gibco

CTS™ Cellmation™ Software for DeltaV™ System

USER GUIDE

for use with: CTS™ Rotea™ Counterflow Centrifugation System

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For Research Use or Manufacturing of Cell, Gene, or Tissue- Based Products.

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The information in this guide is subject to change without notice.

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Contents

CHAPTER 1 Product information 6

Product description 6
Operational description 7
Licenses 7
Definitions 7
Toolbar buttons 9
Hardware overview 10
Physical connection 11
Rotea™ instrument network setup 12
EIOC network setup 13
EIOC OPC UA setup 14
Network connectivity check 15
Rotea™ instrument OPC UA setup 16
Rotea™ OPC UA security settings 17
OPC UA connectivity check 18
User interface 19
Splash screen 20
Overview display 21
Main Rotea™ instrument display 22
Rotea™ instrument interface parameters display 25
Contextual displays (Faceplates) 26

CHAPTER 2 General system operation 36

User login 36
Rotea™ instrument operation 37
Rotea™ instrument protocol parameters 38
Zero value parameters 39
Manual operation 39
Step 1: Acquire the equipment module 39
Step 2: Setup the equipment module 41
Step 3: Setup the equipment module to Run Protocol 43
Step 4: Answer prompts as required 44
Step 5: Enter Protocol parameters 45

Step 6: Monitor Protocol state automatically selected 47
Step 7: Protocol completion 48
Recipe control operation 51
Phases 53
Phase recipe parameters 57
Recipe construction 60
Recipe execution 63

CHAPTER 3 Alarm management 67

Alarm banner 68
Faceplate alarm window 68
Alarms lists 69
Acknowledging and silencing alarms 70
Suppressing alarms 71
Shelving alarms 72
Alarm list shelve 72
Detail faceplate shelve 73
Out of Service (OOS) alarms 73
Alarm list OOS 74
Detail faceplate OOS 75
Suppressed alarm list 75

CHAPTER 4 Maintenance 77

Backup and recovery 77
Computer cleanup 77
Power outage 78

CHAPTER 5 Data storage 79

APPENDIX A Abbreviations/acronyms 83

APPENDIX B Faceplate details 84

GT_MOD_FP 85
GT_EM_FP 87
GT_USM_DT and GT_TimerFB_DT 89
Alarms 91
GT_EM_FM_DT 92
GT_EM_Params_DT 93
GT_EM_Diag_DT 94

APPENDIX C Compatibility matrix 95

APPENDIX D Safety 96

APPENDIX E Documentation and support 97

Customer and technical support 97
Limited product warranty 97

1 Product information

IMPORTANT! Before using this product, read and understand the information in the "Safety" appendix in this document.

Product description

The Gibco™ CTS™ Cellmation™ Software (based on the Emerson DeltaV™ platform) is an open, fully-configurable software solution designed to provide a flexible system for the control of Thermo Fisher Scientific cell therapy manufacturing instruments. CTS™ Cellmation™ Software is powered by the DeltaV™ system from Emerson Process Management, and is fully compatible with DeltaV™ system version 14.LTS. The software has been developed according to GAMP5 methods and conforms to regulatory requirements for use in current good manufacturing practice (cGMP)-compliant processes. It is optimized to allow easy scaling to accommodate R&D, process development, and manufacturing.

The software must be installed on all of the DeltaV™ workstations controlling/viewing cell therapy manufacturing operations. The exceptions are the application stations that may be used for purposes other than control (e.g., continuous history storage).

The CTS™ Cellmation™ Software requires a DeltaV™ MQ, MX, SQ, SX or PK controller and an OPC UA Client interface. The OPC UA Client can reside on an Ethernet Input Output Card (EIOC) or on an Application Station.

Neither Emerson Process Management nor Thermo Fisher Scientific recommend or support installation of any third-party software. Downloading files from the internet is not recommended. See Emerson KBA (knowledge based article) AP-0800-0025.

The software system is intended for use by personnel with a reasonable familiarity with bioprocesses and systems. The user is encouraged to become familiar with the manuals to obtain maximum performance from the system.

The contents of this guide may be copied into customer documents such as standard operating procedures (SOPs) as needed, but only for use with Thermo Fisher Scientific equipment.

Every effort has been made to ensure the accuracy of the information in this document. However, Thermo Fisher Scientific reserves the right to change its products without notice.

The software is designed to provide the user with the ability to use a wide range of cell therapy manufacturing instruments. It will also allow the user to:

- Use different cell therapy manufacturing instruments in the same network with no change in the operator interface.
- Create user specific batch recipes to control workflows across multiple instruments.
- Store historical data for retrieval later on.
- Allow for 3rd party batch reporting packages to retrieve data to produce batch reports containing alarm/events, continuous history and batch recipe information.

Operational description

CTS™ Cellmation™ Software provides a control solution for cell therapy process workflows that is independent of process-control hardware. It can be configured by end users without having to learn process control programming and resides on the DeltaV™ system by Emerson Process Management.

Licenses

CTS™ Cellmation™ Software is licensed per DeltaV™ system.

Definitions

DeltaV™ Books Online

A set of help files included with DeltaV™ systems. These files comprise the official documentation of the standard DeltaV™ system and include parameter and feature definitions.

Process value

Also referred to as process variable or measured variable. In process control, a measurable quality or quantity that, if changed, can cause other changes in the process or make such changes possible. Common process values are pump speed and door position.

OPC UA

Industry standard interface (Open Platform Communications, formerly known as OLE for Process Control Unified Architecture). This protocol is platform independent protocol allowing for greater integration between devices. This is the communication protocol between the DeltaV™ system and a cell therapy manufacturing instrument.

DeltaV™ Live

DeltaV™ Live is an application that provides the GUI to allow operation of the instrument and is the replacement GUI to DeltaV™ Operate. From here a user can control the instrument by the use of faceplates to monitor and enter data.

Contextual displays

Contexual display is a DeltaV™ Live terminology for a faceplate. The contextual display is a pop-up picture that contains the graphics and controls necessary to perform normal or expected control. The appearance of a faceplate varies depending upon the type of module, or device with which it is associated.

Detail faceplate

A detail faceplate is another kind of contextual display. It shows more of the module details (parameter limits, tuning constants, alarm information and diagnostic messages) than the faceplate.

Batch list faceplate

A batch list faceplate is another kind of pop-up. It shows the current list of recipes that are loaded on the Batch Executive. From here recipes can be added and started or aborted.

Toolbar buttons

Table 1 Toolbar button icons and functionality descriptions

Icon	Function
	Opens the suppressed alarm list. Only visible when there are suppressed alarms.
	Exits operator interface.
	Opens the tools list. The following tools are available, Print, Reset Layout, Layout Scale and Themes.
	Refreshes the current display.
	Search button. Use this to search for a tag within the system. When entering the search text, the list of matching tags is displayed. From this list contextual displays, primary displays and process history displays can be selected for the listed tags.
	Navigate forward to the previous Main Screen. Holding the button will display the display history.
	Navigate forward to the previous Main Screen. Holding the button will display the display history.
	Opens the Main Overview graphic, with links to each tower and vessel graphic. An easy way to navigate quickly between vessels.
	Opens the Alarm Summary, showing all active and unacknowledged alarms.
	Opens the Alarm Filter page, excluding alarms from inactive vessels and showing only alarms from active vessels.
	DeltaV™ Utilities, provides access to Emerson Process Management functions.
	Indicates if any errors are present on the current display. If an error exists, the icon turns red.
	Opens the Process History view.
	Opens the Batch Operator Interface (BOI).
	Opens the Batch History view. Only available if the Batch Historian is installed.

Hardware overview

The CTS™ Cellmation™ Software is imported into an existing DeltaV™ system and comprises graphics and controller software modules. The method of communication between the DeltaV™ system and an instrument is OPC UA, with the instrument acting as the server and the DeltaV™ system acting as the client. Due to current DeltaV™ system constraints OPC UA client functionality is only supported on an Application Station or an EIOC controller. The CTS™ Cellmation™ Software has been developed to reside on a typical system architecture as shown with the OPC UA client residing on the EIOC (recommended) or Application Station (further validation may be required).

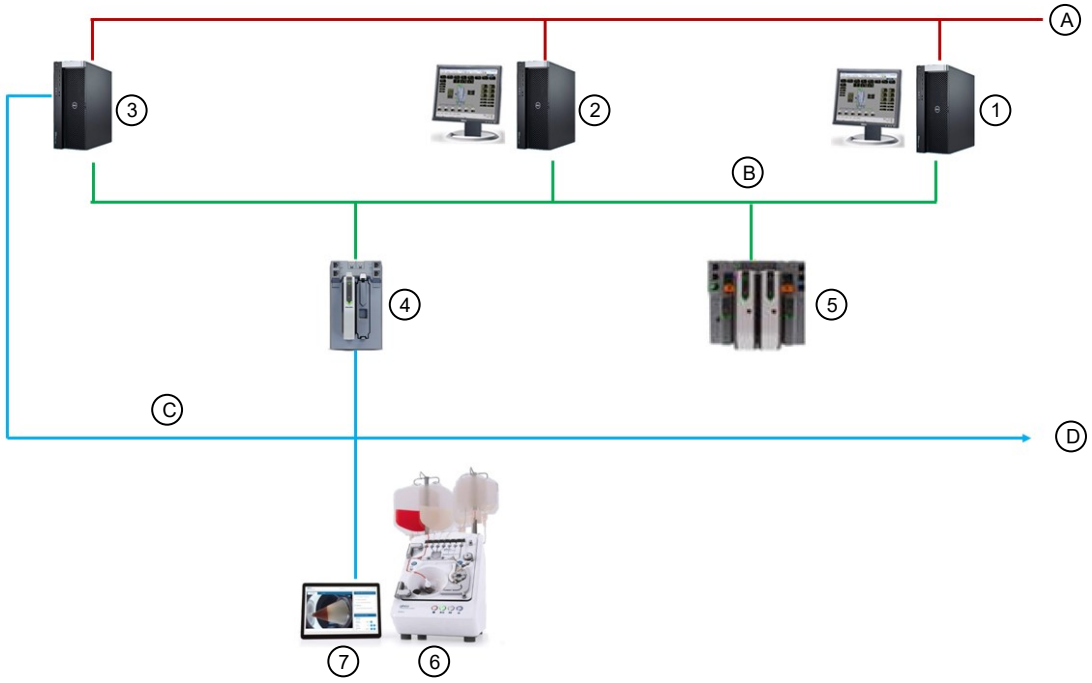


Figure 1 DeltaV™ system architecture

A: Office/Plant network

B: DeltaV™ system Area Control Network (ACN)

C: OPC Network

D: Other OPC Instruments

1. ProPlus workstation with Alarm/Events Chronicle, Batch Executive, Continuous Historian
2. Base Stations with remote sessions, Operation UI
3. Application Station OPC UA Client –Optional if EIOC is not used
4. EIOC OPC UA Client
5. PK/MX/SX Controller
6. Rotea™ instrument
7. Rotea™ instrument companion PC

The intention is that the OPC UA network is a separate network from either the DeltaV™ system Area Control Network or the office/plant network for security reasons.

Physical connection

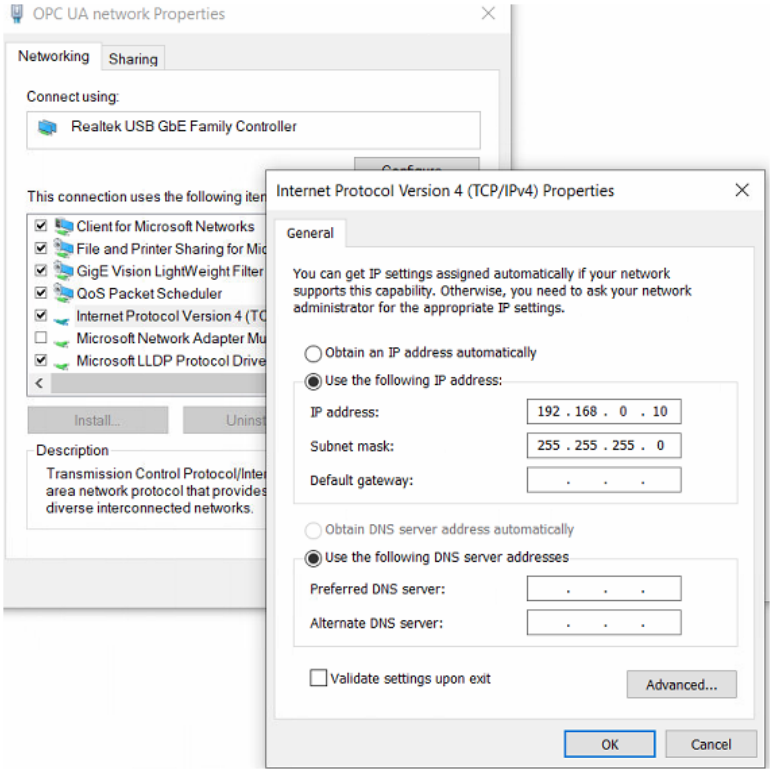
The connection between the DeltaV™ system and the Rotea™ instrument is via an ethernet network, and as such the architecture is dependent on the network infrastructure installed on the system.

To connect the Rotea™ instrument to the network, a CAT6 cable can be inserted into the RJ45 port situated on the rear of the instrument (2nd port from the right) with the other end of the cable connected to a switch or directly to the EIOC if only one instrument is connected.

The rightmost port is the USB connection for the companion PC and the network traffic is passed via this USB connection to the PC.

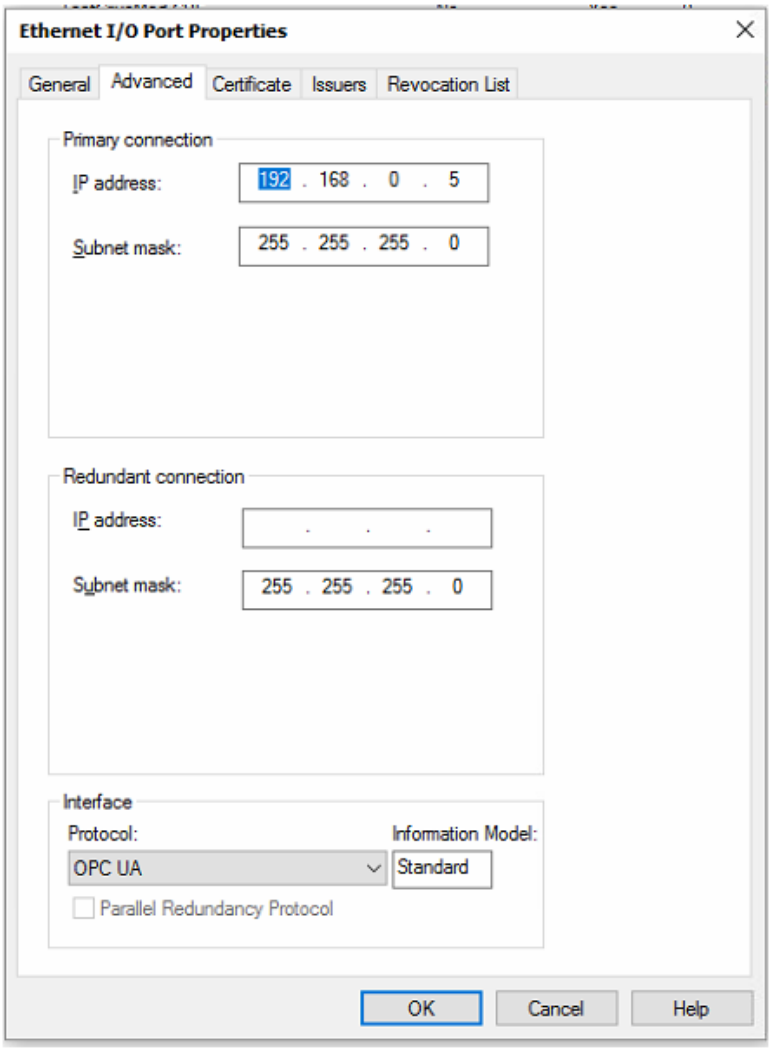
Rotea™ instrument network setup

The network adapter needs to be set up in the companion PC with an IPv4 address for connection to the DeltaV™ system (see the example). This address forms part of the DeltaV™ system OPC UA setup.



EIOC network setup

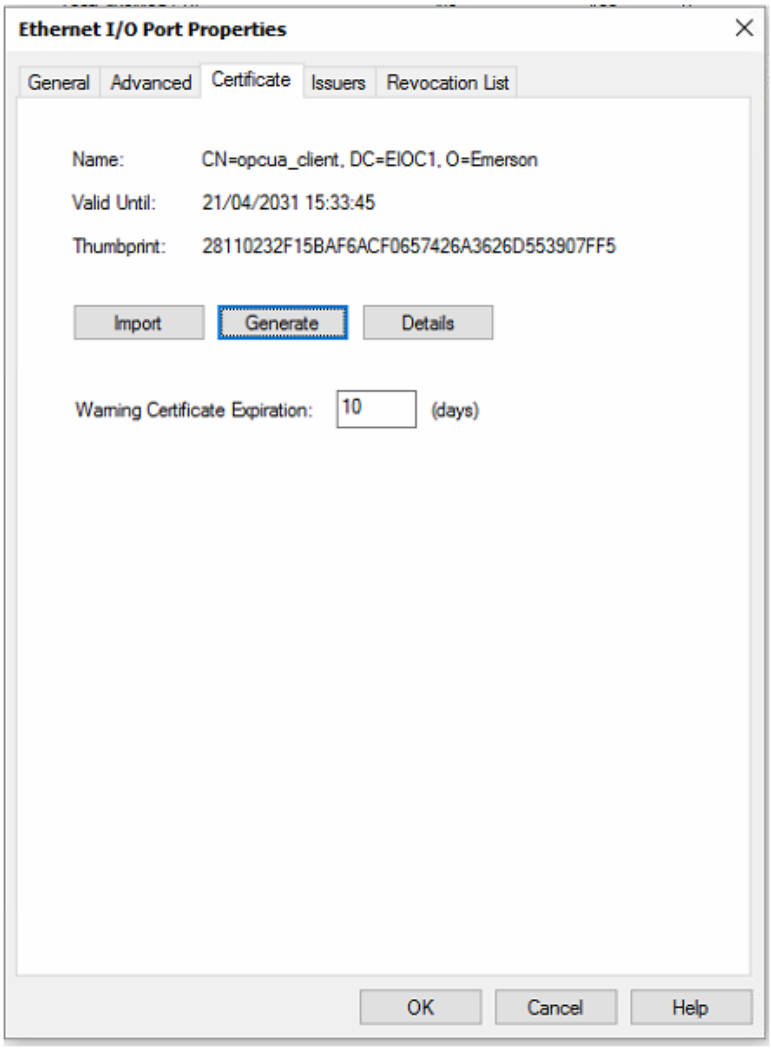
The EIOC network adapter needs to be set up via DeltaV™ Explorer with an IPv4 address. Select **Properties** of the EIOC port (P01) and select the **Advanced** tab. From this tab enter the required IPv4 address. Currently **Redundant connection** is not used so leave this blank.



In the **Interface** drop down box at the bottom, select **OPC UA** as the protocol to be used.

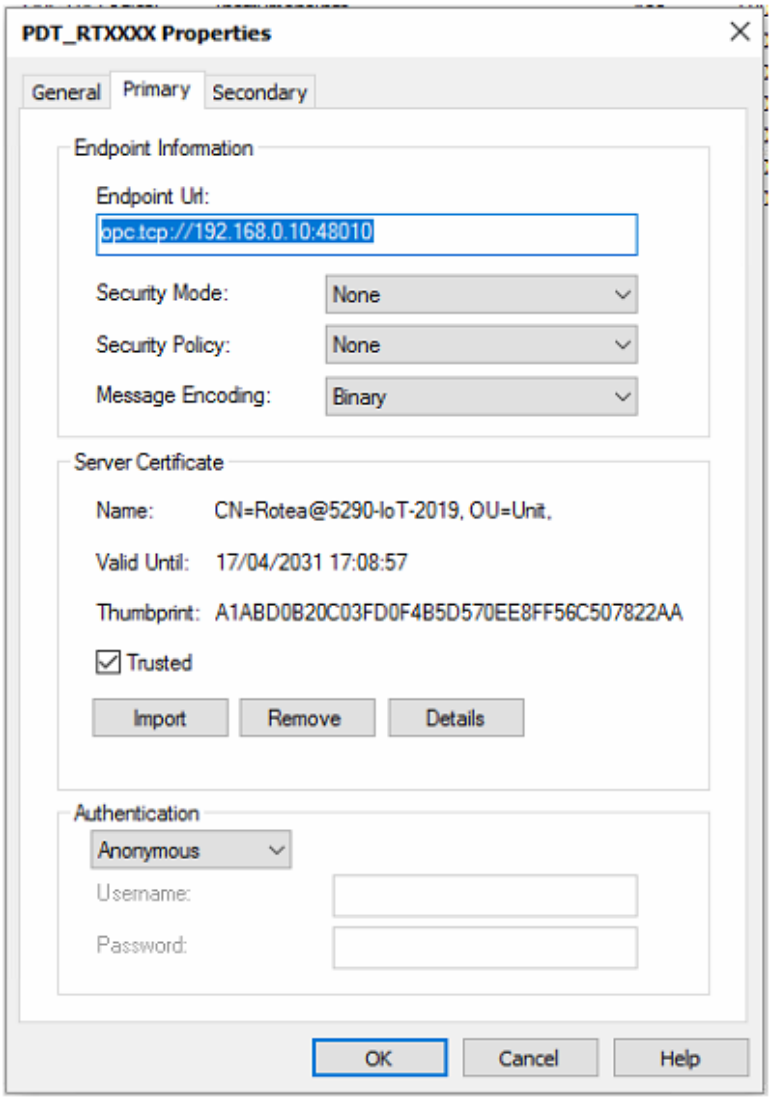
EIOC OPC UA setup

Once the EIOC has been setup to use the OPC UA protocol, if an instrument requires the OPC Client certificate then this can be generated by selecting the **Certificate** tab. Use the **Generate** button to create a certificate.



The CTS™ Cellmation™ Software for DeltaV™ System installation files for the Rotea™ instrument contain a configuration file that has default settings for the Rotea™ instrument OPC UA setup. The default setup creates a Physical Device Tag (PDT) named “PDT_RTXXXX” with all the associated Logical Device Tags underneath it. The PDT properties contain the Endpoint URL of the Rotea™ instrument OPC Server and if this requires modifying, then select properties of the PDT and update the URL by entering the IPv4 address.

Note: The port number is fixed as 48010 and should not be changed.



In addition, the OPC UA Certificate that is provided by the Rotea™ instrument can be imported by selecting the **Import** button. This will ensure that the correct application security settings have been applied.

Network connectivity check

Once the DeltaV™ system configuration has been downloaded, a quick test can be performed on the Rotea™ companion PC to check for network connectivity. Right click the Windows™ icon in the left hand corner of the task bar and select **Command Prompt** from the list when it appears.

In the command window, type “ping” in the black box and hit the space bar. Type the IP address of the EIOC (e.g., 192.168.0.5 in the following figure). If there is connectivity, then a reply will be seen. If not, then the cabling and network settings will need to be checked.

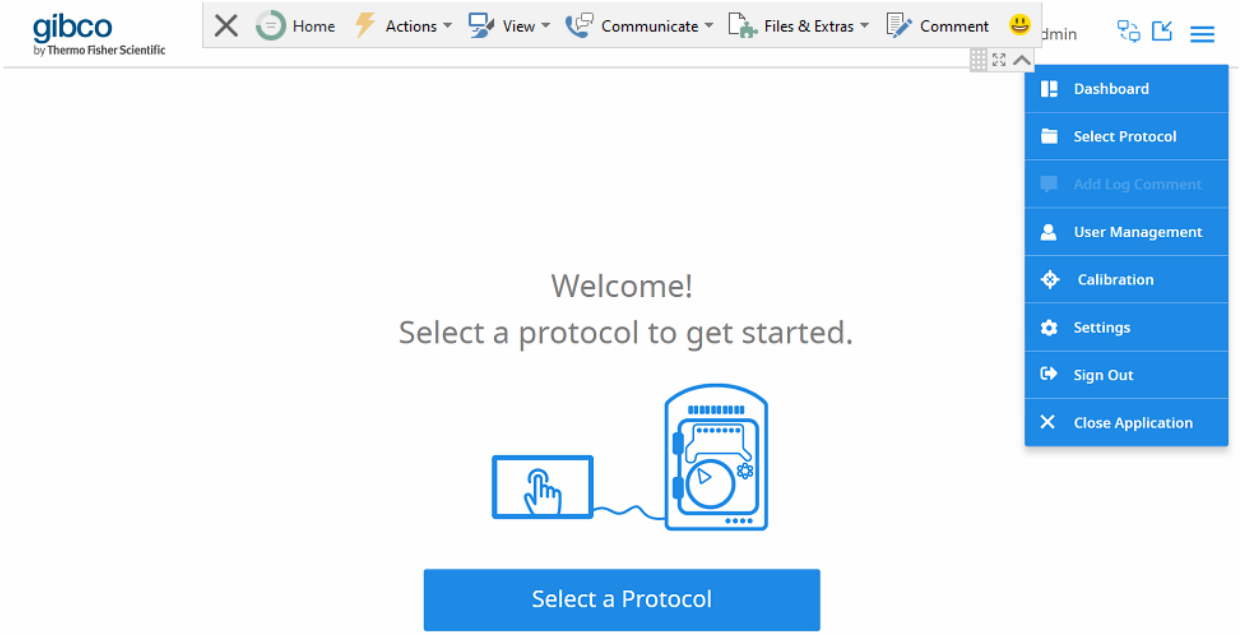
```
D:\Users\Administrator>ping 192.168.0.5

Pinging 192.168.0.5 with 32 bytes of data:
Reply from 192.168.0.5: bytes=32 time=1ms TTL=255
Reply from 192.168.0.5: bytes=32 time=1ms TTL=255
Reply from 192.168.0.5: bytes=32 time=1ms TTL=255
Reply from 192.168.0.5: bytes=32 time=1ms TTL=255

Ping statistics for 192.168.0.5:
    Packets: Sent = 4, Received = 4, Lost = 0 (0% loss),
Approximate round trip times in milli-seconds:
    Minimum = 1ms, Maximum = 1ms, Average = 1ms
```

Rotea™ instrument OPC UA setup

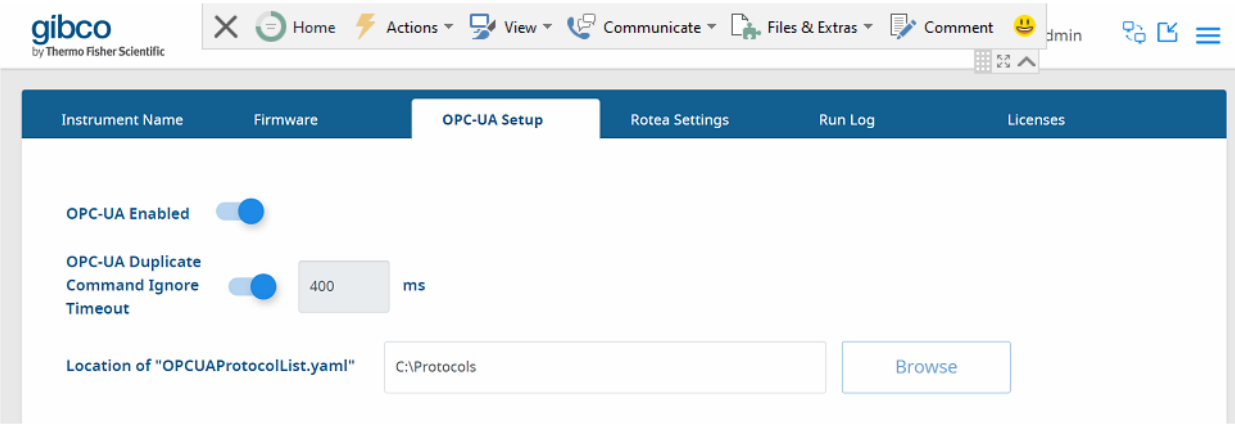
The OPC UA server application resides on the companion PC and is active when the Rotea™ instrument application is running.

Note: If the Rotea™ instrument application is not running, then the OPC UA server will not be running and it will cause communication between the instrument and DeltaV™ system to stop.

To set up OPC UA, start the Rotea™ instrument application on the companion PC. From the initial screen, select **Settings** from the ☰ **(Menu)** on the top right.



From the **Settings** page, select the **OPC-UA Setup** tab and set the entry fields as shown.



The entry field **OPC-UA Duplicate Command Ignore Timeout** is a troubleshooting timer. This entry is used to ignore duplicated commands from the DeltaV™ system within this time. If the scan rate of the DeltaV™ system landing module is less than 1 second then duplicate commands might be issued due to the Rotea™ instrument processing the first command and not responding in time. Scan rates of 1 second, and above should not encounter any issues.

The entry field **Location of OPCUAProtocolList.yaml** defines where the protocol lookup file resides. This file contains the path of each protocol to be run from the DeltaV™ system and its index number.

Rotea™ OPC UA security settings

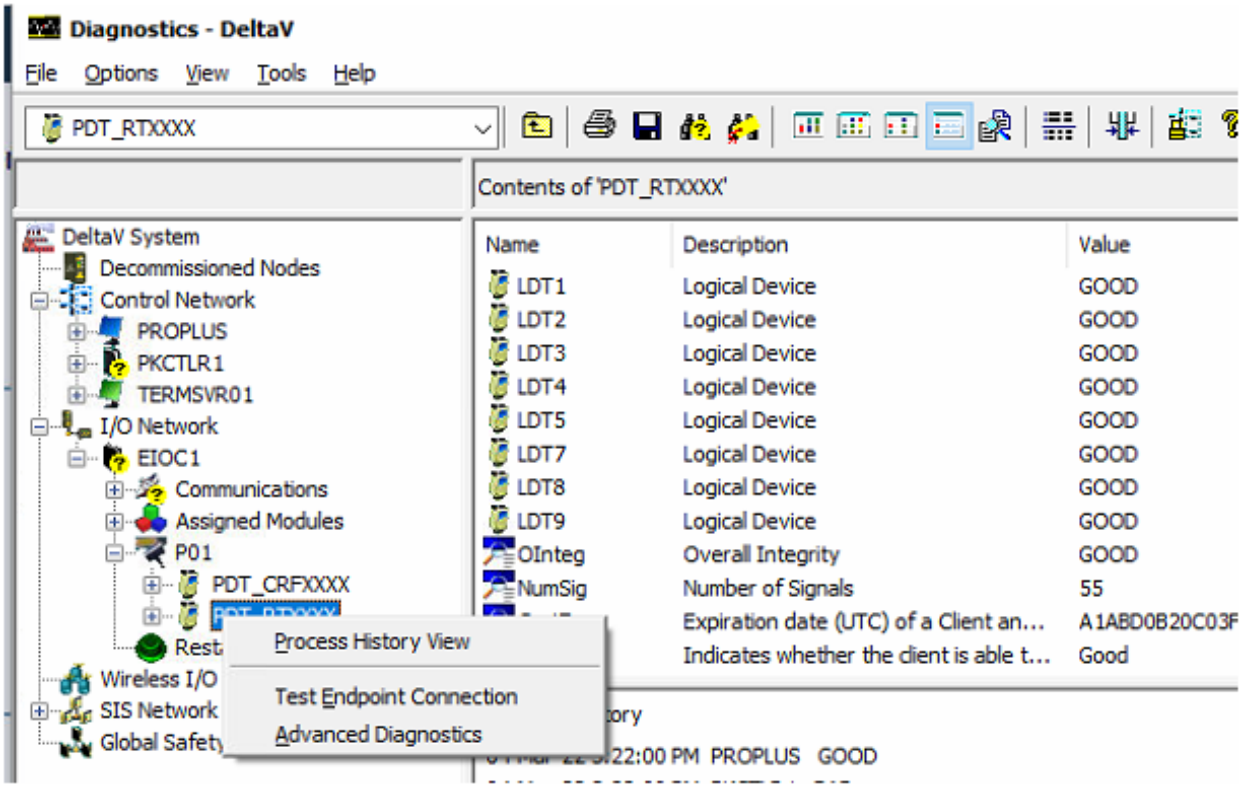
It is recommended to start using the OPC UA server with no security enabled, and once the interface has been tested the security level can be increased. The `opcua_server_config.xml` file has the “no security” option disabled by default, to enable the option uncomment those lines in the xml file.

The file by default is located in the folder “`C:\Program Files (x86)\Rotea\opcua`”.

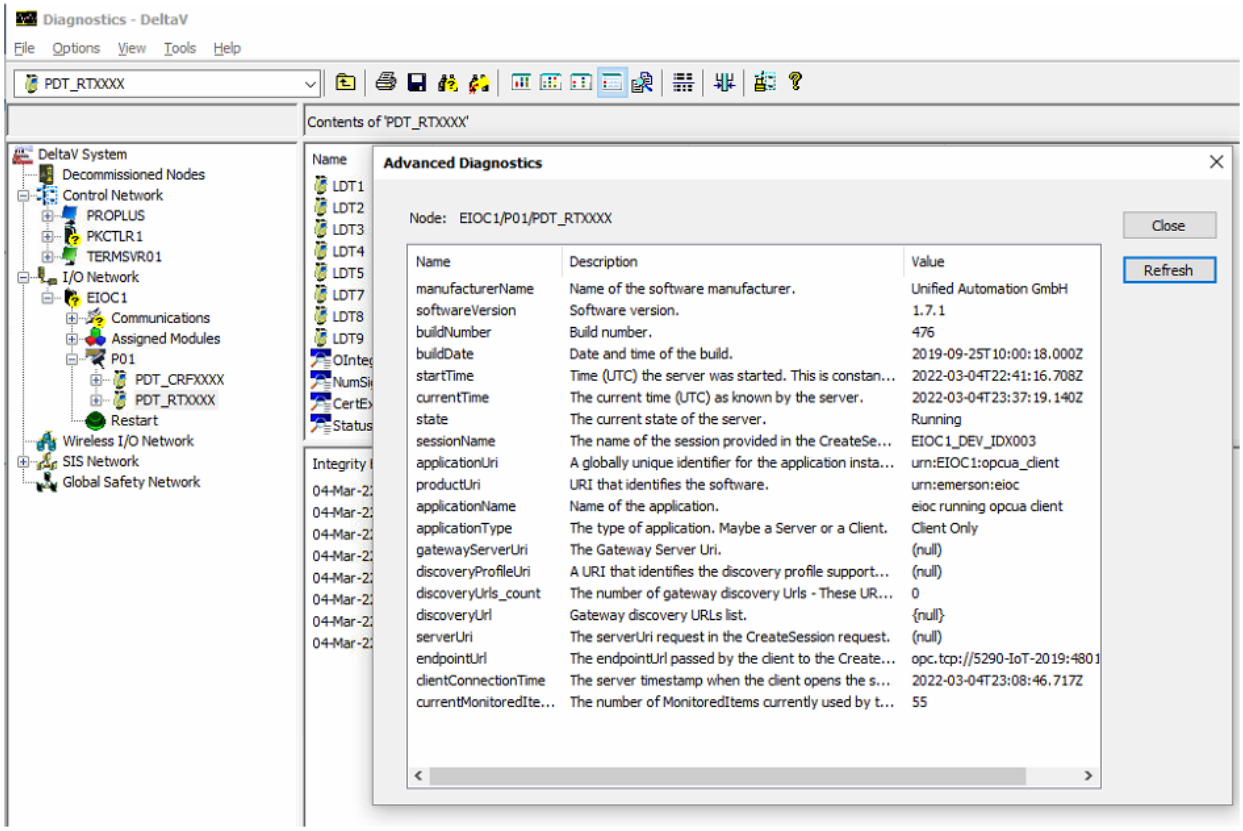
OPC UA connectivity check

Once the DeltaV™ software configuration has been downloaded, a quick test can be performed from the **Diagnostics DeltaV** application. This can be opened by selecting the icon.

From the diagnostics application, browse to the required EIOC and port P01. Browse further to the device, right click and select **Test Endpoint Connection**.



If the OPC UA communications are operating, the following screen will appear detailing the connection diagnostics.



User interface

The user interface consists of a number of screens that enable the user to interact with an instrument and run instrument protocols. DeltaV™ Live is the only supported interface as DeltaV™ Operate is being phased out. These screens are:

- Splash/opening screen
- Overview display
- Main Rotea™ instrument display
- Rotea™ instrument parameter display

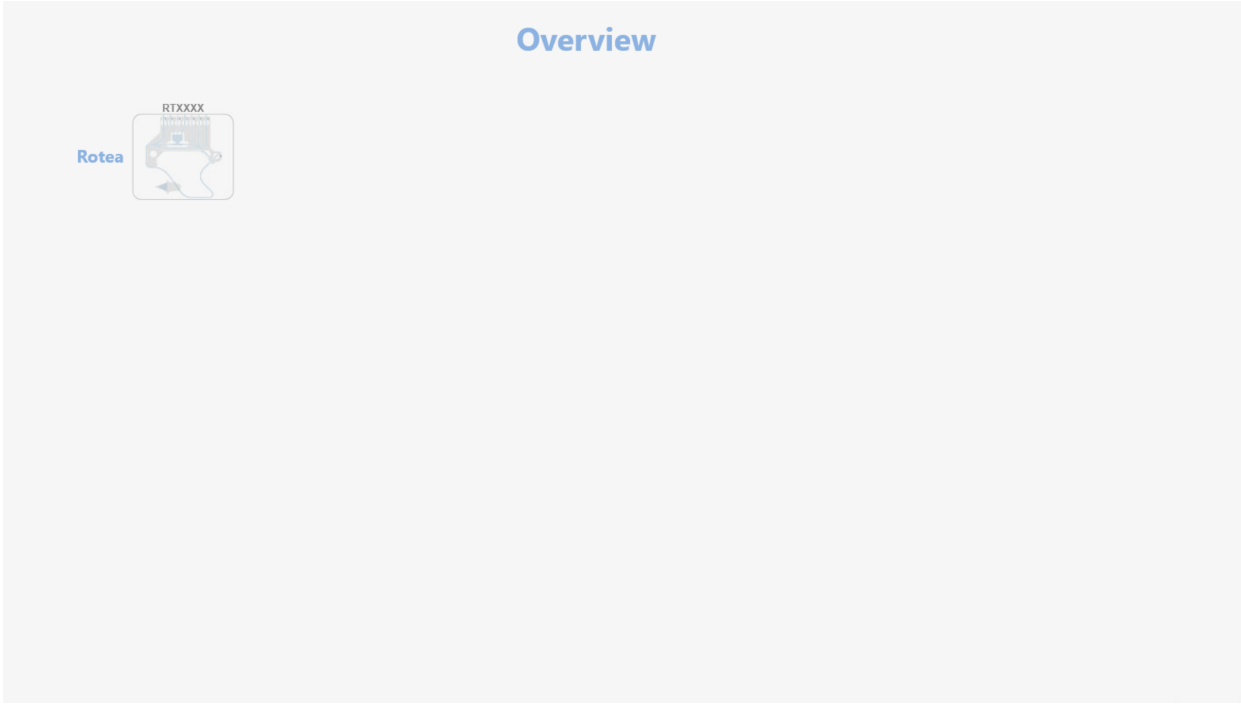
Splash screen

The splash screen appears when the user interface is first started and from here the user can enter the CTS™ Cellmation™ Software overview by clicking anywhere on this screen.

Note: If not using Cellmation™ splash screen, user will have to create an icon in Graphic Studio to open CTS™ Cellmation™ software overview in DeltaV™ Live.

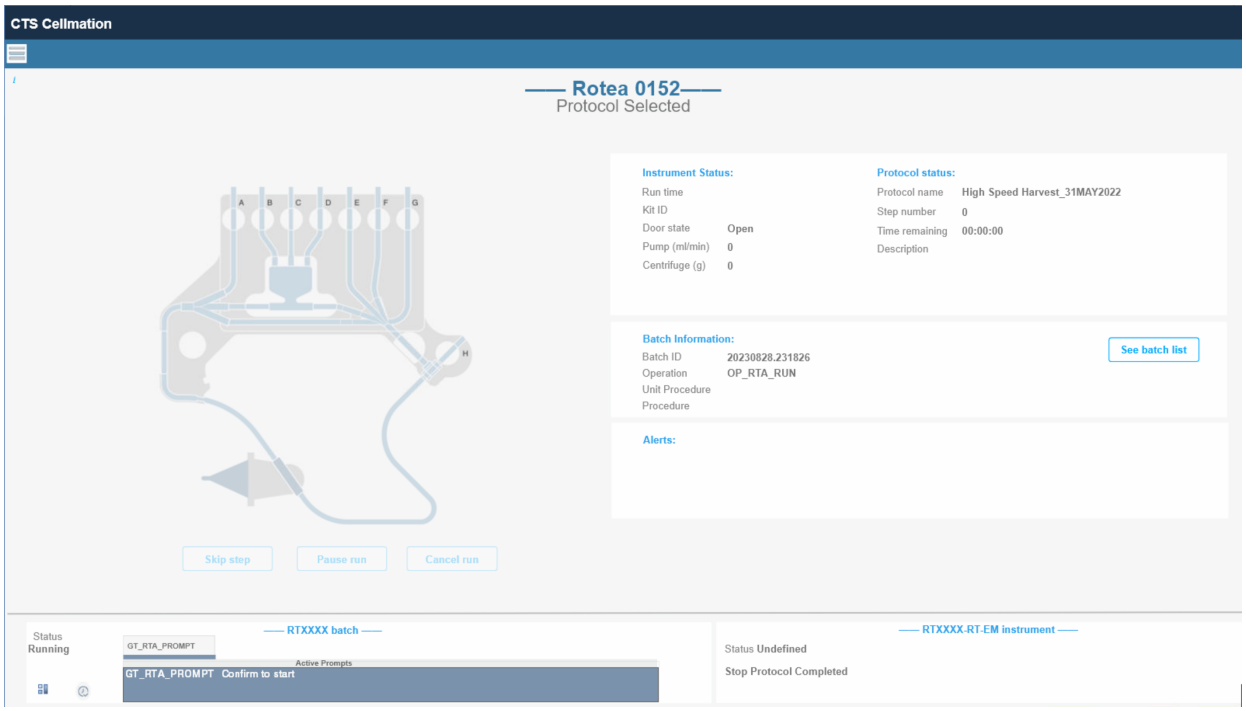
Overview display

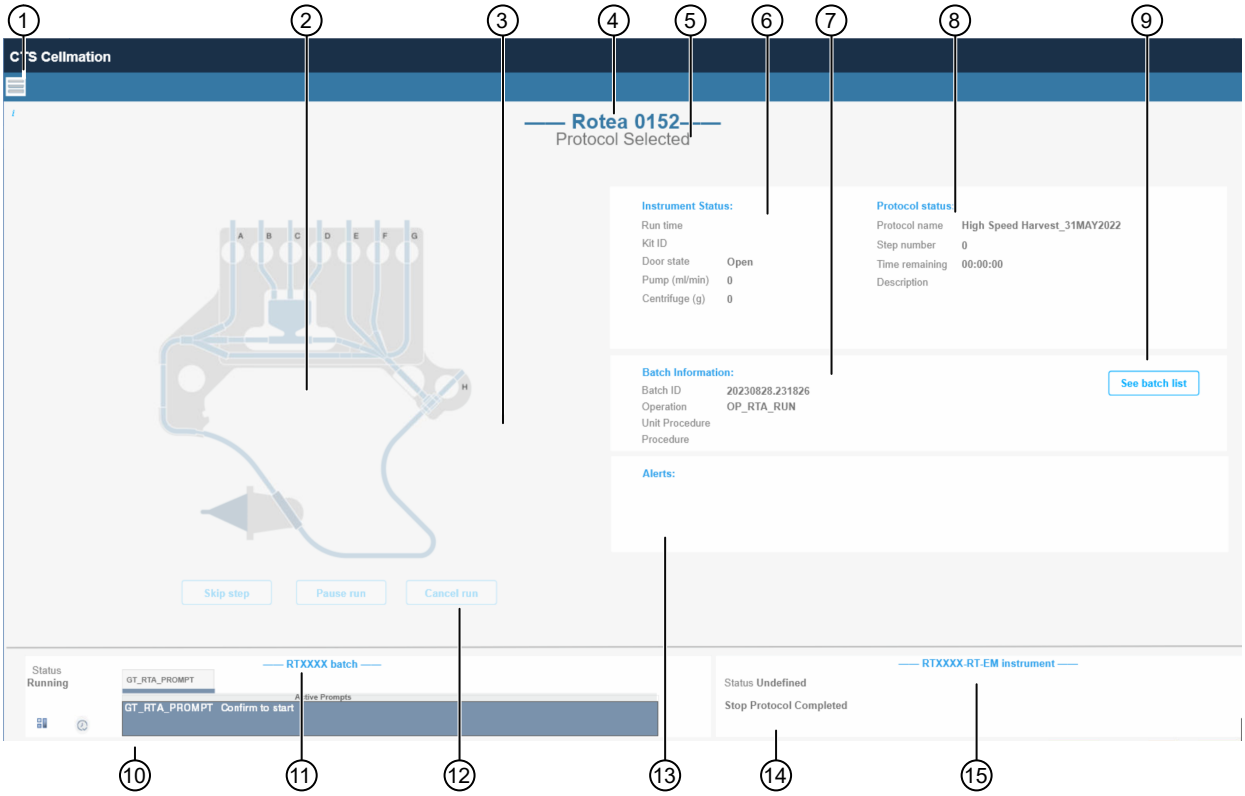
The **Overview** screen allows for an individual instrument to be selected to open more detailed information for that instrument. On the initial installation, the overview screen has a blank screen with guideline boxes. As instruments are added to a system, this overview screen will be modified to add the new instruments.



Main Rotea™ instrument display

The main Rotea™ instrument display shows the key data from the instrument.





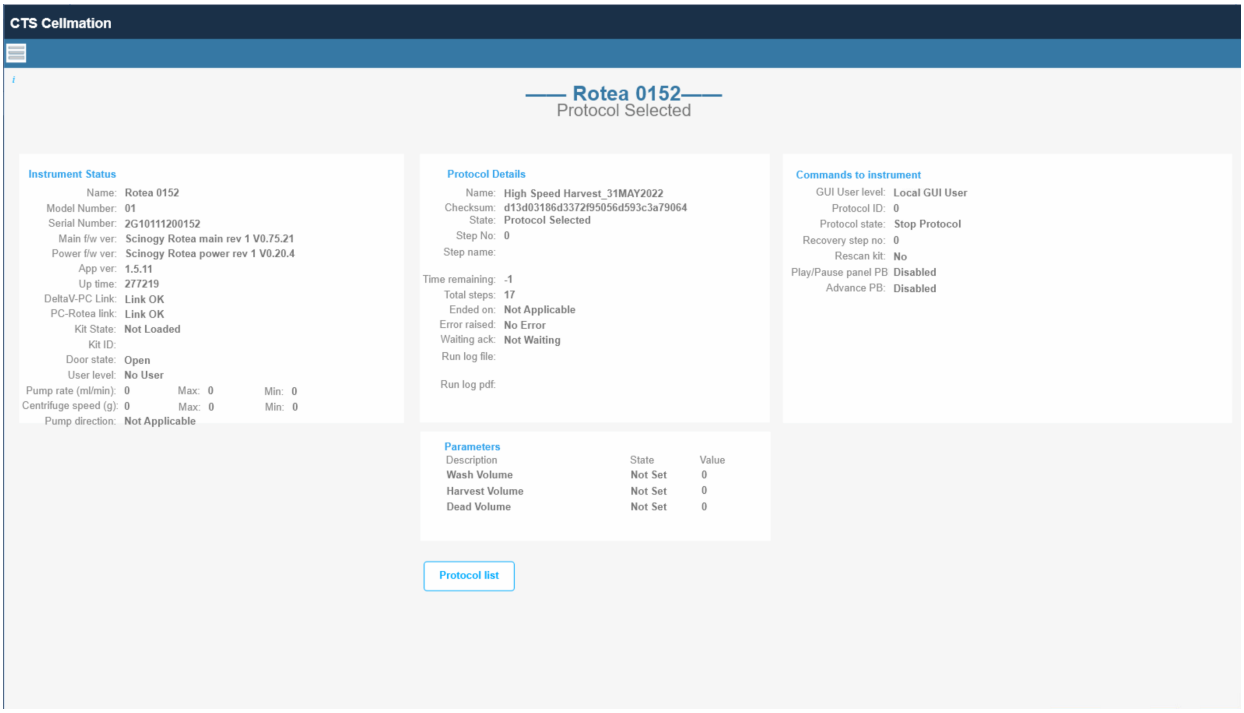
1. Menu display selection. Displays Rotea™ Interface Parameters display and Cellmation Overview display for selection. When one of the options is clicked, the displays are opened.
2. Rotea™ kit representation. When running, the routes animate to indicate the route selection. Green indicates forward pump direction and orange reverse direction.
3. Buttons to change the pump and centrifuge speed, and to reset the step timer target.
4. Instrument name
5. Instrument running state
6. Instrument details. Displays run time, installed kit ID, door state, pump and centrifuge speeds.
7. Batch information. Recipe details are displayed here if a batch recipe is running.
8. Protocol status. Displays the protocol name, step number, description, and the remaining step time.
9. Button to open the batch list view.
10. Messages/prompts from batch/recipe are displayed here.
11. Clicking here opens the Unit Module faceplate.
12. Buttons to skip a step, pause/resume the protocol and cancel a protocol run. Buttons are only enabled when the Rotea™ protocol is running.
13. Displays the active instrument error
14. Messages/prompts from the equipment module are displayed here.
15. Clicking here opens the Equipment Module faceplate.

The display is comprised of three sections.

1. The left hand section represents the Rotea™ kit and is animated to show the current route. Buttons are included to:
    a. Control the protocol, skip, pause/resume and cancel.
    b. Control the pump/centrifuge speed. The speed can be raised/lowered incrementally by pressing the up/down arrowhead icons. If needed a new setpoint can be entered by clicking on the pump/centrifuge text. A pop up appears to enter a new setpoint.
    c. The step target can be reset.
2. The right hand section details data associated with the instrument and protocol running on the Rotea™ instrument.
    a. Pump rate
    b. Centrifuge speed
    c. Kit status and ID
    d. Door state
    e. Protocol name
    f. Protocol step number, description and remaining time
    g. If protocol has been paused, the reason for the pause
    h. Any protocol errors
3. The bottom of the display comprises two message boxes, one for the Rotea™ equipment module and one for the batch recipe. Any messages or prompts are displayed in these boxes, and prompts can be answered. The boxes also provide selection text to open faceplates and other displays to interact with the batch recipe.

Rotea™ instrument interface parameters display

The Rotea™ instrument parameters display shows all the OPC UA data that is available across the communications interface. Its use is primarily for diagnostic purposes or to see more detailed information of the instrument.



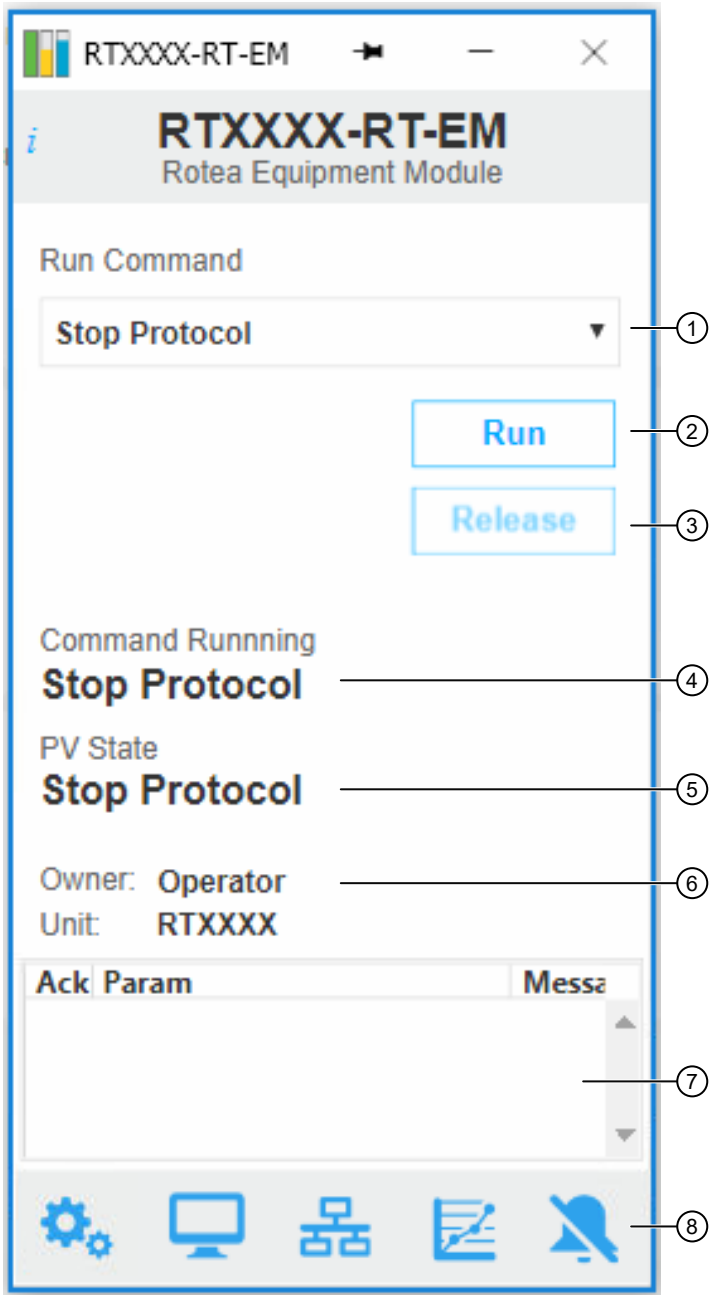
Contextual displays (Faceplates)

Faceplates contextual displays are the preferred method of interacting with CTS™ Cellmation™ Software for control and can be of various types. There are typically two types, faceplates and detail faceplates.

Contextual displays show key information of the software module they are referencing, and typically have detail faceplates that can be called up from the main faceplate to show detailed information available in the module.

Equipment module faceplate

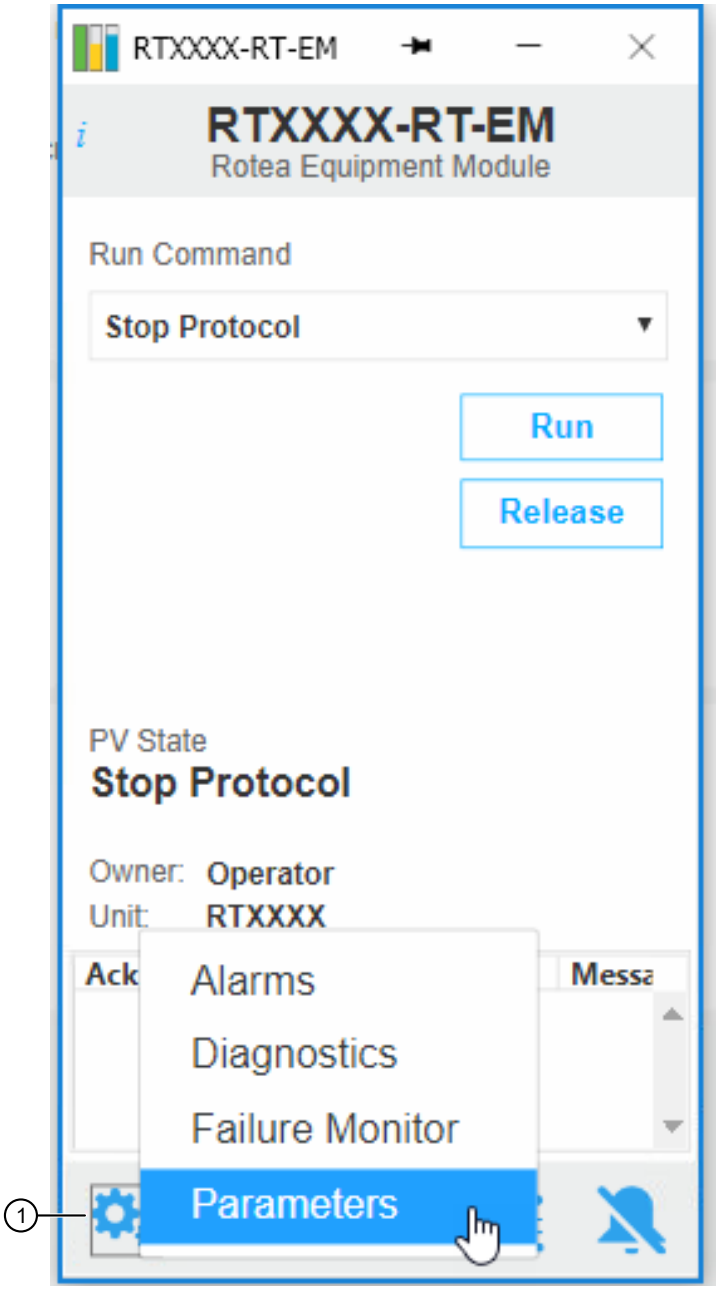
The CTS™ Cellmation™ Software primarily uses an equipment module to control the Rotea™ instrument. The faceplate is shown in the following figure. The most commonly used aspects of the faceplates are noted here. For a full description, see Appendix B, “Faceplate details”.



1. Select a command drop down box
2. Run button: When pressed will set the command to the drop down box selection
3. Release button for ownership of the module
4. Current command being run
5. Current state of the command
6. Displays the current owner of the module
7. Alarm window shows any active or unacknowledged alarms
8. Selection icons

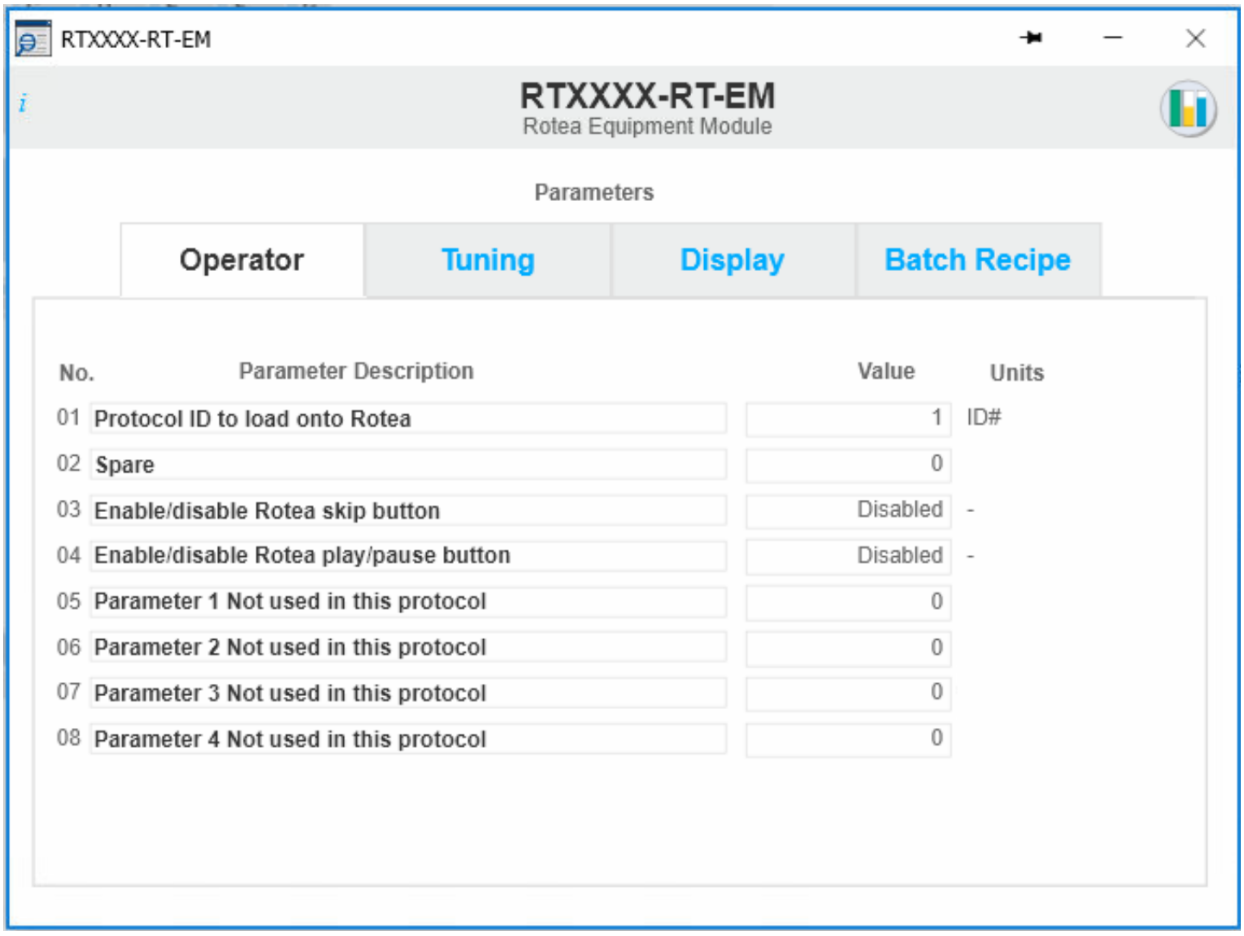
Equipment module detail faceplates

The equipment module detail faceplates show more detailed information of the module. The detail faceplates contains standard objects used within the DeltaV™ system, such as alarms and diagnostics, which can be selected via the selection gear icon on the main faceplate.



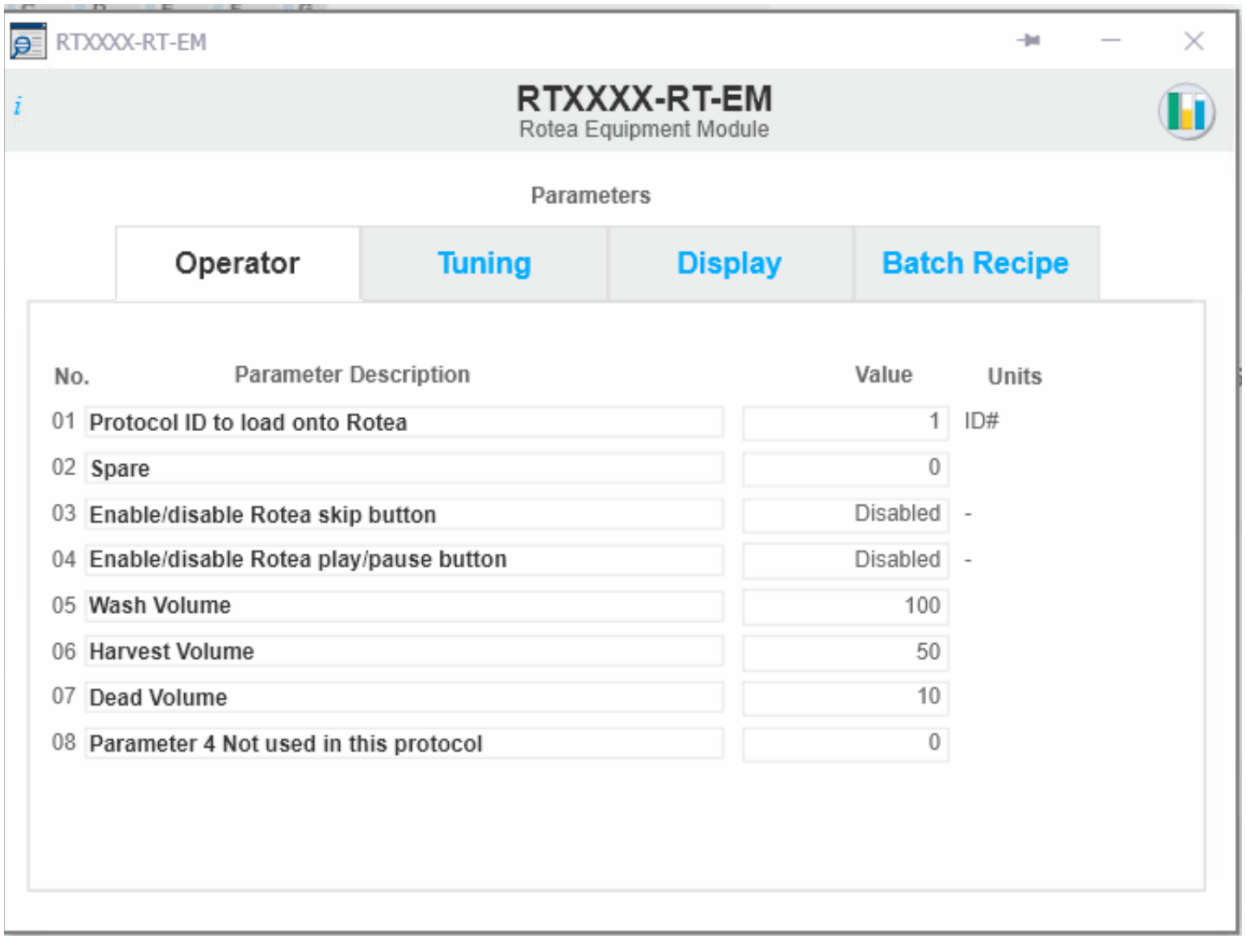
① Clicking on the gear icon (⚙) brings up a context menu allowing for the appropriate detail faceplate to be shown.

The non-standard information displayed are Rotea™ instrument parameters, as show in the following figure.



There are four tabs shown which can be used to select the different types of parameters, **Operator**, **Tuning**, **Display** and **Batch Recipe**.

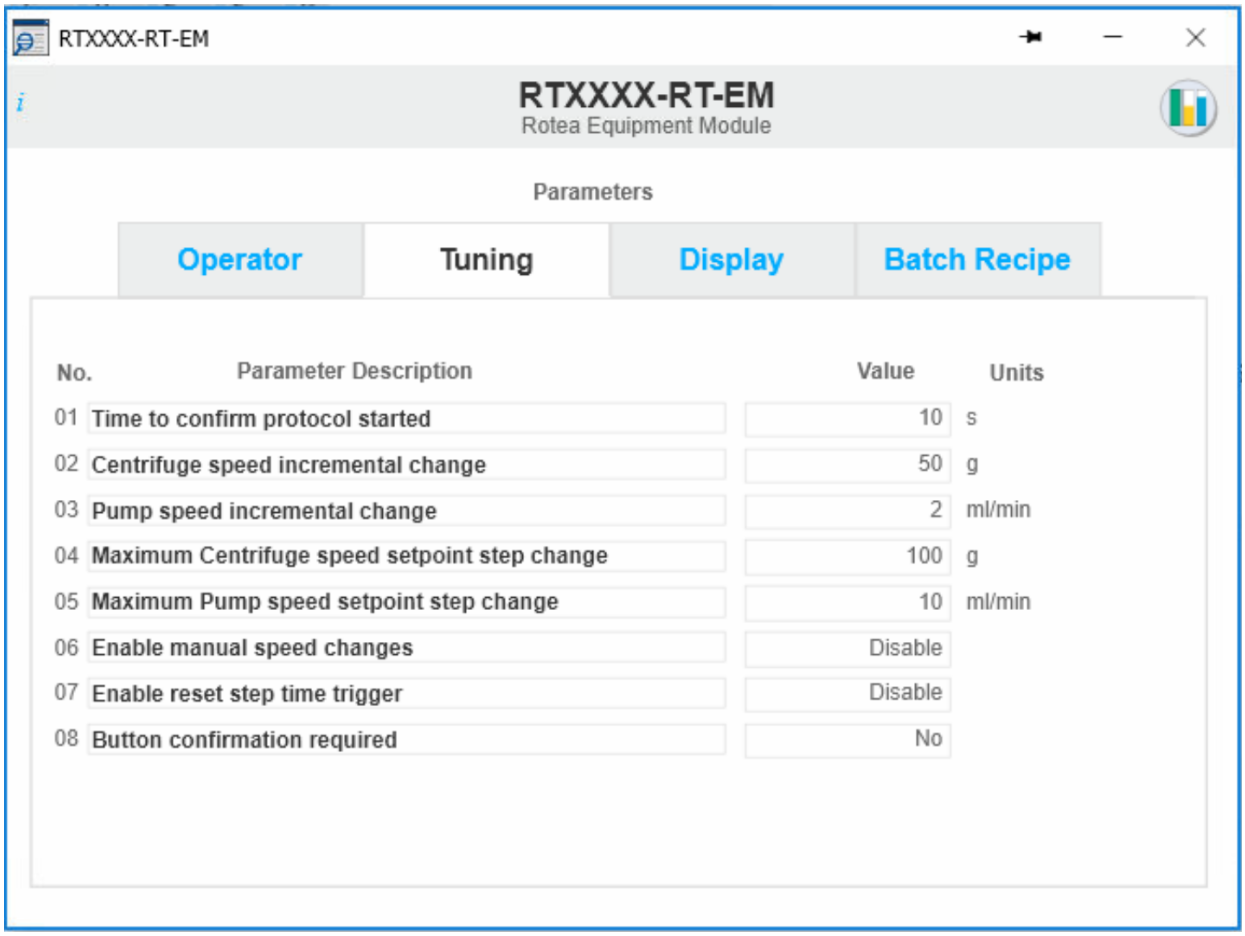
Operator parameters



The parameters shown on this tab can be modified by a user with operator privileges. They are used to control how the protocol runs.

- **Protocol ID to load onto Rotea**: Enter to protocol ID to load onto the Rotea™ instrument.
- **Enable/disable Rotea skip button**: Enable or disabled the skip button on the front panel of the instrument.
- **Enable/disable Rotea play/pause button**: Enable or disable the play/pause button on the front panel of the instrument.
- **Parameter 05 to 08**: Used to set the protocol parameters if required.

Tuning parameters

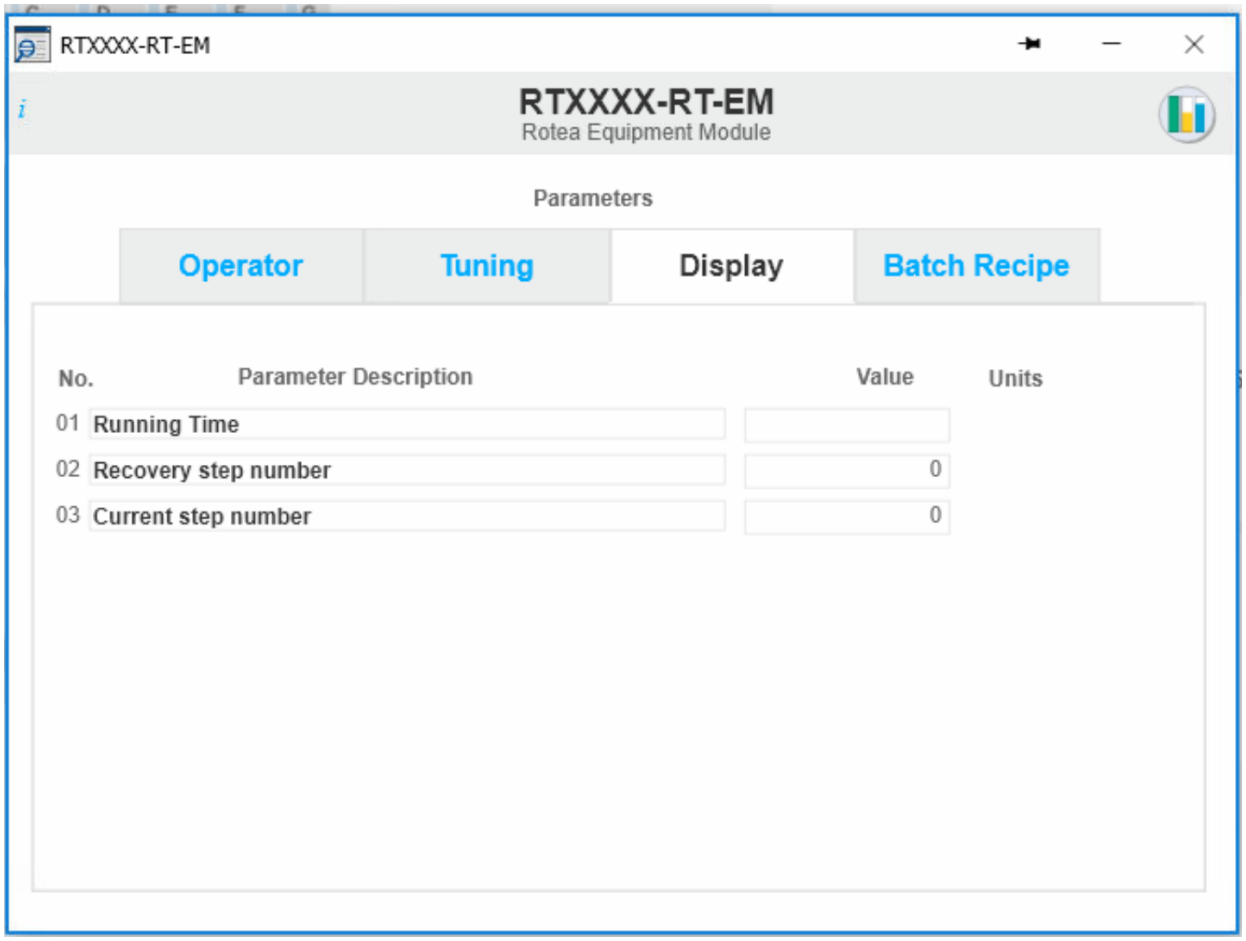


The parameters shown on this tab can only be modified by a user with configuration privileges. This section is used to control how the user interface functions.

- **Time to confirm protocol started**: Time in seconds to wait to monitor for errors before confirming the protocol has started.
- **Centrifuge speed incremental change**: Defines the step change (up or down) when using the incremental up/down buttons on the main display to adjust the centrifuge speed.
- **Pump speed incremental change**: Defines the step change (up or down) when using the incremental up/down buttons on the main display to adjust the pump rate.
- **Maximum Centrifuge speed setpoint step change**: Defines the maximum allowable step change when entering an actual centrifuge speed setpoint from the main display.
- **Maximum Pump speed setpoint step change**: Defines the maximum allowable step change when entering an actual pump speed setpoint from the main display.
- **Enable manual speed changes**: When enabled, the user can modify the speed of the pump and centrifuge from the main display.

- **Enable reset step time trigger**: When enabled, the user can reset the step time trigger from the main display.
- **Button confirmation required**: When set to 'Yes', a confirmation is required before the **Skip**, **Pause** and **Cancel** button actions are performed.

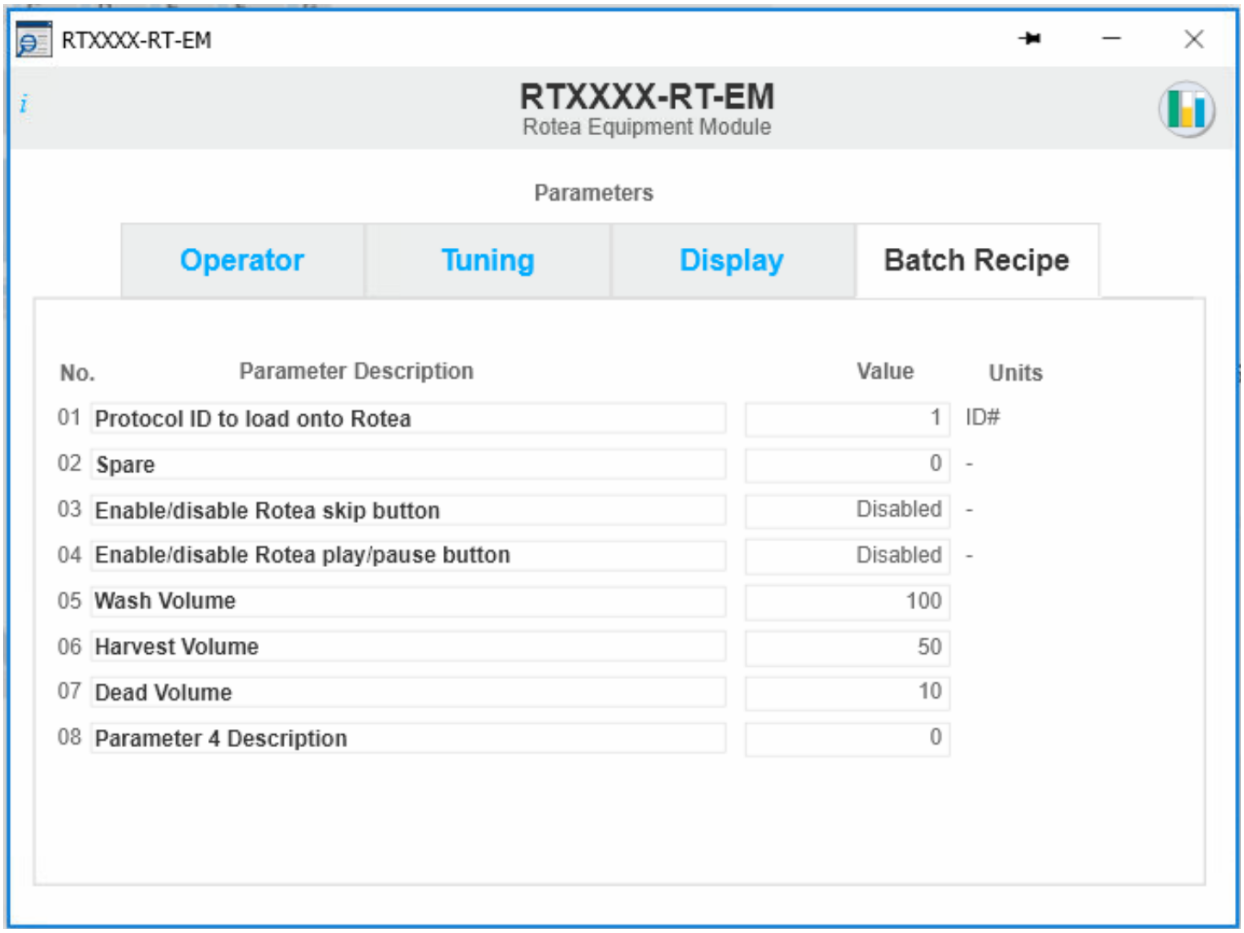
Display parameters



The parameters shown on this tab are internally calculated for display only and cannot be modified.

- **Running Time**: Total time that the protocol has been running. Formatted as HH:MM:SS
- **Recovery step number**: When a protocol completes unsuccessfully, the user is given the option to recover to a step in the protocol. This parameter is used to store the user entered step number.
- **Current step number**: The current running step of the protocol is stored in this parameter. This indicates the step number that was running before a protocol unsuccessful completion.

Batch recipe parameters

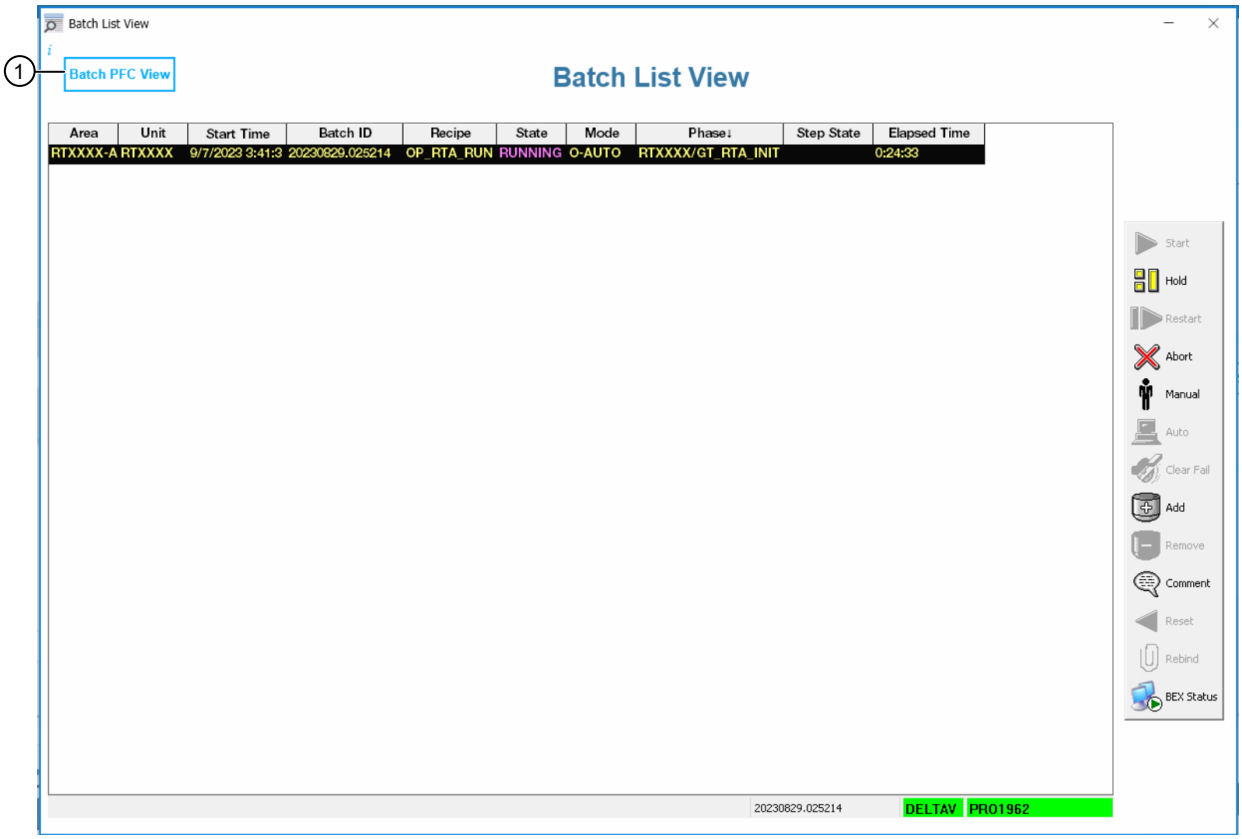


The parameters shown on this tab are updated by a phase running as part of a batch recipe and cannot be modified.

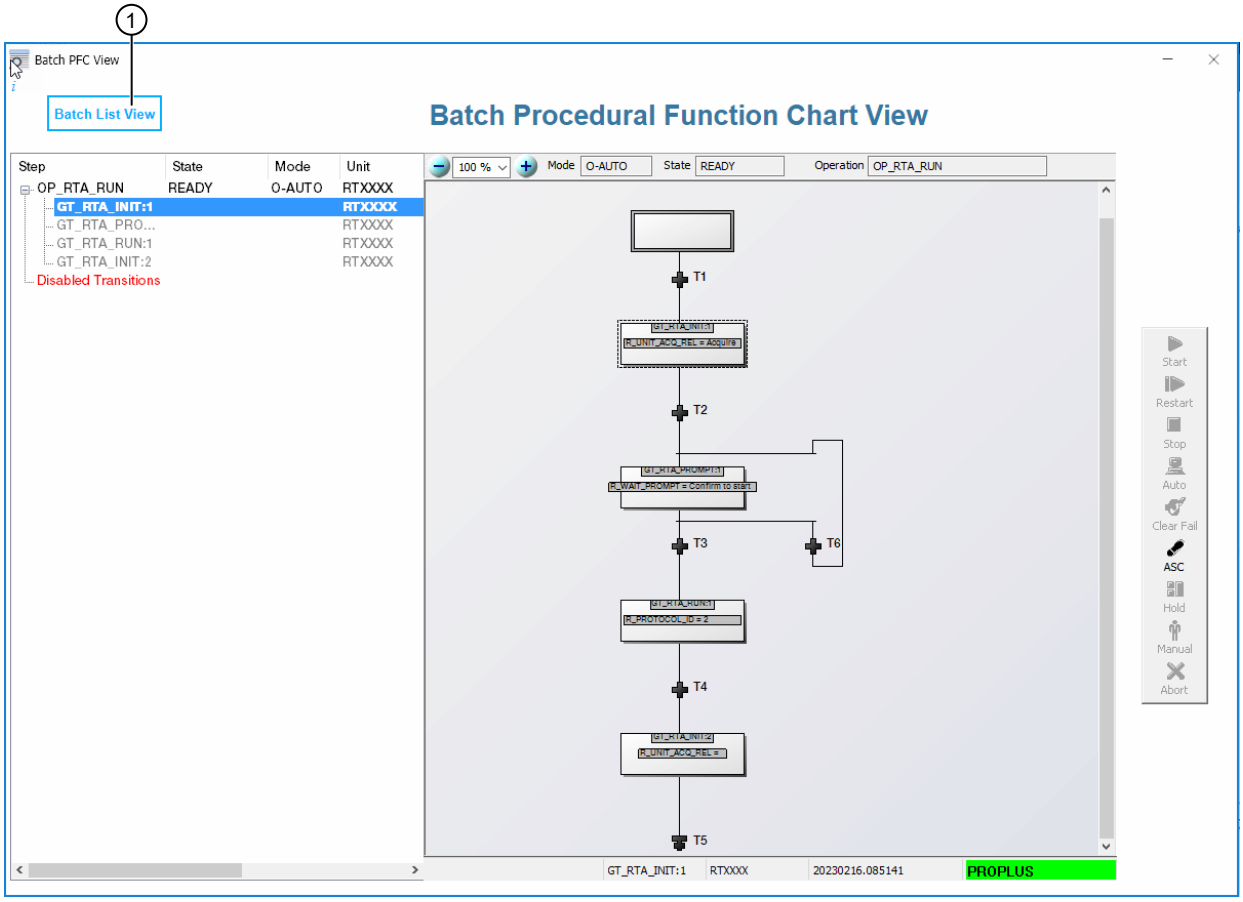
- **Protocol ID to load onto Rotea**: Enter a protocol ID to load onto the Rotea™ instrument.
- **Enable/disable Rotea skip button**: Enable or disabled the skip button on the front panel of the instrument.
- **Enable/disable Rotea play/pause button**: Enable or disable the play/pause button on the front panel of the instrument.
- **Parameter 05 to 08**: Used to set the protocol parameters if required.

Batch faceplates

The batch faceplates are displays that allow for interaction with the batch recipes. From the main Rotea™ display, click on the **See batch list** button to call up the Batch List faceplate as shown.



From this faceplate, new recipes can be selected and run. This display also shows all the batch recipes currently running on the system. Selecting the **Batch PFC View** button (1) calls up the **Batch Procedural Function Chart** faceplate as shown.



This faceplate will show the selected recipe in flow chart mode. The left hand pane shows the structure of the recipe, starting at the Procedure, Unit Procedure and then Operation level. The right hand pane shows the selected recipe item as a flow chart, and from here individual objects can be inspected in more detail.

Selecting the **Batch List View** button 1 calls up the **Batch List View** faceplate.

2 General system operation

User login

Click the user login details found on the right side of the main toolbar. Enter a valid user name and password in the pop-up box. If using Domain in the first line, it is very important to use the correct domain name.

Table 2 Available actions for each user level

Action	Operator	Maintainer	Supervisor	Administrator
Access Window desktop	X	X	X	✓
Exit DeltaV Operate	X	X	X	✓
Access overview page	✓	✓	✓	✓
Access configuration page	✓	✓	✓	✓
View Smart Device info	✓	✓	✓	✓
Access Details displays	✓	✓	✓	✓
Access Control Studio	X	X	X	✓

Table 2 Available actions for each user level *(continued)*

Action	Operator	Maintainer	Supervisor	Administrator
Access Process History view	✓	✓	✓	✓
Change alarm limits	✓	✓	✓	✓
Change conditional alarm settings	X	X	✓	✓
Shelve or remove from service alarms	✓	X	✓	✓
Set alarm priority	X	X	✓	✓
Acknowledge alarms	✓	✓	✓	✓
Bypass interlocks	X	X	✓	✓
Change tuning parameters	X	X	✓	✓
Access Diagnostics	✓	X	✓	✓

To add, change or delete a user or group, click the link **DeltaV Engineering** in the Windows™ toolbar (bottom of the screen), then click on the **User Manager** icon. For more information on the user manager, refer to DeltaV™ Books Online.

Rotea™ instrument operation

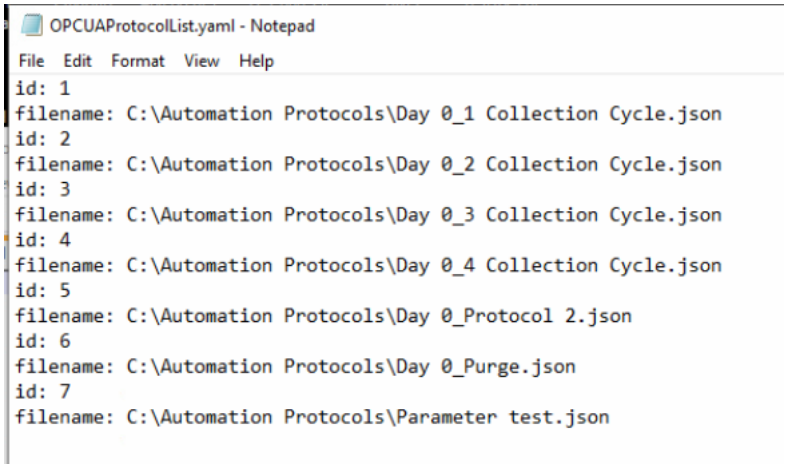
The Rotea™ instrument can be controlled manually or automatically. In either case, the Rotea™ instrument must be configured to allow for remote operation via OPC UA.

The Rotea™ instrument runs protocols which are defined in JSON files and the protocol file is sent to the instrument each time the protocol is run.

Currently the DeltaV™ system does not support writing strings using OPC UA, therefore, a lookup method is used. To remotely select which protocol to run, the DeltaV™ system writes an integer which is the program index number.

A file named `OPCUAProtocolList.yaml` defines the named protocols against an index number and the CTS™ Cellmation™ Software uses this index number to select the protocol to run. Refer to the Rotea™ instrument documentation on creating and locating `OPCUAProtocolList.yaml` files.

The following figure shows an example of the contents of this file on the Rotea™ instrument.



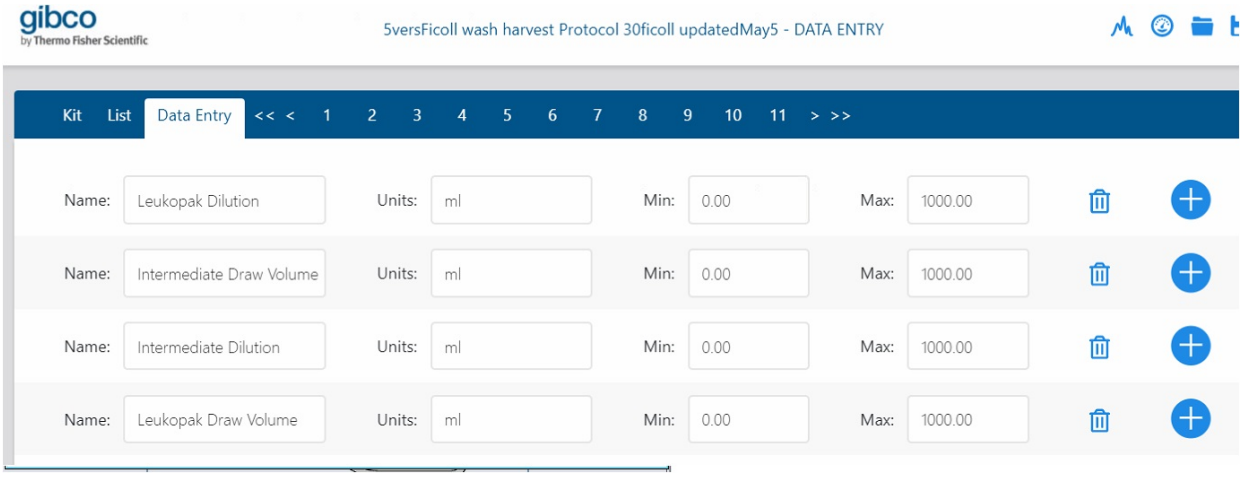
The file needs to be maintained to contain the list of protocols to be run from the DeltaV™ system.

Create a protocol on the Rotea™ instrument using the Protocol Builder application and ensure that the protocol has been entered into the `OPCUAProtocolList.yaml` file. Once this file has been updated, protocols can be selected to run remotely.

Note: For the Rotea™ instrument to use the new `.yaml` file, the OPC UA server needs to be disabled and then enabled. This forces the Rotea™ instrument to load the modified `.yaml` file.

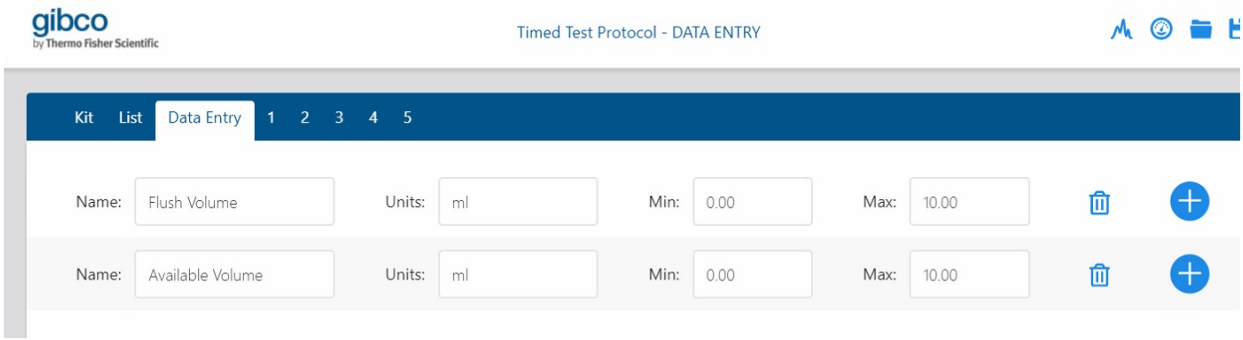
Rotea™ instrument protocol parameters

A Rotea™ instrument protocol can have up to 4 parameters that can be used within the protocol as volumetric end targets. Each of these parameters is configured with a name as shown in the following figure. The DeltaV™ system configuration assumes that parameter 1 is the 1st row, parameter 2 is the 2nd row and so forth.



Zero value parameters

There might be situations where a protocol parameter can be set to zero. This can be set in the Rotea™ instrument Protocol Builder application with a minimum range of zero as shown in the following figure.



Currently, the configuration will not allow for this as the Rotea™ instrument expects a non-zero value to be entered. The minimum value that can be entered is 1. A parameter value of zero in the DeltaV™ system configuration will not allow for a protocol to run as parameter errors will be raised.

Manual operation

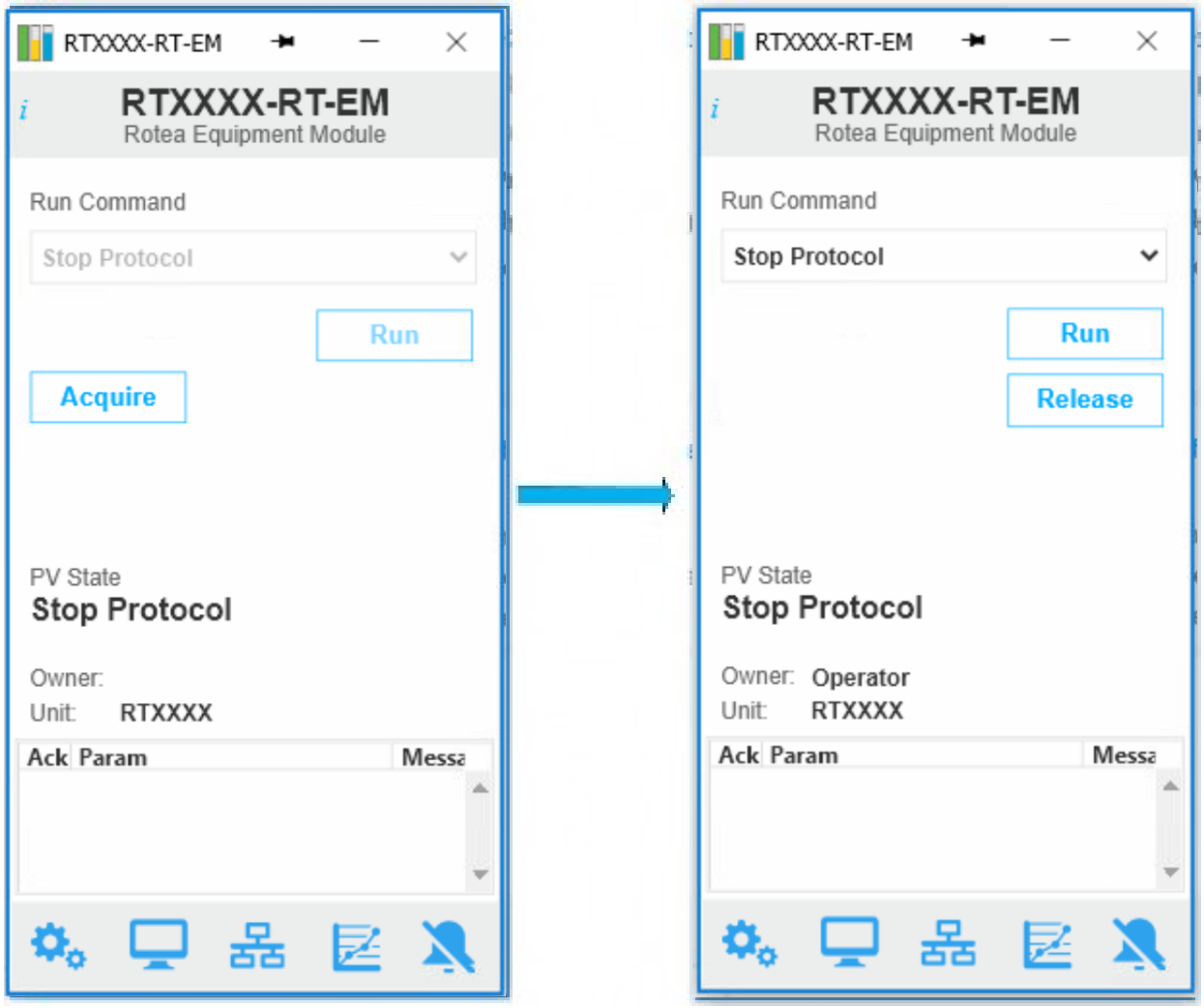
The Rotea™ instrument can be controlled manually from the DeltaV™ system via the equipment module faceplate.

To initiate a protocol to run on the Rotea™ instrument, perform the following steps.

Step 1: Acquire the equipment module

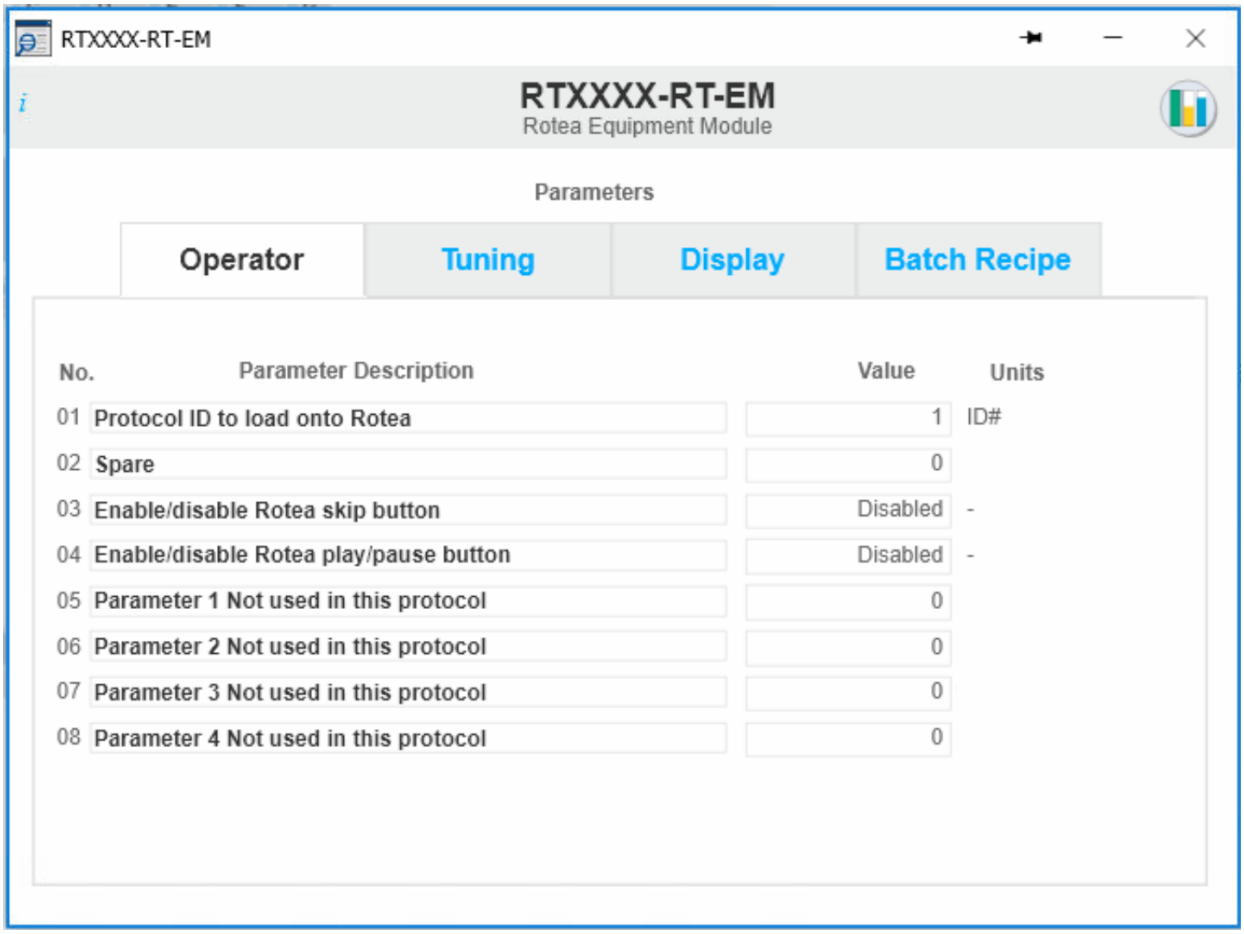
Open the equipment module faceplate and click on the **Acquire** button if available. If the button is not shown, then the module is already owned. If the **Owned by**: field shows **Operator** then proceed to “Step 2: Setup the equipment module” on page 41. If any other owner is identified, then it is most likely owned by a batch recipe and will not be available for acquiring until the batch recipe is complete.

When the user has finished using the Rotea™ instrument the **Release** button can be pressed to relinquish ownership. This means that the module is available to be acquired by a user or a batch recipe. A batch recipe will not be able to acquire the module unless the **Owned by:** field is empty.

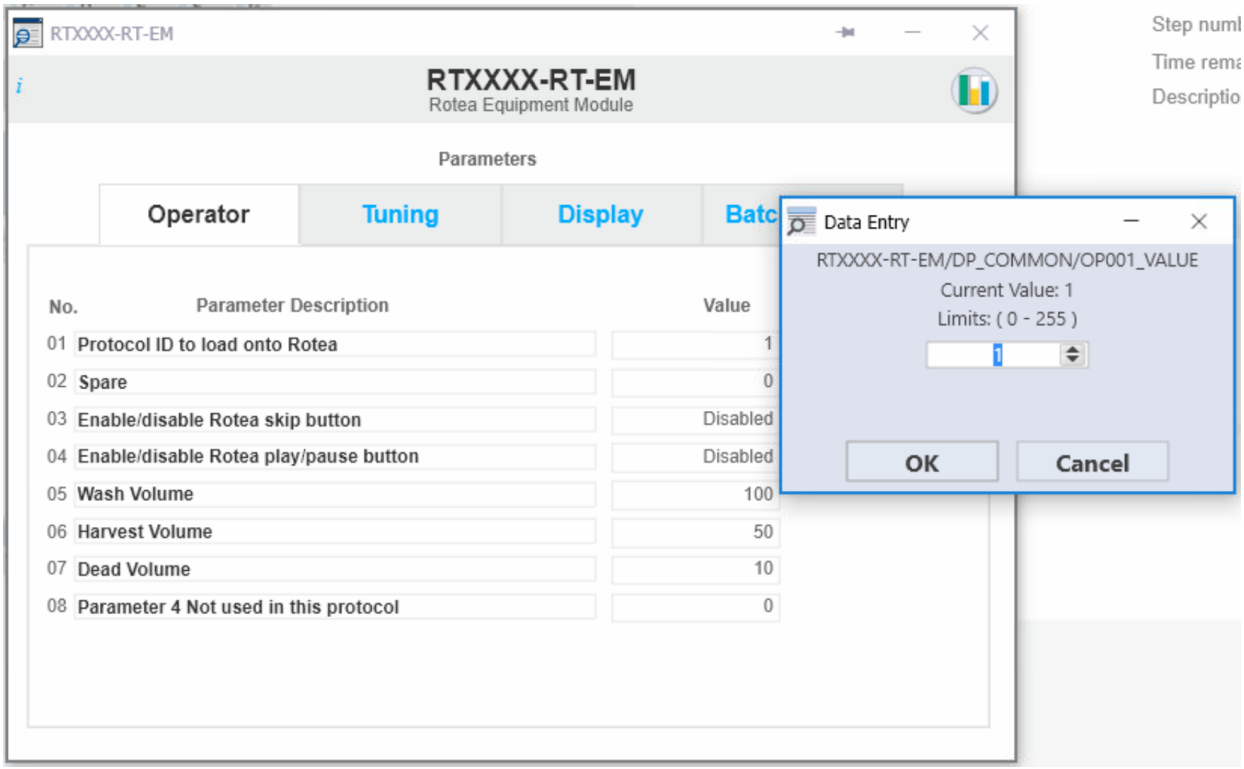

RTXXXX-RT-EM
RTXXXX-RT-EM
Rotea Equipment Module
Run Command
Stop Protocol
Run
Acquire
PV State
Stop Protocol
Owner:
Unit: RTXXXX
Ack Param Messa
RTXXXX-RT-EM
RTXXXX-RT-EM
Rotea Equipment Module
Run Command
Stop Protocol
Run
Release
PV State
Stop Protocol
Owner: Operator
Unit: RTXXXX
Ack Param Messa

Step 2: Setup the equipment module

Open the equipment module detail faceplate and select the **Parameters** button. The display shown in the following figure should appear.



Enter the exact Protocol ID that was entered in the `.yaml` file. See “Rotea™ instrument operation” on page 37. By clicking on the current value field, a data entry form appears as shown in the following figure. From this form enter the ID number and click **OK** to store the value.



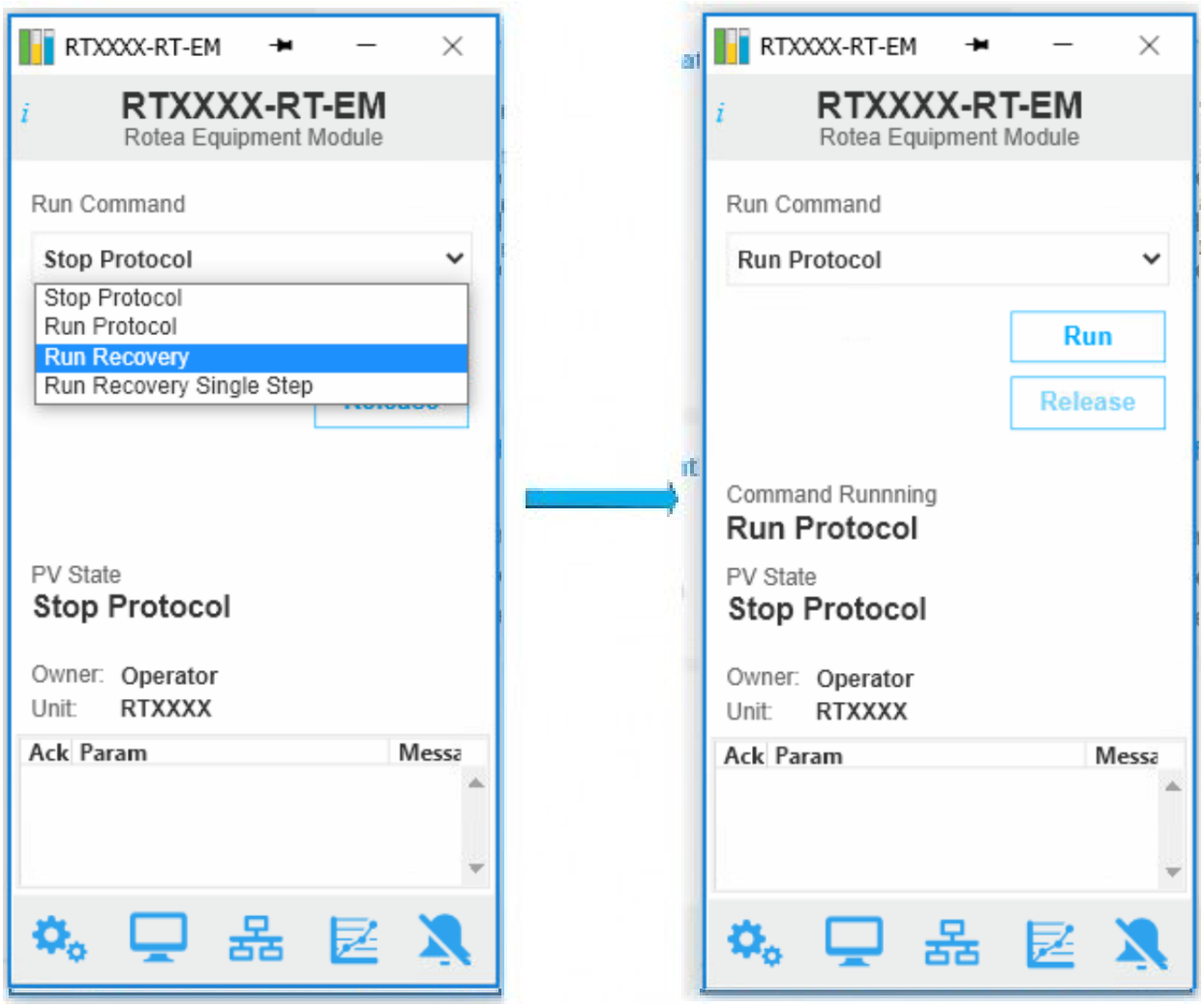
If needed, the parameters to enable/disable the Rotea™ instrument front panel buttons can be set from the parameter list. Values for the rest of the parameters can be either entered in advance or in response to the prompts appearing when **Run Commands** are active on detail faceplate.

Note: The parameters 05 through 08 are updated once the protocol has been selected in step 4.

Step 3: Setup the equipment module to Run Protocol

Open the equipment module faceplate.

From the **Run Command** drop down box, select **Run Protocol** and then click on the **Run** button.

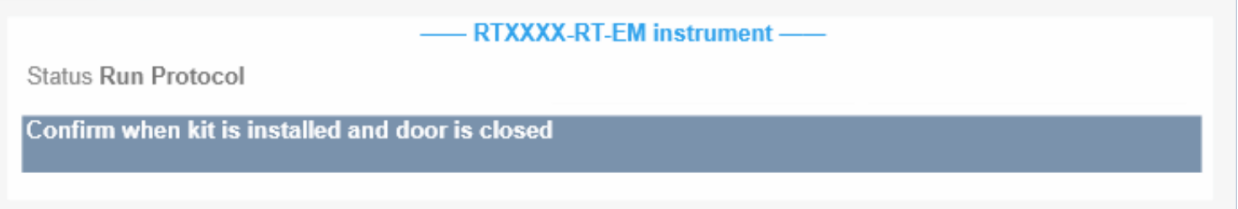


The **Run Protocol** command will now run as shown on the equipment module faceplate.

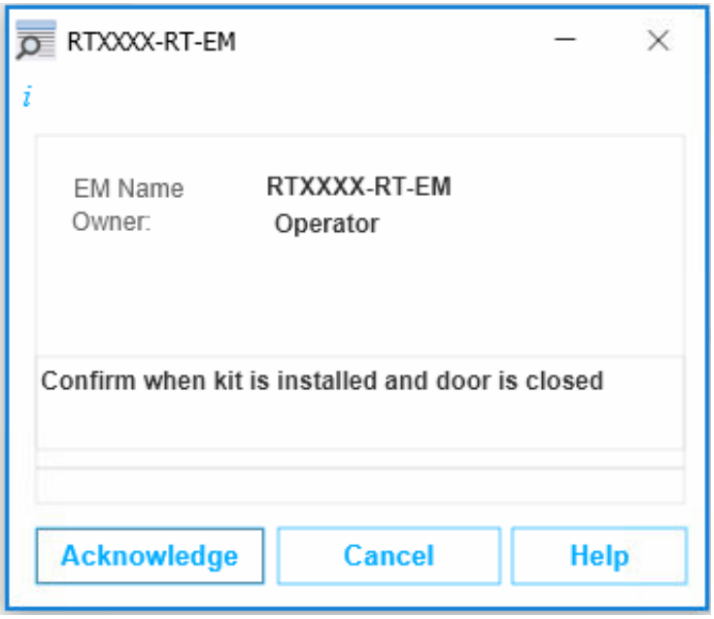
Step 4: Answer prompts as required

Prompts will be generated by the equipment module and displayed in the bottom right hand corner of the main Rotea™ display, as shown in the following figure.

At this point if there are any protocol parameters to pass down to the Rotea™ instrument, the parameters detail faceplate can be opened, and the appropriate parameter values set.



To answer a prompt, click on the prompt text and a new contextual display will appear to answer the prompt. See the following figure.

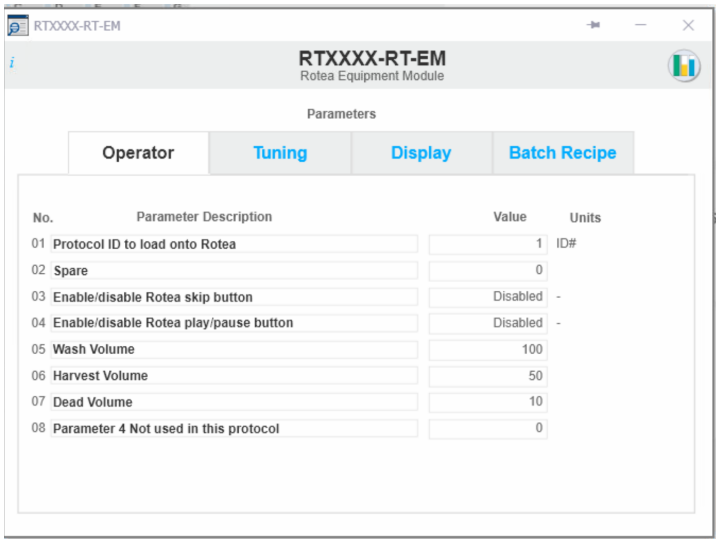


Before a protocol can run the following checks are made:

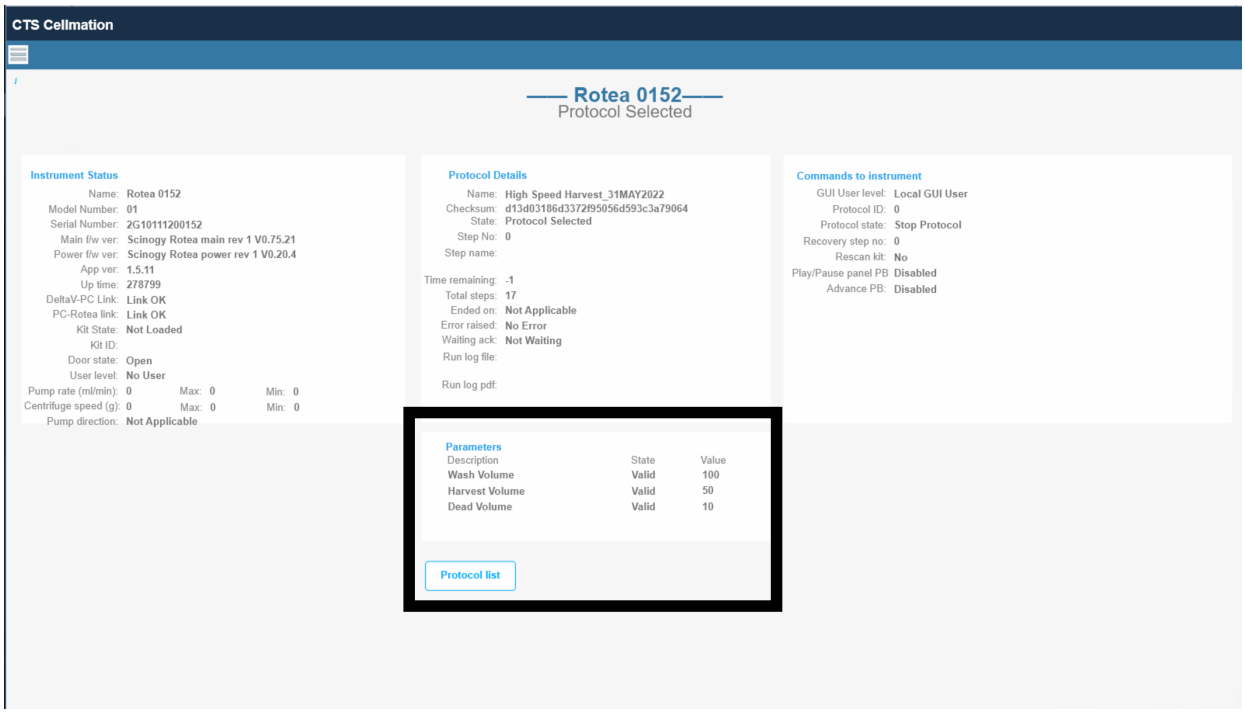
- User prompted to confirm when a kit is installed and the door is closed.
- The correct kit type is checked and if an error is found another prompt is issued to install the correct kit.
- Any protocol parameters that are required are validated.

Step 5: Enter Protocol parameters

If the Rotea™ protocol has parameters, these will be displayed on the equipment module detail faceplate and the main display, as shown in the following figure.



If any of the parameters have errors, use the **Rotea™ Interface Parameters** display to see the parameter status.



To enter a value, click on the parameter current value link on the detail faceplate. When all required parameters have been updated and within range, the display will indicate the parameters as valid on the display. There will be a prompt - **parameter error**, letting the user know that the parameter values have not been entered correctly.

A protocol parameter can be one of the following:

- **Not In Use**: No need to set this parameter value.
- **Not Set**: The parameter value needs to be sent to the Rotea™ instrument.
- **Out Of Range**: The parameter value is outside of the allowable range set in the Rotea™ protocol.
- **Valid**: Parameter values have been accepted by the Rotea™ protocol.

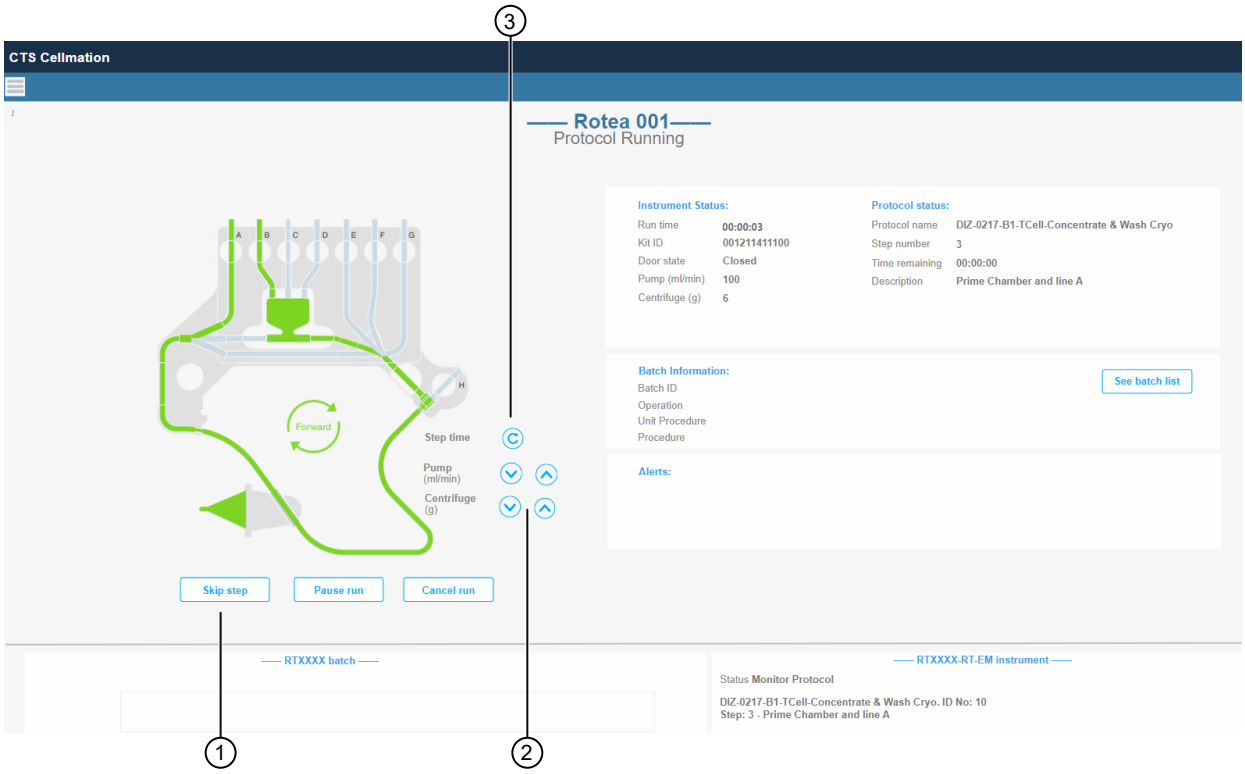
The equipment module will now load the selected protocol onto the Rotea™ instrument and when it is confirmed to be running the module automatically moves to the **Monitor Protocol** state.

Step 6: Monitor Protocol state automatically selected

In this state, the equipment module monitors the progress of the running protocol and the current step description and number are displayed. During this state the **Skip**, **Pause run** and **Cancel run** buttons on the main display are enabled.

If the speed adjustment for the pump and centrifuge has been enabled, then the raise/lower speed buttons are displayed.

If the reset step timer trigger has been enabled,the step time reset button is displayed.



1. **Protocol buttons**: There are three buttons to mimic the buttons on the front panel of the Rotea™ instrument.
   - **Cancel run** will cause the running protocol to discontinue the current step and end the current run.
   - **Pause run** will put the Rotea™ instrument into recirculation mode. In this state, the button text changes to **Resume run** and will cause the protocol to resume the current step.
   - **Skip step** will cause the protocol to skip to the next step. Note that this feature needs to be enabled in the protocol. If this feature is not enabled in the protocol, then this button is not enabled for use.
2. **Speed Control:** The speed of the pump and centrifuge can be modified in two ways.
   - **Up/Down** buttons. Clicking on one of these buttons will incrementally change the speed setpoint up or down by a fixed amount.
   - **Pump/Centrifuge** text. Clicking on the text will bring up a window to allow the speed setpoint to be set to an actual value. Note that on initial display the speed setpoint is shown as -1. Change the value to the required setpoint.

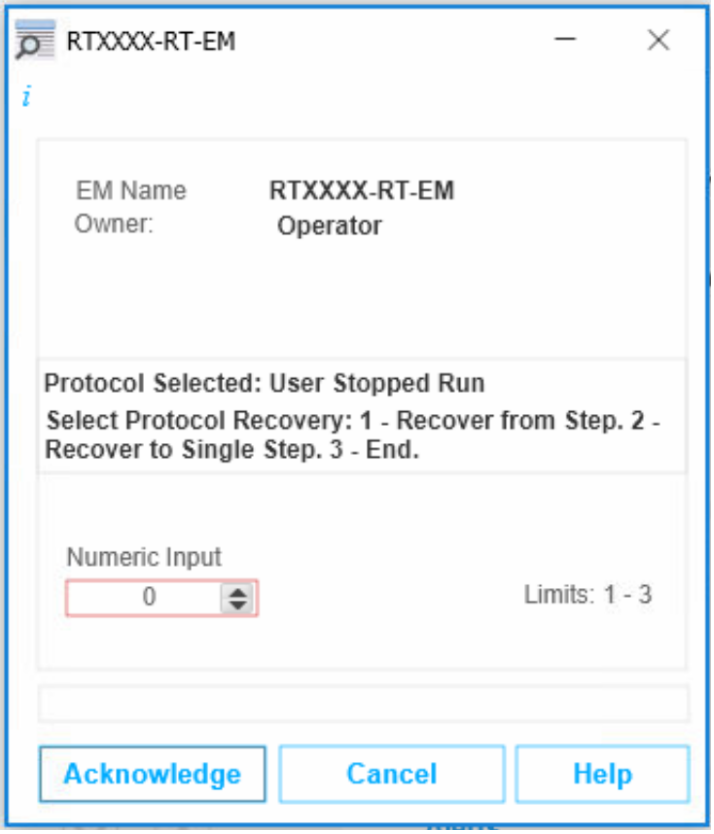
3. **Trigger Reset**: The current step timer can be reset by clicking on the reset button. This will reset the timer to the initial value to extend the step time.

Step 7: Protocol completion

When a Rotea™ protocol completes it can either be successful or unsuccessful. If successful, the equipment module automatically selects the **Stop Protocol** state. If unsuccessful, the equipment module automatically selects the **Recovery Control** state. From this state the user is prompted to select from three options.

The equipment module prompt is shown in the following figure. The first line will indicate the reason for the unsuccessful completion.

By clicking on the prompt text, a data entry form will appear as shown in the following figure.

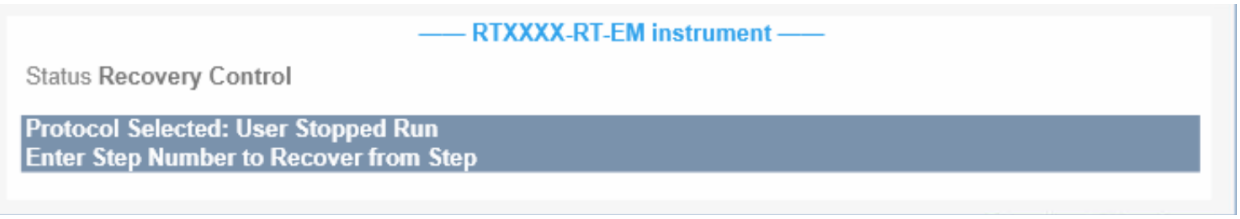


From here, select one the the following options:

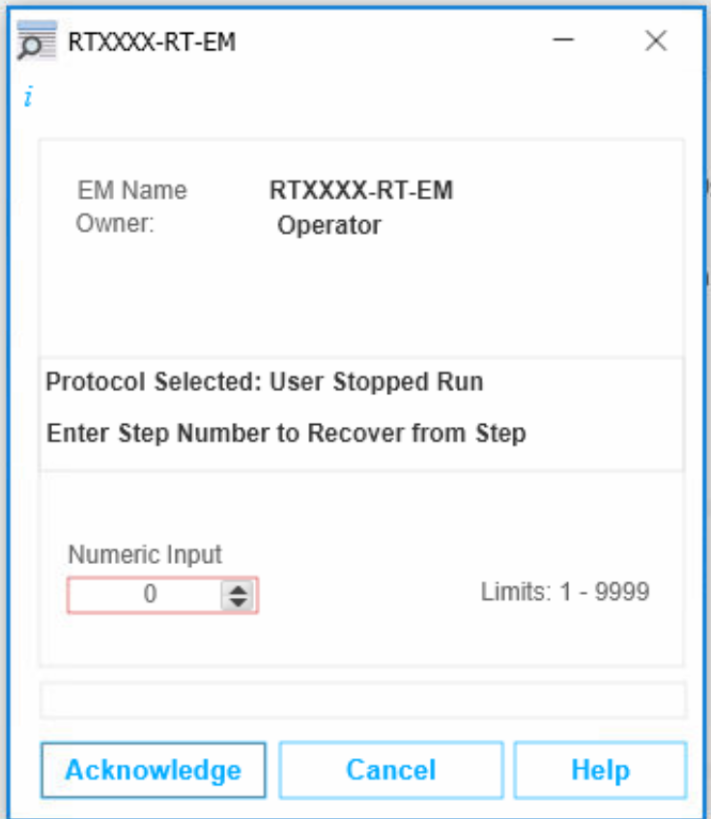
1. **Recover from Step**
2. **Recover to Single Step**
3. **End**

Recover from step

When this option is selected the user is prompted to enter a step number. This step number will be the step where the protocol starts when the protocol runs.



By clicking on the prompt text a data entry form will appear as shown in the following figure.



Enter the step number to define where the protocol will restart from.

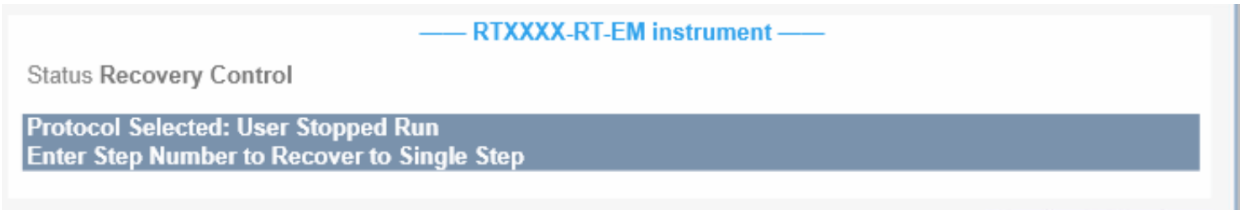
Once this prompt is acknowledged the equipment module will automatically move to the **Run Recovery** state. In this state, the door and kit statuses are checked before loading the selected protocol onto the Rotea™ instrument.

The protocol will restart from the selected step. When confirmed running the module automatically moves back to the **Monitor Protocol** state.

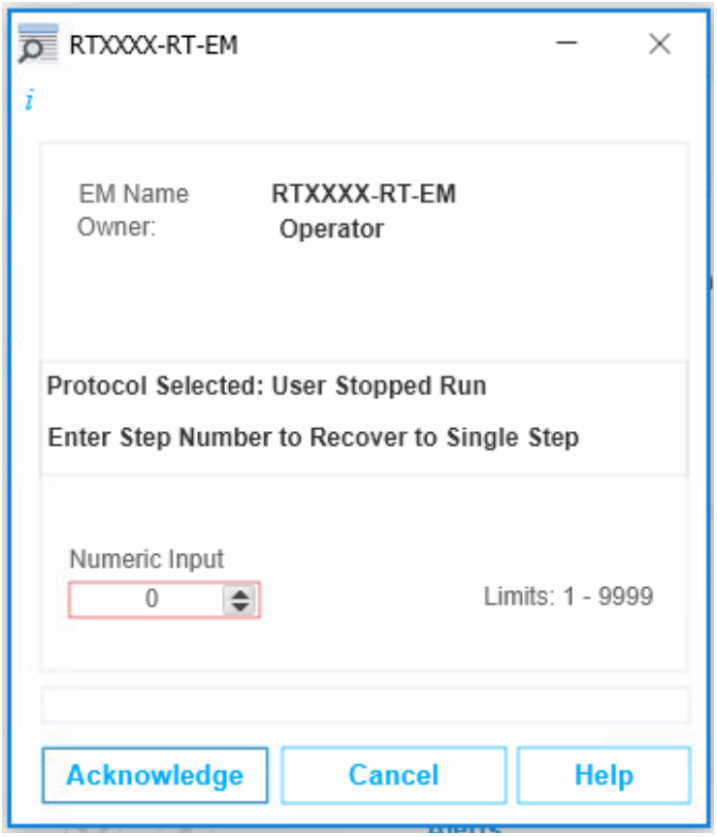
Recover to step

When this option is selected, the user is prompted to enter a step number. This step number will be the step where the protocol starts when the protocol runs.

The difference from the **Recover from step** option is that once the selected step in the protocol has completed, the protocol moves to the pause state where the Rotea™ instrument will be in recirculation mode.



By clicking on the prompt text, a data entry form will appear as shown in the following figure.



Enter the step number to define where the protocol should restart from.

Once this prompt is acknowledged, the equipment module will automatically move to the **Run Recovery Single Step** state. In this state, the door and kit statuses are checked before loading the selected protocol onto the Rotea™ instrument.

The protocol will restart from the selected step and when confirmed running the module automatically moves back to the **Monitor Protocol** state.

When the step completes, the Rotea™ protocol pauses and will be in recirculation mode.

When in the recirculation mode, the **Skip** button will force the protocol to move to the next step in the protocol and resume as normal.

End

When this option is selected, the equipment module will move to the **Stop Protocol** state. This will reset the protocol running on the Rotea™ instrument.

Recipe control operation

DeltaV™ Batch conforms to the ISA-88 standard for batch control and the terminology used within the DeltaV™ software matches the standard definitions.

The Rotea™ instrument can be controlled using DeltaV™ software batch recipes. When controlling the instrument via batch recipes the equipment module is acquired by the batch recipe and can no longer be controlled manually from the equipment module faceplate, or via the Rotea™ instrument companion PC.

The advantage of using batch recipe control is that a consistent approach is applied across each workflow. This means that a single recipe can be constructed and used to perform repeated operations on different batches, with the only difference between them being the recipe parameters used.

The other advantage is that the historical data associated with a recipe can be collated to form a batch report (using 3rd party packages).

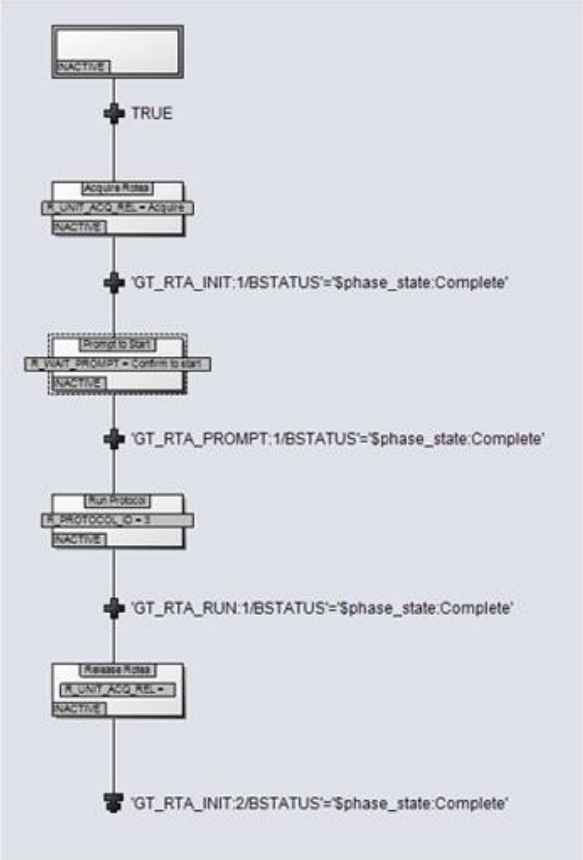
Note: Batch reports are currently not included within the Rotea™ DeltaV™ software.

DeltaV™ batch recipes are organized into three distinct types.

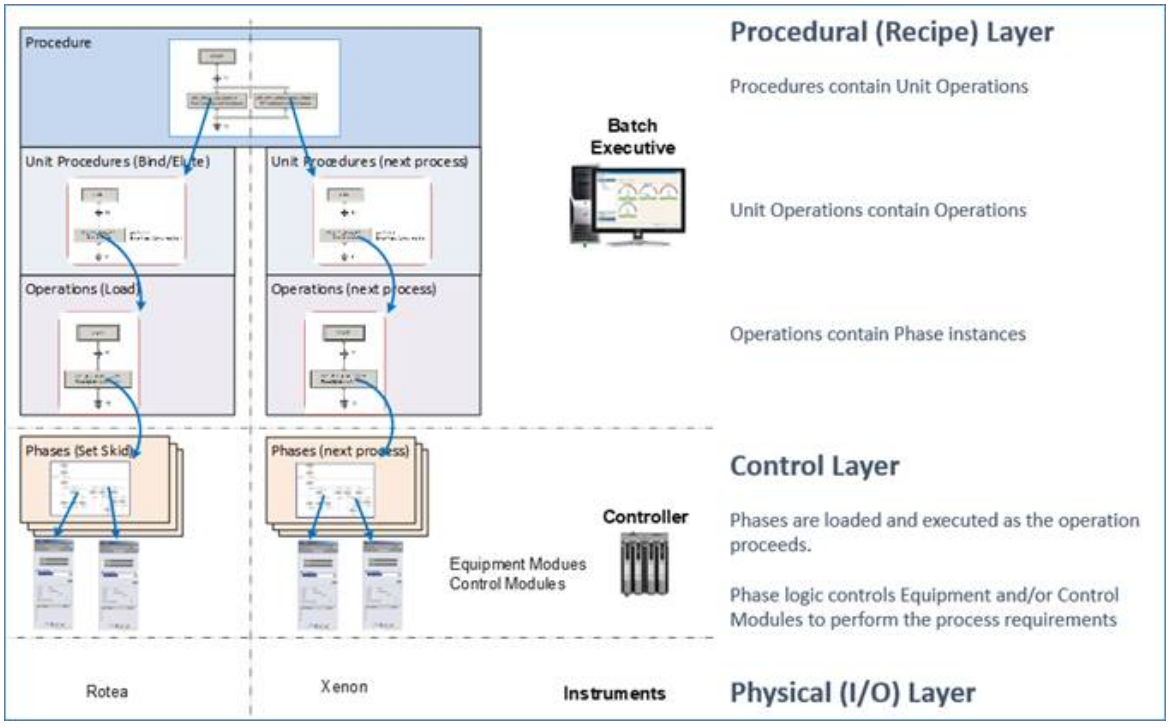
- Operations: These recipes are constructed using phase modules.
- Unit Procedures: These recipes are constructed using Operation recipes.
- Procedure: These recipes are constructed using Unit Procedures recipes.

Batch recipes are stored and ran on an Application Station that has been configured to host the Batch Executive application. Standard DeltaV™ software applications are used to interact with the Batch Executive to start and control batch recipes.

Batch recipes are constructed as Sequential Flow Charts and the following figure is an example of an operation recipe. In an operation, a step is always followed by one or more transitions, and these are arranged to create the required workflow.



The following figure illustrates the DeltaV™ system batch recipe hierarchy and shows how each recipe type is constructed using the lower level software entities.



As can be seen from the previous figure, **Operations** and **Unit Procedures** are used to control specific instruments (the DeltaV™ system terminology is a “Unit”).

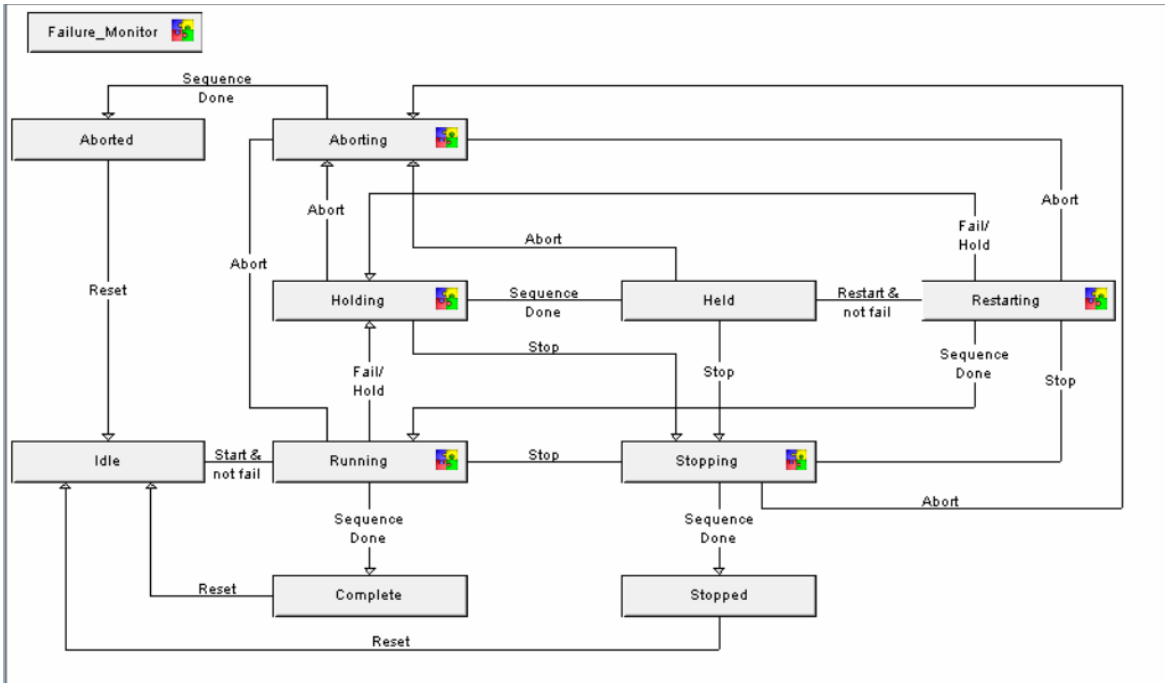
The Procedure recipe (which is the highest level recipe) can contain Unit Procedures from different Units. This feature allows a workflow to control multiple instruments within a single batch run.

To interact with and control instruments, ‘Phases’ are used as the building blocks (steps) for Operations.

Phases

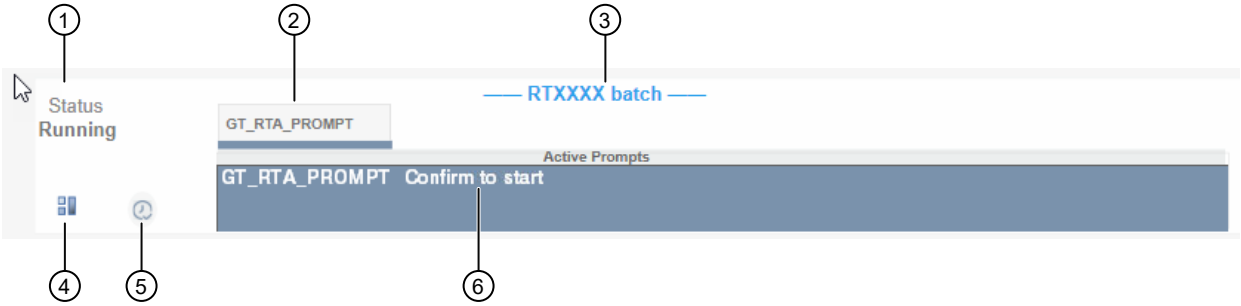
Phases are software modules that conform to the ISA-88 batch standard and run on the DeltaV™ system controllers.

Phases have states when running. The following figure shows the state transition diagram.



In all the Rotea™ instrument phases, the stopped state contains no logic. This allows for active step changes to be performed without causing any disruption to the instrument. Refer to DeltaV™ Books Online for more information on recipe active step changes.

When phases are running on an instrument, the phase status, messages and prompts are displayed on the main Rotea™ system display in the batch banner object, as shown in the following figure.

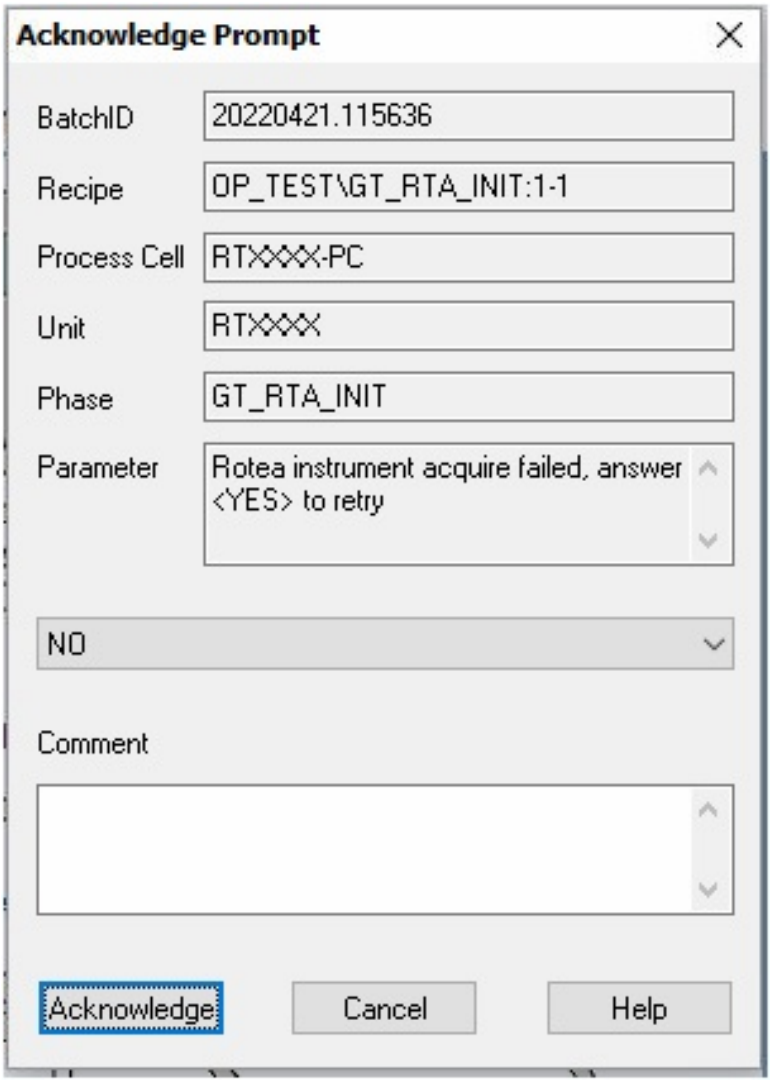


1. Status of the currently selected phase
2. Tab strip that displays the phase name(s). If more than one phase is running on the unit, then this is shown on another tab.
3. Unit Name
4. Hold Button. Pressing this will issue a message box to allow holding the recipe.
5. Timer button. This brings up the support module timers.
6. Message/Prompt box

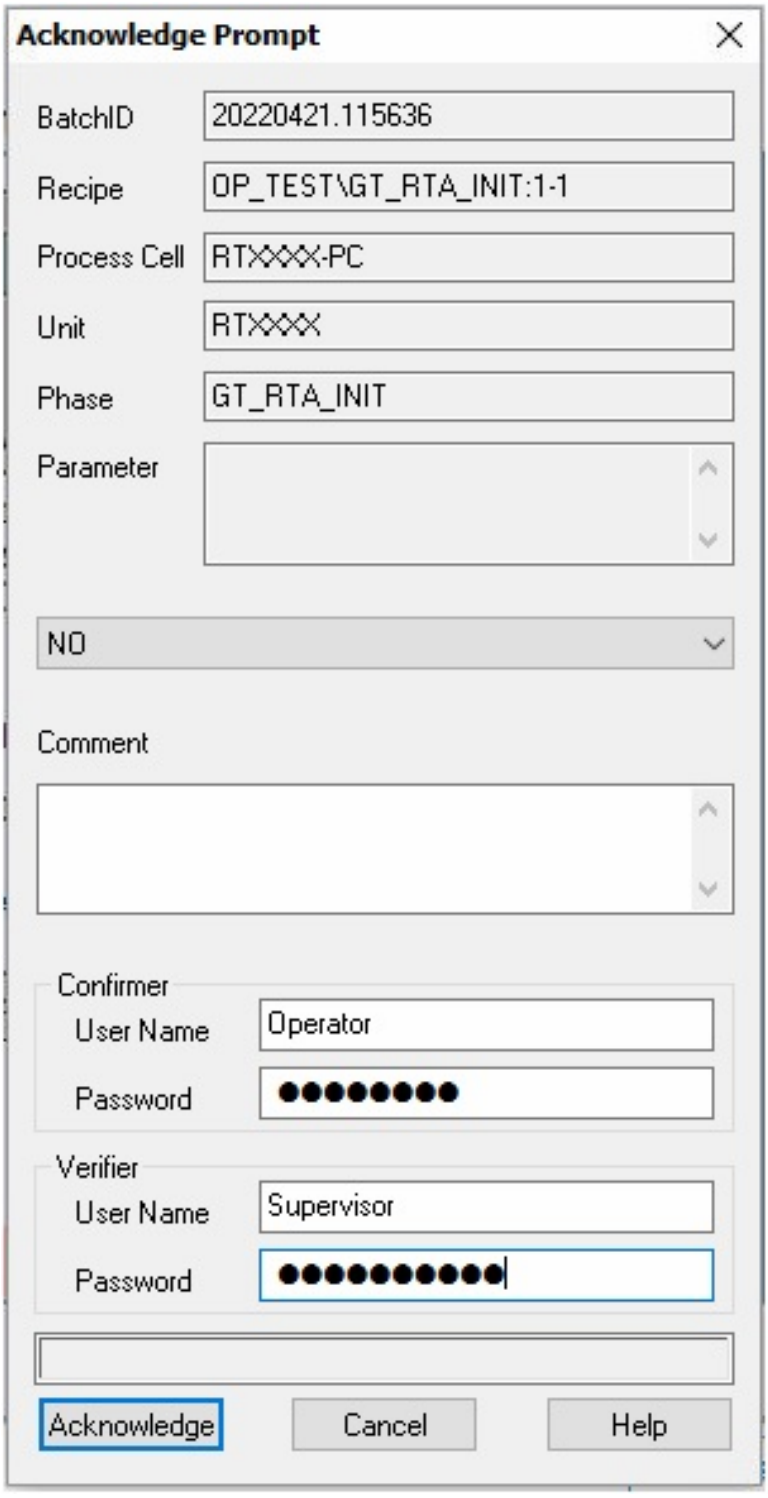
Note: The colored line underneath the text 2 shows the message status.

- Red indicates a failure message
- Yellow indicates a warning message
- Blue indicates a prompt message
- No color indicates standard message

Batch recipe prompts are generated in phases and displayed on the batch banner. When a prompt message is clicked a message box appears as shown in the following figure. Depending on the prompt type some extra fields are displayed to enter numeric or alphanumeric data. In addition, a prompt might require verification using a confirmer or verifier sign off.



Prompts may be configured to have a confirmer and/or verifier. For these prompts, the prompt box will appear as shown in the following figure.



There are three phases that can be used to construct Operations for the Rotea™ instrument.

Phase name	Description
GT_RTA_INIT	This phase acquires the Rotea™ Equipment Module within the DeltaV™ system which disables an operator from interacting with the instrument from the graphical interface. It is also used to release the equipment module when the recipe is complete.
GT_RTA_PROMPT	This phase allows a prompt to be inserted within an operation. A prompt can be configured as one of the following types. • Yes/No • Enter a number • Enter a string
GT_RTA_RUN	This phase will start the selected profile on the Rotea™ instrument via the equipment module and waits until it has completed. In addition, any recipe parameters associated with a Rotea™ instrument protocol can be defined, which are then passed down to the Rotea™ instrument before the protocol starts.

Phase recipe parameters

Every phase has two types of recipe parameters, 'input' (commonly referred to as recipe parameters) and 'report' parameters.

Input parameters are used to define the function of the phase, and report parameters are used to add batch data to the batch journal history file.

Report parameters are updated by the phase logic and do not need to be defined in a recipe.

The following tables define the parameters for each phase.

	GT_RTA_INIT
Input Parameter	**Description**
R_UNIT_ACQ_REL	Setting this parameter to **Acquire** will cause the phase to acquire ownership of the Rotea™ equipment module. This means the equipment module can no longer be used by an operator for manual control from the DeltaV™ system displays.
	Setting this parameter to **Release** will cause the phase to release ownership of the Rotea™ equipment module. This means the equipment module can now be acquired by an operator for manual control from the DeltaV™ system displays.
Report Parameter	**Description**
L_REPORT	Records the reason of a recipe/phase moves to the **Hold** state

	GT_RTA_PROMPT
Recipe Parameter	**Description**
R_PROMPT_TYPE	This parameter defines how the prompt is displayed and what the data entry requirements are. The types are: • YES_NO_PROMPT – The prompt box provides a YES/NO option as an answer. • INPUT_PROMPT – The prompt box provides for a numeric data entry. • STRING_PROMPT – The prompt box provides for an alpha/numeric data entry.
R_MAX_INPUT_VAL	If INPUT_PROMPT is required, then only a number less than this value can be entered.
R_MIN_INPUT_VAL	If INPUT_PROMPT is required, then only a number greater than this value can be entered.
R_VERIFICATION	Defines the electronic signature requirements for the prompt. • None – The prompt requires no electronic signature. • Confirmer – The prompt requires an electronic signature. • Verifier – The prompt requires two electronic signatures from two different users.
R_OPERATOR_MSG	The message entered here appears on the first line of the batch banner.
R_WAIT_PROMPT	The message entered here appears on the second line of the batch banner. It also appears on the prompt message box.
R_ANSWER_UP	This parameter is used to define a unit parameter where the prompt response can be stored. This enables batch recipes to use the prompt responses in the transition logic between recipe steps.
Report Parameter	**Description**
L_REPORT	Records the reason a recipe/phase moves to the **Hold** state.
L_RESPONSE	When a prompt is answered, the response is stored in this parameter.

	GT_RTA_RUN
Recipe Parameter	**Description**
R_PROTOCOL_ID	This parameter defines the protocol ID number to run on the Rotea™ instrument.
R_PROTOCOL_NAME	This parameter can be used instead of the ID number if the protocol name is known.

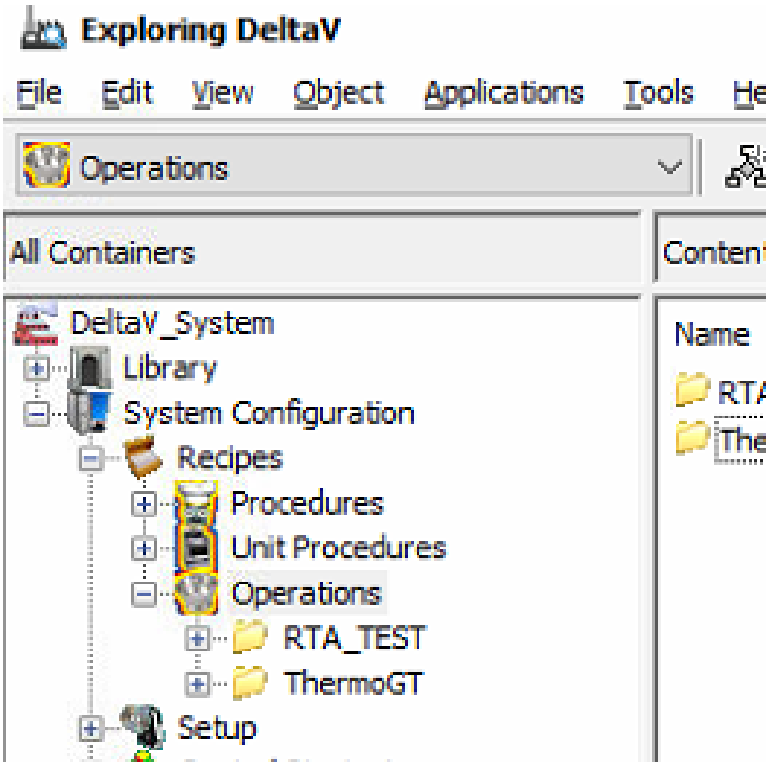
(continued)

	GT_RTA_RUN
R_PROT_PARAM1 through to R_PROT_PARAM4	If the protocol that is to be run on the Rotea™ instrument has input parameters, then these can be used to update the Rotea™ instrument protocol parameters before it is run.
R_PLAY_BUTTON	If disabled, the Play/Resume button on the front panel of the Rotea™ instrument is disabled. If enabled, the Play/Resume button on the front panel of the Rotea™ instrument is enabled.
R_ADVANCE_BUTTON	If disabled, the Skip button on the front panel of the Rotea™ instrument is disabled. If enabled, the Skip button on the front panel of the Rotea™ instrument is enabled.
R_PROT_ID_NAME	If 'Use Protocol ID' is selected, the protocol defined in R_PROTOCOL_ID is used. If 'Use Protocol Name' is selected, the protocol name defined in R_PROTOCOL_NAME is used.
Report Parameter	**Description**
L_REPORT	Records the reason a recipe/phase moves to the 'Hold' state.
L_END_CONDITION	Records the protocol end condition.
L_INST_NAME	Records the instrument name.
L_KIT_ID	Records the Rotea™ instrument Kit ID number.
L_RECOVERY_INFO	Records the step number used to in a Recovery Run.
L_RUN_LOG	Records the Run log file name produced during the protocol run.
L_RUN_PDF	Records the Run log .pdf file name produced during the protocol run.
L_SERIAL_NO	Records the Rotea™ instrument serial number.
L_PROTOCOL_ID	Records the protocol ID used.
L_PROTOCOL_NAME	Records the protocol name used.

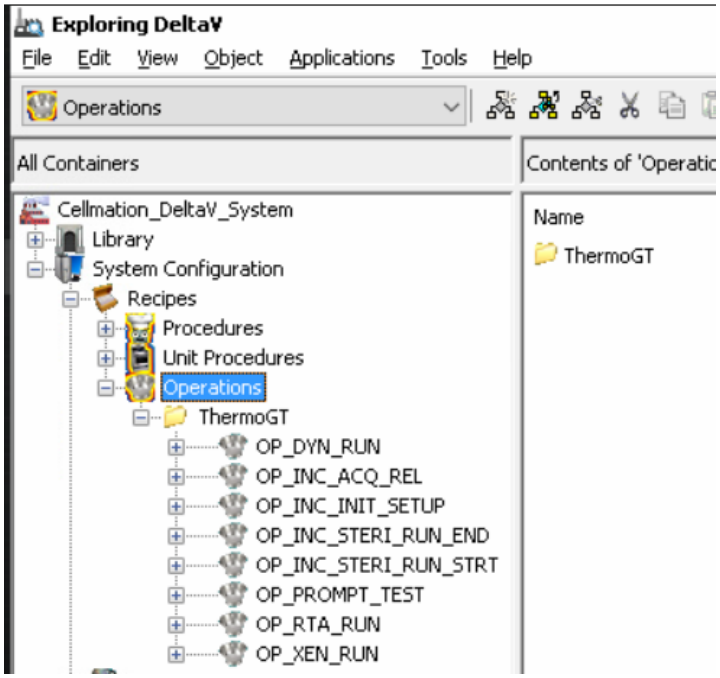
Recipe construction

Recipe Studio is used to create a recipe in the DeltaV™ system. Refer to DeltaV™ Books Online for further information on how to use this application.

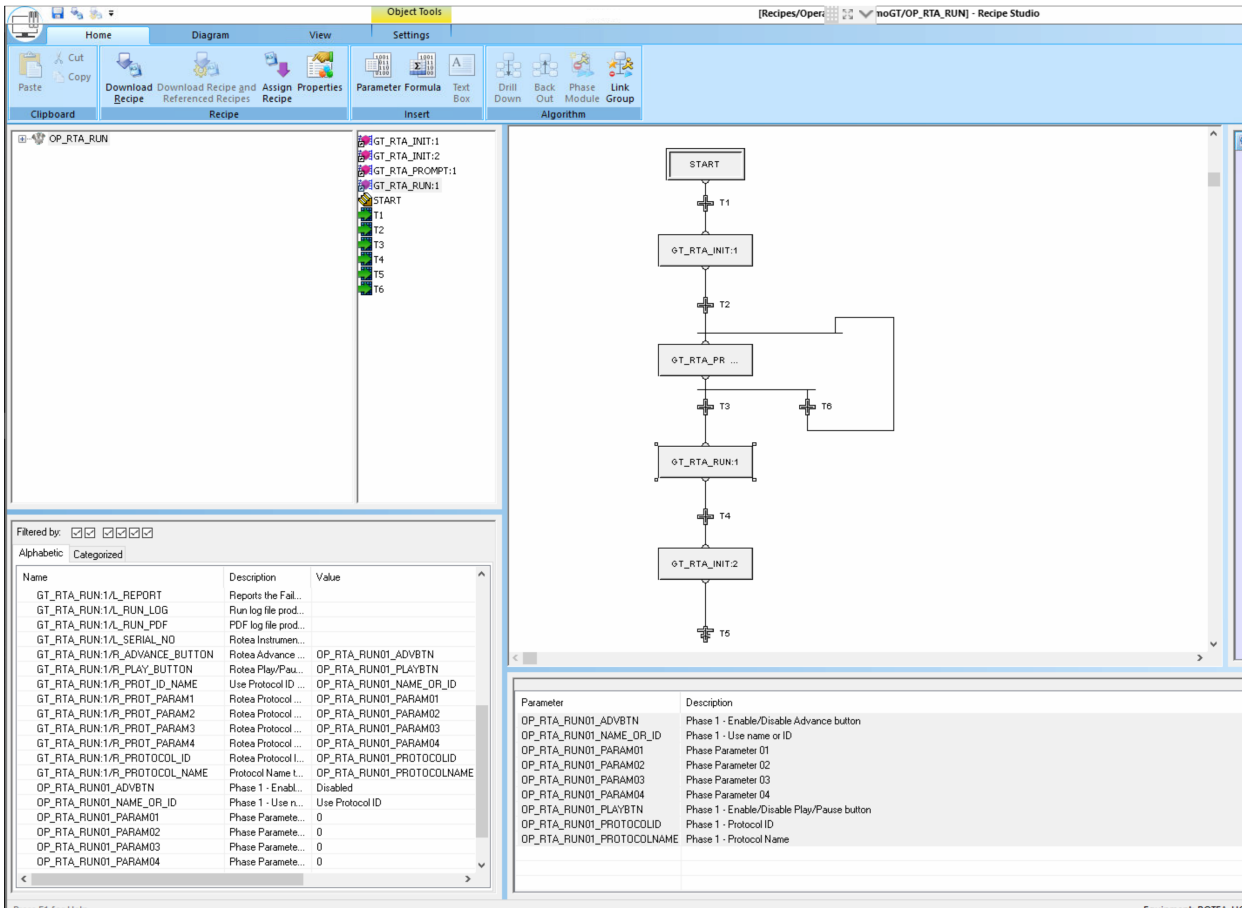
The batch recipes reside in three folders within the DeltaV™ system database and can be located using the DeltaV™ system application DeltaV Explorer. From DeltaV Explorer, the recipe folders appear as shown in the following figure – **Operations**, **Unit Procedures** and **Procedures**.



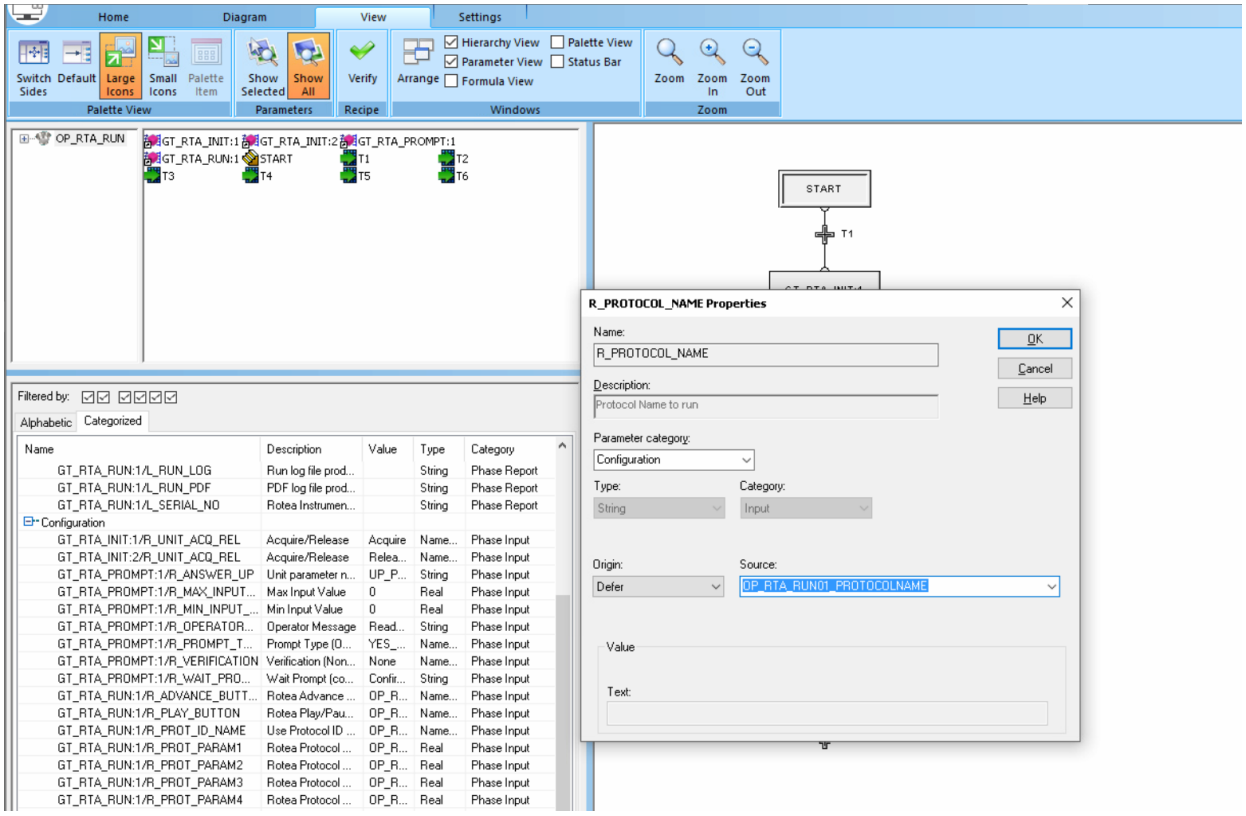
Within these folders, subfolders can be created to help organize batch recipes. In the following figure, two folders have been created and contain Operation recipes.



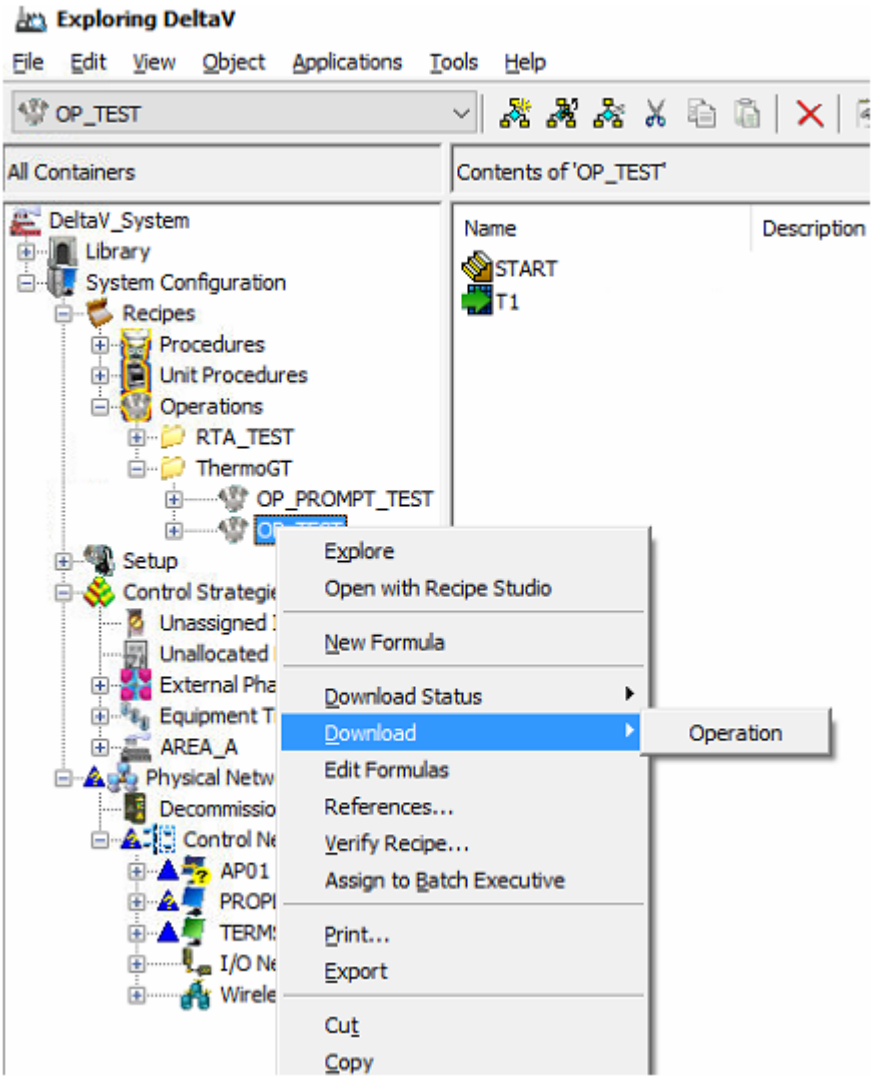
The following figure shows a simple recipe within the **Recipe Studio** application. The layout of each pane can be modified by the user. The default layout is shown in the following figure.



Clicking on a step will cause the recipe parameters for that step to be displayed in the **Parameter View** pane. These parameters can be shown alphabetically or categorized. To enter a recipe value, double click on the recipe parameter and a box will appear to allow the update.



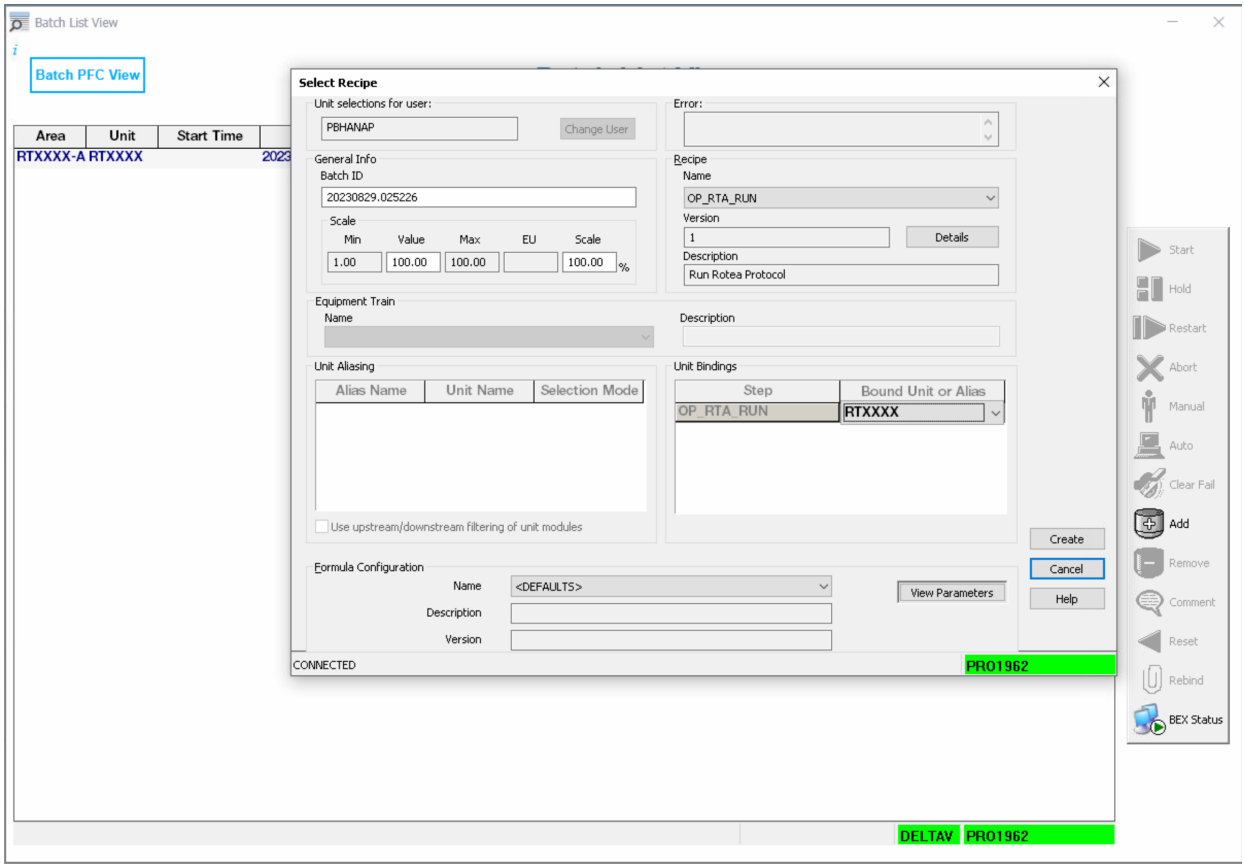
Once all the recipe parameters have been updated, save the recipe and then download to the batch executive. This is achieved by right clicking on the **Operation** and selecting the download option.



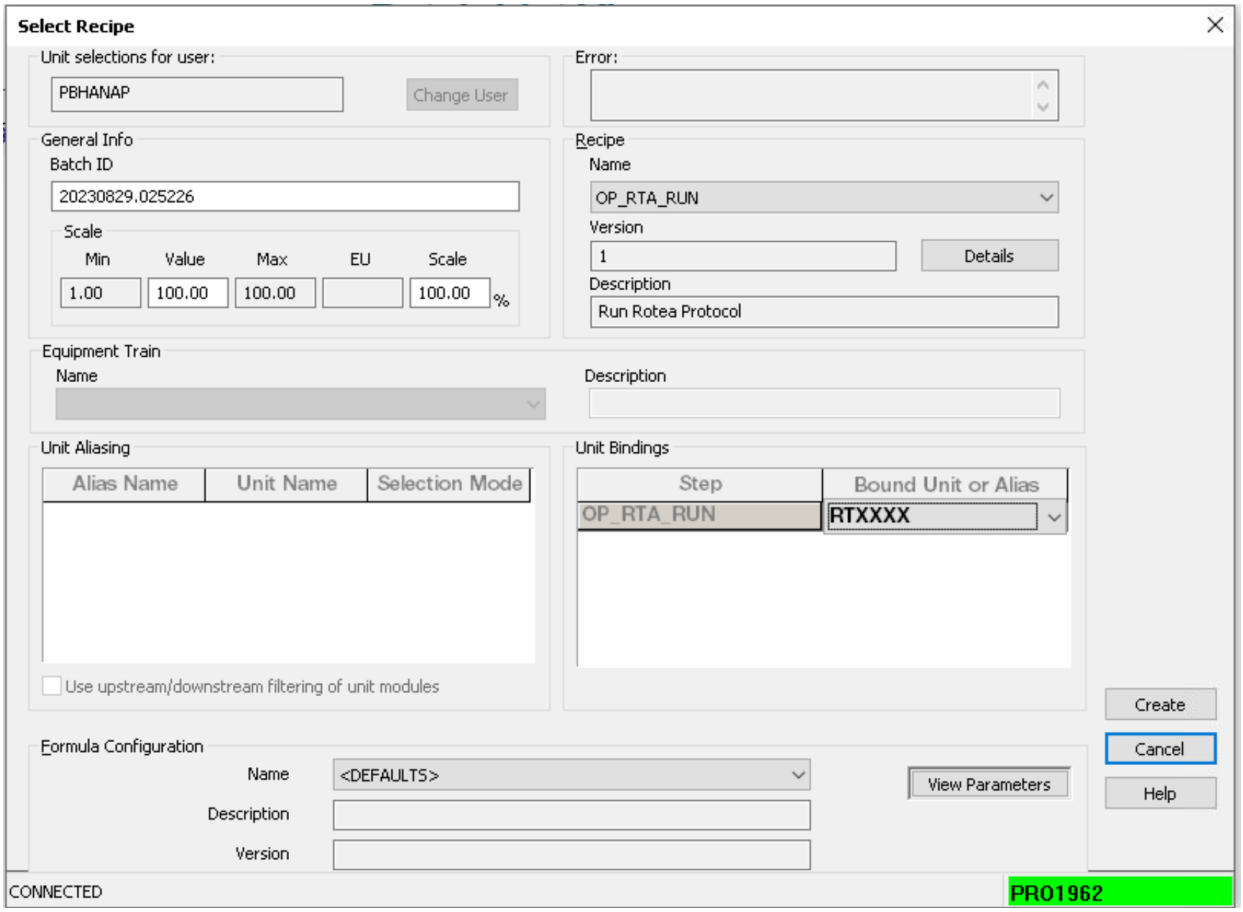
Recipe execution

Once a recipe has been downloaded to the batch executive, it is available to be run on the system. There are two applications available for starting recipes, the graphics displays or the Batch Operator Interface (BOI). Functionally, the BOI is the same as using the graphic displays, but provides more granular detail of the recipe, and also allows for more low level control of the batch. Refer to DeltaV™ Books Online for detailed information on the BOI.

To start a recipe from the graphic displays, select the **Batch List View** button and the batch list view faceplate is displayed as previously shown. To add a batch ready for execution, select the **Add** button and a pop-up window will appear as shown in the following figure.



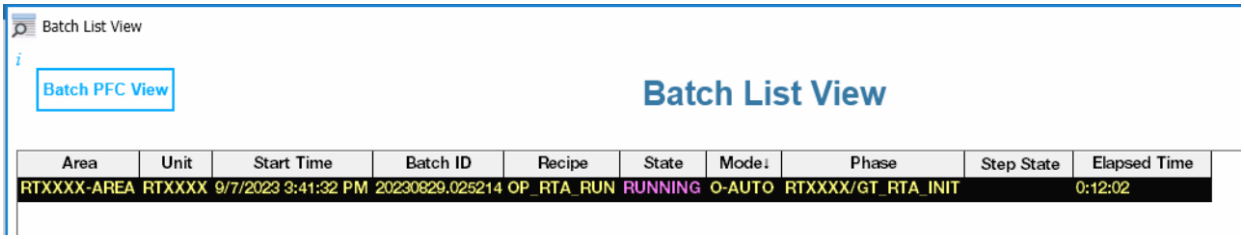
- **Batch ID**: The recipe can be assigned an automatically generated Batch ID (as shown in the following figure) or the user can type a new alphanumeric Batch ID.
- **Scale**: A recipe can be scaled. If this feature is not used, leave it as 100%.
- **Bound Unit or Alias**: Depending on how the recipe is constructed, it can be configured to run on multiple instruments. If this is the case, then the drop down box can be used to select the instrument that this batch will run on.
- **View Parameters**: Selecting this box will show any top level operation parameters that can be modified by the user before starting the run.



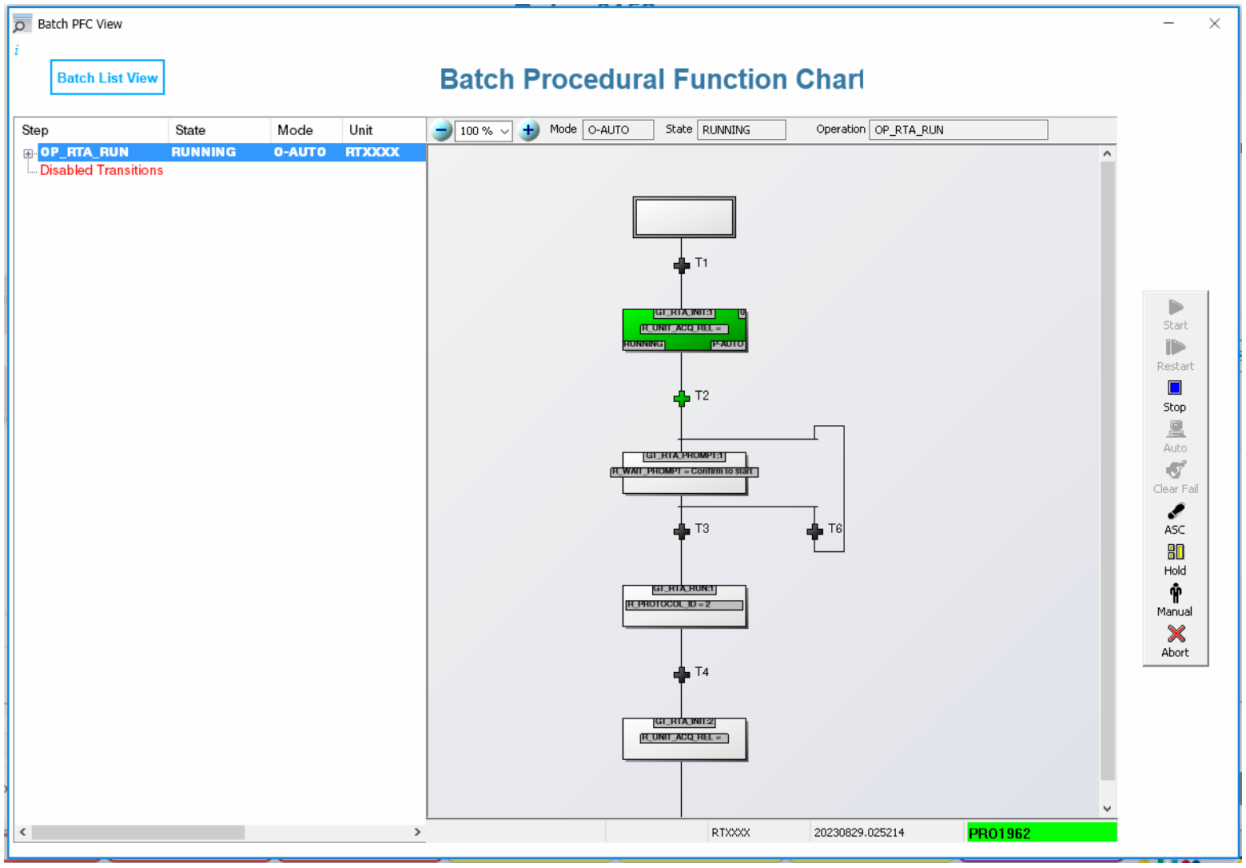
Once the recipe has been created, it will be shown in the **Batch List View**. To start the recipe, highlight it and select the start button. The recipe will now be running and the user can switch to the PFC view to see the recipe progress.

Many recipes can be added to a run.

Note: A recipe can only run on a unit once the previous recipe has been completed.



The PFC view will display the recipe steps and transitions. The active steps are shown in green.


Batch PFC View
Batch List View
Batch Procedural Function Chart
Step
State
Mode
Unit
OP_RTA_RUN
RUNNING
O-AUTO
RTXXXX
Disabled Transitions
100 %
Mode
O-AUTO
State
RUNNING
Operation
OP_RTA_RUN
T1
T2
T3
T4
T6
Start
Restart
Stop
Auto
Clear Fail
ASC
Hold
Manual
Abort
RTXXXX
20230829.025214
PRO1962

3 Alarm management

Alarms are displayed in various locations depending on the type and the module that they are associated with.

An alarm can be in the following states:

- Active and unacknowledged
- Active and acknowledged
- Cleared and unacknowledged
- Cleared and acknowledged

There are 12 possible alarm priority levels: numeric values 4 through 15 plus a special log only priority level (value 3). The highest priority value is 15 (used for the most important alarms). The lowest priority value is 4.

The alarm colors are dependent on the priority and by default are:

- Purple: Priority 4-7
- Yellow: Priority 8-11
- Red: Priority 12-15

The default alarms that exist in the system are shown in the following table.

Level value	Alarm priority name	Auto acknowledged	Auto acknowledged inactive	Horn sound
15	CRITICAL	No	No	WAS-High ©2010HCS.wav
11	WARNING	No	No	WAS-Medium ©2010HCS.wav
7	ADVISORY	Yes	No	WAS-Low ©2010HCS.wav
3	LOG	Yes	No	none

The Rotea™ instrument uses a prompt alarm with a priority of 5 and will appear in alarm windows/lists in purple color.

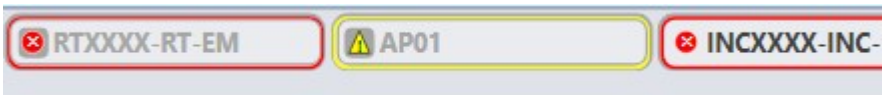
Note: The alarm priority can be changed if priority 5 is already in use by other alarms.

Alarm banner

The alarm banner resides at the bottom of the display.

If there is an active unacknowledged alarm, the alarm banner at the bottom of the screen displays a flashing colored box, as seen on RTXXXX-RT-EM in the following figure. If the alarm is active, but has been acknowledged, the alarm box no longer flashes and will remain in the alarm priority color.

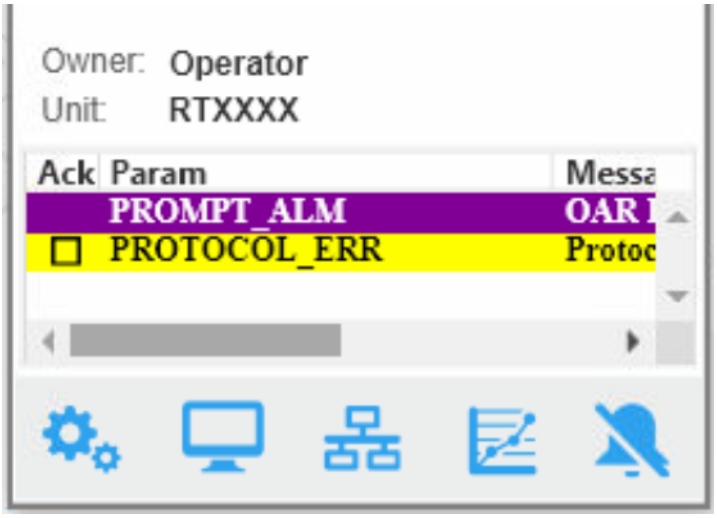
If the alarm is no longer active, and has not been acknowledged, the alarm box still flashes but the alarm symbol on the left of the alarm is crosshatched as seen in the following figure.



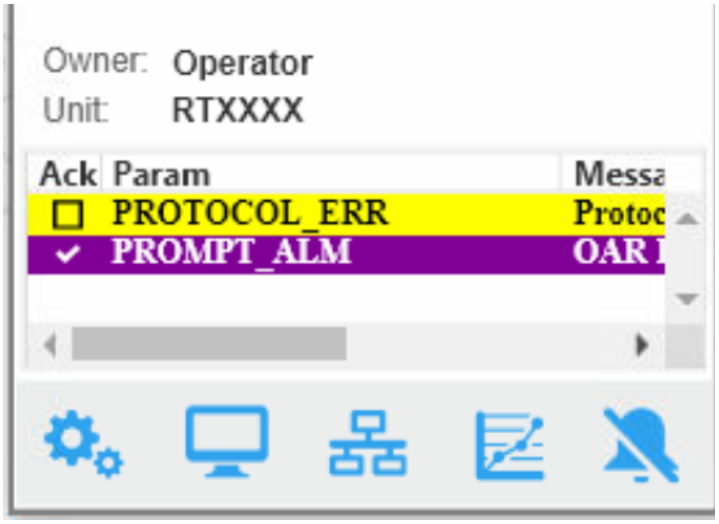
When an alarm is cleared and has been acknowledged, it will no longer appear in the alarm banner.

Faceplate alarm window

If an alarm is part of a module, then the module faceplate will have an alarm window showing the alarms. The following figure shows the alarm window of the Rotea™ equipment module. It shows a prompt alarm that is active and unacknowledged (indicating that a prompt has been raised and requires acknowledgment), and an advisory alarm (indicating a Protocol error) that is no longer active and unacknowledged.



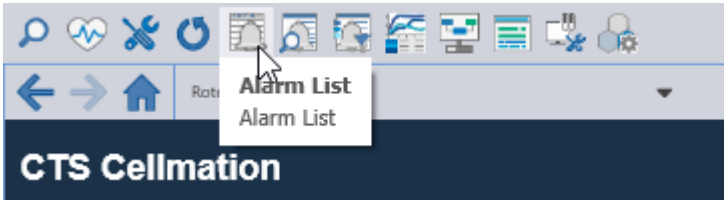
When the prompt alarm is acknowledged, a tick is shown to the right of the alarm as seen in the following figure.



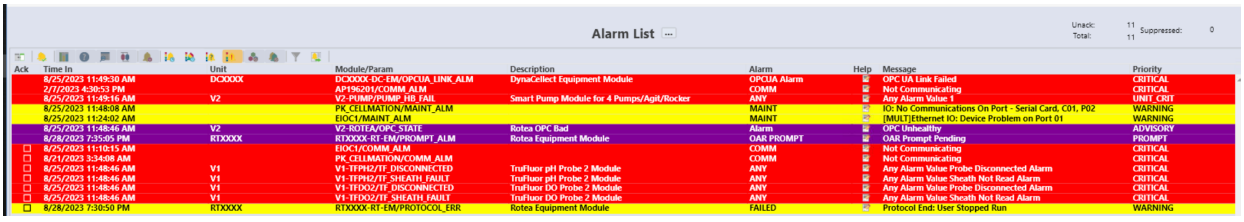
When the advisory alarm is acknowledged, it will disappear from the alarm window.

Alarms lists

The alarm list can be opened by clicking on the **Alarm List** button. This button appears in the toolbar window at the top of the display.



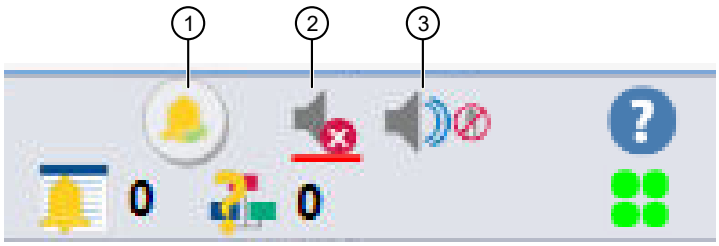
Clicking this button displays a list of all the active alarms the current workstation is monitoring for the current user.



Acknowledging and silencing alarms

At the bottom of all displays there is an alarm banner.

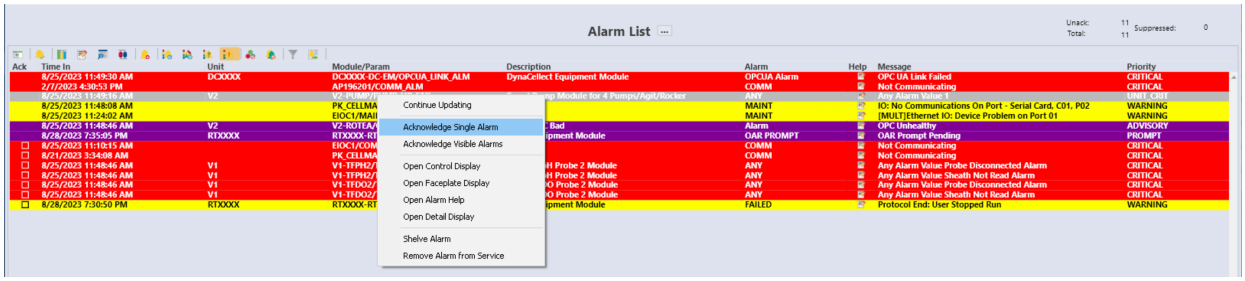
If an alarm is triggered, an audible alarm sounds, if that function has been enabled and the system provides a speaker for the alarm. To turn off the audible alarm, click the icon on the lower right corner of the screen.



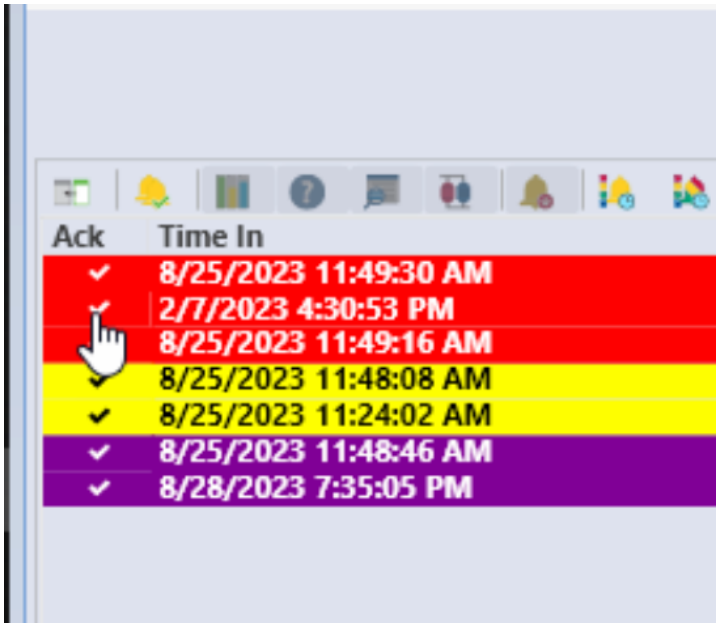
1. This button acknowledges all unacknowledged alarms in the main process graphic when selected. Only alarm parameters that are part of the graphic are acknowledged.
2. Selecting this button stops the horn, but does not acknowledge the alarm. If new alarms become active and the horn is enabled, the horn sounds again.
3. Selecting this button disables or enables the horn. When the horn is disabled, new alarms do not cause the horn to sound. This setting is a parameter of the current user's session. When a new user logs on, the horn is enabled by default.

To acknowledge individual alarms the following actions can be performed.

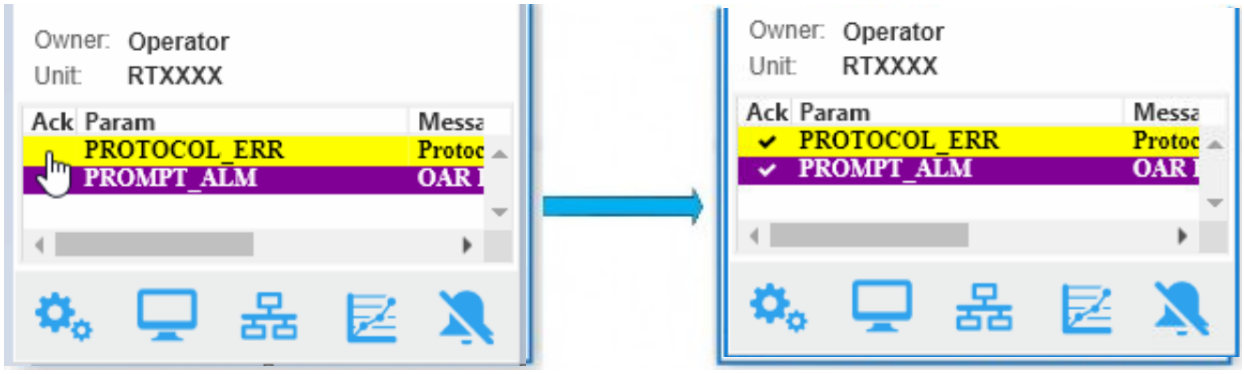
From the **Alarm List** display, right click on the alarm to be acknowledged and select **Acknowledge Single Alarm**.



Alternately, from the **Alarm List** display, move the cursor to the **Ack** column of the alarm to be acknowledged and left click with your mouse.



Otherwise, from the module faceplate alarm window, move the cursor to the **Ack** column of the alarm to be acknowledged and left click with your mouse.



Suppressing alarms

Alarms can be suppressed in two ways, by shelving or placing them out of service.

In general, you should respond immediately to alarms. However, if you are unable to address the issue in the moment, you can temporarily shelve the alarm or permanently remove it from service. Both types of suppression move the alarm from the Alarm Banner and Alarm List pictures to the Alarm Suppress picture.

Shelving alarms

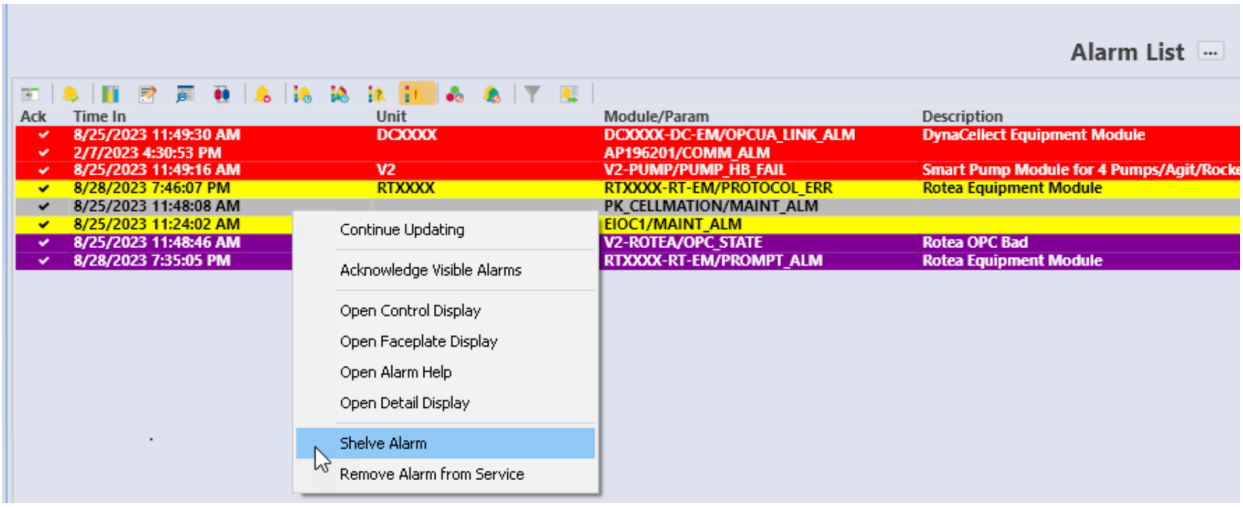
Shelving an alarm typically falls under the control of the operator and is done for the purpose of temporarily suppressing the alarm. When you are ready to respond to the alarm, unshelve the alarm in the Alarm Suppress picture and respond.

If ignored too long or forgotten, the alarm is automatically unshelved when the shelving timer runs out.

There are two ways to shelve an alarm, either from the alarm list or from the detail faceplate.

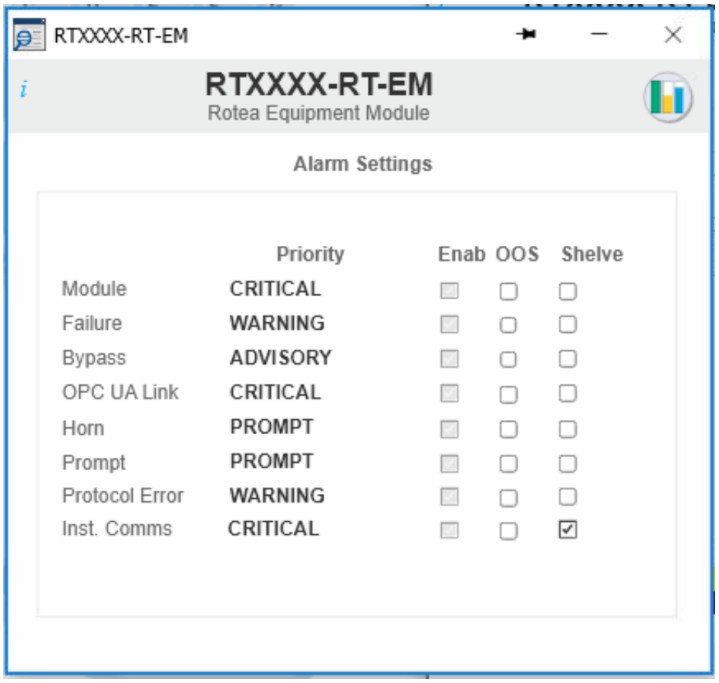
Alarm list shelve

From the **Alarm List**, right click on the alarm to be shelved and select **Shelve Alarm**.



Detail faceplate shelve

Open the detail faceplate associated with **Alarms** button. The detail faceplate will look like the following figure.



Click on the checkbox of the alarm to shelve in the **Shelve** column. The alarm can be unshelved by removing the tick in the alarm checkbox.

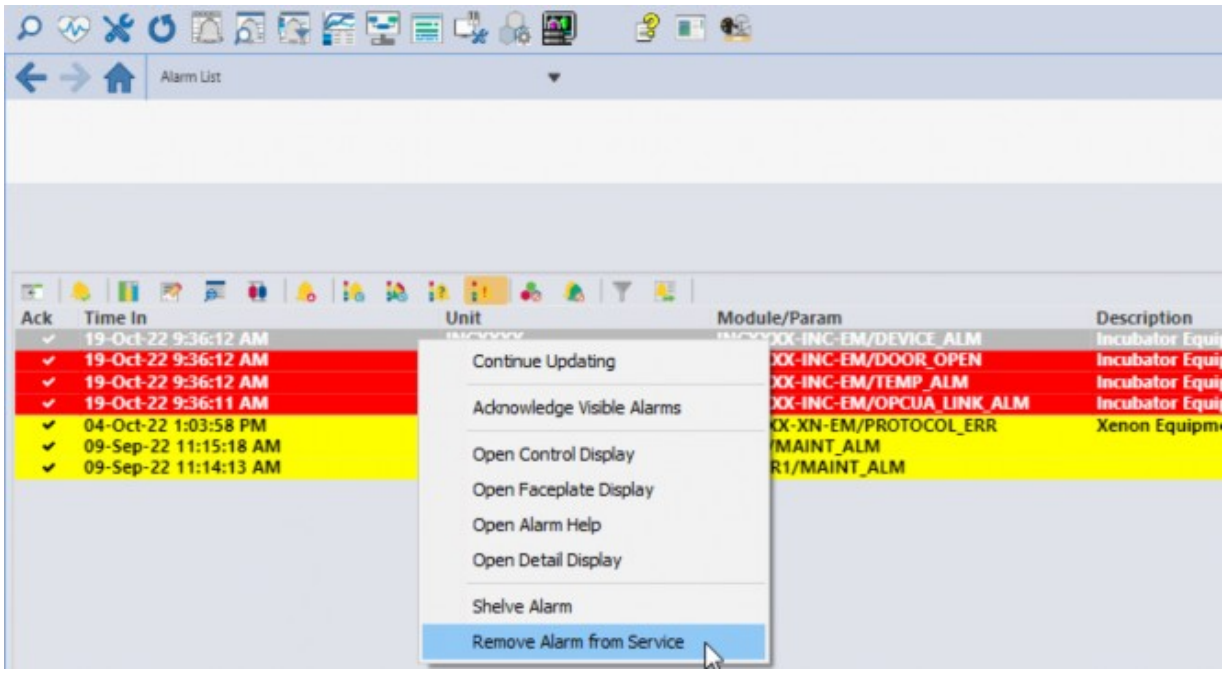
Out of Service (OOS) alarms

Removing an alarm from service falls under the control of maintenance and is used for the purpose of test or repair activities. An out of service alarm remains out of service until it is manually restored to service. In other words, there is no suppression timer. There are two ways to remove an alarm from service, either from the alarm list or from the detail faceplate.

In the default DeltaV™ system configuration, the user must have the Restricted Control key (assigned in the DeltaV™ User Manager) to suppress process alarms.

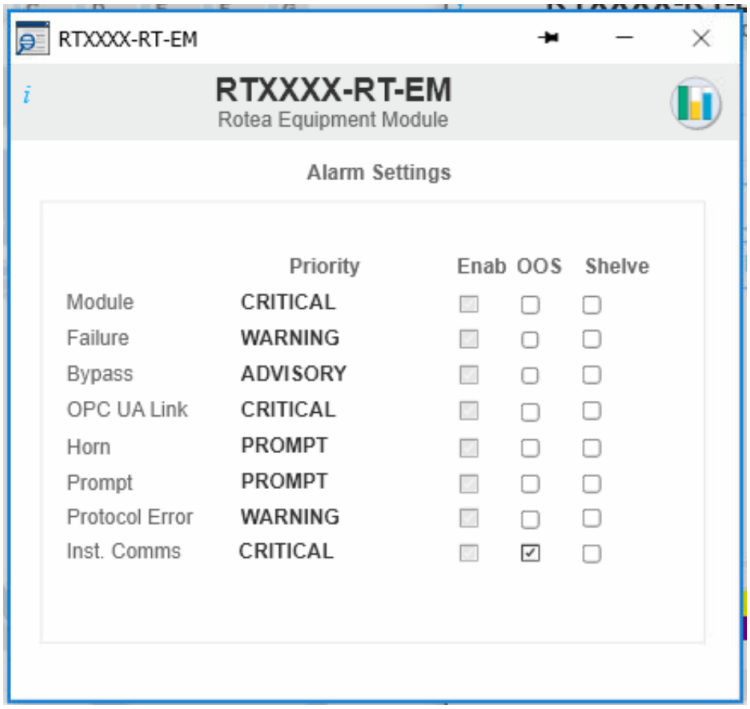
Alarm list OOS

From the alarm list right click on the alarm to be removed from service and select **Remove Alarm from Service**.



Detail faceplate OOS

Open the detail faceplate associated with **Alarms**. The detail faceplate will look like the following figure.

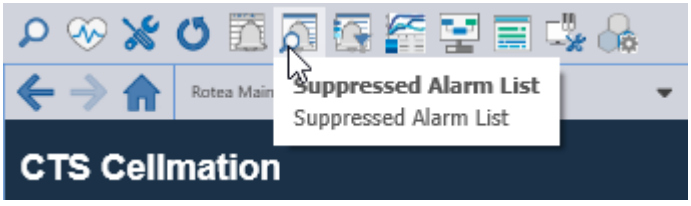


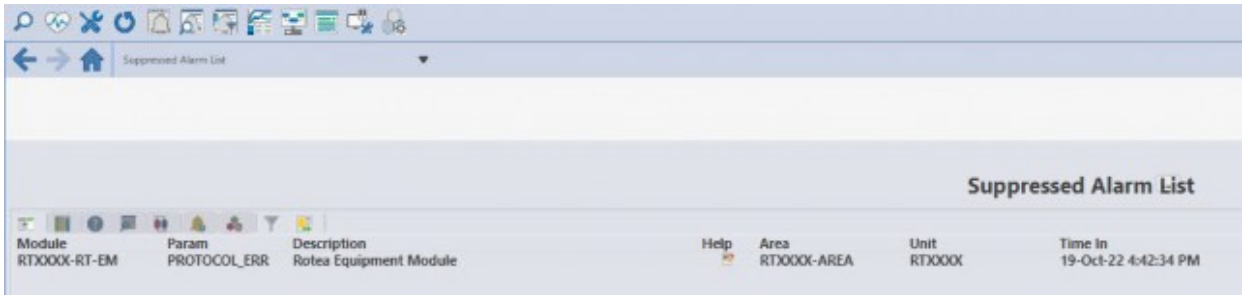
Click on the checkbox of the alarm to remove it from service in the **OOS** column. The alarm can be put back into service by removing the tick in the alarm checkbox.

Suppressed alarm list

Once the alarm has been put out of service it will be removed from all alarm windows/lists and can only be seen in the alarm suppressed display.

The suppressed alarm list can be opened by clicking on the **Suppressed Alarm List** button. This button appears in the toolbar window at the top of the display.




Suppressed Alarm List
Suppressed Alarm List
Module
RTXXXX-RT-EM
Param
PROTOCOL_ERR
Description
Rotea Equipment Module
Help
Area
RTXXXX-AREA
Unit
RTXXXX
Time In
19-Oct-22 4:42:34 PM

4 Maintenance

Backup and recovery

Archiving, backup and disaster recovery procedures should be performed by automation/IT department personnel, in accordance with their SOPs for the system. The following files should be backed up:

- Exported configuration database (FHX text files)
- Native configuration database (objectivity database)
- VCAT SQL database
- DeltaV™ system admin database backups
- DeltaV™ Live displays and library objects
- Historical configuration (charts)
- Historical data archives

The system can be designed to automatically and regularly back up data that is stored on the server or on local PCs, without shutting down the system. If data backups are not automated, they should be performed at specified time intervals. When data is archived, the system has the ability to quickly restore data with a minimal recovery time. If a method is in place to completely restore the main system in the event of a catastrophic failure, successive restores of, for example, the operating system, application, configuration, and data, should not be required.

In addition, the system has archival capability to move data from primary storage to long term or permanent storage. The archived information can be easily retrieved from primary storage for data analysis if desired.

The system includes diagnostic functions that are used to ascertain the overall status of the system.

Computer cleanup

Routine computer maintenance is generally the responsibility of the local automation/IT department. However, if the computer system is slow, the user may consider the following suggestions.

- Check the computer disk space. To access this information, click **Start** on the lower left of the monitor screen, then click **Computer**.
- Perform a disk cleanup. Click the button below the pie chart showing available disk space.
- If the free disk space is greater than 20%, do the following, depending on the computer in question:
  - On the ProPlus workstation: access the DeltaV™ Database Administration menu and run a DeltaV™ Database clean.
  - On the Application Station: ensure that routine database backups are being performed.

- If the free disk space is less than 20%, do the following:
  - On the ProPlus workstation: remove all old files, defragment the hard drive, and run a DeltaV™ Database clean.
  - On the Application Station: remove old files by exporting old datasets to another location. If the system is idle, defragment the hard drive.
- If the previous steps do not solve the problem, or if you are uncertain about performing such maintenance, consult your IT personnel or your service representative.

Power outage

Response to power loss depends on the part of the system that suffers the loss. It is recommended that a DeltaV™ unit incorporates an uninterrupted power supply (UPS) to protect the system in case of brief power interruptions.

In case of a general power loss that extends beyond the UPS capability, the computers must be rebooted, and the DeltaV™ system restarted. In such a case, consultation with your service representative is strongly recommended.

5 Data storage

Data storage is part of the 21 CFR Part 11 (cGMP) requirement. DeltaV™ software data storage is based on the DeltaV™ Continuous Historian and satisfies the cGMP requirements.

Click the **Event Chronicle** button for any parameter at the bottom of the faceplate to open a display of the parameter history. Options are available to select the length of time covered by the record. The data can be printed, or copied and pasted into Microsoft™ Word™ or Excel™ files, to create hard copy documentation.

The Process History Chart can be configured to display data in three formats, Events and Chart, Chart only or Event only. The following figure is an example of the PHV showing events and chart. From this application, current and historical data can be viewed.

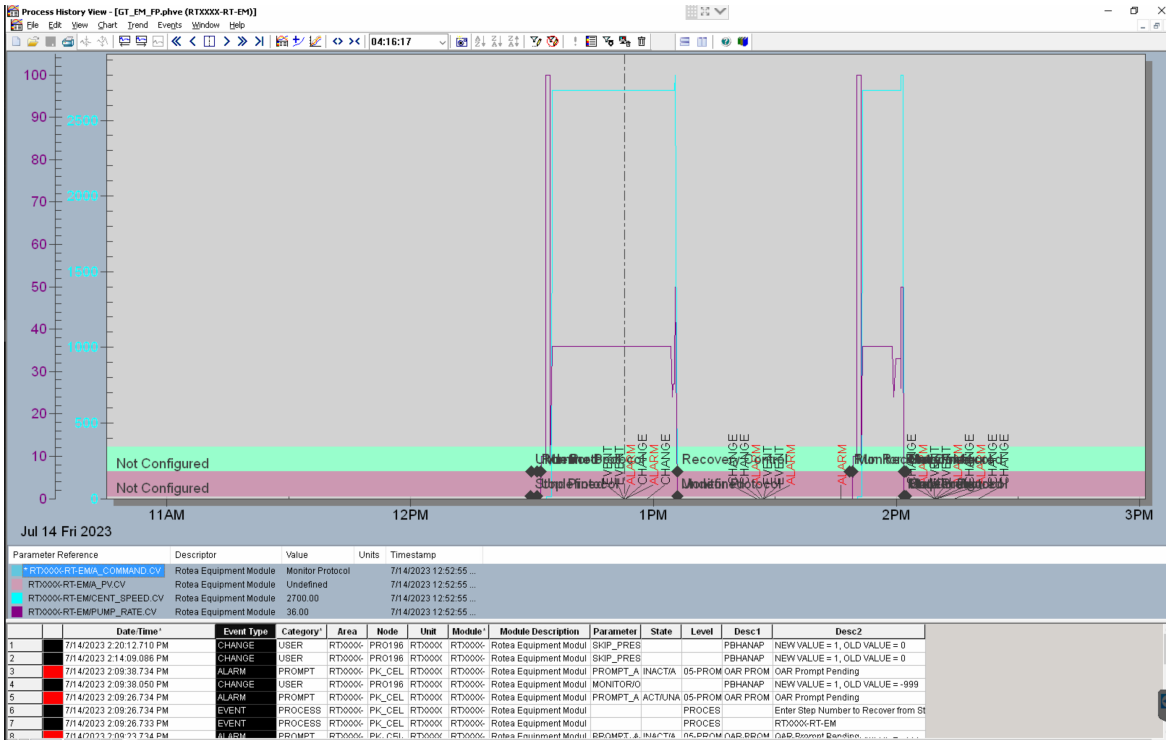


Figure 2 Display of parameter history.

The DeltaV™ Continuous Historian subsystem is used for the continuous collection and storage of process data. It is included with CTS™ Cellmation™ Software and can be configured to perform the following:

- Create a single historical database
- Open an unlimited number of trend screens with up to eight user definable values per screen
- Display trends either horizontally or vertically
- Display either process trends, alone or a combination of process trends and the associated event log
- Display trends in seconds, minutes, hours, days or weeks

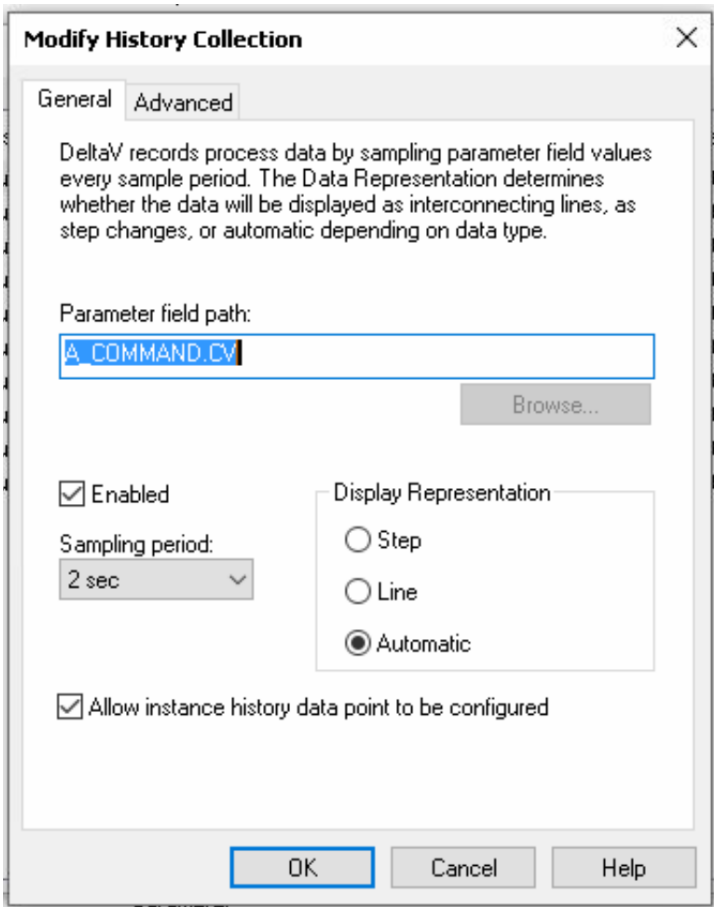


Figure 3 General settings for modifying history collection.

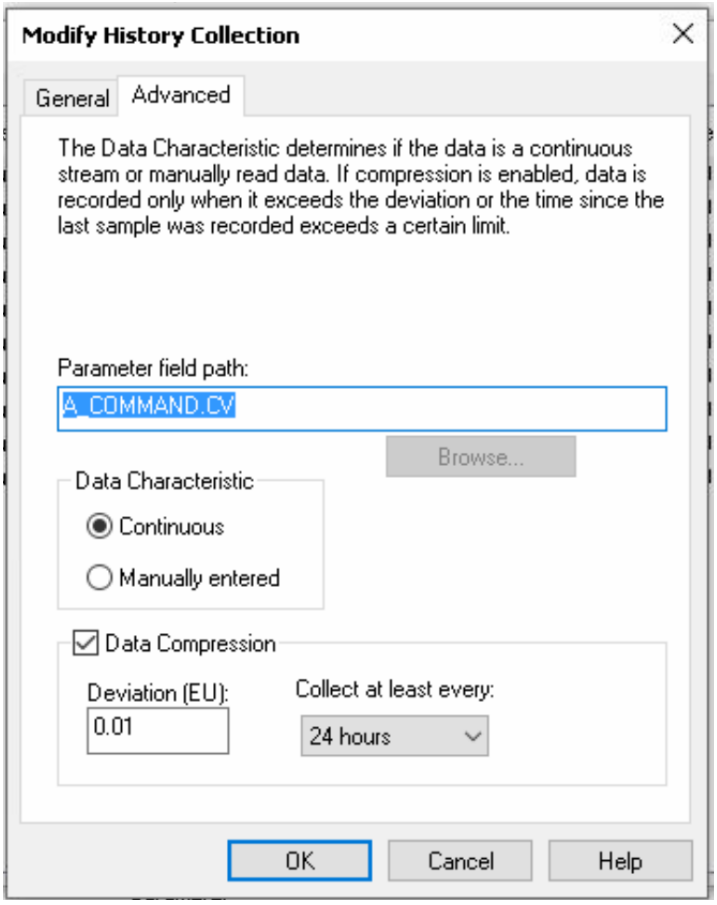


Figure 4 Advanced settings for modifying history collection.

Table 3 History collection properties for DeltaV™ system parameters.

Settings	Description
General settings	
Parameter field path	The path of the module parameter whose history is being collected.
Enable	Activates collection of field values specified in the parameter field path.
Display representation	• **Step**: Displays the values as step changes on the trend chart. Step representation is typically used for discrete values. • **Line**: Displays the data collected with point-to-point connection. • **Automatic**: Determines the representation based on data type.
Sampling period	Available sampling frequencies are 1, 2, 5, 10, 30, and 60 seconds and 5 minutes.

Table 3 History collection properties for DeltaV system parameters. *(continued)*

Settings	Description
Advanced settings	
Data characteristic	• **Continuous**: Continuously collected data, represented with interconnecting lines. • **Manually entered**: Values entered by a user, displayed as markClics on the trend, with no interconnecting lines.
Enable (data compression)	Enables data compression.
Collect at least every (data compression)	Controls the maximum time between stored values, even if values change very little. Options are 15 minutes, and 1, 4, 8, 24 and 72 hours.

To exit the historian view, click **X** in the upper right corner twice.

A Abbreviations/acronyms

Abbreviation	Description
BOI	Batch Operator Interface
cGMP	Current Good Manufacturing Process
DV	DeltaV
FRS	Functional Requirement Specification
GUI	Graphical User Interface
JSON	A JSON file is a file that stores simple data structures and objects in JavaScript Object Notation (JSON) format, which is a standard data interchange format.
KBA	Knowledge-Based Article
LDT	Logical Device Tag. Software items that reside under the PDT that are used to map the data exchange between the OPC UA client and server.
MQ	DeltaV Controller M-Series
MX	DeltaV Controller M-Series
OOS	Out of Service
OPC UA	Open Platform Communications Unified Architecture. Ethernet based open industry standard for data exchange between systems/applications.
PDT	Physical Device Tag. A software item that contains the OPC UA device communicate with.
PHV	Process History View
PK	DeltaV Controller that also contains ethernet ports for connectivity to external devices
PV	Process Value (or Process Variable)
SFC	Sequential Flow Chart
SP	Setpoint
SQ	DeltaV Controller S-Series
SX	DeltaV Controller S-Series
URL	Uniform Resource Locator (URL), colloquially termed a web address, is a reference to a web resource that specifies its location on a computer network

B

Faceplate details

- GT_MOD_FP 85
- GT_EM_FP 87
- GT_USM_DT and GT_TimerFB_DT 89
- Alarms 91

Faceplates that are in addition to the standard DeltaV™ system faceplates are described below. For details of the standard faceplates, refer to DeltaV™ Books Online.

GT_MOD_FP

1. Alarm indications
2. Diagnostics
3. Unit field
4. Toolbar

Figure 5 GT_MOD_FP

- **Alarm indications**: This is a scrollable list of the current alarms that functions like the first two columns of an alarm summary. The first column shows the state of the alarm represented by one of the following symbols:
  - Active/unacknowledged -- blank field
  - Active/acknowledged -- checkmark
  - Inactive/acknowledged -- empty box

  The second column is the alarm name or parameter. The text and colors are as configured for the alarm's current state.
- **Diagnostics**: This section displays visible text for active conditions in the module's MERROR, MSTATUS and BLOCK_ERR parameters. There is a tab for each parameter. The parameter name on the tab is underlined when an active condition for that parameter is displayed. When an error has occurred in the module, a **Clear Error** button is displayed on the **MERROR** tab. Click this button to clear active errors.
- **Unit field** : This field displays the unit name.
- **Toolbar**: Click the icons from left to right to perform the following functions, respectively:
  - **Detail Display** button: open the detail display for the module.
  - **Primary Control Display** button: open the primary control display. Note, this is not visible in the CTS™ Cellmation™ Software.
  - **Control Studio** button: open Control Studio.
  - **Acknowledge Alarms** button: acknowledge all alarms on this module.

GT_EM_FP

① Drop down command list
② Run button Current state
③ Acquire and Release buttons
④ Current running command
⑤ Current end command state
⑥ Current owner
⑦ Unit field
⑧ Alarm indications
⑨ Toolbar

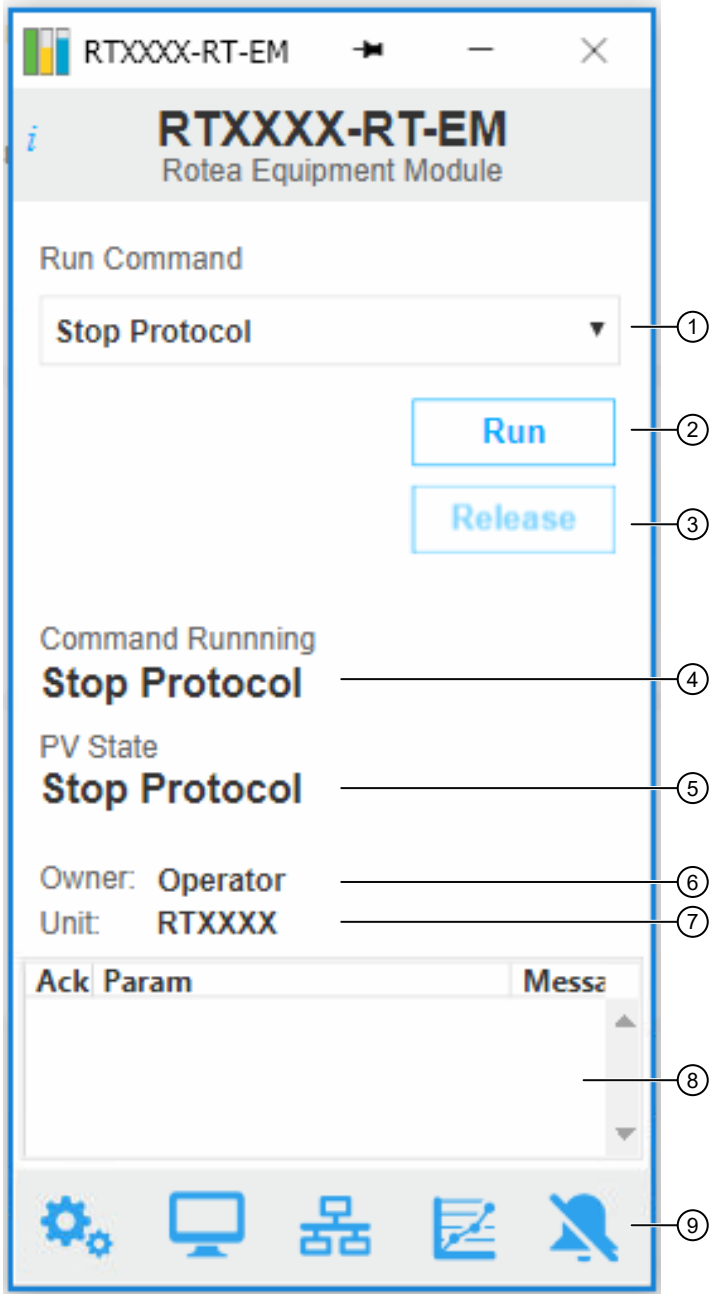


Figure 6 GT_EM_FP

- **Current command**: This displays the command that is currently being executed.

- **Current state**: This displays the current state after the current command has completed.
- **Drop down command list**: This displays the list of available commands when operating the module manually from the faceplate.
- **Run button**: Used to activate the selected command.
- **Acquire & Release buttons**: The acquire button (not shown) is used to acquire the module. Once acquired, manual commands can be selected. The release button will relinquish ownership of the module.
- **Current owner**: This displays the name of the current owner of the module.
- **Unit field**: This field displays the unit name.
- **Alarm indications**: This is a scrollable list of the current alarms that functions like the first two columns of an alarm summary. The first column shows the state of the alarm represented by one of the following symbols. The second column is the alarm name or parameter. The text and colors are as configured for the alarm's current state.
  - Active/unacknowledged -- blank field
  - Active/acknowledged -- checkmark
  - Inactive/acknowledged -- empty box

The second column is the alarm name or parameter. The text and colors are as configured for the alarm's current state.

- **Toolbar** - Click the icons from left to right to perform the following functions, respectively:
  - **Detail Display** button: opens a menu allowing for selection of the required detailed display for the module.
  - **Primary Control Display** button: open the primary control display. Note, this is not visible in the CTS™ Cellmation™ Software.
  - **Control Studio** button: open **Control Studio**.
  - **Event Chronicle** button: open the **Process History View**.
  - **Acknowledge Alarms** button: acknowledge all alarms on this module.

GT_USM_DT and GT_TimerFB_DT

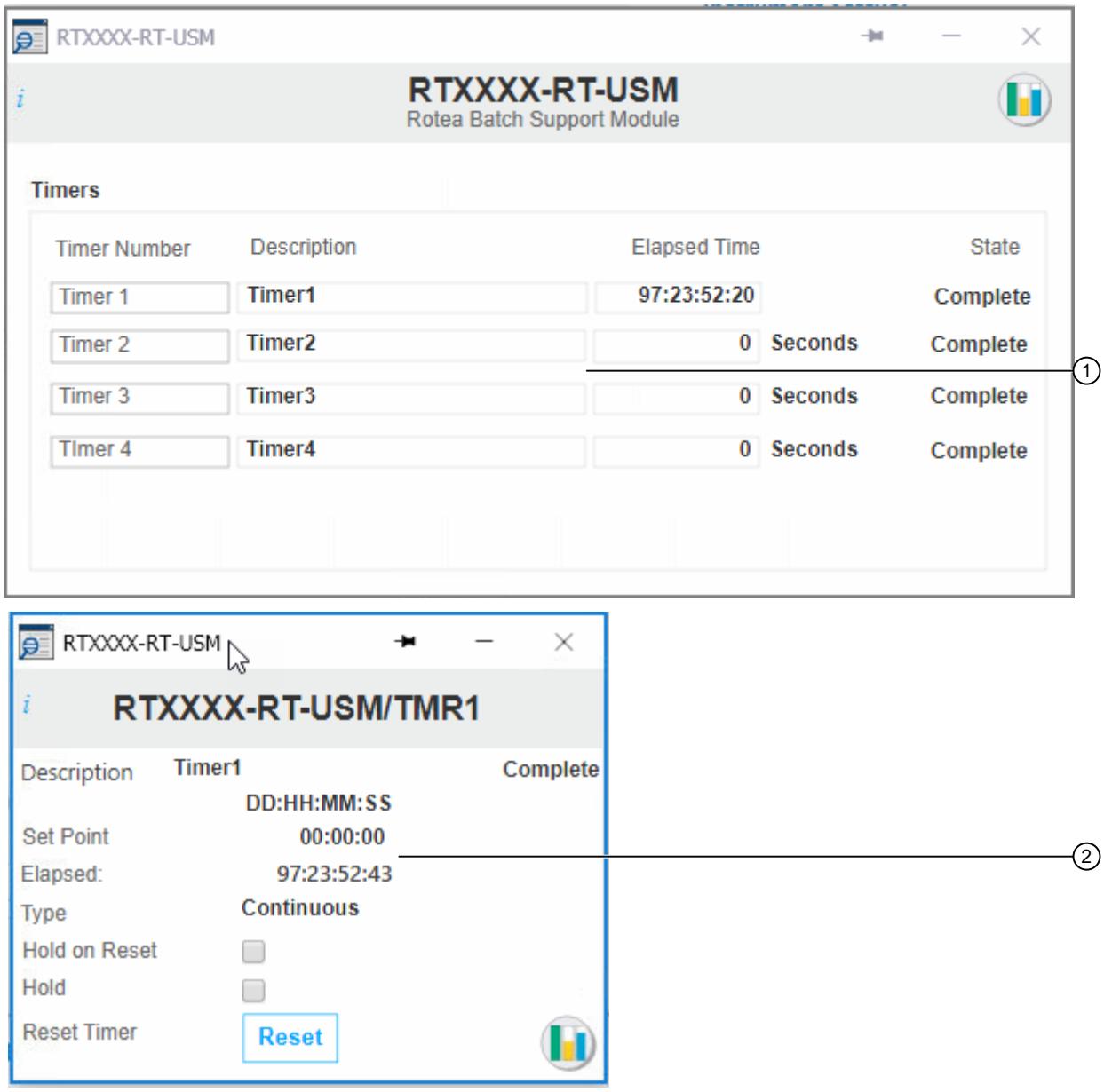


Figure 7 Timer

① Timer overview
② Timer details

- Timer overview: This displays the key timer information.
  - **Timer Number**: Shows the timer number. Clicking on this field will bring up the timer details detail GT_TimerFB_DT.
  - **Decription**: Timer description
  - **Elapsed Time**: Shows how long the timer has been running.
  - **State**: Shows complete when the timer has reached the target.

- Timer details: Contextual display GT_TimerFB_DT. This displays detailed timer information.
  - **Description**: Shows the current description of the timer.
  - **Set Point**: Shows the target setpoint for the timer. Only valid when the timer type is set to Time Out.
  - **Elapsed**: Shows how long the timer has been running.
  - **Type**: Shows the timer type, Continuous or Time Out.
  - **Hold on Reset**: If this is ticked, then when the timer is reset, the timer value is not cleared and stays at the last value.
  - **Hold**: When ticked the timer is held.
  - **Reset Timer**: This button stops the timer and reset internal timer values unless **Hold on Reset** is ticked.

Alarms

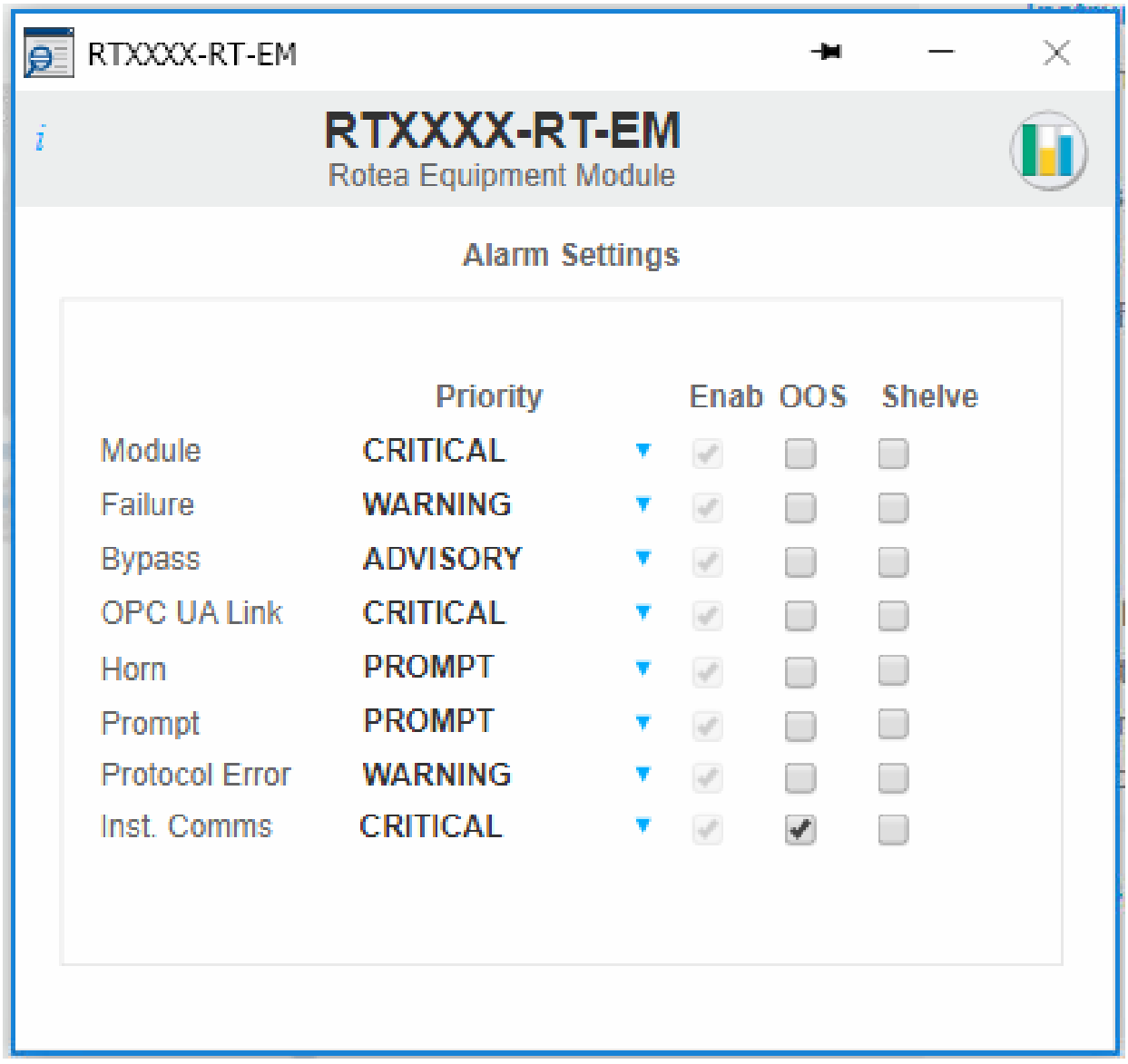


Figure 8 Alarm details

Alarm details: Each alarm that exists in the module is shown on this display. Each alarm has the following fields.

- **Name**: The alarm name
- **Priority**: The current priority of the alarm
- **Enab**: A read only checkbox that, when checked, indicates that the alarm is enabled within the module.
- **OOS**: A read/write checkbox that, when checked, indicates the alarm is currently out of service.
- **Shelve**: A read/write checkbox that, when checked, indicates the alarm is currently shelved.

GT_EM_FM_DT

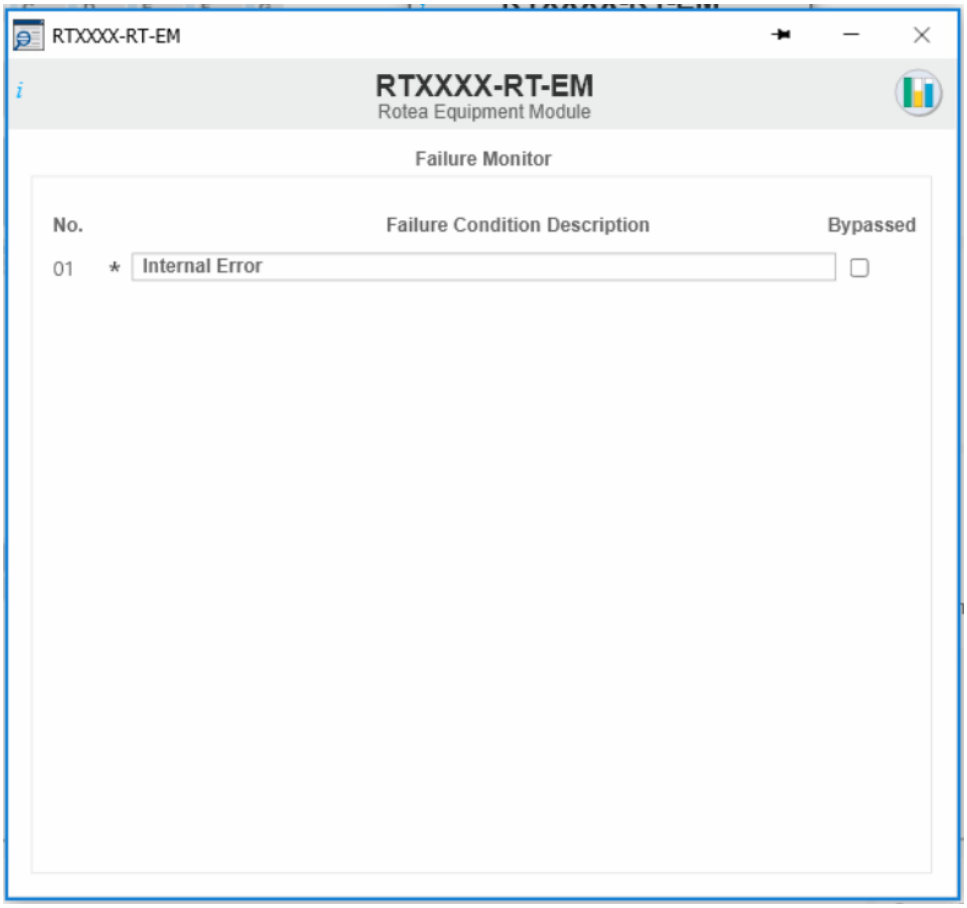


Figure 9 Failure monitor

Failure monitor: This display shows up to 16 individual failure conditions, and the associated failure description. If a failure is active, the text will turn red.

- **No.**: Individual failure monitor number. An asterisk (*) next to the number indicates that the failure monitor condition is enabled.
- **Failure Condition Description**: The description of the failure condition. This text color will turn red when the pre-out condition is true. This means if the condition is bypassed, it will still indicate that if the bypass is removed the condition will activate.
- **Bypassed**: This checkbox can be used to bypass a failure condition. Bypassing a failure condition will raise a bypass alarm to log the action.

GT_EM_Params_DT

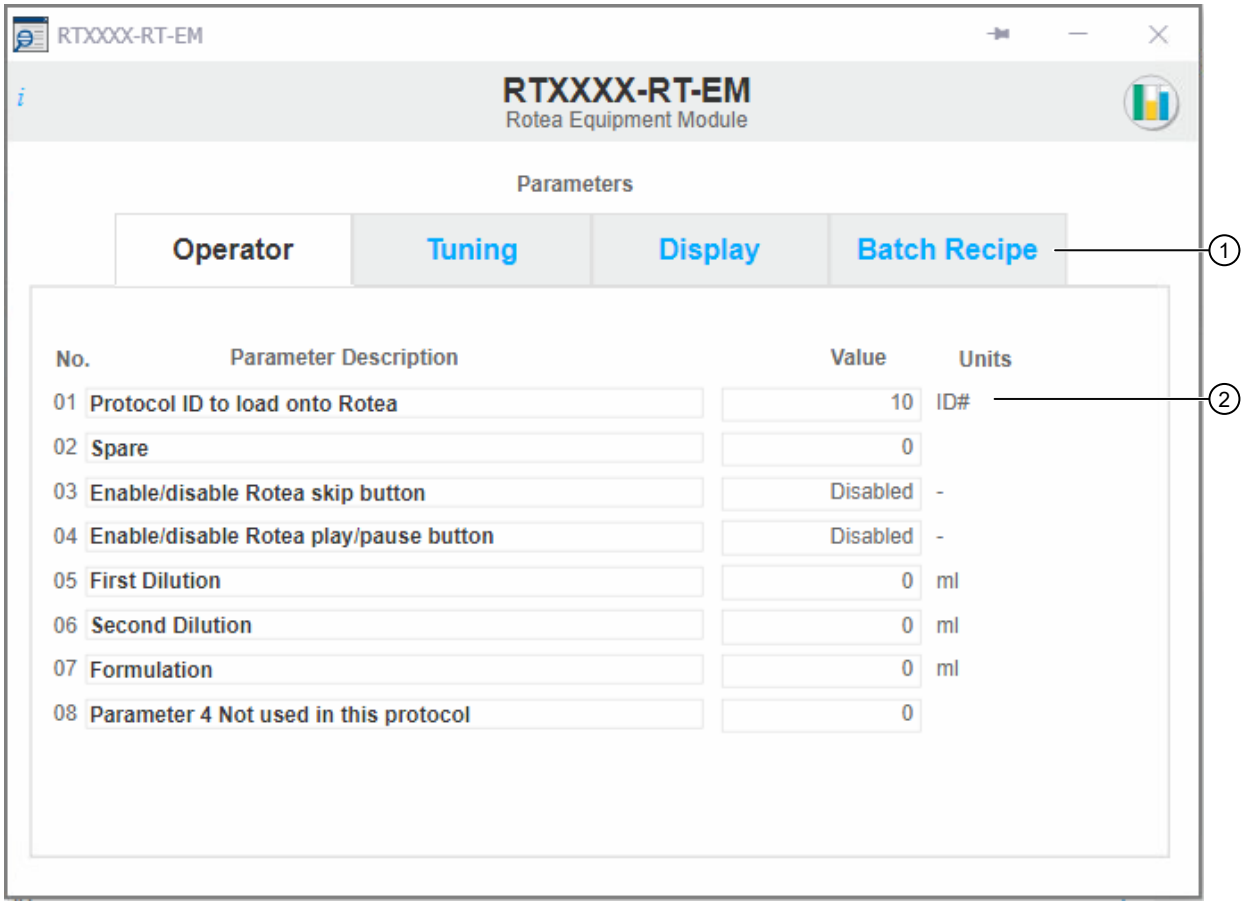


Figure 10 Parameters

① Parameter types
② Individual parameters

1. Parameter types: These buttons allow the selection of the parameters for a particular type. The following types are provided.
   - **Operator**: Clicking on this button will display parameters in the window that can be modified by an operator. To modify a parameter, click on the value and a popup will appear to allow data entry.
   - **Tuning**: Clicking on this button will display parameters in the window that can be modified only by a user with tuning rights.
   - **Display**: Clicking on this button will display parameters in the window that are internal parameters that are used as part of calculations.
   - **Batch Recipe**: Clicking on this button will display parameters in the window that are written by batch recipes and used when the batch recipe owns the module.
2. Individual parameters: If a parameter is present it will be shown as a single line with the following fields.
   - **No.**: Individual parameter number
   - **Parameter Description**: A description of the parameter.

- **Current Value**: Displays the current value of the parameter.
- **Units**: Displays the engineering units of the parameter.

GT_EM_Diag_DT

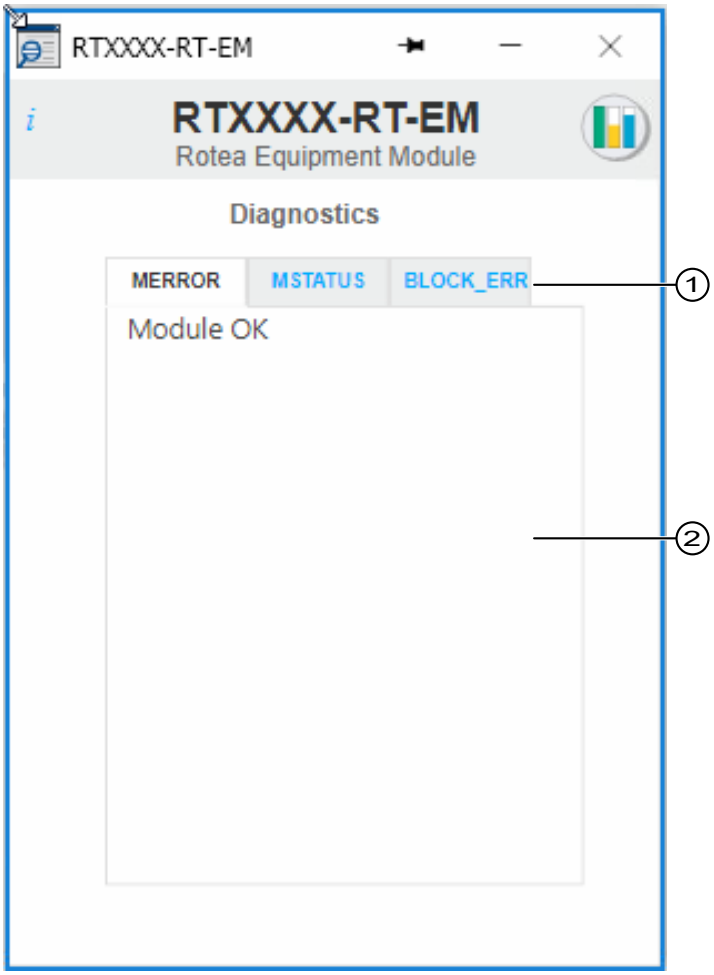


Figure 11 Diagnostics

① Tab strip to select the various diagnostic parameters.
② Diagnostic parameters are shown in this window.

C Compatibility matrix

The following table lists the software compatibility of CTS™ Cellmation™ Software, DeltaV™ system and the Rotea™ instrument firmware. The versions listed below have been tested against the DeltaV™ and Rotea™ software versions.

CTS™ Cellmation™ software release	DeltaV™ system version	Rotea™ instrument version
Build 2.0.0.xx	DeltaV™ system 14.LTS EIOC sw rev 13.3.1.7456.xr	Version 1.3.xx Main Firmware: Rotea™ main rev 1 V0.73.10 PSU Firmware: Rotea™ power rev 1 V0.20.4

D

Safety

WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit **thermofisher.com/support**.

E Documentation and support

Customer and technical support

Visit **thermofisher.com/support** for the latest service and support information.

- Worldwide contact telephone numbers
- Product support information
  - Product FAQs
  - Software, patches, and updates
  - Training for many applications and instruments
- Order and web support
- Product documentation
  - User guides, manuals, and protocols
  - Certificates of Analysis
  - Safety Data Sheets (SDSs; also known as MSDSs)

  Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.