SARTORIUS

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Content

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 2.1 in the Validation plan.

This patch validation complements the full validation of SIMCA 17 (version 17.0.0. 24543).

1.1 Notation and notes

'US' followed by a number refers to a User Story in Azure DevOps.

'WI' followed by a number refers to a Work Item in Azure DevOps. May be Bug, User Story, Feature etc.

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 17.0.1 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 17.0.1 validation documentation pdf, including this validation report.

- Bugs folder – Lists details for the bugs referenced in the validation package, if any.

- Projects folder – SIMCA project files (.usps) used during the validation.

- Numerical validation folder – Holding the background to the numerical comparisons.

3 Validation task results

3.1 Numerical comparison

In the numerical comparison versus specification, no differences were found. Rounding differences are not included.

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 17.0.1.26957.

2. Open one of the .pdfs in the Graphical validation folder in the full validation of SIMCA 17.

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 the Umeå office as well as in the safe of a local bank.

6 Routines

The relevant routines are stored in Azure DevOps in the QualityManual and QualityManagementSystem folders.

7   Bug handling

Work items describing bugs found are stored electronically in Azure DevOps. Bugs that require a corrective action, if any, are listed in the tables in paragraph 3.

8   Validation conclusion

The bugs listed in paragraph 2.1 in the Validation plan were verified fixed and closed.

All differences that require a corrective action are listed under paragraph 3, and the WIs referenced to are stored in Azure DevOps and available in the Bugs-folder.

None of the found differences are serious. The used routines together with the validation ensure that SIMCA 17.0.1 gives correct results and is reliable.