RJG

MOLD SMART

Validation Summary Report: 2025-001

For CoPilot® Software Version 10.2.1 (Application Processor 4.0 (AP4.0) Hardware), and The Hub® Version 10.2.1

1. PURPOSE

The purpose of this document is to outline the protocol that was used to complete the design, installation, operational and performance qualification for the implementation of injection molding auxiliary hardware and software.

2. BACKGROUND

RJG Inc. wished to continue its commitment to the healthcare industries by supplementally validating the CoPilot software version 10.2.0 (Application Processor 4.0 (AP4.0), and The Hub version 10.2.0, as some of the targeted customers for this product would include Medical/Pharmaceutical molders, contract manufacturers, and device manufacturer OEMs. The products' intended users are anywhere from small to large part, and single to high cavitation molds. Prior to CoPilot software version 10.2.0, RJG Inc. has released previous validated version (10.0.0). This is the reasoning behind the risk-based testing approach (GAMP®5) to the testing involved in this supplemental validation. Due to a software code update, found in deviation #1 for 10.2.1 release, this release was revved from 10.2.0 to 10.2.1.

3. SCOPE

The scope of this document is limited to the Protocol DQ/IQ/OQ/PQ of the RJG Inc. CoPilot software version 10.2.0 (Application Processor 4.0 (AP4.0), and The Hub version 10.2.0 in English translation only at this time.

The following applications/functions represent the typical installation and are included in the scope of this validation.

COPILOT SYSTEM

• Control Tools: Alarm Settings, V→P Transfer, Excessive Rejects, Inject Enable and Valve Gate Control
• Setup Tools: Mold Setup, Machine Setup, Process Setup, Template Match tolerances, Set Screw Bottom
• Analysis Tools: Templates, Template Match
• General System Tools: Security, Cross-Copy
• Communication Between Sensors and CoPilot System(s)
• System Wide Units
• Summary Variable Calculation

SENSORS

• Lynx Stroke, Hydraulic, Strain Gage Button, Strain Gage Sensor Adapter, Piezo Adapter
• Sequence Input Module, Relay Output Module, Analog Input Module, Analog Output Module
• Serial Interfaces: Temperature Control Units

Note that a maximum of 30 sensors per CoPilot System port may be used.

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THE HUB SOFTWARE

- Security Tools: User Assignment and User Roles
- Data Storage: Database Storage
- System Wide Units
- Mold Transfer Software: Mold to Machine Match, Process Sheet Conversion, Machine Setup Sheet Conversion
- The Hub Job Report
- The Hub Job Data Backup
- The Hub Archiving Records
- The Hub Part Samples
- The Hub Critical to Quality Characteristics

3.1. Not in scope for this validation:

3.1.1. Using MAX, the Process Advisor™ within the CoPilot software could leave the customers process in a non-validated state.

3.1.2. Heat and Cool feature within the CoPilot software.

3.1.3. Information Technology (IT) Security for The Hub as it is recommended to be housed on customers networks.

3.1.4. Using The Hub Connect, OPC UA for communication with other systems.

3.1.5. Using The Hub Restful API for communication with other systems.

3.1.6. RJG Inc. eDART® capabilities, hardware, and software.

4. RESPONSIBILITES

4.1. PROJECT TEAM is responsible for risk assessments, and risk-based test planning.

4.2. SME is responsible for working with Product Compliance and Quality to facilitate validation.

4.3. TESTING PERSONNEL are responsible for participating in the validation to test the required test plan and reporting the results.

4.4. PRODUCT COMPLIANCE is responsible in the validation to adhere to the standard practices and requirements of medical/pharmaceutical entities.

4.5. QUALITY will be responsible for reviewing and approving all final validation materials for adherence to this protocol.

5. EXECUTIVE SUMMARY

The validation was based on the following activities:

- Formal in-house testing of a typical configuration with all applications running.
- Formal User Acceptance Testing
- Formal Regression Test Results of CoPilot System v10.2.1 and The Hub Software v10.2.1

• Analysis of RJG's internal SPR (Software Problem Report) database

FORMAL IN-HOUSE TESTING

For formal in-house testing, formal test plans were prepared for each application within the scope of the validation. Test plans were written using the "CoPilot System URS and The Hub Software URS" as defined for each feature/function as the primary basis. Test plans, specification documentation, and a summary of test cases are kept on file at RJG, Inc.

During testing, a typical configuration was chosen to represent a typical installation, as follows:

• Seven CoPilot Systems connected by an Ethernet network with cross-copy enabled, and with The Hub Software server connected to the network.

• Five sensors per machine (stroke, hydraulic, ID7-M-SEQ sequence input, OR2-M relay output, and OA1-M-V analog output).

• Required sequence inputs: Injection Forward, 1st Stage, Screw Run and Mold Clamped

• Minimum two sensors per mold.

• All applications running during the test (regardless of the test focus)

Deviations from this configuration were made as necessary to evaluate the functionality of the system, generally by adding or removing sensors and sequence inputs to evaluate system stability under extreme conditions. Test results were documented and summary reports generated for each application. Test records and summary reports are maintained on file at RJG, Inc.

ASSESSMENT OF OVERALL SOFTWARE QUALITY

Over 100 CoPilot Systems at over 12 customer sites have been in the field for nearly three years, and currently the system proves to be quite stable. This is due in part to the rigorous Alpha Test Plans and Regression Test Plans Implemented by RJG for each Software Release. Each CoPilot System software version is released based on these test plans.

RECOMMENDATIONS

To provide the highest level of system stability and performance, the following recommendations are made to users:

• All hardware installation and software configuration recommendations should be followed using the following: *CoPilot System Hardware Installation Checklist, CoPilot System Machine Sensor and Module Configuration Checklist, CoPilot System Mold Sensor Configuration Checklist, and CoPilot System and The Hub Software Networking Checklist*. Reliable sequence inputs must be available, with Injection Forward; 1st Stage, Screw Run, and Mold Clamped provided at a minimum.

• Users should verify that all sensors used are within the scope of the validation. In particular, the maximum number of cavity pressure sensors should not exceed 30 per CoPilot System port for a typical installation (30 sensors per port includes all

mold sensors and machine sensors connected to the CoPilot System). For example, a 64-cavity mold with a sensor in each cavity will require two CoPilot System devices.

• When using V→P Transfer to control transfer on the press, the user must ensure that adequate safety backups are set on the press in the event that communication with the CoPilot System is interrupted.

• Ensure that Failsafe Sorting is selected by assigning an OR2-M as Good Control.

• The CoPilot System is validated for use only in English with a US English keyboard layout.

- Through the software validation activities reported here, RJG, Inc. has made every attempt to assess and report on the quality of the CoPilot System software to the best of our ability. However, it is possible that other issues are present which have not been discovered here. It is important for users to implement appropriate safeguards as necessary.

6. DEVIATIONS

6.1. Deviation Listing for 10.2.1 Release

6.1.1. Deviation #1- (Test FC-25946 CoPilot IQ) (Risk Assessed = Low)

- Previous cycle values widget fails to show current summary variables and values after "Pack Time" is able to be calculated.
- Corrective Action Implemented- Software update allowing the refresh after the pack time summary value starts to calculate due to enabling "Fill Volume at Cursor".
- Result of retest- Pass.

6.1.2. Deviation #2- (Test FC-25990 Hub IQ) (Risk Assessed = Low)

- Missing preconditions
- Added precondition that user needs to be logged in.
- Result of retest- Pass.

6.1.3. Deviation #3- (Test FC-25967 CoPilot IQ) (Risk Assessed = Low)

- Missing test step
- Corrective Action Implemented- Added step to inform the tester how to have the updating screen populated.
- Result of retest- Pass.

6.1.4. Deviation #4- (Test FC-25968 CoPilot IQ) (Risk Assessed = Low)

- Missing test step
- Corrective Action Implemented- Added step to inform the tester how to have the updating screen populated.
- Result of retest- Pass.

6.1.5. Deviation #5- (Test FC-25996 CoPilot IQ) (Risk Assessed = Low)
- Missing test step
- Corrective Action Implemented- Added step to inform the tester how to have the updating screen populated.
- Result of retest- Pass.

6.1.6. Deviation #6- (Test FC-25955 CoPilot OQ) (Risk Assessed = Low)
- Missing preconditions for advanced settings.
- Corrective Action Implemented- Added preconditions for advanced settings.
- Result of retest- Pass.

6.1.7. Deviation #7- (Test FC-25965 CoPilot OQ) (Risk Assessed = Low)
- Missing step
- Corrective Action Implemented- Added step for how to access copilot remotely.

6.1.8. Deviation #8- (Test FC-25954 CoPilot OQ) (Risk Assessed = Low)
- Test step needs revision for Integration Period Timing setting.
- Corrective Action Implemented- Revised test step to have the Integration Period Timing set to "Start of Injection" to a time value that is occurring before peak cavity pressure is hit, to see a difference in calculated values.
- Result of retest- Pass.

6.2. **Deviation Listing for 10.0.0 Release**

6.2.1. Deviation #1- (Test FC-21238 CoPilot IQ) (Risk Assessed = Low)
- Summary graph missing when user navigates away.
- Corrective Action Implemented- Software patch.
- Result of retest- Pass.

6.2.2. Deviation #2- (Test FC-21642 Hub IQ) (Risk Assessed = Low)
- Hub landing page does not match pictorial reference due to software update after test was created.
- Corrective Action Implemented- Updated testing parameters to reflect software update.
- Result of retest- Pass.

6.2.3. Deviation #3- (Test FC-24126 CoPilot OQ) (Risk Assessed = Low)
- Out of date process will no longer be automatically loaded on the CoPilot.
- Corrective Action Implemented- Updated testing parameters to reflect software update.
- Result of retest- Pass.

6.2.4. Deviation #4- (Test FC-21401 CoPilot OQ) (Risk Assessed = Low)
- Cancellation of the part sample feature will no longer direct user to the part sample setup screen.
- Corrective Action Implemented- Updated testing parameters to reflect software update.
- Result of retest- Pass.

6.2.5. Deviation #5- (Test FC-21528 CoPilot OQ) (Risk Assessed = Low)
- Using part sample and excessive rejects the notification remains displayed
- Corrective Action Implemented- Updated testing parameters to reflect software update.
- Result of retest- Pass.

6.2.6. Deviation #6- (Test FC-21882 Hub OQ) (Risk Assessed = Low)
- Missing preconditions to specify CTQ Characteristics.
- Corrective Action Implemented- Preconditions added.
- Result of retest- Pass.

6.2.7. Deviation #7- (Test FC-21884 Hub OQ) (Risk Assessed = Low)
- Missing preconditions to specify CTQ Characteristics.
- Corrective Action Implemented- Preconditions added.
- Result of retest- Pass.

6.2.8. Deviation #8- (Test FC-21844 Hub OQ) (Risk Assessed = Low)
- Part samples widget has a "Type" not called out in the expected results.
- Corrective Action Implemented = updated testing parameters to reflect software update.
- Result of retest- Pass.

6.2.9. Deviation #9- (Test FC-21536 CoPilot OQ) (Risk Assessed = Low)
- Missing several steps in the test.
- Corrective Action Implemented- Added testing steps.
- Result of retest- Pass.

6.2.10. Deviation #10- (Test FC-21535 CoPilot OQ) (Risk Assessed = Low)
- Missing several steps in the test.
- Corrective Action Implemented- Added testing steps.
- Result of retest- Pass.

6.2.11. Deviation #11- (Test FC-21824 Hub OQ) (Risk Assessed = Low)
- Test missing preconditions for taking a part sample.
- Corrective Action Implemented- Preconditions added.
- Result of retest- Pass.

6.2.12. Deviation #12- (Test FC-21803 Hub OQ) (Risk Assessed = Low)
- Test missing preconditions for taking a part sample.
- Corrective Action Implemented- Preconditions added.
- Result of retest- Pass.

6.2.13. Deviation #13- (Test FC-21885 Hub OQ) (Risk Assessed = Low)
- Test missing preconditions for taking a part sample.
- Corrective Action Implemented- Preconditions added.
- Result of retest- Pass.

6.2.14. Deviation #14- (Test FC-21883 Hub OQ) (Risk Assessed = Low)
- Test missing preconditions for taking a part sample.
- Corrective Action Implemented- Preconditions added.
- Result of retest- Pass.

6.2.15. Deviation #15- (Test FC-21843 Hub OQ) (Risk Assessed = Low)
- Test missing preconditions for taking a part sample.
- Corrective Action Implemented- Preconditions added.
- Result of retest- Pass.

6.3. Deviation Summary

6.3.1. This validation release 10.2.1 included 8 total Low Risk deviations (five Installation Qualification tests, and three Operational Qualification tests). All deviations were retested following the corrective action implemented, with passing statuses.

6.3.2. The validation release 10.0.0 included 15 total Low Risk deviations (two Installation Qualification tests, and 13 Operational Qualification tests). All deviations were retested following the corrective action implemented, with passing statuses.

7. DESIGN QUALIFICATION (DQ)

Design Qualification is considered as a documented demonstration that focuses on various specifications including user requirement, functional, operational and vendor. This included software TEST EXECUTION CoPilotv8.9.0 UAT Software Testing Prior To CoPilot system version 10.0.0 and The Hub version 10.0.0 for an understanding of the current state of the software. Test records and summary reports are maintained on file at RJG, Inc.

7.1. 10.0.0 Release DQ Testing Results (Jira FC-19150 CoPilot, Jira FC-19153 The Hub)

7.1.1. All Testing Passed.

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8. INSTALLATION QUALIFICATION (IQ)

Installation Qualification consisted of risk-based testing based on criticality and complexity of all User Requirement Specifications (URS), CoPilot and The Hub. Location of RJG equipment used in this validation reside in Kannapolis, NC Rowan Cabarrus Community College (RCCC) and Traverse City, MI RJG Inc. Test records, summary reports, equipment calibration, and features risk assessment are maintained on file at RJG, Inc.

8.1. 10.2.1 Release IQ Testing Results (Jira FC-25992 CoPilot, Jira FC-25994 The Hub)

8.1.1. 27 Installation Qualification tests executed with five deviations documented and retested following the implementation of corrective actions. All tests are now passing.

8.1.2. 25.5 hours were recorded for the IQ portion of this validation.
- 16.5 hours testing.
- 9 hours of support.

8.2. 10.0.0 Release IQ Testing Results (Jira FC-20844 CoPilot, Jira FC-21592 The Hub)

8.2.1. 205 Installation Qualification tests executed with two deviations documented and retested following the implementation of corrective actions. All tests are now passing.

8.2.2. 98 hours were recorded for the IQ portion of this validation.
- 60 hours testing (10 hours for six testers).
- 38 hours of support.

9. OPERATIONAL QUALIFICATION (OQ)

Operational Qualification verified that the software and hardware worked as intended. The Operational Qualification (OQ) rationale was to evaluate the user experience and the effectiveness the product provides. This OQ consisted of risk-based testing, as well as testing the control limits built into the software. Location of RJG equipment used in this validation reside in Kannapolis, NC Rowan Cabarrus Community College (RCCC) and Traverse City, MI RJG Inc. Test records and summary reports are maintained on file at RJG, Inc.

9.1. 10.2.1 Release OQ Testing Results (Jira FC-25993 CoPilot, Jira FC-25995 The Hub)

9.1.1. 23 Operational Qualification tests executed with three deviations were documented and retested following the implementation of corrective actions. All tests are now passing.

9.1.2. 26.5 hours were recorded for the IQ portion of this validation.
- 16.5 hours testing.

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- 10 hours of support.

9.2. Results (Jira FC-20844 CoPilot, Jira FC-21592 The Hub)

9.2.1. 214 Operational Qualification tests executed with 13 deviations were documented and retested following the implementation of corrective actions. All tests are now passing.

9.2.2. 147 hours were recorded for the OQ portion of this validation.

- 92 hours of testing (approximately 15.5 hours for 6 testers)
- 55 hours of support.

10. PERFORMANCE QUALIFICATION (PQ)

The PQ testing will be performed to evaluate the long-term consistency of the CoPilot and The Hub to meet predetermined specifications and acceptance criteria.

10.1. 10.2.1 Release PQ Testing Results (Jira FC-26028 CoPilot, Jira FC-26029 The Hub)

10.1.1. Four Performance Qualification tests executed with 0 deviations.

- CoPilot PQ testing consisted of five consecutive days of the machine in running state, followed by two days machine down, and then machine back up and running to simulate production atmosphere.
  - **10.1.1..1.** 32 cavity mold with multiple alarm limits set.
- The Hub PQ testing consisted of three testers running 300 plus shots on live machines and subsequently verifying all data was accessible in The Hub.

10.1.2. 26 hours were recorded for the PQ portion of this validation.

- 11 hours testing (approximately two hours for six testers).
- 15 hours of support.

10.2. 10.0.0 Release PQ Testing Results (Jira FC-20844 CoPilot, Jira FC-21592 The Hub)

10.2.1. Four Performance Qualification tests executed with 0 deviations.

- CoPilot PQ testing consisted of five consecutive days of the machine in running state, followed by two days machine down, and then machine back up and running to simulate production atmosphere.
  - **10.2.1..1.** 32 cavity mold with multiple alarm limits set.
- The Hub PQ testing consisted of three testers running 300 plus shots on live machines and subsequently verifying all data was accessible in The Hub.

10.2.2. 26 hours were recorded for the PQ portion of this validation.

- 11 hours testing (approximately two hours for six testers).
- 15 hours of support.

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11. CONCLUSIONS (A consolidated listing of the primary validation findings are listed by application:)

11.1. Internal Stress Test

11.1.1. A formal plan was prepared for evaluating the stability and performance of the system. The stress conditions identified included:

Fastest Cycle Time	Approximately 2.5 seconds
Longest Cycle Time	Approximately 4200 seconds
Maximum Number of Sensors on One Mold	48 Sensors
Maximum Alarm Setpoints (single output)	240 Alarm Settings

11.1.2. Fastest Cycle Time/ Maximum Number of Sensors on One Mold: The system performed well in this application with no issues noted.

11.1.3. Longest Cycle Time: The system performed well in this application with no issues noted.

11.1.4. Maximum Alarm Setpoints (single output): The system performed well in this application with no issues noted. The test was completed with 240 individual alarm limits, triggering a single sorting output device.

11.2. Client Stress Test

Fastest Cycle Time	Approximately 10 seconds
Maximum Number of Sensors on One Mold	32 Sensors
Maximum Alarm Settings (single output)	70 Alarm Settings

11.2.1. The system performed well in this application with no issues noted. The test was completed with 240 individual alarm limits, triggering a single sorting output device.

12. ANALYSIS OF SPR DATABASE

12.1. A complete record of Software Problem Reports is kept on file at RJG, along with a detailed review of this database which was performed as part of this software validation effort.

13. DEVELOPMENT AND QA PROCESS

13.1. RJG development follows the Scrum Agile Framework. Within the Scrum Agile Framework is our development, quality assurance, and release process. The process is outlined here:

- Define User Requirements in Confluence and Jira.
- Define Functional Specifications in Confluence and Jira
- Conduct and Document Risk Assessment
- Design Software. Software Design is captured in Confluence.

- Develop Software.
- Test and Deploy Software. RJG's Internal QA develops a test plan for each user requirement and software requirement in Jira.
- RJG QA team lead approves the software for User Acceptance Testing.
- RJG Product Owners perform User Acceptance Testing. Results of testing are captured in XRay
- RJG Product Owners approve the software for Alpha Testing
- RJG Customer Support and/or RJG Lab personnel perform Alpha Testing. Results are captured in XRay.
- RJG Product Owners approve software for release.
- RJG QA team deploys the software into production and onto the RJG Website at www.rjginc.com.
- The detailed ISO Process is found in RJG ISO Document "Software Development Process".

14. FORMAL IN-HOUSE TESTING

Formal testing was completed for all applications within scope.

While Regression Testing and Formal Alpha Testing are completed for each software version, it is not always possible to retest each version with the exact same number or type of sensors. These sensors and sensor types varied depending on availability at the time of test execution.

15. SOURCE CODE MANAGEMENT

All source code, including modifications to code, is controlled through the use of GitHub®, a third-party source control software. No other code can be deployed to the CoPilot System or The Hub Software product.

16. VERSIONING SYSTEM

RJG uses semantic versioning to track CoPilot and The Hub releases and versions. The method used is Major.Minor.Patch Version (8.0.0).

- Major version changes are related to architecture and incompatible changes.
- Minor version changes are related to new functionality and features in a backward-compatible manner.
- Patch version are changes are related to bug fixes and improvements that are also backward compatible.
- System version changes are related to updates or changes made to the underlying operating system such as security patches.

The detailed ISO Process is found in RJG ISO Document "CoPilot/HUB Release Information."

17. REVISION HISTORY

Revision	Revision Date	Revision Made By	Revision Summary
A	03/03/2025	Cory Hoeppner	Initial Summary Report
B	07/15/2025	Cory Hoeppner	Added Deviation Listing
C	09/18/2025	Cory Hoeppner	Supplemental Validation Release 10.2.1

Signatures and Approvals:

Prepared By:		
Title	**Name**	**Signature/Date**
Product Compliance Engineer	Cory Hoeppner	*Cory Hoeppner* 10/01/2025

Approver's signatures indicate that, as subject matter experts, they have reviewed the content of this document and agree that it is adequate. It further indicates that:

- The document is accurate and comprehensive with respect to the area for which they are responsible;
- The activities outlined and listings created are complete and appropriate with respect to the area for which they are responsible;
- Approvers agree with and take responsibility for the completion of all actions to which they or their areas of responsibility have been assigned;
- Approvers have provided any comments regarding this document to the Preparer;
- This validation will not adversely impact the safety and efficacy of the products manufactured;
- Appropriate personnel reviewed the document (protocol/report).

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