

USER'S MANUAL

ELITE™

20-5061-00 (110V)

20-5066-00 (220V)



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General Description

The ELITESeries™ Aspirator and Infiltration System is a combination of the 2 most reliable machines in the medical field - the Hercules™ and the Wells Johnson Infiltration Pump.

Aspiration in the ELITE™ is a high-powered suction system with three (3) oil-less piston vacuum pumps. The system is designed to pull a vacuum on any closed container or any open process system. Vacuum is accomplished by mounting the vacuum pumps in parallel. When the system is connected, the air flow will be from the tip of the cannula through the tubing, collection system, overflow trap, bacterial filter and finally to the pumps evacuate the air from the lines, creating a vacuum pulling aspirated material in the same direction as the air flow. Aspirated material continues to the collection system under normal suction until the cannula is exposed to air again.

Infiltration in the ELITE™ incorporates a totally enclosed, permanent magnet D.C. motor that has a long brush life, with permanent lubrication and quiet operation. The pump control unit features a belt speed reduction system. Motor control is via SCR circuitry featuring indirect velocity feedback for good load/line regulation which assures dependable speed (flow) control. Power on/off and motor speed adjustment is accomplished using push buttons, with tactile and auditory feedback, located on the front panel. “Soft-start” and smooth, gradual acceleration to speed setting is provided when power is switched remotely from the unit.

SAFETY INFORMATION

Precautions:

- Read all instructions carefully before operating equipment.
- Motors are thermally protected and will automatically restart when protector resets.
- Current leakage tests are performed and are certified within the AAMI maximum 300uA limit for medical devices.

Cautions:

- Avoid ingesting aspirated material into the pumps. Severe damage can occur to the pumping system upon contact with aspirated material.
- Federal Law restricts this device to sale by or on the order of a physician.

Warnings:

- Always disconnect the power supply to the ELITE™ before servicing.
- Safety checks should be scheduled according to purchaser's policies.
- Additional warnings and power requirements, which are part of the labeling, are located on the back door of the ELITE™.

SPECIFICATIONS

Item number	20-5061-00 (110V) 20-5066-00 (220V)
Weight	118 lbs.
Dimensions	47.5" x 21" x 18"
Maximum Vacuum - Suction	29+ inches of Hg
Maximum Vacuum - Infusion	24 inches
Maximum flow rate - Suction	6.8 cubic feet per minute
Maximum flow rate - Infusion	1200ml/min (with specified tubing)
Display Unit - Suction	inches Hg
Display Unit - Infusion	no units
Overflow Protection	Auto cutoff and in-line filter
Pump Type - Suction	2 cylinder piston
Number of pumps	3
Horsepower	1 hp
Pump Type -Infusion	Peristaltic
Number of Rollers	3

Checklist

Carefully unpack the ELITE™ from its shipping container and check that the following accessories are included in the package and received in good condition:

- ELITE™ (1)
- Power Cord (1)
- Aspirator Foot Switch (1)
- Pneumatic Infusion Foot Switch (1)
- IV Pole (1)
- 2 Bacterial Filters (1 installed in machine)
- 1 Overflow Trap Assembly (Pre-Installed)
- Canister Holder Ring (if needed)
- Canister Adapter (if needed)
- 10 pcs Sterile, Single-Use Suction Tubing
- 10 pcs Sterile, Single-Use Infusion Tubing
- 10 pcs Single-Use Canister Liners
- 2 Infiltration Handles
- 2 Infiltration Cannulas

Note: * You will receive either 1 or 2 canisters, depending on which collection system you ordered:**

1. **Baxter (1500cc's) = 1 Canister**
2. **Sorenson (1900cc's) = 2 canisters**
3. **Quick Fit (3000cc's) = 1 Canister**

Call Customer Service Immediately to report any damaged or missing items: 1-800-528-1597

COMPONENT DESCRIPTIONS

Infusion Pump Head Loading

Sterile solution may be pumped through Infusion Tubing using the following technique to load the pump head:

1. Spike IV bag
2. Clamp Infusion Tubing
3. Rotate the Pump Head lever counter clockwise to open the head.
4. Insert the enlarged center section of the infusion tubing into the pump head opening over the rollers. The flow direction should be from left to right (when facing the side of the machine) or from back to front (when facing the front of the machine)
5. Rotate the pump head lever clockwise to close the pump head and clamp the tubing.
 - a. ****Make sure the tubing is not punctured by the black teeth when the pump head is closed**

Pneumatic Foot Switch

The foot switch tubing is connected to either barb (1 or 2) located below the Infusion Pump Head on the side of the unit.

Infusion Tubing

Use sterile Infusion Tubing only. Manufacturer suggests only using approved Wells Johnson tubing. Please refer to parts list. This tubing is precision-extruded and optically inspected to insure top performance with the pump head. Other commercial tubing may not meet, or perform, to specifications. **Warning: Infusion tubing is sterile, single-use and not intended to be re-sterilized under any circumstances to prevent cross-contamination.**

Infusion Handles

Infusion Handles are designed to accept infusion tubing via luer lock. Standard luer lock needles or infusion cannulas are connected to the handle via conventional luer lock. The Infusion Handle may be gassed, autoclaved, or soaked. When sterilizing, handles cannot exceed 315 degrees.

Infusion Needles and Cannulas

The infusion technique is based on using large volumes of a very dilute concentration of local anesthetic, which produces extremely efficient anesthesia, while minimizing blood loss.

All infiltration needles and cannulas are manufactured from surgical grade stainless steel with luer lock fittings. Specify length and diameter when ordering.

IV Pole

Place the IV Pole into the bracket located on back of the ELITE™. The pole can be adjusted up or down. When pole is in desired position, tighten the knob to hold it in place. Make sure the knob is tight and the pole is secure before hanging a bag.

Infusion Controls

The variable speed drive provides ease of operation. After installing tubing as referred to in "Infusion Pump Head Loading" section, press the "on" button located on the Infusion side of the panel display. Make sure the ELITE™ is plugged into the wall outlet. The infusion display should be illuminated. Adjust the infusion flow rate by pressing the (+) or (-) buttons until the desired flow rate is displayed.

Note: The display numbers are for reference only and do not directly correspond to a unit of flow.

The ELITE™ should remain outside the sterile field. The peristaltic type pump head assures the sterile fluids remain within the tubing, never allowing direct contact with either the pump head or pump control unit.

CAUTION: To prevent air infusion, always prime tubing prior to administering any fluid to the patient.

Vacuum Pumps

The ELITE™ uses three (3) 1/3 hp piston pumps

- Oil-less, non-lubricated piston and cylinder
- Permanently lubricated ball bearings
- Stainless steel valves
- Light weight aluminum components
- Long-life, high performance piston seals
- Twin fan cooling system
- UL recognized motors
- Thermal protected
- Balanced for low vibration operation
- Capacitor

Vacuum Control

Operate Vacuum Control by pressing the (+) or (-) button located on the right hand side of the panel. Adjust up or down until the desired vacuum level is shown on the display.

Note: The ELITE™ system has been calibrated at 2,500 feet above sea level to 26+ in Hg. The maximum vacuum level will decrease by 1" Hg for each 1,000 foot increase in elevation. Conversely, the maximum vacuum level will increase by 1" Hg for each 1,000 foot decrease in elevation.

Volume Control

Operate the volume control by turning the knob located on the right hand side of the unit between High and Low.

Note: Do not leave the Volume Control Knob in the off or Low position when first turning on the aspirator pumps. This restricts the volume of air to nearly zero and since the pumps are so powerful, the High Vacuum Pump could stall.

Foot Switch

The ELITE™ can be operated with or without a foot switch.

- **OPERATION WITH FOOT SWITCH**
Plug the foot switch cord into the unit. Turn the Foot Switch and Power switches to the "ON" position. Press the pedal and the ELITE™ will start. Press the pedal again to stop the power of the unit.
- **OPERATION WITHOUT FOOT SWITCH**
Turn the Power toggle switch to the ON position, leaving the toggle for the Foot Switch OFF.

Note: The power switch on the back of the unit must be in the ON position before the unit will start.

Overflow Trap

The Overflow Trap is designed to catch aspirated material which has by-passed, or overflowed, from the main collection canister. The fluid entering the trap will cause the ball inside the plastic jar to float up into the bell shaped tube, which will cause the vacuum to stop.

Note: The plastic ball only acts as safety mechanism. There is no guarantee that the ball will completely stop the power of the unit.

If there is a problem with the overflow, please check the following:

1. The liner may be collapsing, causing material to overflow into the trap.
2. The collection system may be full.
3. The collection system may not be set up properly.

NO ASPIRATED MATERIAL SHOULD BE ENTERING THE OVERFLOW TRAP AT ANYTIME.

Read the troubleshooting section of this manual for instructions to correct an overflow situation.

Circuit Breaker

To protect the equipment and reduce shock hazard, a re-settable circuit breaker is installed on the back of the unit. This is labeled as "RESET". If there is a voltage surge or the pump motor overheats, the circuit breaker will pop out. To reset the ELITE™, turn the unit off, push in the circuit breaker, and turn the unit on. **If the unit fails to start**, the unit may require a cool-down period or technical repairs may be required.

WARNING: DO NOT LET TECHNICIANS BY-PASS THE CIRCUIT BREAKER

Setup and Operation

1. Carefully remove the ELITE™ from the shipping container. Be sure to save the box and packing material for convenient maintenance returns.
2. Read all instructions carefully before operating the unit.
3. After you have removed the ELITE™, open the accessory box and locate the power cord, both foot switches and the IV pole. Plug the Infusion foot switch and aspirator foot switch into the appropriately labeled ports. The aspiration footswitch should be pushed in and twisted lightly clockwise to lock it into place. The aspiration foot switch is optional as the vacuum pumps will operate without the foot switch. Install the IV pole into the bracket on the back of the unit, tighten knob so pole is secure.
4. Plug the power cord into the back of the ELITE™, then into an appropriate power outlet. Power on the machine by pressing the power switch located on the back of the unit.
5. To power each component of the ELITE™, press "ON" on the corresponding Infusion or Aspiration side. **Note: The controls are separate and control each component separately.**
6. To make sure the vacuum is working properly, place a finger over the tubing coming from the side of the machine labeled "Vacuum Port" and remember the reading of the vacuum display. Note: Keep your finger over the tubing until the vacuum level becomes constant. Also, keep in mind that vacuum changes according to elevation.
7. After checking the vacuum, turn the ELITE™ off.

NEXT:

8. The Overflow Trap and HEPA Filter come pre-installed in the ELITE™. You will need to unscrew the canister from the Overflow Trap and remove the ball from the packing material. Replace the canister with the ball inside and be sure to tighten!
Note: Change the HEPA Filter after 10 procedures or every 24hrs of use.
9. Locate the Collection System. Determine if the system is a Baxter™, Sorenson™ or Quick Fit™ canister system, then read the applicable instructions included in this manual to set up the collection system.

NEXT:

10. **Set up the collection system as described on the following pages.**
11. At this point, the following accessories should now be connected:
 - a. Power cord and foot switches
 - b. IV Pole - which is securely installed in the bracket
 - c. Canister – placed in the canister holder with liner intact

The unit is now ready for operation.

Setup and Operation of Collection System

Quick Fit™ Canister System (3000cc's)

1. Place canister in the canister bracket of the ELITE™ on the right side of the unit.
2. Insert a Quick Fit™ liner into the canister and secure the lid.
Warning: Quick-Fit™ liners are single-use and not intended to be re-used under any circumstances to prevent cross-contamination.
3. Connect the piece of tubing that is connected to the bracket to the top of the lid. (as shown on picture)
4. Connect the 20" piece of silicone tubing from the Vacuum Port on the ELITE™, to the bottom of the bracket on the Canister.
5. The sterile aspiration tubing will connect to the liner lid on the port labeled: **Patient**
Warning: Aspiration tubing is sterile, single-use and not intended to be re-sterilized under any circumstances to prevent cross-contamination.

THE CANISTER SYSTEM IS NOW READY FOR OPERATION.

Caution: Aspirated material should not enter the overflow trap at any time.

If an overflow situation occurs, please do the following:

1. Turn off the power immediately.
2. Check the connections between accessories to make sure the unit was set up correctly.
3. Check for a crack in the canister.
4. Check the volume setting (should be on high).

Sorenson™ Canister System (1900cc's)

1. Place the Sorensen Adapter into the canister bracket of the ELITE™ on the right side of the unit. Next place the canister into the slot of the adapter.
2. Insert a Sorenson™ liner into the canister and secure the lid.
Warning: Sorenson™ liners are single-use and not intended to be re-used under any circumstances to prevent cross-contamination.
3. Connect the piece of tubing that is connected to the liner lid to one end of the Tee connector.
4. Connect the 20" piece of silicone tubing from the Vacuum Port on the ELITE™, to the bottom of the bracket on the Canister.
5. The sterile aspiration tubing will connect to the liner lid on the port labeled: **Patient**
Warning: Aspiration tubing is sterile, single-use and not intended to be re-sterilized under any circumstances to prevent cross-contamination.

THE CANISTER SYSTEM IS NOW READY FOR OPERATION.

Caution: Aspirated material should not enter the overflow trap at any time.

If an overflow situation occurs, please do the following:

1. Turn off the power immediately.
2. Check the connections between accessories to make sure the unit was set up correctly.
3. Check for a crack in the canister.
4. Check the volume settings (should be on high).

Baxter Canister System (1500cc's)

1. Place canister in the canister bracket of the ELITE™ on the right side of the unit.
2. Snap the red Baxter liner lid onto a soft-shell liner. Insert the hard-shell canister.
Warning: Baxter liners and lids are single-use and not intended to be re-used under any circumstances to prevent cross-contamination.
3. Plug the red hose on the canister into the top of the liner lid on the port marked **Vacuum**.
4. Attach the 20" piece of silicone tubing from the Vacuum Port on the ELITE™, to the red spout on the side of the canister.
5. The sterile aspiration tubing will connect to the port labeled: **Patient**
Warning: Aspiration tubing is sterile, single-use and not intended to be re-sterilized under any circumstances to prevent cross-contamination.

THE CANISTER SYSTEM IS NOW READY FOR OPERATION.

Caution: Aspirated material should not enter the overflow trap at any time.

If an overflow situation occurs, please do the following:

1. Turn off the power immediately.
2. Check the connections between accessories to make sure the unit was set up correctly.
3. Check for a crack in the canister.
4. Check the volume settings (should be on high).

Troubleshooting - Aspiration

No Suction

1. Turn Volume Control Knob to High. If this knob is on Low, there will be no noticeable suction.
2. Check for a collapsing liner.
3. Disconnect tube from canister only that attaches to ELITE™ vacuum port. Place finger over the open end of the tube. If there is no suction, turn the unit off, remove finger from hose, wait a moment, then turn the unit on again.

Precaution: Before starting any suction procedure, let the ELITE™ go to full vacuum when switched on. During operation, if the ELITE™ is momentarily turned off, let the vacuum gauge indicator return to “0” before restarting the machine. Air must fill the vacuum lines before all the pumps will start again. Failure to follow this procedure can result in the loss of vacuum.

Overflow Situation

1. Monitor the collection system for fluid level. Do not overflow.
2. A collapsing liner can cause the aspirated material to overflow into the overflow trap.
3. Check for a crack in the canister. This can cause the liner to collapse, resulting in an overflow situation. A collapsing liner bag does not mean that there is something wrong with the ELITE™.

Caution: With proper operation and monitoring, at no time during any procedure, should an overflow situation occur.

Broken Canister

1. Do not use a damaged canister. A damaged canister will cause the liner bag to collapse, causing the aspirated material to overflow into the overflow trap.

Caution

Ingesting aspirated material into the pumping system can severely damage the pumps and void the warranty. If material is going into the overflow trap, check the collection system immediately to see if the liner bag is collapsing or is too full. If further assistance is needed, call technical support at 800-528-1597.

Refer to the collection system section and instructions for proper set up.

Troubleshooting - Infusion

Infusion Pump Head

The black lever on each side of the pump head can be pressed inward, allowing it to slide up or down to adjust to tubing size.

Sliding button upward loosens pump head grip on the infusion tubing. Tubing will have a tendency to “walk”, or bunch-up, in the pump head if the buttons are adjusted too high.

Adjusting the button downward tightens the pump head grip on the tubing. Adjusting the buttons toward the bottom of their excursions may restrict the flow rate.

NOTE: Adjustment of the buttons in the center of their excursion provides an optimum setting.

Maintenance - Aspiration

- All Aspirators are thoroughly checked by the Quality Assurance Department before being released for shipping. Inspect the unit upon receipt to insure the equipment was not damaged during shipping. The vacuum power should also be checked.
- Do not lubricate pumps. The oil-less components are sealed and packed with an optimum level of lubricant, requiring no lubrication.
- Do not let liquid or aspirated material enter the pumping system.
- The mufflers (Part No. 16-5073) should be changed after approximately 80 hours of operation, or whenever the white filter inside the muffler becomes black.
- No scheduled maintenance is recommended. Follow the procedures established by your engineering department.
- Warnings are part of the labeling and are indicated on the ELITE™. The serial number is stamped on a small metal tag, located on the back of the unit. Record the serial number.
- In-services on new equipment can be provided by telephone with either your sales representative, or our technical support staff. If additional information is needed, call Customer Service or Technical Support at 800-528-1597.
- Change HEPA Filter after 10 procedures.

Maintenance - Infusion

- The speed control circuit has solid-state components which do not require service. An excessive load on the system may, however, cause the printed circuit board mounted fuse to blow. Indication of a broken fuse is when the power is applied to the drive, and the speed control on/off button is ON and illuminated, however the motor does not operate when the footswitch is pressed.
- Exact motor brush and commutator life will depend on duty cycle and motor operation speed. Brushes should be inspected every six months, or after 2,000 hours of operation, whichever occurs first. Replace when less than 0.300" long. The commutator should be periodically inspected and cleaned if necessary. If preventative maintenance is not performed, excessive commutator wear or "bridging" between commutator segments will cause excessive current through the controller circuit.

PARTS LIST

ITEM	PART NO.
<u>ELITE™ (110V)</u>	<u>20-5061-00</u>
<u>ELITE™ (220V)</u>	<u>20-5066-00</u>
<u>Power Cord (AC 110V)</u>	<u>20-5100-00</u>
<u>Power Cord (AC 22V)</u>	<u>20-5101-00</u>
Aspiration	
Foot Switch (Single)	20-5102-00
Vacuum Gauge	16-5030-00
HEPA Filters (case of 10)	20-5201-00
Overflow Trap, Assembly, ELITE (with 8" and 12" silicone tubing)	17-5200-00
Overflow Ball	16-5107-00
8" Silicone Tubing	16-9024-08
12" Silicone Tubing	16-9024-12
<u>20" Silicone Tubing</u>	<u>16-9024-20</u>
Canister, Baxter™	20-5153-00
Disposable, Single-Use Soft-Shell Liners, Baxter™	20-5154-00
<u>Baxter™ Canister Holder</u>	<u>20-5159-01</u>
Canister, Sorenson™	20-5157-00
Disposable, Single-Use Liners, Sorenson™	20-5158-00
<u>Sorenson™ Canister Holder</u>	<u>20-5159-00</u>
Canister, Quick-Fit™	20-5156-00
Disposable, Single-Use Liners, Quick-Fit™	20-5155-00
<u>Quick-Fit™ Canister Holder</u>	<u>20-5159-03</u>
Standard Aspiration Tubing, 9ft, sterile	24-5103-00
<u>MB Aspiration Tubing, 9ft, sterile</u>	<u>24-5104-00</u>
Vacuum Pumps, 1/3 hp, piston, hi-vac (2 ea)	18-5057-01
<u>Vacuum Pump, 1/3 hp, piston, hi-vac (1 ea)</u>	<u>18-5058-01</u>
Muffler (MIN) (3per unit)	16-5073-00
<u>Tubing (Internal PVC)</u>	<u>17-5003-00</u>
Infusion	
Infusion Tubing, sterile, single-use disposable	24-6008-00
<u>Multi Hole Infusion Cannulas (specify size)</u>	<u>20-1218-00</u>
Spinal Needles, sterile, disposable	
18g x 6"	24-6002-00
<u>25g x 3"</u>	<u>24-6003-00</u>
20g x 3 ½"	24-6004-00
<u>Infusion Pump Head, single</u>	<u>18-4102-00</u>
Infusion Pump Head, double	18-4102-01
<u>Pneumatic Foot Switch, single</u>	<u>20-5102-00</u>
Pneumatic Foot Switch, dual	20-5103-00
<u>IV Pole</u>	<u>18-4200-01</u>

WARRANTY

- The Wells Johnson Company will void warranty on any products indicating negligence, or noncompliance with operating and maintenance instructions.
- Products are warranted against defect in material and workmanship for a period of one (1) year from date of purchase. If repair or adjustment is necessary, and are not the result of abuse or misuse, please return, freight prepaid, and correction will be performed without charge.
- All returns require prior authorization from the Wells Johnson Quality Assurance Department.
- Any aspirated material found to have been ingested into the pumping system will void the warranty.
- **Retain the custom-made packing box with foam for returns.**
- For questions about the warranty, call the Quality Assurance Dept: 800-528-1597

**For technical assistance call
Customer Service or Technical Support:**

520-298-6069

800-528-1597



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