

URGENT Field Safety Notice TEG MANAGER® with TEG® 5000

March 20, 2020

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

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

Dear Customer:

We are writing to advise you that Haemonetics Corporation is conducting a voluntary correction of all TEG Manager Software used in conjunction with the TEG 5000 device due to a potential discrepancy in the display of out of range alerts.

Reason for the FSN:

We have identified a defect in TEG Manager Software which impacts the displayed alert for out of range test results. Due to this defect, reference range values received from TEG 5000 and displayed on the TEG Manager test result screen are rounded to the nearest whole number. This can lead to TEG Manager displaying an out of range alert when the test result is actually in range, or vice versa.

It is important to note that test results are correctly calculated and displayed on both the TEG 5000 Agent and TEG Manager. The out of range alerts displayed on the TEG 5000 Agent are also correct. Further, TEG Manager used with the Haemonetics TEG 6s device is not impacted – out of range alerts for TEG 6s are correctly shown. This defect only impacts reference range alerts on the TEG Manager software when used with TEG 5000.

Risk to Health:

The population at risk are patients where hemostatic condition is being assessed using a TEG 5000 analyzer that is interfaced with TEG Manager Software. If the clinician relies solely on TEG Manager Software out of range alerts to diagnose the patient's condition, it could lead to misdiagnosis and incorrect treatment or failure to treat. Haemonetics has not received any reports of adverse events associated with this issue.

Action to be taken by the Customer/User:

Haemonetics has developed a patch to correct the issue with the TEG Manager Software. The patch is available to be downloaded from the Haemonetics Download Center.

In the meantime, and as a reminder, customers using TEG Manager with the TEG 5000 device should continue to follow instructions in the TEG 5000 user manual, which state that, "Before

Haemonetics S.A.
Signy Centre
P.O. Box 262
1274 Signy-Centre, Suisse
Tel: +41.22.363.9011
www.haemonetics.com

RCL-100298-IE(AA)

HAEMONETICS®

making any decisions, the attendant physician must consider all clinical information about the patient's condition, the procedure, and previous therapy." Users should rely on the actual value of each test result which is correctly displayed on the TEG 5000 and TEG Manager and should not make clinical decisions based solely on the out of range alerts displayed by TEG Manager software.

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 voluntary correction.

Should you find difficulties downloading the TEG Manager Software patch, please contact Haemonetics at hss-eu-support@haemonetics.com for assistance.

Product and Distribution Information:

This correction is applicable to all TEG Manager Software used in conjunction with a TEG 5000 device. The TEG Manager Software versions used in conjunction with TEG 5000 are 1.1.0, 3.0.0, 4.0.0, 4.1.0, and 4.1.1.

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 a top priority. This action is being performed by Haemonetics with the full knowledge of the regulatory authorities.

If you have any questions about this action please do not hesitate to contact me or send a message to QSELA@haemonetics.com.

Sincerely,



Andrew Sette
VP, Quality Assurance &
Regulatory Affairs, International

If needed, you can contact your local customer service representative at:

Country	Phone	Fax	Email
Austria	0800 29 27 77	0800 29 28 20	info.at@haemonetics.com
Denmark	+41 22 363 9050	+41 22 363 9055	distribution@haemonetics.com
United Kingdom	0808 234 48 17	0808 234 4845	info.uk@haemonetic.com

Field Safety Notice

TEG MANAGER® with TEG® 5000

ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to Haemonetics within 14 days

- I have read the March 2020 notification letter regarding correction of the TEG Manager Software. I understand the instruction to rely on actual test result values displayed on TEG Manager and TEG 5000 and not to treat solely based on reference range alerts.
- I have been able to download and install the TEG Manager Software Patch 4.1.2
- I have not been able to download TEG Manager Software Patch 4.1.2 and need assistance from hss-eu-support@haemonetics.com
- I do not have TEG Manager Software 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 22 363 8703

OR SCAN AND E-MAIL TO

QSELA@HAEMONETICS.COM