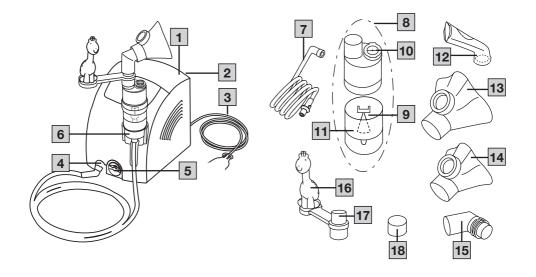
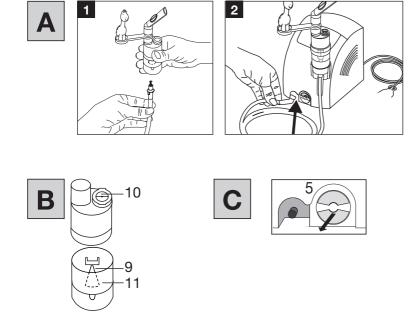
# beurer

# IH 26 Kids



ΕN	Nebuliser	
	Instructions for use	





# **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.

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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 (= 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.

See description of device and atomiser set

- 1 x nebuliser
- 1 x atomiser
- 1 x compressed air hose
- 1 x mouthpiece
- 1 x silicone baby mask
- 1 x silicone children's mask
- 1 x angled fitting
- 10 x replacement filter
- 1 x storage bag
- 1 x set of 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:

# **AWARNING**

Indicates a potentially impending danger. If it is not avoided, there is a risk of death or serious injury.

# **A** 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 system or something in its vicinity may be damaged.



Application part, type BF

(3)	Observe the instructions for use
	Protection class II device
•••	Manufacturer
I	On
0	Off
30 Min. ON/ 30 Min. OFF	30 minutes of operation, then 30 minutes break before operating again.
IP21	Protected against foreign objects ≥ 12.5 mm and against vertically falling drops of water
C€	<b>CE labelling</b> This product satisfies the requirements of the applicable European and national directives.
Z <sub>A</sub>	Marking to identify the packaging material.  A = material abbreviation, B = material number:  1-7 = plastics, 20-22 = paper and cardboard
RECYCLE CON	Separate the product and packaging elements and dispose of them in accordance with local regulations.
1	The electronic device must not be disposed of with household waste
	Date of manufacture
1	Temperature limit
Ø	Humidity limitation
MD	Medical device
UDI	Unique device identifier (UDI) Identifier for unique product identification
REF	Item number
SN	Serial number
(1m)	Single patient multiple use
	Importer
#	Type number
CH REP	Swiss authorised representative

#### 3. INTENDED USE

#### **Purpose**

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 6 months 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 supervisionAs such, it may not be possible to use the device under supervision 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 transported 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 of 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:

- · Rhinitis,
- · Allergic rhinitis,
- Sinusitis,
- · Pharyngitis,
- · Laryngitis.

Examples of lower respiratory system 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 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

# **AWARNING**

- The atomiser has no significant influence on the efficacy and safety of the medication administered and is not intended for the treatment of life-threatening conditions.
- If the device malfunctions, please refer to the "What if there are problems" section.
- The device is not a substitute for medical consultation and treatment. Always consult your doctor first in the event of pain or illness
- If you have health concerns of any kind, consult your GP!
- If the liquid you wish to use is not compatible with PP, silicone and 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 liquid.
- 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 atomiser.
- You should always follow the instructions of your doctor regarding the type of medication to use, the dosage, and the frequency and duration of inhalation.
- Only use medication prescribed or recommended by your doctor or pharmacist.
- For treatment, only use parts indicated by your doctor according to the particular diagnosis.
- 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 gases or if there is a high oxygen concentration.
- The device must be switched off and the plug pulled out before every cleaning procedure.
- Keep packaging material away from children (risk of suffocation).
- Under no circumstances should you open or repair the device yourself, otherwise proper functionality can no longer be guaranteed. Failure to comply will invalidate the warranty.
- The device is only intended for domestic/private use, not for commercial use.
- · Children must not play with the device.
- To avoid the risk of entanglement and strangulation, store cables and air lines out of the reach of small children.
- Do not use any additional parts that are not recommended by the manufacturer.
- The device must only be connected to the mains voltage that is specified on the type plate.
- Never submerge the device in water and do not use it in the bathroom. Under no circumstances may liquid enter the device

- · Protect the device from heavy impacts.
- Never touch the mains cable with wet hands, as you could get an electric shock.
- Do not pull the mains plug out of the socket using the mains cable.
- Do not crush or bend the mains cable, pull it over sharpedged objects or leave it dangling down, and protect it from sources of heat. Do not wrap the mains cable around the device, either during storage or use.
- We recommend that the mains cable is completely unrolled to avoid dangerous overheating.
- If the mains cable of this device is damaged, the device must be disposed of.
- If the device is opened, there is a risk of electric shock. Disconnection from the power supply network is only guaranteed if the mains plug is unplugged.
- Modification of the device and atomiser set is not permitted.
- 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.
- The nebuliser may only be operated with compatible Beurer atomisers and with the appropriate Beurer atomiser set. The use of atomisers and atomiser sets made by other companies may result in less efficient treatment and could damage the device.
- Store the device and atomiser set out of the reach of children and pets.

#### **A** CAUTION

- Power cuts, sudden interferences 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).
- Should you require an adapter or extension lead, this must meet the applicable safety requirements. The power limit and the maximum output specified on the adapter must not be exceeded.
- Never store the device or the mains cable near to sources of heat.
- Do not use the device in a room in which a spray has previously been used. Air the room before carrying out the treatment.
- Do not allow objects to get into the cooling vents.
- Never use the device if it is making an abnormal sound.
- For hygiene reasons, it is essential that every user uses their own atomiser set.
- Always disconnect the mains plug from the mains socket after use.
- Store the device in a location protected against climatic influences. The device must be stored in the environmental conditions specified.

# **FUSE**

- The device is fitted with an overcurrent protection device. This
  may only be replaced by authorised specialist personnel.
- · General notes

# **A** CAUTION

- The device is suitable only:
  - on people
  - for the purpose for which it is designed (aerosol inhalation) and in the manner specified in these instructions for use.
- · Any form of improper use can be dangerous!
- In the event of an acute emergency, providing first aid must take top priority.

- Apart from the medication, only use distilled water or a saline solution. Other liquids may cause a fault in the nebuliser or atomiser.
- This device is not intended for commercial or clinical use; it is designed exclusively for self-treatment in a private home.

#### Prior to initial use

# **A** CAUTION

- Remove all packaging material before using the device.
- Protect the device against dust, dirt and humidity and never cover the device while it is in use.
- Do not operate the device in a very dusty area.
- Switch the device off immediately if it is faulty or not working properly.
- The manufacturer is not liable for damage resulting from improper or incorrect use.
- This device is not intended for commercial or clinical use; it is designed exclusively for self-treatment in a private home.

#### Repairs

#### NOTICE

- Under no circumstances should you open or repair the device yourself, otherwise proper functionality can no longer be guaranteed. Failure to comply with this instruction will void the warranty.
- The device is maintenance-free.
- For repairs, please contact Customer Services or an authorised retailer.

# 5. DEVICE AND ATOMISER SET DESCRIP-TION

#### Nebuliser

The corresponding drawings are shown on page 3.

Carrying handle On/Off switch (back)

Mains connector cable Hose connector

# Atomiser and atomiser set

Compressed air hose Atomiser

Atomiser insert 10 Valve

Medication container Mouthpiece

Silicone children's mask [14] Silicone baby mask

Angled fitting 16 Removable "giraffe"

Adapter Replacement filter

#### NOTICE

The nebuliser can also be used by adults. Adults have the option of using a nasal douche and a separate atomiser set (includes mouthpiece, nosepiece, adult mask, children's mask, atomiser, compressed air hose, filter) for their nebuliser. Neither are included in the scope of delivery of the nebuliser (n/a). Nevertheless, the appropriate use of the nasal douche, nosepiece, etc. is described below. You can find an overview of all replacement items in section "Atomiser set and replacement parts".

#### 6. INITIAL USE

#### Setting up the device

Take the device out of the packaging. Place the device on a flat surface. Make sure that the vents are free from obstructions.

# 6.1 Before using the device for the first time

# NOTICE

Clean and disinfect the atomiser and accessories before using them for the first time. See "Cleaning and disinfection".

- The adapter 17 with the Removable "giraffe" 16 can optionally be attached to the atomiser.
- Connect the compressed air hose 7 to the bottom of the medication container 11 A 1
- Connect the other end of the compressed air hose 7 to the nebuliser hose connection 4 by turning it slightly. A 2

#### 6.2 Mains connection

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

- Insert the mains plug of the mains connector cable 3 into a suitable socket.
- To connect to the mains, fully insert the mains plug into the socket.

# **NOTICE**

- Ensure that there is a mains socket close to the set-up area.
- Arrange the mains connector cable so that no-one will trip over it.
- To disconnect the nebuliser from the mains after inhalation, first switch off the device and then pull the mains plug out of the socket.

#### 7. OPERATION

#### **A** CAUTION

- For hygiene reasons, it is essential to clean the atomiser and the accessories after each treatment and to disinfect them after the last treatment of the day.
- The accessories may only be used by one person; use by several people is not recommended.
- If the treatment involves inhaling several different medications one after the other, please be aware that the atomiser a must be rinsed under warm tap water following every usage. See "Cleaning and disinfection".
- Please observe the notes on changing the filter in these instructions for use.
- Check that hose connectors are firmly attached to the nebuliser 4 and the atomiser 8 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 8, the device is working.

#### 7.1 Installing the atomiser insert

- Open the atomiser 8 by twisting the top anticlockwise against the medication container 11. Place the atomiser insert [9] X into the medication container 11.
- Ensure that the cone for administering medication fits well on the cone for the air duct inside the atomiser 8.

# 7.2 Filling the atomiser

- Fill with an isotonic saline solution or pour the medication directly into the medication container 11. Avoid overfilling. The maximum recommended filling quantity is 8 ml. B
- Use medication only as instructed by your doctor and ask about the appropriate inhalation period and quantity for you.
- If the prescribed quantity of medication is less than 2 ml, top this up to at least 4 ml with isotonic saline solution. Dilution is also necessary with viscous medications. Here too, please observe the instructions of your doctor.

# 7.3 Closing the atomiser

 Close the atomiser 8 by twisting the top clockwise against the medication container 11. Ensure that the connection is correct.

# 7.4 Inserting the valve

 Press the valve 10 into the opening intended for this purpose on the upper side of the atomiser 8.

# NOTICE

The valve system ensures better delivery of the medication to the lungs. Only use the valve 10 with the mouthpiece 12, never with the masks 13 14 or the nosepiece [n/a.].

# 7.5 Connecting accessories to the atomiser

Attach the desired accessory to the atomiser 8. The mouth-piece 12 or nosepiece [n/a] can be directly attached. The children's mask 13 and baby mask 14 must be attached to the atomiser using the angled fitting 15.

# **NOTICE**

The most effective form of nebulisation 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).

When using a mask to inhale, take care to ensure the mask fits well and the eyes are unobstructed.

- Before the treatment, pull the atomiser 8 upwards out of the holder 6.
- Start the nebuliser using the On/Off switch 2.
- Spray mist pouring out of the atomiser indicates that the device is operating correctly.

#### 7.6 Treatment

- Hold or place the baby or infant to be treated in the most upright position possible. Do not use the device when the baby or infant to be treated is lying down.
- When inhaling, older children and adults should 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.

#### **A**CAUTION

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

#### NOTICE

During the treatment, hold the atomiser straight (vertically), otherwise the atomisation will not work and faultless functionality is not guaranteed.

# **A** CAUTION

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). Consult your doctor or pharmacist in relation to this matter.

# 7.7 Stopping 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 switch 2 and disconnect it from the mains.
- Place the atomiser 8 back in its holder 6 after the treatment.

#### 7.8 Cleaning

See "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.

#### **A** CAUTION

- . Do not attempt to clean the used filter and reuse it.
- Only use the manufacturer's original filter, otherwise your nebuliser may become damaged and sufficiently effective treatment cannot be guaranteed.
- Do not repair or maintain the air filter while it is in use.
- Never operate the device without a filter.

To replace the filter, proceed as follows:

#### **A**CAUTION

- First switch the device off and disconnect it from the mains.
- · Allow the device to cool down.
- 1. Remove the filter cap 5 upwards. C

# NOTICE

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.

- 2. Re-insert the filter cap 5 with a new filter.
- 3. Ensure that it is securely in place.

# 9. CLEANING AND MAINTENANCE

#### Atomiser and atomiser set

#### **AWARNING**

Adhere to the following hygiene instructions to avoid health risks.

 The atomiser 3 and the rest of 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 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.
- 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).
- Ensure thorough drying after each cleaning and disinfection process. Residual moisture or wetness can represent an increased risk of bacterial growth.

#### Preparation

- Immediately after each treatment, all parts of the atomiser and the rest of the atomiser set used must be cleaned of medication residues and contamination.
- To do this, dismantle the atomiser 8 into its individual parts.
- Remove the mouthpiece 12, mask 13 14 or nosepiece from the atomiser.
- Disassemble the nosepiece if you have used it with the comfort attachment.
- Dismantle the atomiser by twisting the top anticlockwise against the medication container 11.
- Remove the valve 10 by pulling it out of the atomiser 8.
- Reassembly is carried out in reverse order.

#### Cleaning

# **A** CAUTION

The device must be switched off, disconnected from the mains and allowed to cool down each time before cleaning.

The atomiser and the used atomiser set, such as the mouthpiece, masks, atomiser insert, 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.

Use a soft, dry cloth and non-abrasive cleaning products to clean the **device**.

Do not use any abrasive cleaning products and never submerge the device in water.

# **A** CAUTION

- Make sure that no water gets inside the device!
- · Do not clean the device or atomiser set in the dishwasher!
- Do not touch the device with wet hands when it is plugged in and do not allow water to spray on the device. Only operate the device if it is completely dry.
- Do not spray any liquid into the vents! If liquid penetrates the device this could cause damage to the electrics or other nebuliser parts and lead to a malfunction.

# Condensation, hose care

Condensation may form in the hose depending on the ambient conditions. It is essential to remove the moisture to prevent bacterial growth and ensure proper treatment. To do so, proceed as follows:

- Disconnect the hose 7 from the atomiser 8.
- The hose must remain in the nebuliser 4.

- Operate the nebuliser until the moisture is removed by the air passing through.
- In the event of heavy contamination, replace the hose.

# Disinfection

# **A** CAUTION

Please observe the following points when disinfecting your medication container [1] and the atomiser set. Regular disinfection of the individual parts is recommended. First, clean the medication container [1] and atomiser set as described in the "Cleaning" section.

Parts	Boiling	2% sodium hypochlo- rite (NaOCI) solution
Atomiser	✓	
Mouthpiece	✓	
Nosepiece	✓	
Compressed air hose		✓
Nasal douche (n/a)	✓	
Masks (silicone)	✓	
Masks (PVC)		✓

Use only the method specified for each component.

Method of disinfection	Instructions
Boiling	Place the parts in question in boiling water for 5 minutes. Ideally, distilled water should be used to avoid contamination and limescale formation.  The parts should not come into contact with the hot base of the pan.
2% sodium hypochlorite (NaOCI) solution	Place the parts in question in a container. Immerse everything in a 2% sodium hypochlorite (NaOCI) solution (e.g. Amuchina® disinfectant diluted with distilled water or a solution prepared by the pharmacist). Leave it to take effect for 15 minutes. Finally, clean all parts again with water.

#### Drying

Place the individual parts on a clean, dry and absorbent surface and leave them to dry completely (at least 4 hours).

# **Durability of materials**

- As with any plastic parts, atomisers and the rest of the 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 have a negative effect on the efficiency of the treatment. We therefore advise you to replace the atomiser and the atomiser set no later than one year if the parts are not disinfected more than 360 times a year. Frequent disinfection shortens the service life of the parts.
- The following point should be observed when selecting the cleaning product or disinfectant: Only use a mild cleaning product or disinfectant in the concentration and volume prescribed by the manufacturer.

#### 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 REPLACE-MENT 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	Material	REF
Atomiser set = IH 24 Kids/26 Kids year pack (contains mouthpiece, silicone children's mask,	PP/silicone Silicone/PP	601.19
silicone baby mask, atomiser, compressed air hose, filter, angled fitting)	Silicone/PP PP/silicone PVC PU	
Atomiser set = Standard IH 26 year pack (contains mouthpiece, nosepiece, silicone adult mask, silicone children's mask, atomiser, compressed air hose, filter)	PP/silicone PP/silicone PVC/aluminium PVC/aluminium PP/silicone PVC PU	601.28

# 11. WHAT IF THERE ARE PROBLEMS?

Problems/questions	Possible cause/remedy
What should be taken into account when using the device	On babies, the mask should cover the mouth and nose to ensure effective inhalation.
with babies and children?	On children, the mask should also cover both the nose and mouth.
The atomiser produces no or too little aerosol.	Too much or too little medication in the atomiser.     Minimum: 2 ml,     Maximum: 8 ml.
	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.
	Unsuitable medication fluid added for nebulisation (e.g. too viscous).  The medication fluid should be prescribed by a doctor.
The output is too low.	Kinked hose, clogged filter, too much inhalation solution.
What medications are suitable for inhaling?	Please consult your doctor in relation to this matter. As a rule, all medication that is suitable and approved for device inhalation can be inhaled.
There is inha- lation 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.

Problems/questions	Possible cause/remedy
What should be taken into account when using the device with children?	On children, the mask should cover the mouth and nose to ensure effective inhalation. 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.
	<b>Notice:</b> Inhalation should only be carried out under the supervision of an adult and with their assistance and the child should not be left alone.
Why should the atomiser be replaced regularly?	There are two reasons for this:  1. To ensure a therapeutically effective particle spectrum, the nozzle hole must not exceed a specific diameter. Due to mechanical and thermal stresses, the plastic is subject to a certain degree of wear. The atomiser insert
Should each person have their own atomiser?	Yes, this is absolutely essential for hygiene reasons.

# 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

Model	IH 26 Kids
Туре	IH 26
Dimensions (W x H x D)	166 x 141 x 149 mm
Weight	Approx. 1.4 kg (with accessories)
Operating pressure	Approx. 0.5 - 1.45 bar
Atomiser filling volume	Max. 8 ml Min. 2 ml
Medication flow rate	Approx. 0.35 ml/min
Sound pressure	Approx. 52 dBA
Mains connection	230 V~; 50 Hz; 230 VA UK: 240 V~; 50 Hz; 240 VA
Operating conditions	Temperature: +10 °C to +40 °C Relative humidity: 10% to 95% Ambient pressure: 700 to 1060 hPa
Storage and transportation conditions	Temperature: -25°C to +70°C Relative humidity: 10% to 95%
Expected service	Information on the service life of the product

Aerosol values according to EN 27427:2019 based 3) Fill volume dispensed in percent per min. on adult breathing patterns with

sodium fluoride

(NaF):

- 1) Aerosol delivery: 0.11 ml
- 2) Aerosol delivery rate: 0.07 ml/min

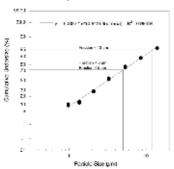
3.27%

- 4) Residual volume: 1.68 ml
- 5) Particle size (MMAD): 3.07 µm
- 6) GSD (geometrical standard deviation): 2.03
- 7) RF (respirable fraction < 5 µm): 75%
- 8) Large particle range (>5 µm): 25%
- 9) Medium particle range (2 to 5 µm): 47.8% 10) Small particle range (<2 µm): 27.2%

The serial number is located on the device or in the battery compartment.

Subject to technical changes.

#### 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

If the device is not used according to the specifications, perfect functionality cannot be guaranteed! 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 61000-4-7, IEC 61000-4-8, IEC 61000-4-11) and is 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.

#### 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 limited in the presence of electromagnetic disturbances. As a result, the device may fail.
- · 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.

# 14. WARRANTY/SERVICE

Further information on the warranty and warranty conditions can be found in the warranty leaflet supplied.

# **Notification of incidents**

For users/patients in the European Union and identical regulation systems EU Medical Device Regulation, 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 the you are located.



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