# **HK Aspirator**Operating Manual

AP230-III



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# **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

(+/- dB)

VOLUME



**MANUFACTURER** 

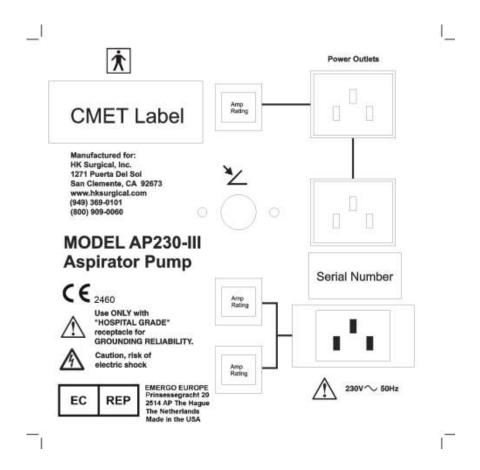
CONSULT INSTRUCTIONS FOR USE OR OPERATING INSTRUCTIONS





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 Aspirator!

This manual provides instruction for operation, maintenance, and troubleshooting procedures for the HK SURGICAL Aspirator III. Users should be trained in its use and applicable medical procedures.

#### INDICATIONS FOR USE

HK Aspirator is intended to interface with the HK Surgical accessories to provide surgeons with a system to perform liposuction surgery.

In addition to the liposuction intended use (which can be considered medically necessary in the treatment of morbid obesity), the aspiration and infiltration tubing sets are utilized for many other general surgical procedures that require aspiration of body fluids and/or tissue or infiltration of fluids.

These conditions include but are not limited to:

- Lymphedema a chronic or long-term condition in which excess fluid known as lymph collects in tissues, causing edema, or swelling. The edema commonly occurs in the arms or legs. Liposuction is used to reduce swelling, discomfort, and pain.
- Gynecomastia-removal of fat accumulation under a man's breast
- Lipomas Removal of benign fatty tumors
- Breast Reduction medically indicated breast reduction to resolve chronic conditions.
- General surgical Aspiration and Infiltration

The HK Aspirator is intended to be used for the following conditions:

- Intended patient population The device is intended for use in adult surgical patients.
- Intended users The device is intended to be used by surgeons.
- Intended use environment The device is intended for use in a surgical environment.

#### CONTRAINDICATIONS

There are no absolute contraindications for use of the Infiltration/Aspiration Equipment and Disposables System. Some patients may be unsuitable for liposuction, including patients with minimal localized adiposity, patients with existing medical conditions that preclude surgical intervention (e.g., certain blood dyscrasias, risk for hernia), patients with unrealistic expectations, and youths and adolescents

Liposuction is contraindicated in patients with severe systemic disease, cardiovascular disease, severe coagulation disorders including thrombophilia, and during pregnancy

Bleeding diathesis, emboli, thrombophlebitis, infectious diseases, poor wound healing, and diabetes mellitus should be ruled out prior to surgery. The HK Surgical Infiltration/Aspiration Equipment and Disposable System are not intended to be used in pediatric population or with pregnant women.

#### 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.

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

**WARNING** — Risk of electrical shock. Do not open case. Refer to proper authorized personnel for servicing.

**WARNING** – Do not install more than two Abbott Canisters (p/n AC-02) or more than four Baxter Canisters (p/n BC-02). Do not transport unit with filled canisters attached.

**WARNING** – There is a risk of pinching when opening or closing the peristaltic pump.

#### **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.

#### GENERAL DESCRIPTION

The HK Surgical Aspirator III is a powered suction pump/Aspirator that uses an electrically (AC) driven vacuum pump generating a negative pressure for the removal of fat/adipose, soft tissue, and general surgical waste.

#### DESCRIPTION OF COMPONENTS

- Main power ON/OFF switch is located on the front 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, one on the left and one on the right.
- Power connector is located on the rear panel of the unit.
- Pump suction (flow rate) is set by a user adjustable single turn potentiometer located on the front of the panel.

#### SETUP AND USER INSTRUCTIONS

- To remove aspirator from shipping carton, pull aspirator straight upholding firmly on the handgrips half-way down both sides of the aspirator. Save original shipping box.
- Screw the included collection canister rod into the threaded hole on top of the aspirator, attach the brackets and
  insert your collection canister. For Baxter Canisters, remove the white Delrin ring from the inside edge of the
  bracket.
- Attach one silicone tube to each end of the aspiration filter. Attach the other end of one of the silicone tubes to the
  vacuum port on top of the aspiration pump. Attach the other end of the second silicone tube to the vacuum port on
  the canister.
- Plug in the pneumatic foot switch line into the front of the aspirator. Be sure the main rocker switch is in the off position.

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- Plug the main power cord into the back of the aspirator. Plug the other end into any AC outlet with the same voltage as noted on your machine.
- Attach your 3/8" suction hose (10 or 12 ft.) to the 3/8" hose barb on your collection canister.
- Attach the other end to your suction instrument.
- Press main power rocker switch to the ON position. The green LED should glow, and exhaust fan will turn on.
- Press rocker the button on front panel to "Foot Switch" setting and press the foot pedal to start the pump. The blue light will illuminate to indicate that motors are running. Pressing it again will turn the vacuum pump off. If suction is too great, the vacuum control knob may be turned to the low position to decrease the suction.
- If any damage occurs to the pneumatic footswitch line, the unit may be turned on and off by using the foot switch rocker button.
- When the aspirator is ready to be stored, stop the pump off by using the foot switch pedal and turn the main power off. Unplug the power cord from AC outlet. Dispose of the filter.

# **TUBING**

Item #: AT6-10 - HK Aspiration Tubing is lightweight, flexible, and extra-long for easy maneuvering in the operating room. (10 per case). Diameter - .250" x .370", Length – 12 feet, Latex Free/Non DPEH

Item #: AT375 - HK Heavy Aspiration Tubing is 12 feet in length and compatible with Abbott canisters. This tubing is also compatible with the Vaser machines/technique. (10 per case). Diameter - .375" x .562", Length – 12 feet, Latex Free/Non DPEH

Item #: ATF-20 - HK Fine Touch Aspiration Tubing is ideal for fine delicate work on areas such as the face and chin. (20 per case). Length – 36 inches. Contains luer lock and universal feeding adapter.

# **CANNULAS**

#### **Aspiration Cannulas - Capistrano Cannulas**

| HK10C15 - 10g, 15cm/6" | HK12C23 - 12g, 23cm/9" | HK16C5 - 16g, 5cm/2"      | HK16C15 - 16g, 15cm/6" |
|------------------------|------------------------|---------------------------|------------------------|
| HK10C23 - 10g, 23cm/9" | HK14C15 - 14g, 15cm/6" | HK16C8 - 16g, 8cm/3"      | HK18C5 - 18g, 5cm/2"   |
| HK12C15 - 12g, 15cm/6" | HK14C23 - 14g, 23cm/9" | HK16C12 - 16g, 12cm/4.75" | HK18C8 - 18g, 8cm/3"   |

#### **Aspiration Cannulas - Finesse Cannulas**

| HK10F15 - 10g, 15cm/6" | HK12F15 - 12g, 15cm/6" | HK14F10 - 14g, 10cm/4" | HK16F5 - 16g, 5cm/2" |
|------------------------|------------------------|------------------------|----------------------|
| HK10F23 - 10g, 23cm/9" | HK12F23 - 12g, 23cm/9" | HK14F15 - 14g, 15cm/6" | HK16F8 - 16g, 8cm/3" |
| HK12F10 - 12g, 10cm/6" |                        | HK14F23 - 14g, 23cm/9" |                      |

#### **CANNISTERS & FILTERS**

#### Cannister(s)/Liner(s)

BC -02 Baxter Cannister BL -20 Baxter Liner AC 02 Abbott Canister AL -10 Abbott Liner

Filter(s) AF-6

# **USER MAINTENANCE**

You MUST unplug the unit from its power source prior to cleaning with any solution.

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- Dirt, dried materials, and other stains 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.
- DO NOT use any flammable solutions to clean the machine
- DO NOT pour any solution directly onto the aspirator, to do so may cause some solution to leak into the enclosure
  and cause electrical shock.
- Filter MUST be changed after each procedure to ensure proper flow rate and to prevent the accidental overflow of
  aspirant into the pump. Failure to change filters with each procedure will affect the performance of the machine
  and will render your warranty void.
- Suction tubing used with the aspirator MUST be sterile and single use only. You must change the tubing with each
  patient.
- An HK service technician must conduct any additions or changes that need to be made to your aspirator to meet your needs. Any additions or changes made to the aspirator without prior clearance from HK will render your warranty void.

#### TROUBLESHOOTING

Should any problems arise with your aspirator, there are several items you can check prior to calling our service center. Please review the following questions and verify all are correct. Most problems are very minor and can easily be corrected without having to return the unit.

- 1. Is the unit plugged in?
- 2. Is the unit plugged into the correct power source?
- 3. Is the main power switch in the correct position?
- 4. Is the foot switch connected properly?
- 5. Is there any foreign object inside the connection for the foot switch?
- 6. Is all tubing correctly connected?
- 7. Is something blocking the inside opening of the tubing?
- 8. Is any of the tubing bent or kinked?
- 9. Has the filter been installed correctly?
- 10. Is something blocking or is something plugged inside the suction instrument?
- 11. Is only one filter at a time being used in the unit?

If all the above items are in correct working order, call HK Surgical at +1.949.369-0101 or +1.800.909 0060 or Fax to +1.949.369-9797.

# **TECHNICAL SPECIFICATIONS**

#### The HK Aspirator:

• **Dimensions:** 19" x 13 ½" x 16 high (34.3" high with canister pole attached)

Weight: 22 kg (50 lbs.)

Mode of operation: Continuous or toggle

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• **Humidity (non-condensing):** Maximum relative humidity 80% for temperature up to 31 degrees C to 40 degrees C

• Operating Temperature: 5° 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 – operating indicator

• Dual Foot switches with 12 ft hose, air activated

#### **Power Requirements:**

Appropriately rated IEC 320 hospital grade power cord.

Use only cordage terminated in hospital grade plugs to ensure power grounding.

Model # AP230-III 230Vac, 50Hz, 6A

Leakage Current – within IEC 60601-1

# **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 IEC 60601-1, 2005, 4th Edition)

**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 or +1.949.369.0101

Fax: +1.949.369.9797

#### INSPECTION UPON RECEIPT OF PRODUCT

Examine all shipment upon receipt for any external damages. Note any damages on the shipping receipt. The merchandise is carefully packaged to prevent shipping damage; however, if the product package is damaged, please notify HK Surgical, as soon as possible.

#### 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 HK Surgical immediately so that we can contact the shipping agent. Most freight and shipping companies have a limited time period for accepting this type of damage claim. The carrier reserves the right to refuse

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any loss or concealed damage claim made beyond that time. HK SURGICAL is responsible for the collection of claims or replacement of damaged merchandise.

# RETURN PROCEDURE

Contact HK Surgical before 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 for 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.

#### REQUESTING ASSISTANCE OR SERVICE

If you need assistance or service, please call HK at (949) 369-0101 and ask to speak to the aspirator technician. We are always willing to help in any way we can.

Our aspirator is believed to be the quietest, most powerful and user-friendly machine on the market today. We always welcome comments and suggestions for the improvement of the aspirators.

# **REPLACEMENT PARTS**

Aspiration tubing is a sterile/ single use component of the HK Aspirator. You may obtain any and all replacement parts for the HK Aspirator from:



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



**C€** 2460

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