Welcome

System Engineers' Copilot:
AI-driven Intelligent System Design

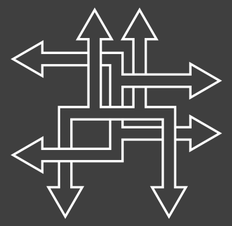
April 17, 2024

Xiaofan Mai, CEO & CO-Founder
IntelliU LLC
xiaofan.mai@msintell.com
Victoria, MN

IntelliU

Digital era system design challenges

Increased complexity and **shortened cycle** causes more failures (28% of recalls are caused by software design failures)



Manual design review is **time consuming and prone to error**

Missing design scenarios for verification forces re-work at later stage or cause patient adverse events in the field

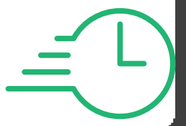
Solution

AI-driven intelligent system design that analyzes the design requirements automatically to

Prevent Failure

30-70% Fewer defects

Expedite Design



Analysis in hours not weeks

Retain Expertise

Digitized domain expertise for faster and easier access

Design Activities

OLD versus NEW

Review coveragae against standards

- Rely on consultants
- Precious engineering hours

- Line-by-line coverage analysis
- Repeated runs with updates

Review coverage across req. levels

- Manual analysis
- Analyze in silos

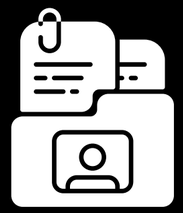
- AI-driven analysis
- Integrated analysis

Generate design scenarios for testing

- Engineer-heavy brainstorm
- Missing "corner cases"

- Computerized auto-generation
- Comprehensive corner cases

Pull design analysis history



- Scramble to find design history data

- One-click report

INCOSE IntelliU

Analysis Modules - align with QMS/V&V

System Req. Analysis

User Needs

Device Description

→ Basic product knowledge

Regulation Standards

dFMEA

System Requirements

→ Standards, user needs and risk management coverage analysis

System &sub-system Req. Analysis

System Requirements

→ Design Variables Analysis

Industry best practices gap analysis

Sub-system Requirements

→ System requirements coverage analysis

Design variables & best practice gap analysis

Design Scenarios for Verification Testing

Prioritization Inputs (exp. risks mgmt)

Single req. file or two req. files at same level

→ System level Verification scenarios (happy path, corner cases)

→ Sub -system Verification scenarios (happy path, edge cases)

Customer Data Inputs

IntelliU Data Output

INCOSE IntelliU

ISD Use Cases

Coverage Analysis - Industry Standard

Customer inputs: Software requirements specifications (SRS)
Standard processed: FDA Cybersecurity Guide

Standard ID	Standard Description	Coverage Level	SRS ID	SRS Description	Note
FDA_CYBER_001	Medical device and system shall handle software and firmware upgrade failure.	High	SRS023	The device firmware shall be able to recover from an error state.	
			SRS025	The device firmware shall be able to be updated through software updates initiated by the user through the device mobile app application.	
			SRS052	The device app shall allow user to retry firmware upgrade if the previous upgrade fails or interrupted.	
FDA_CYBER_002	Medical device and system shall require authentication and permission before permitting software or firmware updates.	Gap	N/A	N/A	Need to review
FDA_CYBER_003	Medical device and system shall check the integrity of the execution state of currently running software.	Low	SRS023	The device firmware shall be able to recover from an error state.	Need to review

INCOSE IntelliU

Customer Benefits study - 60601-1-8

Customer Standard Process

- Time spent to interpret the standards with other resources: 20 hours
- Manual gap analysis by 1 FTE
- Estimated 80% of time spent on
- checking requirements: 40 hours
- Time to re-check: 5 hours
- Total no. of hours: 65
- Total cost using $100/hr:
- $100x65=$6,500

Standard Process with ISD (not limited to 60601-1-8)

- Admin upload standards and engineer upload requirements
- Automated analysis by AI-driven algorithm
- Time took to process analysis: 2-3 hours
- Time to review the results: 5 hours
- Re-run the analysis if needed
- Total no. of hours saved: 65-8=57
- Savings in total cost: $100*(65-8)=$5,700

INCOSE IntelliU

Coverage assessment - Cross-level Req.

Customer Device: Wearable hardware, embedded software
Documents processed: User needs, system requirements, software requirements

User Need_req_id	User Need_req_desc	coverage level	System_req_id	System_req_desc
USRN_011	The device will have the ability to sense and record patient data	Low	SYRS0513	The device will have a tool to download the sensor data.

System_req_id	System_req_desc	coverage level	SRS_req_id	low_level_req_desc
SYRS0513	The device will have a tool to download the sensor data.	Gap	N/A	N/A

INCOSE IntelliU

Design/test scenarios - patient monitoring device

SRS#	SRS Description	Design Factor	Scenario ID	Scenario
SRS5813	The patient monitoring device shall upload the interrogation data to the server after a scheduled interrogation completes.	scheduled interrogation	1-1005	If a scheduled interrogation is canceled by clinician, When the interrogation completes, Then how should the system handle upload the interrogation data to the server
			1-1007	If a scheduled interrogation is changed **(both directions)** by clinician, When the interrogation completes, Then how should the system handle upload the interrogation data to the server
		patient monitoring device	1-1101	If the patient monitoring device loses power, When the interrogatino completes, Then how should the system handle upload the interrogation datat to the server
			1-1105	If the patient monitoring device malfunction, When the interrogatino completes, Then how should the system handle upload the interrogation datat to the server
		interrogation data	1-1201	If the interrogation data is incomplete, When the interrogatino completes, Then how should the system handle upload the interrogation datat to the server
			1-1203	If the interrogation data is corrupted, When the interrogatino completes, Then how should the system handle upload the interrogation datat to the server
SRS7051	The patient monitoring device shall initiate its firmware upgrade within the time window of 2 am to 4 am of the next morning after it receives the new firmware upgrade packet.	scheduled interrogation	2-1005	If scheduled interrogation happens, Then how should the system initiate its firmware upgrade within the time window of 2 am to 4 am of the next morning.
		patient monitoring device	2-1007	If patient monitoring device lose power, Then how should the system initiate its firmware upgrade within the time window of 2 am to 4 am of the next morning.

IntelliU

Design factors category

Hardware & components

- Battery
- Sensor
- Clock

Human factors

- Patients
- Physician
- Operator

Environment factors

- Temperature
- Humidity
- Interference

Cybersecurity

IntelliU

Innovation Speed
Quality by Design
Patient Safety

https://intelliutech.com
xiaofan.mai@msintell.com
952-201-3556

Class II orthotic device case study

Coverage analysis

Case study background

Customer needs: Customer is a VC-backed start-up. Requirements developed by the start-up team need to be evaluated against FDA cybersecurity. In addition, customer want to make sure requirements across the different levels have consistent coverage.

IntelliU solution: Use IntelliU's AI-driven auto-engine to run line-by-line coverage and gap analysis using self provided FDA guidance and customer provided requirements documents including user needs, system and software requirements.

INCOSE IntelliU

Class II device case study

Coverage analysis benefits

Benefits study background

Customer needs: Customer is a nearly $1 billion device company. Requirements developed by the third party engineering firm were in poor quality and need to be checked against 60601-1 sub-standards. Benefits study is based on 60601- 1-8 and time quoted by the Sr. engineering lead. He spent significant more hours on 60601-1.

IntelliU solution: Use IntelliU's AI-driven auto-engine to run line-by-line coverage and gap analysis using customer provided standards and requirements documents including system and software requirements.

INCOSE IntelliU

Test scenarios generation - Blood Warmer

100 requirements; >700 test stories

IntelliU

Quantitative variable analysis - blood temp alarm

Design Input

SRS0035

The blood warmer shall declare Alarm T0810 if it cannot heat patient blood to the target temperature within 20 minutes after entering the treatment phase or after the target temperature is changed in treatment phase.

Impacting requirements analysis

SRS0005 Clinician shall set the following information in setup phase.

- target blood temperature (35.0 to 38.7 Celsius Degree)

Target temperature range

SRS0007 Clinician can change the following information in setup or treatment phase.

- target blood temperature (35.0 to 38.7 Celsius Degree)

Target temperature change

Change direction – increase, decrease, change and reverse back

Outputs: Design/test stories

ST0001
If the target temperature is set to 37 degree before entering the treatment phase and blood warmer cannot achieve the target temperature for 19 minutes in treatment phase,
When target temperature increase to 38 degree
Then shall the blood warmer software continue process the alarm?

Harder to achieve the new threshold

ST0002:
If the target temperature is set to 37 degree before entering the treatment phase and blood warmer cannot achieve the target temperature for 19 minutes in treatment phase,
When target temperature decrease to 36 degree
Then shall the blood warmer software continue process the alarm?

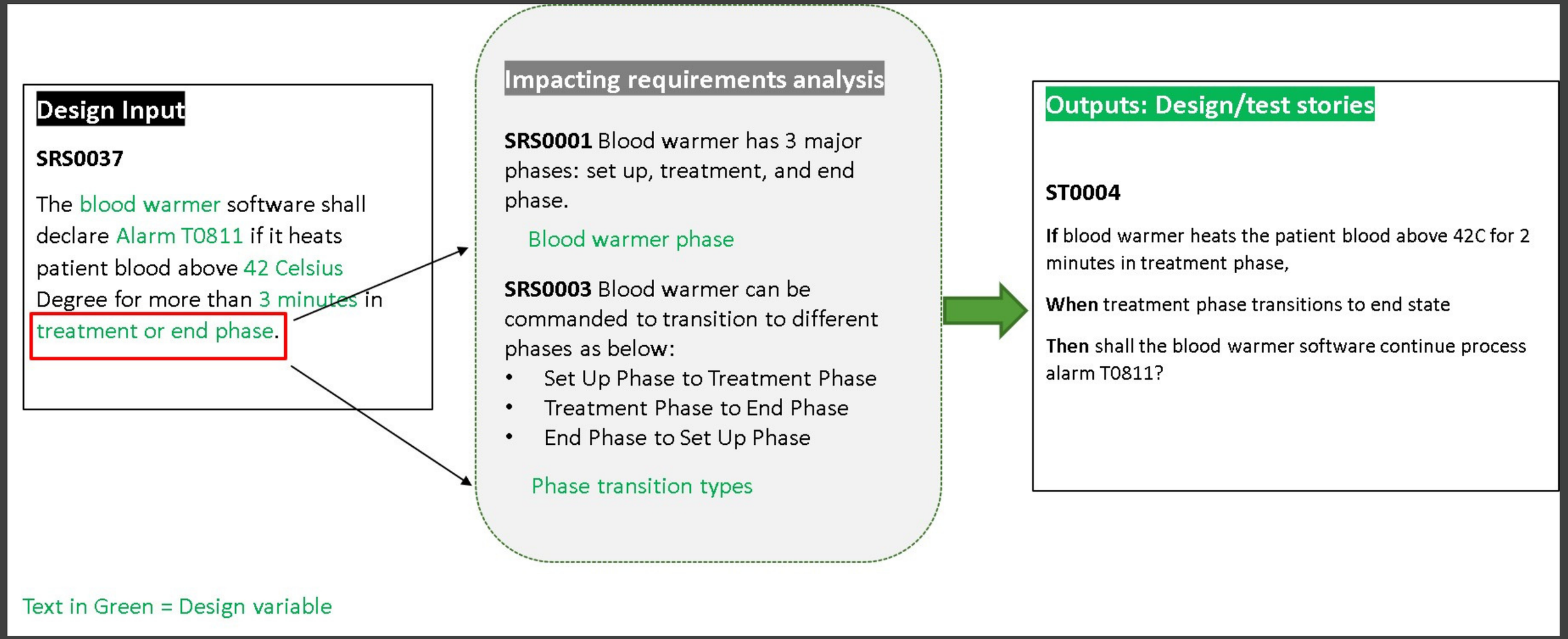
Easier to achieve the new threshold

ST0003:
If the target temperature is set to 37 degree before entering the treatment phase and blood warmer cannot achieve the target temperature within 20 minutes in treatment phase,
When target temperature changes but then gets reversed back to 37 degree
Then shall the blood warmer software continue process the alarm?

Text in Green = Design variable

IntelliU

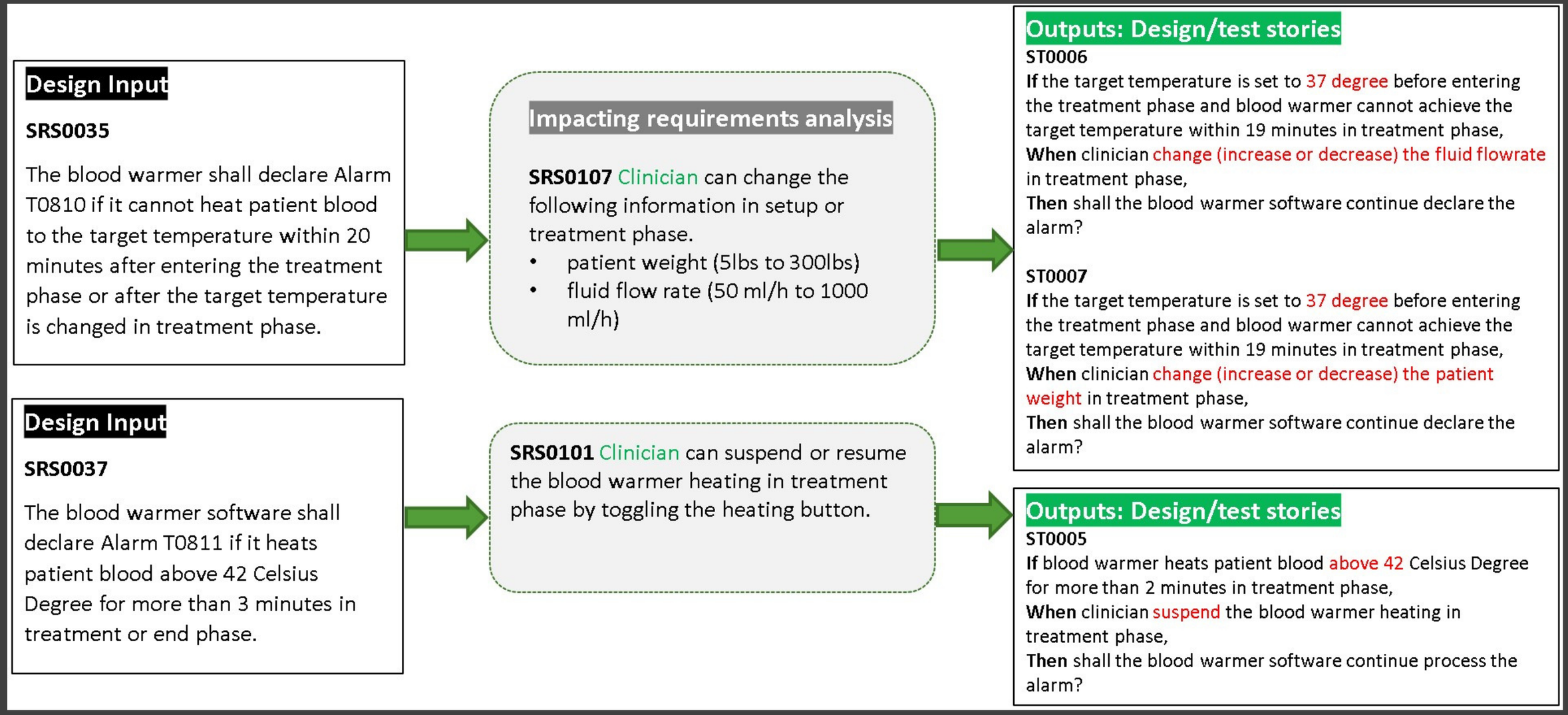
Qualitative variable analysis – overheating alarm



Text in Green = Design variable

IntelliU

Human behavior analysis – clinician actions



IntelliU

Separate sets of components requirements analysis – interaction with controller

Controller Design Input

SRS-C-0053

The controller shall declare urgent alarm P3008 if it does not receive the periodic heating message from the paired blood warmer for 15 seconds in treatment phase.

Warmer design inputs

SRS0009 Blood warmer shall send out periodic heating status message to the controller machine in treatment phase at 1 Hz rate.

SRS0010 Blood warmer shall wait up to 1 minutes to begin heating and sending out the heating status message after it enters the treatment phase from setup phase.

Outputs: Design/test stories

ST0009
If the controller does not receive the periodic heating message from the paired blood warmer for 15 seconds in treatment phase,
When blood warmer wait for 1 minute to begin heating and sending out heating message after entering the treatment phase,
Then shall the controller report the communication loss alarm?

Contradicting requirements?

Controller Design Input

SRS-C-0081

The controller shall report blood leak alarm to the user if it receives the positive alarm status in the communication message from the connected blood warmer.

Warmer design inputs

SRS3001. The blood warmer shall perform the periodic test for the blood leak sensor at 2 Hz rate during the treatment and end phases.

SRS3003. The periodic blood leak sensor test shall change the blood leak sensor pin value to positive, and then change it back to negative

Outputs: Design/test stories

ST0008

If the controller receives the positive alarm status in the communication message from the connected blood warmer,
When blood warmer conducts the periodic blood leak sensor test,
Then shall the controller report the blood leak alarm to the user?

IntelliU

Requirements Analysis is the most important step yet to be automated to optimize product design