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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.

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 Defect, User Story, Feature etc.

'VTC' followed by a number refers to a Test Case in Azure DevOps that has been written as a Validation Test Case, VTC. All files referenced here can be found in the New functionality folder in the validation package.

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

2 Validation Report Summary

The Validation plan defines the validation tasks to perform. The results from the validation tasks are included in the validation package and all found differences requiring a corrective action are listed under paragraph 3.

The numerical validation of SIMCA 18 was done versus specification using CompareSimcaData, and the report was saved and included in the validation package.

The graphical validation versus SIMCA 17 was done on a number of projects and models. The copied/printed plots and lists are included electronically in the validation package.

New functionality was validated versus specification.

2.1 Validation Package Content

The validation package includes files and folders as follows:

- SIMCA 18 validation documentation pdf, a compilation of validation documents including this document, SIMCA 18 Validation report.
- Defects folder – Lists details for the defects referenced in the validation package, if any.
- Graphical validation folder – Documents containing the compared graphs, lists and tables.
- New functionality folder – New functionality and improvements have been validated and available in a folder named 'New functionality' in the validation package.
- Numerical validation folder – Holding the results to the numerical comparisons.
- Verification of installed software folder – Holding projects for installation verification

3 Validation Task Results

The numerical validation of SIMCA 18 was done versus specification, using TestComplete and CompareSimcaData under Windows 10. The outcome is included in the validation package. Differences due to rounding are not listed.

3.1 Data Analytics Correctness – Numerical Validation

In the numerical comparison versus specification and comparing lists in Excel versus SIMCA 17, no differences that require a corrective action were found.

3.2 Data Analytics Correctness – Desktop Graphical

In the graphical comparison of plots and lists versus SIMCA 17, no differences that require a corrective action were found.

3.3 New Functionality

New functionality described in features closed during the development of SIMCA 18 was validated and can be found in **Validation of new functionality summary** and New functionality folder.



The results from the VTCs run during the validation are documented in the files found in the New functionality folder.

No differences that require a corrective action were found when running the validation test cases.

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 18.0.0.372.
2. Open one of the .pdfs in the Graphical validation folder in the full validation of SIMCA.
3. Open the corresponding project in the software, found in the Verification of installed software 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 in a safe storage externally.

6 Routines

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

7 Defect Handling

Work items describing defects found are stored electronically in Azure DevOps. Defects that require a corrective action are listed in the tables in paragraph 3.

8 Validation Conclusion

All defects found during this development life cycle that remain unsolved were considered noncritical to the user of the system and therefore remain open.

All deviations compared to specifications that require a corrective action are stored in the defect database with details about the planned action.

None of the deviations found are serious. The performed quality activities throughout the life cycle of the software development, in accordance with the outlined testing and validation strategy in the Quality Management System (QMS), secures that the requirements perform according to specification and that SIMCA 18 gives correct results and is reliable.

