



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

Dear Distributor:

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.

Actions to be taken by Distributor: Our records indicate that you have distributed one or more of the devices affected by this notice. We therefore ask you to perform the following activities:

1. Inform all your impacted customers. For convenience, we attached a sample customer letter.
2. If required by your local regulations, inform the appropriate authorities.
3. Complete the attached acknowledgement form in its entirety **Whether or Not** you have distributed affected product. 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.

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

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 ACD24@haemonetics.com.

Sincerely,

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



HAEMONETICS®
THE Blood Management Company

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

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

- I have informed all affected customers of this Safety Alert
- I have informed the competent authorities of this Safety Alert if required by national regulations

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**

Sample Customer letter

Date

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 solutions containing the following active ingredients 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

Sample Customer letter

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 "enter your information here"

Sincerely,

XXXX

Sample Customer letter

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

Please complete this form in its entirety and return to "**your company name**":

- 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 **YOUR CONTACT INFORMATION**