

	Role	Name	Date
Issued by:	Software quality	Lisa Gabrielsson	2019-11-12
Revised by:	Software quality	Anders Lindegren	2019-11-12
	Program manager	Therese Ringvall	2019-11-12
	Product manager/owner	Jonas Elfving	2019-11-12
Approved by:	Head of Development	Jonas Andersson	2019-11-13
	Head of Quality	Andreas Norén	2019-11-13

Content

1	Introduction.....	2
2	Validation report summary.....	2
2.1	Validation package content.....	2
3	Validation task results.....	2
3.1	Numerical comparison.....	2
3.2	Graphical comparison.....	3
3.3	New functionality.....	3
4	Verification of installed software.....	3
5	Source code.....	3
6	Routines.....	3
7	Bug handling.....	3
8	Validation conclusion.....	3



1 Introduction

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

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

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®-online 16 was done versus SIMCA®-online 15.1 and specification.

The graphical validation versus SIMCA®-online 15 and SIMCA® 16 was done on a number of projects and models under Windows 10. 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®-online 16 Validation documentation.pdf, a compilation of validation documents including this document, SIMCA®-online 16 Validation report.
- Bugs folder – Lists details for the bugs referenced in the validation package, if any.
- Graphical validation folder – Documents containing the compared graphs
- Projects folder – SIMCA project files (.usps) used during the validation.
- New functionality folder – New functionality and improvements have been validated and the VTC run results and result log files are available in the folder named ‘New functionality’ in the validation package.
- Numerical validation folder – Holding the background to the numerical comparisons.

3 Validation task results

3.1 Numerical comparison

In the numerical comparison versus SIMCA®-online 15.1, no differences were found. The differences versus specification listed below are known deviations that were present also in previous versions. Rounding differences are not included.

No.	Feature/Vector	Projects, models	Explanation	Action
1.	T2Range	Lubrizolow and BatchProjectDynamicLags (using phase models with predicted batches that are longer than the maximum aligned maturity in the BEM).	T2Range for prediction batches should be missing when exceeding the maximum aligned maturity in the BEM when the SIMCA project is created with the option “Cut long and extrapolate short batches” set to “No”. Difference found between SIMCA-online and SIMCA, but not between SIMCA-online 16.0 and 15.1.	Reported in bug 9703 (moved to user story 9738). This may be fixed in a future version.



3.2 Graphical comparison

In the graphical comparison of plots versus SIMCA®-online 15 and SIMCA 16, no differences that require a corrective action were found.

NOTE! Differences found in the numerical comparison that are also present in the graphical are omitted.

3.3 New functionality

New functionality described in features closed during the development of SIMCA®-online 16 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®-online, click **File | Help** and under About SIMCA®-online ..., verify that the version is SIMCA®-online 16.0.0.9953.
2. Open one of the .pdfs in the Graphical validation folder.
3. Open the corresponding project in the software, found in the Projects folder, use DBMaker as database and let it provide data. Use for instance Sovring for continuous and Lubrizolow for batch.
4. Create and compare one of the plots. The plots should content wise be identical.

For SIMCA-online Web Client:

1. In the desktop client, with the project used for the above verification, click Web Client on the Home tab.
2. Using one of the supported browsers (Chrome, Edge, Safari), log in using your SIMCA-online user credentials.
3. Click About on the main menu/user menu and verify that the version is SIMCA-online Client version 16.0.0 (build 9948).
4. Open one of the trend plots. 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

All bugs found between the release of SIMCA®-online 15.1 and the release of SIMCA®-online 16 that remain not fixed were considered unimportant and therefore not fixed.

All differences found during the validation process are described in detail in the **Validation task results** document.

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.

None of the found differences are serious. The used routines together with the validation ensure that SIMCA®-online 16 gives correct results and is reliable.

