

***B89025 VITRUVIAN™ ULTIMATE  
ASPIRATOR  
120V/230V***



**Instructions for Use Manual**

## CONGRATULATIONS

You have purchased one of the finest aspirators available. Utilizing two piston driven ½ HP motors assures that you are able to achieve and maintain the highest vacuum levels that the laws of physics allow. Beyond that you will have complete control over the vacuum level giving you much more versatility in how you use the device. The motors that were selected for this device are also some of the quietest available utilizing a muffler on each along with noise insulated cabinet which make it one of the quietest aspirators available. Read this entire booklet before trying to use your aspirator.

## CALL US

*Our customer service department is staffed with friendly, knowledgeable people who are ready to help. Whether you need replacement disposables or assistance in troubleshooting an issue, they will help you or put you in touch with someone who can.*



TOLL FREE: 1-877-252-2517  
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FAX: 1-770-414-4879  
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# Instructions for Use

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


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## I. Introduction

### Symbol Definitions

The following symbols appear on the exterior of the product or elsewhere in this User's Manual.

	Attention: Consult accompanying documents
<b>O</b>	Power OFF
<b>I</b>	Power ON
~	Alternating Current
	Fuse
	Attention: Consult User's Manual <b>USE PROPER GROUNDING: Use only receptacle marked "hospital Grade"</b>
	<b>Warning: Hot surfaces inside. Contact may cause burn. Do not touch.</b>
	<b>Risk of Electric Shock. No user serviceable parts inside. Refer servicing to qualified personnel.</b>
	<b>Danger: Risk of explosion. DO NOT use in the presence of flammable anesthetics</b>

### Use of This Documentation

This manual provides instruction for operation, maintenance, and troubleshooting procedures. Users should be thoroughly trained in using this product and applicable medical procedures.

Instruction manuals should be made available to the user(s) during the procedure. Follow all instructions contained in this manual pertaining to the device, with particular attention given to the WARNINGS and PRECAUTIONS.

### **Warnings**

Warnings are statements about conditions that could cause serious injury or death. The following warnings apply:

**Read this User's Manual completely prior to use.**

- **Do not use the aspirator in the presence of flammable anesthetics.**
- This device will not, in and of itself, produce significant weight reduction.
- This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity.
- The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

### **Precautions**

- This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.
- Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- Results of this procedure may or may not be permanent.
- The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
- All reusable components of the device must be sterilized and all disposable components replaced before using the device system on another patient.
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- When performing a procedure, ensure that the collection canister(s) does not overfill. **Aspirant or other material entering the vacuum system may cause damage.**

- **Operate the B89025 VITRUVIAN™ Ultimate Aspirator only with the supplied B89030 Hospital Grade Power cord (or equivalent) “hospital grade” power cord.**
  1. Insert the universal end of the power cord into the receptacle on the back of the aspirator.
  2. Connect the remaining end of the power cord to your AC outlet.
  3. Black & Black Replacement Cord **Part # B89030**
- **Electrical connection should be made to a grounded outlet only.**
- Operate the B89025 VITRUVIAN™ Ultimate Aspirator only at the specified voltage (110-120 or 220-230 VAC). The aspirator’s operating voltage is user selectable and has been pre-set to the voltage required at user site. **Operating the B89025 at a voltage other than that for which it was manufactured is dangerous and may damage or destroy the aspirator.**
- **Never attempt to bypass or disable the B89025’s circuit breaker.**
- **Do not restrict cooling fan.**
- **Do not use the B89025 for a purpose other than that for which it was designed.**
- **Do not attempt to service the B89025 unless advised Black & Black to do so.**
- **Always use a biofilter(s) when performing aspiration. Replace biofilter(s) after each case. Optional Black & Black Replacement Filter Part Number is B89104.**

**Contact Black & Black Surgical Customer Service at 770-414-4880 or 877-252-2517 if you have any questions.**

### **Operational Safety**

- The B89025 VITRUVIAN™ Ultimate Aspirator needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the B89025 VITRUVIAN™ Ultimate Aspirator.
- The use of accessories, transducers and cables other than those specified by Black & Black Surgical may result in increased EMISSIONS or decreased IMMUNITY of the B89025 VITRUVIAN™ Ultimate Aspirator
- The B89025 VITRUVIAN™ Ultimate Aspirator should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the B89025 VITRUVIAN™ Ultimate Aspirator should be observed to verify normal operation in the configuration in which it will be used.
- A thorough review of this entire instruction manual is essential prior to using this product. Black & Black has taken great care to ensure the safety of the patient and staff. However, features may not be readily discernible without reviewing this documentation. Use of this equipment should therefore not be under taken until the user(s) is fully familiarized with the instructions for assembly and operation. If you have any questions, contact Black & Black Surgical at (877)-252-2517, or at [info@blackandblacksurgical.com](mailto:info@blackandblacksurgical.com)

### **Modifications**

Modifications of any kind are NOT recommended and will void all warranties.

### **Damage or Loss in Shipment**

Thoroughly inspect shipment immediately upon arrival. If goods are received short or in damaged condition, it is important that you notify the transportation company and insist on a notation of the loss or damage on the freight bill. Otherwise, it may be difficult to make a claim against the Transportation Company.

If concealed loss or damage is discovered, retain all packaging materials, notify the transportation company immediately, and request an inspection. The agent will make an inspection and grant a concealed damage notation. A concealed damage report must be made within seven (7) days of shipment delivery. After seven (7) days, the transportation company reserves the right to refuse any claim for loss or damage.

### **Incorrect Items Shipped by Black & Black Surgical**

Please check your shipment immediately for any shortage or incorrect items. If any discrepancies exist, notify Black & Black Surgical, (770) 414-4880, or [info@blackandblacksurgical.com](mailto:info@blackandblacksurgical.com), at once. Your prompt attention will ensure credit or exchange.

**ALL DISCREPANCIES BETWEEN THE PACKING LIST AND THE PRODUCTS RECEIVED MUST BE REPORTED WITHIN 48 HOURS OF RECEIPT OF THE PACKAGE TO QUALIFY FOR A CREDIT.**



### **Policy on Returned Goods**

NO RETURNS OR EXCHANGES WILL BE ACCEPTED UNLESS YOU HAVE RECEIVED A RETURN OF MERCHANDISE AUTHORIZATION NUMBER (RMA) FROM BLACK & BLACK. THIS NUMBER MUST BE ON THE RETURN SHIPPING LABEL AND ALL WRITTEN COMMUNICATION.

Call Black & Black toll-free at 1-877-252-2517 to get a Return Merchandise Authorization (RMA) number for your order. You may also send an email to **info@blackandblacksurgical.com** to obtain your RMA.

**ANY RETURN(S) WITHOUT RMA NUMBERS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO THE SENDER.**

RETURN AUTHORIZATIONS ARE VALID FOR 30 DAYS.

Full credit will be issued for any item returned in 30 days that is in undamaged and saleable condition.

A restocking charge of 25% will be charged to any product returned between 31-90 days. A credit memo, based on the dollar amount, will be issued to the account.

OPENED PACKAGES OR BOXES containing disposable items are not returnable for credit or exchange. Each package or sales unit specifically states **“Not Returnable if Package Seal is Broken.”**

**NO CREDIT WILL BE ISSUED ON ANY ITEM RETURNED AFTER 90 DAYS.**

### **Return Shipping**

Return shipping, insurance, and handling is the responsibility of the customer. Credits will not be issued until the product is received in acceptable condition. It is strongly recommended that the customer use a traceable freight shipping method.

Please ship products in their original packaging, including documentation with all tags attached. Failure to do so may result in a restocking fee to enable us to return the merchandise to a saleable condition.

Black & Black cannot be responsible for return shipping losses.

Each return must include the following information:

- Purchaser's name, telephone number and address
- B&B invoice number
- Invoice date
- RMA Number
- Purchaser purchase order number
- Quantity, catalog number and description of item
- Reason for return

## **Repair Program**

If repairs are necessary due to damage other than that incurred during initial shipment (see section labeled DAMAGE OR LOSS IN SHIPMENT), contact Black & Black to return your unit. A Return of Goods Authorization number must be obtained from Black & Black's Customer Service Department prior to returning any merchandise. When requesting a Return Goods Authorization number, please follow the return policy as listed under the section labeled POLICY ON RETURNED GOODS. Then, please carefully repack and return it prepaid freight to:

Black & Black Surgical, Inc  
Attn: repairs  
RMA# \_\_\_\_\_  
5175 South Royal Atlanta Dr.  
Tucker, GA 30084  
(770) 414-4880  
(877) 252-2517

Repairs must be made by Black & Black Surgical or by an approved authorized agent. Attempting repair without prior authorization nullifies all warranties.

## **Warranty Policy**

Black & Black products are manufactured for use only by qualified medical personnel who are trained in their use. This equipment carries a one-year warranty against defects from date of sale, which warrants it to be free from defects in material and workmanship. This warranty is valid only to the original purchaser, and will be voided if transferred to a third party.

Any Black and Black product with such defects returned will be promptly repaired or replaced at no charge to the customer. However, you are responsible for the cost of shipping the product to us. The warranty does not apply to damage caused by misuse, mishandling, improper operation, excessive voltage, and/or abuse of the product. Repairs or modifications performed other than by Black & Black or an approved authorized repair facility will nullify this warranty.

For details and warranty information, call Customer Service Department, (770) 414-4880 or (877) 252-2517.

## II. Operation

### **Intended Use**

The VITRUVIAN™ Ultimate Aspirator is intended to be used for: Aesthetic Body Contouring.

### **Intended User /Patient Population / Environment**

Black & Black Surgical's VITRUVIAN™ Ultimate Aspirator should be handled and operated by healthcare professionals completely familiar with use of the device. For prescription use only.

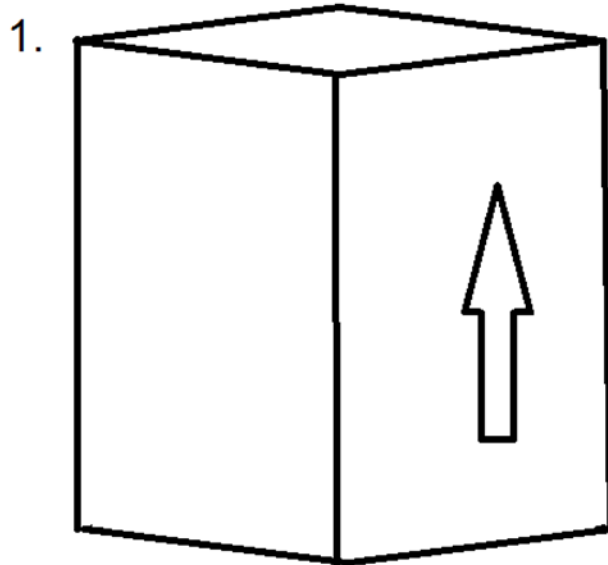
The intended patient population for this device includes any person seeking surgical, plastic, or liposuction procedures for body contouring.

This device should be used in a hospital, clinical, surgical environment. **NOT INTENDED FOR HOME USE.**

### **Contraindications**

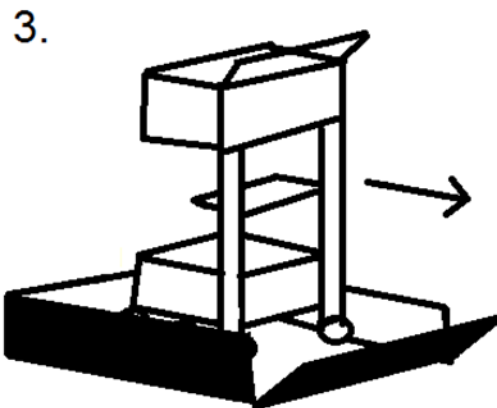
The devices are contraindicated for all the intended uses other than the ones claimed in these instructions for use.

## **Unpacking**



**Figure 1**

2. Remove foam



**Figure 2**

Your new VITRUVIAN™ Ultimate Aspirator will come packaged similar to picture in Figure 1 shown above.

1. Lift the carton vertically as shown in Figure 1 to remove.
2. Carefully remove foam protection pieces from side of device.
3. Cut the flap on the rear side of the base carton as shown in Figure 2. Remove the foam from around the base of the aspirator. Carefully move the aspirator off of the support foam and roll out of box.

Please do not throw away / break down the rest of the packaging until device has been inspected and tested.

### **Items Included with your device:**

- (1) Aspirator
- (1) Power cord
- (1) IV pole
- (1) Foot pedal
- (1) Accessories Basket

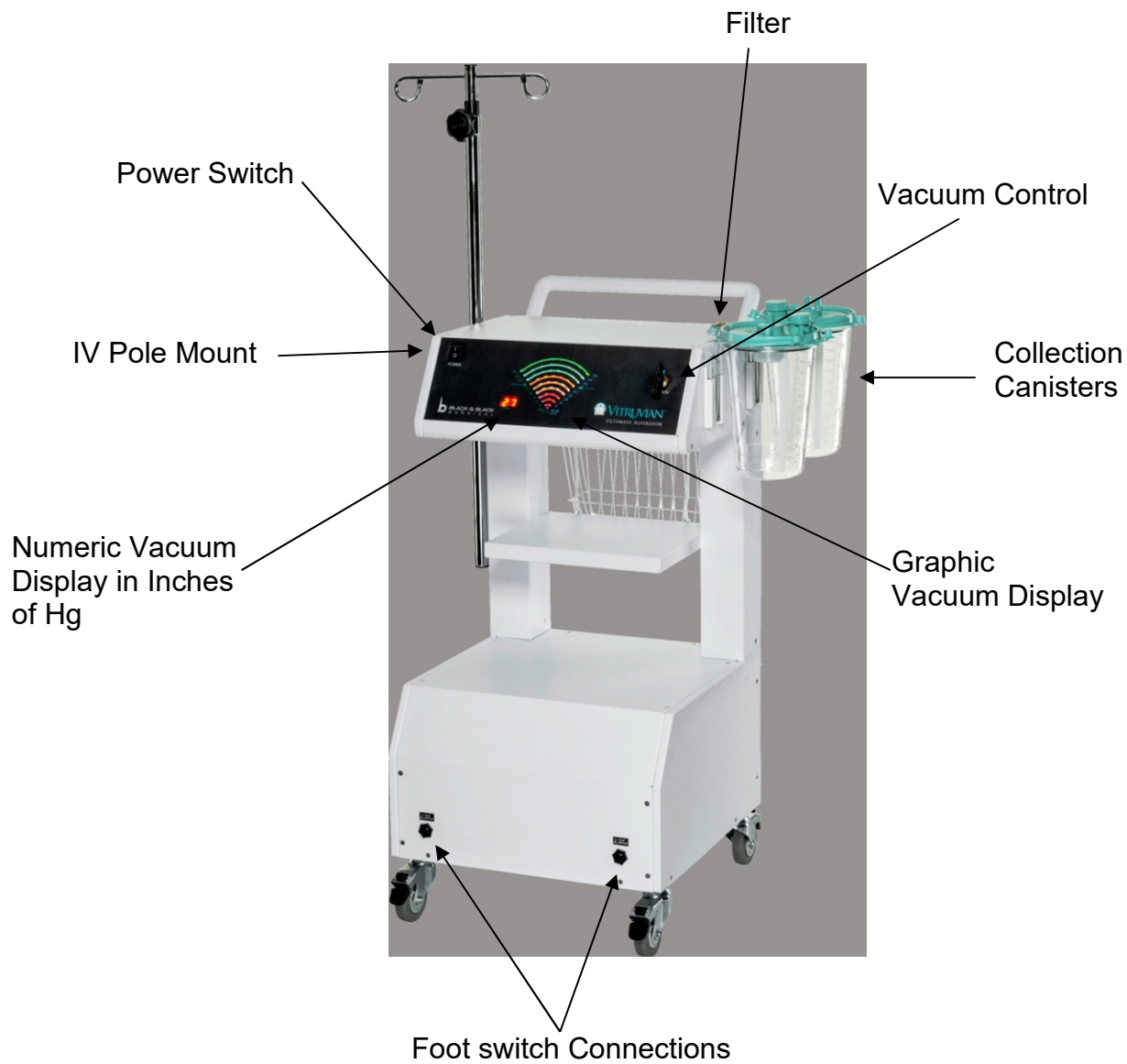
## **Initial Inspection, Set Up, and Testing**

Your new aspirator was made to the highest standard and packaged to prevent shipping damage. However, please perform the following before using.

- Visually inspect the entire exterior for dents, scratches or any other damage.
- Attach power connection on rear of device and connect cord
- Insert the foot switch cord with tightening nut into the foot switch connections on either side of the front of the device as seen on page 16.
- Locate Vacuum control lever on front of machine and rotate clockwise all the way. This is the highest level of vacuum.
- Locate the power switch on front of device and switch to the “ON” position.
- Locate the filter connection port on top of device and occlude the air flow.
- At this point the numerical gauge on the front of the device should read:
  - Approximately 29 inch (760 mm) of mercury at sea level. Subtract 1 inch (25.4 mm) for every 1000 feet (305 m) of altitude.
- Once the above test is complete attach the dual canister basket to the mount on the side of the device and place canister(s) into the basket.
- Attach the filter to the top by screwing it on to the fitting.
  - Tighten filter until snug.
  - Caution: Do not over tighten the filter. Over tightening can damage threads.
- Attach canister connection tubing as shown on pages 18-19.
- Occlude port P on canister 1 and repeat vacuum test. If all tubing is connected properly the vacuum level will return to the same level as in the first test.
- You are now ready to use the device.

## Operative Controls and Components

### Front View



## Front Panel

Power Switch

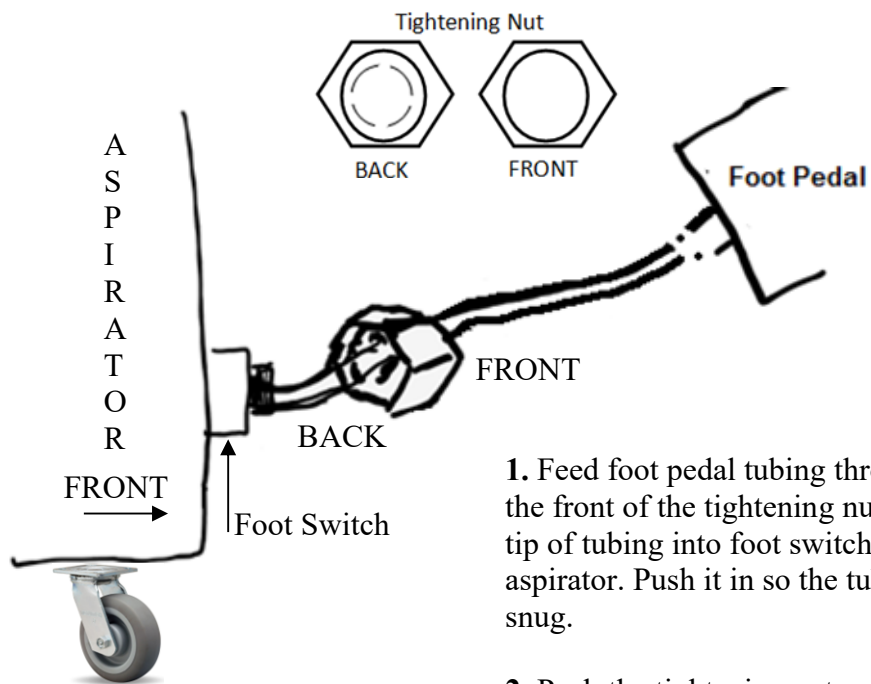
Vacuum Control



Numeric Vacuum  
Display in Inches  
of Hg

Graphic Vacuum  
Display  
(IN Hg / mm Hg.)

## Foot switch Pictures

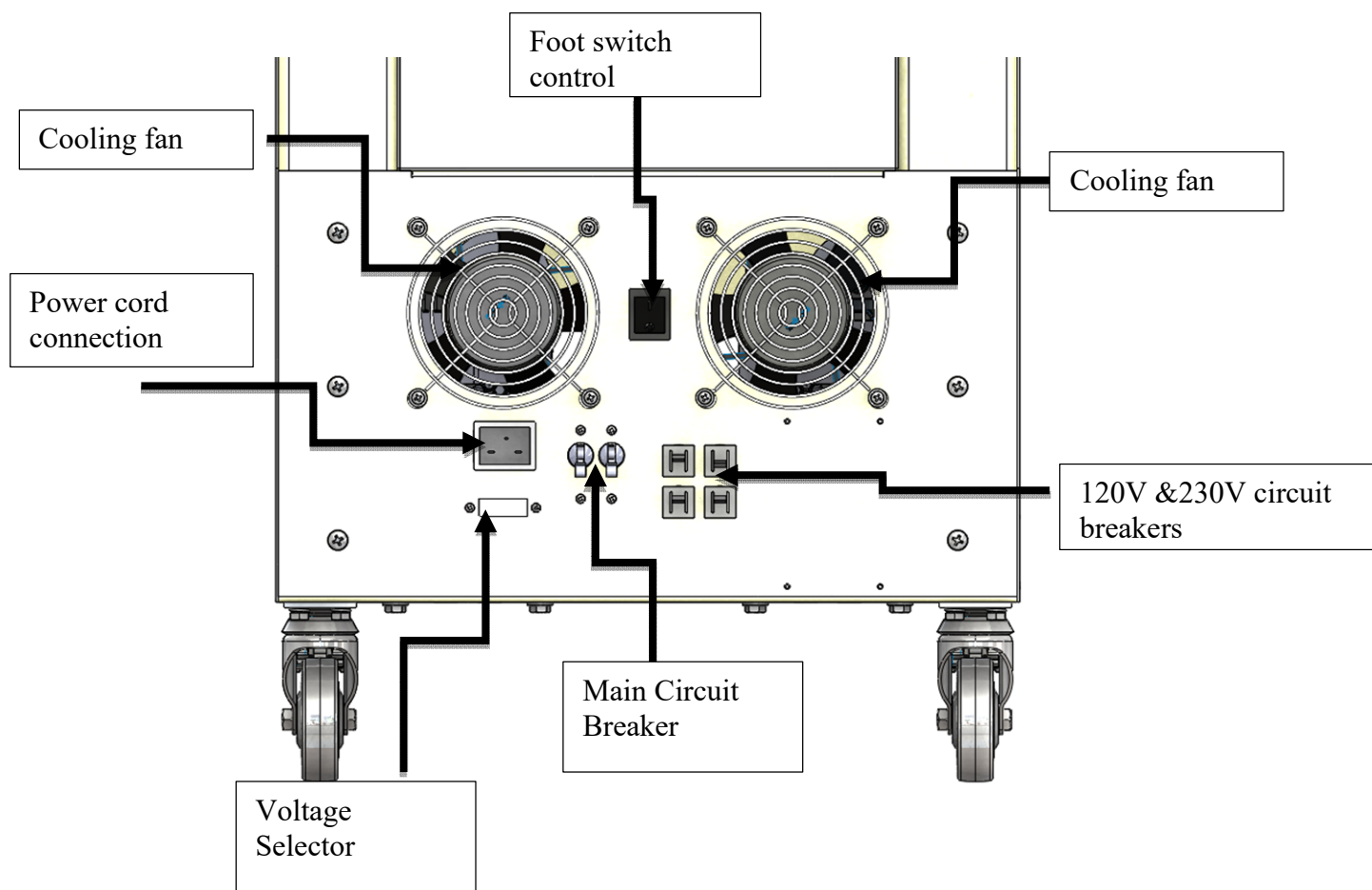


1. Feed foot pedal tubing through the front of the tightening nut. Insert tip of tubing into foot switch on aspirator. Push it in so the tubing is snug.

2. Push the tightening nut onto the foot switch and tighten by turning the nut clockwise.

3. Put 2<sup>nd</sup> tightening nut on unused foot switch for backup





**Rear View**

For replacement canisters, filters or tubing contact Black & Black Surgical  
Phone: 770-414-4880 Toll Free: 877-252-2517

### **Additional Features**

1. A main breaker is installed which will cut power in the event of a severe power surge or some other catastrophic event.
2. Each motor will work on either 120V or 230V.
3. Since each motor will operate on either 120V or 230V a separate circuit breaker for each voltage and motor has been installed. In the event only one motor is affected by some event, the remaining motor will continue to work. If the loss of one motor is noticed, immediately check for an overflow situation. If there has been an overflow, change the canister, connection tubing and filter. You should then be able to finish your case with the remaining motor.

Because of the features listed you should have years of safe and effective use, and hopefully should never experience any of these circumstances.

### **Backup Operation of Device**

- Your device comes set up to use a foot pedal to control the power of the device
- If for any reason the foot switch controls stop working, go to the rear of the unit and turn the power switch labeled “FOOT SWITCH CONTROL” to the “OFF” position. Your device will now be in aspiration mode until you turn the main power on the front of the device to the “OFF” position.

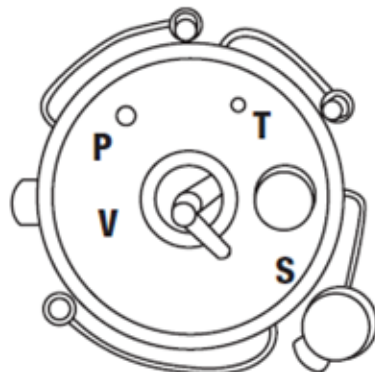
**(If using Black & Black parts) Canister Set-Up Illustration**

**B89140 VITRUVIAN**  
**LipoSuction Canisters (2000 cc)**

**INTENDED USE:** For the collection and disposal of aspirated fluids.

**DIRECTIONS FOR USE**

1. Gently shake lid to verify shut-off mechanism moves freely.
2. Place lid on canister and press firmly around entire perimeter.
3. Apply pour spout cap firmly over pour spout and apply tandem port cap tightly over tandem port if not being used.
4. Attach patient tube to patient port and vacuum tube to vacuum port. Be sure tubing fits snugly.
5. Check all caps and connections for proper seal. Test the assembly for vacuum leaks by turning on vacuum source and occluding the patient tubing with finger or thumb.
6. To eliminate fluid contamination in vacuum line, make sure vacuum line is attached to vacuum port.



P = PATIENT  
V = VACUUM  
T = TANDEM  
S = POUR SPOUT

**DISPOSAL**

1. Turn off vacuum source and disconnect all tubing.
2. Seal vacuum and patient ports with attached port caps.
3. Remove canister from bracket and transport to disposal area.  
**Do not lift canister by lid.** The weight of the contents may cause the lid to separate from the canister.
4. Dispose of according to hospital policy.

**⚠ CAUTION**

- **Single Use Only. Do not attempt to clean, sterilize or reuse canister.** Possible consequences of reuse include: 1) implosion, 2) fluid bypass, and 3) exposure to bloodborne pathogens.
- **Do not exceed vacuum level of 29" (736mm) Hg.**
- **Do not apply continuous vacuum longer than 1 hour.**
- Not intended as a measuring device, only for general reference, not specific measurement.
- Canister contents are considered potentially hazardous. Use appropriate PPE and handle accordingly.
- Store in a dark place. Long term exposure to light may compromise product performance and result in breakage during use.

**Loss of Vacuum:** Check that vacuum is on, canister is properly sealed, and that all connections are tight and tubing is not kinked. If loss continues, replace canister.

Report any product malfunctions or complaints to Black & Black Surgical using the contact information on back page.



## **Usage Instructions**

- Make sure that Power Cord and Foot Switch(es) are connected.
- Double check the tubing connections are correct per diagram and instructions on pages 18-19.
- One end of suction tubing will need to be handled out of sterile field to be connected to the patient (see page 18).
- A sterile cannula will be connected to the opposite end when the surgeon is ready.
- For **liposuction only** it is generally accepted that the vacuum be set to the highest level. Be sure to check with your surgeon regarding this setting.
- **Watch the canister(s) for overflow. The device is setup to hold 1 or 2 canisters. If while using either 1 or 2 canisters, the canister overflows, biologic material may reach the motors and cause damage that is not covered under the warranty**

## **Suggestions**

- The filter and canister connection tubing are subjected to biologic material in each surgery. We recommend that they be changed with every case.
- Specifications for Accessories used with the VITRUVIAN™ Ultimate Aspirator
  - TUBING: .36" I.D. x .59" O.D. x 10 feet long
  - CANISTER: canister should be able to withstand 29in of Hg
  - FILTER: .3 MICRON FILTER
- Optional Black & Black disposable accessories compatible with the VITRUVIAN™ Ultimate Aspirator
  - B89200 HIGH FLOW ASPIRATION TUBING, 10' - BOX OF 10
  - B89140 VITRUVIAN LIPOSUCTION CANISTERS; SINGLE USE, NON-STERILE, 2000CC – BOX OF 12
  - B89104 ASPIRATOR FILTER, .3 MICRON FILTER
- Some types of cannulas that may be purchased separately from Black & Black include:

Mercedes	Accelerator	Standard	Candy Cane	Spatula
Becker Basket	Basket	Fat Disruptor	Las Vegas	Sattler

For further details call Black & Black or go to [www.blackandblacksurgical.com](http://www.blackandblacksurgical.com)

### **III. Maintenance**

#### **Cleaning Instructions**

The unit exterior should be wiped down with a damp cloth and germicide. **DO NOT** use cleaning solutions containing **ALCOHOL OR SOLVENTS!**

**Warning** – Do not immerse in liquid. Store the aspirator covered, in a clean dry place. Contact proper authorized person for servicing.

**DO NOT** autoclave or ETO sterilize the aspirator, canister, filter or single use items.

## **Troubleshooting Guide**

Problem	Possible Cause	Solution
No Power	Footswitch not connected.	Connect footswitch and retry
	Power cord loose or not plugged in.	Check to be sure that power cord is plugged into both the aspirator and power outlet
	Power switch in the off (O) position	Move switch to on ( ) position
	Circuit breaker tripped	Check circuit breaker on back of machine. With power cord disconnected switch breaker off and then back on. Plug power cord back in and turn power on. If problem persists call Customer Service.
Low Vacuum	Vacuum adjust knob set on low	Rotate knob to the right for higher vacuum.
	Air Leak	Remove filter from top of machine and occlude the opening. If maximum vacuum is reached replace filter and repeat at all connections.
	Canister lid is not properly sealed	With vacuum "ON" gently push down on lid. Release vacuum by venting with air and restart.
	For customers operating on 115V, the voltage selector is set to 230V	Switch the selector back to 115V. The voltage selector being set to 230V will make the pump run at half power on a 115V socket.
Aspirator stalls after quick restart.	Aspiration pumps still under load (vacuum).	Release vacuum by venting with air and restart.
<b>If problems persist contact Black &amp; Black Surgical, (877) 252-2517 or (770) 414-4880.</b>		

## IV. Warranty Provisions

- The B89025 VITRUVIAN™ Ultimate Aspirator is warranted for a period of 1 year from the date of purchase.
- The B89025 VITRUVIAN™ Ultimate Aspirator is warranted to be free of defects in materials and workmanship and of functional defects when used under normal conditions for its intended surgical purpose.
- Any B89025 subsystem proving to be defective during the warranty period will be replaced or repaired. If at any time you feel the B89025 system needs repairs, we can help arrange to have it picked up for repairs. You are responsible for the cost of shipment to and from Black & Black Surgical.

This warranty **does not** cover:

Add-on products

Consumables

Problems that result from:

Misuse

Aspirant entering the vacuum and/or pump system

Accidents, abuse, or problems with electrical power

Inappropriate servicing

Please contact Customer Service for more information.



## **APPENDIX – A**

### **VITRUVIAN™ Ultimate Aspirator Specifications**

<b>VITRUVIAN™ Ultimate Aspirator 120V/230V</b>	
Size	18"x18"x38" (45cm x 45cm x 97cm)
Weight	Approximately 100 lbs (47KG)
Power Cord	10 ft / 3 m Hospital Grade IEC
AC Power Input	120 /230 VAC, 50/60 Hz
Fuse	T 20A
Maximum Vacuum	27.5 in of Hg. / 711 mm of Hg
Maximum Flow Rate	6.4 CFM (Cubic feet per minute)
Sound Level	55 dB
Maximum Compressor Air	29inHg 736.6mmHg
Pump Type(s)	½ HP , Two Cylinder Piston
IEC Classification	Class I type B

**Table 1 – Guidance and manufacturer’s declaration – electromagnetic emissions**

(Table 1)

<b>Guidance and manufacturer’s declaration – electromagnetic emissions</b>		
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The EQUIPMENT 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.
RF emissions CISPR 11	Class A	The EQUIPMENT is 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	


**Table 2 – Guidance and manufacturer’s declaration – electromagnetic immunity**

(Table 2

<b>Guidance and manufacturer’s declaration – electromagnetic immunity</b>			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±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 domestic, 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	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 5 sec	<5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 5 sec	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery.
(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 domestic, commercial or hospital environment.
NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

**Table 4 – Guidance and manufacturer’s declaration – electromagnetic immunity**

(Table 4)

Guidance and manufacturer’s declaration – electromagnetic immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.2\sqrt{P}</math></p> <p><math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz <math>d = 2.3\sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div></div>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p><sup>a</sup> 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 EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EQUIPMENT.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the VITRUVIAN™ Ultimate Aspirator**

(Table 6)

Recommended separation distances between portable and mobile RF communications equipment and the VITRUVIAN™ Ultimate Aspirator			
The VITRUVIAN™ Ultimate Aspirator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VITRUVIAN™ Ultimate Aspirator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VITRUVIAN™ Ultimate Aspirator 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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 rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			