

Cressier, January 13, 2017,

FSN 002-15 follow-up letter

Affected device

Product name: Lyra MP Reader II
Product REF: 854002
Lyra software version: all versions

Dear colleagues,

We would like to update you on the last developments of the FSCA 002-15.

In November 2015, the Lyra MP Reader II version 08.01.00 was released, but we have received few complaints indicating some residual events related to the one described in the FSN 002-15.

Hence, as a precautionary measure, we advise the laboratories that currently use this released version and the previous ones to keep the recommendations given in the FSN 002-15.

In case of black and white images, the instructions provided in the User Manual and in the procedure *Lyra_II_Procedure_In_Case_Of_B&W_Image_v4* have to be followed.

A new software version is on development. We will keep you update on the date of this release.

We would like to apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.



Jérémy Poropane

Acting Director RA
EMEA



Ivo Dietrich

Technical Product Support Supervisor



Cressier, July 17, 2015

Urgent: Field Safety Notice / 002-15

Dear **Distributors / Subsidiaries**,

This letter contains important information that requires your **immediate** attention.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

Affected device

Product name:	Lyra MP Reader II
Product REF:	854002
Lyra II software pack:	all versions

This information only concerns the Lyra II Software pack

Description of the problem:

Following a customer report, we have been made aware that, in exceptional circumstances, the system may incorrectly assign the results of the previously read microplate to the microplate being processed.

In this specific context, the misallocated results are displayed in black and white instead of color as would be expected.

This issue could in the worst case lead to a mismatch between the test result issued and the true result of the sample.

Our in-depth investigations indicate that this issue is related to the Lyra II Software pack and to an exceptional context related to the files management.

Impact on the patient:

The potential for reporting an erroneous result is very limited because the occurrence of this issue is dependent on several exceptional random factors operating together. To date, no incident with patient outcome has been reported.

Nevertheless, we are informing you so that you can take the appropriate protective measures pending a definitive software solution.

Permanent corrective action:

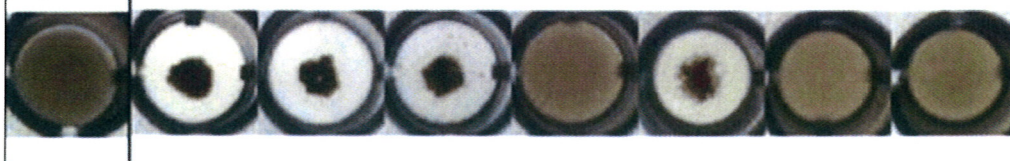
We will provide a permanent solution in the next Lyra II software pack, which will be released as soon as it has been thoroughly validated. We expect to release it within a maximum of three months.

Immediate Action:

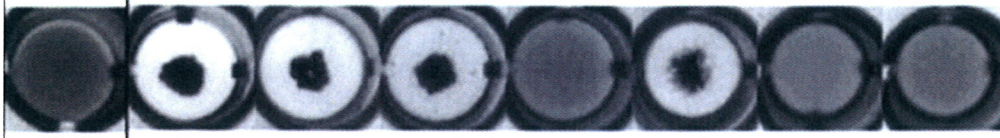
In the meantime, customers should immediately:

- Only use an empty microplate for balance purpose (i.e. when only one microplate has to be read);
- Deactivate the automatic validation of results for the Lyra reader MP II ;
- Check the color of the results displayed by IH-Com or Maestro before validation ;
- Do not validate the results if the images of wells appear in black and white.

Expected results in color :



Results in Black and White → **do not validate**



In case of black and white image of wells, customers have to follow the procedure called "***Lyra_II_Procedure_In_Case_Of_B&W_Image_v4***".

Actions to be taken by the distributor / Subsidiary:

- Please translate the above text into your national language(s) and share this information with the concerned customers.
- Please complete the Field Safety Notice Reply Form (Annex I) and return to DiaMed GmbH.
- Retain this notification as part of your Quality System documentation as well as the completed Field Safety Notice forms of your respective customers (Annex II).

Actions to be taken by the customer:

- Please complete the Field Safety Notice reply form (Annex II) and return to your distributor.
- Please share this information with the relevant laboratory staff, to ensure that the appropriate protective measures are taken.

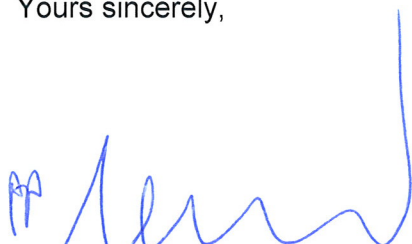
In case of questions, in the first instance, please contact our Help desk:

+41 (0) 26 674 51 60
support.instr_cressier@bio-rad.com

Our technical representatives are briefed to help you manage this situation.

We would like to apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,



DiaMed GmbH
RA/QA Manager
Agnes Eude Goethals



DiaMed GmbH
IHD Division Manager
Ann Madden

Annex I

Urgent: Field Safety Notice Reply Form for Distributors / Subsidiaries / 002-15

Product name: Lyra Reader MP II
Product REF: 854002
Lyra II software pack: all versions

Please fill out and sign the information below and return the completed form to DiaMed GmbH including a copy of the translated letter within 5 working days:

- by email at RA-request_Cressier@bio-rad.com
- by Fax at: + 41 26 674 54 69

I have read and understood this Field Safety Notice, and shared this information with concerned laboratories.

Distributor / Subsidiary Name

Address

Phone Number

Completed by: Name / Signature / Title / Date

Annex II

Urgent: Field Safety Notice Reply Form for Customers / 002-15

Product name: Lyra Reader MP II
Product REF: 854002
Lyra II software pack: all versions

Please fill out and sign the information below and return the completed form to your [distributor](#) within 10 working days.

I have read and understood this Field Safety Notice, and shared this information with laboratory staff that uses this product.

Hospital / Laboratory

Address

Phone Number

Completed by: Name / Signature / Title / Date