INTEGRATED **DEVICES**

HAEMONETICS®

Cell Saver® Elite®+

Quick Reference Guide

This guide is not intended as a substitute for the Cell Saver® Elite®+ System Operation Manual or authorized training.

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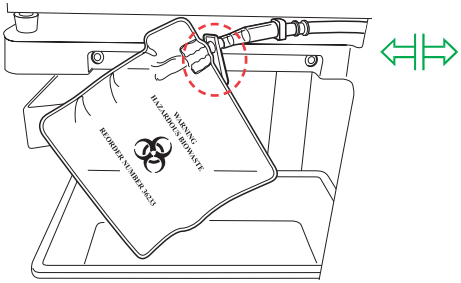
Supply	Storage location
☐ Cell Saver® Elite®+ system	
☐ Wash solution 1 liter or 3 liter bag of sterile 0.9% saline for injection, USP	
☐ Anticoagulant ACD, CPD, or 25'000-30'000 IU Heparin/1 liter bag sterile 0.9% saline for injection, USP	
☐ Cell Saver Elite + processing set	
☐ Surgical collection reservoir	
☐ Aspiration and anticoagulant (A&A) line	
☐ Filtered vacuum line	
☐ Vacuum source Regulated to -150 to -200 mmHg for Intra-op use, or use integrated SmartSuction®	
☐ Centrifuge chuck adaptor Reusable; for 70 mL bowl only	Store with device.

Supplies

Prepare the device:

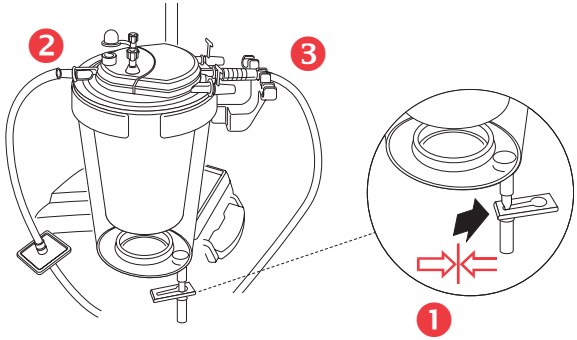
1. Unfold biohazard waste bag, stored in tray on underside of device.
2. Ensure biohazard waste bag is connected to and hanging from drain tube and **open** clamp.



3. Ensure pump platen lever and device cover are **closed** and valve module cover and centrifuge header arm are **closed** and **locked**.
4. Power on device and allow system self test to finish.
5. Select bowl size or scan processing set when prompted.

Load reservoir and A&A line:

1. Place reservoir in weigher and **close** drain port slide clamp.
2. Connect vacuum line to device vacuum port and yellow-capped port on reservoir. If using external suction, connect external vacuum to yellow-capped port on reservoir.
3. Receive and attach A&A line to blue-capped port on reservoir and insert into tubing support.



4. Turn on suction. If using manual suction, set to minimal acceptable level (<200 mmHg).
5. **Close** roller clamp on A&A line.
6. Hang and spike anticoagulant bag.
7. Prime reservoir until breakthrough (150-200ml). Adjust roller clamp on anticoagulant bag to 1 drop/sec.

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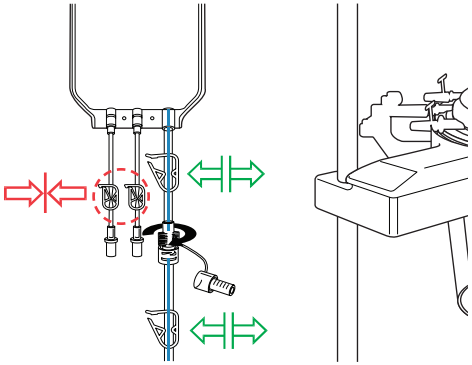
Load processing set:

1. **Open** Cell Saver Elite + processing set and check for integrity.
2. Hang RBC bag on right IV pole and **close** small clamps.



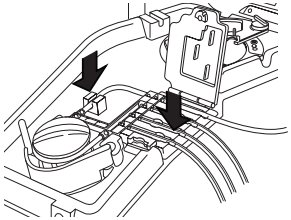
NOTE: Ensure blue line tubing clamps are open and twist-lock connection is secure.

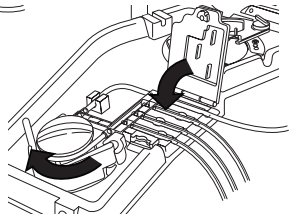
3. Thread pump tubing around pump and place tubing manifold into position.
4. Floss tubing into air detector and insert clear tubing and color-coded lines into grooves in valve module.
5. **Close** pump platen and **close** and **latch** valve module cover.
6. Place bowl firmly into centrifuge with lower inlet port facing left.

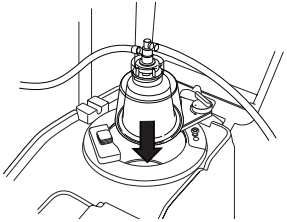
NOTE: If using 70 mL bowl, first place white chuck adapter firmly into centrifuge.

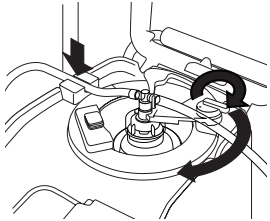
NOTE: Spin bowl to ensure proper loading.

7. **Lock** header arm around top of bowl and floss effluent tubing into line sensor.









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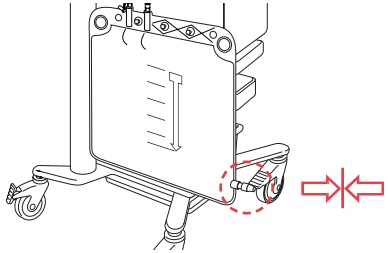
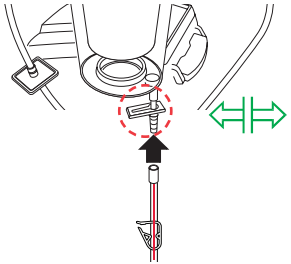
8. Hang waste bag on support pins to relieve strain on header; ensure drain port on bag is securely **closed**.

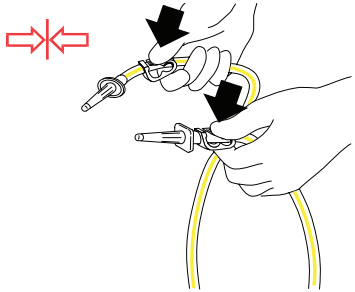


9. Connect red line tubing to bottom of reservoir and **open** drain port slide clamp.



10. Hang wash solution on lower pigtail of right IV pole.

11. **Close** both yellow line tubing clamp(s) and spike saline bag(s).



12. **Open** yellow line clamp(s) on saline bag(s) to be used.

Initiate procedure:

1. **Close** device cover.
2. Touch **Active Settings**: Haemonetics Default or Fat reduction.
3. Touch **Start Procedure.**

NOTE: System will begin processing when minimum fluid level is collected. Or touch Fill to begin processing early.

NOTE: Place a patient label on RBC bag; when unit is processed, write date and time.

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⚠ WARNING: Do not pressure infuse. May cause fatal infusion of air.

- ☐ Transfuse each RBC bag according to hospital policies/procedures and AABB Guidelines, using a filter capable of retaining particles potentially harmful to the patient.
- ☐ Physician in charge must make all decisions regarding reinfusion.

Blood may be transfused by one of two methods:

Direct from RBC bag:

- ☐ RBCs may be transfused by placing a reinfusion line with filter between the RBC bag and patient.
- ☐ Infusion must be performed by gravity drip only.

⚠ WARNING: Do not allow the Cell Saver Elite + RBC bag to become empty between the reinfusions to the patient. If air does enter the reinfusion line, it must be purged before starting reinfusion.

From secondary transfer pack:

- ☐ RBCs may be transferred from the RBC bag to a secondary transfusion pack and then reinfused to the patient according to hospital policy.
- ☐ Prior to disconnecting the transfer pack, express any air back to the reinfusion bag to prevent loss of displacement air from the processing set.

Blood transfusion

After surgery is complete:

Follow the steps below to transition the device to postoperative operation.

1. Turn off suction.
2. If necessary, connect filtered vacuum line to vacuum port on back of device and vacuum inlet port on reservoir.
3. Open Post-op suction set, receive, and attach Y-connector to wound drain tubing.
4. Disconnect A&A line and discard according to the facility's policies and procedures for handling of biohazardous materials.
5. Connect Post-op suction set to reservoir.
6. Power down device, disconnect from power, lower IV poles, and transport device to PACU.

NOTE: Do not select End Procedure.

7. Connect device to power, power on, and touch **Resume Procedure**.
8. Touch **Suction** and select **Post-op suction** from drop-down list (default: 75 mmHg).

NOTE: System will begin processing when minimum fluid level is collected.

When procedure is complete:

1. Touch **End Procedure**, then confirm by touching again **End Procedure**. System empties blue line and **Procedure Complete** screen appears.
2. Purge extra air from RBC bag (optional): Touch **remove air** from the procedure complete screen and follow screen instructions.
3. Close all clamps on all disposable tubing.
4. Cap all ports on collection reservoir.

NOTE: Tubing stubs and caps included with reservoir and processing set may be used for closing open ports.

5. Remove waste bag from support pins (may be emptied before removing).
6. Remove bowl from centrifuge well.
7. Remove remaining tubing harness.
8. Remove collection reservoir; keep tubing harness connected to reservoir outlet to avoid fluid spill.
9. Discard Cell Saver Elite + disposables/waste according to the facility's policies and procedures for handling of biohazardous materials.

Disconnect and clean up

NOTE: When emptying/changing waste bag, do not lose the displacement air from the system; if this occurs, the bowl may not empty properly. To ensure this does not happen do not empty the waste bag below the indicated line.

Various methods may be used to empty the contents of the waste bag or change the waste bag during a procedure. Here are some precautions.

Emptying the waste bag:

- ☐ Drain waste fluid into empty container (such as irrigation solution bottles) for discard.

NOTE: Unless the bowl is completely empty, keep fluid level in the waste bag above the 1 liter mark on the waste bag. This prevents loss of displacement air.

Changing the waste bag:

To prevent loss of displacement air, the waste bag can be changed ONLY at the end of the EMPTY cycle. You should only change the waste bag when there are no RBC's in the bowl. If there are RBC's in the bowl, press return so that they are returned to the reservoir.

- ☐ Prior to removing the full waste bag, touch **Start/Pause** to ensure that processing does not begin.
- ☐ Once new bag is installed, touch **Start/Pause** to resume.

Emptying and changing the waste bag

Use this mode when the reservoir is filling too fast due to rapid blood loss and it is necessary to process blood urgently for immediate transfusion.

NOTE: EMERGENCY mode is not available with the 70 mL bowl.

NOTE: The line sensor is not active during EMERGENCY mode.

To enter EMERGENCY mode:

1. Touch **Emergency Mode**.
2. Touch **On** to confirm.
   - Pump speed increases to process faster.
   - RBCs may spill into waste bag during EMERGENCY mode.
   - Device will continue FILL-WASH-EMPTY until no more RBCs remain in reservoir.

NOTE: Once the reservoir is empty it will return to automatic mode. When it starts processing again, EMERGENCY mode will be turned off.

To exit EMERGENCY mode before reservoir is empty:

1. Touch **Emergency Mode**.
2. Touch **Off** to confirm.

EMERGENCY mode

Use this method to process a partial bowl of blood at the end of a Cell Saver Elite + procedure or whenever it is necessary to process blood before a full bowl has been collected.

1. Touch **Wash** to begin partial bowl wash. An event message appears.
2. You will have 3 options
   concentrate, double wash volume or Single wash.

NOTE: Blood processed using a partial bowl may have a lower hematocrit than blood processed using a normal full bowl.

Partial bowl option

Use this method if it is not clear that sufficient volume will be collected during a procedure to process for reinfusion.

1. Load reservoir into bracket and close slide clamp.
2. Connect vacuum line to device vacuum port and yellow-capped port on reservoir. If using external suction, connect external vacuum to yellow-capped port on reservoir.
3. Receive and attach A&A line to a blue-capped port on reservoir.
4. Turn on suction. If using manual suction, set to minimal acceptable level (<200 mmHg).
5. Close roller clamp on A&A line.
6. Hang and spike anticoagulant bag.
7. Prime reservoir until breakthrough (150-200 mL).
8. Adjust roller clamp on anticoagulant bag to 1 drop/sec.

NOTE: Load Cell Saver Elite + processing set if sufficient blood volume is collected.

Collect first option

Using the Active Settings, you can pre-configure multiple settings and save them as a settings group.

Change settings group:

1. Touch **Active Settings**:
2. Choose the setting from the drop-down list.

Create new settings group:

1. Select "settings"from drop-down list.
2. Touch **New**.
3. Enter name for new settings group.

Edit settings group:

1. Touch "settings" group to edit.
2. Touch "view".
3. Use arrows to select a parameter.
4. Use arrows to change parameter.
5. Touch "done" to save parameters.

NOTE: Haemonetics Default and Fat reduction are settings groups that cannot be edited or deleted.

Return to Cell Salvage screen:

1. Touch "done".

Protocol settings

The Records screen displays information about the consumables, procedures and device and allows you to enter additional information and export it to an external storage device.

NOTE: The barcode reader is active when the device is in the Records screen.

1. Touch **Records** from the drop-down list.
2. If you want to view all procedures, select history, then select the desired procedure and press **"view"**.
   You can access procedures, events and device records.
   - ☐ Consumables
     Includes list number, lot number, and expiration date for disposables and solutions
   - ☐ Procedure
     Includes procedure volumes, times, surgery type, surgeon, operator ID, and patient ID
   - ☐ Device
     Includes software versions and device serial number
3. Touch **Edit** to edit the record.

NOTE: Consumable information, operator ID, and patient ID can be scanned using the barcode reader or entered manually.

NOTE: Device records are automatically populated.

4. To export procedure records, connect an external storage device, touch **Export**, and select desired export option.

Procedure records

⚠ WARNING: Avoid suction of the following substances into the Cell Saver Elite + system reservoir in accordance with AABB Guidelines. A more complete list can be found in the operation manual.

Clotting agents	
Substance	**Examples**
Microfibrillar products	Avitene®, Helitene®, Oxycel™, Gelfoam® Powder, Instat® MCH
Sponge/fabric materials	Surgicel®, Surgicel Nu-Knit®, Gelfoam® Sponge, Helistat®, Instat®, Hemopad™, SuperStat®, HemoFoam™
Topical liquids	Thrombin-JMI®, Thrombostat™, Thrombogen™

Irrigating solutions	
Substance	**Examples**
Alcohol	
Antibiotics*	Bacitracin, Neomycin, Polymyxin
Betadine®	
Hypertonic solution	3% NaCl, 7% NaCl, Dextrose solutions
Hypotonic solution	Sterile water, Glycine
Lactated Ringers (in presence of Citrate Anticoagulant)	

Bone cement	
Substance	**Examples**
Methyl Methacrylate	Hardened, liquid, powdered

Contaminants
Amniotic fluid

Malignancy
Tumor cells

Recommended action:

- ☐ Avoid aspiration in the presence of these substances.
  *For antibiotics, increase wash volume by 500 mL.
- ☐ Aspiration may resume after copious irrigation with 0.9% Sodium Chloride solution to an alternate suction container.
- ☐ For tumor cells, avoid aspiration at tumor site.
- ☐ Physician in charge must make all decisions regarding reinfusion.

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Substances of concern

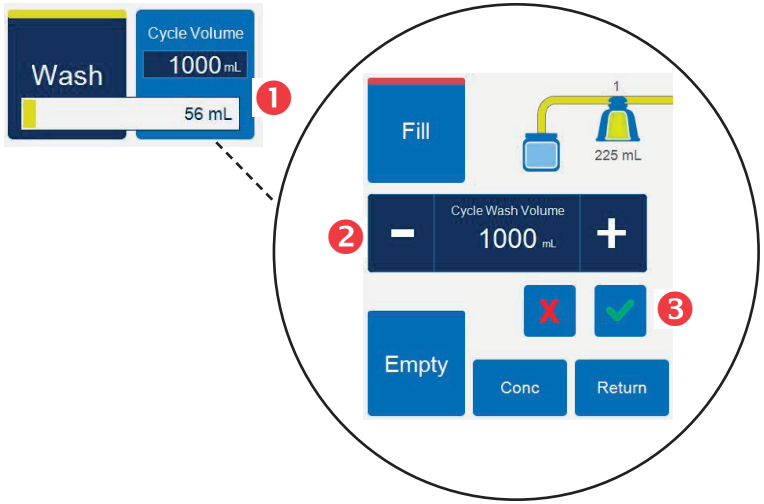
Troubleshooting scenarios		
Problem	**Possible cause**	**Action**
Decreased air flow / aspiration problems	☐ Air leak	1. Ensure vacuum line is securely connected to device and reservoir and check for leaks. 2. Check that reservoir has no open tubes or ports. 3. Ensure A&A line has been correctly connected. 4. Check reservoir for leaks. 5. If problem persists, use alternate suction source.
	☐ Obstruction	1. Check vacuum tubing for obstruction or kinking. 2. Check A&A line for obstruction or kinking. 3. Have surgeon check suction wand for possible occlusion. 4. Check junction of A&A line and reservoir for occlusion. 5. Ensure reservoir is not full. 6. Try briefly increasing suction to clear line. 7. If problem persists, use alternate suction source.
Touch screen problems	☐ The screen is not refreshing properly and parts of the screen appear to be frozen.	1. Touch **Menu**. 2. Select an option from the drop-down list that is different from the one currently displayed. The screen should refresh properly to display new screen. 3. Touch **Menu**. 4. Select previous option from drop-down list. The screen should refresh properly to display the first screen.
	☐ The screen has locked up and is not responding when touched.	1. Restart the device. 2. Upon restarting, the operator is presented with the option to continue with the previous procedure or to start a new procedure. Select the desired option.

Event messages	
Message	**Action**
Waste Bag Full	1. Empty or replace the waste bag. 2. Touch **Continue** to continue. NOTE: When emptying waste bag, ensure fluid level in bag stays above 1 liter mark. NOTE: When replacing waste bag, ensure bowl is empty. If bowl is not empty, its contents must be returned to reservoir and processed again.
Air Detected During Fill	1. Ensure red line clamp is open. 2. Check tubing for kinks and occlusions. 3. When additional fluid is in reservoir, touch **Fill** to resume filling bowl. **OR** Touch **Conc** to continue filling bowl with red cells from RBC bag. **OR** Touch **Wash** to wash a partial bowl.
Long Empty	1. Check tubing for placement in effluent line sensor and air detector. 2. Check for occlusions in effluent, red and blue lines. NOTE: If kink or occlusion is found in blue line, QC RBC product to ensure no hemolysis occurred. 3. Ensure fluid is not transferring from waste bag to bowl. NOTE: If fluid is transferring from waste bag to bowl, contents of RBC bag should be returned to bowl to be washed again. 4. Touch **Continue** to continue.

NOTE: For more extensive event message troubleshooting information, refer to the operation manual.

Changing target wash volume during a procedure:

1. Touch **Cycle Wash Volume**. A dialog box appears.
2. Use arrows to change target wash volume for current wash cycle.
3. Touch **Accept** to save change.



Changing processing sets during a procedure:

1. Touch **End Procedure**.
2. Remove current processing set.
3. Install new processing set.
4. Touch **Resume Procedure**.

NOTE: All procedure statistics from the procedure will be retained, and suction can remain on throughout this process.

Changing bowl size during a procedure:

If an error message appears **"Bowl Size Mismatch"**

1. Check the bowl for proper installation in the centrifuge.
2. Touch **Keep Bowl Size** or
3. Touch **Change Bowl Size**.
4. Select the new bowl size or scan the processing set barcode.

Refer to the
Haemonetics® Cell Saver® Elite®+ Autotransfusion System Operation Manual
for extensive troubleshooting information.

Please contact customer service or the local Haemonetics representative to:

- ☐ Request product information
- ☐ Place an order
- ☐ Track a shipment
- ☐ Return products
- ☐ Report a problem
- ☐ Request clinical support
- ☐ Ask a question or issue a complaint

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Hotline help

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