

## SIMCA®-online

Validation plan and report SIMCA-online 16.1.1

2020-06-30 08:33

		<b>Name</b>	<b>Initial</b>	<b>Date</b>
Issued by:	Software quality	Lisa Gabrielsson	LG	2020-06-18
Reviewed by:	Software quality	Anders Lindegren	ALi	2020-06-22
	Program manager, PM	Therese Ringvall	TR	2020-06-22
Approved by:	Product manager/owner, PO	Jonas Elfving	JE	2020-06-29
	Head of Development	Jonas Andersson	JA	2020-06-30
	Head of Quality, HdQ	Andreas Norén	AN	2020-06-29



## Contents

1.	Introduction and background.....	3
1.1	Overview of the System.....	3
2.	Validation activities/tasks.....	3
3.	Accepting the validation .....	3
4.	Validation conclusion.....	3
5.	Validation procedure details .....	4
5.1	Validation process .....	4
5.1.1	Validation assessment and validation risk assessment.....	4
5.1.2	Electronic Data/Electronic Signatures.....	4
5.1.3	Version control.....	4
5.1.4	Validation traceability matrix .....	4
5.1.5	Exceptions.....	4
5.1.6	Dependencies .....	4
5.1.7	Revalidation criteria.....	4
5.1.8	Source code.....	4
5.1.9	Routines .....	4
5.1.10	Bug handling.....	4
5.1.11	Acceptance criteria.....	4
5.1.12	Tools.....	5
6.	Verification of installed software .....	5
7.	Electronic data in SIMCA-online.....	5
8.	Reference documents.....	6



## 1. Introduction and background

This document describes the validation plan, tasks and report listing the outlined validation tasks, activities performed and their results.

The validation activities are outlined in conformance with the QMS. The outlined test and validation activities aim to build in quality activities early in the life cycle of the software development, to build confidence throughout the development by testing/validating activities in the different layers of the software architecture (test matrix) in a combination of unit testing, integration testing, system testing, and exploratory testing.

SIMCA-online 16.1.1 (version 16.1.1.16164) will be numerically validated versus specification according to paragraph 2. This patch validation complements the validations of SIMCA-online 16 (version 16.0.0.9953) and 16.1 (version 16.1.0.12741).

The validation is performed by the Software quality group at Sartorius Data Analytics.

### 1.1 Overview of the System

SIMCA-online stores data electronically at a, by the user, specified location and according to the table in paragraph 7.

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 activities/tasks

For SIMCA-online, the validation tests are scripted. Each test is verified versus specification. This specification is created separately and verified for correctness before qualifying to be used in the validation.

The scope of the validation tasks is revised by the Product Manager and the Head of Quality during the development life cycle and approved to be used to build up the validation report.

The validation plan and report (this document) is published for each release. The validation life cycle and its activities are automatically completed when the below criteria are met and passed without deviations:

1. Data analytics correctness – all vectors for the reference validation datasets verified correct according to specification.
2. Use cases validating the key user workflows:
  - a. Audit trail logs actions
3. Verification of fix for bug 28148 – Batch Context Generator locks server for all clients and can cause client error messages.

All identified deviances from expected test results found during the validation life cycle that remain in the released software are reported, classified according to criticality, and included in this document.

## 3. Accepting the validation

The Product Manager, Head of Development and Head of Quality approve and accept the validation when the approved validation activities/tasks have passed according to each acceptance criteria for the final build.

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

## 4. Validation conclusion

All bugs found during this development life cycle that remain not fixed were considered unimportant and therefore not fixed.

All differences that require a corrective action are stored in the bug database and referenced in this document.

None of the found differences are serious. The performed quality activities throughout the life cycle of the software development, in accordance with the outlined testing and validation strategy (test matrix) in the QMS, builds confidence and secures that the requirements according to specification are met, and that SIMCA-online 16.1.1 gives correct results and is reliable.



## 5. Validation procedure details

### 5.1 Validation process

The validation process follows the procedure described in the **Validation phase** document in the QMS available upon request.

#### 5.1.1 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.

#### 5.1.2 Electronic Data/Electronic Signatures

SIMCA-online creates electronic data. Electronic Signatures (ES) are handled by the system.

#### 5.1.3 Version control

Version control is applied throughout the development of the system.

#### 5.1.4 Validation traceability matrix

Table 1 shows the documents, files and test cases with validation tasks that will be produced and completed during the validation life cycle of SIMCA-online 16.1.1.

All documents are continuously reviewed to be kept up to date. 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.

**Table 1. Documents to produce and complete.**

Doc. No.	Document	Approved by
1.	Validation plan and report	HdQ, PM, HdD
	a) Report bugs	
2.	Validation risk assessment	HdQ

#### 5.1.5 Exceptions

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

User guide/help-file listed under paragraph 8 is made available. The user guide holds information concerning the system and no additional documentation will be produced.

#### 5.1.6 Dependencies

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

#### 5.1.7 Revalidation criteria

When a change of the system SIMCA-online is made during the validation activities, this is handled according to paragraph 5.1.1.

#### 5.1.8 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.

#### 5.1.9 Routines

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

#### 5.1.10 Bug handling

Work items describing bugs found during the development life cycle are stored electronically in the bug database.

#### 5.1.11 Acceptance criteria

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



### 5.1.12 Tools

During the validation, the following tools are used:

- TestComplete and TestExecute from SmartBear Software. Automated testing platform.
- Team Foundation Server, TFS, and Excel from Microsoft.

## 6. 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**, verify that the version is SIMCA-online 16.1.1.16164.
2. Open one of the .pdfs in the Graphical validation folder in the full validation of SIMCA-online (16.0.0.9953).
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 the main menu, About, and verify that the version is SIMCA-online Web Client 16.1.0.11996.
4. Open one of the trend plots. The plots should content wise be identical.

## 7. Electronic data in SIMCA-online

Table 2. Electronic data in SIMCA-online.

Data/File	File type/Folder	Content
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.



Data/File	File type/Folder	Content
*.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.

## 8. Reference documents

Document	Description
SIMCA-online help file	(User guide) is included with the software. The help-file holds information concerning the system. Other documentation 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.

