LAINOMEDICAL

NEBURA

Portable vibrating mesh nebulizer with Nebulok® Technology

INSTRUCTIONS FOR USE

N01-IFUS-EN | V06 29/01/2026

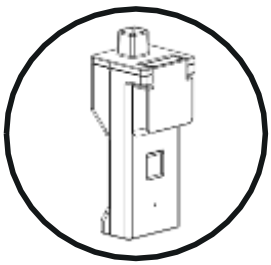
INSTRUCTIONS FOR USE

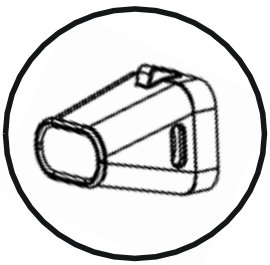
Please read these instructions carefully before first use.
If you do not understand any section of these instructions, contact your distributor.

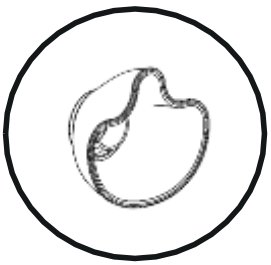
NEBURA

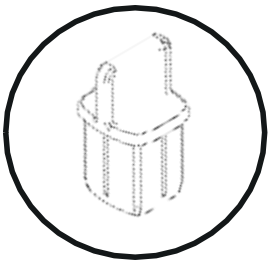
Portable vibrating mesh nebulizer with Nebulok® Technology

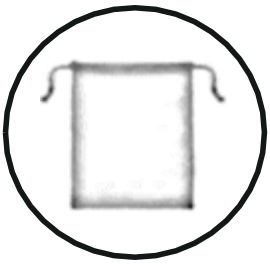
NEBURA KIT CONTAINS:

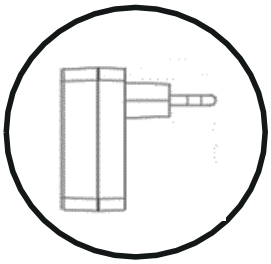

NEBULIZER

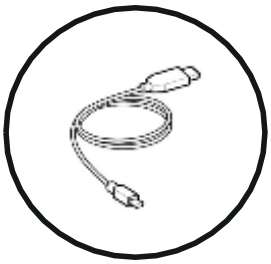

MOUTHPIECE


KID MASK


UPPER PROTECTOR


BAG


CHARGER


CABLE

INDEX

1. PRODUCT DESCRIPTION 04

2. INTENDED USE 04

3. WARNING AND PRECAUTIONS 05

4. HOW TO USE NEBURA 07

5. HOW TO CHARGE THE BATTERY 10

6. CLEANING AND DISINFECTION 10

7. COMPATIBLE SINGLE-USE VIALS 12

8. TROUBLESHOOTING 12

9. DEVICE SPECIFICATIONS 13

10. SYMBOLS 15

11. WARANTEE 17

12. ELECTROMAGNETIC COMPATIBILITY (EMC) 17

1. **PRODUCT DESCRIPTION**

The Nebura mesh nebulizer is a medical device intended to administer liquid solutions with an average drop size between 10-20 microns, facilitating their deposition in the upper airways. The device utilizes vibrating mesh technology with patented systems.

Nebura features a delivery system whereby a single-use vial (blow-fill-seal) is punctured upon insertion from the top of the nebulizer. Additionally, Nebura incorporates an internal auto-disinfection system that is activated automatically when the device is connected to a power supply.

2. **INTENDED USE**

Nebura is intended to administer liquid solutions with an average drop size between 10-20 microns, facilitating their deposition in the upper airways. The device is specifically designed to administer liquid solutions for the treatment or alleviation of upper respiratory tract symptoms (such as cough, irritations, congestion, etc).

It is suitable for use by patients of all ages, including infants. It cannot be used in patients that are unconscious or not breathing spontaneously. Nebura is intended to be used by lay persons in a home environment. The patient is the intended operator.

The device is intended for single patient use and is reusable.

Please keep these instructions for future reference. Additionally, retain the box and packaging materials either for storing the unit or for returning the product if necessary.

3. **CLINICAL BENEFITS**

The drop size aerosolized by the device allows a higher deposition in the upper airway area, in order to treat or alleviate upper respiratory tract symptoms with better efficacy results and less size effects.

The shelf disinfection system, using UVC radiation, improves patient adherence to treatments, as patients do not have to go through the tedious cleaning and disinfection process of current nebulizers.

It is portable, handheld and silent, which allows a comfortable and easy treatment everywhere.

3. **WARNINGS AND PRECAUTIONS**

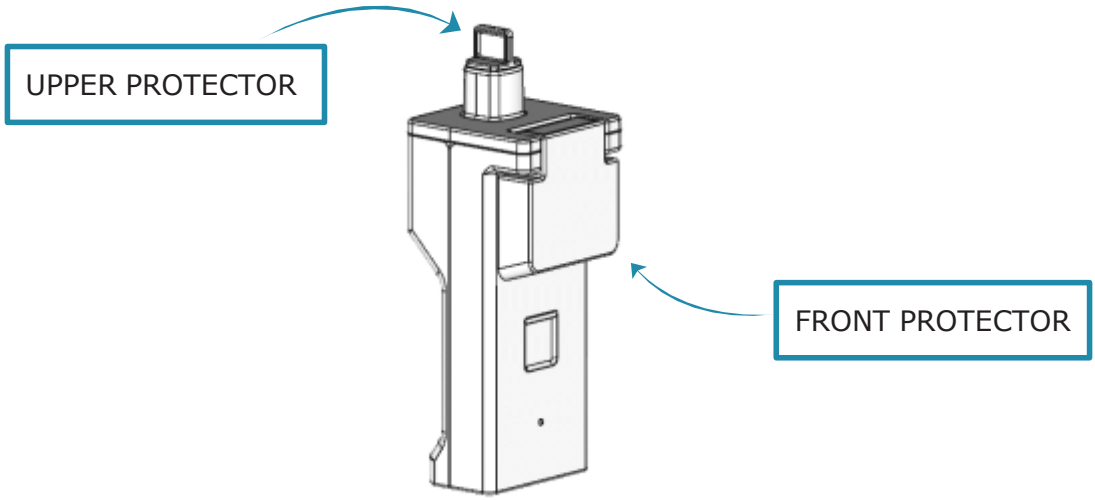
Please carefully read this section:

- Not indicated for patients that are allergic to the material of the mouthpiece (Thermoplastic Elastomer) or mask (PVC).
- It should not be used by patients who are unconscious or unable to breathe spontaneously.
- The product must not be placed or stored where water may run off.
- The nebulizer must not be immersed in water or other liquid cleaning agents. If the device accidentally falls into liquid, immediately disconnect the AC power adapter from the wall outlet before removing the device from the liquid. The device must be allowed to dry.
- Any liquid spilled on the device must be allowed to dry before operating the nebulizer.
- Adult supervision is required when the device is used by or near children, or people with physical disabilities or learning difficulties.
- This product should only be used for its intended purpose. Failure to do so may compromise performance. Use only additional components supplied with the nebulizer and recommended by the manufacturer. Store it in a clean place and out of the reach of children.
- The nebulizer should not be charged or operated if it has a damaged cable or plug, is not functioning properly, has been dropped or damaged, or has fallen into water.
- Do not expose the device or charger to heat sources, open flames or hot surfaces.
- Do not boil the nebulizer or store in high temperatures and with direct sun light.
- Overheating, overcharging, or physical damage may cause battery rupture, combustion, or ejection of hot gases, leading to burns or injury.
- The nebulizer should not be used near flammable substances such as oxygen, nitrous oxide, or in the presence of a flammable anesthetic mixture.
- Never scratch the AGU (Aerosol Generation Unit) or clean it with sharp objects. This could damage the mesh and prevent the device from working properly.

- Precautions should be taken in case of changes in the device's performance.
- Do not use the device if visibly damaged or after a severe drop. Tampering with the device may lead to electric shock, malfunction, or exposure to hazardous substances.
- Respect the conditions of storage, distribution and use of the device as indicated in instructions.
- No attempt should be made to touch the AGU. In addition, the front protector should always be in place when the device is not in use, especially when it is in disinfection mode, as it emits UVC light in this mode.
- No attempt should be made to touch the punch. In addition, the upper protector should always be in place when the device is not in use.
- The device is disinfected when it is connected to the power supply. Once connected, the device is in disinfection mode for the first 21 minutes. The device must not be disconnected from the power supply until charging is complete.
- If the device emits a strong odor, smoke, or liquid, stop using it immediately and avoid contact, as the electrolyte may cause skin, eye, or mucosal irritation.
- The device should only be used with the nebulizer solutions included in this document.
- It is not recommended to stop nebulization until the vial is completely finished and the nebulization has completed. At that time, the nebulizer automatically stops nebulization.
- No nebulizer components should be placed in the mouth, as this may cause choking.
- Always keep the protectors on the nebulizer when it is not in use.
- The Nebura nebulizer and all its components must be disposed of correctly and in accordance with local regulations (e.g., WEEE directive).

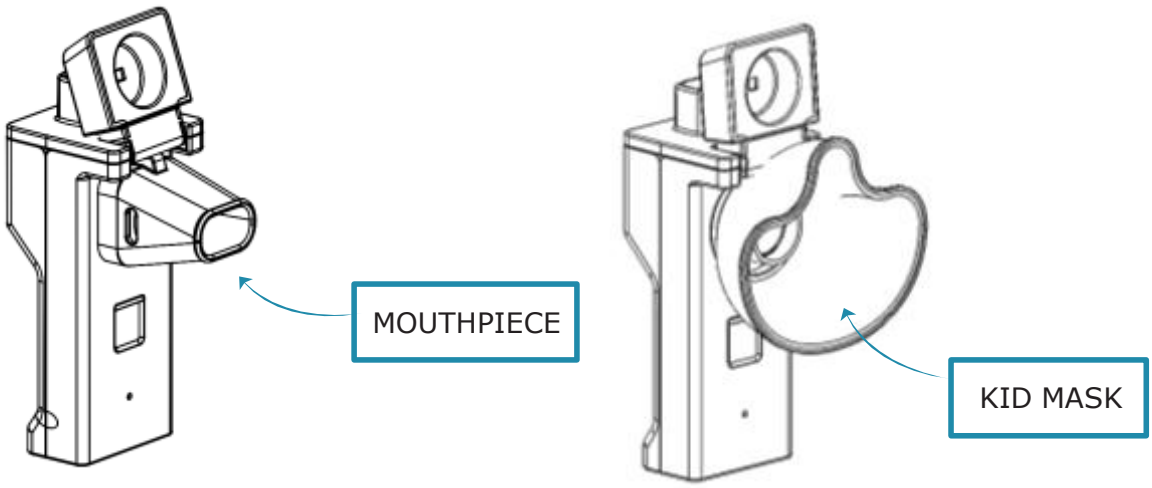
4. HOW TO USE NEBURA

1. When opening the nebulizer box, verify that all components are included and not visibly damaged.
2. Before the first use, fully charge the battery (section 5) and clean the mouthpiece and the kid mask (section 6).
3. Remove the upper protector and lift the front protector in the process of setting up the nebulizer prior to use.



4. A) With mouthpiece: Place the mouthpiece on the front side of the nebulizer.

   B) With kid mask: Place the kid mask on the front side of the nebulizer.

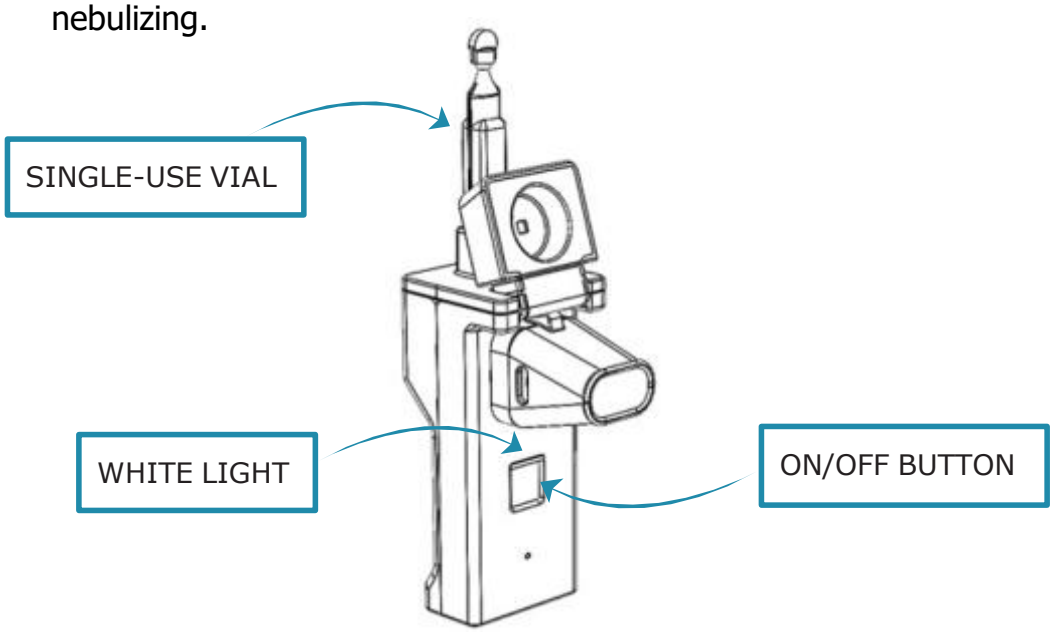


Please note that the mouthpiece and the kid mask only fits in one way.

5. Insert the single-use vial into the upper opening. Ensure that the single-use vial is inserted in the correct position (with the vial label facing forward) into the hole in the top housing.

The single-use vials must have a maximum volume of 5 mL

6. Once the single-use vial is inserted into the nebulizer, ensure that it has been punched correctly and open the breakable part of the single-use vial.
7. Press the on/off button to turn on the nebulizer. The nebulization will start automatically. A solid white light will indicate that the device is nebulizing.



8. Verify that aerosol is coming out of the mouthpiece or kid mask.
9. A) With mouthpiece: Place the nebulizer with the mouthpiece between the teeth and lips. Breathe normally through the mouth.

   B) With kid mask: Place the nebulizer with the kid mask against the face. Breathe normally though the mouth/nose.

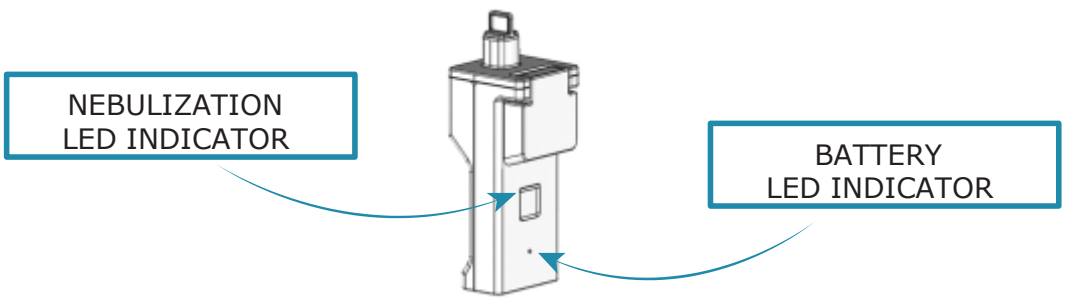
During use, it is normal for some aerosol to come out of the side of the mouthpiece/kid mask. The side holes of are designed to create an optimal flow for the proper deposition of the aerosol in the upper airways. It is important not to cover or block these holes while using the device.

Do not tilt the device in any direction more than 45 degrees during a treatment, as this may prevent the nebulizer from fully nebulizing all the content of the single-use vial. It is important to keep the device in an upright position to ensure effective nebulization.
If the nebulizer shuts off due to improper positioning, place it in an upright position and press the ON/OFF button to restart it.

10. When the nebulization is completed, the nebulization LED indicator will blink, and the device will switch off.
11. Clean the nebulizer as instructed in section 6.
12. Remove the disposable single-use vial and discard it according to the manufacturer's instructions. Place the upper protector back.
13. Remove the mouthpiece/kid mask from the nebulizer lowering the front protector.

INDICATIONS OF THE LEDS

LED	Indication	Meaning
Nebulization LED indicator	Solid white light	Nebulizing
Nebulization LED indicator	Blinking white light and one long beep	No liquid detection
Battery LED indicator	Blinking orange	Battery life less than 20% (last nebulization)
Battery LED indicator (during charging)	Blinking orange	Battery is charging
Battery LED indicator (during charging)	Solid green	Battery charged
Battery LED indicator (during charging)	Solid purple	Disinfection mode
Battery LED indicator	Blinking purple and one long beep	Disinfection process must be done



5. HOW TO CHARGE THE BATTERY

1. Connect the cable to the back of the nebulizer. Please note that the cable connection to the nebulizer is a USB type-C and must be securely fastened.
2. Connect the other end of the cable (USB Type-A) to the charger.
3. Connect the charger to the power supply.
4. The battery LED indicator will turn purple, indicating that the device is undergoing disinfection. After 21 minutes, the battery LED indicator will change to blinking orange (the device is charging).
5. Allow the device to charge until the battery LED indicator turns green. This indicates that the battery is fully charged.
6. Disconnect the charger from the power supply and the charging cable from the nebulizer.

Do not open the front protector during the disinfection process to avoid exposure to ultraviolet light.
Do not open the device. No user-serviceable parts inside.

BATTERY LED INDICATOR

Indication	Meaning
Solid green	Charged
Blinking orange	The battery is charging
Solid purple	The device is auto-disinfecting
Blinking purple	The device needs disinfection

6. CLEANING AND DISINFECTION

- Do not sterilize the nebulizer.
- Do not immerse the device in liquid or steam clean it.
- Never scratch or clean the mesh with sharp objects. This could damage the mesh.
- Do not clean the device while it is in use.
- Make sure it is switched off before cleaning.

DISINFECTION

It must be disinfected before each use using the **Nebura Auto-disinfection system.** To activate the auto-disinfection feature, connect the device to the power supply and follow the instructions outlined in section 5.

Before initiating the disinfection process, ensure that the front protector is in place.

When the device is connected to the power supply, the battery LED indicator will turn purple to indicate the activation of the auto-disinfection system. The auto-disinfection process will last 21 minutes.

It is important not to disconnect the device from the power supply until the battery LED indicator changes to green, indicating that the battery is fully charged.

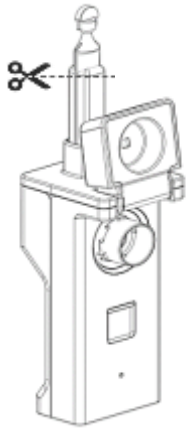
If the device has not been disinfected within 72 hours from the previous disinfection, an error will be displayed (blinking purple and one long beep, as indicated in section 4), and the device will remain blocked until the disinfection process is performed again.

CLEANING

After each use, the device and the mouthpiece/kid mask must be cleaned.

Nebura device:

1. Without removing the last used single-use vial, cut the tip (as shown in the figure) and fill it with distilled water (4 mL)
2. Press the on/off button and wait until the device has completely nebulized the liquid.
3. Remove the single-use vial after the nebulizer switches off.
4. Close the front cover and store the device appropriately.



If the nebulizer is going to be stored without being used, remember to carry out the cleaning and disinfection processes.

Mouthpiece and kid mask:

1. Remove all the additional components (mouthpiece and kid mask) and shake them in warm soapy water for 2 minutes.
2. Rinse well under running water.
3. Allow to air dry completely before storing.

7. COMPATIBLE SINGLE-USE VIALS

NEBURA COMPATIBLE SOLUTIONS INCLUDE:

- Sterile isotonic solution of sodium chloride 0,9% in vials for inhalation
  - Medical device Class IIa
  - Manufactured by Laboratoire UNITHER

The references for the solutions included in the tale have been tested with the nebulizer. Therefore, no other product than the tested solution should be used in combination with the nebulizer.

8. TROUBLESHOOTING

Problems	Causes	Solutions
The device does not nebulize, or the flow is poor.	- There is a droplet clogging the micro holes of the mesh. - The device is not in an upright position.	- Press the on/off button to turn off the nebulizer and press it again to undo the droplet. - Ensure the device is kept upright during nebulization.
The button does not work	- The device is being touched with wet hands. - The housing is wet. - The device has no battery.	- Dry your hands and the device with a cloth. - Charge the device.
Single-use vial does not fit	- The insertion of the capsule is not in the correct direction. - The capsule is not compatible with the device.	- Make sure you are inserting the capsule according to the instructions and using a compatible capsule as described in section.
The device does not charge	- The cable is not well fitted to the nebulizer.	- Check that the cable is securely connected between the charging pins.
When I turn on the device, it emits two beeps with two red blinks and turns off.	- The vibrating mesh or the disinfection system has suffered any damage.	- Contact the distributor for assistance.

If the device continues to have issues even after following the troubleshooting steps mentioned in the table above, it is possible that the device is faulty. In such cases, it is recommended to contact the distributor for further assistance and troubleshooting. They will be able to provide guidance on how to proceed with the faulty device.

9. DEVICE SPECIFICATIONS

TECHNICAL SPECIFICATIONS

Mains power supply	Input = 100-240 V; 50-60Hz Output = 5Vdc; 1.2A
Internal rechargeable battery power supply (lithium polymer)	3.7 V dc; 1150 mAh
Weight	146 g
Size	14 cm x 4,8 cm x 4,8 cm (with front and upper protector)
Class II device internally powered device (double safety insulation). Type BF device (device with specific protection against electrical hazards). Ingress Protection rating IP22 (protected against solid foreign objects of 12.5mm diameter and greater; protected against vertically falling water drops when device titled up to 15°). Nebura and the charger form a Medical Electrical System, where the charger is not Medical Electrical Equipment. The IP22 rating applies only to Nebura, while the charger rating is IPX0. Device housing materials – Polycarbonate (medical PC). Mouthpiece material – medical thermoplastic elastomer (TPE). Kid mask – medical grade PVC.	

CERTIFICATION

Reference to standards
Electric safety standards EN 60601-1
Electromagnetic compatibility according to EN 60601- 1-2

OPERATING CONDITIONS

Temperature range +5ºC to +40ºC
Humidity range of 15% HR to 90% HR, non-condensing
Atmospheric pressure 70 kPa to 106 kPa

STORAGE AND TRANSPORT CONDITIONS

Temperature range of -25ºC to +5ºC
+5ºC to +35ºC at a relative humidity up to 90%, non-condensing
+35ºC to 70ºC at a water vapour pressure up to 50 hPa

TECHNICAL DATA ACCORDING TO ISO 27427

Parameter	Solution	Extraction Flow of 15l/min
Aerodynamic Mass Median Diameter (MMAD) Mouthpiece	Isotonic saline (0.9%)	13 µm
Aerodynamic Mass Median Diameter (MMAD) Kid Mask	Isotonic saline (0.9%)	13 µm
Geometrical standard deviation (GSD)	Isotonic saline (0.9%)	2
Aerosol output	Isotonic saline (0.9%)	4,70 mL
Aerosol output rate	Isotonic saline (0.9%)	1,09 mL/min
Maximum fill volume	Isotonic saline (0.9%)	5 mL
Maximum temperature rises of the solution solution	Isotonic saline (0.9%)	<5ºC
Noise level	Isotonic saline (0.9%)	0,2 dB
Particle distribution >5 µm	Isotonic saline (0.9%)	88%
Particle distribution in the range of 2-5 µm	Isotonic saline (0.9%)	5%
Particle distribution <2 µm	Isotonic saline (0.9%)	7%
Respirable fraction	Isotonic saline (0.9%)	12%
Percentage of fill volume (5 ml) as aerosol output (delivered to the filter) in one minute	Isotonic saline (0.9%)	22%
Residual volume	Isotonic saline (0.9%)	0,30 mL

If the device has been stored at extreme temperatures, it should be allowed at least 1 hour at room temperature before use. Performance information as required by ISO 27427:2013 may not apply to medicinal products in suspension or high viscosity form. In such cases, the supplier of the medicinal product should be consulted for the information.

Additionally, the device's performance may vary based on atmospheric pressure, altitude above sea level, barometric pressure, and temperature. The nebulizer's performance is tested using adult ventilation patterns and may differ for pediatric and infant populations.

Electromagnetic Compatibility (EMC) is an important consideration for Nebura, and it requires special precautions during installation and commissioning. The EMC information provided in the document should be followed to ensure proper functioning and compatibility with other electromagnetic devices.

It's important to note that portable and mobile RF (Radio Frequency) communications equipment can have an impact on medical electrical equipment, including Nebura.

Therefore, it is advisable to be cautious when using such equipment near Nebura to prevent any potential interference. The minimum expected lifetime of Nebura is stated as 3 years. This indicates the estimated duration of reliable performance under normal usage conditions.

10. **SYMBOLS**

The following table describes the symbols that may be printed on the box. Please refer to the package label for applicable symbols in relation to the product.

Symbols	**Description**	**Source of the symbol**
	Instructions for use	ISO 7010-M002
	Manufacturer	ISO 15223-1:2022
	Date of the manufacture	ISO 15223-1:2022
	The CE marking is the manufacturer declaration that the product fulfils the requirements of the CE applicable legislation.	MDR (EU) 2017/745

Symbols	Description	Source of the symbol
REF	Catalog number	ISO 15223-1:2022
LOT	Batch code	ISO 15223-1:2022
SN	Serial Number	ISO 15223-1:2022
MD	Medical Device	ISO 15223-1:2022
UDI	Unique Device Identifier	ISO 15223-1:2022
IP22	Ingress Protection degree	ISO 15223-1:2022
	Separate Collection	ISO 15223-1:2022
	Temperature limit	ISO 15223-1:2022
	Identifies a type BF applied part complying with IEC 60601-1	IEC 60417
5V ⎓ 1.0A	Indicates that the equipment is suitable for direct current only; to identify relevant terminals	IEC 60417
	Identifies equipment meeting the safety requirements specified for Class II equipment according to IEC 61140	IEC 60417
	Indicates the need for caution when using the product	ISO 15223-1:2022

11. **WARRANTY**

Lainomedical, S.L., warrants that the nebulizer and battery are free from the effects of materials and workmanship under normal use and operating conditions for a period of 2 years from the date of purchase.

The warranty is limited to repairing or replacing, at the sole option of Lainomedical, S.L., any component or equipment deemed defective, when the claim is proven to be bona fide as assessed by Lainomedical, S.L.

This warranty does not extend to components or equipment subjected to misuse, improper operation, accidental damage, or unauthorized repairs, nor does it cover labor charges for repairs. All returned items must be properly packaged and sent prepaid by the distributor responsible for providing the service for the unit. Lainomedical, S.L., shall not be liable to the purchaser or any third party for the loss of use of the equipment or for indirect, incidental, or consequential damages that may arise.

Please note that the replacement of any Nebura part by inadequately trained personnel could lead to a hazardous situation of this type.

12. **ELECTROMAGNETIC COMPATIBILITY (EMC)**

NEBURA IS SUITABLE FOR THE ELECTROMAGNETIC HOME ENVIROMENT

CAUTIONS

- Portable RF communications equipment, including peripherals such as antenna cables and external antennas, should not be used within 30cm of any part of the Nebura system, including any cables specified by the manufacturer. Failure to comply with this requirement may degrade the performance of the equipment.
- Nebura should not be used in conjunction with or stored with other equipment. If necessary, normal operations should be verified.
- The use of accessories, transducers, and cables other than those specified or supplied by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, which may lead to improper operation.

ELECTROMAGNETIC EMISSIONS

Nebura is intended for use in the specified electromagnetic environment. It is the responsibility of the customer or user to ensure that Nebura is used in such an environment.

Emissions test	**Compliance**	**Guidance - Electromagnetic environment**
RF emissions CISPR 11	Group 1	Nebura uses RF energy only for its internal operation. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Nebura is suitable for use in all establishments, including domestic establishments and those directly connected to the public, low-voltage electricity network that supplies domestic buildings.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000- 3-3	Complies	

ELECTROMAGNETIC IMMUNITY

Nebura is intended for use in the electromagnetic environment specified below. The customer or user of Nebura must ensure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Level of Compliance**	**Guidance - Electromagnetic environment**
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz 6Vrms 150 kHz to 80 MHz ISM and amateur radio bands	3Vrms 6Vrms	The quality of the power grid should be similar to a home environment.
RF radiated IEC 61000- 4-3	10V/m 80 MHz to 2.7 GHz	10V/m	

Immunity test	IEC 60601 test level	Level of Compliance	Guidance - Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Relative humidity should be at least 5%.
Electrical fast transients /burst IEC 61000-4-4	±2 kV power supply	±2 kV power supply	The quality of the electrical network should be that of a domestic environment.
Surge IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	
Voltage dips, interruptions and voltage variations on input lines IEC 61000-4-11	0% UT: 0.5 cycle at 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º. 0% UT: 1 cycle. 70% UT: 25/30 cycles 0% UT: 250/300 cycles Monophase: 0º	0% UT: 0.5 cycle at 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º. 0% UT: 1 cycle. 70% UT: 25/30 cycles 0% UT: 250/300 cycles Monophase: 0º	The power quality of the mains should be similar to a home environment. If continuous operation during mains power interruptions is required beyond what the battery provides, it is recommended to power Nebura from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields from common household appliances are not expected to affect the device. Power frequency magnetic fields should be at levels typical of a typical location. Keep Nebura away from sources of high levels of power line magnetic fields (greater than 30 A/m) to reduce the possibility of interference.

LAINOMEDICAL

Manufacturer: Lainomedical S.L.
Paseo Miramón 170, San Sebastián, 20014, SPAIN
www.lainomedical.com

CE 1912