

GARANTIE / SERVICE

Nähere Informationen zur Garantie und den Garantiebedingungen finden Sie im mitgelieferten Garantie-Faltblatt.

Hinweis zur Meldung von Vorfällen

Für Anwender/Patienten in der Europäischen Union und identischen Regulierungssystemen gilt: Sollte sich während oder aufgrund der Anwendung des Produktes ein schwerer Zwischenfall ereignen, melden Sie dies dem Hersteller und/oder seinem Bevollmächtigten sowie der jeweiligen nationalen Behörde des Mitgliedsstaates, in welchem Sie sich befinden.

Irrtum und Änderungen vorbehalten

ENGLISH

Read these instructions for use carefully. Observe the warnings and safety notes. Keep these instructions for use for future reference. Make the instructions for use accessible to other users. If the device is passed on, provide the instructions for use to the next user as well.

INCLUDED IN DELIVERY

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or atomiser set (mouthpiece, masks) and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Service address. Nebuliser, Mesh atomiser with medication container (hereinafter referred to as "medication container"), Mouthpiece, Adult mask made from PVC, Children's mask made from PVC, USB-C cable, Storage bag, These instructions for use

SIGNS AND SYMBOLS

The following symbols can be found in these instructions for use:

 WARNING
Indicates a potentially impending danger. If it is not avoided, there is a risk of death or serious injury.
 CAUTION
Indicates a potentially impending danger. If it is not avoided, slight or minor injuries may result.
 NOTICE
Indicates a potentially harmful situation. If it is not avoided, the device or something in its vicinity may be damaged.

The following symbols are used on the packaging and on the type plate for the device and atomiser set:

 Product information Note on important information	 Observe the instructions Read the instructions before starting work and/or operating devices or machines
 Identification of the packaging material. A = material code, B = material number, 1-7 = plastics, 20-22 = paper and cardboard	 CE labelling This product satisfies the requirements of the applicable European and national directives.
 Applied part, type BF	 Importer
 Manufacturer	 Date of manufacture
 Medical device	 Article number
 Serial number	 Article device identifier (UDI) to uniquely identify the product
 The device is protected against foreign objects ≥ 12.5 mm and against dripping water falling at an angle	 Type number
 Air humidity range	 Temperature range
 Atmospheric pressure limit	 Direct current
 Protection class II device	 Separate the product and packaging materials and dispose of them in accordance with local regulations.
 Do not dispose of batteries containing harmful substances with household waste	 The electronic device must not be disposed of with household waste
 Swiss authorised representative	

INTENDED PURPOSE

Intended use

Nebulisers (including compressor, ultrasonic and mesh nebulisers) are medical devices for the nebulisation of liquids and liquid medication (aerosols). This device produces aerosols by combining an oscillating mesh with holes and a liquid medication. The aerosol treatment is for treating the upper and lower airways. By nebulising and inhaling the medication prescribed / recommended by your doctor, you can prevent diseases of the airways, or in the case that you contract such an illness, you can alleviate symptoms and speed up your recovery.

Intended users

The nebuliser is intended for use in the home healthcare environment, not in professional healthcare facilities. The nebuliser can be used on anyone over 2 years of age under supervision; it can be used for self-treatment by anyone over 12 years of age. The shape and size of the person's face determines whether or not the device can be used under supervision. As such, it may be possible to use the device under supervision on someone who is younger, or conversely it may not be possible to use the device until they are older. When using a mask to inhale, take care to ensure the mask fits well and the eyes are unobstructed.

Clinical benefit

Inhalation is the most effective way to administer medication for most respiratory system conditions.

The benefits are:

- The medication is carried directly to the target organs
- The local bioavailability of the medication is significantly increased
- Systemic diffusion is reduced substantially
- Only very low doses of the medication are required
- Quick and effective therapeutic effect
- Side effects are significantly lower compared to systemic administration
- Humidifying the airways
- Loosening and making bronchial secretions more liquid
- Releasing bronchospasms (spasmolysis)
- Relieving swollen and inflamed bronchial mucosa
- Coughing up secretions
- Fighting viruses that affect the upper and lower airways

Indications

The nebuliser can be used for diseases of the upper and/or lower airways.

Examples of upper airway diseases include:

- Nasal mucosal inflammation
- Allergic nasal mucosal inflammation
- Nasal sinus infection
- Pharyngitis
- Laryngitis

Examples of lower airway diseases include:

- Bronchial asthma
- Bronchitis
- COPD (chronic obstructive pulmonary disease)
- Bronchiectasis
- Acute tracheobronchitis
- Cystic fibrosis
- Pneumonia

Contraindications

- The atomiser is not intended for the treatment of life-threatening diseases.
- This device must not be used by children under the age of 12 and by people with reduced physical, sensory (e.g. reduced sensitivity to pain) or mental skills or a lack of experience or knowledge, unless they are supervised or have been instructed on how to use the device safely, and are fully aware of the consequent risks of use.
- Do not use the device on persons who are ventilated and/or unconscious.
- Check whether there are contraindications for use with the usual systems for aerosol treatment on the medication instruction leaflet.
- If the device does not work properly, or if you feel unwell or experience pain, stop using it immediately.

WARNINGS AND SAFETY NOTES

WARNING

- The atomiser has no significant effect on the efficacy and safety of the medication administered and is not intended for the treatment of life-threatening conditions. The atomiser is not suitable for use in anaesthesia or other ventilation systems.

- After proper preparation, the device can be reused. This preparation includes the replacement of all components, including the atomiser. We recommend that you replace the medication container and other components after one year at the latest. This recommendation for the timing of the replacement is based on the assumption that the device is used for a maximum of 2 cycles per day and for ≤ 10 min per cycle and is regularly disinfected and cleaned in accordance with the instructions for use (8. Cleaning and maintenance). For hygiene reasons, it is essential that each user uses their own components.
- Always follow the instructions of your doctor or pharmacist regarding the type of medication to be used, the dosage and the frequency and duration of inhalation. When using with medications/medication nebulisation, observe the conditions and restrictions applicable to these medications. Notice: Use only the medications prescribed by your doctor for treatment according to the respective diagnosis.
- The device is not a substitute for medical advice and treatment. Always consult your doctor first in case of pain or illness.
- If you have any health concerns, consult your GP.
- Do not use liquids with our nebuliser that are not compatible with steel, PP, PC, silicone or PVC. If the information supplied with the liquid does not indicate its compatibility with these materials, contact the liquid manufacturer. Examples of compatible liquids include: Albuterol solution and sodium chloride solution.
- The particle size distribution curve, MMAD, aerosol delivery and/or aerosol delivery rate may change if a different medication, suspension, emulsion or highly viscous solution is used than the one referenced in the technical specifications for the aerosol values.
- Please observe the general hygiene measures when using the nebuliser.
- Before use, ensure that the device or its components show no visible damage. If you have any doubts, do not use the device and contact your retailer or the specified Customer Service address.
- No modifications may be made to the device or its components.
- Use only accessories recommended by the manufacturer.

- The nebuliser may only be operated with compatible Beurer atomisers and with the appropriate Beurer components. The use of nebulisers and components from other manufacturers may impair the effectiveness of the treatment and damage the device.
- Keep the device away from your eyes when it is in use, as the mist of medication could be harmful.
- Never use the device in the presence of flammable or explosive gases, oxygen or nitrous oxide.
- Store the device and components out of the reach of children and pets.
- Keep the packaging material away from children (risk of suffocation).
- The device must be switched off and the plug of the USB-C cable pulled out before every cleaning and/or maintenance.
- If the device has been stored at maximum storage temperature, it must cool for 4 hours before use until it is ready for its intended use. If the device has been stored at minimum storage temperature, it will also take 4 hours until the device is ready for its intended use.
- Never submerge the device in water and do not use it in the bathroom. Under no circumstances may liquid enter the device.
- If the device has been dropped, exposed to high levels of moisture or suffered any other damage, it must no longer be used. If in doubt, contact Customer Services or the retailer.
- Power outages, sudden interference or other unfavourable conditions may cause the device to stop working. We therefore recommend that you stock up on a replacement device or replacement medication (the latter should be agreed with your doctor).
- Keep the cable out of reach of small children to avoid the danger of constriction and strangulation.
- The device must only be connected to the mains voltage that is specified on the type plate.
- Never touch the USB-C cable with wet hands as this could cause an electric shock.
- Do not use the USB-C cable to pull the mains adapter out of the socket.
- Do not crush or bend the USB-C cable, pull it over sharp edges or leave it dangling, and protect it from sources of heat.
- We recommend that the USB-C cable be completely unwound to avoid dangerous overheating.
- If the USB-C cable of this device is damaged, it must be disposed of. Please contact Customer Services or the retailer.
- There is a risk of electric shock when opening the device. The device is not disconnected from the power supply unless the adapter is unplugged (and the USB-C cable has no other power connection).

CAUTION

- Never store the device (or the USB-C cable) near heat sources.
- Do not use the device in a room where a spray has previously been used. Ventilate the room before performing the treatment.
- Never use the device if it makes unusual noises.
- Store the device in a location protected against weather conditions. The device must be stored under the specified ambient conditions.
- Do not operate the device near electromagnetic transmitters.
- Protect the device from heavy impacts.
- Disconnect the device from the power supply after the battery is fully charged.
- If you need an adaptor or extension cable, it must comply with the applicable safety requirements. The power limit and maximum power specified on the adaptor must not be exceeded.

Prior to initial use

- Remove all packaging material before using the device.
- Protect the device from 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 off the device immediately if it is faulty or does not function properly.
- The manufacturer is not liable for damage resulting from improper or incorrect use.

Repairs

- Never open or repair the device yourself. Otherwise malfunctions may occur. Failure to comply with this instruction will invalidate the guarantee.
- The device is maintenance-free.
- For repairs, please contact Customer Services or an authorised retailer.

Notes on handling batteries

WARNING

- **Risk of explosion! Risk of fire!** Failure to comply with the points mentioned can result in personal injury, overheating, leakage, venting, breakage, explosion, or fire.
- Always use the correct or supplied charging cable/charger/mains adapter for charging.
 - Avoid continuous charging or overcharging. Unplug the charger when charging is complete.
- Charge the device under supervision, paying attention to any heat generated, deformation, or release of gases. If in doubt, stop charging.
- If batteries/charging cables/chargers are defective, stop using them and dispose of them properly as soon as possible (see chapter on disposal).
- Do not throw the device or batteries into a fire.
- Never forcibly discharge, heat, disassemble, open, crush, deform, encapsulate, modify, or knock the device or batteries.
- Never short-circuit batteries or the connections of the battery-powered device.
- Protect the device or batteries from direct sunlight, rain, heat, and water.
- Exposure of batteries to an environment with extremely high temperatures or an extremely low air pressure may result in explosion or leakage of flammable liquids and gases.
- If fluid from a battery comes into contact with your skin or eyes, wash the affected areas with water and seek medical assistance.

NOTICE

- This device contains a battery that is not replaceable. Once a battery has reached the end of its service life, the device must be disposed of properly (see chapter on disposal).

Notes on electromagnetic compatibility

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The use of the device may be restricted if electromagnetic disturbance occurs. This could result in issues such as the failure of the device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. If, however, it is necessary to use the device in the manner stated, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of an atomiser set other than that specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Keep portable RF communication devices (including peripheral equipment, such as antenna cables or external antennas) at least 30 cm away from all device parts, including all cables included in delivery.
- Failure to comply with the above could impair the performance of the device.

DEVICE AND ATOMISER SET DESCRIPTION

Atomiser set

Only use the atomiser set recommended by the manufacturer. If this is not respected, the device may not function safely.

CAUTION

Leakage protection

When pouring the medication into the medication container, ensure that you only fill it up to the maximum mark (10 ml). The recommended filling volume for the device is 0.5 to 10 ml.

The substance to be nebulised must be in contact with the mesh for nebulisation to take place. If this is not the case, the nebulisation will stop automatically. Therefore, keep the device as vertical as possible.

INITIAL USE

Before using the device for the first time

NOTICE

- Clean and disinfect the medication container [2] and the atomiser set before first use. See the "Cleaning and maintenance" section in this regard.

Assembly

Remove the device from the packaging.

If the medication container [2] has not been assembled, slide it onto the housing [3] vertically from above.

Charging the nebuliser battery

Proceed as follows to charge the nebuliser battery:

- Connect the USB-C cable [8] included in delivery to the USB-C port [7] on the bottom of the nebuliser and a USB mains adapter (not included in delivery; the mains adapter must comply with protection class 2 and have been tested in accordance with the European standard EN 60601-1; 5V, 500mA). Plug the USB mains adapter into a suitable socket.
- Lie the nebuliser flat on its back during the charging process.
- While charging, the LED display [5] will continuously light up orange. As soon as the battery is fully charged, the LED display will continuously light up green.
- It usually takes approximately 2 hours for the battery to be fully charged.
- As soon as the battery is fully charged, remove the USB-C cable [8] with the USB mains adapter from the socket and the USB-C port [7] on the nebuliser.
- When the battery is fully charged, the battery life is approximately 1.5 hours. If the LED display [5] lights up orange while the device is in use, this indicates low a battery level.
- The type of low battery level display depends on how the device is used. If you have selected a high nebulisation rate, the LED display [5] will be a continuous orange. If you have selected a low nebulisation rate, the LED display [5] will slowly flash orange.
- The nebuliser cannot be used during the charging process.

USAGE

Preparing the nebuliser

- For hygiene reasons, it is essential to clean and disinfect the medication container [2] and the atomiser set regularly. See the "Cleaning and maintenance" section in this regard.
- If the therapy involves inhaling several different medications one after the other, please note that the medication container [2] must be rinsed under warm tap water after each use. See the "Cleaning and maintenance" section in this regard.

Filling the medication container

- Open the lid of the medication container [2] by turning it anti-clockwise and fill the medication container with an isotonic saline solution to pour the medication straight in. Do not overfill the medication container.
- The maximum recommended filling quantity is 10 ml.
- Use medication only as instructed by your doctor and ask about the appropriate inhalation duration and quantity for you.
- If the prescribed quantity of medication is less than 0.5 ml, it must be topped up with isotonic saline solution. Dilution is also required for viscous medication (viscosity < 3). Please follow your doctor's instructions in this case as well.

Closing the medication container

- Close the lid of the medication container [2] by turning the lid clockwise until the markings on the lid and the medication container are aligned.

Connecting the atomiser set

- Securely connect the part of the atomiser set that you would like to use (mouthpiece [1], adult mask [9] or children's mask [10] to the mounted medication container [2]. If you are using the adult mask [9] or children's mask [10], you may use one of the straps included. Ensure that you tie the strap securely to the mask with a knot.

- Now move the device to your mouth and put your lips firmly around the mouthpiece. When using the mask(s), please place it over your nose and mouth.
- Ensure that you have filled it up with liquid before switching on the device. Start the device by pressing the On/Off control [4].
- If the spray mist comes out of the device and the LED display [5] continuously lights up blue, the device is working correctly.

NOTICE

The device is not suitable for continuous operation; after 20 minutes of operation it must be switched off for 40 minutes. The most effective inhalation is when using the mouthpiece. Inhalation when using a mask is only recommended if the use of a mouthpiece is not possible (e.g. for children who are not yet able to inhale with a mouthpiece). When inhaling with a mask, make sure that the mask fits well and that the eyes are not covered. The flow rate for the medication is set to high in the factory settings of the device. You can adjust the medication flow rate during use by pressing and holding the On/Off control [4] for 3 seconds until the LED display [5] flashes blue. You can switch from high to low nebulisation rate and back again. A continuously blinking red LED display [5] indicates a high nebulisation rate of approx. 0.4 ml/min; a slowly flashing blue LED display [5] indicates a low nebulisation rate of approx. 0.2 ml/min. Adjust the medication flow rate to your needs.

Inhaling correctly

Breathing technique

- It is important to use the correct breathing technique to ensure that the particles are distributed as widely as possible throughout the airways. For the particles to reach your airways and lungs, you need to breathe in slowly and deeply, then hold your breath briefly (5 to 10 seconds) and then exhale quickly.
- Only use nebulisers for the treatment of respiratory diseases after consulting your doctor. They will advise you on selecting suitable medications for inhalation therapy, as well as their dosage and usage.
- Certain medications require a prescription. Only liquids and medications indicated for inhalation may be used.

NOTICE

Keep the device as vertical as possible. However, a small angle does not affect usage as the container is leak-proof. Make sure that the medication is in contact with the mesh for proper functioning of the device during use. If the device is tipped gently by 45 degrees with a maximum volume of 10 ml of liquid, the device will work as before.

CAUTION

For health reasons, essential oils, cough mixtures, gurgling solutions and drops for rubbing into the skin or for use in steam baths are completely unsuitable for inhalation with a nebuliser. These additives are also often viscous and can impair the correct functioning of the device and therefore the effectiveness of its usage in the long term.

In people with a hypersensitive bronchial system, medications that contain essential oils can sometimes cause acute bronchospasm (a sudden cramp-like narrowing of the bronchi with shortness of breath). Talk to your doctor or pharmacist about this.

Stopping the inhalation

a) Manually ending nebulisation:

- When you have finished the treatment, switch off the device using the On/Off control [4].
- The LED display [5] will go out.

b) Automatically ending nebulisation:

- If the inhalant has been nebulised, the LED display [5] will flash blue quickly and the device will automatically switch off. For technical reasons, a small amount of the medication remains in the medication container. Do not use this.

Cleaning

See section "Cleaning and maintenance".

Automatic switch-off

The device has an automatic switch-off function. When there is only a very small amount of medication or liquid left or when the substance to be nebulised is no longer in contact with the mesh, the device switches off automatically to prevent damage to the mesh. If nebulisation ends automatically, the automatic switch-off has been activated. The LED display [5] flashes blue quickly and the device then switches off. After a nebulisation period of 20 minutes, the device switches off automatically.

Do not use the device if the medication container [2] is empty. The device detects when there is no medication in the medication container and will switch off automatically.

LED display colour	Meaning
 Green	Fully charged: As soon as the battery is fully charged, the LED display continuously lights up green.
 Orange	Charging in progress: While the battery is charging, the LED display continuously lights up orange. Low battery level: If the LED display lights up orange while the device is in use, this indicates low a battery level. • At a high nebulisation rate: The LED display continuously lights up orange. • At a low nebulisation rate: The LED display flashes orange slowly. Self-cleaning mode: If you press and hold the On/Off control for 3 seconds while the device is switched off, the LED display flashes orange quickly and the device switches to self-cleaning mode.
 Blue	Operation and medication flow: The blue LED display indicates that the device is functioning correctly. • At a high nebulisation rate of approx. 0.4 ml/min: The LED display continuously lights up blue. • At a low nebulisation rate of approx. 0.2 ml/min: The LED display flashes blue slowly. Insufficient medication and automatic switch-off: When the inhalant has been nebulised, the LED display will flash blue quickly and the device will automatically switch off.

CLEANING AND MAINTENANCE

WARNING

Follow these hygiene instructions to avoid health risks.

- The medication container [2] and the atomiser set are intended for multiple use. Please note that different areas of application involve different requirements in terms of cleaning and hygienic preparation.

NOTICE

- Do not clean the mesh or the atomiser set mechanically with a brush or similar devices, as this can lead to irreparable damage and optimal treatment results can no longer be guaranteed.
- Ask your doctor for additional requirements regarding hygienic preparation (hand cleaning, handling of medications/inhalation solutions) for high-risk groups (e.g. patients with cystic fibrosis).
- The water mentioned later in the cleaning instructions should be as soft as possible. Distilled water is suitable for all cleaning steps except self-cleaning.

Disassembling

- Hold the device with one hand. The button [6] on the back of the device should face towards you. Press the button [6] with your thumb and pull the medication container [2] vertically upwards with your free hand.
- Remove the mouthpiece [1] or the mask [9] or [10] from the medication container [2].
- Open the lid of the medication container [2] by turning the lid anti-clockwise.
- Assembly is carried out in reverse order.

Cleaning

The medication container [2] and the used parts of the atomiser set such as the mouthpiece [1] or mask [9] or [10] must be cleaned after each use with warm (ideally distilled) water at a maximum temperature of 40°C for about 5 minutes.

To clean the medication container, follow the self-cleaning instructions below. Dry the parts carefully using a soft cloth. When completely dry, reassemble the parts and place in a dry, sealed container or disinfect them.

- Please perform the self-cleaning function afterwards (see "Self-cleaning function" section).

CAUTION

Never hold the entire device under running water to clean it.

When cleaning, ensure that any residue is removed and dry all parts carefully.

Do not use cleaning products that can be potentially toxic in contact with skin or mucous membranes if swallowed or inhaled.

If required, clean the housing of the device using a slightly damp cloth, which you can moisten with a mild soapy solution.

- If there is any residue from medical solutions or contamination on the silver/gold contacts of the device or medication container [2], clean with a cotton bud moistened with ethyl alcohol.
- The device must be switched off and cooled down before each cleaning.
- Do not use any abrasive cleaning products.

CAUTION

- Ensure that no water enters the device!
- Do not clean the device and atomiser set in the dishwasher.
- Avoid the device coming into contact with splash water. Only operate the device when it is completely dry.

CAUTION

We recommend continuous inhalation, as the inhalant can clog the medication container [2] during prolonged interruptions of treatment, which may impair the effectiveness of the administration.

Self-cleaning function

You can use the device's self-cleaning function to completely remove medication residues and any blockages.

To do so, proceed as follows:

1. Disassemble the device as described above.
2. Open the lid of the medication container [1] and pour out the remaining liquid.
3. Pour a sufficient amount (3-6 ml) of tap water (soft water) into the medication container [2]. Close the lid. Shake the medication container slightly so that the remaining liquid mixes well with the cleaning liquid. Run the device at a high nebulisation rate for one minute, then turn it off.
4. Open the lid of the medication container and pour out all of the liquid.
5. Pour 1.5 to 2.0 ml of tap water or distilled water mixed with vinegar (1/4 vinegar and 3/4 distilled water) into the opening in the mesh atomiser.
6. Press and hold the On/Off control [4] for 3 seconds when the device is switched off. The LED display [5] then flashes orange quickly and the device switches to self-cleaning mode. The cleaning liquid is now sucked out of the opening in the mesh atomiser into the medication container (reverse operation). During this process, droplets of this liquid may leak out of the medication container. Therefore, place some protection under the nebuliser if necessary. The device will automatically run for 3 minutes.

Disinfection

Please observe the following points when disinfecting your medication container [2] and the atomiser set. Regular disinfection of the individual parts is recommended.

First, clean the medication container [2] and atomiser set as described in the "Cleaning" section. Then proceed with disinfection.