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# PLA 2.1

Release Notes PLA 2.1 (build 605 SR1)

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## TABLE OF CONTENTS

Copyright.....	2
Contact.....	2
Table of Contents.....	3
Welcome .....	4
Release Dates.....	5
PLA 2.1 (build 605 SR1) Release Notes .....	6
Issues Fixed .....	6
PLA 2.1 (build 604) Release Notes .....	7
Enhancements.....	7
Issues Fixed .....	7
PLA 2.1 (build 603) Release Notes .....	8
Enhancements.....	8
Issues Fixed .....	8
PLA 2.1 (build 602) Release Notes .....	9
Issues Fixed .....	9
PLA 2.1 (build 601) Release Notes .....	10
Issues Fixed .....	10
PLA 2.1 (build 600) Release Notes .....	11

## WELCOME

Welcome to the Release Notes of PLA 2.1 (build 605 SR1). This document contains the cumulated Release Notes showing all enhancements and fixed issues for all versions of PLA 2.1 since its initial release.

This document is primarily intended for Functional and System Administrators.

**NOTE: Before upgrading backup your databases!**

The release notes are structured into chapters for each release.

### REMARK

The B-parameter of the 4- and 5-parameter logistic fit is commonly called "slope" or "Hill-Slope". Unfortunately, the B-parameter does not characterize the slope in the inflection point of these curves. The first derivate of the 4- and 5-parameter logistic fit involves the parameter A, B and D resp. A, B, D and G.

PLA 3.0 has changed all labels of these tests with the introduction of Biological Assay Package 25. In PLA 2.1 we have decided to stick with the traditional labels for backward compatibility. This decision was also driven by the lifecycle of PLA 2.1: PLA 2.1 is a maintenance-only product which is not under active development and it reaches its formal end of life (support) date on May 8, 2023. After this date Stegmann Systems will no longer provide updates to the system. PLA 3.0 should be considered as a replacement.

## RELEASE DATES

Build	Released
605 SR1	30.09.2019
605	23.08.2019
604	21.12.2015
603	20.12.2013
602	22.10.2013
601	24.09.2013
600	08.05.2013

Versions not listed here are internal versions and have never been released to the public.

The release notes document changes between the listed versions.

## PLA 2.1 (BUILD 605 SR1) RELEASE NOTES

Version: 2.1 (build 605 SR1). Previous Version: PLA 2.1 (build 604).

### ISSUES FIXED

- Calculations of certain equivalence tests have been corrected. For the tests “Equivalence Test: Ratio of Dynamic Range”, “Equivalence Test: Difference of Asymptotes (upper-lower)” and “Equivalence Test: Scaled Asymptote Range” a specification error has been corrected which has a slight impact on calculated margins depending on the size of the covariance of the parameters (FBA-1935).
- Calculations of the confidence intervals for certain equivalence tests made use of the standard error and degrees of freedom of the residual error ANOVA regardless of the selected ANOVA type. This has been corrected. This has a small impact on the calculated margins (BPLA-654).
- A problem in the implementation of the Dixon test for outliers has been fixed. For assay elements with eight or more replicates per dose step extreme values might not have been removed from analysis due to an algorithmic problem. (BPLA-650)
- A problem in the implementation of the equivalence test “Ratio of Slopes” applied to linear parallel-line assays with asymmetric design has been fixed (BPLA-665)
- Inspector role could not apply additional signatures to a document.
- Add-function in account management could lead to unintended modification of the current user.
- Modification of current account details allowed demotion of the group of the current administrative user.
- A stop error in the import wizard has been fixed.
- OQ and PQ failure reports are now reporting identification information for a failing object.
- SR1 Solved a technical problem with the test system editor setting significance levels to 0.

## PLA 2.1 (BUILD 604) RELEASE NOTES

Version: 2.1 (build 604). Previous Version: PLA 2.1 (build 603).

### ENHANCEMENTS

- Equivalence test for Ratio of Dynamic Ranges added.
- Additional messages if Fieller calculation returns imaginary values.

### ISSUES FIXED

- Import Wizard crash
- Problems in Range Optimizer with excluded values.
- Stop error during 50% response calculation.
- Stop error during response value transformation.
- Duplicated document entries during PNF import.
- Unclear audit trail entries in account management.
- Missing error information during ratio of lower asymptote calculation. (Fieller calculation delivered imaginary results)
- Protection for tests not correctly applied.
- Optional response adjustment not correctly applied to Range Optimizer
- Stop error during linear range check
- Stop error in navigator
- Error in registration dialog.
- Stop error during database compaction
- Unnecessary audit trail entries for f-tests
- Unnecessary audit trail entries for x-values of controls
- Audit trail detail view not automatically updated
- Account Management detail view not updated when selecting a different user
- PNF import into empty database does not apply the user level GxP protection

## PLA 2.1 (BUILD 603) RELEASE NOTES

Version: 2.1 (build 603). Previous Version: PLA 2.1 (build 602). PLA 2.1 (build 603) is a performance update with minor corrections of the Complete Statistics Reports.

### ENHANCEMENTS

- ImportSource and ImportTimestamp are now written into objects created by the Import Wizard for documentation and traceability

### ISSUES FIXED

- Audit Trail Viewer displayed an error message under some circumstances with MS SQL Server databases.
- Updated Exception Handling of the graphical user interface
- Updated behavior of the database manager dialog when defining SQL databases.
- Export-Wizard displayed a false wizard page when stepping back during database backup.
- GxP properties are now displayed correctly in the Complete Statistics Reports
- Substance and BatchID are now displayed on the summary pages in the Complete Statistics Reports
- UNC paths can now be select in the options dialog



## PLA 2.1 (BUILD 602) RELEASE NOTES

Version: 2.1 (build 602). Previous Version: PLA 2.1 (build 601). PLA 2.1 (build 602) is a performance update.

### ISSUES FIXED

- A memory leak has been corrected. Memory consumption while Database consistency check and in other larger operations has been reduced.

## PLA 2.1 (BUILD 601) RELEASE NOTES

Version: 2.1 (build 601). Previous Version: PLA 2.1 (build 600). PLA 2.1 (build 601) is a recommended update.

### ISSUES FIXED

- Installation Support URL is deinstallation corrected.
- Runtime error during test execution fixed.
- Array out of bounds exception in update check was fixed.
- Equivalence margin report corrected.
- Enablement of properties in data editor corrected.

## PLA 2.1 (BUILD 600) RELEASE NOTES

Version: 2.1 (build 600). PLA 2.1 (build 600) is the Initial Revision of PLA 2.1.