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URGENT: Field Safety Notice (FSN)
BloodTrack® Software Version 4.12.0

January 18, 2021

Dear Customer,

We are writing to advise you that Haemonetics Corporation is preventing the implementation of BloodTrack software version 4.12.0 due to an error that came to our attention during internal testing of the software post release. Haemonetics understands that the software update has not yet been installed in a production environment by any of our customers.

The hazard associated to this software update is that an incompatible blood product could be issued to a patient if the software update was used in production. The likelihood of occurrence is very low, since a very specific flow of events and system configurations are required for the hazard to occur. More specifically, the hazard could only occur during the Electronic Issue workflow when the BloodTrack software version 4.12.0 is used to control a 3rd party refrigerator (a refrigerator other than a BloodTrack HaemoBank® storage device) and configured to enable blood group substitution.

Product & Distribution Information:
This notice is applicable to BloodTrack software version 4.12.0, which was originally released and placed on the Haemonetics Download center on November 17th, 2020. It was removed from the Haemonetics Download Center on the 16th December 2020.

Reason for the Field Notice:
Haemonetics identified an anomaly in the BloodTrack software version 4.12.0 that may allow the issuance of an incompatible blood product to a patient. In order for this anomaly to occur, the BloodTrack software must be configured so that:

- The interface with the Laboratory Information Management System (LIMS) / Blood Bank Information System (BBIS) fully supports automated Electronic Issue workflows.
- The storage device controlled by the BloodTrack software is not a HaemoBank (e.g. the storage device must be a 3rd party device with only door level access control).
- Blood group substitution rules must be created for at least two different product groups (e.g. Red Cells and Plasma) and assigned to the same door level access control storage device.
- The assigned blood group substitution rules assigned are applied to the wrong product group (e.g. Red Cells or Plasma).
- There must be unallocated units of each product group available in the storage device which only has door level access control.

If the BloodTrack software is configured as outlined above, the anomaly can only occur under the following scenario:

1. A user removes and scans a blood unit that is of the desired product group, but is blood group incompatible with the patient (e.g. removes an A-positive unit of Red Cells for an O-positive patient).
2. The blood unit removed meets the blood group substitution rules for the other product group (e.g., an A-positive unit of Plasma would be compatible with an O-positive patient).
3. Either the BloodTrack software is configured to: not request an electronic crossmatch; or to request the LIMS/BBIS to complete an electronic crossmatch for the removed blood unit and the LIMS/BBIS approves the crossmatch (e.g. the LIMS/BBIS does not stop the BloodTrack software from issuing the incompatible unit).

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4. The user completes the steps necessary to complete the Electronic Issue and label the blood unit.

Risk to Health:
Our health risk assessment concluded that if the BloodTrack software 4.12.0 is installed in a production environment, and is configured as mentioned above, and an incompatible blood product is transfused into a patient, then a severe hemolytic transfusion reaction may occur.
The software version 4.12.0 has not been installed in a production environment, and due to the configuration and sequence of events that would be needed to occur in order to lead to patient harm, it has been determined that this outcome is unlikely.

Actions to be taken by all potential BloodTrack software version 4.12.0 Users:
We request all customers for whom Haemonetics installed the BloodTrack software version 4.12.0 or may have downloaded it from the Haemonetics Download Center to confirm that they have not, and will not install this version into their production environment, until a patch is released to correct the anomaly.
We require 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 voluntary correction taken out of an abundance of caution and our commitment to Quality. This correction is being made with the knowledge of the Competent Authority.

Follow Up Action by Haemonetics:
Haemonetics removed BloodTrack software version 4.12.0 from the Haemonetics Download Center. A patch to the software will be released to remove the possibility of retrieving an incompatible unit during an Electronic Issue workflow. We expect to communicate the available date of this patch by the end of January 2021.
We apologize for any disruption this situation may cause your organization. Haemonetics is committed to continually improving its products and services, with safety and quality as the top priority.
Thank you for your business and continued support. Please contact your Haemonetics Account Manager or customer service if you have any questions.

Sincerely,

Andrew Sette
VP QA & RA International

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ACKNOWLEDGEMENT FORM

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

☐ I have read the instructions provided in the January 2021 notification regarding the BloodTrack software version 4.12.0. I confirm that we have not and will not use the BloodTrack software version 4.12.0 in a production environment.

Name of person completing this form: _____

Title:_____

Phone Number:_____ Email:_____

Institution Name:_____

Institution Address:_____

City:_____ State:_____ Country:_____

_____ _____

SIGNATURE DATE

PLEASE RETURN BY EMAIL TO:

QSELA@haemonetics.com