

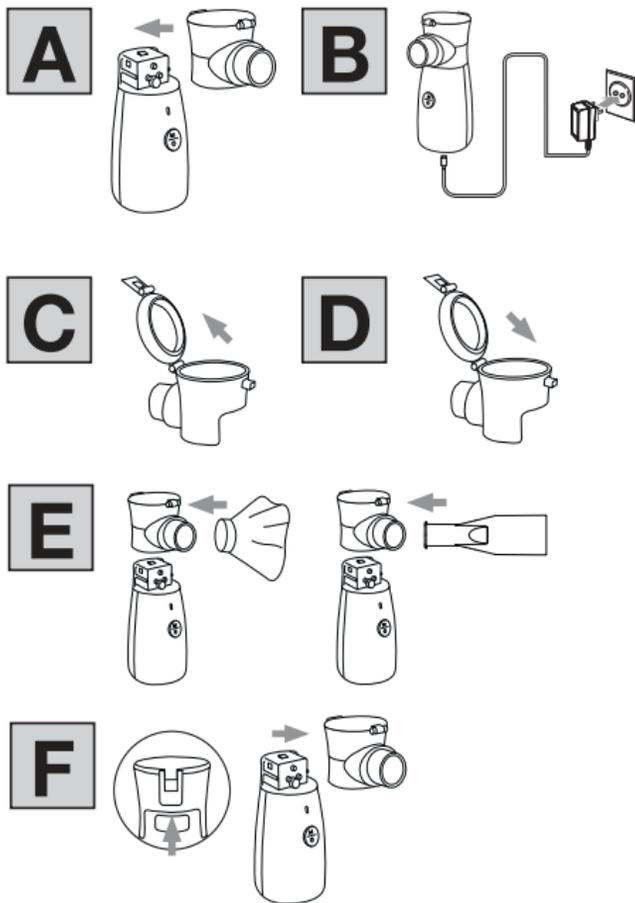
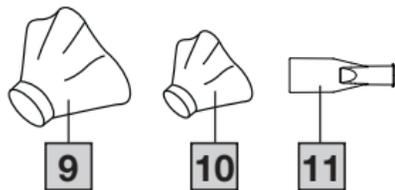
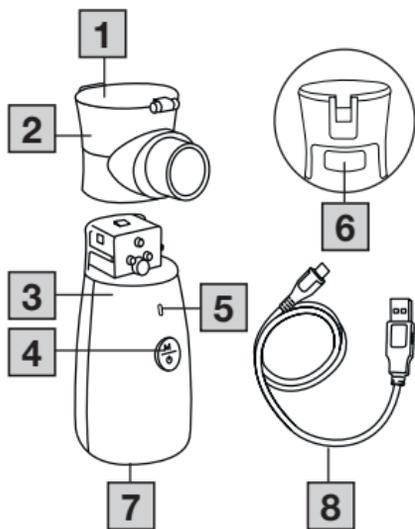
beurer

IH 47



EN Portable mesh atomiser
Instructions for use..... 3

CE 0483



ENGLISH



Read these instructions for use carefully. Follow 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.

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1. 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

2. SIGNS AND SYMBOLS

The following symbols are used on the device, in these instructions for use, on the packaging and on the type plate for the device:

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		Unique 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		Protection class II device

	Separate the packaging materials and dispose of them in accordance with local regulations.	 	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
	Direct current		Importer

3. INTENDED PURPOSE

Intended use

Nebulisers (including compressor, ultrasonic and mesh nebulisers) are medical devices for the nebulisation of liquids and liquid medication. 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 or 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.

Target group

The nebuliser is only intended for medical care in the domestic environment.

The nebuliser is not intended for health care in professional facilities.

The nebuliser can be used under supervision by people over 2 years of age and for self-treatment by people over 12 years of age.

The shape and size of the person's face determine whether the device can be used under supervision. Therefore, the device may be used under supervision by a younger person or only by a person older

than indicated. When inhaling with a mask, make sure that the mask fits well and that the eyes are not covered.

Clinical benefits

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

It offers the following benefits:

- The medication is transported directly to the target organs
- The local bioavailability of the medication is significantly increased
- Systemic diffusion is significantly reduced
- Only very low doses of the medication are required
- Fast and effective therapeutic effect
- Side effects are significantly lower compared to systemic administration
- Humidifying the airways
- (Bronchial) secretions are loosened and liquefied
- Bronchospasms (spasmolysis) are released
- Swelling and inflammation of the bronchial mucosa is alleviated
- Secretions can be coughed up
- Respiratory infection pathogens are combated

Indication

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.
- Children under 12 years of age or persons with reduced physical, sensory (e.g. reduced sensation of pain) or mental abilities, or lack of experience and knowledge, should only use this device under supervision, or if they have been instructed on the safe use of the device and are fully aware of the risks involved.
- Do not use the device on ventilated and/or unconscious persons.
- Refer to the leaflet of the medication for possible contraindications for use with the usual systems for aerosol treatment.
- If the device does not work properly, if you feel unwell or if you experience pain, stop using it immediately.

4. WARNINGS AND SAFETY NOTES

⚠ GENERAL WARNINGS

- 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. Compatible liquids include, for example, albuterol 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).

⚠ GENERAL PRECAUTIONS

- 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 adapter or extension cable, it must comply with the applicable safety requirements. The power limit and maximum power specified on the adapter 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 the device off immediately if it is faulty or not working properly.
- The manufacturer is not liable for damage resulting from improper or incorrect use.

Repairs

- Under no circumstances should you open or repair the device yourself. If you do so, it may no longer function correctly. Failure to comply with this instruction will void the guarantee.
- The device is maintenance-free.
- For repairs, please contact Customer Services or an authorised retailer.

Notes on handling batteries

- If fluid from a battery cell comes into contact with your skin or eyes, wash the affected areas with water and seek medical assistance.

- **Choking hazard!** Small children could swallow and choke on batteries. Therefore, keep batteries out of the reach of small children!
- Protect batteries from excessive heat.
- **Risk of explosion!** Never throw batteries into a fire.
- Do not disassemble, split or crush the batteries.
- Batteries must be charged correctly prior to use. The instructions from the manufacturer and the specifications regarding correct charging in these instructions for use must be observed at all times.
- Fully charge the battery prior to initial use (see “Warnings and safety notes” section).
- To obtain the maximum battery life, fully charge the battery at least 2 times a year.
- Fully charge the battery prior to initial use (see “Warnings and safety notes” section).
- To achieve the maximum battery life, fully charge the battery at least twice a year.

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.

5. DEVICE AND ATOMISER SET DESCRIPTION

The associated drawings are shown on page 2.

Device overview

- | | |
|---------------------------------------|--|
| 1 Lid for medication container | 2 Mesh atomiser with medication container (hereinafter referred to as “medication container”) |
| 3 Housing | 4 On/Off control |
| 5 LED display | 6 Button for unlocking the medication container (“PRESS”) |
| 7 USB-C connection | 8 USB-C cable |

Atomiser set overview

- | | |
|-----------------------------------|---|
| 9 Adult mask made from PVC | 10 Children’s mask made from PVC |
| 11 Mouthpiece | |

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.

6. 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** is not assembled, slide it horizontally **A** from above onto the housing **3**.

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). Plug the USB mains adapter into a suitable socket. **B**
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 1.5 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 hour and 15 minutes. 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.

7. USAGE

7.1 Preparing the nebuliser

- For hygiene reasons, it is essential to clean and regularly disinfect the medication container **2** and the atomiser set after each treatment. For this purpose, see section “Cleaning and maintenance”.
- If the therapy involves inhaling several different medications one after the other, it should be noted that the medication container **2** must be rinsed under warm tap water following every usage. For this purpose, see section “Cleaning and maintenance”.

7.2 Filling the medication container

- Open the lid of the medication container **2** by lifting up the flap **1** on the rear **C** and fill the medication container with an isotonic saline solution or 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.

7.3 Closing the medication container

- Close the lid of the medication container **2** by pressing the flap on the rear down and locking it. **D**

7.4 Connecting the atomiser set

- Securely connect the part of the atomiser set that you would like to use (mouthpiece **11**, adult mask **9** or children's mask **10**) to the mounted medication container **2** **E**. 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 straps 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 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 blue illuminated LED display **5** indicates a high nebulisation rate of ≥ 0.25 ml/min; a slowly flashing blue LED display **5** indicates a low nebulisation rate of ≥ 0.15 ml/min.

Adjust the medication flow rate to your needs.

7.5 Inhaling correctly

Breathing technique

- It is important to use the correct breathing technique to ensure that the aerosols are distributed as widely as possible throughout the airways. For the aerosols 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 tilted slightly by 45 degrees with a maximum fluid volume of 10 ml, the device will work as usual.

⚠ CAUTION

Pentamidine preparations, essential oils and medicines containing oils and lipids must not be used with this atomiser. Otherwise the nebuliser will be damaged. For health reasons, 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.

7.6 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.

7.7 Cleaning

See section “Cleaning and maintenance”.

7.8 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 15 minutes, the device switches off automatically. Do not operate 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.

LED display colour	Meaning
<p>Orange</p> 	<p>Charging in progress: While the battery is charging, the LED display continuously lights up orange.</p> <p>Low battery level: If the LED display lights up orange while the device is in use, this indicates low a battery level.</p> <ul style="list-style-type: none"> • At a high nebulisation rate: The LED display continuously lights up orange. • At a low nebulisation rate: The LED display flashes orange slowly. <p>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.</p>
<p>Blue</p> 	<p>Operation and medication flow: The blue LED display indicates that the device is functioning correctly.</p> <ul style="list-style-type: none"> • At a high nebulisation rate of ≥ 0.25 ml/min: The LED display continuously lights up blue. • At a low nebulisation rate of ≥ 0.15 ml/min: The LED display flashes blue slowly. <p>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.</p>

8. 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, 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** horizontally forwards with your free hand. **F**
- Remove the mouthpiece **11** or the mask (**9** or **10**) from the medication container **2**.
- Open the lid of the medication container **2** by lifting up the flap **1** on the rear **C**.
- Assembly is carried out in the reverse order.

Cleaning

The medication container **2** and the used parts of the atomiser set such as the mouthpiece **11** 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, please follow the self-cleaning instructions described 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 performing the inhalation without interruption, 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 (4–6 ml) of tap water (soft water) into the medication container **2**. Close the lid. Shake the container slightly so that the remaining liquid mixes well with the cleaning liquid.
4. Open the lid of the medication container, pour out all the liquid and then fill it with enough tap water (soft water) again.
5. Place the medication container on the housing **3**.
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 device will automatically run for 10 minutes. Please make sure that there is enough liquid in the medication container.

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.

CAUTION

Ensure that you do not touch the mesh if possible, as this may destroy it.

Do not use sodium hypochlorite disinfectant for disinfection as it may damage the atomiser.

Disinfection with ethyl alcohol (70–75%)

- Place the mouthpiece **11** and masks **9** **10** in a container and cover all parts with ethyl alcohol. Leave it to take effect for 10 minutes.
- Finally, clean all parts again with water.
- Then dry all parts thoroughly. For more information, see the “Drying” section.

Disinfection with boiling water

- The medication container **2**, lid **1** and the mouthpiece can be placed in boiling water for 15 minutes in order to disinfect them. Ideally, distilled water should be used to avoid contamination and

limescale formation on the mesh. The parts should not come into contact with the hot base of the pan.

- Then dry all parts thoroughly. For more information, see the “Drying” section.
- The medication container **2** must not be placed in the microwave.
- We guarantee 52 disinfection cycles with boiling water per medication container.

NOTICE

The masks must not be placed in hot water!

- We recommend disinfecting the masks with 70–75% ethyl alcohol.

Drying

- Dry the parts carefully using a soft cloth.
- Gently shake the medication container **2** a few times so that any water is removed from the tiny holes in the mesh.
- Place the individual parts on a clean, dry and absorbent surface and leave them to dry completely (for at least 4 hours).
- Do not use a microwave, dish dryer or hair dryer for drying or disinfection.

NOTICE

Please ensure that the parts are completely dried after cleaning, otherwise there is a high risk of bacterial growth.

When completely dry, reassemble the parts and place in a dry, sealed container.

Durability of materials

- Like all plastic parts, the medication container **2** and the atomiser set are subject to a certain degree of wear and tear if used frequently and prepared hygienically. Over time, this may lead to a change in the aerosol, which may reduce the effectiveness of the treatment. We therefore recommend that you replace the medication container **2** and atomiser set after one year at the most.

Storage

- Do not store in damp conditions (such as in a bathroom) and do not transport with any damp items.
- Protect from direct sunlight during storage and transport.

9. SERVICE PARTS AND/OR REPLACEMENT PARTS

The parts of the atomiser set and/or replacement parts are available from the service address specified (in the service address list). Please state the corresponding order number.

Name	Material	REF
Mouthpiece (PP), adult mask (PVC), children's mask (PVC), mesh atomiser with medication container (PC)	PP/PVC/PC	110.126

10. WHAT IF THERE ARE PROBLEMS?

Problem/question	Possible cause/remedy
The nebuliser produces no or too little aerosol.	1. Too little medication in the medication container 2 .
	2. The nebuliser is not being held vertically.
	3. Medication liquid has been poured in that is not suitable for nebulisation (e.g. too viscous. The viscosity must not be greater than 3. Ask your pharmacist about the viscosity.) The medication liquid should have been prescribed by a doctor.
	4. The battery is flat. Charge it.

Problem/question	Possible cause/remedy
The output is too low.	<ol style="list-style-type: none"> 1. There are air bubbles in the medication container that prevent continuous contact with the mesh. Please check this and remove any air bubbles. 2. Particles on the mesh are hindering output. In this case, you should pause the inhalation process and remove the mask or mouthpiece. Then clean and disinfect the medication container (see “Cleaning and maintenance” section). 3. The mesh is worn. Replace the medication container 2.
What medications are suitable for inhaling?	<p>Naturally, only your doctor can decide which medication should be used for treating your condition.</p> <p>Please consult your doctor in relation to this matter.</p> <p>With the IH 47, you can nebulise medications with a viscosity of less than 3. Medications containing oil (particularly essential oils), pentamidine preparations and medications containing lipids, should not be used, as these affect the material of the medication container, which can lead to faults.</p>
There is inhalation solution residue in the medication container 2 .	<p>This is normal and due to technical reasons. Stop the inhalation as soon as the atomiser makes a significantly different noise or the device switches off automatically due to a lack of inhalant.</p>
What should be taken into account when using the device with infants and children?	<ol style="list-style-type: none"> 1. For infants, the mask should cover the nose and mouth to ensure effective inhalation. 2. For children, the mask should also cover the nose and mouth. It is not advisable to use the nebuliser on a sleeping person because too little medication enters the lungs. <p>Notice: Inhalation should only be carried out under the supervision of an adult and with their assistance, and the child should not be left alone.</p>

Problem/question	Possible cause/remedy
Should each person have their own atomiser set?	Yes, this is absolutely necessary for hygiene reasons.

11. DISPOSAL

Battery disposal

- Empty, completely flat batteries must be disposed of in specially designated collection boxes, at recycling points or at electronics retailers. You are legally required to dispose of the batteries.
- The codes below are printed on batteries containing harmful substances:
 - Pb = battery contains lead
 - Cd = battery contains cadmium
 - Hg = battery contains mercury



General disposal

For environmental reasons, do not dispose of the device in household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point in your country. Dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.



12. TECHNICAL SPECIFICATIONS

Type	IH 47
Dimensions (L x W x H)	48 x 59 x 115 mm
Weight	0.0926 kg ± 0.005 kg
Input	5 V DC; 1.2 A

Energy consumption	≤ 2.5 W
Filling volume	Min. 0.5 ml Max. 10 ml
Medication flow rate	Low nebulisation rate: ≥ 0.15 ml/min High nebulisation rate: ≥ 0.25 ml/min
Vibration frequency	110 kHz ± 10 kHz
Sound pressure	Approx. ≤45 dB(A)
Operating conditions	Temperature: +5°C – +40°C Relative humidity: 15–90%, non-condensing Ambient pressure: 700 – 1060 hPa
Storage and transportation conditions	Temperature: -25°C – +55°C Relative humidity: 15–90%, non-condensing
Expected service life of the device	Information on the service life of the product can be found on the homepage
Battery:	
Capacity	600 mAh
Nominal voltage	3.7 V
Type designation	Lithium-ion

Aerosol values according to ISO 27427:2023 with salbutamol:

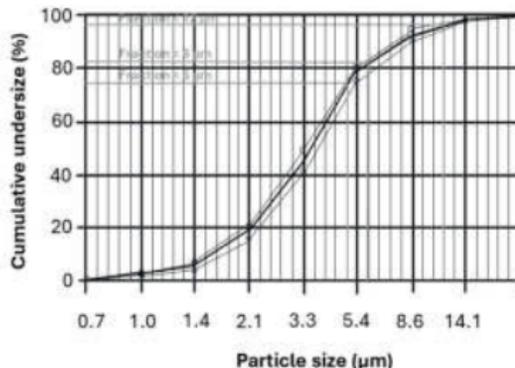
- Aerosol delivery: 0.72 ml
- Aerosol delivery rate: 0.13 ml/min
- Fill volume dispensed in percent per minute: 6.47%
- Residual volume: 0.04 ml
- Particle size (MMAD): 3.43 μm
- GSD (geometrical standard deviation): 1.77
- RF (respirable fraction < 5 μm): 74.67%
- Large particle range (> 5 μm): 25.33%
- Medium particle range (2 to 5 μm): 57.27%
- Small particle range (< 2 μm): 17.40%

Software version V1.0.3.

The serial number is located on the device.

Subject to technical changes. (see “Cleaning and maintenance” section).

Particle size chart



Measurements were performed using a salbutamol 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.

NOTICE

If the device is not used according to the specifications, it may not work correctly! We reserve the right to make technical changes to improve and develop the product.

This device and its atomiser set conform with the European standard EN 60601-1-2 (Group 1, Class B, in accordance with CISPR 11, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8, IEC 61000-4-11) and are subject to particular precautions with regard to electromagnetic compatibility.

13. GUARANTEE / SERVICE

More information on the guarantee and guarantee conditions can be found in the guarantee leaflet supplied.

Notification of incidents

For users/patients in the European Union and identical regulation systems (EU Medical Device Regulation (MDR) 2017/745), the following applies: If a major incident occurs during or through use of the product, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which you are located.



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