

System Requirements:

Generic Patient Controlled Analgesic Infusion (GPCA) System

DRAFT Version

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Chapter 1

Introduction

This document contains an exemplar of how a system level requirements document for an infusion pump could be written. In this case, it the infusion pump is a low volume Patient Controlled Analgesia Pump (PCA). Since the particular pump described in this document is not based on any existing model currently on the market, we call the pump described in this document the Generic Patient Controlled Analgesia Pump (GPCA).

1.1 Document Purpose

This document shall serve as a complete and up-to-date requirements document for the Generic Patient Controlled Analgesic (GPCA) Infusion system. Together with items referenced within the document, it shall provide a detailed description of the functionalities and constraints of the GPCA system in its intended environment of use.

The scope of this document is limited to the behavioral, non-behavioral requirements, and constraints of the GPCA system along with the assumptions about its users and environment. The regulatory and certification requirements are not in scope of this document. The assumptions listed in this document are not controlled by the system.

1.2 Document Organization

The GPCA Requirements Document is organized in four main chapters. Chapter 2 contains an overview of the GPCA system and intended to give the reader a high-level overview of the GPCA system, its operating environment, and its main functionality. This chapter is not a substitute for the actual system requirements in the subsequent chapters. Chapter 3 defines the context of the GPCA system, defines the interfaces between the GPCA system and the environment, and defines all variables in this interface, that is, Chapter 3 defines the system scope. Chapters 4 and 5 define the behavioral and non-behavioral requirements for the system. Appendix A contains a glossary and definition of terms.

1.3 Intended Audience

As mentioned earlier, this document is an exemplar of what a production document might look like. Thus, the intendance audience for this document are researchers and practitioners that want to study a model document capturing system level requirements in a format and style the authors of this document find appealing and appropriate. We are fully aware that others may disagree with our organization, style, and content; we welcome feedback and spirited discussion. We request that feedback on this document be directed to Mats Heimdahl at heimdahl@cs.umn.edu.

1.4 Document Conventions

To be both brief and precise, the document contains many abbreviations, acronyms and symbols; all abbreviations, acronyms and symbols are detailed in the glossary in Appendix A.

Since we are not experts in the domain of infusion pumps, we have not attempted to prioritize the requirements in this document. Furthermore, information that should normally be captured in a requirements document, for example, the author of a requirement, the source of the information for the requirement, the date of creation, reference to use-cases used in elicitation, etc. are omitted from this document. The focus is on demonstrating a suitable organization and proper formulation of functional and non-functional requirements. .

Naming of Data Items: Throughout the document, data elements are represented as variables and are defined in section 3 in the following format. The identifier for the variable is named in the format $\langle \textit{GeneralName} \rangle - \langle \textit{SpecificDescription} \rangle_{\langle \textit{source} \rangle}$; 'General Name_Specific description' represents Name followed by specific instance of occurrence and source represents the origin of the data. For example $\textit{VTBI}_{\textit{basal}_{\textit{prog}}}$ represents VTBI in basal mode that is programmed. $\textit{DrugConcentration}_{\textit{low}_{\textit{hd}}}$ represents Drug Concentration low that is from hospital database. The description section in the definition gives a brief explanation of the variable.

Identifier of the Data	<i>Units:</i> Unit of Data Item	<i>Type:</i> Data type
<i>Description:</i> A brief description of the data		
<i>Source:</i> Indicates the origin of the data		<i>Dependency :</i> [Assumption that this data is dependent upon.]
<i>Values :</i> Minimum Value of the data	<i>Condition:</i> Specifies conditions and constraints on the value of the data.	

Numbering: The chapter and section numbering is as per Latex Book style. Interfaces, Assumptions, Requirement statements are numbered sequentially with a letter prefix I, A, REQ respectively. Each statement is numbered uniquely for traceability.

Chapter Organization: Each Chapter is organized into nested sections each numbered sequentially. Each chapter and its sections begins with a description and specific conventions followed in that chapter/section. The organization is hierarchical, hence the child section inherits all its parent section description and conventions unless explicitly stated.

Cross Referencing: The variable names used throughout the document are cross referenced to their definition. For e-readers, variable names are hyper linked to their definition. Related sections or statements needed in context are cross referenced in respective location.

Figures: Figures are introduced in appropriate sections to complement the description and have a better clarity while reading the section.

Color Coding: Variable names are italicized and colored blue throughout the document for better readability.

Formal Statements: In the Requirement chapters wherever possible the requirement statement is complemented with a formula in terms of the variables used; This is done in order to ensure that the user is clear about the right data element referred in the requirement. For example, "when the total volume of drug output is more than the drug safe value VTBI high, the system shall...", is complemented with $\textit{ActualVolume}_{\textit{Infused}_{\textit{macro}}} > \textit{VTBI}_{\textit{hi}_{\textit{hd}}}$.

Chapter 2

Generic Patient Controlled Analgesia (GPCA) System Description

This chapter gives an overview of the system, providing a brief description of the components of the system, the system's high level functions, description of the types of users of the system and the intended usage environment. Note that the descriptions in this chapter are intended as an overview only, the requirements on the system are defined in subsequent chapters.

2.1 GPCA Overview

GPCA Infusion system is a cyber physical system that controls the rate of infusion of analgesia and enables the patient to self-administer their own analgesic according to the programmed dosage of medication. The system normally delivers the drug as a basal infusion level set by the clinician. The GPCA can be programmed to provide clinician defined bolus injections (extra boost of the drug) at certain intervals. In addition, the patient can request boluses injections in case the programmed injection is insufficient to address the pain.

The GPCA has the capability to notify the clinician of exceptional conditions, for example, if the drug reservoir is running low or if there are air bubbles in the system. Below we provide an overview of the GPCA system, its interfaces with the external environment, its intended users, and its main functionality.

The GPCA in its intended environment is illustrated in Figure 2.1

As discussed above, the **GPCA** system allows drug administration through a Patient Controlled Analgesia infusion method. The GPCA is connected to the patient, hospital pharmacy database, and drug reservoir as illustrated in Figure 2.1. The clinician operates the system and is responsible for entering the prescribed delivery into the GPCA pump. Below we briefly describe each external system that interacts with the GPCA. The detailed description of the interface between the GPCA pump and its environment is provided in Chapter 3.

Patient: The patient is the person who receives the medication. The patient is connected to the GPCA pump through a **needle** (in this case an intravenous needle). The needle is used to infuse the drug intravenously to the patient. It is inserted into the patient by the clinician. The clinician also connects the needle to the GPCA to allow drug flow to the patient.

The patient can self administer prescribed amounts of additional drug through bolus request. The patient requests a bolus injection by pressing a bolus request button provided by the bed. To prevent overdose of pain medication, the GPCA pump limits the number and frequency of patient bolus requests.

Hospital Pharmacy Database: The hospital pharmacy database is a repository of drug information capturing the drug information provided by the drug manufactures. This typically has the range of values for all the parameters of the drugs to be used for infusion. For example, for patient safety, the dosage of the drug to the patient should never exceed the safe limits of the particular drug being infused. The GPCA is connected to this repository through an interface to access the drug data.

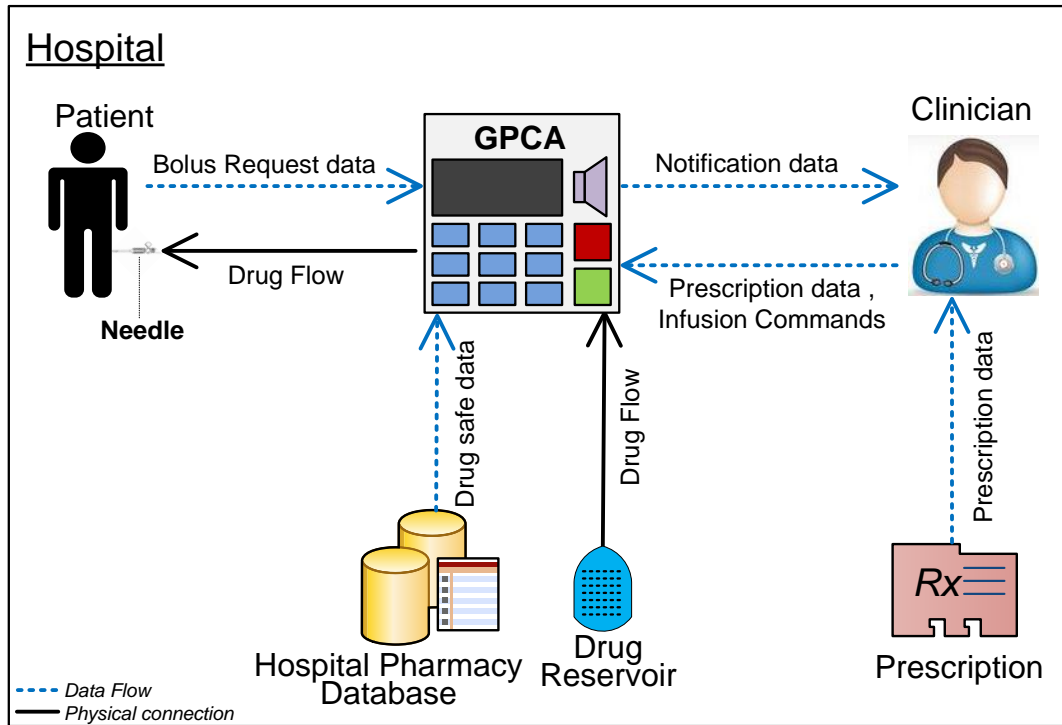


Figure 2.1: GPCA Infusion system overview.

Prescription: The prescription is the form of instructions that govern the plan of care for an individual patient. This would typically capture the drug to be infused and all details related to drug administration. The prescription is provided by a medical practitioner certified to prescribe analgesic.

Clinician: The clinician is a hospital staff member who is certified and trained to operate the system and administer the drug. The clinician enters the prescription information into the GPCA system. The clinician is also the intended recipient of notifications from the system when exceptional conditions occur and is the person responsible to take appropriate actions in response to the notifications. The clinician is the main operator of the GPCA pump.

Drug Reservoir: The drug reservoir is an apparatus that stores the liquid analgesic drug to be infused. This is filled according to the prescription and connected to the GPCA system by the clinician as per instructions.

2.2 Main GPCA System Functions

The GPCA pump has three primary functions (1) deliver the liquid analgesic drug based on the prescribed schedule or patient requests, (2) prevent the patient from overdosing through excessive bolus requests, and (3) notify the clinician of any exceptional conditions in the system.

2.2.1 Drug Delivery

The system is used to deliver drug in Basal, Square bolus and Patient bolus modes to the patient as per the programmed prescription. The basal infusion is a constant flow of the liquid analgesic drug to the patient. This is the normal mode of delivery. The GPCA pump can be configured so that it at predefined intervals delivers an extra amount of drug—called a square bolus—and then resumes the basal infusion. Should the basal infusion and programmed square boluses be insufficient to relieve pain, the patient can request a patient bolus above and beyond the programmed dosage.

Drug delivery may be interrupted under certain exceptional conditions—when alarms are raised the GPCA pump is generally paused. When paused, a very low flow is delivered to keep the vein open. The clinician can at this point check the alarm, address the exceptional condition, clear the alarm, and resume the interrupted drug delivery.

The requirements governing the drug delivery are defined in Sections 4.1.

2.2.2 Overdose Protection

Although the patient can request bolus delivery, the GPCA is responsible for ensuring that bolus requests are delivered in a safe manner, that is, not too frequently and not too many over the course of the therapy. In addition, the GPCA must ensure that the clinician does not request an unsafe dosage for a specific drug.

2.2.3 Exceptional Condition Notification

The system performs monitoring of the drug infusion and if there are exceptional conditions, the GPCA will notify the clinician. Examples of exceptional conditions are, too frequent patient bolus requests, VTBI over-infusion, low drug level in the drug reservoir, and air detected in the hose. The requirements related to clinician notification are detailed in Section 4.3.

2.3 GPCA User Characteristics

The users of the GPCA pump are the clinician setting up and monitoring the therapy, and the patient receiving therapy and—possibly—requesting bolus injections.

Clinician: The clinician is an authorized hospital staff member who operates the system and responds to notifications. The clinician is assumed to be trained in the general use of infusion pumps and trained specifically in how to use the GPCA pump.

Patient: The person in the hospital who receives medication and can self administer bolus injections of the drug. The patient is assumed to have no knowledge of infusion or the GPCA.

2.4 GPCA Operating Environment

The intended usage environment of the GPCA system is in a hospital. The system will be in a fixed location when in use (not ambulatory). The hospital has authorized clinicians to administer drug to the patient using the system. The hospital also has a pharmacy database that stores all the drug safe values.

Chapter 3

GPCA System Interfaces

This section describes the interfaces of the GPCA system and the assumptions placed on these interfaces. We define all data items exchanged between the GPCA and its environment. Figure 3.1 illustrates the various interfaces provided by the system. Each interface is explained in detail in this section. **Note:** *The interfaces for the GPCA system at the “systems” level of abstraction are all physical quantities, for example, flow of drug through the delivery hose, actual time (as opposed to clock time), etc.)*

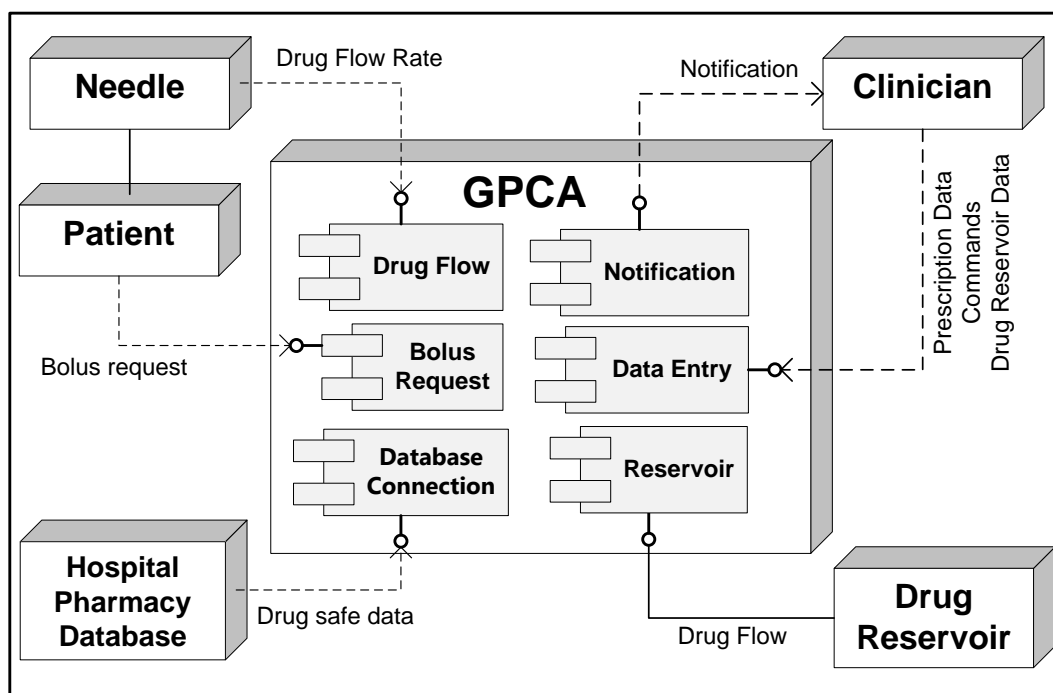


Figure 3.1: GPCA System Interfaces

3.1 Data Entry Interface

The GPCA pump provides an interface to the primary user—the clinician—where dosage information, starting and stopping of the pump, displaying and clearing of notifications, etc. takes place. This interface provides three main sets of interactions with the clinician: (1) prescription data entry, (2) GPCA control commands, and (3) drug reservoir data entry.

3.1.1 Prescription Data

I 1 The GPCA system shall provide a Data Entry Interface to allow the clinician to enter, edit, and save prescription data.

<i>PatientID_{prog}</i>	<i>Units:</i> NA	<i>Type:</i> String
<i>Description:</i> Identifier of the Patient in the Hospital.		
<i>Source:</i> This ID is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default:Empty	<i>Condition:</i> Cannot be empty. Entered value must be alphanumeric values without space	

<i>DrugName_{prog}</i>	<i>Units:</i> NA	<i>Type:</i> String
<i>Description:</i> Name of the drug prescribed for infusion		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default:Empty	<i>Condition:</i> Cannot be empty. Should be a string of X to Y characters. The entered value must match with the <i>DrugName_{hd}</i> in the hospital drug database.	

<i>DrugConcentration_{prog}</i>	<i>Units:</i> mg/ml	<i>Type:</i> Positive Integer
<i>Description:</i> Concentration of the drug in the solution prescribed for infusion		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default:0	<i>Condition:</i> Cannot be empty. This value must be between <i>DrugConcentration_{lo_{hd}}</i> and <i>DrugConcentration_{hi_{hd}}</i> for the drug <i>DrugName_{prog}</i> in the hospital database.	

<i>VTBI_{total_{prog}}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> Maximum total volume of the drug solution that can be infused for that prescription		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default:0	<i>Condition:</i> Cannot be empty. This value must be between <i>VTBI_{lo_{hd}}</i> and <i>VTBI_{hi_{hd}}</i> for the drug <i>DrugName_{prog}</i> in the hospital database.	

<i>Duration_{total_{prog}}</i>	<i>Units:</i> minutes	<i>Type:</i> time
<i>Description:</i> Prescribed total duration of drug infusion. Total duration of infusion refers to the total time when system is infusing drug to the patient. All time spent in any delivery mode, such as BASAL, SQUARE BOLUS, and PATIENT BOLUS delivery modes, is is counted.		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default:0	<i>Condition:</i> Cannot be empty. Should be ≥ 0 .	

<i>FlowRate_basal_{prog}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> Prescribed rate of flow of drug during BASAL delivery mode		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default- <i>FlowRate_lo_{hd}</i>	<i>Condition:</i> Cannot be empty. This value must be between <i>FlowRate_lo_{hd}</i> and <i>FlowRate_hi_{hd}</i> for the drug <i>DrugName_{prog}</i> in the hospital database. This value should be $< VTBI_total_{prog} / Duration_total_{prog}$	

<i>FlowRate_sbolus_{prog}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> Prescribed flow rate of drug during SQUARE bolus delivery		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Cannot be empty and should be ≥ 0 ; If <i>Duration_sbolus_{prog}</i> or <i>Interval_sbolus_{prog}</i> is > 0 , this value must be between <i>FlowRate_lo_{hd}</i> and <i>FlowRate_hi_{hd}</i> for the drug <i>DrugName_{prog}</i> in the hospital database.	

<i>Duration_sbolus_{prog}</i>	<i>Units:</i> minutes	<i>Type:</i> Time
<i>Description:</i> Maximum duration of a single square bolus delivery. Maximum duration refers to time between initiation and end of an uninterrupted square bolus. (The square bolus may be interrupted or cancelled by a patient bolus, alarm condition, infusion inhibit or end of <i>Duration_total_{prog}</i>)		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Cannot be empty and should be ≥ 0 ; if <i>FlowRate_sbolus_{prog}</i> or <i>Interval_sbolus_{prog}</i> is > 0 , then this value must be $< Interval_sbolus_{prog}$ and <i>Duration_total_{prog}</i>	

<i>Interval_sbolus_{prog}</i>	<i>Units:</i> minutes	<i>Type:</i> Positive Integer
<i>Description:</i> Minimum time interval between two consecutive square bolus initiation during the <i>Duration_total_{prog}</i> . The first square bolus starts at <i>Interval_sbolus_{prog}</i> minutes after the infusion is initiated for that prescription.		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Cannot be empty and should be ≥ 0 ; if <i>FlowRate_sbolus_{prog}</i> or <i>Duration_sbolus_{prog}</i> is > 0 , then this value must be $> Duration_sbolus_{prog}$	

<i>FlowRate_pbolus_{prog}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> Prescribed flow rate of drug during patient bolus delivery		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Cannot be empty and should be ≥ 0 ; if <i>Duration_pbolus_{prog}</i> or <i>LockOutPeriod_pbolus_{prog}</i> is > 0 , then this value must be between <i>FlowRate_lo_{hd}</i> and <i>FlowRate_hi_{hd}</i>	

<i>Duration_pbolus_{prog}</i>	<i>Units:</i> minutes	<i>Type:</i> time
<i>Description:</i> Maximum duration of a single patient bolus delivery. Maximum duration refers to time between initiation and end of un-interrupted patient bolus. (The patient bolus may be interrupted or cancelled by an alarm condition, infusion inhibit or end of <i>Duration_total_{prog}</i>)		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Cannot be empty and should be ≥ 0 ; if <i>FlowRate_pbolus_{prog}</i> or <i>LockOutPeriod_pbolus_{prog}</i> is > 0 , then this value must $<$ <i>LockOutPeriod_pbolus_{prog}</i> and <i>Duration_total_{prog}</i>	

<i>LockOutPeriod_pbolus_{prog}</i>	<i>Units:</i> minutes	<i>Type:</i> Positive Integer
<i>Description:</i> Minimum time interval between two consecutive patient bolus delivery during the <i>Duration_total_{prog}</i> for that prescription. This value refers to the minimum time interval between two patient bolus initiations, irrespective of the two patient bolus interruptions or successful completions. It is also called the lockout period.		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Cannot be empty and should be ≥ 0 ; if <i>FlowRate_pbolus_{prog}</i> or <i>Duration_pbolus_{prog}</i> is > 0 , then this value must be $>$ <i>Duration_pbolus_{prog}</i>	

<i>NumberMax_pbolus_{prog}</i>	<i>Units:</i> per hour	<i>Type:</i> Positive Integer
<i>Description:</i> Maximum total number of patient boluses that are allowed to be initiated during the <i>Duration_total_{prog}</i> for that prescription. The number of patient bolus initiated is irrespective of the patient bolus interruptions or successful completions		
<i>Source:</i> This is provided in the prescription and the Clinician programs this value in the system.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Cannot be empty and should be ≥ 0 . It must be \leq <i>NumberMax_pbolus_{hd}</i> for the drug <i>DrugName_{prog}</i> in the hospital database.	

QUESTION: WE COULD HAVE ADDITIONAL CHECKS FOR THE NUMBER OF PBOLUS - FREQUENCY AND TOTAL DURATION?

3.1.2 Commands

I 2 The GPCA shall provide an interface for the clinician to perform the following commands. These are events, that are set to TRUE when they are commanded at time t and are reset to FALSE at time t +1

<i>System_start_{prog}</i>	<i>Units:</i> NA	<i>Type:</i> Boolean
<i>Description:</i> Command to start the System.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is in OFF mode	

<i>System_stop_{prog}</i>	<i>Units:</i> NA	<i>Type:</i> Boolean
<i>Description:</i> Command to stop the System.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is in ON mode	

<i>Infusion_initiate_{prog}</i>	<i>Units:</i> NA	<i>Type:</i> Boolean
<i>Description:</i> Command to initiate infusion of drug.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is in ON mode	

<i>Infusion_inhibit_{prog}</i>	<i>Units:</i> -	<i>Type:</i> Boolean
<i>Description:</i> Command to inhibit infusion of drug.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is in ON mode	

<i>System_save_{prog}</i>	<i>Units:</i> NA	<i>Type:</i> Boolean
<i>Description:</i> Command to save the prescription and reservoir initial volume data.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is ON mode	

<i>Notification_cancel_{prog}</i>	<i>Units:</i> -	<i>Type:</i> Boolean
<i>Description:</i> Command to cancel a notification. Clinician selects a notification from the list of notifications and then commands it to be canceled.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is in ON mode and if a notification is selected	

<i>Disable_audio_{prog}</i>	<i>Units:</i> String	<i>Type:</i> Numeric
<i>Description:</i> Command to disable audio notifications. It can be permanent or temporary disable.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Values - PERM or TEMP or FALSE. Default-FALSE	<i>Condition:</i>	

<i>Enable_audio_{prog}</i>	<i>Units:</i> -	<i>Type:</i> Boolean
<i>Description:</i> Command to enable audio notifications		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if audio is disabled	

<i>DataCofig_{prog}</i>	<i>Units:</i> -	<i>Type:</i> Boolean
<i>Description:</i> Command to configure prescription data.		
<i>Source:</i> Clinician		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is in ON mode	

3.1.3 Drug Reservoir Data

I 3 The GPCA system shall provide an interface for the clinician to enter, edit, and save the volume of the drug initially in the reservoir when a prescription is configured.

<i>ReservoirInitialVolume_{prog}</i>	<i>Units:</i> ml	<i>Type:</i> Positive Integer
<i>Description:</i> Initial volume of the drug in the drug reservoir at the time of entering the prescription.		
<i>Source:</i> This is displayed in the drug reservoir label and the clinician programs this data in the system		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Mandatory. Shall be \geq Xml.	

QUESTION: SHOULD WE INCLUDE INFORMATION ABOUT RELOADING PRESCRIPTION HERE?

3.2 Bolus Request Interface

I 4 The system shall provide a interface for patient to request a patient bolus.

<i>BolusRequest_{prog}</i>	<i>Units:</i> NA	<i>Type:</i> Boolean
<i>Description:</i> Request by the Patient to deliverer patient bolus.		
<i>Source:</i> Patient.		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-FALSE	<i>Condition:</i> Can be commanded only if the system is in ACTIVE mode	

3.3 Drug Flow Interface

I 5 The system shall have a standard CCC connection point for connecting to Infusion Needle that is inserted in the patient.

I 6 The system shall provide an interface to deliver drug to the patient through the needle connected. It is represented by the flow rate of the drug out of the system.

<i>FlowRate_{output}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Boolean
<i>Description:</i> The flow rate of the drug through the hose delivering the drug measured every X seconds when the system in ON mode.		
<i>Source:</i> GPCA system		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i>	

3.4 Notification Interface

I 7 The system shall provide a visual and audio interface to notify the clinician of exceptional conditions.

I 8 The audio notification shall produce a sound of 50 db for 2 seconds for every notification.

<i>Notification_Visual_{output}</i>	<i>Units:</i> NA	<i>Type:</i> List of String
<i>Description:</i> Visual display of the messages of all active notification in the system.		
<i>Source:</i> GPCA system		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Message shall be displayed only when the system is in ON mode	

<i>Notification_Audio_{output}</i>	<i>Units:</i> -	<i>Type:</i> List of boolean
<i>Description:</i> Audio output of all active notification in the system. It is the audio output to each active notification in the same order as the <i>Notification_Visual_{output}</i>		
<i>Source:</i> GPCA system		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Audio output is possible only when the system is in ON mode	

3.5 Hospital Pharmacy Database Interface

I 9 The system shall provide an interface to the hospital pharmacy database that stores all the safe values of drugs that can be used for infusion with the system

I 10 The system shall retrieve the set of the following values from the hospital database where *DrugName_{hd}* = *DrugName_{prog}*

I 11 If there are no record matching *DrugName_{hd}* = *DrugName_{prog}*, the system shall reset the following values with their default values.

<i>DrugName_{hd}</i>	<i>Units:</i> NA	<i>Type:</i> Strings
<i>Description:</i> Name of the drug that can be used for infusion in the hospital that matches with <i>DrugName_{prog}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-NA	<i>Condition:</i>	

<i>DrugConcentration_{hi_{hd}}</i>	<i>Units:</i> mg/ml	<i>Type:</i> List of Positive Integer
<i>Description:</i> The maximum concentration of the drug in a solution that can be safely used for infusion for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i>	

<i>DrugConcentration_{lo_{hd}}</i>	<i>Units:</i> mg/ml	<i>Type:</i> Positive Integer
<i>Description:</i> The minimum concentration of the drug in a solution that can be safely used for infusion for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i>	

<i>VTBI_{hi_{hd}}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> The maximum volume of drug that is safe to be infused for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i>	

<i>VTBI_{lo_{hd}}</i>	<i>Units:</i> ml/HR	<i>Type:</i> Positive Integer
<i>Description:</i> The minimum volume of drug that is safe to be infused for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0	<i>Condition:</i> Mandatory	

<i>FlowRate_hi_{hd}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> The maximum safe flow rate of the drug that is safe to be infused for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0		<i>Condition:</i> Mandatory

<i>FlowRate_lo_{hd}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> The minimum safe flow rate of the drug that is safe to be infused for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0		<i>Condition:</i> Mandatory

<i>Interval_pbolus_{hd}</i>	<i>Units:</i> minutes	<i>Type:</i> Positive Integer
<i>Description:</i> The minimum time interval between two consecutive patient bolus initiations that is safe to be infused for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0		<i>Condition:</i> Mandatory

<i>NumberMax_pbolus_{hd}</i>	<i>Units:</i> per hr	<i>Type:</i> Positive Integer
<i>Description:</i> The maximum number of patient bolus initiations that is safe to be self-administered by the patient for <i>DrugName_{hd}</i>		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max-999 Default-0		<i>Condition:</i> Mandatory

<i>FlowRate_kvo_{hd}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> The minimum flow rate of the <i>DrugName_{hd}</i> that should be maintained to keep vein open		
<i>Source:</i> Hospital/Pharmacy Drug Database		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Min-0 Max:5 Default-0.1		<i>Condition:</i> Mandatory

Chapter 4

Behavioral Requirements

This section lists the system requirements. The requirements are organized based on the GPCA operational modes.

The following terms will be used in the description of the behavioral requirement. The detailed definition of these terms can be found in Section A.4. Below we provide a short description.

1. *Actual_Infusion_Duration_{macro}*: The cumulative time the system has been infusing a drug for a prescription.
2. *Actual_Volume_Infused_{macro}*: The total volume of drug infused during *Actual_Infusion_Duration_{macro}*.
3. *Tolerance_Max_{const}*: Maximum variation in flow rate that is acceptable in any mode during infusion.
4. *Tolerance_Min_{const}*: Acceptable Variation of flow rate in any mode that can be exceeded for a short duration of time.
5. *FlowRate_Mode_{macro}*: Programmed flow rate of the current mode.
6. *Inhibited_Infusion_{macro}*: All infusion modes inhibited indicator.
7. *Inhibited_Bolus_{macro}*: All BOLUS infusion modes inhibited indicator.
8. *Inhibited_PatientBolus_{macro}*: PATIENT BOLUS infusion mode inhibited indicator.

4.1 Infusion Mode Control Requirements

The functional requirements are organized according to the operational modes of the GPCA. The modes are organized in a hierarchical fashion illustrated in Figure 4.1. The transition conditions in the table following the figure is only explanatory, the detailed requirements describing the transitions are defined later in the respective sections. Requirements of each mode is classified into the behavior and transitions within that mode. Every sub mode is subject to all the requirements defined for its parent mode in addition to the specific requirements defined for the new mode. For example, ACTIVE mode behaviors are common for BASAL, SQUARE BOLUS and PATIENT BOLUS submodes. The transitions between BASAL, SQUARE BOLUS and PATIENT BOLUS modes is described in the ACTIVE mode transition requirements.

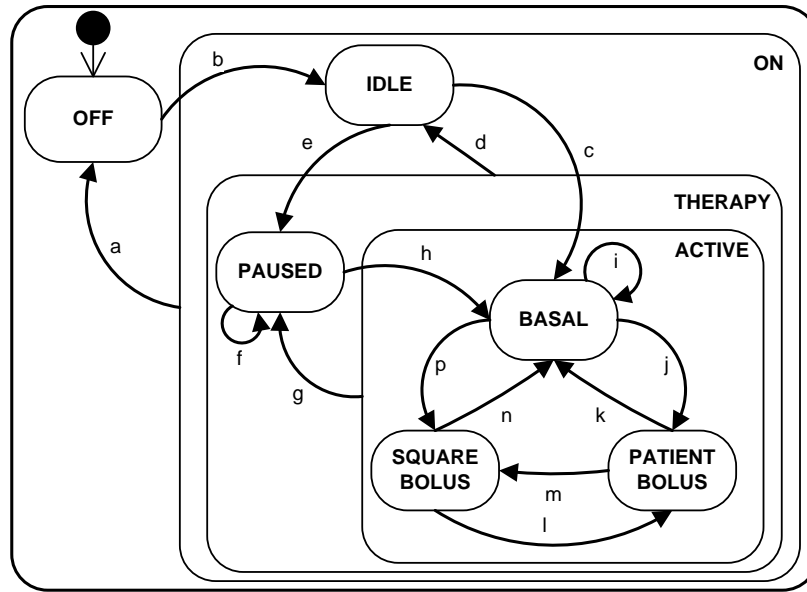


Figure 4.1: System Modes and Transitions

Label	Description	Label	Description
a	System switched Off [REQ 5]	i	Infusion Initiated [REQ 12]
b	System switched On [REQ 4]	j	PATIENT BOLUS Initiated [REQ 32]
c	Infusion Initiated [REQ 12]	k	PATIENT BOLUS complete or Inhibited and BASAL continues [REQ 35] or Infusion Initiated [REQ 12]
d	Infusion Manually Stopped [REQ 47] or Infusion Complete [REQ 28]	l	PATIENT BOLUS complete or Inhibited and SQUARE BOLUS continues [REQ 36]
e	Infusion Manually Initiated but Inhibited by Alarm [??]	m	PATIENT BOLUS complete or Inhibited and BASAL continues [REQ 35] or Infusion Initiated [REQ 12]
f	Infusion Manually Initiated but Inhibited by Alarm [??]	n	SQUARE BOLUS complete or Inhibited and BASAL continues [REQ 34] or Infusion Initiated [REQ 12]
g	Infusion Inhibited Manually [REQ 29] or by alarms [REQ 19 to 23, 30 and 37 to 39 and ??]	p	SQUARE BOLUS initiated [REQ 31]
h	Infusion Resumed [REQ 46] or Infusion Initiated [REQ 12]		

4.1.1 GPCA System

The GPCA system level requirements capture the common behaviors for all GPCA modes. At this level, the GPCA behavior is limited to the turning on and off of the GPCA pump.

4.1.1.1 GPCA Behavior

REQ 1

The system shall always be in only one the following modes: OFF (Default mode), IDLE, PAUSED, BASAL, SQUARE BOLUS or PATIENT BOLUS

REQ 2

If there are mode transitions without change in flow rates between the two modes, the system shall transition within $Max_Mode_Change_Duration_{const}$

REQ 3

If there are mode transitions with change in flow rates between the two modes, the system shall change from the current mode flow rate to the new mode flow rate at a rate not more than $Max_Rateof_Flow_Change_{const}$ or within $Max_Mode_Change_Duration_{const}$ whichever achieves the new desired flow rate the quickest.

4.1.1.2 GPCA Transitions

REQ 4

The system shall transition from OFF mode to ON▷IDLE mode when $System_start_{prog}$ is commanded. At this transition, the variables in A.4 shall be set to their default values.

REQ 5

While in ON mode, when $System_stop_{prog}$ is commanded, the system shall stop infusion, cancel all notifications and transition to OFF mode.

4.1.2 GPCA ▷ OFF Mode

The OFF mode provides no functionality—the GPCA is turned off. The system does not perform any function in this mode.

4.1.2.1 OFF Mode Behavior

REQ 6

While in OFF mode, the system shall not deliver any drug, $FlowRate_{output} = 0$

4.1.2.2 OFF Mode Transitions

There are no transitions inside this mode.

4.1.3 GPCA ▷ ON Mode

The ON mode is the top most operational mode of the GPCA. In this model the GPCA is operational and provides functionality such as basal drug delivery, bolus delivery, monitoring and notification of exceptional conditions, data logging, etc.

4.1.3.1 ON Mode Behavior

REQ 7

While in ON mode, the system shall allow initiation of infusion only when a saved prescription is available.

REQ 8

While in ON mode, system shall allow configuring ($DataCofig_{prog}$) new or saved prescription data and reservoir initial volume, as described in Data Configuration Requirements 4.2

REQ 9

While in ON mode, if *Infusion_initiate_{prog}*, the system shall display the saved prescription values and allow the clinician to confirm the prescription with a another *Infusion_initiate_{prog}*.

REQ 10

While in ON mode, the system shall allow visual and audio notification as described in section 4.3

REQ 11

While in ON mode, the system shall allow logging as described in section 4.4.

4.1.3.2 ON Mode Transitions**REQ 12**

While in ON mode, when the second *Infusion_initiate_{prog}* is commanded as per REQ 9 and *Inhibited_Infusion_{macro}* = *FALSE*, the system shall reset *Actual_Infusion_Duration_{macro}* = 0 and *Actual_Volume_Infused_{macro}* = 0 and shall transition to ON▷THERAPY▷ACTIVE▷BASAL mode

REQ 13

While in ON mode, when the second *Infusion_initiate_{prog}* is commanded as per REQ 9 and *Inhibited_Infusion_{macro}* = *TRUE*, the system shall reset *Actual_Infusion_Duration_{macro}* = 0 and *Actual_Volume_Infused_{macro}* = 0, shall transition to ON▷THERAPY▷PAUSED mode and perform actions as described in REQ 59 for “Infusion Inhibited”.

4.1.4 GPCA ▷ ON ▷ IDLE Mode

This is the default mode when the system transitions from OFF to ON mode. The system shall not perform any infusion in this mode. This mode would typically be used for prescription data set up and also to perform any startup tests to check system readiness. As discussed earlier in this document, when in IDLE, the system must also satisfy all requirements for the higher level mode ON.

4.1.4.1 ON ▷ IDLE Mode Behavior**REQ 14**

While in IDLE mode, the system shall not deliver any drug, *FlowRate_{output}* = 0

REQ 15

While in IDLE mode for more than *Max_IDLE_Duration_{const}*, the system shall take actions as defined in REQ 59 for ‘IDLE Time’.

4.1.4.2 ON ▷ IDLE Mode Transitions

There are no transitions exclusively for this mode. All the related transitions are specified in its parent modes.

4.1.5 GPCA ▷ ON ▷ THERAPY Mode

This is the parent mode of all submodes in which infusion of drug occurs. It has two sub-modes PAUSED and ACTIVE. The *FlowRate_Mode_{macro}* for the respective submodes shall be as follows

- PAUSED Mode: *FlowRate_Mode_{macro}* = *FlowRate_{kvo_{hd}}*
- BASAL Mode: *FlowRate_Mode_{macro}* = *FlowRate_{basal_{prog}}*
- SQUARE BOLUS Mode: *FlowRate_Mode_{macro}* = *FlowRate_{sbolus_{prog}}*
- PATIENT BOLUS Mode: *FlowRate_Mode_{macro}* = *FlowRate_{pbolus_{prog}}*

4.1.5.1 ON ▷ THERAPY Mode Behavior

REQ 16

While in THERAPY mode, the system shall deliver the drug as per the respective sub-mode's programmed flow rate, $FlowRate_{Mode_{macro}}$ within a tolerance of $Tolerance_{Max_{const}}$.

$$FlowRate_{output} < FlowRate_{Mode_{macro}} + Tolerance_{Max_{const}}.$$

REQ 17

While in THERAPY mode, the system shall take actions as defined in REQ 59 for 'Under Infusion FlowRate', if output flow rate :

$$FlowRate_{output} < FlowRate_{Mode_{macro}} - Tolerance_{Min_{const}} \text{ for more than } Max_Duration_UnderInfusion_{const}$$

OR

$$FlowRate_{output} < FlowRate_{Mode_{macro}} - Tolerance_{Max_{const}}$$

OR

$$FlowRate_{output} < FlowRate_{Iohd}$$

REQ 18

While in THERAPY mode, when the current volume of drug in the reservoir is less than $Low_Reservoir_{const}$, the system shall perform the actions defined in REQ 59 for 'Low Reservoir'

4.1.5.2 ON ▷ THERAPY Mode Transitions

Some of the possible flow rate variation scenarios that are handled by the system are illustrated in Fig 4.2.

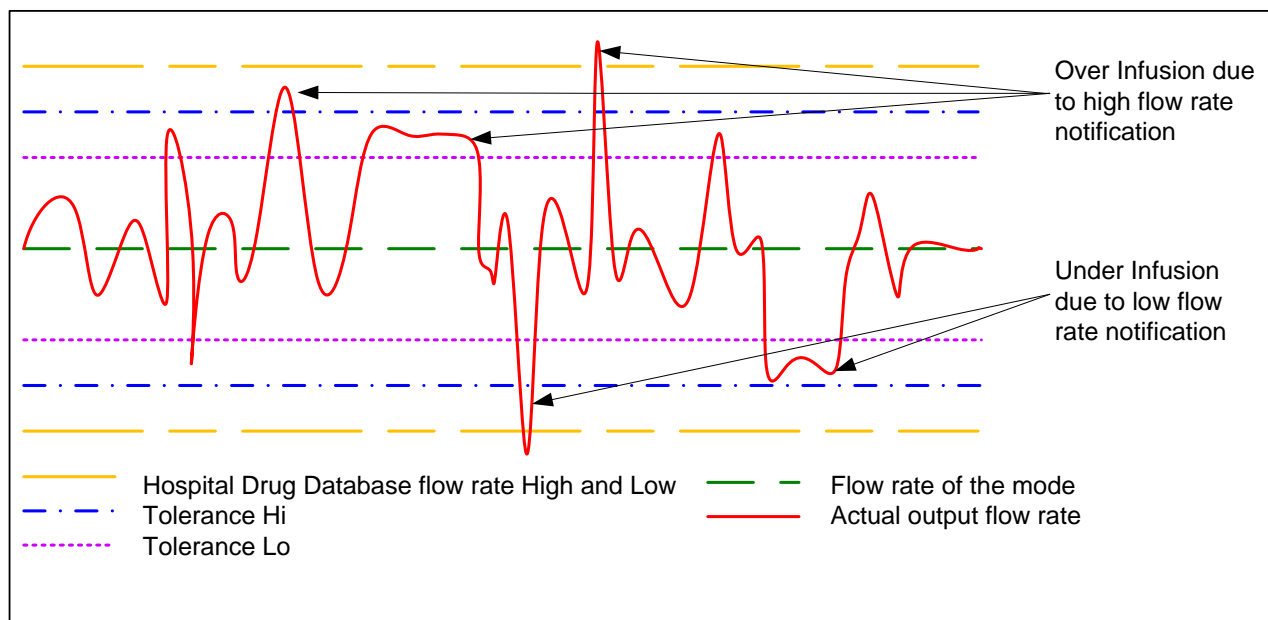


Figure 4.2: Flow Rate Variation Scenarios

REQ 19

While in THERAPY mode, the system shall transition to PAUSED mode and perform the actions described in REQ 59 for 'Over Infusion FlowRate' if the output flow rate is

$$FlowRate_{output} > FlowRate_{Mode_{macro}} + Tolerance_{Min_{const}} \text{ for more than } Max_Duration_OverInfusion_{const}$$

OR

$$FlowRate_{output} > FlowRate_{Mode_{macro}} + Tolerance_{Max_{const}}$$

OR

$$FlowRate_{output} > FlowRate_{hi_{hd}}$$

REQ 20

While in THERAPY mode, the system shall transition to PAUSED mode and take the actions described in REQ 59 for 'Over Infusion VTBI' if

$$Actual_Volume_Infused_{macro} > VTBI_{hi_{hd}}$$

REQ 21

While in THERAPY mode, the system shall transition to PAUSED mode and perform the actions defined in REQ 59 for 'Air embolism' if

1. an air bubble of a volume larger than $Single_Air_Bubble_Volume_{const}$ flows through the hose **OR**
2. the sum of volume of all air bubbles flowing through the hose exceeds $Cumulative_Air_Bubble_Volume_{const}$ (for the same time interval defined for $Cumulative_Air_Bubble_Volume_{const}$).

REQ 22

While in THERAPY mode, the system shall transition to PAUSED mode and perform actions defined in REQ 59 for 'Reverse Delivery' if

1. There is continuous reverse delivery for more than $Rev_Delivery_Continuous_Duration_{const}$ **OR**
2. The cumulative time of all reverse delivery episodes exceeds $Rev_Delivery_Cumulative_Duration_{const}$ (for the same time interval defined for $Cumulative_Air_Bubble_Volume_{const}$).

REQ 23

While in THERAPY mode and if volume of drug in the reservoir is less than $Empty_Reservoir_{const}$, the system shall transition to PAUSED mode and perform actions as listed in REQ 59 for 'Empty Reservoir'

4.1.6 GPCA ▷ ON ▷ THERAPY ▷ ACTIVE Mode

This is the mode in which actual drug infusion therapy through BASAL, SQUARE BOLUS or PATIENT BOLUS occurs. This is also the only mode when patient bolus can be requested. Total Infusion Duration is the the total duration of the system in ACTIVE mode for that prescription. Some of the possible sub-mode interaction scenarios are illustrated in Fig 4.3.

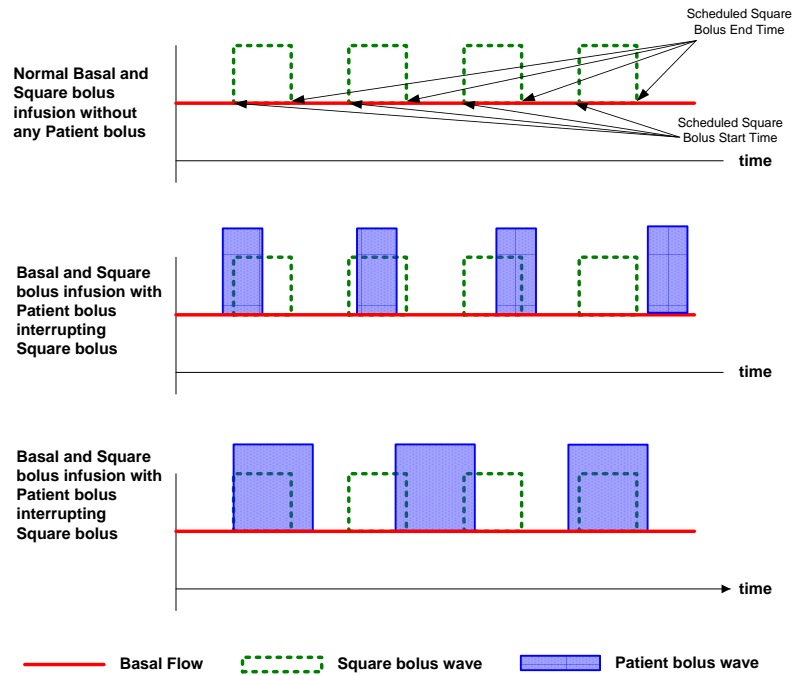


Figure 4.3: Active Sub-Modes Interactions

4.1.6.1 ON ▷ THERAPY ▷ ACTIVE Mode Behavior

REQ 24

While in ACTIVE mode, the system shall schedule to start a SQUARE BOLUS every $Interval_sbolus_{prog}$ and end after $Duration_sbolus_{prog}$ during the $Duration_total_{prog}$ (Refer Fig 4.3 for illustration).

REQ 25

While in ACTIVE mode, when $BolusRequest_{prog}$, the system shall ignore the patient bolus request ($BolusRequest_{prog} = FALSE$), if

1. $Inhibited_Infusion_{macro} = TRUE$ OR
2. $Inhibited_PatientBolus_{macro} = TRUE$ OR
3. The interval between the most recent PATIENT BOLUS mode end time and current $BolusRequest_{prog}$ time is more than the, $LockOutPeriod_pbolus_{prog}$. $\{ (BolusRequest_{prog} \text{ time} - \text{Most recent PATIENT BOLUS mode end time}) > LockOutPeriod_pbolus_{prog} \}$ OR
4. Total number of delivered patient boluses for the current prescription is less than the programmed maximum number of patient boluses. $\{ \text{Sum of occurrences of all PATIENT BOLUS modes} > NumberMax_pbolus_{prog} \}$ OR
5. The system is currently in PATIENT BOLUS mode

REQ 26

While in ACTIVE mode, the system shall perform the actions described in REQ 59 for 'Frequent Bolus Requests' if condition described in REQ 25.3 or REQ 25.5 occurs.

REQ 27

While in ACTIVE mode, the system shall perform the actions described in REQ 59 for 'Bolus Exceeded' if condition described in REQ 25.4 occurs.

4.1.6.2 ON ▷ THERAPY ▷ ACTIVE Mode Transitions**REQ 28**

While in ACTIVE mode, the system shall transition to IDLE and perform actions described in REQ 59 for 'Infusion Complete' if,

- The actual duration of infusion is greater than or equal to the programmed prescription total duration
 $Actual_Infusion_Duration_{macro} \geq Duration_total_{prog}$ **OR**
- The total volume infused during $Actual_Infusion_Duration_{macro}$ is greater than or equal to the programmed prescription maximum VTBI
 $Actual_Volume_Infused_{macro} \geq VTBI_total_{prog}$

REQ 29

While in ACTIVE mode, when $Infusion_inhibit_{prog}$, the system shall transition to PAUSED mode and perform actions described in REQ 59 for 'Infusion Manually Inhibited'

REQ 30

While in ACTIVE mode, when $Inhibited_Infusion_{macro} = TRUE$, $Inhibited_Bolus_{macro} = TRUE$ and $Inhibited_PatientBolus_{macro} = TRUE$, the system shall transition to PAUSED mode

REQ 31

While in BASAL mode, when SQUARE BOLUS is initiated as described in REQ 24, the system shall transition to SQUARE BOLUS mode if

1. $Inhibited_Bolus_{macro} = FALSE$ **AND**
2. $Inhibited_Infusion_{macro} = FALSE$ **AND**
3. Either there is no $BolusRequest_{prog}$ **OR** there is a $BolusRequest_{prog}$ and at-least one of the conditions listed in REQ 25 is true.

REQ 32

While in BASAL mode, the system shall transition to PATIENT BOLUS mode, when $BolusRequest_{prog}$ and none of the conditions listed in REQ 25 are true.

REQ 33

While in SQUARE BOLUS, the system shall transition to PATIENT BOLUS mode, if $BolusRequest_{prog}$ and none of conditions listed in REQ 25 are true.

REQ 34

While in SQUARE BOLUS mode, if $Inhibited_Bolus_{macro} = TRUE$ or the SQUARE BOLUS is scheduled to end (as described in REQ 24), the system shall transition to BASAL mode if

1. $Inhibited_Infusion_{macro} = FALSE$ **AND**
2. There is no $BolusRequest_{prog}$ **OR** $BolusRequest_{prog}$ and at-least one of the conditions listed in REQ 25 is true.

REQ 35

While in PATIENT BOLUS mode, $Inhibited_PatientBolus_{macro} = TRUE$ or Total duration in the current PATIENT BOLUS mode is $\geq Duration_pbolus_{prog}$, the system shall stop the PATIENT BOLUS delivery and transition to BASAL mode , if

1. $Inhibited_Infusion_{macro} = FALSE$ AND
2. No SQUARE BOLUS is scheduled to be in progress (as described in REQ 24) at the time of transition
OR
3. If a SQUARE BOLUS is scheduled to be in progress at the time of transition and $Inhibited_Bolus_{macro} = TRUE$

REQ 36

While in PATIENT BOLUS mode, $Inhibited_PatientBolus_{macro} = TRUE$ or Total duration in the current PATIENT BOLUS mode is $\geq Duration_pbolus_{prog}$, the system shall stop the PATIENT BOLUS delivery and transition to SQUARE BOLUS mode if

1. $Inhibited_Infusion_{macro} = FALSE$ AND
2. If a SQUARE BOLUS is scheduled to be in progress at the time of transition AND
3. $Inhibited_Bolus_{macro} = FALSE$

REQ 37

While in BASAL mode, the system shall transition to PAUSE mode, if $Inhibited_Infusion_{macro} = TRUE$, the system shall transition to PAUSE mode

REQ 38

While in PATIENT BOLUS mode, the system shall transition to PAUSE mode if $Inhibited_PatientBolus_{macro} = TRUE$ and $Inhibited_Infusion_{macro} = TRUE$

REQ 39

While in SQUARE BOLUS mode, the system shall transition to PAUSE mode , if $Inhibited_Bolus_{macro} = TRUE$ and $Inhibited_Infusion_{macro} = TRUE$

4.1.7 GPCA ▷ ON ▷ THERAPY ▷ ACTIVE ▷ BASAL Mode

This mode is used to deliver drug at a constant flow rate for extended periods of time. It also defines the maximum duration of the infusion for each prescription. In this mode, $FlowRate_Mode_{macro} = FlowRate_basal_{prog}$

4.1.7.1 ON▷THERAPY▷ACTIVE▷BASAL Mode Behavior**REQ 40**

While in BASAL mode, the system shall deliver the drug at a flow rate $FlowRate_basal_{prog}$ with a variation upto $Tolerance_Max_{const}$

4.1.7.2 ON▷THERAPY▷ACTIVE▷BASAL Mode Transitions

There are no transitions inside this mode.

4.1.8 GPCA ▷ ON ▷ THERAPY ▷ ACTIVE ▷ SQUARE BOLUS Mode

This mode is used to deliver drug at regular intervals during BASAL infusion duration. This is prescribed. The square bolus does not require any external trigger, it automatically initiates at the frequency specified and ends after the specified duration. In this mode, $FlowRate_Mode_{macro} = FlowRate_sbolus_{prog}$

4.1.8.1 ON▷THERAPY▷ACTIVE▷SQUARE BOLUS Mode Behavior

REQ 41

While in SQUARE BOLUS mode, the system shall deliver the drug at a flow rate $FlowRate_sbolus_{prog}$ with a variation upto $Tolerance_Max_{const}$

4.1.8.2 ON▷THERAPY▷ACTIVE▷SQUARE BOLUS Mode Transitions

There are no transitions inside this mode.

4.1.9 GPCA ▷ ON ▷ THERAPY ▷ ACTIVE ▷ PATIENT BOLUS Mode

This mode is used to deliver prescribed amount of drug when the patient requests for bolus. In this mode, $FlowRate_Mode_{macro} = FlowRate_pbolus_{prog}$

4.1.9.1 ON▷THERAPY▷ACTIVE▷PATIENT BOLUS Mode Behavior

REQ 42

While in PATIENT BOLUS mode, the system shall deliver the drug at a flow rate $FlowRate_pbolus_{prog}$ with a variation upto $Tolerance_Max_{const}$

4.1.9.2 ON▷THERAPY▷ACTIVE▷PATIENT BOLUS Mode Transitions

There are no transitions inside this mode.

4.1.10 GPCA ▷ ON ▷ THERAPY ▷ PAUSED Mode

This is the mode when the infusion is paused due to active notification or inhibited manually by the clinician. In this mode, the clinician would typically see the active notifications, cancel them and restart infusion or stop infusion. In this mode, $FlowRate_Mode_{macro} = FlowRate_kvo_{hd}$, to keep the vein open when infusion is paused.

4.1.10.1 ON▷THERAPY▷PAUSED Mode Behavior

REQ 43

While in PAUSED mode, The system shall allow drug infusion at a flow rate $FlowRate_kvo_{hd}$ with a variation upto $Tolerance_Max_{const}$

REQ 44

While in PAUSED mode for more than $Max_PAUSED_Duration_{const}$, the system shall perform actions as described in REQ 59 for 'PAUSED Time'.

REQ 45

While in PAUSED mode, when $Infusion_initiate_{prog}$ and $Inhibited_Infusion_{macro} = TRUE$, the system shall not perform any transition.

4.1.10.2 ON▷THERAPY▷PAUSED Mode Transition

REQ 46

While in PAUSED mode, when $Infusion_initiate_{prog}$ and $Inhibited_Infusion_{macro} = FALSE$, the system shall transition to ON▷THERAPY▷ACTIVE▷BASAL mode

REQ 47

While in PAUSED mode, when $Infusion_inhibit_{prog}$, the system shall transition to ON▷IDLE mode and perform actions as described in REQ 59 for 'Infusion Stopped Manually'

4.2 Data Configuration Requirements

This section describes the requirements for the configuring the prescription data and drug initial volume data in the system. This capability is available only in the ON mode.

REQ 48

When in ON mode, if *DataConfig_prog* as described in REQ 8, the system shall display the saved prescription and reservoir initial volume values or their default values (if there are no saved prescription and reservoir initial volume values) in the order listed in Sections 3.1.1 and 3.1.3.

REQ 49

When the prescription and reservoir initial volume data are displayed as described in REQ 48, system shall allow editing the values one at a time in the order they are displayed

REQ 50

When the values are modified as described in REQ 49, the system shall allow infusion initiation with the new set of values (*Infusion_initiate_prog*)

REQ 51

When *Infusion_initiate_prog* as described in REQ 50, the system shall validate if all the values are consistent with conditions specified in their respective Type Condition fields in section 3.1.1 and section 3.1.3.

REQ 52

When the system is validating data as described in REQ 51, if the system is unable to access the drug database safe values, the system shall not save the values and perform actions as described in REQ 59 for 'Drug database not reachable'

REQ 53

When the system is validating data as described in REQ 51, If any of the drug database safe values listed in 3.5 is not present, the system shall not perform the validation with respect to that missing field, perform actions as described in REQ 59 for 'Drug safe value not present' and continue validation.

REQ 54

If there are no notifications from REQ 51 and REQ 52, the system shall save the prescription values, clear all the notifications previously generated by REQ 51,REQ 52 and REQ 53 if any, and allow initiate infusion with the new values as described in REQ 9

REQ 55

If REQ 51 or REQ 52 had generated a notification, the system shall not save the prescription values, allow the clinician to edit the values of the fields as described in REQ 49 and then repeat steps from REQ 50 until all validations are passed as described in REQ 54.

REQ 56

While data configuration is in progress, the system shall remain in its current mode with the currently active prescription values, until infusion is initiated with the new prescription values as described in REQ 54.

REQ 57

When the clinician has attempted to configure the data for more than *Config_WarningDuration_const* continuously, the system shall perform actions as per described in REQ 59 for 'Config Time'

REQ 58

When the clinician has attempted to configure the data for more than *Max_Config_Duration_const* continuously, the system shall clear all unsaved prescription values and shall perform actions as per described in REQ 59 for 'Unsaved Configuration Cleared'

4.3 Notification Requirements

This section describes the requirements for the notification of the system. 'Active notification' are the list of all notifications raised by the system and is not canceled by the clinician. 'Canceled notification' are the list of all notifications that are canceled or cleared by the clinician from the list of active notifications manually. 'Notification in effect' is the notification for which the system has currently taken actions.

This section describes the actions taken by the system in response to notifications. The notification requirements have higher precedence over all other requirements in the system. The table 4.3 lists all the notifications generated by the system in the first column, its corresponding priority in the second column and the actions to be taken for that notification in the following columns for that notification. 'Most restrictive' notification is the one that has most restrictive actions to be taken. The order of restriction is Inhibit All Infusion > Inhibit Square Bolus > Inhibit Patient bolus. For example, among two alarms that have Inhibit All Infusion and Inhibit Square Bolus = Y and only Inhibit All Infusion = Y, the former becomes the 'Most restrictive' notification.

REQ 59

The system shall perform all the actions listed below for the respective notification.

Notification Name	Priority	Visual	Audio	Inhibit Infusion	Inhibit Square Bolus	Inhibit Patient bolus	Stop Bolus
Low Reservoir	High	Y	N	N	Y	Y	Y
Empty Reservoir	High	Y	Y	Y	Y	Y	Y
Air embolism	High	Y	Y	Y	Y	Y	Y
Reverse Delivery	High	Y	Y	Y	Y	Y	Y
Over Infusion FlowRate	High	Y	Y	Y	Y	Y	Y
Over Infusion VTBI	High	Y	Y	Y	Y	Y	Y
Bolus Exceeded	Med	Y	Y	N	N	Y	N
Infusion Inhibited	Med	Y	Y	Y	N	N	Y
Infusion Manually Inhibited	Med	Y	Y	Y	N	N	Y
Infusion Stopped Manually	Med	Y	Y	Y	N	N	Y
Under Infusion FlowRate	Med	Y	N	N	N	N	N
Under Infusion VTBI	Med	Y	N	N	N	N	N
Infusion Complete	Low	Y	Y	N	N	N	N
Frequent Bolus Requests	Low	Y	N	N	N	N	N
IDLE Time	Low	Y	Y	N	N	N	N
PAUSED Time	Low	Y	Y	N	N	N	N
Config Time	Low	Y	Y	N	N	N	N
Validation Failed	Low	Y	Y	N	N	N	N
Drug safe value not present [with missing field names]	Low	Y	N	N	N	N	N
Drug database not reachable	Low	Y	Y	N	N	N	N

In the above table,

Inhibit Infusion = Y, \Rightarrow *Inhibited_Infusion_{macro}* = TRUE

Inhibit Square bolus = Y, \Rightarrow *Inhibited_Bolus_{macro}* = TRUE

Inhibit patient bolus = Y, \Rightarrow *Inhibited_PatientBolus_{macro}* = TRUE

Stop Bolus = Y, \Rightarrow Stop all boluses in progress.

REQ 60

When more than one notification having different priorities occurs at the same time, the system shall take actions listed for the the highest priority notification.

REQ 61

When more than one notification having same priorities and different set of actions occurs at the same time, the system shall take actions listed for the most restrictive notification

REQ 62

When more than one notification having same priorities and same set of actions occurs at the same time, the system will take actions for the notification that has the most restrictive actions as listed in REQ 59

REQ 63

While a low priority or less restrictive notification is in effect and if a higher priority or more restrictive same priority notification occurs, the system shall take actions for the high priority or more restrictive notification as listed in REQ 59.

REQ 64

While a high priority notification is in effect and If a low priority notification occurs, the system shall only add the notification to the active notification list and shall not take any other actions for the low priority notification.

REQ 65

The system shall allow the clinician to cancel the active notifications, starting from the first in the list, one at a time. (*Notification_cancel_{prog}*)

REQ 66

When *Notification_cancel_{prog}* for a notification, the system shall cancel and clear the restrictions for that notification.

1. *Inhibited_Infusion_{macro}* = FALSE
2. *Inhibited_Bolus_{macro}* = FALSE
3. *Inhibited_PatientBolus_{macro}* = FALSE
4. cancel and clear the corresponding audio notification

REQ 67

When *Notification_cancel_{prog}* for a notification, the system takes actions for next active notification in order of priority and descending order of occurrence.

4.3.1 Visual Notification

This section describes all the requirements for visual display of the notifications for the clinician

REQ 68

The system shall display all active notifications in order of priority and descending order of occurrence *Notification_Visual_{output}*

REQ 69

The system shall display the name of all the active notifications and the time of the occurrence

REQ 70

When more than one notification occurs at the same time, the system shall display all the notifications as per REQ 68

REQ 71

When *Notification_cancel_{prog}* for a notification, the system shall remove the notification from the list and shall display the list of remaining notifications

4.3.2 Audio Notification

This section describes all the requirements for audio notifications for the clinician

REQ 72

When each notification occurs that requires an audio alarm as listed in REQ 59, the system shall produce a single audible sound of *Audio_Level_{const}*, unless the audio is disabled or silenced

REQ 73

The system shall allow the clinician to disable audible alarm, silence the alarm temporarily and enable a disabled or silenced alarm.

$Notification_Audio_output = \text{FALSE}$ if $Disable_audio_prog = \text{'PERM'}$ (disabled) or 'TEMP' (silenced)

$Notification_Audio_output = \text{TRUE}$ if $Disable_audio_prog = \text{FALSE}$

REQ 74

If $Disable_audio_prog = \text{'PERM'}$ or 'TEMP' , the system shall not produce audible alarm until it is enabled ($Disable_audio_prog = \text{FALSE}$)

REQ 75

If $Disable_audio_prog = \text{'TEMP'}$, the system shall automatically enable it ($Disable_audio_prog = \text{'FALSE'}$) after $Audio_Enable_Duration_{const}$ minutes

REQ 76

For every notification with audio alarm that is active for more than $Audio_Enable_Duration_{const}$ minutes, the system shall produce audible sound as described in REQ 72.

4.4 Log Requirements

These requirements describe the logs that the system should produce when its in operation. This information is typically used for audit purposes. The log is recorded when the system is ON mode. 'operational log' is a log which records all the regular operations of the system and 'error log' is the log that records all the exceptional conditions occurring in the system.

REQ 77

The system shall log all the operational and error data when the system is in ON mode

REQ 78

While in ON mode, every $Log_Interval_{const}$ minutes or when mode transition occurs, the system shall record the following information in a 'Operational log' :

1. Date in (dd/MM/yy) format
2. Time in (HH:MM:SS GMT)
3. Patient ID
4. Prescription information
5. Current mode of the system
6. Current flow rate of the system

REQ 79

When infusion is completed as per 28 the system shall record the following information in addition to information listed in REQ 78 in the 'Operational log' :

1. Total Volume Infused for that prescription
2. Total duration of Infusion for that prescription (Total duration in ACTIVE mode)

REQ 80

When any notification condition listed in REQ 59 occurs, the system shall record the following information in an error log :

1. Date in (dd/MM/yy) format

2. Time in (HH:MM:SS GMT)
3. Notification description
4. Current mode of the system
5. Remaining drug volume

REQ 81

When a notification is cancelled as described in REQ 66, the system shall record the following information in the 'Operational log' :

1. Date in (dd/MM/yy) format
2. Time in (HH:MM:SS GMT)
3. Description of the Notification cancelled

4.5 Security Requirements

REQ 82

The system shall allow only authorized clinicians to configure the system

Chapter 5

Non-Behavioral Requirements

5.1 Other Requirements

REQ 83

The system shall be unbreakable it is dropped on a laminate floor from y m of height with no additional force than gravity

REQ 84

The system shall be waterproof to non-acidic liquid of less than x ml in any side of the pump for maximum of 2 hours

REQ 85

The system shall persist most recent 30 days error log data and 15 days operational log data

REQ 86

The system shall persist the last saved prescription data for 15 days

Appendix A

Glossary

A.1 Acronyms

- G 1** CPS : *Cyber Physical Systems*
G 2 GPCA : *Generic Patient Controlled Analgesic*
G 3 PCA : *Patient controlled analgesia*

A.2 Definitions

- G 4** ACCURACY : *The degree to which the instrument is capable of delivering the volume of analgesic drug that is displayed or targeted to be delivered. Accuracy is specified as the maximum allowable delivery error from a targeted or displayed value.*
- G 5** BASAL DELIVERY : *Prescribed Infusion therapy characterized by a constant fixed-rate dose*
- G 6** BOLUS DELIVERY : *Prescribed additional amount of medication given to patient for a short period of time.*
- G 7** DRUG SAFE LIMITS : *The actual drug safe usage information provided by the drug manufactures. This will typically provide the maximum and minimum values for the drug usage. For patient safety, the dosage of the drug to the patient should never exceed these values.*
- G 8** OCCLUSION : *The maximum pressure observed in response to a patient line occlusion*
- G 9** PATIENT BOLUS DELIVERY : *Prescribed additional amount of medication given to patient for a short period of time, when the patient requests for one.*
- G 10** SQUARE BOLUS DELIVERY : *Prescribed additional amount of medication at specific intervals given to patient for a short period of time.*

A.3 Text Macros Conditions

These are internal variables used to represent conditions within the system. These are used to simplify explaining the state of the system.

<i>Actual_Infusion_Duration_{macro}</i>	<i>Units: minutes</i>	<i>Type: Time</i>
<i>Description: Total duration the system has been in ACTIVE mode since infusion is initiated with the current prescription</i>		
<i>Source: System calculated value</i>		<i>Dependency : [Assumption None]</i>
<i>Values : -</i>	<i>Condition: Internal variable. It is reset to 0, every time infusion is initiated with a new prescription.</i>	

<i>Actual_Volume_Infused_{macro}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> The total volume of drug infused during <i>Actual_Infusion_Duration_{macro}</i>		
<i>Source:</i> System calculated value		<i>Dependency :</i> [Assumption None]
<i>Values :</i> Default-0	<i>Condition:</i> Internal variable. It is reset to 0, every time infusion is initiated with a new prescription.	

<i>FlowRate_Mode_{macro}</i>	<i>Units:</i> ml/hr	<i>Type:</i> Positive Integer
<i>Description:</i> Programmed flow rate of the respective mode. This is used as a common variable to simplify representation of the flow rate.		
<i>Source:</i> System sets this value when entering respective modes.		<i>Dependency :</i> [Assumption None]
<i>Values :</i>	<i>Condition:</i> Internal variable	

<i>Inhibited_Infusion_{macro}</i>	<i>Units:</i> -	<i>Type:</i> Boolean
<i>Description:</i> This is set true if all types of infusions is inhibited by some alarm condition. System sets value TRUE if the current active notification action requires all infusion to be inhibited. It is set to FALSE, when the active notification causing this inhibit is cancelled or system transitions to OFF		
<i>Source:</i> System set this value in response to the action for the notification in effect as per 'Inhibit All Infusion' column [REQ 59]		<i>Dependency :</i> [Assumption None]
<i>Values :</i>	<i>Condition:</i> Internal variable	

<i>Inhibited_Bolus_{macro}</i>	<i>Units:</i> -	<i>Type:</i> Boolean
<i>Description:</i> System sets this value to TRUE if the current active notification action requires Square boluses to be inhibited. It is set to FALSE, when the active notification causing this inhibit is cancelled or system transitions to OFF		
<i>Source:</i> System set this value in response to the action for the notification in effect as per 'Inhibit Square Bolus' column in [REQ 59]		<i>Dependency :</i> [Assumption None]
<i>Values :</i>	<i>Condition:</i> Internal variable	

<i>Inhibited_PatientBolus_{macro}</i>	<i>Units:</i> -	<i>Type:</i> Boolean
<i>Description:</i> System sets this value to TRUE if the current active notification action requires PATIENT BOLUS inhibit. It is set to FALSE, when the active notification causing this inhibit is cancelled or system transitions to OFF		
<i>Source:</i> System set this value in response to the action for the notification in effect as per 'Inhibit Patient Bolus' column in [REQ 59]		<i>Dependency :</i> [Assumption None]
<i>Values :</i>	<i>Condition:</i> Internal variable	

A.4 Constants

These are constants that are predetermined for the system. These are provided by customers and have a domain justification for using them, which is outside the scope of the system.

<i>Max_Rateof_Flow_Change_{const}</i>	<i>Units:</i> ml/sec ²	<i>Type:</i> Numeric
<i>Description:</i> Maximum rate of change of flow of drug in the hose		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Max_Mode_Change_Duration_{const}</i>	<i>Units:</i> sec	<i>Type:</i> Time
<i>Description:</i> Maximum time to be taken for mode transition		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Config_Warning_Duration_{const}</i>	<i>Units:</i> sec	<i>Type:</i> Time
<i>Description:</i> Recommended duration of prescription values configuration		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Max_Config_Duration_{const}</i>	<i>Units:</i> sec	<i>Type:</i> Time
<i>Description:</i> Maximum time allowed for configuration		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Max_IDLE_Duration_{const}</i>	<i>Units:</i> sec	<i>Type:</i> Time
<i>Description:</i> Maximum duration the system is allowed to be in IDLE mode continuously		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Max_Duration_UnderInfusion_{const}</i>	<i>Units:</i> sec	<i>Type:</i> Time
<i>Description:</i> Maximum cumulative duration the system can infuse below respective mode's flow rate - <i>Tolerance_Min_{const}</i> in any δ time interval		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Max_Duration_OverInfusion_{const}</i>	<i>Units:</i> sec	<i>Type:</i> Time
<i>Description:</i> Maximum cumulative duration the system can infuse above respective mode's flow rate + <i>Tolerance_Min_{const}</i> in any δ time interval		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Low_Reservoir_{const}</i>	<i>Units:</i> ml	<i>Type:</i> Numeric
<i>Description:</i> Volume in the Drug reservoir that needs notification for Low reservoir		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant. Should be greater than the <i>Empty_Reservoir_{const}</i>	

<i>Empty_Reservoir_{const}</i>	<i>Units:</i> ml	<i>Type:</i> Numeric
<i>Description:</i> Volume in the Drug reservoir that needs notification for empty reservoir		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant. Should be greater than the <i>FlowRate_kv_{hd}</i>	

<i>Single_AirBubble_Volume_{const}</i>	<i>Units:</i> ml	<i>Type:</i> Numeric
<i>Description:</i> Maximum volume of a single air bubble that is safe to be infused		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Cumulative_AirBubble_Volume_{const}</i>	<i>Units:</i> ml	<i>Type:</i> Numeric
<i>Description:</i> Maximum volume of air bubbles cumulatively in a δ time interval that is safe to be infused		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Rev_Delivery_Continuous_Duration_{const}</i>	<i>Units:</i> minutes	<i>Type:</i> Time
<i>Description:</i> Maximum duration the system is acceptable to be in reverse delivery continuously		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Rev_Delivery_Cumulative_Duration_{const}</i>	<i>Units:</i> minutes	<i>Type:</i> Time
<i>Description:</i> Maximum duration the system is acceptable to be in reverse delivery cumulatively in a δ time interval		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Max_PAUSED_Duration_{const}</i>	<i>Units:</i> sec	<i>Type:</i> Time
<i>Description:</i> Maximum duration the system is allowed to be in PAUSED mode continuously		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> -	<i>Condition:</i> Constant	

<i>Tolerance_Max_{const}</i>	<i>Units:</i> %	<i>Type:</i> Positive Integer
<i>Description:</i> Maximum acceptable variation in flow rate in any mode. The tolerance is specified as % of the respective mode's flow rate. (For example, if acceptable tolerance = 10%, then a mode's flow rate 10ml/hr, the acceptable variation = 9ml/hr to 11ml/hr)		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> 20 %	<i>Condition:</i> Constant	

<i>Tolerance_Min_{const}</i>	<i>Units:</i> %	<i>Type:</i> Positive Integer
<i>Description:</i> Tolerance in flow rate variation that is acceptable for certain duration of time. (<i>Max_Duration_OverInfusion_{const}</i> , <i>Max_Duration_UnderInfusion_{const}</i>). Calculation of variation is same in <i>Tolerance_Max_{const}</i>		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> 5 %	<i>Condition:</i> Constant	

<i>Audio_Level_{const}</i>	<i>Units:</i> decibels	<i>Type:</i> Positive Integer
<i>Description:</i> Acceptable level of sound for audio notification.		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> 5 %	<i>Condition:</i> Constant	

<i>Audio_Enable_Duration_{const}</i>	<i>Units:</i> minutes	<i>Type:</i> Positive Integer
<i>Description:</i> Audio notification temporary silencing duration.		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> 30	<i>Condition:</i> Constant	

<i>Log_Interval_{const}</i>	<i>Units:</i> minutes	<i>Type:</i> Positive Integer
<i>Description:</i> Intervals at which operational information should recorded.		
<i>Source:</i> Constant Defined		<i>Dependency :</i> [Assumption None]
<i>Values :</i> 5	<i>Condition:</i> Constant	

Appendix B

Questions

1. What happens if Infusion duration ends and notifications are still active?
2. what happens to notifications if prescription values are changed during infusion?
3. Should there be additional actions for uncleared notifications?
4. Mode displayed to clinician - is it a requirement?
5. What are the actions if Drug DB is not available or some data is missing?
6. Can there be only square bolus or patient bolus without basal - right now basal is mandatory?
7. Are there any restrictions on frequency and duration of p and s bolus ?
8. What happens if Drug reservoir is changed ? Should there be requirements on how the system should handle this?
9. What is the total duration of infusion. Is the duration increased due to boluses?
10. How is a clinician bolus configured. Is it frequency or total number of boluses?
11. Is it a requirement that basal flow rate < square bolus < patient bolus?