Validation Summary Report: 2026-001

For CoPilot® Software Version 11.0.0 (Application Processor 4.0 (AP4.0) Hardware), and The Hub® Version 11.0.0

1. PURPOSE

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

2. BACKGROUND

RJG Inc. wishes to continue its commitment to the healthcare industries by fully re-validating the CoPilot software version 11.0.0 (Application Processor 4.0 (AP4.0)), and The Hub version 11.0.0, 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 11.0.0, RJG Inc. has released previous validated versions (10.0.0 & 10.2.1). This is the reasoning behind the risk-based testing approach (GAMP®5) to the testing involved in this supplemental validation. The validation team deemed the changes from 10.2.1 to 11.0.0 to be high risk with potentially a large impact on the user, therefore full validation is needed at this time. This major change now includes Hub Connect (OPC-UA) and Hub Restful API for communication with other systems.

3. SCOPE

The scope of this document is limited to the Protocol IQ/OQ/PQ of the RJG Inc. CoPilot software version 11.0.0 (Application Processor 4.0 (AP4.0)), and The Hub version 11.0.0 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 Lynx® devices per CoPilot System port may be used.

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.
- Using The Hub Connect, OPC-UA for communication with other systems.
- Using The Hub Restful API for communication with other systems.

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. 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 v11.0.0 and The Hub Software v11.0.0.
- Analysis of RJG's internal SPR (Software Problem Report) database and Jira.

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 (LE-R-50 for Stroke and Velocity, LS-H-1/4NPT-3K for Hydraulic Pressure (Hydraulic Machine's), IA1-M-V 0-10v for Injection Pressure (Electric Machines), ID7-M-SEQ Sequence Input, OR2-M Relay Output, OA1-M-V Analog output).
- Required sequence inputs: Injection Forward, 1st Stage, Screw Run and Mold Clamped.
- Minimum two cavity pressure 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 a thousand CoPilot systems at numerous customer sites have been in the field for nearly nine 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:

- Utilize RJG's Customer Guided Validation Procedure to ensure that all systems have been installed and are working as intended.
  - The above procedure utilizes all hardware installation and software configuration recommendations including: *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 11.0.0 Release

6.1.1. Deviation #1- (Test FC-24128 CoPilot IQ) (Risk Assessed = Low).

- The test assumes that navigating to The Hub IP address will default the user to the Process Development dashboard, instead of the Process Monitoring page. Functionality of the feature works, the test steps were simply not updated.
- Corrective Action Implemented- Screenshot updated to reflect the Hub Process Monitoring Page.
- Result of retest- Pass.

6.1.2. Deviation #2- (Test FC-21161 CoPilot IQ) (Risk Assessed = Low).

- Test pre-conditions were out of order.
- Corrective Action Implemented- Rearranged pre-conditions to reflect the correct order of operation.
- Result of retest- Pass.

6.1.3. Deviation #3- (Test FC-21118 CoPilot IQ) (Risk Assessed = Low).

- Step 13 indicates the max cavity limit should be 99 when its actually 512. Step 14 for max valve gates is also not 99, but 256.
- Corrective Action Implemented- Update steps 13 & 14 to reflect URS callout.
- Result of retest- Pass.

6.1.4. Deviation #4- (Test FC-21657 Hub IQ) (Risk Assessed = Low).

- Step 2 indicates to select parts from the left side menu but after logging in I am taken to the process monitoring dashboard and not the process development dashboard in additional step 3 indicated the toast message will display, "You don't have permission" but says, "You do not have permission to perform this action. "
- Corrective Action Implemented- Add steps to test and update screenshot.
- Result of retest- Pass.

6.1.5. Deviation #5- (Test FC-21847 Hub IQ) (Risk Assessed = Low).

- Step 1 shows invalid screenshot/expected result for Hub landing page.
- Corrective Action Implemented- Screenshot updated to reflect the Hub Process Monitoring Page.
- Result of retest- Pass.

6.1.6. Deviation #6- (Test FC-21645 Hub IQ) (Risk Assessed = Low).

- Missing test specificity indicating that the UPD needs to be uploaded before the button is clickable.
- Corrective Action Implemented- Added to test step for specificity.
- Result of retest- Pass.

6.1.7. Deviation #7- (Test FC-24478 Hub IQ) (Risk Assessed = Low)

- Incorrect image for the expected result in step 2 of the test the image is outdated, where there needs to be a new settings page screenshot of the Hub.
- Corrective Action Implemented- Screenshot updated to reflect the Hub Process Monitoring Page.
- Result of retest- Pass.

6.1.8. Deviation #8- (Test FC-24476 Hub IQ) (Risk Assessed = Low).

- Test assumes that logging out of the Hub will change the current page to the process development dashboard, instead of the process monitoring page.
- Corrective Action Implemented- Screenshot updated to reflect the Hub Process Monitoring Page.
- Result of retest- Pass.

6.1.9. Deviation #9- (Test FC-21043 CoPilot OQ) (Risk Assessed = Low).

- Precondition: Take and Error. Step #5 says "Select 'submit'", button on CoPilot actually says "Save".
- Corrective Action Implemented- Update the pre-condition to reflect the Copilot interface.
- Result of retest- Pass.

6.1.10. Deviation #10- (Test FC-21293 CoPilot OQ) (Risk Assessed = Low).

- Test uses screenshots of old toast messages throughout and doesn't match the current design.
- Corrective Action Implemented- Update screenshots to reflect current toast messaging.
- Result of retest- Pass.

6.1.11. Deviation #11- (Test FC-21875 Hub OQ) (Risk Assessed = Low)

- Screenshot in step 1 Hub landing page is incorrect.
- Corrective Action Implemented- Screenshot updated to reflect the Hub Process Monitoring Page.
- Result of retest- Pass.

6.1.12. Deviation #12- (Test FC-26682 Hub OQ) (Risk Assessed = Low).

- Missing a step necessary to correctly view the custom field variable.
- Corrective Action Implemented- Added a test step requiring the user to run a reset command.
- Result of retest- Pass.

6.1.13. Deviation #13- (Test FC-21843 Hub OQ) (Risk Assessed = Low)

- Pre-conditions are in the wrong order.
- Corrective Action Implemented- Rearrange pre-conditions to reflect the current interface.
- Result of retest- Pass.

7. 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.

7.1. 11.0.0 Release IQ Testing Results (Jira FC-26587 CoPilot, Jira FC-26590 The Hub)

7.1.1. 229 Installation Qualification tests executed with eight deviations documented and retested following the implementation of corrective actions. All tests are now passing.

7.1.2. 89.5 hours were recorded for the IQ portion of this validation.

- 73.5 hours testing.
- 16 hours of support.

8. 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.

8.1. 11.0.0 Release OQ Testing Results (Jira FC-26588 CoPilot, Jira FC-26591 The Hub)

8.1.1. 263 Operational Qualification tests executed with five deviations were documented and retested following the implementation of corrective actions. All tests are now passing.

8.1.2. 243.5 hours were recorded for the OQ portion of this validation.

- 201.5 hours testing.
- 42 hours of support.

9. 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.

9.1. 11.0.0 Release PQ Testing Results (Jira FC-26593 CoPilot, Jira FC-26592 The Hub)

9.1.1. 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.
  9.1.1..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.

9.1.2. 15.5 hours were recorded for the PQ portion of this validation.

- 9.5 hours testing (approximately two hours for six testers).
- 6 hours of support.

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

10.1. Internal Stress Test

10.1.1. 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

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

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

10.1.4. 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.

10.2. 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

10.2.1. 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.

11. ANALYSIS OF SPR DATABASE

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

12. DEVELOPMENT AND QA PROCESS

12.1. 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".

13. 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.

14. 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.

15. 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.”

16. 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
D	02/19/2026	Cory Hoeppner	Full Re-Validation 11.0.0 with changes throughout the report

Signatures and Approvals:

Prepared By:		
Title	**Name**	**Signature/Date**
Product Compliance Engineer	Cory Hoeppner	 02/19/2026

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).

Title	Name	Signature/Date
Quality Assurance Analyst I	Keith Molloseau	Keith Molloseau 02/19/2026
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