

HAEMONETICS®

Urgent Field Safety Notice (FSN)

TEG® 6s Analyser - Thermal Printer Misprint with PlateletMapping® ADP & AA assays

July 11, 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 S.A. is conducting a voluntary field action of the use of thermal printers with the TEG® 6s analyser (item #: 07-690) and PlateletMapping ADP & AA assay cartridge (item #: 07-614). Errors in the text of the printed results have been identified for **non-English languages** when using analyser software version 1.7.2.

The issue is limited to the printed results only. The correct results are displayed on the TEG 6s analyser and in TEG Manager.

Reason for the Field Notice:

For the PlateletMapping ADP & AA cartridge, four (4) calculations are printed on the lower portion of the thermal print-out: ADP Aggregation, ADP Inhibition, AA Aggregation, and AA Inhibition.

1. In all TEG 6s analysers using non-English languages and the software version 1.7.2, instead of correctly printing the text 'ADP Inhibition', the device prints 'AA Inhibition'. This mislabeling of the ADP inhibition as AA inhibition may cause confusion about which result has been printed. The correctly labeled result is displayed on the TEG 6s analyser and in TEG Manager.
2. In the TEG 6s analysers using the Spanish language and the software version 1.7.2, the device does not print the result for AA inhibition, instead printing the text 'AA Inhibition' again. The result for AA Inhibition cannot be seen on the print out. The correct result is generated and displayed on the TEG 6s Analyser and in TEG Manager.

See Attachment 1 for example of the affected print-off text.

Product & Distribution Information:

The actions defined in this FSN are pertinent to customers using a thermal printer with TEG 6s analysers with software version 1.7.2 to print PlateletMapping assay cartridge results in non-English languages.

Risk to Health:

The population at risk are patients where hemostatic condition is being assessed using TEG 6s PlateletMapping ADP & AA cartridge (item #: 07-614) when solely using a result printed on a thermal printer with non-English versions of the TEG 6s analyser software on version 1.7.2. Risk

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to patient is eliminated when results are obtained directly from the TEG 6s analyser, TEG Manager or electronic medical records (EMR) systems.

The potential harm to patient is increased risk of bleeding, thrombosis, unnecessary treatment, wrongful treatment or delay in treatment which could potentially lead to moderate injury to patient, but the likelihood of the hazardous situation occurring is rare.

Haemonetics has not received any reports of adverse events associated with this issue.

Actions to be taken by the Customer/User:

Customers may continue to perform Haemonetics TEG 6s testing using all assays available for the analyser including the PlateletMapping assay cartridges.

Customers who print results in non-English languages using a thermal printer attached to the TEG 6s analyser should discontinue use of the thermal printer when testing with TEG 6s PlateletMapping ADP & AA assay cartridges (Item #: 07-614).

Results may be viewed directly from the TEG Analyser, within TEG Manager or through integrated electronic medical records (EMR) systems. Where print-outs are required, printing the results using TEG Manager printing functions or via integrated EMR systems are acceptable.

As a reminder,

Results from the TEG 6s analyser should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, other coagulation tests.

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.

Haemonetics is preparing a patch for the TEG 6s analyser software which is expected to be available early September 2022. The new software version will be installed by Haemonetics Field Service.

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.

Sincerely,



VP International Regulatory & Government Affairs
QSELA@haemonetics.com

Attachment 1: Example of print-off text

<p>French</p> <p>1. Should be Inhibition ADP (%)</p>	<p>→</p>	<p>Agrégation ADP (%) 64,9! 35,0 - 40,0 Inhibition AA (%) 35,1! 0,0 - 17,0 Agrégation AA (%) 33,5! 20,0 - 30,0 Inhibition AA (%) 66,5! 0,0 - 11,0</p>
<p>Danish</p> <p>1. Should be ADP-inhibering (%)</p>	<p>→</p>	<p>ADP-akkumulering (%) 44,9! 55,0 - 70,0 AA-inhibering (%) 5,1! 60,0 - 87,0 AA-akkumulering*(%) 43,5! 60,0 - 70,0 AA-inhibering (%) 56,5! 60,0 - 71,0</p>
<p>German</p> <p>1. Should be ADP-Inhibition (%)</p>	<p>→</p>	<p>ADP-Aggregation (%) 64,9! 35,0 - 40,0 AA-Inhibition (%) 35,1! 0,0 - 17,0 AA-Aggregation (%) 33,5! 20,0 - 30,0 AA-Inhibition (%) 66,5! 0,0 - 11,0</p>
<p>Italian</p> <p>1. Should be Inibizione ADP (%)</p>	<p>→</p>	<p>Aggregazione ADP (%) 44,9! 55,0 - 70,0 Inibizione AA (%) 5,1! 60,0 - 87,0 Aggregazione AA (%) 43,5! 60,0 - 70,0 Inibizione AA (%) 56,5! 60,0 - 71,0</p>
<p>Portuguese</p> <p>1. Should be Inibição de ADP (%)</p>	<p>→</p>	<p>Agregação de ADP (%) 44,9! 55,0 - 70,0 Inibição de AA (%) 5,1! 60,0 - 87,0 Agregação de AA (%) 43,5! 60,0 - 70,0 Inibição de AA (%) 56,5! 60,0 - 71,0</p>
<p>Japanese</p> <p>1. Should be ADP Inhibition (%)</p>	<p>→</p>	<p>ADP Aggregation (%) 64.9! 35.0 - 40.0 AA Inhibition (%) 35.1! 0.0 - 17.0 AA Aggregation (%) 33.5! 20.0 - 30.0 AA Inhibition (%) 66.5! 0.0 - 11.0</p>
<p>Spanish</p> <p>1. Should be Inhibición de ADP (%)</p> <p>2. Should have Inhibición values printed instead of repeating text</p>	<p>→</p> <p>→</p>	<p>Agregación ADP (%) 100,0 83,0 - 100,0 Inhibición de AA (%) 0,0 0,0 - 17,0 Agregación de AA (%) 100,0 89,0 - 100,0 Inhibición de AA (%) Inhibición de AA(%) - 11,0</p>

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ACKNOWLEDGEMENT and RECEIPT FORM

TEG® 6s Analyser - Thermal Printer Misprint with PlateletMapping® ADP & AA assays

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

- I have read and understand this FSN regarding a correction of the TEG® 6s analyser software when used with PlateletMapping® ADP & AA assay cartridges and printed using a thermal printer.
- I do not use a thermal printer to print TEG® 6s PlateletMapping® ADP & AA results.
- I only use the English version for printing TEG® 6s PlateletMapping® ADP & AA results.

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