

PRO-110 PRO-115



COMPRESSOR NEBULIZER

EN Instruction for Use

1. INTRODUCTION

Thank you for purchasing the Compressor Nebulizer B.Well PRO-110 / PRO-115. The B.Well Nebulizer is a reliable device. It creates a stream of air that travels through clear tube to the nebulizer. When air enters the nebulizer, it will convert the prescribed medication into aerosol mist for easy inhalation. The B.Well company guarantees this device was made of high-quality materials and meets national and international safety standards. The Nebulizer is a medical device therefore it should be used under the supervision of a licensed physician and/or a respiratory therapist. Please, read this Instruction for Use carefully before use and follow the recommendations.

2. INTENDED USE

Your nebulizer is intended for use in treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy. Please consult with your physician and/or pharmacist to determine if your prescription medication is approved for use with this nebulizer. For type, dose, and regime of medication follow the instructions of your doctor or respiratory therapist. It is a compact medical device designed to efficiently deliver physician prescribed medication to the bronchial lung passages. The particle size is less than 5 µm that allows treating lower respiratory tracts.

3. CONTRAINDICATIONS AND USE LIMITATION

- The following is strictly forbidden to use as nebulizer therapy medicine:
 - substances and solutions containing suspended particles (herbal infusions, suspensions, extracts, etc.) Suspended particles are significantly larger than the particles of respirable fraction. Using it in nebulizer can bring harm to health;
 - oil-containing solutions (including ester oils). Oil particles form the finest films when entering lower respiratory tract and this increases the risk of the so called "oil pneumonia";
 - anaesthetic mixture inflammable with air, oxygen or nitrogen protoxide;
 - flavoring substances.

Use the device only as described in this Instruction for Use and therefore as an aerosol therapy system, following the indications of your doctor.

⚠ MEDICAL DISCLAIMER:

This Instruction for Use and product are not meant to be a substitute for advice provided by your doctor or other medical professionals. Don't use the information contained herein or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your doctor.

4. PRECAUTIONS

Read this Instruction for Use carefully before use. Keep it for future reference during the life cycle of the device. Use the device only as described in this Instruction for Use and therefore as an aerosol therapy system, following the indications of your doctor. Any use different from the intended one is to be considered improper and hence dangerous. Do not operate the unit in presence of any anaesthetic mixture inflammable with oxygen or nitrogen protoxide. Device not suitable for use in anaesthesia or lung ventilation systems. The manufacturer cannot be held liable for any damage caused by improper, incorrect and/or unreasonable use, or if the equipment is connected to electrical installations which do not comply with current safety regulations.

Rules of use the Nebulizer

For the B.Well Compressor Nebulizer PRO-110 and PRO-115 can be used all the medicines allowed using with common aerosol therapy systems. Use this device only with medicines prescribed by your doctor and according to his instructions. Make the treatment using only the accessory recommended by your doctor depending on the pathology. Use the nosepiece accessory only if expressly indicated by your doctor and paying attention to NEVER introduce the bifurcations in the nose, but only bringing them as close as possible. Check in the medicine package leaflet for possible contraindications for use with common aerosol therapy systems.

⚠ Cautions:

- Closely follow the shelf-life instructions of the solutions which are allowed for use. Do not use solutions with expired shelf-life.
- For greater hygienic safety, we recommend you to avoid using the same accessories for more than one person.
- If you use the accessories for the first time, after long period of storage, and/or after every use cleaning and disinfection of the accessories should be performed! Make sure that all the components are properly disinfected and dried, and after that store it in clean place.
- Components and device have to be cleaned according to the point 9. **Cleaning, Maintenance and Storage** of current Instruction for Use.
- Always clean the nebulizer and its components from remaining drug and washing substances. Never leave cleansing solution in chamber, mouthpiece or aerosol tube!
- Nebulizer and its components should not be dried in microwave oven, with hair dryer and other household appliances.
- When using nebulizer do not close ventilation holes of the device. Do not cover the nebulizer with a blanket, towel, etc. when using it. Never put the device in a place with the possibility of blocked entry of air to these holes.
- Some parts of the unit are so small that they may be swallowed by children; keep the equipment out from children's reach. The use of this device by children and disabled requires always the close supervision by an adult with full mental faculties. To avoid strangulation and entanglement, keep cable and air tubes out of reach of children.
- Do not expose to harmful vapors or volatile substances.
- Do not pour more than 8 ml of drug solution into the container.
- Do not incline the nebulizer at more than 45 degrees when using, do not shake it.
- Do not over bend the air tube while both storing and using.
- Do not drop the device and expose to damage.
- Do not block the cap of air filter.
- The device is approved only for human use. Use it only for the purpose intended.

Electric shock hazard

- Use only original accessories and components;
- Never wet the device, it is not protected against water penetration;
- Never touch the unit with wet or moist hands;
- Do not leave the unit exposed to the weather elements;
- Before performing any maintenance or cleaning operation, turn off the device and disconnect the plug from the main supply.
- Do not leave the unit plugged in when not in use; unplug the device from the wall socket when it is not operated.
- Do not disconnect the Nebulizer when the device is on;
- Place the unit on a stable and horizontal surface during its operation;
- Never submerge the unit in water;
- The power supply cord should always be fully unwound in order to prevent dangerous overheating. The power cord of this device cannot be replaced by the user. In case of a power cord damage, address to a technical service center authorized by the manufacturer for its replacement.
- Do not allow contact of the power cord with hot surfaces.
- Do not pull the power cord or the device itself to unplug it from the power socket;
- For repair operations address only to a technical service center authorized by the manufacturer and require the use of original spare parts. The non-observation of the above mentioned indications can compromise the device safety.

The correct functioning of the equipment can be affected by electromagnetic interferences which exceed the limits indicated by the European standards in force. In case this device interferes with other electrical devices, move it and plug it to a different power socket. In case of failure and/or malfunction, read the "11. Troubleshooting" section. Do not handle or open the compressor housing. Before plugging in the device, make sure that the electrical rating, shown on the rating plate on the bottom of the unit, corresponds to the mains rating.

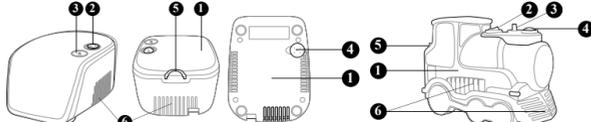
In case the power plug provided with the device does not fit your wall socket, address to qualified personnel for the problem solving. In general, the use of extension cables is not recommended. If their use is indispensable, it is necessary to use types complying with safety regulations.

The installation must be carried out according to the instructions of the manufacturer. An improper installation can cause damage to persons, animals or things, for which the manufacturer cannot be held responsible.

If you decide not to use the device any longer, it is recommended to dispose of it according to the current regulations. Do not position the equipment so that it is difficult to operate the disconnection device.

5. COMPONENTS

- Compressor housing
- ON/OFF switch
- Air outlet
- Filter case
- Nebulizer holder
- Air-vent openings



Complete set

Components	Complete set PRO-110	Complete set PRO-115	Components	Complete set PRO-110	Complete set PRO-115		
	1. Compressor nebulizer	1 pcs.	1 pcs.		7. Child mask	1 pcs.	1 pcs.
	2. Nebulizer Basic	1 pcs.	1 pcs.		8. Infant mask	-	1 pcs.
	3. Air tube	1 pcs.	1 pcs.		9. Spare air filter	5 pcs.	5 pcs.
	4. Mouthpiece	1 pcs.	1 pcs.		10. Accessories bag	1 pcs.	1 pcs.
	5. Nosepiece	1 pcs.	1 pcs.		11. Instruction for Use	1 pcs.	1 pcs.
	6. Adult mask	1 pcs.	1 pcs.		12. Stickers	-	2 pcs.

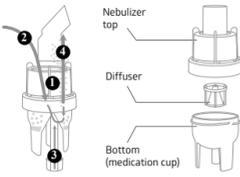
Nebulizer Basic

Thank for the Venturi effect, the air ② is taken from the environment through top opening ① in addition to the air supplied by the compressor ③, thereby increasing nebulization speed and decreasing treatment time ④.

6. PREPARATION FOR USE

The device must be checked before each use, in order to detect possible functioning anomalies and/or damages due to transport and/or storage. During inhalation, sit upright and relaxed at a table and not in an armchair, in order to avoid compressing your respiratory airways and impairing the treatment effectiveness. The accessories must be used only with a single patient, it is not recommended to use them with several patients.

- Wash your hands carefully before using the device.
- After unpacking the device, check it for visible damages or defects; pay particular attention to cracks in the plastic housing, which may expose electrical components. Check for accessories integrity.
- Wash and disinfect the Nebulizer, mouthpiece, nosepiece, mask (if they are used for the first time after long period of storage and/or if they are used by several persons). Before using the device, proceed with the cleaning operations as described in the «9. Cleaning, maintenance and storage» section.
- Place the device on a stable and horizontal surface so that you can easily reach the Nebulizer, Accessories and ON/OFF Switch when you do the inhalation.



Before using of the device make sure that:

- all the components are properly assembled;
- air filter is inside of the filter cap;
- air filter is clean (if air filter has changed the color or has been used for a long period of time, replace it with a new one).

Nebulizer kit preparation for use

- Open the nebulizer by turning counterclockwise the top
- Make sure that the medicine conduction cone is properly fitted on the air conduction cone inside the nebulizer
- Put the prescribed quantity of medicine into the nebulizer
- Close the nebulizer by turning clockwise the two parts, paying attention that they are thoroughly sealed



⚠ NOTICE! Capacity of container for drugs is equal to 2-8 ml. There is a scale on the container for drugs. It serves for rough estimate of drug solution capacity.

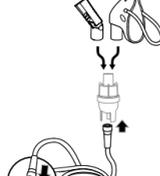
Air tube connection

Connect one end of the air tube to the nebulizer and the other end to the air outlet on the device. Make sure that air tube is properly attached in order to avoid air leakage.

⚠ WARNING! Hold the nebulizer strictly vertically, do not spill the drug when attaching the air tube.

Insert the mask or mouthpiece directly onto the nebulizer.

- Make sure the switch ON/OFF switch into the «O» position.
- Plug the device into the wall socket, making sure that the main supply corresponds to the electrical rating of the device.
- Press the power-switch to the position ON «I».



7. OPERATING

⚠ WARNING! Do not incline the nebulizer at more than 45 degrees. If the angle is greater than 45 degree, the drug can flow out to your mouth.

To start the treatment, set the switch into the «I» position. The compressor will start working and a nebulizing will begin.

Do the treatment in accordance with your doctor's instructions. Inhale the aerosol solution using the prescribed accessory.

⚠ WARNING! The temperature of inhaled aerosol depends on the temperature of the ambient atmosphere and the temperature of the drug solution. If the solution was stored in refrigerator for a long period of time, it is recommended to raise the temperature to 16-20°C.

Use of mouthpiece:

Take the mouthpiece to your mouth and breathe smoothly during the inhalation. Using of mouthpiece is recommended in treatment of lower respiratory tract in grownups and children above 5 years old.

Use of masks:

Put on a mask in the way that it will close your nose and mouth, and conduct inhalation of the drug. Inhale and exhale through the mask. Using of mask is recommended in treatment of upper respiratory tract. It allows for irrigation of the nasal and pharynx cavities, and also larynx and trachea. Child mask is recommended for use in children aged from 1 to 5 years old. Infant mask for children under 1 year old. When the treatment has been completed, switch the unit off by setting the switch into the «O» position and disconnect the plug from the wall socket.

Wash the nebulizer and its accessories as described in the section «9. Cleaning, Maintenance and Storage». Condensate can form in the air tube. In this case detach the air tube from the nebulizer, turn on the compressor and dry the air tube till the elimination of all the liquid.

⚠ WARNING! Do not store the air tube if there is condensate or liquid inside. It can lead to bacterial infection. Switch off the device from the socket. Rinse your mouth with boiled water of the ambient temperature after the procedure. If you used mask – rinse your eyes and face with water.

⚠ WARNING! The device can work for 30 min without a pause, than you should let the device to cool down for 30 min.

8. REPLACEMENT OF THE AIR FILTER

The Air filter must be replaced in case of damage or severe contamination. In normal usage conditions, the air filter must be replaced approximately after 500 working hours or after each year. It is recommended periodically checking the air filter (10 – 12 treatments) and, if the filter shows a grey or brown color or is wet, replace it.

- Turn the air filter cover counterclockwise (only for PRO-115)
- Extract the air filter bladder from the device by pulling it up
- Extract the filter and replace it with a new one (for example with the help of tweezers)
- Set the air filter bladder on its place
- Turn the cover clockwise to fix it (only for the PRO-115)

⚠ WARNING! The use of dirty filter or filter made of another material, for example, cotton, may lead to device damage. Use original filters only.

- Do not use the device without filter.
- Do not try to clean the filter for reusing it. If the filter is wet replace it.
- The air filter shall not be serviced or maintained while in use with a patient.
- To avoid the air filter cover obstruction clean it regularly.

⚠ WARNING! Air filters cannot be cleaned or washed.

9. CLEANING, MAINTENANCE AND STORAGE

Cleaning the device and the accessories

The cleaning of the device must be carried out by using a soft and dry cloth and non-abrasive cleansers.

⚠ ATTENTION! During cleaning operations, make sure the internal parts of the unit are not in contact with liquids and that the power plug is disconnected.

Follow carefully the cleaning and disinfection instructions of the accessories as they are very important for the device performances and the therapy success.

⚠ ATTENTION! Before first using of the device and after each treatment it is necessary to clean all the accessories according to the following instructions:

- Disassemble the nebulizer by turning counterclockwise the top and remove the medicine conduction cone.
- Wash the components of the disassembled nebulizer, the mouthpiece and nosepiece by using tap water; dip in boiling water for 5 minutes.
- Reassemble the nebulizer components and connect it to the air-outlet, switch the device on and let it work for 10-15 minutes or put on the clean paper towel for drying on the air.
- The masks and air tube must be washed with warm water. Does neither boil nor autoclave the air tube and masks!

Sterilization:

- Use cold disinfecting liquids following the instructions of the sterilization liquids' manufacturer.
- Wash your hands and take the components out from disinfection solution, wash the components in warm running water, lay the components on paper towel and dry.
- Do not wipe disinfected parts of the device with a towel; do not use hair dryer, microwave oven or other household appliances for drying. The outer surface of wet parts can be wiped with a clean dry cloth.

⚠ Caution: in order to avoid spread of infections it is recommended to conduct disinfection of device components before first and after every use. Use for treatment only the drugs prescribed by your attending doctor and strictly follow his/her indications.

Opening of the device is prohibited. Repair of the device should be conducted only in technical service centers recommended by B.Well company.

⚠ Note: The nebulizer need to be replaced after 6-12 months depending on the usage.

The nebulizer must be replaced after a long period of inactivity, in case it shows deformations or breakings, or when the nebulizer nozzle (diffuser) is obstructed by dry medicine, dust, etc. Use original nebulizers only.

Maintenance and storage

- If you want your device to serve you for years, follow the following indications:
 - do not store the device at extremely high or low temperatures, high humidity or under direct sunlight;
 - do not bend or wrap the air tube.

Operation and storage conditions – please see «12. Specifications» section. Utilization of the device and any of its components should be performed in accordance with the local regulations.

10. DISPOSAL

The unit must be disposed in accordance with current standards separately from domestic wastes. For disposal it is necessary to contact special organizations licensed to make utilization.

11. TROUBLESHOOTING

Contact an authorized Customer Service Centre in case you need help about the use and the maintenance of the equipment. In case of any malfunction look at the table and try to eliminate it.

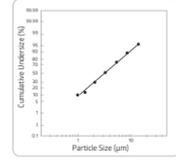
Problems	Solutions
The device does not switch on	<ul style="list-style-type: none"> Make sure the power plug is firmly fitted to the wall socket. Make sure that the device has been operating within operating limits indicated in this instruction for Use (30 min ON / 30 min OFF).
The device does not nebulize or nebulizes weakly	<ul style="list-style-type: none"> Make sure that the ends of the air tube are tightly fitted to the main unit and nebulizer. Verify that the nebulizer is not empty or has been filled with the proper quantity of medicine (max 8 ml). Verify that the nebulizer nozzle is not obstructed.

In case of the device not start working properly again, address to authorities Service center.

Maintenance and repairs

In case of failure, address to qualified personnel authorized by B.Well. Do not open the device in any case. The unit has no user-serviceable parts within and does not need internal maintenance or lubrication.

12. SPECIFICATIONS



Power supply:	230 V – 50 Hz, 1A
Maximum filling volume:	8 ml
Minimum filling volume:	2 ml
Particle size (MMAD):	approx. 3.16 µm
	% of particle size <5 µm – more than 70%
	0.4 ml/min.
	1 ml
	54 dBa
	1,345 Kg (without accessories)
	1,562 Kg (in the gift box with accessories)
	1,510 Kg (without accessories)
	1,786 Kg (in the gift box with accessories)
	2.2 bar
	137 x 173 x 96mm
	224 x 112 x 170 mm
	30 min ON / 30 min OFF
	Temperature: MIN +10 °C – MAX +40 °C
	Humidity: MIN 10% RH – MAX 95% RH
	Atmospheric pressure: 700 hPa – 1060 hPa
	Temperature: MIN -25 °C – MAX +70 °C
	Humidity: MIN 10% RH – MAX 95% RH
	Atmospheric pressure: 700 hPa – 1060 hPa

Storage conditions:

Durable periods:

Durable periods are as follows, provided the product is used to nebulize 2ml of medication 2 times a day for 5 minutes each time at room temperature (23°C). Durable period may vary depending on usage environment. Compressor (main unite) > 10 years (or ~1000 hours)

Nebulizer kit, air tube, mouthpiece, nosepiece, masks – 1 year
Air filter – 60 days

- Class II device as regards protection against electric shocks.
- Nebulizer, mouthpiece and masks are type BF applied parts.
- Device not protected against sprinkles.
- Device for intermittent use (30 min ON / 30 min OFF)

The information defined above is advisory and can change depending on physical properties (temperature, viscosity, density) of the nebulized substance.

The manufacturer may change technical specifications and design of the device without prior notice.

13. APPLIED STANDARDS

Electric Safety Standards EN 60601-1. Electromagnetic Compatibility according to EN 60601-1-2. Class IIa Medical Device according to the 93/42/EEC European Directive on Medical Devices. This device fulfils the provision of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN 13544-1:2007-A1:2009 Respiratory therapy equipment – Part 1: Nebulizing systems and their components.

14. WARRANTY

Warranty period is 3 years from the date of purchase. This warranty doesn't cover any damages caused by improper use, and also battery, protective cover and storage bag, packaging and the accessories supplied with the device (nebulizer kit, air tube, mouthpiece, nosepiece, masks, air filters) and those parts subject to normal wear and tear.

The warranty does not apply to damage caused by using adapters not recommended by the B.Well company and the overvoltage. When a manufacturing defect is revealed during the warranty period a faulty unit would be repaired or, if repairing is impossible, replaced with another one.

The manufacturer may change units partially or completely if necessary, without prior notice. Manufacturing date is encoded in the SN number at the bottom of the device: two first numbers are numbers of the week, two other numbers are last numbers of the year.

Manufacturing date of the spare parts, which can be bought separately from the device is encoded in the LOT number on the sticker: two first numbers are numbers of the week, two other numbers are last numbers of the year.

15. SYMBOL INFORMATION



ELECTROMAGNETIC COMPATIBILITY INFORMATION

Guidance and manufacturer's declaration – electromagnetic emissions

The PRO-110/PRO-115 is intended for use in the electromagnetic environment specified below. The customer or the user of the PRO-110/PRO-115 should assure that it is used in such an environment

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The PRO-110/PRO-115 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 PRO-110/PRO-115 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	⚠ WARNING! This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the PRO-110/PRO-115 or shielding the location.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions

The PRO-110/PRO-115 is intended for use in the electromagnetic environment specified below. The customer or the user of the PRO-110/PRO-115 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	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. The electrical fast transient burst (EFT) is generated by the switching of inductive loads. Separation between the equipment and other loads shall be considered before installation. Mains filter is required, if necessary.
Surge IEC 61000-4-5	+1 kV line(s) to line(s) +2 kV line(s) to earth	±1 kV line(s) to line(s)	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 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (-95% dip in UT) for 5s	<5% UT (-95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (-95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PRO-110/PRO-115 requires continued operation during power mains interruptions, it is recommended the PRO-110/PRO-115 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 emissions

The PRO-110/PRO-115 is intended for use in the electromagnetic environment specified below. The customer or the user of the PRO-110/PRO-115 should assure that it is used in such an environment

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3Vrms 150KHz to 80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the PRO