

CONTENTS

Symbols	2
Rear Panel Illustration	3
Introduction	4
Indications for Use	4
Warnings and Cautions	5
Modifications	5
Description of Components	5
Setup Instructions	5
Unloading Approved Tubing for use	6
Equipment Operating Procedures	6
User Maintenance	6
Cleaning the Pump Case	6
Troubleshooting Guide	7
Technical Specifications	8
Approvals	8
Technical Manuals	8
Inspection Upon Receipt of Product	9
Reporting Concealed Shipping Damage or Missing Parts	9
Return Procedure	9
Warranty	9

SYMBOLS



MET LABORATORIES



ELECTRIAL SHOCK HAZARD – <u>DO NOT REMOVE COVER</u> (Refer servicing to qualified service personnel)



FUSE



TYPE OF EQUIPMENT



ALTERNATING CURRENT



OFF (POWER: DISCONNECTED FROM THE MAINS)



ON (POWER: CONNECTED TO MAINS)



EXPLOSION RISK IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETIC.



FOOT SWITCH / PEDAL



VOLUME



MANUFACTURER

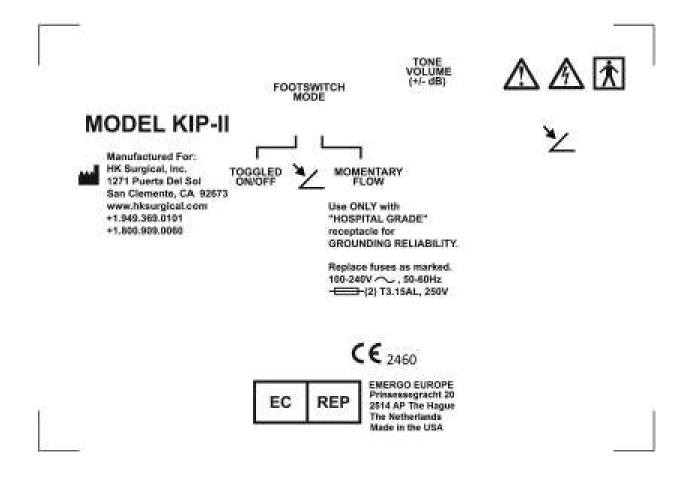


CONSULT INSTRUCTIONS FOR USE OR OPERATING INSTRUCTIONS



PER M5 DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 SEPTEMBER 2007, THE TUBING USED IN CONJUNCTION WITH THE KLEININFILTRATION PUMP IS DESIGNED FOR SINGLE USE ONLY. THE REUSE OF TUBING CAN LEAD TO BACTERIAL INFECTION AND POSSIBLE SEVERE HEALTH EFFECTS.

REAR PANEL ILLUSTRATION



INTRODUCTION

Thank you for choosing the HK Surgical Klein Pump II[™] Infiltration Pump!

The Klein Pump II[™] is a peristaltic pump using three rollers to create pumping action in a silicone section of tubing. This manual provides instruction for operation, maintenance, and troubleshooting procedures for the HK SURGICAL Klein Pump II. Users should be trained in its use and applicable medical procedures.

INDICATIONS FOR USE

The Klein Pump is an infiltration pump used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional. The Klein Pump is not intended to be used as an IV infusion pump.

WARNINGS AND CAUTIONS

General Warnings and Cautions are labeled on the housing and in the manual. All warnings and cautions should be familiar to, and reviewed by, all personnel prior to a procedure. These cautions and warnings are considered essential to the safety of personnel, patients, equipment, and property. If you have any questions, please contact HK Surgical.



DANGER ANESTHETICS - Risk of Explosion if used in the presence of flammable anesthetics!



CAUTION – Risk of electrical shock. Do not open case. Refer to proper authorized personnel for servicing.



The use of any tubing other than that supplied with the pump may result in a change in the flow characteristics of the pump.



Per M5 Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, the tubing used in conjunction with the Klein Infiltration Pump is designed for single use only. The reuse of tubing can lead to bacterial infection and possible severe health effects.

MODIFICATIONS

Modifications to any component of this device may create possible hazards and/or impair the safe use of this product during a procedure. Any requests for changes in design or use should be sent or communicated to the proper HK Surgical personnel.

DESCRIPTION OF COMPONENTS

- Main power ON/OFF switch is located on the rear panel with a "power on" green LED indicator on the front panel. Plug the main power cord into the back of the Infiltration Pump. Plug the other end into any AC outlet with the same voltage as noted on your machine. The Infiltration coupler shall also be used as a separator from the mains.
- Footswitch connectors are located on the front panel, under the pump head.
- Power connector is located on the rear panel of the unit.
- Pump speed (flow rate) is set by a user adjustable single turn potentiometer located on the front of the panel.
- The drive is a single direction with a clockwise Pump Head operation and not user selectable.

SETUP INSTRUCTIONS

- 1. The infiltration fluid, tubing, handle/ needle, and spike must be sterile.
- 2. Open the pump head lid to allow loading of the peristaltic tubing/tubing section.
- 3. Peristaltic tubing/tubing specifications:
- 4. Place tubing on roller section ensuring flow direction is from left to right when facing the unit.
- 5. Lower Pump Head lid to the down (closed) position and lock in place.
- 6. Connect pneumatic foot switch tubing to ports located on the front of the pump, under the pump head.
- 7. Turn power to the Klein Infiltration Pump ON.
- 8. Select desired pneumatic foot switch mode (toggled or momentary) located on the back of the pump.
- 9. In toggle mode, depress foot switch to start the pump's operation. Depress again to discontinue pump operation. In momentary mode, the foot switch must be held down to enable pump operation.
- 10. Adjust flow rate, as necessary, using the potentiometer speed control dial.
- 11. For additional setup and user instructions, please go to https://www.hksurgical.com/video-gallery#kleinpump
- **NOTE:** Rotating dial clockwise (CW) will increase flow rate. Rotating the dial counterclockwise (CCW) will decrease flow rate. Dial indicator numbers are relative and do not indicate a specific flow rate. Flow rate must be empirically correlated to dial indicator number.

APPROVED TUBING FOR USE

Item #: ITS-10 (ITS-20/ITS-10-RS) (10 or 20 per case) Latex Free/Non DPEH The Single Spike Infiltration Tubing is 15.5 feet in length and used in conjunction with the KIP-II Pump. Diameter - IV Tubing Section = ID (.110) x OD (.160) Diameter - Silicone Sleeve Section = .187 x .375

Item #: CVT-10 (CVT-20/CVT10-VS/CVT20-VS) (10 or 20 per case) Latex Free/Non DPEH HK CVT Infiltration Tubing is tubing 15.5 feet in length specifically design for Dr's performing vein ablations. Diameter - IV Tubing Section = ID (.110) x OD (.160) Diameter - Silicone Sleeve Section = .187 x .375

Item #: ITD-20 (20 per case) Latex Free/Non DPEH Double Spike Infiltration Tubing for use with 2 IV bags, 15.5 feet in length. Diameter - IV Tubing Section = ID (.110) x OD (.160) Diameter - Silicone Sleeve Section = .187 x .375.

Item #: IT2X-10 (10 per case) Latex Free/Non DPEH 2X Infiltration Tubing for use with 2 Cannulas, Nominal Length of 44 inches. Diameter - IV Tubing Section = ID (.110) x OD (.160) Diameter - Silicone Sleeve Section = .187 x .375.

UNLOADING TUBING

1. Open pump head lid to open mechanism and remove tubing. (Note: the pump is deactivated when the lid is not in the closed position.)

EQUIPMENT OPERATING PROCEDURES

- 1. The pneumatic foot switches control the peristaltic pump when the unit main power switch is on.
- 2. The pump mechanism lid must be in locked position to operate pump. Lifting the lid de-activates the pumping action.
- 3. 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.

4. Shut down procedure: If in toggle mode depress footswitch to turn pump off, or if in momentary mode, remove pressure from foot switch. Turn main power switch to off.

USER MAINTENANCE

- 1. NO PUMP MAINTENANCE IS REQUIRED. ALL COMPONENTS are lifetime lubricated. Do NOT lubricate.
- 2. Check condition of power cord and footswitch tubing annually. Replace if cracked or worn.

CLEANING THE PUMP CASE

- 1. Dirt, stains, and dried materials can be removed from the case by using any mild nonabrasive cleanser. Ground in materials should be scrubbed with a soft bristled brush. If using a stronger cleaner or bristled brush, test in an inconspicuous area (such as the bottom) before using on entire unit.
- 2. The surface may then be wiped clean with a damp cloth.

TROUBLESHOOTING GUIDE

Please contact HK Surgical for assistance if the following solutions do not resolve the problem.

PROBLEM	POSSIBLE CAUSES	SOLUTION
Pump not operating	 Power switch not on. Power cord not plugged into wall outlet. Power cord not plugged into unit. Foot switch not activated. 	 Turn power switch to "on." Plug power cord into outlet. Plug power cord into connector in rear of unit. Depress foot switches.
Foot switches will not activate pump.	 Foot switch tubing not connected. Foot switch broken or leaking Power switch not on. 	 Connect foot switch tube to connector in front of power unit. Check for tear or broken tubing. Replace foot switch. Turn power switch to "on."
Inadequate flow when foot pedal is pressed.	 Speed control set too low. Wrong tubing in pump. 	 Turn speed control clockwise to increase speed. Press foot switch to turn on. Only use tubing specified and approved by HK Surgical. Turn speed control to 5 and then dial back down to desired setting.
Tubing continues to drip after pump is stopped.	1. Gravitational flow	1. Hang the IV bag level with the pump.

TECHNICAL SPECIFICATIONS

- Rated Speed Range: 0-600 RPM
- Rated Torque: 50 oz-in
- Flow rate: Up to 1000 mL/min depending upon tubing and pump speed.
- Mode of operation: Toggled or Momentary
- Power Requirements:
 - 100-240 VAC, Inlet Hospital power cord
 - IEC 320, Use only cordage terminated in hospital grade plugs to ensure power grounding.
 - AC Frequency- 50 to 60 HZ single phase.
 - Mains Power Input Fusing: (2) T 3.15 A2, 250V
- Leakage Current within IEC 60601-1
- Humidity (non-condensing): 10% to 90 %
- Operating Temperature: 0° to 40°C
- Storage & Shipping Temperature: -45°to 60°C
- Atmospheric Pressure Range: 500kPa to 1060kPa
- Protection against shock: Class I, Type BF
- Enclosure rating: Ordinary equipment
- Display: Green LED power indicator

Blue LED – speed indicator

- Dual Foot switches with 12 ft hose, air activated
- Dimensions: 12" x 9" x 6"
- Weight: 10 lbs
- Pollution Degree: 2 per IEC 664(Indoor Usage Lab, office)
- Installation Category: Category II per IEC 664
- Warning: Use only the specified power cord supplied by HK Surgical.

APPROVALS

SAFETY: MET LABS tested per AAMI ES 60601-1:2005 ®2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)(R). Medical Electrical Equipment- Part 1 General Requirements for Safety (Based on EIC/EN 60601-1-2:2015 ed. 4.0)

EMC: IEC/EN 60601-1-2:2007 Medical Electrical Equipment – General Requirements for Safety: Electromagnetic Compatibility.

TECHNICAL MANUALS

Repairs must be made by HK SURGICAL or authorized facility. No service manuals are available for this reason. Replacement disposable tubing, foot pedals and power supply cords may be purchased from:

HK Surgical, Inc. 1271 Puerta del Sol San Clemente, CA 92673-6310 Ph: +1.800.909.0060 / Fax: +1.949.369.9797

INSPECTION UPON RECEIPT OF PRODUCT

Examine shipment upon receipt for any external damage. Note any damage on the shipping receipt. The merchandise is carefully packaged to prevent shipping damage; however, our responsibility ends with the delivery of the shipment in good condition to the transportation company. If the product package is damaged, retain all packaging materials, notify the transportation company and make a notation on the shipping receipt.

REPORTING CONCEALED SHIPPING DAMAGE OR MISSING PARTS

Please set up and operate the product as soon as possible to discover any hidden shipping damages. If damage is revealed, contact the carrier to have an agent inspect the damage. <u>Most freight and shipping companies have a</u> <u>limited time period for accepting this type of damage claim. Contact your carrier immediately.</u> The carrier reserves the right to refuse any loss or concealed damage claim made beyond that time. HK SURGICAL is not responsible for the collection of claims or replacement of damaged merchandise. We will aid you in any way possible to achieve a satisfactory outcome for your damage claim. FILING AND HANDLING THE CLAIM IS YOUR RESPONSIBILITY.

Be sure to keep all original packaging materials in the event that the items need to be returned.

RETURN PROCEDURE

Contact HK Surgical prior to returning any merchandise. Have the following information available at that time.

- Invoice or relevant information to invoice.
- Contact person and phone number.
- Product information, number.
- Serial number
- Reason for return.

If the product has been exposed to any bio-hazardous materials or used in surgery or surgical related area, it must be CLEANED and STERILIZED and HAVE A WRITTEN STATEMENT OF CONFORMATION OF STERILITY accompanying the returned product.

WARRANTY

HK Surgical products are manufactured to be used by qualified medical personnel trained and skilled in their use.

HK Surgical products are warranted to be free from manufacturing defects in materials and workmanship for a period of one year from date of purchase. HK Surgical will repair or replace, free of charge, any part, or parts that are defective in material or workmanship during that time period. Transportation charges on parts submitted for repair or replacement under this warranty must be borne by purchaser. This warranty does not apply to damages caused by misuse, mishandling, improper operation, and/or by abuse of the product. There is no other expressed Warranty including those of fitness or a particular purpose, to the extent permitted by law and all implied Warranties are excluded.

Please note, the warranty for any HK Infiltration Pump is void if HK tubing is not being used in all scenarios

Manufactured For:

HK Surgical, Inc. 1271 Puerta del Sol San Clemente, CA 92673-6310 Ph: +1.800.909.0060 or +1.949.369.0101 Fax: +1.949.369.9797

Caution: Federal (USA) Law restricts this device to use by, or on the order of, a physician. Rx Only