

2019 July 4th

Ref. PQN 12-19 IDD

IMPORTANT PRODUCT INFORMATION

This information is intended for the end user of this product
If you are not the end user, please forward this information
to the appropriate laboratory personnel

Subject: PR4100 Magellan software version 7.0 (code 94195)

Cc Chairman Medical Board and relevant Head of Departments

Dear valued customers,

Tecan manufacturer has informed Bio-Rad about a potential issue with the Magellan software version 7.0 which is running on PR4100 Microplate reader.

The issue concerns “print layout import” function.

Please note this software defect does not affect the PR4100 Bio-Rad Assays Protocol Files (APF) since none of them is using this function.

Implication will be that the respective test will be run with the parameters from the imported print layout instead of the parameters originally entered by the user thus potentially generating invalid test results.

The risk assessment is very low and depends on the use of non Bio-Rad assays on the PR4100 Magellan software.

We recommend to not program your own APFs using the “print layout import” function.

In addition we remind you that each laboratory must validate its own custom assay to ensure valid results are being obtained.

This software issue is going to be fixed in the next version of PR4100 Magellan software.
You will be informed by your Bio-Rad sales representative when released.

We apologize for any inconvenience and thank you for your understanding.

Regards

Michel GUNZBURGER
IDD International Instrumentation Product Manager



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CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: 12-19

Bio-Rad Division: IDD

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date	Software Version
	PR4100 Magellan software	94195	NA	NA	7.0

CUSTOMER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address :	
Telephone Number / Fax :	
Customer Account Number :	

STATEMENT:

- ☐ I am aware of the information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.

Date:

Customer Signature (and Stamp if applicable)

Please return this form to: [enter local details]