

SCC SOFTBANK®

Operational Qualification (OQ) Validation:

BC Solutions uses the R.F. Nozick Blood Bank Validation developed by a team of Blood Bank experts & laboratory clinicians. This proven system of validation is key in providing the efficiency that saves valuable time and resources while maintaining a high degree of patient safety. With the R.F. Nozick Validation Program you can rest assured you are audit ready & operationally safe for your patients.

SCC SoftBank:

In this type of Validation Testing, the computer system and process operating parameters will be challenged to ensure that they will result in a product that meets all defined user requirements under all anticipated conditions. All Validations include our Matrix Analysis & Validation Report providing easy access to evidence of validation & corresponding regulatory requirements, making your next visit from an auditor as simple as possible.

Functions & Workflows Tested:

Patient Transfusions Patient Maintenance Admit

Patient Maintenance Link Patient Orders
Patient Edit Demographics Patient Multisite

Patient History Review Management Exceptions
Inventory POS Select Inventory POS Issue
Inventory POS Emergency Issue Inventory IN/Out Delivery
Inventory IN/Out Batch Delivery Inventory IN/Out Unit Recall

Inventory Edit Status Inventory Edit Unit

Inventory Segment Inventory POS Create Products

Inventory Edit Create Products Inventory POS Return

Electronic Crossmatch Bit-Locking
Patient Maintenance Merge/Stay Merge/Stay Move

Test Resulting: Patient Orders, Inventory Orders, Result Worksheets,

Mother/Baby Link

Elements of the R.F. Nozick (OQ) Validation

System Review

Regulatory Requirements

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Risk Assessment

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Customized Test Plans

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Matrix Analysis & Validation Report

Relationships
Quality
Innovation

