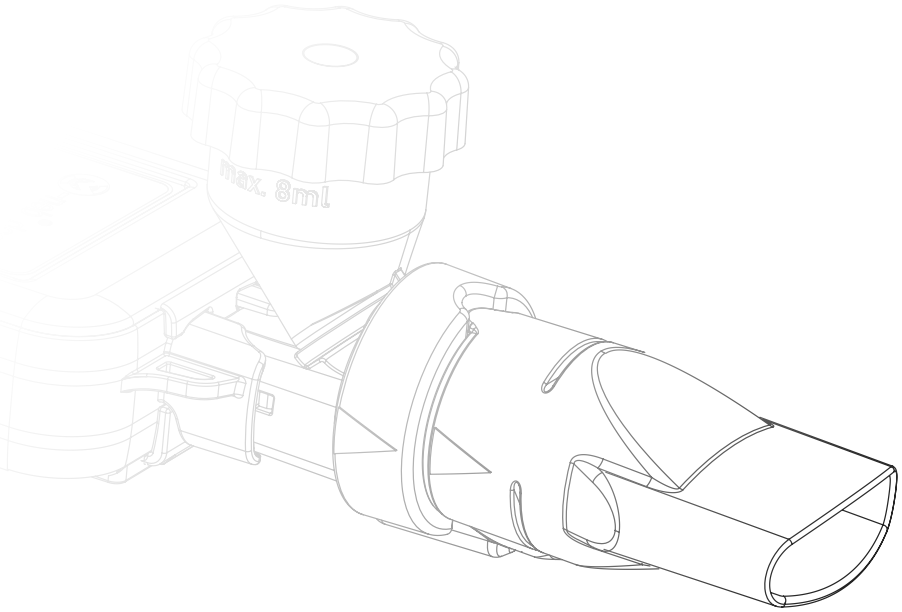
M-neb® dose+

OPERATING MANUAL

M-neb® dose+ mesh nebulizer MN-300/8

HOMECARE



OVERVIEW

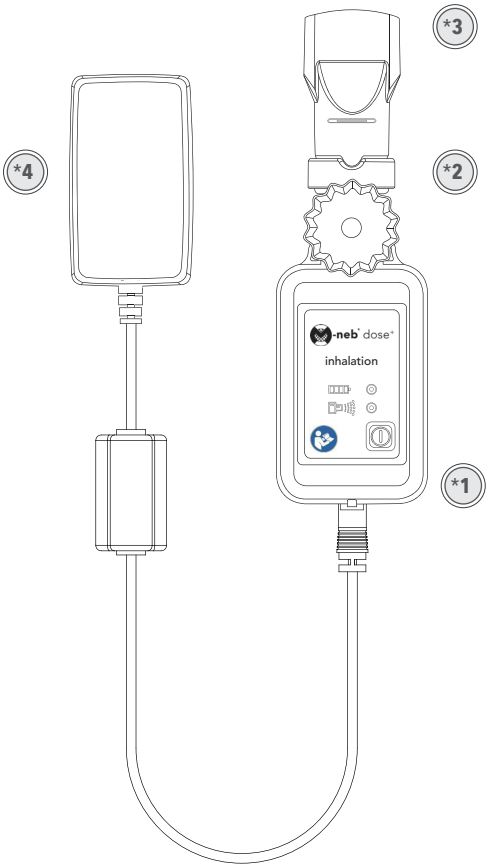


Fig. 01 - MN-300/8 - Overview M-neb® dose+ mesh nebulizer MN-300/8

Legend	Item number	Designation
*1	20100262	M-neb® dose+ mesh nebulizer MN-300/8 control unit
*2	20100268	M-neb® dose+ mesh nebulizer MN-300/8 nebulizer unit HOMECARE (incl. M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti)
*3	20100320	M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti - available as an option -
*4	20100206	M-neb® mesh nebulizer MN-300/X Power cord (type: GTM96060-0606-1.0)

If, as a non-specialised operator or non-specialised responsible organisation, you require assistance with the first use, use or maintenance of this medical device, please contact the address given under „Manufacturer“ at any time.

In accordance with the European Medical Device Regulation (2017/745), NEBU-TEC med. Produkte Eike Kern GmbH is obliged to inform you of the following:

All serious incidents occurring in connection with the product must be reported to NEBU-TEC med. Produkte Eike Kern GmbH and the competent authority of the Member State in which the user and/or the patient is established.

NOTE

Serious incidents mean the death of a patient, user or other person, or the temporary or permanent serious deterioration of the health of a patient, user or other person. It does not matter whether these have occurred or could occur. The exact definition can be found in Regulation (EU) 2017/745 Article 2 (65). You can find the contact details of the competent authority in your Member State on the internet using the search terms „Competent Authorities for Medical Devices EU“.

MANUFACTURER

NEBU-TEC med. Produkte Eike Kern GmbH
Kreuzfeldring 17
63820 Elsenfeld – Germany

Tel.: +49 (0) 6022 – 610 62 -0
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Email: info@nebu-tec.de
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M-neb® dose+ mesh nebulizer MN-300/8

Made in Germany

TABLE OF CONTENTS

1.0 ICONS

The icons shown below can be seen on your M-neb® dose+ mesh nebulizer MN-300/8, the respective accessories and the respective packaging.

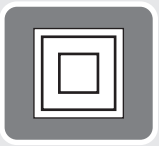
Figure	Definition
	Manufacturer; displays the manufacturer of the medical device.
	Caution; stresses the need for the user to review the instructions on important safety-related information such as warnings and precautions which cannot be placed on the medical device itself for a variety of reasons.
	Device of protection class II
	Type BF applied part
	IP protection class IP2X: Protection against the penetration of solids Ø ≥ 12.5 mm IPX2: Protected against dripping water to 15° inclination
	CE mark including designation of the identification number of the notified body which has performed the conformity assessment procedure.

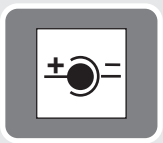
Figure	Definition
	Follow instructions for use; stresses the need for the user to consult the instructions for use. The icon is blue/white in the original.
	Do not dispose of in normal household waste.
	Item number; displays the order number of the manufacturer, so that the medical device can be identified.
	Batch number; displays the batch number of the manufacturer, so that the batch or lot can be identified.
	Serial number; displays the serial number of the manufacturer, so that a specific medical device can be identified.
	Medical device
	DC connection

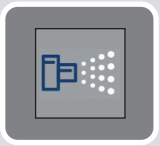
Figure	Definition
	Battery status indicator (Explanation on this in Chapter 11.0 “Diode displays“)
	Operating mode status indicator (Explanation on this in Chapter 11.0 “Diode displays“)
	On/Off button
	Do not use if packaging is damaged; displays a medical product that should not be used if the packaging is damaged or opened.
	Keep away from sunlight; designates a medical device that needs protection from light sources.
	Store in a dry place; designates a medical device that must be protected against moisture.
	Temperature range; the temperature range is designated in which the medical device can be safely used.

Figure	Definition
	Air pressure range; identifies the range of atmosphere pressure in which the medical device can be safely used.
	Humidity range; identifies the range of humidity to which the medical device can be safely exposed.
	Quantity; indicates the number of components included.
	Single patient reuse; indicates a medical device that may be used multiple times (for multiple applications) on a single patient.
	Do not reuse; indicates a medical device that is intended for single use only

2.0 SAFETY INFORMATION

Each handling of this medical device assumes precise knowledge and observance of these instructions for use. Liability for the safe operation of the device passes in any case to the operator if a third-party intervention is carried out or a handling which does not correspond to the intended use.

Important information is highlighted by the following expressions:

WARNING
Important safety information on hazards that can cause personal injury.

ATTENTION
Important information on operation steps that can cause malfunctions of the medical device.

NOTE
Information, which you should pay special attention to.

CAUTION
Information, which prevents damage to the product.

NOTE

Please carefully read through the instructions for use before first use of the M-neb® dose+ mesh nebulizer MN-300/8. Store the instructions for use carefully.

WARNING

1. Do not immerse the control unit, the power cord or the nebulizer unit in water or other liquids. The mouthpiece is excluded from this warning.

2. Place the control unit, the power cord and the nebulizer unit so that they cannot fall into water.

3. Do not use the control unit, the power cord and the nebulizer unit if they have fallen into water.

4. Do not use the medical device while bathing.

5. Do not use the medical device near flammable substances.

6. The medical device is not suitable for use in the vicinity of flammable, anaesthetic mixtures with air or nitrous oxide.

7. Do not bring the medical device into contact with heated surfaces.

8. The inhalation substances must be approved for inhalation by vibrating nebulization (mesh nebulization). Only inhalation substances prescribed by a doctor may be used.

9. Before beginning each treatment and before each use, check the battery level of the control unit.

10. Only use accessories certified by the manufacturer.

11. Ensure that the inhalation substance has been filled in the nebulizer unit prior to starting treatment.

12. Before starting any treatment, make sure that the control unit's internal rechargeable battery (lithium-ion battery) is charged, otherwise the remaining capacity may not be sufficient for a complete inhalation process. However, there is no hazard of serious injury or death.

13. Never connect a humid or wet nebulizer unit to the control unit; prior to each use check that the nebulizer unit is dry.

14. The medical device must not be used directly next to other devices. If necessary, the medical device should be observed to verify its intended operation in this used arrangement.

15. Do not open the casing of the control unit or the power cord. All repairs or maintenance may only be done by a dealer qualified by NEBU-TEC med. Produkte Eike Kern GmbH. Failure to follow this leads to the loss of the warranty claim.

16. The control unit's internal rechargeable battery (lithium-ion battery) must not be charged if damage or defects are visible on the power cord.

17. Protect the medical device and its accessories against unsupervised access.

18. The USB port of the control unit is only for connecting the nebulizer unit. Do not connect any other commercially available USB cables to the control unit's USB port.

19. The medical device and its accessories contain small parts that can be swallowed. Always keep the medical device and its accessories out of the reach of children or pets. If parts are accidentally swallowed, consult a doctor immediately.

20. The medical device and its accessories contain parts that pose a risk of strangulation. Always keep the medical device and its accessories out of the reach of children or pets.

21. Please observe the environmental regulations for the transport of the medical device. Make ensure that the transport of the medical device is always carried out within the framework of these environmental conditions. Transporting the medical device outside these environmental conditions could cause damage to the medical device.

22. Please observe the environmental regulations for the storage of the medical device. Make ensure that the storage of the medical device is always carried out within the framework of these environmental conditions. Storing the medical device outside these environmental conditions could cause damage to the medical device.

23. Do not store the medical device in your car under extreme environmental conditions as it may become too hot in summer and too cold in winter. This may cause the product to exceed or fall below the storage limits and cause damage to the medical device.

24. Please observe the environmental regulations for the operation of the medical device. Make ensure that the operation of the medical device is always guaranteed within the framework of these environmental conditions. Do not operate the medical device outside these environmental conditions as this may cause damage to the medical device.

25. The control unit may only be operated using the internal rechargeable battery (lithium-ion battery). The control unit may not be operated using the power cord and the 230 VAC power supply. The power cord is used exclusively to charge the control unit's internal rechargeable battery (lithium-ion battery).

26. The control unit must not be used directly next to wireless communication devices such as wireless home network devices, mobile phones or cordless telephones and their base stations. A minimum distance should be maintained between the medical device and the wireless communication device. If this is nevertheless necessary, the medical device should be observed to see if it operates properly in this arrangement. Minimum distances to common wireless communication devices are shown in the table „Representative list of current frequencies and radio services and their relationship to maximum output and interference immunity test levels".

27. To charge the internal rechargeable battery (lithium-ion battery), use only the supplied power cord.

28. The medical device and its components should be kept in the original packaging between applications until needed again.

29. The medical device is not suitable for use in an anaesthesia breathing system or a ventilator breathing system.

30. The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is not intended for the treatment of life-threatening conditions.

31. Before starting each therapy session, make sure that the cap is correctly positioned and closed.

32. Please note that inhalation solutions released into the air can affect people present.

33. Please ensure that the mouthpiece is connected to the nebulizer unit in the correct position.

34. Do not stop the inhalation process of aerosol production prematurely. Aerosol production is indicated by the LED on the operating mode status display.

35. If condensed aerosol accumulates in the mouthpiece after a prolonged inhalation session, avoid ingesting this condensed aerosol.

36. Do not exhale into the mouthpiece during aerosol production.

37. Do not share used nebulizer units or used mouthpieces with other patients or persons present.

38. Please note that uncleaned nebulizer units can cause infection.

39. Please note that control units that have not been disinfected may cause infection or an allergic reaction.

ATTENTION

1. An electrical medical device such as the M-neb® dose+ mesh nebulizer MN-300/8 should never be operated unsupervised.

2. Special caution is required if the medical device is used by or in the vicinity of children or seriously ill patients.

3. The medical device is exclusively and only to be used for the intended purposes listed in these instructions. Do not use accessories that are not recommended by the manufacturer.

4. Never operate this medical device when:
   a) the power cord or the plug is damaged.
   b) the medical device does not function properly.
   c) the medical device has been dropped or damaged.
   d) the medical device has fallen in water.

   In such cases, the medical device is to be sent to a dealer qualified by NEBU-TEC med. Produkte Eike Kern GmbH for the purpose of inspection and repair.

5. Keep the power cord away from heated surfaces.

6. Never insert objects into openings.

7. The medical device is not suitable for use in the vicinity of flammable, anaesthetic mixtures with air or nitrous oxide.

8. The control unit is powered exclusively by the internal rechargeable battery (lithium-ion battery).

9. Only use the power cord supplied.

10. The charging of the internal rechargeable battery (lithium ion) is carried out exclusively with the supplied power cord.

11. During use, check that the medical device is functioning properly.

12. The control unit's internal rechargeable battery (lithium-ion battery) must not be charged if damage or defects are visible on the power cord.

13. Medical electrical devices are subject to specific precautions with regard to electromagnetic compatibility (EMC) and must be installed and used in accordance with the remarks contained in these instructions for electromagnetic compatibility.

14. After using the continuous mode, a rest period of one hour must be observed, as otherwise the electronics of the control unit could heat up too much.

15. If unusual changes in inhalation times are detected, or if there are noticeable changes in the residual quantity in the medication container, the device must be sent or taken to a NEBU-TEC med. Produkte Eike Kern GmbH qualified dealer for inspection or repair.

16. Use only inhalation substances approved for inhalation by vibrating nebulization (mesh nebulization). Use of inhalation substances (solutions, suspensions or emulsions) that deviate from this recommendation may alter the particle size distribution curve, the mass median aerodynamic diameter (MMAD), the aerosol delivery and/or the rate of aerosol delivery and thus affect the efficacy of treatment.

17. When nebulizing inhalation solutions that tend to form foam during aerosol production, the automatic shut-off may be triggered prematurely and the control unit may switch off even though inhalation solution is still present. In this case, switch the control unit back on and continue inhalation. Repeat this process until all the inhalation solution has been fully nebulized.

18. If you breathe out through the mouthpiece, the automatic shut-off may be triggered prematurely and the control unit may switch off even though inhalation solution is still present. In this case, switch the control unit back on and continue inhalation. Repeat this process until all the inhalation solution has been fully nebulized.

19. When nebulizing inhalation solutions that tend to form foam during aerosol production, the automatic shut-off may not activate and the control unit may not switch off even though no more inhalation solution is present. In this case, switch off the control unit by pressing the On/Off button (> 1 second).

20. Only use the nebulizer (control unit and nebulizer unit) for inhalation in a horizontal or slightly inclined position (20° to 45° sloping towards the mouthpiece). This is the only way to ensure that the inhalation solution is connected to the aerosol generator. Incorrect positioning may result in a malfunction of the medical device.

21. Do not stop cleaning the nebulizer unit until the distilled water has been completely nebulized.

CAUTION

1. Do not touch the aerosol generator in the nebulizer unit.

2. Never insert objects into the nebulizer unit.

3. The control unit's internal rechargeable battery (lithium-ion battery) must not be charged if damage or defects are visible on the power cord.

4. Medical electrical devices are subject to specific precautions with regard to electromagnetic compatibility (EMC) and must be installed and used in accordance with the remarks contained in these instructions for electromagnetic compatibility.

5. To avoid damage to the product and to ensure compliance with the EMC directives, only the original power cord may be used.

6. The USB port of the control unit is only for connecting the nebulizer unit. Do not connect any other commercially available USB cables to the control unit's USB port.

7. The use of a cannula to fill the M-neb® dose+ nebulizer unit may damage the aerosol generator or the M-neb® dose+ nebulizer unit.

NOTE

1. Please check the scope of delivery for completeness before using the medical device for the first time. Also, check the delivered components for obvious, visible defects, impurities, cracks or damage. Never use the medical device or its components if they have visual defects or flaws. In this case, contact the manufacturer or your dealer.

2. The control unit may heat up on the underside during prolonged use.

3. The maximum runtime is 1 hour in continuous mode. The maximum standby time (readiness to starting the triggered mode) is 240 seconds or 4 minutes. When the maximum runtime in the respective mode is reached, the control unit is automatically switched off.

4. This note is based on the requirements of the ElektroG in Germany. In other countries, the applicable disposal regulations of the respective country must be observed.

   This product falls within the scope of the act governing the sale, return and environmentally sound disposal of electrical and electronic equipment (Waste Electrical and Electronic Equipment Act - ElektroG) and is classified in the category 5 (small devices – small medical devices). Therefore, the electronic components of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit and power cord) must not be disposed of with household waste. Disposal of these electronic components is carried out according to the national waste disposal regulations.

   The M-neb® dose+ nebulizer unit MN-300/8 and the M-neb® dose+ mouthpiece can be disposed of in accordance with the Waste Catalogue Ordinance (AVV) Regulation under waste code 20 03 01, other municipal waste, mixed municipal waste.

5. The charging time for the control unit's internal rechargeable battery (lithium-ion battery) is depending on the initial state:
   a) for a 80 % battery capacity, approx. 2 hours
   b) for a 100 % battery capacity, approx. 3 hours.

6. Only use accessories certified by the manufacturer.

7. The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system does not change the mode of action, efficacy and safety of the administered inhalation solution, provided it is approved for nebulization.

8. Do not use a syringe with a cannula to fill the M-neb® dose+ nebulizer unit. If a syringe with a cannula is used to fill the M-neb® dose+ nebulizer unit, the cannula must be removed before injecting the inhalation solution into the M-neb® dose+ nebulizer unit.

9. Never use the M-neb® dose+ mesh nebulizer MN-300/8 or its components if they show any visual defects, contamination or damage.

3.0 PURPOSE

3.0.1 Intended use

The M-neb® dose+ mesh nebulizer MN-300/8 is a vibrating nebulizer system for treatment of the lower respiratory tract. The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system enables dose-precise delivery of the inhalation substances (e.g. suspensions or emulsions) prescribed by the doctor as an aerosol for inhalation.
The inhalation substances must be approved for inhalation by vibrating nebulization (mesh nebulization).

The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system may be used by all patients who can inhale with a mouthpiece.

3.0.2 Contraindications

Persons who are unable to use the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system safely, such as children or persons with limited abilities (e.g. physical, mental, sensory), must be assisted in its use by a person responsible for their safety.

There are no indications of product-related side effects. The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system does not change the mode of action, efficacy and safety of the administered inhalation solution, provided it is approved for nebulization.

The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is not suitable for patients who cannot breathe on their own.

The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is not intended for the treatment of life-threatening conditions.

3.0.3 Notes in connection with the intended purpose

The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer unit HOMECARE (incl. M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti) is intended for reuse for up to 30 applications (maximum) or 7 days and may only be used by one patient for hygienic reasons. The frequency of use depends on the inhalation therapy prescribed by the doctor. The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is a reusable medical device with an intended service life of 6 years. The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system may be used in a domestic environment.

3.1 Functional description M-neb® dose+ mesh nebulizer MN-300/8

The M-neb® dose+ mesh nebulizer MN-300/8 has two nebulization modes (triggered mode and continuous mode). The default setting of the M-neb® dose+ mesh nebulizer MN-300/8 is the triggered mode.

Each aerosol production of the M-neb® dose+ mesh nebulizer MN-300/8 is indicated by the blue LED of the operating mode status indicator and the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer unit HOMECARE (incl. M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti) lighting up.

3.2 Nebulization modes

The specific nebulization modes of the M-neb® dose+ mesh nebulizer MN-300/8 are explained in this chapter.

3.2.1 Triggered mode

In triggered mode, aerosol production is triggered by inhalation through the M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti. The M-neb® dose+ mesh nebulizer MN-300/8 only produces aerosol during the inhalation phase (synchronisation).

In triggered mode, the LED of the operating mode status indicator and the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer unit HOMECARE (incl. M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti) light up during each phase of aerosol production for the duration of inhalation. The duration of an aerosol production phase is 1.5 seconds.

The triggered mode is set as the default at the factory for the M-neb® dose+ mesh nebulizer MN-300/8 device.

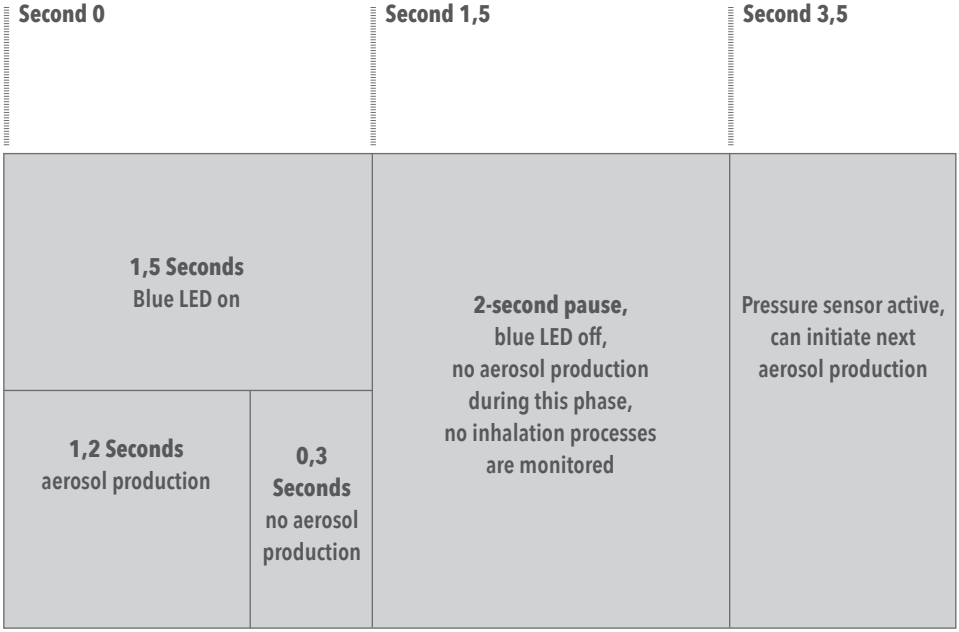
3.2.1.1 Representation of aerosol production in triggered mode

The time limit between two inhalations is:

Minimal 3,5 Seconds – If the interval is shorter, no signal from the pressure sensor is evaluated and no aerosol production is initiated.

Maximum 239 Seconds – If the interval is longer, automatic shutdown is triggered after 240 seconds.

The following figure shows aerosol production in triggered mode. This figure shows the time limitation, the interaction of the diode displays, the active and passive phases of aerosol production, and the monitoring of the inhalation processes via the pressure sensor.



3.2.2 Continuous mode

In continuous mode, the M-neb® dose+ mesh nebulizer MN-300/8 device produces aerosol continuously. In continuous mode, the blue LED of the operating mode status indicator lights up for the duration of the aerosol production time.
The continuous mode is available in the M-neb® dose+ mesh nebulizer MN-300/8 device. The continuous mode must be selected in the M-neb® dose+ mesh nebulizer MN-300/8 device. You can find out more on how the continuous mode is selected in the following Chapter „6.5 Changing the operating modes".

3.3 Automatic switch-off

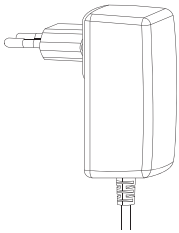
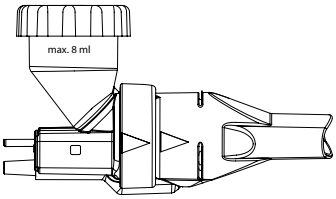
Regardless of the nebulization mode, the M-neb® dose+ mesh nebulizer MN-300/8 switches off automatically once the filled inhalation substance has been completely aerosolised. Each nebulization mode is equipped with the automatic switch off.

3.4 Maximum runtimes

The maximum runtime in continuous mode is 1 hour. The maximum standby time (readiness to start the triggered mode) is 240 seconds or 4 minutes. When the maximum runtime in the respective mode is reached, the M-neb® dose+ mesh nebulizer MN-300/8 switches off automatically.

4.0 DELIVERY SCOPE FOR YOUR M-NEB® DOSE+ MESH NEBULIZER MN-300/8

The following components belong to your M-neb® dose+ mesh nebulizer MN-300/8 delivery scope:

Quantity	Item no.	Designation	Figure
1 pc.	20100262	M-neb® dose+ mesh nebulizer MN-300/8 control unit	
1 pc.	20100206	M-neb® mesh nebulizer MN-300/X power cord (type: GTM96060-0606-1.0)	
2 pcs.	20100268	M-neb® dose+ mesh nebulizer MN-300/8 nebulizer unit HOMECARE (incl. M-neb® dose+ mesh nebulizer MN - 300/8 mouthpiece opti)	

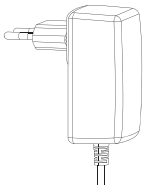
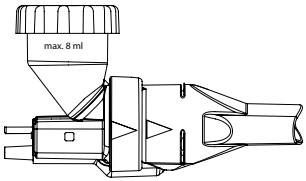
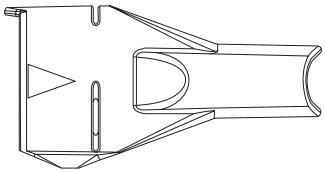
NOTE

Before the first use of the M-neb® dose+ mesh nebulizer MN-300/8, please check the delivery scope for completeness. Also, check the delivered components for obvious, visible defects, impurities, cracks or damage. Never use the M-neb® dose+ mesh nebulizer MN-300/8 or its components if they show visual defects or faults.
In this case, contact the manufacturer or your dealer.

5.0 THE MOST IMPORTANT COMPONENTS OF YOUR M-NEB® DOSE+ MESH NEBULIZER MN-300/8

Before you use your M-neb® dose+ mesh nebulizer MN-300/8 for the first time, take some time to familiarise yourself with the device and the accessories.

All components of the M-neb® dose+ mesh nebulizer MN-300/8 are listed in the table below.

Item no.	Designation	Figure
20100262	M-neb® dose+ mesh nebulizer MN-300/8 control unit Hereafter designated as " M-neb® dose+ control unit".	
20100206	M-neb® mesh nebulizer MN-300/X power cord (Type: GTM96060-0606-1.0) Hereafter designated as "M-neb® power cord".	
20100268	M-neb® dose+ mesh nebulizer MN-300/8 nebulizer unit HOMECARE (incl. M-neb® dose+ mesh nebulizer MN- 300/8 mouthpiece opti) Hereafter designated as "M-neb® dose+ nebulizer unit".	
20100320	M-neb® dose+ mesh nebulizer MN- 300/8 mouthpiece opti Hereafter designated as " M-neb® dose+ mouthpiece". - available as an option -	

The M-neb® dose+ control unit connected to the M-neb® dose+ nebulizer unit with M-neb® dose+ mouthpiece is defined as the application part.

6.0 FIRST USE OF YOUR M-NEB® DOSE+ MESH NEBULIZER MN-300/8

6.1 Fill the M-neb® dose+ nebulizer unit

Open closing cap using an 80° rotation counter clockwise and then lift the cap upwards.

Pour the substance into the medication chamber. Observe the maximum filling volume of the medication chamber. The maximum filling volume is 8.0 ml.

Replace the closing cap and close it by turning it clockwise by 80°.

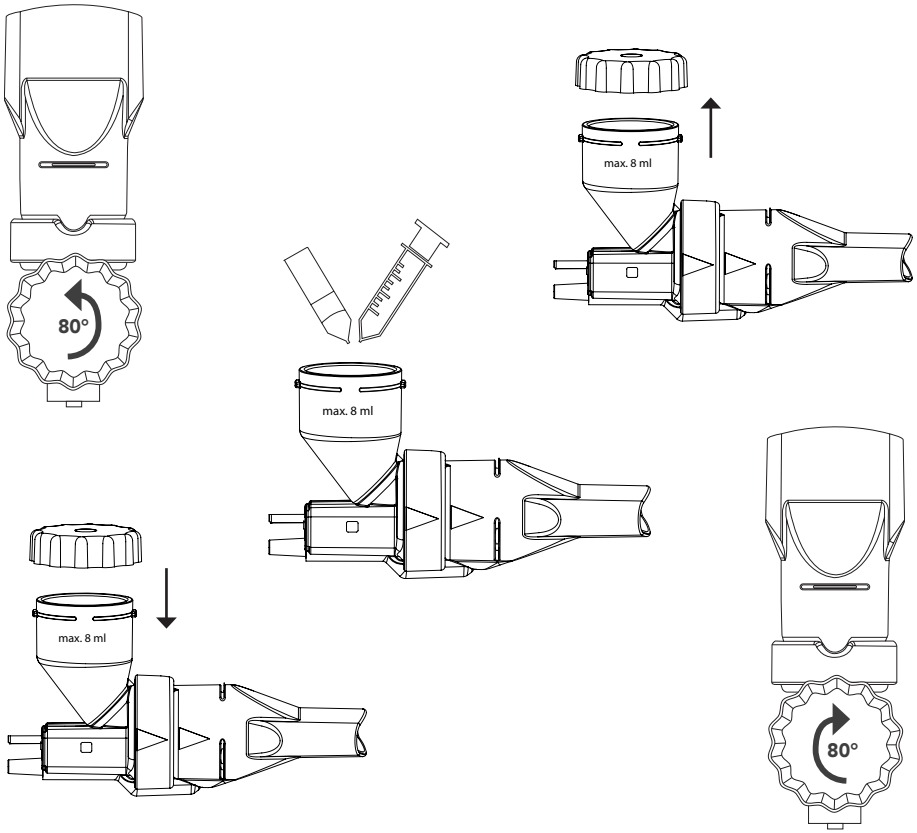


Fig. 02 - MN-300/8 - Fill the M-neb® dose+ nebulizer unit

NOTE

Do not use a syringe with a cannula to fill the M-neb® dose+ nebulizer unit. If a syringe with a cannula is used to fill the M-neb® dose+ nebulizer unit, the cannula must be removed before injecting the inhalation solution into the M-neb® dose+ nebulizer unit.

CAUTION

The use of a cannula to fill the M-neb® dose+ nebulizer unit may damage the aerosol generator or the M-neb® dose+ nebulizer unit.

6.2 Connecting M-neb® dose+ nebulizer unit to the M-neb® dose+ control unit

After this, connect the filled M-neb® dose+ nebulizer unit to the M-neb® dose+ control unit. To do this, connect the female USB socket of the M-neb® dose+ control unit to the male USB connector of the M-neb® dose+ nebulizer unit.

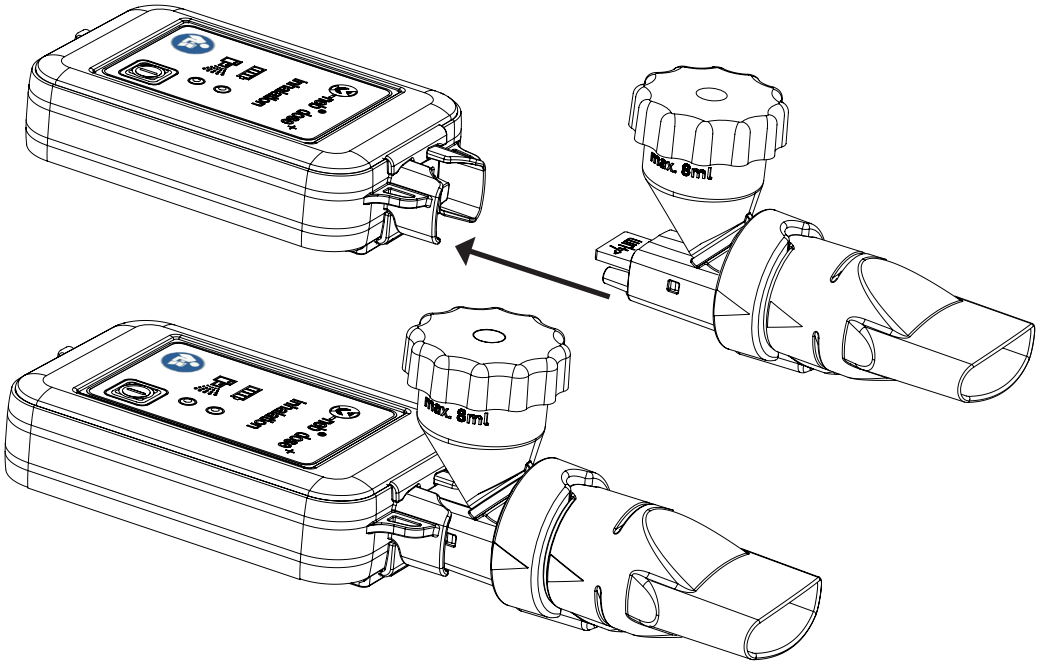


Fig. 03 - MN-300/8 - Connecting M-neb® dose+ nebulizer unit with M-neb® dose+ control unit

6.3 Starting and carrying out inhalation

Press (> 1 second) the On/Off button on the M-neb® dose+ control unit. The M-neb® dose+ control unit switches on. This is indicated by a short acoustic signal and the battery status indicator lighting up green continuously.

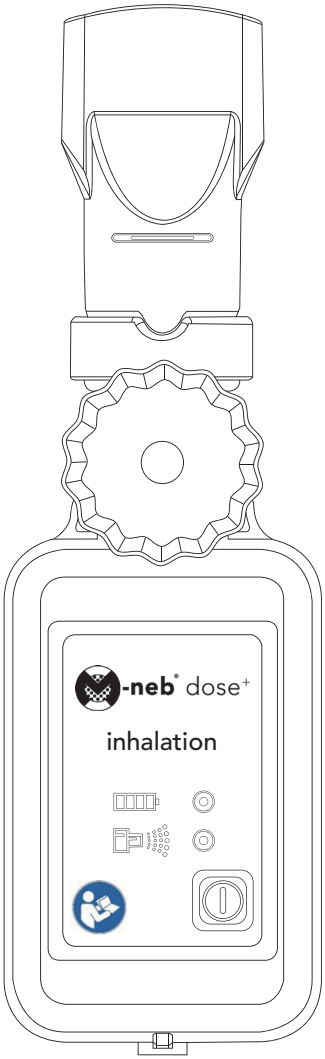


Figure	Definition
	Battery status indicator (Explanation on this in Chapter 11.0 "Diode displays")
	Operating mode status indicator (Explanation on this in Chapter 11.0 "Diode displays")
	On/Off button

Fig. 04 - MN-300/8 - Definition of status displays and buttons

The operational readiness of the M-neb® dose+ control unit is established after the operating mode status indicator has briefly flashed blue three times.

The M-neb® dose+ control unit can now monitor your inhalation and produce inspiration-triggered aerosol delivery. This aerosol is then available for every single breath for inhalation. To do this close your mouth around the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit and inhale through your mouth. (Use a nose clip for an inhalation session if needed.)

While you carry out an inhalation process using the M-neb® dose+ mouthpiece, the operating mode status display LED and the M-neb® dose+ nebulizer unit light up blue for the duration of the inhalation with each phase of the aerosol production. Please note that the duration of an aerosol production phase is 1.5 seconds.

Do not exhale through the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit. Put the mouthpiece down to exhale.

In order to carry out the next inhalation, close your mouth around the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit again and inhale through your mouth. To exhale, put down the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit again and do not exhale through the M-neb® dose+ mouthpiece.

Repeat this procedure until the filled substance has been completely aerosolised by the M-neb® dose+ nebulizer unit. The M-neb® dose+ control unit switches off automatically.

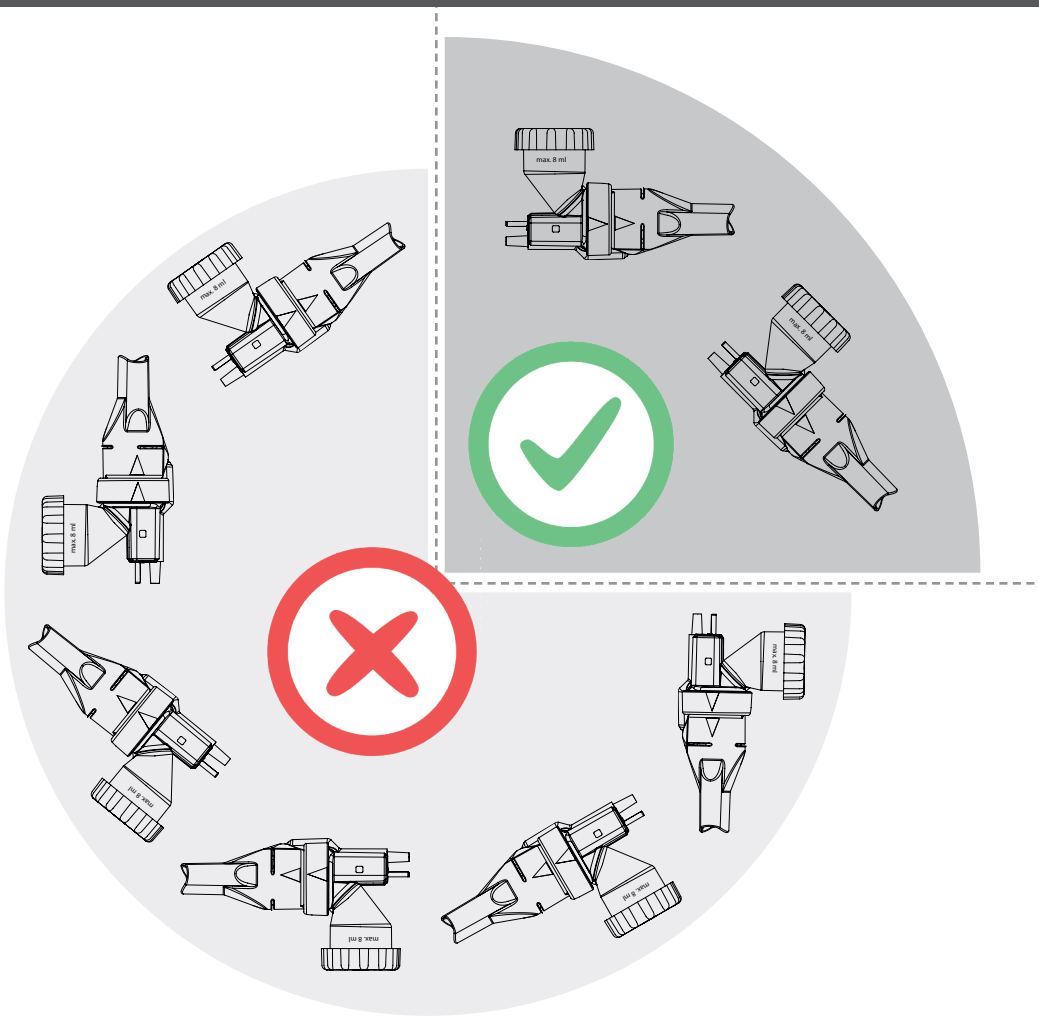


Fig. 05 - MN-300/8 - M-neb® dose+ - The above illustration shows the correct alignment of the device.

ATTENTION

When nebulizing inhalation solutions that tend to form foam during aerosol production, the automatic shut-off function may be triggered prematurely and the control unit may switch off even though there is still inhalation solution available. In this case, switch the control unit back on and continue the inhalation. Repeat this process until the entire inhalation solution has been completely nebulized.

ATTENTION

If you breathe out through the mouthpiece, the automatic shut-off may be triggered prematurely and the control unit may switch off even though inhalation solution is still present. In this case, switch the control unit back on and continue inhalation. Repeat this process until all the inhalation solution has been fully nebulized.

ATTENTION

When nebulizing inhalation solutions that tend to form foam during aerosol production, the automatic shut-off may not activate and the control unit may not switch off even though no more inhalation solution is present. In this case, switch off the control unit by pressing the On/Off button (> 1 second).

ATTENTION

Only use the nebulizer (control unit and nebulizer unit) for inhalation in a horizontal or slightly inclined position (20° to 45° sloping towards the mouthpiece). This is the only way to ensure that the inhalation solution is connected to the aerosol generator. Incorrect positioning may result in a malfunction of the medical device.

NOTE

At every stage of the aerosol production, the operating mode status indicator and the nebulizer unit will light up blue for the duration of the aerosol production.

In the triggered mode, the duration of an aerosol production phase is 1.5 seconds.

Note the two arrows on the M-neb® dose+ nebulizer unit and on the M-neb® dose+ mouthpiece. These arrows indicate the direction of the gas volume flow.

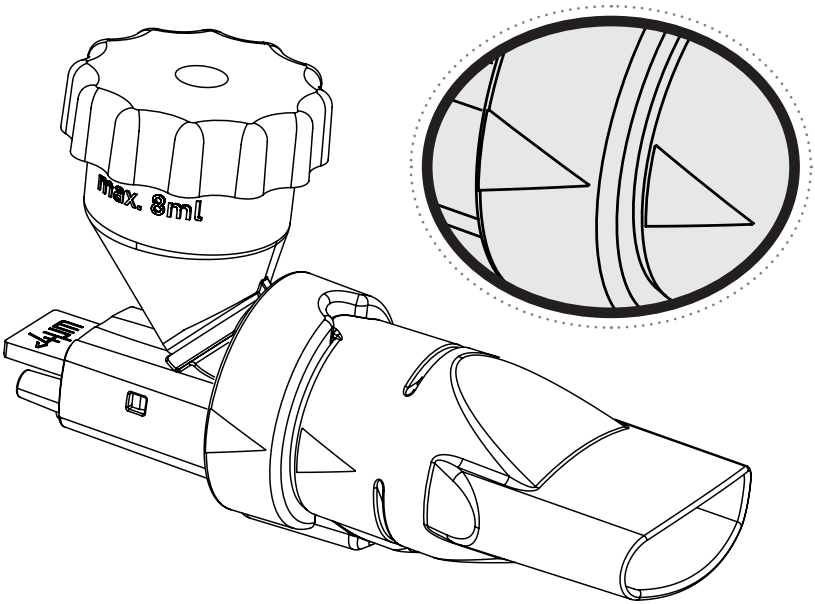


Fig. 06 - MN-300/8 - Direction of the gas volume flow

6.4 Switching off the M-neb® dose+ control unit

In order to stop or pause the nebulization before it is finished, the M-neb® dose+ control unit must be switched off. Press the On/Off button of the M-neb® dose+ control unit (> 1 second). The M-neb® dose+ control unit switches off. As an indication, you will hear a short acoustic signal tone and the battery status indicator turns off.

For a definition of the status displays and buttons, please refer to Figure 04 and the table on page 28.

6.5 Changing the operating modes

The default setting of the M-neb® dose+ control unit is the triggered mode. When you have switched on the M-neb® dose+ control unit and the operational readiness is established, the M-neb® dose+ control unit is in triggered mode.

The change of the operating modes is described below if the operational readiness of the M-neb® dose+ control unit is not established and the device is in the switched off state.

Press the On/Off button of the M-neb® dose+ control unit (> 1 second).
The M-neb® dose+ control unit switches on. As indication, you will hear a short acoustic signal tone and the battery status indicator continuously lights up green.

The operational readiness of the M-neb® dose+ control unit is established after the operating mode status indicator has briefly flashed blue three times. For a definition of the status displays and buttons, please refer to Figure 04 and the table on page 28.

The M-neb® dose+ control unit is now in triggered mode and ready for inhalation.

Now you can change the operating mode from the triggered mode to continuous mode in a time window of 240 seconds or 4 minutes which is equivalent to the maximum standby time.

To do this, press the On/Off button on the M-neb® dose+ control unit (< 1 second).
Two consecutive, short, acoustic signal tones sound and the operating mode status indicator lights up continuously blue. The M-neb® dose+ control unit is now in continuous mode and continuously nebulizes (provided that the substance is filled in the M-neb® dose+ nebulizer unit).

If you want to switch back from continuous mode to triggered mode, press the On/Off button of the M-neb® dose+ control unit (< 1 second).
A short acoustic signal tone will sound and the blue LED of the operating mode status indicator turns off, lights up briefly again three times and turns off again.

To switch off the M-neb® dose+ control unit, press the On/Off button of the M-neb® dose+ control unit (> 1 second). A short, acoustic signal will sound, the battery status indicator goes out and the M-neb® dose+ control unit is switched off.

Please note: The M-neb® dose+ control unit can also be switched off by automated shut-down procedures. These procedures are, on the one hand, the automatic switching function and on the other hand, the maximum runtimes of the M-neb® dose+ control unit.

Regardless of the nebulization mode set, the automatic switching function of the M-neb® dose+ control unit switches off automatically once the filled substance has been completely aerosolised.

The maximum runtimes automatically switch the M-neb® dose+ control unit off as soon as its time limits are reached.

- In continuous mode, the maximum runtime is 1 hour.
- Furthermore, the maximum standby time (readiness to start the triggered mode) switches off the M-neb® dose+ control unit after 240 seconds or 4 minutes of inactivity.

6.6 Use of the continuous mode

To operate the M-neb® dose+ control unit in continuous mode, this must be selected. To do this, the operational readiness of the M-neb® dose+ control unit must first be established. To do this, proceed as follows:

Press the On/Off button of the M-neb® dose+ control unit (> 1 second).
The M-neb® dose+ control unit switches on. As indication, you will hear a short acoustic signal tone and the battery status indicator continuously lights up green.

The operational readiness of the M-neb® dose+ control unit is established after the operating mode status indicator has briefly flashed blue three times.

Now you can change the operating mode from the triggered mode to continuous mode in a time window of 240 seconds or 4 minutes which is equivalent to the maximum standby time.

To do this, press the On/Off button on the M-neb® dose+ control unit (< 1 second).
Two consecutive, short, acoustic signal tones sound and the operating mode status indicator lights up continuously blue. The M-neb® dose+ control unit is now in continuous mode and continuously nebulizes provided that the substance is filled in the M-neb® dose+ nebulizer unit.

To perform the next inhalation process, place your mouth around the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit. Inhale the aerosol produced during inhalation. When inhalation is finished, put down the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit. Do not exhale through the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit.

During exhalation, the unit continues to produce aerosol. To perform the next inhalation process, place your mouth around the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit. Inhale the aerosol produced during inhalation. When inhalation is finished, put down the M-neb® dose+ mouthpiece of the M-neb® dose+ nebulizer unit and breath out.

NOTE

To aerosolise the inhalation solution efficiently and without loss, the aerosol can be prevented from escaping during the exhalation phase by using the triggered mode.

Repeat this procedure until the filled medication has been completely aerosolised by the M-neb® dose+ control unit. The M-neb® dose+ control unit switches off automatically.

ATTENTION

After using the continuous mode, a rest period of one hour must be observed, as otherwise the electronics of the M-neb® dose+ control unit could heat up too much.

7.0 POWER SUPPLY

The M-neb® dose+ control unit is operated exclusively via the internal, rechargeable battery (lithium-ion battery).

The M-neb® dose+ control unit may not be operated via the M-neb® power cord and the 230 VAC power supply.

The M-neb® power cord is only used to charge the internal rechargeable battery (lithium-ion battery) of the M-neb® dose+ control unit.

WARNING

The M-neb® dose+ control unit is operated exclusively via the internal, rechargeable battery (lithium-ion battery).

The M-neb® dose+ control unit may not be operated via the M-neb® power cord and the 230 VAC power supply.

The M-neb® power cord is only used to charge the internal rechargeable battery (lithium-ion battery) of the M-neb® dose+ control unit.

8.0 CHARGING OF THE M-NEB® DOSE+ CONTROL UNIT

The capacity status of the M-neb® dose+ control unit is displayed on the battery status indicator of the M-neb® dose+ control unit as follows:

- If the capacity is greater than 30 %, the battery status indicator lights up continuously green.
- If the capacity is less than the limit of 30 %, the battery status indicator lights up alternately red and green.
- If the capacity is less than the limit of 10 %, the battery status indicator briefly lights up red accompanied by an audible signal. The M-neb® dose+ control unit switches off automatically.

ATTENTION

If the M-neb® dose+ control unit shows a battery capacity of 30 % or less via the battery status display, it is recommended to charge the battery of the M-neb® dose+ control unit. If the capacity falls below the limit of 10 %, the battery of the M-neb® dose+ control unit must be charged. Otherwise, the remaining capacity of the M-neb® dose+ control unit may not be sufficient for a complete inhalation process.

To charge, first connect the M-neb® power cord to the M-neb® dose+ control unit.

Fig. 07a- MN-300/8 - Charging the M-neb® dose+ control unit

Then connect the M-neb® power cord to the 230 VAC power supply.
The charging of the battery starts now.

If the M-neb® dose+ control unit battery is charging, the battery indicator light flashes green (ratio: 1 second green/1 second pause).

If the M-neb® dose+ control unit has completed charging, the battery indicator light flashes green (ratio 1/10 seconds green/1 second pause).

Now disconnect the M-neb® power cord from the M-neb® dose+ control unit and the 230 VAC power supply.

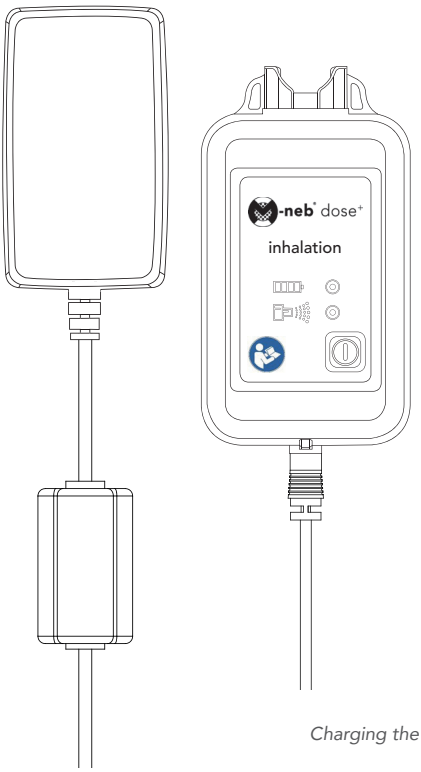
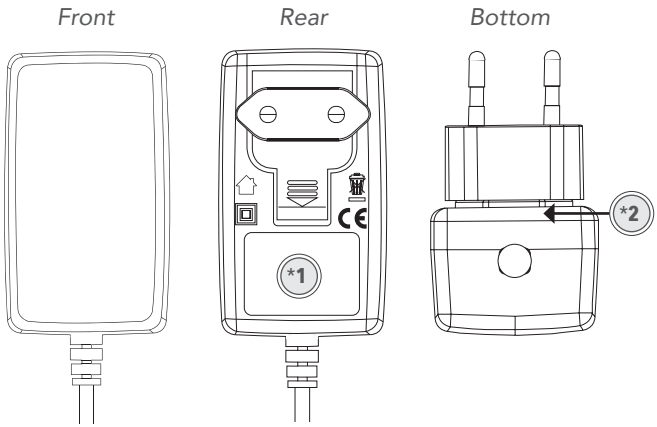
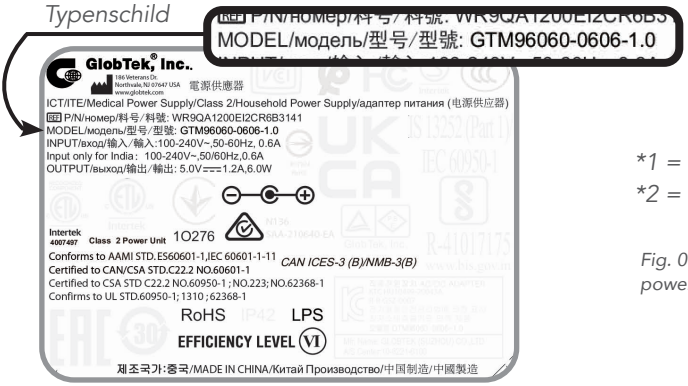


Fig. 07b- MN-300/8 -
Charging the M-neb® dose+ control unit

WARNING

The charging of the internal rechargeable battery (lithium-ion) is carried out exclusively with the supplied M-neb® power cord MN-300/X (type: GTM96060-0606-1.0).





**1 = Type plate*
**2 = Serial number*

Fig. 08 - MN-300/8 - M-neb® power cord MN-300/X

NOTE

The charging time for the internal, rechargeable battery (lithium-ion) of the M-neb® dose+ control unit is approx. 3 hours for 100% charging capacity depending on the initial state.

CAUTION

To avoid damage to the M-neb® dose+ control unit and ensure compliance with the EMC Directive, only use the original M-neb® power cord.

9.0 CLEANING AND DISINFECTION

9.1 Disinfection of the M-neb® dose+ control unit

The M-neb® dose+ control unit must be disinfected after every third use or once a day.

9.1.1 Preparation

- Remove the M-neb® power cord from the M-neb® dose+ control unit.
- Remove the M-neb® dose+ control unit from the M-neb® dose+ nebulizer unit.

9.1.2 Disinfection

- Wipe the outer surfaces of the M-neb® dose+ control unit with ready-to-use alcohol-based disinfectant wipes (for example Bode Bacillol® 30 Tissues disinfectant wipes) after every third use or once a day.
- Let the M-neb® dose+ control unit dry on a dry and clean surface.

NOTE

Penetration of liquids can cause a defect in the device. Do not immerse the M-neb® dose+ control unit in liquids.

9.1.3 Visual inspection

Check the M-neb® dose+ control unit after disinfection. Replace a defective M-neb® dose+ control unit.

9.1.4 Storage

Store the M-neb® dose+ control unit in a dry and dust-free place.

9.2 Cleaning and disinfection of the M-neb® dose+ nebulizer unit and the M-neb® dose+ mouthpiece

The M-neb® dose+ nebulizer unit must be thoroughly cleaned immediately after each use.

9.2.1 Preparation

Disassemble the nebulizer system into its individual parts:

- Remove the M-neb® dose+ nebulizer unit from the M-neb® dose+ control unit.
- Remove the M-neb® dose+ mouthpiece from the M-neb® dose+ nebulizer unit.
- Remove the closing cap of the M-neb® dose+ nebulizer unit.

9.2.2 Cleaning

- Place the M-neb® dose+ mouthpiece in warm tap water (approx. 30°C) with some commercial dishwashing detergent for approx. 5 minutes.
- Rinse the M-neb® dose+ mouthpiece thoroughly under running water until you can no longer see any visible residue of the rinsing agent.
- Then place the M-neb® dose+ mouthpiece on a dry, clean and absorbent surface (e.g. a tea towel) to dry.

NOTE

Do not put the M-neb® dose+ mouthpiece or the M-neb® dose+ nebulizer unit in the microwave or in the dishwasher, as this will damage the M-neb® dose+ mouthpiece or the M-neb® dose+ nebulizer unit. Do not use brushes to clean the M-neb® dose+ mouthpiece or the M-neb® dose+ nebulizer unit in this way, otherwise the M-neb® dose+ mouthpiece or the M-neb® dose+ nebulizer unit will be damaged.

The aerosol generator is a technical component in the M-neb® dose+ nebulizer unit and must be rinsed with distilled water following cleaning after every third use.

- Open the M-neb® dose+ nebulizer unit, by rotating the closing cap 80° counterclockwise and then lifting it off.

- Fill the medication chamber of the M-neb® dose+ nebulizer unit with a small amount of distilled water (0.5 ml to a maximum of 2.0 ml) and close the M-neb® dose+ nebulizer unit by putting on the closing lid and closing it by turning it clockwise by 80°.

- After this, connect the filled M-neb® dose+ nebulizer unit to the M-neb® dose+ control unit. To do this, connect the female USB socket of the M-neb® dose+ control unit to the male USB connector of the M-neb® dose+ nebulizer unit.

- Switch on the M-neb® dose+ control unit. To do this, press the On/Off button on the M-neb® dose+ control unit (> 1 second). The M-neb® dose+ control unit switches on. As indication, you will hear a short acoustic signal tone and the battery status indicator continuously lights up green. The operational readiness of the M-neb® dose+ control unit is established after the operating mode status indicator has briefly flashed blue three times. The M-neb® dose+ control unit is now in triggered mode.

- Now you can change the operating mode from the triggered mode to continuous mode in a time window of 240 seconds or 4 minutes which is equivalent to the maximum standby time. To do this, press the On/Off button on the M-neb® dose+ control unit (< 1 second). Two consecutive, short, acoustic signal tones sound and the operating mode status indicator lights up continuously blue.

- The M-neb® dose+ control unit is now in the continuous mode and continuously nebulizes the filled distilled or sterile water. Once the filled distilled or sterile water has been completely nebulized, the auto off function automatically switches off the M-neb® dose+ control unit.

WARNING

Do not inhale the aerosolised distilled or sterile water.
Ensure sufficient ventilation of the room in which you perform the cleaning.

- Disconnect the M-neb® dose+ nebulizer unit from the M-neb® dose+ control unit. Open the M-neb® dose+ nebulizer unit closing cap and place the M-neb® dose+ nebulizer unit on an absorbent dry surface to dry.

- After the M-neb® dose+ nebulizer unit has dried in the air, you can close the M-neb® dose+ nebulizer unit again with the closing cap. You can then reconnect the M-neb® dose+ mouthpiece to the M-neb® dose+ nebulizer unit.

9.2.3 Disinfection

The M-neb® dose+ mouthpiece must be disinfected after every third use or once a day following cleaning. Only cleaned parts can be effectively disinfected.

- Place the M-neb® dose+ mouthpiece in boiling water for at least 5 minutes. Use a clean boiling pot and distilled water.
- Then remove the M-neb® dose+ mouthpiece from the water with a tool (for example a spoon) and place the M-neb® dose+ mouthpiece on a dry, clean and absorbent surface (for example a tea towel) to dry.

NOTE

Make sure that there is a sufficient amount of water in the cooking pot, otherwise the plastic may melt if it comes into contact with the hot bottom of the pot. Do not place the M-neb® dose+ mouthpiece in a water kettle for disinfection, otherwise the M-neb® dose+ mouthpiece will be damaged.

9.2.4 Visual inspection

Check all parts after cleaning and disinfection. Replace broken or badly discoloured parts.

9.2.5 Storage

Store all parts in a dry and dust-free place.

10.0 MAINTENANCE

The M-neb® dose+ control unit should be inspected after a maximum of 24 months and subjected to a technical safety inspection. All repairs or maintenance may only be done by a dealer qualified by NEBU-TEC med. Products Eike Kern GmbH.

WARNING

The M-neb® dose+ control unit may not be maintained in a ready-to-operate mode.

WARNING

The M-neb® dose+ control unit may not be maintained while being used by a patient.

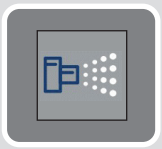
WARNING

Do not open the housing. All repairs or maintenance may only be done by a dealer qualified by NEBU-TEC med. Produkte Eike Kern GmbH.
Failure to follow this will result in the loss of the warranty claim.

The patient can do the following maintenance measures themself:
Replacement of spare parts/accessories as listed in Chapter 18.0 „Accessories / Ordering information" in order to maintain the operational readiness of the medical device and to be able to carry out the first use according to Chapter 6.0 „First use of your M-neb® dose+ control unit". Apart from this, the patient cannot carry out any further maintenance measures themself.

11.0 DIODE DISPLAYS

Illustration	Diode	Significance
	Battery status indicator	The battery status indicator [red/green LED] is controlled so that: - the green LED lights up during operation when the battery capacity is above 30 %. - the green LED flashes alternately with the red LED (flashing ratio 1 second : 1 second) when the battery capacity is greater than 10 % and less than 30 %. -the red LED flashes briefly, accompanied by an acoustic signal, when the battery capacity falls below 10 %. The control unit switches off. - the green LED flashes at intervals (1 second : 1 second) when charging is activated. - the green LED flashes intermittently (1/10 s on : 1 s off) when charging is complete. - the red LED flashes briefly, accompanied by an acoustic signal, when the standby time (240 seconds or 4 minutes) has been exceeded. - the red LED flashes briefly, accompanied by an acoustic signal, when the maximum running time in continuous mode (60 minutes) has been exceeded. - the red LED flashes briefly, accompanied by an acoustic signal, when automatic shutdown has occurred.

Illustration	Diode	Significance
	Operating mode status indicator	The operating mode status indicator [blue LED] lights up: - three short blue flashes when the boot phase is complete. (When switching on the control unit and when changing mode from continuous to triggered.) - solid blue when the RF output stage is activated (power indicator). - permanently blue, accompanied by an acoustic signal tone, when the mode has changed from triggered to continuous mode. - turns off, accompanied by an acoustic signal tone, when the mode has been changed from continuous to triggered mode.

12.0 AMBIENT CONDITIONS

In the following chapters, the ambient conditions of the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system are listed which are required for the proper functioning in accordance with the intended use of this device.

12.1 Operating conditions

The operation of the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is guaranteed in the following ambient conditions:

Ambient temperature:	**+10° C to +30° C**
Relative humidity:	**25 % to 75 %**
Air pressure:	**800 hPa to 1015 hPa**

12.2 Transport and storage conditions

Transport and storage of the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is ensured in the following ambient conditions:

Ambient temperature:	**-10° C to +50° C**
Relative humidity:	**25 % to 75 %**
Air pressure:	**450 hPa to 1100 hPa**

13.0 TREATMENT DURATION AND INTENDED OPERATING LIFE

13.1 Treatment duration

The M-neb® dose+ nebulizer unit and the M-neb® dose+ mouthpiece are consumables and may be used for a maximum of 7 days per patient (m/f/d). They should be replaced with new consumables after this maximum treatment period.

The administration of 1 ml (NaCl) can take up to 4 minutes in continuous mode. In triggered mode, administration depends heavily on the respiratory rate and therefore cannot be generalised.

13.2 Intended operating life

The intended operating life of the components is defined as follows:

Components	Intended operating life
M-neb® dose+ control unit M-neb® power cord	6 years
M-neb® dose+ nebulizer unit M-neb® dose+ mouthpiece	30 applications (maximum) or 7 days

The components must be replaced at the latest when the specified operating life is reached. The operating life of the components may be reduced with more intensive use and higher usage and several treatments are carried out in a shorter period of time by the patient.

The M-neb® dose+ control unit and the M-neb® power cord are subject to maintenance within the intended operating life.

14.0 DISPOSAL

Information requirements towards private households

This note is based on the requirements of the ElektroG in Germany. In other countries, the applicable disposal regulations of the respective country must be observed.
With these instructions, we, as the manufacturer of the medical devices M-neb® dose+ mesh nebulizer MN-300/8 and M-neb® mobile mesh nebulizer MN-300/9, fulfill our information obligations in accordance with the ElektroG.
These instructions are valid for the medical devices M-neb® dose+ mesh nebulizer MN-300/8 and M-neb® mobile mesh nebulizer MN-300/9 when used in a domestic environment.

1. Disposal of electrical and electronic equipment
The „crossed-out wheeled garbage can" symbol means that you are required by law to dispose of this equipment separately from unsorted municipal waste.
Disposal via household waste, such as the residual waste garbage can or the yellow garbage can, is prohibited. Avoid misdirected waste by disposing of it correctly at special collection and return points.

2. Removal of batteries and lamps
If the products contain batteries and accumulators or lamps that can be removed from the old device without destroying it, these must be removed before disposal and disposed of separately as batteries or lamps. The following batteries or accumulators are contained in this electrical device: Lithium-ion battery, which is permanently installed.

3. Possibilities for returning old devices
Owners of old devices can return them free of charge within the framework of the possibilities for the return or collection of old devices set up and available by public waste management authorities, so that the proper disposal of old devices is ensured. In addition, return is also possible from distributors under certain conditions:

a) The return takes place free of charge with the purchase of a similar new device (1:1 return).
b) Independently of this, there is the possibility of returning the old devices to us free of charge. The condition for this is that the external dimensions are not larger than 25 centimeters and the return is limited to three old devices per type of device (0:1 take-back).

4. Data privacy
We point out to all end users of old electrical and electronic equipment that you are responsible for deleting personal data on the old devices.

5. WEEE registration number
Under the registration number DE25154520, we are registered with the stiftung elektro-altgeräte register, Nordostpark 72, 90411 Nuremberg, Germany, as a manufacturer of electrical and/or electronic equipment.

6. Collection and recovery rates
According to the WEEE Directive, the EU member states are obliged to collect data on old electrical and electronic devices and to transmit this data to the European Commission. You can find more information on this on the BMUV website.

15.0 TECHNICAL DATA

M-neb® dose+ control unit:

Size (L x W x H)	99 x 54 x 23 mm
Weight	82 g
Electrical supply	Internal: 3,6V ≤ 4,2 W
	External:100-240 VAC / 50-60 Hz / 0,6 A / 144 W
	5V / 1,2 A
Power consumption during operation	≤ 1000 mA
Working frequency	110 KHz
Relevant sensitivity (pressure sensor)	6,95 mBar
	Maximum 750 mBar
Electrical protection class	II type BF
Used battery type	lithium-ion / 3,7V / 1200mAh (AE653450P)
The maximum A-weighted sound pressure level:	47.0 dBA
Specification of the material used:	acrylonitrile butadiene styrene (ABS) and
	Polycarbonate (PC), High Consistency Rubber (HCR),
	Polyethylene Terephthalate (PET)

M-neb® power cord:

Size (L x W x H)	74 x 44 x 75 mm
Cable length	1,9 m
Weight	126 g
Specification of the material used:	Polycarbonate (PC)

M-neb® dose+ nebulizer unit:

Size (L x W x H)	56 x 33 x 56 mm *(Nebulizer unit without mouthpiece)*
	95 x 33 x 56 mm *(Nebulizer unit with mouthpiece)*
Maximum filling quantity	8,0 ml
Weight	21 g *(Nebulizer unit without mouthpiece)*
	27 g *(Nebulizer unit with mouthpiece)*
Nebulizer performance	< 0,5 ml/min
Specification of the material used:	
Nebulizer unit (nebulizer)	Polycarbonate (PC), thermoplastic elastomer (TPE)
Mouthpiece	Polycarbonate (PC)

16.0 PERFORMANCE DATA

16.1 Performance data EN 13544-1

Aerosol delivery and particle size in accordance with EN ISO 13544-1/Annex CC were determined and established for the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system.

Performance data of the M-neb® dose+ control unit when using the M-neb® dose+ nebulizer unit

The aerosol delivery according to EN ISO 13544-1/Annex CC - CC.1.4 is 1.17+/- 0.04 mg sodium chloride per minute when using the M-neb® dose+ nebulizer unit.
The aerosol delivery according to EN ISO 13544-1/Annex CC - CC.2 is 1.86 mg sodium chloride per minute when using the M-neb® dose+ nebulizer unit.
This corresponds to an aerosol delivery of 0.4 ml sodium chloride per minute when using the M-neb® dose+ nebulizer unit.

16.2 Performance data EN 27427

The aerosol delivery and the rate of aerosol delivery specified in these instructions for use were determined in accordance with EN ISO 27427 using salbutamol.
If other inhalation solutions or medications are used for nebulization, the stated aerosol delivery and the rate of aerosol delivery may differ from the values stated here.

The following values are based on the test according to the standard EN ISO 27427 Annex C - Test method for aerosol delivery and rate of aerosol delivery, which is based on an adult breathing pattern. If other populations, children and infants, inhale with a different breathing pattern, these values are likely to differ from the values given here.

The aerosol delivery and rate of aerosol delivery according to EN ISO 27427 Annex C - Test method for aerosol delivery and rate of aerosol delivery has been determined and established for the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system.

Normative requirement	Value
in the case of a gas-operated nebulizer, the test gas used;	The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is not a gas-operated nebulizer. No test gas was used.
The test solution	salbutamol 0.1 % (in 0.9 % sodium chloride) Sxact concentration: 1.017 mg / ml Density: 1.00414 g / ml
the filling volume and the volume flow used	Filling volume: 2.0 ml Volume flow used: not applicable Breathing simulator settings: Breaths per minute: f = 15 breaths / min Inspiration/expiration ratio: 1:1 Tidal volume (displacement) (Vt): 500 ml
the aerosol delivery, expressed as the mass of test substance collected by the filter(s);	1620 µg
the rate of aerosol delivery, expressed as the mass of test substance collected by the filter(s) per minute;	306 µg / min
the nebulization duration;	330 sec.
the residual volume	20 µl
the percentage of the filling volume delivered in 1 min, expressed as the aerosol delivery in 1 min divided by the filling volume recommended by the manufacturer or 2 ml if no filling volume is recommended (e.g. 20 % of the filling volume per minute).	15 %

17.0 AEROSOL SPECTRUM

17.1 Aerosol spectrum EN 13544-1

Particle size in accordance with EN ISO 13544-1/Annex CC was determined and established for the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system.

Aerosol spectrum of the M-neb® dose+ control unit when using the M-neb® dose+ nebulizer unit

The particle size of the M-neb® dose+ mesh nebulizer MN-300/8 according to EN ISO 13544-1/Annex CC is on average 3.68 µm MMD at a GSD of 1.64 when using the M-neb® dose+ nebulizer unit.

17.2 Aerosol spectrum EN 27427

The particle sizes given in these instructions for use were determined with salbutamol according to EN ISO 27427.
If other inhalation substances or medications are used for nebulization, the particle sizes may differ from the values given here.

The values below are based on the EN ISO 27427 Annex D test method for particle size, which uses an adult breathing pattern. If other populations, children and infants, inhale with a different breathing pattern, these values are likely to differ from the values given here.

Particle size in accordance with EN ISO 27427/Annex D was determined and established for the M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system.

The particle size of the M-neb® dose+ mesh nebulizer MN-300/8 in accordance with EN ISO 27427 Annex D - Test method for particle size is on average 4.4 µm MMD at a GSD of 2.08 with salbutamol.

Normative requirement	Value
MMAD (mass median aerodynamic diameter) - particle size at which 50 % of the mass of the active ingredient is contained in droplets of smaller or equal aerodynamic diameter	4.4 µm
GSD (geometric standard deviation) calculated as MMAD/D(-1) or D(1)/MMAD	2.08
Respirable fraction in % - Aerosol particles ≤ 5 µm	56.5 %
Aerosol fraction in % - aerosol particles < 5 and > 2 µm	42.5 %
Aerosol fraction in % - aerosol particles ≤ 2 µm	14.0 %
in the case of a gas-operated nebulizer, the test gas used;	The M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system is not a gas-operated nebulizer. No test gas was used.
the filling volume and the volume flow used	Filling volume: 2.0 ml Volume flow rate used: 15 l/min

The following figure shows the diagram of the cumulative size distribution from the results.

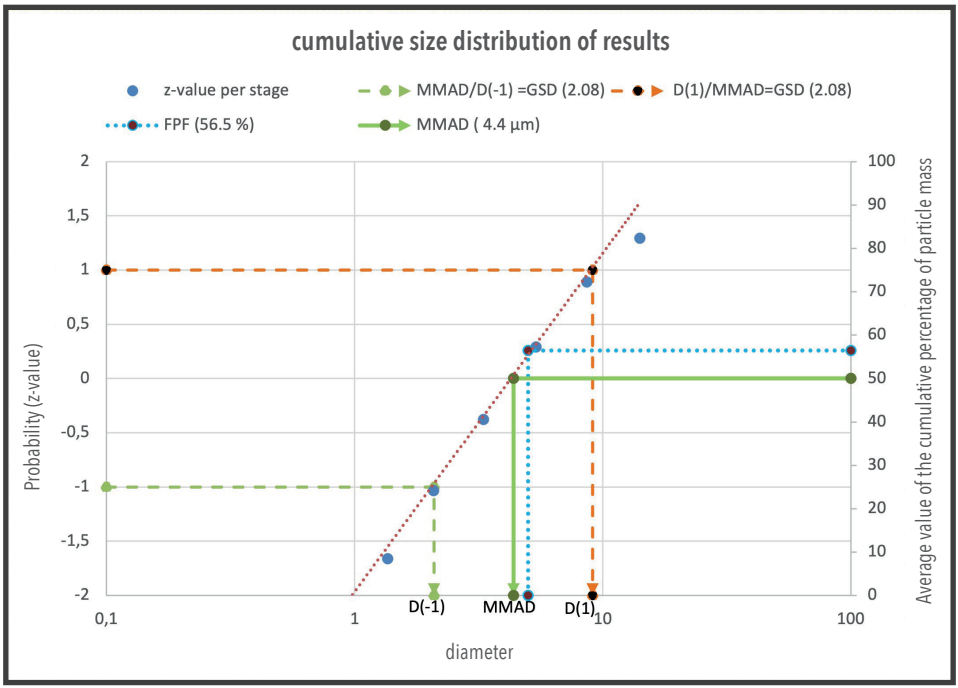


Fig. 09 - MN-300/8 - Cumulative size distribution of the results.
The mean value of three different devices is shown.

18.0 ACCESSORIES / ORDERING INFORMATION

The following accessories are available from the manufacturer or dealer for your M-neb® dose+ mesh nebulizer MN-300/8 nebulizer system:

Quantity	Item number	Designation
1 pc.	20100023	M-neb® dose+ mesh nebulizer MN-300/8 Starter-Kit HOMECARE
1 pc.	20100104	M-neb® dose+ mesh nebulizer MN-300/8 consumable materials for a duration of 3 months HOMECARE
1 pc.	20100206	M-neb® mesh nebulizer MN-300/X power cord (type: GTM96060-0606-1.0)
1 pc.	20100262	M-neb® dose+ mesh nebulizer MN-300/8 control unit
1 pc.	20100268	M-neb® dose+ mesh nebulizer MN-300/8 nebulizer unit HOMECARE (incl. M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti)
1 pc.	20100320	M-neb® dose+ mesh nebulizer MN-300/8 mouthpiece opti

WARNING

The use of accessories other than those specified as original accessories by the manufacturer (see table above) may result in electromagnetic emissions or reduced interference immunity of the equipment and may result in incorrect operation.

19.0 SERVICE

If you need technical or advisory service, please contact the manufacturer or your dealer.

20.0 MANUFACTURER

NEBU-TEC
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Kreuzfeldring 17
63820 Elsenfeld – Germany

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Fax: +49 (0) 6022 – 610 62 -99

Email: info@nebu-tec.de
Web: http://www.nebu-tec.de

21.0 INFORMATION ON ELECTROMAGNETIC COMPATIBILITY

Guidelines and manufacturer's declaration – electromagnetic transmissions		
The nebulizer MN-300/8 is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or the user of the nebulizer MN-300/8 should ensure that it is used in such an environment.		
Electromagnetic interference measurements	Conformity	ELECTROMAGNETIC ENVIRONMENT- guidelines
HF emission according to CISPR 11	Group 1	The nebulizer MN-300/8 uses RF energy only for its internal FUNCTION. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF emission according to CISPR 11	Class B	The nebulizer MN-300/8 is designed for use in all areas of home healthcare and professional healthcare facilities.

WARNING

Portable HF communication devices including antennas, such as wireless home network devices, mobile phones or cordless telephones and their base station, should not be used within 30 cm of the M-neb® dose+ mesh nebulizer MN-300/8 and its accessories. Non-observance can lead to a reduction in the performance characteristics.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The nebulizer MN-300/8 is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or the user of the nebulizer MN-300/8 should ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidelines**
DISCHARGE STATIC ELECTRICITY (ESD) According to IEC 61000-4-2 [electrostatic discharge immunity test]	+ 8 kV contact discharge + 2 kV air discharge + 4 kV air discharge + 8 kV air discharge + 15 kV air discharge	+ 8 kV contact discharge + 2 kV air discharge + 4 kV air discharge + 8 kV air discharge + 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated HF disturbance variables according to IEC 61000-4-3	Professional environment: 3 V/m 80 MHz to 2.7 GHz Domestic environment: 10 V/m 80 MHz to 2.7 GHz	Professional environment: 3 V/m 80 MHz to 2.7 GHz Domestic environment: 10 V/m 80 MHz to 2.7 GHz	

Representative list of current frequencies and radio services and their relationship to maximum output and interference immunity test levels.						
Test frequency	**Frequency band**	**Radio service**	**Modulation**	**Maximum power**	**Distance**	**Immunity level V/m**
386	380 to 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3 m	27
450	430 to 470	GMRS 460	FM ± 5kHz Hub 1kHz Sin.	2	0,3 m	28
710	704 to 787	LTE band 13,17	Pulse modulation 217 Hz	0,2	0,3 m	9
745						
780						
810	800 to 960	GMS 800/900 TETRA 800 iDEN820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0,3 m	28
870						
930						
1720	1700 to 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3 4,25; UTMS	Pulse modulation 217 Hz	2	0,3 m	28
1845						
1970						
2450	2400 to 2570	Bluetooth WLAN 802.11 RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0,3 m	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3 m	9
5500						
5785						

22.0 WARRANTY

The manufacturer grants a limited manufacturer's warranty to consumers under the following conditions and to the extent described. The manufacturer's warranty applies in addition to the statutory warranty.

Our products are quality products manufactured in Germany. The materials used have been carefully selected and, like the production process, are under constant control. We therefore guarantee that our products do not have any manufacturing-related material or processing defects when used as intended.

If, by way of exception, a defect should occur, we will repair, replace or refund the purchase price of the component at our discretion, with repair taking priority. The replacement or repair does not create a new warranty. All replaced components or old equipment become the property of NEBU-TEC.

Only defects that can be proven to be due to a material or manufacturing defect will be repaired under this warranty. Should a product defect prove not to be covered by this warranty, the costs incurred are to be borne by the consumer. In addition, the consumer shall bear the costs incurred in examining the product, including any labour costs.

The warranty period starts from the date of purchase. When purchasing our products from one of our dealers, a sales receipt showing the date of purchase must be presented as proof of this.

- M-neb® dose+ control unit
- M-neb® power cord

A six-month warranty applies from the date of purchase for the following products:

- Integrated lithium-ion battery of the M-neb® dose+ control unit

The M-neb® dose+ nebulizer unit and the M-neb® dose+ mouthpiece are wearing parts and are therefore not covered by the warranty provided.

NOTE

Consumable items are subject to normal wear and tear. Usual signs of wear and tear due to age or use do not constitute defects and therefore do not give rise to any guarantee or warranty rights.

The warranty will also not be granted if

- the product has not been properly commissioned, used and maintained in accordance with the instructions in this user manual.
- damage is present that can be attributed to external influences, e.g. water.
- damage is present which is due to deliberate or intentional damage, negligence or carelessness.
- the damage was caused by improper transport or falling, the serial number on the product has been altered, removed or made unrecognisable or the warranty seal has been broken.
- unauthorised persons have made repairs, adjustments or modifications to the product.

23.0 RELEASE NOTES

Version: NT_MN-300-8_IFU-HOMECARE-ENG_F / July 2025

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NEBUTEC®
Innovative Inhalationsgeräte

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