

Urgent Field Safety Notice

SBN-CPS-2016-026

CPS / Coagulation
Version 1
21-Dec-2016

Multiplate® Analyzer: Wrong printout of reference/target range graphical bar

Product Name	Multiplate® Analyzer
GMMI / Part No	06675069001
Device Identifier	
Production Identifier (Lot No./Serial No.)	n/a
SW Version	2.04
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that Multiplate® Analyzers used with software version 2.04.37 and software version 2.04.39 may generate a wrong reference range and target range graphical printout.

The Multiplate® Analyzer software contains a functionality that allows the reference range and target range to be displayed in the form of horizontal graphical bars. When this functionality is enabled, sample result will be displayed as a black vertical line within the reference/target range graphical bars to indicate its position relative to the set ranges. When sample results are printed, the graphical bars and the sample result line will be printed as well (see Figure 1).

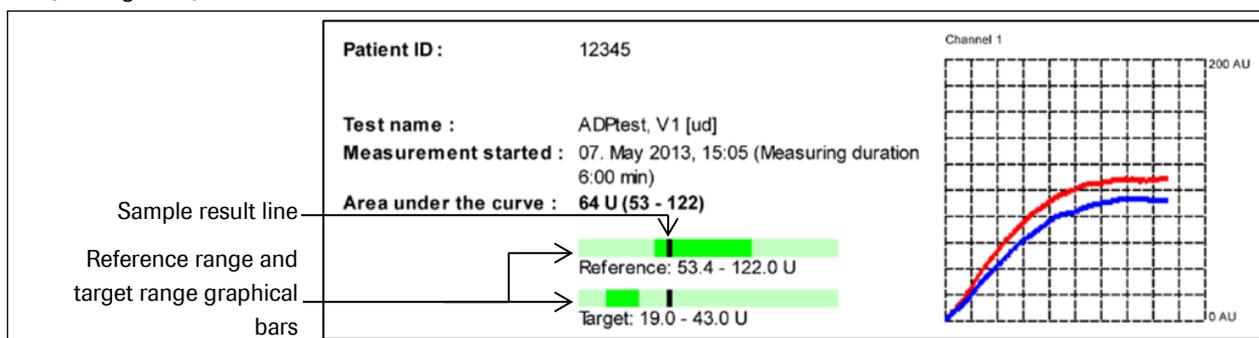


Figure 1: Example of result printout with reference range, target range and result line

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By the default, the print settings for paper-size and paper orientation are set to A4 format and Portrait respectively.

When an end-user changes the print settings to

- paper size: other than A4,
- print orientation: Landscape

then the position of the result line shown within the reference and target range graphical bars may not be correct.

The numerical reference range (shown in brackets following the numerical sample result value), and the numerical sample result remain correct (see Figure 2).

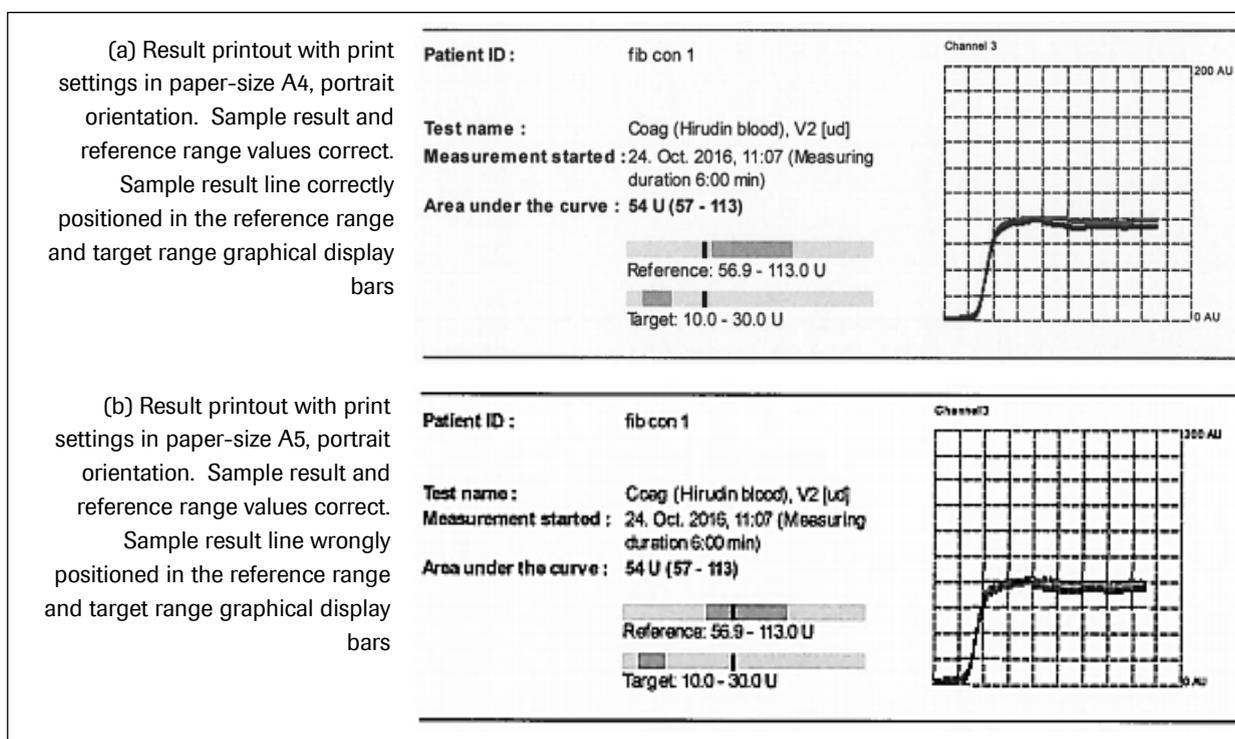


Figure 2: Example of result printouts with reference range, target range and result line (a) correctly displayed when printed using default print settings of paper-size A4 in portrait orientation, and (b) incorrectly displayed when printed using A5 paper

This erroneous graphical representation of the result line and reference and target ranges is due to a software bug, which will be corrected with a new software version is foreseen to be released in Q2/2017.

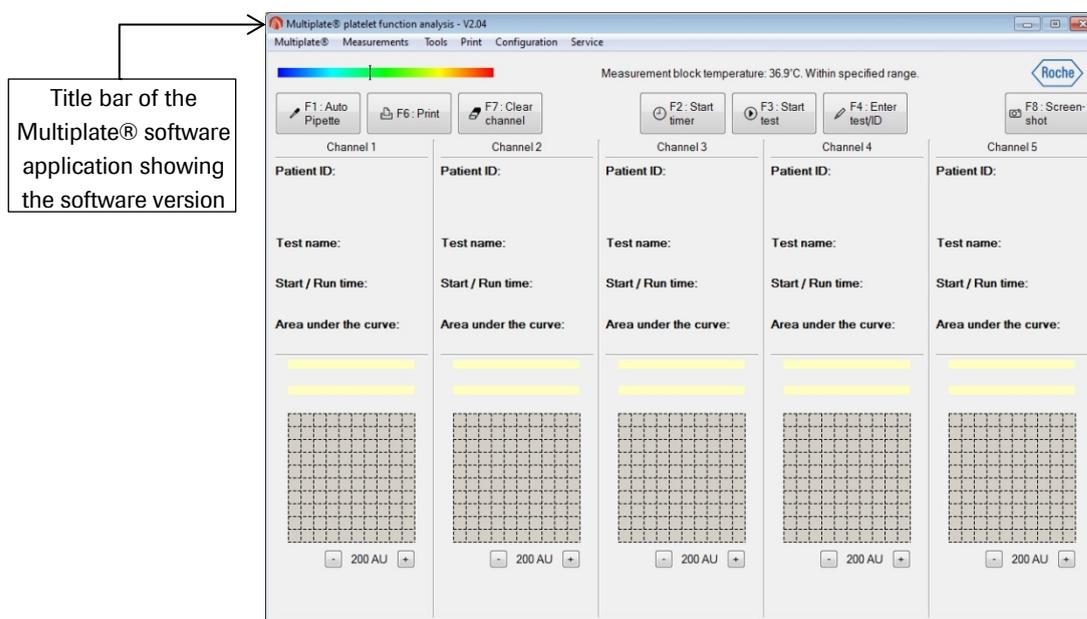
This problem occurs only when the result is printed immediately after result measurement. Result printouts done using archived results does not have this problem.

However, in clinical situations correct information by numeric results and the correct visual representation of results is essential and failures may raise a medical risk for the patient.

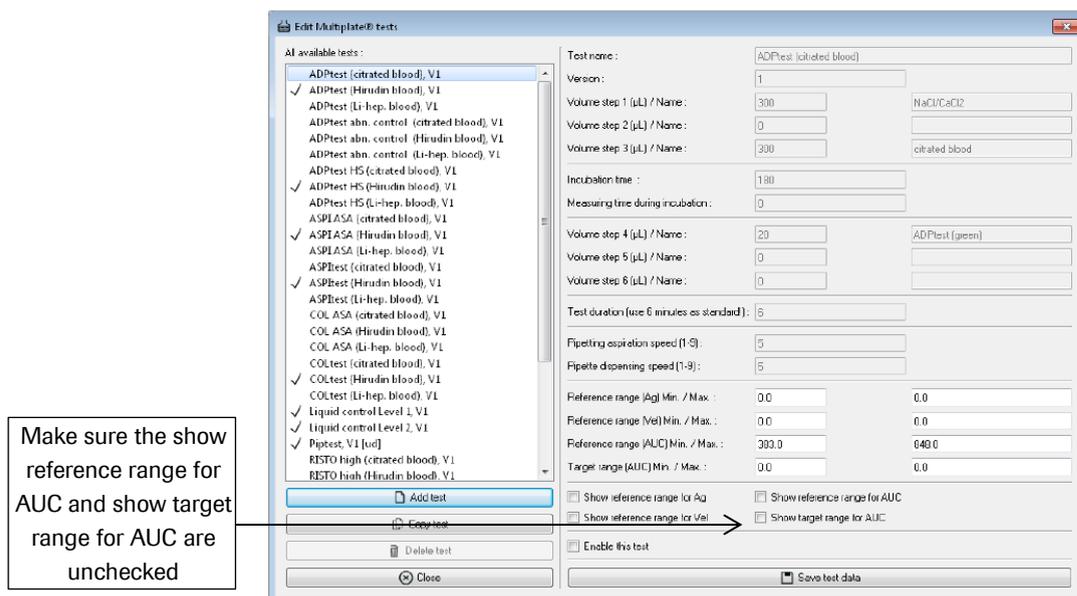
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Instructions

If you are using the Multiplate® Analyzer with software version 2.04, please only print using paper size A4, portrait orientation. You can check which software version you are using by looking at the title bar of the Multiplate® software application (see Figure below).



If you are using paper size other than A4, please do not use the functionality to display reference and target range in graphical format. This functionality has to be deactivated for every test parameter, using the **Edit Multiplate tests** window. To deactivate this functionality, per test setting, follow the instructions as described in Operators Manual (V2.0, SW 2.04, Chapter Operation/Configuration/Editing test parameters, page 128).



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Please note, switching off the reference range display will also switch off the numerical display of the range shown in brackets behind the final result.

Actions taken by Roche Diagnostics (if applicable)

- We work with highest priority on appropriate corrective actions to rectify the printing defect.
- The software bug will be corrected with the development, validation and release of a new software iteration by 2Q 2017.

Actions to be taken by the customer/user

- Use only A4 paper and portrait orientation to print results
- If you do not have access to A4 paper, deactivate the reference range and target range graphical display functionality
- The Confirmation/Feedback Form is to be sent back to Roche to confirm actions have been completed.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

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Email name@roche.com