

Portable Suction Unit

Model No: AL-01



User Guide

www.medimport.com.tr

Product features

1. General

The Armoline AL-01 Portable Aspirator is an electrical device designed for medical usage to aspirate body fluids in adults and children. The device, in addition to being utilized to aspirate liquids such as purulence and blood during clinical applications conducted in operating rooms, patient rooms, infirmaries and emergency departments, is also suitable for the usage of patients who suffer from sputum production during home medical care.

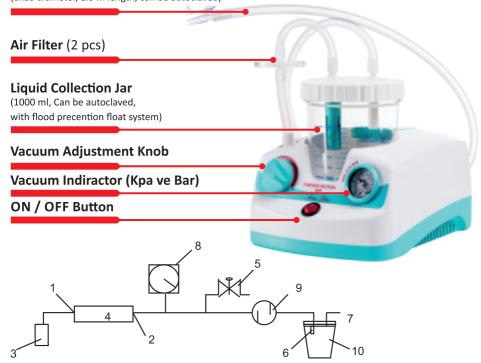
2. Structure and Operation Principle of the Device

- Does not contaminate the environment with oil mist thanks to the maintenance and lubrication-free air pump thereof.
- It has a very low operation sound and does not create noise in the environment used.
- The device has an autoclavable polycarbonate liquid collection jar, plastic jar lid with flood prevention float system and negative pressure gauge.
- The built-in control knob on the front panel allows vacuuming at the required amount.
- It suitable for external treatment because it is light and easily carryable.

System Diagram and the easy-to-understand visual of the device are below.

Silicon Hose

(6x10 diameter, 1.5 m length, can be autoclaved)



System Diagram

1. Air evacuation, 2.Vacuum input, 3.Muffler Exhaust, 4.Vacum pump, 5.Vacuum adjustment knob, 6.Flood prevention float system, 7.User (patient) vacuum connection, 8.Vacuum indicator, 9.Air filter, 10. Liquid collection jar

Technical Specifications

1. Model AL-01

2. Device Class Class Class II a Medical Device

(Medical Device Directive No. 93/42/EEC)

3. EN ISO 10079-1 High vacuum/Low air flow
 4. Power Supply AC 200-240V ± 10% - 50Hz ± 2%

5. Input Power 180VA

6. Fuse F 1 x 1.6AL 250 V

7. Maximum vacuum Pressure -0.75bar -75kPa -563mmHg

Limit (without jar)

8. Maximum free airflow rate 15 L/min.
9. Noise ≤55dB (A)
10. Liquid collection jar 1000 ml
11. Weight 2.41 kg

12. Dimensions 240x190x130 mm
13. Operation system Continuous operation

> The device must not be used in environments with flammable and explosive gas.

SYMBOLS

SYMBOL	SYMBOL DESCRIPTIONS		
\sim	Production Date		
SN	Serial Number		
REF	Model / Reference No		
•••	Producer		
	Fuse		
Ţ <u>i</u>	Refer to User's Manuel		
	Class II İnsulated Equipment		
\triangle	General Warnings and/or Technical Specifications		
*	Applied Part Type BF (Suction Probe)		
<u>X</u>	This symbol on the device and box indicates that electrical and electronic devices are collected seperately.		
€ 1984	EC Directive NO 93/42/EEC and compliance CE mark and code of the certifying body		
VACUUM	This word on the liquid collection jar indicates wacum input point		
PATIENT	This word on the lid of the liquid collection jar indicates input point for Patient connection		
IP20	International Protection Code. This code determines the resistance of electrical devices against outer effects (Solid - Liquid)		

Normal Operation Conditions

Ambient temperature $: +5^{\circ}\text{C} \sim +35^{\circ}\text{C}$ Relative Humidity $: 30\% \sim 80\%$ Atmospheric pressure $: 86 \text{ kPa} \sim 106 \text{ kPa}$

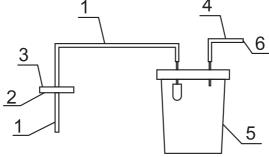
Installation and Operation

1. Checking the product and accessories

The user should carefully check the product in order to ensure that it looks good and the type and quantity of the device parts match the ones specified on the parts list prior to installing and operating the device. If any damage or defect is seen, the supplier or manufacturer should be informed in a timely manner.

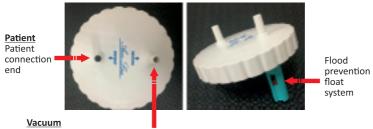
2. Installation of the device

(See the pipe connection diagram, the sputum suction catheter is not connected in the following diagram)



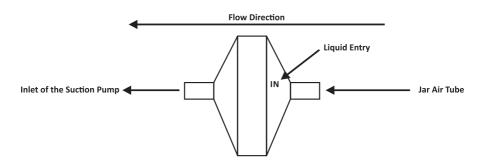
Pipe Connection Diagram

- 1. Suction tube, 2. Air filter, 3. "IN" mark, 4. Silicone hose, 5. Liquid collecting jar,
- 6. Connected to the ballast suction catheter.
- > Connect the short silicone hose with the antibacterial filter to the suction connector.
- > Connect the longer silicone hose to "PATIENT" output at the top of the jar lid.
- Connect the other end of the long silicone hose to the plastic connector, and then connect it to the aspiration probe (suction carheter).
- > Other hose connected to the filter must be connected to the "VACUUM" (vacuum) output on the top of the jar lid where the turquoise float (security float) is fixed,
- "IN" phrase on the air filter must be facing up and the filter has to be connected to the silicone hose coming from VACUUM exit of the fluid collection jar. Wrong connection of the filter can cause sudden damage in the device in case of contact with the absorbed liquids.



Vacuum-suction connection end. The hose coming from the filter is connected to this inlet.

Installation of the Filter



Note: Slightly wetting the silicone seal placed on the cover of the fluid collection jar with distilled water during assembly will help fitting the cover tightly and improve impermeability. Open the jar lid and fill the jar with 1/3 water (this is for cleaning easily and rapid functional vacuuming) and then close the lid properly.

3. Electrical Connection

- Connect the power cord to the device and then connect the plug to the mains.
- Turn to "I" position to start sucking.

4. Checking the connector

- Turn the vacuum adjustment knob clockwise strongly and tighten the air intake inlet with your finger or bend the suction tube and hold in that manner;
- > Start the aspirator, the device should not make a different sound when it is operating; the vacuum metric will quickly rise to the negative pressure limit value. When you open the suction inlet the pointer will drop below 150mmHg. The connector is deemed to be in good condition in this case.

Note: If the suction catheter is clogged clean it with the following method:

Bend the silicone hose in the form of "V" (no liquid must be in the liquid collection jar) and leave it to return to its original position when the negative pressure reaches its maximum value. Repeat this until blockage in the catheter is opened.

5. Setting the negative pressure

Close the suction inlet, bring the knob of aspirator to open position and adjust the negative pressure valve; the values shown by the pressure gauge will be between 150mmHg~ and the negative pressure limit value.

- Check negative pressure needed by suction during clinical application by the negative pressure valve;
- Increase negative pressure turning the valve clockwise;
- Decrease negative pressure to 150mmHg prior to cutting off the electrical connection.

6. Checking and testing of the flood prevention float system

- ➤ Open the cover of the liquid collection jar and clean the point where the float system is connected to the jar lid and ensure that the brown silicone seal on the float is placed properly (the seal is bowl shaped and the correct position is the position where the bowl looks up). It should be able to move freely without encountering any obstacles within the float's nest;
- To control the float system it is necessary to contact it to the water surface vertically. For this, close the cover firmly subsequent to putting the floats on the jar door,
- Complete the silicone hose connections in line with the pipe connection diagram above and turn the adjustment valve tightly and the run the aspirator;
- ➤ Place the patient connection hose in a bucket full with clean water or perform a similar of the actual application by collecting the liquid in liquid collection jar. As a result, when the liquid level rises, the float will also rise till the silicone seal is closed and the suction will automatically stop. The last position of the fluid level will depend on the applied suction procedure;
- Open the adjustment valve, turn the aspirator knob off, open the lid of the liquid collection jar and empty the liquid in the container. It must be located at the bottom of the float recess when the liquid collection jar lid is tightly closed and the silicone seal valve must be in the open position;

Note: Check if the silicone seal of float remains stuck to jar lid following the cleaning; in addition you must use the float and seal after cleaning without fail if they are dirty. The overflow obstruction system is deemed to be in normal condition in this case and can be used in clinical practice.

7. Stopping the Device (Cutting the electrical connection)

Turn the on/off button to 0 and remove the plug when the aspiration process is finished.

Maintenance and Cleaning of Device-Accessories 1.a Cleaning the Device

- > Use a piece of soft dry cloth. Do not use abrasive or solvent detergents. The device must be unplugged from the wall outlet prior to performing any cleaning operation.
- Pay particular attention should to the internal parts of the device to avoid contact with liquids. Never clean the device with water.
- Put on protective gloves and gowns (if necessary, in face masks and goggles) during all cleaning procedures in order to avoid contact with contaminants (after each use of the device).

1.b Maintenance of the device

Armoline AL-01 portable aspirator device does not need maintenance or lubrication. It is necessary to control the operation and safety of the device prior to each use. The use and operation of the device is easy and understandable in accordance with the instructions provided in the user manual, therefore any kind of training is not need to use the device.

Switch on the device and always check the power of the power cable as well as the plastic parts that may have been damaged in the previous use; attach the cable to the outlet and push the button.

Close the aspiration outlet with your finger and control if the vacuum indicator reaches maximum -75 kPa (-0.75 bar) when the vacuum control knob is in the maximum vacuum position.

Turn the vacuum adjustment knob from right to left and pay attention to the aspiration regulation control. The vacuum indicator should fall to -25 kPa (-0.25 bar). Note that there is no high noise which means malfunction.

There is an externally accessible protection fuse (F lxL.6A L 250V) and located inside the socket to which the power cable is connected at the back of the device, which protects the fuse. Always replace with the specified type and range fuse during replacement.

2.a Cleaning of Accessories

Do not wash, sterilize or autoclave the antibacterial air filter. Wash and/or clean the jar as follows;

- Wear gloves and apron (if necessary, goggles and face mask) to avoid pollutants.
- Remove the jar from the device. Remove the silicone hoses which are attached to the jar cover and device at the same time.
- Open the jar cover by turning it clockwise.
- Remove all parts of the jar cover (by turning flood prevention float system anti-clocking float system clockwise, remove silicone which provides impermeability and transparent ring shaped seal).

After disposing the disposable items and after removing the jar and its parts, wash in cold running water and thoroughly rinse. Soak in hot water (temperature should not be higher than 60 °C). Use a non-abrasive brush to remove the inner calcification.

Rinse in hot water and dry all parts with a soft cloth. The jar can be autoclaved, preferably in an autoclave and sterilized at 121 °C. The jar must be upside down during processing.

The mechanical resistance of the jar is guaranteed by cleaning up to 30 sterilization cycles and under specified conditions (EN ISO 10079-1). The physical-mechanical properties of the plastic can be reduced beyond this limit, and replacement of the part recommended.

Ensure that all parts are not damaged after sterilization and cooling at environment temperature. Assemble the jar in line with the following description.

- > The flood prevention float system (seal and turquoise color float tube placed on it)
- > Place it firmly (Vacuum inlet) by turning clockwise to its house in the jar cover.
- > Place the seal ring in the form of a silicone transparent ring which provides impermeability inside the house around the lid

Be sure to tightly close the cap by turning it clockwise to prevent vacuum permeability or fluid escape after the installation is complete.

Ensure to follow the instructions written in the other connection and also installation section of the in the user manual. The device is ready is ready for re-use.

2. Warnings as to the use-maintenance and replacement of accessories

Antibacterial Air Filter: Filter is produced by a hydrophobic material (PTFE) that prevents the fluid entry to pneumatic circuit. It is not possible to use the device when the filter is wet therefore replace the filter immediately. In the event of contamination or discoloration, also replace the filter immediately. Do not use the suction unit without the protection filter. The filter should be replaced subsequent to each use, in case of emergency or when used in a patient the risk of contamination of whom is unknown.

Aspiration Catheter: The disposable unit is only used for the sole use of the patient. Do not wash it or re-sterilize it. Repeated use may cause contracting infection.

Aspiration Jar: The mechanical strength of the part is guaranteed up to 30 cleaning and sterilization periods. Physical-chemical properties of the plastic material may be deteriorated above this limit. As such, we recommend replacement.

Silicone Hoses: The number of sterilization and cleaning periods is directly related to the use of the mentioned hose. As such, after each cleaning period, the final user gives the decision as to whether the tubing is suitable for reuse. This unit must be replaced if there is any visible deterioration in the material forming the unit.

Conical Connection: The number of sterilization and cleaning periods is directly related to the use of the mentioned hose. As such, after each cleaning period, the final user gives the decision as to whether the tubing is suitable for reuse. This unit must be replaced if there is any visible deterioration in the material forming the unit.

FAILURE TYPE	REASON	SOLUTION	
1. Device does	Cable damaged	Change the cable	
not work	External power supply cut	Check the external power supply	
2. No Aspiration	The jar cover is not closed well	Turn off cover, reinstall properly	
3. Aspiration	Cover seal is not seated well	Open the cover and insert the seal properly to its seat	
	a) Vacuum setting knob is set to minimum	a) Turn the vacuum value adjustment knob on clockwise and check the vacuum value on the vacuum gauge	
4. No or little	b) Protection filter is disabled or damaged	b) Change the filter	
vacuum strength in the patient side.	c) Silicone hoses are bent or not connected c) Change or reconnect silicon and check the jar connections		
	d) Float gasket is impaired or damaged	d) Empty the jar, or remove seat of the float from the jar and donot block the float seal.	
	e) The pump motor is damaged	e) Call the authorized service.	
5. Float does not close	Check if the float detaches if the cover is washed	Place the float to its place	
6. Float does not close	Float is covered with dirt	Open the cover and put it in the autoclave	
7. Low suction	a) Foam in the jar	a) Fill 1/3 of the cover with water	
	b) Filter is clogged	b) Change the filter	
Failure 1-2-3-4-5-6-7	None of the solutions provided the desired results	Apply to your seller or after sales support services of Medimport Sağlık Ürünleri San. ve Tic. Ltd. Şti.	

EMC (Electromagnetic Compatibility) Statement

This device generates, uses and can radiate radio frequency (RF) energy. This device may cause electromagnetic interference if this device is not installed and used as specified in the manual. This device has been tested in line with EN 60601-1-2 Standard for Medical Devices and determined to comply with acceptable limits. These limits show that if the device is utilized in the manner specified in this manual, the device provides protection at an acceptable level against electromagnetic interference (EMC).

This device may be affected by portable and mobile RF communication devices.

This device must not be stored with other equipments.

Please examine the table below to learn more about this device and EMC.

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.

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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 ar directly connected to the low-voltage city network intended for use in houses and premises within house category	
Harmonic emissions IEC 61000-3-3	Class A		
Voltage Fluctuation/ Vibration Emissions IEC 61000-3-3	Compatible		

Guide and manufacturer's declaration - electromagnetic immunity

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

Immunity Test	IEC 60601 Test Level	Compatibility Level	Electromagnetic environment - guide
Electrostatic discharge (ESD)	± 6 kV contact	± 6 kV contact	The floors must be wooden, concrete or ceramic tile. The relative humidity should be at least 30% for floors covered
IEC 61000-4-2	± 8 kV air	± 8 kV air	with synthetic material.
Electricity fast temporary / disintegrating	For lines with ± 6 kV power source	Power source ± 6 kV for lines	Mains power quality should be in typical commercial or hospital environment quality
immunity IEC 61000-4-4	± 1 kV for input/ output lines	± 1 kV for input/ output lines	
Shock IEC 61000-4-5	± 1 kV differential Mode - ± 2 kV Common mode	± 1 kV differential Mode - ± 2 kV Common mode	Mains power quality should be in typical commercial or hospital environment quality
Voltage at Deviations input line's power source, short	<%5 <i>U</i> T (>95% decrease in <i>U</i> T) for 0,5 cycles	<%5 <i>U</i> T (>95% decrease in <i>U</i> T) for 0,5 cycles	Mains power quality should be in typical commercial or hospital environment quality
Interruptions and voltage Differences	40% <i>U</i> T (>60% decrease in <i>U</i> T) for 5 cycles	40% <i>U</i> T (>60% decrease in <i>U</i> T) for 5 cycles	
IEC 61000-4-11	70% <i>U</i> T (30% decrease in <i>U</i> T) for 25 cycles	70% <i>U</i> T (30% decrease in <i>U</i> T) for 25 cycles	
	<%5 <i>U</i> T (>95% decrease in <i>U</i> T) for 5 seconds	<%5 <i>U</i> T (>95% decrease in <i>U</i> T) for 5 seconds	
Power frequency (50/60 Hz) Magnetic field	3 A/m	3 A/m	The magnetic fields of the power freuency should be in typical commercial or hospital environment quality
IEC 61000-4-8			

Note: UT is the AC mains voltage prior to application of the test level.

Guide and manufacturer's declaration - electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. This device must be operated by the customer or the user in such an environment.

Immunity Test	IEC 60601 Test Level	Compatibility Level	Electromagnetic environment - guide
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 Mhz outside ISM band ^a	3 V	Portable and mobile RF communication equipment, including cables. This device should not be closer than recommended separation distance calculated by the equation applicable to the transmitter frequency
Radiated RF IEC 61000-4-3	10 V rms 150 kHz to 80 Mhz inside ISM band ^a 10 V/m 80 Mhz to 2,5 Ghz	10 V/m	Recommended separation distance: $d=1,16 \ \sqrt{P}$ $d=1,20 \ \sqrt{P}$ $d=1,2 \ \sqrt{P}$ 80 MHz to 800 MHz $d=2,3 \ \sqrt{P}$ 800 MHz to 2,5 GHz Here, P is the Maximum output transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The field strength of RF constant transmitters determined by an electromagnetic field analysis must be less than the compliance level in each frequency range Interference may occur near an equipment marked with the following symbol:

Note 1: The higher frequency range is valid at 80 MHz and 800 MHz,

Note 2: These guidelines may not apply in all circumstances. Electromagnetic propagation is affected by absorption or reflection created by buildings, objects and people.

- a. ISM (industrial, scientific and medical) bands between 150 kHz 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.
- b. The suitability levels of the ISM frequency bands from 150 kHz to 80 MHz and the frequency range from 80 MHz to 2.5 GHz are intended to reduce the likelihood of interference when mobile/portable communications equipment is accidentally brought into the area of the patient. For this reason, an additional factor of 10/3 is used by the receivers to calculate the recommended separation distance in this frequency range.
- c. Field strengths from fixed transmitters such as radio (cellular/cordless) telephones and mobile radios, ameteur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted in advance from the theoretically. An electromagnetic ground survey should be considered to evaluate the electromagnetic environment due to fixed RF transmitters. The measured field strength at the location where this device is used indicates that the current RF compliance level above is normal for the operation of this device. Normal operation of this device should be observed and controlled. Additional measures like changing the direction or position of this device may be required if abnormal performance is observed.
- d. The field strengths over the frequency range from 150 kHz to 80 MHz must be less than 3 V/m.

Recommended separation distance between portable and mobile RF communication equipments and this device

This device is intended for use in the electromagnetic environment in which the radiating RF interference can be controlled. Owner or user of this device must maintain the minimum distance recommended below for protection from electromagnetic interference depending on the maximum output of the communication equipment, between portable or mobile RF communication devices (transmitters) and this device

Calculated	Separation distance according to the frequency of the transmitter (m)				
Maximum output Power (W) of the Transmiter	outside 150 kHz to 80 MHz, ISM bands	inside 150 kHz to 80 MHz, ISM bands	80 MHz to 800 MHz	80 MHz to 800 MHz	
	$d=1,16 \sqrt{P}$	$d = 1,20 \sqrt{P}$	$d = 4\sqrt{P}$	$d = 7,66 \sqrt{P}$	
0,01	0,12	0,12	0,12	0,23	
0,1	0,37	0,38	0,38	0,73	
1	1,16	1,20	1,20	2,30	
10	3,67	3,79	3,79	7,27	
100	11,60	12,00	12,00	23,00	

The appropriate equation for the frequency of the transmitter is used and d which is the recommended separation distance can be calculated in meters (m) for the transmitters maximum output power of which are measured and which are not included in the above list; here P is the Maximum output transmitter rate in watts (W) provided by the transmitter manufacturer

Note 1:separation distance for the higher frequency range is applied at 80 MHz and 800 MHz,

Note 2:ISM (industrial, scientific and medical) bands between 150 kHz 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

Note 3: An additional factor of 10/3 is used to calculate the recommended separation distance between the ISM frequency bands from 150 kHz to 80 MHz and reduce the likelihood of interference when mobile/portable communication equipments within the frequency range from 80 MHz to 2.5 GHz are accidentally brought into the area of the patient.

Note: These guidelines may not apply in all circumstances. Electromagnetic propagation is affected by absorption or reflection created by buildings, objects and people.

Notes and General Warnings



- The aspirator should be used in strict compliance with the instructions provided by the medical personnel according to the usage (installation) and operation procedures listed in the user manual. Please contact the supplier or manufacturer if there is any issue.
- Please read the instructions prior to usage of the aspiration probe supplied with the aspirator.
- > The appropriate aspiration probe will be selected according to the clinical requirements of the medical personnel.
- If the flood prevention float system is in operation, do not perform liquid aspiration.
- The home use of the device should be performed by an adult and/or home caregiver who is mentally healthy.
- The device must not be disassembled.

Safety Rules

- Pay attention to the integrity of the device and check the plastic parts for damage during unpacking. Otherwise, there may be access to the internal active parts while the power supply cable may be damaged at the same time. Do not put plug into socket in such cases. Make these checks prior to each use.
- > Control that the electrical data indicated on the label and the type of plug used are suitable for the network to which you are connecting prior to connecting the device.
- Please observe the safety regulations for electrical equipment and, in particular perform the following:

Use original accessories and parts supplied by the manufacturer (Medimport Sağlık Ürünleri San. ve Tic.Ltd.Şti to use the device at peak efficiency and guarantee the security.

The device can only be used with a bacteriological filter.

Never expose the device to water.

Do not put or place the aspirator in places where it may fall into the tub or sink because it can be pulled to such places. In case of an accidental fall, do not attempt to remove the device from the water while the plug is still plugged in; turn off the main switch, take the plug out of the power source and contact the Medimport technical service department. Do not try to operate the device without being thoroughly checked by skilled/qualified personnel and/or Medimport technical service department.

Place the device on a plane surface.

Position the device so that the air intakes at the back are not obstructed.

Do not use in environments where air, oxygen or nitric oxide or flammable anesthetic mixtures are present.

Do not touch the device with wet hands and prevent exposing the device to liquid. If any liquid or solid particles enter into the vacuum pump inside the device as a result of improper handling or the disabling of safety parts such as overflow preventing float and air filter on the device, immediately turn off the device and remove the plug from socket and contact a competent technical service for repair.

Prevent access by children or unauthorized persons without supervision.

Disconnect the device from the socket when not in use.

Do not pull the cable while removing the socket from the plug.

Keep and use the medical device away from atmospheric factors and heat sources.

It is not recommended to use single or multiple adapters and/or extension cables in general. If they have to be used, you have to use the ones that match the safety regulations, but be careful not to exceed the maximum allowable power supply indicated on the adapter and extension cords.

- > Contact only technical service of Medimport Sağlık Ürünleri San. ve Tic.Ltd.Şti. for repair and request original spare parts. Not to observe this may risk the safety of the device.
- This medical device is designed for use only as described in thid Manuel. Every kind of misuse is considered to be inaccurate and therefore dangerous; the manufacturer shall in no way be liable for damages resulting from improper, incorrect and/or unreasonable use, or for damage caused by use in electrical installations that do not comply with the applicable regulations of the device.
- This symbol on the device indicates that electrical and electronic equipment is collected separately. Do not dispose of it with mixed municipal waste at the end of the life cycle, send it to the special collection center in your area, or dispose of it by returning it to the distributor/manufacturer/dealer while buying a new device with the same functions. Disposal of the device must be made in accordance with the laws and regulations in force in each country where it is used.
- Do not change the device without the permission of the manufacturer Medimport Sağlık Ürünleri San. ve Tic.Ltd.Şti. No electrical or mechanical parts are designed to be repaired by the customer or the end user. Do not open the device or use the electrical/mechanical parts incorrectly. Always receive technical support.
- Usage of the device under different environmental conditions other than those specified in this manual can seriously damage its safety and technical featues.
- For Home Use: Keep all accessories of the device out of reach of children under 36 months, as they may contain small items that can be swallowed.
- Do not leave the device unattended near children and/or mentally ill people since the patient may strangle themselves with the hose and/or power cord.
- The medical device contacts the patient through a disposable probe (provided with the device) with the relevant CE conformity certification according to the requirements of the ISO 10993-1 regulation, so that no allergic reaction or skin irritation occurs.
- The manufacturer cannot be held liable for damages caused by improper use of the products which are repaired, updated and processed by unauthorized persons. Any kind of update or repair device is out of warranty. MDD does not guarantee compliance with the technical requirements provided by 93/42/EEC (and subsequent amendments).

Manufacturer Company and Technical Service Contact Information

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