# INSTRUCTIONS FOR USE

DIAGNOSTIC®

# Nano

PISTON COMPRESSOR NEBULIZER


Diagnosis S.A.
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www.diagnosis.pl

CE 0197

MD REF 7015

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## Table of contents

## 1. INTENDED PURPOSE

Thank you for purchasing the Diagnostic NANO nebulizer for inhalation therapy. Inhalation therapy is an effective and safe method of treating diseases of the respiratory tract. Start treatment after consultation with your doctor. Read the instructions for use carefully before using the nebulizer for the first time. The Diagnostic NANO nebulizer is a compact medical device designed for intermittent operation (30 min on, 30 min off). It allows the inhaled medical preparation to reach the bronchi and lungs immediately and directly. If appropriate precautions are taken, the nebulizer will provide appropriate quality of treatment for a number of years.

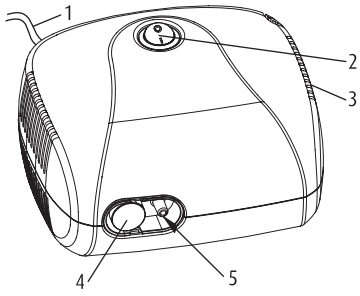
Carefully read these instructions for use before using the product. Use the product only for its intended use as described in these instructions. Keep the instructions for use for reference in case of need. Do not take any action of a medical nature without first consulting your doctor. If you have any questions about how to use the device or report any unforeseen events, please contact the Helpline at the telephone number indicated in the instructions.

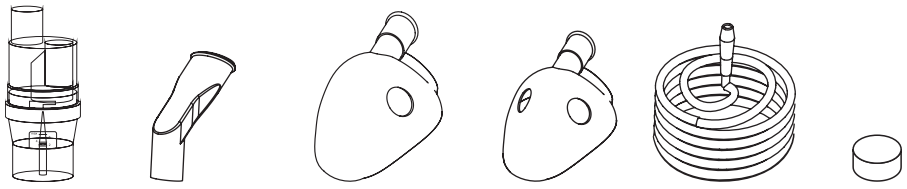
## 2. WORKING PRINCIPLE

The Diagnostic NANO nebulizer was developed to treat asthma, allergies and other respiratory diseases. The device produces a stream of air guided through an air tube into a nebuliser. Once the air is injected into the nebuliser, the medical preparation will be atomised, creating an easy-to-inhale mist.

**MAIN UNIT (COMPRESSOR)**

1. Power cable
2. On/off button
3. Air vents
4. Filter and filter cover
5. Air line entry



| PARTS AND MATERIALS | | | | | |
|---|---|---|---|---|---|
| Nebuliser (atomizer) | Mouthpiece | Mask for adults | Mask for children | Air tube | 5 × Filter air |
| PP | PP | PVC | PVC | PVC | Sponge |

## 3. IMPORTANT SAFETY INSTRUCTIONS

**IMPORTANT WARNINGS: Failure to comply with the warnings and contents of this manual may expose the user to risks such as deterioration of health, burns, electric shock, recurrent infections, death, fire, environmental pollution.**

**The use of any electrical appliance requires the following basic principles:**

### 3.1 GENERAL SAFETY INSTRUCTIONS

1. Use the device only for the intended use (aerosol inhalation) and in the manner described in these instructions.
2. In matters concerning the type, dose and regimen of use, follow the recommendations of your doctor or respiratory therapist. The intensity of use must always be consulted with the doctor.
3. Inhalations of any substance should be carried out with the permission of the doctor, who decides on the doses and use.
4. If you experience worrying symptoms while using the device, stop using it immediately and consult your doctor.
5. Lack of electricity, sudden failure or other adverse conditions can cause malfunction; it is therefore advisable to have a device or medication (as recommended by your doctor) that could be used interchangeably.
6. Do not expose the unit to the elements; store it in room conditions.
7. Do not store the device at extremely high or low temperatures. Protect it from direct sunlight.
8. Always store the appliance in a clean place to avoid contamination. Do not use the appliance if it has been stored in a contaminated area.
9. The power cord and air tube can pose a strangulation risk due to their length.
10. Do not use the device near flammable objects or explosives.
11. Do not use the device in an environment where sprays have been used recently; in this case, ventilate the room before starting treatment.
12. The equipment must not be stored or used where it could be exposed to harmful fumes or volatile substances.
13. Do not block or obstruct the air inlets of the unit, and do not place it on soft surfaces such as a bed or couch. Do not cover the compressor with a blanket, towel or other coverings during use.
14. Do not insert any object into the ventilation openings.
15. Do not use the device if it makes abnormal sounds.
16. Always remove any leftover medication after use and use freshly prepared medication every time.
17. The product should not be used on patients who are unconscious or without spontaneous respiratory function. The device is not intended for anaesthesia or lung ventilation.
18. If any abnormalities occur, stop using the device immediately until it has been checked and repaired.
19. The nebulising system is not suitable for use in an anaesthetic or a ventilator breathing system.

### 3.2 TO AVOID THE RISK OF ELECTRIC SHOCK

1. Observe the electrical specifications on the unit.
2. Do not use the appliance if the plug or power cord is damaged.
3. Keep the device away from water. Do not use the device with wet or damp hands.
4. The device should not be used while bathing.
5. The compressor and power cord are not waterproof. If liquid spills on these parts, immediately disconnect the power cord and wipe off the liquid with gauze or other soft absorbent material.
6. Never immerse the appliance or power cord in water or other liquids; do not use the appliance if it has been accidentally wet. In this case, send the device to the service centre with a description of the situation for examination and repair.
7. Never reach for an appliance that has fallen into water – disconnect the power plug immediately.
8. Do not pull on the power cord or the appliance itself to remove the plug from the socket.
9. The device must not be used or stored in damp areas.
10. The device and the power cable should be kept away from heat sources.
11. Do not use extension cords. Plug the power cord directly into an electrical outlet.
12. Unplug the device from the power supply before cleaning, filling with medication and after each use.

### 3.3 SAFETY INSTRUCTIONS FOR USE OF ACCESSORIES

1. Clean all accessories before using them for the first time after purchase or if the device has not been used for a long time.
2. In order not to impair the functionality of the appliance, use only original accessories supplied by the Manufacturer in accordance with the instructions for use of this appliance.
3. Accessories should only be used by one person. If the nebulizer is used by other family members, we recommend purchasing additional accessories for individual use only.
4. Do not use the device in combination with accessories other than those described in the instructions.
5. Do not use a damaged nebuliser, mouthpiece or masks.
6. Do not use or store the unit with the air duct bent.
7. No more than 8 ml of medication should be poured into the medication container.

### 3.4 STORAGE


1. Keep the appliance out of the reach of unsupervised infants and children and pets. The appliance contains small parts which may be dangerous if swallowed.
2. Close supervision must be provided if the appliance is used by or near children or people with disabilities.

### 3.5 RESPONSIBILITY

In matters of safety, efficiency and reliability, the responsibility lies with the manufacturer only if:

- installation, calibration, repairs or modifications are carried out by authorised persons;
- the electrical installation complies with current standards;

- the instructions for use have been followed. Producer is not responsible for improper, erroneous or unreasonable use of the device.

### 3.6 FUSE

There is a fuse inside the appliance which should be replaced in the event of failure. The replacement operation, like all other possible repairs, should be carried out by the manufacturer or personnel authorised by the manufacturer.

### 3.7 ELECTROMAGNETIC COMPATIBILITY

The device complies with current EMC standards and is suitable for use in all buildings, including residential buildings. The radio frequency emission level of the device is very low and is unlikely to cause interference with nearby equipment. However, it is recommended not to place it on or near other equipment. If interference with other electrical appliances arises, the device should be moved away from them or plugged into a different socket. Radio communication devices can affect the functioning of the appliance. Keep them at least 3 m away from the appliance.

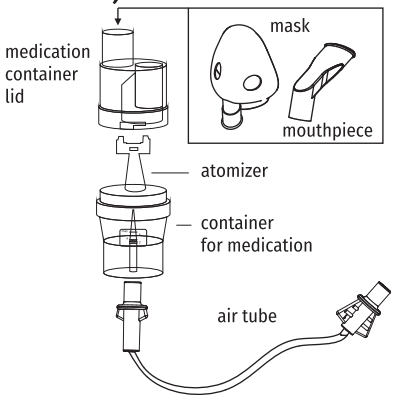
## 4. METHOD OF USE

To pour the medicine into the nebuliser, follow the following steps:

1. Open the medicine container.
2. Fill the medication container as directed by your doctor. Make sure the medicine does not exceed a volume of 8 ml. The allowable refill volume of the medicine is a minimum of 2 ml and a maximum of 8 ml.
3. Close the medicine container.
4. Connect a mouthpiece or mask.

**NOTE: The mouthpiece is intended for oral inhalation use. Masks should not be used in children over 3 years of age. Use of a mouthpiece is recommended.**

**CONSTRUCTION OF THE NEBULISER (ATOMISER)**



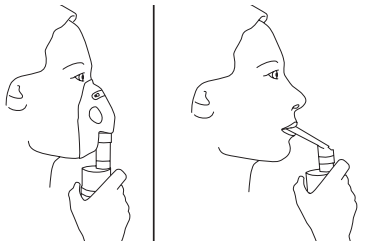

**NOTE: Remember to use the atomiser in the nebuliser (in the medication container). This is necessary for the nebuliser to work properly.**

## 5. OPERATION OF THE DEVICE

1. To start the device, perform the following steps:
   - Plug in the compressor power plug, but do not plug in the nebuliser.
   - Make sure the air filter is clean and placed in the compressor.
   - Add the correct amount of the prescribed medicine to the nebuliser.
   - Connect the nebuliser using the air line to the compressor.
   - Place the compressor on a hard surface. Do not block the air inlets. Switch on the power supply.
   - Once the compressor is started, nebulisation and aerosol generation will be initiated.

2. Sit comfortably and relax your muscles completely, keeping your upper body upright.
3. Start inhaling as directed by your doctor. Inhale and exhale calmly while inhaling.

- Do not lie down during inhalation.
- The compressor operates in mode: 30 min operation / 30 min break. After 30 min of operation, the unit should be switched off for 30 minutes to prevent the compressor from overheating.
- Inhalation is completed when there is no more medicine in the medicine container.



4. When you have finished inhaling, switch off the power and unplug the compressor from the mains socket, disconnect the other components.

## 6. COMPRESSOR CLEANING

1. ⚠ All cleaning of the device should be carried out with the device disconnected from the mains socket. To avoid malfunctions of the appliance and the inhalation of undesired substances, clean the appliance and accessories immediately after therapy.
2. Cleaning of the compressor should be done with a cloth slightly moistened with alcohol. After cleaning the unit, wait for the alcohol to evaporate completely before using it.
3. Do not use other liquids or other cleaning substances. Do not use excessively wet cloths, as contact of the liquid with the electrical components of the appliance may cause malfunctions, irreparable damage, as well as being hazardous to health.

## 7. CLEANING OF ACCESSORIES

1. Before first use and each time after use, wash the accessories (except the air hose) thoroughly with lukewarm water and dry them with a cloth.
2. Then put them away in a clean place. When cleaning, make sure that any residue of the substance to be inhaled is removed, and then dry the accessories thoroughly.
3. Do not, under any circumstances, use cleaning and disinfecting agents that may have a toxic effect if they come into contact with the skin or mucous membranes, if swallowed or if inhaled.
4. If the air duct is dirty, it must be replaced. If the air tube loses its tightness, replace it immediately with a new one.
5. To ensure that the nebuliser works properly, perform the following steps after each use:
   - Disconnect the mouthpiece or mask after disconnecting the air line.
   - Open the lid of the medication container and empty the medication container. Wash the nebuliser under running water or leave it in warm water for 15 minutes. For better cleaning, add some vinegar to the water (mixture of 1/3 vinegar, 2/3 water).
6. Remove condensed liquid from the air tube. Remove any moisture or liquid remaining in the air line by running the compressor for a few minutes without the nebuliser connected.

**CAUTION: Do not boil the accessories, this may damage them.**

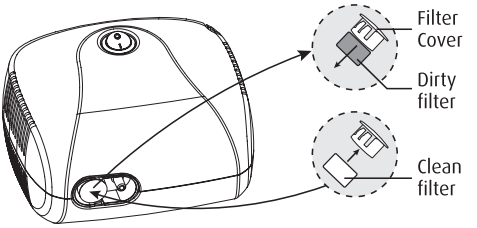
- **Do not put accessories in the dishwasher.**
- **The appliance's accessories must be completely dried before prolonged storage.**

## 8. FILTER REPLACEMENT

1. Do not use cotton or other materials. Do not wash or clean the filter. Use only filters supplied by Diagnosis S.A. Do not use the device without a filter.
2. The filter should be changed every 30 days or when it turns grey.
3. Make sure the air filter is clean and dust-free before inserting a new air filter. Do not use the appliance without an air filter. Use only the filter designed for this appliance.

**Replacement procedure:**

- Pull the air filter cover to remove it from the rear of the compressor.
- Remove the dirty air filter.
- Replace the used filter with a new one.
- Put the air filter cover back on the compressor.




## 9. REPLACEMENT ACCESSORIES

Use only original accessories intended for this device to ensure inhalation efficiency, correct operation and safety. All accessories are suitable for direct skin contact. They do not contain phthalates. To order the following accessories, please contact your distributor or the product manufacturer.

## 10. RECOMMENDED FREQUENCY OF ACCESSORY REPLACEMENT

To maintain the high efficiency of the device, it is recommended:

- Replace the accessory kit: medication container, children's mask, adult mask, mouthpiece and air tubing every **3 years. All damaged accessories should be replaced immediately.**

## 11. PROBLEM SOLVING

| Symptom | Probable cause | Solution |
|---|---|---|
| The device does not start. | The main compressor switch is off. | Switch on the device. |
| Working too loudly. | No filter in the unit. | Place the filter in the unit. |
| | Nebuliser not cleaned after previous use. | Clean the unit. |
| | The air duct is kinked. | Remove any kinks or knots in the cable. |
| | The filter is clogged. | Replace the filter. |
| | No drug. | Add the appropriate amount of medicine, as prescribed by the doctor, to the medicine container. |

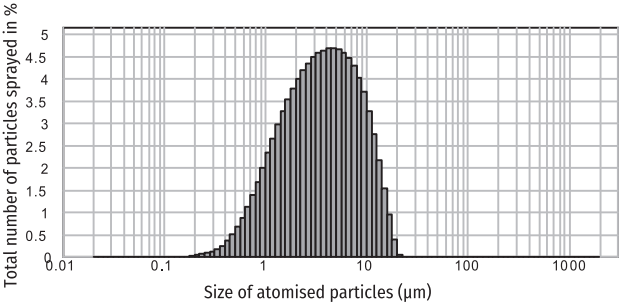
| | | |
|---|---|---|
| Water droplets form in the air duct. | Too much drug was added. | Adjust the amount of medicine in the medicine container to the appropriate level, connect the air line to the compressor and switch on the device. |
| | The air duct has not been dried out. | Any moisture remaining in the air tubing can be removed by running the device for a few minutes without the nebuliser connected. If the tube is dirty, replace it. |

**NOTE: If the suggested repair action does not solve the problem, do not attempt to repair the unit yourself. Return the device to the point of sale or send it to the service address.**

**Helpline: +48 800 70 30 11 or +48 85 874 60 45, +48 85 874 69 28 (8 am to 4 pm; Polish language only)**

## 12. ATOMISED PARTICLE SIZES

Measurements were made using MALVERN technology and saline solution. Particle size distribution according to EN 13544-1




**NOTE: This device complies with the requirements of Directive 93/42/EEC and European Standard EN 13544-1: 2007+A1: 2009 Respiratory therapy equipment – Part 1: Nebulisation systems and their components.**

**The use of a fluid type other than the recommended one, in particular a suspension and/or a high viscosity solution, may alter the particle size distribution curve, the aerodynamic particle diameter (MMAD), the aerosol efficiency and/or the aerosol performance index. Refer to the leaflet accompanying the medicine.**

## 13. TECHNICAL DATA

| | |
|---|---|
| Power supply | 230 V AC, 50 Hz |
| Energy consumption | Below 65 W |
| Nebuliser flow rate | 6 l |
| Compressor flow | 8–10 l |
| Capacity of medicine container | 2–8 ml |
| Particle size | 0,5 do 6 µm |
| MMAD | 2,44 µm |
| Speed of nebulisation | 0,4 ml/min |
| Residual volume | 0,15 ml |
| Working time | 30 min. operation / 30 min. breaks |
| Noise level | Below 72 dB |
| Compressor pressure | 23–32 psi / 160–220 kPa / 1,6–2,2 bara |
| Conditions of use | Temperature: 10–40°C (50–104°F)<br>Humidity: 10–95% RH<br>Atmospheric pressure: 850–1060 hPa |
| Transport and storage conditions | Temperature: -20–70°C (-4–158°F)<br>Humidity: 10–95% RH<br>Atmospheric pressure: 850–1060 hPa |
| Safety classification | Type BF device |
| IP classification | IP21 – Protection against objects with a diameter of 12.5 mm and larger, protection against vertically falling water droplets. |
| Device class | Class II |
| Product lifetime | 5 years (compressor), 3 years (accessory kit) |
| Dimensions (L × W × H) | 167×142×93 mm |
| Product weight | 1,51 kg |
| Kit contents | Compressor, nebuliser, adult mask, children's mask,<br>5 × air filter, 1.5 m air hose, mouthpiece, instructions for use |

All accessories in contact with the patient comply with the standard: EN ISO 10993-1

**NOTE: Specifications are subject to change without prior notice**

## 14. EXPLANATION OF THE SYMBOLS USED

| Symbol | Explanation | Symbol | Explanation |
|---|---|---|---|
|  | Important warnings |  | Protect against humidity |
|  | Class II insulation |  | Keep away from sunlight |
|  | Application part type BF |  | Before use, read the instructions for use |
|  | Manufacturer |  | Date of manufacture |
| SN | Serial number |  | Temperature limit |
| MD | Medical device |  | Humidity limit |
| REF | Reference number |  | Atmospheric pressure limit |
| Rev. | Date of last update | IP | IP classification – indicates the degree of protection provided by the enclosure in accordance with the requirements of IEC 60529 |
|  | Dispose of the used product at a waste collection point. It contains components that are hazardous to the environment. Correct disposal of the device allows you to preserve valuable resources and avoid negative impacts on health and the environment, which may be endangered by inappropriate waste handling. If you have any doubts about where to dose of the used device, contact Diagnosis S.A. | LOT | Batch number |

**TECHNICAL DATA REQUIRED BY THE STANDARD FOR ELECTROMAGNETIC COMPATIBILITY EMC**

The device requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided, and the device may be affected by portable and mobile RF communications equipment.

**EMC Warning:**

1. The portable nebulizer is intended for use in hospital and family environments, except in the vicinity of active HF SURGICAL EQUIPMENT and the RF shielded ME SYSTEM magnetic resonance imaging room, where the intensity of EM INTERFERENCE is high.
2. Do not use a mobile phone or other devices that emit electromagnetic fields near the device. This may cause the device to malfunction.
3. Caution: This device has been thoroughly tested and inspected to ensure proper performance and operation.

4. Caution: Avoid using this device adjacent to or stacked with other devices as it may cause improper operation. If such use is necessary, observe this device and the other devices to verify that they are operating properly.
5. The use of accessories other than those specified or supplied by the nebulizer manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of the nebulizer.
6. Do not expose the device to RFID systems.

**NOTE!**
**Technical data required by the standard regarding electromagnetic compatibility EMC are available at: http://diagnosis.pl/normy/emc-bobo-neb-i-diagnostic-nano/**

**Reporting of serious incidents**
**Any serious incident that has occurred in relation to this device should be reported to the manufacturer and to the competent authority of the Member State where the reporter is resident.**

DIAGNOSIS S.A.
Gen. W. Andersa 38A,
15-113 Białystok, Poland
Helpline: +48 800 70 30 11
www.diagnosis.pl

MAIN SERVICE DIAGNOSIS S.A.
ul. Przemysłowa 8, 16-010 Wasilków, Poland
tel. +48 85 874 60 45
serwis@diagnosis.pl

shop stamp and seller's signature

## WARRANTY CARD

DEVICE NAME .....MODEL.....

SERIAL NUMBER.....SALE DATE .....

WARRANTY CONDITIONS

1. Diagnosis S.A. guarantees:
   - 2 years for NANO compressor (excluding accessories)
   - 12 months for nebulizer accessories

Defects in the equipment revealed during the guarantee period will be rectified free of charge within 21 days. The period is calculated from the date of delivery of the equipment to the service centre.

2. The buyer has the right to replace the equipment with a defect-free one if:
   - the repair was not completed within the time specified in point 1
   - an authorized service point found a manufacturing defect that could not be repaired
   - 4 repairs were made during the warranty period, and the equipment still exhibits defects that prevent it from being used as intended.

The term repair does not include activities related to checking and cleaning equipment.

3. The warranty does not cover: batteries, products with illegible or damaged factory number, damage caused by use and storage not in accordance with the operating instructions, ingress of liquids or foreign bodies, overvoltages in the power supply network, repairs by unauthorized persons and random events.
4. The purchaser should deliver the defective equipment to the main service address.
5. The warranty for the sold consumer goods does not exclude, limit or suspend the buyer's rights resulting from the non-conformity of the goods with the contract.
6. The only basis for warranty rights is the warranty card with the date of sale, stamp and signature of the seller. A card that is not filled in, is filled in incorrectly, has traces of corrections and entries by unauthorized persons, is illegible due to destruction – is invalid.

**NOTE! Before sending the device for repair, please clean it of any dirt. Do not send items or accessories that are not subject to complaint, e.g. air hose, masks, mouthpiece, power supply, etc.**

## SERVICE POINT ANNOTATIONS

| L.p. | Date of filing | Date of repair | Warranty extended to | Description of the activity | Stamp and signature of the contractor |
|---|---|---|---|---|---|
| | | | | | |

# Diagnostic Nano

**MANUFACTURER**

Diagnosis S.A.
Gen. W. Andersa 38A,
15-113 Białystok, Poland
www.diagnosis.pl
tel. : + 48 85 732 22 34
fax : + 48 85 732 40 99
email: info@diagnosis.pl

**Helpline**

## +48 800 70 30 11

for landlines, only in Polish

## +48 85 874 69 28

## for mobile phones

(the call cost is borne by the caller according to the operator's tariff), only in Polish

**MAIN SERVICE**

Diagnosis S.A.
Przemysłowa 8, 16-010 Wasilków, Poland
tel. +48 85 874 60 45
serwis@diagnosis.pl