RJG
MOLD SMART

COPILOT® SYSTEM AND THE HUB®
SOFTWARE RELEASE NOTES
Build No. v10.0.0

The Hub Validation Protocol

The Hub Software Validation Protocol, in conjunction with the CoPilot system software release v10.0.0, 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.

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 v10.0.0 release, The Hub Validation Protocol.

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The Hub Validation Protocol Installation

Debian systems may download The Hub Software v10.0.0 from www.rjginc.com.

Release Channels for NixOS

The Hub Validation Protocol (The Hub v10.0.0, and CoPilot system v10.0.0) 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 Protocol (v10.0.0), 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 Protocol.

The Hub Validation Protocol Updates

Currently, The Hub Validation Protocol is the only 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 v10.0.0 The Hub and CoPilot system software releases.