Validation report SIMCA 16.0.2 2020-06-09 13:49

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Content

1 Introduction 2
1.1 Notation and notes 2
2 Validation report summary 2
2.1 Validation package content 2
3 Validation task results 2
3.1 Numerical comparison 2
4 Verification of installed software 2
5 Source code 2
6 Routines 2
7 Bug handling 3
8 Validation conclusion 3

1 Introduction

The purpose of the **Validation report** is to summarize and document the found differences that require corrective actions from the validation activities performed.

The scope of the validation tasks performed are described in paragraph 6.4 in the Validation plan.

This patch validation that complements the full validation of SIMCA 16 (version 16.0.0.7738) and the patch SIMCA 16.0.1 (version 16.0.1.7928).

1.1 Notation and notes

'US' followed by a number refers to a User Story in the TFS database.

Note: Approving this document includes approval of all subdocuments and results referred to in this document.

2 Validation report summary

The purpose of the **Validation report** is to summarize and document the found differences that needs corrective actions from the validation activities performed and listed in the Validation plan.

The numerical validation of SIMCA 16.0.2 was done versus specification using CompareSimcaData.

The CompareSimcaData report was saved and included in the validation package.

2.1 Validation package content

The validation package includes files and folders as follows:

- SIMCA 16.0.2 validation documentation pdf, a compilation of validation documents including this document, Validation report SIMCA 16.0.2.
- Bugs folder – Lists details for the bugs referenced in the validation package, if any.
- Numerical validation folder – Holding the background to the numerical comparisons.

SIMCA projects (.usps) used during the validation are not included. See the SIMCA 16 validation package (full version) for project files.

3 Validation task results

3.1 Numerical comparison

In the numerical comparison versus specification, using CompareSimcaData, no differences that require a corrective action were found.

4 Verification of installed software

To verify that your license of the software has been correctly installed follow the instruction here:

1. In SIMCA, click **File | Help** and under About SIMCA ..., verify that the version is SIMCA 16.0.2.10561.
2. Open one of the .pdfs in the Graphical validation folder in the SIMCA 16 validation package.
3. Open the corresponding project in the software, found in the Projects folder.
4. Create and compare one of the 2D plots (column, line, or scatter) and one 3D plot (3D scatter, response surface, or wavelet power spectrum). The plots should content wise be identical.

5 Source code

All source code for the final version of a full release is transferred to electronic media and kept both at Sartorius Stedim Data Analytics AB as well as in the safe of a local bank.

6 Routines

The relevant routines are stored in TFS in the QualityManagementSystem folders.

7 Bug handling

Work items describing bugs found are stored electronically in the database TFS. Bugs that require a corrective action are listed in the tables in paragraph 3.

8 Validation conclusion

The bugs listed in paragraph 6.4 in the Validation plan were verified fixed and closed.

No differences were found. The used routines together with the validation ensure that SIMCA 16.0.2 gives correct results and is reliable.