



October 2019

SAFETY NOTIFICATION
FOR 125ml and 225ml Centrifuge Bowls

Attention: Risk Management Director, Materials Manager and Director Biomedical Engineering
Please forward this communication to all potential users of the products.
cc Chairman Medical Board and/or Relevant Head-of- Departments

Dear Customer,

Haemonetics makes continuous efforts to supply our customers with products that meet the highest levels of product quality and reliability. We have recently identified a potential issue with Cell Saver® 5/5+ and Cell Saver® Elite®/Elite® + 125ml and 225ml bowl sets. The investigation has determined that a small number of bowl sets may have the potential to develop leaks at the inner core, which could result in fluid becoming trapped inside the bowl core, causing a “long empty” device error message with the possibility of incomplete washing.

Note: The likelihood of experiencing an inner core leak is low, and no fluid has been found to exit the bowl into the Cell Saver device. We have a dedicated team implementing corrective actions to resolve this issue.

What to do if experiencing “Long Empty” error code on your device:

If an error code indicates “Long Empty,” complete the troubleshooting guidance provided on Page 3 in this communication. 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. See Page 4 for photo example of where to inspect:

-If no cracks are observed and procedure is complete, proceed with using the blood in the reinfusion bag. No further action is required. If continuing with the procedure, use a new processing set.

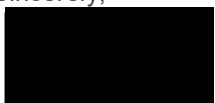
-If cracks are confirmed, the user should assume incomplete washing of the bowl contents, and the wash cycle should be repeated on blood that is in the reinfusion bag. Take any residual RBCs in the reinfusion bag, and empty its contents into the cardiotomy reservoir to repeat the wash cycle using a new processing set. The salvaged blood may be reinfused to the patient.

**PLEASE ACKNOWLEDGE YOU HAVE RECEIVED THIS COMMUNICATION BY COMPLETING THE
ACKNOWLEDGEMENT FORM RECEIVED WITH THIS LETTER AND RETURN BY FAX TO +1-781-356-3558 OR
SCAN AND E-MAIL TO CORPORATEREGULATORY@HAEMONETICS.COM**

Please retain the disposable and report a product complaint by contacting our Customer Care Hotline at 800-537-2802, Option 4 or send an email to the PIRDesk@haemonetics.com. Request biohazard shipping material to ensure proper return of the disposable.

Please reach out to your local sales representative or customer service at 1-800-537-2802 with questions regarding the notification. This action is being performed by Haemonetics with the full knowledge of the U.S. Food and Drug Administration and other regulatory authorities. We sincerely apologize for any disruption this situation may cause you.

Sincerely,



Ian Purdy, PhD
Senior Vice President, Global Quality and Regulatory Affairs



SAFETY NOTIFICATION ACKNOWLEDGEMENT FORM
125ml and 225ml Centrifuge Bowls

Please complete this form in its entirety and return to Haemonetics:

☐ We acknowledge receipt of this notification.

Affected Product

FG Item Number	Description
00260-00	CS5/5+ FASTPACK, 225ML150U RES
00261-00	CELL SAVER 5/5+ BOWL KIT-125ML
00263-00	CELL SAVER 5/5+ BOWL KIT-225ML
00265-00	CS5/5+ FASTPACK, 125ML150U RES
0260F-00	CS5/5+ FASTPACK,225ML, 20U RES
0261J-00	LOW VOL(125ML) CS5 SET,LN 261J
0263A-00	HIGHSPEED CELLSAVER5/5+BOWLSET
0263J-00	BASIC HI SPEED CS5 SET,LN 263J
0265F-00	CS5/5+ FASTPACK, 125ML, 20U RE
261J-SET	DISP SET, 261J, 205J, 208
261J-SS-SET	DISP SET, 261J, 205J, HAR
263J-SET	DISP SET, 263J, 205J, 208
263J-SS-SET	DISP SET, 263J, 205J, HAR
CSE-FP-125V	CS ELITE FASTPACK,125ML,150U
CSE-FP-125V-JA	FASTPACK DISP. SET - 125ML
CSE-FP-225F	CS ELITE FASTPACK, 225ML, 20U
CSE-FP-225V	CS ELITE FASTPACK,225ML,150U
CSE-FP-225V-JA	JAPAN CS ELITE FASTPACK, 225ML
CSE-P-125	CS ELITE PROCESSING KIT, 125ML
CSE-P-125-JA	CELL SAVER ELITE SET - 125ML
CSE-P-225	CS ELITE PROCESSING KIT, 225ML
CSE-P-225-JA	CELL SAVER ELITE SET - 225ML

Name of person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

City: _____ Country: _____ State: _____

SIGNATURE _____

DATE _____

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Troubleshooting Guidance for “Long Empty” Error Message

Reminder: If working through the troubleshooting steps does not resolve the issue, check the base of the bowl for cracks extending from the ribs.

Cell Saver® Elite®+ “Long Empty” Error Message Troubleshooting Guidance

The device is programmed to detect abnormally long Empty and Return phases and notify the user with an alert. If the user visually confirms that the bowl is still not empty, a sample should be taken from the RBC bag prior to transfusion to the patient to determine the presence of free hemoglobin.

If the bowl is empty, this could indicate a problem with the air detector and the user should contact the local Haemonetics representative.

Explanation: The air detector did not sense air when expected, indicating that the device may have pumped more than the expected volume of fluid from the bowl or that a tubing occlusion could be preventing fluid from emptying as expected.

Corrective Action:

1. Ensure that 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.

Cell Saver 5+ “Long Empty” Error Message Troubleshooting Guidance

The Cell Saver 5+ is programmed to detect abnormally long EMPTY and RETURN modes and to notify the operator by displaying a warning.

Corrective Action:

1. Check tubing placement.
2. Check for occlusions in effluent, blue and red tubing.
3. Check for bowl displacement air in waste bag.
4. Verify bowl size recognition.

How to Check for Cracks in the Base

If an Error code indicated “Long Empty,” complete the troubleshooting guidance provided in this communication or in the User Manual. 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

