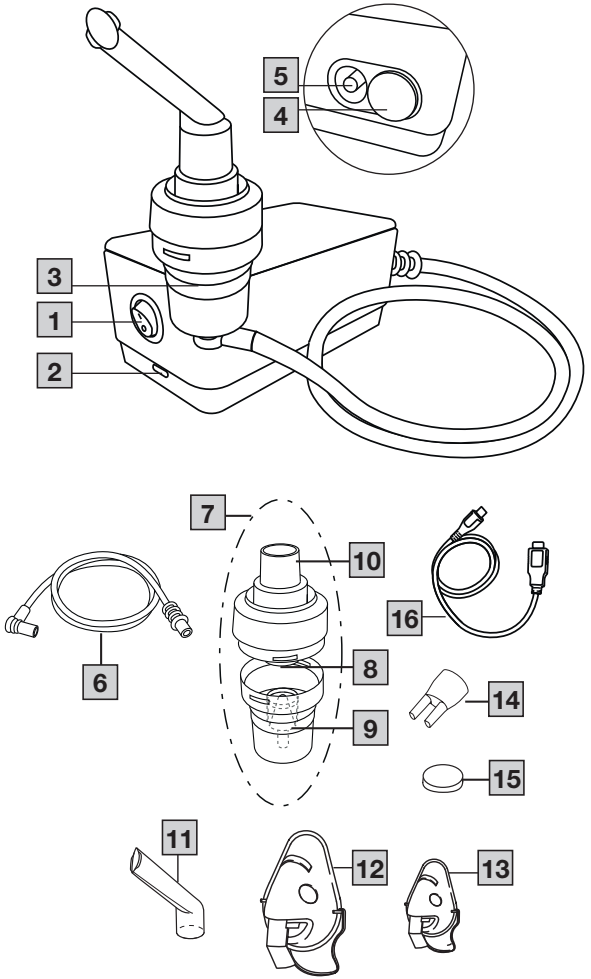
beurer

IH 15

EN Nebuliser
Instructions for use

CE 0483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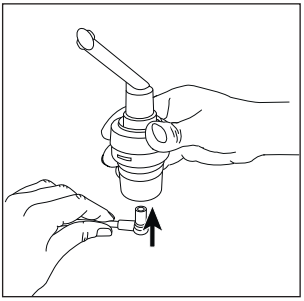

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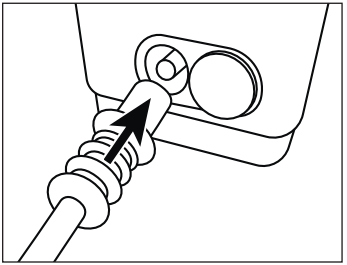

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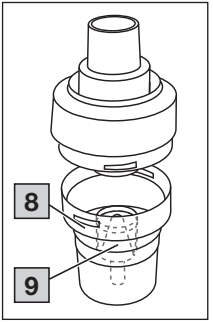

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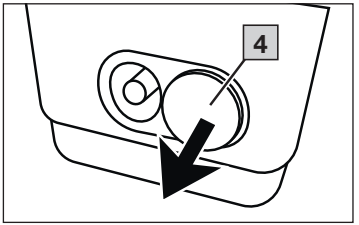


ENGLISH

Read these instructions for use carefully and keep them for later use. Make them accessible to other users and note the information they contain.

Table of contents

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 (= year pack) 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, atomiser, compressed air hose, mouthpiece, adult mask, children's mask, nosepiece, 5 x replacement filters, USB-C cable, instructions for use

2. SIGNS AND SYMBOLS

The following symbols are used on the packaging and on the type plate for the device and accessories.

⚠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.

	**Product information** Note on important information
	Applied part, type BF
	**Observe the instructions** Read the instructions before starting work and/or operating devices or machines
	Protection class 2 device
	Manufacturer
I	On
O	Off
SN	Serial number

30 min. ON / 30 min. OFF	30 minutes of operation, then 30 minutes break before operating again.
IP21	Protected against solid foreign objects 12.5 mm in diameter and larger, and against vertically falling drops of water
CE	**CE labelling** This product satisfies the requirements of the applicable European and national directives.
B A	Marking to identify the packaging material. A = material abbreviation, B = material number: 1–7 = plastics, 20–22 = paper and cardboard
RECYCLE	Separate the product and packaging elements and dispose of them in accordance with local regulations.
	The electronic device must not be disposed of with household waste.
	Temperature range
%	Humidity range
MD	Medical device
UDI	Unique device identifier (UDI) Identifier for unique product identification
REF	Article number
#	Type number
1	Reuse on a single patient
	Date of manufacture
CH REP	Swiss Authorised Representative
	Importer

3. 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 compressed air and liquid medication. The aerosol treatment is suitable for treating the upper and lower airways. By nebulising and inhaling the medication prescribed/recommended by your doctor, you can prevent diseases affecting 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 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 benefits

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 reduced

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

Indication

The nebuliser can be used for diseases of the upper and/or lower airways. Examples of upper respiratory system diseases include Nasal mucosal inflammation, Allergic nasal mucosal inflammation, Nasal sinus infection, pharyngitis and laryngitis. Examples of lower respiratory system diseases include bronchial asthma, bronchitis, COPD (chronic obstructive pulmonary disease), bronchiectasis, acute tracheobronchitis, cystic fibrosis and pneumonia.

Contraindications

- The device is not intended for the treatment of life-threatening conditions.
- 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.

4. WARNINGS AND SAFETY NOTES

⚠ WARNING

- If the device is not used according to the specifications, it may not work correctly!
- The device has no significant effect on the efficacy and safety of the medication administered.
- Once it has been properly prepared, the device can be used again. Preparation involves replacing all the components, including the atomiser and air filter, and disinfecting the surface of the device using a standard disinfectant. We recommend that you replace the atomiser and other components after one year at the latest. For hygiene reasons, it is essential that every user uses their own components.
- To avoid health risks, follow the general hygiene instructions as well as those listed below.
- The device is not a substitute for medical consultation and treatment. For this reason, always consult your doctor first if you have health concerns of any kind or if anything is unclear.
- You should always follow the instructions of your doctor or pharmacist regarding the type of medication to use, the dosage, and the frequency and duration of inhalation.
- In the event of use with medication/nebulisation of medication, the conditions and restrictions applicable to such medication must be adhered to.
- Please consult your doctor about the additional requirements in terms of the hygienic preparation needed (hand care, handling of medication/inhalation solutions) for high-risk groups (e.g. patients with cystic fibrosis).
- Essential oils, cough syrups, gargling solutions and drops to be used as a rub or in a steam bath are wholly unsuitable for inhalation using a nebuliser. These

additives are often viscous and can impair the correct functioning of the device and therefore the effectiveness of the application in the long term. For individuals with a hypersensitive bronchial system, medications containing essential oils may under certain conditions cause an acute bronchospasm (a sudden cramp-like restriction of the bronchi with shortness of breath). Talk to your doctor or pharmacist about this.

- 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.
- If the liquid you wish to use is not compatible with PP, PC or PVC, do not use this liquid with our nebuliser. If the information provided with the liquid does not indicate whether the liquid is compatible with these materials, please contact the liquid manufacturer. Sodium fluoride is an example of a compatible substance.
- Changes to the device and the components are not permitted.
- If the device is opened, there is a risk of electric shock. Disconnection from the power supply network is only guaranteed if the mains adapter is unplugged (and the cable has no other power connection).
- The device must be switched off, the plug pulled out and the device cooled down before every cleaning and/or maintenance procedure.
- The nebuliser may only be operated with compatible Beurer atomisers and with the appropriate Beurer components. The use of atomisers and components made by other companies may result in less efficient treatment and could damage the device.
- Keep the device away from your eyes when it is in use, as the mist of medication could be harmful.
- Do not operate the device in the presence of flammable or explosive gases, oxygen or nitrogen oxide.
- Store the device and components out of the reach of children, pets and pests. Children must not play with the device.
- Keep packaging material away from children (risk of suffocation).
- Store the cable and compressed air hose out of the reach of children (danger of strangulation).
- Never submerge the device in water and do not use it in the bathroom. Under no circumstances may liquid enter the device.
- Never touch the USB cable, device or mains adapter with wet hands, as you could get an electric shock.
- To reduce the risk of electric shock or fire, only use the device when it is dry.
- Do not spray water on the device.
- If liquid penetrates the device this could cause damage to the electrics or other nebuliser parts and lead to a malfunction.
- If the device has been dropped, exposed to high levels of moisture or heavy impacts or suffered any other damage, it must no longer be used. If in doubt, contact Customer Services or the retailer.
- Power cuts, sudden interference or other unfavourable conditions could lead to the device becoming inoperable. We therefore recommend that you obtain a replacement device or medication (the latter should be agreed with your doctor).
- The device must only be connected to the mains voltage that is specified on the type plate.
- Do not pull the mains adapter out of the socket by the cable.
- Do not crush or bend the cable, pull it over sharp-edged objects or leave it dangling down, and protect it from sources of heat.
- Fully unroll the cable to avoid dangerous overheating.

- Do not wrap the cable around the device, either during storage or use.
- Do not use the device if the cable or mains adapter is damaged.
- Do not boil or autoclave the compressed air hose or the masks.
- It is not very useful to carry out nebulisation on someone who is sleeping, as in this case not enough of the medication will reach the lungs.

⚠ CAUTION

- The device is not suitable for continuous operation; after 30 minutes of operation it must be switched off for 30 minutes.
- Never operate the device without a filter.
- The used filter must not be cleaned and reused.
- Do not use the device in a room in which a spray has previously been used. Air the room before carrying out the treatment.
- Never use the device if it is making an abnormal sound.
- Always disconnect the device from the mains connection after use.
- Should you require a mains adapter or extension lead, this must meet the applicable safety requirements. The power limit and the maximum output specified on the mains adapter must not be exceeded.
- Do not clean the device or atomiser set in the dishwasher!
- Store the device (and the cable) in a location protected against climatic influences. The device must be stored in the environmental conditions specified. Do not store it near to sources of heat.
- 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.

Prior to initial use

- Protect the device from dust, impacts, drastic changes in temperature, direct sunlight, 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 (e.g. unusual noises).
- 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 electromagnetic compatibility

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The device may not be fully usable in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/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 outlined above, 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 3.

Overview of nebuliser

1	On/Off control
2	USB-C port
3	Holder for atomiser
4	Filter cap with filter
5	Hose connection

Overview of atomiser and accessories

6	Compressed air hose
7	Atomiser
8	Medication container
9	Atomiser insert
10	Atomiser attachment
11	Mouthpiece
12	Adult mask
13	Children's mask
14	Nosepiece
15	Replacement filter
16	USB-C cable

6. 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

NOTICE

Clean and disinfect the atomiser and atomiser set before using them for the first time (section "Cleaning and maintenance").

- Connect the compressed air hose 6 to the bottom of the medication container 8. A
- Connect the other end of the compressed air hose 6 to the nebuliser hose connection 5 by turning it slightly. B
- Connect the USB-C cable 16 included in delivery to the USB-C port 2 on the bottom of the nebuliser and a USB mains adapter (not included in delivery; the mains adapter must comply with protection class 2, with 5V / 2A and have been tested in accordance with the European standard EN 60601-1). Plug the USB mains adapter into a suitable socket.

NOTICE

In order to achieve optimum device performance and safety, the USB mains adapter must be used in accordance with the stated specifications.
If the voltage or current is not 5V/2A, this may change the device performance, which may result in a lower nebulisation rate and a shorter service life for the device, for example.

Switching on the nebuliser

To switch on the nebuliser, press the On/Off control 1 on the nebuliser. The nebuliser is now operational.

7. USAGE

⚠ CAUTION

- For hygiene reasons, it is essential to clean the atomiser 7 and the atomiser set after each treatment and to disinfect them after the last treatment of the day (section "Cleaning and maintenance").
- If the therapy involves inhaling several

different medications one after the other, please be aware that the atomiser 7 must be rinsed under warm tap water following every usage (section “Cleaning and maintenance”).
- Check that the hose connectors are firmly attached to the nebuliser 5 and the atomiser 7 before each use of the device.
- Before use, check the device is working correctly by briefly switching on the nebuliser (together with the connected atomiser, but without medication). If air comes out of the atomiser 7, the device is working.

NOTICE

- The most effective way of nebulising is by using the mouthpiece. Nebulisation 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 using a mouthpiece). If you are using a mask 12 13, you can secure it to your head with the strap. When using a mask to inhale, take care to ensure the mask fits well and the eyes are unobstructed.
- During the treatment, hold the atomiser straight (vertically), otherwise the atomisation will not work and faultless functionality is not guaranteed.

7.1 Inserting the atomiser insert

- Open the atomiser 7 by twisting the top 10 anticlockwise against the medication container 8. Place the atomiser insert 9 in the medication container 8.
- Ensure that the cone for administering medication fits well on the cone for the airflow inside the atomiser 8.
- Proceed in reverse order to subsequently disassemble the parts.

7.2 Filling the atomiser C

- Pour an isotonic saline solution or the medication directly into the medication container 8. Avoid overfilling.
- 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. Please observe the instructions of your doctor in this case, too.

7.3 Closing the atomiser

Close the atomiser 7 by twisting the top clockwise against the medication container 8. Ensure that the connection is correct.

7.4 Connecting the atomiser set to the atomiser

Connect the atomiser 7 to the desired atomiser set (mouthpiece 11, adult mask 12, children’s mask 13 or nosepiece 14).

7.5 Treatment

- Before the treatment, pull the atomiser upwards out of the holder 3.
- Start the nebuliser using the On/Off control 1.
- Spray mist pouring out of the atomiser indicates that the device is operating correctly.
- When inhaling, sit upright and relaxed at a table and not in an armchair to avoid compressing the airways and therefore impairing the effectiveness of the treatment.
- Breathe in the atomised medication deeply.

7.6 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.
- Certain medications require a prescrip-

tion. Only liquids and medications indicated for inhalation may be used.

7.7 Stopping the inhalation

Once the mist is only coming out in an irregular flow or if the sound changes when inhaling, you can stop the treatment.

- Switch off the nebuliser after treatment using the On/Off control 1 and disconnect it from the mains.
- Place the atomiser 7 back in its holder 3 after the treatment.

7.8 Cleaning

See section “Cleaning and maintenance”.

8. CHANGING THE FILTER

In normal operating conditions, the air filter must be replaced after approx. 200 operating hours or one year. Please check the air filter regularly (after 10–12 nebulisation procedures). Replace the used filter if it is very dirty or clogged. If the filter has become damp, it must also be exchanged for a new filter.

To replace the filter, proceed as follows:

1. Pull off the filter cap 4 towards the front. D
2. If the filter remains in the device after the cap has been removed, take the filter out of the device, e.g. with tweezers or similar.
3. Re-insert the filter cap 4 with a new filter.
4. Ensure that it is securely in place.

9. CLEANING AND MAINTENANCE

NOTICE

- Do not clean the atomiser or the atomiser set mechanically using a brush or similar device, as this could cause irreparable damage and it will mean that the best treatment results can no longer be guaranteed.
- Ensure thorough drying after each cleaning or disinfection process. Residual moisture or wetness can represent an increased risk of bacterial growth.

Atomiser and atomiser set

The atomiser 7 and atomiser set are intended for multiple use. Please note that different areas of application involve different requirements in terms of cleaning and hygienic preparation.

Preparation C

- Immediately after each treatment, all parts of the atomiser 7 and the used atomiser set must be cleaned of residual medication and contamination.
- To do this, dismantle the atomiser 7 into its individual parts.
- Remove the mouthpiece 11, mask 12 13 or nosepiece 14 from the atomiser.

Cleaning

To clean the **device**, use a soft, dry cloth and a cleaning product that is not abrasive or harsh.

The **atomiser** and the **atomiser set** used such as the mouthpiece, mask, etc. must be washed with hot but not boiling water after each use. Dry the parts carefully using a soft cloth. Put the parts together again when they are completely dry and place them in a dry, sealed container or disinfect them.

When cleaning, ensure that any residue is removed. Never use any substances for cleaning that could potentially be toxic if they came into contact with the skin or mucous membranes, or if they were swallowed or inhaled.

Disinfection

The following table shows which disinfection method is suitable for which part. The details of the disinfection method are listed below.

Parts	Boiling	Mixture of vinegar essence and water
Mouthpiece	✓	✓
Adult mask		✓
Children's mask		✓
Nosepiece	✓	✓
Atomiser	✓	✓
Compressed air hose		✓

Please carefully observe the points below when disinfecting your atomiser and the atomiser set. We recommend disinfecting the individual parts on a daily basis after the last usage as a minimum measure.

- First, clean the atomiser and atomiser set as described in the "Cleaning" section.
- Place the disassembled **atomiser**, **mouthpiece** and **nosepiece** in boiling water for 5 minutes.
- For the rest of the atomiser set, use a vinegar solution consisting of ½ vinegar essence (25% acidity) and ½ distilled water. Make sure that the volume is sufficient to fully submerse the parts, such as the atomiser, mask and mouthpiece, in the solution.
- Leave the parts in the vinegar solution for 30 minutes.
- Rinse the parts with water and dry them carefully with a soft cloth.

Condensation, hose care

Condensation may form in the hose depending on the ambient conditions. To remove the moisture, proceed as follows:

- Disconnect the compressed air hose [6] from the atomiser [7].
- The hose must remain in the nebuliser [5].
- Operate the nebuliser until the moisture is removed by the air passing through.
- In the event of heavy contamination, replace the hose.

Drying

- Place the individual parts on a clean, dry and absorbent surface and leave them to dry completely (at least 4 hours).
- Put the parts together again when they are completely dry and place them in a dry, sealed container.

Durability of materials

As with any plastic parts, the atomiser and atomiser set are affected by a certain amount of wear and tear when used and hygienically prepared on a frequent basis. Over time, this can lead to a change in the aerosol, which can reduce the effectiveness of the treatment. We therefore recommend that you replace the atomiser and any atomiser set after a year at the latest.

Storage

- Do not store in damp conditions (such as in a bathroom) and do not transport with any damp items.
- When storing and transporting, protect from prolonged direct sunlight.
- Store the device in a dry place, ideally in the original packaging.

10. ACCESSORIES AND/OR REPLACEMENT PARTS

To purchase accessories and/or replacement parts, visit www.beurer.com or contact the corresponding service address (as per the service address list) for your country. Accessories and/or replacement parts are also available from retailers.

Designation	REF
Atomiser set (= year pack) (contains mouthpiece (PP), nosepiece (PP), adult mask (PVC), children's mask (PVC), atomiser (PC, PP), compressed air hose (PVC), filter (polyester cotton))	110.125
IH 15 mains adapter (EU)	110.247

11. WHAT IF THERE ARE PROBLEMS?

Problems/ questions	Possible cause/remedy
The atomiser produces no or too little aerosol.	1. Too much or too little medication in the atomiser (minimum: 2 ml, maximum: 6 ml).
	2. Check nozzle for blockages. Clean nozzle if necessary (e.g. by rinsing out). Then start using the atomiser again. **IMPORTANT:** Carefully pierce the fine holes only from the underside of the nozzle.
	3. Atomiser not held vertically.
	4. Unsuitable medication fluid added for nebulisation (e.g. too viscous).
	5. Kinked hose, clogged filter, too much inhalation solution.
There is inhalation solution residue in the atomiser.	This is normal and is due to technical reasons. Stop inhalation once the atomiser starts to make a notably different sound.
Inhalation using the mask takes longer.	This is due to technical reasons. You breathe in less medication per breath through the holes of the mask than via the mouthpiece. The aerosol is mixed with ambient air via the holes.

12. DISPOSAL

For environmental reasons, do not dispose of the device in the household waste. Please 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.

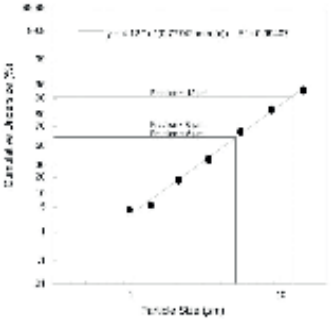
13. TECHNICAL SPECIFICATIONS

Type	IH 15
Dimensions (W x H x D)	112 x 59 x 46 mm
Weight	175 g (without atomiser set or cable)
Operating pressure	Approx. 0.35–0.6 bar
Atomiser filling volume	Min. 2 ml Max. 6 ml
Medication flow rate	Approx. 0.25 ml/min
Sound pressure	Max. 48 dBA
Power input	5 V; 2 A
Expected service life of the device	Information on the service life of the product can be found on the website.

Aerosol values according to EN ISO 27427:2023 based on adult breathing patterns with sodium fluoride (NaF):	• Aerosol delivery: 0.15 ml • Aerosol delivery rate: 0.03 ml/min • Fill volume dispensed in percent per min.: 1.49% • Residual volume: 1.66 ml • Particle size (MMAD): 4.12 ± 0.09 µm • GSD (geometrical standard deviation): 2.07 ± 0.03 • RF (respirable fraction < 5 µm): 59.8 ± 1.29% • Large particle range (>5 µm): 40.2% • Medium particle range (2 to 5 µm): 43.8 ± 0.84% • Small particle range (<2 µm): 15.9 ± 0.80%
Operating conditions	Temperature: +10°C to +40°C Relative humidity: 10% to 95% Ambient pressure: 700 to 1060 hPa
Storage and transportation conditions	Temperature: –20°C to +60°C Relative humidity: 10% to 95%

The serial number is located on the device or in the battery compartment.
We reserve the right to make technical changes to improve and develop the product.

Particle size diagram



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. Aerosol values are based on adult breathing patterns and are likely to vary for paediatric or infant populations.

NOTICE

This device and its atomiser set conform with the relevant national regulations and with 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, IEC 61000-4-39) and are subject to particular precautions with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this device. For more details, please contact our Customer Services at the address indicated.

14. 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, 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.

UK Importer: Beurer UK Ltd., Suite 16, Stonecross Place, Stonecross Lane North, WA3 2SH Lowton, United Kingdom

Beurer GmbH • Söflinger Str. 218 • 89077 Ulm, Germany
www.beurer.com • www.beurer-healthguide.com
www.beurer-gesundheitsratgeber.com

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