HAEMONETICS®

Urgent Field Safety Notice (FSN)
NexSys® PCS (1.4.2 and earlier) - Interruption during "Smart Last Cycle"

July 18, 2022

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

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

Dear Customer,

The purpose of this FSN is to advise you that Haemonetics Corporation is conducting a voluntary field action following the identification of a software defect affecting the NexSys PCS version 1.4.2 and earlier when the instrument is configured to run "Smart Last Cycle" and Red Blood Cell (RBC) Loss estimator.

Reason for the Field Notice:

This software defect, under certain conditions, can affect the calculation of estimated Red Blood Cell (RBC) Loss and the associated system flags, when a "Smart Last Cycle" is interrupted.

This may occur if a plasma donation procedure is aborted; or has an unrecoverable interruption during the "Smart Last Cycle". Under these circumstances, then;

- The Red Blood Cell Loss Estimation algorithm may not accurately indicate if red blood cell loss is greater than; or equal to 200mL (≥200mL),

- The system flag for RBC Loss will not be a reliable indicator for donor deferral.

If this situation were to occur, then it could result in a failure to defer a donor per local requirements.

Product & Distribution Information:

The actions defined in this FSN are applicable to all customers who have activated the "Smart Last Cycle" and Red Blood Cell loss estimator on NexSys PCS devices (software versions 1.4.2 and earlier).

What is the "Smart Last Cycle"?

"Smart Last Cycle" is a configurable option in the system settings and refers to a calculated final Draw and Return Cycle designed to process less blood in order to reach the target collection volume faster and more efficiently.

"Smart Last Cycle" is indicated by a "*" next to the cycle count during Smart Last Cycle Return of a NexSys PCS device.

What is Red Blood Cell (RBC) Loss estimator?

RBC loss estimator is a feature of the NexSys software that provides the calculation of RBC volume remaining in the bowl in the case of an aborted procedure. It is intended to indicate if the RBC volume is equal or greater than or less than 200mL through a displayed message at the end of an incomplete procedure.

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Risk to Health:

The population at risk are donors who donate plasma more than once at a collection site that uses a NexSys PCS device configured to use the "Smart Last Cycle" and the RBC Loss system flags as the basis for donor deferral.

In an interrupted procedure, a donor may lose ≥200ml of RBC. Consequently, depending on local regulations, the donor may have to be deferred by local procedures.

The risk is that if the deferral conditions are not met due to an incorrect RBC loss flag, then a donor may donate earlier than anticipated and if the second procedure is interrupted again, the compounded RBC loss could result in anemia.

Actions to be taken by the Customer/User:

Customers may continue to use the NexSys PCS device as instructed per the Operator's Manual. If you use a NexSys PCS device with software prior to and including version 1.4.2, and have enabled the option for "Smart Last Cycle" and use the Red Blood Cell (RBC) Loss flag as a way to defer donors, then please follow the instructions below:

In the case that an unrecoverable interruption or an aborted procedure occurs during the "Smart Last Cycle" and the Red Blood Cell Estimator is enabled, it should be attempted to return red blood cells to the donor as described in the Operator's Manual and/or per local SOPs.

If the procedure was aborted and it cannot be excluded that the procedure was aborted during the last cycle and the operator is unaware if the device was in a "Smart Last Cycle" when aborted, it should be assumed that "Smart Last Cycle" had been activated.

If the operator is unsure of the amount of RBC remaining in the bowl, they should review local procedures and protocols for donor management and deferral.

We ask that **all recipients of this notice complete the attached acknowledgement form in its entirety**. Once complete, please return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this FSN.

We apologize for any disruption this situation may cause your organization and we thank you for your business and continued support. Haemonetics is committed to continually improving its products and services, with safety and quality as our top priority. This action is being performed by Haemonetics in full transparency with regulatory authorities. Please contact your Haemonetics representative or customer support if you have any questions.

QSELA@haemonetics.com

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ACKNOWLEDGEMENT and RECEIPT FORM

NexSys® PCS (1.4.2 and earlier) - Interruption during "Smart Last Cycle"

Please complete this form in its entirety and return to Haemonetics within 7 days.

☐ I have read and understand this FSN

☐ I have NOT enabled the option for "Smart Last Cycle" or Do NOT use the Red Blood Cell (RBC) Loss flag as a way to defer donors

☐ I do not have any NexSys PCS devices at this site.

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 22 594 8558** OR SCAN AND E-MAIL TO QSELA@HAEMONETICS.COM