



URGENT
Field Safety Notice
125ml and 225ml Cell Saver Centrifuge Bowls

October 30th, 2019

To the attention of: **Materiovigilance correspondent**, Risk Management Director and Material Management

Please forward this communication to all potential users of the products.

Dear Customer:

Haemonetics makes continuous efforts to supply our customers with products that meet the highest levels of product quality and reliability. In accordance with this principle, Haemonetics is voluntarily issuing a Field Safety Notice (FSN) on a potential issue with Cell Saver[®] 5/5+ and Cell Saver[®] Elite[®]/Elite[®]+ 125ml and 225ml bowl sets.

Reason for the FSN:

Haemonetics Post-Market Surveillance has indicated a new root cause for one of the equipment's error messages which has not been previously described in the equipment user manual.

Investigations into the root cause have managed to replicate the issue and determined that a small number of the associated disposable bowl sets may have the potential to develop leaks (cracks) in the inner core under the centrifugal forces applied by the device. As a result this can lead to fluid becoming trapped inside the bowl. The equipment identifies this issue and issues an error message to the user which reads as "Long Empty". At present the manual already identifies the necessary steps the user must undertake to clear this message. However these steps are insufficient to clear the error message should cracks have developed in the bowl during use.

This communication is intended to provide the user with the necessary additional steps which must be undertaken should this unlikely event occur.

Risk to Health:

It has been determined that if the user does not undertake the additional steps indicated in this communication and ignores the error code presented by the equipment to mitigate the risk; and then continues to return the blood to the patient this could result in a health risk.

Returned blood under these specific conditions may be at risk of containing haemolysed red blood cells and free haemoglobin. Furthermore should the cracked bowl have led to a leak into the inner core there is a possibility of returning recovered blood which has not been completely washed.

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Note: The likelihood of experiencing an inner core leak is low. In no circumstances has fluid been found to leak from the bowl into the Cell Saver device.

Action to be taken by the Customer/User:

1. Additional guidance is provided in Annex I (Elite/Elite+) and Annex II (CS5/5+) which we recommend should be printed and added to the respective equipment manuals until such a time as Haemonetics can update the equipment manual with the new information.
2. Users of the equipment should be made aware of the additional troubleshooting guidance in the unlikely occurrence they experience this error code and cannot clear the alert from the equipment.
3. Should you experience radial crack development in disposable sets Haemonetics request that you retain the disposable set and report a product complaint by contacting your local customer service representative or directly to complaintsEU@Haemonetics.com. This step will help us further investigate this rare occurring event.
4. Please acknowledge you have received this notice by completing the acknowledgement form attached. Once complete, return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this FSN.

Product and Distribution Information:

The products impacted by this FSN are the following:

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
0265F-00	CS5/5+ FASTPACK, 125ML, 20U RE
CSE-FP-125V	CS ELITE FASTPACK,125ML,150U
CSE-FP-225V	CS ELITE FASTPACK,225ML,150U
CSE-P-125	CS ELITE PROCESSING KIT, 125ML
CSE-P-225	CS ELITE PROCESSING KIT, 225ML

Thank you for your business and continued support. We apologize for any disruption this situation may cause you. This action is being performed by Haemonetics with the full knowledge of the regulatory authorities.



If you have any questions about this action please do not hesitate to contact me or send a message to QSELA@haemonetics.com.

Sincerely,

Andrew Sette
VP, Quality Assurance &
Regulatory Affairs, International

If needed, you can contact your local customer service representative at:

Country	Phone	Fax	Email
Austria	0800 29 27 77	0800 29 28 20	info.at@haemonetics.com
Belgium	0800 754 80 (French) 0800 754 82 (Dutch)	0800 755 12	info.be@haemonetics.com
Bulgaria	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Croatia	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Czech Republic	800 143 243	800 143 250	info.cz@haemonetics.com
Denmark	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Estonia	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Finland	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
France	0800 90 11 58	0800 91 48 76	info.fr@haemonetics.com
Germany	0800 180 88 90	0800 182 80 64	info.de@haemonetics.com
Greece	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Ireland	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Italy	800 870 200	800 870 375	info.it@haemonetics.com
Latvia	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Lithuania	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Luxembourg	0802 64 90	8002 64 97	info.lu@haemonetics.com
Netherlands	0800 0222 707	0800 0223 066	info.nl@haemonetics.com
Norway	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Poland	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Portugal	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Romania	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Slovenia	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Spain	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Sweden	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
Switzerland	0800 89 88 98	0800 89 88 92	info.ch@haemonetics.com
Turkey	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
United Kingdom	0808 234 48 17	0808 234 4845	info.uk@haemonetic.com



Field Safety Notice

125ml and 225ml Cell Saver Centrifuge Bowls

ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to Haemonetics within 14 days

I acknowledge receipt of this notification.

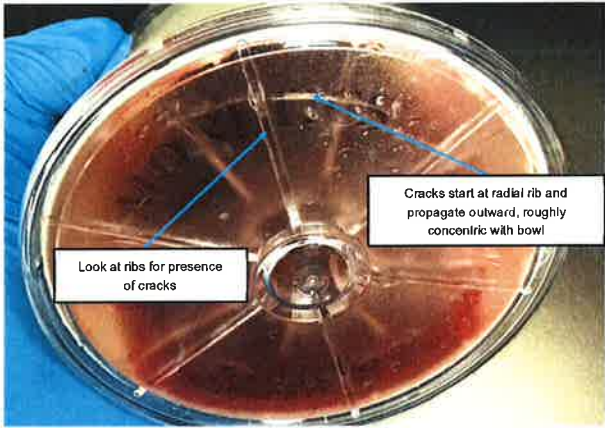
Name of person completing this form: _____
Title: _____
Phone Number: _____ Email: _____
Institution Name: _____
Institution Address: _____
Institution city: _____
Institution Country: _____
SIGNATURE _____ DATE: _____

PLEASE RETURN BY FAX TO **+41 22 363 9058**

OR SCAN AND E-MAIL TO

QSELA@HAEMONETICS.COM

ANNEX I – Additional Troubleshooting Guidance for a “Long Empty” Error Message
ELITE/ELITE+ MANUAL

CURRENT TROUBLESHOOTING	<p>Long Empty</p> <ul style="list-style-type: none"> • Check effluent tubing for correct placement and occlusions. • Ensure no fluid transfer from waste bag to bowl. • Check blue and red line for occlusions. <p>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.</p>	<p>Corrective action:</p> <ol style="list-style-type: none"> 1. Check effluent tubing for correct placement in the effluent line sensor. 2. Check effluent tubing for kinks and occlusions. 3. Ensure that fluid is not transferring from the waste bag to the bowl. <p>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.</p> <ol style="list-style-type: none"> 4. Check tubing for correct placement in air detector. 5. Check blue and red tubing for kinks and occlusions. <p>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.</p> <ol style="list-style-type: none"> 6. Touch Continue to continue.
NEW TROUBLESHOOTING TO BE ADDED	<ul style="list-style-type: none"> • Check the base of the bowl for cracks extending from the ribs. <p>Explanation: The disposable set has been damaged by the centrifugal forces applied and developed cracks on the inner core. There should be no blood external to the bowl. This however may lead to fluid becoming trapped inside the bowl which may contain hemolysed blood or blood that has not been sufficiently washed. The alert prompts the user to take the following corrective actions.</p>	<ol style="list-style-type: none"> 7. If an error code continues to indicate “Long Empty,” after the above steps the user should remove the bowl, tilt upside down and visually check the base for cracks directly on or extending from the ribs. See photo below for where to inspect: <ol style="list-style-type: none"> a. <u>If no cracks are observed</u> Proceed with using the blood in the reinfusion bag. No further action is required. If the problem persists contact your technical service centre. b. <u>If cracks are observed</u> The user should assume incomplete washing of the bowl contents. The wash cycle should be repeated on the blood that is in the reinfusion bag. Remove the processing set and install a new processing set. Contact your customer service representative to return the set. <p>Take any residual RBCs in the reinfusion bag and empty the contents into the cardiotomy reservoir to repeat the wash cycle using a <u>new</u> processing set. The salvaged blood may be reinfused to the patient.</p>
		

ANNEX II – Additional Troubleshooting Guidance for a “Long Empty” Error Message for the CS5/5+ MANUAL

CURRENT TROUBLESHOOTING	<p>Long empty cycle The device is programmed to detect an abnormally “Long Empty” and RETURN states and notify the user with an alarm while displaying the following message: LONG EMPTY CYCLE</p> <p>Explanation: Empty/Return cycle too long. Empty/Return cycle did not complete after the nominal bowl size +50 ml were pumped out of the bowl.</p>	<p>Corrective Action:</p> <ol style="list-style-type: none"> 1. Check tubing placement. 2. Check for occlusions on the effluent side. 3. Check for transfer of air from waste bag to bowl. <p>Warning: If the operator visually confirms that the bowl is still not empty, a sample should be taken from the reinfusion bag prior to transfusion to the patient to determine the presence of plasma hemoglobin. If the bowl is empty, this could indicate a problem with the air detector and the operator should contact the local Haemonetics technical representative.</p>
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