Validation plan and report for MODDE 13 2021-02-16 17:38

		Name	Initial	Date
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Contents

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.

MODDE 13 will be validated versus specification.

1.1 Overview of the System

MODDE stores data electronically at a, by the user, specified location. While running MODDE, temporary data are also stored in a temporary directory on the local hard drive.

2. Validation activities/tasks

The validation plan and report (this document) is published for each release.

2.1 Planned activities and tasks

For MODDE, a selection of numerical validation tests are automatically run with each build. Each numerical test has been verified versus specification. This specification was created separately and verified for correctness before qualifying to be used in the validation.

The validation life cycle and its activities are automatically completed when the below criteria are met and passed without serious deviations:

1. Requirements – the listed features execute according to specification.
2. Unit tests – function/numerical verification.
3. System/integration test – numerical verification.
4. Use cases – scenario scripts validating key user workflows.
5. Data analytics correctness – all plots, vectors and lists for the reference validation investigations execute correctly according to specification.

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.

2.2 Validation task results

This section summarizes the results from the performed validation tasks. Differences due to intentional changes introduced during the development are listed in **MODDE 13 Validation task results**.

2.2.1 Numerical comparison

In the numerical comparison of MODDE 13 versus specification using TestComplete, MATLAB and Excel, no differences were found.

The COM interface was numerically validated versus specification using MODDECompare, no differences were found.

2.2.2 Graphical comparison

In the graphical comparison of plots and lists versus MODDE 12.0, no differences requiring a corrective action were found.

2.2.3 MODDE-Q functionality

MODDE-Q was numerically validated versus specification using MODDECompare. No differences were found.

2.2.4 New functionality

New functionality, described in user stories closed during the development of MODDE 13, was validated. The results can be found in **Validation of new functionality summary**, with references to the validation test cases, and the New

functionality folder. The Validation test case results file is a pdf-printing of the validation test case runs, while the feature named documents and folders hold complementing documentation and projects.

The differences found are listed below:

No.	Feature	VTC	Scenario	Description of bug	Action
1.	26542 New design wizard	27569 VTC: New design wizard	Scenario: Response definition dialog entries show in spreadsheet (Step 3)	The entries on the Power page in the Response definition dialog cannot be seen in the Response list. Bug 29097.	This is not important for the feature. May be fixed in a future release.
2.	26542 New design wizard	28304 VTC: Design selection and new defaults	Scenario: Recommendation is the three designs with lowest number of runs among those that fulfill the criteria (Step 3)	The definitive screening design does not end up among the Recommended designs even though it has fewer Total runs than one of the three designs there. Bug 29084.	This is not important for the feature. May be fixed in a future release.
3.	Feature 25595: Response specification	26515: VTC Response criteria	Scenario: Optimizer Response list calculated limits correctness - REQUIRED	All calculated limits are correct. The automatic update of the Objective for responses that lack Min and Max results in 'Inside' instead of the user defined objective. Bug 30854.	This is not important for the feature. May be fixed in a future release.
4.	Feature 23989 Optimization wizard	26565 VTC Optimization wizard	Scenario: Optimization wizard with derived responses	Bug 29104. Setpoint comparison plot opened, it only displays the regular responses, not the derived.	This is not important for the feature. May be fixed in a future release.

2.2.5 Regression

The Audit Trail is implemented in compliance with rules for keeping electronic records (CFR part 11), logging all events in a project/investigation for each and all sessions. The registered actions were verified versus specification.

The differences found are listed below:

No.	Feature	VTC	Scenario	Description of bug	Action
5.	Audit trail	26458 VTC: Audit trail in MODDE	Scenario: Response change (Step 9)	The change is registered as a Factor change. Bug 30856.	This is not important for the feature, but is likely to be fixed in a future release.

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 are 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, secures that the requirements perform according to specification and that MODDE 13 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

MODDE creates electronic data. Electronic Signatures (ES) are not 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 MODDE 13.

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	Reference	Approved by
1.	Validation plan and report	**Approval of this document approves the validation for release.** TC 29040.	PM/PO, HdD, HdQ
	a) Report bugs	Deviations from the specification	
2.	Numerical validation	TC 20993.	
	a) mip-file	MODDE files.	
	b) .xls, xlsx, docx, .txt result-files	Result files from MODDECompare and TestComplete	
3.	Graphical validation	TC 19969, 19972.	
	a) Content…	Content graphical validation.	
	b) Plot files	Plots for graphical validation.	
4.	Validation of new functionality summary	TC 18289.	HdQ
	a) .xlsx-file, .m-file	Calculation files if applicable.	
	b) VTC	All in Test suite VTC with Suite ID 26508.	HdQ, PM/PO
	c) VTC log	Result from running the VTC.	
5.	Validation of MODDE-Q	TC 29098.	HdQ
	a) .stg-file	Settings-files to create validation .mips.	
	b) .dif-file, *.txt	Result files.	
6.	Projects, models	TC 21036.	
7.	Validation task results	TC 18267.	HdQ

Doc. No.	Document	Reference	Approved by
	a) Task results bugs	Bugs reports mentioned in **Validation task results**.	
8.	Validation revision	TC 28971.	
9.	Validation risk assessment	TC 21019.[1]	HdQ
10.	Validation package	A compilation of the files produced in steps 1-10.	
	a) Content	Content of the validation package.	

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 7 is made available. The user guide holds information concerning the system and no additional documentation will be produced.

5.1.6 Dependencies
MODDE is completely independent software.

5.1.7 Revalidation criteria
When a change of the system MODDE 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.
- Azure DevOps and Excel from Microsoft.
- MODDECompare written by Sartorius Data Analytics. Compares data extracted from MODDE and MODDE-Q using the COM-interface to data extracted from the user interface.
- MATLAB from Mathworks.

5.1.13 Operating systems
All validation tasks are performed under Windows 10.

6. Verification of installed software
To verify that your license of the software has been correctly installed follow the instruction here:

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

1. In MODDE, click **File | Help** and under About MODDE ..., verify that the version is MODDE 13.0.0.24874.
2. Open one of the .pdfs in the Graphical validation folder.
3. Open the corresponding investigation in the software, found in the Projects folder.
4. Create and compare one of the 2D plots (column, line, or scatter) and one 3D plot (3D scatter, response surface, or wavelet power spectrum). The plots should content wise be identical.

7. Reference documents

Document	Description
MODDE help file	(User guide) is included with the software. The help-file holds information concerning the system. No additional documentation will be produced. Other documentation is available from the web page.
Validation phase	Describes the validation process.
Quality manual list	Lists all documents in the quality manual. Available upon request.

8. 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 and report	An overview of the validation plan and the performed validation tasks including conclusion and report for the specific software version. This document includes a description of how the user can verify that the installed software was correctly installed. TC 29040. **Approval of this document approves the validation for release.**
	a) Report bugs	Bug descriptions extracted from the bug database of the bug reports mentioned in the **Validation plan and report**.
2.	Numerical validation	Verification of numerical correctness versus previous version or specification. TC 20993.
	a) mip-file	MODDE file holding the factors, responses, worksheet, and other investigation data.
	b) .xlsx, .xls, .docx, .txt result-files	A summary of comparisons made by MODDECompare or TestComplete for each project.
3.	Graphical validation	Verification of correctness of plots versus previous version or specification. TC 19969, 19972.
	a) Content...	A file showing which copied plots are included in the graphical validation.
	b) Plot files	Files holding the printed-to-pdf plots in the graphical validation for the specific project and model.
4.	Validation of new functionality summary	A document listing the implemented features including a summary of the validation results. TC 18289.
	a) .xlsx-file, .dif-file	New vectors are calculated from the specification either in Matlab or in Excel. The result is saved in an excel-file or a .dif-file to compare against in the future.
	b) VTC	PDF of the executed the Validation Test Cases (VTC) for the new features. All in Test suite VTC with Suite ID 26508.
	c) VTC log	Result log from running the VTC.

Doc. No.	Document	Explanation
5.	Validation of MODDE-Q	Verification of numerical correctness in MODDE-Q versus specification. TC 29098.
	a) .stg-file	Settings-files holding all properties necessary to create validation .mips matching the .mips created in point 2a.
	b) .dif-file	Result-files.
6.	Projects, models	A document describing the projects and models selected for the validation. TC 21036.
7.	Validation task results	A summary of the outcome of points 2-4. TC 18267.
	a) Task results bugs	Bug descriptions extracted from the bug database of the bugs mentioned in **Validation task results**.
8.	Validation revision	Lists all components to revise, TC 28971.
9.	Validation risk assessment	Validation risk assessment is carried out if applicable. TC 21019.
10.	Validation package	A compilation of the files produced in steps 1-10.
	a) Content	Content of the validation package.