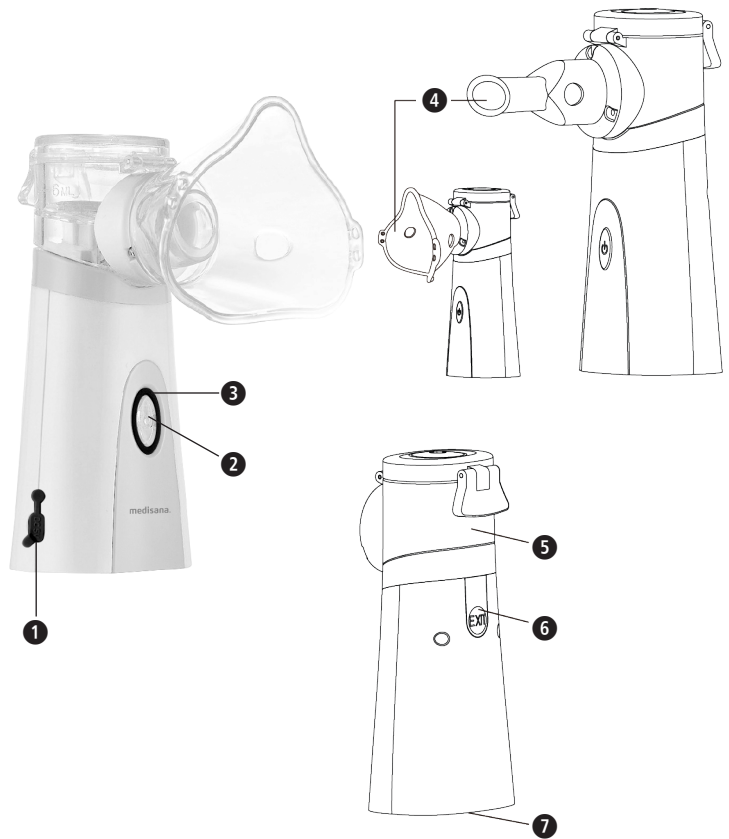




Device and controls

- 1 USB-C port
- 2 On/OFF button
- 3 Indicator light
- 4 Mouthpiece / mask
- 5 Active ingredient tank
- 6 Release button
- 7 Battery compartment lid

Explanation of symbols

This instruction manual belongs to this device. It contains important information about starting up and operation. Read the instruction manual thoroughly. Non-observance of these instructions can result in serious injury or damage to the device.

CAUTION

Device classification: type BF

Batch code

Serial number

Medical device

Authorized representative in the European Community

Mannufacturer

Complies with the European Medical Devices Directive (93/42/EEC and amended Directive 2007/47/EC).
Notified body: SGS

Disposal in accordance with Directive 2012/19/EU (WEEE)

IP code of the device: The degree of protection of this device against ingress of solid foreign bodies ≥ 12.5 mm diameter (and that against access to dangerous parts with the finger); the degree of watertightness (dripping water; 15° inclined)

Unique device identification

Temperature range

Ambient pressure limitation

Humidity range

Date of manufacture

Switzerland authorized representative

Importer

Recycling symbols/codes:
These are used to provide information about the material and its proper use and recycling.

Intended use

- The medisana portable ultrasonic nebuliser IN 515 is intended for oral or nasal inhalation therapy with medication aerosol in private households. The device may only be used by patients who have thoroughly familiarised themselves with the function of the device or who have been supervised or instructed by qualified medical personnel.
- The user must first read these instructions for use and have understood their content and the operation of the device.

Scope of delivery and packaging

Please check first of all that the device is complete and is not damaged in any way. In case of doubt, do not use the appliance and contact your dealer or your service centre. The following parts are included:

- 1 medisana Portable ultrasonic nebuliser IN 515

- 1 adult and 1 child mask, 1 mouthpiece

- 2 batteries (size AA/LR6, 1.5V)

- 1 USB-C cable

- 1 Instruction manual

The packaging can be reused or recycled. Please dispose properly of any packaging material no longer required. If you notice any transport damage during unpacking, please contact your dealer without delay.

GB IMPORTANT INFORMATION! RETAIN FOR FUTURE USE!



Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use. Should you give this device to another person, it is vital that you also pass on these instructions for use.

Safety Information



- When using an electronic appliance, basic precautions should always be followed, including the following.
- Use the device only according to its intended purpose as specified in the instruction manual. The warranty will be invalidated if used for purposes other than those for which it is intended.
- Any application other than the herewith described is improper and therefore considered dangerous. If the appliance is not used according to the instructions, the user is liable for the safe operation of the unit.
- Only use genuine accessories and spare parts provided by the manufacturer.
- Use only liquid medications that have been approved for use in inhalation therapy. Before starting therapy, discuss the length, dosage, frequency of use and the selection of the medication with your doctor or pharmacist.
- Close supervision is required when this device is used by children, disabled persons or invalids. In addition, the dosage and frequency of use must be determined by the prescribing doctor.
- Do not use the device under a blanket or pillow. Excessive heating may result in fire, electric shock or personal injury.
- For the duration of the treatment, please follow the doctor's advice and take the medication recommended by the doctor.
- Do not insert any fingers or objects (e.g. cotton buds or similar) into the opening of the device - risk of damage!
- In the event of faults, do not repair the appliance yourself. Only have repairs carried out by authorised service centres.
- Do not open the appliance and do not make any modifications.
- This device is not suitable for use in an anaesthetic breathing system or a ventilator breathing system.

Before use

- The device is designed for operation in accordance with the ambient conditions specified in the technical data. Ensure that these are complied with accordingly.
- If the appliance is damaged or has fallen into water, do not use it, but contact customer service or send it in for repair.
- Make sure that all accessories are clean or disinfected. Clean the device and accessories in accordance with the instructions in the 'Cleaning and care' and 'Disinfection' chapters to avoid the risk of infection.
- The maximum filling quantity of the active ingredient tank 5 is 10 ml. Never fill the tank beyond the marked maximum quantity.
- Never use the mouthpiece, the mask for adults and the mask for children together with several people to avoid bacterial infections. Each user should use their own mask or mouthpiece.

During use

- Never switch on the device if there is no aerosol in the active ingredient tank 5.
- Keep the device balanced and steady during operation to prevent spillage.
- Do not open the tank cover during operation.
- If you experience any discomfort during use, stop use immediately and consult your doctor.
- This appliance has a built-in 20-minute switch-off timer. This is restarted each time the device is switched on.
- If the timer runs out or another problem (e.g. insufficient power supply, used aerosol) causes the device to switch off, the indicator light 3 lights up red.

After use

- Clean and disinfect the appliance and accessories in accordance with the 'Cleaning and care' and 'Disinfection' sections in these instructions. Failure to do so can lead to infections caused by microorganisms.
- Do not store the device and accessories in places exposed to direct sunlight or in hot or humid places.
- The appliance and accessories must not be cleaned in dishwashers or dried in microwave ovens.
- Always keep the appliance away from children.

SAFETY NOTES FOR BATTERIES

- Do not disassemble batteries!
- Never leave any low battery in the battery compartment since it may leak and cause damage to the unit.
- Increased risk of leakage! Avoid contact with skin, eyes and mucous membranes! If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of fresh water and seek medical attention immediately!
- If a battery has been swallowed, seek medical attention immediately!
- Replace all of the batteries simultaneously!
- Only replace with batteries of the same type, never use different types of batteries together or used batteries with new ones!
- Insert the batteries correctly, observing the polarity!
- Remove the batteries from the device if it is not going to be used for an extended period of 3 months or more!
- Keep batteries out of children's reach!
- Do not attempt to recharge batteries! There is a danger of explosion!
- Do not short circuit! There is a danger of explosion!
- Do not throw into a fire! There is a danger of explosion!
- Do not throw used batteries into the household refuse; put them in a hazardous waste container or take them to a battery collection point, at the shop where they were purchased!

WARNING
Please ensure that the polythene packing is kept away from the reach of children!
Risk of suffocation!

Important information when using preparations / medications

NOTES

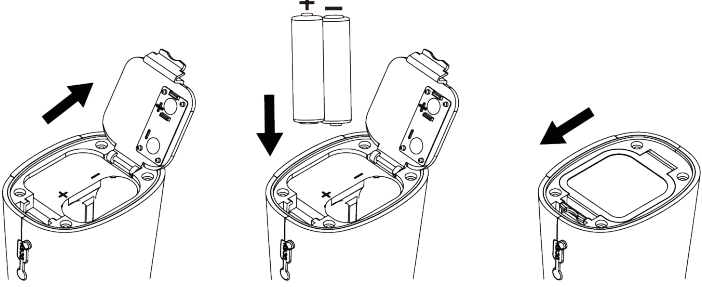
- Consult your doctor before using any medicinal products or medicines to ensure that they are suitable for your needs or alternatively only use the medicinal products/medicine prescribed for you by your doctor.
- The medisana ultrasound nebulizer is suitable for use with all common aerosol products (aerosols) with the exception of:
 - Products with solid constituents (suspensions)
 - Viscous solutions (high viscosity)
 - Volatile oils
- Do not use any volatile oils since this may lead to damage to the nebulizer mesh.
- Use only water-soluble products/medicines or those which have an alcohol base.
- Use only isotonic saline solution to dilute the inhalant; otherwise bronchial spasms may occur in certain circumstances.
- Do not use oil-based inhalants.
- After using the device for salt solution inhalation, it must be cleaned and rinsed out, according to section „Cleaning and care“.

Use: Establish power supply

The medisana IN 515 ultrasonic nebuliser can be powered either with 2 x AA 1.5V batteries or using the USB-C cable.

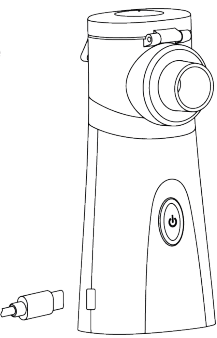
a) Power supply with batteries:

Open the battery compartment lid 7 on the underside of the device in the direction of the arrow (see illustration). Insert the two batteries supplied (type AA/LR6 1.5V). Pay attention to the direction in which the batteries are positioned. Close the battery compartment lid 7 again. If the indicator light 3 flashes orange when the device is switched on, insert new batteries as soon as possible.



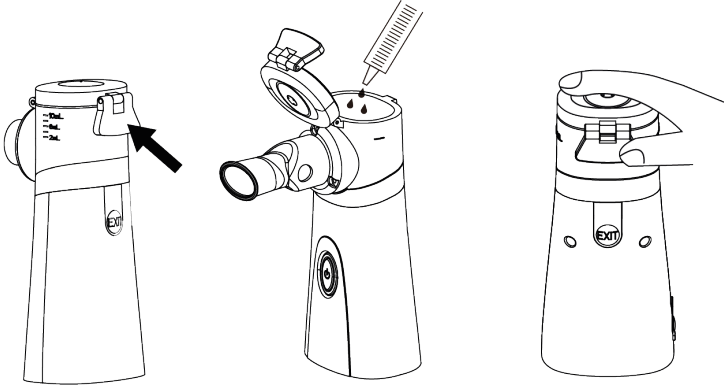
b) Power supply via USB-C cable:

Open the cover of the USB-C port 1 and connect the USB-C cable to a suitable power source. The device cannot be used to charge rechargeable batteries.



Preparation for use

- Make sure, the device is switched off.
- Open the cover of the active ingredient tank 5 and fill it with the inhalant (maximum content 10 ml = 10 ccm). Observe the application and dosage instructions on the package leaflet of the medication you are using.
- Close the cover of the active ingredient tank 5 again. Ensure that the active ingredient tank 5 is positioned correctly and keep the device as level as possible to prevent leakage.



Inhalation using the mouthpiece

- Sit as upright as possible.
- Put the mouthpiece 4 onto the device base and enclose the mouthpiece completely with your lips.
- Switch on the device by pressing the ON/OFF button 2. The indicator light 3 lights up in green.
- Now breathe in slowly and deeply through your mouth and out through your nose. You can improve the effectiveness of the therapy, if you hold your breath for a short time after breathing in. However, this is not necessary for general success of the therapy. It is only important that you keep quiet and relaxed while breathing Do not inhale too fast. If you need a break, stop using the device for a short time and take the mouthpiece 4 out of your mouth. Then put it into your mouth again (lips enclosing it tightly) and breathe slowly in and out again.

NOTES

- Hold the device as upright as possible. A slight tilt does not affect its use. However, take care during inhalation to only tilt the device slightly in any direction.
- Tilt the device slightly when the remaining aerosol is almost exhausted to make sure the residual quantity will be spread through the mesh and sprayed completely.

5. An inhalation application should not exceed 20 minutes.

6. If the active ingredient tank 5 is empty, the indicator light 3 lights up red and the device switches off after a short time. You can also switch off the device manually by pressing the ON/OFF button 2 when you have finished inhaling - even if you have not used up all the inhalation solution.

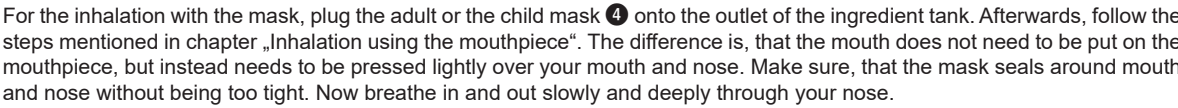
7. Pour out the remaining inhalation solution. Do not use it again. Clean the device immediately after each use. (See also 'Cleaning and care' or 'Disinfection'.) After the mouthpiece 4 has been used for a while, 2 - 3 drops of inhalation may collect in the mouthpiece's neck tube during use. However, this has no effect on the operation and function of the device. Remove the drops with a soft cloth after use.

Inhalation using the mask

Alternatively, a child- and an adult inhalation mask is supplied with the device. These masks may be used for inhaling aerosol through the nose. This method is particularly suitable for elderly people.

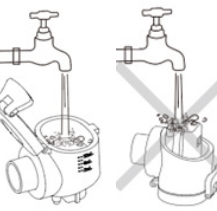
NOTE

A larger amount of aerosol remains on the mucosa of the nasal pharynx when using the mask than when using the mouthpiece.



Cleaning and care

- If necessary, remove the mask or mouthpiece from the device and pour out any residual inhalation.
- Never hold the entire device or the nebuliser unit under running water to clean it and, if necessary, ensure that no water enters the device.
- Start cleaning mode of the device as follows: In shutdown state, add 3-6 ml of clean water into the active ingredient tank 5. Press and hold ON/OFF button 2 for 3 seconds to activate the cleaning mode. The indicator light 3 flashes slowly in green. The device will be working for 3 minutes and then automatically shuts down to end the cleaning mode.
- Now disconnect the power supply (take out the batteries and/or remove the USB-C cable).
- Press the release button 6 on the back of the device and remove the active ingredient tank 5.
- Rinse the interior of the active ingredient tank 5 with clean water for a minimum of 3 minutes, avoiding rinsing the base of the cup, as depicted in the figure.
- Clean the housing of the device with a slightly damp cloth soaked in mild soapy water.
- Clean the mask or mouthpiece under running water.
- Then allow all parts to air dry thoroughly on a dry, soft surface (e.g. a towel).
- You should also carry out this cleaning if the device has not been used for a long time and before using it for the very first time.



Disinfection

In the case of infectious illnesses, you need to follow below steps for disinfection additionally. We recommend, that this measure is performed regularly either in the morning or the evening at a fixed time:

- Rinse the mask(s) and the mouthpiece with distilled water.
- Boil some distilled water in a pot.
- Put the mouthpiece into the boiling water for 5 minutes.
- Remove the pieces from the water and let them dry and cool down on the open air (e.g. on a towel).
- Alternatively (instead of using distilled water) you may disinfect the pieces with a solution of 75% cleaning alcohol - with this, the time to put the pieces into the liquid reduces to 1 minute only. Afterwards, rinse the pieces with distilled water and let them dry on the open air.
- Make sure that no disinfectant residues are left behind on the parts of the device to ensure safe inhalation when next used.

WARNING

- NEVER put the ingredient tank 5 into the boiling water.
- Solutions with alcohol are highly flammable. Therefore, NEVER clean the device near open fire or smoke.



Transportation and storage

- Store the appliance with all parts in a dry and clean place.
- Make sure, that no residual liquids are in the ingredient tank 5 during storage or transportation.
- Remove the batteries if you do not use the device for a longer time.
- Avoid storage locations with direct sun exposure, extreme temperatures and high humidity.
- Always keep the device away from fire, electromagnetic radiation and from children.

Troubleshooting

Problem: No or low nebulization.

Solution: Replace the batteries or check whether the power supply is sufficient. Check that the active ingredient tank 5 is correctly mounted on the appliance base and that there is sufficient aerosol in the tank. Carry out a cleaning.

Problem: The indicator light 3 flashes green and then switches off

Solution: The appliance has been working for too long. Switch off the appliance and wait a few minutes before using it again.

Problem: The indicator light 3 flashes red and then switches off

Solution: The active ingredient tank 5 is empty or power not sufficient.

Problem: The indicator light 3 flashes orange and then switches off

Solution: Replace the batteries or connect the USB-C cable correctly and ensure that there is sufficient aerosol in the active ingredient tank 5.

If above points do not help to solve the problem, contact the customer service.

Electromagnetic compatibility

The device fulfils the requirements of the EN 60601-1-2 standard for electromagnetic compatibility. Details of these measurement data can be found in the supplement to the article.

Disposal

This product must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner. Please remove the batteries before disposing of the device/unit. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop. Consult your municipal authority or your dealer for information about disposal.

Technical specifications

Name and model: medisana Portable ultrasonic nebuliser IN 515 (model: NBM-1)

Power supply: 3V ≈, 2 x 1.5V batteries AA LR6 or 5V / 1A (via USB-C)

Power consumption: < 2VA

Power consumption in standby mode: < 0.1mA

Ultrasound frequency: 110 kHz ±10 kHz

Nebulizing output: >0.2 ml/minute

Particle Size(MMAD): <5µm

Respirable fraction performance: ≥60%

Types of nebulize liquids: Solution and suspension

The spatial orientation at which the nebulizer functions as intended: Vertical

Filling volume inhalant: 10 ml

Automatic switch-off: after 20 minutes

Operating conditions: +10°C - +40°C, relative humidity 10-95 %, air pressure 86-106 kPa

Storage conditions: -20°C - +70°C, relative humidity 10-95 %, air pressure 50-106 kPa

Weight appr.: 108 g (without batteries)

Product service life: 3 years

Article no.: 54590

EAN-Number: 40 15588 54590 0

Spare Parts: Art. 54591 Children Mask for IN 515, EAN 40 15588 54591 7

Art. 54592 Adult Mask for IN 515, EAN 40 15588 54592 4

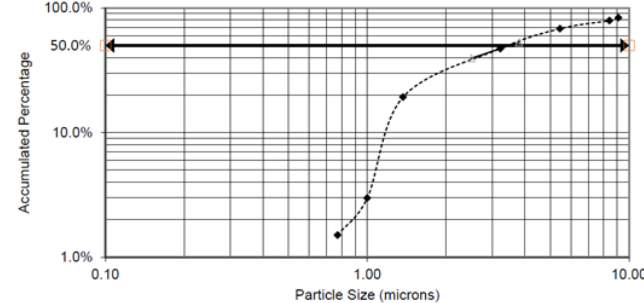
Art. 54593 Mouth piece for IN 515, EAN 40 15588 54593 1

In accordance with our policy of continual product improvement, we reserve the right to make technical and optical changes without notice.

The current version of this instruction manual can be found under www.medisana.com

Particle size distribution:

Particle size distribution compliant with ISO 27427



Mass Median Aerodynamic Diameter (MMAD, µm):	3.5
Geometric Standard Deviation (GSD):	2.1
Less than 5 µm (%):	65%
Test solution: Albuterol 0.1 % (M/V) concentration in 0.9 % sodium chloride solution	
Filling volume (ml):	3 ml
Percentage of fill volume emitted in 1 min (%/min):	7.3%
Aerosol output rate (ml/min):	0.220

Note 1: Using a solution, suspension, or emulsion different from that recommended by the manufacturer, in particular, a suspension and/or high-viscosity solution, can alter the particle size distribution curve, the mass median aerodynamic diameter (MMAD), aerosol output, and/or aerosol output rate, which can then be different from those disclosed by the manufacturer.

Note 2: The disclosures for performance are based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for paediatric or infant populations.

Warranty and repair terms

Your statutory warranty rights are not restricted by our guarantee below. Please contact your dealer or the service centre in case of a claim under the warranty. If you have to return the unit, please enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

- The warranty period for medisana products is three years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
- Defects in material or workmanship will be removed free of charge within the warranty period.
- Repairs under warranty do not extend the warranty period either for the unit or for the replacement parts.
- The following is excluded under the warranty:
 - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instructions.
 - All damage which is due to repairs or tampering by the customer or unauthorised third parties.
 - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
 - Accessories which are subject to normal wear and tear.
- Liability for direct or indirect consequential losses caused by the unit are excluded even if the damage to the unit is accepted as a warranty claim.

Service information is available here: <https://www.medisana.com/servicepartners>



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