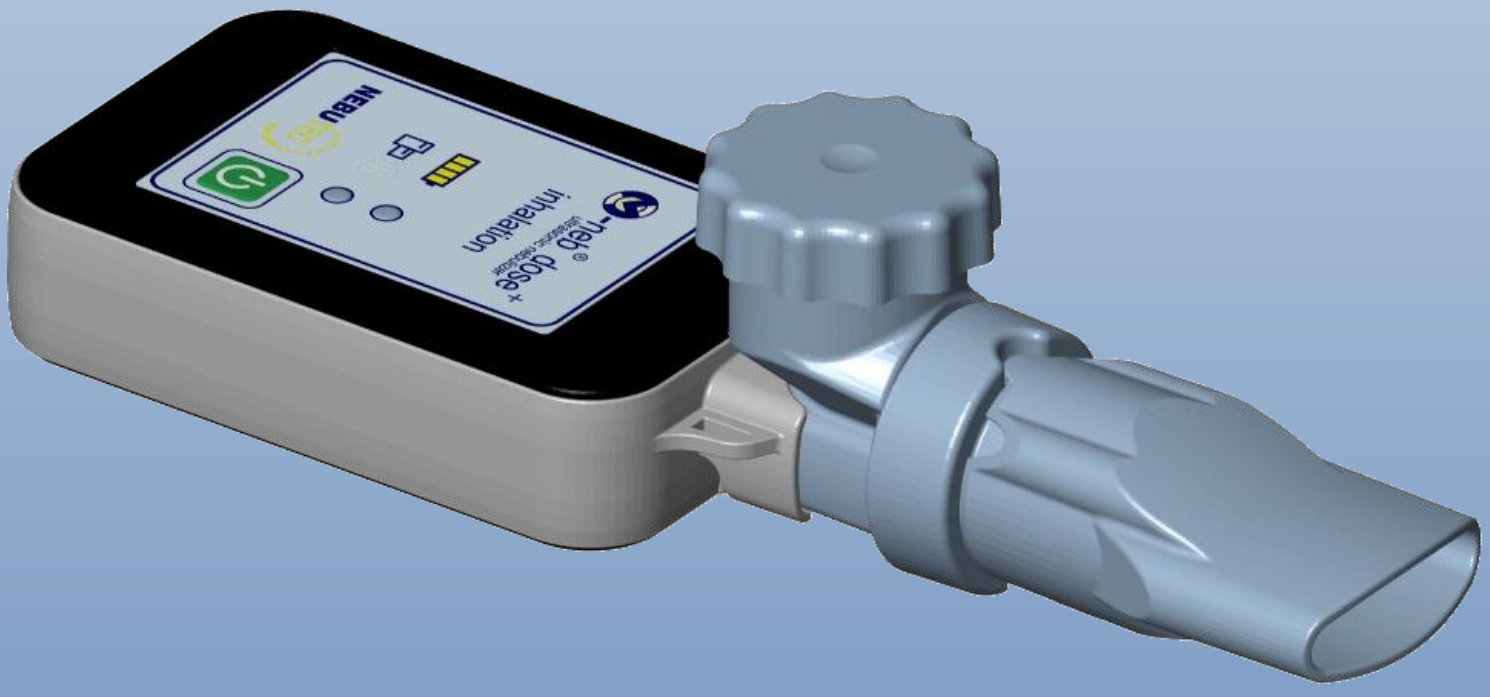
M-neb®

ultrasonic nebulizer



Instructions for use:
M-neb® dose+ mesh nebulizer MN-300/8

Key:	Number:	Designation:
*1	20100262	M-neb® dose+ mesh nebulizer MN-300/8 (control unit)
*2	20100206	M-neb® power cord MN-300/X (type: GTM41076-0605-A)
*3	20100268	M-neb® dose+ nebulizer unit MN-300/8 (incl. M-neb® dose+ mouthpiece MN-300/8)
*4	20100269	M-neb® dose+ mouthpiece MN-300/8 *available as an option*

M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 01

Manufacturer

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M-neb® dose+

mesh nebulizer

MN-300/8

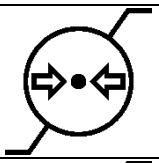
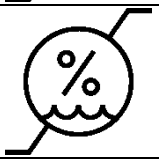
Made in Germany

Table of contents

1.0 Icons

The icons are shown below that you see on your M-neb® dose+ mesh nebulizer MN-300/8, the respective accessories and their packaging.

Figure	Definition
	**Manufacturer; displays the manufacturer of the medical device.**
	**Caution; stresses the need for the user to review the instructions for use on important safety-related information such as warnings and precautions which cannot be applied to the medical device for a variety of reasons.**
	**Device of protection class II**
	**Type B applied part**
CE0197	**CE mark including designation of the identification number of the notified body which has performed the conformity assessment procedure.**
	**Follow instructions for use; stresses the need for the user to consult the instructions for use.**
	**Do not dispose of in normal household waste.**
REF	**Item number; displays the order number of the manufacturer, so that the medical device can be identified.**
LOT	**Batch number; displays the batch number of the manufacturer, so that the lot can be identified.**
SN	**Serial number; displays the serial number of the manufacturer, so that a specific medical device can be identified.**

Figure	Definition
	**DC connection**
	**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.**
	**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.**

2.0 Safety information

Each handling of this 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 device.

 **CAUTION**
Information, which prevents damage to the product.

 **NOTE**
Information, which you should pay special attention to.

 **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 device in water or any other liquids.
2. Place the device so that it cannot fall into water.
3. Do not use the device if it has fallen into water.
4. Do not use the device while bathing.
5. The device is not suitable for use in the vicinity of flammable, aesthetic mixtures with air or nitrous oxide.
6. Do not bring the device into contact with heated surfaces.
7. The medications used must be approved for use with aerosols by the drug manufacturers. Only medications prescribed by the physician which are approved for use with medication nebulizers may be used.
8. Before beginning each treatment and before each use, check the battery level of the device.
9. Only use accessories certified by the manufacturer.
10. Protect the device against uncontrolled access.
11. Ensure that the medication has been filled in the nebulizer unit prior to starting treatment.
12. Ensure that the device's internal battery has been charged prior to starting treatment.
13. Never connect humid or wet nebulizer units to the control unit; prior to each use check that the nebulizer unit is dry.
14. The M-neb® dose+ mesh nebulizer MN-300/8 may not be placed directly next to other devices. If necessary, the device should be observed to verify its proper operation in the configuration used.
15. 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 observe this leads to the loss of the warranty claim.
16. Do not operate the M-neb® flow mesh nebulizer MN-300/3 when damage or defects to the M-neb® power cord MN-300/X (type: GTM41076-0605-A) are visible.
17. Protect the device and its accessories against uncontrolled access.

ATTENTION

1. An electrical device such as the M-neb® dose+ mesh nebulizer MN-300/8 should never be operated unattended.
2. Special caution is required if the device is used by or in the vicinity of children or seriously ill patients.
3. The device is exclusively and only to be used for the intended purposes listed in these instructions for use. Do not use accessories that are not recommended by the manufacturer.
4. Never operate this device when:
   a) the power cord or the plug is damaged.
   b) the device does not function properly.
   c) the device has been dropped or damaged.
   d) the device has fallen in water.
   In such cases, the 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 device is not suitable for use in the vicinity of flammable, aesthetic mixtures with air or nitrous oxide.

8. The M-neb® dose+ mesh nebulizer MN-300/8 (control unit) is operated exclusively via the internal, rechargeable battery.
9. Only use the supplied M-neb® power cord MN-300/X (type: GTM41076-0605-A).
10. The charging of the internal rechargeable battery (lithium ion battery) is carried out exclusively with the supplied M-neb® power cord MN-300/X (type: GTM41076-0605-A).
11. During the use of the M-neb® dose+ mesh nebulizer MN-300/8, check the proper function of the nebulizer.
12. Do not operate the M-neb® dose+ mesh nebulizer MN-300/8 when damage or defects to the M-neb® power cord MN-300/X (type: GTM41076-0605-A) are visible.
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 use for electromagnetic compatibility.
14. The USB connection of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) is only used for the connection to the M-neb® dose+ nebulizer unit MN-300/8. Do not use any other commercially available USB cable with the USB connection of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) (REF: 20100262).

CAUTION

1. Do not touch the aerosol generators in the M-neb® dose+ nebulizer unit MN-300/8 (with the M-neb® dose+ mouthpiece MN-300/8).
2. Never insert objects into the M-neb® dose+ nebulizer unit MN-300/8 (with the M-neb® dose+ mouthpiece MN-300/8).
3. Do not operate the M-neb® dose+ mesh nebulizer MN-300/8 when damage or defects to the M-neb® power cord MN-300/X (type: GTM41076-0605-A) are visible.
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 use for electromagnetic compatibility.
5. To avoid damage to the device and ensure compliance with the EMC Directive, only the original M-neb® power cord MN-300/X (type: GTM41076-0605-A) is used.
6. The USB connection of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) is only used for the connection to the M-neb® dose+ nebulizer unit MN-300/8. Do not use any other commercially available USB cable with the USB connection of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) (REF: 20100262).

NOTE

1. 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.
2. The bottom of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) can heat up during prolonged use.
3. In the triggered mode, the maximum runtime is 2 hours.
   In continuous mode, the maximum runtime is 1 hour.
   The maximum standby time (readiness to start the triggered mode) is 60 seconds.
   If the maximum runtime in the respective mode is reached, the M-neb® dose+ mesh nebulizer MN-300/8 is switched off automatically.
4. 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 8 (medical devices without implantable and infectious products). Therefore, the electronic components of the M-neb® dose+ mesh nebulizer MN-300/8 (M-neb® dose+ mesh nebulizer MN-300/8 control unit and M-neb® power cord MN-300/X [type: GTM41076-0605-A]) may not be disposed of in the household waste. Disposal of these electronic components is carried out according to the local waste disposal regulations.
   The component M-neb® dose+ nebulizer unit MN-300/8 (using M-neb® dose+ mouthpiece MN-300/8) can be added to the municipal waste, including separately collected fractions, plastics according to the Waste Catalogue Ordinance (AVV) Regulation under the disposal code 20 01 39.
5. The charging time for the internal, rechargeable battery (lithium ion battery) of the M-neb® dose+ mesh nebulizer MN-300/8 depending on the initial state is:
   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 USB connection of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) is only used for the connection to the M-neb® dose+ nebulizer unit MN-300/8. Do not use any other commercially available USB cable with the USB connection of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) (REF: 20100262).

3.0 Intended use

The M-neb® dose+ mesh nebulizer MN-300/8 is a medication nebulizer which is intended to bring medication in the form of a precise dose even into the smallest air passages of the lungs.

The M-neb® dose+ mesh nebulizer MN-300/8 provides aerosol doses for inhalation using the mouthpiece. Aerosol production is triggered by breathing through the mouthpiece (triggered mode). The maximum length of a single aerosol production phase is 1.5 seconds (triggered mode). The production of the aerosol dose may be affected by the duration of the inhalation session (triggered mode).

The selection of the medication, which is used for the generation of the aerosols by the M-neb® dose+ mesh nebulizer MN-300/8, may only be made by the physician.

The selected medication must be approved for this type of application (inhalation on the principle of mesh nebulisation) by the (pharmaceutical) manufacturers.

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

The M-neb® dose+ mesh nebulizer MN-300/8 has two modes of nebulisation (triggered mode and continuous mode). The basic setting of the M-neb® dose+ mesh nebulizer MN-300/8 is the triggered mode.
Any aerosol production of the M-neb® dose+ mesh nebulizer MN-300/8 3 is indicated by the signalling of the blue LED of the operating mode status indicator as well as the blue lighting up of the M-neb® dose+ nebulizer unit MN-300/8 (with the M-neb® dose+ mouthpiece MN-300/8).

3.2 Nebulizer modes

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

3.2.1 Triggered mode

In the triggered mode, the aerosol production is triggered by breathing through the mouthpiece. The M-neb® dose+ mesh nebulizer MN-300/8 only produces aerosol during the inhalation phase (synchronisation).
In the triggered mode, the operating mode status display LED and the nebulizer unit light up for the duration of the inhalation with each phase of the aerosol production.
The maximum duration of an aerosol production phase is 1.5 seconds.
The production of the aerosol dose may be affected by the duration of the inhalation session.
The triggered mode is set as the default at the factory for the M-neb® dose+ mesh nebulizer MN-300/8 device.

3.2.2 Continuous mode

In continuous mode, the device produces aerosol continuously. In continuous mode, the blue LEDs of the operating mode status indicator and the nebulizer unit light up continuously 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

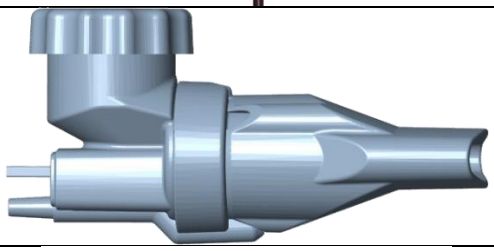
Regardless of the nebulisation mode, the M-neb® dose+ mesh nebulizer MN-300/8 switches off automatically once the filled medication has been completely aerosolised. Each nebulisation mode is equipped with the automatic switch off.

3.4 Maximum runtimes:

In the triggered mode, the maximum runtime is 2 hours.
In continuous mode, the maximum runtime is 1 hour.
The maximum standby time (readiness to start the triggered mode) is 60 seconds.
If the maximum runtime is reached in the respective mode, the M-neb® dose+ mesh nebulizer MN-300/8 is switched off automatically.

4.0 Delivery scope of the 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	Number	Designation	Figure
1 pc.	20100262	M-neb® dose+ mesh nebulizer MN-300/8 (control unit)	
1 pc.	20100206	M-neb® power cord MN-300/X (type: GTM41076-0605-A)	
2 pc.	20100268	M-neb® dose+ nebulizer unit MN-300/8 (incl M-neb® dose+ mouthpiece MN-300/8)	
1 pc.	20100207	M-neb® Etui MN-300/X	

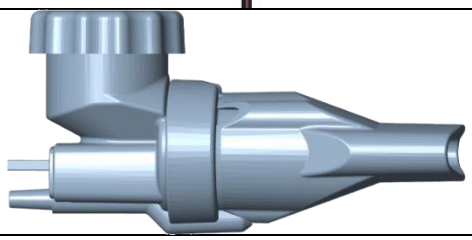
NOTE

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.

Number	Designation	Figure
20100262	M-neb® dose+ mesh nebulizer MN-300/8 (control unit)	
20100206	M-neb® power cord MN-300/X (type: GTM41076-0605-A)	
20100268	M-neb® dose+ nebulizer unit MN-300/8 (incl. M-neb® dose+ mouthpiece MN-300/8)	
20100269	M-neb® dose+ mouthpiece MN-300/8 *available as an option*	
20100207	M-neb® Etui MN-300/X	

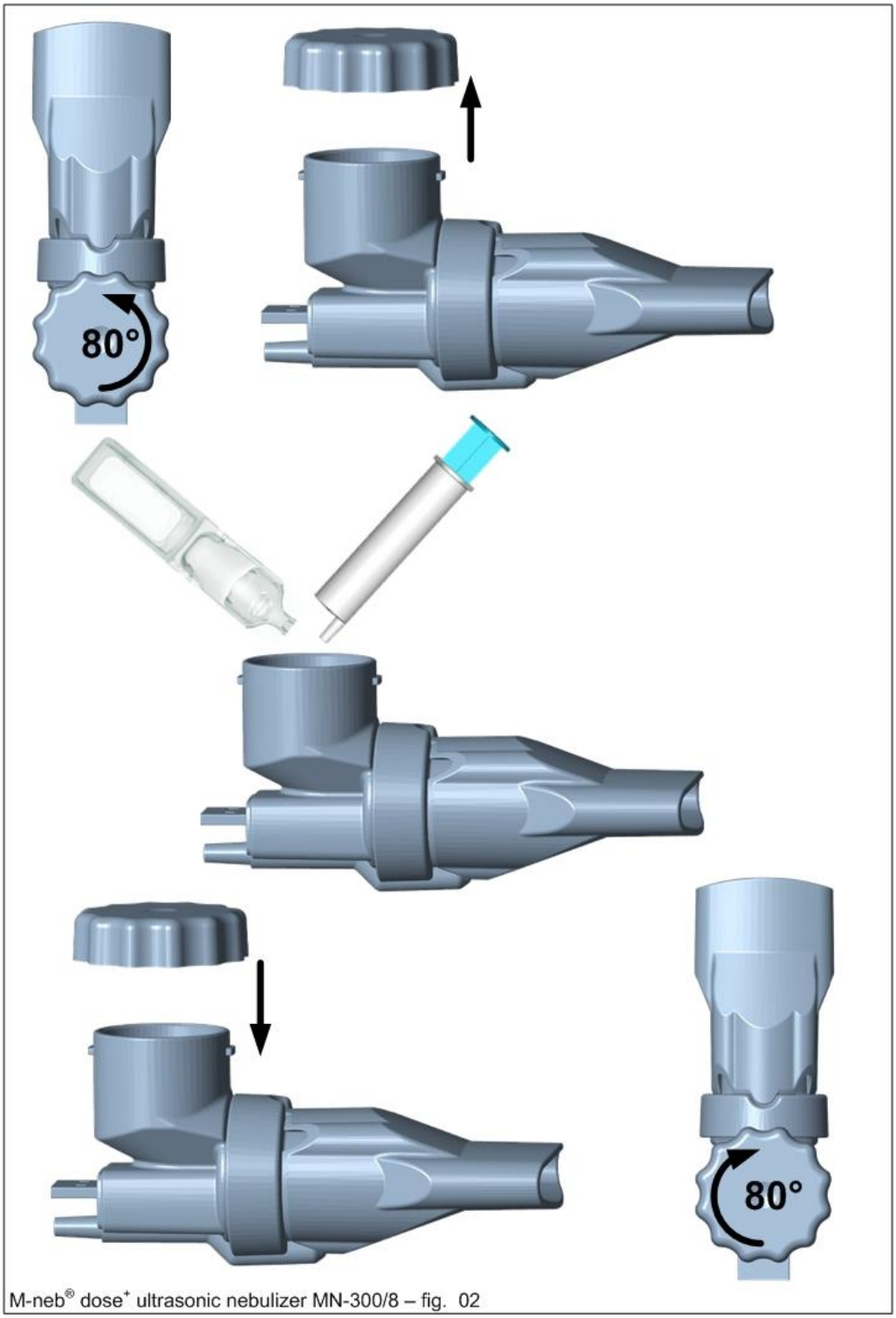
6.0 Start-up of the M-neb® dose+ mesh nebulizer MN-300/8

6.1 Filling the M-neb® dose+ nebulizer unit MN-300/8

6.1.1 Open screw cap using an 80° rotation counter clockwise then lift the cap upwards.

6.1.2 Pour medication into the medication chamber.

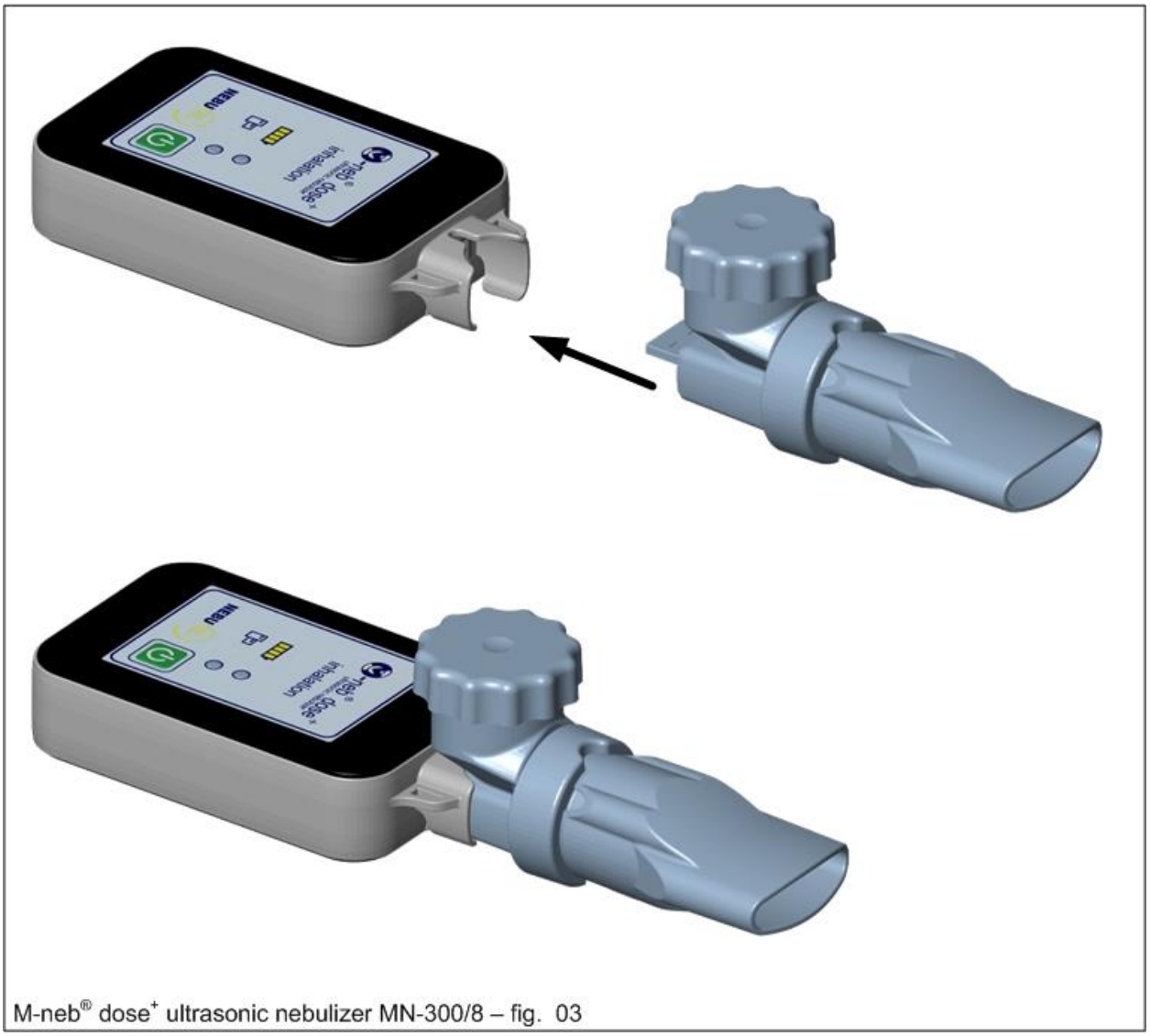
6.1.3 Place screw cap back on and close with an 80° rotation in clockwise direction.



M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 02

6.2 Connect M-neb® dose+ nebulizer unit MN-300/8 with the M-neb® dose+ mesh nebulizer MN-300/8 (control unit)

After this, connect the filled M-neb® dose+ nebulizer unit MN-300/8 with the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). To do this, connect the female USB socket of the control unit with the male USB connector of the nebulizer unit.



M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 03

6.3 Start medication nebulisation and carry out inhalation

6.3.1 Press (> 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). The M-neb® dose+ mesh nebulizer MN-300/8 (control unit) switches on automatically. As indication, you will hear a short acoustic signal tone and the battery status indicator continuously lights up 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

M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 04

6.3.2 The operational readiness of the M-neb® dose+ mesh nebulizer MN-300/8 is established after the operating mode status indicator has flashed three times blue briefly.

6.3.3 The M-neb® dose+ mesh nebulizer MN-300/8 can now monitor your inhalation and produce inspiration-triggered aerosol delivery. This aerosol is then available for inhalation with every single breath. To do this, close your mouth around the mouthpiece of the M-neb® flow mesh nebulizer MN-300/3 and inhale through your mouth. (Use a nose clip for an inhalation session, if needed.)

6.3.4 While you carry out an inhalation session using the mouthpiece, the operating mode status display LED and the nebulizer unit light up blue for the duration of the inhalation with each phase of the aerosol production. Please note that the maximum duration of an aerosol production phase is 1.5 seconds.

6.3.5 Do **not** exhale through the mouthpiece of the M-neb® dose+ mesh nebulizer MN-300/8. Put it down to exhale.

6.3.6 In order to carry out the next inhalation, close your mouth around the mouthpiece of the M-neb® dose+ mesh nebulizer MN-300/8 3 again and inhale through your mouth. To exhale, put down the mouthpiece of the M-neb® dose+ mesh nebulizer MN-300/8 again and do **not** exhale through the mouthpiece.

6.3.7 Repeat this procedure until the filled medication has been completely aerosolised by the M-neb® dose+ mesh nebulizer MN-300/8. The M-neb® dose+ mesh nebulizer MN-300/8 then switches off automatically.

NOTE

At every stage of the aerosol production, the operating mode status indicator and the nebulizer unit for aerosol production will light up blue for the duration.
In the triggered mode, the maximum duration of an aerosol production phase is 1.5 seconds.

6.4 Switch off M-neb® dose+ mesh nebulizer MN-300/8

In order to stop or pause the nebulizer before it is finished, the M-neb® dose+ mesh nebulizer MN-300/8 must be switched off. Press (> 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). The M-neb® dose+ mesh nebulizer MN-300/8 switches off automatically. As indication, you will hear a short acoustic signal tone and the battery status indicator goes off.

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

M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 05

6.5 Changing the operating modes

The basic setting of the M-neb® dose+ mesh nebulizer MN-300/8 is the triggered mode. If you have switched on the M-neb® dose+ mesh nebulizer MN-300/8 and the operational readiness is established, the M-neb® dose+ mesh nebulizer MN-300/8 is in triggered mode.

The change of the operating modes is described below if the operational readiness of the M-neb® dose+ mesh nebulizer MN-300/8 is not established and the device is in the switched off state.

6.5.1 Press (> 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). The M-neb® dose+ mesh nebulizer MN-300/8 switches on automatically. As indication, you will hear a short acoustic signal tone and the battery status indicator continuously lights up 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

M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 06

6.5.2 The operational readiness of the M-neb® dose+ mesh nebulizer MN-300/8 is established after the operating mode status indicator has flashed three times blue briefly.

6.5.3 The M-neb® dose+ mesh nebulizer MN-300/8 is now in the triggered mode and controls the inhalation in this mode.

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

6.5.5 For this, press (< 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). Two consecutive, short, acoustic signal tones sound and the operating mode status indicator lights up continuously blue. The M-neb® dose+ mesh nebulizer MN-300/8 is now in continuous mode and continuously nebulised (provided that the medication is filled in the M-neb® dose+ nebulizer unit MN-300/8).

6.5.6 If you want to switch back from continuous mode to triggered mode, press (< 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). A short acoustic signal tone will sound and after operational readiness, the operating mode status indicator lights up again three times briefly.

6.5.7 In order to switch off the M-neb® dose+ mesh nebulizer MN-300/8, press (> 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). A short, acoustic signal will sound, the battery status indicator goes out and the M-neb® dose+ mesh nebulizer MN-300/8 is switched off.

6.5.8 Please note: The M-neb® dose+ mesh nebulizer MN-300/8 can also be switched off by automated shut-down procedures. These procedures are, on the one hand, the automatic switching and on the other hand, the maximum runtimes of the M-neb® dose+ mesh nebulizer MN-300/8.
Regardless of the set nebulisation mode, the M-neb® dose+ mesh nebulizer MN-300/8 switches off automatically once the filled medication has been completely aerosolised.
The maximum runtimes automatically switch the M-neb® dose+ mesh nebulizer MN-300/8 off as soon as its time limits are reached.
- The maximum duration is 2 hours in triggered mode.
- The maximum duration is 1 hour in continuous mode.
- Furthermore the maximum standby time (readiness to start the triggered mode) switches the M-neb® dose+ mesh nebulizer MN-300/8 off after 60 seconds of flow inactivity.

6.6 Use of the continuous mode

To operate the M-neb® dose+ mesh nebulizer MN-300/8 in continuous mode, this must be selected after M-neb® dose+ mesh nebulizer MN-300/8 has been placed in operational readiness. To do this, proceed as follows:

6.6.1 Press (> 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). The M-neb® dose+ mesh nebulizer MN-300/8 switches on automatically. As indication, you will hear a short acoustic signal tone and the battery status indicator continuously lights up 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

M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 07

6.6.2 The operational readiness of the M M-neb® dose+ mesh nebulizer MN-300/8 (control unit) is established after the operating mode status indicator has flashed three times blue briefly.

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

6.6.4 For this, press (< 1 second) the on/off button of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit). Two consecutive, short, acoustic signal tones sound and the operating mode status indicator lights up continuously blue. The M-neb® dose+ mesh nebulizer MN-300/8 is now in continuous mode.

6.6.5 If the filled medication has been completely aerosolised, the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) switches off automatically.

7.0 Power supply

The M-neb® dose+ mesh nebulizer MN-300/8 (control unit) can be operated via the internal, rechargeable battery or the M-neb® power cord MN-300/X (type: GTM41076-0605-A) via the 230 VAC power supply.
The internal, rechargeable battery of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) may only be charged via the M-neb® power cord MN-300/X (type: GTM41076-0605-A).
The M-neb® dose+ mesh nebulizer MN-300/8 (control unit) may only be operated via the M-neb® power cord MN-300/X (type: GTM41076-0605-A).

8.0 Charging of the M-neb® mesh nebulizer MN-300/8 (control unit)

The capacity status of the M-neb® dose+ mesh nebulizer MN-300/8 is displayed on the battery status indicator of the M-neb® dose+ mesh nebulizer MN-300/8. 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 lights up continuously red. The M-neb® dose+ mesh nebulizer MN-300/8 switches off automatically.
If the capacity has reached the limit of 10%, the battery of the M-neb® dose+ mesh nebulizer MN-300/8 must be charged.

8.0.1 Connect the supplied M-neb® power cord MN-300/X (type: GTM41076-0605-A) for charging first with the M-neb® dose+ mesh nebulizer MN-300/8 (control unit).

M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 08

8.0.2 Then connect the M-neb® power cord MN-300/X (type: GTM41076-0605-A) with the 230 VAC power supply.

M-neb® dose⁺ ultrasonic nebulizer MN-300/8 – fig. 09

8.0.3 The charging of the battery starts now.

8.0.4 If the M-neb® dose⁺ mesh nebulizer MN-300/8 3 is charging, the battery indicator light flashes green (ratio: 1 second green/1 second pause).

8.0.5 If the M-neb® dose⁺ mesh nebulizer MN-300/8 has completed charging, the battery indicator light flashes green (ratio 1/10 seconds green/1 second pause).

8.0.6 Separate the supplied M-neb® power cord MN-300/X (type: GTM41076-0605-A) from the M-neb® dose⁺ mesh nebulizer MN-300/8 and the 230 VAC power supply.

ATTENTION

The charging of the internal rechargeable battery (lithium ion battery) is carried out exclusively with the supplied M-neb® power cord MN-300/X (type: GTM41076-0605-A).

M-neb® dose+ ultrasonic nebulizer MN-300/8 – fig. 10

NOTE
The charging time for the internal, rechargeable battery (lithium ion battery) of the M-neb® dose+ mesh nebulizer MN-300/8 is approx. 3 hours for 100% charging capacity depending on the initial state.

CAUTION
To avoid damage to the M-neb® dose+ mesh nebulizer MN-300/8 and ensure compliance with the EMC Directive, only use the original M-neb® power cord MN-300/X (type: GTM41076-0605-A).

9.0 Cleaning

9.1 Cleaning the M-neb® dose+ mesh nebulizer MN-300/8 (control unit)

9.1.1 Wipe the housing of the M-neb® dose+ mesh nebulizer MN-300/8 with a damp cloth.

9.1.2 Then dry off the housing of the M-neb® dose+ mesh nebulizer MN-300/8 with a dry cloth or let it air dry on a dry absorbent surface.

WARNING
Before each cleaning of the M-neb® dose+ mesh nebulizer MN-300/8, ensure that the M-neb® power cord MN-300/X (type: GTM41076-0605-A) has been disconnected.
Never immerse the housing of the M-neb® dose+ mesh nebulizer MN-300/8 in water or a cleaning solution.

9.2 Cleaning of the M-neb® dose+ nebulizer unit MN-300/8 and the M-neb® dose+ mouthpiece MN-300/8

9.2.1 Disconnect the M-neb® dose+ nebulizer unit MN-300/8 and the M-neb® dose+ mouthpiece MN-300/8.

9.2.2 Rinse of the M-neb® dose+ mouthpiece MN-300/8 under warm tap water.

9.2.3 Then let the M-neb® dose+ mouthpiece MN-300/8 air dry on an absorbent, dry surface.

9.2.4 Clean the M-neb® dose+ nebulizer unit MN-300/8, by pouring a small amount (0,5 ml till maximum 2,0 ml) of distilled or sterile water into the medication chamber and allow it to nebulise in continuous mode. To do this, proceed as follows:

9.2.4.1 Open the M-neb® dose+ nebulizer unit MN-300/8, by rotating the screw cap 80° counter clockwise and then lifting it off.

9.2.4.2 Fill a small amount (0,5 ml till maximum 2,0 ml) of distilled or sterile water into the medication chamber and close the M-neb® dose⁺ nebulizer unit MN-300/8, by replacing the screw cap and closing it by rotating clockwise 80°.

9.2.4.3 After this, connect the filled M-neb® dose⁺ nebulizer unit MN-300/8 with the M-neb® dose⁺ mesh nebulizer MN-300/8 (control unit). To do this, connect the female USB socket of the control unit with the male USB connector of the nebulizer unit.

9.2.4.4 Switch the M-neb® dose⁺ mesh nebulizer MN-300/8 (control unit) on. For this, press (> 1 second) the on/off button of the M-neb® dose⁺ mesh nebulizer MN-300/8 (control unit). The M-neb® dose⁺ mesh nebulizer MN-300/8 switches on automatically. 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⁺ mesh nebulizer MN-300/8 (control unit) is established after the operating mode status indicator has flashed three times blue briefly.
The M-neb® dose⁺ mesh nebulizer MN-300/8 is now in triggered mode.

9.2.4.5 Now you can change the operating mode from the triggered mode to continuous mode in a time window of 60 seconds, which is equivalent to the maximum standby time. For this, press (< 1 second) the on/off button of the M-neb® dose⁺ mesh nebulizer MN-300/8 (control unit). Two consecutive, short, acoustic signal tones sound and the operating mode status indicator lights up continuously blue.

9.2.4.6 The M-neb® dose⁺ mesh nebulizer MN-300/8 is now in the continuous mode and continuously nebulises the filled distilled or sterile water. Once the filled distilled or sterile water has been completely nebulised, the auto off function automatically switches off the M-neb® dose⁺ mesh nebulizer MN-300/8.

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

9.2.4.7 Now disconnect the M-neb® dose⁺ nebulizer unit MN-300/8 from the M-neb® dose⁺ mesh nebulizer MN-300/8. Disconnect the screw cap of the M-neb® dose⁺ nebulizer unit MN-300/8 and put the M-neb® dose⁺ nebulizer unit MN-300/8 on a dry, absorbent surface to dry.

9.2.4.8 After the M-neb® dose⁺ nebulizer unit MN-300/8 has dried in the air, you can reconnect the screw cap of the M-neb® dose⁺ nebulizer unit MN-300/8. Reconnect the M-neb® dose⁺ mouthpiece MN-300/8 again with the M-neb® dose⁺ nebulizer unit MN-300/8.

10.0 Maintenance

The M-neb® dose⁺ mesh nebulizer MN-300/8 should be checked 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
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 observe this leads to the loss of the warranty claim.

11.0 Diode displays

Symbol	Diode	Meaning
	**Battery status indicator**	The battery status indicator [LED red/green] is controlled so that: - the green LED lights up when the capacity of the battery is over 30%. - the green LED lights up alternately with the red LED (exchange rate 1 second: 1 second) if the capacity of the battery is greater than 10% and less than 30%. - the red LED stays lit when the capacity of the battery is less than 10%. - the green LED blinks in intervals (1 second: 1 second) when charging is enabled. - the green LED blinks in intervals (1/10 s lit: 1 s not lit) when charging is completed.
	**Operating mode status indicator**	The operating mode status indicator [LED blue] lights: - blue three times briefly when the boot phase is terminated. - blue once briefly when the FLOW recording is activated. - continuously blue if the RF power amplifier is enabled (power indicator).

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

12.1 Operating conditions
Operating the device is guaranteed under the following environmental conditions:

Ambient temperature:	+10°C to +40°C,
Relative humidity:	25 % to 75 %
Air pressure:	450 hPa to 1100 hPa

12.2 Transport and storage conditions
The transport and storage of the device is ensured under the following environment conditions:

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

13.0 Duration of use

The M-neb® dose+ nebulizer unit MN-300/8 (incl. the M-neb® dose+ mouthpiece MN-300/8) (Item no. 20100268) and the M-neb® dose+ mouthpiece MN-300/8 (Item no 20100269) are consumables and may only be used for the maximum duration of 7 days per patient (m/f). They should be replaced after this maximum duration use with new consumables.

14.0 Disposal

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 8 (medical devices without implantable and infectious products). Therefore, the electronic components of the M-neb® dose+ mesh nebulizer MN-300/8 (M-neb® dose+ mesh nebulizer MN-300/8 [control unit] [Item no 20100262] and M-neb® power cord MN-300/X [type: GTM41076-0605-A] [Item no 20100206]) may not be disposed of in the household waste. Disposal of these electronic components is carried out according to the local waste disposal regulations.
The components M-neb® dose+ nebulizer unit MN-300/8 (incl. M-neb® dose+ mouthpiece MN-300/8) (Item no 20100268) and the M-neb® dose+ mouthpiece MN-300/8 (Item no 20100269) can be added to the municipal waste, including separately collected fractions are, plastics according to the Waste Catalogue Ordinance (AVV) under the disposal code 20 01 39.

15.0 Technical specifications

M-neb® dose+ mesh nebulizer MN-300/8 (control unit):

Size	85 x 54 x 18 mm
Weight	75 g
Electrical supply	Internal: 3,6V/500 mA External: 5V/1,2 A
Power consumption during operation	500 mA maximum
Working frequency	110 KHz
Nebulizer output	< 0,6 ml/min
MMAD	< 4,0 µm
Electrical protection class	II type B
Used battery type	Lithium-ion, 3,7V, 1200mAh

M-neb® power cord MN-300/X (type: GTM41076-0605-A):

Size	74 x 44 x 73 mm
Cable length	1,8 m
Weight	165 g

M-neb® dose+ nebulizer unit MN-300/8:

Size	57 x 56 x 30 mm
Maximum filling quantity	8 ml
Weight	20 g

16.0 Performance data

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

16.1 Performance data of the M-neb® dose+ mesh nebulizer MN-300/8 with use of the M-neb® dose+ nebulizer unit MN-300/8 (Item no. 20100268)

The aerosol dispensing according to DIN EN 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 MN-300/8 (Item no. 20100268).
The aerosol dispensing according to DIN EN 13544-1/Annex CC - CC.2 is 1.86 mg sodium chloride per minute when using the M-neb® dose+ nebulizer unit MN-300/8 (Item no. 20100268).
This corresponds to an aerosol dispensing of 0.4 ml sodium chloride per minute when using the M-neb® dose+ nebulizer unit MN-300/8 (Item no. 20100268).

17.0 Aerosol spectrum

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

17.1 Aerosol spectrum of the M-neb® dose+ mesh nebulizer MN-300/8 when using the M-neb® dose+ nebulizer unit MN-300/8 (Item no. 20100268)

The particle size of the M-neb® dose+ mesh nebulizer MN-300/8 according to DIN EN 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 MN-300/8 (Item no. 20100268).

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:

Item number	Designation	Quantity
20100008	M-neb® dose+ Starter-Kit MN-300/8	1 pc.
20100104	M-neb® dose+ consumption material for a period of 3 months MN-300/8	1 pc.
20100206	M-neb® power cord MN-300/X	1 pc.
20100207	M-neb® Etui MN-300/X	1 pc.
20100262	M-neb® dose+ mesh nebulizer MN-300/8	1 pc.
20100268	M-neb® dose+ nebulizer unit MN-300/8 (incl. M-neb® dose+ mouthpiece MN-300/8)	1 pc.
20100269	M-neb® dose+ mouthpiece MN-300/8	1 pc.

19.0 Service

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

20.0 Manufacturer

Manufacturer:

NEBU-TEC med. Produkte Eike Kern GmbH
Kreuzfeldring 17
63820 Elsenfeld – GERMANY
Tel.: +49 (0) 6022-610620
Fax: +49 (0) 6022-6106299
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
RF emissions 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.
RF emissions according to CISPR 11	Class B	The nebulizer MN-300/8 is suitable for use in all establishments, including those in the living area and those that are directly connected to the PUBLIC SUPPLY NETWORK that supplies buildings used for residential purposes.
Emissions of harmonics according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3	Complies	

WARNING

The M-neb® dose+ mesh nebulizer MN-300/8 may not be placed directly next to other devices. If necessary, the device should be observed to verify its proper operation in the configuration used.

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.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidelines**
ELECTROSTATIC DISCHARGE (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 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%.
Rapid transient electrical interference bursts according to IEC 61000-4-4	± 2 kV for mains lines ± 1 kV for input and output leads	± 2 kV for mains lines ± 1 kV for input and output leads	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Surge voltage/surges according to IEC 61000-4-5	± 1 kV phase-to-phase voltage/phase conductor ± 2 kV phase to earth	± 1 kV phase-to-phase voltage/phase conductor ± 2 kV phase to earth	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Voltage dips, short interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	< 5% U_T (> 95% dip of the U_T) for ½ periods 40% U_T (60% dip of the U_T) for 5 periods 70% U_T (30% dip of the U_T) for 25 periods < 5% U_T (> 95% dip of the U_T) for 5 s	< 5% U_T (> 95% dip of the U_T) for ½ periods 40% U_T (60% dip of the U_T) for 5 periods 70% U_T (30% dip of the U_T) for 25 periods < 5% U_T (> 95% dip of the U_T) for 5 s	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment. When the user of the nebulizer MN-300/8 requires continued operation during interruptions of energy supplies, it is recommended to power the nebulizer MN-300/8 of an uninterruptible power supply or a battery.

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.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment guidelines
Magnetic field of the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should comply with the typical values, as they correspond to the commercial and hospital environment.

NOTE U_T is the AC mains voltage prior to application of the test level.

Guidelines and manufacturer's declaration – electromagnetic immunity

The model MN-300/8 is intended for use in the electromagnetic environment specified below. The customer or the user of the model MN-300/8 should ensure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile radio equipment should not be used in closer proximity with the nebulizer MN-300/8 (including power cord) than the recommended safety distance. That distance is calculated according to the equation appropriate to the transmission frequency. **Recommended safety distance:**
Conducted RF disturbance according to IEC 61000-4-6	$3V_{eff}$ 150 kHz to 80 MHz	$3V_{eff}$	$D = 1.2\sqrt{P}$
Radiated RF disturbance according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$D = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$D = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the rated output of the transmitter in watts (W) as stated by the transmitter manufacturer and D is the recommended safe distance in meters (m). The field strength of fixed radio transmitters at all frequencies should be below the compliance level based on on-site measurements. [a] [b] Interference is possible in the vicinity of equipment that carries the following icon. 

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2: This guideline may not be applicable in all cases. The propagation of electromagnetic energy is affected by absorption and reflection by buildings, objects and people.

a The theoretical field strength of fixed transmitters such as radio telephone and mobile agricultural radio equipment base stations, amateur radio transmitters, AM and FM radio and TV transmitters cannot be precisely determined in advance. In order to determine the electromagnetic environment with respect to fixed transmitters, a study of the location should be considered. If the measured field strength at the location of the nebulizer MN-300/8 exceeds the compliance levels, the nebulizer MN-300/8 should be observed to verify that it is FUNCTIONING as intended. If unusual performance characteristics are observed, additional measures may be required such as modifying or changing the location of the nebulizer MN-300/8.

b Above the frequency range of 150 kHz to 80 MHz. the field strength should be less than 3 V/m.

Recommended safe distances between portable and mobile RF telecommunications equipment and the nebulizer MN-300/8

The nebulizer MN-300/8 is intended for use in an electromagnetic environment in which the RF disturbances are controlled. The customer or the user of the nebulizer MN-300/8 can help prevent electromagnetic interference by adhering to the minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the nebulizer MN-300/8 - depending on the output power of the communications equipment, as specified below.

Rated output of the transmitter **W**	**Safety distance dependent on transmission frequency**		
	150 kHz to 80 MHz D = 1.2√P	**80 MHz to 800 MHz** D = 1.2√P	**800 MHz to 2.5 GHz** D = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated output is not specified in the table above, the recommended safety distance can be determined D in meters (m) using the equation, which belongs to the respective column where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 With 80 MHz and 800 Hz, the higher frequency range applies

NOTE 2 These guidelines may not be applicable in all cases. The spread of electromagnetic variables is affected by absorption and reflections of the buildings, objects and people.

22.0 EC Certificate of Conformity

Product	**M-neb® dose+ mesh nebulizer MN-300/8**
REF	**MN-300/8**
Classification	The device M-neb® dose+ mesh nebulizer REF MN-300/8, is classified as a product of the class **IIa** pursuant to the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, as last amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 in accordance with the classification criteria of Rule 11 listed in Annex IX.
UMDNS number	**12-719 (nebulizer, ultrasonic)**
Manufacturer	**Nebu-Tec med. Produkte Eike Kern GmbH** **Kreuzfeldring 17 - 63820 Elsenfeld – Germany**

We hereby declare, as the exclusive responsible manufacturer, that the aforementioned device conforms to the relevant EC Directive 93/42/EEC Annex II, Section 3 (complete QM system).

Notified body	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Germany** **ID 0197**
Conformity assessment procedure	**EC Directive 93/42/EEC Annex II, Section 3**
EC certificate	**HD 60101825 0001**
CE mark since	**2016**

23.0 Warranty

We grant you a warranty of 24 months from the date of purchase on your M-neb® dose+ mesh nebulizer MN-300/8.
We can grant you this warranty on the M-neb® dose+ mesh nebulizer MN-300/8 (control unit) (Item no. 20100262) and the M-neb® power cord MN-300/X (type: GTM41076-0605-A) (Item no. 20100206).
We grant you a warranty of 6 months on the integrated rechargeable batteries of the M-neb® dose+ mesh nebulizer MN-300/8 (control unit).
The M-neb® dose+ nebulizer unit MN-300/8 (with M-neb® dose+ mouthpiece MN-300/8) (Item no. 20100268) and the M-neb® dose+ mouthpiece MN-300/8 (Item no. 20100269) are wear parts and thus excluded from the warranty.
Damage caused by improper handling of the device is not covered by the warranty. The warranty terminates upon unauthorized interference to the device.

24.0 Release notes

Version: NT_MN-300-8_IFU-E_A

Your notes:

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