



HAEMONETICS®
THE Blood Management Company

February 22, 2016

Field Safety Notice

for multiple lots of references 994CF-E, 998CF-E and 0970E-00

Attention: Risk Management Director and Material Management
Please forward this communication to all potential users of the product.

Dear Customer:

Haemonetics Corporation is voluntarily initiating a Field Safety Corrective Action (FSCA) on multiple lots of reference 994CF-E and 998CF-E and one lot of reference 0970E-00 (see table below for details).

Reason for the FSCA: In some of these sets the tubing between the dual pump manifold and blood line air detector may be too long. The excess length prevents proper mounting of the disposable on the machine which could cause the tubing to kink and obstruct blood flow.

Risk to Health: If the defective sets are not mounted on the MCS machine, there is no risk as products will not be used. If the tubing is either forced into the air detector or the tubing is force fitted between the pump manifold and the air detector, there is a potential risk of hemolysis.

Action to be Taken by Customer: Please discontinue the use of these lots and return any unused product to Haemonetics. Contact your local customer service representative at the following numbers to coordinate the return and the shipment of replacement product to ensure a seamless exchange of goods.

Region	Contact	Phone
Germany	info.de@haemonetics.com	0800 180 8890
Italy	info.it@haemonetics.com	800 870 200
Netherlands	info.nl@haemonetics.com	0800 0222 707
Distribution countries	distribution@haemonetics.com	N/A

Product and Distribution Information: The affected product lot was shipped to you between November 2015 and February 2016. This recall applies **ONLY** to the product IDs and lot numbers listed below. No other products or lots are affected by this action.

Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Tel: 781.848.7100
www.haemonetics.com

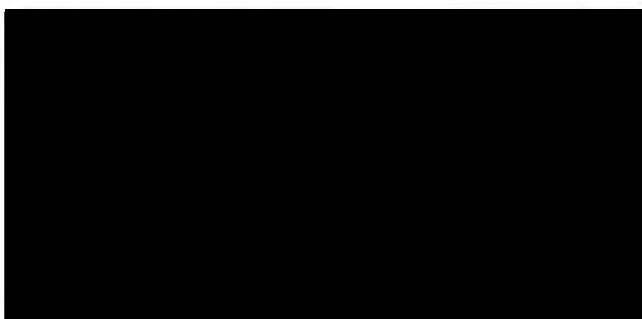
RCL-100190-IE
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Product ID	Description	Lot #		
994CF-E	MCS+/LDP W/FILTER	8415003	8515011	8615068
		8415006	8515015	8615073
		8415007	8515019	8615077
		8415019	8515049	8615081
		8415020	8515050	8715007
		8415025	8515054	8715013
		8415026	8515063	8715021
		8415027	8515067	8715025
		8415028	8515068	8715029
		8415030	8515072	8715033
		8415035	8515076	8715037
		8415038	8515080	8715070
		8415059	8515084	8715072
		8415060	8515088	8715074
		8415079	8615003	8715077
		8415080	8615007	
			8515007	8615011
998CF-E	CONC PLT & PLS SET W/FILTER		8515001	
			8515005	
			8515009	
			8515013	
			8515047	
			8515048	
			8715034	
	8715042			
0970E-00	PBSC SET (225ML LATHAM)		8515057	

We ask that ALL CUSTOMERS complete the attached customer acknowledgement form in its entirety **whether or not** you have affected product at your site. 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 FSCA.

Thank you for your business and continued support. We apologize for any disruption this situation may cause your organization. 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.





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ACKNOWLEDGEMENT FORM

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

- We do not have any of the following products on hand
- We have the following Lots in inventory and will dispose of them as instructed in this letter

Name of person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

City: _____ Country: _____

I acknowledge receipt of this Field Safety Notice and understand the instructions provided.

SIGNATURE

DATE

PLEASE RETURN BY FAX TO +41 22 363 9058
OR SCAN AND E-MAIL TO QSELA@HAEMONETICS.COM