PROFESSIONAL MEDICAL PRODUCTS

ISTRUCTIONS

Thank you for purchasing the NB-222C Compact Compressor Nebulizer.
This product was developed for the successful treatment of asthma, allergies and other respiratory disorders. The compressor forces air to the nebulizer. When the air enters the nebulizer, it converts the prescribed medication into an aerosol of microscopic droplets that can eas ly be nhaled.
The Patient is an intended operator Contraindiation: None

SYMBOLS

Symbols	Meaning
	Manufacturer
EC REP	Rappresentante autorizzato nella comunità Europea
	WEEE disposal
	Class II device
CE 0123	Product compliant with the European Directive
	Keep in a cool and dry place
	Follow the instructions for use
	Applied part of type BF

SAFETY INFORMATIONS

To assure the correct use of the product, basic safety measures should always be followed including the warnings and cautions listed in this instruction manual.

WARNING

- For regime of medication shall follow the instructions of your physician or licensed healthcare practitioner.
- Do not cover the compressor with a blanket, towel, or any other type of cover during using. This could result in the compressor overheating or malfunctioning.
- Do not use the device where the device may be exposed to flammable gas or vapors.
- Do not use mineral water in the nebulizer for nebulizing purposes.
- Always dispose of any remaining medication in the medication tank after each use. Use fresh medication each time you use the device.
- Do not leave the device or its parts where it will be exposed to extreme temperatures or changes in humidity, such as leaving the device in a vehicle during warm or hot months, or where it will be exposed to direct sunlight.

CAUTION

- Limit the use of the device to 20 minutes at a time, and wait 40 minutes before using the device again.
- Provide close supervision when this device is used by, on, or near infants, children or compromised individuals.
- Do not insert any object into the compressor.
- Make sure that the air filter is clean. If the air filter has changed color or has not been used for 60 days, replace the filter.
- Make sure that the nebulizer kit is correctly assembled, the air filter is properly installed, and the air tube is correctly connected to the compressor and the nebulizer kit. Air may leak from the air tube during use if not securely connected.
- Inspect the compressor (main unit) and the nebulizer parts each time before using the device. Make sure no parts are damaged, the nozzle and a r tube are not blocked and the compressor operates normally.
- Do not use the device if the air tube is bent.
- Do not block the air filter cover.
- Do not alter the baffle, the nozzle in the medication tank or any part of the nebulizer kit
- Do not add more than 10ml of medication to the medication tank.

CAUTION

- Do not operate the device at temperatures greater than 40”C.
- Do not tilt the nebulizer kit so the angle of the kit is greater than 45°. Medication may flow into the mouth.
- Do not shake the nebulizer kit while using the device.
- Do not subject the compressor, or any of the components to strong shocks, such as dropping on the floor.
- This device is approved for human use only.
- Do not disassemble or attempt to repair the device or components.
- Use the device only for its intended use as described in the instruction manual. Do not use attachments not recommended by the manufacturer.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
- Make sure that the air tube is securely attached to the compressor (main unit) and nebulizing parts, and does not come loose. Twist the air tube slightly when inserting it into the connectors to avoid the tube disconnecting during use

RISK OF ELECTRICAL SHOCK

- Do not use the compressor (main unit) and the power cord while they are wet.
- Do not plug or unplug the power cord into the electrical outlet with wet hands.
- Do not immerse the compressor (main unit) in water or other liquid.
- Do not spill water or other liquids on the compressor.These parts are not waterproof. If liquid spills on these parts, please unplug the power cord and wipe off the liquid with gauze or other soft absorbent material immediately.
- Do not use or store the device in humid locations or outdoors. Use the device within the operating temperature and humidity.
- Do not overload power outlets. Plug the dev ce nto the appropr ate voltage outlet.
- Do not use extension cords. Plug the power cord directly into the electrical outlet.
- Unplug the power cord from the electrical outlet after using the device. Never leave this product unattended when plugged in.
- Unplug the power cord from the electrical outlet before cleaning the device.
- Completely read all of the instructions included the optional accessories before using them.
- Not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.
- The power switch is used to isolate the device from the supply mains.
- The direction of movement of the actuator of the supply mains switch is comply with IEC 60447

MAINTENANCE AND STORAGE

- Keep the device out of the reach of unsupervised infants and children. The device may contain small parts that can be swallowed.
- Do not leave the cleaning solution in the nebulizer parts. Rinse the nebulizer parts with clean hot tap water after disinfecting.
- Wash the nebulizer parts after each use. Dry the parts immediately after washing.
- Do not store the air tube with moisture or medication remaining in the air tube. This could result in infection as a result of bacteria.
- Store the device and the components in a clean, safe location.
- Do not carry or leave the nebulizer with medication in the medication tank.
- Do not place or attempt to dry the device, components or any of the nebulizer parts in a microwave oven.
- Do not wrap the power cord around the compressor (main unit).

SAFETY INFORMATIONS

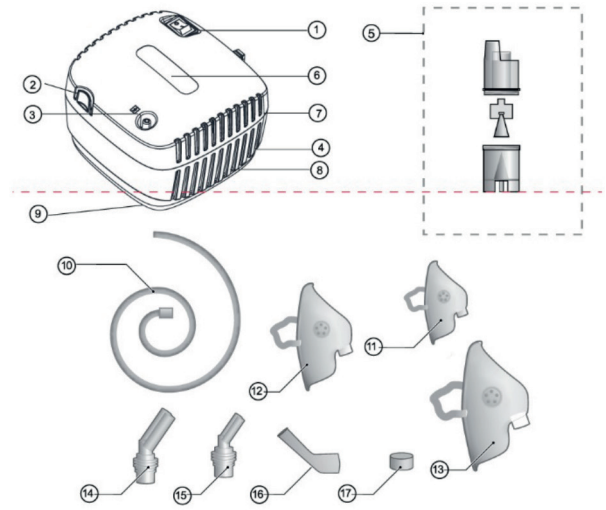
The followings are maintenance and repair which can be taken by operator, or which must be operated by manufacturer or distributor..

Overhaul and maintenance	Responsabile
Change the inhalation tube	ID operator
Cambiare la parte applicata	ID operator
Change the applied part	ID operator
Change the surface of the device	ID operator
Daily cleaning and disinfection	ID operator
Work on any of the components (including fuses and the power cable) for which repair or replacement requires dismantling the device	Distributor or productor

WARNING:

- Do not modify this equipment without authorizaiton of the manufacturer
- Do not service or maintenance the device while in use with the patient

MAIN UNIT



1. Power switch
2. Holder for Nebulizer
3. Air plug
4. Dust Screen Cover
5. Nebulizer Kit
6. Logo
7. 8Via thermal
8. Rubber Foot
9. Tubo di inalazione
10. Mask(Optional)
11. Child Mask(Optional)
12. Adult Mask(Optional)
13. Adult Nasal-piece(Optional)
14. Child Nasal-pieces(Optional)
15. Inhalation Mouthpiece
16. Air Filter

The nebulizer kit and mask, nasal-piece, mouthpiece are applied part

PREPARING THE NEBULIZER FOR USE

CAUTION

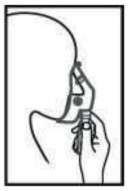
- Clean and disinfect the nebulizer kit and optional masks before using them for the first time after purchase.
- If the device has not been used for a long period of time, please cleans and disinfects the nebulizer kit and optional masks before using them.
- To prevent the risk of cross infection, different persons should never use the same nebulizer kit..

1. At normal use, place the dev ce on a stable, sturdy and flat surface horizontally, such that the unit can be easily reached when you are seated. Caution: place the device at least 10cm distance from walls.
2. Make sure that the unit is in the “off “(0) position by pressing on the right side of switch.
3. Insert the power plug into the electrical outlet.
4. Rotate the inhalation top counterclockwise to remove the inhalation top from the medication tank.
5. Add the correct amount of prescribed medication to the medication tank.
6. Turn the inhalation top clockwise until securely closed.
7. Attach the desired inhalation accessory.

ATTACHING THE AIR TUBE

1. Push the Air Plug on one end of the Air Tube onto the Air Connector on the front side of the compressor.
2. Push the Air Plug on the other end of the Air Tube onto the Air Tube Connector on the bottom of the Nebulizer Kit.

USING THE DEVICE



1. Switch on the power.
2. Plug the inhalation tube into the air plug under cover of device.
3. Plug the other side of tube into the vent port of bottom of nebulizer kit.
4. Plug the nebulizer kit into the holder on the device.
5. Add the medicine into the nebulization tank.
6. Open the 0/1button.
7. The device begins to nebulizer.
8. Press the 0/1 button to safely terminate the operation of nebulizer
9. Unplug the power cord from the electrical outlet after using the device

CAUTION

The patient and operator must keep a distance from the device within 20cm to 50cm in normal use.

USING THE CHILD MASK or THE ADULT MASK

Place the mask over the nose and mouth. Pull the elastic strap over the head. Gently pull on the strap to securely hold the mask over the nose and mouth. Inhale the medication. Exhale normally through the mask.

NOTE: the mask is outsourcing product, it purchased from professional manufacturers by CE certification

CLEANING

Following the cleaning instructions after each use will prevent any remaining medication in the bottle from drying resulting in the device not nebulizing effectively and will help prevent infections.

Wash the nebulizer parts after each use. Dry the parts immediately after washing.

1. Remove the inhalation accessory (mask or mouthpiece) from the nebulizer kit.
2. Disconnect the air tubing from the nebulizer.
3. Gently twist the inhalation top counterclockwise and lift to separate the nebulizer into two sections.
4. Remove the baffle.
5. Discard remaining medication.
6. Rinse all the parts of accessaries (nebulizer kit, the mouthpiece and mask) in warm water and a mild detergent. Finally rinse thoroughly with warm water.
7. Hand dry or air dry in a clean environment using a soft, clean lint-free cloth.
8. CLEANING THE DEVICE AND THE TUBE'S OUTER SURFACE Only use a cloth dampened with antibacterial detergent (non-abrasive and free of solvents of any kind).
9. Assembly the nebulizer and store the nebulizer kit in a dry, sealed bag.

CAUTION:

The nebulizer kit should be replaced every 6 months.

DISINFECTING

You can disinfect daily by soaking the parts in medical disinfectant which are commercially available in all pharmacies. If your physician or respiratory therapist specifies a different cleaning procedure follow their instructions.Effective disinfection is only possible if the nebulizer has been cleaned.

Disinfect accessaries (nebulizer kit, mask, mouthpiece) after the last treatment of the day.

1. Disconnect the all parts according to the above 1-5 steps.
2. Fill a container, suitable to contain all the individual components to be disinfected, with a solution of drinking water and disinfectant, while respecting the proportions indicated on the packaging of the disinfectant itself.
3. Completely immerse each individual component in the solution, taking care to avoid the formation of air bubbles in contact with the components. Leave the components immersed for the period of time indicated on the packaging of the disinfectant, and associated with the concentration chosen to prepare the solution.
4. Remove the components now disinfected and rinse thoroughly with lukewarm drinking water.
5. Hand dry or air dry in a clean environment using a soft, clean lint-free cloth.
6. Assembly the nebulizer and store accessaries in a dry, sealed bag.

CARING FOR THE DEVICE

To Keep your device in the best condition and protect the unit from damage follow these directions:

CLEANING THE DEVICE

Clean the casing of the main unit by using a soft cloth moistened with water or a mild detergent. Do not use abrasive cleaners. Dry the casing immediately using a soft clean cloth.

CHANGE THE AIR FILTER

Change the air filter every 60 days even if the air filter does not appear dirty. If the air filter appears dirty, or if water or medication has spilled on the air filter, replace with a new air filter immediately.

1. Pull the air filter cover to remove from the front side of the compressor.
2. Remove the dirty filter with hand.

CAUTION

Do not attempt to wash or clean the air filter. Damp air filters can cause blockages. Do not substitute cotton or any other material for the air filter.

CAUTION

Wash the air filter cover regularly to prevent any blockage in the cover. Do not boil. Make sure the cover is dry before inserting the new air filter.

3. Insert a new air filter into the air filter cover.

CAUTION

Before inserting the new air filter makes sure the air filter is clean and free of dust. Do not operate the device without the air filter.

4. Put the air filter cover back on the compressor.
5. Do not maintain or service the device while it is in using.

DEVICE STORAGE

1. Put the nebulizer kit and the inhalation accessory (mouthpiece, or mask) in a dry, sealed bag. Place the bag in the storage pocket of the carrying bag.
2. Coil the air tubing and place in the storage pocket.
3. Place the compressor in the carrying bag.
4. Zipper the bag closed.
5. Store the device in a safe, clean location. Do not store the device in extreme hot or cold temperature, high humidity or in direct sunlight.

WARNING

Do not leave the device or its parts where it will be exposed to extreme temperatures or changes in humidity, such as leaving the device in a vehicle during warm or hot months, or where it will be exposed to direct sunlight.

Keep the device out of the reach of unsupervised infants and children. The device may contain small parts that can be swallowed.

CAUTION

Do not carry or leave the nebulizer with medication in the medication tank.

Do not disassemble or attempt to repair the device or components

TROUBLESHOOTING

TROUBLESHOOTING GUIDE

PROBLEM	CAUSE	SOLUTION
No power on unit when the power switch is on.	The AC power cord is not plugged into an electrical outlet.	Turn the power switch off. Plug the power plug into an electrical outlet. Turn the device on.
No nebulization or low nebulization rate when the power is on.	No medication in the medication tank. Too much or too little medication in the medication tank.	Add the correct amount of prescribed medication to the medication tank.
	The nebulizer kit is not correctly assembled.	Make sure the nebulizer kit is correctly assembled and the inhalation accessory is correctly attached.
	The nebulizer kit is tilted at an incorrect angle.	Hold the nebulizer kit correctly. Do not tilt the nebulizer kit so the angle of the kit is greater than 45 degrees.
	The air tube is incorrectly attached.	Make sure the air tube is correctly attached to the compressor and the nebulizer kit.
	The air tube is folded or damaged. The air tube is blocked.	Make sure the air tube is not folded, kinked or bent. Inspect the air tube for any damage. Replace the air tube if damaged.
The device is very hot.	The compressor is covered. The device has been used for longer than 20 minutes.	Do not cover the compressor with any type of cover during use. Turn the device off. Wait 40 minutes before using the device again.

WARRANTY OBLIGATIONS

1. Warranty for this compact compressor nebulizer is 12 months since the date of purchase.
2. The warranty obligations are prescribed by warranty certificate for buyer.
3. The addresses of organizations for guarantee maintenance are present in the warranty certificate.

CLASSIFICATION

Equipment Classification with respect to protection from electric shock: CLASS II

Degree of protection from electric shock: TYPE BF

Degree of protection against ingress of water is rated as IPXO. Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

Intermittent operation: 20minutes ON, 40 Minutes OFF.

PERIODIC SAFETY CHECKS

Preventive inspection and maintenance to be performed including the frequency of such maintenance.

1. Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.
2. The following safety checks should be performed at least every 24 months by a manufacturer's engineer who has adequate training, knowledge, and practical experience to perform these tests.

a) Inspect the equipment and accessories for mechanical and functional damage.

b) Inspect the safety relevant labels for legibility.

c) Inspect the fuse to verify compliance with rated current and breaking characteristics.

d) Check that the device works correctly as described in the instructions for use.

e) Testare la corrente di contatto conformemente alla norma IEC 60601-1 Limite: NC 100 uA, SFC: 500uA.

f) Test touch current according to IEC 60601-1 Limit: NC 100uA, SFC: 500uA.

g) Test patient leakage current under single fault condition according to IEC 60601-1 Limit: for AC: 0.5 mA, for DC: 50uA.

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

SPECIFICATIONS

Model	**NB-222C**
Rated Voltage	CA 230 V, 50 Hz, 0,7 A
Extreme Pressure	210Kpa~400Kpa
Free Flow Range	>7 l/min
Nebulizing Pressure	60Kpa~180Kpa
Noise Level	ca. 55dB
Rated Power	≤ 80 W
Max capacity of nebulizer kit	10ml
Particle Size	S 5pm e 60%
Nebulizing Rate	ca. 0,35 ml/min
Operating temperature, humidity and atmospheric pressure	20 minutes on, 40 minutes off
Transport & storage temperature, humidity and atmospheric pressure	10'C " 40'C, 85% max, 860~1060hPa
Transport and storage temperature, humidity and atmospheric pressure	-10'C ~4O'C, 95% max, 500-1060hPa
Size	140 mm x 140 mm x 100 mm
Pollution Degrees	Gradi 2
Overvoltage Category	Category II
High Altitudes (m)	2000 m
Accessories	Nebulizer kit, inhalation mouthpiece, inhalation tube

NOTES

- Subject to technical modification without prior notice.
- Please note that specifications may vary with medication type used.
- Do not use the device where it may be exposed to flammable gas.
- This unit confirms to EMC Standard IEC60601-1-2. However, if it is used together with other medical devices or electrical equipment, they may influence the operations of one of devices. Please follow any instructions in the manuals and use all devices correctly.

COMPRESSOR NEBULIZER With respect to electric shock, fire and mechanical hazards only in accordance with IEC60601-1.

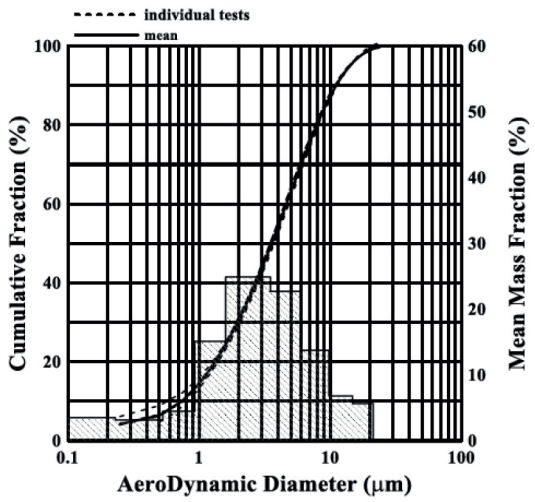
TECHNICAL DATA FOR NB-222C

Particle Size: MMAD Appr ox. 3.4µm (MMAD..... Mass Median Aerodynamic Diameter)

Medication Tank Capacity: 10ml maximum

Appropriate Medication Quantities: 2ml minimum - 10ml

maximum Aerosol Output: 1.98ml (2ml, 2.5%NaF)
Aerosol Output Rate: 0.46ml/min (2ml, 2.5%NaF)



Plot of cumulative size distribution of results

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS - FOR ALL EQUIPMENT AND SYSTEMS

Warning:

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necess- ary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
- Portable RF communications equipment (including peripherals such as ant- enna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the nebulizer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."
- Under the test conditions specified in Immunity, the product can provide the basic safety and essential performance.
- The Emissions characteristics of this equipment make it suitable for use in home healthcare environment (CISPR11 Class B).

COMPLIANCE INFORMATION FOR EACH CEM TEST

Electromagnetic Emission (Home Healthcare Environment)	
Emission test (EC606O1-1-22014)	**Compliance**
Conducted and radiated RF Emission	+CISPR 11 Group 1 Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flickeremissions IEC 61000-3-3	Complies

COMPLIANCE INFORMATION FOR EACH CEM TEST

Declaration - Electromagnetic Immunity (Home Healthcare Environment)		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6 :2013	3V 150 kHz to 80 MHz 6 V in ISM and between 0.15 MHz and 80 MHz	3V 150 kHz to 80 MHz 6 V in ISM and between 0.15 MHz and 80 MHz
Radiated RF IEC61000-4-3 :2006+A1:2007+ A2:2010	10 V/m 80 MHz to 2,7 GHz	10 V/m

Declaration - Electromagnetic Immunity (Home Healthcare Environment)		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2 :2008	±8kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air

COMPLIANCE INFORMATION FOR EACH CEM TEST

Declaration - Electromagnetic Immunity (Home Healthcare Environment)		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrical fast transient/burst IEC 61000-4-4 :2012	±2kV for power supply lines	±2kV for power supply lines
Surge IEC 61000-4-5 :2005	± 0.5kV, ± 1 kV line(s) to lines	± 0.5kV, ± 1 kV line(s) to lines
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 :2004	0% Ut,0,5 Cycle at 0°, 45°, 90°, 135°, 180°,225°,270° e 315° 0% Ut,1 cicle and 70% Ur, 25/30 cycles single phase: at 0° 0% Ur,250/300 cicli	0% Ur ,0,5 Cycle at 0°,45°,90°, 1350,180°,225°,270° e 315° 0% Ur, 1 cicle e 70% Ur, 25 cycles single phase: at 0° 0% Ur, 250 cicli
Power frequency (50760 Hz) IEC 61000-4-8:2009	30 A/m	30 A/m

EUT is the AC supply voltage before the test level is applied.

The following phenomenon still complies with the basic essential safety performance requirements.

*UT:230V ~/50Hz. The EUT pressure is the deviation of the normal value, but the value is still higher than 10psi when the flow is 4.5l/min.

**UT:230V~/50Hz, EUT stops working when 0% UT is added, but EUT can automatically restore normal mode.

COMPLIANCE INFORMATION FOR EACH EMC TEST

Dichiarazione - IMMUNITÀ ai campi di prossimità provenienti da apparecchiature di comunicazione wireless RF

Immunity test	Test frequency	Modulation	Maximum power	Immunity level	Compliance level
Radiated RF IEC 61000-4-3: 2006+A1:2007 +A2:2010	385 MHz	**Pulse Modulation: 18Hz	1,8 W	27 V/m	27 V/m
	450 MHz	* FM +5Hz deviation: 1 kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0,2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	27 V/m	27 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	"Modulazione a impulsi: 217Hz 2W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0,2 W	9 V/m	9 V/m

Note* - 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.

Note•• - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Symbols	
REF	Codice prodotto
LOT	Numero di lotto
SN	Numero di serie
	Data di fabbricazione

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Made in China

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