Contents SIMCA®-online 17.0.1 Validation

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Validation report SIMCA®-online 17.0.1 2022-06-14 16:45

	Role	Name	Date
Issued by:	Software quality	Lisa Gabrielsson	2022-06-13
Revised by:	Release Train Manager	Therese Ringvall	2022-06-14
Approved by:	Product manager	Jon Gabrielsson	2022-06-14
	Head of Development	Annika Finck	2022-06-14
	Head of Quality	Andreas Norén	2022-06-14

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-online 17 (version 17.0.0. 55175).

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-online 17.0.1 was done versus SIMCA-online 17.0.0 and specification using TestComplete under Windows 10. The outcome is included in the validation package.

2.1 Validation Package Content

The validation package includes files and folders as follows:

- SIMCA-online 17.0.1 validation documentation pdf, a compilation of validation documents including this document, SIMCA-online 17.0.1 Validation Report.
- Bugs document – Lists details for the bugs fixed in the patch.
- Numerical validation folder – Holding the background and results to the numerical comparisons.
- Automatic regression folder – Holding the background and results from the automated workflows validated

3 Validation Task Results

3.1 Data Analytics Correctness – Desktop Numerical

In the numerical comparison versus SIMCA-online 17.0.0, no differences were found. Rounding differences are not included.

3.2 Automated Regression

In the automated regression covering group permissions, audit trail, Python preprocessing plugin and reset alarm in the web client, no differences requiring 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-online, click **File | Help** and under About SIMCA-online ..., verify that the version is SIMCA-online 17.0.1.27.
2. Open one of the .pdfs in the Graphical validation folder in the full validation of SIMCA-online.
3. Request validation project and DBMaker files from Sartorius and 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 the main menu, About, and verify that the version is SIMCA-online Web Client version 17.0.0 (build 52356).
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 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/defects found are stored electronically in Azure DevOps. Bug reports that require a corrective action are listed in the tables in paragraph 3.

8 Validation Conclusion

The defects listed in Bugs Fixed document were verified fixed and closed. Test cases were added for future verification of the functionality.

No differences that require a corrective action were found, and none of the remaining differences are serious.

The used routines together with the validation ensure that SIMCA-online 17.0.1 gives correct results and is reliable.

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Validation Plan SIMCA®-online 17.0.1 2022-06-07 13:06

		Name	Date
Issued by:	Software quality	Gabrielsson, Lisa	2022-06-03
Revised by:	Development	Simon Dannelöw	2022-06-03
	Release Train Engineer	Therese Ringvall	2022-06-03
Approved by:	Head of Quality, HdQ	Andreas Norén	2022-06-07
	Product manager	Jon Gabrielsson	2022-06-07

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Contents

1. Introduction

The purpose of this validation plan is to specify the validation activities to be performed for the SIMCA®-online life cycle.

The validation plan describes the process of producing documented evidence that SIMCA®-online gives correct results according to specification.

1.1 Background

SIMCA®-online 17.0.1 will be released to address recently found bugs listed under paragraph 2.1.

1.2 Overview of the System

SIMCA-online stores data electronically at a, by the user, specified location and according to **Table 2**.

SIMCA-online is also dependent upon the SimApi which collects data from the external database. No additional validation of the SimApi in use will be done.

2. Validation tasks and activities

For SIMCA®-online, the validation will be completed according to the validation documents and tasks listed in **Table 1**. The acceptance criteria will be met upon the completion of the tests described.

All identified deviances from expected test results found during the validation life cycle will be reported and classified according to criticality. All deviations requiring a corrective action will be listed in the **Validation report**.

2.1 Validation tasks

The following validation tasks will be performed to verify the correctness of SIMCA®-online 17.0.1.

1. **Numerical verification** – all vectors for the validation projects will be verified to be identical to specification.
2. **Bugs** – the bugs listed in SIMCA® -online 17.0.1 bugs fixed.docx will be verified and closed.

2.2 Validation traceability matrix

Table 1 shows the documents, files and test cases with validation tasks that will be produced and completed during the validation of SIMCA®-online 17.0.1. Some files are work files and not included in the validation.

Note that only documents that require approval have an entry in the Approved by column. All documents are reviewed, and that is documented in the individual document. The document number used in this section is not used in other documents, but in the more thorough description of the table content in the last paragraph of this document.

Indented rows list resulting files when completing that section. All test cases are positioned in test suites: Validation documents and tasks, VTC, or Automatic regression.

Table 1. Documents and test cases to produce and complete.

Doc. No.	Document	Reference	Approved by
1.	Validation plan	TC 18265.	HdQ, PM/PO
2.	Numerical validation	TC 20993.	
	a) usp-file	SIMCA files.	
	b) .xls, xlsx, docx, .txt result-files	Result files from TestComplete.	
	c) .pjs, .scpp	TestComplete related files.	
3.	Validation report	TC 18266.	PM, HdD, HdQ
	a) Report bugs	Azure DevOps bugs mentioned in the **Validation report**.	

Doc. No.	Document	Reference	Approved by
4.	Validation revision	TC 40281.	
5.	Validation risk assessment	TC 21019.[1]	HdQ
6.	Validation package	A compilation of the files produced in steps 1-9.	
	a) Content	Content of the validation package.	

3. Accepting the validation

The validation package is made available to the Product Manager, Head of Development and Head of Quality for revision and acceptance. They will approve the validation report provided that the acceptance criteria are met.

The validation report should hold a summary of the validation work, documentation of the found deviations versus the validation plan, acceptance criteria and conclusions. It should also hold summarizing information concerning outcome of performed validation tasks. All differences, compared to previous version or specification, should be described in detail and include planned action.

Software may not be released with known critical bugs.

The Head of Development and Head of Quality approve the validation by signing the validation report electronically using Azure DevOps.

3.1 Specific acceptance criteria

The acceptance criteria for this version are:

1. **Numerical verification** – vectors for the validation projects are identical to specification.
2. **Verification of bugs** - the bugs listed were verified and test cases added for future verification.

All differences, compared to previous version or specification, should be described in detail and include planned action.

3.2 General acceptance criteria

The general Acceptance criteria are described in detail in Validation phase, paragraph 6.7, in the Quality manual stored in Azure DevOps.

4. Validation process

The validation process will follow the procedure described in the **Validation phase** document in the Quality manual available upon request.

4.1 Validation assessment and validation risk assessment

No validation assessment is carried out. Risk assessment, for changes done that may affect the validation outcome, is carried out and revalidation activities performed.

4.2 Electronic Data/Electronic Signatures

SIMCA®-online creates electronic data. Electronically generated data are defined in Table 2. Electronic Signatures (ES) are handled by the system.

Table 2. Electronic data in SIMCA®-online.

File	File type/Folder	Content
Project	*.usp	File holding dataset spreadsheets, models, and results.

[1] Validation risk assessment is carried out if applicable.

SIMCAonlineserver.ini	Server ProgramData	Settings for the server.
SIMCAonlineserver.log	Server Database	Server log.
SIMCAonlineserver.log.N.bak	Server Database	Server log backup. N is a number from 0 to 9.
System.db	Server Database	Server audit trail, user database.
VarLim.bin	Server Database	Configuration of the variable limits.
*.usp	Server Database	Copy of the original SIMCA project file. Can also be created in SIMCA-online.
*.solproject	Server Database	Summary information of the project.
*.solconfig	Server Database	Summary information of the project configuration.
*.solconfig.db	Server Database	Audit trail and metadata (such as batches and alarms) of the project configuration.
*.sbdb, *.scdb, *.sddb, *.db	Server Database	Internal database files of the project configuration.
SIMCAonlineclient.ini	Client ProgramData	Settings for the client.
SIMCAonlineclient.log	Client AppData	Client log.
SIMCAonlineclient.log.bak	Client AppData	Client log backup.

4.3 Version control

Version control during the validation will be partly applied. Version control is applied throughout the development of the system.

4.4 Handling of issues, logging of errors and actions

Changes and actions that influence the validation progress will be handled but not documented. Such changes can be that other projects take priority and the validation of SIMCA®-online is therefore delayed.

4.5 Operating systems

All validation tasks are performed under Windows 10.

4.6 Prerequisites

SIMCA®-online creates electronic data according to Table 1.

4.7 Exceptions

No validation assessment (note [1)] in **Table 1**) will be carried out.

The validation scope excludes documentation surrounding the software, such as help-file, user guide and onboarding.

User guide/help-file, listed under paragraph 5 Reference documents is available from the website. The user guide holds information concerning the system and no additional documentation will be produced.

4.8 Dependencies

SIMCA®-online is dependent upon SIMCA, which is validated according to its validation plan.

SIMCA®-online is also dependent upon the SimApis which collects data from the external database.

4.9 Revalidation criteria

When a change of the system SIMCA®-online is made during the validation activities, this is handled according to paragraph 4.1.

4.10 Tools

During the validation, the following tools will be used:

- TestComplete and TestExecute from SmartBear Software. Automated testing platform.
- ReadyAPI from SmartBear Software.
- Azure DevOps and Excel from Microsoft.

5. Reference documents

Document	Description
SIMCA®-online help file	User guide in the form of a help-file (.chm-file) is included with the software. The help-file holds information concerning the system. Other documentation such as technical guide and implementation guide are available from the web page.
Validation phase	Describes the validation process.
Quality manual list	Lists all documents in the quality manual. Available upon request.

6. Appendix: Validation traceability matrix details

Description of documents and files in the Validation traceability matrix. The Validation traceability matrix in the appendix is generic and does not indicate which documents and files that are applicable to the version validated.

Doc. No.	Document	Explanation
1.	Validation plan	An overview of the validation of the specific software version. TC 18265.
2.	Numerical validation	Verification of numerical correctness versus previous version or specification. TC 20993.
	a) usp-file	SIMCA file holding the datasets and all models. One .usp for each selection of datasets.
	b) .xlsx, .xls, .docx, .txt result-files	A summary of comparisons made by TestComplete for each configuration. A set of .xlsx-files are saved for each configuration to support future comparisons and is included in the validation package.
	c) .pjs, .scpp	The project suite file (*.pjs) in TestComplete is the main file type for the automatic testing of SIMCA. The actual script.files (*.scpp) are included in the project suite. These files are created, but not included in the validation package.

Doc. No.	Document	Explanation
3.	Validation report	An overview of the performed validation tasks and a conclusion of the outcome. This document includes a description of how the user can verify that the installed software was correctly installed. TC 18266.
	a) Report bugs	Bug descriptions extracted from Azure DevOps of the bugs mentioned in the **Validation report**.
4.	Validation revision	Lists all components to revise.
5.	Validation risk assessment	Validation risk assessment is carried out if applicable. TC 21019.
6.	Validation package	A compilation of the files produced in steps 1-9.
	a) Content	Content of the validation package.

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Risk Assessment for SIMCA-online 17.0.1

2022-06-17 10:22

		Name	Date
Issued by:	Software Quality	Lisa Gabrielsson	2022-06-16
Revised by:	Release Train Engineer	Therese Ringvall	2022-06-16
Approved by:	Head of Quality	Andreas Norén	2022-06-17

Contents

1 Introduction

This document covers the assessment of the risk that the changes made after the SIMCA-online 17.0, build 55175 release, and until SIMCA-online 17.0.1, build 27 affect the validation and quality of the product. The risk assessment covers each commit or merged pull request (when the pull request is for a single self-contained issue) done during this time with regards to potential bugs introduced in the validated parts. The risk assessment was done by Therese Ringvall, RTE, and Lisa Gabrielsson, Senior Software Quality Engineer, in collaboration with the developers introducing changes, and approved by Andreas Norén, Head of Quality.

1.1 Background and objective

The validation activities may be started before the last build. If an introduced change warrants rerun of a task according to the Risk response strategy in the table in paragraph 2.5 Status, the rerun is documented in the table in paragraph 3 Testing and validation tasks.

2 Risk assessment

Th table lists all changes in scope. In the cases where a VTC has been rerun, the last time the rerun was needed is bold in this table, and the build used for the latest run is listed in the table in paragraph 3.

2.1 Risk

Risk is the estimated likelihood for introduced bug. High risk is considered a risk for the release. Medium risk means that there is a risk, but the actions required are limited. Low means that there is no risk that the change introduces a bug. Risk None is for changes that do not affect code and validation.

2.2 Impact

The Impact column lists the estimated impact on the product had the bug remained unfixed. Impact does not reflect impact on the validation. High means that incorrect calculations were found, the software crashes or lacks vital functionality. Medium impact means either business critical or there was an unexpected workflow deemed necessary to improve. Low impact means that not fixing the bug will have little or no impact on the product for the end user. Impact None is for changes that do not affect code and validation.

2.3 Risk response strategy

Accept the risk means that the mandatory actions are performed, that is, the commit will be verified, code reviewed, and automated tests run. Avoid means that, additionally, the risk is eliminated by performing the required actions.

2.4 Actions required

When Risk response strategy is specified as Avoid, the Actions required column lists the actions deemed necessary to perform. When Risk response strategy is Accept the risk, the Action required is None and the mandatory actions, described in the previous paragraph, are performed.

2.5 Status

After the last build of the product, and all required actions have been performed, OK is the expected entry in the Status column, for all Risk response strategy types.

2.6 Risk assessment for individual changes

This table lists all changes in scope. In the cases where a VTC has been rerun, the last time the rerun was needed is bold in this table, and the build used for the latest run is listed in the table in paragraph 3.

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Table 1. Risk assessment

Commit SHA id/PR id and description	Risk (e.g. High, Medium, Low)	Impact (e.g. High, Medium, Low)	Risk response strategy (e.g. Avoid or Accept the risk)	Actions required	Status
SIMCA-online server and desktop client					
Commit 8d4f4376: Merged PR 13246: Fix active batches (after the first batch) not being picked... - Repos (azure.com)	Medium	High	Avoid	**Run VTC: Batch context generator**	OK
Commit 8d5667cf: Merged PR 13095: Keep batches found outside scanRange if batchIDTag is config... - Repos (azure.com)	Medium	High	Avoid	Run VTC: Batch context generator	OK
Commit 397da0db: Merged PR 13097: Do not create 'Activation ID' in the setup program, because... - Repos (azure.com)	Low	Low	Accept the risk	None	OK
Commit f91d8e70: Merged PR 12979: Add special case for 17.0.1 so that it still gets installed... - Repos (azure.com)	Low	Low	Accept the risk	None	OK
Commit df7adf70: Merged PR 12870: Fix: no longer incorrectly save ALL alarms for active and ov... - Repos (azure.com)	Low	High	Avoid	**VTC Overview - Production overview batch (Desktop)**	OK

Commit SHA id/PR id and description	Risk (e.g. High, Medium, Low)	Impact (e.g. High, Medium, Low)	Risk response strategy (e.g. Avoid or Accept the risk)	Actions required	Status
Commit 1a462654: Merged PR 12759: Filtered batch level variables incorrectly displayed in SOL... - Repos (azure.com)	Low	Medium	Accept the risk	None	OK
Commit 580aef97: Merged PR 12594: Batch Context Generator bug fixes... - Repos (azure.com)	Medium	High	Avoid	Run VTC: Batch context generator	OK
Commit 79b7588f: Merged PR 12750: Validate is same document for ScoresPropertyGroup as it coul... - Repos (azure.com)	Low	Low	Accept the risk	None	OK
Commit 66f15e3a: Merged PR 12546: Fix variable list bug and bump version to 17.0.1... - Repos (azure.com)	Low	Low	Accept the risk	None	OK
NC-lib					
Commit 9af4c877: Merged PR 12751 and Merged PR 11820: fix for filtered batch level datasets in... - Repos (azure.com)	Low	Medium	Accept the risk	None	OK

3 Testing and validation tasks

The tasks performed before the release SIMCA-online are listed below with information about which build they were executed on.

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Table 2. Tasks with execution details

Order	ID	Title	Tester	Run on build
1	18237	VTC: Batch context generator	Lisa Gabrielsson	27
2	25785	VTC Overview - Production overview batch (Desktop)	Lisa Gabrielsson	27
3	33888	Automatic regression - Audit trail – ERES	Lisa Gabrielsson	27
4	33890	Automatic regression – Reset Alarms Web	Lisa Gabrielsson	27
5	33887	Automatic regression - Group permissions	Lisa Gabrielsson	27
6	33889	Automatic regression – Python filter	Lisa Gabrielsson	27
7	20993	Numerical validation	Lisa Gabrielsson	27