Infusion Pump Requirements

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1   Generic Infusion System

1.1   Overview

An external infusion pump is a medical device used to deliver fluids into a patient body in a controlled manner. Infusion pumps are capable of delivering fluids in large or small amounts, and may be used to deliver nutrients or medications such as insulin or other hormones, antibiotics, chemotherapy drugs, and pain relievers.

A patient-controlled analgesia (PCA) pump is an external infusion pump used to deliver pain medication, which is equipped with a feature that allows patients to self-administer a controlled amount of medication, in addition to a to a normal drug dosage, as prescribed by a Physician/Prescriber.

This document lists the overall system goal, requirements and specifications of a *generic patient-controlled analgesia (GPCA) pump system.*
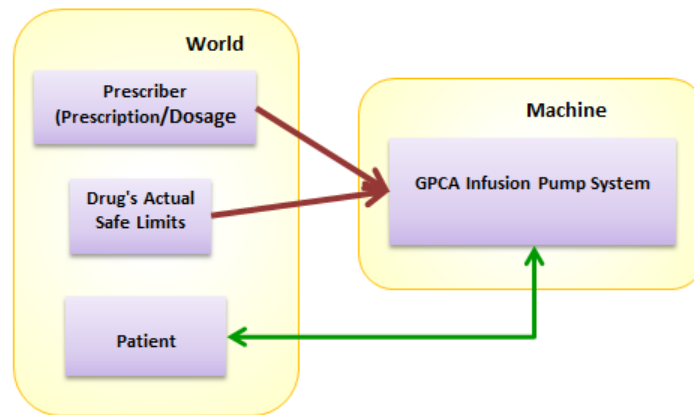
Figure 1: World-Machine Model of the Infusion Pump

The system designed for delivering liquid drug to the patient is a Patient controlled Analegic Infusion pump system. It is intended for use in a hospital setting. The environment of the Infusion pump system is the patient, the prescription information from a Prescriber and the actual drug to be Infused to the patient. The Infusion pump is *physically connected* to the patient so that the pain medication is delivered/infused at the prescribed dosage.

Prescriber: A Practicioner, who is certified to prescribe drug dosage to be delivered to the patient.

Prescription/Dosage: The form of instructions that govern the plan of care for an individual patient. This would typically list down all details realted to how to admister the drug

Patient: A person in hospital who would receive the medication.

Drug Safe Limits: The actual drug safe usage information provided by the drug manufactures. This will typically provide the maximun and minimun values for the drug usage. For patient safety, the dosage of the drug to the patient should never exceed these values.

1.2 System Variables

The system variables are external inputs that are used by the system to produce outputs that affect the environment of the system. The Inputs variables are given to the system from external actors and the output from the system are visible these external actors.

To Do: ADD A CLARIFICATION OF THE NAMING SCHEME.

1.2.1 Input Variables

Drug Safe Limits Variables Description: The safe limit variables of a drug are the standard safe values provided by the manufacturer.

$Drug_{safe\_name}$: **Drug Name**		
Type:	String	Units:
Description:	Actual name of the drug to be infused	
Source	Actual Drug Safe Limits	

$Drug_{safe\_con\_hi}$: **Drug concentration Upper Limit**		
Type:	Numeric	Units: g/ml
Description:	Safe Upper limit of drug concentration that can be used to infuse the drug to the patient. This is the maximum concentration of the drug in the solution used to infused.	
Source	Actual Drug Safe Values	

$Drug_{safe\_con\_lo}$: **Lower limit of drug concentration**		
Type:	Numeric	Units: g/ml
Description:	Safe lower limit of drug concentration that can be used to infuse the drug to the patient. This is the minimum concentration of the drug in the solution used to infused.	
Source	Actual Drug Safe Limits	

$VTBI_{safe\_basal\_lo}$: **Lower limit of Basal drug volume to be infused**		
Type:	Numeric	Units: ml/hr
Description:	Safe lower limit of drug volume to be infused for basal.	
Source	Actual Drug Safe Limits	

$VTBI_{safe\_basal\_hi}$: **Upper limit of drug volume to be infused**		
Type:	Numeric	Units: ml/hr
Description:	Safe Upper limit of drug volume to be infused for basal.	
Source		

$FlowRate_{safe\_basal\_lo}$: **Lower limit of basal Flow rate**		
Type:	Numeric	Units: ml/hr
Description:	Lower limit of drug Flow rate for basal. .	
Source	Actual Drug Safe Limits	

$FlowRate_{safe\_basal\_hi}$: **Upper limit of basal flow rate**		
Type:	Numeric	Units: ml/hr
Description:	Upper limit of drug Flow rate for basal. .	
Source	Actual Drug Safe Limits	

$VTBI_{safe\_sbolus\_lo}$: **Lower hard limit of VTBI for square bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Lower hard limit of drug volume to be infused for Single square bolus. .		
Source	Actual Drug Safe Limits		

$VTBI_{safe\_sbolus\_hi}$: **Upper hard limit of VTBI for square bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Upper hard limit of drug volume to be infused for Single square bolus. .		
Source	Actual Drug Safe Limits		

$FlowRate_{safe\_sbolus\_lo}$: **Lower limit of square bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug Flow rate for Single square bolus. .		
Source	Actual Drug Safe Limits		

$FlowRate_{safe\_sbolus\_hi}$: **Upper limit of square bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug Flow rate for Single square bolus. .		
Source	Actual Drug Safe Limits		

$Duration_{safe\_sbolus\_hi}$: **Upper limit of Time over which square Bolus is applied**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of Time over which Bolus is applied		
Source	Actual Drug Safe Limits		

$Number_{safe\_sbolus\_hi}$: **Maximum number of square bolus**			
Type:	Numeric	Units:	
Description:	Maximum number of square bolus that can be admisterd to the patient.		
Source	Actual Drug Safe Limits		

$VTBI_{safe\_pbolus\_lo}$: **Lower hard limit of VTBI for patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Lower hard limit of drug volume to be infused for Single patient bolus. .		
Source	Actual Drug Safe Limits		

$VTBI_{safepbolus\_hi}$: **Upper hard limit of VTBI for patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Upper hard limit of drug volume to be infused for Single patient bolus. .		
Source	Actual Drug Safe Limits		

$FlowRate_{safe\_pbolus\_lo}$: **Lower limit of patient bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug Flow rate for Single patient bolus. .		
Source	Actual Drug Safe Limits		

$FlowRate_{safepbolus\_hi}$: **Upper limit of patient bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug Flow rate for Single patient bolus. .		
Source	Actual Drug Safe Limits		

$Duration_{safe\_pbolus\_hi}$: **Upper limit of Time over which patient Bolus is applied**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of Time over which patient Bolus is applied		
Source	Actual Drug Safe Limits		

$Number_{safe\_pbolus\_hi}$: **Maximum number of patient bolus**		
Type:	Numeric	Units:
Description:	Maximum number of patient bolus that can be admisterd to the patient.	
Source	Actual Drug Safe Limits	

$Frequency_{safe\_pbolus\_hi}$: **Maximum frequency between patient bolus**		
Type:	Numeric	Units:
Description:	Maximum frequency between patient bolus that can be self admisterd by the patient.	
Source	Actual Drug Safe Limits	

Prescribed Infusion Variables Description: The infusion variables that are prescribed by Prescriber for the specific drug and patient

$Drug_{prescribed\_name}$: **Prescribed Name of the Drug**		
Type:	String	Units:
Description:	Drug Name that is prescibed for infusion	
Source	Prescription for Infusion	

$Drug_{prescribed\_con}$: **Prescribed drug concentration**			
Type:	Numeric	Units:	g/ml
Description:	Prescribed drug concentration that should be adminstered for the patient		
Source	Prescribed Value		

$VTBI_{prescribed_{t}otal}$: **Prescribed Total Volume to be Infused**			
Type:	Numeric	Units:	ml/hr
Description:	Prescribed Total Volume to be Infused		
Source	Prescribed Value		

$Duration_{prescribed\_basal}$: **Prescribed duration for basal infusion of drug**			
Type:	Numeric	Units:	ml/hr
Description:	Prescribed duration for basal infusion of drug		
Source	Prescribed Value		

$FlowRate_{prescribed\_basal}$: **Prescribed basal flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Prescribed basal flow rate		
Source	Prescribed Value		

$TOL_{prescribed\_basal}$: **Prescribed tolerance of basal flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Prescribed tolerance of Fbasal over X time		
Source	Prescribed Value		

$VTBI_{prescribed\_basal}$: Prescribed basal Volume to be Infused

Type:	Numeric	Units:	ml/hr
Description:	Prescribed Volume to be Infused for basal		
Source	Prescribed Value		

$FlowRate_{prescribed\_pbolus}$: Prescribed flow rate of patient bolus

Type:	Numeric	Units:	ml/hr
Description:	Prescribed Patient bolus flow rate,		
Source	Prescribed Value		

$TOL_{prescribed\_pbolus}$: Prescribed tolerance of patient bolus flow rate

Type:	Numeric	Units:	ml/hr
Description:	Prescribed tolerance of patient bolus flow rate over X1 time		
Source	Prescribed Value		

$VTBI_{prescribed\_pbolus}$: Prescribed VTBI for patient bolus

Type:	Numeric	Units:	ml/hr
Description:	Prescribed Volume to be Infused for patient bolus		
Source	Prescribed Value		

$Duration_{prescribed\_pbolus}$: Prescribed Duration of patient bolus flow

Type:	time	Units:	ml/hr
Description:	Prescribed Duration of patient bolus flow		
Source	Prescribed Value		

$Frequency_{prescribed\_pbolus}$: Prescribed frequency of patient bolus flow

Type:	time	Units:	ml/hr
Description:	Prescribed frequency of patient bolus flow		
Source	Prescribed Value		

$Number_{prescribed\_pbolus}$: Prescribed Max number of patient bolus

Type:	Numeric	Units:	
Description:	Prescribed Max number of patient bolus		
Source	Prescribed Value		

$FlowRate_{prescribed\_sbolus}$: Prescribed square bolus flow rate

Type:	Numeric	Units:	ml/hr
Description:	Prescribed Square bolus flow rate,		
Source	Prescribed Value		

$TOL_{prescribed\_sbolus}$: Prescribed tolerance of square bolus flowrate

Type:	Numeric	Units:	ml/hr
Description:	Prescribed tolerance of F sbol over X1 time		
Source	Prescribed Value		

$VTBI_{prescribed\_sbolus}$: Prescribed Volume to be Infused for Square bolus

Type:	Numeric	Units:	ml/hr
Description:	Prescribed Volume to be Infused for Square bolus		
Source	Prescribed Value		

$Duration_{prescribed\_sbolus}$: **Prescribed Duration of square bolus flow**			
Type:	time	Units:	time
Description:	Prescribed Duration of square bolus flow		
Source	Prescribed Value		

$Number_{prescribed\_sbolus}$: **Prescribed Max number of square bolus**			
Type:	Numeric	Units:	
Description:	Prescribed Max number of square bolus		
Source	Prescribed Value		

$FlowRate_{prescribed\_kvo}$: **Minimum keep vein open flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	minimum keep vein open flow rate that is needed to keep the vein open when infusion is not in Progress		
Source	Prescribed Value		

Actual Infusion Control Variables Description: These are the Actual Infusion initiation/inhibit actions

IN_{sys_start}: **Infusion Initiation**		
Type:	Boolean	Units:
Description:	Initiate Infusion	
Source	Infusion Inhibit Command	

IN_{sys_stop}: **Infusion Inhibit**		
Type:	Boolean	Units:
Description:	Inhibit Infusion	
Source	Infusion Inhibit Command	

Actual Patient Information Description: These are actual patient parameters

$Bolus_{patient\_request}$: **Bolus Request by patient**		
Type:	Boolean	Units:
Description:	Bolus Request	
Source	Bolus Request by Patient	

$Patient_{name}$: **Actual Name of the patient**		
Type:	String	Units:
Description:	Actual Name of the patient	
Source	Actual Patient Information	

$Patient_{dob}$: **Actual Date of birth of the patient**		
Type:	String	Units:
Description:	Actual Date of birth of the patient	
Source	Actual Patient Information	

$Patient_{weight}$: **Actual weight of the patient**		
Type:	Numeric	Units:
Description:	Actual Weight of the patient	
Source	Actual Patient Information	

$Patient_{gender}$: **Actual gender of the patient**		
Type:	String	Units:
Description:	Actual Gender of the patient	
Source	Actual Patient Information	

1.2.2 System Output Variables

Description: These are the actual output of the system.

$FlowRate_{patient}$: **Actual Flow rate**		
Type:	Numeric	Units:
Description:	Actual flow rate of the drug into the patient	
Source	Drug that is flowing into the patient.	

$VolumeInfused_{patient}$: **Actual Volume**		
Type:	Numeric	Units:
Description:	Actual Total Volume of drug into the patient	
Source	Total Volume Drug that is flowing into the patient.	

Log_{actual}: **Actual logging data**		
Type:	String	Units:
Description:	Log data created	
Source		

1.3 Enviroment Assumptions

A 1   Prescriptions provided by the physician are assumed to be correct.

A 2   All Infusion parameters are available in the prescription.

A 3   Only safe drugs shall be used for infusion

A 4   Neccessary Infrastructure for the system is available

A 5   The drug will be admistered to the patient in a hospital room or similar clinical setting

A 6   The hospital room or similar clinical setting will have certified Clinician to adminster the drug by infusion

A 7   The system shall allow drug infusion to one patient at a time

A 8   Only one drug shall be used per infusion setting/duration

1.4 System Requirements

In this section, the Requirements are defined as set of statements that describe what needs to be achieved in the World/Domain interms of of the domain variables.

SR 1 The patient shall recieve prescribed dosage of the drug in one of the three modes of Infusion : Basal, Square Bolus and Patient Bolus

> **SR 1.1** The Patient shall be infused with the drug at a prescribed flow rate $FlowRate_{prescribed\_basal}$ for a prescribed duration ,$Duration_{prescribed\_basal}$
>
> **SR 1.2** The Patient shall be also be automatically infused with prescribed additional volume of the drug, $VTBI_{prescribed\_sbolus}$, at a prescribed flow rate $FlowRate_{prescribed\_sbolus}$ at prescribed time intervals **??**
>
> **SR 1.3** The Patient shall also self-adminster prescribed additional volume of the drug, $VTBI_{prescribed\_pbolus}$, at a prescribed flow rate $FlowRate_{prescribed\_pbolus}$
>
> **SR 1.4** Only one more of Infusion shall exisit with the precedence: Patient bolus - Square Bolus - Basal Infusion. The lower precedence infusion shall be paused when a higher precedence infusion starts. Once the higher precedence infusion is complete, the infusion paused shall resume in order

SR 2 During infusion, for all infusion modes, the patient shall receive the drug with a flow rate precision of p % of the respective prescribed flow rate with the following tolerances :

1. The patient shall never receive the drug at a flow rate u ml/hr above the prescribed flow rate + precision more than x seconds in any y hour interval

2. The patient shall never receive the drug at a flow rate more than max ml/hr above the prescribed flow rate + precision

3. The patient shall never receive the drug at a flow rate l ml/hr below the prescribed flow rate - precision more than x seconds in any y hour interval

4. The patient shall never receive the drug at a flow rate more than min ml/hr below the prescribed flow rate - precision

5. The patient shall never receive drug at flow rate less than or equal to 0ml/hr for more than x second

> $FlowRate_{patient} = FlowRate_{prescribed\_basal} +/- \text{p}$
> $FlowRate_{patient} = FlowRate_{prescribed\_sbolus} +/- \text{p}$
> $FlowRate_{patient} = FlowRate_{prescribed\_pbolus} +/- \text{p}$

> **SR 2.1** The patient shall never receive the drug in a flow rate more or less than the Drug's Actual flow rate Limit with a flow rate precision of p % of Drug's Actual flow rate Limit for cumulatively more than x seconds in any y hour
>
> $FlowRate_{safe\_basal\_lo} - \text{p} <= FlowRate_{patient} <= FlowRate_{safe\_basal\_hi} + \text{p}$
> $FlowRate_{safe\_pbolus\_lo} - \text{p} <= FlowRate_{patient} <= FlowRate_{safepbolus\_hi} + \text{p}$

SR 3 During Infusion, for all infusion modes, the patient shall receive the drug with a Volume precision of v ml with the following tolerances:

1. The patient shall never receive the drug volume more than u ml/hr above the prescribed VTBI of the respective infusion mode

2. The patient shall never receive the drug volume more than max ml/hr above the prescribed VTBI of the respective infusion mode

3. The patient shall never receive the drug volume less than l ml/hr below the prescribed VTBI of the respective infusion mode

4. The patient shall never receive the drug volume less than min ml/hr below the prescribed VTBI of the respective infusion mode

5. The patient shall never receive more than the total prescribed VTBI +/- precision.

$VolumeInfused_{patient} = VTBI_{prescribed\_basal}$ +/− v
$VolumeInfused_{patient} = VTBI_{prescribed\_pbolus}$ +/− v
$VolumeInfused_{patient} = VTBI_{prescribed\_sbolus}$ +/− v
Total $[VolumeInfused_{patient}] = VTBI_{prescribed_total}$ +/− v

SR 3.1 The patient shall never receive drug volume more or less than the Drug's Actual VTBI with a volume precision of v ml

$VTBI_{safe\_basal\_lo} - v <= FlowRate_{patient} <= VTBI_{safe\_basal\_hi} + v$
$VTBI_{safe\_sbolus\_lo} - v <= FlowRate_{patient} <= VTBI_{safe\_sbolus\_hi} + v$
$VTBI_{safe\_pbolus\_lo} - v <= FlowRate_{patient} <= VTBI_{safepbolus\_hi} + v$

SR 4 The patient shall never self-adminster bolus drug more than the prescribed number for boluses in the prescribed duration and more than the safe number for boluses in the safe duration

$Bolus_{patient\_request} <= Number_{prescribed\_pbolus}$
Frequency of $Bolus_{patient\_request} <= Frequency_{prescribed\_pbolus}$
$Bolus_{patient\_request} <= Number_{safe\_pbolus\_hi}$
Frequency of $Bolus_{patient\_request} <= Frequency_{safe\_pbolus\_hi}$

SR 5 During Infusion, there shall be no downstream occlusion more than x psi and upstream occlusion of more than y psi for more than z minutes

SR 6 During any state of Infusion, The patient shall never be infused with more than cumulatively x ml of air bubbles in y seconds in any z hour duration or more than max ml of single air bubble

SR 7 The drug availability for infusion shall never be less than y ml

SR 8 Manual Infusion start and stop shall be possible. IN_{sys_start}, IN_{sys_stop}

SR 9 The patient shall always receive a minimum KVO (keep vein open) flow rate $FlowRate_{prescribed\_kvo}$ with a flow rate precision of p % of the KVO flowrate of the drug, when patient is connected to infusion hardware and infusion is not in progress.

SR 10 A log of the infusion history and hazardous conditions shall be recorded Log_{actual} for audit purposes.

SR 10.1 When Infusion is started first time or restarted with new Patient or Drug or Infusion Parameters , the following shall be recorded : Date in (dd/MM/yy) format, Time in (HH:MM:SS GMT), Operator Name/ID, Prescriber Name Patient Name, Drug Name, Infusion Flow rate.

SR 10.2 Every x minutes or when infusion resumes after error, an event log is recorded with Date in (dd/MM/yy) format, Time in (HH:MM:SS GMT), Drug Name, Infusion Flow rate, Total Volume Infused to Patient.

SR 10.3 When any error occurs, an error log is recorded with Date in (dd/MM/yy) format, Time in (HH:MM:SS GMT), Drug Name, Infusion Flow rate, Total Volume Infused to Patient, Error description.

SR 11 Only authorized persons can adminster drug for the patient.

2 GPCA System

2.1 Overview

A patient-controlled analgesia (PCA) pump is an external infusion pump used to deliver pain medication, which is equipped with a feature that allows patients to self-administer a controlled amount of medication, in addition to a to a normal drug dosage, as prescribed by a Physician/Prescriber.

This section describes the overall system goal, requirements and specifications of a *generic patient-controlled analgesia (GPCA) pump system*
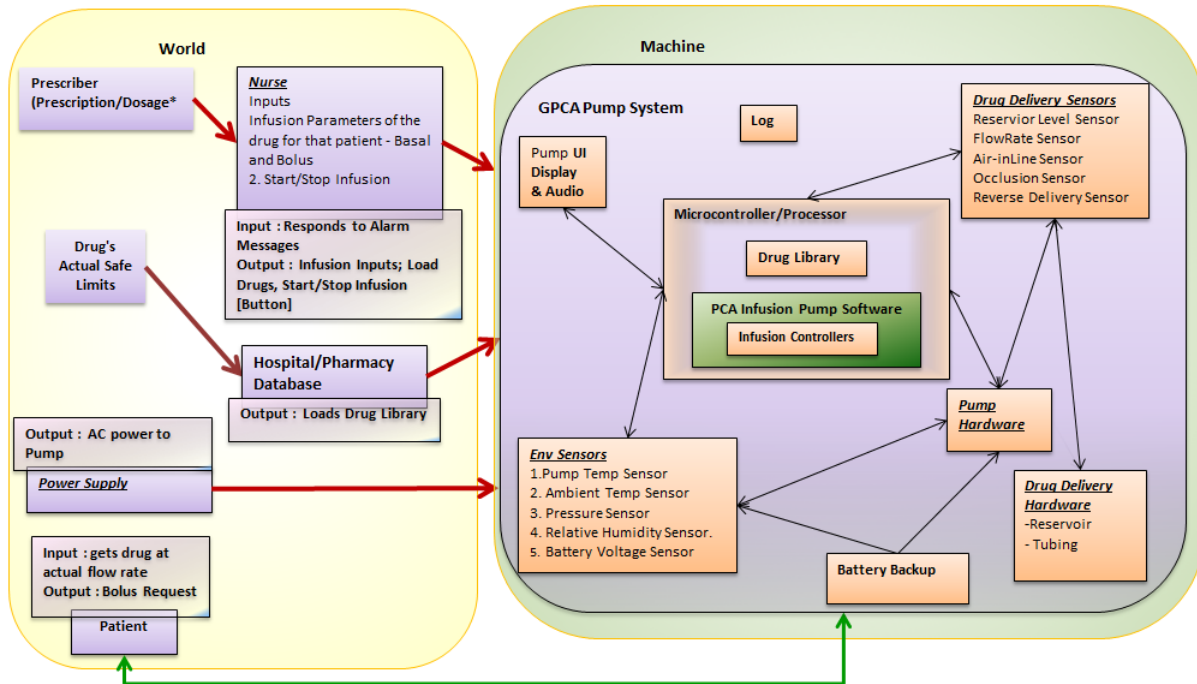

Figure 2: GPCA Infusion Pump Overview

Components of GPCA Pump Enviroment

Hospital Database: The hospital Database stores the actual safe limits of the drug.

Clinician/Drug Adminstrator A trained staff who operated the GPCA pump system.

Power The AC power source used to supply input power to the system.

Patient Patient recieves the drug and can also requests for bolus dose.

Components of GPCA Pump System

Bolus Request: The system has a mechanism for the patient to request bolus.

The infusion delivery mechanism: Infusion Hardware such as Pump, Drug Reservoir, Pump tubing and connectors.

User Interface: The system is provided with a user Interface that has a programming unit, display unit, audio and tactile. The system is equiped with a keypad and display for the clinician to program the infusion dosage information. The display is also used to view the dosage values. The display and audio output system is provided for notifying the clinician about hazardous conditions, detected by the system. The bolus mechanism: The system is equiped with a mechanism that allows patient to request bolus.

Battery: The system is equiped with a battery to power the system, as a back up for AC power supply

Sensors: Various sensors for monitoring, such as Flow Rate Sensor, Battery Voltage sensor etc. are equiped in the system to monitor the system outputs and enviroment

Log : A log system records all major operations on the pump, as defined in the logging requirements.

Controller : A Central Controller where Software is embedded to control the pump.

2.2 GPCA System Goals

In addition to the Infusion System requirements, the GPCA system has additional goals.

G 1 The GPCA system shall allow automatic infusion of drugs with limited interference from Clinicians.

G 2 The GPCA system shall never allow Infusion of the Drugs whose Safe limits are unknown or missing partially/completely in the hospital database.

G 3 The GPCA system shall ensure that there is no interruption of drug delivery to patient when in use.

G 4 The GPCA system shall detect and notify the clinician of hazardous conditions that would harm the patient when the system is in use.

G 5 The GPCA system shall allow audit of its past X days operations and error conditions

G 6 The GPCA system shall be easy to use.

G 7 The GPCA system shall be safe to operate.

G 8 The GPCA Pump shall be waterproof.

G 9 The GPCA Pump shall be unbreakable.

2.3 GPCA Variables

The GPCA variables are inputs that are used by the GPCA system to produce outputs . The Inputs variables are given to the system by the Clinician, Hospital Database and Patient.

2.3.1 Input Variables

Hospital Database Variables

Description: These are the safe drug values in the hospital/pharmacy drug database

$Drug_{hd\_name}$: **Drug Name**			
Type:	String	Units:	
Description:	Name of the drug to be infused		
Source	Hospital/Pharmacy Drug Database		

$Drug_{hd\_con\_hi}$: **Upper limit of drug concentration**			
Type:	Numeric	Units:	g/ml
Description:	Safe Upper limit of drug concentration that can be used to infuse the drug to the patient. This is the maximum concentration of the drug in the solution used to infused.		
Source	Actual Drug Safe Values		

$Drug_{hd\_con\_lo}$: **Lower limit of drug concentration**			
Type:	Numeric	Units:	g/ml
Description:	Safe lower limit of drug concentration that can be used to infuse the drug to the patient. This is the minimum concentration of the drug in the solution used to infused.		
Source	Hospital/Pharmacy Drug Database		

$VTBI_{hd\_basal\_lo}$: **Lower limit of Basal drug volume to be infused**			
Type:	Numeric	Units:	ml/hr
Description:	Safe lower limit of drug volume to be infused for basal.		
Source	Hospital/Pharmacy Drug Database		

$VTBI_{hd\_basal\_hi}$: **Upper limit of basal drug volume to be infused**			
Type:	Numeric	Units:	ml/hr
Description:	Safe Upper limit of drug volume to be infused for basal.		
Source			

$FlowRate_{hd\_basal\_lo}$: **Lower limit of basal Flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug Flow rate for basal. .		
Source	Hospital/Pharmacy Drug Database		

$FlowRate_{hd\_basal\_hi}$: **Upper limit of basal flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug Flow rate for basal. .		
Source	Hospital/Pharmacy Drug Database		

$VTBI_{hd\_sbolus\_lo}$: **Lower limit of VTBI for square bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug volume to be infused for Single square bolus. .		
Source	Hospital/Pharmacy Drug Database		

$VTBI_{hd\_sbolus\_hi}$: **Upper limit of VTBI for square bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug volume to be infused for Single square bolus. .		
Source	Hospital/Pharmacy Drug Database		

$FlowRate_{hd\_sbolus\_lo}$: **Lower limit of square bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug Flow rate for Single square bolus. .		
Source	Hospital/Pharmacy Drug Database		

$FlowRate_{hd\_sbolus\_hi}$: **Upper limit of square bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug Flow rate for Single square bolus. .		
Source	Hospital/Pharmacy Drug Database		

$Number_{hd\_sbolus\_hi}$: **Maximum number of square bolus**			
Type:	Numeric	Units:	
Description:	Maximum number of square bolus that can be admisterd to the patient.		
Source	Hospital/Pharmacy Drug Database		

$VTBI_{hd\_pbolus\_lo}$: **Lower limit of VTBI for patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug volume to be infused for Single patient bolus. .		
Source	Hospital/Pharmacy Drug Database		

$VTBI_{hd\_pbolus\_hi}$: **Upper limit of VTBI for patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug volume to be infused for Single patient bolus. .		
Source	Hospital/Pharmacy Drug Database		

$FlowRate_{hdpbolus\_lo}$: **Lower limit of patient bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug Flow rate for Single patient bolus. .		
Source	Hospital/Pharmacy Drug Database		

$FlowRate_{hd\_pbolus\_hi}$: **Upper limit of patient bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug Flow rate for Single patient bolus. .		
Source	Hospital/Pharmacy Drug Database		

$Number_{hd\_pbolus\_hi}$: **Maximum number of patient bolus**		
Type:	Numeric	Units:
Description:	Maximum number of patient bolus that can be admisterd to the patient.	
Source	Hospital/Pharmacy Drug Database	

$Frequency_{hd\_pbolus\_hi}$: **Maximum frequency between patient bolus**		
Type:	Numeric	Units:
Description:	Maximum frequency between patient bolus that can be self admisterd by the patient.	
Source	Hospital/Pharmacy Drug Database	

Infusion Variables - Programmed

Description: These are the infusion variables programmed by the clinician

$Drug_{prog\_name}$: **Clinician Programmed Name of the Drug**		
Type:	String	Units:
Description:	Drug Name that is Programmed for infusion	
Source	Prescription for Infusion	

$Drug_{prog\_con}$: **Clinician Programmed drug concentration**		
Type:	Numeric	Units: g/ml
Description:	Clinician Programmed drug concentration that should be adminstered for the patient	
Source	Clinician Programmed Value	

$VTBI_{total\_prog}$: **Clinician Programmed Volume to be Infused**		
Type:	Numeric	Units: ml/hr
Description:	Clinician Programmed Volume to be Infused	
Source	Clinician Programmed Value	

$FlowRate_{prog\_basal}$: **Clinician Programmed basal flow rate**		
Type:	Numeric	Units: ml/hr
Description:	Clinician Programmed basal flow rate	
Source	Clinician Programmed Value	

TOL_{prog_basal}: **Clinician Programmed tolerance of basal flow rate**		
Type:	Numeric	Units: ml/hr
Description:	Clinician Programmed tolerance of Fbasal over X time	
Source	Clinician Programmed Value	

$VTBI_{prog\_basal}$: **Clinician Programmed basal Volume to be Infused**		
Type:	Numeric	Units: ml/hr
Description:	Clinician Programmed Volume to be Infused for basal	
Source	Clinician Programmed Value	

$Duration_{prog\_basal}$: **Duration of basal flow**			
Type:	time	Units:	time
Description:	Clinician Programmed Duration of basal flow		
Source	Clinician Programmed Value		

$FlowRate_{prog\_sbolus}$: **Clinician Programmed square bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Clinician Programmed Square bolus flow rate,		
Source	Clinician Programmed Value		

TOL_{prog_sbolus}: **Clinician Programmed tolerance of square bolus flowrate**			
Type:	Numeric	Units:	ml/hr
Description:	Clinician Programmed tolerance of F sbol over X1 time		
Source	Clinician Programmed Value		

$VTBI_{prog\_sbolus}$: **Clinician Programmed Volume to be Infused for Square bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Clinician Programmed Volume to be Infused for Square bolus		
Source	Clinician Programmed Value		

$Duration_{prog\_sbolus}$: **Clinician Programmed Duration of square bolus flow**			
Type:	time	Units:	time
Description:	Clinician Programmed Duration of square bolus flow		
Source	Clinician Programmed Value		

$Number_{prog\_sbolus}$: **Clinician Programmed Max number of square bolus/time**		
Type:	Numeric	Units:
Description:	Clinician Programmed Max number of square bolus/time	
Source	Clinician Programmed Value	

$FlowRate_{prog\_pbolus}$: **Clinician Programmed flow rate of patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Clinician Programmed Patient bolus flow rate,		
Source	Clinician Programmed Value		

TOL_{prog_pbolus}: **Clinician Programmed tolerance of patient bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Clinician Programmed tolerance of patient bolus flow rate over X1 time		
Source	Clinician Programmed Value		

$VTBI_{prog\_pbolus}$: **Clinician Programmed VTBI for patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Clinician Programmed Volume to be Infused for patient bolus		
Source	Clinician Programmed Value		

$Duration_{prog\_pbolus}$: **Clinician Programmed Duration of patient bolus flow**			
Type:	time	Units:	ml/hr
Description:	Clinician Programmed Duration of patient bolus flow		
Source	Clinician Programmed Value		

$Number_{prog\_pbolus}$: **Clinician Programmed Max number of patient bolus**		
Type:	Numeric	Units:
Description:	Clinician Programmed Max number of patient bolus	
Source	Clinician Programmed Value	

$Frequency_{prog\_pbolus}$: **Clinician Programmed Frequency of patient bolus**		
Type:	Numeric	Units:
Description:	Clinician Programmed Frequency of patient bolus	
Source	Clinician Programmed Value	

$FlowRate_{prog\_kvo}$: **minimum keep vein open flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	minimum keep vein open flow rate		
Source	Clinician Programmed Value		

Infusion Control Variables - Programmed

Description: These are the infusion command signals provided to the system that are initiated by the clinician

IN_{gpca_start}: **Infusion Start/Resume**		
Type:	Boolean	Units:
Description:	Initiate Infusion	
Source	Infusion Command	

IN_{gpca_start}: **Infusion Pause**		
Type:	Boolean	Units:
Description:	Pause Infusion	
Source	Infusion Command	

IN_{gpca_stop}: **Infusion Inhibit**		
Type:	Boolean	Units:
Description:	Inhibit Infusion	
Source	Infusion Inhibit Command	

Patient Variables - Programmed

Description: These are patient parameters programmed into the system by the clinician

$Patient_{prog\_bolus}$: **Bolus Request**		
Type:	Boolean	Units:
Description:	Bolus Request	
Source	Bolus Request by Patient	

$Patient_{prog\_name}$: **Actual Name of the patient**		
Type:	String	Units:
Description:	Actual Name of the patient	
Source	Actual Patient Information	

$Patient_{prog\_dob}$: **Actual Date of birth of the patient**		
Type:	String	Units:
Description:	Actual Date of birth of the patient	
Source	Actual Patient Information	

$Patient_{prog\_weight}$: **Actual weight of the patient**		
Type:	Numeric	Units:
Description:	Actual Weight of the patient	
Source	Actual Patient Information	

$Patient_{prog\_gen}$: **Actual gender of the patient**		
Type:	String	Units:
Description:	Actual Gender of the patient	
Source	Actual Patient Information	

2.3.2 Output Variables

$FlowRate_{output}$: **Output Flow rate**		
Type:	Boolean	Units:
Description:	flow rate of the drug flowing in the infusion tube	
Source	commanded flow rate of the drug in the infusion tubing	

$VolumeInfused_{output}$: **VTBI**		
Type:	Boolean	Units:
Description:	Total Volume of drug flown through the infusion tubing	
Source	Total Volume of drug flown through the infusion tubing	

$Alarm_{output}$: **Notification To Clinician**		
Type:	Boolean	Units:
Description:	Notification from the system when there is a error condition	
Source	The clinician is notified if there is an error condition	

Log_{output}: **Actual logging data**		
Type:	String	Units:
Description:	Log data created	
Source		

2.3.3 GPCA system constraints

$FlowRate_{max}$: **Max flow rate of the pump**			
Type:	Numeric	Units:	ml/hr
Description:	Max flow rate of the pump		
Source	Max flow rate of the pump		

$Battery_{safelife}$: **Safe Battery Life**			
Type:		Units:	hours
Description:	Safe Battery Life		
Source			

$OcclusionPressure_{safeup}$: **Safe upstream occlusion pressure**			
Type:		Units:	psi
Description:	Safe upstream occlusion pressure		
Source			

$OcclusionPressure_{safedown}$: **Safe downstream occlusion pressure**			
Type:		Units:	psi
Description:	Safe downstream occlusion pressure		
Source			

$Temp_{opmin}$: **Safe Pump operating temprature min**			
Type:		Units:	C
Description:	Pump operating temprature min		
Source			

$Temp_{opmax}$: **Safe Pump operating temprature max**			
Type:		Units:	C
Description:	Pump operating temprature max		
Source			

$Pressure_{opmin}$: **Safe Pump operating pressure min**			
Type:		Units:	psi
Description:	Pump operating pressure min		
Source			

$Pressure_{opmax}$: **Safe Pump operating pressure max**			
Type:		Units:	psi
Description:	Pump operating pressure max		
Source			

$Humidity_{opmin}$: **Safe Pump operating humidity min**			
Type:		Units:	
Description:	Pump operating humidity min		
Source			

$Humidity_{opmax}$: **Safe Pump operating humidity max**		
Type:	Units:	
Description:	Pump operating humidity max	
Source		

$Voltage_{opmin}$: **Safe Pump operating voltage min**		
Type:	Units:	volts
Description:	Pump operating voltage min	
Source		

$Voltage_{opmax}$: **Safe Pump operating voltage max**		
Type:	Units:	volts
Description:	Pump operating voltage max	
Source		

2.4 GPCA System Assumptions

A 9 The bolus request would have higher precedence than the basal. The Patient bolus has higher precedence than Clinician Bolus

A 10 The system shall be powered by AC supply

A 11 Internal interuptions to Infusion considered are limited to Drug Availability, AirBubble, Occlusion, Insufficinet Drug Flow

A 12 Safe AirBubble Infusion , Safe Occlusion Pressure Values ,Safe Duration "continuous" for reverse delivery are available

A 13 The Clinician will always be available to respond to error conditions

A 14 Clinician would take care of alternate actions for infusion within the safe duration during hazardous situations

A 15 The audit will be conducted by a trained personal. Its expected that if this trained personnel finds an issue in the audit, he should take appropriate action.

A 16 The physical system is easily accesible to others apart from the Clinician

A 17 The enviroment of use of the system has exposure to fluids. Accidental exposure to fluids is possible.

A 18 The system will be operated in an setting which will be between X and Y above the floor level.

A 19 Only one drug that can be used for both basal and bolus infusions at a time by a single infusion pump.

2.5 GPCA Requirement Specifications

2.5.1 Infusion Mode Requirements

S2.5.1.1 The system shall allow drug infusion in any one of the three modes of infusions : Basal, square bolus and patient bolus

S2.5.1.2 The system shall allow only one mode of infusion at a time.

S2.5.1.3 The precedence of infusion would be in the order : Patient Bolus - Square Bolus - Basal

S2.5.1.4 If basal infusion is in progress when bolus request is initiated, the basal infusion shall be paused and will resume after the bolus delivery is complete.

S2.5.1.5 If clinician commanded bolus is in progress when patient bolus request is initiated, the clinician commanded bolus infusion shall be paused and will resume after the patient bolus delivery is complete.

S2.5.1.6 All the other infusions will be paused until the patient bolus is complete and are resumed in order

2.5.2 Drug Configuration Requirements

S2.5.2.7 The system shall allow only a single drug infusion at a time

S2.5.2.8 The system shall allow the clinician to configure drug parameters for infusion $Drug_{prog\_name}$, $Drug_{prog\_con}$

S2.5.2.9 The system shall not initate Infusion with an Unknown Drug. $Drug_{prog\_name} = Drug_{hd\_name}$

S2.5.2.10 The system shall notify the Clinician, if the Drug concentration of the drug infused to the patient is not within the Safe Limits.

$$Drug_{hd\_con\_lo} < Drug_{prog\_con} < Drug_{hd\_con\_hi}$$

S2.5.2.11 The system shall not allow infusion of drugs which doesnt have safe values in the hospital database

S2.5.2.12 The system shall not initate Infusion if the $Drug_{prog\_name}$ does not have any values for $FlowRate_{hd\_basal\_hi}$, $FlowRate_{hd\_sbolus\_hi}$, $FlowRate_{hd\_pbolus\_hi}$, $Drug_{hd\_con\_hi}$, $Number_{hd\_sbolus\_hi}$, $Number_{hd\_pbolus\_hi}$, $VTBI_{hd\_basal\_hi}$, $VTBI_{hd\_sbolus\_hi}$, $VTBI_{hd\_pbolus\_hi}$ in the hospital database library.

S2.5.2.13 The system shall notify the Clinician, if the $Drug_{prog\_name}$ does not have any values for $FlowRate_{hd\_basal\_lo}$, $FlowRate_{hd\_sbolus\_lo}$, $FlowRate_{hdpbolus\_lo}$, $Drug_{hd\_con\_lo}$, $VTBI_{hd\_basal\_lo}$, $VTBI_{hd\_sbolus\_lo}$ $VTBI_{hd\_pbolus\_lo}$ in the hospital database library.

2.5.3 Infusion Requirements

S2.5.3.14 The system shall allow the clinician to configure infusion parameters for basal, square bolus and patient bolus infusions

S2.5.3.15 The system shall allow the clinician to configure drug infusion of $VTBI_{prog\_basal}$ by basal infusion at a flow rate $FlowRate_{prog\_basal}$ for a duration of $Duration_{prog\_basal}$

S2.5.3.16 The system shall also allow the clinician to configure drug infusion of $VTBI_{prog\_sbolus}$ by square bolus infusion at a flow rate $FlowRate_{prog\_sbolus}$ for a duration of $Duration_{prog\_sbolus}$ for $Number_{prog\_sbolus}$ number of times

S2.5.3.17 The system shall also allow the clinician to configure drug infusion of $VTBI_{prog\_pbolus}$ by patient bolus infusion at a flow rate $FlowRate_{prog\_pbolus}$ for a duration of $Duration_{prog\_pbolus}$ for $Number_{prog\_pbolus}$ number of times at a maximum allowable frequency between bolus request as $Frequency_{prog\_pbolus}$

S2.5.3.18 The programmed values of the drug shall never exceed the drug safe limits in the hospital database for all infusion modes

$$FlowRate_{hd\_basal\_lo} <= FlowRate_{prog\_basal} <= FlowRate_{hd\_basal\_hi}$$
$$FlowRate_{hdpbolus\_lo} <= FlowRate_{prog\_pbolus} <= FlowRate_{hd\_pbolus\_hi}$$
$$FlowRate_{hd\_sbolus\_lo} <= FlowRate_{prog\_sbolus} <= FlowRate_{hd\_sbolus\_hi}$$
$$VTBI_{hd\_basal\_lo} <= VTBI_{prog\_basal} <= VTBI_{hd\_basal\_hi}$$
$$VTBI_{hd\_sbolus\_lo} <= VTBI_{prog\_sbolus} <= VTBI_{hd\_sbolus\_hi}$$
$$VTBI_{hd\_pbolus\_lo} <= VTBI_{prog\_pbolus} <= VTBI_{hd\_pbolus\_hi}$$
$$Number_{hd\_sbolus\_hi} <= Number_{prog\_sbolus}$$
$$Number_{hd\_pbolus\_hi} <= Number_{prog\_pbolus}$$

S2.5.3.19 During infusion, for all infusion modes, the output flow of drug shall be at the programmed flow rate and with a flow rate precision of p % of the respective flow rate with the following tolerances :

1. The output flow rate shall never exceed programmed flow rate + precision beyond x seconds cumilatively in any y hour interval
2. The output flow rate shall never be more than max ml/hr above the prescribed flow rate + precision
3. The output flow rate shall never be less than programmed flow rate - precision beyond x seconds cumilatively in any y hour interval
4. The output flow rate shall never be less than or equal to 0ml/hr for more than x second

$$FlowRate_{output} = FlowRate_{prog\_basal} +/- p$$
$$FlowRate_{output} = FlowRate_{prog\_sbolus} +/- p$$
$$FlowRate_{output} = FlowRate_{prog\_pbolus} +/- p$$

S2.5.3.20 During Infusion, for all infusion modes, the patient shall receive the drug with a Volume precision of v ml with the following tolerances:

1. The output volume of drug shall never exceed more than the prescribed VTBI +/- precision for the respective infusion mode.
2. The total output volume of drug shall never exceed more than the total prescribed VTBI +/- precision

$$VolumeInfused_{output} = VTBI_{prog\_basal} +/- v$$
$$VolumeInfused_{output} = VTBI_{prog\_pbolus} +/- v$$
$$VolumeInfused_{output} = VTBI_{prog\_pbolus} +/- v$$
$$\text{Total } [VolumeInfused_{output}] = VTBI_{total\_prog} +/- v$$

S2.5.3.21 The patient shall never receive more than maximum number of patient bolus as programmed

$$Patient_{prog\_bolus} <= Number_{prog\_pbolus}$$

S2.5.3.22 The system shall notify the clinician if the drug flow rate or volume infused is beyond the allowable tolerance as described above

S2.5.3.23 The system shall not allow Underinfusion dute to Occlusion. The system shall detect Occlusion and notify the clinician

S2.5.3.24 The system shall not allow Air Embolism. The system shall detect Air bubbles more than X units and notify the clinician

S2.5.3.25 The system shall not allow Reverse Delivery. If reverese delivery occurs,the system shall stop infusion and the system shall notify the Drug Adminstrator

S2.5.3.26 Modifying any infusion related settings and patient information during infusion shall require confirmation.

S2.5.3.27 If the pump is idle for more than t minutes while programming a dose setting, the pump shall issue an alarm and clear the dose parameters defined.

2.5.4 Drug Reservior

S2.5.4.28 All filled prescriptions (liquid, narcotic pain-killer dispensed by the hospital pharmacy) must be labeled with basic information about the drug.

S2.5.4.29 The system shall notify the clinican if the drug volume in the drug reserviour is below Y ml

S2.5.4.30 If the volume of the reservoir is less than X ml, and an infusion is in progress, the system shall notify the Clinician of low reserviour

S2.5.4.31 If the volume of the reservoir is Y ml, and an infusion is in progress the system shall notify the Clinician of empty reserviour

2.5.5 Drug Database

S2.5.5.32 The system shall notify the clinician if the The drug data in the hospital database is older than Y days

2.5.6 Log

S2.5.6.33 The system shall maintain an electronic log of its last X minutes of operation. Infusion parameters and Notifications shall be recorded in the log for the last X minutes. (The log shall be used for audit purposes)

2.5.7 Power

S2.5.7.34 The system shall be powered by AC supply and also shall have a battery backup of X minutes

S2.5.7.35 The backup battery shall be rechargeable. If the battery doesnt get charged when in AC power, the Clinician will be notified

S2.5.7.36 The system shall notify the Clinician, if the operating voltage is not within the operating voltage limits of the pump.

2.5.8 Enviromental

S2.5.8.37 The system shall monitor the ambient temprature, Pressure and Humidity and make sure they are within the pump' safe limits. If the values are outside the safe range, the system shall notify the system adminstrator

S2.5.8.38 The system shall detect and notify the Clinician if the patient leakage current greater than x mA

S2.5.8.39 If the pump door is tampered the system shall notify the Clinician

2.5.9 User Interface

S2.5.9.40 The user interface shall have display, keypad and audio output

S2.5.9.41 The System shall have a start and stop mechanisms, to manually initiate and stop Infusion.

S2.5.9.42 The system shall be easy to use for the Drug Administrator

2.5.10   Notification

S2.5.10.43   All notification messages shall appear in the display and recorded in the log with time stamp and severity.

S2.5.10.44   The notification shall clearly indicate the specific problem causing the alarm condition.

S2.5.10.45   Error notifications should be displayed highest priority. Clinician can choose to hide the message for a temporary time, but the message should reappear on the screen after X minutes

S2.5.10.46   Warning messages shall be indicated to the Clinician, but the Clinician may view them if he requests them.

S2.5.10.47   The system shall respond to the respective notifications as described in the table below

Severity	Alarm Name	Alarm Display	Stop Infusion	Allow Bolus
High	Flow rate more than tolerance for more than X units of time	Y	Y	N
High	Flow rate less tolerance for more than X units of time	Y	Y	Y
High	Free flow	Y	Y	N
High	Dose limit exceeded due to too many bolus requests	Y	Y	N
High	Low Reservoir Volume	Y	Y	N
High	Drug reservoir empty	Y	Y	N
Medium	Occlusion	Y	Y	N
High	Flow rate less than KVO	Y	Y	N
High	Air-in-line embolism	Y	Y	N
Medium	continuous reverse delivery	Y	Y	N
High	Pump hot	Y	Y	Y
High	Ambient temperature out range	Y	Y	Y
High	Ambient humidity out range	Y	Y	N
High	Ambient air pressure out range	Y	Y	N
High	Battery life remaining too low	Y	Y	N
Medium	Battery charging problem	Y	Y	N
High	Power supply voltage out of range	Y	Y	N
High	Power Supply failure	Y	Y	N
Low	POST execution time exceed	Y	N	N
Low	POST failed	Y	N	N
Medium	Patient Leakage Current	Y	Y	N
Medium	Tampered door	Y	Y	N

2.5.11   Self Test

S2.5.11.48   The system shall include the execution of the following tests at start up and after every Y minutes of time during Infusion. CPU test, ROM / RAM CRC test, Battery test, Stuck key test, Watchdog test, Real Time Clock test, Tone test - called POST

S2.5.11.49   If POST runs for more than X time, the POST is aborted and system shall notify the Clinician.

S2.5.11.50   Any failure of a test step during POST shall abort the remaining test steps and notify the Clinician'

S2.5.11.51   Existing Infusion shall not be interuppted by POST steps

S2.5.11.52   New Bolus dose shall not be possible during the POST.

S2.5.11.53   POST or Self Test shall not affect the performance of the system

S2.5.11.54   If the hardware such as pump, sensors etc malfunctions , then the approriate error message is sent to the alaram component.

S2.5.11.55   A RAM test shall periodically check different sections of the RAM through low-level drivers.

S2.5.11.56   A ROM CRC test shall periodically check different sections of the ROM through low-level drivers.

S2.5.11.57   A CPU test shall be performed once every t minutes to check the processors code register.

2.5.12   Data Retention

S2.5.12.58   The patient's prescription shall be retained for at least X hours after the pump is turned-off and unplugged.

S2.5.12.59   Information in event and fault logs shall be retained for at least log X hours after the Pump is turned-off and unplugged.

S2.5.12.60   If the pump is turned off, it shall retain the programmed dose settings and patient data for at least t hours

2.5.13   Others

S2.5.13.61   The GPCA Pump shall be waterproof.

S2.5.13.62   The GPCA Pump shall be unbreakable.

S2.5.13.63   The Clinician shall securely log in to the system for operating the pump

3 GPCA Software

3.1 Overview

3.2 GPCA Software Variables

The GPCA software variables are inputs that are used by the GPCA software . The source of the input variables are from the various sensors and devices. The output of the software are software commands to the respective devices.

3.2.1 Input Variables

Drug Libray Database Variables

D_{dl_name}: **Drug Name**		
Type:	String	Units:
Description:	Name of the drug to be infused in the drug library database	
Source	Actual Drug Safe Limits	

$D_{dl\_con\_hi}$: **Upper limit of drug concentration in drug library database**		
Type:	Numeric	Units: g/ml
Description:	Safe Upper limit of drug concentration that can be used to infuse the drug to the patient. This is the maximum concentration of the drug in the solution used to infused.	
Source	Actual Drug Safe Values	

$D_{dl\_con\_lo}$: **Lower limit of drug concentration in drug library database**		
Type:	Numeric	Units: g/ml
Description:	Safe lower limit of drug concentration that can be used to infuse the drug to the patient. This is the minimum concentration of the drug in the solution used to infused.	
Source	Actual Drug Safe Limits	

$VTBI_{dl\_basal\_lo}$: **Lower limit of Basal drug volume to be infused in drug library database**		
Type:	Numeric	Units: ml/hr
Description:	Safe lower limit of drug volume to be infused for basal.	
Source	Actual Drug Safe Limits	

$VTBI_{dl\_basal\_hi}$: **Upper limit of drug volume to be infused in drug library database**		
Type:	Numeric	Units: ml/hr
Description:	Safe Upper limit of drug volume to be infused for basal.	
Source		

$F_{dl\_basal\_lo}$: **Lower limit of basal Flow rate in drug library database**		
Type:	Numeric	Units: ml/hr
Description:	Lower limit of drug Flow rate for basal. .	
Source	Actual Drug Safe Limits	

$F_{dl\_basal\_hi}$: **Upper limit of basal flow rate in drug library database**		
Type:	Numeric	Units: ml/hr
Description:	Upper limit of drug Flow rate for basal. .	
Source	Actual Drug Safe Limits	

$VTBI_{dl\_bolus\_lo}$: **Lower hard limit of VTBI for bolus in drug library database**			
Type:	Numeric	Units:	ml/hr
Description:	Lower hard limit of drug volume to be infused for Single bolus. .		
Source	Actual Drug Safe Limits		

$VTBI_{dl\_bolus\_hi}$: **Upper hard limit of VTBI for bolus in drug library database**			
Type:	Numeric	Units:	ml/hr
Description:	Upper hard limit of drug volume to be infused for Single bolus. .		
Source	Actual Drug Safe Limits		

$F_{dl\_bolus\_lo}$: **Lower limit of bolus flow rate in drug library database**			
Type:	Numeric	Units:	ml/hr
Description:	Lower limit of drug Flow rate for Single bolus. .		
Source	Actual Drug Safe Limits		

$F_{dl\_bolus\_hi}$: **Upper limit of bolus flow rate in drug library database**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of drug Flow rate for Single bolus. .		
Source	Actual Drug Safe Limits		

$T_{dl\_bolus\_hi}$: **Upper limit of Time over which Bolus is applied in drug library database**			
Type:	Numeric	Units:	ml/hr
Description:	Upper limit of Time over which Bolus is applied		
Source	Actual Drug Safe Limits		

$N_{dl\_bolus\_hi}$: **Maximum number of bolus in drug library database**			
Type:	Numeric	Units:	
Description:	Maximum number of bolus that can be admisterd to the patient.		
Source	Actual Drug Safe Limits		

Infusion Variables

D_{sw_name}: **Software Received Name of the Drug**			
Type:	String	Units:	
Description:	Drug Name that is Programmed for infusion		
Source	Prescription for Infusion		

D_{sw_con}: **Software Received drug concentration**			
Type:	Numeric	Units:	g/ml
Description:	Software Received drug concentration that should be adminstered for the patient		
Source	Software Received Value		

ed

F_{pre}: **Software Received flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received flow rate		
Source	Software Received Value		

TOL_{pre}: **Software Received tolerance of flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received tolerance over X time		
Source	Software Received Value		

$VTBI_{pre}$: **Software Received Volume to be Infused**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received Volume to be Infused		
Source	Software Received Value		

$Time_{pre}$: **Software Received time when drug to be Infused**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received time when drug to be Infused		
Source	Software Received Value		

F_{sw_basal}: **Software Received basal flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received basal flow rate		
Source	Software Received Value		

TOL_{sw_basal}: **Software Received tolerance of basal flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received tolerance of Fbasal over X time		
Source	Software Received Value		

$VTBI_{sw\_basal}$: **Software Received basal Volume to be Infused**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received Volume to be Infused for basal		
Source	Software Received Value		

T_{sw_basal}:			
Type:	time	Units:	time
Description:	Software Received Duration of basal flow		
Source	Software Received Value		

F_{sw_pbolus}: **Software Received flow rate of patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received Patient bolus flow rate,		
Source	Software Received Value		

TOL_{sw_pbolus}: **Software Received tolerance of patient bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received tolerance of patient bolus flow rate over X1 time		
Source	Software Received Value		

$VTBI_{sw\_pbolus}$: **Software Received VTBI for patient bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received Volume to be Infused for patient bolus		
Source	Software Received Value		

T_{sw_pbolus}: **Software Received Duration of patient bolus flow**			
Type:	time	Units:	ml/hr
Description:	Software Received Duration of patient bolus flow		
Source	Software Received Value		

F_{sw_sbolus}: **Software Received square bolus flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received Square bolus flow rate,		
Source	Software Received Value		

TOL_{sw_sbolus}: **Software Received tolerance of square bolus flowrate**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received tolerance of F sbol over X1 time		
Source	Software Received Value		

$VTBI_{sw\_sbolus}$: **Software Received Volume to be Infused for Square bolus**			
Type:	Numeric	Units:	ml/hr
Description:	Software Received Volume to be Infused for Square bolus		
Source	Software Received Value		

T_{sw_sbolus}: **Software Received Duration of square bolus flow**			
Type:	time	Units:	time
Description:	Software Received Duration of square bolus flow		
Source	Software Received Value		

T_{sw_pbolus}: **Software Received Duration of patient bolus flow**			
Type:	time	Units:	time
Description:	Software Received Duration of patient bolus flow		
Source	Software Received Value		

F_{sw_kvo}: **minimum keep vein open flow rate**			
Type:	Numeric	Units:	ml/hr
Description:	minimum keep vein open flow rate		
Source	Software Received Value		

N_{sw_sbolus}: **Software Received Max number of square bolus/time**			
Type:	Numeric	Units:	
Description:	Software Received Max number of square bolus/time		
Source	Software Received Value		

N_{sw_pbolus}: **Software Received Max number of patient bolus/time**		
Type:	Numeric	Units:
Description:	Software Received Max number of patient bolus/time	
Source	Software Received Value	

Infusion Control Variables

IN_{gpca_start}: **Infusion Initiation**		
Type:	Boolean	Units:
Description:	Initiate Infusion	
Source	Infusion Inhibit Command	

IN_{gpca_stop}: **Infusion Inhibit**		
Type:	Boolean	Units:
Description:	Inhibit Infusion	
Source	Infusion Inhibit Command	

Patient Variables

B_{ac_pbolus}: **Bolus Request**		
Type:	Boolean	Units:
Description:	Bolus Request	
Source	Bolus Request by Patient	

P_{sw_name}: **Actual Name of the patient**		
Type:	String	Units:
Description:	Actual Name of the patient	
Source	Actual Patient Information	

P_{sw_dob}: **Actual Date of birth of the patient**		
Type:	String	Units:
Description:	Actual Date of birth of the patient	
Source	Actual Patient Information	

P_{sw_weight}: **Actual weight of the patient**		
Type:	Numeric	Units:
Description:	Actual Weight of the patient	
Source	Actual Patient Information	

P_{sw_gen}: **Actual gender of the patient**		
Type:	String	Units:
Description:	Actual Gender of the patient	
Source	Actual Patient Information	

3.2.2 Output Variables

F_{sw}: **Commanded Flow rate**		
Type:	Numeric	Units:
Description:	flow rate of the drug - software command sent to the pump	
Source	Software command to pump	

$Alarm_{sw}$: **Alarm Notification To Clinician**		
Type:	String	Units:
Description:	Notification from the system when there is a error condition	
Source		

Log_{sw}: **Log Message**		
Type:	String	Units:
Description:	Log messages	
Source	Log messages	

3.2.3 GPCA system constraints

F_{max}: **Max flow rate of the pump**		
Type:	ml/min	Units:
Description:	Max flow rate of the pump	
Source	Max flow rate of the pump	

$B_{safelife}$: **Safe Battery Life**			
Type:		Units:	hours
Description:	Safe Battery Life		
Source			

P_{safeu}: **Safe upstream occlusion pressure**			
Type:		Units:	psi
Description:	Safe upstream occlusion pressure		
Source			

P_{safed}: **Safe downstream occlusion pressure**			
Type:		Units:	psi
Description:	Safe downstream occlusion pressure		
Source			

T_{opmin}: **Safe Pump operating temprature min**			
Type:		Units:	C
Description:	Pump operating temprature min		
Source			

T_{opmax}: **Safe Pump operating temprature max**		
Type:	Units:	C
Description: Pump operating temprature max		
Source		

P_{opmin}: **Safe Pump operating pressure min**		
Type:	Units:	psi
Description: Pump operating pressure min		
Source		

P_{opmax}: **Safe Pump operating pressure max**		
Type:	Units:	psi
Description: Pump operating pressure max		
Source		

H_{opmin}: **Safe Pump operating humidity min**		
Type:	Units:	
Description: Pump operating humidity min		
Source		

H_{opmax}: **Safe Pump operating humidity max**		
Type:	Units:	
Description: Pump operating humidity max		
Source		

V_{opmin}: **Safe Pump operating voltage min**		
Type:	Units:	volts
Description: Pump operating voltage min		
Source		

V_{opmax}: **Safe Pump operating voltage max**		
Type:	Units:	volts
Description: Pump operating voltage max		
Source		

3.3   GPCA Software Assumptions

3.4 Software Requirements Specifications

3.4.1 Infusion Configuration

SW3.4.1.1   The application shall allow the Clinician to configure Patient information , Drug Information and Infusion parameters for basal, patient bolus and square bolus Infusion

  SW3.4.1.1.1   The application shall allow the Clinician to enter new patient data only when the infusion pump is in Off or Paused State

  SW3.4.1.1.2   The application shall perform all Patient data validatalions 5 after the Clinician enters the values

  SW3.4.1.1.3   The application shall perform all drug data validations 8 after the Clinician enters the values

  SW3.4.1.1.4   The application shall request clinician confirmation of the the patient and drug information before initiating infusion

  SW3.4.1.1.5   If Infusion is in progress during the configuration, the system shall continue infusion with existing parameters, until the new configuration is confirmed by the Clinician

SW3.4.1.2   The application shall perform Infusion Ready validations 15 after the initiate infusion signal is received

SW3.4.1.3   The application shall send the infusion output commands to the pump after the Infusion ready validations are passed

  SW3.4.1.3.1   The application shall maintain the current status of infusion mode at all times

3.4.2 Patient Data Validations

SW3.4.2.4   The application shall only allow Patient Data to be changed when Infusion is not in progress

SW3.4.2.5   The application shall not allow the Patient data to be empty

SW3.4.2.6   The application shall validate the patient data shall be checked for their respective data types Eg: Date of birth shall be in date format

SW3.4.2.7   If any of the above validations fails, the application shall notify the clinician with alert message and shall proceed only if the Drug adminstrator enters acceptable values and revalidates the new values

3.4.3 Drug Data Validations

SW3.4.3.8   The system shall not allow change of Drug Name and concentration when Infusion is in progress.

SW3.4.3.9   The system shall accept drug names only if they are present in the Drug library $D_{sw\_name} = D_{dl\_name}$.

  SW3.4.3.9.1   During Infusion configuration, The application shall notify the clinician with 'Outdated Database' alert if the Drug database updated date is more than X days for that drug

  SW3.4.3.9.2   If the clinician overrides the alert, the alert is recorded in the log

SW3.4.3.10   The application shall notify the clinician with 'Drug Concentration not in safe range' alert, if the configured concentration of the drug is not within the Safe Limits.

$$D_{dl\_con\_lo} <= D_{sw\_con} <= D_{dl\_con\_hi}$$

SW3.4.3.11   If the configured Flow rate is not within the safe range of the drug in the drug library, the application shall alert the clinician.

$$F_{dl\_basal\_lo} <= F_{sw\_basal} <= F_{dl\_basal\_hi}$$

$$F_{dl\_bolus\_lo} <= F_{sw\_pbolus} <= T_{dl\_bolus\_hi}$$
$$F_{dl\_bolus\_lo} <= F_{sw\_sbolus} <= T_{dl\_bolus\_hi}$$

SW3.4.3.12 If the configured VTBI is not within the safe range of the drug ,the application shall alert the clinician.

$$VTBI_{dl\_basal\_lo} <= F_{sw\_basal} * T_{sw\_basal} <= VTBI_{dl\_basal\_lo}$$
$$VTBI_{dl\_bolus\_hi} <= F_{sw\_pbolus} * T_{sw\_pbolus} <= VTBI_{dl\_bolus\_lo}$$
$$VTBI_{dl\_bolus\_hi} <= F_{sw\_sbolus} * T_{sw\_sbolus} <= VTBI_{dl\_bolus\_lo}$$

SW3.4.3.13 If the configured maximum number of bolus requests is more than the safe number of bolus of the drug, the application shall alert the clinician

$$?? >= N_{sw\_pbolus}$$

SW3.4.3.14 If any of the above alerts occur, the application shall proceed only if the Clinician re-enters acceptable values

3.4.4 Infusion Ready Validations

SW3.4.4.15 The application shall perform Infusion ready check when Infusion Start Request command is received, before Infusion is commanded to the pump

SW3.4.4.16 The application shall command hardware checks

SW3.4.4.17 The application shall verify if the Remaining Volume of the drug is more than X percent of the total volume

SW3.4.4.18 The application shall check if Door open command is false

SW3.4.4.19 If any of the above validations fails, The application shall command an alarm message and shall not initiate Infusion

3.4.5 Infusion Monitoring

SW3.4.5.20 When Infusion is in progress, The application shall always maintain the current Infusion status and mode

SW3.4.5.21 When Infusion is in progress, The application shall check if the flow rate is within tolerance and within the drug safe limit

SW3.4.5.21.1 Every x seconds, flow rate from the sensors shall be requested

SW3.4.5.21.1.1 If the input is not received in x seconds of time for more than y time, the system shall send an 'No Flow Sensor Data', alarm

SW3.4.5.21.2 The application shall validate during all infusion modes if the received flow rate is within programmed flow rate with flow rate precision of p % of the programmed flow rate of the respective infusion mode

1. The received flow rate shall never exceed programmed flow rate + precision beyond x seconds cumilatively in any y hour interval

2. The received flow rate shall never be more than max ml/hr above the prescribed flow rate + precision

3. The received flow rate shall never be less than programmed flow rate - precision beyond x seconds cumilatively in any y hour interval

4. The received flow rate shall never be less than or equal to 0ml/hr for more than x second

$$F_{sw} = F_{sw\_basal} +/- p$$
$$F_{sw} = F_{sw\_sbolus} +/- p$$
$$F_{sw} = F_{sw\_pbolus} +/- p$$

SW3.4.5.21.3 The application shall trigger alarms if the flow rates are not within the above mentioned tolerances

SW3.4.5.22 if infusion is not in progress, or if Infusion is paused $F_{sw} = F_{sw\_kvo}$

    SW3.4.5.22.1 Every x seconds, the application shall calculate the volume infused with the respective flow rates and duration

    SW3.4.5.22.2 The application shall validate during all infusion modes if the calculated drug volume is within programmed VTBI with volume precision of v % of the programmed VTBI of the respective infusion mode

        Calculated VTBI_basal $= VTBI_{sw\_basal}$ $+/-$ v
        Calculated VTBI_sbolus$= VTBI_{sw\_pbolus}$ $+/-$ v
        Calculated VTBI_pbolus $= VTBI_{sw\_pbolus}$ $+/-$ v

    SW3.4.5.22.3 The application shall validate during all infusion modes if the total calculated drug volume is within programmed VTBI with volume precision of v % of the programmed VTBI of all the infusion modes comulatively

        Total [Calculated VTBI] $= VTBI_{pre}$ $+/-$ v

    SW3.4.5.22.4 The application shall trigger alarms if the VTBI validations fail

SW3.4.5.23 If the number of patient bolus requests exceeds the maximum number of patient bolus allowed, the system shall trigger a 'Patient Bolus Exceed' alarm and shall not command bolus infusion

        $B_{ac\_pbolus} <= N_{sw\_pbolus}$

SW3.4.5.24 When Infusion is in Progress, An air-in-line alarm shall be triggered if air bubbles larger than the configured Air bubble threshold volume is infused into the patient

SW3.4.5.25 When Infusion is in Progress, An upstream occlusion alarm shall be triggered if the upstream (fluid-container side) occlusion pressure is more than the safe upstream pressure.

SW3.4.5.26 When Infusion is in Progress, A downstream occlusion alarm shall be triggered if the downstream (patient side) occlusion pressure is more than the safe downstream pressure.

SW3.4.5.27 When Infusion is in Progress, A reverse delivery alarm shall be triggered if there is continuous reverse delivery for more than X units of time

3.4.6 Drug Reservior

SW3.4.6.28 The system shall maintain the initial volume of drug in the reserviour before all infusion is started. [Initial Volume]

SW3.4.6.29 At equal intervals of time during infusion and when paused remaining drug reserviour Volume is calcuated as :

        Remaining Volume = Initial Volume - Calculated VTBI

    SW3.4.6.29.1 If the Remaining Volume is less than X percent of the initial volume, the application shall command "Low Reserviour" Alarm.

    SW3.4.6.29.2 If the Remaining Volume is less than Y percent of the initial volume, the application shall command "Empty Reserviour" Alarm.

3.4.7 Others

SW3.4.7.30 If the dooropen is true, the application shall command a 'Door Open' alarm

3.4.8 Enviromental

SW3.4.8.31 If patient leakage current indicator is true, the application shall command a 'Patient Leakage Current' alarm.

SW3.4.8.32 When Infusion is in Progress, Pump's operating conditions should be within the configured range [Voltage, Temp, Overheating temprature, Atm Pressure , Relative Humidity]. If the values are not within the range, respective alarm is triggered

SW3.4.8.33   the application receives data from temperature, pressure and humidity sensors at X intervals of time and if the values are beyond the desireable range, then the respective alarm is commanded by the application

3.4.9   Log

SW3.4.9.34   The application logs infusion start, stop and pause, infusion parameters and Alarm messages of the system with time stamp

SW3.4.9.34.1   If log file is not updated, the application shall command 'No logging' alarm

SW3.4.9.35   When the log file is full, the application automatatically creates a new log file and logging continues.

SW3.4.9.35.1   If new log file is not created, the application shall command 'new log file creation' alarm

SW3.4.9.36   The application shall not overwrite on existing log file

3.4.10   Self Test

SW3.4.10.37   At power on, the application shall command a POST / power on self-test command

SW3.4.10.37.1   The application shall receive the result of Post checks within Y units of time

SW3.4.10.37.2   If the application doesnt receive Post Results flag within t units of time, the application shall trigger 'Post Over Time' alarm

SW3.4.10.37.3   If the application receives POST fail message, the application shall abort the remaining test steps and trigger 'Post Failed' alarm

SW3.4.10.37.4   The application shall not allow patient bolus dose during the POST.

SW3.4.10.38   The application commands periodic checks of the following and sends appropriate alarm message if any fails : System hardware, watchdog, the CPU, the memory or the real time clock becomes corrupted, drug reservoir door is open.

3.4.11   Power

SW3.4.11.39   The application shall indicate the power source of the system - AC or Battery at all times during operation

SW3.4.11.39.1   If the system works with AC power suppy then the application shall check supply voltage every X units of time and commands 'Voltate Out of Range' alarm message , if the voltage is not in the desired range.

SW3.4.11.39.2   If system has battery, the application receives battery charge information at X intervals of time. If the charge level is below a Y units or if the battery charge is not increasing, the application commans 'Battery Charging Issue' Alarm

SW3.4.11.39.3   If the system works with Battery power suppy then the application shall check voltage every X units of time and commands 'Voltate Out of Range' alarm message , if the voltage is not in the desired range.

3.4.12   Access Control

SW3.4.12.40   All functionalities of the application shall be access controlled.

SW3.4.12.40.1   Only operation possible on the application without logging in shall be viewing alarm messages and manual Stop/Pause Infusion,all other operations on the application shall be after loging in

3.4.13 Alarm

SW3.4.13.41 Alarm Specifications as table.

Severity	Alarm Name	Alarm Display	Stop Infusion	Allow Bolus
High	Flow rate more than tolerance for more than X units of time	Y	Y	N
High	Flow rate less tolerance for more than X units of time	Y	Y	Y
High	Free flow	Y	Y	N
High	Dose limit exceeded due to too many bolus requests	Y	Y	N
High	Low Reservoir Volume	Y	Y	N
High	Drug reservoir empty	Y	Y	N
Medium	Downstram Occlusion	Y	Y	N
Medium	Upstream Occlusion	Y	Y	N
High	Flow rate less than KVO	Y	Y	N
High	Air-in-line embolism	Y	Y	N
Medium	continuous reverse delivery	Y	Y	N
High	Pump hot	Y	Y	Y
High	Ambient temperature out range	Y	Y	Y
High	Ambient humidity out range	Y	Y	N
High	Ambient air pressure out range	Y	Y	N
High	Battery life remaining too low	Y	Y	N
Medium	Battery charging problem	Y	Y	N
High	Power supply voltage out of range	Y	Y	N
High	Power Supply failure	Y	Y	N
Low	POST execution time exceed	Y	N	N
Low	POST failed	Y	N	N
Medium	Patient Leakage Current	Y	Y	N
Medium	Tampered door	Y	Y	N

4   Traceability

This subsection will have traceability between " Specifications - Assumptions - Requirements "

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