



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 Sporidicin® 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 |



**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**