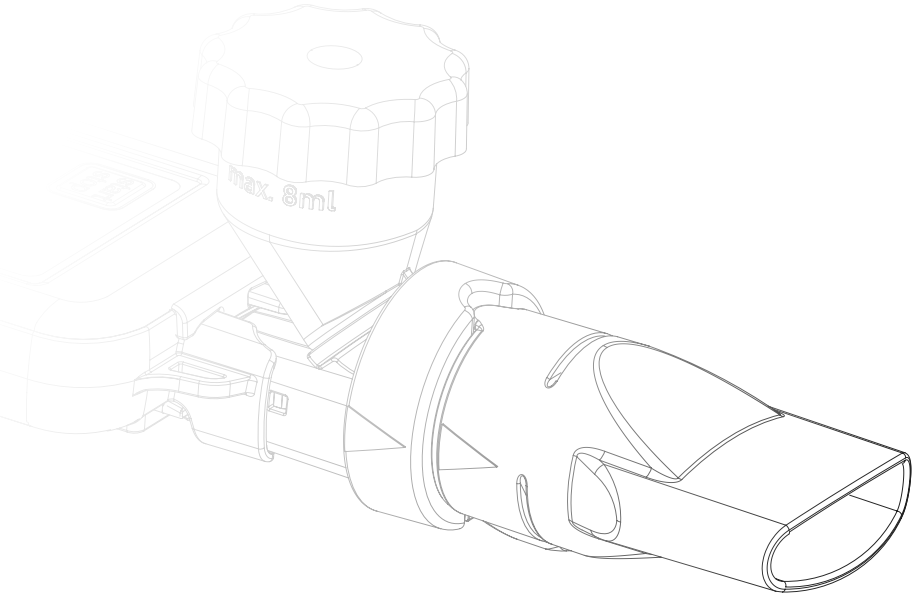
M-neb® mobile
mesh nebulizer

OPERATING MANUAL

M-neb® mobile mesh nebulizer MN-300/9

PROFESSIONAL



OVERVIEW

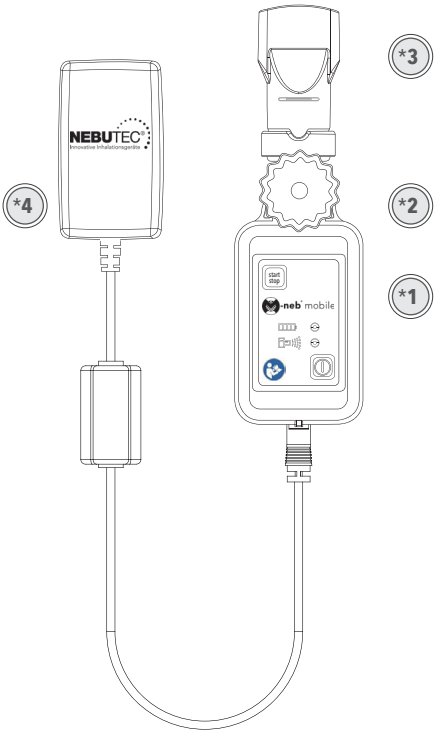


Fig. 01 - MN-300/9 - Overview M-neb® mobile mesh nebulizer MN-300/9

Legend	Item number	Designation
*1	20100263	M-neb® mobile mesh nebulizer MN-300/9 control unit
*2	20100331	M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. 3x M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti PROFESSIONAL)
*2	20100332	M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 6.0 µm PROFESSIONAL (incl. 3X M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti PROFESSIONAL) - available as an option -
*3	20100351	M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti PROFESSIONAL - 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
Fax: +49 (0) 6022 – 610 62 99

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

M-neb® mobile mesh nebulizer MN-300/9

Made in Germany

TABLE OF CONTENTS

1.0 ICONS

The icons shown below can be seen on your M-neb® mobile mesh nebulizer MN-300/9, the respective accessories and the respective packaging.

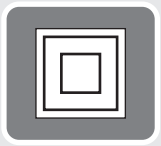
Figure	Definition
	Manufacturer; displays the manufacturer of the medical device.
	Caution; stresses the need for the user to review the instructions on important safety-related information such as warnings and precautions which cannot be placed on the medical device itself for a variety of reasons.
	Device of protection class II
	Type BF applied part
	IP Schutzklasse [protection class] IP2X: Protection against the penetration of solids Ø ≥ 12.5mm 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.

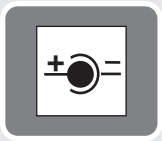
Figure	Definition
	Follow instructions for use; stresses the need for the user to consult the instructions for use. The icon is blue/white in the original.
	Do not dispose of in normal household waste.
	Item number; displays the order number of the manufacturer, so that the medical device can be identified.
	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
	Start-/Stop 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.

Figure	Definition
	Temperature range; the temperature range is designated in which the medical device can be safely used.
	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.

ATTENTION

Please carefully read through the instructions for use before first use of the M-neb® mobile mesh nebulizer MN-300/9. 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. Before commencing treatment, make sure that the nebulizer unit is filled with the correct volume of inhalation solution.

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. Before commencing treatment, make sure that the cap is correctly replaced and closed.

31. Please note that inhalation solutions released into the air may affect any persons present.

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

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

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

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

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

37. 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® mobile mesh nebulizer MN-300/9 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.

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 nebulizer unit may damage the aerosol generator or the 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 30 minutes in the manual mode. The maximum nebulization time per session (per press of the Start/Stop button) in manual mode is 60 seconds. If the Start/Stop button is pressed for longer than this, the control unit switches off automatically. The maximum running time in continuous mode is 30 minutes. The maximum standby time (readiness to start manual mode or change the operating mode) is 60 seconds. 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® mobile mesh nebulizer MN-300/9 (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® mobile nebulizer unit MMD 4.0 µm, the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm and the M-neb® mobile 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. Do not use a syringe with a cannula to fill the nebulizer unit. If a syringe with a cannula is used to fill the nebulizer unit, the cannula must be removed before injecting the inhalation solution into the nebulizer unit.

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

3.0 PURPOSE

The M-neb® mobile mesh nebulizer MN-300/9 is a vibrating nebulizer system for treatment of the lower respiratory tract. The M-neb® mobile mesh nebulizer MN-300/9 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® mobile mesh nebulizer MN-300/9 nebulizer system may be used by all patients who can inhale with a mouthpiece.

Persons who are unable to use the M-neb® mobile mesh nebulizer MN-300/9 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.

The M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. 3x M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti) may only be used by one patient for hygienic reasons. The M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL without mouthpiece is intended for reuse for up to three applications. The M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti is a single-use product. The frequency of use depends on the inhalation therapy prescribed by the physician.

The M-neb® mobile mesh nebulizer MN-300/9 nebulizer system is a reusable medical device with an intended operating life of 6 years.

The M-neb® mobile mesh nebulizer MN-300/9 nebulizer system may be used in professional healthcare facilities.

There are no indications of product-related side effects. The M-neb® mobile mesh nebulizer MN-300/9 nebulizer system is not suitable for patients who cannot breathe on their own.

3.1 Functional description M-neb® mobile mesh nebulizer MN-300/9

The M-neb® mobile mesh nebulizer MN-300/9 has two nebulization modes (manual mode and continuous mode). The default setting of the M-neb® mobile mesh nebulizer MN-300/9 is the manual mode.

All aerosol production of the M-neb® mobile mesh nebulizer MN-300/9 is triggered by pressing the Start/Stop button and is indicated by the blue LED of the operating mode status indicator and of the M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti).

3.2 Nebulization modes

The specific nebulization modes of the M-neb® mobile mesh nebulizer MN-300/9 are explained in this chapter.

3.2.1 Manual mode

In manual mode, aerosol production is triggered by pressing the Start/Stop button.

In manual mode, the blue LED of the operating mode status indicator and the M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti) light up during each phase of the aerosol production during inhalation.

The manual mode is set as the default at the factory for the M-neb® mobile mesh nebulizer MN-300/9 device.

3.2.1.1 Aerosol production in manual mode

	Second 0 Action: Start/Stop button pressed	**Second 60** Release (maximum 60 seconds [standby time]) and press the Start/Stop button again (within 60 seconds).	**Second 60 +** Maximum nebulization time -> the control unit switches off
Blue LED	**As long as you hold down the Start/Stop button, the blue LED will light up for the duration of aerosol production.**	**As long as you hold down the Start/Stop button again, the blue LED will light up for the duration of aerosol production.**	**The blue LED and the control unit switch off.**
Aerosol production	**The device will produce aerosol as long as you hold down the Start/Stop button.**	**As long as you hold down the Start/Stop button again, the device will produce aerosol.**	**Aerosol production stops and the control unit switches off.**
	First aerosol production	**Second and subsequent aerosol production**	**Switch off after maximum running times**

3.2.2 Continuous mode

In continuous mode, the M-neb® mobile mesh nebulizer MN-300/9 continuously produces aerosol. In continuous mode, the blue LED of the operating mode status indicator and the M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti) light up continuously for the time of aerosol production.

The continuous mode is available in the M-neb® mobile mesh nebulizer MN-300/9 device. The continuous mode must be selected in the M-neb® mobile mesh nebulizer MN-300/9 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® mobile mesh nebulizer MN-300/9 switches off automatically once the filled inhalation substance has been completely aerosolised. Each nebulization mode is equipped with the automatic switch off.

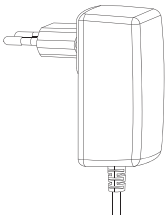
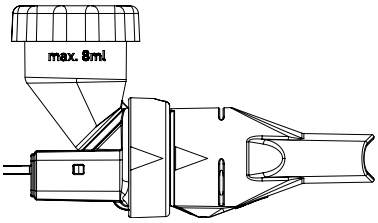
3.4 Maximum runtimes

The maximum runtime is 30 minutes in the manual mode. The maximum nebulization duration at one time (per pressing of the Start/Stop button) in manual mode is 60 seconds. If the Start/Stop button is pressed for longer, the M-neb® mobile mesh nebulizer MN-300/9 switches off automatically. The maximum runtime is 30 minutes in the continuous mode.

The maximum standby time (readiness to starting the manual mode or changing to the operating mode) is 60 seconds. If the maximum runtime in the respective mode is reached, the M-neb® mobile mesh nebulizer MN-300/9 is switched off automatically.

4.0 DELIVERY SCOPE FOR YOUR M-NEB® MOBILE MESH NEBULIZER MN-300/9

The following components belong to your M-neb® mobile mesh nebulizer MN-300/9 delivery scope:

Quantity	Item no.	Designation	Figure
1 pc.	20100263	M-neb® mobile mesh nebulizer MN-300/9 control unit	
1 pc.	20100206	M-neb® mesh nebulizer MN-300/X power cord (type: wGTM96060- 0606-1.0)	
1 pc.	20100331	M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. 3X M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti PROFESSIONAL)	

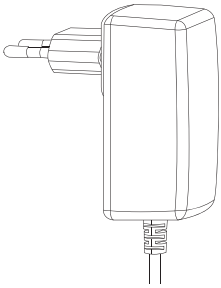
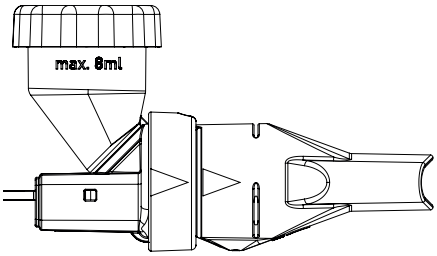
NOTE

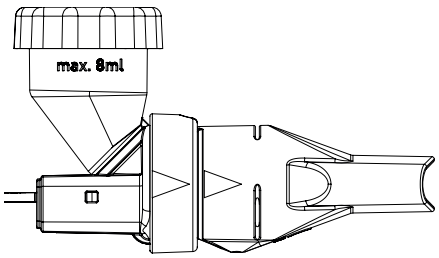
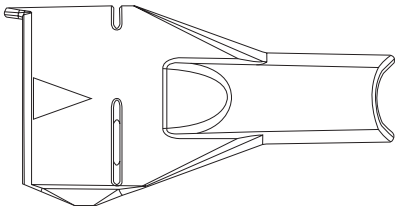
Before the first use of the M-neb® mobile mesh nebulizer MN-300/9, please check the delivery scope for completeness. Also, check the delivered components for obvious, visible defects, impurities, cracks or damage. Never use the M-neb® mobile mesh nebulizer MN-300/9 or its components if they show visual defects or faults.
In this case, contact the manufacturer or your dealer.

5.0 THE MOST IMPORTANT COMPONENTS OF YOUR M-NEB® MOBILE MESH NEBULIZER MN-300/9

Before you use your M-neb® mobile mesh nebulizer MN-300/9 for the first time, take some time to familiarise yourself with the device and the accessories.

All components of the M-neb® mobile mesh nebulizer MN-300/9 are listed in the table below.

Item no.	Designation	Figure
20100263	M-neb® mobile mesh nebulizer MN-300/9 control unit Hereafter referred to as "M-neb mobile control unit".	
20100206	M-neb® mesh nebulizer MN-300/X power cord (Type: GTM96060-0606-1.0) Hereafter designated as "M-neb® power cord".	
20100331	M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. 3X M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti PROFESSIONAL) Hereafter referred to as "M-neb® mobile nebulizer unit MMD 4.0 µm".	

Item no.	Designation	Figure
20100332	**M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 6.0 µm PROFESSIONAL (incl. 3x M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti PROFESSIONAL) Hereinafter referred to as "M-neb® mobile nebulizer unit MMD 6.0 µm".** **- available as an option -**	
20100351	**M-neb® mobile mesh nebulizer MN-300/9 mouthpiece opti PROFESSIONAL Hereinafter referred to as "M-neb® mobile mouthpiece".** **- available as an option -**	

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

If the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm is used, this is included in the definition of the application part instead of the M-neb® mobile nebulizer unit MMD 4.0 µm.

6.0 FIRST USE OF YOUR M-NEB® MOBILE MESH NEBULIZER MN-300/9

NOTE

The commissioning of the M-neb® mobile control unit is described in this chapter using the M-neb® mobile nebulizer unit MMD 4.0 µm. This information is also valid when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm.

6.1 Fill M-neb® mobile nebulizer unit MMD 4.0 µm

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°.

NOTE

Do not use a syringe with a cannula to fill the M-neb® mobile nebulizer unit MMD 4.0 µm. If a syringe with a cannula is used to fill the M-neb® mobile nebulizer unit MMD 4.0 µm, the cannula must be removed before injecting the inhalation solution into the M-neb® mobile nebulizer unit MMD 4.0 µm.

CAUTION

The use of a cannula to fill the M-neb® mobile nebulizer unit MMD 4.0 µm may damage the aerosol generator or the M-neb® mobile nebulizer unit MMD 4.0 µm.

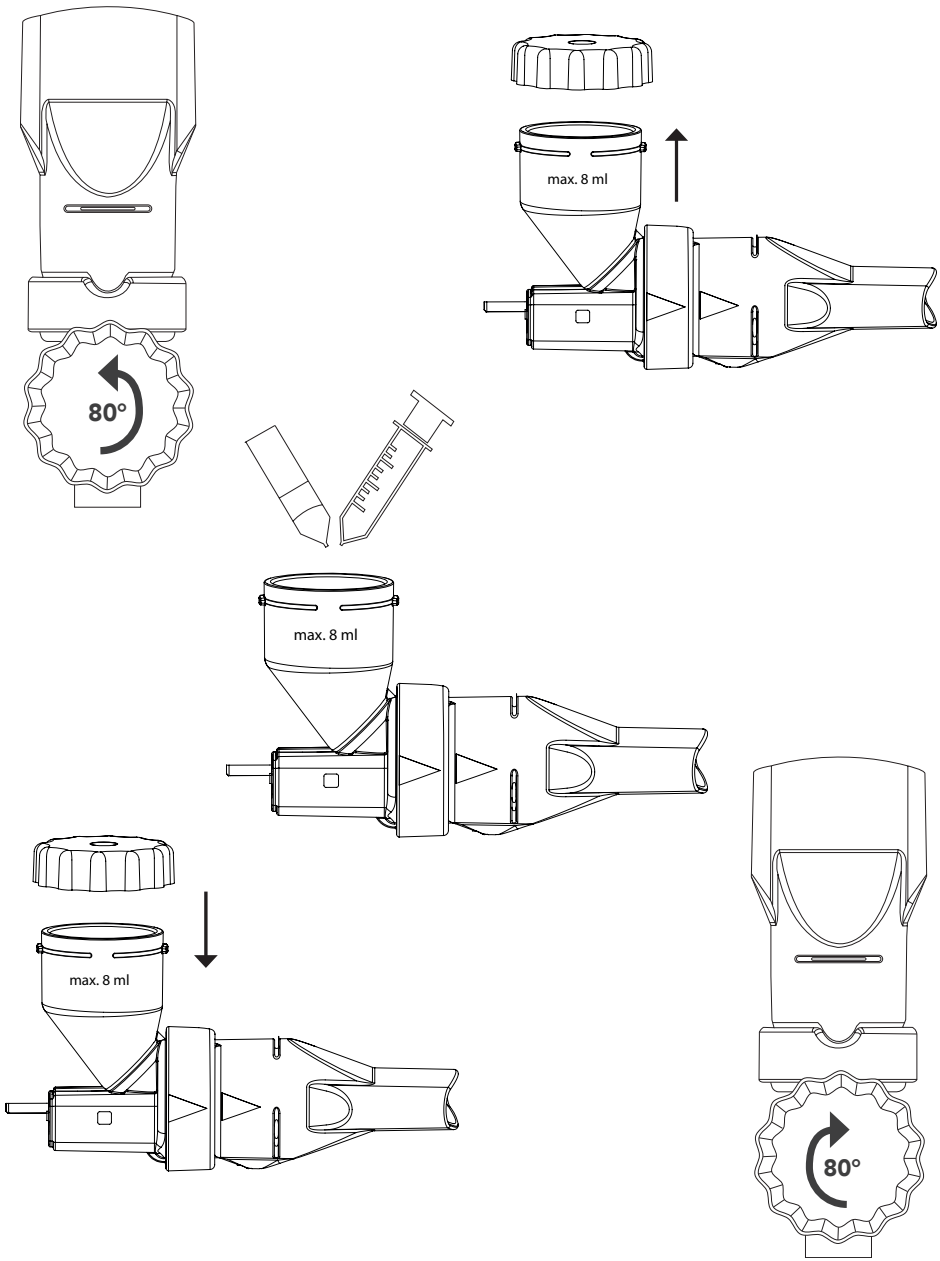


Fig. 02 - MN-300/9 - Fill M-neb® mobile nebulizer unit MMD 4.0 µm

6.2 Connect M-neb® mobile nebulizer unit to the M-neb® mobile control unit

Then connect the filled M-neb® mobile nebulizer unit MMD 4.0 µm to the M-neb® mobile control unit. To do this, connect the female USB socket on the M-neb® mobile control unit to the male USB connector on the M-neb® mobile nebulizer unit MMD 4.0 µm.

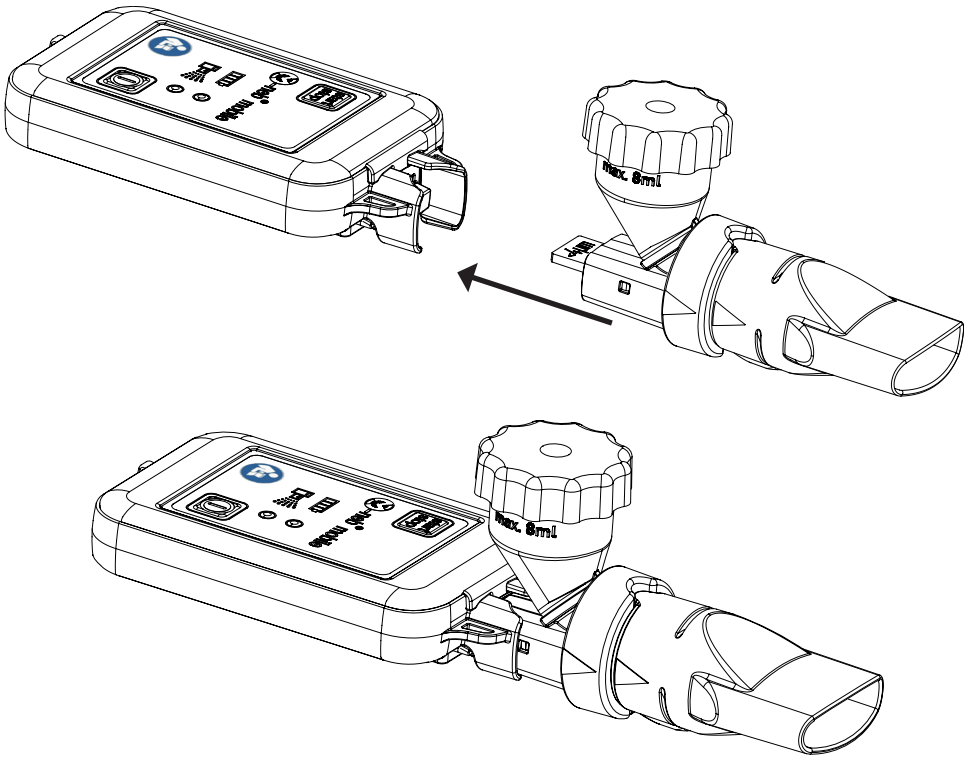


Fig. 03 - MN-300/9 - Connect M-neb® mobile nebulizer unit MMD 4.0 µm to M-neb® mobile control unit

6.3 Starting and carrying out inhalation

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

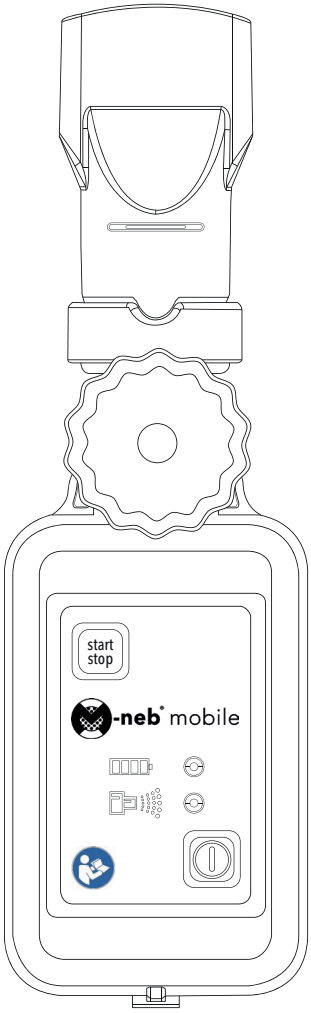


Figure	Definition
	Battery status indicator (Explanation on this in Chapter 11.0 "Diode displays")
	Operating mode status indicator (Explanation on this in Chapter 11.0 "Diode displays")
	On/Off button
	Start/Stop button

Fig. 04 - MN-300/9 - Definition of the status displays and buttons

For inhalation in manual mode, coordinate inhalation and exhalation by pressing the Start/Stop button.

First exhale. Then place your mouth around the M-neb® mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm. Now press the Start/Stop button to trigger aerosol production. As long as you keep the Start/Stop button pressed, the unit produces aerosol. Inhale the aerosol produced. Release the Start/Stop button again when the inhalation is completed and the aerosol production stops.

Do **not** exhale through the M-neb® mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm. Put the mouthpiece down to exhale.

To perform the next inhalation process, place your mouth around the M-neb® mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm. Then press the Start/Stop button to trigger the production of another aerosol dose. Inhale the aerosol produced as long as you press the Start/Stop button. To exhale, put down the M-neb® mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm again and do **not** exhale through the M-neb® mobile mouthpiece.

Repeat this procedure until the filled medication has been completely aerosolised by the M-neb® mobile nebulizer unit MMD 4.0 µm.
The M-neb® mobile control unit switches off automatically.

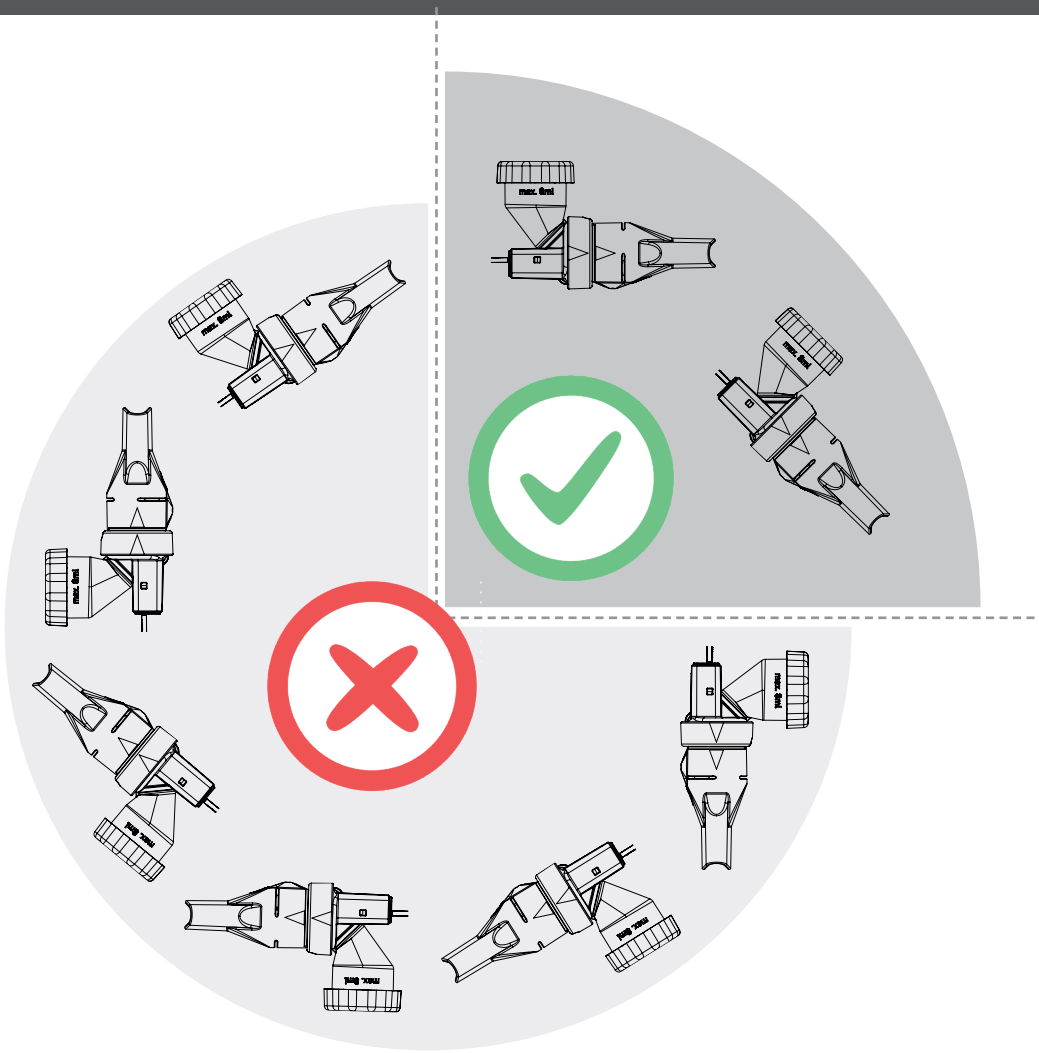


Fig. 05 - MN-300/9 - M-neb® mobile - the above illustration shows the correct alignment of the device.

ATTENTION

When nebulizing inhalation solutions that tend to form foam during aerosol production, the automatic shut-off 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

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 M-neb® mobile nebulizer unit MMD 4.0 µm will light up blue for the duration of the aerosol production.

Note the two arrows on the M-neb® mobile nebulizer unit MMD 4.0 µm and on the M-neb® mobile mouthpiece. These arrows indicate the direction of the gas volume flow.

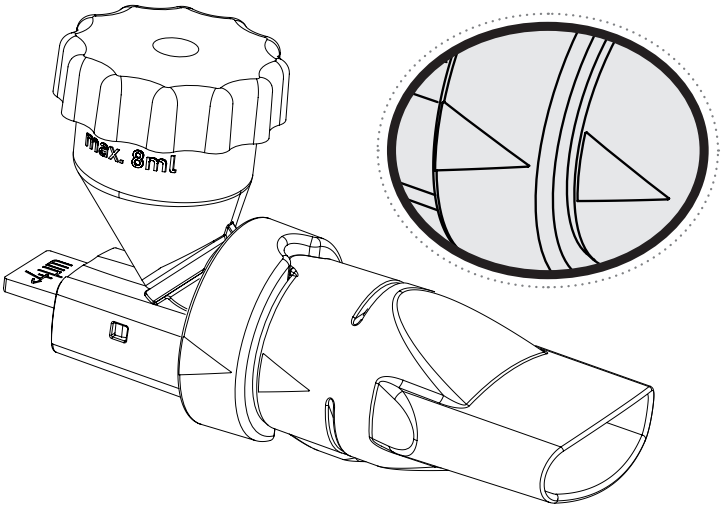


Fig. 06 - MN-300/9 - Direction of the gas volume flow

6.4 Switching off the M-neb® mobile control unit

To stop or pause nebulization prematurely, the M-neb® mobile control unit must be switched off. To do this, press (> 1 second) the On/Off button on the M-neb® mobile control unit. The M-neb® mobile control unit switches off. This is indicated by a short acoustic signal and the battery status display turns off.

For a definition of the status displays and buttons, please refer to Figure 04 and the table on page 31.

6.5 Changing the operating modes

The default setting of the M-neb® mobile control unit is the manual mode. When you have switched on the M-neb® mobile control unit, the M-neb® mobile control unit is in manual mode.

The following describes how to change the operating modes when the M-neb® mobile control unit is in the switched-off state.

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

The M-neb® mobile control unit is now in the manual mode, where the aerosol production is triggered by using the Start/Stop button.

Now you can change the operating mode from the manual mode to continuous mode in a time window of 60 seconds, which is equivalent to the maximum standby time.

To do this, press (< 1 second) the On/Off button on the M-neb® mobile control unit. Two consecutive, short, acoustic signal tones will sound and the operating mode status indicator will light up continuously in blue. The M-neb® mobile control unit is now in continuous mode and nebulizes continuously (provided the medication is filled into the M-neb® mobile nebulizer unit MMD 4.0 µm).

If you want to switch back from continuous mode to manual mode, press (< 1 second) the On/Off button on the M-neb® mobile control unit again. A short, audible signal tone sounds and the blue LED of the operating mode status display goes out.

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

Please note that the M-neb® mobile control unit may also shut down automatically through the following functions:
Auto Shut-Off: The device will automatically power down regardless of the selected nebulization mode once the filled medication has been completely aerosolized.
Maximum Runtime Limits: The device will shut off automatically upon reaching its predefined maximum operating time.

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

- The maximum duration is 30 minutes in manual mode.
- The maximum nebulization duration at one time (per pressing of the Start/Stop button) in manual mode is 60 seconds. If the Start/Stop button is pressed for longer, the M-neb® mobile control unit switches off automatically.
- The maximum duration is 30 minutes in continuous mode.
- The maximum standby time (readiness to start the manual mode or change to the operating mode) switches the M-neb® mobile control unit off after 60 seconds of inactivity.

6.6 Use of the continuous mode

The M-neb® mobile control unit has two nebulization modes (manual mode and continuous mode). The default setting of the M-neb® mobile control unit is the manual mode. To operate the M-neb® mobile control unit in continuous mode, this must be selected. To do this, proceed as follows:

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

Now you can change the operating mode from the manual mode to continuous mode in a time window of 60 seconds which is equivalent to the maximum standby time.

To do this, press the on/off button on the M-neb® mobile control unit (< 1 second). Two consecutive, short, acoustic signal tones sound and the operating mode status indicator lights up continuously blue. The M-neb® mobile control unit is now in continuous mode.

In continuous mode, the unit nebulizes continuously (provided the medication is filled into the M-neb® mobile nebulizer unit MMD 4.0 µm). To perform the next inhalation process, place your mouth around the M-neb® mobile mouthpiece of the M-neb mobile nebulizer unit MMD 4.0 µm. Inhale the aerosol produced during inhalation. When inhalation is finished, put down the M-neb mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm.

Do **not** exhale through the M-neb® mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm.

During exhalation, the device continues to continuously produce aerosol. To carry out the next inhalation process, enclose the M-neb® mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm with your mouth again. During inhalation, inhale the aerosol produced. When inhalation is complete, put the M-neb® mobile mouthpiece of the M-neb® mobile nebulizer unit MMD 4.0 µm back down and breathe 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® mobile control unit. The M-neb® mobile 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® mobile control unit could heat up too much.

7.0 POWER SUPPLY

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

The M-neb® mobile 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® mobile control unit.

WARNING

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

The M-neb® mobile 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® mobile control unit.

8.0 CHARGING OF THE M-NEB® MOBILE CONTROL UNIT

The capacity status of the M-neb® mobile control unit is displayed on the battery status indicator of the M-neb® mobile 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® mobile control unit switches off automatically.

ATTENTION

If the M-neb® mobile 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® mobile control unit. If the capacity falls below the limit of 10%, the battery of the M-neb® mobile control unit must be charged. Otherwise, the remaining capacity of the M-neb® mobile control unit may not be sufficient for a complete inhalation process.

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

Fig. 07a - MN-300/9 - Charging the M-neb® mobile control unit

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

When the battery of the M-neb® mobile control unit is being charged, the battery status indicator flashes green (ratio: 1 second green / 1 second pause).

When the battery of the M-neb® mobile control unit is charged, the battery status indicator flashes green (ratio 1/10 second green / 1 second pause).

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

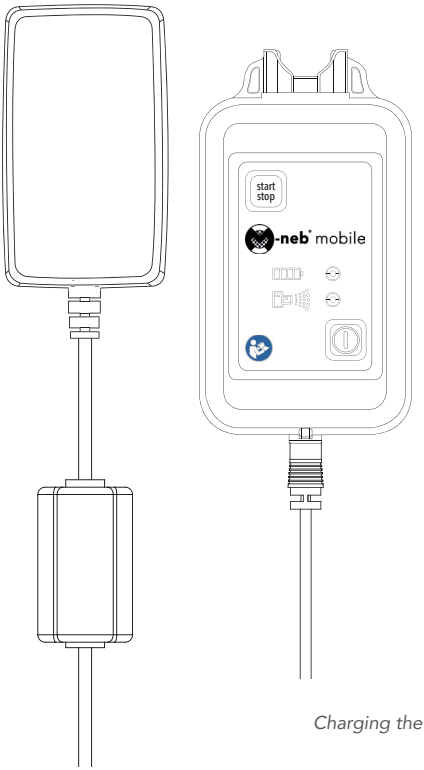
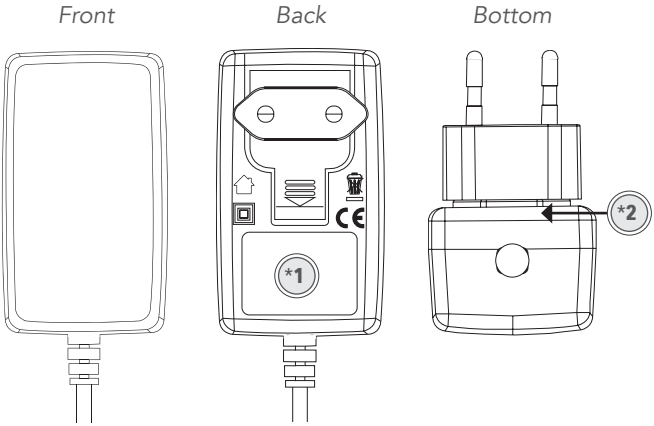
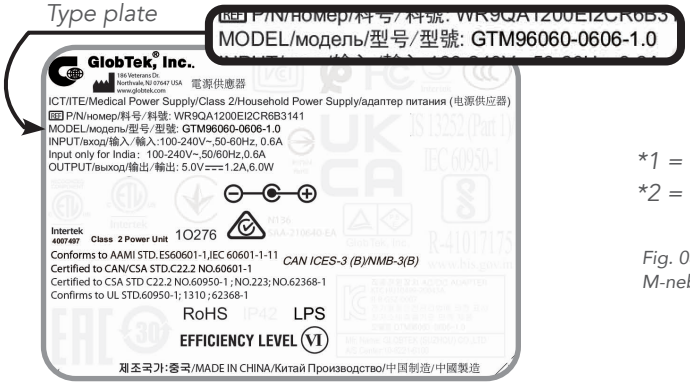


Fig. 07b - MN-300/9 -
Charging the M-neb® mobile control unit

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-300/9 -
M-neb® power cord MN-300/X

NOTE

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

CAUTION

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

9.0 CLEANING AND DISINFECTION

NOTE

Cleaning and disinfection is described in this chapter using the M-neb® mobile nebulizer unit MMD 4.0 µm. This information is also valid with the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm.

9.1 Disinfection of the M-neb® mobile control unit

No cleaning or disinfection is intended for the M-neb® mobile nebulizer unit MMD 4.0 µm. The M-neb® mobile nebulizer unit MMD 4.0 µm may be used a maximum of three times within one day by a single patient; the M-neb® mobile mouthpiece must be replaced after each use. Store the M-neb® mobile nebulizer unit MMD 4.0 µm in a dry and dust-free place between uses.

9.2 Disinfection of the M-neb® mobile control unit

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

9.2.1 Preparation

- Remove the M-neb® power cord from the M-neb® mobile control unit.
- Remove the M-neb® mobile control unit from the M-neb® mobile nebulizer unit MMD 4.0 µm.

9.2.2 Disinfection

- Wipe the outer surfaces of the M-neb® mobile control unit after every third use or once a day with ready-to-use alcoholic disinfectant wipes (e.g. Bode Bacillol® 30 Tissues disinfectant wipes).
- Allow the M-neb® mobile control unit to dry on a dry and clean surface.

NOTE

Penetrated liquids can cause a device defect.
Do not immerse the M-neb® mobile control unit in liquids.

9.2.3 Visual inspection

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

9.2.4 Storage

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

10.0 MAINTENANCE

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

WARNING

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

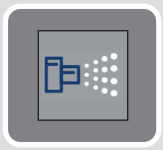
WARNING

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® mobile 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 is controlled so that: - the green LED lights up during operation when the capacity is above 30 %. - the green LED flashes alternately with the red LED (flash ratio 1 second : 1 second) when the battery capacity is between 10 % and 30 %. - the red LED flashes briefly, accompanied by an acoustic signal when the battery capacity is below 10 %. Control unit switches off. - the green LED flashes intermittently (1 second : 1 second) when the charging process is active. - the green LED flashes intermittently (1/10 second on, 1 second off) when the charging process is complete. - the red LED flashes briefly, accompanied by an acoustic signal when the standby time (60 seconds or 1 minute) has been exceeded. - the red LED flashes briefly, accompanied by an acoustic signal when the maximum runtime in continuous mode (30 minutes) has been exceeded. - the red LED flashes briefly, accompanied by an acoustic signal when the maximum runtime in manual mode (30 minutes or 60 seconds of Start/Stop button activation) has been exceeded. - the red LED flashes briefly, accompanied by an acoustic signal when automatic shutdown has occurred.

Illustration	Diode	Significance
	Operating mode status display	The operating mode status indicator [LED blue] lights up: - permanently blue when the HF amplifier is activated (power indicator). - permanently blue, accompanied by an acoustic signal when the mode has been changed from manual to continuous mode. - turns off, accompanied by an acoustic signal when the mode has been changed from continuous to manual mode.

12.0 AMBIENT CONDITIONS

In the following chapters, the ambient conditions of the M-neb® mobile mesh nebulizer MN-300/9 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® mobile mesh nebulizer MN-300/9 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® mobile mesh nebulizer MN-300/9 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 + INTENDED OPERATIONS LIFE

13.1 Treatment duration

The M-neb® mobile nebulizer unit MMD 4.0 µm and the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm are consumables and may be used for a maximum of three applications per patient (m/f/d). The M-neb® mobile mouthpiece is a consumable item and may be used once per patient (m/f/d).

They should be replaced with new consumable items after this maximum therapy duration.

The administration of 1 ml of saline solution can take up to 4 minutes in continuous mode. In manual mode, the duration depends heavily on how often and for how long the delivery is started and stopped by pressing the start-stop button – it cannot therefore be generalised.

13.2 Intended operating life

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

Components	Intended operating life
M-neb® mobile control unit M-neb® power cord	6 years
M-neb® mobile nebulization unit MMD 4,0 µm M-neb® mobile nebulization unit MMD 6,0 µm M-neb® mobile mouthpiece	3 applications (maximum) 3 applications (maximum) 1 application (maximum)

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

14.0 DISPOSAL

Information requirements towards companies

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 professional healthcare facilities.

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) Return is subject to a fee via our own take-back scheme with NOEX, for which the costs are charged separately.
   The processing of each disposal order is carried out via a supply chain system specially designed for such take-backs, which also ensures the traceability of all disposal orders carried out and monitoring in accordance with §27 Para. 1 No. 5 et seq. of ElektroG.

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 SPECIFICATIONS

M-neb® mobile control unit:

Size (L x W x H)	99 x 54 x 19 mm
Weight	73 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 / 6 W
Power consumption during operation	≤ 1000 mA
Working frequency	110 KHz
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® mobile nebulizer unit MMD 4.0 µm or MMD 6.0 µm:

	MMD 4,0 µm	MMD 6,0 µm
Size (L x W x H) without mouthpiece Size (L x W x H) with mouthpiece	56 x 33 x 53 mm 95 x 33 x 53 mm	56 x 33 x 53 mm 95 x 33 x 53 mm
Maximum filling quantity	8 ml	8 ml
Weight without mouthpiece Weight with mouthpiece	20 g 27 g	20 g 27 g
Nebulizer output	< 0,5 ml/min	< 0,6 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® mobile mesh nebulizer MN-300/9 nebulizer system.

16.1.1 Performance data of the M-neb® mobile control unit when using the M-neb® mobile nebulizer unit MMD 4.0 µm

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® mobile 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® mobile nebulizer unit.
This corresponds to an aerosol delivery of 0.4 ml sodium chloride per minute when using the M-neb® mobile nebulizer unit MMD 4.0 µm.

16.1.2 Performance data for the M-neb® mobile control unit when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm

The aerosol delivery according to DIN EN 13544-1/Annex CC - CC.1.4 is 5.0+/- 0.02 mg sodium chloride per minute when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm. The aerosol delivery according to DIN EN 13544-1/Annex CC - CC.2 is 2.97 mg sodium chloride per minute when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm. This corresponds to an aerosol delivery of 0.57 ml sodium chloride per minute when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm.

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® mobile mesh nebulizer MN-300/9 nebulizer system.

16.2.1 Performance data for the M-neb® mobile control unit when using the M-neb® mobile nebulizer unit MMD 4.0 µm

Normative requirement	Value
in the case of a gas-operated nebulizer, the test gas used;	The M-neb® mobile mesh nebulizer MN-300/9 nebulizer system is not a gas-operated nebulizer. No test gas was used
The test solution	Salbutamol 0.1 % (in 0.9 % sodium chloride) Exact 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 %

16.2.2 Performance data of the M-neb® mobile control unit when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm

Normative requirement	Value
with a gas-powered nebulizer test gas used;	The M-neb® mobile mesh nebulizer MN-300/9 nebulizer system is not a gas-powered nebulizer No test gas was used;
the sample solution	Salbutamol 0.1% (in 0.9% sodium chloride) Exact concentration: 1,018 mg / ml Density: 1.00414 g/ml
the filling volume and the flow rate used	Filling volume: 2.0 ml Flow rate used: not applicable Breath Simulator Settings: Breaths per minute: f = 15 breaths/min Inspiration/expiration ratio: 1:1 Tidal volume (stroke volume) (Vt): 500 ml
the aerosol output expressed as the mass of the test substance collected by the filter or filters;	1628 µg
is the rate of aerosol delivery expressed as the mass of the test substance collected by the filter(s) per minute;	806 µg / min
the nebulization time;	127 sec.
the remaining volume	15 µl
the percentage of the given Fill volume in 1 min, expressed as the aerosol delivery in 1 min divided by the manufacturer's recommended fill volume, or 2 mL if no fill volume is recommended (e.g. 20% of the filling volume per minute).	40 %

17.0 AEROSOL SPECTRUM

17.1 Aerosol spectrum EN 13544-1

The particle size was determined and specified according to EN ISO 13544-1 / Annex CC for the M-neb® mobile mesh nebulizer MN-300/9 nebulizer system.

17.1.1 Aerosol spectrum of the M-neb® mobile control unit when using the M-neb® mobile nebulizer unit MMD 4.0 µm

According to EN ISO 13544-1 / Annex CC, the particle size of the M-neb® mobile mesh nebulizer MN-300/9 averages 3.68 µm MMD with a GSD of 1.64 when using the M-neb® mobile nebulizer unit MMD 4.0 µm.

17.1.2 Aerosol spectrum of the M-neb® mobile control unit when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm

According to EN ISO 13544-1 / Annex CC, the particle size of the M-neb® mobile mesh nebulizer MN-300/9 averages 6.32 µm MMD with a GSD of 2.00 when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm.

17.2 Aerosol spectrum EN 27427

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

The values below are based on testing according to the standard EN ISO 27427 Annex D - "Test methods 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.

The particle size was determined and specified according to EN ISO 27427 Annex D - "Test method for particle size" for the M-neb® mobile mesh nebulizer MN-300/9 nebulizer system.

17.2.1 Aerosol spectrum of the M-neb® mobile control unit when using the M-neb® mobile nebulizer unit MMD 4.0 µm

The particle size of the M-neb® mobile mesh nebulizer MN-300/9 nebulizer system is according to EN ISO 27427 Appendix D - "Test method for particle size" on average 4.4 µm MMAD with a GSD of 2.08 with Salbutamol when using the M-neb® mobile nebulizer unit MMD 4.0 µm.

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® mobile mesh nebulizer MN-300/9 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.

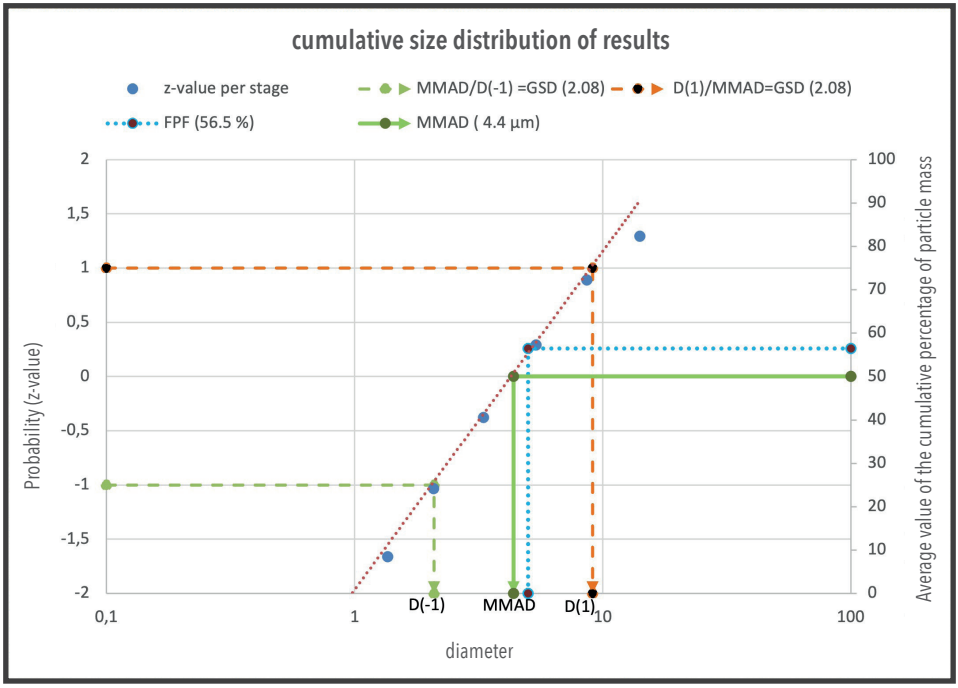


Fig. 09 - MN-300/9 - Cumulative size distribution of the results.
The mean value of three different devices is shown.

17.2.2 The aerosol spectrum for the M-neb® mobile control unit when using the M-neb® mobile nebulizer unit 6 µm

The particle size of the M-neb® mobile mesh nebulizer MN-300/9 in accordance with EN ISO 27427- 1/Annex D "testing of particle size" is on average 6.2 µm MMD at a GSD of 2.42 with Salbutamol when using the optionally available M-neb® mobile nebulizer unit MMD 6.0 µm.

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	6.2 µm
GSD (geometric standard deviation) calculated as MMAD/D(-1) or D(1)/MMAD	2.42
Respirable fraction in % - Aerosol particles ≤ 5 µm	39.8 %
Aerosol fraction in % - aerosol particles < 5 and > 2 µm	31.3 %
Aerosol fraction in % - aerosol particles ≤ 2 µm	8.5 %
in the case of a gas-operated nebulizer, the test gas used;	The M-neb® mobile mesh nebulizer MN-300/9 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.

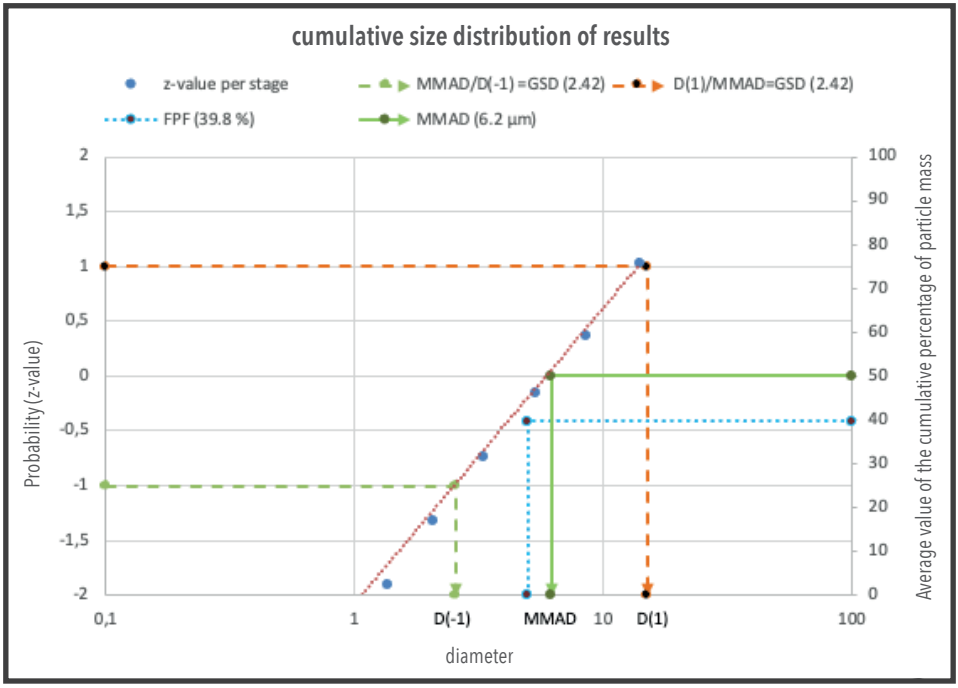


Fig. 10 - MN-300/9 - Cumulative size distribution of the results.
The mean value of three different devices is shown.

18.0 ACCESSORIES / ORDERING INFORMATION

The following accessories are available from the manufacturer or dealer for your M-neb® mobile mesh nebulizer MN-300/9 nebulizer system:

Amount	Item number	Designation
1 pc.	20100026	M-neb® mobile mesh nebulizer MN-300/9 Starter kit PROFESSIONAL
1 pc.	20100263	M-neb®mobile mesh nebulizer MN-300/9 control unit
1 pc.	20100206	M-neb mesh nebulizer MN-300/X power cord (type: GTM96060-0606-1.0)
1 pc.	20100331	M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 4.0 µm PROFESSIONAL (incl. 3x M-neb® mobile mesh nebulizer MN-300/9 Mouthpiece opti PROFESSIONAL)
1 pc.	20100332	M-neb® mobile mesh nebulizer MN-300/9 nebulizer unit MMD 6.0 µm PROFESSIONAL (incl. 3x M-neb® mobile mesh nebulizer MN-300/9 Mouthpiece opti PROFESSIONAL)
1 pc.	20100351	M-neb® mobile mesh nebulizer MN-300/9 Mouthpiece opti PROFESSIONAL

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

Tel.: +49 (0) 6022 – 610 62 -0
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-300/9 is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or the user of the nebulizer MN-300/9 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-300/9 uses HF 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-300/9 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® mobile mesh nebulizer MN-300/9 and its accessories. Non-observance can lead to a reduction in the performance characteristics.

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The nebulizer MN-300/9 is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or the user of the nebulizer MN-300/9 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 Stroke 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.

The following products are covered by a warranty period of 24 months from the date of purchase:

- M-neb® mobile 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® mobile control unit

The M-neb® mobile nebulizer unit and the M-neb® mobile 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-300-9_IFU-PROFESSIONAL-ENG_E / July 2025

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

Tel.: +49 (0) 6022 – 610 62 -0
Fax: +49 (0) 6022 – 610 62 -99

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