

	Role	Name	Date
Issued by:	Software quality	Lisa Gabrielsson	2019-05-23
Revised by:	Software quality	Anders Lindegren	2019-05-28
	Program manager	Therese Ringvall	2019-05-29
	Product manager	Stefan Rännar	2019-05-29
Approved by:	Head of Development	Jonas Andersson	2019-05-29
	Head of Quality	Andreas Norén	2016-05-29

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1 Introduction

The purpose of the **Validation report** is to summarize and document the found differences that needs 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 complements the full validation of SIMCA 16 (version 16.0.0.7738).

1.1 Notation and notes

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

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

'VTC' followed by a number refers to a Test Case in the TFS database 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 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 CompareSimcaData report was saved and included in the validation package.

2.1 Validation package content

The validation package includes files and folders, organized alphabetically as follows:

- Validation of SIMCA 16.0.1 pdf, which includes Validation report SIMCA 16.0.1 (this document).
- 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 SIMCA 16.0.0 and 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 16.0.1.7928
2. Open one of the .pdfs in the Graphical validation folder found in the full validation of SIMCA 16.0.0.7738.
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 QualityManual and 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. Test cases were added for future automatic verification of these bugs.

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

No differences were found. The used routines together with the validation ensure that SIMCA 16.0.1 gives correct results and is reliable.

