COPILOT® SYSTEM AND THE HUB®
SOFTWARE RELEASE NOTES
Build No. v10.2.1

This release of The Hub software and CoPilot system has been validated by RJG to streamline manufacturer validation processes; refer to "The Hub Software and CoPilot System Validation" on page 3.

VALIDATED
FOR MEDICAL

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Overview

This release of The Hub software and CoPilot system has passed an RJG-conducted installation, operational, and performance qualification validation to streamline manufacturer validation processes that are required by the FDA for medical device process validation.

This release of the CoPilot® system also features a bug fix for the Previous Cycle Values widget.

CoPilot System: Bug Fixes

Previous Cycle Values Widget

When a user running a job with Velocity to Pressure Control (V→P) active and fill volume set on the Cycle Graph navigated to the Previous Cycle Values widget to access the mold variable process pack time, all other machine, mold, composite, and template variables were missing from the widget.

The Hub Software and CoPilot System Validation

Validation

The FDA defines validation as the establishment of evidence that a process produces results while meeting the required specifications. RJG has completed a validation to streamline manufacturer validation processes.

Installation, Operational, and Performance Qualification (IQ/OQ/PQ)

Installation Qualification (IQ) tests and documents that process equipment and ancillary system are design and code compliant, follow manufacturer recommendations, and functions as expected. Operational Qualification (OQ) tests and documents that process equipment and sub-systems consistently operate within state limits and tolerances. Performance Qualification (PQ) tests and documents that the product or process meets all release requirements for functionality and safety in an effective and reproducible manner for the production environment.

RJG has completed IQ/OP/PQ testing and documentation for the validation of The Hub software and CoPilot system v10.2.1 release.

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The Hub Software and CoPilot System Validation Installation

Debian systems may download The Hub Software v10.2.1 from www.rjginc.com.

Release Channels for NixOS

The Hub Validation (The Hub v10.2.1, and CoPilot system v10.2.1) must be selected from The Hub Software system settings under the Release Channel option. This applies only to NixOS systems.

1. Log in to The Hub software.

2. Navigate to and open the sidebar menu; select Settings.

3. Within the System Settings, navigate to and select the System: Updates tab on the top of the page.

4. On the System: Updates page, scroll down to "Release Channels".

5. To select The Hub Validation (v10.2.1), hover the cursor over the Validated row, then select the Make Active Button.

6. Enter the user password in the field, then click the CONFIRM button to apply The Hub Validation.

The Hub Software and CoPilot System Validation Updates

Currently, The Hub software and CoPilot system v10.2.1 is the current release validated by RJG. While future releases of The Hub software and CoPilot system may not be immediately validated, users who wish to take advantage of the streamlined validation that The Hub Validation Protocol provides are able to remain on the v10.2.1 The Hub and CoPilot system software releases.