

EN Instruction for Use

Dear customer.

Thank you for purchasing the Nebulizer model MED-120/TH-130 B Well. 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.

1. WARNINGS AND SAFETY NOTES

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 thereafter 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. 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.

⚠ Warning

Before use, ensure that there is no visible damage to the device or accessories. If you have any doubts, do not use the device and contact the specified Customer Service address.

In the event of device faults, please see Chapter **10 Troubleshooting**.

Consult a doctor if:

The device is not a substitute for medical consultation and treatment. Always consult your doctor first if you are experiencing any pain or are suffering from an illness.

If you have health concerns of any kind.

Regarding the type of medication to use, the dosage, and the frequency and duration of inhalation.

Only medication prescribed or recommended by your doctor or pharmacist.

Please note:

If the device does not work properly, or you feel unwell or experience pain, stop using it immediately.

Keep the device away from your eyes when it is in use, as the mist of medication could be harmful.

Never use the device near oxygen or oxygen oxide.

Do not expose to harmful vapors or volatile substances.

This device is not intended for use by children or people with restricted physical, sensory (e.g. reduced sensitivity to pain) or mental skills or a lack of experience and/or lack of knowledge, unless they are supervised by a person who is responsible for their safety or are instructed by such a person in how to use the device.

The device must be switched off and the plug pulled out before every cleaning and/or maintenance process.

To avoid the risk of entanglement and strangulation, store cables and air lines out of the reach of small children.

Do not use any additional parts that are not recommended by the manufacturer.

The device must only be connected to the mains voltage that is specified on the type plate.

Never submerge the device in water and not use it in the bathroom. Under no circumstances may liquid enter the device.

Protect the device from heavy impact.

Never touch the micro USB cable with wet hands, as you could get an electric shock.

Do not pull the mains adapter out of the socket using the micro USB cable.

Do not crush or bend the micro USB cable, pull it over sharp-edged objects or leave it dangling down, and protect it from sources of heat.

We recommend that the micro USB cable is completely unrolled to avoid dangerous overheating.

If the micro USB cable or the mains adapter of this device is damaged, it must be disposed of it properly.

Making modifications to the device or accessories is not permitted.

If the device has been damaged, broken, disassembled, or suffered any other damage, it must no longer be used. If in doubt, contact Customer Service or the retailer.

The nebulizer may only be operated with nebulizer kit appropriate recommended producer's accessories. The use of nebulizer kit and accessories made by other companies may result in less efficient treatment and could damage the device.

Keep the device and accessories out of the reach of children and pets.

⚠ Important

Power cuts, sudden interference or other unfavourable conditions could lead to the device becoming inoperable.

Should you require an USB-adapter or extension lead, this must meet the applicable safety requirements.

The power limit and the maximum output specified on the adapter must not be exceeded.

Do not store the device or the power cable near to sources of heat.

Do not use the device in a room in which a spray has previously been used. Air the room before carrying out the inhalation.

No modification of this equipment is allowed.

Never use the device if it is making an abnormal sound.

For a hygiene reasons, recommended for users to use their own accessories.

Always disconnect the mains adapter from the device after use.

The device must be stored in the environmental conditions specified in this instruction manual.

Protect batteries from excessive heat (for TH-130).

Risk of explosion: Never throw the device into a fire.

Only use chargers specified in this instruction for Use (for TH-130).

Batteries must be charged prior to use. The instructions from the manufacturer and the recommendations in these instructions for Use regarding correct charging must be observed at all times (for TH-130).

Fully charge the battery prior to initial use (for TH-130).

In order to achieve as long a battery service life as possible, fully charge the battery at least twice per year (for TH-130).

General notes

⚠ Important

The device is only to be used:

- On humans
- For the purpose for which indicated in these instructions for use.

Any form of improper use can be dangerous.

In the event of an acute emergency, the provision of first aid has top priority.

Apart from the medication, only use distilled water or a saline solution. Other liquids may cause a fault in the nebulizer or nebulizer kit.

Prior to initial use

⚠ Important

Remove all packaging material before using the device.

Protect the device against dust, dirt and humidity and never cover the device while it is in use.

Do not operate the device in a very dusty area.

Switch the device off immediately if it is faulty or not working properly.

The manufacturer is not liable for damage resulting from improper or careless use.

Repairs

⚠ Note

Under no circumstances should you open or repair the device yourself, as faultless functionality can no longer be guaranteed thereafter. Failure to comply these instruction manual will result in voiding of the warranty and removal of responsibility from the manufacturer.

For repairs, please contact Customer Services.

2. INDICATION AND CONTRAINDICATION

Nebulizers model MED-120/TH-130 with accessories are intended for inhalation therapy aimed at the prevention and treatment of acute respiratory diseases, chronic respiratory disease, for example, chronic obstructive pulmonary disease (COPD), cystic fibrosis, bronchial asthma, pneumonia and other diseases of the respiratory system both adult patients and children. Nebulizers MED-120/TH-130 with accessories can be used in the doctor's practice in clinics, hospitals, as well as successfully used by patients at the outpatient stage for the prevention and treatment of exacerbations of diseases of the upper and lower respiratory tract.

Scope: prevention and treatment facility and personal use at home.

3. DESCRIPTION OF THE DEVICE AND ACCESSORIES

Overview of nebulizer

① On/Off switch

② Micro USB port

③ Battery status indicator (TH-130 only)

④ Hoseconnector

⑤ Filter cap

⑥ Holder for nebulizer kit

⑦ Compressed air hose

⑧ Mouthpiece

⑨ Adult mask

⑩ Children's mask

⑪ Nozzlepiece

⑫ Set of filters

⑬ USB power mains part

⑭ USB cable

Nebulizer kit

⑮ Nebulizer cup

⑯ Medication container

⑰ Diffuser

4. INITIAL USE

Setting up the device

Take the device out of the packaging. Place the device on a flat surface.

Before using the device for the first time

⚠ Note

Clean and disinfect the nebulizer and accessories before using them for the first time. See Chapter **7 Cleaning and disinfection**.

Connect the compressed air hose to the bottom of the medication cup.

Connect the other end of the compressed air hose to the nebulizer hose connection by turning it slightly.

Charging the nebulizer battery (for TH-130)

To charge the nebulizer battery:

Plug the micro USB cable included in delivery into the micro USB port on the nebulizer as shown.

Plug the other end of the micro USB cable into the USB port on the mains adapter and insert the mains adapter into the socket.

⚠ Note

For TH-130: During the charging procedure, between one (battery almost empty) and four (battery fully charged) LEDs on the battery status indicator [3] flash according to the battery charge status. As soon as the battery is fully charged, all four LEDs are permanently illuminated.

For MED-120: Connect the inhaler to the mains with the required voltage using the USB power mains part and the USB cable, after using to disconnect and remove the USB power mains part and the USB cable.

Switching on the nebulizer

To turn on the nebulizer, proceed as follows:

Press the ON/OFF button on the nebulizer. The ON/OFF button illuminates blue. The nebulizer is now operational.

Only for TH-130: The battery must be sufficiently charged for the nebulizer to function correctly.

Note: The blue LEDs on the battery status indicator show the current battery state:

■ 1 blue LED flashes – Battery is almost flat, nebulizer will soon switch off

■ ■ 1 blue LED lights up – Battery capacity 25%

■ ■ ■ 2 blue LEDs light up – Battery capacity 50%

■ ■ ■ ■ 3 blue LEDs light up – Battery capacity 75%

■ ■ ■ ■ ■ 4 blue LEDs light up – Battery capacity 100%

5. OPERATION

⚠ Important

For hygiene reasons, it is essential to clean the nebulizer and the accessories after each treatment and to disinfect them after the last treatment of the day.

If the treatment involves inhaling several rent medications one after the other, please be aware that the nebulizer must be rinsed under warm tap water following every use. See Chapter **7 Cleaning and disinfection**.

Please observe the notes on changing the filter in these instructions for use.

Check that those connectors are firmly attached to the nebulizer and the nebulizer before each use of the device.

Before use, check the device is working correctly by briefly switching on the nebulizer (together with the connected nebulizer, but without medication). If air comes out of the nebulizer, the device is working.

When using nebulizer do not close ventilation holes of the device.

Open the nebulizer kit by twisting the top anticlockwise against the medication container. Place the diffusor into the medication container.

Ensure that the cone for administering medication fits well on the cone for the air duct inside the nebulizer.

Filling the nebulizer

Pour the medication directly into the medication cup. Avoid overfilling. The maximum recommended quantity is 6 ml.

Use medication only as instructed by your doctor and ask about the appropriate inhalation period and quantity.

If the prescribed quantity of medication is less than 2 ml, top this up to at least 2 ml with isotonic saline solution. Dilution is also necessary with viscous medications. Here too, please observe the instructions of your doctor.

Closing the nebulizer

Close the nebulizer by twisting the top clockwise against the medication container. Ensure that the connection is correct.

Connecting accessories to the nebulizer kit

Connect the nebulizer to the desired accessory (mouthpiece, mask, nozzlepiece)

⚠ Note

The most effective form of nebulization is by using the mouthpiece. Nebulization using a mask is only recommended if it is not possible to use a mouthpiece (e.g. for children who are not yet able to inhale medication using a mouthpiece).

Use the nozzlepiece accessory only if expressly indicated by your doctor and paying attention to NEVER introduce the bifurcations in the nose, but only bring them as close as possible.

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. If you are using the adult mask, you can secure it to your head with the adult mask strap. There is also a strap for the children's mask.

Do not use the nebulizer with the strap.

Spray the inhaler using the switch.

⚠ Important: The device is not suitable for continuous operation; after 30 minutes of operation it must be switched off for 30 minutes.

*Hereafter referred to as «inhaler», «device», consider the same.

Measurements were performed using a sodium fluoride solution with a "Next Generation Impactor" (NGI).

The diagram may therefore not be applicable to suspensions or highly viscous medications.

You can obtain more detailed information from the manufacturer of your medication.

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