



HAEMONETICS®
THE Blood Management Company

December 2015

Urgent Medical Device Safety Notice
For ACP215, MCS+9000, MCS+8150, PCS2 Devices

Attention: Risk Management Director, Material Management, Director Biomedical Engineering
Please forward this communication to all potential users of the products shown.

Dear Customer:

Haemonetics Corporation is sending this notification to increase awareness of the proper cleaning process for the pump rotors on the devices listed in this letter.

Reason for Safety Alert: Haemonetics has become aware of customers using harsh chemicals to clean the pump rotor assembly of the ACP215, MCS+9000, MCS+8150 and PCS2 devices. Improper cleaning may damage the pump rollers leading to device malfunction.

Risk to Health: Damage to pump rollers caused by the use of harsh chemicals may cause the incorrect ratio of anticoagulant (AC) to be mixed with blood or blood components collected from the patient/donor. Using these devices, collected blood may be separated into components and directed into collection containers for conservation, or returned to the donor, or transfused to a patient. Elevated levels of AC could lead to a citrate reaction.

Action to be Taken by Customer: Our records indicate that you are using one or more of the devices affected by this notice. Haemonetics is providing additional information to clarify the proper cleaning agents to use on the pump rotors. In the case of a fluid spill, only the following solutions should be used:

Acceptable Cleaning Solutions	
Active Ingredient	Example of Trade/Common Name
Quaternary ammonium	Coverage Plus NPD®, Super Sani-Cloth® Wipes
Benzyl ammonium chloride	Med-Chem Pink Germicide, CaviCide™
Glutaraldehyde	MetriCide™
Potassium Peroxymonosulfate	Virkon® S

Cleaning solutions that contain **phenolic compounds**, such as Sporicidin® and Supergard®, should not be used. In addition, **10% chlorine solutions and very warm water** should not be used as these solutions will attack the pump rotors.

Please ensure that all personnel/users are made aware of this cleaning procedure. Retain the User Manual Addendum attached to this letter. In the event that you distributed these devices to other consignees, we request that you notify those consignees of this Safety Alert.

Product and Distribution Information: This notice applies to all serial numbers of the following devices:

- ACP215 Automated Cell Processor
- MCS+9000 Mobile Platelet Collection System
- MCS+8150 Multicomponent Collection System
- PCS2 Plasma Collection Device

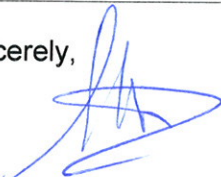
We ask that ALL CUSTOMERS complete the attached customer acknowledgement form in its entirety **Whether or Not** you have affected product at your site. Once complete, return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this action.

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 contact our Technical Support team at:

Region	Contact	Phone	Fax
Austria	tsadmin.at@haemonetics.com	0800 292 778	0800 292 820
Belgium	tsadmin.be@haemonetics.com	0800 754 73 (FR) 0800 754 81 (NL)	0800 755 12
Switzerland	tsadmin.ch@haemonetics.com	0800 898 898	0800 898 892
Germany	tsadmin.de@haemonetics.com	+49 89 785807 24	+49 89 785807 25
France	tsadmin.fr@haemonetics.com	0800 90 11 58	0800 91 48 76
UK	tsadmin.uk@haemonetics.com	0808 234 4817	0808 234 4845
Italy	tsadmin.it@haemonetics.com	800 870 251	800 870 375
Luxemburg	tsadmin.be@haemonetics.com	8002 64 90	8002 64 97
Netherlands	tsadmin.nl@haemonetics.com	0800 0222 707	0800 0223 066
Denmark	tsadmin.scan@haemonetics.com	8088 7112	8088 9078
Finland	tsadmin.scan@haemonetics.com	+46 46 286 23 20	+46 46 286 23 21
Norway	tsadmin.scan@haemonetics.com	800 18 453	800 19 825
Sweden	tsadmin.scan@haemonetics.com	020 797 150	020 794 670
Czech Republic	info.cz@haemonetics.com	800 143 243	800 143 250
Slovakia	info.cz@haemonetics.com	N/A	N/A
Distribution countries	ACD24@haemonetics.com	N/A	N/A

Sincerely,



Andrew Sette
Senior Director, Quality Assurance & Regulatory Affairs
EMEA and Distribution



**SAFETY ALERT ACKNOWLEDGEMENT FORM
ACP215, MCS+9000, MCS+8150, PCS2**

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

- We do not have any of the following products on hand
- I have read and understand the cleaning instructions provided in this Safety Alert letter
- Please have a Technical Service representative contact me

Affected Product

- ACP215 Automated Cell Processor
- MCS+9000 Mobile Platelet Collection System
- MCS+8150 Multicomponent Collection System
- PCS2 Plasma Collection Device

Name of person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

City: _____ Country: _____ State: _____

SIGNATURE

DATE

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