KlariFi™ Control Software

Data Sheet

The KlariFi Control Software is an intuitive, recipe-driven platform that unlocks the full potential of your unit operation with advanced configurations and unparalleled automation capabilities. Optimized for filtration, chromatography, and perfusion, the KlariFi software is used across Repligen KrosFlo® TFF Systems and KRM™ Chromatography Systems.

Enjoy ease of navigation with a flow diagram-based interface that mirrors your system hardware. System controls, user settings, and process data are available at a glance with the ability to visualize, pause, and adjust during a run without compromising batch integrity. Build recipes from the ground up or customize from an extensive library of pre-built templates designed by bioprocessing experts.

Key Features

- Intuitive point and click user-interface
- Autogenerated batch records and trends stored in SQL database
- Integrated data historian for enhanced data security and accessibility
- Transfer recipes between systems
- Available on all KrosFlo RS, KTF+, KRM™ and RS RPM™ Systems

KlariFi Software Modules

- HMI Application: P&ID-based interface to control system hardware and load recipes
- Recipe editor: Create, modify, and submit recipes for approval
- Trending tool: Customizable plots of live and historical process data
- Query tool: View, transfer, or export raw data for additional analysis
- Reports: Access SQL database to review batch records run, print, and review batch records and recipe reports

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HMI Application

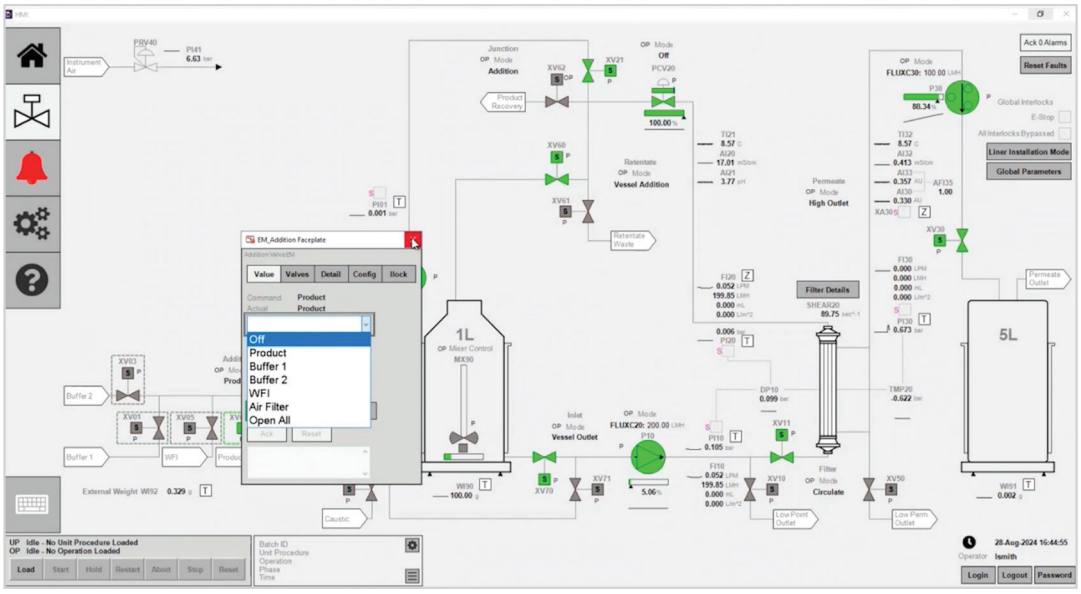


Figure 1. HMI Application screen on KrosFlo RS 10 TFF System.

The HMI Application within the KlariFi software leverages an interactive visual diagram of the system hardware to control all pumps, valves, mixers, and analytical devices. Use the HMI Application for loading and managing recipes, as well as reviewing information about active recipes. Operators can review and acknowledge notifications for current system alarms, as well as review alarm and event history. Update configurations, global parameters, and run manual operations with ease.

Recipe Editor

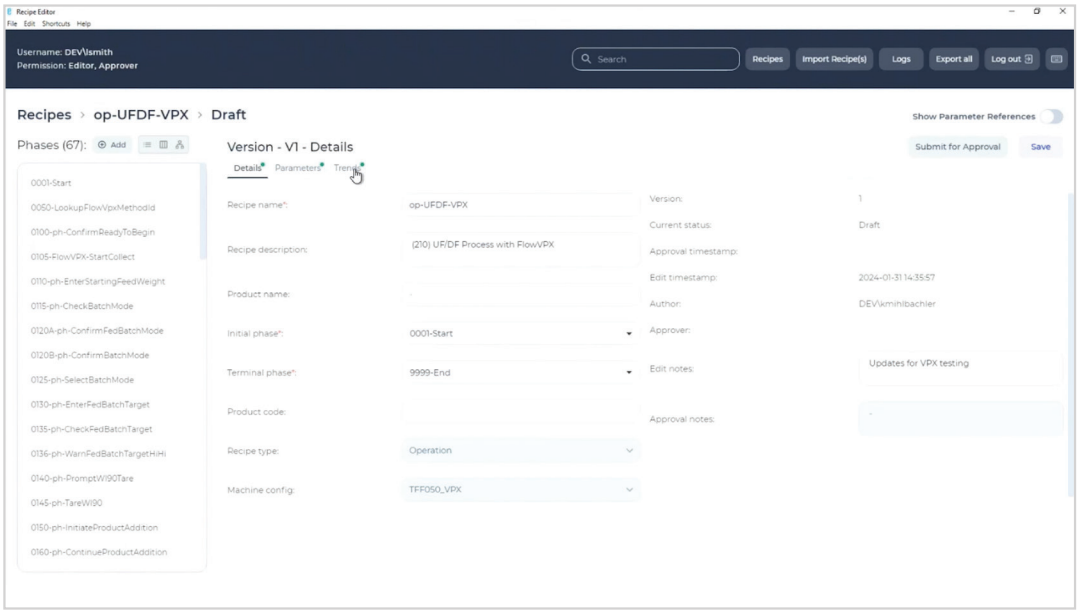


Figure 2. Recipe Editor screen.

Dependent on the type of system purchased, KlariFi software will arrive preloaded with a series of template recipes for common process steps within a unit operation. These recipes are fully configurable and may be adjusted by the end-user to suit their specific needs. These preloaded recipes consist of the following operational sequences:

Filtration

- Fed-batch Concentration
- Batch Concentration
- Diafiltration
- Sanitization
- WIFI/Buffer Flushing
- NWP/NBP Measurement
- Product Recovery
- CIP
- Online Membrane Integrity Testing
- Flow Path Integrity Testing

Chromatography

- System CIP
- Column CIP
- System WIFI Flush
- Column Equilibration
- Product Loading
- Wash(es)
- Linear/Step Gradient Elution
- Post-elution Wash(es)/Sanitization(s)
- HETP

Build Recipes From Scratch

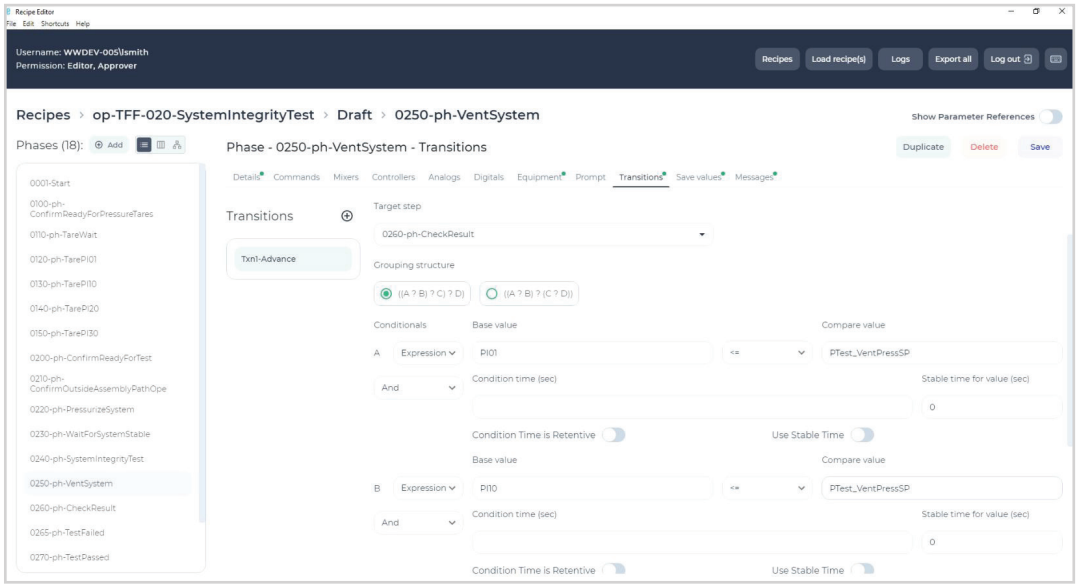


Figure 3. Editing phases within the Recipe Editor.

Recipe builders have finite control by creating phases, named parameters, and transitions.

Phases: Commands for the system, including pump and valve control modes, resetting sensors and totalizers, and more.

Names parameters: Allow recipes to be flexible by giving the operator the ability to change process values without adapting the recipe. They also limit the number of recipes that need to be maintained. Parameters can also be based on sensor data or calculated values collected during the run.

Transitions: Instructions for moving to the next phase can be based on elapsed time, parameter values, operator input, sensor values, totalizer values, and more. Multiple transition conditions can be combined to create nearly infinitely flexible recipe operations to account for any scenario your production might require.

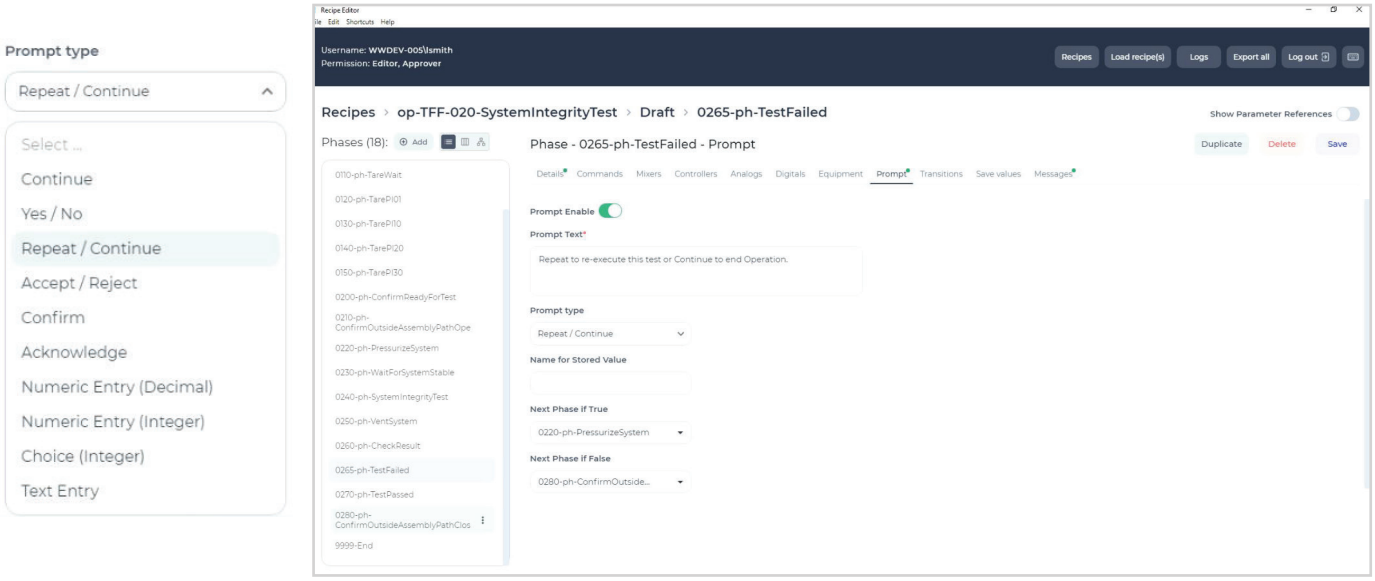


Figure 4. Updating prompts within Recipe Editor.

Prompts and Messages: Fully customizable prompts and messages make operator involvement easy and keep them fully informed. Recipes can be linked to an automated string of operating procedures, meaning your whole unit operation can be completed by loading only one recipe.

Recipe Visualization

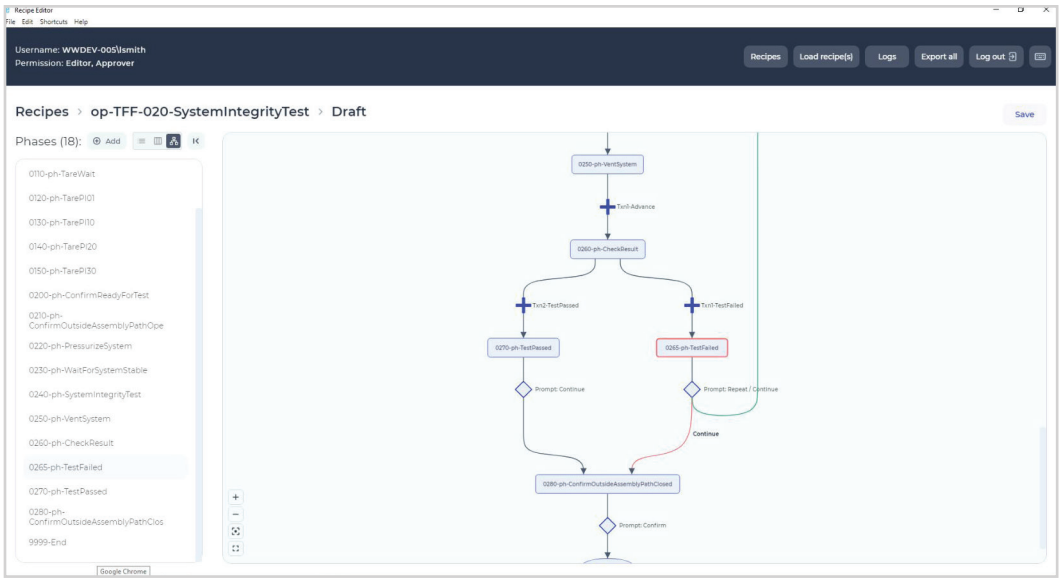


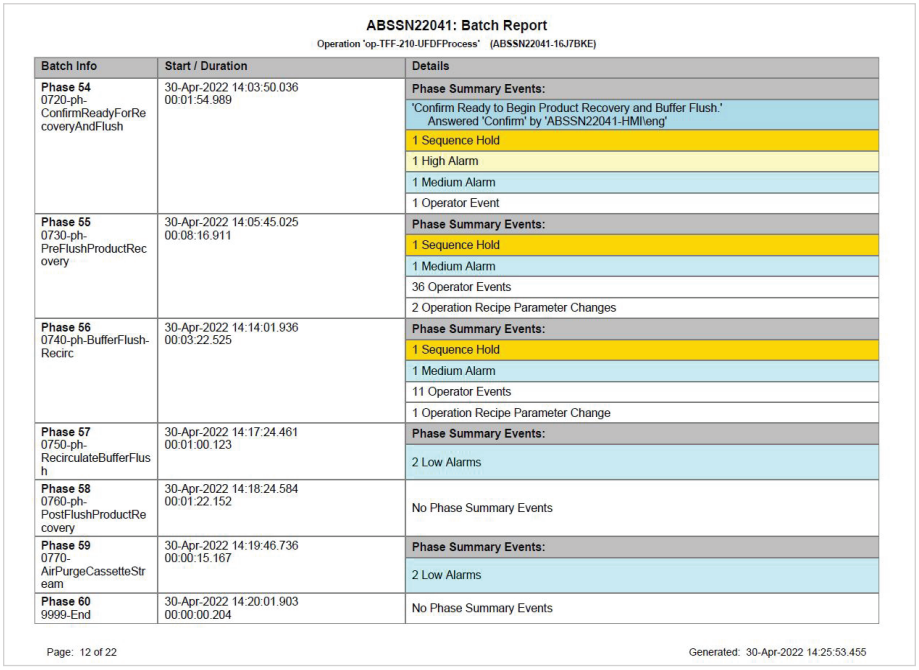
Figure 5. Sequential flow chart within Recipe Editor.

Sequential flow charts allow for easy recipe phase navigation, visualization, and quality control inspection.

Version Control

Built-in approval process and version control. With controlled access so operators will always run the latest approved recipes, while engineers and admins can develop, test and improve without worry.

Custom Batch Record Trends



ABSSN22041: Batch Report

Operation 'op-TFF-210-UFDFProcess' (ABSSN22041-16J7BKE)

Batch Info	Start / Duration	Details
Phase 54 0720-ph-ConfirmReadyForRecoveryAndFlush	30-Apr-2022 14:03:50.036 00:01:54.989	**Phase Summary Events:**
		'Confirm Ready to Begin Product Recovery and Buffer Flush.' Answered 'Confirm' by 'ABSSN22041-HMI\eng'
		1 Sequence Hold
		1 High Alarm
		1 Medium Alarm
		1 Operator Event
Phase 55 0730-ph-PreFlushProductRecovery	30-Apr-2022 14:05:45.025 00:08:16.911	**Phase Summary Events:**
		1 Sequence Hold
		1 Medium Alarm
		36 Operator Events
		2 Operation Recipe Parameter Changes
Phase 56 0740-ph-BufferFlush-Recirc	30-Apr-2022 14:14:01.936 00:03:22.525	**Phase Summary Events:**
		1 Sequence Hold
		1 Medium Alarm
		11 Operator Events
		1 Operation Recipe Parameter Change
Phase 57 0750-ph-RecirculateBufferFlush	30-Apr-2022 14:17:24.461 00:01:00.123	**Phase Summary Events:**
		2 Low Alarms
Phase 58 0760-ph-PostFlushProductRecovery	30-Apr-2022 14:18:24.584 00:01:22.152	No Phase Summary Events
Phase 59 0770-AirPurgeCassetteStream	30-Apr-2022 14:19:46.736 00:00:15.167	**Phase Summary Events:**
		2 Low Alarms
Phase 60 9999-End	30-Apr-2022 14:20:01.903 00:00:00.204	No Phase Summary Events

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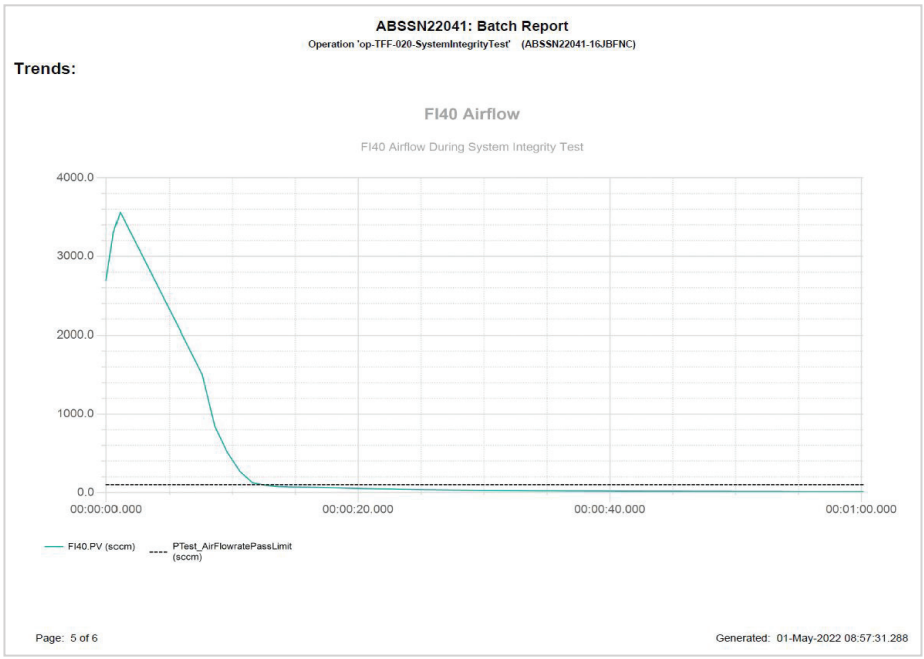

Batch records can be enhanced with custom trends for improved analysis and comparison.

Modes of Operation

Designed to execute all functions without requiring any external connectivity, KlariFi Software supports both manual and automated modes of operation. The following options enable process control by authorized users:

- In automatic mode, pre-configured recipes with logic and transitions direct the actions of all devices on the equipment
- Automated recipes can be developed/modified using the KlariFi Recipe Editor. The Recipe Editor implements user security based on Windows credentials, versioning, and a life cycle that requires recipe approval before allowing operators to run a recipe. Recipes may be shared between skids via export/import functions.
- In manual mode, an operator with proper security privileges may direct the action of any individual instrument, pump, valve, equipment module, etc.

Reporting

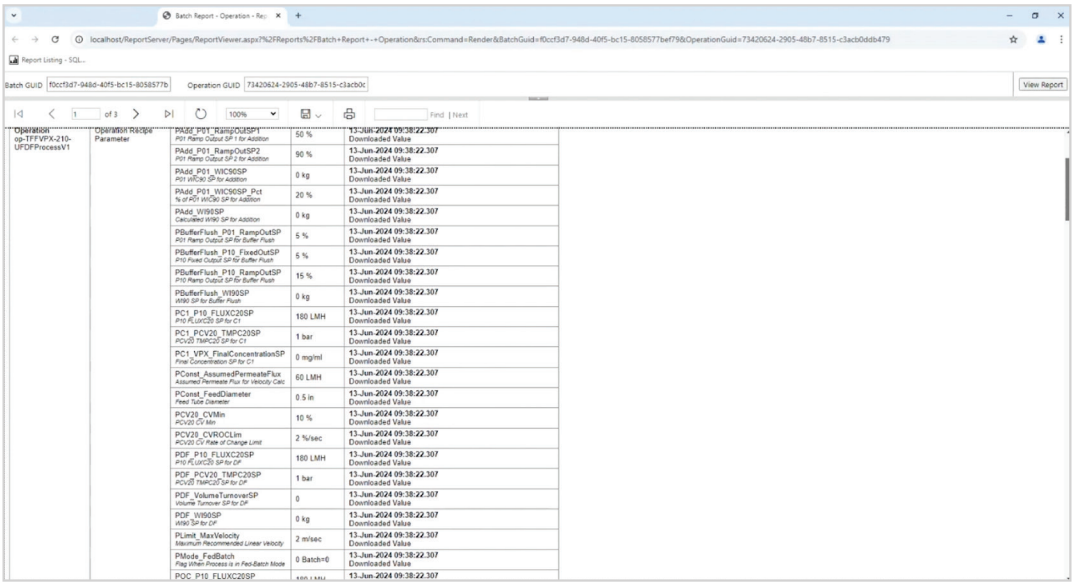

Figure 6. Sample batch report.

All processes within KlariFi software are monitored, controlled, and automatically documented via the PLC (Programmable Logic Controller) and SCADA (Supervisory Control and Data Acquisition). KlariFi software enables pre-configured electronic batch and recipe reports, as well as access to live data through Ethernet communication via Ethernet/IP directly to the PLC. The KlariFi software stores electronic batch, alarm, and event data in a local database that can be queried directly by customer reporting systems.

Network Integration

When delivered, the system has dedicated network connections for both the PLC and the HMI. These can be configured to connect to customer networks with no impact on system operations. Users can integrate with a networking reporting program such as OSI PI for network enabled process information analysis. The system may also be joined to a customer Active Directory domain for consolidated logons, or simply connect to the network for easy file transfer. Systems powered by KlariFi come DCS integration ready enabling external control and monitoring capabilities including batch start, stop and hold.

Specification	Description
Operating system	Windows 10 LTSC
Regulatory support	• RoHS, REACH, 21 CFR Part 11 • GAMP 5- Category 4 • UL/CE • ISA-88 Standards • ALCOA+
Networking capabilities	• Ethernet/IP, OPC/OPCUA • SCADA, DCS, MES
Safety	Capable of performing predefined safety measures automatically when critical parameters are out of defined limits
Backups	System provides Acronis to allow for routine machine level backups
Access Control	Controlled user levels for HMI application and recipe editor: • Operator • Supervisor • Engineer • Admin • Approver • Support

Customer Service

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