Allegro™ Connect Buffer Management System Unit Operation Editor (UOE) Instruction Manual
User Manual

Restricted - Company Proprietary

Contents

1 Introduction

This document describes the functionality of the Unit Operation Editor (UOE) of the Allegro Connect buffer management system.

1.1 Related Documents

Title	Document Number
HMI instruction manual	
IFU	USD3416

1.2 Acronyms

Acronym	Definition
BMS	Buffer management system
HMI	Human machine interface
IFI	Instructions for installation
IFU	Instructions for use
SU	Single-use
UOE	Unit operation editor
WFI	Water for injection

1.3 Definitions

Phrase	Definition
Unit operation (unit procedure)	A strategy for carrying out a contiguous process within a unit. It consists of contiguous operations and the algorithm necessary for the initiation, organization, and control of those operations.
XML file	An XML file is an extensible mark-up language file, and it is used to structure data for storage and transport.
Operation	A major processing activity that usually results in a chemical or physical change in the material being processed and that is defined without consideration of the actual target equipment configuration.
Phase	The lowest level of procedural element in the procedural control model.
Parameter	The smallest element of procedural control that can accomplish a process-oriented task is a phase.
Transition	An editable value defined to meet the specific needs of the process.

2   Accessing the Unit Operations Editor

The Unit Operations Editor (UOE) software should be installed in accordance with the installation instructions prior to use of the UOE as described within this document.

The Unit Operations Editor is a web-based tool and can be accessed via the Mozilla Firefox application. Launch the application and navigate to the following address:

http://localhost:3000/uom/MB01/nosidebar to open the UOE.

3   Unit Operations Overview Screen

The Unit Operation Overview screen (Figure 1) provides a tabulated view of the individual recipes created within the Unit Operations Editor.

Unit operations may be filtered by "Name" field by using the search field at the top of the page.

To clear a filtered search, select the "Clear" button positioned to the side of the search entry field.

A tabular view of existing unit operations provides the following detail:

- Unit operation name (max. 16 characters)
- Unit operation description
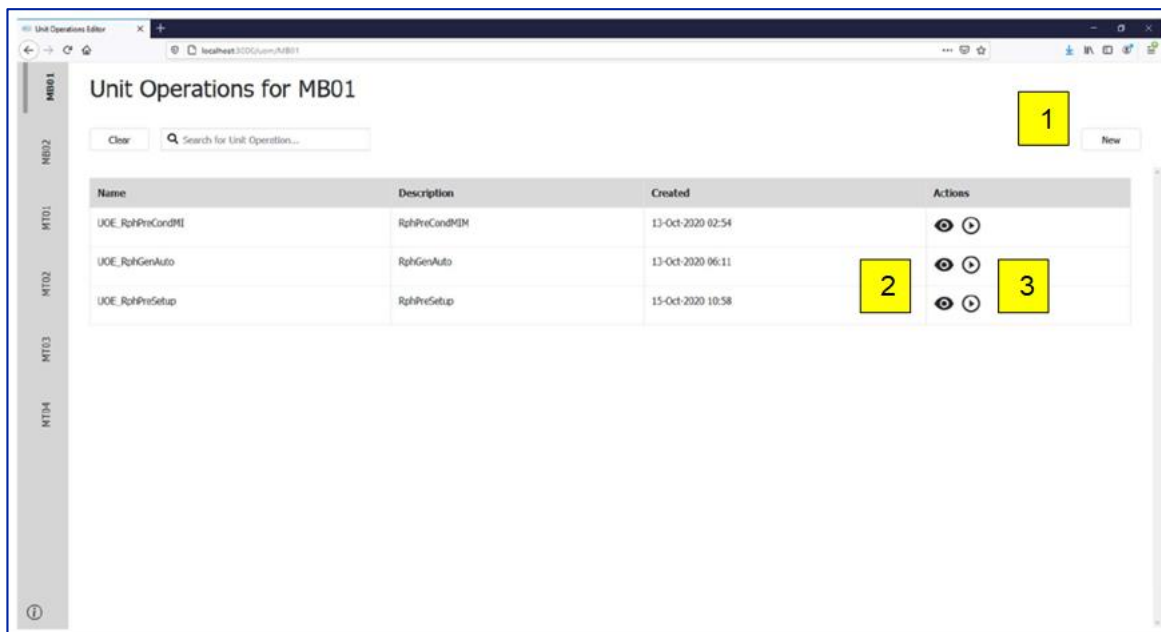- Date unit operation initially created

Two functions are accessible from the "Actions" column of the table.

By clicking on the "eye" symbol the Unit Operations screen is accessed and the Unit Operation is opened in the edit mode.

By clicking on the "play" symbol the unit operation is exported as an XML-file.

Figure 1

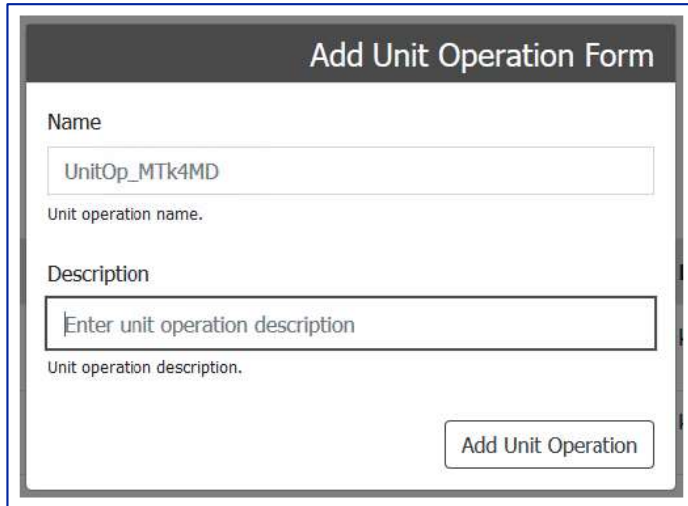Unit Operations Overview screen

3.1   Creating a New Unit Operation

From the Unit Operations Overview screen select the New button (Figure 1 [1]) to open the Add Unit Operation Form.

Figure 2

Add Unit Operation Form

From the Add Unit Operation Form (Figure 2) the user must specify a Unit operation name (max. 16 characters) and Unit operation description.

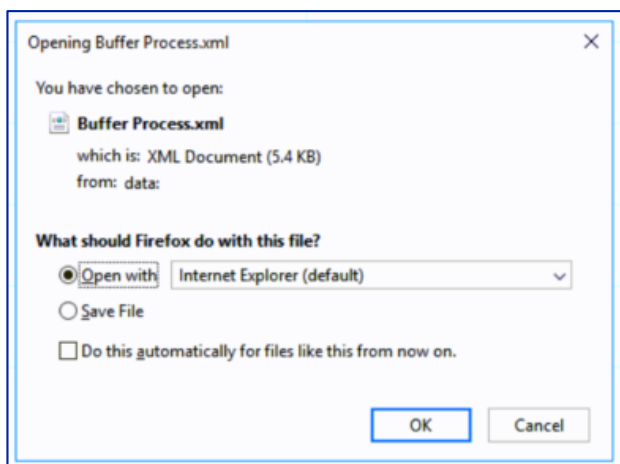Select the Add Unit Operation button to add the unit operation to the overview table.

The unit operation should now be listed in the table on the Unit Operations Overview screen.

3.2   Generating an XML file

From the Unit Operations Overview screen, select the "Play" symbol (Figure 1 [3]) for the required unit operation to open the XML file generation form (Figure 3).

Figure 3

XML file generation form

To save the XML file click the "Save File" radio button and click OK.

All generated files will be saved to the Downloads folder on the host computer.

3.3   Editing a Unit Operation

From the Unit Operations Overview screen select the "eye" symbol (Figure 1 [2]) for the required unit operation to open the Unit Operation Screen and begin editing. Refer to Section 4 - Unit Operation Screen.
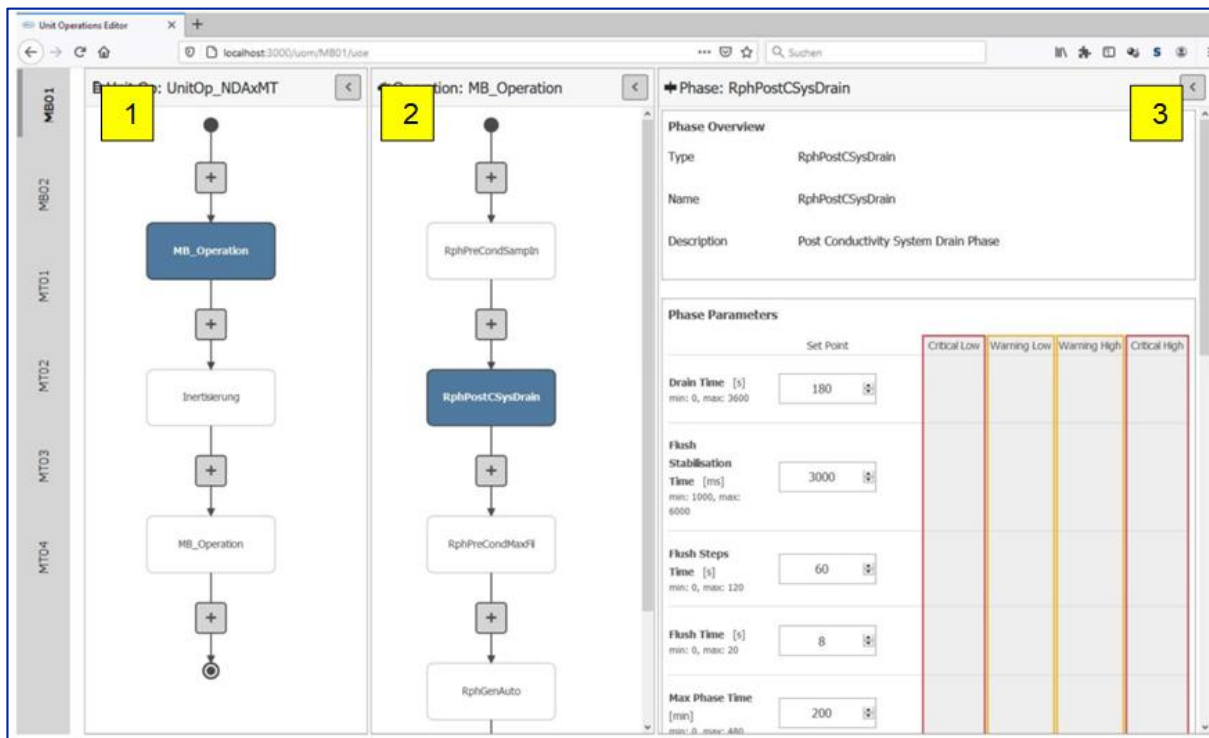
4   Unit Operation Screen

The Unit Operation Screen (Figure 4) is separated in to 3 columns

·   Unit Operation (UnitOp), consisting of one or more operations (Figure 4 [1])

·   Operation column, consisting of one or more phases (Figure 4 [2])

·   Phase column, which details the phase overview and parameters for the selected operation (Figure 4 [3])

Figure 4
Unit Operations Screen

4.1   Unit Operation Column

Displays an editable flowchart of existing operations (if present).

The start of the recipe execution is symbolized by a solid black circle. Operations are run sequentially from top to bottom with completion symbolized by the outlined black circle.

4.2   Operation Column

Displays a flowchart of existing phases for a selected operation. It uses the same flowchart design as the Unit Operation column.

4.3 Phase Column

The Phase column is separated into two parts:

·   Phase Overview:

Here the phase type, name and description are shown. The name and description can be changed.

·   Phase Parameters

The phase specific parameters for the selected phase are listed with name, unit, minimum and maximum input value. A parameter will typically have an editable setpoint and up to four editable alarm values (High High (HH), High (H), Low (L), Low Low (LL)) dependent upon its associated function.

5   Creating and Adding an Operation to a Unit Operation

5.1   Creating an Operation

At the Unit Operations column navigate to the flow chart of operations. Select the plus-symbol to create a new operation in the required position of the flow chart.

The add operation form will appear (Figure 5).

Figure 5

Add Operation

5.1.1   Add Operation Form

The "Add Operation" form is separated into two columns.

·   Operations (Figure 5 [1])

·   Selected Operation (Figure 5 [2])

5.1.2 Operations

In the Operations column, all operations previously built within the UOE are shown, providing the option to reuse existing operations.

Included at the top of the list is a blank operation template (MB_Operation) should an existing operation not be required.

Select an operation by highlighting the required tick box to populate the "Selected Operation" column.

5.1.3 Selected Operation

"Selected Operation" is separated into two parts; Operation Overview and Phase Sequence Graph.

In the Operation Overview the user can add/edit the name (max. 16 characters) and description of the operation.

Below the Operation Overview, the Phase Sequence of the operation is shown. This graphic is for information only and is non-editable. For existing operations, the graphic shows the sequence of the phases used in this operation.

Select the "Add Operation" button (Figure 5 [3]) to add the selected operation to the unit operation. The operation will appear in the appropriate position within the Unit Operation flow chart on the Unit Operation Screen.

NOTE: Due to the limited functionality of this β-release, once an operation has been added to the Unit Operation flow chart it CANNOT be removed.

6   Creating and Adding a Phase to an Operation

To add a phase to a specific operation first click and highlight that operation within the Unit Operation flowchart on the Unit Operation Screen.

From the Operation flowchart select a plus-symbol to create a new phase at that selected position of the flow chart (Figure 4 [2]).

The "Add Phase" form (

Figure 6) will appear and a phase may be selected from the following list of phase templates.

6.1　Phase Types

6.1.1　Pre-Processing Phases

1. **Pre-Setup (MB_RPHPRESETUP)**

Setup the predefined path parameters including parameters for conductivity and pH set-points for stock and process buffer solutions. This MUST be the first phase specified within a new recipe.

2. **Manifold Installation (MB_RPHPRECONDMIM)**

The phase allows the user to install the single-use (SU) manifold and associated hardware by following step-by-step, visual on-screen instructions for installation (IFI).

3. **Preconditioning (MB_RPHPRECONDIT)**

The phase will perform a pressure decay manifold leak test as well as the renature / wetting of the SU Hamilton◆ pH probe prior to initiating any processing phases.

4. **Sampling (MB_RPHPRECONDSAMPIN)**

The phase is an optional verification phase which samples and checks the conductivity and pH of the active stock buffer solutions connected to each of the inlet valves against set-points defined by the user recipe. The system will provide feedback as to whether all connections are correct.

5. **Preconditioning Maximum Fill (MB_RPHPRECONDMAXFILL)**

Within the phase, the system will fill the process solution biocontainers to the level set-point specified in the set-up phase. An in-line dilution process is initiated for each stock buffer solution in-turn, with the diluted solution diverted from waste to the process solution biocontainer after stabilization (once conductivity and pH meet the set-points defined in the user recipe). This is completed once for each process buffer solution.

6. **Fill Manifold (MB_RPHPRECONDFIMANI)**

Within the phase, the required WFI inlet valve is opened along with the WFI routing valve and waste valve for a user specified time.

7. **Process Flush (MB_RPHPROCFLUSH)**

Within the phase, the Allegro Connect buffer management system will flush the SU components and manifolds until a defined conductivity set-point is reached.

1.   **Draw Fill Operation (MB_RPHPROCDRAWFILL)**

Within the phase, the Allegro Connect buffer management system will monitor each of the process buffer solution biocontainer levels (up to 6 buffer types per batch). When a level drops below the specified tolerance around the level set-point, the system will initiate buffer dilution to refill the biocontainer to the set-point and match the draw rate of the downstream operation for that process buffer.

2.   **Cycle Fill Operation (MB_RPHPROCCYCLFILL)**

In the phase, the Allegro Connect buffer management system will sequentially index through all active process buffer solutions in sequence starting from 1 through to 6 (where active). Each biocontainer will be filled sequentially at the maximum flow rate for the set dilution ratio.

6.1.2.1 Post-Processing Phases

1.   **Post Concentrate Drain (MB_RPHPOSTCONCDRAIN)**

The phase allows draining of the contents of each the stock buffer solution biocontainers in turn within the Allegro Connect buffer management system and is sent to drain.

2.   **System Flush (MB_RPHPOSTCONDFLUSH)**

In this optional phase, the Allegro Connect buffer management system will flush the single-use manifolds. The WFI Inlet, Integrity WFI Flush and Waste valves are opened and both pumps are set to a constant running speed.

3.   **System Drain (MB_RPHPOSTCONDSYSDRAIN)**

The phase allows draining of the contents of the Allegro Connect buffer management system and is diverted to drain. Each process buffer solution biocontainer is sequentially drained by gravity.

4.   **Uninstall Manifolds (MB_RPHPOSTUNINSTALL)**

The phase allows the user to uninstall the single-use manifolds and associated hardware from the Allegro Connect buffer management system by following step-by-step, visual on-screen instructions on the HMI.

6.1.2.2 Generic Configurable Phases

1.   **Generic Auto Phase (MB_RPHGENAUTO)**

The following editable allows the user to configure a phase according to their exact requirements to an EM level (refer also to Section 6.4**Error! Reference source not found.**).

6.2   Add Phase Form

The "Add Phase" form (

Figure 6) is separated into three sections.

· Phases (

Figure 6 [1])

- Phase Overview (

Figure 6 [2])

- Phase Parameters (

Figure 6 [3])

Figure 6

Add Phase form

6.2.1 Selecting a Phase

In the Phases section all available phase types are shown (refer to Phase Types in section 6.1 for list of phases).

Select a phase by highlighting the required tick box (

Figure 6 shows an example of RphPostConcDrain phase selected). A new instance of that phase can now be created.

Alternatively, where instances of a specific phase with pre-defined parameters have been previously created, these will be listed for re-use. Select an existing phase by clicking the plus symbol (Figure 7 [1]).

Figure 7

Selecting existing phases
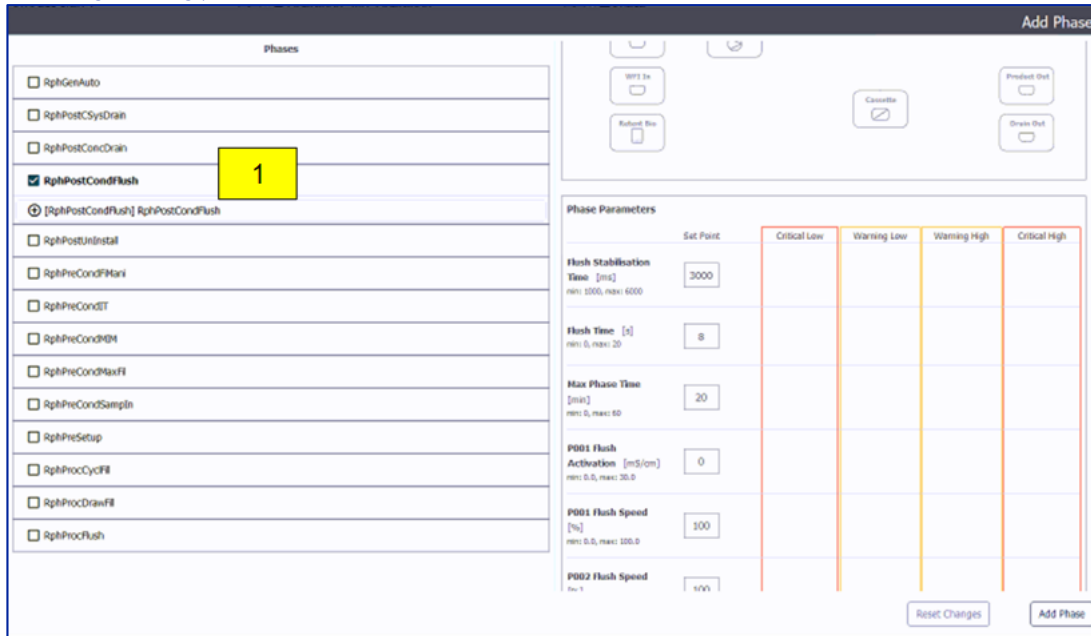
6.2.2   Phase Parameters

Selecting a phase populates the Phase Overview and Phase Parameter sections (Figure 86, 2 & 3)).

In "Phase Overview" the user can edit the name (max. 16 characters) and description of the phase.

Below the "Phase Overview" is the "Phase Parameters" section. Here the phases parameters are shown and can be edited according to the requirements of the specific phase.

Figure 8

Phase Parameters

The Phase Parameters section allows the user to define phase parameter setpoints (Figure 8 [1]) and as well as critical and warning alarm values (Figure 8 [2]).

Optional parameters can be activated by toggling the selection switch (Figure 8 [3]), once selected, alarms associated to these parameters can be activated and specified in the same way (Figure 8 [4]).

6.3   Storing a Phase

Once completed select the "Add Phase" button to add the selected phase to the operation, the phase will appear in the appropriate position within the Operation flow chart on the Unit Operations Screen (Figure 4).

NOTE: Due to the limited functionality of this β-release, once an operation has been added to the Unit Operation flow chart it CANNOT be removed.

6.4   Creating Transitions (Generic Automated Phase)

When building operations using the Generic Automated phase, the user can create and specify their own transitions by using the Transition Editor (
Figure 9). The Transition Editor is accessible from the Phase Parameter section of the Add Phase form (

Figure 6) when editing a Generic Automated phase.

It is possible to create a transition from 4 single terms that can be combined with "and" or "or" statements.

Each term consists of:

- a resource (PLC tag),
- an evaluation type (greater, equal, less etc.)
- and the value, a reference value to check the resource against.

Figure 9

Transition Editor

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