

CTS™ Compleo™ OPC-UA Connectivity USER GUIDE

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Chapter 1 Product Information

1.1 Introduction

- CTS™ Rotea™ Counterflow Centrifuge System (Rotea™) and CTS™ Compleo™ Formulation, Fill & Finish System (Compleo™), both instruments require user input to operate. The instruments can operate in a stand-alone GUI mode or with a Supervisory Control and Data Acquisition (SCADA) system, which will “supervise” the operation. This supervision will include items like sending protocols to instruments, setting protocol configuration parameters, start and stopping the instrument, and logging instrument status.
- Each instrument includes a dedicated Windows Operating System compatible computer that is required to run instrument control software. The control software features an integrated OPC-UA server, allowing SCADA software to control the instrument. This document outlines the OPC-UA communication interface.
- The instrument control software is required to run the instrument; and the instrument cannot be directly controlled by a SCADA device.
- There are several elements that are common to both Compleo™ and Rotea™. These elements are divided into common sections and instrument-specific sections. One SCADA system is Emerson’s DeltaV System. DeltaV System is technically a Process Control System (PCS), but it incorporates all functionalities of a SCADA system. DeltaV supervisory control is used for clinical and commercial manufacturing, and the OPC-UA interface is designed to operate with the DeltaV System.

1.2 Definitions

SAE User Roles	Role Description
DeltaV	A Process Control System (PCS) made by Emerson
ERP	Enterprise Resource Planning
MES	Manufacturing Execution System
PCS	Process Control System

PLC	Programmable Logic Controller
Protocol	A series of equipment instructions
Rotea	Cell processing instrument made by Scinogy™
Compleo™	Fill & Finish formulation instrument made by Scinogy™
Run	The execution (running) of a protocol, from beginning to end.
SCADA	Supervisory Data Acquisition and Control

1.3 Scope of system

To use the Compleo™ or Rotea™ instruments, the user will require:

- Instrument hardware inventory
- The computer provided to interface with the instrument with Windows OS installed
- Single-use kit with connected tubing and bags and vessels
- Protocol file
- Protocol configuration data

1.4 Instrument hardware configuration

- The instrument features an embedded microcontroller that manages its operation. Each application version will have accompanying firmware versions that will need to be downloaded to the instrument. Failure to use the correct firmware-application compatible versions may result in undefined behavior. General safety features are built into every firmware version and operate independently of the application version.
- The Compleo™ instrument includes an optional mixing device, which continuously stirs the contents of the mixing bag.

1.5 Single-use kit definition

- The single-use kit defines:
 - The fluidic connections between instrument components such as the pump and valves.
 - The size of the pump tubing for each pump
 - Optionally the volume capacity of each attached bag/vessel
 - Optionally the priming volume for each valve line

- Optionally, the required minimum volume for each reagent supply to be attached.
- The single-use kit is identified by a barcode read from a label attached to the kit.
- The kit identification includes a unique number, batch identification number and kit type specifier.
- The “kit type” specifier is utilized to verify the kit type against protocol requirements. The scope of a single use kit may extend beyond the base instrument to include tubing connections to external systems such as bioreactors or electroporation systems that are not managed by the control software.

1.6 Protocol file

- Protocol files are stored and transmitted in JSON format.
- The user is not expected to parse or read the protocol file.
- The instrument supports only one protocol file at a time.

1.7 Rotea™

Rotea™ Protocol files are built with the Rotea™ Protocol Builder tool. Rotea™ protocols are low level and configurable. A protocol file contains:

- Attached bags
- A list of steps. A step is a collection of settings until something happens to trigger a transition to another step.
- Step Triggers: Step triggers tell the instrument what will cause a transition to the next step
- Step Pump Speed
- Step Centrifuge speed and ramp times
- Step Fluid paths
- Step loops
- Buttons enabled during steps
- Meta data used to configure loops and triggers.

1.8 Compleo™

Compleo™ protocol files are built using the Compleo™ Protocol Builder tool. Compleo™ protocols are referred to as Dose Plans, which are high level and define how a set of inputs will be mixed and dispensed into output doses.

A Dose Plan includes the following:

- Number of output doses (could be several types)
- Output dose concentration and tolerances
- Output dose volumes and tolerances
- Output dose active ingredient percentage (such as DMSO)
- Attached medias and active ingredient percentage
- Residual formulation handling
- Mixing parameters
- Formulation sampling configuration

There are two types of Dose Plans:

- **Calculated Dose Plan:** The input cell volume and concentration are provided at runtime, and an internal algorithm calculates the required formulations to optimize dose tolerance parameters.
- **Manual Dose Plan:** The user sets the concentration of the formulation manually, when the protocol is generated.

1.9 The Protocol “MetaData”

There are two types of protocol Dose Plans:

- **Rotea™:**
 - Rotea™ protocol metadata entries allow for the adjustment of fixed, qualified protocols in response to process conditions.
 - Metadata is provided when the protocol is transferred to the instrument, populating the variables needed to complete the protocol definition.
- **Compleo™:**
 - Compleo™ Dose Plan metadata allows for the adjustment of a qualified dose plan configuration based on the input cell volume, concentration, and percentage of active ingredient measured during protocol operation.

Chapter 2 OPC-UA interface to Rotea™

2.1 Purpose

OPC-UA interface enables a "manufacturing execution system" (MES) to connect to an instrument and facilitate processing within a qualified clinical cGMP system.

2.2 Background

Instruments and associated software are not qualified for clinical use.

For a clinical application, the instrument, single use kit and protocol must be qualified and maintained to ensure they are fit for purpose.

Whenever a qualified protocol is executed, a record is required to verify that the process was performed as formally defined. Any variations in process operations must be documented and formally reviewed before the resulting product can be accepted as clinical grade.

The OPC-UA interface for an instrument is a communication system that connects the application software to a formally qualified electronic batch management system and associated data capture and record management functions.

The MES system is responsible for the formal identification of users, their level of training, recording of equipment, consumables and events associated with each processing run.

By design, the instrument software does not support this formal data capture activity. If an automated electronic interface is part of the implementation plan for Rotea™ or Fill & Finish clinical operations, then the MES interface provides that capability.

2.3 Electronic communications

It is assumed that MES applications will be located externally to the computer running the instrument application.

Any communications from an MES system to the instrument will occur through the application residing on the computer connected to the instrument.

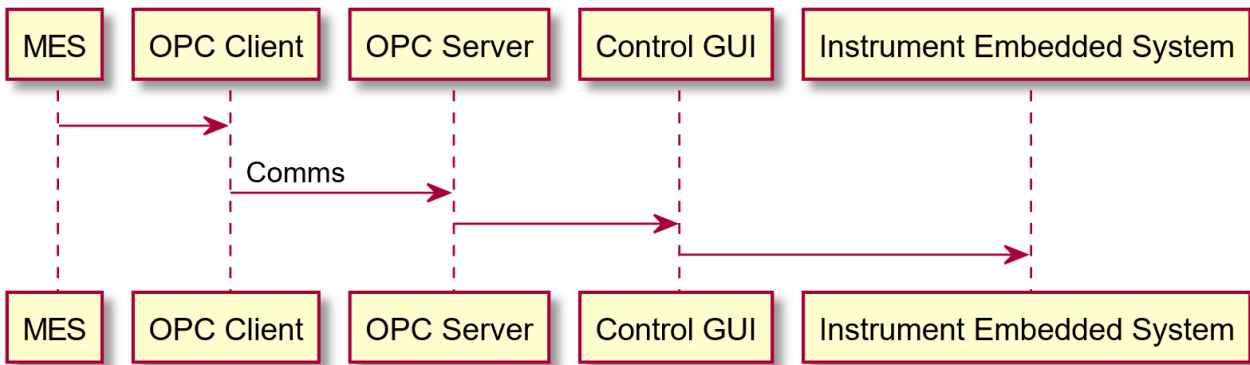


Figure 1. Example Rotea™ System components

Chapter 3 OPC-UA commands and reports overview

3.1 Enabling OPC-UA

- After a successful log-in, the user will land on the main screen known as the Protocol Dashboard (see image below). This screen allows users to browse and select protocols and use the Manual Mixer functionalities. Additionally, it hosts several control options in the header bar. The OPC-UA interface is not enabled by default. The enable button is available to an administrator under the Settings -> OPC-UA Setup tab. The OPC-UA server only supports one OPC-UA client writing to it. Multiple connections can write to the server but the behavior is undefined. The Rotea™ application uses a Unified Automation OPC-UA stack which supports a number of configurable parameters, including encryption level, security level, certificate configuration, valid certificates, end point addresses, server names, server URL, etc. The full list of parameters can be found at the following link.

http://documentation.unifiedautomation.com/uasdkcpp/1.7.0/html/L2ServerSdkServerConfig.html#server_config_xml_file

- The application configuration file is available on the tablet under:

Application	Configuration file location
Rotea™	C:\Program Files (x86)\Rotea\opcua\opcua_server_config.xml
Compleo™	C:\Program Files (x86)\Compleo\opcua\opcua_server_config.xml

- The user can modify the configuration file to suit their needs. The configuration file is loaded either when the computer is started with the

OPC-UA server enabled or when the OPC-UA server is enabled under the OPC-UA Setup tab.

- There is an “Ignore duplicate command timeout” setting available in the Settings -> OPC-UA Setup tab. This setting can only be configured, when the OPC-UA server is disabled and will cause the server to ignore any duplicate commands sent during the timeout period. If the admin is using this timeout, ensure the user is aware that any duplicate commands sent within the timeout period will be ignored.

3.2 Connecting Client to OPC-UA Server

We recommend starting with the OPC-UA server security disabled. Once the interface has been tested, disable the “no security” option. The `opcua_server_config.xml` file has the “no security” option disabled by default; to enable it, uncomment the relevant lines in the XML file.

Use the OPC-UA client to browse for the server. The default OPC-UA server addresses are:

- `opc.tcp://localhost:48010` on the local host
- `opc.tcp://<tablet-ip-address>:48010` from an external computer

3.3 Log in to the instrument

The MES can login to the GUI at any time, by modifying **theSetGuiUserLevel** node. Full details of the **SetGuiUserLevel** values are provided in Section 6.

3.4 Instrument information

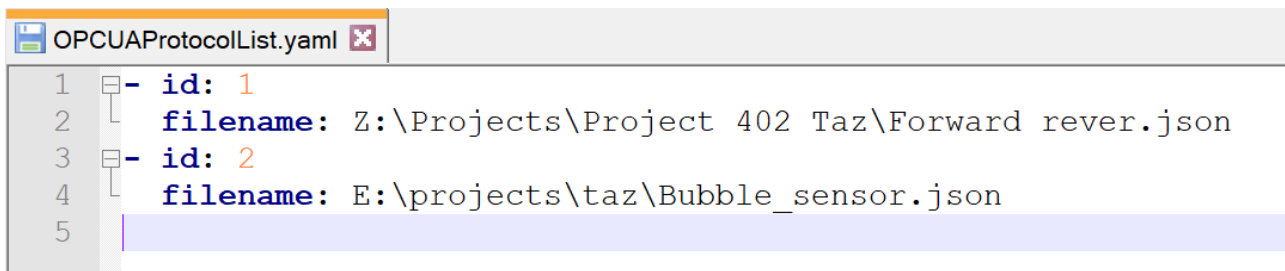
When the OPC-UA connection is established, the instrument information should be available, such as `AppVersion`, `LinkUp`, `ErrorRaised`, `MainFirmwareVersion`, etc.

The OPC-UA client should continuously monitor the **LinkUp** state, as commands will fail when **LinkUp** is false. The Error Raised field will indicate if and why a command failed after it was sent.

3.5 Load protocol

A Protocol can be loaded by 3 different methods:

1. **SetLocalProtocolFilePath** – Specifies the file path on the tablet where the protocol file is located.
2. **SetProtocolFileContents** – Provides the protocol file contents to transfer to the Rotea™ GUI and the instrument.
3. **SetProtocolFileByLookupTableId** – Selects a protocol based on the ID in a lookup table. The user must generate a YAML file called OPCUAProtocolList.yaml with the IDs and filenames. This is an example OPCUAProtocolList.yaml file with two entries:



```
OPCUAProtocolList.yaml
1  - id: 1
2    filename: Z:\Projects\Project 402 Taz\Forward rever.json
3  - id: 2
4    filename: E:\projects\taz\Bubble_sensor.json
5
```

The user must specify the directory where the OPCUAProtocolList.yaml file is located. This is done on the OPC-UA settings page.

Note: The YAML file can be modified in any text editor. The freeware program NotePad++ is used in the illustration above.

Confirmation of protocol loading can be obtained from the **ProtocolName** and **ProtocolChecksum** reports.

ProtocolChecksum can be used to verify integrity of protocol file transfer from uncontrolled repositories.

The protocol checksum is a hexadecimal number with 32 characters.

Example: **e152abb59e4949980731c5bbf7194ffb**

It can be saved and compared as a string.

After a protocol is loaded, the **ProtocolState** report should indicate **ProtocolSelected**.

3.6 Kit Loading

The instrument verification process requires the instrument door to be closed and a valid kit to be detected. The kit ID is read by the instrument when the door is closed.

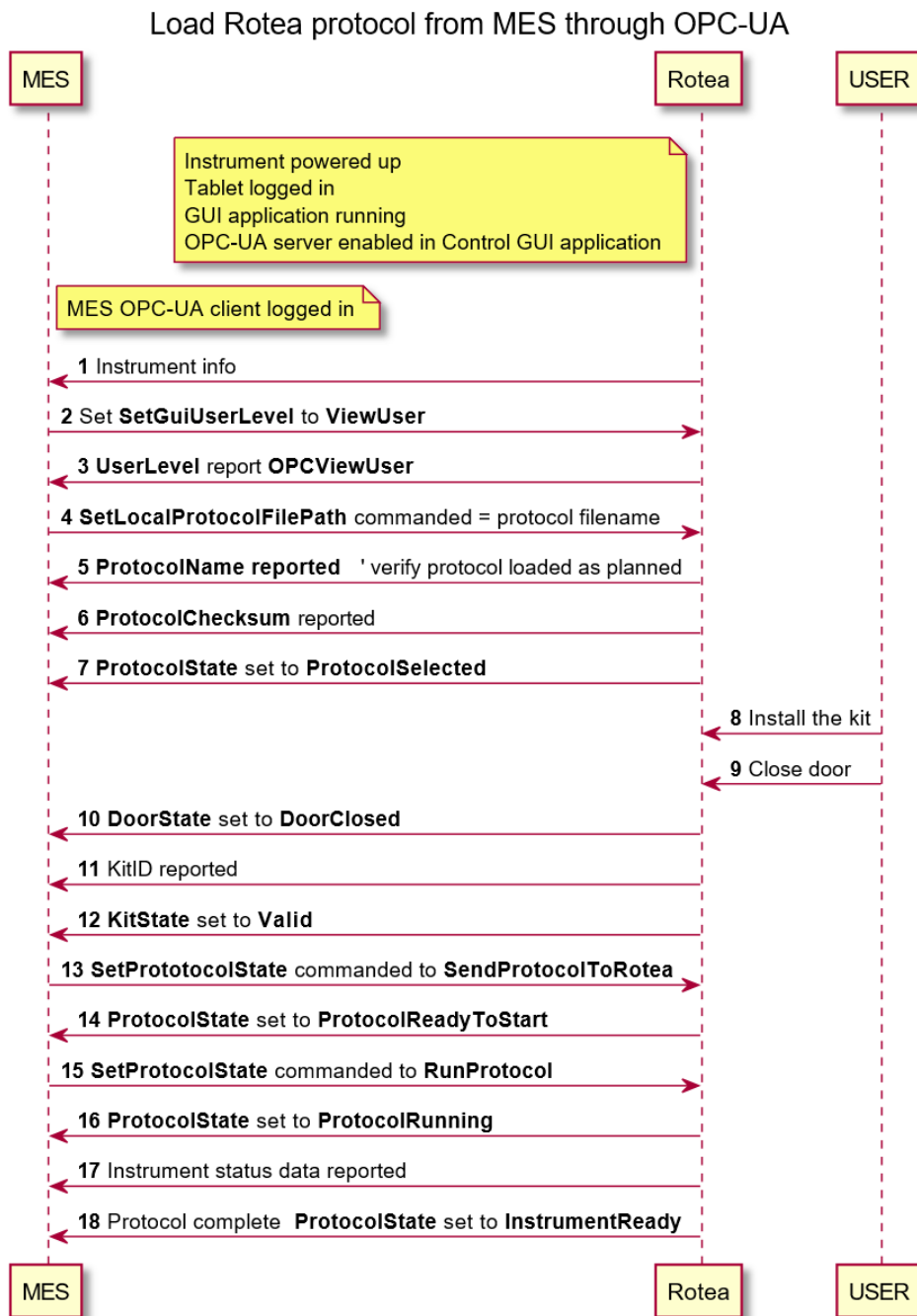
The DoorState is reported Closed, and the KitID string is validated by the KitState report which checks the kit type against that required for the protocol. If the kit ID is valid and aligned to the protocol then the KitState is reported as valid.

3.7 Batch Record/Run Log

- The Control Application captures the run history data into a unique file for each kit used.
- Run history contains details of the process conditions throughout the run.

3.8 Rotea™ operation

Executing a protocol is expected to follow this workflow:



3.9 Transfer metadata

Protocols can be defined with metadata or parameters that allow a qualified recipe to respond to changing input materials and output targets. Refer to the sequence diagram in section 7.3. After the protocol Information is loaded, Rotea™ will set **ParameterNameN** to the names of the variables, **ParameterMinN** to the minimum allowed value, and **ParameterMaxN** to the maximum allowed value needed to be set in the protocol metadata where $N \in \{1, \dots, 20\}$ (for example, **ParameterName1**).

The MES can check **ParameterValidN** to determine the status of metadata definition for the protocol. indicating if the parameter is in use, has been set, and if the setting is valid. To set the value, use **SetParameter1** through **SetParameter20** and supply an **Int32** value.

3.10 Initializing protocol onto the instrument

Once the protocol has been specified, the kit loaded, and any metadata defined within acceptable ranges, set **SetProtocolState** to **SendProtocolToRotea**.

The protocol definition is then sent to the instrument and **ProtocolState** will report **ProtocolReadyToStart**.

3.11 Start/Stop/Pause/Resume protocol

- The MES can START, STOP and PAUSE/RESUME the instrument with SetProtocolState variable.
- The ProtocolState will report ProtocolRunning.
- These actions are available through the buttons on the instrument when enabled.
- The MES can disable Start, Pause and Advance functions with the **SetSkipButtonEnable** and **SetPlayPauseButtonEnable**. When the buttons are enabled, they will follow the configuration in the protocol file, if they are disabled then the buttons on the instrument are disabled.
- When the instrument completes the protocol or is stopped for any other reason, the instrument state will be reported as InstrumentReady. This provides the option for the protocol to be re-started using StartatStep or other administrator actions from the InstrumentReady state.
- When a user with administrator authority is logged in via the MES or without MES supervision, the Pause and Advance instrument buttons become active, independent of protocol settings.

3.12 Instrument run status

The instrument status can be monitored on the GUI or via the exposed OPC-UA variables.

- The **ProtocolState** will report **ProtocolRunning** or **ProtocolPaused**.
- The **ProtocolStepNumber** reports the current step.
- **WaitingUserAck** indicates if the instrument is waiting for verification to proceed to the next step or repeat the current step. The MES uses **SetProtocolState** to **RunProtocol** to repeat the same step, or **SkipToNextStep** in response to this state.

3.13 Adjustment step speeds

To adjust the current protocol speed:

- Set the type of adjustment to **SetProtocolAdjustType**
- Set the current step number to **SetProtocolAdjustStepNumber**
- Set the speed at either **SetProtocolAdjustPumpSpeed** or **SetProtocolAdjustCentrifugeSpeed**

3.14 Resetting step triggers

To reset the step triggers and extend the current step:

- Set the current step number **SetProtocolAdjustStepNumber**
- Set the **SetProtocolRestartStep**

3.15 Alarm recovery tools

Errors/Alarms can occur during a run. The MES can recover and intervene to resolve these situations. Some recovery options include:

- **Alarm reset commands:** Setting the SetProtocolState to StopProtocol will clear errors raised on the instrument.
- **Continue running options:**
 - Restart the protocol at a specified step. The protocol can contain dedicated blocks of code independent of the main process.
 - Download a new protocol and start it at a specified step
 - Execute the settings of a single step in the existing protocol.
- The MES can also log in a qualified user with “administrative privileges” to manually operate the instrument from the GUI.
 - All actions are recorded in the history files and instrument status is reported to the MES.
 - To return to MES managed operations, the administrator logs out of the MES. The MES then logs in as ViewUser again. (The instrument can continue running the protocol while users/MES log in and out)

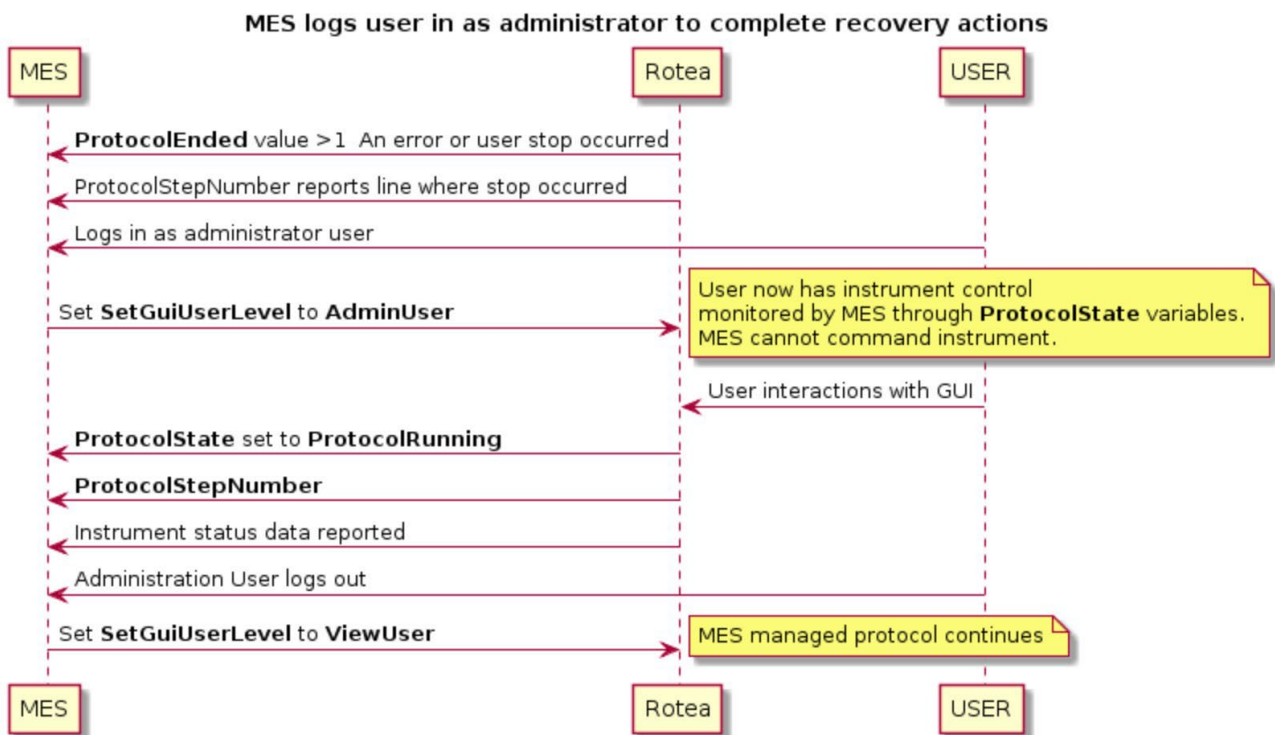


Figure 2. OPC-UA enabled Admin to perform recovery

3.16 Compleo™ Operation

Compleo™ protocols have different workflows enabled or disabled based on protocol configurations.

All user interaction steps (boxes with parallel lines at the edge) will need to be performed by the OPC-UA client when it is in control of the system. Running a protocol is expected to follow the following workflow:



3.17 Dose Plan Submission Initial

Before a protocol can be started the user must enter a valid dose plan and provide information about the cells and/or attached media. This is used to determine if valid formulations can be made, and if the bag volumes and capacity are enough to execute the protocol. The required information varies depending on whether the protocol is a manual or calculated dose plan.

All "Set" input nodes have an associated "Validity" node to determine the state of the "set" node.

The "Set" nodes can have any of the following values:

- **NotInUse**
- **NotSet**
- **OutOfBounds**
- **Valid**

The user should make sure that each node is in the "NotInUse" or "Valid" state before submitting a dose plan.

Once the dose plan has been submitted the valid fields will be set:

1. **DosePlanCalculationsValid** - Indicates if the input values can produce a valid dose plan
2. **DosePlanCalculationsInRange** - Indicates if enough media volume and the bag sizes provided are large enough to meet the requirements of the dose plan.
3. **DosePlanCalculationErrors** - Tells the user where the calculations are invalid if it's possible to determine.
4. **EstimatedMediaVolumeUsedmLN** - Tell the user the estimates volume of media required for the dose plan.

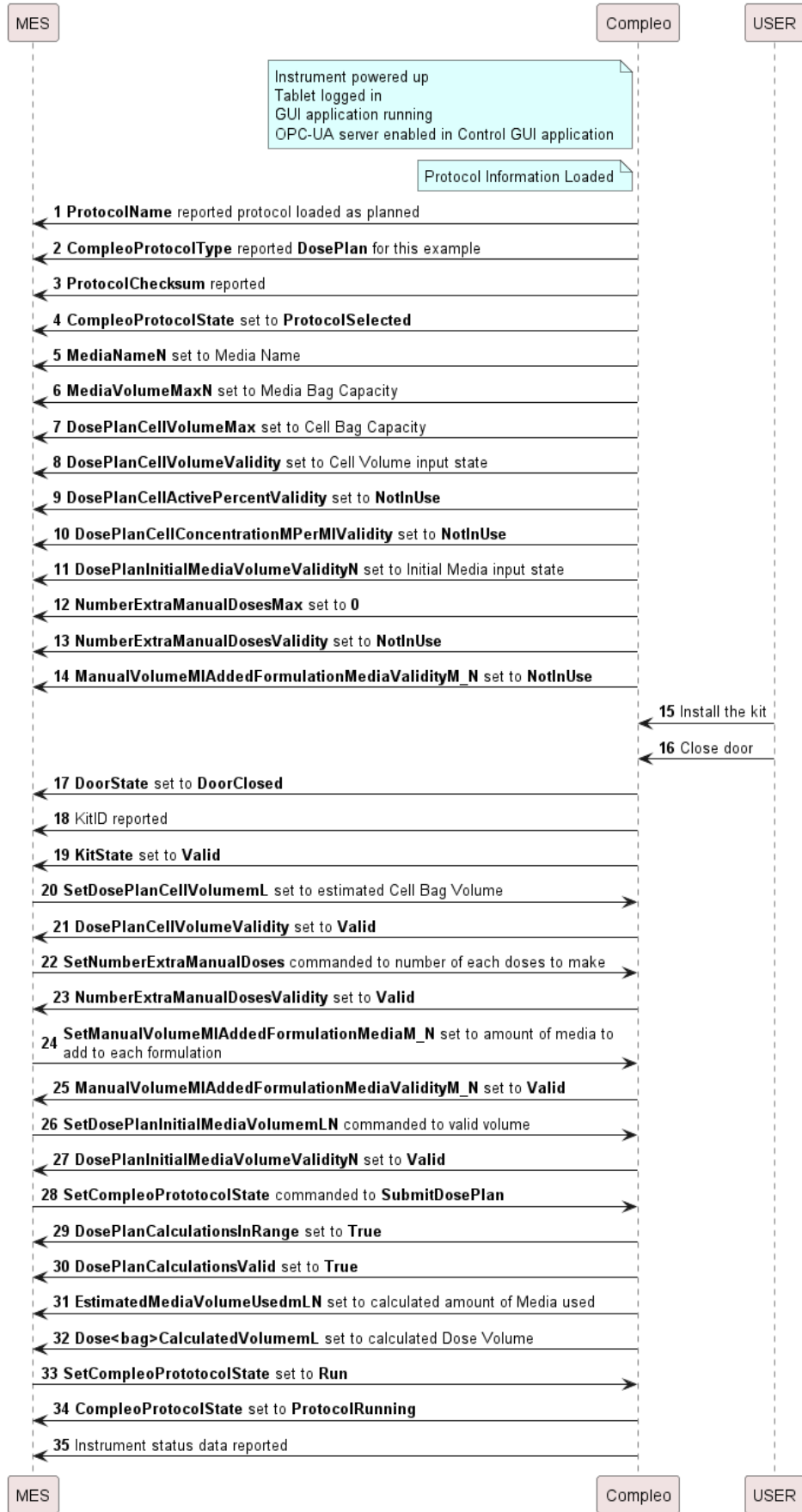
Calculated Dose Plans require the user to set the following nodes:

1. **SetDosePlanCellVolumemL**
2. **SetDosePlanCellConcentrationMPerMl**
3. **SetDosePlanCellActivePercent**
4. **SetDosePlanInitialMediaVolumemLN**

Manual Dose Plans require the user to set the following nodes:

1. **SetDosePlanCellVolumemL**
2. **SetManualVolumeMlAddedFormulationMediaM_N**
3. **SetDosePlanInitialMediaVolumemLN**
4. **SetNumberExtraManualDoses**

Submit Manual Dose Plan



3.18 Dose Plan Submission While Running

There are several times where the user may be required to re-submit the dose plan inputs during the protocol run. This is because the cell bag volume may have changed, or an accurate cell count has been determined from a sample. When the dose plan is submitted while the protocol is running, only certain dose plan fields can be edited.

While running the following Calculated Dose Plans nodes can be updated:

1. **SetDosePlanCellConcentrationMPerMl**
2. **SetDosePlanCellActivePercent**

While running the following Manual Dose Plans nodes can be updated:

1. **SetManualVolumeMlAddedFormulationMediaM_N**
2. **SetNumberExtraManualDoses**

Initial Media Volumes and Cell Bag volumes cannot be changed.

3.19 General

The user is not allowed to set all SetCompleoProtocolState values in every instrument state. There are some states where specific values can be used and others where they cannot. If the command is used when it is not allowed to, an InstrumentNotReady error is raised.

The following are descriptions of when commands can be used:

SetCompleoProtocolState Value	CompleoProtocolState & CompleoWaitingUserAck State
Abort	ReadyToStart, ProtocolRunning, ProtocolPaused, WaitingDosePlanConfirmation, SequenceComplete, ManualBurping, InstrumentError, ProtocolRecoveryError
Run	ReadyToStart or ProtocolPaused and ConfirmMixerMissing, ConfirmKitReuse, NotWaiting
Pause	ProtocolRunning
SubmitDosePlan	ProtocolSelected, WaitingDosePlanConfirmation
Initiate	ProtocolSelected, ReadyToStart
End	SequenceComplete

Continue	WaitingDosePlanConfirmation, ConfirmCellBagEmpty, OpenSampleLine, MixerFailedUserMoveToNextStep, PrepBurpBags, CheckCalibrationValid, KitAdjustValid
Retry	BlockageDetected, EmptyBagDetected, MixerBagEmptyDetected, InstrumentFailure, ConfirmCellBagEmpty, AirVentBubbleSensor, DryPrimeOptionalBlockage, BurpBagBlockage, CheckCalibrationMissedBubbleSensor, BurpMissedBubbleSensor
Skip	DryPrimeOptionalBlockage, BurpBagBlockage
SkipRest	DryPrimeOptionalBlockage
Resample	WaitingDosePlanConfirmation
EnableManualBurp	SequenceComplete
DisableManualBurp	ManualBurping
MixerBagEmpty	MixerBagEmptyDetected
RetryCellTransfer	MeasureVolumeAnalysis, TransferVolumeAnalysis
UnlockDoor	ReadyToStart
EnableManualPurge	ReadyToStart
PurgeLine	ReadyToStart
DisableManualPurge	ManualPurging

3.20 Administrator Level Access

It is recommended that the OPC-UA client limit the following commands to administrator level users, they may be necessary to address issues that arise during the process:

Protocol step name	CompleoWaitingUserAck	Other node values	Admin level command
Confirm Transferred Volume	TransferVolumeAnalysis	CellTransferValveVolumesErrorWithinTolerance == False CellTransferPumpedVolumeErrorWithinTolerance == False	SetCellVolumeSelection - UserDefinedVolume - AvMeasuredVolume - MixerBagValveMeasuredVolume - CellBagValveMeasuredVolume
Confirm Transferred Volume	TransferVolumeAnalysis	CellTransferValveVolumesErrorWithinTolerance == True CellTransferPumpedVolumeErrorWithinTolerance == False	SetCellVolumeSelection - UserDefinedVolume - AvMeasuredVolume - MixerBagValveMeasuredVolume - CellBagValveMeasuredVolume
Confirm Transferred Volume	TransferVolumeAnalysis	CellTransferValveVolumesErrorWithinTolerance == True CellTransferPumpedVolumeErrorWithinTolerance == False	SetCellVolumeSelection - UserDefinedVolume - AvMeasuredVolume - MixerBagValveMeasuredVolume - CellBagValveMeasuredVolume
Confirm Measured Volume	MeasureVolumeAnalysis	CellTransferValveVolumesErrorWithinTolerance == False CellTransferValveVolumesErrorWithinTolerance == True CellTransferPumpedVolumeErrorWithinTolerance == False	SetCellVolumeSelection - UserDefinedVolume - AvMeasuredVolume - MixerBagValveMeasuredVolume - CellBagValveMeasuredVolume

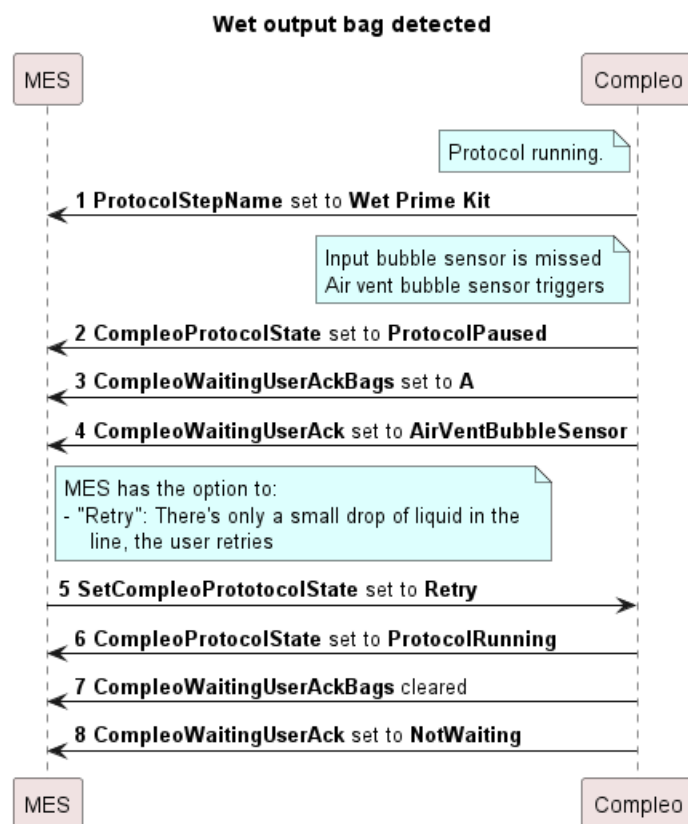
<p>Confirm Measured Volume</p>	<p>MeasureVolumeAnalysis</p>	<p>CellTransferValveVolumesErrorWithinTolerance == False CellTransferPumpedVolumeErrorWithinTolerance == False</p>	<p>SetCellVolumeSelection - UserDefinedVolume - AvMeasuredVolume - MixerBagValveMeasuredVolume - CellBagValveMeasuredVolume</p>
<p>Confirm Measured Volume</p>	<p>MeasureVolumeAnalysis</p>	<p>CellTransferValveVolumesErrorWithinTolerance == False CellTransferPumpedVolumeErrorWithinTolerance == False</p>	<p>SetCellVolumeSelection - UserDefinedVolume - AvMeasuredVolume - MixerBagValveMeasuredVolume - CellBagValveMeasuredVolume</p>

To provide more context around the **TransferVolumeAnalysis** and **MeasureVolumeAnalysis** steps:

- A basic user should not be able to select the **AvMeasuredVolume** if the **CellTransferValveVolumesErrorWithinTolerance** is False.
- A basic user should not be able to select **UserDefinedVolume** if the **CellTransferPumpedVolumeErrorWithinTolerance** is False.
- A basic user should not be able to select **UserDefinedVolume** during **MeasureVolumeAnalysis**.
- **CellTransferPumpedVolumeErrorWithinTolerance** will be False if **CellTransferValveVolumesErrorWithinTolerance** is False.
- A basic user should not be able to select **MixerBagValveMeasuredVolume** or **CellBagValveMeasuredVolume**.

3.21 Wet Output Bag Detected

If a bubble sensor is missing on the input line and liquid is pumped through the kit to the output bubble sensor, then an error is raised. The user can choose to ignore it or abort the protocol. This can happen at several points throughout the protocol and can be handled at any time.



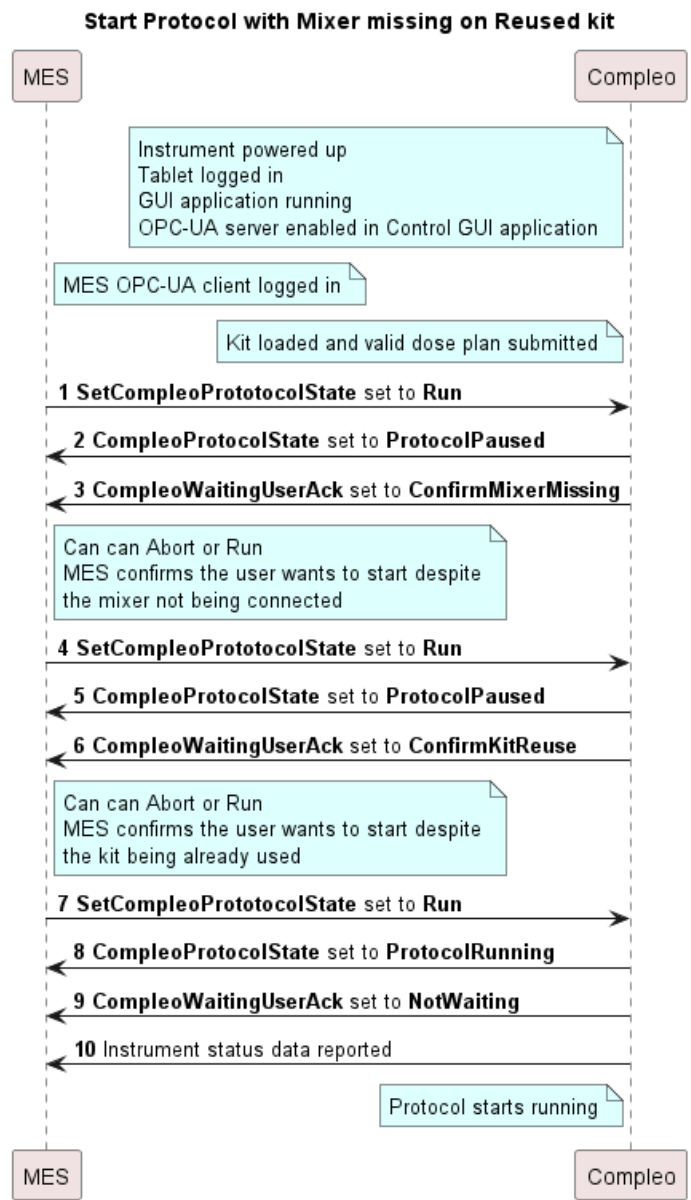
3.22 Starting Protocol

There are two checks performed when the user attempts to start a protocol.

1. If a mixer is configured and not communicating
2. If the kit has already been used for a protocol run

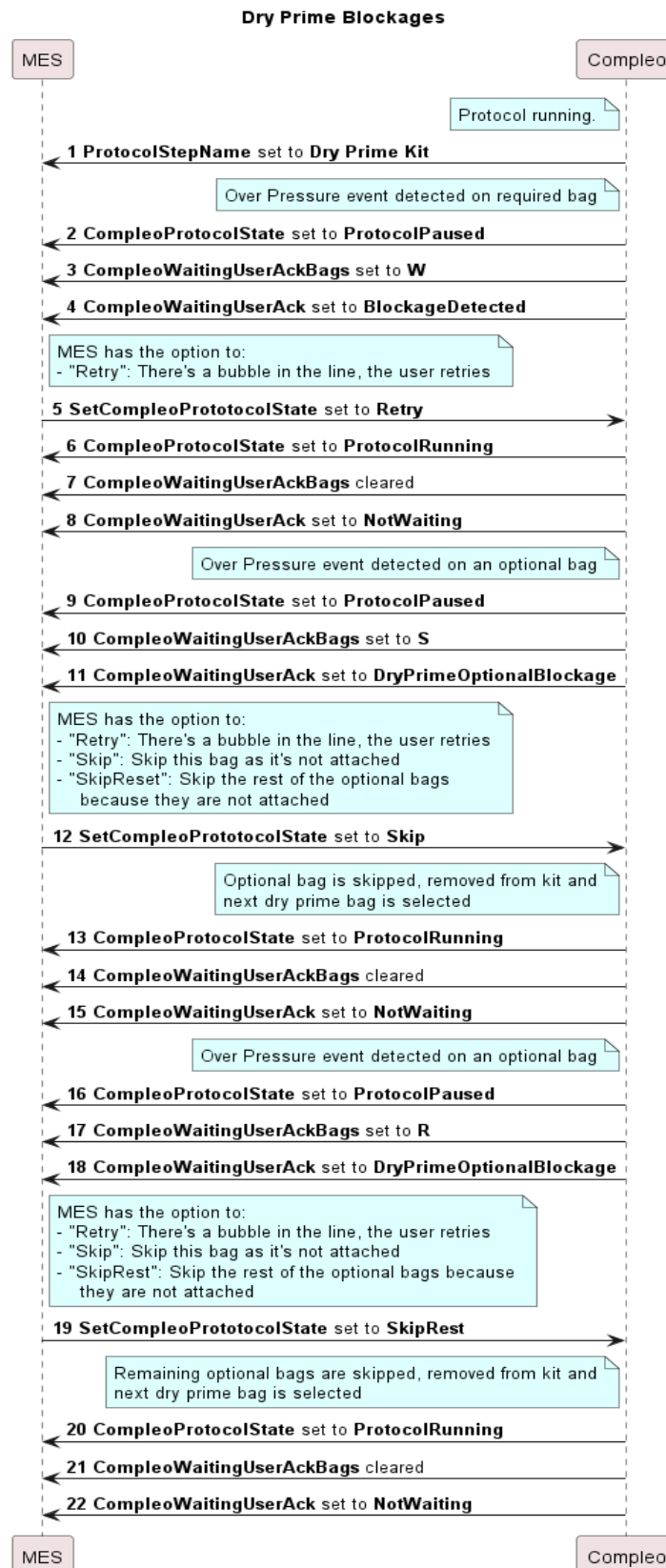
If the mixer is configured and not communicating, the user is required to confirm that they want to start the protocol with a mixer fault.

If the kit is being reused, the user is required to confirm that they have purged the kit before starting.



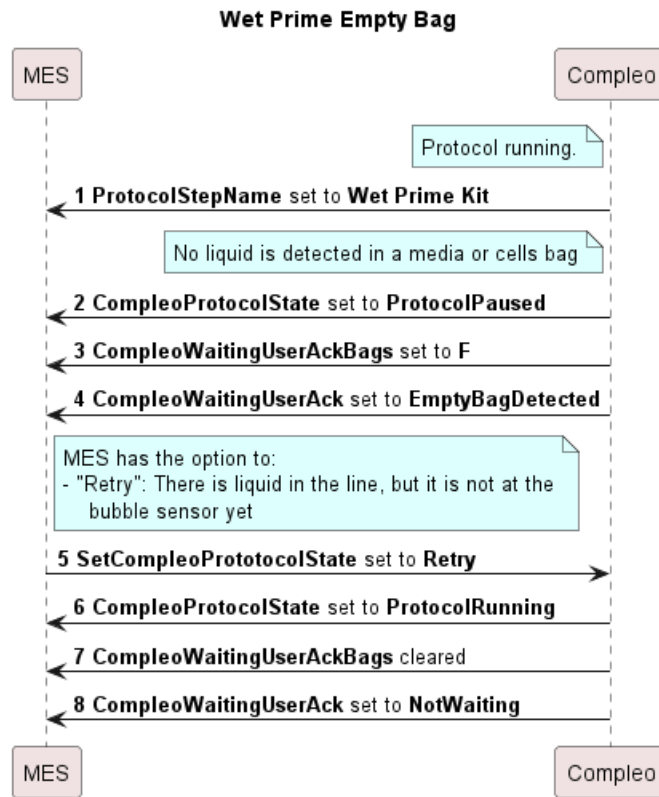
3.23 Dry Priming

Dry priming detects which bags are attached to the kit. Optional bags do not need to be attached to the kit; missing bags will be detected during dry priming and the user will need to skip them.



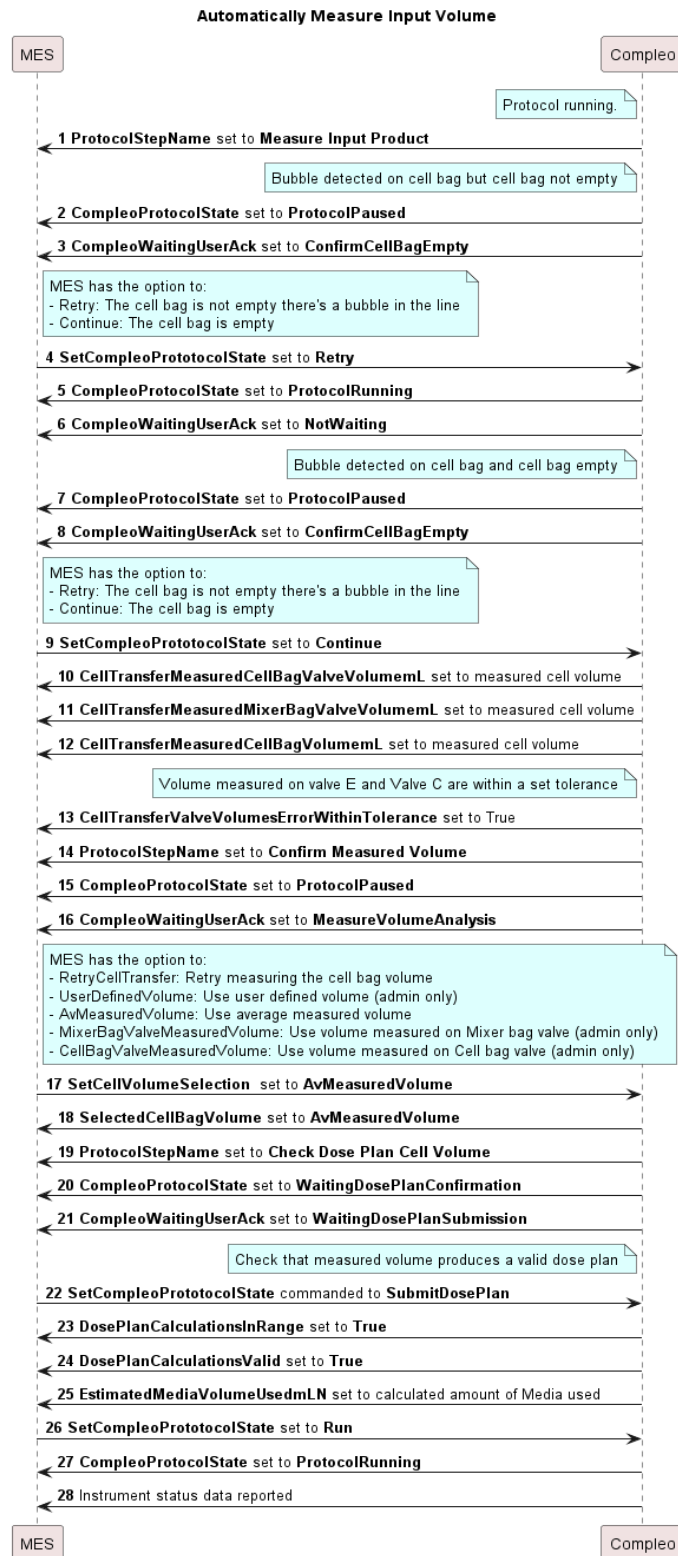
3.24 Wet Priming

Wet priming detects if the media and cell bags contain fluid. If a 'wet' bag is not detected in time, then the user is prompted with an option to retry.



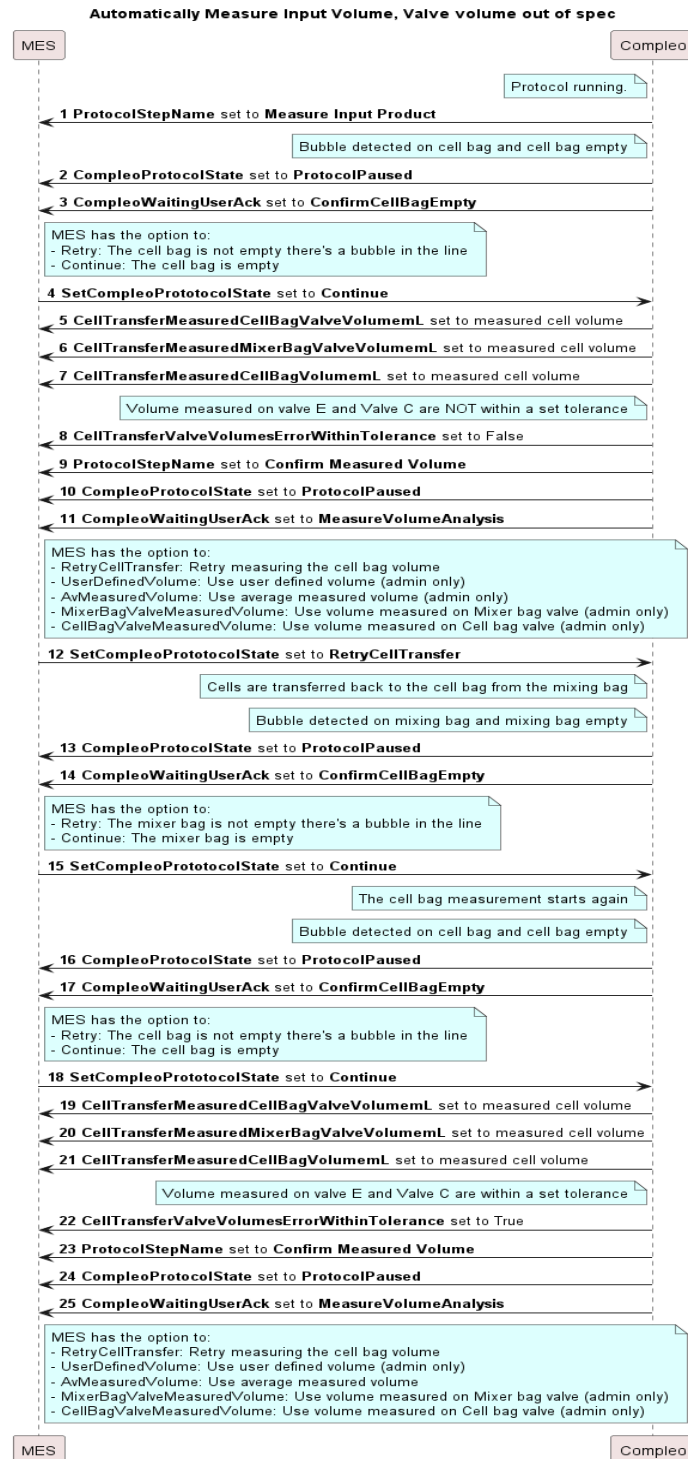
3.25 Auto Measure Cell Volume

The cell bag volume can be automatically measured or manually defined; the sequence below shows how to complete the auto measurement sequence.



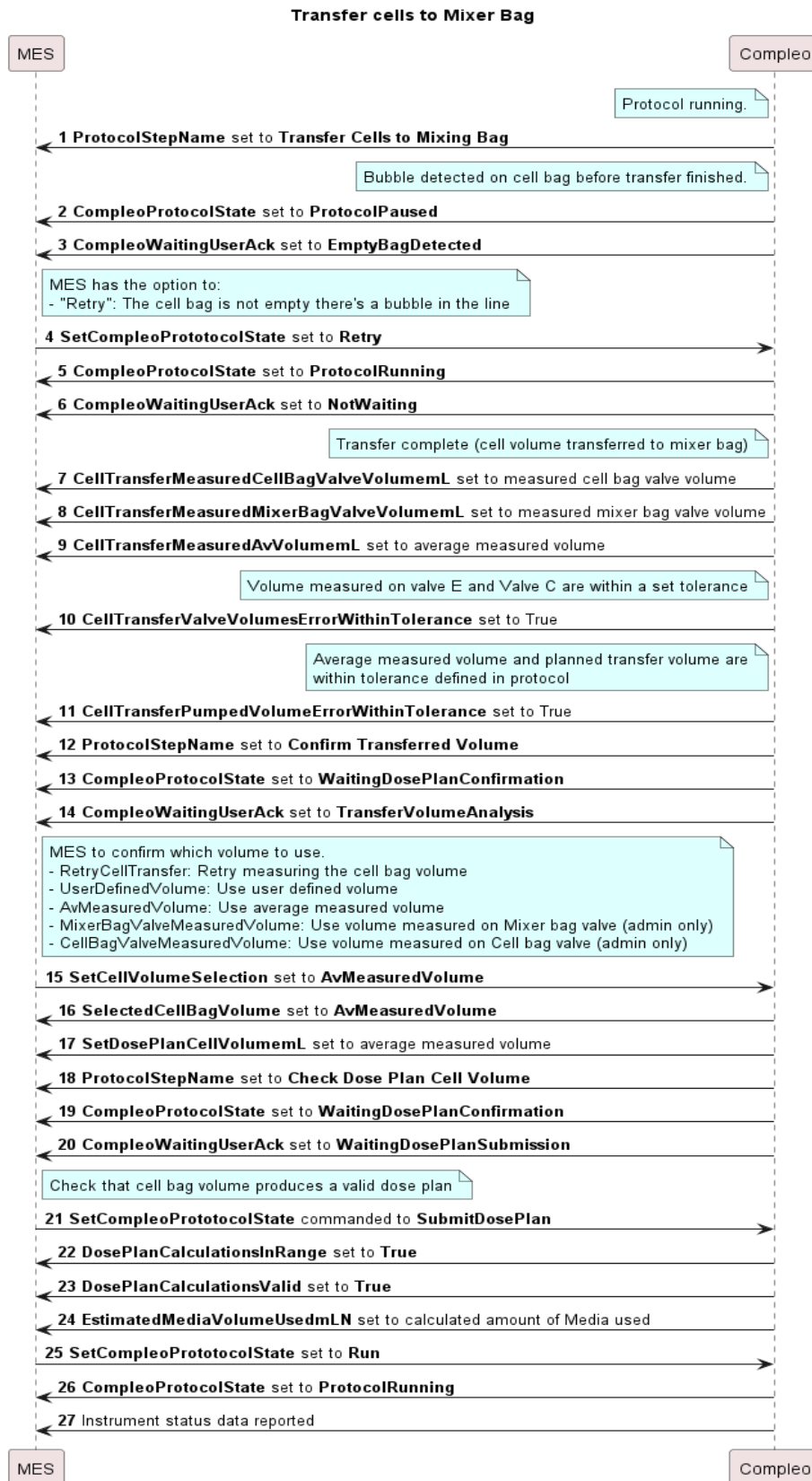
During the cell bag volume measurement step, the valve volumes at B and E are measured and compared with each other. If the valve volumes are not within a set Tolerance, the measured volume is not reliable, and the instrument cannot determine an accurate cell bag volume.

The user must retry the measurement to get a more accurate measurement before continuing.

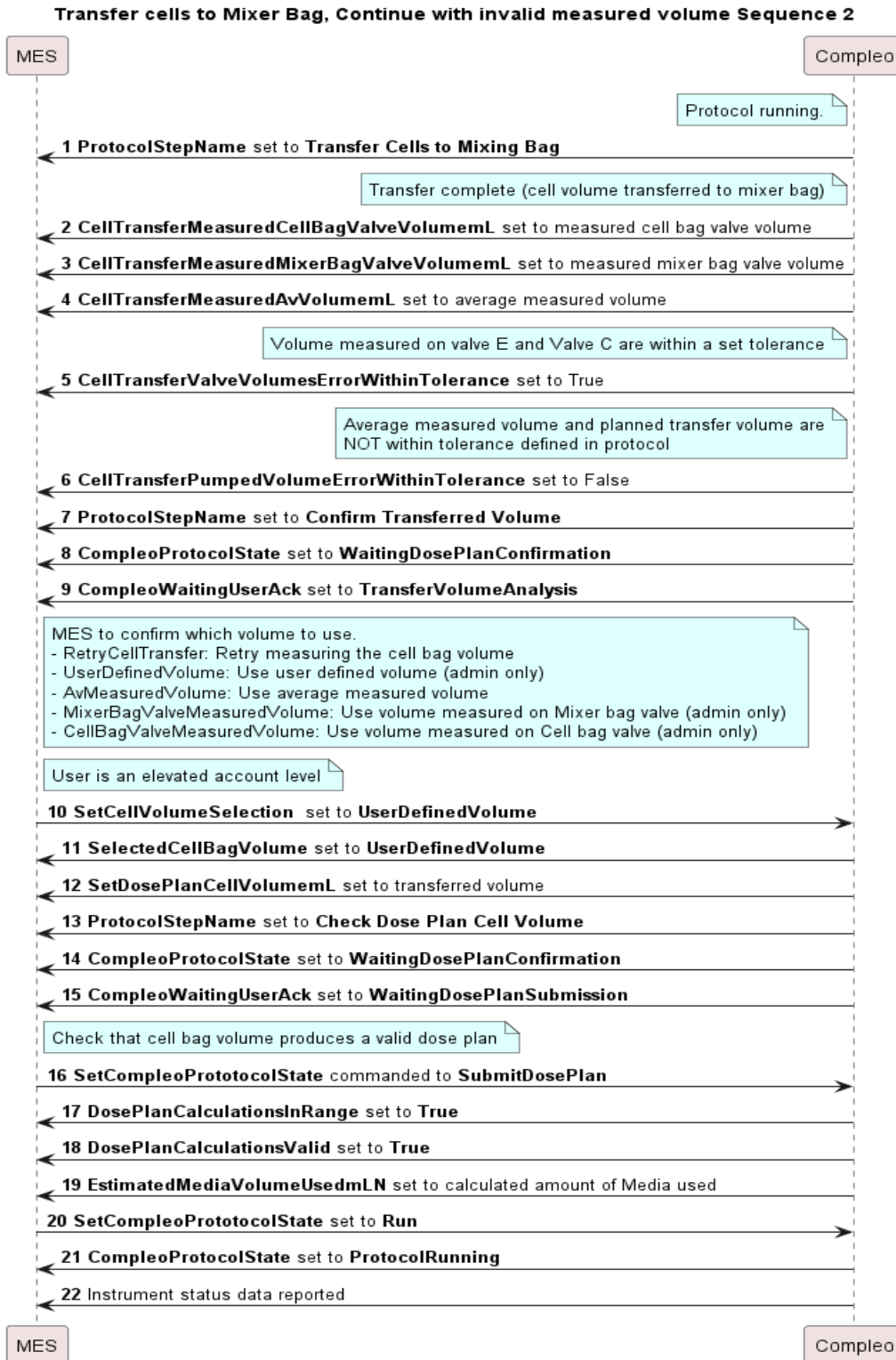


3.26 Transfer Cell Volume

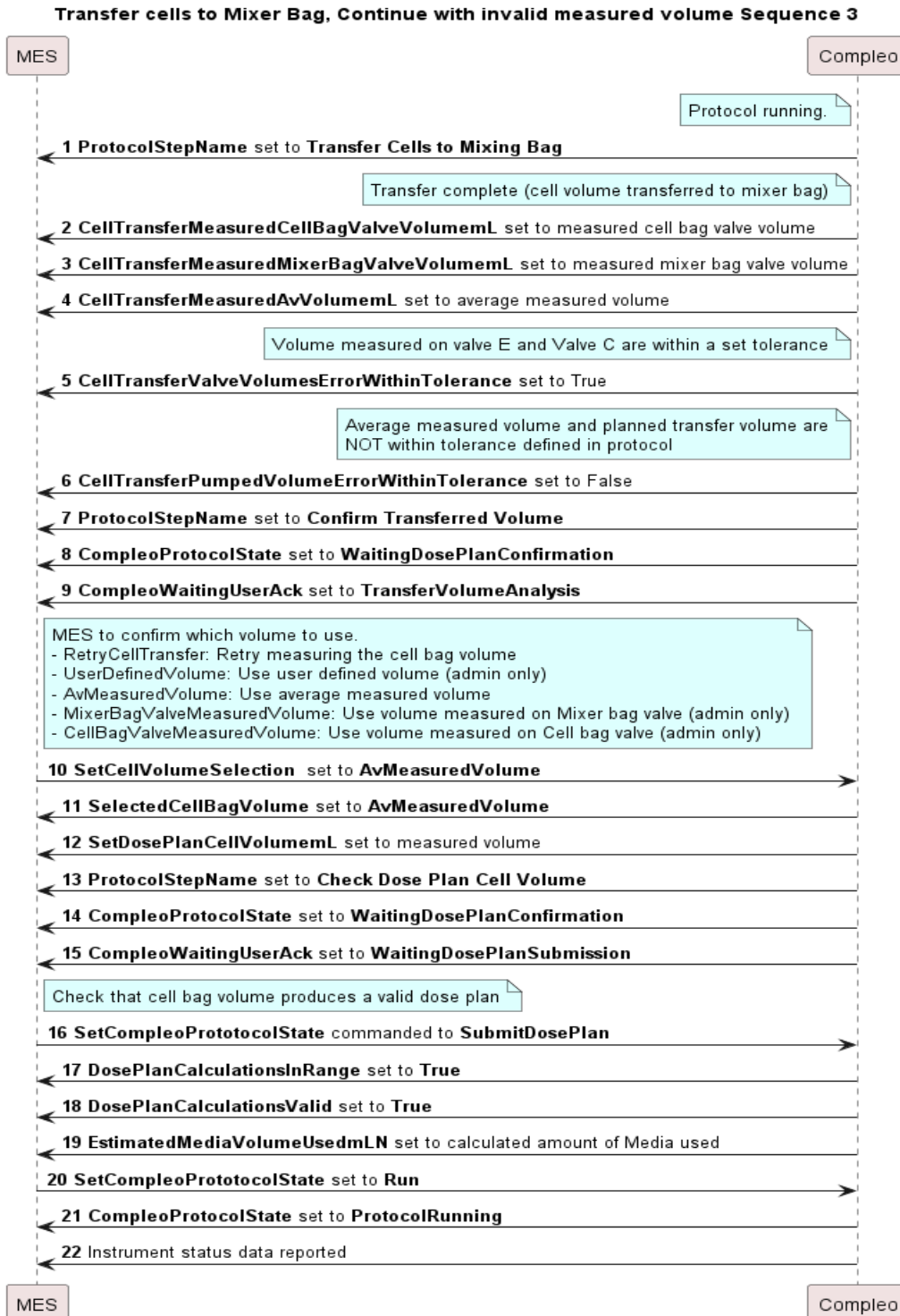
If the cell bag volume is transferred, then the sequence below is followed:



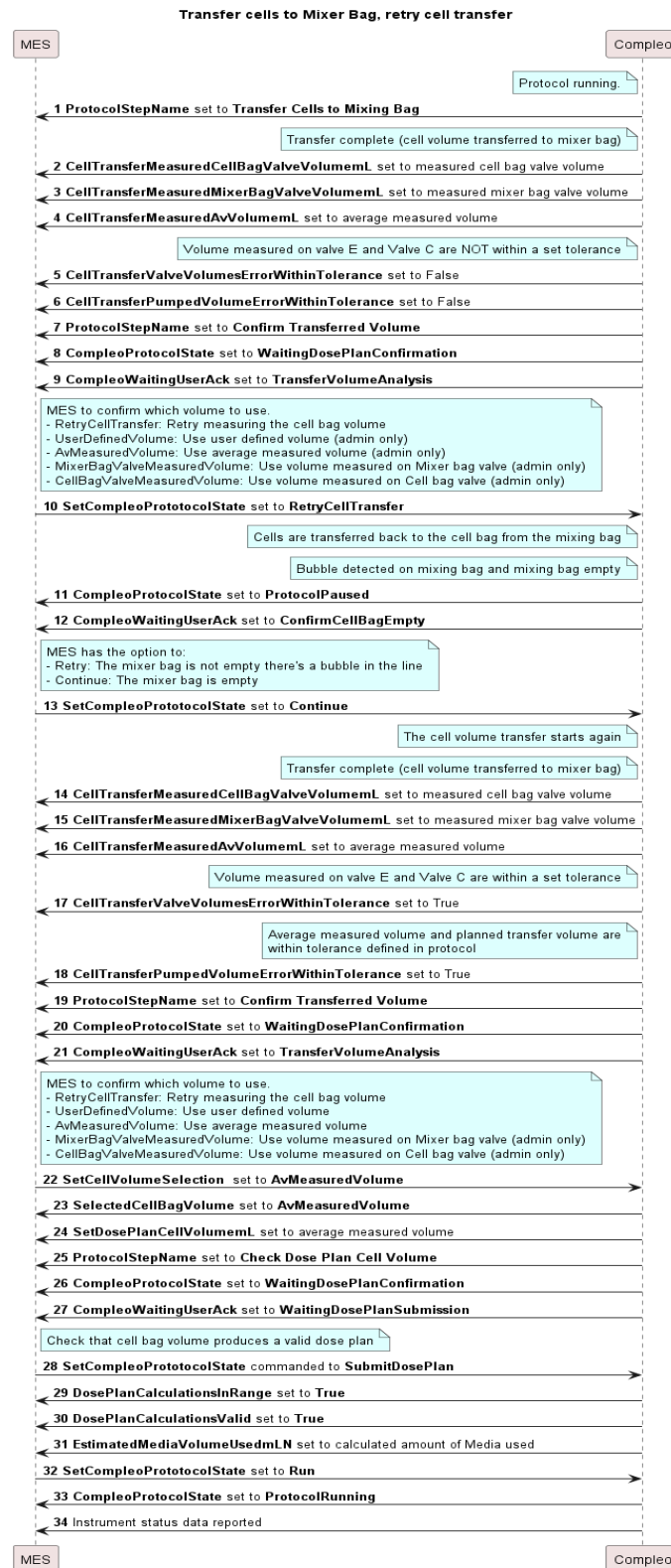
During the cell bag volume transfer step, the valve volumes at E and C are measured and compared with each other. If the valve volumes are not within a set tolerance the measured volume is not reliable, and the instrument cannot determine an accurate cell bag volume. The **Continue** command is only available to an administrator on the GUI, the OPC-UA client should only allow elevated users to issue the **Continue** command.



During the cell bag volume transfer step, the valve volumes at E and C are measured and compared with each other. If the valve volumes are within a set tolerance the measured volume is reliable. The pumped volume and the measured volume must be within the tolerance defined in the protocol to continue using the pumped volume. If the measured volume is accurate, then the user can **AcceptMeasuredVolume** to use the measured volume.

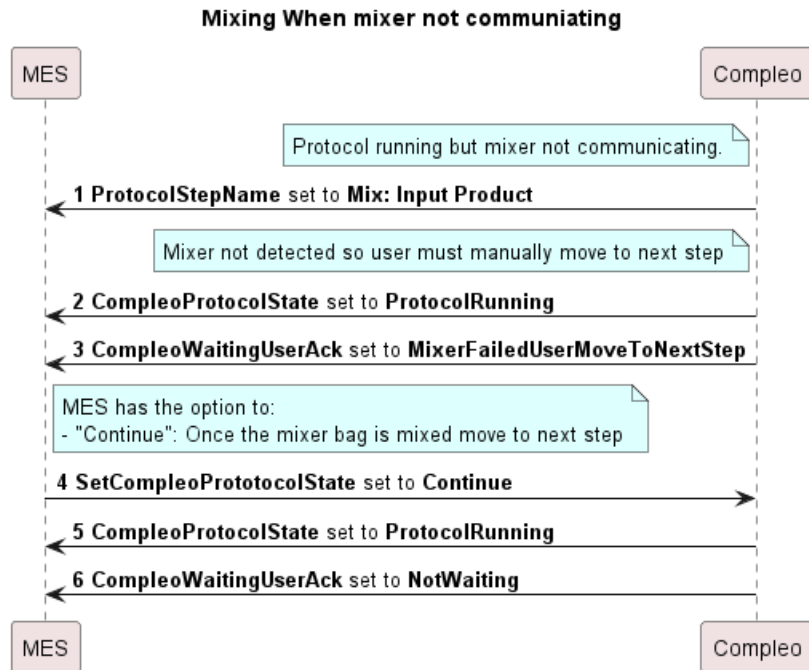


During the cell bag volume transfer step, the valve volumes at E and C are measured and compared with each other. If the valve volumes are not reliable then the user can retry the transfer step. The cells are transferred back into the cell bag, and the cell transfer is started again.



3.27 Mixing

If the mixer stops communicating during a protocol run, the user is given the option to manually mix the mixer bag and continue once completed.



3.28 Dispensing to sample lines

Before the instrument dispenses or primes sample lines, the user is prompted to open a specific sample line.



3.29 Resampling Input Product

After the input samples are dispensed, the user must re-submit a valid dose plan. If there was an issue with the cell count the user may dispense another input sample.

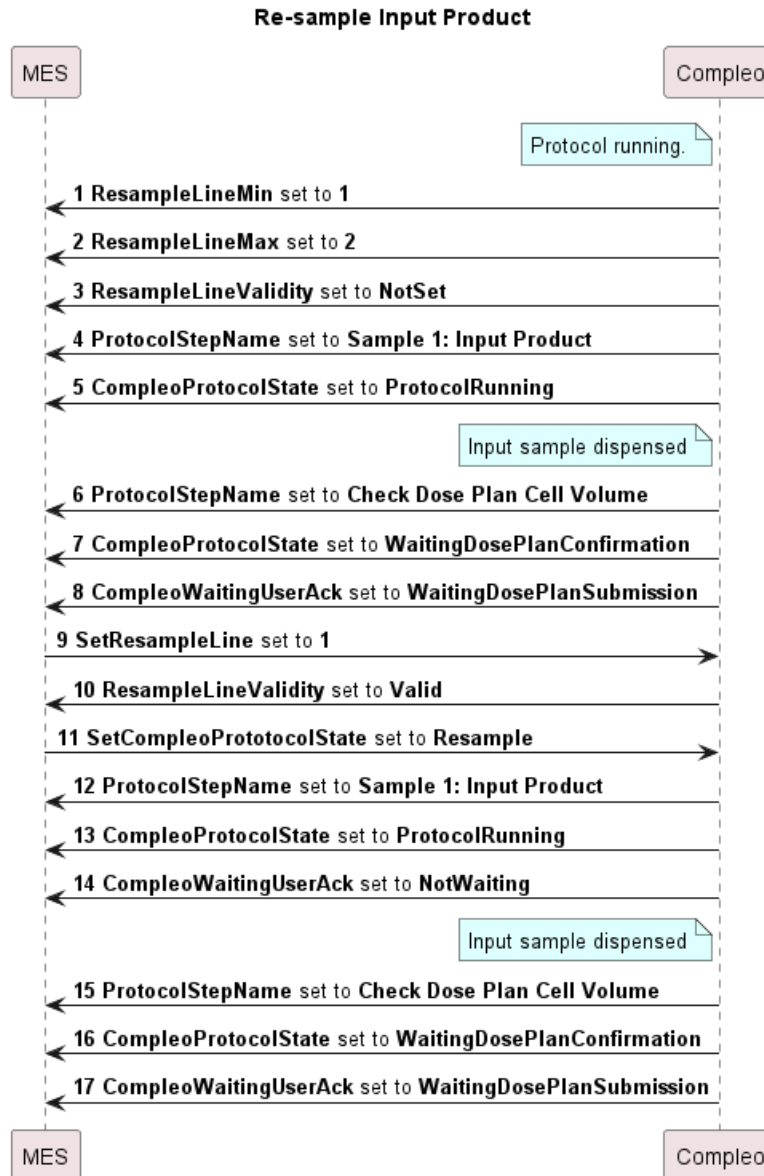
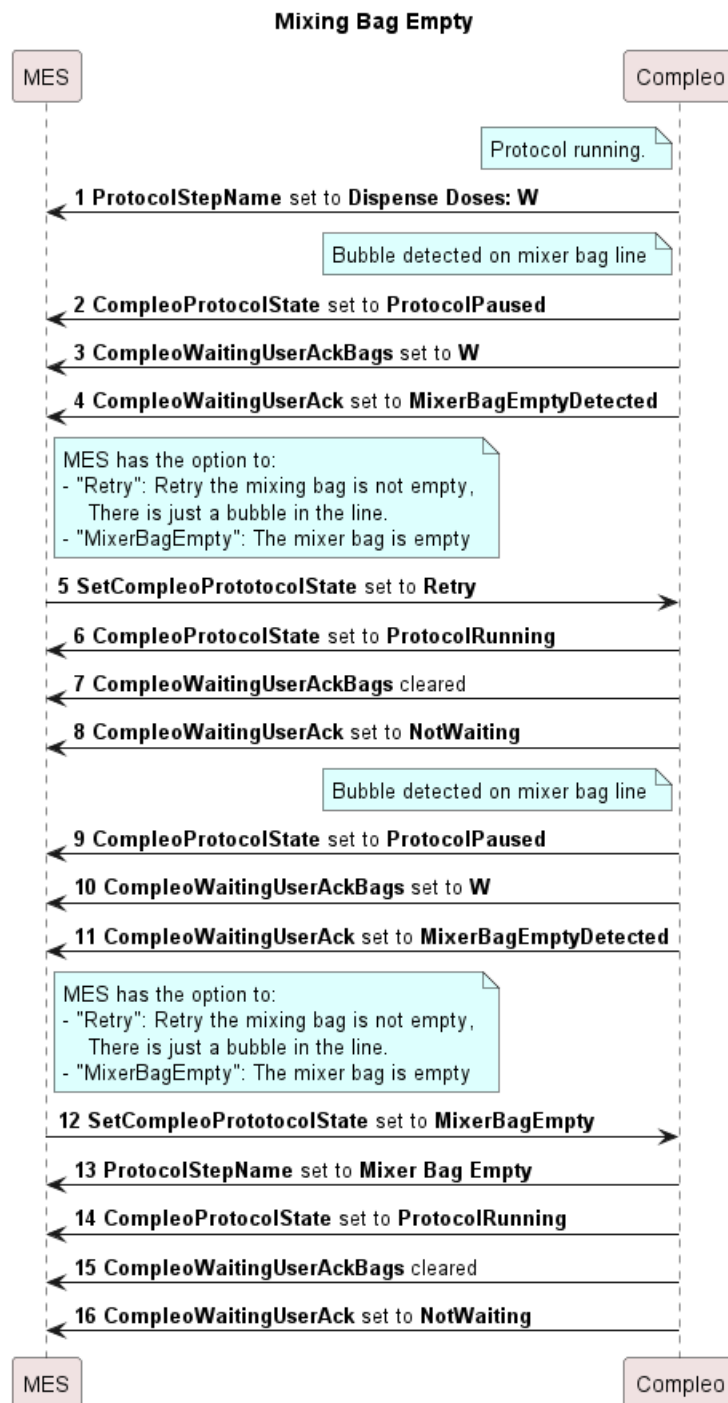


Figure 3 Resample input product

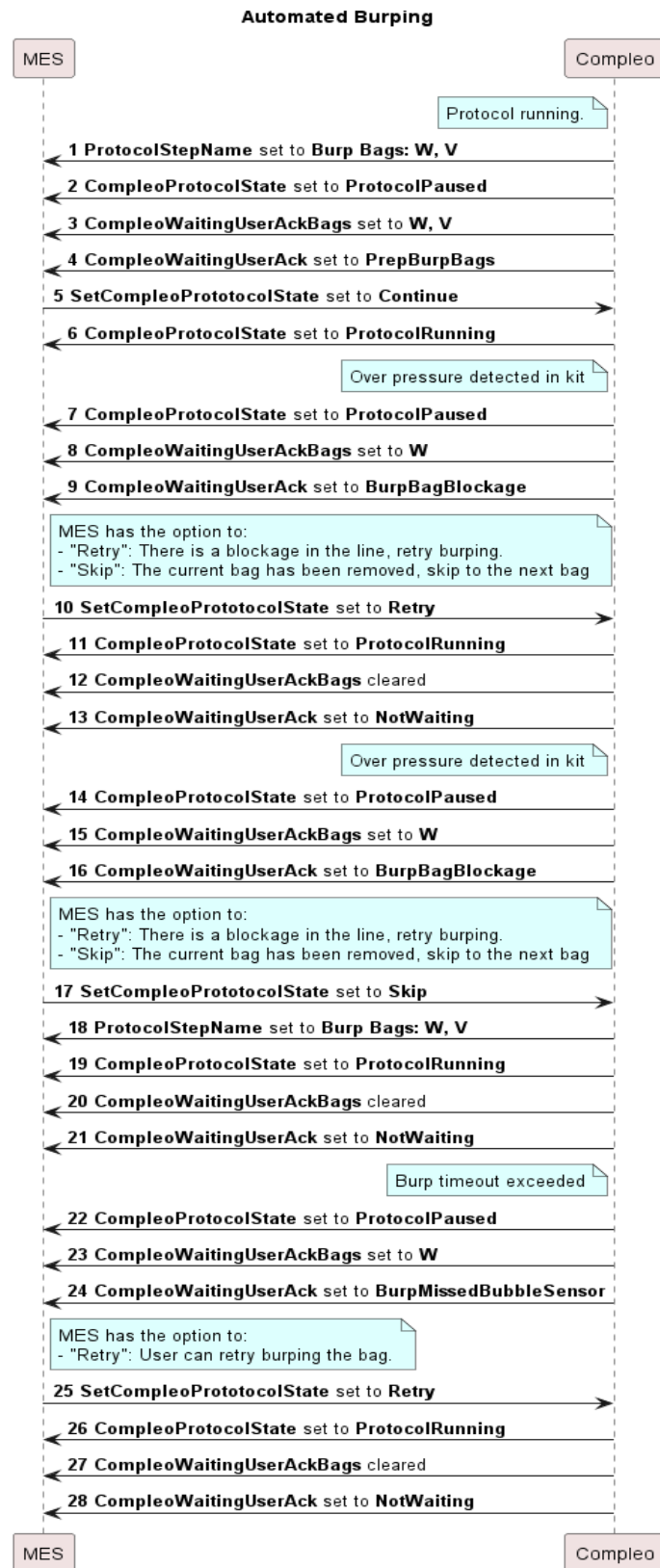
3.30 Dispense Dose or Sample

When the instrument is dispensing samples and doses there is a possibility that the mixer bag may run out of fluid before the last dose is dispensed due to measurement errors. If that happens then the user can choose to finish the protocol which will finish dispensing the current dose and burp the required bags.



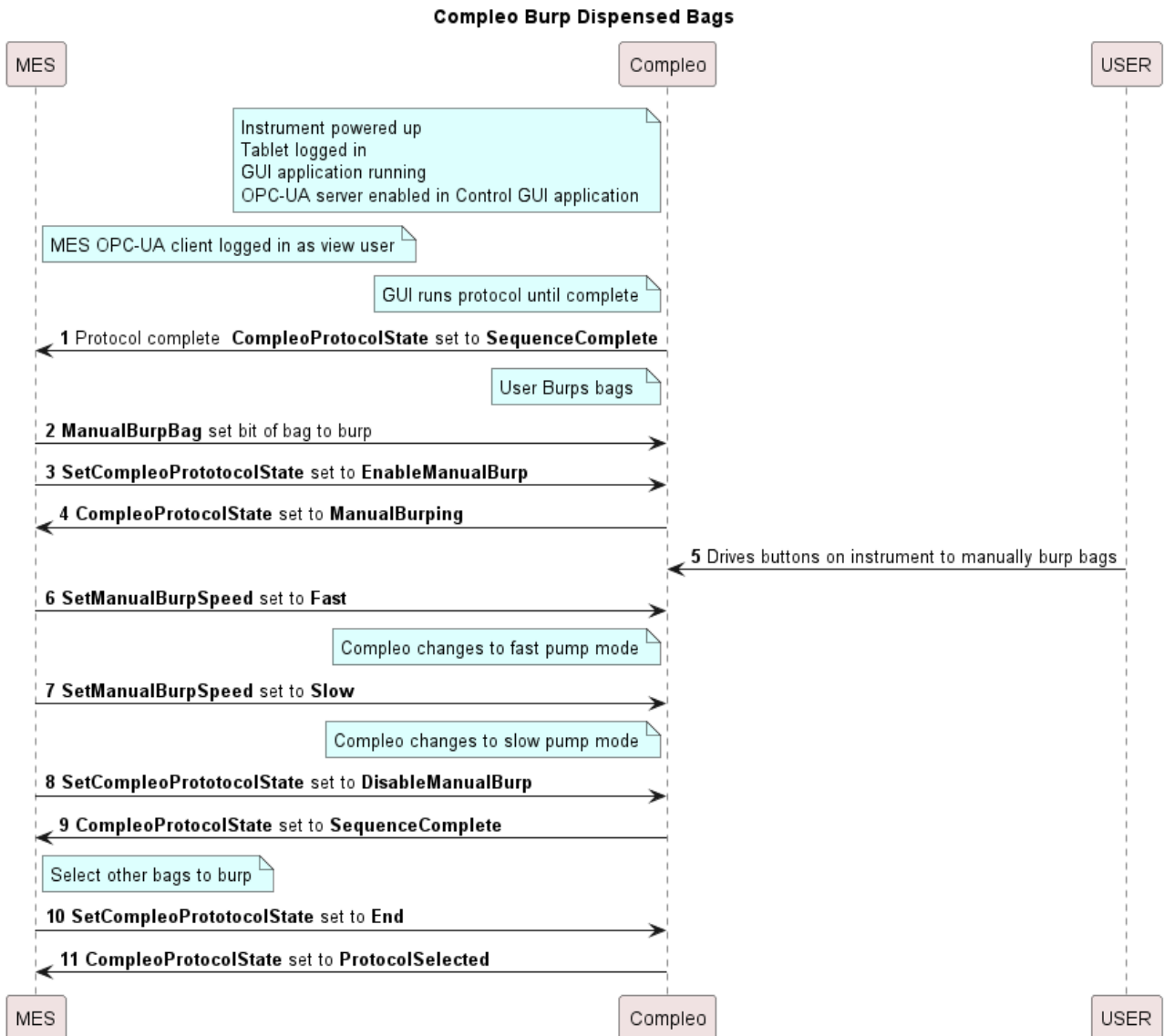
3.31 Automated Burping

During automated burping, if a high-pressure event is detected (that is, the user has removed the bag early), then they are given the option to skip burping.



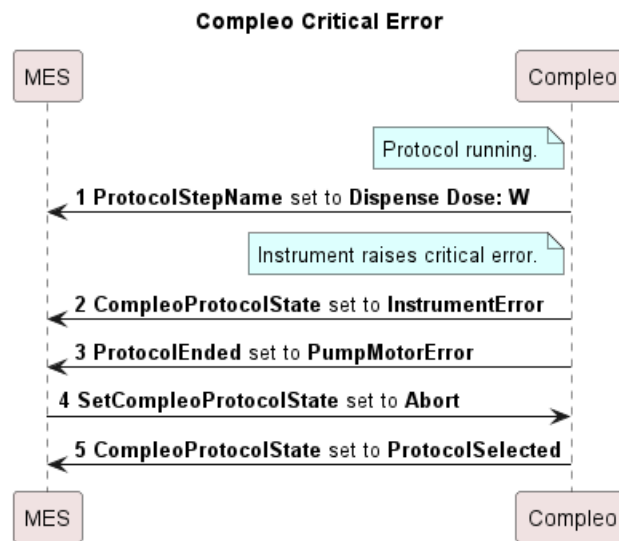
3.32 Manual Burping

The user can manually burp bags once the sequence is complete.



3.33 Critical Error Handling

When a critical error occurs, the user must abort to clear the error on the instrument.



Chapter 4 OPC-UA Interface

The Rotea™ and Compleo™ Control GUIs have similar components and operations. The OPCUA interface is broken down into 3 sub-categories:

- General OPC-UA Nodes. Available on both Rotea™ and Fill & Finish.
- Rotea™-specific OPC-UA Nodes. Available only on Rotea™
- Compleo™-specific OPC-UA Nodes. Available only on Compleo™.

4.1 Command Nodes

The Control GUI listens for values written to command nodes in the GUI.

4.2 Generic OPC-UA Command Nodes

Variable	Type	Values/Description
RescanKit	Boolean	Force a Kit Rescan: <ul style="list-style-type: none"> • True – The instrument will rescan the kit barcode. • False – No action.
SetGuiUserLevel	Enum	0. GUIManagedLogin – Application login is managed by the GUI, OPC-UA commands are ignored in this mode. 1. ViewUser – The MES has control of the Rotea™ and GUI just displays the Rotea™ status. 2. AdminUser – The GUI is logged in as an administrator and has control the Rotea™, OPC-UA commands are ignored in this mode. Note: When OPC-UA is enabled, a SetGuiUserLevel command from the OPC-UA server will override the current instrument login state.
SetLocalProtocolFilePath	String	Set the file name path of the Protocol on the tablet to be loaded to the Rotea™ instrument.
SetProtocolFileContents	String	Send the Protocol file contents to the tablet to be loaded to the Rotea™ instrument.
SetProtocolFileByLookupTableId	UInt32	ID of the protocol file in the OPC-UA look up table. The lookup table is defined in OPCUAProtocolList.yaml
GetProtocolNameByLookupTableId	UInt32	Id of the protocol file in the OPC-UA look up table to get the name of. The lookup table is defined in OPCUAProtocolList.yaml . This sets the ProtocolNameAtLookupTableId node.

4.3 Rotea™ OPC-UA Command Nodes

Variable	Type	Values/Description
SetPlayPauseButtonEnable	Enum	Enable the Play/Pause button on the Rotea™. 0. Disabled 1. AsPerProtocol 2. Enabled
SetParameter1 through SetParameter18	UInt32	The Metadata parameter data for the protocol. The associated name of the parameter can be found in variables ParameterName1 through ParameterName18 after the protocol has been loaded
SetProtocolState	Enum	0. StopProtocol – Stop the Protocol. 1. SendProtocolToRotea – Load the Protocol to the Rotea™ instrument. 2. RunProtocol – Start the protocol, same as pressing the Start button on the instrument. 3. PauseProtocol – Pause the protocol 4. RecoveryRunProtocolFromStep – Start a protocol from the step specified in SetRecoveryStepNumber . 5. RecoveryRunProtocolSingleStep – Start a protocol and run a single step number SetRecoveryStepNumber . 6. SkipToNextStep - advances the protocol to the next step by ending this step.
SetRecoveryStepNumber	UInt32	The recovery step number to start from. Used by SetProtocolState .
SetSkipButtonEnable	Enum	Enable the advance button on the Rotea™. 0. Disabled 1. AsPerProtocol 2. Enabled
SetProtocolAdjustCentrifugeSpeedG	Int32	The centrifuge speed adjustment value. SetProtocolAdjustStepNumber and SetProtocolAdjustType need to be set prior to writing this node.
SetProtocolAdjustPumpSpeedmLPerMin	Int32	The pump speed adjustment value. SetProtocolAdjustStepNumber and SetProtocolAdjustType need to be set prior to writing this node.

SetProtocolAdjustStepNumber	UInt32	The current step number. This field must be set prior to setting speed adjustment. This field is used in case the protocol step changes while the request is in flight.
SetProtocolAdjustType	Enum	Sets the type of adjustment to perform: 0. Absolute. Set the pump or centrifuge speed to value. 1. Incremental. Increment the pump or centrifuge speed by the value
SetProtocolRestartStep	Bool	Writing True to this node will reset the triggers for the current step. SetProtocolAdjustStepNumber must be set prior to writing this node.

4.4 Compleo™ OPC-UA Command Nodes

Variable	Type	Values/Description
SetDosePlanInitialMediaVolumemL1 through SetDosePlanInitialMediaVolumemL4	UInt32	The volume (mL) of media in each bag at the start of the protocol.
SetManualVolumeMlAddedFormulationMedia1_1 through SetManualVolumeMlAddedFormulationMedia10_4	Float	Volume of each media (mL) to be added to each formulation. Indexing N_M: N is the formulation number and M is media number.
SetCellVolumeSelection	Enum	Only available while the CompleoWaitingUserAck is TransferVolumeAnalysis or MeasureVolumeAnalysis . 0. UserDefinedVolume – Use the user defined volume. 0. AvMeasuredVolume – Use the Average measured volume. 1. MixerBagValveMeasuredVolume – Use the volume measured on the mixer bag valve. 2. CellBagValveMeasuredVolume – Use the volume measured on the cell bag valve.

SetCompleoProtocolState	Enum	<ol style="list-style-type: none"> 0. Abort – Abort the protocol or clear an error on the instrument 1. Run – Start a protocol, continue running from a paused state. Unpause only when CompleoWaitingUserAck set to NotWaiting. 2. Pause – Pause the protocol. 3. SubmitDosePlan – Submit the dose plan information for calculations. 4. Initiate – Initiate a protocol 5. End – Once a protocol completes, indicate manual burping has finished. 6. Continue – Continue protocol 7. Retry – Retry the action 8. Skip – Skip an Optional Dose Plan Bag 9. SkipRest – Skip the rest of the Optional Dose Plan Bag 10. Resample – Dispense another sample. 11. EnableManualBurp – Enable Manual Burp mode. 12. DisableManualBurp – Disable Manual Burp mode. 13. MixerBagEmpty – Indicate that the mixer bag has run out of fluid. 14. RetryCheckCalibration – Retry Check Calibration 15. RetryCellTransfer – Retry Cell Transfer/Volume transfer 16. UnlockDoor – Unlock the door. 17. EnableManualPurge 18. DisableManualPurge 19. ManualWetPrime 20. FinishManualWetPrime
SetDosePlanCellActivePercent	Float	<p>Percentage of active ingredients in the input cells.</p> <p>Required if the user specified that the input cells already have active ingredient present with them when they build the protocol.</p>

SetDosePlanCellConcentrationMPerML	Float	Cell concentration of the input cells in Million cells per mL Note. This cannot be edited after the Transfer Cells or Measure Cell Volume step is complete.
SetDosePlanCellVolumemL	Float	Volume (mL) of cells in the input bag
SetManualBurpBag	UInt32	Bits: 0. Not Used - A 1. Not Used - B 2. Not Used - C 3. Valve D 4. Valve E 5. Valve F 6. Valve G 7. Not Used - H 8. Not Used - I 9. Not Used - J 10. Not Used - K 11. Not Used - L 12. Not Used - M 13. Not Used - N 14. Not Used - O 15. Not Used - P 16. Valve Q 17. Valve R 18. Valve S 19. Valve T 20. Valve U 21. Valve V 22. Valve W
SetManualBurpPurgeSpeed	Enum	0. Slow 1. Fast
SetPurgeFromBag	UInt32	Same as SetManualBurpBag
SetPurgeToBag	UInt32	Same as SetManualBurpBag

SetMixerSpeed	UInt32	Manually set the mixer speed. This is only available while a protocol is not running.
SetNumberExtraManualDoses	UInt32	Number of extra doses to make
SetResampleLine	UInt32	The Sample line to resample

4.5 Status Nodes - Generic OPC-UA Status Nodes

Variable	Type	Values/Description
InstrumentName	String	The name of the instrument, stored on the instrument, set by the GUI.
MainFirmwareVersion	String	The main board firmware version on the Instrument
ModelNumber	String	The model number of the instrument, set during manufacture.
PowerFirmwareVersion	String	The power board firmware version on the Instrument
LinkUp	Boolean	Rotea™ link state: <ul style="list-style-type: none"> • True – The Rotea™ application is connected to the instrument and communication is successful. • False – The Rotea™ application cannot communicate with the instrument, all commands will fail and the status is invalid.
SerialNumber	String	The serial number of the instrument, set during manufacture.
UpTime	UInt32	The number of seconds the server has been running, updated every 10 seconds.
DoorState	Enum	<ol style="list-style-type: none"> 0. DoorClosed – The door is closed. 1. DoorOpened – The door is open.

ErrorRaised	Enum	<ol style="list-style-type: none"> 0. NoError – There are no errors. 1. InternalError – An internal application error has occurred 2. FileNotFound – The SetLocalProtocolFilePath file cannot be found. 3. JsonParsingError – The protocol file is corrupted 4. FileCannotBeOpened – The protocol file cannot be opened. 5. CmdFailed – Generic fail, the last command issued did not succeed. 6. ParameterNotSet – A parameter has not been set, protocol not loaded. 7. ParameterOutOfRange – A parameter is out of range, protocol not loaded 8. KitNotLoaded – The kit is not loaded, protocol not loaded. 9. KitNotValid – The kit is not valid, protocol not loaded. 10. InstrumentNotReady – Changing to the specified ProtocolState cannot be performed from the current state. 11. RecoveryStepOutOfRange – The ProtocolStepNumber is not a valid step in the protocol 12. ProtocolListDoesNotExist - OPCUAProtocolList.yaml cannot be found. 13. ProtocolListCannotBeOpen – Cannot open OPCUAProtocolList.yaml 14. ProtocolListParsingError – OPCUAProtocolList.yaml format invalid. 15. ProtocolListIdDoesNotExist – The LookupTableId cannot be found in OPCUAProtocolList.yaml. 16. DosePlanInvalid 17. InvalidBagSelected 18. ParameterNotSettable 19. InstrumentCalibrationInvalid – The protocol cannot run because the instrument pump calibration cannot achieve the pump rate in the protocol
KitId	String	The Kit ID of the loaded kit.

KitState	Enum	<ul style="list-style-type: none"> 0. NotLoaded – Kit not loaded in instrument 1. LoadedNotValid – Kit loaded in instrument but the Kit ID is invalid or kit type cannot be used with this protocol. 2. Valid – Kit is loaded in the instrument and Kit ID is valid. Can now be Sent to the instrument
ProtocolEnded	Enum	<p>The state indicates that the protocol has stopped and the reason that it stopped. Pressing the stop button or writing the ProtocolState to StopProtocol will clear any Errors.</p> <ul style="list-style-type: none"> 0. NotApplicable – Not Applicable 1. CompletedSuccessfully – Protocol completed successfully 2. UserStoppedRun – The user or OPC-UA stopped the protocol 3. DoorUnlatchedError – The instrument has raised a door error; the door failed to close or has opened unexpectedly. 4. PumpMotorError – The instrument has raised a pump motor fault. 5. CentrifugeMotorError -The instrument has raised a centrifuge motor fault. 6. ValveError – The instrument has raised a valve error. A valve may have failed to close or open properly. 7. OutOfBalanceError – The instrument has raised an out of balance error, the centrifuge may be out of balance. 8. MoistureInBowlError – The instrument has raised a moisture in bowl error, the kit may be leaking. 9. OverPressureConditionError – The instrument has raised an over pressure error; excessive pressure has been detected in one of the kit tubes. 10. UnknownError – The instrument is in an unknown error state. 11. ProtocolRecoveryError 12. ProtocolSendError 13. StepOverrideFailure
ProtocolChecksum	String	The Checksum of the loaded Protocol
ProtocolDescription	String	The description of the protocol

ProtocolName	String	The Protocol Name of the loaded protocol
LookupTableLastModifiedTimeS	UInt32	The time in milliseconds when the OPCUAProtocolList.yaml was last Modified
LookupTableProtocolCount	UInt32	Number of protocols in the OPCUAProtocolList.yaml file

<p>OpenValves</p>	<p>UIn32</p>	<p>Bit packed field to indicate which valves are open. A 1 at the bit offset indicates if the valve is open or closed.</p> <p>Bits:</p> <ul style="list-style-type: none"> 0. Valve A 1. Valve B 2. Valve C 3. Valve D 4. Valve E 5. Valve F 6. Valve G 7. Valve H 8. Not Used - I 9. Valve J 10. Valve K 11. Not Used - L 12. Not Used - M 13. Not Used - N 14. Not Used - O 15. Not Used - P 16. Valve Q 17. Valve R 18. Valve S 19. Valve T 20. Valve U 21. Valve V 22. Valve W <p>Note 1: Rotea™ Valves are: A, B, C, D, E, F, G, H, J, K Note 2: Compleo™ Valves are: B, C, D, E, F, G, Q, R, S, T, U, V, W Note 3: On Rotea™, if valves J and K are open, then the protocol is in pause and the fluid is looping in the kit.</p>
<p>UserComment</p>	<p>String</p>	<p>Comment added by the user</p>

UserLevel	Enum	<ol style="list-style-type: none"> 0. NoUser – No user is logged in. OPC-UA has no control. 1. ServiceUser – The service user is logged in. OPC-UA has no control. 2. AdminUser – A GUI Administration user is logged in. OPC-UA has no control. 3. FullUser – A GUI Full user is logged in. OPC-UA has no control. 4. BasicUser – A GUI Basic user is logged in. OPC-UA has no control. 5. ViewUser – A GUI View user is logged in. OPC-UA has no control. 6. OPCViewUser – An OPC-UA View user is logged in. The GUI is in view only mode, the OPC-UA interface has full control. 7. OPCAdminUser – An OPC-UA Administration user is logged in. The GUI has full control of the instrument, OPC-UA has no control.
ProtocolStepNumber	UInt32	The protocol step number
ProtocolStepName	String	The Protocol step name
ProtocolSummary	String	The protocol description summary
ProtocolTotalSteps	UInt32	Total number of steps in the protocol
PumpDirection	Enum	<p>The current pump direction.</p> <ol style="list-style-type: none"> 0. Not Applicable 1. Forward 2. Reverse
PumpRate	UInt32	The current pump speed
RunLogFileName	String	The current text run log file name
PdfRunLogFileName	String	The current PDF run log file name

4.6 Status Nodes - Compleo™ Status Nodes

Variable	Type	Values/Description
ActiveIngredientExposureTime	String	Total time the cells have been exposed to active Ingredient
BagsAvailableToManualBurp	UInt32	Bit packed field to indicate which bags can be manually burped. Bits: 0. Not Used - A 1. Not Used - B 2. Not Used - C 3. Not Used - Valve D 4. Valve E 5. Valve F 6. Valve G 7. Not Used - H 8. Not Used - I 9. Not Used - J 10. Not Used - K 11. Not Used - L 12. Not Used - M 13. Not Used - N 14. Not Used - O 15. Not Used - P 16. Valve Q 17. Valve R 18. Valve S 19. Valve T 20. Valve U 21. Valve V 22. Valve W
BagsAvailableToManualPurge	UInt32	Same as BagsAvailableToManualBurp
CellTransferMeasuredCellBagValveVolumemL	Float	
CellTransferMeasuredMixerBagValveVolumemL	Float	
CellTransferMeasuredAvVolumemL	Float	

CellTransferValveVolumesErrorWithinTolerance	Bool	
CellTransferPumpedVolumeErrorWithinTolerance	Bool	
CompleoProtocolState	Enum	<ol style="list-style-type: none"> 1. NoProtocolSelected 2. ProtocolSelected 3. ReadyToStart 4. ProtocolRunning 5. ProtocolPaused 6. WaitingDosePlanConfirmation 7. SequenceComplete 8. ManualBurping 9. InstrumentError 10. ProtocolRecoveryError 11. ManualPurging 12. ManualWetPrime
CompleoProtocolType	Enum	<p>NotApplicable</p> <p>Calculated</p> <p>Manual</p>
CompleoWaitingUserAck	Enum	<ol style="list-style-type: none"> 0. NotWaiting 1. BlockageDetected 2. EmptyBagDetected 3. AirVentBubbleSensor 4. DryPrimeOptionalBlockage 5. MeasureVolumeAnalysis 6. ConfirmCellBagEmpty 7. WaitingDosePlanSubmission 8. OpenSampleLine 9. BurpBagBlockage

CompleoWaitingUserAck	Enum	10. CheckCalibrationVolumeOutOfBound 11. MixerBagEmptyDetected 12. UnknownPause 13. InstrumentFailure 14. ConfirmMixerMissing 15. MixerFailedUserMoveToNextStep 16. ConfirmKitReuse 17. PrepBurpBags 18. TransferVolumeAnalysis 19. BurpMissedBubbleSensor 20. KitAdjustVolumeInvalid 21. KitAdjustValid 22. KitAdjustFactorInvalid 23. ConfirmKitCorrectionFactorReuse 24. WetPrimeFailed 25. ProtocolSendFailure 26. ProtocolStoppedByUserError 27. DoorFaultError 28. PumpMotorFault 29. ValveErrorFault 30. OverPressureError 31. OtherFaultError 32. StepOverrideFailure 33. ProtocolRecoveryError
CompleoWaitingUserAckBags	String	The bags/sample line ID associated with the CompleoWaitingUserAck
Dose<bag>Name, where <bag> is E, F, G, Q, R, S, T, U, V, W	String	The dose label
DosePlanCalculationErrors	String	A \n separated list of errors with the input values
DosePlanCalculationsInRange	Boolean	Indicated if the dose plan calibrations are in valid ranges or not, ie there is enough media, bags are big enough. The protocol cannot be started until the dose plan is valid
DosePlanCalculationsValid	Boolean	Indicates if the dose plan calculations are valid or not. The protocol cannot be started until the dose plan is valid

DosePlanCellActivePercentValidity	Enum	<ul style="list-style-type: none"> 0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.
DosePlanCellConcentrationMPerMlValidity	Enum	<ul style="list-style-type: none"> 0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.
DosePlanCellVolumeAllowZero	Boolean	Can the user enter a zero value for the cell volume
DosePlanCellVolumeMin	Float	Minimum Cell Volume
DosePlanCellVolumeMax	Float	Cell Bag Capacity (max volume)
DosePlanCellVolumeValidity	Enum	<ul style="list-style-type: none"> 0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.
DosePlanInitialMediaVolumeValidity1 through DosePlanInitialMediaVolumeValidity4	Enum	<ul style="list-style-type: none"> 0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.
EstimatedMediaVolumeUsedmL1 through EstimatedMediaVolumeUsedmL4	Float	Once DosePlanCalculationsValid is true , this is the estimated volume of media used in the dose plan
KitCorrectionForwardFactor	Float	Forward kit correction factor used in the protocol run
KitCorrectionReverseFactor	Float	Reverse kit correction factor used in the protocol run
CellTransferUserDefinedKitCorrection	Float	The User Defined volume kit correction

CellTransferUserDefinedKitCorrectionValid	Float	<ul style="list-style-type: none"> 0. NotInUse 1. ShowVolumeBasicAdminAccess 2. ShowVolumeAdminAccess 3. ShowVolumeCalFactorBasicAdminAccess 4. ShowVolumeCalFactorAdminAccess 5. ShowVolumeCalFactorNoAccess
DosePlanCellConcentrationMPerMlValidity	Enum	<ul style="list-style-type: none"> 0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.
CellTransferAvKitCorrection	Float	Average volume valve kit correction
CellTransferAvKitCorrectionValid	Enum	<ul style="list-style-type: none"> 0. NotInUse 1. ShowVolumeBasicAdminAccess 2. ShowVolumeAdminAccess 3. ShowVolumeCalFactorBasicAdminAccess 4. ShowVolumeCalFactorAdminAccess 5. ShowVolumeCalFactorNoAccess
CellTransferCellValveKitCorrection	Float	Cell valve volume kit correction
CellTransferCellValveKitCorrectionValid	Enum	<ul style="list-style-type: none"> 0. NotInUse 1. ShowVolumeBasicAdminAccess 2. ShowVolumeAdminAccess 3. ShowVolumeCalFactorBasicAdminAccess 4. ShowVolumeCalFactorAdminAccess 5. ShowVolumeCalFactorNoAccess
CellTransferMixerValveKitCorrection	Float	Mixer bag valve kit correction
CellTransferMixerValveKitCorrectionValid	Enum	<ul style="list-style-type: none"> 0. NotInUse 1. ShowVolumeBasicAdminAccess 2. ShowVolumeAdminAccess 3. ShowVolumeCalFactorBasicAdminAccess 4. ShowVolumeCalFactorAdminAccess 5. ShowVolumeCalFactorNoAccess
ManualVolumeMlAddedFormulationMediaValidity1_1 through ManualVolumeMlAddedFormulationMediaValidity10_4	Enum	<ul style="list-style-type: none"> 0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.

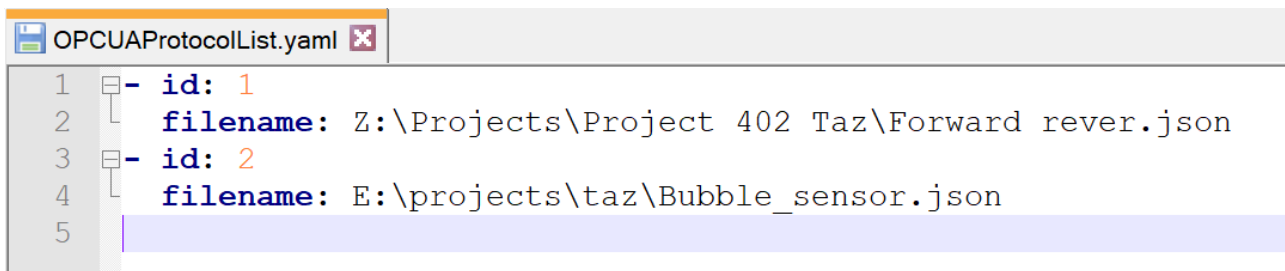
MediaName1 through MediaName4	String	The name of the Media
MediaVolumeMax1 through MediaVolumeMax4	Float	The Media bag capacity
MixerSpeed	UInt32	The current mixer speed
MixerState	Enum	0. Mixer communicating 1. Mixer not communicating 2. Mixer Fault
NumberExtraManualDosesMax	UInt32	Max number of additional doses that can be made
NumberExtraManualDosesValidity	Enum	0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.
ProtocolCompleteWarnings	String	List of warnings about possible out of specification doses and formulations
RunTime	String	Total protocol run time
DoseE CalculatedVolumemL through DoseW CalculatedVolumemL	Float	The calculated volume to be dispensed for doses E through W
DoseE MeasuredVolumemL Through DoseW MeasuredVolumemL	Float	The measured volume dispensed for doses E through W
MixerBagVolumeStepName	String	The step name that the MixerBagCalculatedVolume and MixerBagMeasuredVolume is associated with
MixerBagCalculatedVolume	Float	The mixer bag calculated volume for the MixerBagVolumeStepName step
MixerBagMeasuredVolume	Float	The mixer bag measured volume for the MixerBagVolumeStepName step
ResampleLineMin	UInt32	The minimum sample line available
ResampleLineMax	UInt32	The maximum sample line available

ResampleLineValidity	Enum	0. NotInUse – Parameter not used in protocol 1. NotSet – Parameter needs to be set 2. OutOfRange – Parameter not in valid range 3. Valid – Parameter valid.
SelectedCellBagVolume	Enum	0. NotSet 1. UserDefinedVolume 2. AvMeasuredVolume 3. MixerBagValveMeasuredVolume 4. CellBagValveMeasuredVolume

Chapter 5 Common use case sequence diagrams

5.1 Loading a predefined protocol from a lookup file by index

- The look-up or list file is always named `OPCUAProtocolList.yaml`. The admin user defines the directory where this file is to be found. The directory could be a shared directory on a network drive or a local directory on the tablet running the GUI.
- Here is an example of the file structure being edited by Notepad++.



```
OPCUAProtocolList.yaml
1  - id: 1
2    filename: Z:\Projects\Project 402 Taz\Forward rever.json
3  - id: 2
4    filename: E:\projects\taz\Bubble_sensor.json
5
```

- Each new entry is started with a - (dash)
- **id** is an int32, so potentially a large number. The entries do not need to be in any order. The first match to the id number is used. There is no check for duplicate id entries.
- Filename includes path details.

Load protocol with DeltaV through OPC-UA

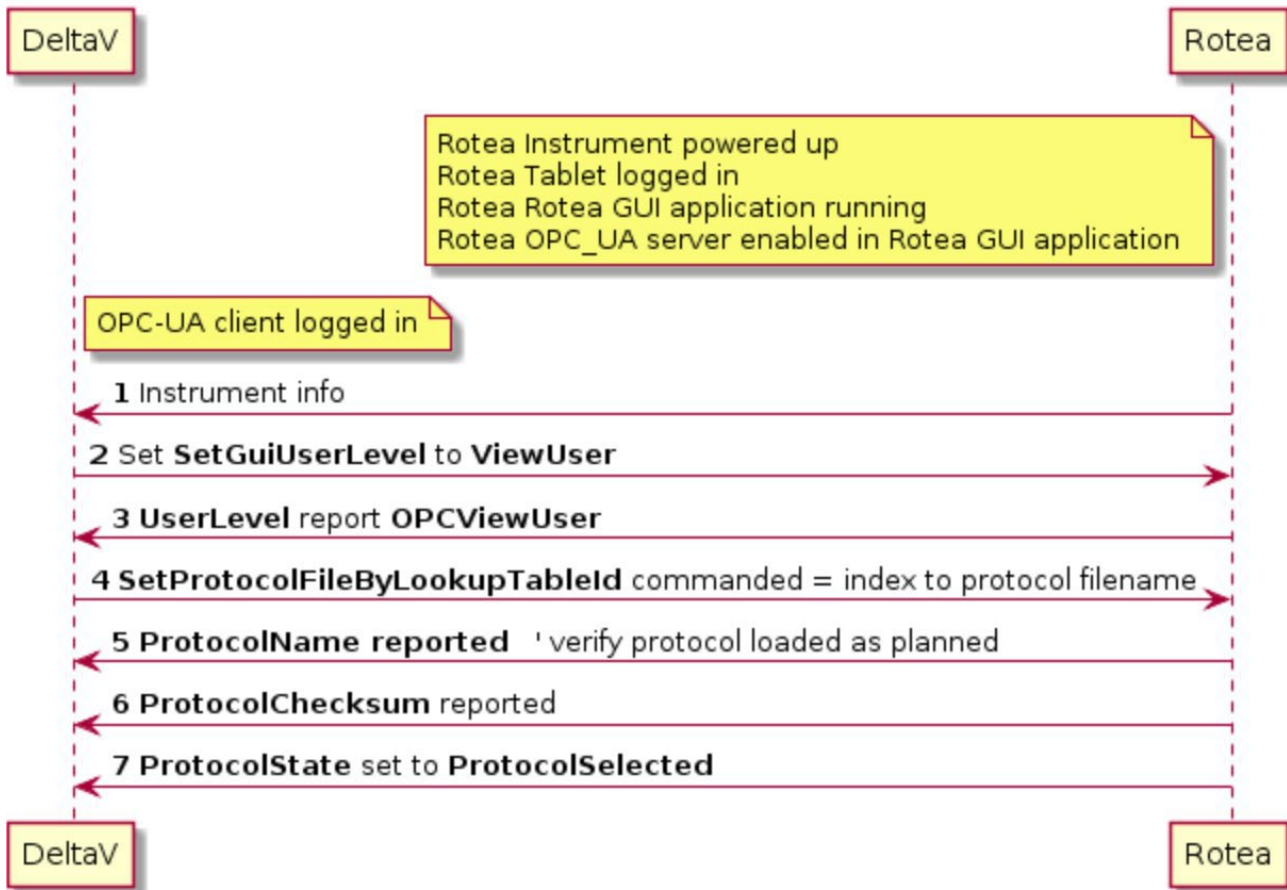


Figure 4 Load protocol with DeltaV through OPC-UA

- When the OPC-UA client sends the index number, Rotea™ GUI searches the pre-defined directory for the file **OPCUAProtocolList.yaml**, opens it and searches for the index number. If the index number is found, the protocol is loaded, and the status is reported to the OPC-UA client.

Chapter 6 Rotea™-specific use case sequence diagrams

6.1 Rotea™ - Running a protocol

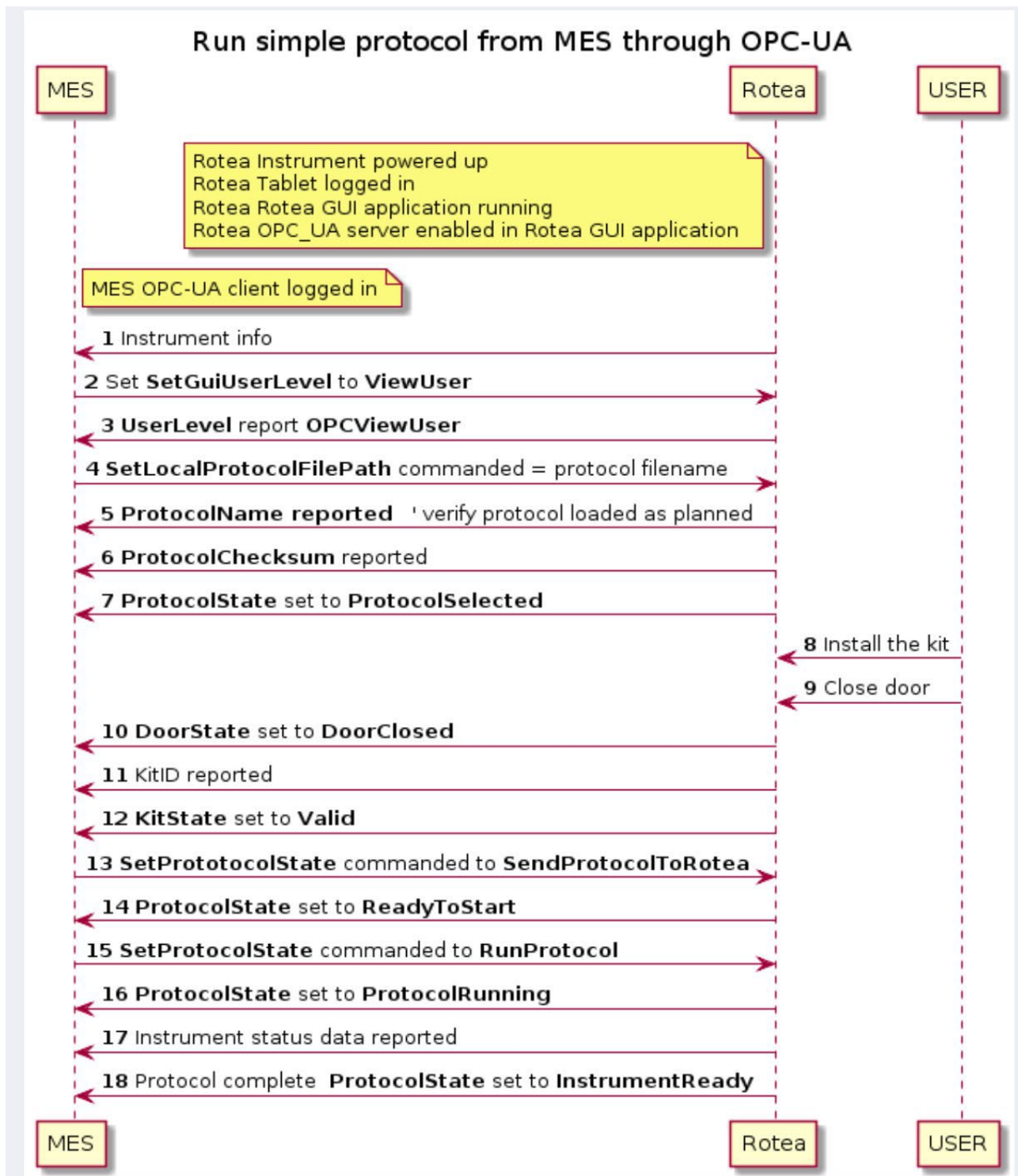


Figure 5 Run simple protocol from MES through OPC-UA

6.2 Rotea™ – Running a protocol with parametric data

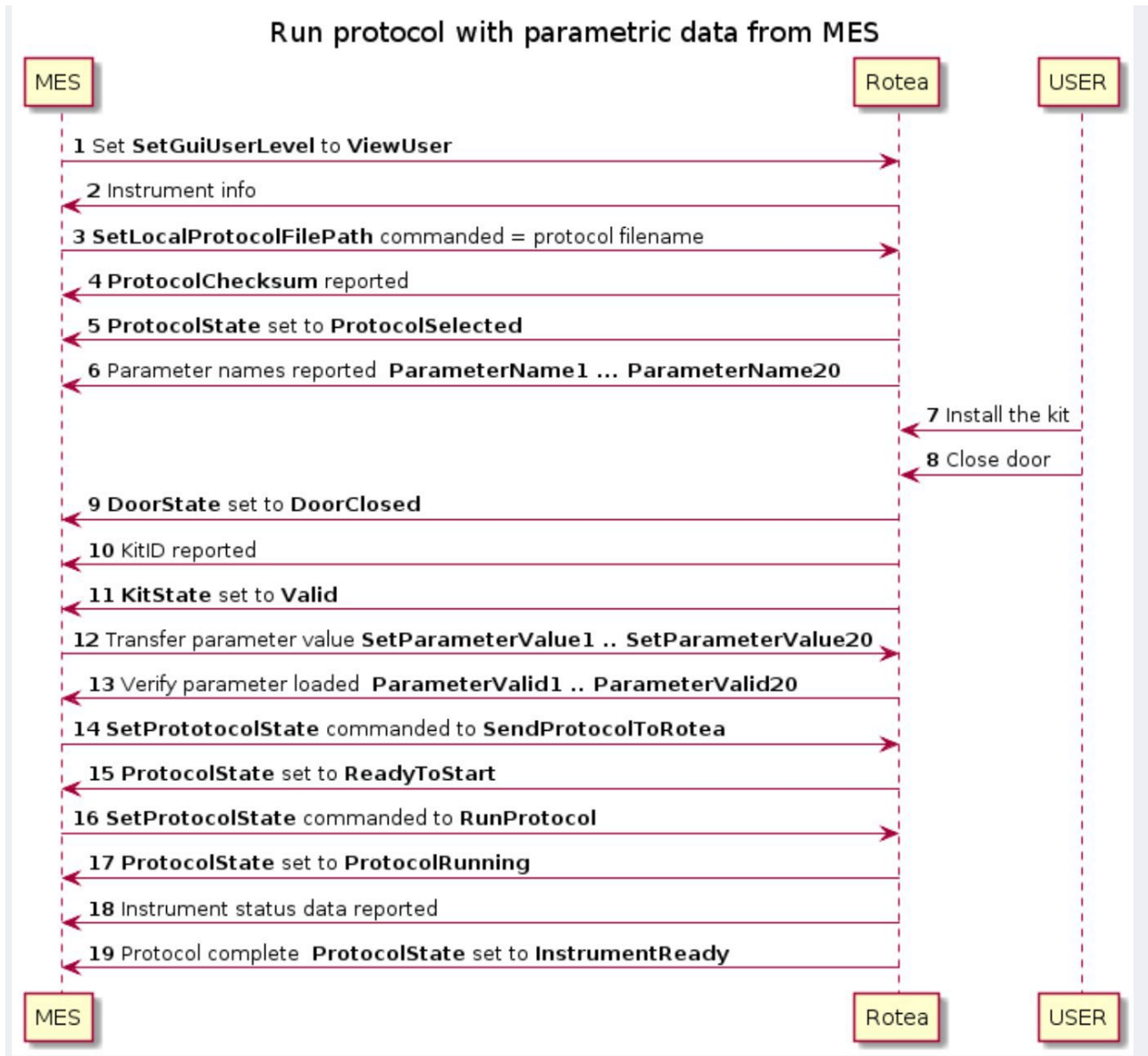


Figure 6 Run protocol with parametric data from MES

6.3 Rotea™ – Pausing a protocol and resuming

MES directs Rotea in support of external systems.

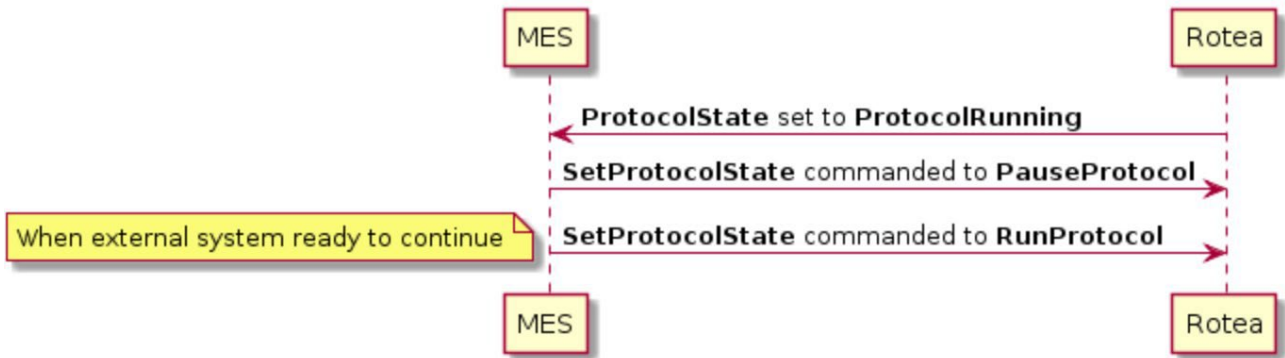


Figure 7 Pause/Play protocol while running

6.4 Rotea™ – Recovery: Running a single step of a protocol

MES directs Rotea to run single step of protocol.



Figure 8 Performing single step recovery operation from OPC-UA while running a protocol

6.5 Rotea™ – Recovery: Starting a protocol part way through a protocol



Figure 9 Performing run from step recovery operations from OPC-UA while running a protocol

6.6 Rotea™ – Allowing a user to access GUI when an error occurs

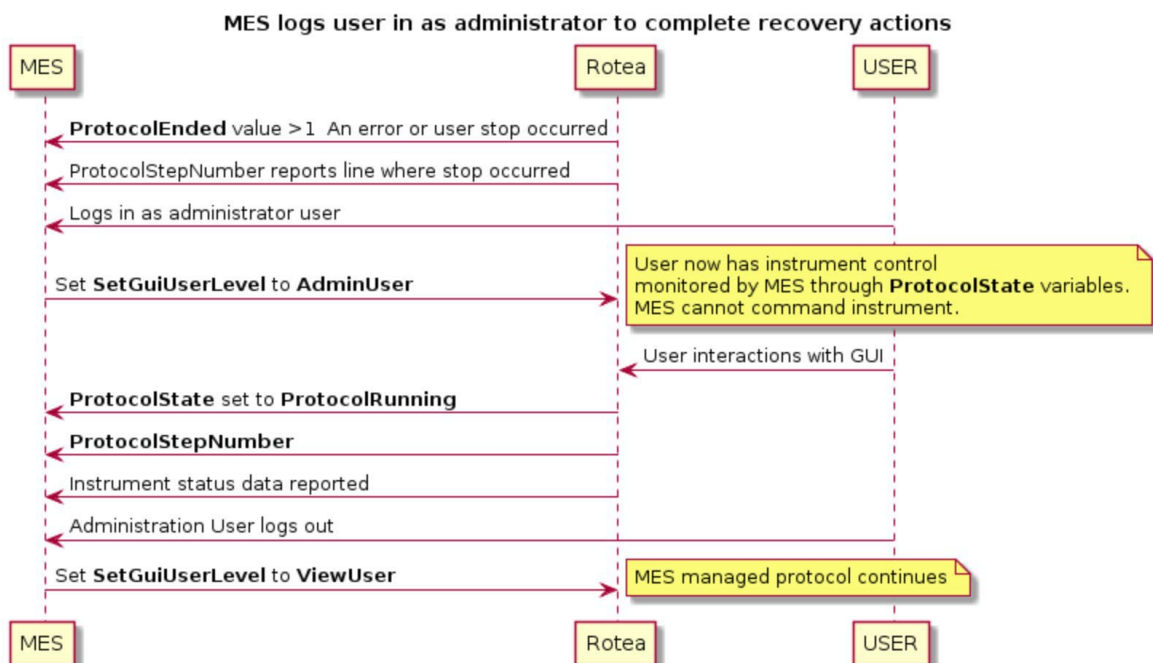


Figure 10 Changing user level to perform recovery with the GUI

Appendix A. AppVersion Issues

ISSUE E35: AppVersion 2.0.XX

- Add MixerBagCapacityReached to CompleoWaitingUserAck
- Add MixerErrorRetry, MixerBagFullContinue to SetCompleoProtocolState
- Add Kit Configuration nodes:
 - Add BagConcentrationX nodes for bags B, C, D, E, F, G, Q, R, S, T, U, V, W
 - Add BagNameX nodes for bags B, C, D, E, F, G, Q, R, S, T, U, V, W
 - Add BagTubeLengthX nodes for bags B, C, D, E, F, G, Q, R, S, T, U, V, W
 - Add BagTypeX nodes for bags B, C, D, E, F, G, Q, R, S, T, U, V, W
 - Add MainVolumeX nodes for bags B, C, D, E, F, G, Q, R, S, T, U, V, W
 - Add SampleVolumeX nodes for sample lines 0, 1, 2, 3, 4, 5, 6, 7, 8, 9
 - Add SecondVolumeX nodes for bags B, C, D, E, F, G, Q, R, S, T, U, V, W
- Add MixerRunState node.
- Add Rotea SetDoorLockButtonEnable node

ISSUE E33: AppVersion 2.0.21

- Add MixerFaultUserMoveToNextStep, ConfirmMixerInstrumentFault to CompleoWaitingUserAck
- Change MixerFailedWaitingContinue to MixerErrorWaitingContinue enum
- Change MixerState to MixerCommsState
- Change MixerFailedContinue to MixerErrorContinue

ISSUE E31: AppVersion 2.0.X

- Add DownloadingCrashDump to CompleoProtocolState
- Add ConfirmMixerBagEmpty, RinseManualMix, RinseVolumeAnalysis to CompleoWaitingUserAck
- Add DownloadingCrashDump to ProtocolState
- Add MixerFailedContinue to SetCompleoProtocolState
- Add MixerFailedWaitingContinue node
- Add MixerSpeedTarget node
- Change MixerSpeed to MixerSpeedCurrent
- Rename ShowVolumeCalFactorBasicAdminAccess to ShowVolumeCalFactorBasicAccess under ShowVolumeFields type
- Rename SelectedCellBagVolume node to SelectedVolume
- Remove 'CellTransfer' from node names:
 - CellTransferMeasuredCellBagValveVolumemL,
 - CellTransferMeasuredMixerBagValveVolumemL,

- CellTransferMeasuredAvVolumemL,
- CellTransferValveVolumesErrorWithinTolerance,
- CellTransferPumpedVolumeErrorWithinTolerance,
- CellTransferUserDefinedKitCorrection, CellTransferAvKitCorrection,
- CellTransferCellValveKitCorrection, CellTransferMixerValveKitCorrection,
- CellTransferUserDefinedKitCorrectionValid,
- CellTransferAvKitCorrectionValid, CellTransferCellValveKitCorrectionValid,
- CellTransferMixerValveKitCorrectionValid
- Change 'KitCorrectionValid' wording in node names:
 - CellTransferUserDefinedKitCorrectionValid,
 - CellTransferAvKitCorrectionValid, CellTransferCellValveKitCorrectionValid,
 - CellTransferMixerValveKitCorrectionValid
- Rename SetCellVolumeSelection node to SetVolumeSelection
- Add UserDefinedVolumemL node. Set during measure and transfer cells to used defined volume

ISSUE D30: AppVersion 2.0.X

- Add ManualWetPrime to CompleoProtocolState
- Add WetPrimeFailed, ProtocolSendFailure, ProtocolStoppedByUserError, DoorFaultError, PumpMotorFault, ValveErrorFault, OverPressureError, OtherFaultError, StepOverrideFailure, ProtocolRecoveryError to CompleoWaitingUserAck
- Add ProtocolRecoveryError, ProtocolSendError, StepOverrideFailure to ProtocolEnded
- Add ManualWetPrime, FinishManualWetPrime to SetCompleoProtocolState

ISSUE D29: AppVersion 1.7.X

- Change CellTransferCellValveKitCorrectionValid, CellTransferMixerValveKitCorrectionValid, CellTransferAvKitCorrectionValid to include permission values
- Add CellTransferUserDefinedKitCorrection, CellTransferUserDefinedKitCorrectionValid nodes

ISSUE D28: AppVersion 1.7.X

- Add EnableManualPurge, DisableManualPurge, PurgeLine to SetCompleoProtocolState.
- Change SetManualBurpSpeed to SetManualBurpPurgeSpeed
- Change ErrorRaised: InvalidBurpBag to InvalidBagSelected
- Add CompleoProtocolState: ManualPurging

- Add BagsAvailableToManualPurge, SetManualBurpPurgeSpeed, SetPurgeFromBag, SetPurgeToBag nodes
- Change BagsAvailableToManualPurge, BagsAvailableToManualBurp to be only set when the user can purge or burp

ISSUE D27: AppVersion 1.7.X

- Change KitAdjustmentForwardFactor, KitAdjustmentReverseFactor nodes to KitCorrectionForwardFactor, KitCorrectionReverseFactor

ISSUE D26: AppVersion 1.7.X

- Add KitAdjustVolumInvalid, KitAdjustValid, KitAdjustFactorInvalid, ConfirmKitCorrectionFactorReuse enum values to CompleoWaitingUserAck
- Change MissedBubbleSensor to CheckCalibrationMissedBubbleSensor
- Add KitAdjustmentForwardFactor, KitAdjustmentReverseFactor nodes
- Add Kit correction sequence diagrams.

ISSUE D25: AppVersion 1.7.X

- Change node name CellTransferMeasuredCellBagVolumemL to CellTransferMeasuredAvVolumemL.
- Removed SetCompleoProtocolState enum value AcceptMeasuredVolume and replace with SelectedCellBagVolume and SetCellVolumeSelection nodes
- Add SetManualBurpSpeed node
- Add BurpMissedBubbleSensor enum to CompleoWaitingUserAck
- Update Sequence diagrams under sections Manual Burping, Automated Burping, Transfer Cell Volume, Auto Measure Cell Volume

ISSUE D24: AppVersion 1.7.X

- Fix Missed Bubble Sensor diagram

ISSUE D23: AppVersion 1.7.X

- Update and add sequence diagrams in sections: Wet Output Bag Detected, Check Calibration, Auto Measure Cell Volume, Transfer Cell Volume

ISSUE D22: AppVersion 1.7.X

- Add MissedBubbleSensor enum value to use table

ISSUE D21: AppVersion 1.7.X

- Add MissedBubbleSensor enum value to CompleoWaitingUserAck
- Add UnlockDoor enum to SetCompleoProtocolState

ISSUE D20: AppVersion 1.7.X

- Add SetMixerSpeed node

ISSUE D19: AppVersion 1.7.X

- Compleo™: Add ResampleLineMax, ResampleLineMin, ResampleLineValidity, SetResampleLine
- Change TransferCellBagEmpty to TransferVolumeAnalysis under CompleoWaitingUserAck
- Added CheckCalibrationValid under CompleoWaitingUserAck
- Added Check Calibration passes diagram
- Change AcceptVolume to AcceptMeasuredVolume
- Added CellTransferMeasuredCellBagValveVolumemL, CellTransferMeasuredMixerBagValveVolumemL, CellTransferMeasuredCellBagVolumemL, CellTransferValveVolumesErrorWithinTolerance, CellTransferPumpedVolumeErrorWithinTolerance
- Added RetryCellTransfer to replace Retry when auto measuring volume
- Update Auto Measure Cell Volume and Transfer Cell Bag contents sequence diagrams
- Update main dose plan workflow diagram

ISSUE D18: AppVersion 1.7.X

- Compleo™: Add DosePlanCellVolumeAllowZero, DosePlanCellVolumeMin
- Compleo™: Change DosePlanCellVolumeMax type to float

ISSUE D17: AppVersion 1.7.X

- Compleo™: Only allow start protocol when ReadyToStart not when ProtocolSelected.
- Compleo™: Add Dose<bag>Name nodes
- Rotea™: decrease number of supported parameters from 20 to 18.
- Rotea™: change SetParameter, ParameterMin, ParameterMax to UInt32
- Add InstrumentCalibrationInvalid enum value to ErrorRaised node
- Add ProtocolDescription and ProtocolSummary nodes

ISSUE D16: AppVersion 1.7.X

- Add PrepBurpBags to CompleoWaitingUserAck enum
- Change CompleoWaitingUserAckBag to CompleoWaitingUserAckBags
- Added Compleo™ nodes: ProtocolEnded, ProtocolCompleteWarnings,
- Dose<bag>CalculatedVolumemL, Dose<bag>MeasuredVolumemL, MixerBagVolumeStepName,
- MixerBagCalculatedVolume, MixerBagMeasuredVolume
- Move Rotea Node ProtocolEnded to common node.

ISSUE D15: App Version 1.7.X

- Add ReadyToStart to Compleo™ state
- Add missing CompleoProtocolState states Fix enum numbering
- Added Manual Mode Volume Commands
- Added Compleo™ Sequence diagrams

ISSUE C14: App Version 1.6.X

- Change Fill & Finish Naming to Compleo™
- Add Compleo™ Workflows

ISSUE C13: App Versions 1.5.5

- Change language to reference both Rotea™ and Fill & Finish devices
- Add Fill and Finish Instrument Nodes

ISSUE C12: Rotea™ App Version 1.5.5

- Change RoteaLinkUp node name to LinkUp
- Change RoteaAppVersion node name to AppVersion

ISSUE C11: Rotea™ App Version 1.5.2

- Rename SetProtocolAdjustPumpSpeed and SetProtocolAdjustCentrifugeSpeed
- Add Pump and Centrifuge Speed adjust bounds
- Update OPC-UA Node structure (no updates in this document)

ISSUE C10: Rotea™ App Version 1.5.0

- Remove 64-bit OPC-UA values
- Change node name for opc-ua lookup table modify time
- Fix DoorState description typo

ISSUE C9: Rotea™ App Version 1.4.0

- Protocol Speed adjustment Nodes
- Add nodes to get OPCUA lookup file protocol names
- Add step time remaining
- Add open valves

ISSUE C8: Rotea™ App Version 1.3.0

- Add Connecting Client to OPC-UA Server section
- Add PdfRunLogFileName node

ISSUE C7: Rotea™ App Version 1.3.0

- Add OPC-UA duplicate command timeout information
- Add OPC-UA Parameter Max/Min values

ISSUE C6:

- UserComment report added

ISSUE C5:

- Pause state origin WaitingUserAck enum expanded

ISSUE C4:

- Corrected skip button to advance button and description of advance button enable.

ISSUE C3:

- Example of file checksum
- Corrected the description of Rotea™ response to kit 'Valid' state and 'InstrumentReady' state
- Defined the YAML file for the "list of files" functionality.
- Added means for protocol file selection through "list of files" and an index number for Delta™ support
- Valid for Rotea™ GUI Release 4.18 or later

