

Validation report SIMCA-online 16.1.2

2021-02-26 14:39

	Role	Name	Date
Issued by:	Software quality	Lisa Gabrielsson	2021-02-24
Revised by:	Software quality	Anders Lindegren	2021-02-25
	Program manager	Therese Ringvall	2021-02-26
	Product manager	Jonas Elfving	2021-02-26
Approved by:	Head of Development	Annika Finck	2021-02-26
	Head of Quality	Andreas Norén	2021-02-26

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	Data analytics correctness.....	2
3.1.1	Versus SIMCA-online 16.1.1.....	2
3.1.2	Versus SIMCA 16.0.2.....	2
3.1.3	Versus specification.....	3
3.1.4	Versus specification Web API.....	3
3.2	Automated regression.....	3
3.3	New functionality.....	3
4	Verification of installed software.....	3
5	Source code.....	4
6	Routines.....	4
7	Bug handling.....	4
8	Validation conclusion.....	4



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 validation is a complement to the full validation of SIMCA-online 16.

1.1 Notation and notes

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

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

'VTC' followed by a number refers to a Test Case in the Azure DevOps 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 numerical validation of SIMCA-online 16.1.2 was done versus SIMCA-online 16.1.1, SIMCA 16.0.2 and specification using TestComplete and ReadyAPI.

New functionality in the web client was validated versus specification.

2.1 Validation package content

The validation package includes files and folders as follows:

- SIMCA-online 16.1.2 validation documentation pdf, a compilation of validation documents 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.
- 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 background to the numerical comparisons.

3 Validation task results

3.1 Data analytics correctness

The validation was performed on a number of projects and models comparing the results to the SIMCA-online 16.1.1, SIMCA 16.0.2 and specification using TestComplete and ReadyAPI.

3.1.1 Versus SIMCA-online 16.1.1

The automated numerical tests were extended with three configuration for SIMCA-online 16.1.2, to verify bugs found in SIMCA-online 16.1.1. Apart from differences originating from bug fixes, no differences were found.

3.1.2 Versus SIMCA 16.0.2

When comparing results to SIMCA 16.0.2 the legacy issue, described below, was found.



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 16.1.2 and 16.x.	Reported in bug 9703 (moved to user story 9738). This may be fixed in a future version.

3.1.3 Versus specification

In the numerical comparison of all vectors for the reference validation datasets versus SIMCA-online 16.1.1, using TestComplete and comparing lists saved in Excel, no differences were found.

3.1.4 Versus specification Web API

In the numerical comparison of the all vectors for the reference validation datasets versus specification, using the Web API, no differences were found.

3.2 Automated regression

The workflows automatically tested using TestComplete scripts all passed and no differences compared to specification were found.

All reference and result files are found in the Automated regression folder in the validation package.

3.3 New functionality

New functionality described in features/user stories implemented during the development of SIMCA-online web client 16.2 was validated and the results can be found under the New functionality header in *Validation task results* and in the 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 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-online, click **File | Help** and verify that the version is SIMCA-online 16.1.2.24780.
2. Open one of the .pdfs in the Graphical validation folder in the validation of SIMCA-online 16.0 (full validation).
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 ProcessCuprum for continuous and BioProcess for batch.
4. Create and compare one of the plots with the pdf content. 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. On the main menu, find the About page, and verify that the version is SIMCA-online Client version 16.2.0 (build 24772).
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 Azure DevOps in the QualityManual and QualityManagementSystem folders.

7 Bug handling

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

8 Validation conclusion

All differences found during the validation process are described in the respective paragraph in this document.

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-online 16.1.2 gives correct results and is reliable.

