COMPRESSOR NEBULIZER

MODEL NO: AL-50

USER GUIDE

ArmoLine

COMPRESSOR NEBULIZER
USER MANUAL

MODEL NO: AL-50

PLEASE READ THIS MANUAL CAREFULLY PRIOR TO USE

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www.medimport.com.tr

CE 1984 01

COMPRESSOR NEBULIZER
MODEL NO.: AL-50

INSTRUCTIONS

1. INTRODUCTION

Thank you for purchasing the Compressor Nebulizer. It is a compact medical device designed to deliver the drug prescribed by a doctor to the bronchial lobes in an efficient manner. Proper care and use will provide you with reliable treatment for many years.

This product has been developed for the successful treatment of asthma, allergies and other respiratory disorders. From the air conduit, the nebulizer creates an air current that flows towards the body. When the air enters the nebulizer, it will turn the medicine into aerosol for easy inhalation.

The Compressor Nebulizer must be used under the supervision of a licensed physician and / or a respiratory therapist. We strongly recommend that you read this manual thoroughly to learn about these product features. This product should always be avoided for any purpose other than its intended use.

Indication:

Compressor nebulizers are used for children and adults by breaking down drugs into small particles by virtue of aerosol method through and giving them to patients by airway for therapeutic purposes by utilization of a mask and mouth piece.

Contraindications:

The device is not suitable for use in patients who are unconscious or cannot breathe by themselves normally. The device also is not suitable for use in anesthetic or spontaneous patients. The device should not be used in anesthetic or ventilated breathing circuits.

Side Effects:

The device has no identified side effect. Side effects of the drugs used with the device are described in the user manual of the device.

Usage Type:

The device is a household appliance and designed for home use.

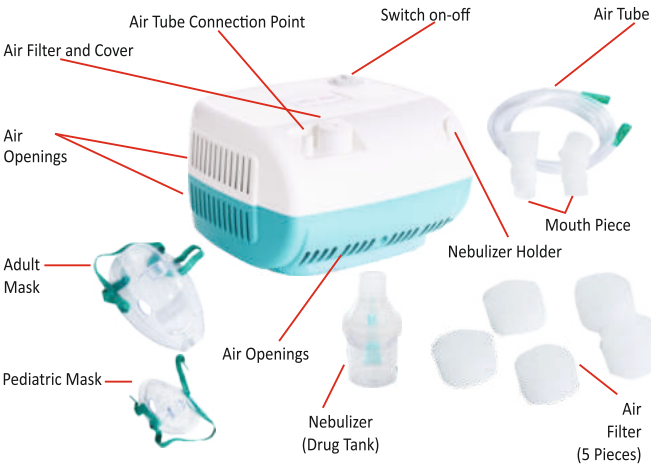
Patient Population:

The device can be used for adults and children and there is no gender discrimination incident thereto.

SYMBOLS

SYMBOL	DESCRIPTIONS
CE 1984	CE marking and notified body number according to Directive 93/42 / EEC (1984)
	Producer
	Production Date
	Class II Device
	Type BF Applicable Parts
	Read the User Manual
REF	Product model number
SN	Product serial number
	It is forbidden to dispose of the device and the parts thereof if the device has completed its service life according to the 2002/96/EC electronic and electrical equipment directive,. Apply to local authorities for its disposal.
	Fuse
	Consider the warnings
IP20	Protection class against dust and liquid
	Fragile
	Keep in a dry place.
	Laying direction

3. PRODUCT INTRODUCTION



4. IMPORTANT SAFETY PRECAUTIONS

Note: Carefully read all instructions before using.
The following basic precautions must be taken when using an electrical product:
Caution: Failure to read this booklet and take all necessary precautions may result in personal injury or equipment damage.

Issues to be considered about the product:

1. To avoid electric shock: Keep the unit away from water * Do not immerse the electric cord or unit in a liquid * Do not use while bathing * Do not try to reach a water-dropping unit - immediately unplug the unit.
2. Never operate the unit if it has any damaged parts (including power cord), it has fallen in water or is actually water. Immediately send it to a service center for inspection and repair.
3. The unit should not be used where flammable gases, oxygen or aerosol spray products are used.
4. Unplug the unit before cleaning, filling and after each use.
5. Do not use any other components which are not recommended by the manufacturer.
6. Prevent access by children or unauthorized persons without being supervised.
7. Home Care & Usage: Keep all accessories of the device out of the reach of children under 36 months since the device contains small parts which can be swallowed.
8. The device contacts the patient's hose and/or power cord with the mask and mouthpiece (supplied with the device) in line with the relevant CE conformity certification and in this way there is no allergic reaction and skin irritation.
9. According to the requirements of the Medical Device ISO 10993-1 regulation, the relevant CE conformity certification contact with the patient thanks to the mask and mouthpiece (supplied with the device), so that no reaction and skin irritation.
10. Keep the device and its accessories away from pets.

Issues to be considered during use:

1. Connect this product to an appropriate voltage outlet according to the model you are using.
2. Do not operate this product while no aatendant is present.
3. Never use this unit if it has a damaged cord or plug, has fallen into water, or is in any way in water, or does not function properly. Return it to a service center for repair.
4. If any abnormality arises, stop using it immediately until the unit is inspected and repaired.
5. Always unplug the product immediately after use.
6. Never close the air vents of the main unit or place the unit where the air vents can be blocked.

Issues to be considered during storage:

1. Do not store the unit in direct sunlight, high temperature or exposed to moisture.
2. Store the unit in places where small children can not reach it.
3. Always keep the unit unplugged when not in use.

Issues to be considered during cleaning:

1. Do not immerse the unit in water. This can lead to damage to the unit.
2. Disconnect the unit from the electrical outlet before cleaning.
3. Clean all necessary parts after each use as described in this manual.

5. USE OF THE COMPRESSOR NEBULIZER

1. The nebulizer (drug tank) works up to an angle of 45°. Ensure that the angle is not more than 45°.
2. Open the product box and take the accessories of the device out.
3. Important: Before starting the first time, the nebulizer should be cleaned thoroughly by looking at the "Cleaning Procedures" section of this manual.

	To open the nebulizer, unscrew it counterclockwise.
	Fill the prescribed amount of medication into the nebulizer and screw it clockwise to close it again. Make sure the parts are in place. Furthermore, ensure that the drug tank does not exceed the temperature of 45° during usage.
	Connect the air tube. Connect one end to the bottom of the nebulizer and the other end to the connection point on the device.
	Connect the mouth piece or mask as desired to the top of the nebulizer.
	Plug the power cord into a suitable power outlet.
	Be sure the switch is set to "Off" for the procedure above.
	Hold the nebuliser in your hand and connect the mouthpiece or mask as desired. To begin the prescribed treatment, switch the switch to "On".
	Turn off the device and remove the plug as soon as the treatment is complete.

Important:

The motor of the compressor has a thermal protector which closes the unit before the unit overheats. As the thermal protection unit is switched off, please do the following:

a. Switch the unit off.
b. Unplug the unit from the socket.
c. Wait 30 minutes for the engine to cool down before proceeding to the next treatment. The correct operating system is operating the device for 20 minutes and making the device rest for 30 minutes. Make sure the air openings are unobstructed.

6. CLEANING

It is recommended that the nebuliser, mouthpiece and mask should be cleaned thoroughly with hot water after each use and also with a mild detergent after the last use. If your doctor or respiratory therapist specifies a different cleaning procedure, follow their instructions.

Washing (after each treatment)

1. Unscrew air pipe, nebuliser, mouthpiece and mask.
2. Gently turn the nebulizer to open it.
3. Wash the nebulizer, mouthpiece and mask with water.
4. Dry with a clean soft towel or leave to dry outdoors.
5. When fully dry, reassemble the nebuliser and place these pieces in a dry, closed container.

Disinfection:

Unless otherwise specified by your doctor, please follow the steps below to purify your nebulizer from microorganisms. It is recommended that the unit be disinfected after the last treatment.

1. Use a solution consisting of one volüme of white vinegar and 3 volumes of pure water. Make sure that this mixture solution is sufficient to immerse the nebuliser, the mouthpiece and the mask.
2. Keep the pieces in the vinegar-water solution for 30 minutes.
3. Wash the nebulizer, mouthpiece and mask with warm water and a mild detergent. Then wash them in hot tap water.

Cleaning the compressor

1. Wipe with a damp piece of cloth everyday.
2. Do not use any powder detergent or soap which could damage the body of the appliance.

Changing filter

1. Do not use cotton or any other material. Do not wash or replace the filter. Only use filters supplied by the manufacturer and / or dealer / distributor and do not operate without a filter.
2. Change the filter every 30 days or when the filter begins to turn gray.
3. Changing procedure
   A. Remove the filter cover.
   B. Replace the used filter with a new one.
   C. Replace the filter cover.

7. TECHNICAL SPECIFICATIONS

Voltage and frequency values	AC200-240V / 50-60 Hz
Power consumption	180 VA
Drug Capacity	8 ml
Particle size	0.5 to 10 µm
MMAD	<3µm
Sound Level	≤ 55 dBA
Average Spray Rate	Min. 0.25 ml/min.
Compressor Pressure Range	35 to 50 Psi (210 to 345 KPa/ 2.1 to 3.4 bar)
Operating Pressure Range	8 to 16 Psi (50 to 100 KPa/ 0.5 to 1.0 bar)
Liter Flow Rate	8~10 lpm
Working Temperature Range	10 C° to 40 C° (50 F° to 104 F°)
Working Humidity Range	% 10 dan 95 RH e
Storing Temperature Range	-20 C° to 70 C° (-4 F° to 158 F°)
Storing Humidity Range	10 to 95% RH
Nebulization Rate	Minimum 0.25ml / min
Electrical Class	Class II
Applied Part Type	Type BF
Dust and liquid protection class	IP 20
Fuse	F 1.6A L 250 V
Measurements (L x W x H)	90 x 125 x 145 mm (35.43" x 49.21" x 57.08")
Weight	1060 g (without accessories)
Gift Box Measurements	167 x 160 x 145 mm
Gift Box Weight	1335 g
Outer Carton Box Measurements	455 x 350 x 330 mm
Outer Carton Box Wight	17.00 kg
Outer Carton Box Content	A carton box has 12 devices
Accessories	In a single package Drug container (nebulizer), adult and child (pediatric) mask, air tube (hose), mouth piece and 5 filters
Product Life	10 Years

This symbol on the device indicates that electrical and electronic equipment is collected separately. At the end of the lifetime, do not dispose it with mixed municipal waste, direct it to the special collection center in your area, or dispose of it by returning it to the distributor / manufacturer / dealer while taking a new device with the same functions. The disposal of equipment and accessories must be carried out in accordance with applicable laws and regulations in each country where it is used.

8. EMC STATEMENT

This device generates, uses and can radiate radio frequency (RF) energy. If this equipment is not used as instructed in the manual, it may cause electromagnetic interference.

This device has been tested in accordance with EN 60601-1-2 Standard for Medical Devices and its suitability for acceptable limits has been determined. These limits indicate that if the device is used in the manner specified in the manual, the device provides protection at an acceptable level against electromagnetic interference (EMC).

This device has been designed and manufactured in accordance with the requirements of EN 60601-1-2, EN 13544-1.

This device may be affected by portable and mobile RF communication devices. This device must not be stored with other equipment.

For more information about this device and EMC, (see below) Tables 1, 2, 3 and 4.

Guide and manufacturer's declaration - electromagnetic emissions		
This device is intended for use in the electromagnetic environment specified bellow. This device must be operated by the customer or the user in such an environment.		
Emission Test	**Compatibility**	**Electromagnetic environment - guide**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal functions. For this reason, RF emissions are very low and therefore this device is not expected to cause electromagnetic interference to electronic devices nearby.
RF emissions CISPR 11	Class B	This device is suitable for use in organizations all of which are directly connected to the low-voltage city network intended for use in houses and premises within house category
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuation/ Vibration Emissions IEC 61000-3-3	Compatible	

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.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**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 supply lines: ±2 kV Input/output lines: ±1 kV 100 kHz repetition frequency	Power supply lines: ±2 kV Input/output lines: ±1 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-line IEC 61000-4-5	± 0,5 kV, ± 1kV	± 0,5 kV, ± 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-ground IEC 61000-4-5	± 0,5 kV, ± 1kV ± 2 kV	± 0,5 kV, ± 1kV ± 2 kV	
Voltage dips IEC 61000-4-11	0%*U*t; 0.5 cycle 0°,45°,90°,135°, 180°,225°,270° and 315°	0%*U*t; 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%*U*t; 1 cycle and 70% *U*t; 25/30 cycle Single phase: 0°	0%*U*t; 1 cycle and 70% *U*t; 25/30 cycle Single phase: 0°	
Voltage interruptions IEC 61000-4-11	0%*U*t; 250/300 cycle	0%*U*t; 250/300 cycle	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz/ 60 Hz	30 A/m 50 Hz/ 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Not: *U*T is the a.c. mains voltage prior to application of the test level.			

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.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conduced RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	150kHz to 80MHz: 3Vrms 6 Vrms (in ISM and amateur radio bands) 80% Am at 1kHz 10V/m 80% Am at 1kHz	150kHz to 80MHz: 3Vrms 6 Vrms (in ISM and amateur radio bands) 80% Am at 1kHz 10V/m 80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency the transmitter. **Recommended separation distance:** $d = 0,35\ \sqrt{P}$ $d = 1,2\ \sqrt{P}$ $d = 1,2\ \sqrt{P}$ 80 Mhz to 800 Mhz $d = 2,3\ \sqrt{P}$ 800 Mhz to 2,5 GHz Where P is the 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, as determined 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: 

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) $d = 1,2\ \sqrt{P}$	**150 kHz to 80 MHz (out ISM and amateur radio bands)** $d = 0,6\ \sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\ \sqrt{P}$	**800 Mhz to 2.7 GHz** $d = 2,3\ \sqrt{P}$
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 d 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 manufacturer.

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.

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.

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipments	Test Frequency (MHz)	Band a) (Mhz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m
	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	704-787	LTE Band 13.17	Pulse modulation b) 217 Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, IDEN 820, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS	Pulse modulation b) 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n. RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
	5240						
	5785						

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:

$$E = 6/d\sqrt{P}$$

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.

TROUBLESHOOTING

FAILURE TYPE	REASON	SOLUTION
1. The device does not work	a) The power adapter may not be plugged in. b) The device may be overheated.	a) Make sure that the connection is made. b) Unplug the device and let it cool down.
2. No spraying or not enough spraying	The cover of the drug tank is not closed.	Open the cover and refit it properly.
	Air Tube dislodged	Plug the Air Tube to the connection point on the device.
	Drug inside the drug tank is finished or too much drug has been added in the drug tank.	Add the correct amount of medication to the medication tank.
	Air Filter is clogged or dirty	Make sure that the sponge Filter under the Air Filter Cover is changed regularly and is not clogged.
	Angle of the drug tank is more than 45 degrees	Ensure that the medication tank is less than 45 degrees in an upright position
	Air Tube curled	Make sure that the Air Tube is not curled and clogged so as not to block the air flow
	The engine does not start	Contact the authorized service
3. The device does not work when the On-Off Button is set to '1' (one).	a) The power adapter may not be plugged into the socket on the back of the device. b) The device may be overheated. c) Doesn't work after both processes.	a) Make sure that the connection is made. b) Unplug the appliance and let it cool down. c) Contact the authorized service.
4. Device overheats	a) The device is covered with some object. b) The device has been running without turning it off for a long time.	a) While the device is in working condition, make sure it is not covered by an object. b) If you need to use the device for a long time, cool the device for 30 minutes. The correct operating system is operating the device for 20 minutes and making the device.rest for 30 minutes.
5. The device works noisily.	Since a compressor motor is used in this type of devices, it is normal to produce a certain amount of sound. But if it sounds more than usual,	Contact the authorized service.
Failures 1-2-3-4-5	None of the solutions suggested above gave the desired result.	Contact your dealer or Medimport Sağlık Ürünleri San. ve Tic. Ltd. Şti. after sales support department.

COMPRESSOR NEBULIZER

MODEL NO: AL-50

ArmoLine

Manufacturer Company and Technical Service Contact Information :

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