|  |  |  |  |
| --- | --- | --- | --- |
| **Department** | **Printed Name** | **Signature** | **Date** |
| Author/ LSD | Prakruthi Rao Chavali | See electronic signature | See stamp |
| PQ | David Johnson | See electronic signature | See stamp |
| Systems R&D | Derek Neiman | See electronic signature | See stamp |
| RA | Tiffany Lin | See electronic signature | See stamp |
| PRMO | Alexandra Delazio | See electronic signature | See stamp |
| Service | Simon Fontana | See electronic signature | See stamp |
| Human Factors | John Battista | See electronic signature | See stamp |
| Software | Lalu Krishnan | See electronic signature | See stamp |
| Marketing | Jason Knox | See electronic signature | See stamp |
| Medical | Ionna Vella | See electronic signature | See stamp |
| Systems Engineering | Joey West | See electronic signature | See stamp |

**Abstract**:

This CADV report documents the modification to the PrisMax software, to allow the operator to change the Auto Effluent (AE) disposable during a treatment session. The AE disposable consists of the AE set, bags, and tubing.

| **Table of Contents**  [1 Introduction 5](#_Toc168328700)  [1.1 Purpose and Scope 5](#_Toc168328701)  [1.2 Summary 5](#_Toc168328702)  [1.3 Terms and Definitions 5](#_Toc168328703)  [1.4 References 5](#_Toc168328704)  [1.5 Entities Impacted 6](#_Toc168328705)  [1.6 Individuals Involved 6](#_Toc168328706)  [2 Change Analysis (CA) 7](#_Toc168328707)  [2.1 Design Inputs (CA1) 7](#_Toc168328708)  [2.1.1 Background 7](#_Toc168328709)  [2.1.2 Approaches Considered 7](#_Toc168328710)  [2.1.3 Selected Approach and Rationale 7](#_Toc168328711)  [2.1.4 Other Considerations 7](#_Toc168328712)  [2.2 Description of Change 8](#_Toc168328713)  [2.2.1 Workflow Changes 9](#_Toc168328714)  [2.2.2 Internal Processing Changes 23](#_Toc168328715)  [2.2.3 Safety Processor Changes 24](#_Toc168328716)  [2.3 Use Case Analysis 27](#_Toc168328717)  [2.4 HFE Assessment 31](#_Toc168328718)  [2.5 Risk Analysis 31](#_Toc168328719)  [2.6 Product Requirement Analysis 34](#_Toc168328720)  [2.7 System Requirement Analysis 36](#_Toc168328721)  [3 Sub-System Requirements Analysis (CA2) 44](#_Toc168328722)  [3.1 Hardware Requirement Analysis 44](#_Toc168328723)  [3.2 Software Requirement Analysis 44](#_Toc168328724)  [3.3 Labeling Requirement Analysis 64](#_Toc168328725)  [4 Change Description (CD) 64](#_Toc168328726)  [4.1 Design Description 64](#_Toc168328727)  [4.1.1 Change Auto Effluent Set 81](#_Toc168328728)  [4.1.2 Drain Auto Effluent Bags 81](#_Toc168328729)  [4.1.3 Auto Effluent Status 81](#_Toc168328730)  [4.1.4 Clamp and Disconnect Auto Effluent Lines 81](#_Toc168328731)  [4.1.5 Clamp Auto Effluent Drain Line 81](#_Toc168328732)  [4.1.6 Unload and Discard Set, Bags, and Lines 82](#_Toc168328733)  [4.1.7 Scan New Auto Effluent Set 82](#_Toc168328734)  [4.1.8 Scan Failed Auto Effluent Set 82](#_Toc168328735)  [4.1.9 Load New Auto Effluent Set 82](#_Toc168328736)  [4.1.10 Check Tubing Alignment 82](#_Toc168328737)  [4.1.11 Hang Auto Effluent Bags 83](#_Toc168328738)  [4.1.12 Connect Extension Line and Drain Hook 83](#_Toc168328739)  [4.1.13 Connect and Unclamp Auto Effluent Set 83](#_Toc168328740)  [4.1.14 Sequence Diagram 83](#_Toc168328741)  [4.1.15 Class Diagrams 84](#_Toc168328742)  [4.1.16 Change Auto Effluent Set Workflow 96](#_Toc168328743)  [4.1.17 Constraints During AE Set Change 98](#_Toc168328744)  [4.2 Change List 98](#_Toc168328745)  [4.2.1 Implementation Description 101](#_Toc168328746)  [4.2.2 Unit Test Case 114](#_Toc168328747)  [4.3 Labeling Update 114](#_Toc168328748)  [4.4 Reviews 117](#_Toc168328749)  [4.4.1 PrisMaxCP Pull Request 117](#_Toc168328750)  [4.4.2 PrisMaxGUIAssets Pull Request 117](#_Toc168328751)  [5 Change Verification (CV) 118](#_Toc168328752)  [5.1 System Requirement Verification 118](#_Toc168328753)  [5.2 Software Requirement Verification 119](#_Toc168328754)  [5.3 Integration Testing 130](#_Toc168328755)  [5.4 Informal Testing 131](#_Toc168328756)  [5.4.1 Regression Analysis 133](#_Toc168328757)  [5.4.2 Regression Test Descriptions 141](#_Toc168328758)  [5.4.3 System Regression Analysis 143](#_Toc168328759)  [5.4.4 Test Execution 143](#_Toc168328760) |
| --- |
| Table of Figures | |

[Figure 1 - Proposed Screen Changes to Initiate AE Set Replacement 9](#_Toc168398465)

[Figure 2 - Proposed Confirmation Dialog to Initiate AE Set Change 10](#_Toc168398466)

[Figure 3 - Proposed AE Drain Yes/No Pop-Up 11](#_Toc168398467)

[Figure 4 - Proposed Pause Dialog for AE Drain Option 11](#_Toc168398468)

[Figure 5 – Proposed AE Drain Resume/Cancel 12](#_Toc168398469)

[Figure 6 - Proposed AE Clamp and Disconnect Step 13](#_Toc168398470)

[Figure 7 - Proposed AE Clamp Drain Line Step 14](#_Toc168398471)

[Figure 8 - Proposed AE Unload and Discard Step 15](#_Toc168398472)

[Figure 9 - Proposed Scan Set Dialog 16](#_Toc168398473)

[Figure 10 - Proposed AE Load Set Dialog 18](#_Toc168398474)

[Figure 11 - Proposed Tubing Alignment Check Step 19](#_Toc168398475)

[Figure 12 - Proposed Hang Bags Dialog 20](#_Toc168398476)

[Figure 13 - Proposed Extension Line and Drain Line Dialog 21](#_Toc168398477)

[Figure 14 - Proposed Line Connection and Continue Dialog 22](#_Toc168398478)

[Figure 15: FluidPumpCtrl\_Subsystem for PrisMax SW V3.0 (SVN revision 4590) 67](#_Toc168398479)

[Figure 16: FluidPumpCtrl\_Subsystem for PrisMax SW V3.4 (SVN Revision 5379) 68](#_Toc168398480)

[Figure 17: AESetChange sub-system 69](#_Toc168398481)

[Figure 18: ScaleOffset sub-system 70](#_Toc168398482)

[Figure 19: FrontScale parallel state 71](#_Toc168398483)

[Figure 20: SideScale parallel state 72](#_Toc168398484)

[Figure 21: Function Calc\_Offset 73](#_Toc168398485)

[Figure 22 - Pinch Valve Faults / Effluent\_Fill\_And\_Drain\_PV\_Failures sub-system for PrisMax SW V3.2 (SVN revision 4985) 75](#_Toc168398486)

[Figure 23 - Pinch Valve Faults / Effluent\_Fill\_And\_Drain\_PV\_Failures sub-system for PrisMax SW V3.4 (SVN revision 5324 76](#_Toc168398487)

[Figure 24 - Blood and Fluid Pump Faults / Scale\_Open\_Failures sub-system for PrisMax SW V3.2 (SVN revision 4985) 77](#_Toc168398488)

[Figure 25 - Blood and Fluid Pump Faults / Scale\_Open\_Failures sub-system for PrisMax SW V3.4 (SVN revision 5324) 78](#_Toc168398489)

[Figure 26 - Weight Scale Faults / Patient\_Fluid\_Removal\_Failure sub-system for PrisMax SW V3.2 (SVN revision 4985) 79](#_Toc168398490)

[Figure 27 - Weight Scale Faults / Patient\_Fluid\_Removal\_Failure sub-system for PrisMax SW V3.4 (SVN revision 5324) 80](#_Toc168398491)

# Introduction

## Purpose and Scope

The purpose of this CADV report is to document the modification implemented in the PrisMax software as part of the PrisMax SW 3.4 release to allow the operator the ability to change the AE disposable during a treatment session.

This CADV report contains the reason for the modification, a summary description of the change, the impact to program risks and requirements, and any impact to labeling.

*Note: This CADV document only identifies and describes the changes being applied. Where necessary, additional background material will be provided.*

## Summary

There are several cases where it is desirable to replace the AE disposable without ending the current treatment session. This change is being implemented to allow the operator to change the AE disposable without having to change the main disposable and go through the entire setup process. This change will provide detailed instructions to guide the operator through this process while automating as much as possible in the software.

## Terms and Definitions

| **Term** | **Definition** |
| --- | --- |
| AE | Auto Effluent |
| CP | Control Processor |
| UI | User Interface |
| SP | Safety Processor |

## References

| **No** | **ID** | **Title** |
| --- | --- | --- |
| R1 | RACT8000 | Risk Assessment and Control Table for PrisMax System, TherMax BWU, AE, AEE and 5L Bag |
| R2 | CRS8001 | Customer Requirements Specification |
| R3 | TRS8001 | Therapy Requirements Specification, PrisMax System V3 |
| R4 | PRD8002 | Product Requirements Document, PrisMax Monitor V3 |
| R5 | HSHA-AE-THERAPIES | ACUTE EXTRACORPOREAL THERAPIES HAZARDOUS SITUATION AND HARM ANALYSIS |

## Entities Impacted

This section contains a list of documents impacted by the change.

| **Document** | **Yes** | **No** | **Comments** |
| --- | --- | --- | --- |
| RACT | X |  | Adding new risk mitigation for AE change as well as some cleanup to existing items to make them clearer. |
| TRS | X |  | Update existing requirement to allow AE to be changed in Treatment. |
| CRS | X |  | Update existing requirement to allow AE to be changed in Treatment. |
| PRD | X |  | Update for new AE workflow and requirement gap for reusing AE. |
| HRD |  | X |  |
| SRS | X |  | Updating for new AE workflow. |
| PDD |  | X |  |
| SDS | X |  | Updating for new AE workflow. |
| Operator’s Manual | X |  | Updating Op Man with section on AE change workflow. |
| Service Manual |  | X |  |
| Code | X |  | Updating for new AE workflow. |
| Licensing |  | X |  |
| Labeling | X |  | New labels for system workflow and OpMan . |
| Error Code List |  | X |  |
| Test Protocols | X |  | Updating for new AE workflow. |
| Other: |  |  |  |

## Individuals Involved

The names of the primary individuals involved in the creation of this document are as follows:

|  |  |
| --- | --- |
| **Name** | **Section (CA, CD, or CV)** |
| Derek Neiman | CA |
| Alexandra Delazio | CA |
| Lalu Krishnan | CD |
| Shilpa Dwarakinatha | CV |

*.*

# Change Analysis (CA)

## Design Inputs (CA1)

### Background

The PrisMax system provides an optional accessory to automatically dispose of effluent to a hospital drain instead of to a disposable bag, which the operator must change when it becomes full. This accessory disposable is used in conjunction with the main filter set and replaces the effluent bag with a disposable consisting of a set, two bags, and the relevant tubing. The AE feature was implemented to reduce the workload on the nurse, since the effluent bag fills and requires changing most frequently.

The current workflow allows the AE disposable to be used across multiple treatment sessions (multiple main sets for the same patient) in some cases. However, there is currently no workflow to allow changing the AE disposable while keeping the main set and other disposables. This means that if there is a problem with the AE disposable, the user is forced to end the treatment and discard both the AE and main disposables.

One of the main drivers behind this feature is that there have been several reported instances of AE sets that start to leak while in use. This feature can also be leveraged when the AE set has been used longer than its recommended usage time or if there are flow issues caused by partially loaded tubing segments that weren’t detected before the start of treatment.

Allowing the AE disposable to be changed during treatment would allow for fewer interruptions to the ongoing therapy while also cutting down on cost and materials used.

### Approaches Considered

There were three different approaches that were considered to address this use case:

1. Allow the operator to change from AE to a standard effluent bag during treatment.
2. Allow the operator to change the AE disposable during treatment.
3. A combination of options #1 and #2.

### Selected Approach and Rationale

Option #2 (allow the operator to change the AE disposable during treatment) was selected. This option has the following advantages:

* Allow the user to continue using Auto Effluent for the remainder of the treatment
* Smaller development and test impact than other options

Option #1 (allow the operator to change from AE to a standard effluent bag during treatment) was not selected because it required more work for a less desirable outcome. This option had the following disadvantages:

* Larger system impact since current architecture doesn’t easily support changing accessory options in treatment. This would result in additional analysis and testing.
* Forces the operator to stop using the AE accessory and increases the workload on the operator to now deal with additional bag changes.
* “Same Patient” setup/teardown would become more complex to handle the variations of switching from AE to non-AE.

Option #3 (combination of options 1 and 2) was not selected since the small additional benefit didn’t outweigh the additional technical load.

### Other Considerations

Another element of this change that was considered is how long the average time to drain the effluent bags will take. The maximum flow rate of the pump will allow approximately 1 L of solution to be drained every 5 minutes. If the drain time were to take too long on average, other considerations would have to be examined, such as instructing the operator to attempt to drain the bags while treatment was being performed.

The worst-case scenario would be when the rear and side bags are completely full (~6 L), but the “normal” case was assumed to be about 2 L of fluid between the bags. To confirm this assumption, an analysis of log data was performed to see what the typical case looked like. The plot below shows the maximum effluent scale weight when using AE for each treatment log. As expected, the typical weight is between 1000g and 2000g. With this data it was decided that stopping the system while the drain was ongoing was sufficient and, in the cases where the drain time will take longer than expected, the operator will have the option to skip or discontinue the drain sequence as they see fit.

A graph of weight scale

Description automatically generated

## Description of Change

The system will provide the operator with an option to change the AE disposable while in the treatment state. The operator can access the AE change workflow from the change screen, the same way they can initiate bag changes from the UI. This screen is accessed by tapping on the main Operations screen.

### Workflow Changes

A computer screen shot of a computer

Description automatically generatedFigure 1 - Proposed Screen Changes to Initiate AE Set Replacement

The AE Set change is initiated from the UI similarly to how a bag change can be initiated from the UI; the user can click the “Change AE widget” from the change screen. This will raise a dialog that asks the user if they want to continue with the change or cancel it. Once the change is confirmed by the user, the system will enter a safe state where only the blood pump will continue to run (and the syringe pump when using systemic anticoagulation). The system will then provide instructions for each individual step as listed below:  
**1. Confirm Auto Effluent Set Change**

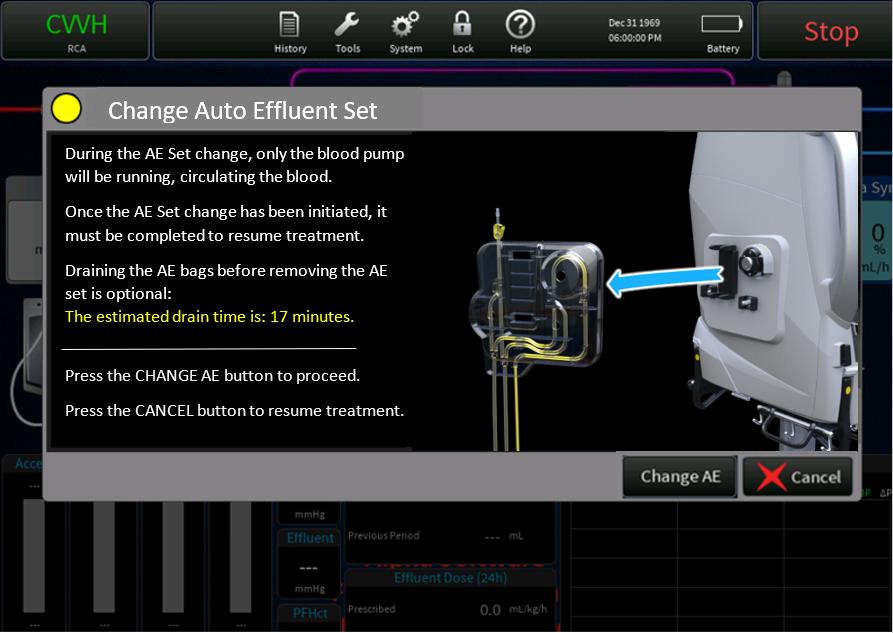
* Inform the user that once they confirm they want to change the AE set, they will not be able to resume treatment until it is complete.
* The dialog should inform the operator that only the blood pump will be running during the change.
* The dialog will also show the estimated time it will take to drain the AE bags.
  + This number will be dynamic depending on the amount of fluid currently in the AE bags.
* Provide a Confirmation button that will initiate the first step of the process.
* Provide a Cancel button to take them back to the operations screen

Figure 2 - Proposed Confirmation Dialog to Initiate AE Set Change

1. **Drain Auto Effluent Bags**

* Provide an option to the user to confirm if they wish to Drain the AE bags.
* Display the status dialog with estimated time remaining until bags are drained.
* Provide an option to pause/resume the drain.
* Provide an option to cancel the drain if they wish to discard the bags with any remaining fluid.
* A screenshot of a computer

  Description automatically generatedA screenshot of a computer

  Description automatically generatedWhen the drain is complete or canceled, the next step in the process will be displayed.

Figure 3 - Proposed AE Drain Yes/No Pop-Up

Figure 4 - Proposed Pause Dialog for AE Drain Option

A screenshot of a computer

Description automatically generated

Figure 5 – Proposed AE Drain Resume/Cancel

1. **Clamp and Disconnect Auto Effluent Lines**

* Clamp the end of the main filter set effluent line.
* Clamp the connector at the top of the AE set.
* Disconnect the main filter effluent connection from the top of the AE set.

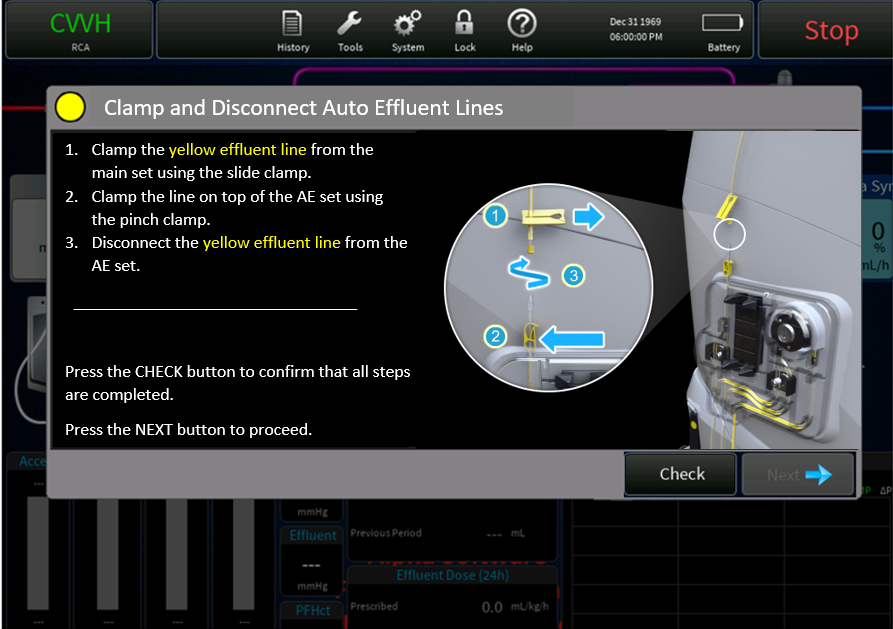


Figure 6 - Proposed AE Clamp and Disconnect Step

1. **Clamp AE Drain Line**

* Clamp the AE drain line.A screenshot of a computer

  Description automatically generated

Figure 7 - Proposed AE Clamp Drain Line Step

1. **Unload Auto Effluent Set and Bags**

* Press “Unload Set” to unload the AE set from the loader
* Remove both AE fluid bags
* Remove the set from the loader and discard the set and attached bags
* User confirmation when all steps are completed

A screenshot of a computer program

Description automatically generated

Figure 8 - Proposed AE Unload and Discard Step

1. **Scan New Auto Effluent Disposable**

* Remove new AE disposable from packaging and scan the barcode on the set.
* Automatically moves to next step once scan is recognized.
* Provide information and a Next button to continue if scanning fails.
* Similar to setup workflow where the user has to attempt to scan the set, or a timeout must occur before.

A screenshot of a computer

Description automatically generated*Note that we do not need to add the “select set” step if a scan fails since there is only 1 option for this change.*

Figure 9 (a) - Proposed Scan Set Dialog

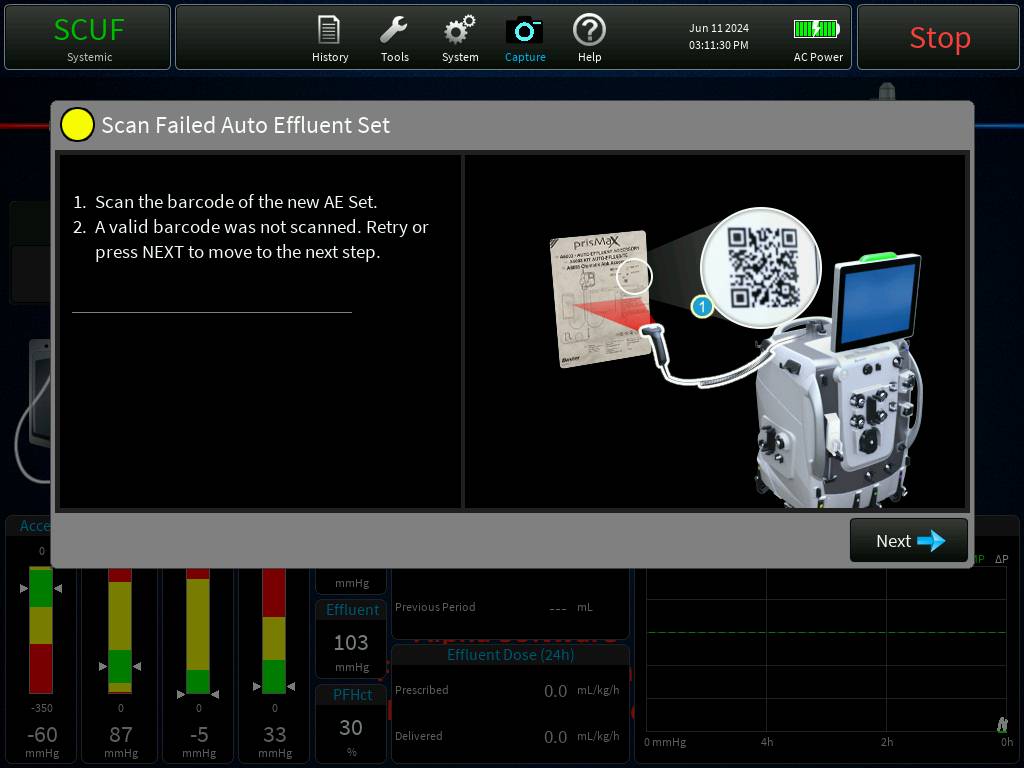


Figure 9 (b) - Proposed Scan Failed Dialog

1. **Load New Auto Effluent Set**

* Place the new set on the loader.
* Press “Load Set” button when ready to load.
* Automatically move to next step when loaded.

A computer screen shot of a computer program

Description automatically generated

Figure 10 - Proposed AE Load Set Dialog

1. **Check Tubing Alignment**

* Check to ensure the tubing segments seated properly in the pinch valves
* Press “Unload Set” button if tubing segments are NOT properly seated
  + This will bring the user back to the previous screen
* Press “Next” button if loading was successful
  + A screenshot of a computer program

    Description automatically generatedThis will bring the user to the next step

Figure - Proposed Tubing Alignment Check Step

1. **Hang Auto Effluent Bags**

* Hang both bags on the proper scales.
  + Use same/similar workflow as in setup with bag detection sequence for the scales.
* Enable the next button when the system detects the bags have been hung properly.
* A computer screen shot of a machine

  Description automatically generatedUser confirmation to move to next step.

Figure 12 - Proposed Hang Bags Dialog

1. **Connect Auto Effluent Extension**

* Step to add additional extension line
  + Don’t show in image due to confusion encountered in HF Formative study
* User confirmation to move to next step

Figure 13 - Proposed Extension Line and Drain Line Dialog



1. **Connect and Unclamp Auto Effluent Set**

* Connect yellow effluent line to the AE set
* Unclamp the lines and connectors
* Instruct the operator to check all connections again before continuing treatment
* Press the “Start Treatment” button when ready to resume treatment

Figure 14 - Proposed Line Connection and Continue Dialog

A screenshot of a computer

Description automatically generated

### Internal Processing Changes

A high-level overview of the needed SW changes needed for each step is listed below:

1. **Confirm Auto Effluent Set Change**

This step will include a GUI change to display the dialog. The number of minutes it will take to drain the AE bags will be calculated and displayed on the screen as well.

If the “Change AE” button is pressed, the SW will set the safe state to stop all the fluid pumps (including the syringe if RCA is being used). The blood pump will continue to recirculate blood.

1. **Drain Auto Effluent Bags**

The GUI will reuse the existing “AE Drain” workflow that already exists for end mode. The same options to pause, resume, and cancel the drain will be available.

If the drain option is selected, the SW will leverage the existing AE Drain routine handled by the priming model. The main change to this is that the priming model will need to have a special case that will be able to run the drain pump while the safe state is set to stop the other pumps.

1. **Clamp and Disconnect Auto Effluent Lines**

This step will be purely a GUI change.

1. **Clamp AE Drain Line**

This step will be purely a GUI change.

1. **Unload Auto Effluent Set and Bags**

The SW will need to be modified to move the AE pinch valve and also allow the AE loader to extend and the AE drain pump to spin to unload the AE set during Treatment.

There will also need to be a check done to determine if the bags have successfully been removed from the scales before enabling the “Next” button.

1. **Scan New Auto Effluent Disposable**

This will use a similar workflow to the scanning process in Setup. The only difference is that the user will not have to select the AE set from the dropdown menu if the scan happens to fail. The logic for a failed scan or a timeout will be the same as in setup where a “Scan Failed” button will be displayed to allow the user to continue.

1. **Load New Auto Effluent Set**

Again, The SW will need to be modified to allow the AE loader to extend/retract and the AE drain pump to spin to load/unload the AE set during Treatment.

1. **Check Tubing Alignment**

The SW will need to be modified to allow the AE loader to extend and the AE drain pump to spin to unload the AE set during Treatment. If the user unloads the set the instructions from step 7 should be displayed again.

1. **Hang Auto Effluent Bags**

For this step SW will need to be modified to suppress the AE scale open alarms.

The same check that is done in Setup to detect the correct weight change is seen on the scales will be done before enabling the “Next” button.

The LED lights on the scale will flash during this step as well until the bags are successfully hung.

1. **Connect Auto Effluent Extension**

This step will be purely a GUI change.

1. **Connect and Unclamp Auto Effluent Set**

This step will be purely a GUI change.

* A sanity check to ensure the bags were hung on the scale, loader was retracted, etc. was considered for this step but the ultimate decision was to allow them to resume treatment and let any applicable alarms guide them.

Once treatment is resumed, the system will automatically attempt to fill the AE lines to remove the air in the new set. During this time there will be no feedback on the scales, so SW will have to temporarily compensate for that. Should any issues be encountered during or after this “filling” process, the system will raise the corresponding weight alarm and/or collect any uncertainty calculated during the step.

In addition to these main changes, the following subset of changes will be made:

* Add a “Change Set” button to the T2119 - AE Set Life Exceeded alarm
  + Pressing this button will initiate the same workflow as stated above
* Reuse AE for Same Patient
  + Update limits to allow the reuse of an AE set up to 100% of its life or revolutions (previously set to 55% of set life or revolutions)
* The recirculation state will NOT be allowed while an AE set change is ongoing to simplify the workflow.
* Therapy recovery will NOT be allowed if an AE set change is ongoing (no change to processing since safe state will be set)
* The effluent drain over torque alarms will be modified to become a therapy alarm instead of a BIOT alarm while the set is un/loading. This is done in case the tubing catches on the rotor and stops the pump. The same implementation is done during set loading in setup.

### Safety Processor Changes

The safety processor is responsible for making sure unexpected situations aren’t encountered during the Treatment phase. Specifically relating to this change, it monitors the pinch valve positions and the loader positions. Since the CP will now be allowing these to change to “unexpected” positions during treatment, the SP needs to be updated to consider this behavior as expected during the AE set change.

There will be no interface message change between the CP and SP as the decision was to keep the 2 processors as independent as possible. Instead, the logic in the SP will be updated to stop fault detection for the AE pinch valve positions if the effluent pump is stopped.

**Modified SP alarms**

**S1708 / SDS-2460**

Original requirement:

The SP will fault if Patient is attached, AED is enabled, and AED or EFF pinch valves are in a center position (neither CCW nor CW) for 5 seconds or greater.

Modified requirement:

The SP will fault if Patient is attached, AED is enabled, Effluent pump is running, and AED or EFF pinch valves are in a center position (neither CCW nor CW) for 5 seconds or greater.

Justification:

To unload and load the AE-set during therapy (when the patient is attached, and AED enabled) the AED and EFF pinch valves will have to be in the center position for longer than 5 seconds. This SP alarm is in place to prevent filling and/or emptying of both effluent bags at the same time to protect the patient from excessive fluid gain or loss due to an incorrect response by the CP.

Since the effluent pump is not running during the AE-set change (only the drain pump needs to run to unload the AE-set), the effluent pump was added to the alarm definition. The modified alarm will still prevent filling of both bags at the same time, which is critical for patient fluid gain / loss, but it will not be triggered when the AE-set is being changed.

**S1792 / SDS-2445**

Original requirement:

The SP will fault if:

A patient is attached, and AE is disabled, and the Effluent pump is running, and the Effluent scale is open for longer than 5 seconds.

Or

A patient is attached, and AE is enabled, and the Effluent or drain pumps are running, and the Effluent or drain scales are open for longer than 5 seconds.

Modified requirement:

The SP will fault if:

A patient is attached, and AE is disabled, and the Effluent pump is running, and the Effluent scale is open for longer than 5 seconds.

Or

A patient is attached, and AE is enabled, and the Effluent pump is running, and the Effluent or drain scales are open for longer than 5 seconds.

Justification:

To unload and load the AE-set during therapy (when the patient is attached, and AED enabled) the effluent and drain scales will be open for longer than 5 seconds. This SP alarm is in place to check that fluid pumps are not running while a scale is open and a patient is attached, because the scales only meet their accurate requirements in the closed position.

During treatment, the drain pump is only running when the effluent pump is also running. Since the effluent pump is not running during the AE-set change, the drain pump can be removed from the alarm definition. Maintaining the effluent pump in the alarm definition will ensure that no patient fluid balance changes take place while the scales are open.

**S1019 / SDS-2414**

Original requirement:

The SP will fault if the following conditions are true for greater than or equal to 10s:

* The calculated PFR error is greater than (110% of the gain loss limit +5g)
* The effluent pump is running
* Patient is attached

*Notes:*

1. *This only applies to CRRT.*
2. *Scales and pumps which are unused based on selected therapy and AE status will be excluded from the PFR error calculation.*
3. *Makeup rate will account for body weight.*

Modified requirement ():

The SP will fault if the following conditions are true for greater than or equal to 10s:

* The calculated PFR error is greater than (110% of the gain loss limit +5g)
* The effluent pump is running
* Patient is attached
* Therapy type is CRRT

*Notes:*

1. *Scales and pumps which are unused based on selected therapy and AE status will be excluded from the PFR error calculation.*
2. *Makeup rate will account for body weight.*

Justification:

This modification clarified the requirement by moving one of the notes into the requirement definition.

**Related SP alarms**

**S1828 / SDS-2463**

The SP will fault if patient is attached, and AED enabled while the pinch valves were set to use only the rear effluent bag and either the effluent or AED pump has been running for longer than 5 seconds.

**S1829 / SDS-2464**

The SP will fault if patient is attached, and AED enabled while the pinch valves were set to use only the front effluent bag and either the effluent or AED pump has been running for longer than 5 seconds.

## Use Case Analysis

The following actors are common to several of the use case definitions:

* Operator – typically a nurse, who either initiates self-tests, performs manual adjustments of the liquid level, enables or disables automatic leveling, and responds to alarms raised by the monitor.
* PrisMax monitor – the PrisMax system, in particular the User Interface and components such as pumps, loaders, etc.

| **Name** | **Preconditions** | **Sequence** | **Variations** | | **Expected Outcome** |
| --- | --- | --- | --- | --- | --- |
| Initiate AE Set Change | System is running a CRRT treatment with an AE set | Operator taps on the Ops screen to display the “Change Screen”. Operator then selects Change AE option | None | | AE set change workflow will begin |
| Initiate Effluent Bag Change | System is running a CRRT treatment without AE | Operator taps on the Ops screen to display the “Change Screen”. Operator then selects Effluent bag change option | None | | Effluent bag change workflow will begin |
| AE Set Change Confirmation | System is running a CRRT treatment with an AE set | Operator initiates the AE set change from the “Change Screen” | 1. Select Confirm (RCA Anticoag) 2. Select Confirm (Systemic Anticoag) 3. Select Cancel | | 1. The system enters a safe state that stops the fluid pumps (Ca infusion stops with RCA) 2. The system enters a safe state that stops the fluid pumps, but systemic syringe will keep delivering 3. AE set change dialog closes and operator is brought back to the operations screen with treatment resumed |
| AE Drain | AE Set change is confirmed, and the drain sequence is being performed | Operator is shown a progress dialog indicating the time remaining for the drain with option to pause | 1. No actions selected 2. Pause Selected 3. Resume Selected 4. Cancel Selected | | 1. The progress timer counts down to 0 and the next step in the set change process is displayed 2. Drain sequence is paused and timer stops counting down 3. Drain sequence resumes and the timer continues counting down 4. Drain sequence is terminated.   AE bags may not be drained of all fluid.  Next step in the AE set change process is displayed |
| Clamp and Disconnect AE and Effluent Lines | AE set change is in progress and the drain sequence step has completed | Operator is shown instructions to clamp the applicable lines and disconnect the effluent line on the main set from the AE set | None | | Operator can select the “Next” button when all steps are completed, and the UI will display the next step |
| Unload Original AE Set and Discard Set, bags and lines | AE set change is in progress and the clamp and disconnect lines step is complete | Operator presses the Unload Set button | 1. Full unload 2. Partial unload 3. No unload | | 1. The Next button is enabled once the loader is completely extended 2. The Next button is disabled if the loader does not completely extend.   Alarm is raised indicating set unload failure   1. The Next button is disabled while the set is still loaded |
| Scan New AE Set | AE set change is in progress and the set is unloaded.  AE bags, Set and lines are discarded. | Operator scans a new AE set barcode | 1. Scan pass 2. Scan fail 3. Scan timeout | | 1. The next step is automatically displayed if a new set has been successfully scanned 2. The Next button becomes available, and the instruction text is updated to say that the scan failed 3. The Next button becomes available, and the instruction text is updated to say that the scan failed |
| Load New AE Set | AE set change is in progress and the new set has been scanned | Operator follows on screen instructions to load the new set and presses the Load Set button | 1. Set Loaded 2. Set Partially Loaded | | 1. Set is successfully loaded, and the next step is automatically displayed 2. Set is partially loaded with the Load button enabled   Alarm is raised indicating set load failed |
| Confirm AE Tubing | New AE set is loaded | Operator presses “Load Set” and set loading completes | 1. Set Loaded as Expected 2. Set not loaded as expected | | 1. User can press Continue to go to next step 2. User has option to unload the set and go back to previous step |
| Hang New AE Bags | AE set change is in progress and the new set is fully loaded | Operator follows instructions to hang new AE bags | 1. Both Bags Correctly Hung 2. 0 or 1 Bag Hung | | 1. Next button is enabled when both bags are on the correct scales 2. Next button is disabled if both bags are not on their correct scales |
| Connect Extension Line | AE set change is in progress and the new set loaded and bags installed | Operator follows on screen instructions to connect/route the drain line | None | | Operator can optionally add an extension line and is instructed how to connect the drain line |
| Connect New AE Set | AE set change is in progress and the new set loaded and bags installed | Operator follows on screen instructions to make the remaining connections and selects the Confirm All button | None | | Start Treatment button is enabled when the Confirm All button is selected |
| AE Set Resume Treatment | AE set change is in progress and the new set is installed and all connections confirmed | Operator presses the Continue button | None | | Set change is complete, AE lines are automatically filled, and Treatment is resumed |
| Blood Pump Alarm While Set Change in Progress | AE set change is in progress | Raise an alarm that stops the blood pump | 1. Pressure alarm 2. Air in Blood Alarm with air removal attempt 3. ECCOR/TherMax + Air in Blood | | 1. Alarm is declared on top of the AE set change instructions.   AE set cannot be drained/loaded/unloaded while alarm is active   1. After air removal is complete and the air in blood alarm is cleared, the AE set change dialog is displayed in the same state it was before the alarm raised 2. Air detect alarm is raised and system requires user confirmation to clamp the return inlet line before attempting air removal |
| Fluid Pump Alarm while Set Change in Progress | AE set change is in progress | Raise an alarm that has a safe state of STOP\_FLUID\_PUMPS | None | | Alarm is declared on top of the AE set change instructions.  AE set can be drained/loaded/unloaded while the alarm is docked |
| Effluent Drain Pump Over torque Alarm | AE set change is in progress | Operator presses button to load/unload the set and then forces the AE pump to stop | 1. Loading 2. Unloading | | 1. Alarm T2331 AEE Pump Fail Setup is raised.   Alarm can be cleared, and operator can retry loading   1. Alarm T2331 AEE Pump Fail Setup is raised.   Alarm can be cleared, and operator can retry unloading |
| AEE Loader Motor Failure | AE set change is in progress | Operator starts to load/unload the set but stops it before it can get to the desired position | 1. Loading 2. Unloading | | 1. Alarm T1138 AEE Loader Motor Fail is raised.   Alarm can be cleared, and operator can retry   1. Alarm T1138 AEE Loader Motor Fail is raised.   Alarm can be cleared, and operator can retry |
| AE Set Change Complete, Bags Incorrect | AE set change has just completed and therapy about to resume | Operator hangs bags incorrectly as defined in variation and then clicks button to resume treatment | 1. Bags Swapped 2. No bags 3. Bags not empty but on correct scale | | Flow problem alarm declares  Flow problem alarm declares  Fluid pump model accounts for new weights but does not declare an alarm and no additional weight error is observed |
| AE Set Change Complete, Line Clamped | AE set change has just completed and therapy about to resume | Operator clamps the AE lines and then clicks the button to resume treatment | 1. Clamp main effluent line 2. Clamp effluent drain line 3. Clamp effluent fill line 4. Disconnect effluent line from AE set | | 1. Flow problem alarm declares 2. Flow problem alarm declares 3. Flow problem alarm declares 4. Flow problem alarm declares |
| AE Set Change in Progress, transition states | AE set change is in progress | Operator presses End button and attempts to move to a new therapy state while set change is in progress | 1. End mode 2. Blood Return 3. Recirc | | 1. End mode is allowed, but no option to reuse AE 2. Blood return is allowed 3. Recirc (blood and saline) are not allowed   In all variations the user should not be allowed to select the reuse AE option |
| AE Set Life Exceeded Alarm | AE Set Life Exceeded alarm T2119 is raised during treatment | Operator presses “Change Set” button | 1. Change AE 2. Alarm Off 3. Discard Set | | 1. The new AE workflow is initiated and the alarm T2119 is cleared once the user confirms the AE workflow 2. Alarm is overridden and treatment continues 3. Alarm is cleared and user is brought to End mode |
| AE Set Life Exceeded Alarm Followed by Set Change | AE Set Life alarm T2119 declared during treatment and the operator successfully changed the set | User ends treatment | 1. New set has been used for < 1 hour 2. New set has been used for > 144 hours | | 1. User is allowed to reuse AE set in End mode 2. User is NOT allowed to reuse AE set in End mode |
| AE Set Time After AE Set Change | System in CRRT Treatment with AE | Operator initiates an AE set change | 1. User completes the set change 2. User cancels the set change | | 1. AE Set usage time is reset 2. AE set usage time is NOT reset |
| AE Set Therapy Recovery | System in CRRT Treatment with AE | Operator initiates an AE set change | 1. AE change is completed, and a system halt occurs  2. AE change is NOT completed, and a system halt occurs | | 1. Therapy Recovery is allowed, and all set life data is correctly restored on continuation of Treatment  2. Therapy Recovery is NOT allowed |
| Bag change attempt during AE Set Change | AE set change is in progress | User opens a scale to initiate a bag change while AE set change is in progress | 1. Bag change complete 2. Scale closed | | Scale open alarm declares over AE workflow.   1. Bag change completes and AE change continues 2. Scale open alarm clears, and AE change continues |
| TherMax flow parameters during AE Set Change | System in CRRT Treatment with AE | Operator initiates an AE set change | 1. N/A | Flow rate inputs to TherMax are updated to 0 when the change is initiated, and the fluid pumps stop | |

## HFE Assessment

This change affects user interaction with the device, changes the user facing Graphical User Interface (GUI), and introduces a new feature (the ability to change the AE set mid-treatment). Since it is a change to the clinical user facing GUI, the addition of the feature will be analyzed with respect to use related risk. Subsequent HF activity will be based on this risk analysis and may include formative and summative (HF validation) testing.

## Risk Analysis

All modifications described in this CADV report will either decrease risk or not affect the risk of harm to the patient. There is no identified increase in risk or new hazards being introduced.

In the review of risk documentation, it was identified that there are 2 types of updates required to the risk file documentation.

* The first includes changes such as new and modified risk controls along with their traces created to address changes introduced with CADV8138.
* The other includes updates to the current version of the risk file to include existing risk controls that were previously captured in legacy risk file documents but were not fully captured in the current risk file. These updates are not connected to changes for SW3.4 and strictly for continuous improvement of the RACT8000 document. See PFAL-2416 for additional detail.

The HSHA-AE-THERAPIES [R9] was reviewed for Hazard relevant to the modifications described in this CADV report. These hazard definitions are carried into the RACT8000 [R1] where they are further defined with sequence of event descriptions and applicable risk control measures that demonstrate how the risks of each hazard are being mitigated. Applicable Risk Control Measures are highlighted in **Table 1** below. Refer to [R1] for the Hazards that the **Table 1** RCMs mitigate.

Risk control measures from current and legacy risk documentation were assessed for relevance.

* Relevant risk control measures from RACT8000 [R1] are identified in **Table 1**.
* Modification to existing Risk control measures as a result of the changes outlined herein are shown in **Table 2**
* New risk control measures created as a result of the changes outlined herein are shown in **Table 3**

All RCMs trace to product requirements (PRDs). Non-labelling linked PRDs affected by CADV8138 will be verified as part of the change process. RCM's that have been affected by the CADV8138 changes (related, modified or new) have been noted as requiring testing in **Tables 1-3**. Other RCM's that were previously implemented in the product and verified, are being included for completeness but not impacted by this CADV change, therefore do not require regression testing.

Table 1 Related Risk Control Measures

|  |  |  |
| --- | --- | --- |
| **RCM ID** | **Risk Control Measure** | **(Regression) Testing Needed?** |
| RCM-2940 | Information for safety reminds the user of potential treatment delays if the bag handles are lost. | No |
| RCM-1807 | Information for safety reminds that scale perturbations, floor vibrations or swinging bags are possible sources for scales weight alarm. | No |
| RCM-1868 | Software design allows a bag to be changed even if the bag is not empty. | Yes |
| RCM-1874 | Information for safety reminds us to verify that bags are hanging freely without touching other bag or stand and to not disturb the scales and bags e.g. not to compromise the scale weight by foreign objects. | No |
| RCM-2550 | The weight control loops (infusion and removal) are resistant to (and accurate after) scale perturbations such as floor vibrations and bag swinging. | Yes |
| RCM-2532 | Information for safety instructs Operator to route AE drain line to avoid line obstructions. | No |
| RCM-1858 | Control unit design compliance with specified IEC 60601-1 version for electrical and mechanical requirements. | No |
| RCM-1733 | Software monitors the actual weight change for each scale and compares measurement with the expected weight change over a specified time period. Protective action is taken if the difference is greater than specified tolerance. Protective action is also taken if the difference error occurs repeatedly outside of specification. | Yes |
| RCM-1833 | Software measures total patient fluid removal deviation. If the maximum allowed deviation limit (set by the Operator during setup) is reached during a specified time rang e, protective action is taken and suspends the therapy. | Yes |
| RCM-1834 | The PrisMax software accumulates the errors associated with flow problem alarms that occur during a single treatment and takes protective actions when the error becomes excessive | Yes |
| RCM-1897 | Software design prevents fluid pumps from being started from a stop condition until all scales are stable.  Protective action is taken if a specified time-out is reached. | Yes |
| RCM-1736 | Software verifies the weight of each solution bag when installed or changed according to the default specified weight. Protective action is taken if the measured weight is outside of specified tolerance. | Yes |
| RCM-1875 | Information for safety informs the Operator of possible flow problem alarm causes and how to correct the problem. | Yes |
| RCM-1748 | Software identifies and verifies entered disposable set by reading the bar code. Protective actions are taken if the bar code is unreadable or the disposable set differs from the entered or is incorrect for the treatment. | Yes |
| RCM-1702 | Control unit hardware, software, and disposables are designed to allow automated loading enabling correct installation of pump segments in their raceways and lines in pinch valves | Yes |

Table 2 Existing RCMs to be replaced with modified RCMs for SW3.4

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **RCM ID** | **Original Text** | **New RCM ID** | **New RCM Text** | **Risk ID** | **(Regression) Testing Needed?** |
| RCM-2994 | Software limits makeup flow rate based on patient body weight, user set PFR rate and accumulated PFR downtime. Note: Makeup temporarily increases the PFR to compensate for PFR downtime due to alarms and bag changes. | RCM-3228 | Software limits makeup flow rate and volume based on patient body weight, user set PFR rate and accumulated PFR downtime. Note: Makeup temporarily increases the PFR to compensate for PFR downtime due to alarms, bag changes and AE set changes. | PMX-RACT-553  PMX-RACT-554  PMX-RACT-555  PMX-RACT-556  PMX-RACT-557  PMX-RACT-558  PMX-RACT-552  PMX-RACT-551  PMX-RACT-550  PMX-RACT-549  PMX-RACT-548  PMX-RACT-547  PMX-RACT-546  PMX-RACT-545 | Yes |
| RCM-1839 | Information for safety instructs the handling steps for change of a full effluent bag or empty solution bag. | RCM-3229 | Information for safety instructs the handling steps for change of a full effluent bag, empty solution bag, or AE set. | PMX-RACT-129  PMX-RACT-109  PMX-RACT-80  PMX-RACT-143  PMX-RACT-572 | Yes |
| RCM-3047 | Software verifies the effluent scale weight after an effluent bag installation or change. Protective action is taken if effluent bag weight is outside of specified allowed tolerance. | RCM-3230 | Software verifies the effluent scale weights after an effluent bag or AE set installation or change. Protective action is taken if effluent bag weight or auto-effluent bag weights are outside of specified allowed tolerance. | PMX-RACT-255  PMX-RACT-256  PMX-RACT-653  PMX-RACT-654  PMX-RACT-655  PMX-RACT-257  PMX-RACT-253  PMX-RACT-254  PMX-RACT-656  PMX-RACT-657  PMX-RACT-658  PMX-RACT-659  PMX-RACT-344  PMX-RACT-660 | Yes |
| RCM-1828 | Software verifies the empty effluent bag weight and takes protective action if bag weight is outside of specified tolerance | RCM-3231 | When using a effluent bag or AE set, software verifies the empty effluent bag weights and takes protective action if bag weights are outside of specified tolerance. | PMX-RACT-344  PMX-RACT-660 | Yes |
| RCM-1829 | Software measures the increasing Effluent bag weight and takes protective action when the weight has reached the ‘full bag’ specified weight. | RCM-3232 | When using a effluent bag or AE set, software measures the increasing Effluent bag weight or auto-effluent bag weights and takes protective action when the weights reach the ‘full bag’ specified weight. | PMX-RACT-109  PMX-RACT-344  PMX-RACT-660  PMX-RACT-80  PMX-RACT-143 | Yes |
| RCM-1699 | Information for safety reminds that the disposable set is for single use only and not for reuse. | RCM-3233 | Information for safety reminds us that the disposable filter set is for single use only and not for reuse. | PMX-RACT-696 | Yes |

Table 3 New Risk Control Measures

|  |  |  |  |
| --- | --- | --- | --- |
| **RCM ID** | **Original Text** | **Risk ID** | **(Regression) Testing Needed?** |
| RCM-3218 | Information for safety instructs about AE set preparation and connection when changing an AE set during therapy. | PMX-RACT-109  PMX-RACT-80  PMX-RACT-143 | Yes |
| RCM-3219 | Information for safety instructs the Operator to change disposable sets in case of leaks or visible damage | PMX-RACT-109  PMX-RACT-80  PMX-RACT-143 | Yes |

## Product Requirement Analysis

*This section should contain, as applicable, modified, new and deleted TRS/CRS requirements for the device affected by the change. Add or delete tables as required.*

Table 4 Related CRS

|  |  |
| --- | --- |
| ID | Requirement Text |
| CRS-35 | PrisMax shall provide the capability of determining the type of installed disposable set using the barcode scanner. |
| CRS-39 | PrisMax shall manage the Auto Effluent Accessory such that it does not impact prescribed effluent, or ultrafiltration, or patient fluid removal targets |
| CRS-130 | PrisMax shall not inhibit the ability of the Auto Effluent Accessory to withstand no less than 560,000 auto effluent pump revolutions |
| CRS-131 | PrisMax shall go from selection of the New Patient soft key to connection of patient in the same or less time than PrisMax V2 for all similar therapy types. This includes use of either manual or auto effluent modes. |
| CRS-176 | PrisMax shall provide a barcode reader to allow users to automate disposable inputs for set selection of Baxter blood and auto effluent sets. |
| CRS-163 | PrisMax shall not inhibit the Automatic Effluent (AE) accessory from functioning for more than 72 hours and up to 6 days |
| CRS-154 | PrisMax shall provide an optional Automatic Effluent emptying capability with no stoppage of treatment time. |

**Table 5 Modified CRS**

|  |  |  |  |
| --- | --- | --- | --- |
| **ID** | **Original Text** | **Proposed Text** | **Rationale** |
| CRS-271 | PrisMax shall provide the capability to empty both Auto Effluent Bags at the end of therapy. | PrisMax shall provide the capability to empty both Auto Effluent Bags at the end of therapy or during an Auto Effluent Set Change in Treatment | Update to mention AE drain is available for new AE set change feature |

Table 6 New CRS

|  |  |  |
| --- | --- | --- |
| **ID** | **Proposed Text** | **Rationale** |
| CRS-300 | PrisMax shall provide the capability for the user to change the AE disposable (set, bags, and tubing) during Therapy Mode. | High level Req for AE change in treatment |

Table 7 Related TRS

|  |  |
| --- | --- |
| ID | Requirement Text |
| TRS-281 | The PrisMax system shall allow the operator to pause the draining of the AE disposable accessory during treatment. |
| TRS-129 | The PrisMax system shall have a semi-automatic mechanism for loading and unloading the disposable set and AE disposable accessory i.e. to load and unload the line segments into the peristaltic pumps. |

Table 8 Modified TRS

|  |  |  |  |
| --- | --- | --- | --- |
| **ID** | **Original Text** | **Proposed Text** | **Rationale** |
| TRS-295 | PrisMax shall provide the capability to empty both Auto Effluent Bags at the end of therapy. | PrisMax shall provide the capability to empty both Auto Effluent Bags at the end of therapy or during an Auto Effluent Set Change in Treatment | Update to mention AE drain is available for new AE set change feature |

Table 9 New TRS

|  |  |  |
| --- | --- | --- |
| **ID** | **Proposed Text** | **Rationale** |
| TRS-341 | PrisMax shall support changing of the Auto-Effluent disposable (set, bags, and tubing) upon the operator’s request | High level Req for AE change in treatment |

## System Requirement Analysis

*This section should contain, as applicable, modified, new and deleted system (PRD) requirements for the device affected by the change. Add or delete tables as required.*

Table 10 Related PRD

|  |  |  |
| --- | --- | --- |
| ID | Product Requirements Document - Monitor | Out-links |
| PRD-4803 | 3 General |  |
| PRD-4806 | 3.3 Architectural description |  |
| PRD-1799 | 3.3.1 Monitor Modes |  |
| PRD-1804 | 3.3.1.2 Start Mode |  |
| PRD-4710 | The capability to resume a therapy session shall only be available if at the time of the unexpected shutdown the Monitor was actively performing treatment. | CRS-292    TRS-128    RCM-3109    RCM-3110 |
| PRD-2980 | 4 Features/Capabilities |  |
| PRD-3118 | 4.3 Auto Effluent (AE) |  |
| PRD-3119 | The Monitor shall support an Auto Effluent accessory, which allows for automatic emptying of the effluent bag for more than 72 hours. | CRS-130    CRS-163    TRS-42    TRS-215    TRS-225    TRS-267    ICD-2811 |
| PRD-2284 | The Monitor shall have an Auto Effluent (AE) function with no stoppage time of treatment. | CRS-39    CRS-154    CRS-164    TRS-225 |
| PRD-3127 | The Monitor Auto Effluent feature shall be capable of being temporarily suspended. | CRS-2    CRS-164    TRS-281 |
| PRD-195 | 4.5 Safety |  |
| PRD-676 | 4.5.1 Alarms |  |
| PRD-679 | 4.5.1.1 General |  |
| PRD-2051 | The Monitor shall trigger an incorrect weight change alarm and guide the user for resolution, if detecting a weight change on a scale that is different from the expected weight change. | CRS-161    TRS-180 |
| PRD-3711 | 4.5.1.5 System Alarms |  |
| PRD-3733 | PrisMax software shall take protective action if a ’non flow’ condition is detected. | RCM-1894 |
| PRD-3727 | The Protective System (CP and SP) shall monitor the position of the pinch valves (dialysate, replacement, Automatic Effluent (AE)) and take protective action if the valves are in an incorrect position for the current operation of the system. | RCM-1703 |
| PRD-3740 | The Protective System (CP) shall monitor for occlusions on the AE extension line during operation. | RCM-2535 |
| PRD-4832 | 4.7 GUI |  |
| PRD-3652 | 4.7.2 GUI labeling |  |
| PRD-3648 | The GUI and labeling shall inform the operator if the return line is misconnected during prime when re-using the AE accessory. | RCM-2942 |
| PRD-4801 | 7 Qualities/Attributes |  |
| PRD-2425 | 7.3 Human Factors |  |
| PRD-4838 | 7.3.1 Information Portrayal |  |
| PRD-4068 | The Monitor shall display the disposable set usage time to the operator. | TRS-138 |
| PRD-4839 | 7.3.2 Required Operator Interactions |  |
| PRD-4754 | In the case of a confirmed barcode scanner failure trying to scan the circuit set, the software shall provide the user with the ability to manually select the set type for confirmation with the prescription configuration. | CRS-10    RCM-1741 |
| PRD-4841 | 7.3.4 Ease of Use |  |
| PRD-2581 | The Monitor GUI shall allow the user to effect a change by touching the displayed schematic elements. | CRS-141 |
| PRD-2452 | 7.7 Labeling |  |
| PRD-1222 | 7.7.4 User Manual |  |
| PRD-2670 | 7.7.4.2 Setup |  |
| PRD-3639 | Labeling shall instruct the Operator to place AE line where it cannot be occluded by bystander stepping on it or by other equipment rolling on it. | RCM-2532 |
| PRD-2442 | 7.8 Mechanical and Electrical |  |
| PRD-4828 | 7.8.1 Components |  |
| PRD-1857 | 7.8.1.1 Motors |  |
| PRD-1851 | 7.8.1.1.3 Loader Motor |  |
| PRD-2123 | The Monitor shall have a semi-automatic mechanism (loader) for loading and unloading the CRRT disposable sets and AE accessory.  i.e. To load and unload the line segments into pumps (except for the anticoagulation syringe pump) with the disposable set attached to the machine. | CRS-4    CRS-10    TRS-129    RCM-1702 |
| PRD-2510 | 7.8.1.5 Weight Scales |  |
| PRD-3406 | The AE scale shall be provided with a static hook that interfaces with the AE bag. |  |
| PRD-1853 | 7.8.1.12 Code Reader |  |
| PRD-2135 | The Monitor shall include a handheld code reader to read data from the following:  - Patient ID  - Disposable sets  - Auto-Effluent (AE)  - Blood warmer accessories  - GUI on the Display Assembly | CRS-10    CRS-176 |

Table 11 Modified PRD

| ID | Product Requirements Document - Monitor | Proposed Text | Out-links | Rationale |
| --- | --- | --- | --- | --- |
| PRD-2980 | 4 Features/Capabilities | N/A - Existing Header |  |  |
| PRD-3118 | 4.3 Auto Effluent (AE) | N/A - Existing Header |  |  |
| PRD-3126 | The Monitor Auto Effluent feature shall empty effluent without disruption of effluent flow.  *Note: A pause while switching PVs between bags is acceptable.* | The Monitor Auto Effluent feature shall empty effluent without disruption of effluent flow.  *Note: A pause while switching PVs between bags or during an AE Set change is acceptable.* | CRS-39  CRS-164  TRS-225 | Updated note for clarity |
| PRD-3141 | The Monitor Auto Effluent accessory shall be changed when its life is exceeded.  *Note: AE set is only changed when a front set is being changed.* | The Monitor shall provide an option to change the Auto Effluent accessory, when its set life is exceeded. | TRS-42  TRS-267 | Remove note since AE set can now be changed without replacing front set |
| PRD-3378 | The Monitor shall provide the capability to empty both the AE and Effluent bags at the end of therapy. | The Monitor shall provide the capability to empty both the AE and Effluent bags at the end of therapy or during an Auto Effluent Set Change in Treatment | CRS-2  CRS-271  TRS-295 | Update to include AE drain during set change |
| PRD-195 | 4.5 Safety | N/A - Existing Header |  |  |
| PRD-676 | 4.5.1 Alarms | N/A - Existing Header |  |  |
| PRD-679 | 4.5.1.1 General | N/A - Existing Header |  |  |
| PRD-4216 | The Monitor shall give the user the capability to change the syringe at any time during therapy and syringe empty alarms.  *Note: Exceptions are during air bubble detect alarm, and during bag changes.* | The Monitor shall give the user the capability to change the syringe at any time during therapy and syringe empty alarms.  *Note: Exceptions are during air bubble detect alarm, during bag changes, or AE Set changes.* | TRS-297 | Update note to include AE Set Change |
| PRD-3854 | The Protective System (CP) shall detect that the 1L AE bag and 5L AE bag have been hung in the correct positions during setup. | The Protective System (CP) shall detect that the 1L AE bag and 5L AE bag have been hung in the correct positions during setup or during an AE set change when in treatment | CRS-2  RCM-2931 | Update to indicate the same bag weight check will be performed during AE set change |
| PRD-3711 | 4.5.1.5 System Alarms | N/A - Existing Header |  |  |
| PRD-3729 | The Monitor shall warn the user if the set on the loader does not remain at the home position while the patient is connected | The Monitor shall warn the user if the set on the loader does not remain at the home position while the patient is connected  *With the exception being for the AE loader during an AE Set Change in Treatment* | RCM-3021 | Update to allow AE loader to move during set change |
| PRD-4818 | 4.6 Performance | N/A - Existing Header |  |  |
| PRD-4820 | 4.6.1 PFR Makeup | N/A - Existing Header |  |  |
| PRD-3816 | PrisMax shall limit the makeup rate flow based upon:  1) the user set PFR rate and  2) the patient’s body weight.  The makeup volume shall also be limited to 10 minutes of accumulated PFR downtime.  *Note: Makeup temporarily increases the PFR to compensate for PFR down time due to alarms and bag changes.* | PrisMax shall limit the makeup rate flow based upon:  1) the user set PFR rate and  2) the patient’s body weight.  The makeup volume shall also be limited to 10 minutes of accumulated PFR downtime.  *Note: Makeup temporarily increases the PFR to compensate for PFR down time due to alarms, bag changes, and AE set changes.* | CRS-106  TRS-39  RCM-2994 | Update note to include AE set change since Treatment will be paused |
| PRD-4832 | 4.7 GUI | N/A - Existing Header |  |  |
| PRD-3652 | 4.7.2 GUI labeling | N/A - Existing Header |  |  |
| PRD-3828 | Change Bag and Caution: Bag Empty screens shall instruct for handling steps (open scale, clamp/unclamp lines). | Change Bag and Caution: Bag Empty and AE set change screens shall instruct for handling steps (open scale, clamp/unclamp lines). | CRS-11  RCM-1839 | Update to include AE Set change |
| PRD-3903 | The software shall monitor for any unexpected weight increase on the scales. | The software shall monitor for any unexpected weight change on the scales | RCM-2949 | Change weight “increase” to “change” since it is valid for a weight decrease as well |
| PRD-2678 | 7.7.4.1.1 Warnings and Cautions | N/A - Existing Header |  |  |
| PRD-3636 | Labeling shall warn the user that PrisMax sets are single use, and that they shall not be reused. | Labeling shall warn the user that PrisMax filter sets are single use, and that they shall not be reused.  Note: This does not include the Auto Effluent Set | RCM-1699 | Clarification that this is only for the filter set, not AE |

Table 12 New PRD

| ID | Product Requirements Document - Monitor | Proposed Text | Out-links | Rationale |
| --- | --- | --- | --- | --- |
| PRD-2980 | 4 Features/Capabilities | N/A - Existing Header |  |  |
| PRD-3118 | 4.3 Auto Effluent (AE) | N/A - Existing Header |  |  |
| PRD-5019 |  | The Monitor shall provide the capability to replace the AE disposable (set and connected lines and bags) during an active treatment session | CRS-300 | New high-level requirement to support AE change feature |
| PRD-4979 |  | The Monitor shall temporarily pause the fluid pumps and allow the blood pump to run while an AE Set Change is in progress.  *Note that the AE Drain pump can still run to complete bag draining and set load/unloading* | CRS-300 | Stop fluid pumps during change but allow blood to recirculate |
| PRD-4975 |  | The Monitor shall provide the capability to reuse the AE disposable between treatments when Same Patient is selected | RCM-1766 | Adding to cover a gap in old requirements (not a new feature) |
| PRD-4832 | 4.7 GUI | N/A - Existing Header |  |  |
| PRD-3652 | 4.7.2 GUI labeling | N/A - Existing Header |  |  |
| PRD-4981 |  | The monitor shall perform a check to ensure the AE disposable is properly installed after an AE Set Change in Treatment.  The monitor shall provide step by step instructions (Draining AE bag, clamping lines, unloading/loading AE set etc.) involved in changing an AE accessory when in treatment | RCM-1702  RCM-1875  RCM-1894 | Check by fluid pump model to make sure set and bags are loaded correctly |
| PRD-4801 | 7 Qualities/Attributes | N/A - Existing Header |  |  |
| PRD-2425 | 7.3 Human Factors | N/A - Existing Header |  |  |
| PRD-4839 | 7.3.2 Required Operator Interactions | N/A - Existing Header |  |  |
| PRD-4976 |  | The Monitor shall display instructions to remove the AE disposable from the system during an Auto Effluent Set change | RCM-3218 | Tear down instructions |
| PRD-4977 |  | The Monitor shall display instructions to install the new AE disposable onto the system during an Auto Effluent Set change | RCM-3218 | Setup instructions |

# Sub-System Requirements Analysis (CA2)

*This section applies only if the proposed change affects project requirements. If this section does not affect project requirements, then complete this section with an explanation of why this phase does not apply.*

*This section should contain, as applicable, modified, new and deleted HRD/SRS/SDS/LRD requirements for the device affected by the change. Add or delete tables as appropriate.*

## Hardware Requirement Analysis

N/A

## Software Requirement Analysis

Table 13 Related SRS

|  |  |  |
| --- | --- | --- |
| ID | Software Requirements Specification | Out-links |
| SRS-7550 | 3 Components |  |
| SRS-7843 | 3.1 Loaders |  |
| SRS-2956 | Software shall drive the disposable set loader motor to take less than 20 seconds to load or unload a set. | PRD-2127 |
| SRS-6367 | Software shall ensure that the loader motors are working correctly to load/unload a set.  Note: motors are tested any time they are used | PRD-2066    PRD-3728 |
| SRS-6411 | Software shall allow loader motor movement to be interrupted, with the following options for resumption:  - resume the motion  - reverse the motion | PRD-3856 |
| SRS-7195 | Software shall monitor the position of each of the loader motors, and if their position changes from the commanded position, try to position them back to the commanded position for 5 seconds. | PRD-3729 |
| SRS-8035 | The software shall generate an alarm for a failure of a loader motor as follows:  Alarm is raised if any of the following conditions occur with a loader motor: loss of communications, failure to maintain position, or an invalid position reported.  The alarm priority is HIGH.  The automatic reaction is to halt the system. | PRD-2636 |
| SRS-7932 | Message Event: software shall generate Set Loaded and Set Unloaded event messages. | PRD-1861 |
| SRS-7552 | 3.2 Fluid and Blood Pumps |  |
| SRS-8025 | The software shall generate an alarm for a failure of a fluid pump as follows:  Alarm is raised if any of the following conditions occur with a fluid pump: loss of communications, failure reported by the pump hardware, incorrect movement.  Alarm is disabled for speed response or over torque fault during set load/unload.  The alarm priority is HIGH.  The automatic reaction is to halt the system. | PRD-2774    PRD-3264    PRD-3268    PRD-3761    PRD-3885 |
| SRS-9632 | The software shall generate an alarm for failure of the set tubing to correctly engage with a pump rotor as follows:  Alarm is raised if any of the following conditions occur with a fluid pump when it is being rotated during a load/unload operation: incorrect speed response or over torque reported.  The alarm priority is INFO.  The automatic reaction is to stop all pumps.  The alarm is cleared on operator acknowledgement. | PRD-3885 |
| SRS-7554 | 3.4 Scales and Bags |  |
| SRS-8023 | The software shall generate an alarm when the actual flow rate through a fluid pump is lower than expected as follows:  The alarm is raised if the measured flow rate is less than half the commanded flow rate.  The alarm priority is LOW.  The automatic reaction is to stop all fluid pumps.  The alarm is cleared on operator acknowledgement. | PRD-3733 |
| SRS-8542 | The software shall generate an alarm for an effluent line clamped issue as follows:  The alarm is raised if the effluent motor RPM is outside command limits.  The alarm priority is LOW.  The automatic reaction is to stop all fluid pumps.  The alarm is cleared on operator acknowledgement.  Note: this is not considered a hardware malfunction because the is no pressure sensor on the effluent line after the pump to detect a clamped line. | PRD-3733 |
| SRS-8050 | The software shall generate an alarm for scale weight error as follows:  Alarm is raised if the error between the actual and commanded scale weight exceeds the threshold.  The alarm priority is MEDIUM.  The automatic reaction is to stop the fluid pumps.  The alarm is cleared on operator acknowledgement. | PRD-2051 |
| SRS-8051 | The software shall generate an alarm for unexpected fluid change as follows:  Alarm is raised if the scale weight indicates fluid flow while the pump is paused.  The alarm priority is HIGH for the effluent and effluent drain scales, and MEDIUM otherwise.  The automatic reaction is to stop all pumps and clamp the return line for the effluent and effluent drain scales and stop the fluid pumps otherwise.  The alarm is cleared on operator acknowledgement. | PRD-2051    PRD-3526    PRD-3903 |
| SRS-8516 | The software shall declare an alarm if both effluent bags are full during treatment as follows:  Alarm is raised when auto-effluent is enabled but paused, and the amount of fluid in each effluent bag based upon the scale weight is too large.  The priority is LOW.  The automatic reaction is to stop all fluid pumps.  The alarm is cleared when the operator stops the pause on the effluent auto-drain. | PRD-1832 |
| SRS-8059 | The software shall generate an alarm for effluent drain line clogged as follows:  Alarm is raised if the flow rate from the bag being drain is less than expected.  The priority is LOW.  The automatic reaction is to stop all fluid pumps.  The alarm is cleared upon user acknowledgement. | PRD-3740    PRD-3760 |
| SRS-7562 | 3.12 Barcode Reader |  |
| SRS-5960 | The code reader ignores all scans except:  - during patient ID entry  - during set identification (filter set and AE)  - during service mode code reader testing  Note: this list will expand in the future, for example barcodes on bag changes. |  |
| SRS-7919 | Message Event: Barcode Read Success shall be generated when the barcode reader reads a barcode from any of these Baxter approved accessories:  Front circuit set  Auto Effluent set  PrismaLung+ cartridge | PRD-2135    PRD-4761 |
| SRS-7920 | Message Event: Barcode User Override shall be generated when the operator uses the GUI to identify the circuit or the auto-effluent set to load. | PRD-2135 |
| SRS-7566 | 4 Control Processor (CP) |  |
| SRS-7569 | 4.3 Modes of Operation |  |
| SRS-7572 | 4.3.2 Setup |  |
| SRS-7669 | 4.3.2.4 Sets |  |
| SRS-9686 | The software shall track a timeout since the operator was requested to scan the circuit set barcode to facilitate indication of barcode scan failures.  Note: The timeout will be used in coordination with a GUI button for the operator to indicate whether the barcode scanner isn’t working, or the scan attempt did not work, possibly due to an obscured barcode image. | PRD-3820 |
| SRS-7680 | 4.3.2.4.4 Auto Effluent |  |
| SRS-6192 | In the Auto Effluent sub-step software shall instruct the user on how to scan and install the AE set. | PRD-2299 |
| SRS-6733 | Software shall verify that the AE 1L and 5L bags are hung on the appropriate scales before the AE set is primed.  Note: "Before the AE set is primed" means that the AE set is dry at this point. In this state, the 1L bag will not fulfil the minimum mass needed to satisfy the 5L mass on the front scale. | PRD-2511    PRD-3854 |
| SRS-7573 | 4.3.3 Treatment |  |
| SRS-9578 | 4.3.3.1 Circuit and Treatment Time accumulators |  |
| SRS-7446 | Software shall start the Circuit Set Time timer at the start of treatment for any set and stop it when the treatment is concluded.  Note: treatment concluded is defined as when the user presses the stop button. However, if the treatment is subsequently resumed, then the time spent in that paused state is considered part of the Set Time. | PRD-2766    PRD-3487 |
| SRS-7577 | 4.3.6 End Mode |  |
| SRS-7355 | The software shall provide the ability to pause, resume, and cancel the drain operation of the AE set. | PRD-3378 |

Table 14 Modified SRS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ID | Software Requirements Specification | Proposed Text | Out-links | Rationale |
| SRS-7550 | 3 Components |  |  |  |
| SRS-7843 | 3.1 Loaders |  |  |  |
| SRS-7269 | Software shall run the pumps at these times:  - when performing the LOAD or UNLOAD operations during SETUP  - when performing UNLOAD operations during END mode.  The patient is not connected at these times. | Software shall run the pumps at these times:  - when performing the LOAD or UNLOAD operations during SETUP  - when performing UNLOAD operations during END mode.  - when performing Auto Effluent (AE) LOAD or UNLOAD operations during TREATMENT  The patient is not connected at these times or is in a blood recirculation state in the AE case | PRD-3728 |  |
| SRS-7270 | Software shall reposition the loaders as necessary when the patient is connected. | Software shall reposition the loaders as necessary when the patient is connected, and the AE set is not actively being changed. | PRD-3729 |  |
| SRS-9517 | The software shall generate an alarm for circuit set out of position as follows:  Alarm is raised if the patient is not attached, and the loader motor for the circuit set is not at the correct position.  The alarm priority is HIGH for the main circuit set, and MEDIUM for the AEE circuit set.  The automatic reaction is to stop all pumps and clamp the return line for the main circuit set, and to stop the fluid pumps for the AEE circuit set.  The alarm is cleared on operator acknowledgement. | The software shall generate an alarm for circuit set out of position as follows:  Alarm is raised if the loader motor for the set is not at the correct position.  The alarm priority is HIGH for the main circuit set, and MEDIUM for the AEE circuit set.  The automatic reaction is to stop all pumps and clamp the return line for the main circuit set, and to stop the fluid pumps for the AEE circuit set.  The main circuit alarm is only applicable if the patient is attached  The alarm is cleared on operator acknowledgement. | PRD-3728 |  |
| SRS-7554 | 3.4 Scales and Bags |  |  |  |
| SRS-6162 | Software shall set the scale LEDs on/off state as follows:  - on if scale is open and bag change is in progress for this scale  - flashing if scale is open and bag change is not needed for this scale  - flashing if active alarm is associated with this scale and alarm necessitates human interaction with the scale | Software shall set the scale LEDs on/off state as follows:  - on if scale is open and bag change is in progress for this scale  - flashing if scale is open and bag change is not needed for this scale  - flashing if active alarm is associated with this scale and alarm necessitates human interaction with the scale  - flashing for the effluent and effluent drain scales if an Auto Effluent (AE) set change is in progress | PRD-3763 |  |
| SRS-8054 | The software shall generate an alarm for scale opening unexpectedly as follows:  Alarm is raised if scale is opened, and a bag change is not in progress.  The priority is LOW.  The automatic reaction is to stop all fluid pumps.  The alarm is cleared if a bag change operation is initiated, or the scale is closed. | The software shall generate an alarm for scale opening unexpectedly as follows:  Alarm is raised if scale is opened, and a bag change is not in progress.  The priority is LOW.  The automatic reaction is to stop all fluid pumps.  The alarm is cleared if a bag change operation is initiated, or the scale is closed.  Note: Alarm isn't raised for effluent scales when an AE set change is in progress | PRD-2149 |  |
| SRS-7562 | 3.12 Barcode Reader |  |  |  |
| SRS-9652 | The software shall require two failed barcode scan attempts of the blood circuit set followed by indications of failure from the operator before the manual selection of the set type becomes available. | The software shall require two failed barcode scan attempts of the blood circuit set followed by indications of failure from the operator before the manual selection of the set type becomes available.  Note: During Auto Effluent (AE) set change in treatment, only one indication of a failure is required. | PRD-4754 |  |
| SRS-7566 | 4 Control Processor (CP) |  |  |  |
| SRS-7569 | 4.3 Modes of Operation |  |  |  |
| SRS-7572 | 4.3.2 Setup |  |  |  |
| SRS-7669 | 4.3.2.4 Sets |  |  |  |
| SRS-9687 | The software shall require two indications of a barcode scan failure before the operator is allowed to choose from a list of sets to identify the circuit set. | The software shall require two indications of a barcode scan failure before the operator is allowed to choose from a list of sets to identify the circuit set, with the exception of an Auto Effluent (AE) set change in treatment, where only one indication of a failure is needed. | PRD-3749 |  |
| SRS-7577 | 4.3.6 End Mode |  |  |  |
| SRS-1217 | In the End Mode instructions for discarding the set and or accessories software shall include the following steps:  1) Allow user to select the following:  - Same Patient (if a patient had been attached in this session, CRRT only)  - New Patient  - Discard All (if a patient had been attached in this session)  2) Blood Return: user is allowed to return blood if selected and allowed. See blood return requirements in section 4.3.5 for details on when this feature is allowed  3) Keep Fluid: Only selectable if same patient selected in 1).  4) Keep AE - only selectable if same patient is selected in 1). | In the End Mode instructions for discarding the set and or accessories software shall include the following steps:  1) Allow user to select the following:  - Same Patient (if a patient had been attached in this session, CRRT only)  - New Patient  - Discard All (if a patient had been attached in this session)  2) Blood Return: user is allowed to return blood if selected and allowed. See blood return requirements in section 4.3.5 for details on when this feature is allowed  3) Keep Fluid: Only selectable if same patient selected in 1).  4) Keep AE - only selectable if same patient is selected in 1 and an AE set change is not in progress). | PRD-1973    PRD-3116    PRD-3378    PRD-3842    PRD-4975 |  |
| SRS-6335 | If the user is changing the disposable set and continuing therapy, software shall require the user to change the AE accessory if the AE accessory has been used for over 79.2 hours (55% of its max life of 144 hours) or over 308K revolutions (55% of its 560K life) of the AE pump.  Note that the user may choose the change the AE accessory much earlier than the hard limit specified above. | If the user is changing the disposable set and continuing therapy, software shall require the user to change the AE accessory if the AE accessory has been used for over 144 hours or over 560K revolutions of the AE pump.  Note that the user may choose the change the AE accessory much earlier than the hard limit specified above. | PRD-3141 |  |
| SRS-7592 | 4.3.6.3 Remove Set |  |  |  |
| SRS-2458 | In the Unload step software directs the user to perform the following actions:  - Confirm all lines are clamped  - Confirm patient is disconnected  - Unload the set  - Unload AE accessory (if present, optional, unless 55% of its life has expired) | In the Unload step software directs the user to perform the following actions:  - Confirm all lines are clamped  - Confirm patient is disconnected  - Unload the set  - Unload AE accessory (if present, optional) |  |  |
| SRS-6359 | 4.3.8 System Reset |  |  |  |
| SRS-9615 | 4.3.8.2 Therapy Recovery from System Failure |  |  |  |
| SRS-9626 | After an unexpected shutdown the operator choice to resume the previous session shall be enabled if the following conditions are true:  System was in the treatment state.  The system safe state was Nominal before being set to System Halt.  The system shutdown record was recovered.  Less than ten minutes have expired from the blood pump stopping to the resumption of treatment.  The error in fluid balances was within acceptable limits.  There were no previous recovery attempts in the previous power cycle.  There were no system configuration changes before the operator resumed the treatment session. | After an unexpected shutdown the operator choice to resume the previous session shall be enabled if the following conditions are true:  System was in the treatment state.  The system safe state was Nominal before being set to System Halt.  An Auto Effluent Set change was not being performed at the time of the malfunction.  The system shutdown record was recovered.  Less than ten minutes have expired from the blood pump stopping to the resumption of treatment.  The error in fluid balances was within acceptable limits.  There were no previous recovery attempts in the previous power cycle.  There were no system configuration changes before the operator resumed the treatment session.  The button to display manual blood return instructions has NOT been pressed |  |  |
| SRS-7578 | 4.4 Therapies |  |  |  |
| SRS-7579 | 4.4.2 CRRT |  |  |  |
| SRS-1258 | Software shall provide the capability to the operator to compensate for lost patient fluid removal due to a stopped effluent pump.  Note 1: Pump may be stopped to change bag or other reasons.  Note 2: Option to the user is provided at resumption of stopped pump. | Software shall provide the capability to the operator to compensate for lost patient fluid removal due to a stopped effluent pump.  Note 1: Pump may be stopped to change bag, AE Set change, or other reasons.  Note 2: Option to the user is provided at resumption of stopped pump. | PRD-2545    PRD-3816 |  |
| SRS-7597 | 4.7 Accessories |  |  |  |
| SRS-9560 | The software shall alarm in CRRT for auto-effluent set life exceeded as follows:  The alarm is raised when the auto-effluent set usage, either time used or number of drain pump revolutions, exceed the respective thresholds.  The alarm priority is MEDIUM.  ·The alarm is cleared when treatment is stopped or on operator override. | The software shall alarm in CRRT for auto-effluent set life exceeded as follows:  The alarm is raised when the auto-effluent set usage, either time used or number of drain pump revolutions, exceed the respective thresholds.  The alarm priority is MEDIUM.  ·The alarm is cleared when treatment is stopped, on operator override, or when the AE change button is pressed. | PRD-3141 |  |
| SRS-7598 | 4.8 Display Requirements |  |  |  |
| SRS-7603 | 4.8.3 Making Changes |  |  |  |
| SRS-1159 | Software shall display the relevant Change Bag or Change Syringe screen when one of the graphical bag/syringe icons on the operations screen is touched. | Software shall display the relevant Change Bag, Change Syringe, or Change AE Set screen when one of the graphical bag/syringe icons on the operations screen is touched.  This bag change is a directed bag change. | PRD-2581 |  |

Table 15 New SRS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ID | Software Requirements Specification | Proposed Text | Out-links | Rationale |
| SRS-7550 | 3 Components |  |  |  |
| SRS-9825 | N/A | Message Event: AE Set Change Started shall be generated when the Auto Effluent (AE) set change is initiated in treatment | PRD-1861 |  |
| SRS-9826 |  | Message Event: AE Set Change Complete shall be generated when the Auto Effluent (AE) set change has completed in treatment | PRD-1861 |  |
| SRS-7566 | 4 Control Processor (CP) |  |  |  |
| SRS-7569 | 4.3 Modes of Operation |  |  |  |
| SRS-7573 | 4.3.3 Treatment |  |  |  |
| SRS-9578 | 4.3.3.1 Circuit and Treatment Time accumulators |  |  |  |
| SRS-9857 | N/A | Software shall reset the AE Set Time to 0 after an AE Set Change has completed in treatment. | PRD-4068 |  |
| SRS-7575 | 4.3.5 Recirculation |  |  |  |
| SRS-9877 | N/A | Software shall restrict the capability to initiate the following secondary workflows while an Auto Effluent (AE) set change is in progress:  - Flow rate change  - Bag change  - Syringe change  - Blood or Saline recirculation | PRD-1974 |  |
| SRS-9886 | N/A | Software shall not allow to start or proceed with AE set change when a blood pump is stopped  due to alarm condition or emergency stop. |  |  |
| SRS-7584 | 4.5 Disposables |  |  |  |
| SRS-7586 | 4.5.1 Automatic Effluent Set (AE) |  |  |  |
| SRS-9829 | N/A | Software shall allow the user to change the Auto Effluent (AE) accessory during TREATMENT | PRD-4974 |  |
| SRS-9855 | N/A | Software shall compensate for any weight errors while filling the effluent lines directly after an AE Set Change has completed | PRD-2051 |  |
| SRS-7598 |  |  |  |  |
| SRS-7603 | 4.8.3 Making Changes |  |  |  |
| SRS-9835 | N/A | Auto Effluent Change Screens |  |  |
| SRS-9836 | N/A | Software shall stop all fluid pumps when the Change Auto Effluent workflow is confirmed by the operator  The AE Drain pump will temporarily be allowed to spin while loading/unloading the set or draining the bags | PRD-4979 |  |
| SRS-9875 | N/A | Software shall display the estimated time to complete the drain sequence before the user is asked to confirm the change |  |  |
| SRS-9837 | N/A | Software shall allow the user to Confirm or Cancel the AE change before initiating the process  Once the operation is confirmed the process must be completed (no cancelling after that point) | PRD-4974 |  |
| SRS-9838 | N/A | Software shall allow the option to drain the AE bags before unloading the AE set | PRD-3378 |  |
| SRS-9887 | N/A | Software shall provide option to pause and resume AE drain operation | PRD-4976 |  |
| SRS-9888 | N/A | Software shall display time remaining until the end of AE drain operation | PRD-4976 |  |
| SRS-9840 | N/A | Software shall automatically move to the next step when the AE drain has completed, or the operator cancelled the drain | PRD-4976 |  |
| SRS-9841 | N/A | Software shall include instructions and illustrations for clamping and disconnecting the applicable AE lines/connections before unloading the set. The next step shall be displayed when the operator confirms the actions are complete. | PRD-4976 |  |
| SRS-9843 | N/A | Software shall disable the action to move to the Scan New AE Set step until the loader is fully extended and the bags are removed from the scales. | PRD-4976 |  |
| SRS-9844 | N/A | Software shall instruct the operator to scan the new AE disposable before loading the new set. The next step will automatically be displayed after a successful scan. | PRD-2135 |  |
| SRS-9845 | N/A | Software shall allow the user to continue loading the set if the barcode scan fails or times out | PRD-4754 |  |
| SRS-9847 | N/A | Software shall disable the action to move to the Hang Bags step until the loader is fully retracted. The next step shall be displayed when the operator confirms the set and tubing segments are loaded successfully | PRD-4977 |  |
| SRS-9849 | N/A | Software shall flash the Effluent and Drain scale LEDs during the Hang Bags step until the scale has been closed and sufficient weight is detected on the scale | PRD-4977 |  |
| SRS-9850 | N/A | Software shall disable the action to move to the Connections Steps until the scales are closed and sufficient weight is detected | PRD-4977 |  |
| SRS-9851 | N/A | Software shall instruct the operator to connect a new AE extension line if desired | PRD-4977 |  |
| SRS-9852 | N/A | Software shall include instructions and illustrations for connecting and unclamping the applicable AE connections/lines before completing the AE Set Change | PRD-4977 |  |
| SRS-9853 | N/A | SW shall resume treatment upon the user confirmation indicating the AE set change is complete | PRD-4978 |  |
| SRS-9854 | N/A | Software shall allow all fluid pumps to resume once the AE Set Change has completed  Note: If an alarm is active when the change completes, the safe state shall be set to that of the highest priority alarm | PRD-4979 |  |

Table 17 Related SDS

|  |  |  |
| --- | --- | --- |
| ID | Detailed software requirements derived from the SRS8000 specification | Out-links |
| SDS-2306 | 3 Components |  |
| SDS-2327 | 3.2 Fluid and Blood Pumps |  |
| SDS-190 | 3.2.2 Alarm: Low AEE Effluent Flow Rate |  |
| SDS-191 | Alarm shall be declared if all of the following are true:  - AEE is in use  - Front or side/rear effluent bag is being drained or filled  - the following conditions are true for the estimated flow rate for the low flow rate timeout period:  - The estimated flow rate is less than 50% of the commanded flow rate; and  - Either the weight error is > 10 g, or the change in the weight error is > 2 g. | SRS-8023 |
| SDS-192 | The CONTINUE button shall be enabled immediately.  The Alarm shall be cleared when CONTINUE is pressed. Alarm is disabled while the switchover between which bag is filling and which is draining is in progress, and for 1.0 seconds afterward. | SRS-8023 |
| SDS-193 | The alarm priority is LOW. The safe state is automatically set to STOP\_FLUID\_PUMPS when the alarm is raised. | SRS-8023 |
| SDS-3227 | 3.2.15 Pump fault during set load/unload operation |  |
| SDS-3228 | Alarm shall be generated if a fluid pump motor is being rotated as part of a set load/unload operation, and either of the following conditions occurs:  Measured motor RPM is outside the command limits (see below) for 3.0 seconds.  Speed error (SE) fault indicated in the pump status message.  Over torque (OTQ) fault indicated in the pump status message  Command limits are determined as follows (based upon the absolute value of the command):  Command = 0.0, position differs from initial stopped position by 0.1 revolutions.  Command <= 0.2 RPM, command limits are 0 to command + 0.2 RPM (this allows for noise in encoder values).  Command <= 1.0 RPM, command limits are command +/- 0.2 RPM, with a minimum value for the lower limit of 0.0 RPM.  Command > 1.0 RPM, command limits are command +/- 20% of command. | SRS-9632 |
| SDS-3229 | The Alarm is cleared when the CONTINUE button is pressed. The CONTINUE button is enabled immediately. | SRS-9632 |
| SDS-3230 | The alarm priority is INFO. The safe state is automatically set to STOP\_ALL\_PUMPS when the alarm is raised. | SRS-9632 |
| SDS-2329 | 3.4 Scales and Bags |  |
| SDS-222 | 3.4.1 Alarm: Predicted Weight Error |  |
| SDS-223 | Alarm shall be declared if the magnitude of the scale weight error is greater than the weight error threshold for 5.5 seconds. | SRS-8050 |
| SDS-224 | The CONTINUE button shall be enabled when the scale has been weight stable for 6 seconds, and all scales with non-zero flow commands have been Kalman filter stable for 2 seconds.  The Alarm shall be cleared when the CONTINUE button is pressed. | SRS-8050 |
| SDS-225 | The alarm priority is MEDIUM. The safe state is automatically set to STOP\_FLUID\_PUMPS when the alarm is raised. | SRS-8050 |
| SDS-250 | 3.4.2 Alarm: Weight Change |  |
| SDS-251 | Alarm shall be declared if the difference between the scale weight and the weight when the controller was paused (reference weight) is greater than 20g for 4 seconds, and the standard deviation of the scale weight over any 2 second window remained less than 5 g.  *Note:*  *If the scale weight is unstable (standard deviation exceeds 5 g), then when the scale stabilizes the reference weight is reset to the new weight.* | SRS-8051 |
| SDS-252 | The CONTINUE button shall be enabled immediately.  The Alarm shall be cleared when CONTINUE is pressed. | SRS-8051 |
| SDS-253 | Weight reference is reset to the current weight.  Actually performed by model immediately after alarm is raised. | SRS-8051 |
| SDS-254 | If the scale weight change is detected on the effluent or effluent drain scale, then the alarm priority is HIGH, and the safe state is automatically set to STOP\_PUMPS\_AND\_CLAMP when the alarm is raised. Otherwise, the alarm priority is MEDIUM, and the safe state is automatically set to STOP\_FLUID\_PUMPS. | SRS-8051 |
| SDS-982 | 3.4.16 Alarm: Front Effluent Drain Clogged |  |
| SDS-983 | Alarm shall be generated if the measured flow rate for the front effluent bag is less than 5000 ml/hr minus the blood pump flow rate (if any) for 4.0 seconds while the drain pump is commanded to remove fluid from the bag at 13000 ml/hr. | SRS-8059 |
| SDS-986 | 3.4.17 Alarm: Rear Effluent Drain Clogged |  |
| SDS-987 | Alarm shall be generated if the measured flow rate for the rear effluent bag is less than 5000 ml/hr minus the blood pump flow rate (if any) for 4.0 seconds while the drain pump is commanded to remove fluid from the bag at 13000 ml/hr. | SRS-8059 |

Table 18 Modified SDS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ID | Current Text | Proposed Text | Out-links | Rationale |
| SDS-2306 | 3 Components |  |  |  |
| SDS-2325 | 3.1 Loaders |  |  |  |
| SDS-643 | 3.1.1 Alarm: Circuit Loader Failure - Patient Not Attached |  |  |  |
| SDS-644 | Alarm shall be generated if the patient is not attached, and either of the following conditions occur:  If after being commanded to move to a new position, the circuit loader motor does not achieve the requested position within 10 seconds.  If after having successfully moved to the commanded position, the circuit loader motor is out of position for 5 seconds. | Alarm shall be generated if either of the following conditions occur:  If after being commanded to move to a new position, the circuit loader motor does not achieve the requested position within 10 seconds.  If after having successfully moved to the commanded position, the circuit loader motor is out of position for 5 seconds.  *Note: The main circuit loader alarm is only applicable if the patient is not attached.* | SRS-9517 | Clarify that AE loader alarm is applicable when patient is attached (should only happen during an AE set change) |
| SDS-2329 | 3.4 Scales and Bags |  |  |  |
| SDS-308 | 3.4.3 Alarm: Weight Unstable |  |  |  |
| SDS-309 | Alarm shall be declared if either of the following conditions is true:  - Fluid pumps have been operating for 60 seconds, and a bag weight stable condition has been false for 60 seconds.  - Fluid pumps have been paused without either an operator stop or alarm that stops the pump being active for 60 seconds; and a scale is unstable. | Alarm shall be declared if either of the following conditions is true:  - Fluid pumps have been operating for 60 seconds, and a bag weight stable condition has been false for 60 seconds.  - Fluid pumps have been paused without either an operator stop (emergency stop or AE set change) or alarm that stops the pump being active for 60 seconds; and a scale is unstable. | SRS-8052 | Updated to clarify the AE set change is considered an operator stop |
| SDS-393 | 3.4.9 Alarm: Scale Open |  |  |  |
| SDS-394 | Alarm shall be declared if the scale's position sensor indicates that its handle is open, and a bag change is not currently in progress. | Alarm shall be declared if the scale's position sensor indicates that its handle is open, and a bag change or AE set change (for effluent scales) is not currently in progress. | SRS-8054 | Scale open alarm for effluent should not declare when AE change is in progress |
|  | 4.3.5.4 Alarm: AEA Maximum Life Exceeded |  |  |  |
| SDS-980 | Alarm shall be cleared by transitioning to End Mode or ALARM OFF is pressed.  Alarm shall force the user to unload the AEA during end mode. | Alarm shall be cleared if any of following occurs  -Transitioning to End Mode  -ALARM OFF is pressed.  -Change AE set is confirmed.  Alarm shall force the user to unload the AEA during end mode. | SRS-9560 | Updated for AE set change behavior |
| SDS-2310 | 5 Safety Processor (SP) |  |  |  |
| SDS-2349 | 5.1 Monitoring |  |  |  |
| SDS-2460 | The SP will fault if Patient is attached, AED is enabled, and AED or EFF pinch valves are in a center position (neither CCW nor CW) for 5 seconds or greater. | The SP will fault if Patient is attached, AED is enabled, Effluent pump is running, and AED or EFF pinch valves are in a center position (neither CCW nor CW) for 5 seconds or greater. | SRS-7192 | Pinch valves need to be centered to unload set. As long as the effluent pump is stopped, this is acceptable |
| SDS-2445 | The SP will fault if:   * A patient is attached and AE is disabled and the Effluent pump is running and the Effluent scale is open for longer than 5 seconds   Or   * A patient is attached and AE is enabled and the Effluent or drain pumps are running and the Effluent or drain scales are open for longer than 5 seconds. | The SP will fault if:  A patient is attached, and AE is disabled, and the Effluent pump is running, and the Effluent scale is open for longer than 5 seconds.  Or  A patient is attached, and AE is enabled, and the Effluent pump is running, and the Effluent or drain scales are open for longer than 5 seconds. |  | Drain pump needs to spin temporarily to unload set. This is acceptable as long as the effluent pump is stopped |
| SDS-2414 | The SP will fault if the following conditions are true for greater than or equal to 10s:   * The calculated PFR error is greater than (110% of the gain loss limit +5g) * The effluent pump is running * Patient is attached   *Notes:*  *(1) This only applies to CRRT.*  *(2) Scales and pumps which are unused based on selected therapy and AE status will be excluded from the PFR error calculation.*  *(3) Makeup rate will account for body weight.* | The SP will fault if the following conditions are true for greater than or equal to 10s:   * The calculated PFR error is greater than (110% of the gain loss limit +5g) * The effluent pump is running * Patient is attached * Therapy type is CRRT   *Notes:*  *(1) Scales and pumps which are unused based on selected therapy and AE status will be excluded from the PFR error calculation.*  *(2) Makeup rate will account for body weight.* |  | Requirement clarification |

Table 19 New SDS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ID | Current Text | Proposed Text | Out-links | Rationale |
| SDS-2307 | 4 Control Processor (CP) |  |  |  |
| SDS-3454 | N/A | 3.4.21 AE Set Change Accuracy  Note: Each of the AE bags/lines are filled individually. The 2nd bag will not start the filling sequence until the 1st bag is full |  |  |
| SDS-3455 | N/A | Upon resuming Treatment after an AE set change, the SW shall execute a line fill sequence where the AE lines are filled with approximately 7 mL of fluid, or until the weight change on the scale is greater than 3.5 grams | SRS-9855 |  |
| SDS-3456 | N/A | After completing the line fill step from SDS-3455, if the weight on the scale has increased by at least 30.0 grams, the line filling step of that tubing segment shall be completed.  *Note: This indicates that the effluent line was not completely clamped and at least some fluid flow occurred and purged the air from the lines* | SRS-9855 |  |
| SDS-3458 | N/A | If the line fill sequence of a tubing segment is interrupted by a subsequent AE set change (before SDS-3456 is met), the SW shall accumulate the estimated volume processed for that tubing segment as uncertainty. Additionally, the weight offset calculated in SDS-3465 shall be maintained as part of the next AE change.    *Note: This is the assumed worst case since we won't have any feedback to indicate how much volume was really processed.* | SRS-9855 |  |
| SDS-3465 | N/A | During the line fill sequence from SDS-3455, SW shall accumulate a virtual weight offset between 0 and 7 mL to account for the effluent volume processed in the lines but not yet registered on the scale. |  |  |
| SDS-3466 |  | The virtual offset calculated in SDS-3465 shall be cleared if the line fill sequence is repeated, or upon draining of the bag |  |  |
| SDS-2318 | 4.6 Accessories |  |  |  |
| SDS-3447 | 4.6.1 | 4.6.1 Auto Effluent |  |  |
| SDS-3448 | 4.6.1.1 | 4.6.1.1 AE Set Change |  |  |
| SDS-3449 | N/A | The software shall set the safe state to STOP\_FLUID\_PUMPS when the operator confirms the AE set change during treatment. | SRS-9836 | Need to set safe state to stop fluid pumps. |
| SDS-3464 | N/A | During an AE set change, software shall stop the drain pump when an issue is detected with the drain pump or AE loader. | SRS-9836 | Need to stop drain pump if an issue with the component is observed |

## Labeling Requirement Analysis

Table 20 New LRD

|  |  |  |
| --- | --- | --- |
| ID | Proposed Text | Allocating PRD Requirement |
| LRD-1745 | During an AE Set Change in Treatment, the GUI shall instruct the user to:  - Clamp and Disconnect Auto-Effluent Lines  - Clamp AE Drain Line  - Unload the AE Set and Attached Bags  - Scan new AE Set  - Load the new AE Set  - Check Tubing Alignment of AE Set  - Hang AE bags  - Optionally connect AE Extension Line  - Reconnect Effluent Line and Unclamp  - Press a button to resume Treatment | PRD-4974 |

# Change Description (CD)

*This section should describe the design changes necessary for the proposed change. The design changes originate from the requirement changes described in the CA section of this document, if applicable.*

## Design Description

There were software, controls, and safety processor changes needed to implement this feature. A summary of the changes is listed below.

**MatLab Mode Changes**

MatLab Mode is a build option that allows Controls engineers to execute models on their PC while directly interfacing with the PrisMax hardware. When the MatLab Mode build option is set, the PrisMax will, by default, boot into MatLab mode. Note: Using boot options from the PrisMax front panel power control buttons, the PrisMax can be commanded to boot into Service or Therapy modes. While in MatLab Mode, a task is run that sends UDP commands and data to and from the PC running a MatLab model. The MatLab mode task and associated code is compiled out when the MatLab Mode build option is not set.

The MatLab Mode UDP interface is being updated to include hardware resets of devices located on the Power System Control board. These power board resets include:

* ADC Converter
* JTAG Master
* GPMS Bus Arbiter
* Power I/O Signals
* Venus Clamp
* Processor

**Controls Model Changes**

When a new AE set is installed during treatment there is a small amount of fluid that gets pumped from the effluent line into the AE set before the scales can detect a weight change. It was experimentally determined that this amount of fluid is approximately 7 g for each of the two lines (to the front and side scale bags of the AE set). A new sub-system, AESetChange, was added at the highest level of the FPC Simulink model (FluidPumpCtrl\_Subsystem) . The purpose of the AESetChange sub-system is to intercept the scale response from the effluent and drain scales and to add an offset that corrects for this unobservable weight change. No other changes were made to the original FPC algorithm.

All other model changes at the highest level were for clear signal routing only (See Figure 1 and Figure 2 for original and new FluidPumpCtrl\_Subsystem, respectively):

* Inputs 5, 7, 11 were previously connected to AutoEffluentCoordinator sub-system. They are now routed to Go-To blocks. Corresponding From blocks now connect to the original AutoEffluentCoordinator sub-system and the new AESetChange sub-system.
* Inputs 6 and 8 were previously connected to AutoEffluentCoordinator sub-system and a BusCreator. They are now routed only to AESetChange. Two outputs from AESetChange, EffSideScale and EffFrontScale replace the original inputs 6 and 8. They are both routed to Go-To blocks with corresponding From Blocks connected to AutoEffluentCoordinator and BusCreator.
* Output 6 was previously connected to AutoEffluentCoordinator. The AutoEffluentCoordinator CmdOut\_AutoEff output is now connected to a Go-To block and corresponding From blocks are connected to output 6 and AESetChange.
* Output 11 was previously connected to WeightManagement. The WeightManagement FaultWgt output is now connected to a Go-To block. Corresponding From blocks are connected to output 11, ClosedLoopPumpControl, and AESetChange

AESetChange sub-system consists of the following components (See Figure 3):

* Inputs 1 and 2 – original side and front scale inputs from hardware
* Inputs 3-8 – additional inputs related to AE-set change logic
* Stateflow sub-system ScaleOffset – implements the logic to determine the scale offsets
* Two Simulink sub-systems to filter the original scale inputs. Both the original and the filtered scale signals are inputs to ScaleOffset sub-system
* Outputs 1 and 2 – corrected side and front scale outputs to the unchanged part of the FPC algorithm
* Output 3 (AESetChangeOut) – bus consisting of control signals to higher level SW and debug signals.

ScaleOffset sub-system consists of two parallel states, one for each scale, and one function to calculate the weight increase during each sampling period when liquid is pumped without scale response, see Figure 4.

The two parallel states FrontScale, see Figure 5, and SideScale, see Figure 6, implement the corrective scale offsets logic. They are copies of each other with minor editing to point to the correct scale. Each scale has its own state because the filling of the AE set is determined by the unchanged portion of the FPC algorithm.

Logic implemented in the parallel states:

* Upon entry, the **Normal** state (#1) is entered. If AE-set is not used, the Normal state is not exited, and the offset will remain at zero. If AE-set is used and a (AE-set) bag change occurs, the logic will transition to **SetChange** .
* The purpose of the **SetChange** state (#2) is to wait until the user has completed the (AE-set) bag change (all implemented in higher level SW). When the bag change is completed, the logic transitions to **WaitFilling**.
* The logic remains in the **WaitFilling** state (#3) until the corresponding bag is being filled. The AutoEffState from the unchanged portion of the FPC algorithm is monitored to make that determination. When the bag is filled, the logic transitions to **LineFilling**. During the transition to **LineFilling** the initial scale weight is stored.
* While in the **LineFilling** state (#4), the logic increments the corrective scale offset each sampling period and monitors two exit conditions:
  + If the offset has grown to 7 g it transitions to **Monitoring**.
  + If the scale weight has increased by more than 3.5 g as compared to the initial scale weight, the filtered scale rate is at least half the commanded flow rate, and the maximum scale rate is less than three times the commanded flow rate (the last two conditions check scale stability), then the logic transitions to **WgtCheckFilling**.
* The purpose of **WgtCheckFilling** state (#5) is to confirm the scale weight increase and scale stability. If confirmed it transitions to **Monitoring**.
* The purpose of **Monitoring** state (#6) is to monitor for a clamped effluent line condition. There are three primary exits:
  + If an effluent low flow alarm occurs, it transitions to **LowFlowCheck** state (#11). After one cycle in **LowFlowCheck** it transitions to **WaitClearLineClamped** state (#12) and resets the offset to zero. It remains in **WaitClearLineClamped** until the user has resolved the issue and pressed the Continue button (all implemented in higher level SW) and then the logic returns to the **LineFilling** state (#4). During the transition to **LineFilling** a new initial scale weight is stored.
  + If the scale weight has increased by more than 30 g as compared to the initial scale weight, and the two scale stability checks are met, then the logic transitions to **WgtCheckMonitoring** state (#7). The purpose of **WgtCheckMonitoring** is to confirm the scale weight increase and scale stability. If confirmed, it transitions to **LineFilled.**
  + If the scale weight has increased by more than 60 g, even if the scale stability criteria are not met, the logic transitions to **LineFilled**. This path was added to prevent the logic from getting stuck at **Monitoring**. 60 g was chosen because it is larger than the criterion for an unexpected weight change (50 g). 30 g was chosen as a sufficient weight increase to rule out low flow alarm / clamped line caused by the AE set change.
* The algorithm remains in **LineFilled** state (#8) until the bag is drained.
* When the bag is drained the algorithm transitions to **Draining** state (#9). After one cycle in **Draining** the algorithm transitions to **Normal** and resets the offset to zero.
* The algorithm also monitors if a second bag change occurs, while the first bag change is still in progress. In this case, the algorithm transitions back to **SetChange**. If this occurs from states 4-7 or 11-12, the algorithm transitions via **UnCertain** state (#21) and the accumulated offset is added to uncertain weight by higher level SW.

A computer screen shot of a diagram

Description automatically generated

Figure 15: FluidPumpCtrl\_Subsystem for PrisMax SW V3.0 (SVN revision 4590)

A diagram of a computer

Description automatically generated

Figure 16: FluidPumpCtrl\_Subsystem for PrisMax SW V3.4 (SVN Revision 5379)

A diagram of a cell phone

Description automatically generated

Figure 17: AESetChange sub-system

A screenshot of a computer

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Figure 18: ScaleOffset sub-system

A screenshot of a computer program

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Figure 19: FrontScale parallel state

A screenshot of a computer program

Description automatically generated

Figure 20: SideScale parallel state

A screenshot of a computer

Description automatically generated

Figure 21: Function Calc\_Offset

**Safety Processor Changes**

**1708 / SDS-2460 modification**

All changes were contained inside the Pinch Valve Faults / Effluent\_Fill\_And\_Drain\_PV\_Failures sub-system:

* A new condition, that the commanded effluent rate is greater than 0.02 RPM, was added to the AND-block of the SDS-2460 algorithm. This implemented the requirement modification.
* In addition, two inputs to the algorithms for SDS-2463 and SDS-2464, were converted to From-blocks and corresponding Goto-blocks were added to the sub-system. One of the From-blocks was also used to add the new condition to the SDS-2460 algorithm.
* Illustrations of the Effluent\_Fill\_And\_Drain\_PV\_Failures sub-system before and after the V3.4 modifications are depicted in Figure 1 and Figure 2, respectively.

**S1792 / SDS-2445 modification**

The following changes were made to the Blood and Fluid Pump Faults / Scale\_Open\_Failures sub-system:

* The condition, that the commanded drain pump speed is greater than 0.02 RPM, was removed from the AND-block of the SDS-2445 algorithm. (It was one of two conditions connected to an OR-block. The other OR-condition, that commanded effluent speed is greater than 0.02 RPM is now connected directly to the AND-block.) This implemented the requirement modification.
* The AED\_CMD input was removed because the commanded drain pump speed is no longer needed in the sub-system.
* Illustrations of the Scale\_Open\_Failures sub-system before and after the V3.4 modifications are depicted in Figure 3 and Figure 4, respectively.

**S1019 / SDS-2414 modification**

The following changes were made to the Weight Scale Faults / Patient\_Fluid\_Removal\_Failure sub-system:

* PFR\_RESET output: Removed TPE-From block and replaced it with new CRRT-From-block. When CRRT is false, the output from the AND-block will be false, resulting in PFR\_RESET being true. When PFR\_RESET is true, no error will accumulate and FLT\_PFR will never be true.
* The logic based on the THERAPY input was updated. A Goto-block for CRRT was added. The Goto-blocks for TPE, NO\_PBP, and NO\_SYR were eliminated (no longer needed with CRRT input to PFR\_RESET).
* The switch at the PBP\_WGT input was eliminated since it only applied to TPE and HP treatments.
* The switch at the STR\_VOL\_DLVRD input was eliminated since it only applied to TPE and HP treatments.
* The four changes above implemented the requirement modification. The last two changes modified details of the algorithm implementation that were not directly covered by requirements but were made to implement the AE-set change during treatment.
* The drain scale open signal (AED\_OPEN) was added to the Patient\_Fluid\_Removal\_Failure sub-system and to the OR-block defining the SCALE\_OPEN-Goto-block, because the SCALE\_OPEN-From-Block is an input to the UNEXPECTED\_SCALE\_CHANGE sub-system. This was added since the drain scale is now also opened during AE-set change.
* EFF\_PAUSE output: Removed the AED\_CMD input so that AE-set loading would not interfere with this signal, i.e. unnecessarily un-pause during the AE-set change, when the drain pump is running. During treatment, the drain pump is only running when the effluent pump is also running, so this change does not affect the functionality of the PFR fault algorithm outside an AE-set change.
* Illustrations of the Weight Scale Faults / Patient\_Fluid\_Removal\_Failure sub-system before and after the V3.4 modifications are depicted in Figure 5 and Figure 6, respectively.

A screenshot of a computer

Description automatically generated

Figure 22 - Pinch Valve Faults / Effluent\_Fill\_And\_Drain\_PV\_Failures sub-system for PrisMax SW V3.2 (SVN revision 4985)

A diagram of a flowchart

Description automatically generated

**Figure 23 - Pinch Valve Faults / Effluent\_Fill\_And\_Drain\_PV\_Failures sub-system for PrisMax SW V3.4 (SVN revision 5324)**

**A computer screen shot of a diagram

Description automatically generated**

Figure 24 - Blood and Fluid Pump Faults / Scale\_Open\_Failures sub-system for PrisMax SW V3.2 (SVN revision 4985)

A diagram of a computer

Description automatically generated

Figure 25 - Blood and Fluid Pump Faults / Scale\_Open\_Failures sub-system for PrisMax SW V3.4 (SVN revision 5324)

A computer screen shot of a diagram

Description automatically generated

Figure 26 - Weight Scale Faults / Patient\_Fluid\_Removal\_Failure sub-system for PrisMax SW V3.2 (SVN revision 4985)

A diagram of a computer

Description automatically generated

Figure 27 - Weight Scale Faults / Patient\_Fluid\_Removal\_Failure sub-system for PrisMax SW V3.4 (SVN revision 5324)

**Software Changes**

The system provides the operator with an option to change the AE disposable while in the treatment state. The operator can access the AE change workflow from the Ops screen, the same way they initiate bag changes from the UI. From the Ops Screen, the operator can click on ‘Change AE’ icon, which will ask for the change AE confirmation from the operator.

The system also provides the operator with an option to change the AE disposable from the T2119 alarm (AE Set Life Exceeded Alarm).

Once the operator confirms the AE Set change during treatment, it is carried out with sequence of steps which are as follows:

### Change Auto Effluent Set

The screen allows the operator to either start the AE change workflow or to cancel it. It also highlights the below information.

* + It informs the operator that once they confirm AE Set change, they will not be able to resume treatment until it is completed.
  + It informs the operator that only blood pump will be running during the change.
  + The screen shows the estimated time to drain AE bags.

### Drain Auto Effluent Bags

The Screen allows the operator to confirm if they wish to Drain the AE bags by clicking on “Yes/No” buttons. It also displays the estimated time remaining until bags are drained.

### Auto Effluent Status

This screen is displayed if the operator has selected an option to Drain the AE bags. It also provides an option to Pause, Resume and Cancel AE Drain. Auto Effluent Status displays the progress of the time remaining until the bags are drained.

### Clamp and Disconnect Auto Effluent Lines

This screen is displayed automatically when the AE Drain is completed or when the Drain is cancelled by the operator. It provides operator to provide the confirmation on the below instructions by clicking on “Check” button.

* + Clamp the Effluent Line from the Main Filter Set using the slide Clamp.
  + Clamp the line at the top of the Auto Effluent Set using the Pinch clamp.
  + Disconnect the Main Filter Effluent connection from the top of the Auto-Effluent Set.

Once all steps are completed and “Check” button is clicked, “Next” button is enabled and operator is allowed to proceed further.

### Clamp Auto Effluent Drain Line

This screen is displayed when “Next” is pressed on “Clamp and Disconnect Auto Effluent Line” screen. It allows operator to provide the confirmation on the below instructions by clicking on “Check” button.

* + Clamp the Auto Effluent Drain Line

Once the step is completed and “Check” button is clicked, “Next” button is enabled, and operator is allowed to proceed further.

### Unload and Discard Set, Bags, and Lines

This screen is displayed when “Next” is pressed on “Clamp Auto Effluent Drain Line” screen. It allows operators to unload the Auto-Effluent Set by pressing the “Unload” button. When the Auto-Effluent set is unloaded, and AE bags are removed from the scales and scales are closed, “Next” button is enabled, and operator is allowed to proceed further. This screen provides the below instructions to the operator.

* + Press “Unload Set” button to unload the Auto-Effluent Set.
  + Remove both the Auto-Effluent fluid bags from the Scales.
  + Remove the Auto-Effluent Set from the Loader and discard the Set and attached bags.

### Scan New Auto Effluent Set

This screen is displayed when “Next” is pressed on “Unload and Discard Set, Bags, and Lines”. It allows operators to Scan the New Auto-Effluent Set using the Barcode Scanner. Once the AE barcode is scanned, then the operator is allowed to proceed further.

### Scan Failed Auto Effluent Set

This screen is displayed when a wrong Auto-Effluent barcode is scanned or when there is a timeout on scanning the New Auto-Effluent Set. The Scan Failed screen provides the “Next” button to override the AE Set scan and allows the operator to proceed further.

If the operator scans the correct AE barcode on this screen, then he is allowed to proceed further. This screen provides the below information.

* + Scan the barcode of the new Auto-Effluent Set.
  + A valid barcode was not scanned. Retry or press “Next” to move to the next step.

### Load New Auto Effluent Set

This screen is displayed after Auto-Effluent Set is scanned or AE Scan set is Overridden. It allows the operator to Load the new AE Set. Once the new AE Set is loaded, the operator automatically proceeds to the next step. This screen is provided with the below information.

* + Attach the new AE set to the AE side panel loader and press the “Load Set” button to load the set.

### Check Tubing Alignment

This screen is displayed after the AE set is loaded or failed to load. “Check Tubing Alignment” screen asks the operator to validate the AE set tubing is properly loaded in AE motor and pinch valves. This screen provides an option to unload the AE set if the tubing is not properly aligned in the AE pump and pinch valves. If the tubing is loaded properly, the operator can proceed to the next step by clicking on “Next button”.

Check Tubing Alignment dialog provides the below information to the operator:

* + Verify the tubing is positioned correctly around both pinch valves near the AE loader.
  + If tubing is not loaded properly, follow the instructions to unload the set and correct the tubing alignment.
  + Press “Next” button to proceed if tubing segments are aligned.
  + Press the “Unload Set” button to unload the set and reposition the tubing.

### Hang Auto Effluent Bags

This screen is displayed when “Next” is pressed on “Check Tubing Alignment” screen. It instructs the operator to

* Open the scales
* Hang the bags
* Close the scales

The “Next” button will be disabled until AE bags are hung and scales are closed.

### Connect Extension Line and Drain Hook

If the operator needs to add AE extension line, it can be done, following the instructions in this screen. It instructs the user to route the drain line properly.

### Connect and Unclamp Auto Effluent Set

This screen asks the operator to

* Connect the effluent line on the top of the AE set.
* Unclamp the effluent line using the slide clamp.
* Open the pinch clamp on the top of the AE set.

After verifying that all the connections are proper, the operator can press “Confirm All” button. The “Resume Treatment” button will be enabled, following this. The user can continue treatment from this screen after the AE set is changed.

### Sequence Diagram

Figure 15 has an attachment which represents the sequence diagram of AE Set change during treatment.

When AE set change is confirmed from the confirmation dialog, *fromGuiStartStopAESetChange* is set to true, and AE\_SET\_CHANGE\_*START* is published by *TherapyStateManager* object.

When yes to drain is selected from the Drain Yes/No dialog box, START\_AE\_END\_DRAIN is published by *TreatmentSessionController* which is received by the *PrimingManager* Object, which periodically updates the remaining drain Time to GUI using *toGuiAeDrainTimeRemaining* Dictionary. *fromGuiAeDrainPaused* and *fromGuiCanceAeDrain* dictionaries are added for pause/resume and cancel for AE draining.

When Drain is completed or aborted, *AE\_DRAIN\_COMPLETED\_OR\_ABORTED* is published and status is updated to GUI to proceed to next step of AE Workflow.

Two dictionaries *fromGuiAeSetChangeStatusCmd* and *toGuiAeSetChangeStatus* are added to maintain the different states during AE Set change. Newly added states are mentioned below using *ChangeAESetMsgFromGUI* and *ChangeAESetMsgToGUI* enums. States mentioned for added enums are described in the implementation details section.

### Class Diagrams

* **Treatment Session Controller**

The Session Controller (or Treatment Session Controller) maintains the notion of "sessions of therapies". It owns all data that might accumulate over multiple sessions on the same patient. It maintains a history of all fluids processed in all prior therapies on the current patient, as well as the fluids processed during the current therapy.

The Session Treatment Controller is implemented as a singleton class. It implements periodic processing, event handling, and observer handling inherited from the TherapyProcessor class. mpChangeAESetInProgress is added to this class to determine whether the AE Set change is in progress or not.

Below are the newly member functions and data members added to the Treatment Session Controller class

* GetSetTimeAE() member function is newly added. It gives the current AE Set Time
* HandleAESetChangeStatus() will set the AE status to GUI from therapy.
* UpdateAEStateChange() will set the mpChangeAESetCurrentState with proper AE states based on messages received from GUI.
* mIsAeSetScaleOpen - Verifies if the AE and Drain AE scales are open
* isDrainCompleteOnHighPriority - verify if CHANGE\_AE\_DRAINING\_COMPLETED is published by priming model controller when system is in Emergency Stop State
* mpChangeAEActionButtonsDisable - To disable Controls when System is in Safe State change
* mpChangeAESetInProgress - AE Set change process is in progress.

A diagram of a computer program

Description automatically generated

* **Priming Manager**

The Priming Manager is responsible for getting current state information from the Priming Model Controller and determining which priming step to execute.

The Priming Manager is implemented as a singleton class. It implements periodic processing, event handling and observer handling inherited from the TherapyProcessor class. It contains Alarm Handler classes to handle the processing of priming related alarms. mAESetChangeInProgress is added to Priming Model Controller class to determine whether the AE Set change is in progress or not.

Below are the newly member functions and data members added to the Priming Manager and Priming Model Controller class.

* ReturnTimeRemainingFlagForAESet() – returns the value of mGetRemainingTimeForAESetChange.
* mGetRemainingTimeForAESetChange – indicates that the query for drain remaining time is in progress.
* mRemainingTimeReqCount – a counter which helps to determine that querying for drain remaining time will happen for five times.
* mAEDrainPaused – determines if AE drain is paused or resumed.
* mAESetChangeInProgress - AE Set change process is in progress.
* mSafeStateByte – Safe set during for AE Set change
* mFinalDrainLowFlowAlarmStatus – Determines the status of T2060 and T2161 alarm. Is any of the alarm raised or not.

A diagram of a computer

Description automatically generated

* **Bag Controller**

The Bag Controller is responsible for the operator usage of the individual scales and their associated bags.The Bag Controller maintains current volume levels and time until empty, which is fed back to the GUI and ultimately displayed to the operator. The Bag Controller also controls bag changes, and when bag changes are legal. There is a significant amount of logic surrounding the bag change operation and ensuring that the operator performs the necessary steps correctly.

The Bag Controller is implemented as a singleton class. It implements periodic processing, event handling, and observer handling inherited from the TherapyProcessor class. It contains an Alarm Handler class to handle the processing of bag related alarms. mAESetChangeInProgress is added to Bag Controller class to determine whether the AE Set change is in progress or not.

Below are the newly member functions and data members added to the Bag Controller class

* mAESetChangeInProgress - AE Set change process is in progress.

A diagram of a company

Description automatically generated

* **Fluid Pump Controller**

The FluidPumpController class is responsible for handling the five fluid pumps (excluding the blood pump), effluent, pre-blood, dialysate, replacement, and effluent drain. There will be one instance of a FluidPumpController for each pump.

The FluidPumpController inherits from the PumpController base class to provide an interface to a specific pump motor. It also implements periodic processing and event handling inherited from the TherapyProcessor class. There is one instance of FluidPumpController for each of the fluid pump motors (excluding the blood pump). mAESetChangeInProgress is added to Fluid Pump Controller class to determine whether the AE Set change is in progress or not. Below are the newly member functions and data members added to the Fluid Pump Controller class.

* mAESetChangeInProgress - AE Set change process is in progress.
* mStopResumeDrainPump - Stop or Resume Drain Pump when T1138, T2160 & T2161 are Active or Inactive during AE set change is in progress.
* mAEStChangeAborted - verifies if AE set change is aborted.

A diagram of a computer

Description automatically generated

* **Loader Controller**

The loader controller is responsible for managing the loader motor and handling all loader motor related events and alarms.

The Loader Controller is implemented as a singleton class. It implements periodic processing, event handling and observer handling inherited from the TherapyProcessor class. It contains an Alarm Handler class to handle loader motor related alarms. mAESetChangeInProgress is added to Loader Controller class to determine whether the AE Set change is in progress or not. Below are the newly member functions and data members added to the Loader Controller class.

* mStoppedBySafeStateAE – AE Loader is stopped by Safe State during AE Set change
* mAESetChangeInProgress - AE Set change process is in progress.
* mStopResumeDrainPump – Stop or Resume Drain Pump when T1138, T2160 & T2161 are Active or Inactive during AE set change is in progress.

A diagram of a computer program

Description automatically generated

* **Pinch Valve Controller**

This Controller is responsible for managing the positioning of the four pinch valves, Effluent Fill, Effluent Drain, Dialysate and Replacement. The commanded positions are retrieved from either the Priming Model Controller or the Fluid Pump Model Controller, and the appropriate commands are sent to the pinch valve Interface Components to move the valve into the desired position. Alarm handling related to the pinch valves is also performed.

The Pinch Valve Controller is implemented as a singleton class. It implements periodic processing, event handling, and observer handling inherited from the TherapyProcessor class. It contains an Alarm Handler class to handle the processing of pinch valve related alarms. mAESetChangeInProgress is added to Pinch Valve Controller class to determine whether the AE Set change is in progress or not. Below are the newly member functions and data members added to the Pinch Valve Controller class.

* mLoadUnloadInProgress – determines if loader or unloading of AE Set is in progress
* mAESetChangeInProgress- AE Set change process is in progress.

A screenshot of a computer program

Description automatically generated

### Change Auto Effluent Set Workflow

Please refer to the figure below for Change AE Workflow.

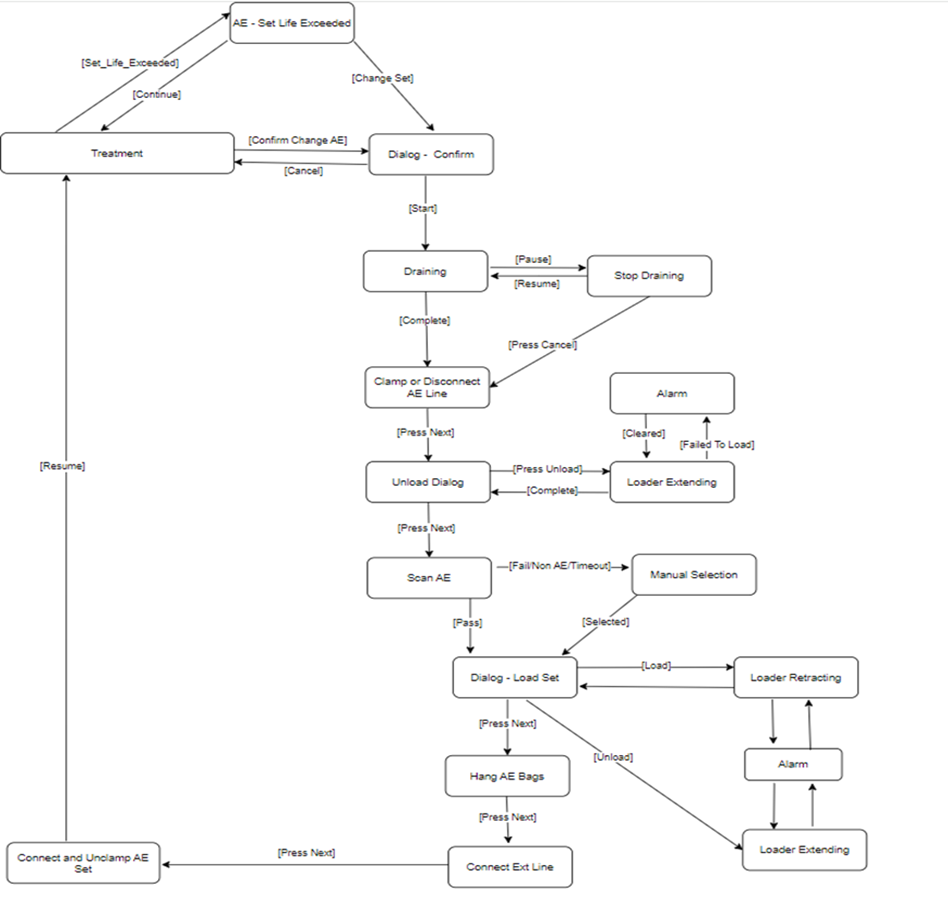
AE Set change can be initiated from “Change AE” icon from OpsView Screen or from “AE Set Life Exceeded Alarm (T2119)”. When operator presses “Change AE” from the confirmation screen or “Change Set” from T2119 alarm AE Set change is started and a Drain confirmation dialog is displayed on the screen. The operator has a choice to skip the Drain of AE bags. While Draining, the operator has the option to “Pause”, “Resume” and “Cancel” the Drain. Once drain is completed or skipped, “Clamp and Disconnect AE Line” is displayed on the screen. When the “Next” button is pressed on this screen, operator is navigated to “Unload AE Set Dialog”. Initially, the “Next” button is displayed on this dialog.

Once the operator presses the “Unload” button, AE Set will start unloading i.e. AE loader starts extending and AE pump will unload the AE Set. Once the operator removes the AE bags the Scales, the “Next” button is enabled. If during unload “Loader failure” alarm is raised, then pressing on “continue” button will automatically unload the AE set. If during unload “Hardware failure” alarm is raised, the pressing on “Continue” button will only clear the alarm and operator has the select “unload” to re-initiate the unloading of AE Set.

When “Next” is pressed on “Unload AE Set” Dialog, operator navigates to “Scan AE Set” dialog. Here the operator has to scan the New AE Set. Once the New AE Set is scanned, the operator navigates to “Load AE Set” Screen. If the operator scans the wrong AE Set or there is a timeout on scanning new AE filter set, then operator is navigated to “Scan Failed” Screen. Here the operator has an option to override the AE Scan step.

Once the operator pressed the next button on “Scan Failed” Screen, operator navigates to “Load Set” Screen. In the “Load AE Set” step, Operator must attach the new AE Set to AE Loader and press “Load Set” button to load the AE filter Set. If during load “Loader failure” alarm is raised, then pressing on “continue” button will automatically load the AE set. If during load “Hardware failure” alarm is raised, the pressing on “Continue” button will only clear the alarm and operator has the select “unload” to re-initiate the unloading and loading of AE Set. When the Set is loaded or failed to load, then operator is navigated to “Tubing check” dialog. In this step the operator has to verify that AE Set is loading properly with tubing aligned on the AE Pumps. Once the operator presses “Next” button on “Tubing Check” dialog, he is navigated to “Hang AE Bags” dialog. The operator has to hang the AE Bags on AE and Drain Scale. Once the bags are properly hung on Scales, “Next” button is enabled on “Hang AE Bags” dialog and the operator is allowed to proceed to the next step. When “Next” button is pressed on “Hang AE Bags” dialog, operator navigates to “Connect Extension Line” dialog. Here the operator has the connect the extension and press “Next” button to proceed in the AE workflow.

When “Next” button is pressed on “Connect Extension Line”, operator is navigated to “Connect and Unclamp AE Set” dialog. Here operator has to press “confirm all” button after verifying that AE set is attached and connected. Once the operator presses the “Confirm All” button, “Resume Treatment” button gets enabled. To resume back to treatment, operator has to press “Resume Treatment” button.



### Constraints During AE Set Change

To achieve the Auto-Effluent Set change during treatment various constraints have been added to the existing design.

Below are the constraints added to the system.

* During AE Set change other options to change the fluid bags have been disabled. For example – If AE set change is in progress, then change of Dialysate Bag, replacement Fluid Bag and PBP bag is disabled. However, operator is allowed to change these bags using the Drive-by method.
* During AE Set changes, Recirculate Saline and Blood Recirculation is disabled.
* In case of any high Priority alarm, the user is not allowed to proceed with Change AE in the OpsScreen. Change AE is disabled.
* Operator is not allowed to change AE if any Bag change is already in progress. For example – An operator is not allowed to change AE if Change Bag for Dialysate is already in progress.
* If any high priority alarm is active or raised during change AE, then user is not allowed to proceed further in the AE workflow until the High priority alarm is clear.
* Change Syringe is not allowed during AE Set change
* If user clear that alarm by pressing continue the loader will not retract and draining option will not be available. This behavior is similar to previous versions of the software in setup.

## Change List

**PrisMax Source Code Changes**

| **File** | **Type of Change** | | |
| --- | --- | --- | --- |
| **Added** | **Modified** | **Deleted** |
| DictionaryOtherSettings.cpp |  | X |  |
| DictionaryOtherSettings.h |  | X |  |
| DictionarySetupGroup.h |  | X |  |
| DictionaryTeardownGroup.cpp |  | X |  |
| DictionaryTeardownGroup.h |  | X |  |
| DictionaryTherapyStateGroup.cpp |  | X |  |
| DictionaryTherapyStateGroup.h |  | X |  |
| TherapyDictionarySetup.cpp |  | X |  |
| AsynchronousTherapyRecovery.cpp |  | X |  |
| AsynchronousTherapyRecovery.h |  | X |  |
| PatientClass.cpp |  | X |  |
| PatientClass.h |  | X |  |
| PrisMaxBitmaps.h |  | X |  |
| PrismaxStrings.h |  | X |  |
| AlarmDisplayDataConst.inc |  | X |  |
| AlarmManagerGUI.cpp |  | X |  |
| AlarmView.cpp |  | X |  |
| CMakeLists.txt |  | X |  |
| DefaultMarkupSupport.cpp |  | X |  |
| DialogAEEEmptyScreen.cpp |  |  |  |
| DialogChangeAESetConfirmScreen.cpp | X |  |  |
| DialogChangeAESetConfirmScreen.h | X |  |  |
| DialogChangeAESetConfirmView.cpp | X |  |  |
| DialogChangeAESetConfirmView.h | X |  |  |
| DialogChangeAESetDrainConfirmScreen.cpp | X |  |  |
| DialogChangeAESetDrainConfirmScreen.h | X |  |  |
| DialogChangeAESetDrainConfirmView.cpp | X |  |  |
| DialogChangeAESetDrainConfirmView.h | X |  |  |
| DialogAEEEmptyScreen.cpp |  |  | X |
| DialogChangeAESetDrainScreen.cpp | X |  |  |
| DialogChangeAESetDrainScreen.h | X |  |  |
| DialogChangeAESetWizardScreen.cpp | X |  |  |
| DialogChangeAESetWizardScreen.h | X |  |  |
| DialogChangeAESetWizardView.cpp | X |  |  |
| DialogChangeAESetWizardView.h | X |  |  |
| EndModeSchedulePanel.cpp |  | X |  |
| EndModeSchedulePanel.h |  | X |  |
| GuiMsgIds.h |  | X |  |
| OpsView.cpp |  | X |  |
| OpsView.h |  | X |  |
| PrisMaxGUI.gpj |  | X |  |
| RemoveSetView.cpp |  | X |  |
| ScreenDriver.cpp |  | X |  |
| ScreenDriver.h |  | X |  |
| FluidPumpControllerTop\_data.cpp |  | X |  |
| FluidPumpControllerTop.cpp |  | X |  |
| FluidPumpControllerTop.h |  | X |  |
| rtwtypes.h |  | X |  |
| zero\_crossing\_types.h |  | X |  |
| FluidPumpModelInterface.cc |  | X |  |
| FluidPumpModelInterface.h |  | X |  |
| AlarmDialogRequests.h |  | X |  |
| FluidBalanceError.cpp |  | X |  |
| FluidBalanceError.h |  | X |  |
| AlarmsConst.inc |  | X |  |
| BagController.cpp |  | X |  |
| BagController.h |  | X |  |
| FluidPumpController.cpp |  | X |  |
| FluidPumpController.h |  | X |  |
| FluidPumpModelController.h |  | X |  |
| LoaderController.cpp |  | X |  |
| LoaderController.h |  | X |  |
| PinchValveController.cpp |  | X |  |
| PinchValveController.h |  | X |  |
| PrimingManager.cpp |  | X |  |
| PrimingManager.h |  | X |  |
| PrimingModelController.cpp |  | X |  |
| PrimingModelController.h |  | X |  |
| TherapyRecoveryController.cpp |  | X |  |
| TherapyRecoveryController.h |  | X |  |
| TreatmentSessionController.cpp |  | X |  |
| TreatmentSessionController.h |  | X |  |
| BagClass.cc |  | X |  |
| BagClass.h |  | X |  |
| FluidPumpModelAlarms.cpp |  | X |  |
| FluidPumpModelAlarms.h |  | X |  |
| TherapyStateManager.cpp |  | X |  |
| TherapyStateManager.h |  | X |  |
| TherapyEventPublisher.h |  | X |  |
| TherapyEvents.inl |  | X |  |
| DesktopCP.cmake |  | X |  |

### Implementation Description

* DictionaryOtherSettings.h
* Declares one new dictionary which are as follows.
* toGUIChangeAEActionButtonsDisable - Therapy informing GUI to disable change AE button in case of safe state change.
* DictionaryOtherSettings.cpp
* Defines and initializes one new dictionary added in DictionaryOtherSettings.h
* DictionaryTeardownGroup.h
* Declares 5 new dictionaries and 2 new enum which are as follows.
* fromGuiAeGetDrainRemainingTime – GUI Informing Therapy that the Change AE button is pressed from operation screen.
* toGUIChangeAESetMsg – Therapy informing GUI that AE set change status (The dialogue changes, event publish, AE empty started/skipped etc.)
* fromGUIChangeAESetMsg – GUI Informing therapy the run time status of AE set change.
* fromGUIChangeAESetInProgress – GUI informing whether the AE set change is in progress or not.
* toGuiAEScalesOpenStatus – Therapy informing GUI that the status of the AE scales both effluent and effluentdrain.
* ChangeAESetMsgToGUI – This enum contains the possible states of AE set changes from therapy to GUI.
* ChangeAESetMsgFromGUI – This enum contains the possible states of AE set changes from GUI to therapy.
* DictionaryTeardownGroup.cpp
* Defines and initializes one new dictionary added in DictionaryTeardownGroup.h
* DictionaryTherapyStateGroup.h
* Declares 1 new dictionaries which are as follows:
* fromGuiStartStopAESetChange – GUI informing therapy that the AE set change is starting or stopping.
* TherapyDictionarySetup.cpp
* Describes the sideActions for 7 new dictionaries added in DictionaryOtherSettings.h,

DictionaryTeardownGroup.h and onaryTherapyStateGroup.h.

* AsynchronousTherapyRecovery.h
* Added mAESetTimeStarted as a new member of AsynchronousTherapyRecovery class to save the time the AE set has been in use.
* AsynchronousTherapyRecovery.cpp
* Modified the AsynchronousTherapyRecovery Copy constructor, assignment operator, comparison operators, EncodeObj(), Decode () and Size () functions for new members added to AsynchronousTherapyRecovery Class.
* PatientClass.h
* Two new member function are added in PatientClass class:
* UpdateAESetTime(const TimeSpanQty& setTime) – Updates the time for the AE set.
* ResetAEUsageTime(void) – Reset the time for the AE set.
* PatientClass.cpp
* Defined the two new member functions added in PatientClass class.
* PrisMaxBitmaps.h
* New BID’s are added which is required for AE set change. Below are the new BID’s newly added.
* BID\_dialog\_change\_ae\_set\_pt2\_beam\_3
* BID\_dialog\_change\_ae\_set\_pt2\_beam\_2
* BID\_dialog\_change\_ae\_set\_pt2\_beam\_1
* BID\_dialog\_change\_ae\_set\_pt2\_machine
* BID\_dialog\_ae\_connect\_unclamp
* BID\_Dialog\_change\_ae\_set\_pt3
* BID\_dialog\_change\_ae\_set\_pt5
* BID\_dialog\_change\_ae\_set\_pt6
* BID\_dialog\_clamp\_disconnect\_ae\_set\_pt7
* BID\_dialog\_unload\_ae\_set\_pt3
* BID\_AESetChangeStarting
* BID\_dialog\_disconnect\_ae\_drain\_pt6
* BID\_tubing\_checkfinal
* BID\_ScanSet\_SetBag\_back
* PrismaxStrings.h
* New SID’s are added which is required for AE set change. Below are the new SID’s newly added.
* SID\_MSG\_X0721\_TITLE
* SID\_MSG\_X0722\_TITLE
* SID\_CHANGE\_AE\_SET\_DIALOG\_TITLE
* SID\_AE\_SET\_CHANGE\_DESC\_EFF
* SID\_AE\_TUBING\_CHECK\_TITLE
* SID\_AE\_CLAMP\_DRAIN\_STATUS\_HEAD
* SID\_AE\_SCAN\_NEW\_SET\_STATUS\_FAIL\_HEAD
* SID\_AE\_SCAN\_NEW\_SET\_UPDATED\_BODY
* SID\_HANG\_AE\_BAGS\_TITLE
* SID\_HANG\_AE\_BAGS\_BODY
* SID\_AE\_SET\_EXTENSION\_LINE\_CONNECTION\_CHECK\_TITLE
* SID\_AE\_SET\_EXTENSION\_LINE\_CONNECTION\_CHECK\_BODY
* SID\_LOAD\_AE\_BODY
* SID\_LOAD\_AE\_TUBE\_CHECK\_BODY
* SID\_LOAD\_AE\_TITLE
* SID\_AE\_CONNECT\_AND\_UNCLAMP\_STATUS\_HEAD
* SID\_AE\_SET\_CONNECT\_AND\_UNCLAMP\_BODY
* SID\_AE\_SCAN\_ERROR
* SID\_AE\_SCAN\_WRONG\_SET
* SID\_AE\_SCAN\_TIMEOUT\_MESSAGE
* SID\_AE\_SCAN\_NEW\_SET\_BODY
* SID\_AE\_SCAN\_NEW\_SET\_STATUS\_HEAD
* SID\_AE\_SET\_UNLOAD\_BODY
* SID\_AE\_SET\_UNLOAD\_TITLE
* SID\_AE\_CLAMP\_DISCONNECT\_STATUS\_HEAD
* SID\_AE\_CLAMP\_DISCONNECT\_BODY
* SID\_AE\_CLAMP\_DISCONNECT\_BODY\_PAGE\_2
* SID\_DRAIN\_AE\_BAG\_TITLE
* SID\_DRAIN\_AE\_BAG\_DIALOG\_MSG
* SID\_CHANGE\_AUTO\_EFFLUENT
* AlarmDisplayDataConst.inc
* Two new events are added for AE set change, below are the events.
* AE Set Change Started
* AE Set Change Completed
* The related events SID’s are added in AlarmDisplayData::mEventSIDS[MAX\_EVENTS], which are SID\_MSG\_X2381\_TITLE and SID\_MSG\_X2382\_TITLE.
* AlarmManagerGUI.cpp
* A new case is added in function AlarmManagerGUI::HandleDialogRequest() which is case ALARM\_DIALOG\_CHANGE\_AE\_SET. Inside the case below are operations.
* Setting fromGuiAeGetDrainRemainingTime dictionary to query the drain remaining time to show to user.
* Calling GotoScreen() to pop up the initial screen of AE set change to show the drain remaining time.
* AlarmView.cpp
* Added action ALARM\_ACTION\_CHANGE\_AE\_SET to AlarmView::SetButtonEnable(), which will take care that the Change AE button will be disabled when GUI has below LANES.
* SYSCONFIG\_LANE
* DIALOG\_LANE
* PRESCRIPTION\_LANE
* CHANGE\_LANE\_1
* CHANGE\_LANE\_2
* CHANGE\_LANE\_3
* PRI\_DIALOG\_LANE
* REMOVE\_AIR\_LANE
* REMOVE\_AIR\_POPUP\_LANE
* Added one condition that will handle that, the Change AE button will get disable when GUI mode is Recirculate.
* CMakeLists.txt
* New cpp files are added to CMakeLists.txt which are required for AE set change.
* PrisMaxGUI/DialogAEEEmptyScreen.cpp
* PrisMaxGUI/DialogChangeAESetDrainConfirmScreen.cpp
* PrisMaxGUI/DialogChangeAESetDrainConfirmView.cpp
* PrisMaxGUI/DialogChangeAESetDrainScreen.cpp
* PrisMaxGUI/DialogChangeAESetConfirmScreen.cpp
* PrisMaxGUI/DialogChangeAESetConfirmView.cpp
* DefaultMarkupSupport.cpp
* One new string is added in External parameter support list. Which is "EMPTY\_TIME\_AEE".
* New constant EMPTY\_TIME\_AEE are added in enum spExternalParamIndexs, Indexes of the external parameter support list.
* New case EMPTY\_TIME\_AEE is added in method DefaultMarkupSupport::ExternalControl(), which will display the drain remaining time to user when Change AE button is pressed from operational screen.
* DialogChangeAESetConfirmScreen.h
* Defines a new class for change AE set confirmation Dialog which is derived from IScreen and ObserverMessage Class.
* The Screen ID for Advisory Dialog 666 in ScreenDriver class.
* DialogChangeAESetConfirmScreen.cpp
* It implements the DialogChangeAESetConfirmScreen class for the change AE set confirmation Dialog.
* DialogChangeAESetConfirmView.h
* Defines a new screen view class for change AE set confirmation Dialog which is derived from IView
* DialogChangeAESetConfirmView.cpp
* implements the DialogChangeAESetConfirmView class for the change AE set confirmation Dialog.
* DialogChangeAESetDrainConfirmScreen.h
* Defines a new class for change AE set drain confirmation Dialog which is derived from IScreen, HeartbeatClient and ObserverMessage Class.
* The Screen ID for Advisory Dialog 667 in ScreenDriver class.
* DialogChangeAESetDrainConfirmScreen.cpp
* It implements the DialogChangeAESetDrainConfirmScreen class for the change AE set drain confirmation Dialog.
* DialogChangeAESetDrainConfirmView.h
* Defines a new screen view class for change AE set drain confirmation Dialog which is derived from IView
* DialogChangeAESetDrainConfirmView.cpp
* implements the DialogChangeAESetDrainConfirmView class for the change AE set drain confirmation Dialog.
* DialogChangeAESetDrainScreen.h
* Defines a new class for change AE set draining Dialog which is derived from IScreen, MarkupSupport and ObserverMessage Class.
* The Screen ID for Advisory Dialog 668 in ScreenDriver class.
* DialogChangeAESetDrainScreen.cpp
* It implements the DialogChangeAESetDrainScreen class for the change AE set draining Dialog.
* DialogChangeAESetWizardScreen.h
* Defines a new class for change AE set wizard screen which is derived from IScreen and ObserverMessage Class.
* This class handles all the AE set changes related screen variations other than confirmation dialog, Drain confirmation dialog and AE draining screen.
* The Screen ID for Advisory Dialog 667 in ScreenDriver class.
* DialogChangeAESetWizardScreen.cpp
* It implements the DialogChangeAESetWizardScreen class for the change AE set wizard Dialog.
* This class handles all the GUI therapy interactions as well as all the screen variations except confirmation dialog, Drain confirmation dialog and AE draining screen.
* DialogChangeAESetWizardView.h
* Defines a new screen view class for change AE set drain confirmation Dialog which is derived from IView and HeartbeatClient.
* DialogChangeAESetWizardView.cpp
* It implements the DialogChangeAESetWizardView class for the change AE set wizard Dialog.
* EndModeSchedulePanel.h
* mpChangeAESetInProgress - Added mpChangeAESetInProgress as a new member variable in SchedulePanel class to check whether AE set change is in progress or not.
* mpSendEffluentDrainBagCancelMsg – Added mpSendEffluentDrainBagCancelMsg as a new member variable in SchedulePanel class to sending BAG\_EFFLUENTDRAIN bag change cancelled.
* EndModeSchedulePanel.cpp
* Modified the constructor for setting mpSendEffluentDrainBagCancelMsg to true and send BAG\_EFFLUENT bag change cancelled through setting fromGUIChangeAESetMsg dictionary. It will be clearing all the dialogs when discard set is pressed from any priority alarm.
* Modified the destructor for resetting fromGUIChangeAESetInProgress dictionary when AE set change is in progress.
* Modified SchedulePanel::Message for Send BAG\_EFFLUENTDRAIN bag change dictionary to set cancelled when newpatient box or same patient box or discard set box is pressed.
* Modified SchedulePanel::EvaluateConditional(), added mpChangeAESetInProgress flag in existing condition for override AUTODRAIN markup conditionals for the screen.
* Modified SchedulePanel::UpdatePatientMode() that when same patient box is clicked, the REUSE\_AEE\_YES\_BOX will get disabled when AE set change is in progress and REUSE\_AEE\_NO\_BOX will also get disabled with value enabled.
* Modified SchedulePanel::IsAEEEmptyRequired() for adding a new condition for determine the AEE emptying is required or not, the new condition added is to check whether the AE set is attached or not.
* GuiMsgIds.h
* Modified the GuiMessageId enum which Defines the message IDs in the Gui, the below new constants are added.
* ID\_GUI\_CHANGE\_AE\_BTN,
* ID\_GUI\_CHANGE\_AE\_CANCEL\_BTN,
* ID\_GUI\_CHANGE\_AE\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_CANCEL\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_SCREEN\_UPDATE\_FROM\_VIEW,
* ID\_GUI\_CHANGE\_AE\_CONFIRM\_ACK,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_REMAINING\_TIME\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_CONFIRM\_SCREEN\_CLOSE,
* ID\_GUI\_CHANGE\_AE\_ACTION\_BUTTONS\_DISABLE,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_DIALOG\_YES\_BTN,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_DIALOG\_NO\_BTN,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_DIALOG\_YES\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_DIALOG\_NO\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_CANCEL\_BTN,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_PAUSE\_BTN,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_RESUME\_BTN,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_PAUSED\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_SET\_MSG\_TO\_GUI,
* ID\_GUI\_CHANGE\_AE\_DRAIN\_REMAINING\_TIME,
* ID\_GUI\_CHANGE\_AE\_EMERGENCY\_STOP\_STATUS,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_NEXT\_BTN,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_CHECK\_BTN,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_LOAD\_BTN,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_UNLOAD\_BTN,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_CONFIRM\_ALL\_BTN,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_RESUME\_TREATMENT\_BTN,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_NEXT\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_LOAD\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_UNLOAD\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_SCAN\_FAILED,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_CONFIRM\_ALL\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_RESUME\_TREATMENT\_BTN\_CLK,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_DIALOG\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_NEXT\_BTN\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_UNLOAD\_BTN\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_LOAD\_BTN\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_SCAN\_NEW\_SET\_FRAMES\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_SCAN\_SET\_FAILED\_FRAMES\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_SCAN\_SET\_TIMEOUT\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_AE\_SCALES\_OPEN\_STATUS\_UPDATE,
* ID\_GUI\_CHANGE\_AE\_WIZARD\_AE\_LOADER\_POSITION\_UPDATE,
* OpsView.cpp
* Modified OpsView::Message() for adding a new case for AD\_BAG\_ID. When the user pressed the AEE bag from the operation screen the software is setting one dictionary and calling one method, which are,

fromGuiAeGetDrainRemainingTime – GUI querying therapy to query the drain remaining time to show the remaining time it to the user.

ScreenDriver::Instance().GotoScreen – which will pop up the initial screen of AE set change which will show the drain remaining time. Two buttons are available to the user for this screen which are Start AE and Cancel.

* Added a new function as a member function of OpsView class. This function will show the box around AEE, when AEE is selected by the user. This box will have a button to initiate the change AE. If user is not selected AEE the box will not present around AEE in operation screen.
* Modified OpsView::Configure(). The new added function is calling from this OpsView::Configure().
* OpsView.h
* Added one new method in the Opsview class.
* PrisMaxGUI.gpj
* The below new files are added to PrisMaxGUI.gpj.
* DialogChangeAESetWizardScreen.cpp
* DialogChangeAESetWizardView.cpp
* DialogChangeAESetDrainScreen.cpp
* DialogChangeAESetDrainConfirmScreen.cpp
* DialogChangeAESetDrainConfirmView.cpp
* DialogChangeAESetConfirmScreen.cpp
* DialogChangeAESetConfirmView.cpp
* RemoveSetView.cpp
* Modified RemoveSetView::ConfigureButtons(). One condition is removed from the case REMOVE\_FILTER\_SET to show the next button availability if not reusing the AEE.
* ScreenDriver.cpp
* Screen driver constructor is modified that, new factories are added to screendriver. Below are the added items,
* DialogChangeAESetConfirmScreen
* DialogChangeAESetWizardScreen
* DialogChangeAESetDrainScreen
* DialogChangeAESetDrainConfirmScreen
* Screen driver destructor is modified that destroying the newly added factories.
* ScreenDriver.h
* New screen ID’s are assigned for new screens which are added as part of AE set change.
* AlarmDialogRequests.h
* Enum AlarmDialogRequests is modified that the change AE set initial dialogue can be initiated from an alarm ALARM\_AEA\_MAX\_LIFE\_EXCEEDED.
* FluidBalanceError.h
* Modified FluidBalanceError class that a new member function is added which is CaptureAEChangeUncertainty.
* FluidBalanceError.cpp
* Defined the new member function here. This function will capture the errors on both the front and side scales under effluent scale.
* AlarmsConst.inc
* Modified mApplicability, it defines the applicability characteristics for each alarm. Changed the alarm characteristics of two alarms (2160 and 2161). These alarms will raise in therapy state treatment also with the new modification.
* BagController.h
* Modified BagController class, new member variable mAESetChangeInProgress added in class.
* BagController.cpp
* BagController constructor is modified. mAESetChangeInProgress is initialized and two new therapy events are subscribed, which are TherapyEvents::AE\_SET\_CHANGE\_START and TherapyEvents::AE\_SET\_CHANGE\_END.
* Modified BagController::EventHandler. The two new subscribed events are added to event handler.
* Modified BagController::TherapyStateChange(). Added a condition that ConfigureDriveByEnable() function will get called only when the AE set change is not in progress.
* Modified BagController::TweakLatentBagChanges(). This function will return when AE set change is in progress.
* FluidPumpController.h
* Modified FluidPumpController class that two new member variables are added. mAESetChangeInProgress and mStopResumeDrainPump.
* FluidPumpController.cpp
* Modified constructor that the added member variable mStopResumeDrainPump is initialized here.
* Four new events are subscribed in FluidPumpController constructor. Which are.
* AE\_SET\_CHANGE\_START
* AE\_SET\_CHANGE\_END
* STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE
* RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE
* Modified FluidPumpController::Initialize() that the new member variable mAESetChangeInProgress is initialized here.
* FluidPumpController::EventHandler is modified, the modifications are below.
* When the therapy events are

TherapyEvents::START\_MAIN\_CIRCUIT\_LOAD and case TherapyEvents::

START\_AEA\_LOAD the condition will get true when mAESetChangeInProgress is set. Similarly, when TherapyEvents::START\_MAIN\_CIRCUIT\_UNLOAD and

TherapyEvents::START\_AEA\_UNLOAD case the comdtion will get true when mAESetChangeInProgress is set.

* The subscribed four new events STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE, RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE, AE\_SET\_CHANGE\_START and AE\_SET\_CHANGE\_END are added.
* In TherapyEvents::THERAPY\_STATE\_CHANGE case, the case case TherapyStates::END: is modified that if the AE set change is in progress set the flag mAESetChangeInProgress to false.
* Modified FluidPumpController::SetStoppedState(). Added a local safe state “LocalSafeState”. Below are the possible cases.
* When mAESetChangeInProgress flag is set and mStopResumeDrainPump is set based on T2160 and T2161 alarm ACTIVE state, the LocalSafeState flag is set to

STOP\_FLUID\_PUMPS.

* When mAESetChangeInProgress flag is set and mStopResumeDrainPump is not set based on T2160 and T2161 alarm INACTIVE state, the LocalSafeState flag is set to

STOP\_ALL\_PUMPS.

* If the flag mAESetChangeInProgress is false, then the LocalSafeState flag is set to
* STOP\_ALL\_PUMPS
* LoaderController.h
* Modified LoaderController class. Added new three member variables to LoaderController class.
* LoaderController.cpp
* LoaderController constructor is modified to initialize the newly added member variables and subscribe to four new events. Which are, TherapyEvents::AE\_SET\_CHANGE\_START,

TherapyEvents::STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE, TherapyEvents::RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE and

TherapyEvents::AE\_SET\_CHANGE\_END.

* Modified LoaderController::TherapyObserver function for keys USER\_ATTACHING\_AEA and USER\_ATTACHING\_AEA\_OVERRIDE. The change for both the cases are If AE Set change is in progress, set will be unloaded already, so no need to publish START\_AEA\_UNLOAD event.
* Modified LoaderController::TherapyObserver function for case UNLOAD\_AEA and LOAD\_AEA. The existing condition is modified with a newly added flag mStoppedBySafeStateAE, which is updated from LoaderController::ProcessSafeStateChange based on mSafeState.
* Modified LoaderController::EventHandler. The changes are below,
* case TherapyEvents::SAFE\_STATE\_CHANGE. The condition mTherapyState == TherapyStates::TREATMENT added in to already existing condition for AttachObservers() to get called even in treatment.
* In case TherapyEvents::START\_AEA\_LOAD and TherapyEvents::START\_AEA\_UNLOAD, the changes made are If we are in a safe state then cancel the unload immediately and set the dictionary toGUIChangeAEActionButtonsDisable for disable all button actions.
* The newly subscribed events changes are also added.
* Modified LoaderController::StopEvent function for setting the mLoaderMotorStatus[loader] to LOADER\_MOTOR\_STATE\_UNKNOWN when the mStoppedBySafeStateAE is set to true and loader == LoaderName::AEA.
* Modified LoaderController::MoveLoader for ignoring move commands. Added condition that mStoppedBySafeState && loader == LoaderName::MAIN for main loader and mStoppedBySafeStateAE && loader == LoaderName::AEA for AE loader.
* Modified LoaderController::ProcessSafeStateChange() for,
* updating safe state for AE set change. If mAESetChangeInProgress is true and mStopResumeDrainPump is true mStoppedBySafeStateAE will update based on mSafeState >= STOP\_FLUID\_PUMPS. If mStopResumeDrainPump is false then mStoppedBySafeStateAE will get update based on mSafeState >= STOP\_ALL\_PUMPS. If mAESetChangeInProgress is set to false then mStoppedBySafeStateAE will get update based on mSafeState >= STOP\_FLUID\_PUMPS.
* Added logics, that If there is any safestate change, stop loading/unloading the AEA loader and If we are coming from a safe state with the patient connected, ensure the loader gets commanded to be retracted. If we are coming from a safe state with the patient connected, ensure the loader gets commanded to be retracted.
* Modified LoaderController::ProcessAlarmUserRequests for if the AE set change is in progress Do not spin the pumps if the patient is connected or if the loader is not in use.
* Modifed user notifier switch case ALARM\_ACTION\_CONTINUE for adding one logic for publishing TherapyEvents::RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE in case of AE set change is in progress and alarm handled is ALARM\_AEE\_LOADER\_MOTOR\_FAIL. similarly added one case for CONDITION\_UPDATE\_EVENT for publishing

TherapyEvents::STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE when AE set change is in progress and the alarm state is ACTIVE for ALARM\_AEE\_LOADER\_MOTOR\_FAIL alarm.

* PinchValveController.h
* Modified PinchValveController class that added two new member variables to the class. mAESetChangeInProgress and mLoadUnloadInProgress.
* PinchValveController.cpp
* Modified constructor for subscribing events. AE\_SET\_CHANGE\_START

AEA\_LOADED, AE\_SET\_CHANGE\_END and AEA\_UNLOADED.

* Modified PinchValveController::Initialize() methos for initializing newly added member variables. mAESetChangeInProgress and mLoadUnloadInProgress.
* Modified PinchValveController::EventHandler for setting mLoadUnloadInProgress to true in event TherapyEvents::START\_AEA\_UNLOAD: or TherapyEvents::START\_AEA\_LOAD. Added TherapyEvents::AEA\_LOADED and TherapyEvents::AEA\_UNLOADED for setting mLoadUnloadInProgress to false.
* Added two new events. TherapyEvents::AE\_SET\_CHANGE\_START event is for setting mAESetChangeInProgress to true and TherapyEvents::AE\_SET\_CHANGE\_END is for setting mAESetChangeInProgress to false.
* Modified PinchValveController::PeriodicProcessing() in case TherapyStates::TREATMENT. If mPerformingFinalDrain and mUsingAE flags are set, calling the SetPosition method for setting the position of both the pinch valves EFFLUENTFILL and EFFLUENTDRAIN.
* PrimingManager.h
* Modified PrimingManager class. Added one member function.

ReturnTimeRemainingFlagForAESet() and added two new keys to enum eKeys. Two new member variables are also added, mGetRemainingTimeForAESetChange and mRemainingTimeReqCount.

* PrimingManager.cpp
* Modified PrimingManager constructor for subscribing new event AE\_SET\_CHANGE\_END and attaching new two dictionaries, fromGuiAeGetDrainRemainingTime and fromGuiStartStopAESetChange.
* Modified PrimingManager::Initialize() for initializing new added member variables mGetRemainingTimeForAESetChange and mRemainingTimeReqCount.
* Modified EventHandler for adding AE\_SET\_CHANGE\_END event. It will set mDrainPaused flag to false.
* Modified HandleTherapyConfigurationEvent(). Setting mGetRemainingTimeForAESetChange to false in TherapyStates::END.
* Modified TherapyObserver() for handling newly added keys DRAIN\_GET\_REMAINING\_TIME\_KEY and START\_AE\_BUTTON\_PRESSED\_KEY. fromGuiAeGetDrainRemainingTime will set to true when when change AE button is pressed from Opsscreen by the user.
* fromGuiAeGetDrainRemainingTime will set to false when user press cancel from change AE initial dialogue.
* fromGuiStartStopAESetChange will set to true when change AE is pressed from initial AE set change screen.
* Modified PrimingManager::UpdateTimeRemaining(). Added a condition that the dictionary

toGuiAeDrainTimeRemaining will set only when mstep is not equal to STEP\_DRAIN\_REQS.

* Modified PerformStepCompleteTasks() for updating toGuiAeDrainTimeRemaining dictionary with drain remaining time immediately when the model gives the time after calculation.
* Modified AdvanceToNextStep() in case of STEP\_DRAIN\_REQS. Here runs a counter for 4 times and query the drain remaining time from model. Some scenarios the time is getting properly from model after some query, so added a counter to query 4 times.
* Defined ReturnTimeRemainingFlagForAESet() member function.
* PrimingModelController.h
* Modified PrimingModelController class for adding new member variables. mAEDrainPaused, mAESetChangeInProgress, mSafeStateByte and mFinalDrainLowFlowAlarmStatus.
* Added one member variable mStopPublished to AeeDrainAlarms class which is a nested class of PrimingModelController.
* PrimingModelController.cpp
* Modified PrimingModelController constructor for subscribing new four events. That are,

AE\_SET\_CHANGE\_START, AE\_SET\_CHANGE\_END,

RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE and

STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE.

* Modified PrimingModelController::Initialize() for initializing the newly added member variables, mAESetChangeInProgress, mAEDrainPaused and mSafeStateByte.
* Modified PrimingModelController:: EventHandler for therapy event TherapyEvents::SAFE\_STATE\_CHANGE. DetermineControllerPauseState() and DetermineModelPauseState() will get called based on the mSafeStateSet setting. mSafeStateSet will be based on mSafeState.
* The member variable mAEDrainPaused will set to true or false based on mUserPauseSet in TherapyEvents::PAUSE\_PRIME and TherapyEvents::RESUME\_PRIME.
* New member variable mAESetChangeInProgress will set to true or false in the TherapyEvents::AE\_SET\_CHANGE\_START and TherapyEvents::AE\_SET\_CHANGE\_END.
* TherapyEvents::STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE and TherapyEvents::RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE will set the mFinalDrainLowFlowAlarmStatus to true or false and calls DetermineControllerPauseState() and DetermineModelPauseState().
* Modified HandleTherapyStateChangeEvent() in switch case TherapyStates::END for setting the mAESetChangeInProgress to false and publish the event ABORT\_PRIME\_STEP in case if user has aborted AE drain.
* Modified DetermineControllerPauseState(). Variable localmSafeStateSet, localmAnyBagChanging is added in function. localmSafeStateSet and localmAnyBagChanging will get update based on mSafeState >= STOP\_ALL\_PUMPS or mFinalDrainLowFlowAlarmStatus.
* Modified DetermineModelPauseState(). If local\_safestate is set to true, then the model is paused. local\_safestate will get set to true or false based on mSafeState >= STOP\_ALL\_PUMPS or mFinalDrainLowFlowAlarmStatus flag set to true.
* Modified ControlSequence(). localmSafeStateSet will get update based on mSafeState >= STOP\_ALL\_PUMPS or mFinalDrainLowFlowAlarmStatus.
* Modified MonitorActivity() case PrimeModelInterface::PRIME\_OP\_FAILING. If prime step is equal to STEP\_FINAL\_DRAIN and mAESetChangeInProgress is true, setting the activityDone to false.
* AeeDrainAlarms constructor is modified that member variable mStopPublished is initialized.
* AeeDrainAlarms::UserNotifier is modified that added two new cases. LATCH\_CLEARED and CONDITION\_UPDATE\_EVENT. In LATCH\_CLEARED, if the action is ALARM\_ACTION\_CONTINUE and mAESetChangeInProgress is true, then mPrimeError and mStopPublished is setting to false. It will publish event RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE. In CONDITION\_UPDATE\_EVENT,

If mAESetChangeInProgress is true and ALARM\_FINAL\_DRAIN\_FRONT\_LOW\_FLOW and

ALARM\_FINAL\_DRAIN\_REAR\_LOW\_FLOW are INACTIVE state then mStopPublished is setting to true and STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE is published.

* TherapyRecoveryController.h
* Modified TherapyRecoveryController class. Few member variables are added and one enum is added. mAEused, mPatientNewAESet, mReuseAE and mPatientAESet.
* TherapyRecoveryController.cpp
* Modified constructor that newly added member variables are initialized.
* Modified EventHandler() case TherapyEvents::NEW\_PATIENT: and TherapyEvents::SAME\_PATIENT. Flag mPatientAESet is getting updated here.
* In case TherapyStates::TREATMENT, mAESetTimeStarted is updated with current time.
* TreatmentSessionController.h
* New member variables, member functions and enums are added.
* TreatmentSessionController.cpp
* TreatmentSessionController constructor is modified that the newly added member variables are initialized and subscribed four events.
* Modified Initialize() function that three dictionaries are attached here.
* Modified destructor that the added dictionary is detached here.
* Modified TherapyObserver() that case AE\_STATE\_CHANGE\_CMD will call the member function UpdateAEStateChange(). Key KEY\_UNLOAD\_AE\_SET will publish the event START\_AEA\_UNLOAD and key KEY\_LOAD\_AE\_SET will publish the event START\_AEA\_LOAD.
* EventHandler() is modified that if mSafeState >= STOP\_ALL\_PUMPS toGUIChangeAEActionButtonsDisable dictionary will set to true. If there is any high prioriy alarm the change AE button will get disabled with this change and mpChangeAEActionButtonsDisable member variable is set to true.
* toGUIChangeAEActionButtonsDisable dictionary will get clear when T1138, T2060 and T2061 are in inactive state.
* Logic added that, If isDrainCompleteOnHighPriority is set to true then stop Sending AE Drain ABORT status to GUI if therapy state changed to END mode during drain.
* In case TherapyEvents::AE\_END\_DRAIN\_COMPLETE. If AE set change is in progress then member variable mpChangeAESetCurrentState is updated with state CHANGE\_AE\_DRAINING\_ABORTED.
* In case AE\_SET\_CHANGE\_START, mpChangeAESetCurrentState is updated with a state CHANGE\_AE\_STARTED, will call function HandleAESetChangeStatus() and will generate a message event MSG\_AE\_SET\_CHANGE\_STARTED.
* In case AE\_SET\_CHANGE\_END, mpChangeAESetCurrentState will get update with a state of CHANGE\_AE\_SET\_COMPLETED, generate a message event MSG\_AE\_SET\_CHANGE\_COMPLETED. Will clear the overridden AE set life exceeded alarm after AE change and call function HandleAESetChangeStatus().
* Modified PeriodicProcessingOneHz() function for calling function HandleAESetScaleStatus() in case mpChangeAESetCurrentState is set to CHANGE\_AE\_UNLOAD\_AE\_SET or CHANGE\_AE\_HANG\_AE\_BAGS.
* Modified AECanBeReused() that AE\_MIN\_REUSE\_LIFE is removed from the revsExceeded and timeExceeded logic.
* Modified UpdateSetTime() for updating mAESetTimeStarted and mHasTreatmentBeenStartedForAESet. mAESetTimeStarted will update with current time when Treatment is being started for the first time for this AE set and mHasTreatmentBeenStartedForAESet will set to true.
* After treatment has already been started and as long as user has not stopped treatment, then update the most recent date/time in treatment. mAESetTimeNow will get update to currentTime and UpdateAESetTime() will get call.
* Newly added member function GetSetTimeAE() is defined.
* InitializeCircuits() is modified that the member variables mHasTreatmentBeenStartedForAESet

mAESetTimeStarted and mAESetTimeNow is initialized.

* UserNotifier() is modified that added OPERATOR\_ACTION , ALARM\_ACTION\_CHANGE\_AE\_SET. this action from alarm will initiate the change AE set process.
* Modified PerformAeAlarmProcessing() that enable change AE button if in TREATMENT and Disable CHANGE AE button if not in TREATMENT based on mTherapyState.
* Modified GetTherapyRecoveryData() that mHasTreatmentBeenStartedForAESet will set to true and mAESetTimeNow will get update with GetCurrentDateTime() and mAESetTimeStarted is updated with saved value.
* Newly added member functions HandleAESetChangeStatus(), HandleAESetScaleStatus() and UpdateAEStateChange() is defined here.
* HandleAESetChangeStatus() will set the AE status to GUI from therapy and UpdateAEStateChange() will set the mpChangeAESetCurrentState with proper AE states based on messages received from GUI.
* BagClass.h
* BagClass class is modified with new member function and member variable, AESetChangeState(bool AESetChange) and mpChangeAESetInProgress.
* BagClass.cpp
* BagClass constructor is modified for initializing member variable mpChangeAESetInProgress.
* Modified SetLED() for flashing the LED when AE set change is in progress. LED will flash when AE bag change is happening during AE set change.
* UpdateState() function is modified that when AE set change is in progress we don’t allow a drive by bag change.
* New member function AESetChangeState() Is defined.
* FluidPumpModelAlarms.h
* Modified FluidPumpModelAlarms for adding one new member function ProcessAEChangeErrors(void).
* FluidPumpModelAlarms.cpp
* Member function ProcessAEChangeErrors() is defined and called here.
* TherapyStateManager.h
* TherapyStateManager class is modified for adding one member variable and one key.
* TherapyStateManager.cpp
* TherapyStateManager constructor is modified for attaching a dictionary fromGuiStartStopAESetChange attached to key START\_AE\_SET\_CHANGE.
* Modified Initialize() function to initialize mpChangeAESetInProgress flag.
* Modified UpdateSafeState() to add a new logic for setting the safe state to STOP\_FLUID\_PUMPS when AE set change is started.
* Modified UpdateAllowedTherapyState() case TherapyStates::TREATMENT. Will not allow it to change the stateAllowed to RECIRCULATE when AE set change is in progress.
* TherapyStates::RETURN case, stateAllowed will not allow stateAllowed to TREATMENT when AE set change is in progress.
* Modified UpdateTherapyState() if mTherapyState is TherapyStates::END and mpChangeAESetInProgress is set to true, then publishing the event AE\_SET\_CHANGE\_END. User change the therapy state to END during AE set change is in progress, so publishing the AE set END event.
* Modified TherapyObserver() function with key START\_AE\_SET\_CHANGE. When fromGuiStartStopAESetChange is set to true, updating mpChangeAESetInProgress falg to true, calling UpdateSafeState() and publishing AE\_SET\_CHANGE\_START.
* If fromGuiStartStopAESetChange set to false, mpChangeAESetInProgress flag will set to false, UpdateSafeState() will get call for changing safeState to NOMINAL or other state based on safeState.
* TherapyEventPublisher.h
* Modified The maximum number of event subscriptions (msMAXIMUM\_EVENT\_SUBSCRIPTIONS) to 560.
* TherapyEvents.in
* therapyEvents list is modified with four new events. Which are, AE\_SET\_CHANGE\_START, STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE, RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE and AE\_SET\_CHANGE\_END.

### Unit Test Case

|  |  |  |  |
| --- | --- | --- | --- |
| **File** | **Type of Change** | | |
| **Added** | **Modified** | **Deleted** |
| [BagController\_UT.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Therapy/Controllers/BagController/BagController_UT.cpp) | N/A | X | N/A |
| [FluidPumpController\_UT.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Therapy/Controllers/FluidPumpController/FluidPumpController_UT.cpp) | N/A | X | N/A |
| [PinchValveController\_UT.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Therapy/Controllers/PinchValveController/PinchValveController_UT.cpp) | N/A | X | N/A |
| [PrimingModelController\_UT.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Therapy/Controllers/PrimingModelController/PrimingModelController_UT.cpp) | N/A | X | N/A |
| [TherapyRecoveryController\_UT.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Therapy/Controllers/TherapyRecoveryController/TherapyRecoveryController_UT.cpp) | N/A | X | N/A |
| [TherapyStateManager\_UT.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Therapy/StateManagers/TherapyStateManager/TherapyStateManager_UT.cpp) | N/A | X | N/A |
| TreatmentSessionController\_UT.cpp | N/A | X | N/A |
| [FluidPumpController\_Stub.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Stubs/src/Therapy/Controllers/FluidPumpController_Stub.cpp) | N/A | X | N/A |
| [PrimingManager\_Stub.cpp](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Stubs/src/Therapy/Controllers/PrimingManager_Stub.cpp) | N/A | X | N/A |
| [BagClass\_Stub.cc](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/diff#UnitTest/Stubs/src/Therapy/Helpers/BagClass_Stub.cc) | N/A | X | N/A |

## Labeling Update

*The table below defines all string changes.*

Table 21 String Updates

| **String ID** | **Type of Change** | | | **Content** |
| --- | --- | --- | --- | --- |
| **Added** | **Modified** | **Deleted** |
| SID\_MSG\_X0721\_TITLE | X |  |  | AE Set Change Started |
| SID\_MSG\_X0722\_TITLE | X |  |  | AE Set Change Completed |
| SID\_ALARM\_2119\_BODY |  | X |  | Added instruction to press change AE from AE Set life exceeded alarm dialog |
| SID\_CHANGE\_AE\_SET\_DIALOG\_TITLE | X |  |  | Change Auto Effluent Set |
| SID\_AE\_SET\_CHANGE\_DESC\_EFF | X |  |  | Instructions in AE Set change confirmation dialog |
| SID\_AE\_TUBING\_CHECK\_TITLE | X |  |  | Check Tubing Alignment |
| SID\_AE\_CLAMP\_DRAIN\_STATUS\_HEAD | X |  |  | Clamp Auto Effluent Drain Lin |
| SID\_AE\_SCAN\_NEW\_SET\_STATUS\_FAIL\_HEAD | X |  |  | Scan Failed Auto Effluent Set |
| SID\_AE\_SCAN\_NEW\_SET\_UPDATED\_BODY | X |  |  | Instructions in Scan Failed Auto Effluent Set dialog |
| SID\_HANG\_AE\_BAGS\_TITLE | X |  |  | Hang Auto Effluent Bags |
| SID\_HANG\_AE\_BAGS\_BODY | X |  |  | Instructions in Hang Auto Effluent Bags dialog |
| SID\_AE\_SET\_EXTENSION\_LINE\_CONNECTION\_CHECK\_TITLE | X |  |  | Connect Extension Line And Drain Hook |
| SID\_AE\_SET\_EXTENSION\_LINE\_CONNECTION\_CHECK\_BODY | X |  |  | Instructions in Connect Extension Line And Drain Hook dialog |
| SID\_LOAD\_AE\_BODY | X |  |  | Instructions in the Load New Auto Effluent Set dialog |
| SID\_LOAD\_AE\_TUBE\_CHECK\_BODY | X |  |  | Instructions in the Verify Tubing Alignment dialog |
| SID\_LOAD\_AE\_TITLE | X |  |  | Load New Auto Effluent Set |
| SID\_AE\_CONNECT\_AND\_UNCLAMP\_STATUS\_HEAD | X |  |  | Connect and Unclamp Auto Effluent Set |
| SID\_AE\_SET\_CONNECT\_AND\_UNCLAMP\_BODY | X |  |  | Instructions in the Connect and Unclamp Auto Effluent Set dialog |
| SID\_AE\_SCAN\_ERROR | X |  |  | Error Scanning AE Set. Press Next Button to continue. |
| SID\_AE\_SCAN\_WRONG\_SET | X |  |  | Wrong Set Scanned. Please Scan the correct AE Filter or Press Next Button. |
| SID\_AE\_SCAN\_TIMEOUT\_MESSAGE | X |  |  | Scan Timed Out. Please Scan the correct AE Filter or Press Next Button. |
| SID\_AE\_SCAN\_NEW\_SET\_BODY | X |  |  | Instructions in the Scan New Auto Effluent Set dialog |
| SID\_AE\_SCAN\_NEW\_SET\_STATUS\_HEAD | X |  |  | Scan New Auto Effluent Set |
| SID\_AE\_SET\_UNLOAD\_BODY | X |  |  | Instructions in the Unload and Discard Set, Bags and Lines dialog |
| SID\_AE\_SET\_UNLOAD\_TITLE | X |  |  | Unload and Discard Set, Bags, and Lines |
| SID\_AE\_CLAMP\_DISCONNECT\_STATUS\_HEAD | X |  |  | Clamp and Disconnect Auto Effluent Lines dialog |
| SID\_AE\_CLAMP\_DISCONNECT\_BODY | X |  |  | Instructions in the Clamp and Disconnect Auto Effluent Lines |
| SID\_AE\_CLAMP\_DISCONNECT\_BODY\_PAGE\_2 | X |  |  | Instructions in the Clamp Auto Effluent Drain Line dialog |
| SID\_DRAIN\_AE\_BAG\_TITLE | X |  |  | Drain Auto Effluent Bags |
| SID\_DRAIN\_AE\_BAG\_DIALOG\_MSG | X |  |  | Instructions in the Drain Auto Effluent Bags dialog |
| SID\_CHANGE\_AUTO\_EFFLUENT | X |  |  | Change AE |
| SID\_ChangeAESet | X |  |  | Change AE |
| SID\_BACK\_BUTTON | X |  |  | Back |

*The table below lists all of the user interface screen changes. Instead of reproducing the figures here, use cross-references to the actual figures.*

Table 22 Screen Updates

| **Screen Name** | **Screen Number** | **Type of Change** | | | **Reference** |
| --- | --- | --- | --- | --- | --- |
| **Added** | **Modified** | **Deleted** |
| DialogChangeAESetConfirm | 666;0 | X |  |  | Change AE start screen |
| DialogChangeAESetDrainConfirm | 667;0 | X |  |  | Yes/No screen |
| DialogChangeAESetDrain | 668;0 | X |  |  | Emptying in progress |
| DialogChangeAESetWizard | 669;0 | X |  |  | Clamp and disconnect dialog |
| DialogChangeAESetWizard | 669;1 | X |  |  | Clamp AE Drain Line |
| DialogChangeAESetWizard | 669;2 | X |  |  | Unload AE |
| DialogChangeAESetWizard | 669;3 | X |  |  | Scan New AE |
| DialogChangeAESetWizard | 669;4 | X |  |  | Scan Failed |
| DialogChangeAESetWizard | 669;5 | X |  |  | Load New AE |
| DialogChangeAESetWizard | 669;6 | X |  |  | Tubing Check |
| DialogChangeAESetWizard | 669;7 | X |  |  | Hang AE |
| DialogChangeAESetWizard | 669;8 | X |  |  | Connect Extension Line and drain hook |
| DialogChangeAESetWizard | 669;9 | X |  |  | Connect and unclamp |

## Reviews

### PrisMaxCP Pull Request

[Pull Request #580: CADV-8138 Change AE Set Dev - Baxter Bitbucket](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxcp/pull-requests/580/overview)

### PrisMaxGUIAssets Pull Request

[Pull Request #217: CADV-8138 Dev Common - Baxter Bitbucket](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxguiassets/pull-requests/217/diff#Strings/English.xml)

[Pull Request #250: Updated v3.4 MarkUpDef.xml - Baxter Bitbucket](https://bitbucket-prod.aws.baxter.com/projects/PMAX3/repos/prismaxguiassets/pull-requests/250/overview)

# Change Verification (CV)

*This section should reference test cases necessary to be executed to verify a correct implementation of the change or reference a separate document in which it is contained. This section should also reference the verification report where the actual result of the test execution of the listed test cases is presented.*

## System Requirement Verification

Table 23 Verification Test Descriptions

|  |  |  |  |
| --- | --- | --- | --- |
| **Test ID** | **Config ID** | **Requirement ID** | **Test Description** |
| 8332 | 11638 | PRD-3395 | **Overview**: This test will verify the PFR accuracy without PFR makeup and low PFR values. This test case stresses the system by changing the AE for multiple times while in treatment |
| **Stimulus/Stimuli**: Operator will perform the Multiple AE changes in 3hrs of CRRT treatment. |
| **Observation(s):** System maintains flow accuracy of ±30ml/hr and ±70ml/3hr as observed by the external weight of the patient bag. |
| 8333 | 11639 | PRD-3395 | **Overview**: Operator will perform the Multiple AE changes in 3hrs of CRRT treatment. |
| **Stimulus/Stimuli**: Operator will perform the Multiple AE changes in 3hrs of CRRT treatment. |
| **Observation(s):** System maintains flow accuracy of ±30ml/hr and ±70ml/3hr as observed by the external weight of the patient bag. |

## Software Requirement Verification

Table 24 - Software Verification Details

|  |  |  |  |
| --- | --- | --- | --- |
| **Test ID** | **Config ID** | **Requirement ID** | **Test Description** |
| 7805 | 11048 | SRS-7269  SRS-6411  SRS-2539 | **Overview**: This test verifies that   * + - the software runs the pump while loading/unloading the AE set successfully.     - Software allows loader motor movement to be interrupted and resumed.     - AE loader and drain pump stops when Hard Stop Key is pressed. |
| **Stimulus/Stimuli**: Load the set, unload the set, load the set and press the hard stop key while the set is loading. |
| **Observation(s):** It is observed that:   * The drain pump runs during loading and unloading the AE set. * Software allows loader motor movement to be interrupted and resumed. * The AE loader and drain pump stop when hard STOP key is pressed. |
| 8067 | 11339 | SRS-9829  SRS-9837  SRS-9836  SRS-9838  SRS- 9855  SRS-9825  SRS-7919  SRS-8023  SRS-9826 | 1. **Overview:** This test will verify that:  * Software shall allow the user to change the Auto Effluent (AE) accessory during TREATMENT. * Software shall stop all fluid pumps when the Change Auto Effluent workflow is confirmed by the operator. * Software shall allow the user to Confirm or Cancel the AE change before initiating the process * Once the change AE operation is confirmed the process must be completed (no cancelling after that point) * Message Event: AE Set Change Started shall be generated when the Auto Effluent (AE) set change is initiated in treatment. * Message Event: Barcode Read Success shall be generated when AE barcode is scanned while AE set change is performed. * Message Event: AE Set Change Complete shall be generated when the Auto Effluent (AE) set change has completed in treatment. * Software shall allow the option to drain the AE bags before unloading the AE set * Software generates an alarm when the actual flow rate through a fluid pump is lower than expected |
| **Stimulus:**   * Initiate AE change from GUI. |
| **Observation:**   * Software allows the user to change the Auto Effluent (AE) accessory during TREATMENT. * Software stops all fluid pumps when the Change Auto Effluent workflow is confirmed by the operator. * Software allows the user to Confirm or Cancel the AE change before initiating the process. * Once the Change AE operation is confirmed cancelling is not allowed. * Message Event: AE Set Change Started is generated when the Auto Effluent (AE) set change is initiated in treatment. * Message Event: Barcode Read Success shall be generated when AE barcode is scanned while AE set change is performed. * Message Event: AE Set Change Complete is generated when the Auto Effluent (AE) set change has completed in treatment. * Software allows the option to drain the AE bags before unloading the AE set. * Software generates an alarm when the actual flow rate through a fluid pump is lower than expected. |
| 8111 | 11385 | SRS-9857  SRS-9827 | **Overview:** This test will verify that :   * Software shall reset the AE Set Time to 0 after an AE Set Change has completed in treatment. * Software shall restrict the capability to perform saline or blood recirculation while an Auto Effluent (AE) set change is in progress. * Software shall restrict Flowrate change , Syringe change and Bag change when AE set change is in progress. |
| **Stimulus:**   * Initiate AE change from GUI. |
| **Observation:**   * Software resets the AE Set Time to 0 after an AE Set Change has completed in treatment. * Software shall restrict the capability to perform saline or blood recirculation while an Auto Effluent (AE) set change is in progress. * Flowrate change, Syringe change and Bag change is not allowed when AE set change is in progress |
| 8112 | 11386 | SRS-9829  SRS-9875  SRS-9836  SRS-9838  SRS-9854 | **Overview:** This test will verify that:   * Software shall display calculated time to complete drain during AE set change. * Software shall allow all fluid pumps to resume once the AE Set Change has been completed. |
| **Stimulus:**   * Initiate AE change from GUI. |
| **Observation:**   * Software displays calculated time to complete drain during AE set change. * Software allows all fluid pumps to resume once the AE Set Change has completed |
| 8113 | 11387 | SRS-9840 | **Overview:** This test will verify that:   * Software shall automatically move to the next step when the AE drain has completed, or the operator cancelled the drain, or the operator has skipped the drain. |
| **Stimulus:**   * Initiate AE change from GUI. |
| **Observation:**   * Software automatically moves to the next step when the AE drain has completed, or the operator cancelled the drain or the operator has skipped the drain. |
| 8114 | 11388 | SRS-1159  SRS-9841  SRS-2956  SRS-9843  SRS-9844  SRS-9847  SRS-9851  SRS-9852  SRS-9853  SRS-9845 | **Overview:** This test will verify that:   * + - The screens implemented as part of the AE set change shall contain instructions illustrations and buttons as per CADV8138     - It takes less than 20 seconds to load or unload a set when AE set change is initiated. |
| **Stimulus:**   * Initiate AE change from GUI. |
| **Observation:**   * + - The screens implemented as part of the AE set change contains instructions illustrations and buttons as per CADV8138     - Unload and Load while AE set change workflow is initiated takes less than 20 seconds to load or unload a set. |
| 8115 | 11389 | SRS-6162  SRS-9845  SRS-9687  SRS-9849  SRS-9850 | **Overview:** This test will verify that:   * Software shall allow the user to continue loading the set if the barcode scan fails or times out. * Software shall flash the Effluent and Drain scale LEDs when the scales are opened, and sufficient weight is detected on the scale. * Software shall have the scales LEDs ON (non-flashing) during bag change sequence. * Software shall disable the action to move to the Connections Steps until the scales are closed and sufficient weight is detected. |
| **Stimulus:**   * Scan incorrect AE set. * Hang bags on AE scales as directed |
| **Observation:**   * Software allows the user to continue loading the set if the barcode scan fails or times out. * Software flashes the Effluent and Drain scale LEDs during the AE set change and sufficient weight is detected on the scale. * Software has the scales LEDs ON (non-flashing) during bag change sequence. * Software disables the action to move to the Connections Steps until the scales are closed and sufficient weight is detected. |
| 8117 | 11391 | SRS-9559  SRS-6335  SRS-9560  SRS-1134 | **Overview:** This test will verify that "CRRT Maximum Set Life Exceeded" and "AE Maximum Life Exceeded" alarms declare when treatment is performed using the same Filter and AE sets for long hours. |
| **Stimulus**: Perform treatment using the same sets for long hours. |
| **Observations**: The system declares "CRRT Maximum Set Life Exceeded" and "AE Maximum Life Exceeded" alarms |
| 8133 | 11410 | SRS-6324  SRS-9626 | **Overview** – This test will verify that if the system is in treatment and Auto Effluent change is in progress when a system reset occurs; the user is not allowed to recover previous settings. |
| **Stimulus** – Issue Engineering mode command to trigger system reset in " Drain Auto Effluent bags?' dialog “then try recover previous settings. |
| **Observations** – User is not able to recover previous settings. |
| 8139 | 11416 | SRS-6162  SRS-8054  SRS-1134 | 1. **Overview**: Verify that the system declares the Effluent Rear open alarm when the scale is open during Prime. It also verifies that the LED light on the scale changes according to ON/OFF conditions. |
| **Stimulus**: Open the Effluent scale to generate the alarm. |
| **Observation**: The system declares the Effluent Scale open alarm. |
| 8140 | 11417 | SRS-9685  SRS-9686  SRS-9688  SRS-9689  SRS-9887  SRS-9652  SRS-9687  SRS-7920 | 1. **Overview**: This test will verify that:  * For main set two indications of a barcode scan failure is displayed before the operator is allowed to choose from a list of sets to identify the circuit set * For Auto effluent allows the user to Select Set manually. * During Change AE set, user can navigate to load AE screen without scanning AE once scan fails. |
| **Stimulus**:   1. In Scan set screen do not scan the barcodes of the set. |
| **Observation**:   1. For main set two indications of a barcode scan failure displays before the operator is allowed to choose from a list of sets to identify the circuit set 2. For Auto effluent allows the user to Select Set manually. 3. During Change AE set, user can navigate to load AE screen without scanning AE once scan fails. |
| 8141 | 11418 | SRS-1217 | **Overview**: This test will verify that in End Mode:   * Option to select Reuse AE is enabled only if Same patient is selected and AE change was not in progress. * Option to select Reuse AE is disabled even if Same patient is selected but AE change in progress |
| **Stimulus**: Do not initiate AE set change while in treatment and move to End mode, Initiate Ae set change and move to End mode. |
| **Observation**:   * User can select Reuse AE only if Same patient is selected and AE change was not in progress. * User cannot select Reuse AE even if Same patient is selected but AE change in progress. |
| 8142 | 11419 | SRS-2956  SRS-547 | **Overview:** This test will verify that the proper completion of the Sets step. |
| **Stimulus:** Load a set in the Sets screen. |
| **Observation:** The operator can see check mark after each component in the set is attached/inserted. |
| 8144 | 11421 | SRS-9517  SRS-1134 | **Overview:** This test case will verify that "AE Loader Setup Failure" alarm declares when AE set is forcibly pulled away from the Loader. |
| **Stimulus:** AE set is forcibly pulled away from the Loader. |
| **Observation:** The system will declare "AE Loader Setup Failure" alarm. |
| 8145 | 11422 | SRS-6411  SRS-6367 | **Overview:**   * 1. Circuit Loader Setup Failure Alarm (T1137) is declared when the main circuit loader does not achieve the requested position or is moved from the correct position.   2. AE Loader Setup Failure Alarm (T1138) is declared when AEE does not achieve the requested position or is moved from the correct position while in setup or in Change AE state.   3. Software allows loader motor movement to be interrupted and resume successfully. |
| **Stimulus:**   1. While set is loading, pull on the set (obstruct the path) and While unloading push so that it does not load/unload correctly. |
| **Observation:**   1. The operator will observe Circuit Loader Setup Failure Alarm (T1137) been triggered and  AE Loader Setup Failure Alarm (T1138) when load/unload does not work as expected. 2. Software allows loader motor movement to be interrupted and resume successfully. |
| 8146 | 11423 | SRS-9559  SRS-9560 | **Overview:** This test will verify that   * While Change AE is performed in treatment,"CRRT Maximum Set Life Exceeded" and "AE Maximum Life Exceeded" alarms declare when sets reach end of set life. * Overridden alarm T2119 - AE Maximum Life Exceeded is cleared when Change AE is completed in treatment. |
| **Stimulus:** Run the treatment until set life is reached. |
| **Observation:**   * While Change AE is performed in treatment,"CRRT Maximum Set Life Exceeded" and "AE Maximum Life Exceeded" alarms declare when sets reach end of set life. * Overridden alarm T2119 - AE Maximum Life Exceeded is cleared when Change AE is completed in treatment. |
| 8147 | 11424 | SRS-7932  SRS-7931  SRS-7908  SRS-7909  SRS-7936  SRS-7938 | **Overview:** This test will verify that the system message events for Set unload/load, AE Drain Paused/Resumed, Syringe Load/Installed/Removed. |
| **Stimulus:** Load/unload the set and syringe, Change Calcium Compensation, Pause/Resume AE Drain for recording of Message events. |
| **Observations:** The system records message events in History. |
| 8148 | 11425 | SRS-9632  SRS-8025  SRS-6324 | **Overview:** This test will verify that software trigger the alarm T2331 and B1223 Auto Effluent Pump Hardware Failure when the auto effluent motor is outside of command limit and system reset after B1223 is declared. |
| **Stimulus:** Use the flat-head screwdriver to prevent Effluent pump to rotate properly. |
| **Observation:** Effluent Pump Failure is declared   * + - * T2331 is declared during Setup and treatment       * B1223 is declared during treatment.       * System reset |
| 8149 | 11426 | SRS-9632  SRS-8025  SRS-9626 | **Overview:** This test will verify that software trigger the Pump hardware failure alarm when the motor is outside of command limit. |
| **Stimulus:** Use the flat-head screwdriver to prevent pumps to rotate properly. |
| **Observation:** Pump Hardware Failure is declared |
| 8150 | 11427 | SRS-9632  SRS-9643  SRS-8542  SRS-9616  SRS-7405 | **Overview:** This test will verify that:   * Software trigger the alarm T1226 Effluent Pump Failure when the effluent motor is outside of command limit. * The backup speaker does NOT sound for a Therapy alarm. * Once software enters treatment, the current prescription does NOT display on top of the operation screen. * B2222 is NOT declared when an operator shuts down and then power up the system. * In End Mode, only new patient is available to select, and software instructs to disconnect patient, remove the main set, remove the AE set, remove fluid bags and remove syringe. |
| **Stimulus:**   * Use the flat-head screwdriver to prevent Effluent pump to rotate properly. * Power-cycle the system. * Select "End" on the 'Initial' screen. * Follow the on-screen instructions to navigate through End Mode. |
| 1. **Observation:** Effluent Pump Failure is declared  * T2332 is declared during Setup * The backup speaker does NOT sound for a Therapy alarm. * Once software enters treatment, the current prescription does NOT display on top of the operation screen. * T1226 is declared during treatment. * B2222 is NOT declared. * In End Mode, only new patient is available to select, and software instructs to disconnect patient, remove the main set and remove fluid bags |
| 8151 | 11428 | SRS-9632 | **Overview:** This test will verify that software trigger the alarm T2330 Blood Pump Failure when the effluent motor is outside of command limit. |
| **Stimulus:** Pull the Blood tube downward to prevent the blood tube to rotate properly. |
| **Observation:** Blood Pump Hardware Failure is declared |
| 8152 | 11429 | SRS-1134  SRS-8050 | **Overview:** This test case will verify that "Predicted Effluent Drain Weight Error" alarm declares when fluid is removed from the additional bag. |
| **Stimulus:** Fluid is removed from the additional bag. |
| **Observation:** The system will declare the "Predicted Effluent Drain Weight Error" alarm. |
| 8153 | 11430 | SRS-8051  SRS-1134 | **Overview:** This test case will verify that Bag Weight Change alarm declares when scale detects unexpected weight change. |
| **Stimulus:** Fluid is added to the additional bag and flow rate is set to zero. |
| **Observation:** The system will declare the Bag Weight Change alarm. |
| 8154 | 11431 | SRS-8516 | **Overview:** This test will verify:   * T0802 is declared when the AE bags are full and AE drain is paused. |
| **Stimulus:** The following(s) will be performed:   * Run treatment with AE drain paused until AE bags are full |
| **Observation:** The following(s) will be observed:   * T0802 is declared when the AE bags are full and AE drain is paused. |
| 8156 | 11433 | SRS-8059  SRS-1134 | **Overview:** This test will verify that the “Front Effluent Drain Clogged" alarm declares when AE set is attempting to drain and Front Effluent line is clamped. |
| **Stimulus:** Clamp Front Effluent line. |
| **Observation:** The system will declare "Front Effluent Drain Clogged" alarm. |
| 8157 | 11434 | SRS-8059  SRS-1134 | **Overview:** This test will verify that the “Rear Effluent Drain Clogged" alarm declares when AE set is attempting to drain and Rear Effluent line is clamped. |
| **Stimulus:** Clamped Rear Effluent line. |
| **Observation:** The system will declare "Rear Effluent Drain Clogged" alarm. |
| 8158 | 11435 | SRS-6192  SRS-6733 | **Overview:** This test will verify that the auto effluent steps contain the instructions specified in the requirement. |
| **Stimulus:** In Sets screen on Auto Effluent installation sub step, load the AE set |
| **Observation:** The operator is instructed on how to scan and install the AE set and software checks for 1Lbag and 5l bag are hung on their respective scales. |
| 8159 | 11436 | SRS-7355  SRS-9840  SRS-1217  SRS-7354 | **Overview:** This test will verify that   * Change AE when performed software provides pause, resume, and cancel the drain operation of the AE set. * End mode allows the user to discard all fluids, syringe, AE, and empty the AE prior to discarding when Discard All is selected in End mode. |
| **Stimulus:** Perform Change AE while in treatment and End the treatment. |
| **Observation:** Software instructs discarding everything that's attached to the system.   * Change AE provides pause, resume, and cancel the drain operation of the AE set. * End mode allows the user to discard all fluids, syringe, AE, and empty the AE prior to discarding when Discard All is selected in End mode. |
| 8165 | 11442 | SRS-8035 | **Overview:** This test will verify that: Software raises an Alarm if any of the following conditions occur with a loader motor: loss of communications, failure to maintain position, or an invalid position reported |
| **Stimulus:** Initiate AE change from GUI. |
| **Observation:** Alarm are raised when any of the following conditions occur with a loader motor: loss of communications, failure to maintain position, or an invalid position reported |
| 8310 | 11615 | SRS-235  SRS-1258 | **Overview**:  This test will verify that the PFR makeup does not occur when PFR makeup is disabled and that it is possible to enable and disable PFR makeup during treatment. |
| **Stimulus/ Stimuli**: Initiate AE change during treatment and ensure that this stops the fluid pumps, with the PFR makeup is disabled and enabled. |
| **Observation(s)**:  When PFR makeup is disabled the PFR makeup volume is not affected when the fluid pumps are stopped.  When PFR makeup is enabled the PFR makeup volume increases when the fluid pumps are stopped |
| 8311 | 11616 | SRS-7446  SRS-7447 SRS-9857 | **Overview -**  This test will verify that the AE Set Time and Set Treatment Time increment while a set is in use.  AE set time resets when AE change is initiated  AE Set Time and Set Treatment Time increment after AE change Successful. |
| **Stimulus** - Perform AE change. |
| **Observation** -  AE Set Time and Set Treatment Time increment while ae set is in use.  AE set time resets when AE change is initiated  AE Set Time and Set Treatment Time increment after AE change Successful. |
| 8327 | 11633 | SRS-7446  SRS-7447 | **Overview** - This test will verify that the Set Time and Set Treatment Time increment while a set is in use. |
| **Stimulus** - Pause and transition to different therapy states while a set is in use. |
| **Observation** - Set Time and Set Treatment Time increment while a set is in use. |
| 8329 | 11635 | SRS-6962 | **Overview**: This test will verify  Software only allows non-directed bag changes during therapy mode.  Non-directed bag change is not allowed during AE set change. |
| **Stimulus**:  While in treatment perform non-directed bag Change.  While in Recirculation perform non-directed bag Change. |
| **Observation**:  Software only allows non-directed bag changes during therapy mode.  Non-directed bag change is not allowed during AE set change. |

## Integration Testing

Table 25 - Integration Test Details

|  |  |  |
| --- | --- | --- |
| **Test ID** | **Config ID** | **Test Description** |
| 8318 | 11623 | **Overview**: This test will verify  After AE set change, Drive-by method to change bag is allowed.  In between AE set change, Drive-by method to change bag is not allowed.  After AE set change is initiated and canceled, Drive-by method to change bag is allowed.  After AE set change any alarm to stop fluid pumps can be recovered and pumps start working again.  Selecting discard set on flow problem alarm allows the user to drain AE in end state.  After AE set changing Auto drain function of ae is working as expected |
| **Stimulus:** While in treatment perform Change AE. |
| **Observation:**  After AE set change, Drive-by method to change bag is allowed.  In between AE set change, Drive-by method to change bag is not allowed.  After AE set change is initiated and canceled, Drive-by method to change bag is allowed.  After AE set change any alarm to stop fluid pumps can be recovered and pumps start working again.  Selecting discard set on flow problem alarm allows the user to drain AE in end state.  After AE set changing Auto drain function of ae is working as expected. |

## Informal Testing

Table 26 - Informal Test Details

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test ID** | | **Config ID** | | **SDS** | | **Test Description** | |
| 8116 | 11390 | | N/A | | **Overview**: This test will verify  Flow rate inputs to Thermax are updated to 0 when the change is initiated, and the fluid pumps stop  Creation of weight error >10g or change in weight error is >2g declares T2160 and T2161. | |
| **Stimulus**: While in treatment perform Change AE. | |
| **Observation**:  When Change AE is in progress, Flow rate inputs to Thermax are updated to 0 but Thermax heating continues.  When AEE is used in treatment and any weight error >10 g, T2160/T2161 is created. | |
| 8155 | | 11432 | | N/A | | **Overview** - This test will verify:   * T0802 is declared when the AE bags are full in Same Patient treatment. * T0802 does NOT declare in the Recirculation’s | |
| **Stimulus/Stimuli** - The following(s) will be performed:  Run Same Patient treatment with drain paused until AE bag is full. without clearing alarm, navigate to:   * Blood Recirculation * Saline Recirculation   Clear alarm T0802, navigate to Same Patient, pause drain, and wait for T0802 to declare. | |
| **Observation(s)** - The following(s) will be observed:   * T0802 is declared when the AE bags are full in same Patient treatment. * T0802 does NOT declare in the Recirculation. | |
| 8213 | | 11490 | | N/A | | **Overview:** This test case will verify that the various Scale Open alarm declares when the scales are open. It will also verify that the software sets scale LED in proper on/off state. | |
| **Stimulus**: Open the scales. | |
| **Observations**:  The system will declare the scale open alarm and will verify that the software sets scale LED in proper on/off state.  Scale open alarm for effluent should not declare when AE change is in progress. | |
| 8214 | | 11491 | | SDS 191  SDS 223  SDS 251  SDS 644  SDS 309 | | **Overview**: This test will verify that alarms are raised:   * Main set load failed * AE set load not failed * Drain lines clamped * Bag fill lines front and rear clamped * Additional weight placed on the scales * Bags are not stable on the scales. | |
| **Stimulus**: During the setup and treatment perform the create the corresponding conditions. | |
| **Observations**: Alarms are observed when   * Main set load failed * AE set load not failed * Drain lines clamped * Bag fill lines front and rear clamped * Additional weight placed on the scales * Bags not stable on the scales. | |
| 8330 | | 11636 | | SDS-3455  SDS-3456  SDS-3457  SDS-3458 | | Overview: This test will verify that when AE  - change is completed and treatment resumed, there is no weight error observed.  - Blocking the flow created the respective alarms  - respective PDAT signals when AE change is completed, but intentionally effluent line clamped (or close the clamp on the top of the AE set) | |
| Stimulus:  Change AE | |
| Observation:  - No weight error observed after AE change is completed and treatment resumed.  - Blocking the flow created the respective alarms  - respective PDAT signals values are as expected when AE change is completed, but intentionally effluent line clamped (or close the clamp on the top of the AE set) | |
| 8331 | | 11637 | | SDS-980 | | Overview: This test will verify that the Change AE can be performed from T2119 and alarm gets cleared on AE change is completed. | |
| Stimulus:  In Treatment wait for T2119. | |
| Observation:  While in treatment when T2119 is declared, Change AE can be performed from the alarm and the alarm is cleared once AE change is completed. | |

### Regression Analysis

**BagController.cpp**

1. BagController constructor is modified. mAESetChangeInProgress is initialized and two new therapy events are subscribed, which are TherapyEvents::AE\_SET\_CHANGE\_START and TherapyEvents::AE\_SET\_CHANGE\_END.
2. Modified BagController::EventHandler. The two new subscribed events are added to event handler.
3. Modified BagController::TherapyStateChange(). Added a condition that ConfigureDriveByEnable() function will get called only when the AE set change is not in progress.
4. Modified BagController::TweakLatentBagChanges(). This function will return when AE set change is in progress.

**Test**:

1. Complete AE set change, then do a bag change. Drive by should be enabled.
2. During AE set change, abort Ae set change. Drive by should be enabled.

**Verification**: Covered in Test ID 8318

**FluidPumpController.cpp**

1. Modified constructor that the added member variable mStopResumeDrainPump is initialized here.
2. Four new events are subscribed in FluidPumpController constructor. Which are.
3. AE\_SET\_CHANGE\_START
4. AE\_SET\_CHANGE\_END
5. STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE
6. RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE
7. Modified FluidPumpController::Initialize() that the new member variable mAESetChangeInProgress is initialized here.
8. FluidPumpController::EventHandler is modified, the modifications are below.
9. When the therapy events are
   1. TherapyEvents::START\_MAIN\_CIRCUIT\_LOAD and case TherapyEvents::
   2. START\_AEA\_LOAD the condition will get true when mAESetChangeInProgress is set. Similarly, when TherapyEvents::START\_MAIN\_CIRCUIT\_UNLOAD and
   3. TherapyEvents::START\_AEA\_UNLOAD case the comdtion will get true when mAESetChangeInProgress is set.
10. The subscribed four new events STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE, RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE, AE\_SET\_CHANGE\_START and AE\_SET\_CHANGE\_END are added.
11. In TherapyEvents::THERAPY\_STATE\_CHANGE case, the case case TherapyStates::END: is modified that if the AE set change is in progress set the flag mAESetChangeInProgress to false.
12. Modified FluidPumpController::SetStoppedState(). Added a local safe state “LocalSafeState”. Below are the possible cases.
    * + - 1. When mAESetChangeInProgress flag is set and mStopResumeDrainPump is set based on T2160 and T2161 alarm ACTIVE state, the LocalSafeState flag is set to STOP\_FLUID\_PUMPS.
13. When mAESetChangeInProgress flag is set and mStopResumeDrainPump is not set based on T2160 and T2161 alarm INACTIVE state, the LocalSafeState flag is set to
    * + - 1. STOP\_ALL\_PUMPS.
14. If the flag mAESetChangeInProgress is false, then the LocalSafeState flag is set to
15. STOP\_ALL\_PUMPS

**Test:**

1. During AE set change raise alarm 2160 or 2161, without clearing the alarm got to end mode, clear the alarm in end mode. User should bale to drain
2. During AE set change, go to end mode start a new patient/same patient. Start auto drain, pump should work as expected. Check pause/resume.
3. After AE set change, raise alarms with stop fluid pumps and the pumps should work as expected.

**Verification:** Covered in Test ID 8318

**LoaderController.cpp**

1. LoaderController constructor is modified to initialize the newly added member variables and subscribe to four new events. Which are, TherapyEvents::AE\_SET\_CHANGE\_START,
   1. TherapyEvents::STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE, TherapyEvents::RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE and
   2. TherapyEvents::AE\_SET\_CHANGE\_END.
2. Modified LoaderController::TherapyObserver function for keys USER\_ATTACHING\_AEA and USER\_ATTACHING\_AEA\_OVERRIDE. The change for both the cases are If AE Set change is in progress, set will be unloaded already, so no need to publish START\_AEA\_UNLOAD event.
3. Modified LoaderController::TherapyObserver function for case UNLOAD\_AEA and LOAD\_AEA. The existing condition is modified with a newly added flag mStoppedBySafeStateAE, which is updated from LoaderController::ProcessSafeStateChange based on mSafeState.
4. Modified LoaderController::EventHandler. The changes are below,
5. case TherapyEvents::SAFE\_STATE\_CHANGE. The condition mTherapyState == TherapyStates::TREATMENT added in to already existing condition for AttachObservers() to get called even in treatment.
6. In case TherapyEvents::START\_AEA\_LOAD and TherapyEvents::START\_AEA\_UNLOAD, the changes made are If we are in a safe state then cancel the unload immediately and set the dictionary toGUIChangeAEActionButtonsDisable for disable all button actions.
7. The newly subscribed events changes are also added.
8. Modified LoaderController::StopEvent function for setting the mLoaderMotorStatus[loader] to LOADER\_MOTOR\_STATE\_UNKNOWN when the mStoppedBySafeStateAE is set to true and loader == LoaderName::AEA.
9. Modified LoaderController::MoveLoader for ignoring move commands. Added condition that mStoppedBySafeState && loader == LoaderName::MAIN for main loader and mStoppedBySafeStateAE && loader == LoaderName::AEA for AE loader.
10. Modified LoaderController::ProcessSafeStateChange() for,
11. updating safe state for AE set change. If mAESetChangeInProgress is true and mStopResumeDrainPump is true mStoppedBySafeStateAE will update based on mSafeState >= STOP\_FLUID\_PUMPS. If mStopResumeDrainPump is false then mStoppedBySafeStateAE will get update based on mSafeState >= STOP\_ALL\_PUMPS. If mAESetChangeInProgress is set to false then mStoppedBySafeStateAE will get update based on mSafeState >= STOP\_FLUID\_PUMPS.
12. Added logics, that If there is any safestate change, stop loading/unloading the AEA loader and If we are coming from a safe state with the patient connected, ensure the loader gets commanded to be retracted. If we are coming from a safe state with the patient connected, ensure the loader gets commanded to be retracted.
13. Modified LoaderController::ProcessAlarmUserRequests for if the AE set change is in progress Do not spin the pumps if the patient is connected or if the loader is not in use.
14. Modifed user notifier switch case ALARM\_ACTION\_CONTINUE for adding one logic for publishing TherapyEvents::RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE in case of AE set change is in progress and alarm handled is ALARM\_AEE\_LOADER\_MOTOR\_FAIL. similarly added one case for CONDITION\_UPDATE\_EVENT for publishing
    * 1. TherapyEvents::STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE when AE set change is in progress and the alarm state is ACTIVE for ALARM\_AEE\_LOADER\_MOTOR\_FAIL alarm.

**Test:**

1. Check loading/unloading of AE set after AE set change is completed. Same in end mode(unload)/same/new patient.
2. select manual selection instead of scanning AE set.
3. After AE change, if there is any alarms cause fluidpump to stop in end mode/new or same patient, loader has to work as expected.
4. During AE set change, raise T1138 or T2161 or T2160. Go to end mode/new/same patient and verify all are working as expected.

**Verification**: Covered in Test ID 8318 and 8324

**PinchValveController.cpp**

1. Modified constructor for subscribing events. AE\_SET\_CHANGE\_START
   1. AEA\_LOADED, AE\_SET\_CHANGE\_END and AEA\_UNLOADED.
2. Modified PinchValveController::Initialize() methos for initializing newly added member variables. mAESetChangeInProgress and mLoadUnloadInProgress.
3. Modified PinchValveController::EventHandler for setting mLoadUnloadInProgress to true in event TherapyEvents::START\_AEA\_UNLOAD: or TherapyEvents::START\_AEA\_LOAD. Added TherapyEvents::AEA\_LOADED and TherapyEvents::AEA\_UNLOADED for setting mLoadUnloadInProgress to false.
4. Added two new events. TherapyEvents::AE\_SET\_CHANGE\_START event is for setting mAESetChangeInProgress to true and TherapyEvents::AE\_SET\_CHANGE\_END is for setting mAESetChangeInProgress to false.
5. Modified PinchValveController::PeriodicProcessing() in case TherapyStates::TREATMENT. If mPerformingFinalDrain and mUsingAE flags are set, calling the SetPosition method for setting the position of both the pinch valves EFFLUENTFILL and EFFLUENTDRAIN.

**PrimingManager.cpp**

1. Modified PrimingManager constructor for subscribing new event AE\_SET\_CHANGE\_END and attaching new two dictionaries, fromGuiAeGetDrainRemainingTime and fromGuiStartStopAESetChange.
2. Modified PrimingManager::Initialize() for initializing new added member variables mGetRemainingTimeForAESetChange and mRemainingTimeReqCount.
3. Modified EventHandler for adding AE\_SET\_CHANGE\_END event. It will set mDrainPaused flag to false.
4. Modified HandleTherapyConfigurationEvent(). Setting mGetRemainingTimeForAESetChange to false in TherapyStates::END.
5. Modified TherapyObserver() for handling newly added keys DRAIN\_GET\_REMAINING\_TIME\_KEY and START\_AE\_BUTTON\_PRESSED\_KEY. fromGuiAeGetDrainRemainingTime will set to true when when change AE button is pressed from Opsscreen by the user.
6. fromGuiAeGetDrainRemainingTime will set to false when user press cancel from change AE initial dialogue.
7. fromGuiStartStopAESetChange will set to true when change AE is pressed from initial AE set change screen.
8. Modified PrimingManager::UpdateTimeRemaining(). Added a condition that the dictionary
   1. toGuiAeDrainTimeRemaining will set only when mstep is not equal to STEP\_DRAIN\_REQS.
9. Modified PerformStepCompleteTasks() for updating toGuiAeDrainTimeRemaining dictionary with drain remaining time immediately when the model gives the time after calculation.
10. Modified AdvanceToNextStep() in case of STEP\_DRAIN\_REQS. Here runs a counter for 4 times and query the drain remaining time from model. Some scenarios the time is getting properly from model after some query, so added a counter to query 4 times.
11. Defined ReturnTimeRemainingFlagForAESet() member function.

**Test**

1. After Ae set change, go to end mode and check end mode drain remaining time is coming proper.
2. After AE set change, go to end mode and start draining. Raise T1138, T2160 and T2161 and verify all are working as expected during the raise/clear of these alarms.
3. After AE set change, start auto draining. Raise T1138, T2160 and T2161 and verify all are working as expected during the raise/clear of these alarms.

**Verification:** Covered in Test ID 8325

**PrimingModelController.cpp**

1. Modified PrimingModelController constructor for subscribing new four events. That are,
   1. AE\_SET\_CHANGE\_START, AE\_SET\_CHANGE\_END,
   2. RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE and
   3. STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE.
2. Modified PrimingModelController::Initialize() for initializing the newly added member variables, mAESetChangeInProgress, mAEDrainPaused and mSafeStateByte.
3. Modified PrimingModelController:: EventHandler for therapy event TherapyEvents::SAFE\_STATE\_CHANGE. DetermineControllerPauseState() and DetermineModelPauseState() will get called based on the mSafeStateSet setting. mSafeStateSet will be based on mSafeState.
4. The member variable mAEDrainPaused will set to true or false based on mUserPauseSet in TherapyEvents::PAUSE\_PRIME and TherapyEvents::RESUME\_PRIME.
5. New member variable mAESetChangeInProgress will set to true or false in the TherapyEvents::AE\_SET\_CHANGE\_START and TherapyEvents::AE\_SET\_CHANGE\_END.
6. TherapyEvents::STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE and TherapyEvents::RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE will set the mFinalDrainLowFlowAlarmStatus to true or false and calls DetermineControllerPauseState() and DetermineModelPauseState().
7. Modified HandleTherapyStateChangeEvent() in switch case TherapyStates::END for setting the mAESetChangeInProgress to false and publish the event ABORT\_PRIME\_STEP in case if user has aborted AE drain.
8. Modified DetermineControllerPauseState(). Variable localmSafeStateSet, localmAnyBagChanging is added in function. localmSafeStateSet and localmAnyBagChanging will get update based on mSafeState >= STOP\_ALL\_PUMPS or mFinalDrainLowFlowAlarmStatus.
9. Modified DetermineModelPauseState(). If local\_safestate is set to true, then the model is paused. local\_safestate will get set to true or false based on mSafeState >= STOP\_ALL\_PUMPS or mFinalDrainLowFlowAlarmStatus flag set to true.
10. Modified ControlSequence(). localmSafeStateSet will get update based on mSafeState >= STOP\_ALL\_PUMPS or mFinalDrainLowFlowAlarmStatus.
11. Modified MonitorActivity() case PrimeModelInterface::PRIME\_OP\_FAILING. If prime step is equal to STEP\_FINAL\_DRAIN and mAESetChangeInProgress is true, setting the activityDone to false.
12. AeeDrainAlarms constructor is modified that member variable mStopPublished is initialized.
13. AeeDrainAlarms::UserNotifier is modified that added two new cases. LATCH\_CLEARED and CONDITION\_UPDATE\_EVENT. In LATCH\_CLEARED, if the action is ALARM\_ACTION\_CONTINUE and mAESetChangeInProgress is true, then mPrimeError and mStopPublished is setting to false. It will publish event RESUME\_DRAIN\_PUMP\_DURING\_AE\_CHANGE. In CONDITION\_UPDATE\_EVENT,
    1. If mAESetChangeInProgress is true and ALARM\_FINAL\_DRAIN\_FRONT\_LOW\_FLOW and
    2. ALARM\_FINAL\_DRAIN\_REAR\_LOW\_FLOW are INACTIVE state then mStopPublished is setting to true and STOP\_DRAIN\_PUMP\_DURING\_AE\_CHANGE is published.

**TherapyRecoveryController.cpp**

* Modified constructor that newly added member variables are initialized.
* Modified EventHandler() case TherapyEvents::NEW\_PATIENT: and TherapyEvents::SAME\_PATIENT. Flag mPatientAESet is getting updated here.
* In case TherapyStates::TREATMENT, mAESetTimeStarted is updated with current time.

**TreatmentSessionController.cpp**

* TreatmentSessionController constructor is modified that the newly added member variables are initialized and subscribed four events.
* Modified Initialize () function that three dictionaries are attached here.
* Modified destructor that the added dictionary is detached here.
* Modified TherapyObserver() that case AE\_STATE\_CHANGE\_CMD will call the member function UpdateAEStateChange(). Key KEY\_UNLOAD\_AE\_SET will publish the event START\_AEA\_UNLOAD and key KEY\_LOAD\_AE\_SET will publish the event START\_AEA\_LOAD.
* EventHandler() is modified that if mSafeState >= STOP\_ALL\_PUMPS toGUIChangeAEActionButtonsDisable dictionary will set to true. If there is any high prioriy alarm the change AE button will get disabled with this change and mpChangeAEActionButtonsDisable member variable is set to true.
* toGUIChangeAEActionButtonsDisable dictionary will get clear when T1138, T2060 and T2061 are in inactive state.
* Logic added that, If isDrainCompleteOnHighPriority is set to true then stop Sending AE Drain ABORT status to GUI if therapy state changed to END mode during drain.
* In case TherapyEvents::AE\_END\_DRAIN\_COMPLETE. If AE set change is in progress, then member variable mpChangeAESetCurrentState is updated with state CHANGE\_AE\_DRAINING\_ABORTED.
* In case AE\_SET\_CHANGE\_START, mpChangeAESetCurrentState is updated with a state CHANGE\_AE\_STARTED, will call function HandleAESetChangeStatus() and will generate a message event MSG\_AE\_SET\_CHANGE\_STARTED.
* In case AE\_SET\_CHANGE\_END, mpChangeAESetCurrentState will get update with a state of CHANGE\_AE\_SET\_COMPLETED, generate a message event MSG\_AE\_SET\_CHANGE\_COMPLETED. Will clear the overridden AE set life exceeded alarm after AE change and call function HandleAESetChangeStatus().
* Modified PeriodicProcessingOneHz() function for calling function HandleAESetScaleStatus() in case mpChangeAESetCurrentState is set to CHANGE\_AE\_UNLOAD\_AE\_SET or CHANGE\_AE\_HANG\_AE\_BAGS.
* Modified AECanBeReused() that AE\_MIN\_REUSE\_LIFE is removed from the revsExceeded and timeExceeded logic.
* Modified UpdateSetTime() for updating mAESetTimeStarted and mHasTreatmentBeenStartedForAESet. mAESetTimeStarted will update with current time when Treatment is being started for the first time for this AE set and mHasTreatmentBeenStartedForAESet will set to true.
* After treatment has already been started and as long as user has not stopped treatment, then update the most recent date/time in treatment. mAESetTimeNow will get update to currentTime and UpdateAESetTime() will get call.
* Newly added member function GetSetTimeAE() is defined.
* InitializeCircuits() is modified that the member variables mHasTreatmentBeenStartedForAESet, mAESetTimeStarted and mAESetTimeNow is initialized.
* UserNotifier() is modified that added OPERATOR\_ACTION , ALARM\_ACTION\_CHANGE\_AE\_SET. this action from alarm will initiate the change AE set process.
* Modified PerformAeAlarmProcessing() that enable change AE button if in TREATMENT and Disable CHANGE AE button if not in TREATMENT based on mTherapyState.
* Modified GetTherapyRecoveryData() that mHasTreatmentBeenStartedForAESet will set to true and mAESetTimeNow will get update with GetCurrentDateTime() and mAESetTimeStarted is updated with saved value.
* Newly added member functions HandleAESetChangeStatus(), HandleAESetScaleStatus() and UpdateAEStateChange() is defined here.
* HandleAESetChangeStatus() will set the AE status to GUI from therapy and UpdateAEStateChange() will set the mpChangeAESetCurrentState with proper AE states based on messages received from GUI.

**BagClass.cpp**

1. BagClass constructor is modified for initializing member variable mpChangeAESetInProgress.
2. Modified SetLED() for flashing the LED when AE set change is in progress. LED will flash when AE bag change is happening during AE set change.
3. UpdateState() function is modified that when AE set change is in progress we don’t allow a drive by bag change.
4. New member function AESetChangeState() Is defined.

**Test**

1. Verify LED's functioning after AE set change completed. (bag change and next new/same patient set up, etc)

**Verification**: Covered in Test ID 8319

**FluidPumpModelAlarms.cpp**

1. Member function ProcessAEChangeErrors() is defined and called here.

**TherapyStateManager.cpp**

1. TherapyStateManager constructor is modified for attaching a dictionary fromGuiStartStopAESetChange attached to key START\_AE\_SET\_CHANGE.
2. Modified Initialize () function to initialize mpChangeAESetInProgress flag.
3. Modified UpdateSafeState() to add a new logic for setting the safe state to STOP\_FLUID\_PUMPS when AE set change is started.
4. Modified UpdateAllowedTherapyState() case TherapyStates::TREATMENT. Will not allow it to change the stateAllowed to RECIRCULATE when AE set change is in progress.
5. TherapyStates::RETURN case, stateAllowed will not allow stateAllowed to TREATMENT when AE set change is in progress.
6. Modified UpdateTherapyState() if mTherapyState is TherapyStates::END and mpChangeAESetInProgress is set to true, then publishing the event AE\_SET\_CHANGE\_END. User changes the therapy state to END during AE set change is in progress, so publishing the AE set END event.
7. Modified TherapyObserver() function with key START\_AE\_SET\_CHANGE. When fromGuiStartStopAESetChange is set to true, updating mpChangeAESetInProgress falg to true, calling UpdateSafeState() and publishing AE\_SET\_CHANGE\_START.
8. If fromGuiStartStopAESetChange set to false, mpChangeAESetInProgress flag will set to false, UpdateSafeState() will get call for changing safeState to NOMINAL or other state based on safeState.

### Regression Test Descriptions

*This section defines the tests used to verify that there were no unexpected changes, as identified though the regression analysis.*

Table 27 - Regression Test Identification

|  |  |  |  |
| --- | --- | --- | --- |
| **Test ID** | **Config ID** | **Requirement ID** | **Test Description** |
| 8143 | 11048 | 11420 | **Overview**: This test will verify that software monitors and repositions the loaders as necessary when the patient is connected. |

Table 28 - Informal Regression Test Identification

|  |  |  |  |
| --- | --- | --- | --- |
| **Test ID** | **Config ID** | **Requirement ID** | **Test Description** |
| 8319 | 11624 | N/A | Overview: This test will verify  AE change is allowed after therapy recover in new patient.  AE change is allowed after therapy recover in same patient. |
| Stimulus: While in treatment perform Change AE. |
| Observation:  AE change is allowed after therapy recover in new patient.  AE change is allowed after therapy recover in same patient. |
| 8324 | 11630 | N/A | Overview: This test will verify  After AE change, alarm causing the fluid pumps to stop won't impact the unload / load of AE set in successive treatments.  During AE change, AE motor failure, AE loader failure and Flow problems alarms will not impact the unload / load of AE set in successive treatments. |
| Stimulus: Perform AE change in treatment |
| Observation:  After AE change, alarm causing the fluid pumps to stop won't impact the unload / load of AE set in successive treatments.  During AE change, AE motor failure, AE loader failure and Flow problems alarms related to AE will not impact the unload / load of AE set in successive treatments. |
| 8325 | 11631 | N/A | Overview: This test will verify  Time to drain is displayed in end mode on Auto effluent status screen.  AE loader failure, drain motor failure and effluent flow problem alarms in end mode do not impact the AE set change in successive treatment. |
| Stimulus: Perform AE unload in end mode. |
| Observation:  Time to drain is displayed in end mode on Auto effluent status screen.  AE loader failure, drain motor failure and effluent flow problem alarms in end mode do not impact the AE set change in successive treatment. |

### System Regression Analysis

Table 29 - System Regression Tests

|  |  |  |  |
| --- | --- | --- | --- |
| **Test ID** | **Config ID** | **Requirement ID** | **Test Description** |
| 8332 | 11638 | PRD-3395 | **Overview**: This test will verify the PFR accuracy without PFR makeup and low PFR values. This test case stresses the system by changing the AE for multiple times while in treatment |
| **Stimulus/Stimuli**: Operator will perform the Multiple AE changes in 3hrs of CRRT treatment. |
| **Observation(s):** System maintains flow accuracy of ±30ml/hr and ±70ml/3hr as observed by the external weight of the patient bag. |
| 8333 | 11639 | PRD-3395 | **Overview**: Operator will perform the Multiple AE changes in 3hrs of CRRT treatment. |
| **Stimulus/Stimuli**: Operator will perform the Multiple AE changes in 3hrs of CRRT treatment. |
| **Observation(s):** System maintains flow accuracy of ±30ml/hr and ±70ml/3hr as observed by the external weight of the patient bag. |

### Test Execution

**Note:** The results of the test runs indicated in this CADV represent the test run results obtained upon executing the test runs following the CADV development process. The test run results do not represent the current test run results documented in HP-ALM because the process of handling the test run execution and failures in HP-ALM are independent of the CADV development process.

Table 30 - Test Results

|  |  |  |  |
| --- | --- | --- | --- |
| **Configuration: Test ID** | **Configuration ID** | **Run ID** | **Execution Status** |
| 7805 | 11048 | 34241 | Passed |
| 8067 | 11339 | 34235 | Passed |
| 8111 | 11385 | 34246 | Passed |
| 8112 | 11386 | 34256 | Passed |
| 8113 | 11387 | 34255 | Passed |
| 8114 | 11388 | 34273 | Passed |
| 8115 | 11389 | 34250 | Passed |
| 8117 | 11391 | 34282 | Passed |
| 8133 | 11410 | 34231 | Passed |
| 8139 | 11416 | 34280 | Passed |
| 8140 | 11417 | 34237 | Passed |
| 8141 | 11418 | 34244 | Passed |
| 8142 | 11419 | 34248 | Passed |
| 8143 | 11420 | 34439 | Passed |
| 8144 | 11421 | 34272 | Passed |
| 8145 | 11422 | 34274 | Passed |
| 8146 | 11423 | 34314 | Passed |
| 8147 | 11424 | 34260 | Passed |
| 8148 | 11425 | 34254 | Passed |
| 8149 | 11426 | 34239 | Passed |
| 8150 | 11427 | 34247 | Passed |
| 8151 | 11428 | 34233 | Passed |
| 8152 | 11429 | 34230 | Passed |
| 8153 | 11430 | 34242 | Passed |
| 8154 | 11431 | 34253 | Passed |
| 8156 | 11433 | 34261 | Passed |
| 8157 | 11434 | 34238 | Passed |
| 8158 | 11435 | 34243 | Passed |
| 8159 | 11436 | 34267 | Passed |
| 8165 | 11442 | 34251 | Passed |
| 8213 | 11490 | 34270 | Passed |
| 8214 | 11491 | 34271 | Passed |
| 8116 | 11390 | 34479 | Passed |
| 8155 | 11432 | 34495 | Passed |
| 8213 | 11490 | 34475 | Passed |
| 8318 | 11623 | 34476 | Passed |
| 8319 | 11624 | 34488 | Passed |
| 8324 | 11630 | 34477 | Passed |
| 8325 | 11631 | 34483 | Passed |
| 8327 | 11633 | 34480 | Passed |
| 8329 | 11635 | 34489 | Passed |
| 8330 | 11636 | 34494 | Passed |
| 8331 | 11637 | 34498 | Passed |
| 8311 | 11616 | 34508 | Passed |
| 8310 | 11615 | 34509 | Passed |
| 8332 | 11638 | 34520 | Passed |
| 8333 | 11639 | 34526 | Passed |

**DOCUMENT END**