elmaslar

NEBTIME



CN01 - CN02 - CN04

User Guide

CE 1984

Please read this manual thoroughly before use the device.

GENERAL INFORMATION

NEBTIME COMPRESSOR Nebulizer has been developed for the purpose of using of drugs in aerosol form converting from liquid form. Build-in oil-free air compressor produce compressed air in the device. Compressed air generated by the air compressor reaches to the aerosol chamber through a cannula. Thanks to compressed air pressure converts liquid medicine in the aerosol chamber into aerosol form which is used by the patient.

IMPORTANT WARNINGS

Please read carefully a-z of the user manual of the device before using it. We recommend to control the compatibility of electrical line voltage of the plug where the device will be connected. The electrical cable must be disconnected during transportation of the device. Do not run the device keeping it very close to heat sources. Do not put any object inside the air filter hole of the device. Prevent children from interfering the device. When the device is not in use switch off the device by using off/on switch and unplug the power cable from socket. Do not pour water on the device.
If there is any breakdown, please read troubleshooting section of this manual. Do use any other liquid to convert into aerosol form except your doctor prescribed.

INSTALLATION

Please control the packet and device on arrival. If there is any damage in the packet or the content please inform the courier or the seller of the device. Bring out all parts carefully from the carton box and control physically if there is any compressed, broken or damaged parts. Place the device on firm and plan surface and connect with 220 - 230 V AC electrical line.

INTENDED USE OF THE DEVICE

Aerosol therapy is used to relieve breathing and support treatment in lung diseases that cause shortness of breath such as bronchiolitis, bronchitis and asthma. As an example of these diseases are Acute and chronic bronchitis, Bronchial asthma, Pneumonia, Specific and non-specific lung diseases.

SIDE EFFECTS

The compressor nebulizer device has no direct contraindications. However, the drugs that patients use by converting to aerosol with this device may have contraindications. It should not be used in cases where the effects of these drugs on platelets may increase the risk of bleeding (eg. active peptic ulcer, trauma, intracranial bleeding). Severe coronary heart disease or unstable angina, Myocardial infarction within the last 6 months, Decompensated heart failure without close medical monitoring, Serious arrhythmias, Suspected pulmonary congestion. Cerebrovascular events (eg. transient ischemic attack, stroke) within the last 3 months, Pulmonary hypertension due to venous occlusive diseases. Drug inhalation may cause risk of triggering bronchospasm, especially in patients with bronchial hyperactivity. The benefits of the drug have not been proven in patients with concomitant Chronic Obstructive Pulmonary Disease (COPD) and severe asthma. Patients with concomitant acute lung infections, COPD and severe asthma should be carefully monitored. In thromboembolic pulmonary hypertension, the drug should not be used as the first choice if surgical intervention is possible. If signs of pulmonary edema occur when iloprost is given in patients with pulmonary hypertension, the possibility of a pulmonary veno-occlusive disease should be considered. Treatment should be stopped.

PATIENT POPULATION

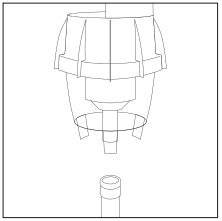
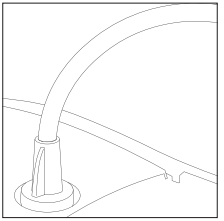
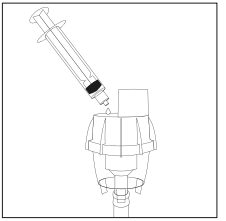
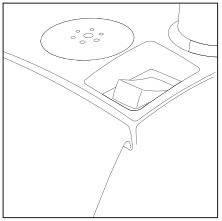
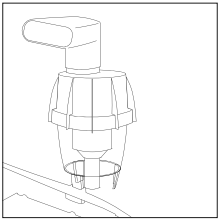
Patients over 2 years of age and more than 10 kg with severe respiratory distress and treatment.

CONTRAINDICATIONS

This product should be used on patients who are unconscious or unable to breathe spontaneously. Should not be used.

USING

Run the device by pressing the off/on switch. You will see the veporized medicine coming out, use this vapor by inhalation. If you want you can use the device by hanging the aerosol chamber at the back of the device.

Shutdown the device using off/on switch once not is use and unplug the power cable from socket. Keep the device away from children.

It has been recommended to use a new aerosol chmaber for fresh use.

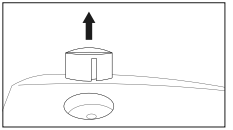
Most of the electronic devices affected by radio frequency (parasite); be careful when using a mobile comunication device around the device.

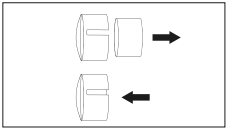
MAINTENANCE AND CLEANING

Please be sure that the device has been switched off and the power cord has been unplugged before proceed for maintenance and cleaning of the device. Wear protective gloves during this procedure.

CLEANING OF THE DEVICE
Each time before using the device disinfect the outer surface of the device, collection jars and lids using medical disinfectant.
The disinfectant should be used as per its own operating instructions.

CLEANING OF AIR FILTER
Pull out the air filter from the edvice.
Replace it with a new one and put in it's place.





TROUBLESHOOTING

Please inform authorised technical service once you face any malfunctioning of the device.

TECHNICAL FEATURES

AVERAGE NEBULIZING SPEED	0,2 ml / min
PARTICLE SIZE	0,5 – 10 µm
MMAD	4 µm
CHAMBER CAPACITY	13 ml (max.)
NOISE LEVEL	< 50 dBA
VOLTAGE / CURRENT	230 VAC / 50 Hz / 0,70 A ± %10
AIR FLOW	6 - 8 l / min
AIR PRESSURE	35 PSI (max.)
WEIGHT	< 2 kg
RUNNING 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

LIST OF ACCESSORIES
1 Pc Nebulizer Set: 1 air cannula, 1 adult mask, 1 pediatric mask, 1 mouth apparatus, 1 T apparatus & 5 pcs. Spare air filters, 1 nebulization cup.

WARRANTY TERMS

1.The warranty period starts from the date of delivery of the device to the consumer and is two years.

2. If the device malfunction within warranty period, the time spent in repairing the device added in the warranty period.

3. In the event of complaint about the device, please send the device to your device provider or send to our company with prepaid courier along with its original packaging and warranty certificate inside.

4. The warranty doesn't cover the faults occurred due to improper use of the device.

5. Opening the device by a non-authorized person will cause invalidity of the warranty.

6. The faults resulting from the use of the device contrary to the clauses mentioned in the user manual, warranty doesn't cover.

7. This warranty given to the devices implies, once all these terms mentioned here are accepted.

8. Consumable parts are not covered under warranty.

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

SN SERIAL NUMBER


TYPE BF


KEEP DRY

CERTIFICATES

CE 1984

ISO 9001:2015

ISO 13485:2016

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

MANUFACTURER COMPANY INFORMATION

elmaslar

İmalat Tıbbi Cihazlar İthalat İhracat A.Ş.

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18. 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.



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