

2018 March 12th

Ref. PQN 08-18

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 potential issues with the Magellan software version 7.0 which is running on PR4100 Microplate reader.

The first issue concerns 5 parameters Marquardt curve fit.

Please note this software defect does not affect the PR4100 Bio-Rad Assays Protocol Files (APF) as none is running with this 5 parameters curve fit.

Resulting Error or Hazard

A concentration of exactly zero may be displayed for samples with high OD values and high concentrations when the 5-parameter Marquardt curve fit is used for non-sigmoid standard curves without high plateau.

The risk assessment is very low and depends on your non Bio-Rad application on the PR4100 Magellan software.

We recommend to not program your own APFs using the 5 parameters curve fit or when using the 5-parameter Marquardt curve fit it must be ensured that the standard curve follows a sigmoidal shape (with upper and lower plateau).

The second issue concerns User Management System (UMS).

Users who have been blocked by administrator are still able to log in.

The risk assessment is very low since usually locked users have no longer physical access to the instrument.

By precautionary measure the administrator must change the user password before locking out the user. This will prevent the locked out from logging in again after the lock out.

Both software issues are 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