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Validation Report MODDE® 13.1

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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.

This partial validation complements the full validation of MODDE 13 (version 13.0.0. 24875).

2 Validation Report Summary

The Validation plan defines the validation tasks to perform. The results from the validation tasks, executed under Windows 10, are included in the validation package. Any 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 in the release.
- Investigations folder The MODDE investigation files (.mips) used during the validation.
- MODDE-Q folder Files and documentation connected to the MODDE-Q 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 results to the numerical comparisons.
- Regression folder Holding the results from the automated workflows validated.

3 Validation Task Results Summary

The numerical validation of MODDE 13.1 was done versus MODDE 13, and thus the current specification, using TestComplete and MODDECompare 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. Testing and validation tasks in the Risk assessment document.

3.1 Data Analytics Correctness

In the numerical comparison versus MODDE 13, no differences that require a corrective action were found.

3.2 MODDE-Q Functionality

MODDE-Q was numerically validated versus MODDE using MODDECompare. No differences that require a corrective action were found.

3.3 Automated Regression

In the automated regression included in the Automated regression folder, no differences requiring a corrective action were found.

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3.4 New Functionality

New functionality described in features closed during the development of MODDE 13.1 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:

- 1. In MODDE, click File | Help and under About MODDE, verify that the version is MODDE 13.1.0.687
- 2. Open one of the .pdfs in the Graphical validation folder in the full validation of MODDE 13.
- 3. Open the corresponding investigation in the software, found in the Investigations folder of the full release.
- 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.

To verify that your license of the software has been correctly installed follow the instruction found below:

- 1. Browse to the folder where MODDE-Q was installed (e.g. C:\Program Files\Umetrics\MODDE-Q 13\lib).
- 2. In Properties | Details for MODDE-Q.dll, verify that the version is MODDE 13.1.0.687.

5 Validation Conclusion

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

All deviations compared to specification that require a corrective action are stored in the defect database with details about the planned action.

None of the deviations found are serious.

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 MODDE 13.1 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.