# CTS™ Cellmation™ Software for DeltaV™ System USER GUIDE

for use with: CTS™ Xenon™ Electroporation System

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# **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<sup>™</sup> 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) – recommended 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 3<sup>rd</sup> 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<sup>™</sup> 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
5	Opens the suppressed alarm list. Only visible when there are suppressed alarms.
D.	Exits operator interface.
*	Opens the tools list. The following tools are available, Print, Reset Layout, Layout Scale and Themes.
O	Refreshes the current display.
ρ	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.
<b>←</b>	Navigate forward to the previous Main Screen. Holding the button will display the display history.
<b>→</b>	Navigate forward to the previous Main Screen. Holding the button will display the display history.
A	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.
<b>_</b>	DeltaV™ Utilities, provides access to Emerson Process Management functions.
<b>®</b>	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).

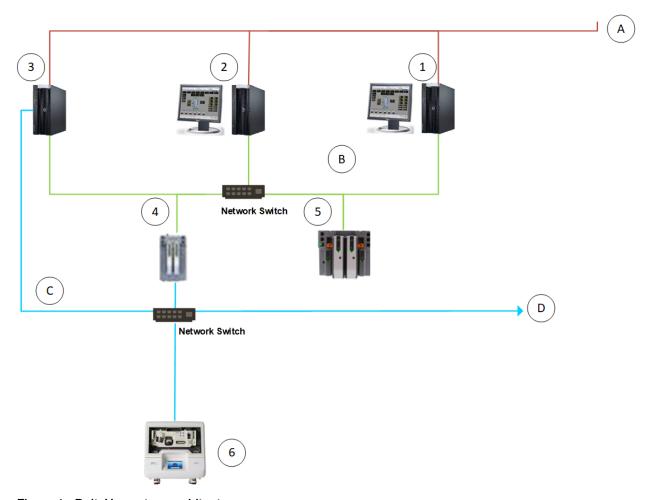


Figure 1 DeltaV™ system architecture

- A: Office/Plant network
- **B**: DeltaV<sup>™</sup> 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 utilized
- 4 EIOC (OPC UA Client)
- (5) PK/MX/SX Controller
- (6) Xenon™ instrument

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.

# Software licensing requirements

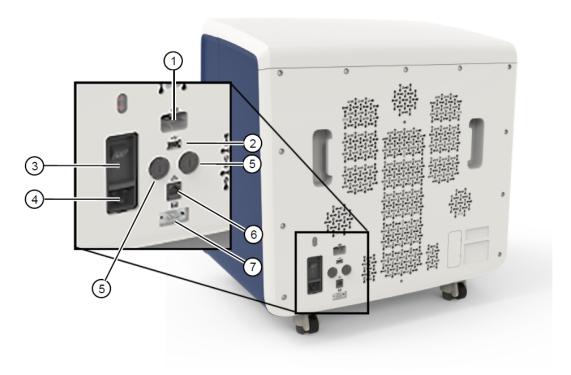
The DeltaV<sup>™</sup> system should be version 14.LTS to support DeltaV<sup>™</sup> Live applications. The DeltaV<sup>™</sup> system should have the Continuous Historian enabled to support continuous historian of at least 50 parameters for the Xenon<sup>™</sup> instrument. Also, the Batch Historian should be enabled if batch data is required for batch reporting. The following is the list of minimal software licenses required.

- 1. ProfessionalPLUS Premium Workstation Software; 100 DST
- 2. DeltaV version 14.LTS
- 3. DeltaV Live DeltaV Live Operations Premium Performance Pack
- (Optional) Application Station 250 DV (Required if using the Application Station for OPC Communication)
- 5. Batch licenses
  - a. Advanced Batch Units, 1 Units (should be 1 for each instrument)
  - b. Advanced Batch Unit Management, 1 Units (should be 1 for each instrument)
  - c. Batch Historian
- 6. Operator/Professional Station, full span of control
- 7. OPC UA related licenses
  - a. OPC UA Activation License (systemwide)
  - OPC UA client for Ethernet connected I/O (EIOC) Optional if using the Application Station for OPC Communication
  - c. OPC UA Client Signal License, 500 Signals (100 per Instrument)
- 8. DST License
  - a. Analog Monitor Input 25 DSTs
  - b. Analog Control Output 25 DSTs
  - c. Discrete Monitor Input 25 DSTs

# **Physical connection**

The connection between the DeltaV<sup>™</sup> system and the Xenon<sup>™</sup> instrument is via an ethernet network, and as such the architecture is dependent on the network infrastructure installed on the system.

To connect the instrument to the network, a CAT6A or CAT5 cable can be inserted into the Ethernet port.

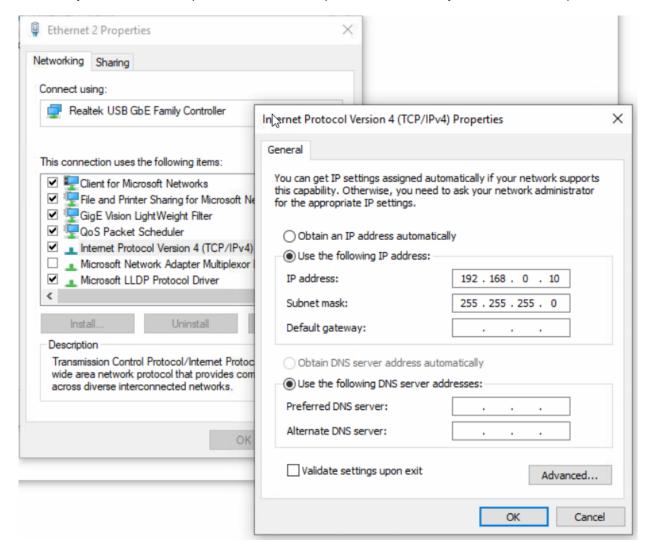


- 1 USB wireless adaptor port
- (2) USB 2.0 port
- 3 Power switch
- 4 Power cable inlet

- (5) Fuse compartment
- 6 Ethernet port
- 7) Peripheral interface port (RS-232)

# **Application Station instrument network setup**

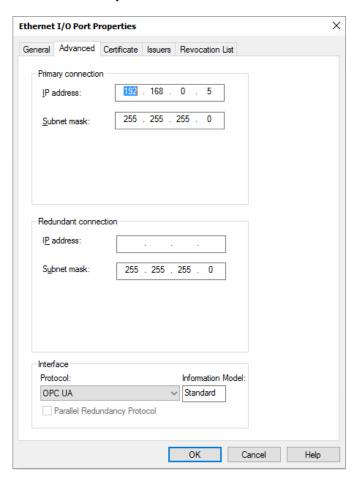
If using an Application Station as the OPC UA Client, the network adapter needs to be set up. Select the Ethernet adapter to be used for OPC UA from 'Control Panel -> Network Connections' and setup an IPv4 address for connection to the DeltaV™ system (see example). This address forms part of the DeltaV™ system OPCUA setup. This address forms part of the DeltaV™ system OPC UA setup.



Note: This IP address shown in the picture can change as per user's EIOC IP address.

# **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.

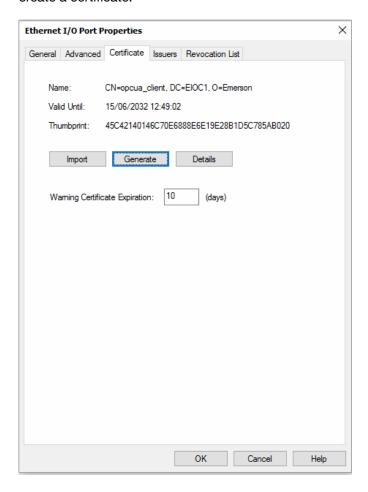


Note: This IP address shown in the picture can change as per user's EIOC IP address.

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

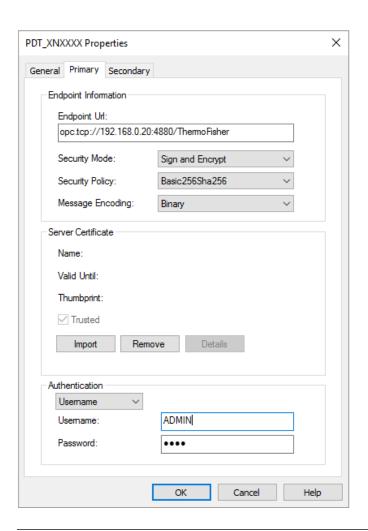
# **EIOC OPC UA setup**

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 Xenon™ instrument contain a configuration file that has default settings for the Xenon™ instrument OPC UA setup. The default setup creates a Physical Device Tag (PDT) named "PDT\_XNXXXX" with all the associated Logical Device Tags underneath it. The PDT properties contain the Endpoint URL of the Xenon™ 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 4880 and should not be changed.



Note: This IP address shown in the picture can change as per user's Xenon™ instrument address.

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<sup>™</sup> system configuration has been downloaded, a quick test can be performed on the Rotea<sup>™</sup> companion PC to check for network connectivity. Right click the Windows<sup>™</sup> 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.

```
Microsoft Windows [Version 10.0.17763.973]
(c) 2018 Microsoft Corporation. All rights reserved.

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

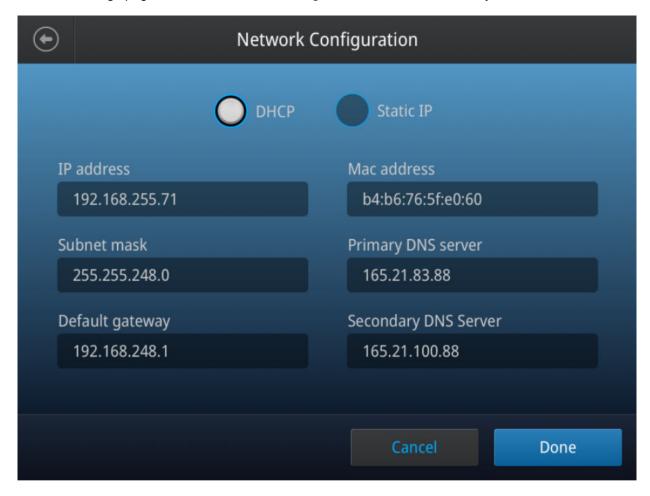
Ping statistics for 192.168.0.5:
Packets: Sent = 4, Received = 4, Lost = 0 (0% loss),
Approximate round trip times in milli-seconds:
Minimum = 1ms, Maximum = 1ms, Average = 1ms
```

Note: This IP address shown in the picture can change as per user's EIOC IP address.

# Xenon™ instrument OPC UA setup

Refer to Xenon™ GUI and Xenon™ Instrument User Manual.

From the settings page select the Network Configuration tab and set the entry fields as shown.



Note: This IP address shown in the picture can change per the site requirement.

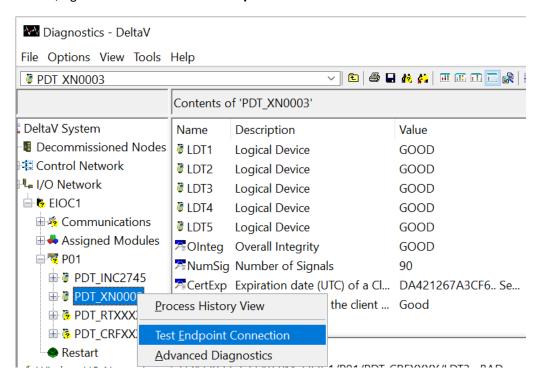
The entry field **OPC-UA Duplicate Command Ignore Timeout** is a troubleshooting timer. This entry is used to ignore duplicated commands from the DeltaV<sup>™</sup> system within this time. If the scan rate of the DeltaV<sup>™</sup> system landing module is less than 1 second then duplicate commands might be issued due to the Rotea<sup>™</sup> 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.

# **OPC UA connectivity check**

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



## User interface

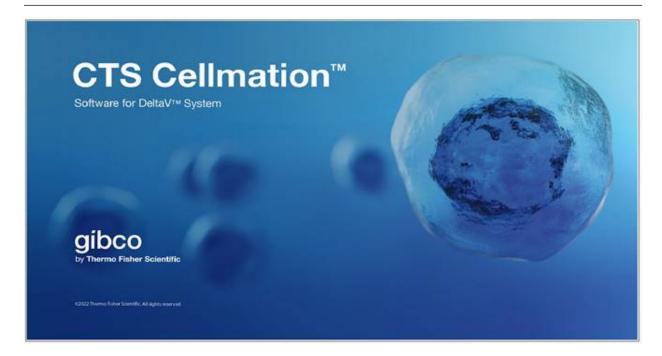
The user interface consists of a number of screens that enable the user to interact with an instrument and run instrument protocols. DeltaV<sup>™</sup> Live is the only supported interface as DeltaV<sup>™</sup> Operate is being phased out. These screens are:

- Splash/opening screen
- Overview display
- Main instrument display
- Instrument parameter display

## Splash screen

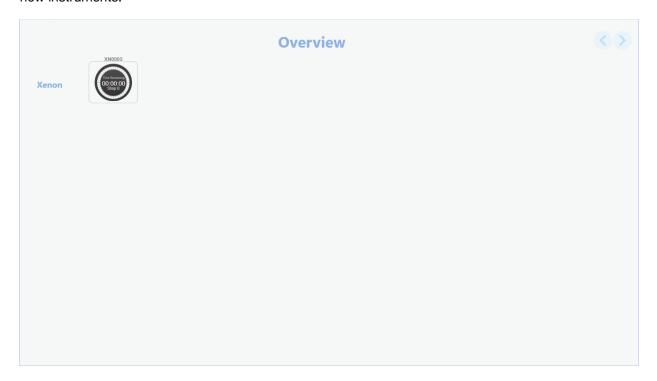
The splash screen appears when the user interface is first started and from here the user can enter the CTS™ Cellmation™ Software overview by clicking anywhere on this screen.

**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.



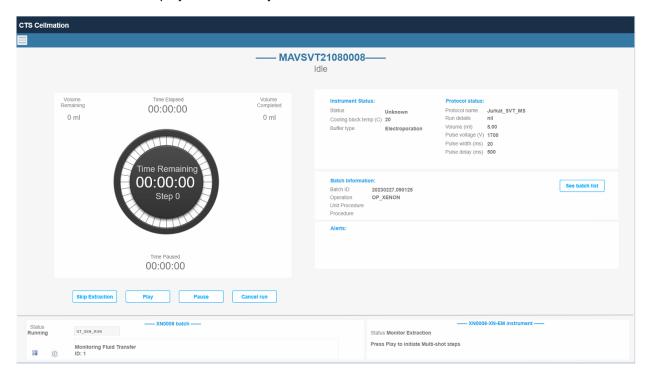
# Overview display

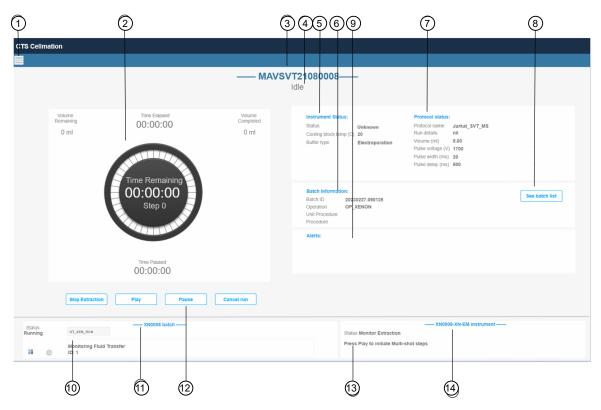
The **Overview** screen allows for an individual instrument to be selected to open more detailed information for that instrument. On the initial installation, the overview screen has a blank screen with guideline boxes. As instruments are added to a system, this overview screen will be modified to add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



# Main Xenon™ instrument display

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





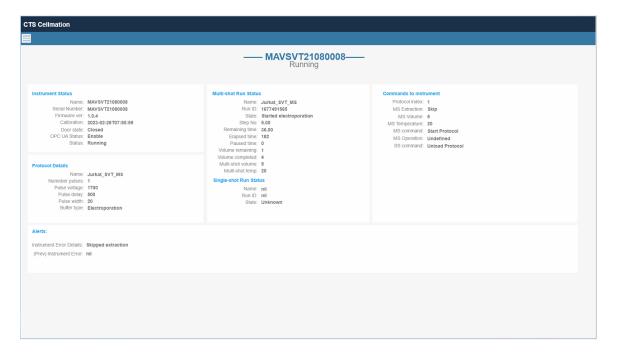
- ① Menu display selection. Displays Xenon™ Interface Parameters display and Cellmation Overview display for selection. When one of the options is clicked, the displays are opened.
- ② Xenon™ instrument representation will indicate Time remaining, Step number, Time Elapsed, Time Paused, Volume Remaining and Volume Completed.
- 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, Status, Cooling Block Temperature, Buffer Type.
- (7) Batch information. Recipe details are displayed here if a batch recipe is running.
- (8) Protocol status. Displays the protocol name, run details, volume, pulse voltage, pulse width and pulse delay.
- (9) Button to open the batch list view.
- 10 Displays the active instrument error.
- (1) Messages/prompts from batch/recipe displayed here.
- (12) Clicking here brings up Unit Module faceplate.
- (13) Buttons to Skip extraction, play, pause the Extraction/Electroporation and cancel a protocol run. Play and Pause Buttons are only enabled when the Xenon multishot protocol is running.
- (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 Xenon™ Dial to show the current Time remaining, step number, Time elapsed, Time paused, Volume remaining, and Volume Completed. Buttons are included to:
  - a. Control the protocol, skip, pause/resume and cancel.
- 2. The right hand section details data associated with the instrument and protocol running on the Xenon™ instrument.
  - a. Protocol name
  - b. Run Details
  - c. Volume
  - d. Pulse Voltage
  - e. Pulse Width
  - f. Pulse Delay
  - 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 Xenon™ 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.

## Xenon™ instrument interface parameters display

The Xenon™ 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.



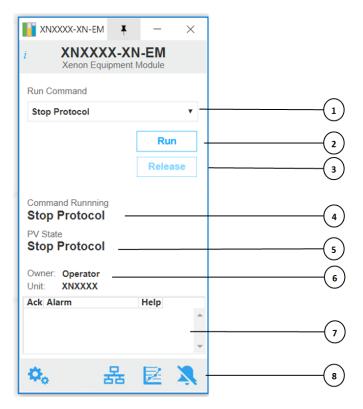
## **Contextual displays (Faceplates)**

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 Xenon™ 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".

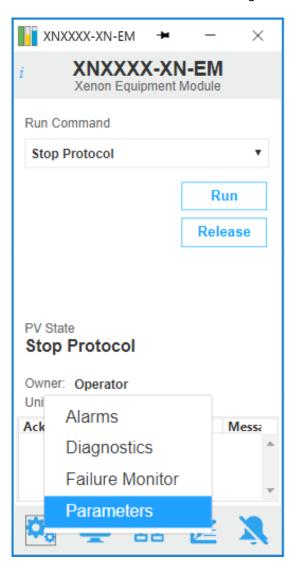


- 1) Select a command drop down box
- ② Run button: When pressed will set the command to the drop down box selection
- (3) Release button for ownership of the module
- 4 Current command being run

- (5) Current state of the command
- (6) Displays the current owner of the module
- Alarm window shows any active or unacknowledged alarms
- (8) Selection icon

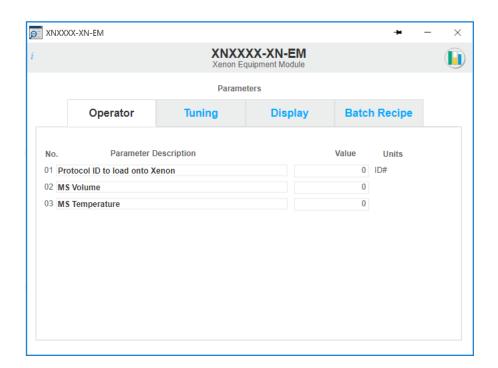
#### Equipment module detail faceplates

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.



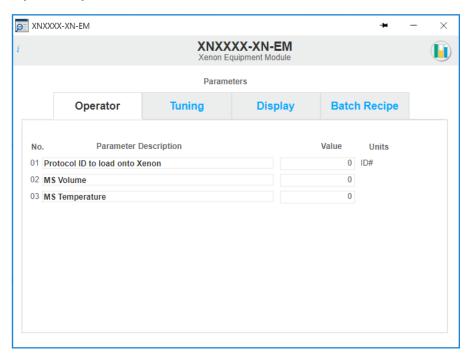
(1) Clicking on the gear icon (\$\frac{\display}{\display}\$) brings up a context menu allowing for the appropriate detail faceplate to be shown.

The non-standard information displayed are Xenon™ 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**.

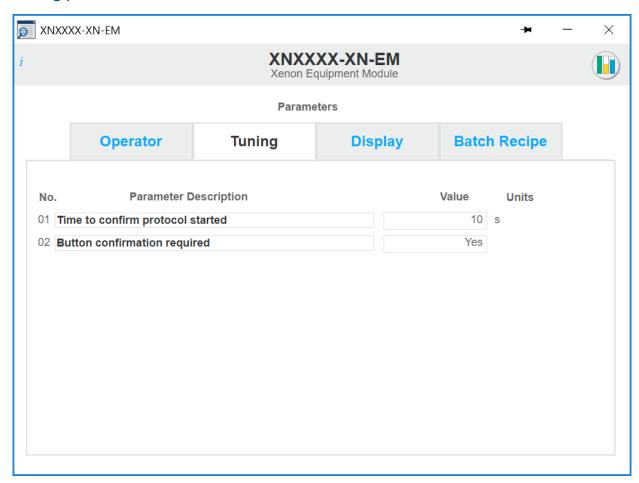
#### **Operator parameters**



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 Xenon: Enter to protocol ID to load onto the Xenon instrument.
- MS Volume:: Define Xenon Multi-Shot Volume.
- MS Temperature: Define Xenon Multi-Shot Temperature.

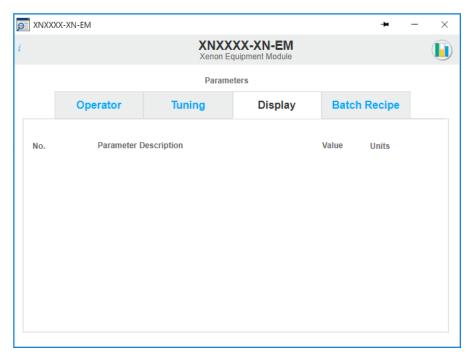
#### **Tuning parameters**



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.

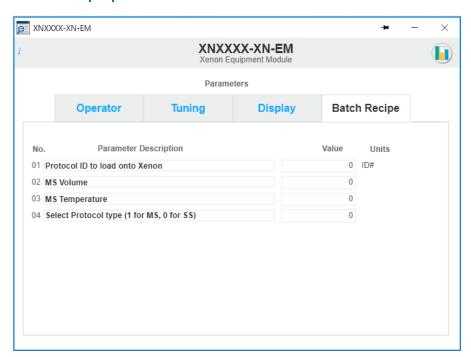
- **Time to confirm protocol started**: Time in seconds to wait to monitor for errors before the confirming the protocol has started.
- **Button Confirmation required**: Enables/Disables button confirmation for Play/Pause/Cancel Run/Skip Extraction.

### **Display parameters**



There are no display parameters for the Xenon™ instrument.

## Batch recipe parameters

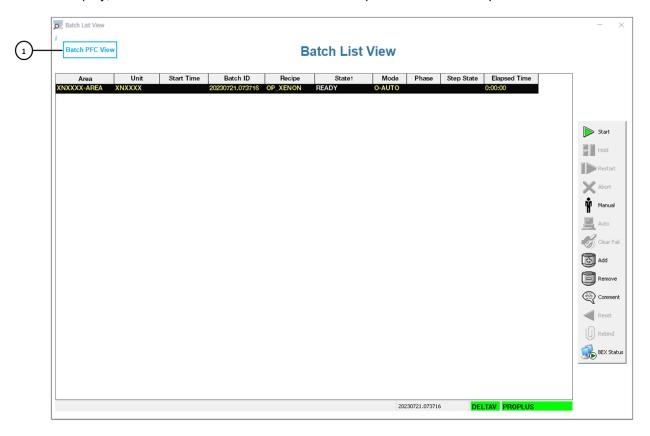


The parameters shown on this tab are updated by a phase running as part of a batch recipe and cannot be modified.

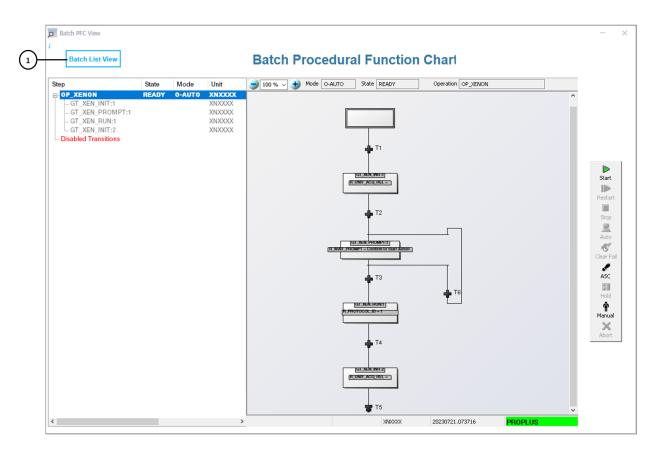
- **Protocol ID to load onto Xenon**: Enter a protocol ID to load onto the Xenon™ instrument.
- **MS Volume**: Define Xenon™ Multi-Shot Volume.
- **MS Temperature**: Define Xenon™ Multi-Shot Temperature.
- Select Protocol type (1 for MS, 0 for SS): Define Protocol type 1 for Multi-Shot, 0 for Single-Shot.

#### **Batch faceplates**

The batch faceplates are displays that allow for interaction with the batch recipes. From the main Xenon™ 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.



# 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. For example, "RIPTIDE.DELTAV.THERMOSIENTIFIC.LOCAL\Emerson", where Domain name is "RIPTIDE.DELTAV.THERMOSIENTIFIC.LOCAL" and username is "Emerson".

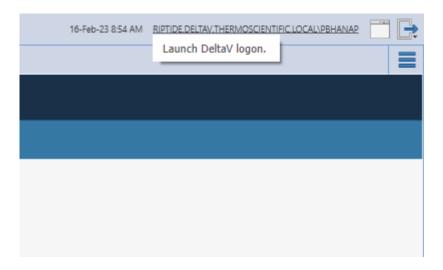


Table 2 Available actions for each user level

Action	Operator	Maintainer	Supervisor	Administrator
Access Window desktop	Х	Х	Х	✓
Exit DeltaV Operate	Х	Х	Х	✓
Access overview page	1	1	1	✓
Access configuration page	1	1	1	✓
View Smart Device info	1	1	1	✓
Access Details displays	1	1	1	✓
Access Control Studio	Х	Х	Х	✓
Access Process History view	1	1	1	✓
Change alarm limits	1	1	1	✓
Change conditional alarm settings	Х	Х	1	1

Table 2 Available actions for each user level (continued)

Action	Operator	Maintainer	Supervisor	Administrator
Shelve or remove from service alarms	1	Х	✓	✓
Set alarm priority	Х	Х	✓	✓
Acknowledge alarms	1	1	✓	✓
Bypass interlocks	Х	Х	✓	✓
Change tuning parameters	Х	Х	✓	✓
Access Diagnostics	1	Х	✓	1

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

## Xenon™ instrument operation

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

The instrument runs protocols which are defined in the instrument itself. Each time a protocol command is manually selected in the DeltaV<sup>™</sup> system, the corresponding protocol is run on the instrument.

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

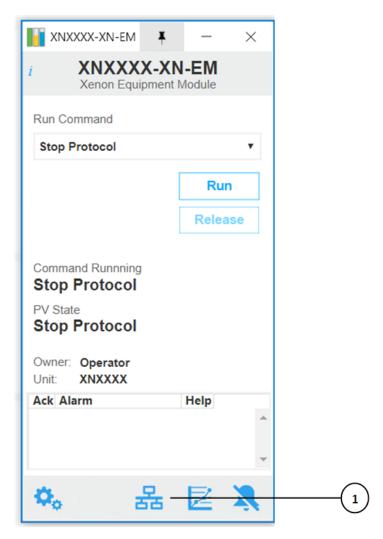
Refer to the Xenon™ instrument documentation on creating and locating protocol files to run.

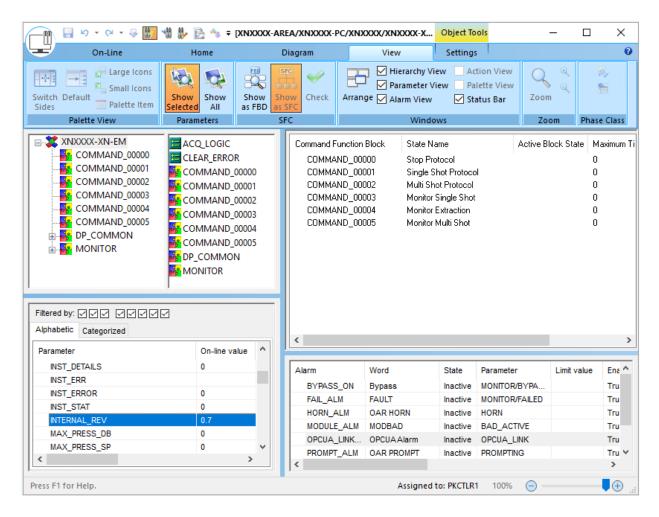
## 2

## Check revision numbers

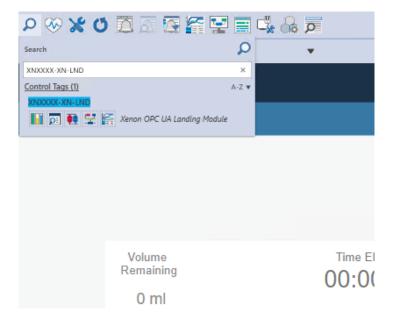
The User can check the revision history of the Xenon™ Equipment Module and Control Module by checking the value of the parameter "Internal Revision" in these modules.

On DeltaV™ Live Graphics, navigate to the Xenon™ Main Display. Click on the Equipment Module XNXXXX-XN-EM to open the faceplate of the Equipment Module. Click on the below icon to open Control Studio. Navigate to the parameter "INTERNAL REV" to get the revision number of this module.



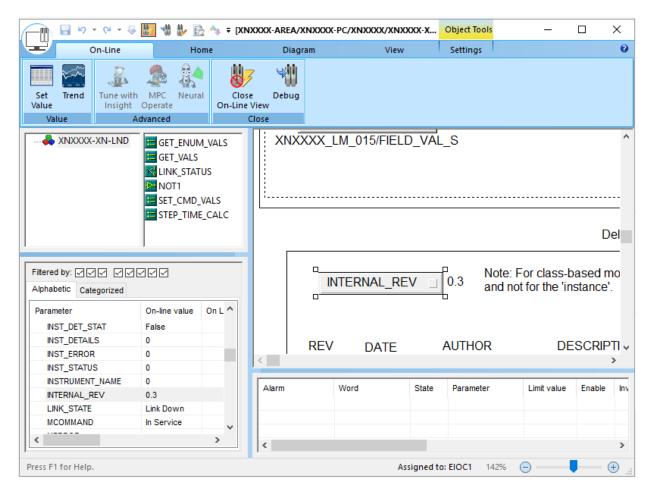


To check the revision number for the control module XNXXXX-XN-LND, navigate to the search bar on the top left corner of the DeltaV Live graphics. Enter "XNXXX-XN-LND" and click on the faceplate of the landing module.

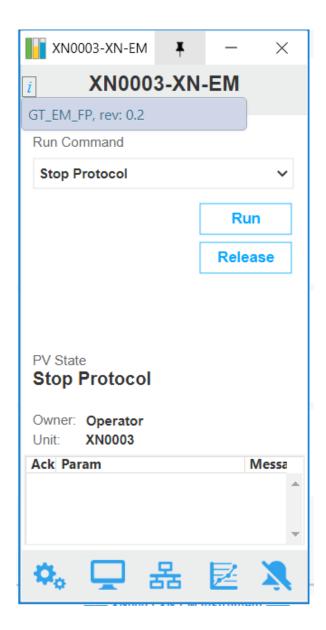




Click on icon 1 and open the control studio. Navigate to the parameter "INTERNAL REV" to get the Revision Number of this module.



To check the revision number of the graphics, navigate to the "i" icon on the top left corner of the graphic and hover over it. The revision number and the name of the graphic display will appear as show in the following figure:



# Xenon™ instrument protocol parameters

A Xenon™ instrument protocol can have up to 7 parameters that can be used within the protocol. Each of these parameters is configured with a name as shown below.

Parameters that can be modified on the instrument include:

- Pulse voltage (range: 500-2,500 V)
- Pulse width (range: 1–30 ms)
- Number of Pulses (range: 1–10 pulses)
- Pulse interval (range: 500 ms-1 second (in 100 ms intervals))
- Cell Type

#### Chapter 2 General system operation Parameter values

- Buffer Type (Gene editing buffer or Electroporation buffer)
- Pulse Type (Conventional, Reverse polarity)

Parameters that can be modified on DeltaV, but not on the instrument include:

- Volume
- Temperature

## Parameter values

The individual parameters (voltage, pulse width, pulse number, pulse interval) have their own independent upper limits. However, certain combinations of these variables will exceed the energy limit of the system even when still within the individual limit. For example, a protocol of 2300 V/30 ms/3-pulses can be entered but not run as it exceeds the energy limit of the system despite each variable being within its limits. A graphical representation of the electroporation parameters can be viewed by selecting Pulse profile when viewing the protocol parameters screen.

# Manual operation

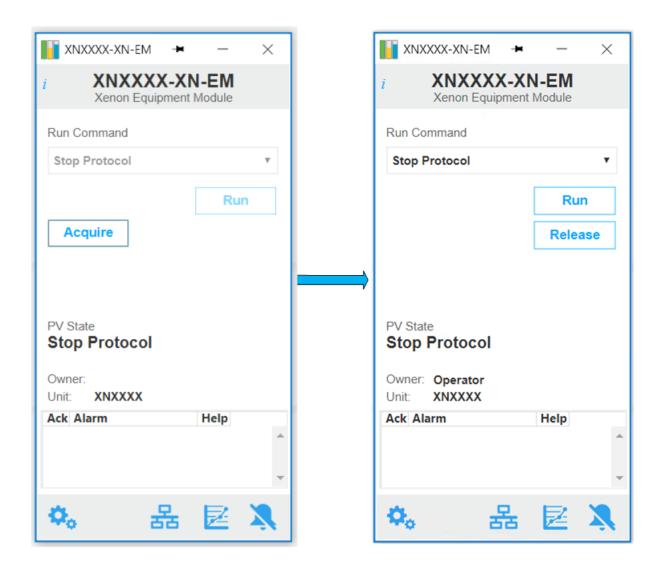
The Xenon™ instrument can be controlled manually from the DeltaV™ system via the equipment module faceplate.

To initiate a protocol to run on the 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. 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 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.

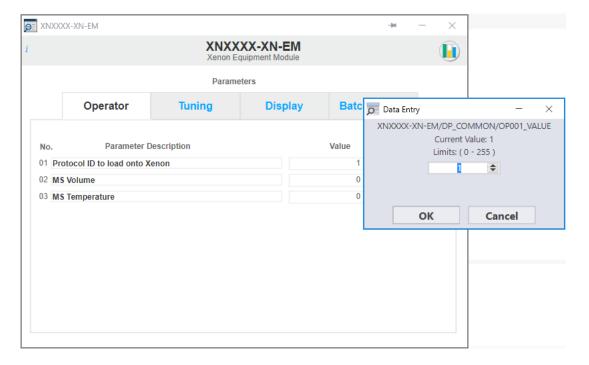


# Step 2: Setup the equipment module and enter protocol parameters

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

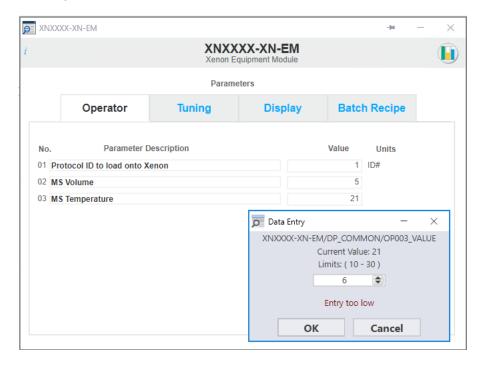


Enter the exact Protocol ID that was entered in the .yaml file. By clicking on the current value field, a data entry form appears as shown in the following figure. From this form enter the protocol number and click **OK** to store the value.

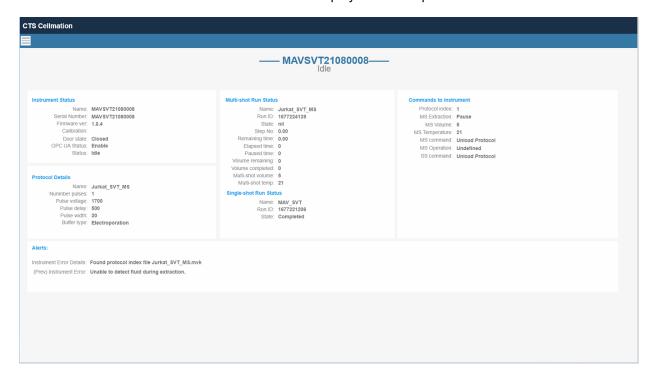


The other parameters values for the Xenon instrument can be set from the parameter list.

If the user wants to run the Multi Shot Protocol, then the MS Volume and MS Temperature must update to the required value. If the user enters the parameter value out of the range of the parameter, then there will be a prompt - parameter error, it lets the user know that the parameter values are not entered correctly.



Use the Xenon™ instrument Interface Parameters display to see the parameter values.

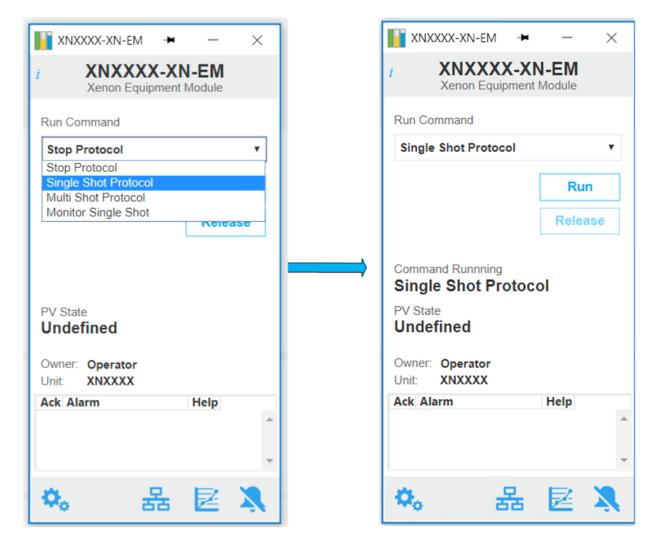


If the User wants to run the Single Shot Protocol, follow Step 3.1 and 4.1. If the User wants to run the Multi Shot Protocol, follow Step 3.2 and 4.2.

## Step 3.1: Setup the equipment module to Run Single Shot Protocol

Open the equipment module faceplate.

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

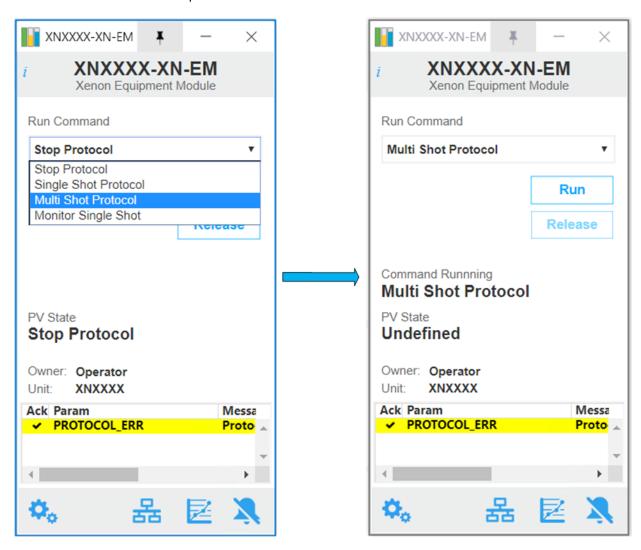


The Single Shot Protocol command will now run as shown on the equipment module faceplate.

## Step 3.2: Setup the equipment module to Run Multi Shot Protocol

Call up the equipment module faceplate.

From the Run Command drop down box select Multi Shot Protocol and then click on the Run button.



The Multi Shot Protocol command will now be running as shown on the equipment module faceplate.

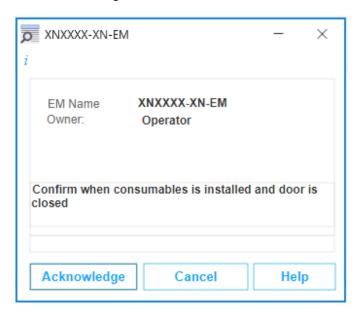
# Step 4.1: Answer prompts as required

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



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

- 1. OPC communication is checked if enabled. If it's not, User is prompted to enable OPC communication before recipe proceeds.
- 2. Instrument is checked for errors. If there are errors, User is prompted to diagnose errors and clear it before recipe proceeds.
- 3. Protocol ID is checked.
- 4. User prompted to confirm the kit is installed, and door closed.
- 5. The door closed status is checked and if an error is found another prompt is issued to close the door.
- 6. Sequence goes to respective protocol Monitor sequence. For single shot protocol, it goes to Monitor Single Shot.



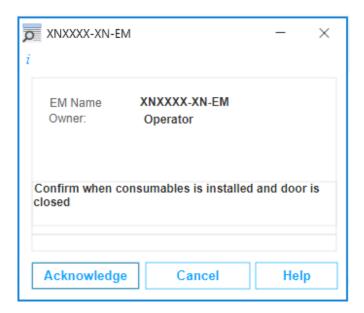
Before a protocol can run the following checks are made:

# Step 4.2: Answer prompts as required

Prompts will be generated by the equipment module and displayed in the bottom right-hand corner of the Main Xenon™ instrument display.



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



Before a protocol can run the following checks are made:

- 1. OPC communication is checked if enabled. If it's not, User is prompted to enable OPC communication before recipe proceeds.
- 2. Instrument is checked for errors. If there are errors, User is prompted to diagnose errors and clear it before recipe proceeds.
- 3. Protocol ID is checked.
- 4. User prompted to confirm the kit is installed, and door closed.
- 5. The door closed status is checked and if an error is found another prompt is issued to close the door.
- 6. For Multi Shot Protocol, protocol parameters temperature and volume are checked for validity and that they are within limits. If it's not, User is prompted to re-send the parameter values.
- 7. Sequence goes to respective protocol Monitor sequence. For Multi Shot Protocol, it goes to Monitor Extraction followed by Monitor Multi shot.

# Step 5.1: Monitor Single Shot

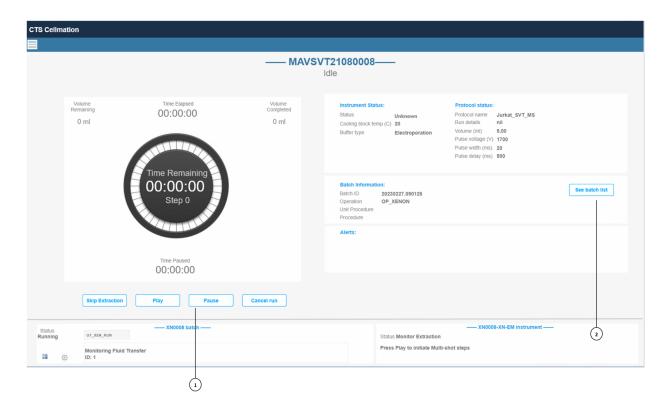
When a Xenon™ Monitor Single Shot protocol runs and there is an error, the **Stop** button and **Play** button is enabled on the graphics. User is prompted to press **Stop** to abort the Single Shot protocol. User must then select Stop for the sequence to complete. The equipment module then runs the **Stop Protocol** command. If there is no error during the Monitor Single Shot protocol, the sequence goes to completion by running the **Stop Protocol** command.

### Step 5.2: Monitor Extraction and Monitor Multi Shot

When a Xenon Monitor Multi shot protocol runs and it enters to **Monitor Extraction** command, it can either be successful or unsuccessful. If successful, then the equipment module automatically runs the **Monitor Multi Shot** command. If unsuccessful due to an error, then the equipment module automatically pauses the **Extraction** state or user can pause the extraction if required by clicking on **Pause** button. From this state the user is prompted to select from two options. Either select **Play** to restart the Monitor Extraction sequence or select **Cancel run** to abort the extraction and run the **Stop Protocol** command.

When the Xenon™ instrument enters to **Monitor Multi Shot** command, it can either be successful or unsuccessful. If successful, then the command completes without any errors. If unsuccessful due to an error, then the equipment module automatically Pauses/Abort the sequence or user can pause the electroporation if required by clicking on **Pause** button. The **Cancel run** and **Play** buttons on the graphics are enabled. The User can press **Play** to restart the sequence or **Cancel run** to abort multi-shot. If **Play** is selected, the Monitor Multi Shot sequence is re-started again. If **Cancel run** is pressed, the sequence run goes to complete automatically.

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 Extraction**, **Pause**, **Play** and **Cancel run** buttons on the main display are enabled.



- Protocol Buttons: There are four buttons to mimic the buttons on the front panel of the Xenon™ instrument
  - Pause run will pause the ongoing Extraction or Electroporation process.
  - Cancel run will cause the running protocol to discontinue the current step and end the current run.
  - Play run will cause the protocol running on the Xenon™ instrument to resume the current step.
  - Skip Extraction will cause the protocol to skip to the next step in the protocol.
- 2. **Batch List**: This button opens the Batch List View page, which allows the User to look at the batches currently running on individual instruments in DeltaV<sup>™</sup> system as well as details such as which step of the recipe is being executed, the status of the recipe step and the time elapsed as well as time the batch started.

# 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 Xenon™ 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 Xenon™ instrument GUI.

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 3<sup>rd</sup> party packages).

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

DeltaV<sup>™</sup> 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.

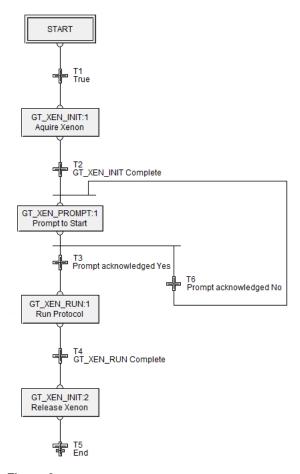
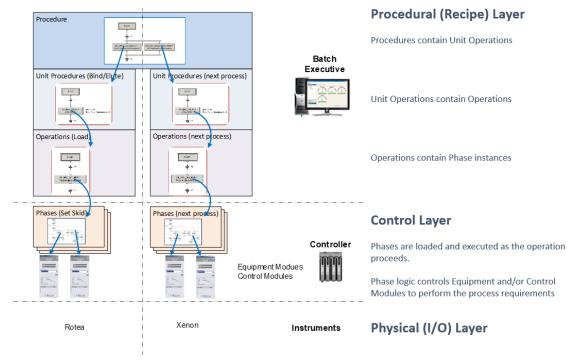


Figure 2

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

# DeltaV Batch Architecture



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

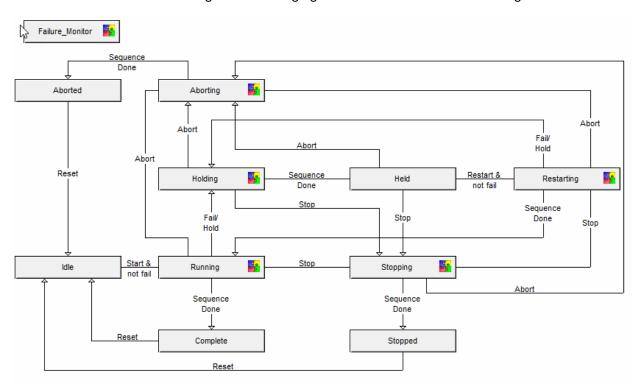
The Procedure recipe (which is the highest level recipe) can contain Unit Procedures from different Units. This feature allows a workflow to control multiple instruments within a single batch run.

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

#### **Phases**

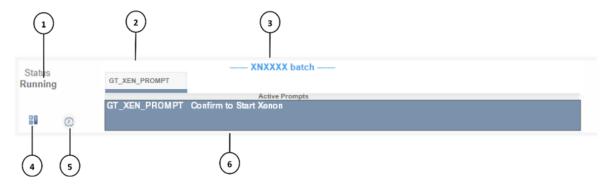
Phases are software modules that conform to the ISA-88 batch standard and run on the DeltaV<sup>™</sup> system controllers.

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



In all the Xenon™ 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 Xenon™ system display in the batch banner object, as shown in the following figure.

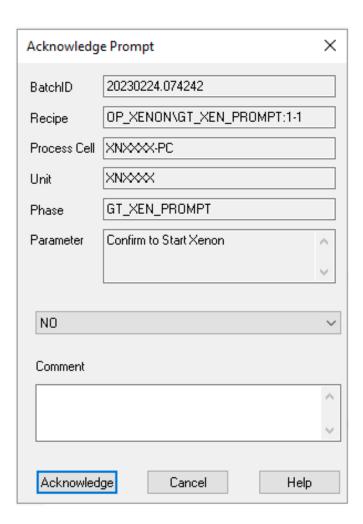


- 1 Status of the currently selected phase
- (2) Tab strip that displays the phase name(s). If more than one phase is running on the unit, then this is shown on another tab.
- (3) Unit Name
- 4 Hold Button. Pressing this will issue a message box to allow holding the recipe.
- (5) Timer button. This brings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

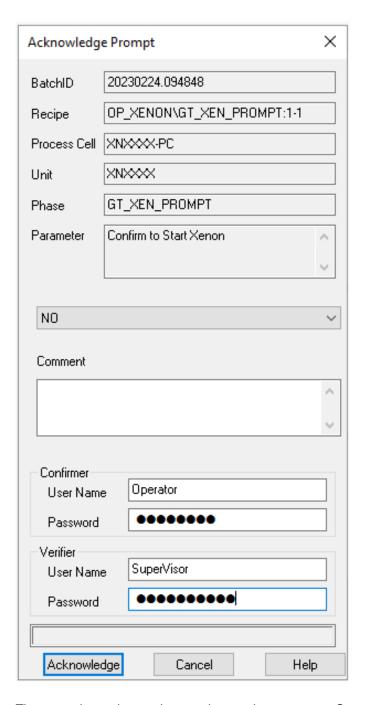
Note: The colored line underneath the text 2 shows the message status.

- 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.



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 Xenon™ instrument.

Phase name	Description			
GT_XEN_INIT	This phase acquires the Xenon™ Equipment Module within the DeltaV™ system which disables an operator from interacting with the instrument from the graphical interfaction. It is also used to release the equipment module when the recipe is complete.			
GT_XEN_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_XEN_RUN	This phase will start the selected profile on the Xenon™ instrument via the equipment module and waits until it has completed. In addition, any recipe parameters associated with a Xenon™ instrument protocol can be defined, which are then passed down to the Xenon™ 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_XEN_INIT		
Input Parameter	Description		
R_UNIT_ACQ_REL	Setting this parameter to <b>Acquire</b> will cause the phase to acquire ownership of the Xenon™ 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 <b>Release</b> will cause the phase to release ownership of the Xenon™ 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_XEN_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 <b>Hold</b> state.				
L_RESPONSE	When a prompt is answered, the response is stored in this parameter.				

	GT_XEN_RUN			
Recipe Parameter	Description			
R_PROTOCOL_ID	This parameter defines the protocol ID number to run on the Xenon™ instrument.			
R_MS_TEMP	This parameter defines Xenon Multi-Shot Temperature.			
R_MS_VOL	This parameter defines Xenon Multi-Shot Volume.			

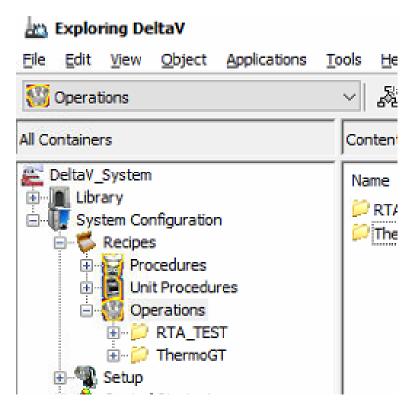
#### (continued)

	GT_XEN_RUN			
R_MSHOT	This parameter Select Protocol type (Yes for Multi-Shot, No for Single-Shot)			
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_RUN_PDF	Records the Run log .pdf file name produced during the protocol run.			
L_SERIAL_NO	Records the Xenon™ instrument serial number.			

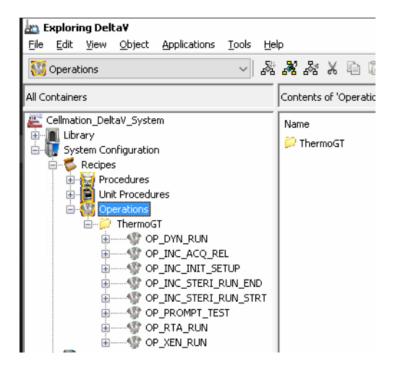
## Recipe construction

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

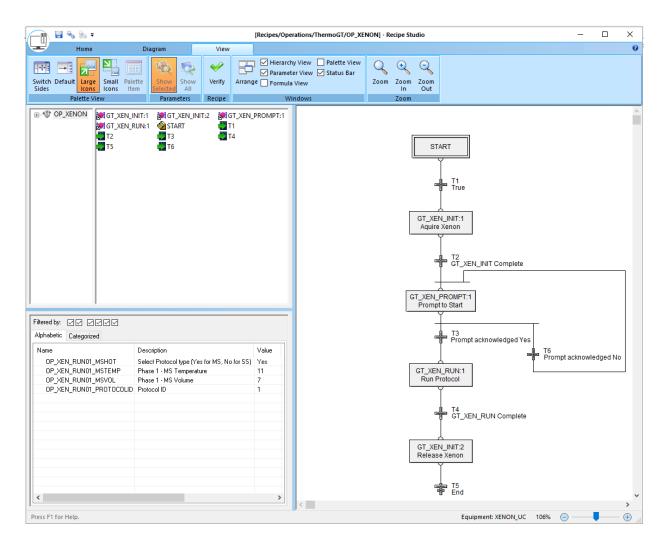
The batch recipes reside in three folders within the DeltaV™ system database and can be located using the DeltaV™ system application DeltaV Explorer. From DeltaV Explorer, the recipe folders appear as shown in the following figure – **Operations**, **Unit Procedures** and **Procedures**.



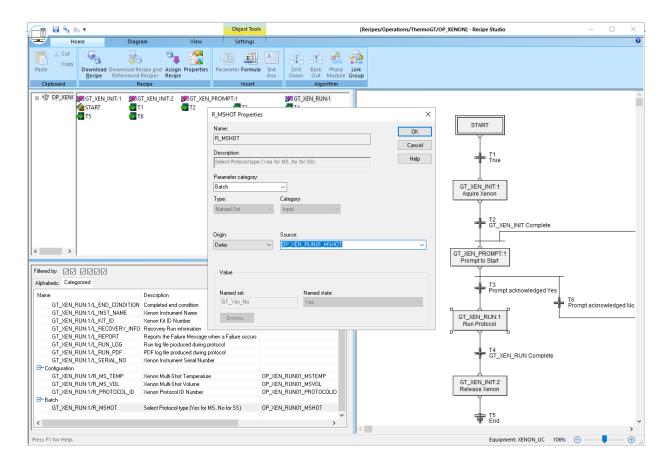
Within these folders, subfolders can be created to help organize batch recipes. In the following figure, two folders have been created and contain Operation recipes.



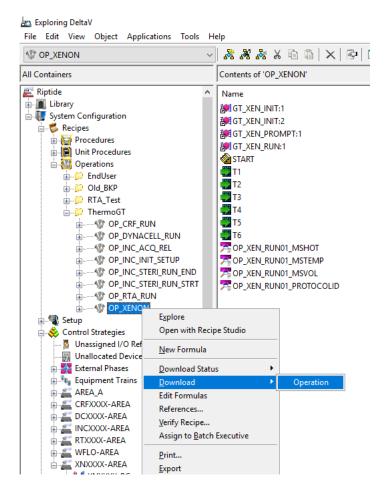
The following figure shows a simple recipe within the **Recipe Studio** application. The layout of each pane can be modified by the user. The default layout is shown in the following figure.



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.



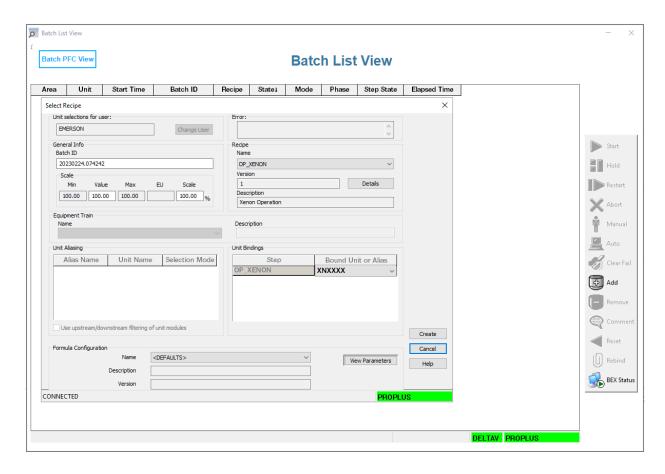
Once all the recipe parameters have been updated, save the recipe and then download to the batch executive. This is achieved by right clicking on the **operation** and selecting the download option.



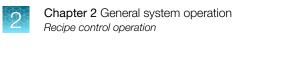
# Recipe execution

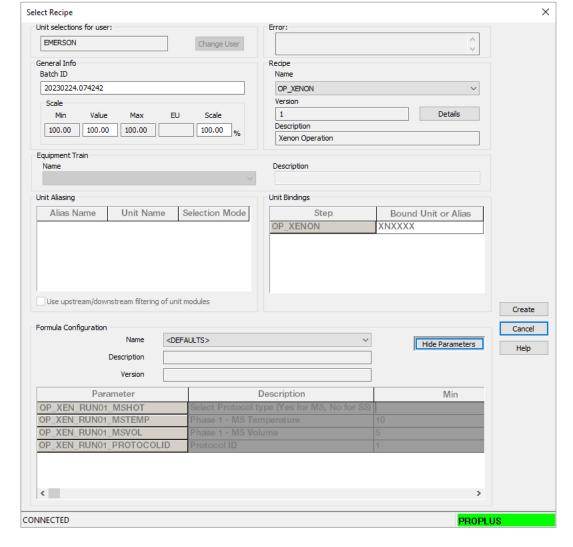
Once a recipe has been downloaded to the batch executive, it is available to be run on the system. There are two applications available for starting recipes, the graphics displays or the Batch Operator Interface (BOI). Functionally, the BOI is the same as using the graphic displays, but provides more 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.

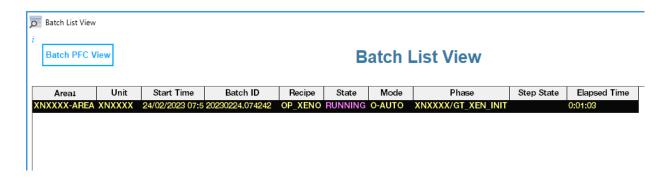




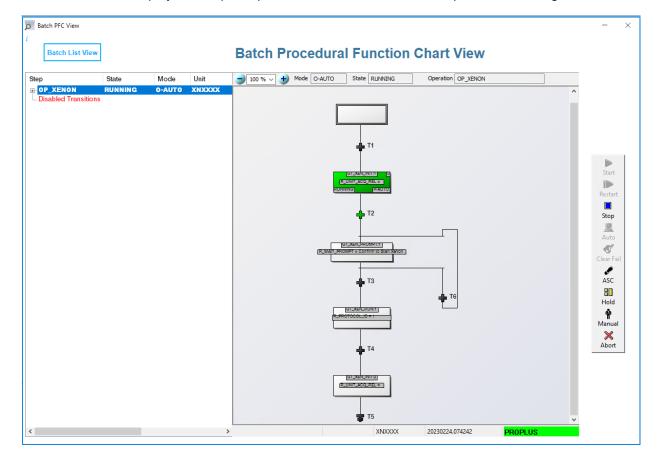
Once the recipe has been created, it will be shown in the Batch List View. To start the recipe, highlight it and select the start button. The recipe will now be running and the user can switch to the PFC view to see the recipe progress.

Many recipes can be added to a run.

Note: A recipe can only run on a unit once the previous recipe has been completed. If the previous recipe Batch Aborted or Stopped, then Before loading the new batch on the same unit the first recipe batch should be removed from Batch List View/BOI.



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





# 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 4-7Yellow: Priority 8-11Red: 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 Xenon™ 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.

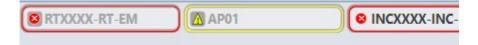
## Alarm banner

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 XNXXXX-XN-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.



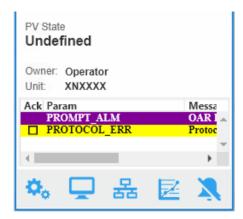
If the alarm is no longer active, and has not been acknowledged, the alarm box no longer flashes, the text is faint, and the alarm symbol on the left of the alarm has a gray box around it as seen in the following figure



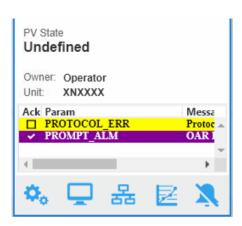
When an alarm is cleared and has been acknowledged, it will no longer appear in the alarm banner.

# 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 Xenon™ 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 Profile error) that is no longer active and unacknowledged.



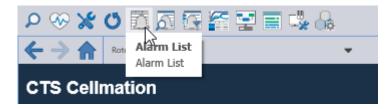
When the prompt alarm is acknowledged, a tick is shown to the right of the alarm as seen in the following figure.



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.



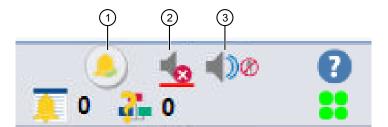
Clicking this button displays a list of all the active alarms the current workstation is monitoring for the current user.



# Acknowledging and silencing alarms

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

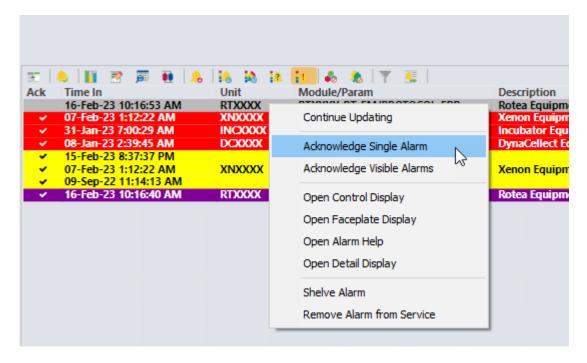
If an alarm is triggered, an audible alarm sounds, if that function has been enabled and the system provides a speaker for the alarm. To turn off the audible alarm, click the icon on the lower right corner of the screen.



- 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.

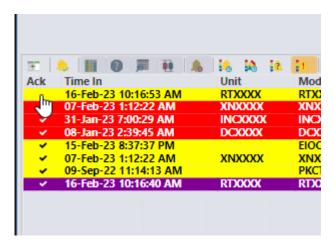
To acknowledge individual alarms the following actions can be performed.

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



#### Chapter 3 Alarm management Suppressing alarms

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

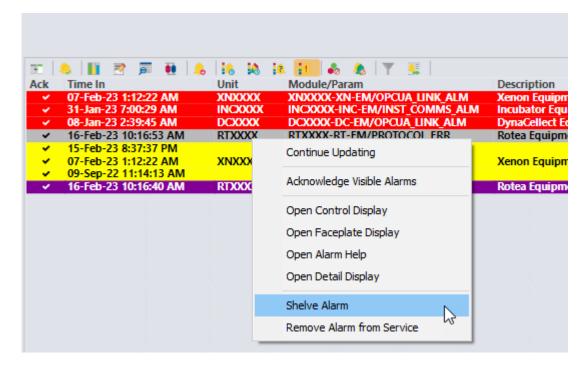
Shelving an alarm typically falls under the control of the operator and is done for the purpose of temporarily suppressing the alarm. When you are ready to respond to the alarm, unshelve the alarm in the Alarm Suppress picture and respond.

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.

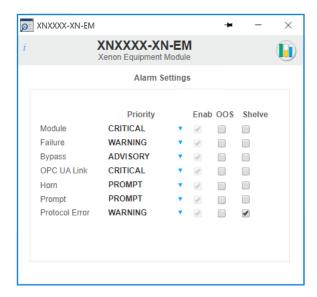
#### Alarm list shelve

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.

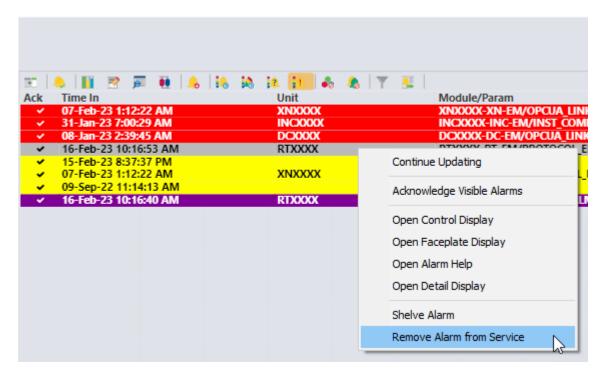
# Out of Service (OOS) alarms

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<sup>™</sup> system configuration, the user must have the Restricted Control key (assigned in the DeltaV<sup>™</sup> 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.

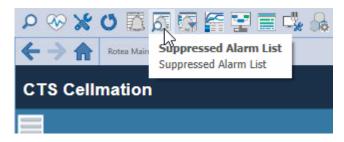


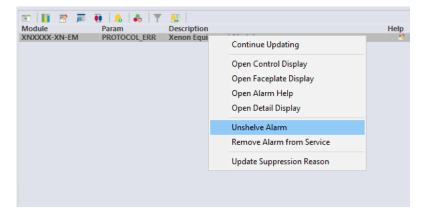
Click on the checkbox of the alarm to remove it from service in the **OOS** column. The alarm can be put back into service by removing the tick in the alarm checkbox.

#### 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.





To unshelve the alarm right mouse click on the alarm and select **Unshelve Alarm**.

# 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<sup>™</sup> system admin database backups
- DeltaV<sup>™</sup> 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<sup>™</sup>
     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.

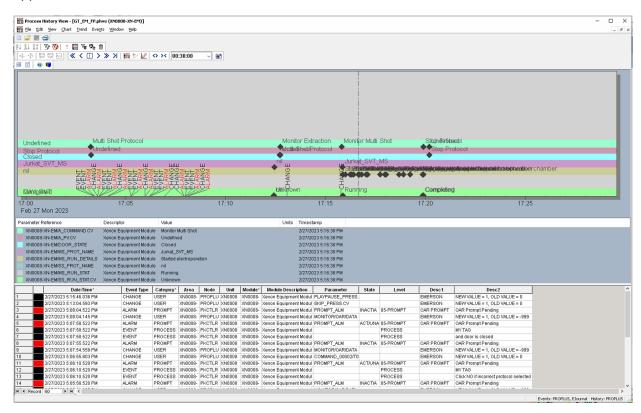


## Data storage

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.



## Chapter 5 Data storage Power outage

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

- Create a single historical database
- Open a large 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

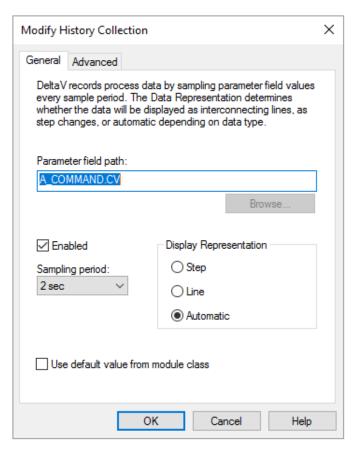


Figure 3 General settings for modifying history collection.

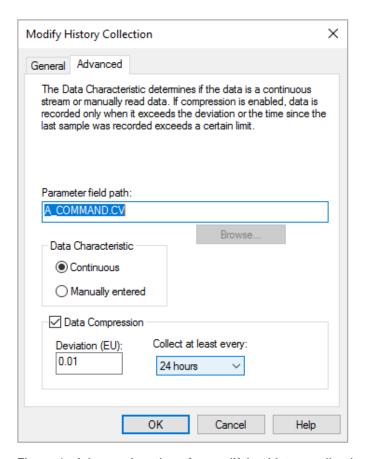


Figure 4 Advanced settings for modifying history collection.

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.	
Advanced settings		
Data characteristic	<ul> <li>Continuous: Continuously collected data, represented with interconnecting lines.</li> <li>Manually entered: Values entered by a user, displayed as markClics on the trend, with no interconnecting lines.</li> </ul>	

## Chapter 5 Data storage Power outage

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

Settings	Description	
Enable (data compression)	Enables data compression.	
Collect at least every (data compression)	Controls the maximum time between stored values, even if values change ver little. Options are 15 minutes, and 1, 4, 8, 24 and 72 hours.	

To exit the historian view, click  $\boldsymbol{X}$  in the upper right corner twice.



# 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	



# Faceplate details

GT_MOD_FP	. 82
GT_EM_FP	84
GT_USM_DT and GT_TimerFB_DT	85
GT FM Alarms DT	87

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

#### **GT\_MOD\_FP**

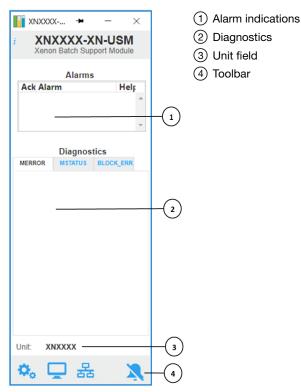


Figure 5 GT\_MOD\_FP

- 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

B

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
- ① Unit field
- 8 Alarm indications
- 9 Toolbar

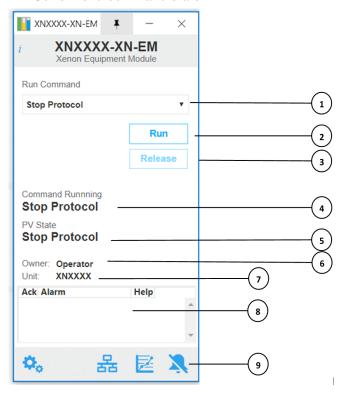


Figure 6 GT\_EM\_FP

- 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

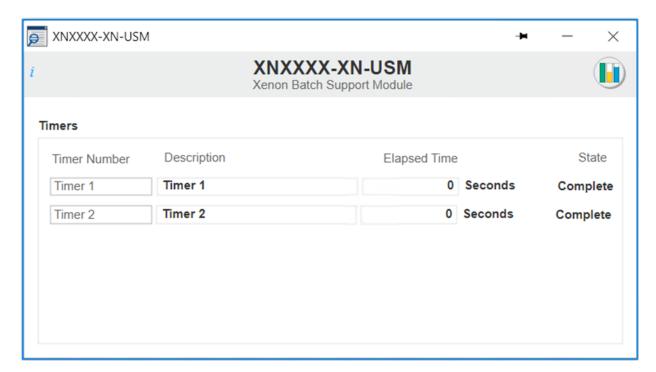


Figure 7 Time overview

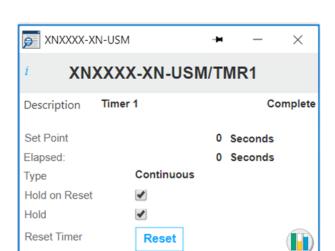


Figure 8 Timer details

- 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.

#### GT\_EM\_Alarms\_DT

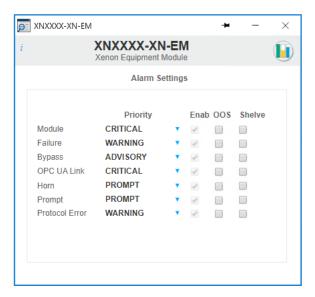


Figure 9 Alarm details

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

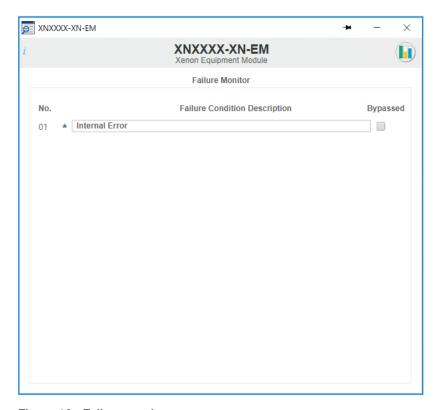


Figure 10 Failure monitor

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

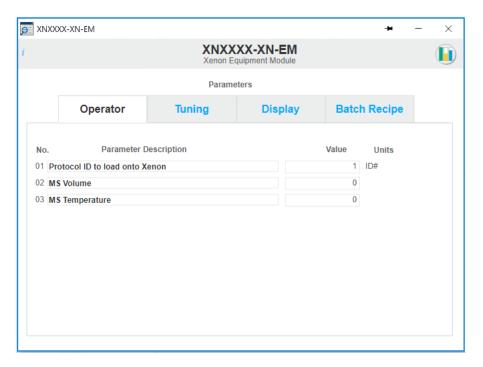


Figure 11 Parameters

- 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

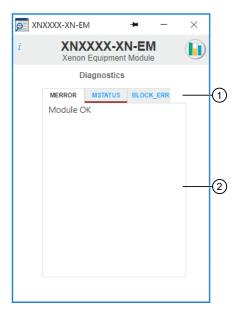


Figure 12 Diagnostics

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



# Compatibility matrix

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

CTS <sup>™</sup> Cellmation <sup>™</sup> software release	DeltaV™ system version	Xenon™ instrument version
Build 2.0.0.xx	DeltaV™ system 14.LTS	Firmware Version
	DeltaV_1431_WS_28_CSS	Main Firmware 1.0.4x:
	DeltaV_1431_EIOC_12_CSS	

# 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.



## 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 <a href="https://www.thermofisher.com/us/en/home/global/terms-and-conditions.html">www.thermofisher.com/us/en/home/global/terms-and-conditions.html</a>. If you have any questions, please contact Life Technologies at <a href="https://www.thermofisher.com/support">www.thermofisher.com/support</a>.

