elmaslar

LIFETIME



SA01PT

User Guide

1984

Please read this manual thoroughly before use the device.

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GLOSSARY OF SYMBOLS


CAUTION CONSULT ACCOMPANYING DOCUMENTS


CLASS II EQUIPMENT


CONFORMITE EUROPE


DATE OF MANUFACTURE

IPX1 PROTECTION AGAINST VERTICALLY FALLING DROPS


SHOULD BE DISPOSED ACCORDING TO WEEE DIRECTIVES


MANUFACTURER


TYPE B

SN SERIAL NUMBER


TYPE BF

1. INTENDED USE

LIFETIME Surgical Aspirator Devices are used for picking up the fluids and particles in surgical stage to a seperate collection jar by the negative pressure generated with the vacuum pump. LIFETIME Surgical Aspirator Devices are used in polyclinics, clinics and by patients at home.

2. CAUTIONS

· Please make sure that you have read and understand this user manual along with its cautions and descriptions before setup.
· The person or the establishment buying this device is responsible for the content of this manual and instructions of the relevant personnel.
· Do not use the device except for intended use.
· The device should be operated by trained personnel.
· High Vacuum and High Flow generating device can be used in continuous or discontinuous modes.
· Perform periodic maintanance of the device on regular basis.
· Replace the filter after septic cases.
· If hydrophobic filter is used in the device, fluid content will stop the aspiration system. In this case, please change the filter.
· Precautions should be taken at the power input against sudden voltage drops. Voltage regulator is recommended.

USAGE AREAS OF THE DEVICE

It is used to aspirate blood, secretions and food particles from the oral cavity, nasal-pharynx and bronchial system.

SIDE EFFECTS

The device should only used by people who has medical training and adequate knowledge of suction technique. Improper use and practices can cause serious bodily harms.
In case of there is a mistake with the suction process, patients may have injuries in their mouth,pharynx especially in their mucosa.
Not using sterile suction catheters can cause infection and bacteriological contamination risks for the patients.

PATIENT POPULATION

All patients aged 2 years and over 10 kg in need of surgical aspiration.

TARGET USER

Qualified medical professionals and their instructors.

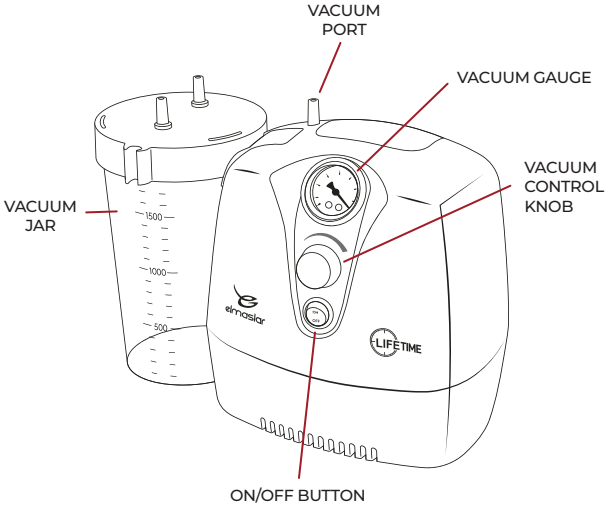
INDICATIONS

It uses accumulations such as blood, secretions and food particles to be aspirated from any body part such as the mouth, nose-pharynx, bronchial system. It is used for aspiration of blood body fluids in surgical operations. It is also used to clean the airway from blood, saliva, vomit or other secretions so that the patient can breathe. Used after treceostomy and treceotomy. Aspiration can prevent pulmonary aspiration that can lead to lung infections. Aspirator is also used in operations such as removal of blood accumulated after intracranial hemorrhages, delivery and abortion in the operating room and clinic that require aspiration.

CONTRAINDICATIONS

The usage level of aspirators is important. Excessive aspiration or prolonged aspiration to the same point causes tissue damage and unwanted bleeding. Not using the tips for the patient or not being sterile creates the risk of contamination and infection. It should not be used when opening the airway in patients with severe bronchospasm or laryngeal spasm, with a gag reflex. Its use on fistulas may increase bleeding. It is not suitable for patients under 2 years of age and weighing less than 10 kg.

3. DEVICE DESCRIPTION



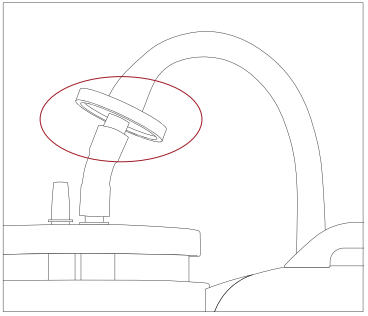
ON / OFF BUTTON: It is used to start up the vacuum pump.

VACUUM PORT: Used for vacuum.

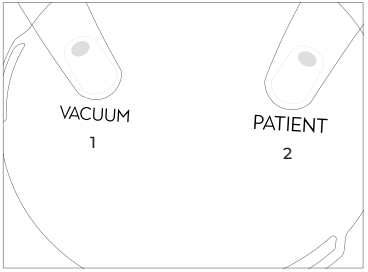
VACUUM CONTROL KNOB: It is used to set the vacuum level.

VACUUM GAUGE: It is used to show the vacuum flow when the device is working.

VACUUM JAR: It is used to collect the aspirated fluids.



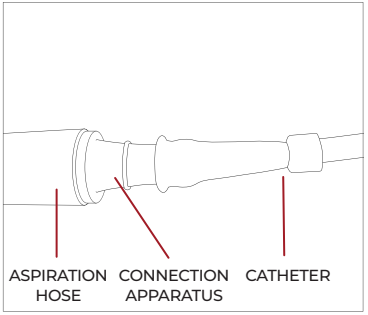
Please make the bacterial filter connection as shown.



Hose connections on the jar:

1.VACUUM: Connect the hose with the bacterial filter.

2. PATIENT: Connect the hose which the patient will use.



Aspiration hose, connection apparatus and catheter connection is carried out as shown in the figure.

4. ACCESORIES

· Silicone hose

· Hydrophobic filter

· Catheter connection

5. TECHNICAL FEATURES

INPUT VOLTAGE	230 VAC ± %10 , 50 Hz - 0,5 A
POWER CONSUMPTION	MAX 100 Watt
JAR CAPACITY	1 lt
FLOW	12 LPM
VACUUM POWER (sea level)	-550 mmHg ± %5
VACUUM GAUGE TOLERANCE	± %2,5
COLLECTION JAR TOLERANCE	± %10
NOISE LEVEL	< 50 dB
PISTON TYPE	OILLESS
ELECTRICAL SAFETY CLASS	CLASS II, TYPE B

6. SETUP AND CONTROLS

Open the box and take out the device and other accessories from the box.

Check for any damages that can be occured during transport. Please refer to the related sales point.

If your device is w/ trolley model, assemble the trolley with the screws provided. Please mount the jars to the device with the holding apparatus. Be sure to make the hose connections.

Please check the following controls in the first setup and before each use.

· Check to see if there is any cracks on the jar lid that will lead to an air leakege.

· Check the jar lid and overflow protection system.

· Make sure the jar lid seal is connected to the jar lid and jar lid is correctly connected to the jar.

· Make sure the jar is correctly mounted to the device.

· Check if there is any wear, opening etc. On the aspiration hose.

· Check for any damages on the electrical cable. Do not use damaged electrical cables.

· Turn on the ON/OFF and make sure the right or left vacuum buttons illimunate.

· Press Start button to run the vacuum pump.

· Check the vacuum gauge by blocking the suction port.

7. APPLICATION

Plug-in the electric cord of the device.

Turn on the OFF/ON button.

After switching ON / OFF button, the device starts running.

To stop the aspiration, press ON / OFF button again.

7.1. Setting the vacuum levels

The vacuum adjustment system is available in the device. This helps you to use the device in the desired vacuum value. To make the adjustment please run the device and the vacuum pump will be activated. Please read the value of vacuum gauge after closing the tip of the suction port. Adjust the setting to desired value using the adjusting knob.

7.2. Evacuation of Collection Jars

During the use of the device please control the waste accumulated in the collection jar in a regular interval. The collected waste level should not exceed the "Maximum" level mark on the jar.

To evacuate the collection jar;

Turn off the device and remove the input-output hoses from the collection jar lid. Take off the collection jar from the plastic holder. Open the lid of the collection jar taking it outside the clinic. Consider the collected waste liquid inside the collection jar as ''contaminated medical waste'' and always evacuate carefully outside clinical zone. Please subject the discharged collection jar disinfection treatment. Cover the lid and be sure that it has been closed tightly otherwise, leakage will occur between the collection jar and its lid causing loss of device's vacuum performance.

This instruction should strictly be followed to avoid overflow of the waste liquid and elope into the pump during evacuation process. Otherwise, as the performance of the device will reduce but this will cause malfunctioning the pump which will shorten the life of the device.

8. SAFETY SYSTEMS

1. Float System: It's located under the collection jar lid. If the accumulated waste exceeds the maximum level in the jar and the evacuation does not take place then the float system activates and protects the vacuum pump from waste. When this system is activated, the device stops working and the jar do not collect excess waste.

2. Bacterial Filter: Mounted on the hose between the device and the collection jar. Filter the air vacuumed from collection jar towards the device and helps to dispose clean air to the environment. At the end of its life the filter is blocked and the devices can't perform suction. Filter should be replaced with a new one.

3. Hydrophobic Filter: This is an optional system mounted on the hose in between the device and the collection jar. It filters the air vacuumed from collection jar towards the device and helps to dispose clear air to the environment. When the filter is blocked and the devices can't perform suction. Filter should be replaced with a new one. It also prevents to escape of waste to the device from the collection jar.

9. REQUIREMENTS DURING APPLICATION

To avoid misuse and applications which may harm the patient, user or device guidelines should be strictly followed.

Do not damage the power cord. Please control robustness of the power cord before use each time. Do not use damaged power cords.

Do not use too long (more than 2 meters) aspiration tube. Increase of aspiration tube length may cause to low vacuum level.

Prevent implementation of any weight or force on the aspiration hose which may cause clogging of the hose.

Please use clean aspiration hose and collection jar each time. In case of emergency please keep enough collection jars and aspiration hose in tow.

At the end of the use of the device the OFF/ON switch located at the back of the device should be turned off.

Do not use the device near explosives or in Oxygen-rich environment. Otherwise, it may elicit the danger of explosion or fire.

Perform the periodic maintenance of the device regularly by authorized personnel.

Do not run the device once the waste level reaches to the maximum before discharge the collection jar.

Do not use the device for the purpose other than described in this manual.

10. 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.

10.1. 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.

10.2. Sterilization

The collection jars of the device can be autoclaved at 121°C after discharging the collected waste and cleaning the jars.

10.3. Change of filter

Replace the bacteria filters and the hydrophobic filters used in the device with new ones when soiled or obstructing the vacuum process.

11. TROUBLESHOOTING

Unplug the power cord of the device from the plug socket and pull off the fuse cover located below the input power socket using a screwdriver. Remove the defective fuse and replace with a new one. Cover the fuse by pushing it off.

FAULT	CAUSE	SOLUTION
Motor is not running	No power in the motor Power cord is disconnected Motor is faulty	Check the fuse of the device check the power cord and the plug contact an authorized technic service
Motor running, low vacuum value	Dirty Filters Filters has been clogged Collection jar filled up Lids of the jars not placed properly Faulty vacuum gauge	Replace the filters Discharge the waste from the jar Check the lids Contact an authorized technic service
Abnormal sound from the device	Defective motor Worn-out motor vibration dampers Waste entered into the motor	Contact authorized technic service

12. HANDLING AND STORAGE

The device and accessories must be transported in its original box. If you have no original box please make a suitable package using Styrofoam and carton box to prevent damage during transport of the device. The device should not be flipped during transport. Please act in accordance with the instructions contained on the box of the device during transportation. Store the device at normal room condition.

13. 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.

14. COPYRIGHT

This document has been prepared by ELMASLAR TIBBI CIHAZ IMALAT A.S. and reserves the right to make changes to product specifications. No part of this publication may be reproduced or copied without weitten permission of the company.

15. CERTIFICATES

CE 1984

ISO 9001:2015

ISO 13485:2016

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

16. 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.

17. MANUFACTURER COMPANY INFORMATION

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