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Disclaimer

Medical Device Resource Corporation provides the following cautions to the reader of this manual:

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- M.D. Resource Corp. assumes no responsibility for damage or injury from use of the K Pump User's Guide not in accordance with the instructions provided in this manual.

Contact Information

Company	Medical Device Resource Corporation
Location	5981 Graham Court, Livermore, Ca. 94550
Customer Support	800.633.8423
Orders / Tech Support	510.732.9950
Fax	510.785.8182
Web Address	http://www.mdresource.com

Overview & Intended Use

Document Overview

This K Pump User's Guide provides information about using the K Pump infiltrator, set-up, performing cleaning / troubleshooting, and obtaining support.

Product's Intended Use

The K Pump is designed to infiltrate tumescent fluid into a patient during cosmetic or plastic surgery practices.

Electronic Accessories and Equipment

Following is a list of approved electrical accessories for the K Pump:

- ✓ Power Supply: Power supply must be IEC 60601-1:1998 compliant medical grade; Input 100-240V~1.6a, Max 50-60Hz; Output 24V~2.1a, 50W Max.
- ✓ Power Cord: Any six foot hospital-grade power cord. Optionally, if using with MD Resource LS system, any one meter universal jumper cord.
- ✓ Air Switch: Only use air switches supplied by MD Resource. To minimize trip hazard, our recommended maximum length is three meters.

Use of accessories, transducers, and cables other than those sold by Medical Device Resource Company may result in system failure, increased EMC emissions, and/or decreased EMC immunity of the K Pump.

Electromagnetic Interference:

This pump should not be used adjacent to or stacked on other equipment except as shown in the LS2 Aspirator pump user guide. If it is used in a stacked configuration, care should be taken to observe normal operation of system components.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put in service according to instructions and the EMC information included in Appendix C.

Portable and mobile radio frequency communication devices (e.g. cell phones) can affect medical equipment.

Safety Information

Safety Guidelines

The K Pump is designed to ensure both the highest level of product quality and safety for the user. To maintain both quality and safety, follow the guidelines and instructions in this document.

- Use the K Pump only as intended.
- Refer all servicing and repairs to M.D. Resource Corp. qualified personnel to maintain your warranty. Any repairs or servicing performed by the customer voids the warranty.
- Store the K Pump within 10 – 32 degrees Celsius (50 - 90 degrees Fahrenheit). Avoid prolonged exposure to direct sunlight.
- If any cord or cable is frayed or damaged, replace it immediately with another of the same type and rating as supplied by M.D. Resource Corp.

To clean the exterior of the K Pump, follow, the UL 60601-1 standard for use in a hospital environment. See “Cleaning the K Pump” for more information.

Warnings & Symbols

Warnings

The information in the following table describes warnings that should be adhered to when operating the K Pump:

Symbol	Description
Rx Only	**THIS SYMBOL INDICATES THE USE OF AUTHORIZED PRESCRIPTION DRUGS ONLY.**
	**USE PROPER HOSPITAL GRADE POWER CORD ONLY.**
	**DANGER: RISK OF EXPLOSION.** DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS
	**WARNING: RISK OF ELECTRIC SHOCK.** DO NOT OPEN CASE. REFER TO PROPER AUTHORIZED PERSONNEL FOR SERVICING.
O	**POWER "OFF"**
I	**POWER "ON"**

Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Chapter 1: Getting Started

This chapter contains information about properly unpacking and setting up your K Pump.

Unpacking the K Pump

When the K Pump arrives, check the shipping box for any apparent damages (i.e., holes in the box or a crushed top). Open the box and inspect each product.

Notes:

- Inspect the K Pump for physical damage while unpacking. Contact M.D. Resource Corp. immediately if any physical damage is observed.
- If the K Pump is for evaluation, keep the shipping box. These are needed to return the unit.

Removing the Product from the Shipping Box:

1. Remove the Styrofoam placed on top of the box.
2. Remove and set aside the K Pump User's Guide. Do not discard.
3. Remove the accessories placed inside of the box.
4. Remove the K Pump and plastic protective cover from the product.

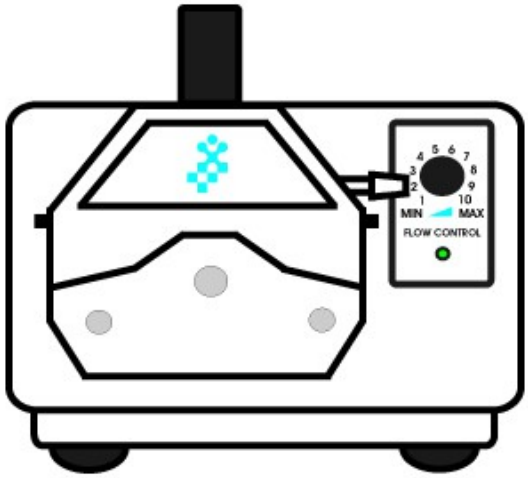
Chapter 2: Identifying the K Pump

This chapter contains information about identifying K Pump features and the accessories required to configure your device for use.

K Pump Features

The following two illustrations (Figure 1) were designed to help you to become familiar with the standard features of your K Pump:

ANTERIOR



POSTERIOR

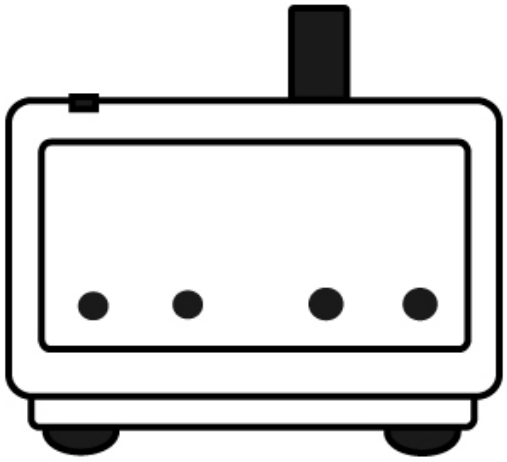


Figure 1: K Pump unit (anterior & posterior) position

Accessories Required

- Standard Accessories Supplied:
  - K Pump Instruction for Use
  - Hospital Grade Power Cord
  - Foot Pedal
  - Power Adapter

- Optional Accessories Supplied:
  - Disposable AutoFuse 3/8" OD Tubing (Sterile)
  - Disposable AutoFuse Tubing with "Y" bifurcation (Sterile)
  - Cannulae (Custom made. Please call for size, shape, tip, and handles)

- Optional Device's Used in Conjunction:
  - Tumescent Measuring Device
  - LS2 Liposuction Aspirator

To place an order for the accessories or the devices listed above, contact M.D. Resource Corp. at 510.732.9950 or call toll free 800.633.8423.

(Refer to Appendix B for further listings of parts & accessories)

Chapter 3: Connecting Accessories / Devices

This chapter contains information about properly routing accessories on your K Pump.

Connecting Standard Accessories

1. Position the posterior side of the K Pump in front of you.
2. Obtain the Power Adapter and insert one end into any one of the Power Inlets (See Figure 1, Page 2 – Power Inlet).

Note - The second Power Inlet is used for the optional Tumescent Measuring Device if purchased.

3. Attach the Hospital Grade Power Cord to the Transformer and the other end to the wall.
4. Lastly, take the Foot Pedal and insert the tubing end into the Bulkhead Connectors (See Figure 1, Page 2 – Bulkhead Connector).

- For safety, only use the specified parts supplied by M.D. Resource Corp. (Refer to Page 9 for Technical Specifications and Page 10 for Parts & Accessories).

Connecting Optional Accessories

<u>Tubing to K Pump, IV Bag, and Cannula</u>:

1. Position the anterior side of the K Pump in front of you.

2.Shift the Pumphead lever to the left. This will enable the channel of the Pumphead to open and unlock.

3. Obtain the sterile AutoFuse Tubing and locate its flexible portion.

Note - This portion will be inserted into the channel of the pumphead.

4.Starting from left to right, carefully insert the tubing through the channel.

5. Now shift the Lever to the right to close and lock the tubing in place.
6. Adjust the Clips accordingly located on the pumphead to stabilize the tubing.
7. Next insert the spiked end of the tubing to the IV Bag.
8. Lastly insert the other end of the tubing to the Cannula.

- **In the event of fluid dripping from the needle after the pump has been stopped, we suggest:**
  - Use a stopcock connector, or trumpet-valve type infiltration handle with infiltration needle attached.
  - Simply bend and kink the tubing when you do not want any flow.
  - Secure the pinch valve included on the tube set near the IV bag.

Connecting Optional Devices

To LS2 Liposuction Aspirator

1. Perform “Connecting Standard Accessories” Steps 1 to 3 (Page 4), but instead of inserting one end of the Power Cord to the wall, insert it into the LS2 socket.

2. Obtain the LS2 Hospital Grade Universal Power Cord and insert one end to the LS2 and the other end to the wall.

Notes: Refer to your LS2 User & Technical Manual for further instructions on how to set-up your aspirator.

To Tumescent Measuring Device, TMD

1. Perform “Connecting Standard Accessories” Steps 1 to 3 (Page 4).

2. Obtain the Conductor Cable and insert one end into the TMD and the other end into one of the Power Inlets of the K Pump.

Notes: Refer to your TMD User Manual for further instruction on how to set-up your tumescent measuring device.

- For safety, only use specified parts supplied by M.D. Resource Corp. (Refer to Page 9 for Technical Specifications and Page 10 for Parts & Accessories). The K Pump uses a power adaptor to isolate itself from the mains. For safe operation, only use genuine MD Resource parts.

Chapter 4: Activating the K Pump

This chapter contains information about activating and deactivating your K Pump.

Activation

1. Turn the main Power Switch “ON”
2. Locate the Control Knob and rotate the speed to #3 setting.
3. Depress the Foot Pedal to activate the K Pump. The Foot Pedal controls the peristaltic pump when the main power switch is “ON”

Note - One or both pneumatic footswitches can be used to turn the pump on and off. The footswitches may be operated in any sequence to activate or deactivate the pumping action.

Deactivation

1. Depress the Foot Pedal to deactivate the K Pump.
2. Turn the main Power Switch “OFF”

Chapter 5: Cleaning the K Pump

This chapter provides information regarding the proper cleaning of your K Pump

Cleaning the External Case

1. When cleaning your K Pump, turn off the main Power Switch and then disconnect from the power source.

2. Wipe down all external surface area with a cloth:

   - For dirt, stains, and/or dried substances - Remove by using any ammoniated cleaner.

     Notes: Use a short stiff-bristled brush if the substances become ingrained in the case.

   - For tough stains – Remove with a solvent-based cleaner.

   - For minor scratches – Remove by using white polishing compounds.

     Notes: Avoid spraying liquid in connection portals.

Warning – Risk of Explosion. Do not use in the presence of flammable anesthetics.

Chapter 6: Support & Warranty Information

This chapter provides information regarding obtaining support, if necessary, from M.D. Resource Corp.

Support

Should your K pump require repair, contact M.D. Resource Corp. to obtain an RMA (Return Merchandise Authorization) to return the unit to M.D. Resource Corp. for servicing to maintain the product's warranty. Any unit received without an RMA will be returned at the owner's expense. See the warranty for more information, or contact M.D. Resource Corp. for questions related to service and/or warranty coverage.

Medical Device Resource Corporation
5981 Graham Court,
Livermore, Ca 94550

800.633.8423 – Toll Free
510.732.9950 – Customer Support
510.785.8182 – Fax

http://www.mdresource.com

Warranty

1 year limited warranty

Chapter 7: Troubleshooting

This chapter contains information about troubleshooting your K pump

The following table describes some of the most common troubleshooting options for the K pump:

Topic	Possible Cause	Possible Solution
Pump not operating	Power Switch not on.	Turn Power Switch “ON”
	Power Adapter not plugged into wall outlet.	Plug Power Adapter into outlet.
	Power Adapter not plugged into unit.	Plug Power Adapter into Power Inlet. Depress Foot Pedal.
	Foot Pedal not activated.	Depress Foot Pedal.
Foot Pedal(s) do not activate the pump.	Foot pedal cable not connected.	Connect Foot Pedal cable to the Bulkhead Connectors.
	Foot pedal broken or torn	Replace Foot Pedal.
	Power Switch not “ON”	Turn Power Switch “ON”
Pump starts when Foot Pedal is depressed.	Fluid flow is too low`.	Increase the speed by turning the control knob clock-wise.
	Wrong tubing in pumphead	Contact M.D. Resource Corp. to obtain proper tubing for the unit.

Appendix A: Technical Specifications

Electrical Specification

Input……..…….. 100 - 240 VAC ~ 1.6A MAX, 50 - 60 Hz (non user-selectable)

Output……. +24V ⎓ 2.1A

Output Power…… 50W MAX

Speed Control……. 1 Min to 10 Max (10 - 600 ml/min)

Mechanical Specification

Flow Rate……..... 10-600 ml/min (depending upon tubing selection and flow setting)

Panel Indicators……...……. Green LED – Power On

Safety

Shock Protection……..…….. Class I

Safety…….…….. Over-speed protector; manual safety cut-off switch

Environmental Conditions

Operating Temperature…… 0° to 40° Celsius

Operating Humidity……...…… 10% to 90% (non-condensing)

Storage Requirements

Storage Temperature……10° to 32° Celsius

Weight Limits & Maximum Dimensions

Dimensions…….…...…… 6 1/2” (L); 9 1/2” (W); 7 1/2” (H) max

Weight…….……. Approximately 5.0 lbs (without accessories)

Appendix B: Parts & Accessories

Topic	Parts & Accessories	Part Number
Standard Accessories	K Pump IFU	KP-Man
	Hospital Grade Power Cord	109-066
	Foot Pedal	AS4500-P Low10
	Power Adapter	109-064
Optional Accessories	Disposable 3/8" OD AutoFuse Tubing	AFTD
	Disposable 3/8" OD AutoFuse Tubing with "Y" bifurcation	AFTDY
	Cannulae	Custom - Pls call for sizes
Optional Devices	Tumescent Measuring Device	TMD
	TMD Conductor Cable	116-093
	LS2 Liposuction Aspirator	LS2-SP or LS2-DP
	LS2 Universal Power Cord	109-070
ą *Replacement Parts*	Bulkhead Connector	160-060
	Power Supply (Globtek Part # TR9C12100CCP-Y-MED)	115-003
	Power Switch	116-026
	Pumphead	165-006
	Handle	165-016
	Control Knob	164-008
	Green Indicator Light	116-064
	Foot Pads	116-028

For *Replacement Parts*, please contact M.D. Resource Corp. to service or repair these parts. Do not attempt to service or repair these items. Refer to Page 7 - Support & Warranty to follow instructions on how to return the unit to M.D. Resource Corp.

ą Warning - Risk of Electric Shock. Do not open case.

Appendix C: EMC & Other Interference

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The K Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the K Pump should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The K Pump uses RF energy only for internal function. Therefore RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	K Pumps are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes,
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The K Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the K Pump should assure that it is used in such an environment. Use of accessories, transducers, power cords, and cables other than those sold by Medical Device Resource Company may result in system failure, increased EMC emissions, and/or decreased EMC immunity of the K Pump. If used adjacent to, or stacked with, other equipment, all such equipment should be closely monitored to ensure normal operation.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Immunity Guidance**
Electrostatic Discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Kpump requires continued operation during power mains interruptions, it is recommended that the Kpump be powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Not applicable – Kpumps are not Life-Supporting / Kpumps not affected by EMI in range from 150 kHz to 80 MHz or 80 MHz to 2.8 GHz

Note: U_T is the a.c. mains voltage prior to application of the test level

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The K Pump is intended for use in the electromagnetic environment specified below. The customer r the user of the K Pup should ensure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the K Pump and K Pump cabling than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance 0 MHz to <80 MHz 80 MHz to <800 MHz 800 MHz to 2.5 GHz
Conducted RF IEC61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less that the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note: 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 broadcast, and TV broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the K Pump is used exceeds the applicable RF compliance level above, the K Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pump.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the K Pump.

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

Rated maximum output power of transmitter (Watts)	**Separation distance according to frequency of transmitter (Meters)**		
	150 kHz to <80 MHz	80MHz to <800 MHz	800 MHz to 2.5 GHz
			800
0,12	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	0,17	1,17	2,33
10	3,70	3,70	7,37
100	11,7	11,7	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance (*d*) in meters (*m*) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rting of the transmitter in watts (W) according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.