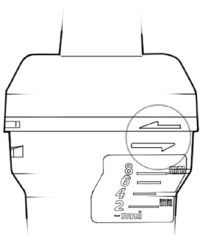
2. Using the guides/alignment blocks on the upper side of the medication tank, gently twist and pull straight up on the base of the inhalation top (the plastic base the mouthpiece/mask is connected to) to separate them into two parts: the medication tank, and the inhalation top.

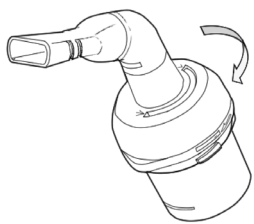


3. Add the correct amount of prescribed inhalation medication to the medication tank. Doses are normally between 2-8 ml. **DO NOT** exceed 8 ml in the medication tank.



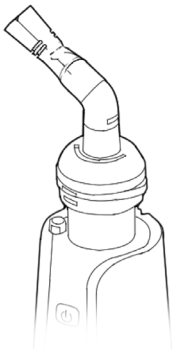
4. Carefully, ensuring no medication is lost; secure the inhalation top, back onto the medication tank. Do this by rotating the inhalation top until the guides/ alignment blocks match up with the slots on the medication tank. Press down and turn to secure in place.



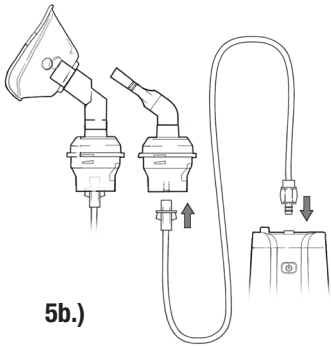


5.a). Take the newly connected upper portion (inhalation top and medication tank), and secure it onto the Nebulizer Device (Main Unit). Do this by lining up the bottom of the medication tank, with the circle on the Nebulizer Device (Main Unit) and pressing down until it does not go further.

5.b). If you are using the air hose, securely attach it to the bottom of the upper portion (inhalation top, and medication tank) and the top of the Nebulizer Device (Main Unit).

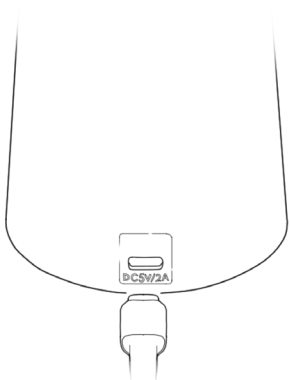


5a.)



5b.)

6. Connect the device to a power source using the USB-A to USB-C power cable. The device **REQUIRES** power connection at all times when in use. The device does not hold a charge itself.

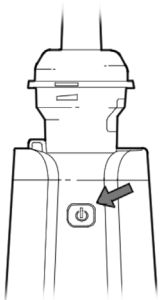


(USB A to C adapter only)

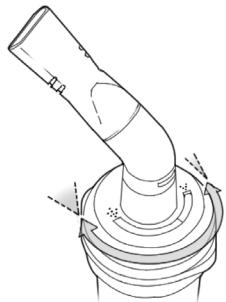
NOTE: Always unplug the device from its power source before cleaning, and when not in use.

NOTE: Do not use if the power cord is damaged. To avoid damage do not store unit with cord wound around the device.

7. Press the power key and make sure that the nebulization begins.
8. The adjustable cover on the inhalation top can be set to change the rate of the airflow simply by turning clockwise, or counter clockwise.



Power key



9. When the treatment is complete, press the power key again to turn the device off.

2.4.2 Child Specific Set Up/Instructions

CAUTION: Children using this device require supervision at all time to ensure nebulization treatment is completed properly.

1. Please first read and follow the assembly steps listed in 2.4.1 General Set Up/Instructions. Make sure to install the Child sized mask onto the Nebulizer. Do this by removing the mouthpiece, and attaching the appropriate sized mask connected to the mask connection tube onto the inhalation top.
2. Secure the mask on to the child's face, ensuring that the mask fits comfortably, but snugly, covering both the mouth and the nose.
3. Begin the treatment ensuring that the child is under constant supervision, and is breathing normally throughout.
4. After completing the treatment, gently clean the child's face using a damp towel, or wipe.
5. Dispose of any unused medication as per disposal guidelines, then follow the cleaning and disinfecting instructions listed in the **3. Cleaning, Disinfecting & Maintenance** section.

6. Ensure that the device and any medication is stored in a safe and secure location where it cannot be accessed by children or pets.

2.4.3 Changing the Air Filter

The device must not be used without an air filter. When the filter needs replacing follow the below instructions.

1. Pull the air filter cover off the device.
2. Remove the old air filter, and replace with a new one.
3. Put the air filter cover back in place.



NOTE: If the filter is grey or brown in colour, or is wet, it needs to be replaced. Extract the filter and replace it with a new one following the instructions above. **DO NOT** try to clean the filter or reuse it. Only use original or genuine filters!

NOTE: Replace the accessories/air filter routinely. Failure to do so, may cause bacterial infection or degradation of the units performance.

NOTE: Make sure that the air filter is clean. If the air filter has been used for more than 90 days, replace it with a new one.

NOTE: DO NOT block the air filter cover.

2.5 Durable Period(s) and Replacement Parts

Provided that the 2-in-1 Nebulizer is used to nebulize 2.5 ml of medication twice per day for 7.5 minutes each session, the durable period(s) for each part are as follows.

NOTE: More frequent use of the 2-in-1 Nebulizer and its parts, may shorten the durable period(s) listed below.

Part	Durable Period	Replacement Part Model #
Nebulizer Device (Main Device)	500 hours	-
Air Filters	3 months	101NB (5 pack)
Mouthpiece	3 months	102NB
Adult Mask	3 months	103NB
Child Mask	3 months	104NB
Air Hose	3 months	105NB

3. Cleaning, Disinfecting & Maintenance

- Thoroughly clean all components to remove medication residue and possible-buildup after each treatment.
- Use a soft dry cloth with non-abrasive cleaners to clean outside of the main unit.
- Make sure that the internal parts of the device do not come into contact with liquids and that the charging cable is disconnected before cleaning.
- Clean the medication tank, vaporizer head, and inhalation top after every use. Disinfect the accessories daily.
- **DO NOT** immerse the main unit in water or other liquids.
- **DO NOT** distort the vaporizer head, or jab the nozzle of the medication tank with a pin, brush or any sharp object.
- **DO NOT** use a microwave oven, dish dryer, or hair dryer to dry the device or the parts.
- **DO NOT** use an autoclave, EOG gas sterilizer, or low temperature plasma sterilizer.
- When disinfecting parts by boiling, make sure that the pot does not boil dry. This may result in a fire and/or damage the parts.

Cleaning

1. Cleaning the Nebulizer Kit (Inhalation Top, Medication Tank), Mouthpiece, and Vaporizer Head
    a. Disassemble all components except for the Nebulizer Device (Main Unit).

b. Prepare a mild detergent with hot water.
c. Wash all components thoroughly in this solution.
d. Rinse all components with regular cold drinking water for approximately two minutes to ensure all detergent is removed from the parts.
e. After the cleaning process is completed, place all parts in a room temperature environment to completely air dry for approximately two hours.

NOTE: The mouthpiece should be cleaned/disinfected daily. It is intended for daily use over a period of three months, or a cleaning limitation of 1000 cycles; whichever is sooner.

2. Cleaning the Nebulizer Device (Main Unit)
    a. Wipe the device with a clean towel moistened with drinking-quality water.
    b. Wipe the device dry with a clean, dry towel.

NOTE: It is recommended to wipe down the device on a daily basis.
NOTE: Be careful not to get any liquid into the charging port on the device.

Disinfecting

1. Disinfecting the Nebulizer Kit (Inhalation Top, Medication Tank), Mouthpiece, and Vaporizer head
    a. Prepare a common household cooking pot.
    b. Put the Mouthpiece, Inhalation Top, Medication Tank, and Vaporizer Head into the pot and fill with tap water.
    c. Bring the water to a boil (100°C).
    d. Continue to keep the water at a boil with the outlined nebulizer parts for 5 minutes.
    e. After 5 minutes, carefully drain the water, and place the accessories in a room temperature environment to completely air dry for approximately 2 hours.

NOTE: The mouthpiece should be cleaned/disinfected daily. It is intended for daily use over a period of three months, or a cleaning limitation of 1000 cycles; whichever is sooner.

Disinfecting the Mask(s)
    a. Prepare an alcohol swab.
    b. Use an alcohol swab to wipe the entire surface area of the face mask(s).

NOTE: The masks should be disinfected daily. They are intended for daily use over a period of three months, or a disinfecting limitation of 100 cycles; whichever is sooner.

CAUTION: DO NOT wash or clean the air filter(s). If the air filter becomes wet, replace it. Damp air filters can cause blockages.

4. Trouble Shooting & Solutions

Problem	Possible Cause	Solution
After pressing the power button, the device does not power on.	The adapter is not plugged into a power source.	Ensure that the unit is plugged into a working power source, then try turning the unit on again.
	There is no medication in the medication cup.	Add the correct amount of the prescription medication into the medication cup. Ensure you do not exceed the maximum capacity.
	An improper amount of medication is in the medication cup	
No nebulization/low nebulization rate when the device is powered on.	The nebulizer kit is not correctly assembled.	Make sure that the nebulizer kit has been put together correctly, and the inhalation accessory (mouthpiece/mask) is correctly attached.
	The vaporizer head is blocked.	Clean and disinfect the nebulizer kit to remove the possible blockage.
	The nebulizer kit is tilted at an incorrect angle.	Ensure that the nebulizer is held or placed on a flat level. Do not tilt while in use.
	The air filter is dirty/clogged.	Replace the air filter with a new clean air filter.

5. Technical Specifications & Symbols

Particle Size	2-5 μm	
Nebulization Rate	approx. 0.3 ml/min	
Noise	≤ 65 dB(A)	
Medication Cup Capacity	max. 8 ml	
Power Supply	5V/2A	
Operating Conditions	+10°C to +40°C (50°F -104°F) 10% to 95% relative humidity (non-condensing) Atmospheric Pressure : 700-1060 hPa	
Storage/Transportation Conditions	-20°C to 60°C (-4°F - 140°F) 10% to 95% relative humidity (non-condensing) Atmospheric pressure : 700-1060 hPa	
Expected Service Life	500 hours	
Shelf Life	3 years	
Unit Dimensions (with mouthpiece)	77.6(L) x 79.3(W) x 241.3(H)mm	
Unit Weight	245g	
Reference to Standards	ISO 27427:2023 ISO 15223-1:2021 ISO 20417:2021 ISO 14971:2019 ISO 18562-1:2017 ISO 18562-2:2017 ISO 18562-3:2017 SOR/98-282 ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-12:2007 ISO 10993-17:2002	ISO 10993-18:2005 CAN/CSA C22.2 NO 60601-1:2014 IEC 60601- 1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2013 IEC 60601-1-11:2010 IEC 62304:2015 IEC 62366-1:2015 ISO 14971:2019 ASTM D4169-16 ASTM F1980-07 ISO 17664-1:2021



Follow Instructions for Use. This document provides important product operation and safety information. Please read this document thoroughly before using the device and keep for future reference.



Type BF applied part.



Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.



IP22: Protected against solid foreign objects of 12.5 mm and greater, and against vertically falling water drops enclosure is tilted up to 15°.



Keep out of direct sunlight.

EMC Tables

100NB is intended for use in the electromagnetic environment specified below. The customer or the user of 100NB must make sure that it is used in such an environment.		
Guidance and manufacturer's declaration - Electromagnetic emissions		
Phenomenon	Professional healthcare facility environment a)	HOME HEALTHCARE ENVIRONMENT a)
Conducted and radiated RF MISSIONS	CISPR 11 Group 1 Class A (Not BLE Function) Group 2 Class A (With BLE Function)	CISPR 11 Group 1 Class B (Not BLE Function) Group 2 Class B (With BLE Function)
Harmonic distortion	Not applicable b) (Note: Power by Battery or DC Input) Only the AC input needs to be tested	

Voltage fluctuations and flickering	Not applicable b) (Note: Power by Battery or DC Input) Only the AC input needs to be tested

a) The equipment is suitable for use in Home Healthcare Environments and Professional Healthcare Environments limited to patient rooms and respiratory treatment facilities in hospitals or clinics. The more restrictive acceptance limits of Group 1 Class B (CISPR 11) have been considered and applied. The equipment is suitable for use in the mentioned environments when directly connected to the Public Mains Network.
b) The test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEM used will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.

Guidance and manufacturer's declaration - Electromagnetic immunity - Enclosure port

Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRON-MENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8kV contact ± 2 kV, ±4kV ±, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	a)	10 V/m b) 80MHz - 2.7 GHz 80% AM at 1kHz

Proximity fields from RF wireless communications equipment	IEC 61000-4-3	COMPLIANT NOTE: Further information about distances to be maintained between portable and mobile RF communications equipment (transmitters) and the 100NB can be requested from supplier using the contact information provided in this manual. However, it is advisable to keep the equipment at an adequate distance of, at least, 0.5 m from mobile phones or other RF communications transmitters to minimize possible interference.
RATED power frequency magnetic fields.	IEC 61000-4-8	30 A/m c) 50 Hz or 60 Hz

a) The equipment is suitable for use in Home Healthcare Environments and Professional Healthcare Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive IMMUNITY acceptance limits have been considered and applied.
b) Before modulation is applied.
c) This test level assumes a minimum distance of at least 15 cm between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic fields.

6. 3 Year Limited Warranty

The BIOS Diagnostics™ 2-in-1 Nebulizer Device (Main Device) has a 3 year limited warranty to be free of manufacturing defects for the life of the original owner. The warranty does not cover accessory parts, or damage from misuse or tampering.

100% Satisfaction Guarantee

If at any time, you are not completely satisfied with the performance of this device, call our BIOS Medical Hotline and speak with a customer service representative, who will make arrangements to have the device tested or replaced to your full satisfaction. If you have questions regarding the operation of your device call the **BIOS Medical Hotline: 1-866-536-2289.** Should correction be necessary, return the unit with all component pieces.

Enclose proof of purchase and $5.00 for return shipping and insurance. Ship the unit prepaid and insured (at owner's option) to:

Thermor Ltd.
Returns Department
16975 Leslie Street
Newmarket, ON L3Y 9A1
www.biosmedical.com
Email: support@biosmedical.com

Please include your name, return address, phone number, and email address. Thermor will test or replace (at Thermor's option) free of charge any parts necessary to correct the defect in material or workmanship.

Please allow 10 days for return shipping.

BIOS | Medical
MANUFACTURED BY/FABRIQUÉ PAR :
THERMOR LTD.
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