With Intelligent Control

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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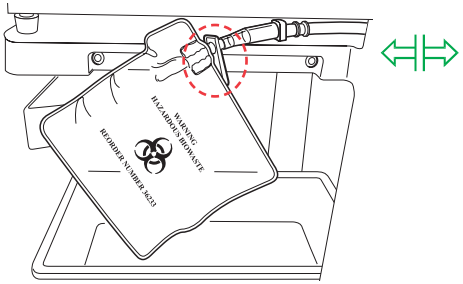
Prepare the device:

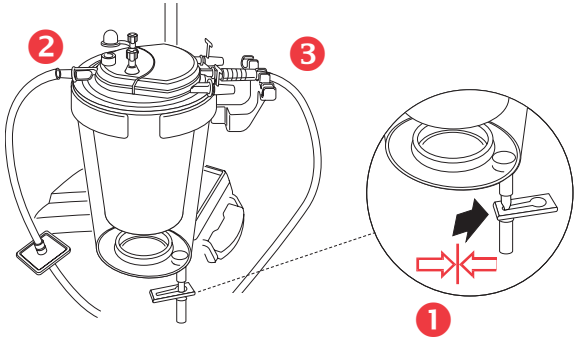
1. Unfold biohazard waste bag, stored in tray on underside of device.
2. Ensure biohazard waste bag is connected to and hanging from drain tube and **open** clamp.



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.

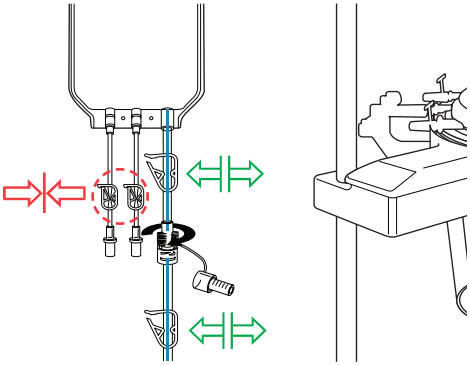
TRN-QRG-100125-US(AC)

Load Disposable / Initiate Procedure (page 1 of 3)

Load Disposable / Initiate Procedure (page 2 of 3)

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.



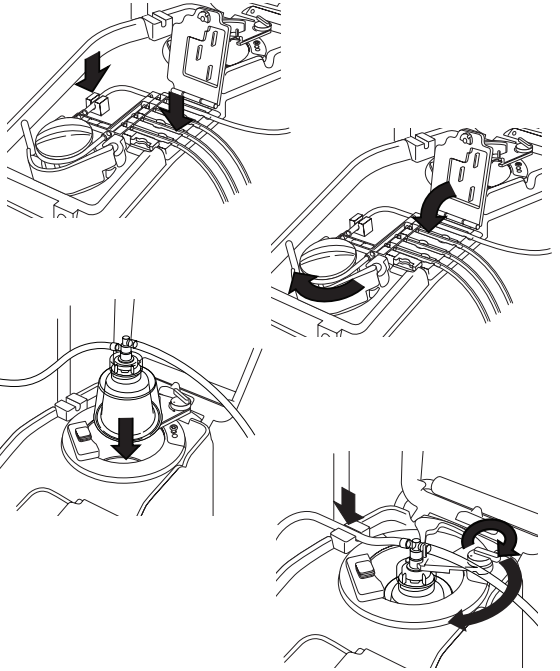
NOTE: Ensure blue line tubing clamps are open and twist-lock connection is secure.

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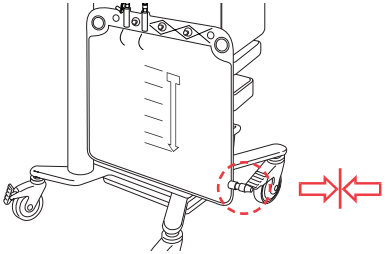
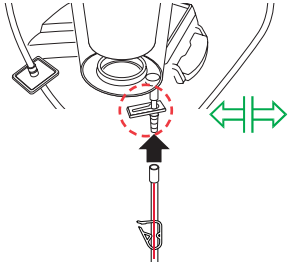
8. Hang waste bag on support pins to relieve strain on header; ensure drain port on bag is securely **closed**.

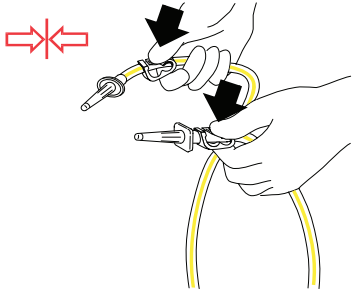


9. Connect red line tubing to bottom of reservoir and **open** drain port slide clamp.



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.

TRN-QRG-100125-US(AC)

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

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.

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

Initiating Manual Mode

NOTE: Manual Mode must be enabled in a settings group before it can be utilized.
Please refer to Operation Manual for instructions to enable access and activate Manual Mode in a new Settings Group.

This feature enables the user to control the Cell Saver Elite+ device manually for cell salvage with minimal sensor monitoring. To control the device, the Fill, Wash, Empty, Concentrate, and Return phases are manually selected by the user.

In Manual Mode:
The line sensor and bowl optics are disabled

The air detector is used for volume accounting in the Fill, Wash, and Concentrate phases, and to determine when to end the Empty and Return phases

To initiate Manual Mode:

1. After starting a procedure using a settings group that has Manual Mode enabled, touch Active Settings.
2. Select **Manual Mode** from the drop-down list. The *Switching to Manual Mode* screen appears.
3. Touch **Confirm** to switch to Manual Mode.
   - The device remains in the same phase it was in prior to the transition to Manual Mode (for example, Fill, Wash, and so on)
   - All processing phases are now available from the touch screen
4. The device is now in **Manual Mode**.

To exit Manual Mode:

1. Touch **Active Settings** to open the drop-down list.
2. Select either the same settings group that was being utilized immediately prior to switching to *Manual Mode* or a different settings group.

NOTE: Upon exiting Manual Mode, if the bowl is not empty and the device is in the Fill or Concentrate phase, the device returns the contents of the bowl to the reservoir; if the bowl is not empty and the device is in the Wash, Return, or Empty phase, the device continues with that phase.

Filling the Bowl

1. Touch **Fill** to initiate the Fill phase.

NOTE: The Fill phase does not stop until the user presses another key, such as the Wash key.

Washing the Cells

As the bowl is filling during either the Fill or Concentrate phase, observe when the RBC/supernatant interface reaches a point just below the neck of the bowl. When this occurs, initiate the Wash phase:

1. Touch **Wash.**

The volume of wash solution required depends upon factors such as the degree of hemodilution and amount of AC solution used. Certain minimum volumes are required per cycle depending on the type of procedure. The user should continue washing until the effluent line is clear.

NOTE: If during the Wash phase, the RBC/supernatant interface disappears and RBCs begin to spill into the waste bag, touch II (Pause) to allow the interface to reappear, then slowly increase to a rate that just maintains this interface (usually, 200mL/min or less).

Emptying the Bowl

1. After the red cells have been processed, touch **Empty** to send them to the reinfusion bag.

The message “Centrifuge Stopping” is displayed until the centrifuge bowl comes to a complete stop. The concentrated RBCs are then pumped from the bowl to the reinfusion bag.

Entering Standby mode

1. The Cell Saver Elite+ device transitions to the Standby mode when it detects the bowl is empty.

NOTE: If the reservoir, contains more blood to be processed, touch Fill to initiate another fill cycle.

NOTE: If the amount of fluid available in the reservoir for processing is insignificant, discard the remaining fluid with the disposable set bowl according to local guidelines.

Operating in Manual Mode

In emergency situations where users are managing high blood-loss, it may be necessary to accelerate the processing time to quickly return blood to the RBC bag for reinfusion to the patient. The Cell Saver Elite+ offers two modes for this purpose:

Emergency Mode:
If time allows for washing the blood, users can initiate Emergency Mode, which accelerates the pump speed and decreases the time required to return the product to the RBC bag. This mode concentrates and washes the blood before reinfusing it back into the bag for delivery. Emergency Mode is available from the Processing screen during the Fill, Wash, Empty, Concentrate, and Return phases. It is not available from a Standby or Stopped state, or when in Manual Mode or Quick Transfer Mode.

Quick Transfer Mode:
When time is of the essence for returning the product to the patient due to trauma, sudden massive blood loss, thoracoabdominal aneurysm, and so on, users can initiate Quick Transfer. This mode quickly moves the shed blood from the reservoir to the reinfusion bag. The device automatically cycles through the Fill and Empty phases continuously with a non-spinning bowl until the reservoir is empty, completely bypassing the wash phase. This feature must be enabled from the Settings menu prior to users being able to execute a procedure using this mode.

ALERT: Quick Transfer Mode produces an unwashed final collection in which the removal of large contaminants such as skin or bone fragments is only possible through the filter reservoir. The use of a microaggregate filter is strongly recommended. Users are fully responsible for evaluating the situation and determining if the conditions justify the use of Quick Transfer Mode.

Emergency Mode

During Emergency Mode the device processes blood continuously at high speeds through the Fill, Wash, and Empty phases until the air detector senses air for the first time in the Fill phase, indicating that the reservoir is empty. The device then reverts to the previous settings group and enters Standby.

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.

Quick Transfer Mode

NOTE: Quick Transfer Mode must be enabled in a settings group before it can be utilized.
Please refer to Operation Manual for instructions to enable access and activate Quick Transfer Mode in a new Settings Group.

ALERT: Quick Transfer Mode is only used to transfer unwashed shed blood into the final collection bag with no processing. The user is responsible for executing Quick Transfer Mode and determining if the product contained in the reinfusion bag is suitable for reinfusion into the patient.

NOTE: Quick Transfer mode is only available for use with the Cell Salvage protocol.

NOTE: Quick Transfer mode is available for use with the 225 mL bowl, **NOT** the 70 mL or 125 mL bowls.

NOTE: Quick Transfer is not available when using Manual Mode.

Before Initiating Quick Transfer Mode

- Ensure the two large, white ratchet clamps on the blue line and the large, white ratchet clamp on the red line are open.
- Ensure the slide clamp on the outlet port of the Reservoir is open.
- Check that the vacuum applied to the reservoir is <250 mmHg (33 kPa).
- Dilution of packed red cells with saline is necessary to decrease viscosity within the Reservoir before initiating Quick Transfer.
- To avoid clotting in the Reservoir, ensure the volume of blood is properly anticoagulated before initiating Quick Transfer.

NOTE: If the device automatically starts the Fill phase, because the reservoir level reached the Fill start volume, then touch (Stop).

Initiating Quick Transfer Mode

1. Touch **Active Settings** at any time during an active cell salvage procedure.
2. Select **Quick Transfer** from the drop-down list. The *Switching to Quick Transfer* screen appears.
3. Touch **Confirm** to begin Quick Transfer.

NOTE: Touch (Pause) to pause Quick Transfer.
The (Play) button pulsates when Quick Transfer is paused.
Touch (Play) to resume Quick Transfer.

4. Touch **End Quick Transfer** to end Quick Transfer and return to the previously selected Active Settings in Standby. If the bowl is not empty, the contents are returned to the reservoir. When the bowl is empty, if necessary, the device first purges the red line, then the blue line, and then returns to the previously selected Active Settings.

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

When Final Cycle is activated, the device continues processing until air is detected in Fill, after which the device automatically completes the procedure according to the selected Final Cycle settings (Double Wash / Single Wash / End Procedure)

The final cycle options are Last Partial Bowl Wash or End Procedure. Only one of these options can be selected to manage the last bowl.

Last Partial Bowl Wash

Double: The device transitions to the Last Partial Bowl Wash phase and automatically doubles the wash volume

Single: The device transitions to the Last Partial Bowl Wash phase using the normal wash volume

Off: The device omits the Last Partial Bowl Wash (defaults to End Procedure option)

End Procedure

On: Once air is detected, contents of the bowl will be returned to the Reservoir, the Blue Line will be purged and ***End Procedure*** will appear on screen. The only option is to end the procedure immediately.

To activate **Final Cycle**

1. Select the Settings mode from the drop down menu
2. Select View to view the Settings Group
3. Select Final Cycle and touch ▲ **(Up)** or ▼ **(Down)** to change the value for that setting

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

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".

⚠ 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.

TRN-QRG-100125-US(AC)

Substances of Concern

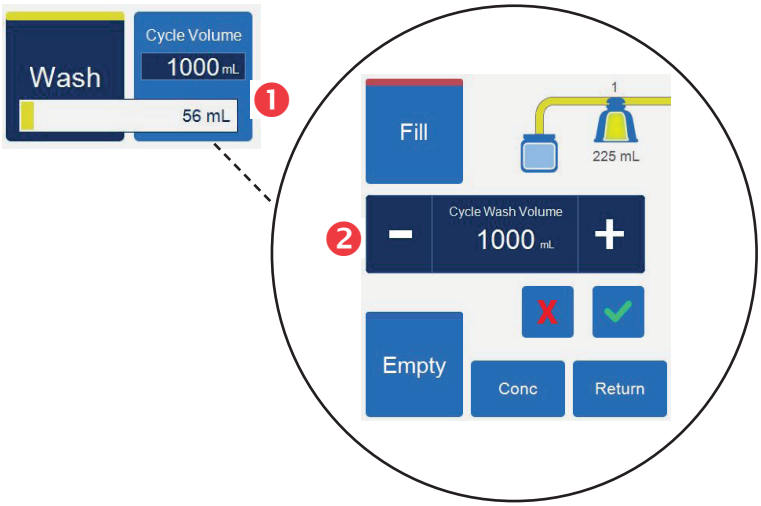
Troubleshooting scenarios		
Problem	**Possible cause**	**Action**
Decreased air flow / aspiration problems	☐ Air leak	1. Ensure vacuum line is securely connected to device and reservoir and check for leaks. 2. Check that reservoir has no open tubes or ports. 3. Ensure A&A line has been correctly connected. 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. Ensure fluid is not transferring from the waste bag to the bowl, which would indicate loss of sterile air. NOTE: If fluid is transferring from the waste bag to the bowl, waste may have reached the RBC bag. The contents of the RBC bag should be returned to the bowl to be washed again. 2. Check the tubing for correct placement in the air detector. 3. Check the effluent tubing for correct placement in the effluent line sensor. 4. Check the effluent tubing for kinks and occlusions. 5. Check the blue and red tubing for kinks and occlusions. NOTE: If a kink or occlusion is found in the blue tubing, it is recommended to QC the RBC product to ensure no hemolysis occurred. 6. Touch Continue to continue. NOTE: If the error message continues, the user should remove the bowl, tilt it upside down and visually check the base for cracks directly on or extending from the ribs. Please refer to the Cell Saver Elite+ System Operation Manual for additional guidance.

TRN-QRG-100125-US(AC)

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.

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

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

To contact Customer Service

Phone: 800.537.2802, Opt 3 ■ Fax: 800.860.1512
Email: CustomerServiceNA@haemonetics.com

Please contact Customer Service or your 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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For a list of worldwide office locations and contact information, visit www.haemonetics.com/officelocations

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