

UN 300A

User Guide

CE 1984

Please read this manual thoroughly before use the device.

CONTENTS

SUBJECTS	PAGE NO
1. GENERAL INFORMATION	5
2. SAFETY GUIDELINES	7
3. STARTING-UP/INSTALLATION	7
4. OPERATING PRINCIPLES	9
5. PREVENTIVE MAINTENANCE	11
6. TROUBLESHOOTING	11
7. TECHNICAL CHARACTERISTICS	11
8. LIST OF ACCESSORIES	11
9. WARRANTY (TERMS & CONDITIONS)	12
10. CERTIFICATES	13
11. EMC DECLARATION	16
12. MANUFACTURER COMPANY INFORMATION	18

GLOSSARY OF SYMBOLS


CAUTION CONSULT ACCOMPANYING DOCUMENTS


CLASS II EQUIPMENT


CONFORMITE EUROPE


NOT MOVED WITH HOOK


DATE OF MANUFACTURE

IPX1 PROTECTION AGAINST VERTICALLY FALLING DROPS


THIS SIDE UP


SHOULD BE DISPOSED ACCORDING TO WEEE DIRECTIVES


MANUFACTURER


TYPE B


FRAGILE, HANDLE WITH CARE


KEEP DRY

SN SERIAL NUMBER

1. GENERAL INFORMATION

NEBTIME is a device designed for the use of ultrasonic devices, liquids for aerosol and steam treatments.

In the transformation of liquids into steam form instead of heating method frequency is applied. Frequencies formed by microprocessors electronic system by means of piezo-ceramic crystal are transformed into mechanical vibrations. By means of those vibrations, liquid preserved in the pot is evaporated without heating. Moreover, a fan located in the device absorbs air from the external environment. That air being absorbed passing along a bacterial filter ispurifiedandpressed into the liquid reservoir. Continuously formed steam in the liquid reservoir is sent to outside via the formed air pressure and by the hose given to patient. That composed steam upon claim may be heated by a heater at the outlet.

NEBTIME ultrasonic nebulizator is manufactured enabling practical use for you with regard to its design composed of microprocessor detection **128*64 LCD, Control panel and key pad, Visual and audio warning systems, Adjustable steam power intensity, fan speed, timer, heater level, Liquid feeding unit, Plastic body, Bacterial filter, Low energy consumption, Piezo-ceramic crystalline practical replenishment, Outlet steam heater, Medicine containing implementation** at the same time single component foot system applied in the devices provide practical installation.

FIELDS OF USE

Moisturizing respiration and narcotic gases
Acute and chronic bronchitis
Bronchial asthma
Pneumonia
Specific and non-specific lung diseases
Pre-bronchoscopy local anesthesia
Drug and water pulverization
Ambient moisturizing

INDICATIONS

Common indications about the usage of ultrasonic nebulizers:
Asthma: More effective delivering bronchodilator and anti-inflammatory drugs used in the treatment of asthma to the respiratory tracts
COPD (Chronic Obstructive Pulmonary Disease): In the implementing of bronchodilator drugs to relieve the symptoms of COPD
Lung Infections: Delivering drugs used in the treatment of bacterial or viral lung infections directly to the areas affected by the infection
Allergic Diseases: In the implementing of drugs used in the treatment of respiratory problems due to allergic reactions such as allergic asthma or allergic rhinitis
Cystic Fibrosis: In the implementing of drugs that help reduce the mucus in the respiratory tract to a thinner consistency

These indications include situations where ultrasonic nebulizers are frequently used. But, each patient's condition is different and the treatment plan for nebulizer usage is determined as a result of doctor's evaluation. So it is important to discuss with a healthcare professional before using these devices. Indications for nebulizer usage are usually determined by a healthcare professional and can be fixed according to the patient's specific condition.

CONTRAINDICATIONS

This product should not be used in patients with unstable and high blood pressure, cardiac irritability, increased heart rate, unconsciousness, or unable to breathe spontaneously.

SIDE EFFECTS

If the device is not cleaned regularly, bacteria which may form in the water reservoir, may affect the patient. In case of using ventolin derivative drugs with cold steam, these drugs may have side effects.

PATIENT POPULATION

Patients over 2 years of age and more than 10 kg with severe respiratory distress and treatment.

TARGET USER

Medical professionals such as doctors, nurses, therapists.
The patient or the patient's caregiver in home treatments under the guidance of a medical professional.
The user also must be able to understand the contents of the user manual.

2. SAFETY GUIDELINES

• Carefully read the use guide book before use entirely.
• You are suggested to inspect the availability of the electrical voltage value of the fuse where the electricity cable going to be mounted compare to the voltage value of the device operation.
• During the transportation of the device definitely take out the electricity cable of the device from the fuse.
• Do not operate the device very close to heat source materials.
• Do not stick in any substance into the air filter holes of the device.
• Keep the device from reach of children.
• Following the completion of the device use, turn off the on/off switch and take out the electricity cable from the fuse.
• Do not pour water on the device.
• In case of any breakdown read the TROUBLESHOOTING section of that guide.
• Except the liquid materials recommended by your doctor never use that device for evaporating any liquid.

ALARM SYSTEM

Liquid Level Alert: If the liquid level in the chamber drops to the minimum level, the device turns off but does not give any audible or visual alert.

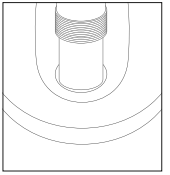
3. INSTALLATION

Please control the packing and the device on arrival. If there is any deformation or damage in the packing or in the inside materials, please inform the courier or the seller of the goods immediately. Take out from the package all components carefully controlling crash, breakage or any other damages.

Let stand four (4) hours in user environment before start using the device.

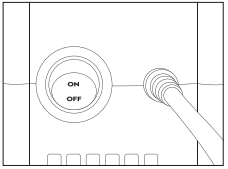
Place the device on plain and solid floor. Connect the power supply cord into the plug of AC 230V.

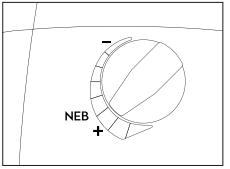




Fill the water flask of the device with cooled boiled or distilled water to the maximum level mark and close the lid and vapor tube connect to lid. Now the device is ready to use.

4. OPERATING PRINCIPLES

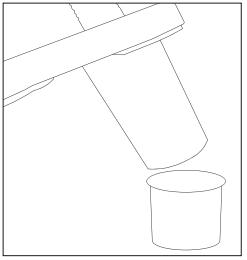




Run the device operating OFF/ON switch to ON positing.

Set the vapour level as per requirement using NEB button of the device.

Take special care keeping water level of the flask above minimum mark unless Piezo Crystal may damage. Water level is low, the device automatically stops and gives an audible alarm. Please add enough water before running on the device.



Device for use with medicine:

Put the medicine into medicine cup attach on lid, close lid, start device.

Switch off the device using OFF/ON switch when not in use and unplug the power supply cord.

Keep the device away from children.

Like most of electronic equipments NEBTIME too effects with Radio Frequency waves (parasite). Please take care of not using mobile phone around the device.

5. PREVENTIVE MAINTENANCE

Please switch off the device & unplug power supply cord before maintenance work.

CLEANING OF OUTER CABINET
Do not use any liquid cleaning agent directly of the device. Using of petroleum based solvents and cleaning agents are prohibited. Clean the outer cabinet with pad wetted with soap water and well twisted.

CLEANING OF WATER FLASK
Please clean the flask with well twisted pad wetted with soap water first and then wash the pad with plenty of water and wipe the flask several times.

6. TROUBLE SHOOTING

Please consult with authorized technical service if you face any unexpected situation with the device.

7. TECHNICAL CHARACTERISTICS

NEBULIZING CAPACITY	0 – 5 ml / min ± % 10
PARTICLE SIZE	0,5 – 6 µm
OSCILLATOR FREQUENCY	1,68 MHz ± % 5
WATER FLASK CAPACITY	max. 300 ml
NOISE LEVEL	< 50 dBA
LINE VOLTAGE / CURRENT	230 VAC / 50 - 60 Hz / 0,20 A ± %10
ELECTRIC CONSUMPTION	40 Watt ± %10
WEIGHT	1.5 kg
WORKING CONDITIONS	10-40°C, % 20 - % 60 RH
STORAGE CONDITIONS	10-60°C, % 10 - % 95 RH
ELECTRICAL SAFETY	TYPE B, CLASS II
CERTIFICATES	ISO 9001, ISO 13485, CE 1984
IP CLASS	IPX1

8. LIST OF ACCESSORIES

1 pc tube
5 pc medicine cup

10. CERTIFICATES

CE 1984

ISO 9001:2015

ISO 13485:2016

Notified Body	Kiwa Belgelendirme Hizmetleri A.Ş. İTOSB 9. Cd. No:15 Tuzla / İstanbul / Türkiye

ELECTROMAGNETIC COMPATIBILITY (EMC) DECLARATION

This equipment generates, uses and can radiate radio frequency (RF) energy. This equipment may cause electromagnetic interference if it is not installed and used in accordance with the manual.This device has been tested for Medical Products in accordance with EN-60601-1-2:2015 and has been determined to comply with acceptable limits. These limits indicate that the device provides an acceptab- le level of protection against electromagnetic interference (EMC) if the device is used as specified in the manual.This device may be affected by portable and mobile RF communication devices. This equipment must not be stored together with other equipment.See the following tables for more information about this device and EMC.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
Emissions RF CISPR 11	Group 1	The device 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.
Emissions RF CISPR 11	Class B	The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions used fordomestic purposes. IEC 61000-3-2	Class A	
Voltage fluctuations/ flickeremissions IEC 61000-3-3	Complies	

KILAVUZ ve İMALATÇININ BİLDİRİMİ - ELEKTROMANYETİK BAĞIŞIKLIK

Bu cihaz aşağıda belirtilen elektromanyetik ortamda kullanılmak amacıyla tasarlanmıştır. Bu cihaz müşterisi ya da kullanıcısı bu gibi ortamlarda kullanıldığından emin olmalıdır.

Immunity test	IEC 60601 Testlevel	Compliancelevel	Electromagnetic environment – guidance
Electrostatic discharges IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV,±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV,±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30
Electrical fast transient/burst IEC 61000-4-4	Power supplylines: ±2 kV Input/output lines:±1 kV 100 kHz repetitionfrequency	Power supplylines: ±2 kV Input/output lines:±1 kV 100 kHz repetitionfrequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-line IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-ground IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	
Voltage dips IEC 61000-4-11	0% UT;0.5 cycle 0°, 45 °, 90 °, 135 °, 180 °,225 °, 270 ° and 315 °	0% UT;0.5 cycle 0°, 45 °, 90 °, 135 °, 180 °,225 °, 270 ° and 315 °	Mains power quality should be that of a typical commercial or hospital environment.
	0% UT; 1 cycle and 70% UT;25/30 cycle Single phase: 0°	0% UT; 1 cycle and 70% UT;25/30 cycle Single phase: 0°	
Voltage interruptions IEC 61000-4-11	0% UT;250/300 cycle	0% UT;250/300 cycle	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Not: UT is the a.c. mains voltage prior to application of the test level.			
Conduced RF IEC 61000-4-6	150kHz to 80MHz: 3Vrms 6 Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150kHz to 80MHz: 3Vrms 6 Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Portable and mobile RF communications equipmentshould be used no closer to any part ofthe device including cables, than the recommendedseparation distance calculated from theequation applicable to the frequency the transmitter.Recommended separation distance: d= 0.35√ d= 1.2√ 80 MHz ile 800 MHz d= 1.2√ 800 MHz ile 2.7 GHz d= 2.3√ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, asdetermined by an electromagnetic site survey, should be less than the compliance level in each frequency range.Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10V/m 80% Am at 1kHz	10V/m 80% Am at 1kHz	

Note 1: 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures,objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio,AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
c. Calibration for current injection clamps shall be performed in a 150 Ω system.
d. If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
e. Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)			
	150 kHz to 80 MHz (out ISM and amateur radio bands) d= 1.2 √ P	150 kHz to 80 MHz (out ISM and amateur radio bands) d= 0.6 √ P	80 MHz to 800 MHz d= 1.2 √ P	800 MHz to 2.7 GHz d= 2.3 √ P
0,01	0,12	0,06	0,12	0,23
0,1	0,38	0,19	0,38	0,73
1	1,2	0,6	1,2	2,3
10	3,8	1,9	3,8	7,3
100	12	6	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacture
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz.21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures,objects and people.

Radiated RF	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	Immunity Test Level(V/m)
IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipments	385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380-390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704-787	LTE BANDI 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870 930	800-960	GSM 800/900, TETRA 800, İDEN 820, LTE Bant 5	Pulse modulation b) 18 Hz	2	0,3	28
	1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Bant1,3,4,25, UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	2450	2400-2570	Bluetooth,WLAN 802.11b/g/n, RFID 2450,LTE Bant 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240 5240 5785	5100-5800	WLAN 802.11a/n	Pulse modulation b) 217 Hz	0,2	0,3	9

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.
b. The carrier shall be modulated using a 50 % duty cycle square wave signal.
c. As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:
E= 6 / d √ P
Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

12. MANUFACTURER

elmaslar

İmalat Tıbbi Cihazlar İthalat İhracat A.Ş.

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01.01.2024 REV08



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