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### Content

1	Introduction.....	2
2	Validation Report Summary.....	2
2.1	Validation Package Content.....	2
3	Validation Task Results.....	2
3.1	Data Analytics Correctness – Desktop Numerical.....	2
3.2	Data Analytics Correctness – Desktop Graphical.....	2
3.3	Data Analytics Correctness – Web API .....	2
3.4	Automated Regression.....	3
3.5	New Functionality.....	3
4	Verification of Installed Software.....	3
5	Validation Conclusion .....	3
6	Approval of validation and release to customer.....	3



## 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 listed in the Validation plan.

## 2 Validation Report Summary

The Validation plan defines the validation tasks to perform. The results from the validation tasks are included in the validation package and all found differences requiring a corrective action are listed under paragraph 3.

### 2.1 Validation Package Content

The validation package includes files and folders as follows:

- Validation Report - This document
- Validation Plan - Scope of the validation
- Risk Assessment - Risks and mitigations
- Validation Task Results - Results from the validation activities
- Validation of New Functionality Summary - Overview over the features/user stories implemented. Details are found in the 'New functionality' folder.
- Validation Projects and Models - Details about the projects and models used in the validation.
- Defects folder - Lists details for defects fixed for the release.
- Verification of installed software folder - Holding projects and other files for installation verification. The full setup of validation projects can be delivered upon request.
- New functionality folder - New functionality and improvements have been validated and available in a folder named 'New functionality' in the validation package.
- Regression and numerical validation folder - Holding the results to the numerical comparisons.
- Automatic regression folder - Holding the results from the automated workflow validated.

## 3 Validation Task Results

The numerical validation of SIMCA-online 18 was done versus SIMCA-online 17.0.3 and the current specification, using TestComplete under Windows 10. The outcome is included in the validation package. Differences due to rounding are not listed.

No differences that require a corrective action were found.

Regression tests were completed as listed in the table in paragraph 3 in the Risk assessment document.

### 3.1 Data Analytics Correctness - Desktop Numerical

In the numerical comparison versus SIMCA-online 17, no differences that require a corrective action were found.

In the numerical comparison versus SIMCA 18, no differences that require a corrective action were found.

In the numerical comparison versus specification, no differences that require a corrective action were found.

### 3.2 Data Analytics Correctness - Desktop Graphical

In the graphical comparison of plots versus SIMCA-online 17, no differences that require a corrective action were found.

### 3.3 Data Analytics Correctness - Web API

In the numerical verification of the Web API used in the SIMCA-online web client, no differences that require a corrective action were found.



## 3.4 Automated Regression

In the automated regression, covering audit trail and Python preprocessing plugin, no differences requiring a corrective action were found.

## 3.5 New Functionality

New functionality described in features closed during the development of SIMCA-online 18 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:

In SIMCA-online, click **File | Help** and under About SIMCA-online, verify that the version is SIMCA-online 18.0.0.226.

1. In the Verification of installed software folder, find folders:
  - a. Sovring for continuous and
  - b. Lubrizolow for batch.
2. Upload the selected project in the software, and configure using the .bcg-file.
3. Import the DBMaker-files as database and let it provide data.
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 executing, 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 18.0.0 (build 820).
4. Open one of the trend plots. The plots should content wise be identical.

## 5 Validation Conclusion

All defects found during this development life cycle that remain unsolved were considered noncritical to the user of the system and therefore remain open.

All deviations compared to specifications are stored in the defect database. There are no known serious deviations.

The performed quality activities throughout the life cycle of the software development, in accordance with the outlined testing and validation strategy in the Quality Management System (QMS), secures that the requirements perform according to specification and that SIMCA-online 18 gives correct results and is reliable.

## 6 Approval of validation and release to customer

When all activities have passed according to acceptance criteria for the final build/package, the Product Manager, Head of Development and Manager of Quality Assurance sign the Release and Validation approval document to approve the release to customer and to approve the validation report via validation conclusion.

