**Issue 1 : Default Transitions in ALARMS.**

**Type:**  Logic

**Severity** : Minor

**Identified Method : Reactis**

**Reason for Change:** If the system at step 1 has an alarm condition, it is not detected, since the default transition is to OFF in every alarm check.

**Change:**  Totally 19 alarms.

**Before Change :**



**After Change:**



**Issue 2 : Check for In\_therapy before issuing alarm (Alarms).**

**Type:**  Previous state check

**Severity** : Minor

**Identified Method : SLDV**

**Reason for Change:** At start up, before infusion has started, we don’t want to issue a low or empty reservoir alarm. This is true for reservoir checks, flow rate checks and vtbi checks.

**Change:**  Add In\_therapy in IsOverInfusionFlowRate, IsOverInfusionVTBI, IsEmptyReservoir, IsLowReservoir, IsUnderInfusion

**Before Change :**



**After Change:**



**Issue 3: Check reservoiur status before infusion begins (Infusion)**

**Type:** Infusion start up checks

**Severity** : Major

**Identified Method: SLDV**

**Reason for Change:** IDLE -> Therapy first time, did not check for empty reservoir. Since we added in\_therpay checks. So Infusion starts when there is no reservoir volume at all.

**Change:**  added

**Before Change :**



**After Change:**



**Issue 4: Infusion cancel and initiate at the same time (Infusion)**

**Type:**  Input not handled

**Severity** : Major

**Identified Method: SLDV**

**Reason for Change:** If infusion initiate and cancel occur at the same time, there was no transition to cover the cancel.

**Change:**  Cancel gets higher priority, hence a self transition at IDLE for cancel. Alternatively I could have also added !cancel in the to therapy transition, but I thought this was simpler.

**Before Change :**



**After Change:**



**Issue 5 : Alarm level 2 => no bolus (Infusion)**

**Type:**  Programming error

**Severity** : Minor

**Identified Method : SLDV**

**Reason for Change:** **: Alarm level 2 => no bolus, but intermittent bolus condition said <= 2**

**Change:**  OFF -> ON condition in intermittent bolus changed to alarm < 2

**Before Change :**



**After Change:**



**Issue 6 : Step Size made a parameter (both models)**

**Type:**  Assumption change

**Severity** : Don’t know

**Identified Method: Inspection**

**Reason for Change:** we assumed that the step size is 1 sec and all the calculations and timer checks were incrementing by 1.

**Change:**  added step size as a parameter and the checks were scaled as per the timing. Changed in multiple places throughout the model.

**Before Change :**



**After Change:**



**Issue 7 : Default transition to Lockout in Patient (Infusion)**

**Type:**  Logic

**Severity** : Major

**Identified Method: Inspection**

**Reason for Change:** When P.bolus is in progress, and infusion is canceled or restarted. System does not go to Lockout. When infusion is started again, p.bolus can be requested. With cycles like these, more patient bolus can be delivered without locking out at all.

**Change:**  added default transition to Lockout state, so that when exiting and entering infusion lockout is maintained. This is not applicable if the machine is completely oFF and ON.

**Before Change :**



**After Change:**



**Issue 8: Counter check logic change. (Infusion)**

**Type:**  Assumption change.

**Severity** : Minor

**Identified Method : SLDV**

**Reason for Change:**. Due to change in scaling factor, the check for counter == is changed to >=.

**Change:**  counter == is changed to >=.

**Before Change :**



**After Change:**



**Issue 9 :** Inhibit and Initiate happens at the same time in Paused state (Infusion)

**Type:**  Input priority.

**Severity** : Minor

**Identified Method: SLDV**

**Reason for Change**: Initiate and Inhibit happens at the same time, Inihibit takes more priority.

**Change:** Default transition to Inhibit + On to OFF condition changed.

**Before Change :**



**After Change:**

