Software Requirements Specification Approval:

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# Introduction

## Purpose

The SmartMedic bed is meant to be used in ICU for measuring the weight of patients. This document defines the software and hardware electronics requirements of the Display Unit of SmartMedic project.

In addition, certain common considerations like external interface specifications, user interface, software interface, performance requirements, attributes such as Reliability & availability and additional requirements are also captured in this document.

## Scope

The scope of the project is to develop the Display Unit for the SmartMedic. The Display Unit will interface with the Slave boards to get the patient data and transfer the telemetry data to the Tablet Gateway application. The scope of this document includes defining specification for Hardware electronics and firmware of the Display Unit board.

The following are out of scope of this project:

Design and development of Slave Boards, Power supply

Tablet Application

Cables between the Display Unit board and the Slave boards.

Mechanical design and development.

## Definitions, acronyms, and abbreviations

This subsection provides the definitions of all terms, acronyms, and abbreviations required to properly interpret this document.

| **Term** | **Definition** |
| --- | --- |
| BT | Bluetooth |
| CPU | Central Processing Unit |
| CRC | Cyclic Redundancy Check |
| EMC | Electro Magnetic Compatibility |
| EMI | Electro Magnetic Interference |
| GPIO | General Purpose Input Output |
| I2C | Inter Integrated Circuits |
| ICU | Intensive Care Unit |
| JTAG | Joint Test Action Group |
| LCD | Liquid Crystal Display |
| LED | Light Emitting Diode |
| MCU | Master Controller Unit |
| NC | No Connect |
| POST | Power on self-test |
| PRD | Product Requirement Document |
| RF | Radio Frequency |
| SPI | Serial Peripheral Interface |
| TAB | Tablet |
| Tablet Gateway Application / Tablet application | Application running on the Tablet which will be interfaced with Display Unit board through BT and Wi-Fi. |
| TFT | Thin Film Transistor |
| TTL | Transistor-Transistor Logic |
| UART (Universal Asynchronous Receiver Transmitter) | Universal Asynchronous receiver-transmitter |

## References

|  |  |
| --- | --- |
| **Doc Type** | **Details** |
| URS (User Requirement Specification) | D001020022 - SmartMedic Phase II User Requirement specification |
| Risk Analysis | D001020010 - SmartMedic Phase II Risk Table & Risk Matrix |
| Screen Flow | SmartMedic\_MCU\_Screenflow.doc – See Appendix |
| Wi-Fi Communication Protocol | Wi-Fi Protocol Document.docx – See Appendix |

# Specifications:

This specification document translates User Requirement Specification of the system/application into detailed functional requirement/functionality necessary to fulfil URS specification.

The following subsections will identify the detailed requirements/functionality and provide a direct reference and traceability to the appropriate user requirements.

## Functions

This sub-section would define the required system functions, modes of operation & behavior. It addresses the following.

### Functions/ business processes required

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.6.1 | RS 1.1.1 | On power on, the firmware shall show Stryker logo for 5 seconds. |
| 2.6.1 | RS 1.1.2 | The firmware shall perform Power on Self-Test during boot up. |
| 2.6.1 | RS 1.1.3 | The firmware shall perform the self-test of the following:   1. Internal Flash test 2. External Flash test 3. SPI test (Wi-Fi Communication) 4. I2C test (Slave Communication) 5. UART test 6. LCD test (no software feedback) 7. Buzzer test (no software feedback) 8. Integrity of Config data |
| 2.5.2 | RS 1.1.4 | On successful completion of all the self-test the firmware shall beep buzzer with test beep. |
| 2.5.2 | RS 1.1.5 | On Failure of Self-test, the firmware shall beep buzzer with Error beep. |
| 2.2.1 | RS 1.1.6 | On Failure of Self-test, the firmware shall show Error screen with Self-test failure code. |
| 2.2.1 | RS 1.1.7 | The firmware shall log all the errors detected with time stamp. Repeated error shall not be logged unless recovered and reoccur. |
| 2.5.2 | RS 1.1.8 | The firmware shall support 5 functional buttons namely   1. Back button 2. Menu button 3. Next button 4. Get Weight button 5. Patient Discharge button |
| 2.1.1, 2.1.2 | RS 1.1.9 | On press of Get Weight button, firmware shall do the following:   * Check if valid pitch and roll. * Display the latest stabilized patient weight on the screen. * Log the calculated weight along with Date and time. * Send the calculated weight along with Date and time to Tablet Gateway application through Wi-Fi. |
| 2.5.2 | RS 1.1.10 | Firmware shall clear the weight information on the display after 1minute timeout in ICU mode. |
| 2.1.1 | RS 1.1.11 | Firmware shall get the weight data from slave boards and calculate the patient weight. |
| 2.1.1, 2.6.1 | RS 1.1.12 | Firmware shall get the pitch and roll data from slave boards. |
| 2.2.2 | RS 1.1.13 | Firmware shall send telemetry data to Tablet Gateway applicationevery 5 seconds. The following data shall be sent:   * Device ID * Date and time * Tare weight * Weight data of each load cell * Pitch and roll data for each slave |
| 2.1.1 | RS 1.1.14 | The firmware shall get the weight data from slave boards and calculate Tare weight when Tare function is initiated. |
| 2.2.1 | RS 1.1.15 | The firmware shall log successful completion of Tare operation with Date and Time. |
| 2.5.2 | RS 1.1.16 | The firmware shall support buzzer with following beeps. The frequency shall be configurable in the firmware.   * Test beep – 1000 hz * Key beep- 440 hz * Error beep- 500 hz * Alert beep – 700 hz   This will be a repeat beep every 5 seconds. The repeat duration needs to be configurable. |
| 2.2.2 | RS 1.1.17 | The firmware shall allow download of Wi-Fi configuration over Bluetooth from the Tablet Gateway application, once Bluetooth connection is successfully established. |
| 2.1.8, 2.6.1 | RS 1.1.18 | On discharge of patient the following shall happen:   * Send Discharge to Tablet Gateway application * Clear patient history |
| 2.2.1 | RS 1.1.20 | The firmware shall support Over the Air upgrade (through Wi-Fi) of   * Display Unit controller * Slave board controllers |
| 2.2.1 | RS 1.1.21 | The firmware shall upgrade the slave board controllers of all slave boards on receipt of a new firmware from Tablet gateway application. |
| 2.2.1, 2.6.1 | RS 1.1.24 | The firmware shall verify new firmware image checksum before switching to the new firmware. |
| 2.2.1 | RS 1.1.25 | If a firmware checksum error is detected or upgrade of any controller fail, and error message shall be logged and same shall be displayed on the screen. |
| 2.6.1 | RS 1.1.26 | The firmware shall be able to revert to the original image in case of checksum error |
| 2.6.1 | RS 1.1.27 | After successful verification of the checksum of the new firmware, the system shall boot into the new firmware.  Note: Once the checksum is verified and booted from second firmware any error may not revert to previous firmware. |
| 2.2.2 | RS 1.1.28 | When in Connectivity screen, firmware shall turn on Bluetooth in discovery mode. It shall stay in discovery mode until connected or until screen timeout. |
| 2.2.2 | RS 1.1.29 | When a connection request is initiated, the firmware shall display a random pairing key. The pairing key shall timeout in 1 minute. |
| 2.2.2 | RS 1.1.30 | The Bluetooth device shall establish the connection when the same pairing key is used for pairing from the Tablet gateway application. |
| 2.6.1 | RS 1.1.32 | Firmware shall validate the Wi-Fi configuration and save it in non-volatile memory. |
| 2.2.2 | RS 1.1.33 | Firmware shall overwrite a Wi-Fi configuration when a new valid Wi-Fi configuration is available from the Tablet Gateway application. |
| 2.6.1 | RS 1.1.34 | The firmware shall check if there is a valid Wi-Fi configuration and connect to the Wi-Fi network automatically. This shall be checked periodically when there is no established Wi-Fi connection. |
| 2.2.2 | RS 1.1.35 | The firmware shall establish a connection with the Tablet Gateway application over Wi-Fi. |
| 2.2.1 | RS 1.1.36 | The firmware shall display and log error, if firmware is not able to connect to the Wi-Fi network using a valid configuration (Wrong password). This shall be an ACK Error Screen. |
| 2.5.2 | RS 1.1.37 | The firmware shall display Wi-Fi connected icon when it is successfully connected to the Wi-Fi router using valid configuration. When it is not connected, it shall show Wi-Fi disconnected icon. |
| 2.1.3, 2.1.5 | RS 1.1.39 | The firmware shall synchronize Date and Time on connection with Server. |
| 2.2.1 | RS 1.1.40 | The firmware shall send the Error logs through Wi-Fi on request from tablet. |
| 2.1.4, 2.5.2 | RS 1.1.41 | When Alert is displayed, the firmware shall toggle the screen brightness between dim (30%) and full bright (100%) every one second. |
| 2.6.1 | RS 1.1.42 | If there is no button press for more than 5 minutes, the screen brightness shall be set to 30%. |
| 2.5.2 | RS 1.1.43 | When the screen is dimmed, the firmware shall set the screen brightness to full when any of the following cases happen   * A key press is detected. * An Alert or error has occurred. |
| 2.6.1 | RS 1.1.44 | The firmware shall utilize the watchdog or similar safety process to detect system hang. The watchdog reset shall be detected on next boot and logged. |
| 2.1.4 | RS 1.1.45 | The firmware shall display the Alert screen when the Turn timer expires. This screen can be dismissed by press of any key.  Note: Once the Turn timer is set, the firmware shall start counting the time, once this expires Alert screen is displayed. |
| 2.1.4 | RS 1.1.46 | The firmware shall reset the turn timer once a turn is detected from the Tablet Gateway application. |
| 2.5.2 | RS 1.1.47 | When the Turn Alert is dismissed, the Alert icon is displayed on the top of the screen until a Turn is detected. |
| 2.1.1 | RS 1.1.48 | Taring shall be done using the Tare value. Tare value is either the calculated Tare value or the Tare over-ridden value. When user selects the Tare over-ride, the following is affected.  Tare with Foam Mattress à Tare value is set to 29.5 kgs (configurable)  Tare with Air Mattress à Tare value is set to 28 kgs (configurable)  Tare using previous session à Tare value is set to the Tare value of previous session.  Note: Tare value of previous session is the last successful Tare. |
| 2.1.1 | RS 1.1.49 | In Dialysis mode, once firmware traverses out of the QR code screen, a secondary taring shall be performed in background while traversing to next screen if the deviation in the weight of the patient is less than 5kgs.  Note: It shall not tare if the delta tare weight is more than 5kg because it might be the patient on the bed. |
| 2.1.4 | RS 1.1.50 | On power reset, the turn timer always restarts from 0. The Alert clears on restart of the device.  Note: While switch off we do not know if the patient has turned hence its safer to clear and start fresh even if its same patient. |
| 2.2.2 | RS 1.1.52 | Data packets must be buffered by the firmware for maximum of 6hrs if WIFI connection to the tablet is unavailable. When connection is established, the buffered data shall be sent to the tablet. |
| 2.5.2 | RS 1.1.53 | When the planks are tilted, the angle of tilt (maximum of pitch and roll) shall be reflected on the screen. |
| 2.2.2 | RS 1.1.54 | If the date and time is not available, the same shall not be shown  Below changes shall apply:   * Weight screens shall not display the date and time. * History (weight and turn) shall not be saved. * Telemetry data shall not be saved. * Error logs shall be saved with 0 for date and time. * History, Turn and Turn history shall not be accessible.   In ICU mode, once date time is available, it shall return to normal.  In Dialysis mode, once data time is available, it shall return to normal only on discharge of patient or on update start weight. Current session shall not show date time if it was not available when Patient is admitted. |
| 2.2.2 | RS 1.1.55 | The selection of mode (ICU or Dialysis) shall be done through Bluetooth connectivity. By default, the mode shall be ICU.  On change of mode the patient shall be discharged, and system shall re-boot in the new mode. |
| 2.2.1 | RS 1.1.56 | Firmware shall have provision to guide through end of line testing accessible from Settings Menu. Once it is completed, factory reset shall be performed. |

### Calculations, including all critical algorithms

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.1.1 | RS 1.2.1 | Firmware shall calculate weight to a precision of 3 decimal places (in Kgs).  Note: Display is only 1 decimal place. |
| 2.1.1 | RS 1.2.2 | Firmware shall display error if weigh data is above 150 Kgs |
| 2.1.1 | RS 1.2.3 | The Taring value shall be the sum of all the strain gauge weight data during the Taring process. This shall be saved by the Display Unit as Tare Value. Tare value shall not be calculated if the pitch and roll values are more than 5 Deg. (Tilt cut off value needs to be configurable)  Note: This is subtracted from the total weight during weight calculation to get the actual patient weight. The actual patient weight may be negative if tared with a weight on bed. |
| 2.6.1, | RS 1.2.4 | The Weight of patient shall be calculated only when the value of Pitch and roll values is less than 5 Deg. (Tilt cut off value needs to be configurable) |
| 2.5.2 | RS 1.2.5 | The firmware shall declare a stable weight only when the calculated patient weight does not vary more than 200 grams over 20 seconds. |
| 2.1.4 | RS 1.2.6 | The firmware shall start turn timer from the selection of turn timer set by user. Once the time reaches the set time an Alert is displayed. The timer will continue to increment until a turn is detected. This will be the total turn duration.  Note: Then the turn timer is set to off, the internal timer is disabled. |
| 2.5.2 | RS 1.2.7 | Turn Alert shall not be displayed when there is no connection detected to Tablet Gateway Application. The timer shall be stopped if the connection is lost for more than 1minute. Once the connection is re-established, the timer shall start from zero. |

### Performance and timing requirements

Note: Unless otherwise specified, all the duration can have 10% tolerance.

## Data

This sub-section shall state the data handling requirements. It shall address the following:

### Definition of data, identification of critical parameters, valid data ranges & limits.

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.2.1 | RS 1.3.1 | The firmware shall log all error data in external flash memory. The error log shall be kept for last 100 values. |
| 2.2.1 | RS 1.3.2 | The firmware shall log the error data with Time and Error Code.  Note: Date time is stored as Epoch time stamp. When Time is not synchronized due to non-availability of server connection, the time stamp shall be defaulted to start at Epoch time 0 on bootup. |
| 2.6.1 | RS 1.3.4 | The firmware shall store Telemetry data with Date and Time |
| 2.6.1 | RS 1.3.5 | The firmware shall save the Wi-Fi Configuration data along with Date and Time stamp. |
| 2.1.1 | RS 1.3.6 | The firmware shall store the Tare data. |
| 2.1.3 | RS 1.3.7 | The firmware shall store the last 5 calculated valid weight data. |
| 2.1.5 | RS 1.3.8 | The firmware shall store the last 5 turn data including:   * Set turn timer data * Total turn time |
| 2.6.1 | RS 1.3.9 | The firmware shall erase the patient data when the discharge button is pressed.  Note: Patient data involves: Last 5 patient weight data. Last 5 Turn data. |

## System Interface

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.2.2 | RS 1.4.1 | The firmware shall configure I2C interface to communicate with slave device. |
| 2.1.8, 2.2.2 | RS 1.4.2 | The firmware shall configure the Wi-Fi network based on the Wi-Fi configuration data received over Bluetooth from the Tablet Gateway application. |

## User Interface

Refer to SmartMedic\_MCU\_Screenflow.doc

## Hardware Interfaces

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.2.1 | RS 1.5.1 | The following reset mechanisms shall be provided on the board:   * Power On reset * Hard reset * Soft reset |
| 2.1.4 | RS 1.5.2 | Buzzer shall be provided and interfaced using PWM (Pulsed Width Modulation). |
| 2.1.3, 2.2.2 | RS 1.5.3 | The external flash shall be interfaced using an SPI bus. |
| 2.5.2 | RS 1.5.4 | The keypad shall be interfaced with the GPIO. The keypad should support 5 keys. |
| 2.2.2 | RS 1.5.5 | The TFT display shall be interfaced using SPI bus. |
| 2.2.2 | RS 1.5.6 | The TFT brightness shall be controlled using SDI (Serial Digital Interface). |
| 2.2.2 | RS 1.5.7 | Slave boards shall be interfaced through I2C. |
| 2.1.8, 2.2.2 | RS 1.5.8 | The Wi-Fi/Bluetooth module shall be interfaced using SPI interface. |
| 2.2.1 | RS 1.5.9 | UART shall be provided for debugging purpose (TTL level) |
| 2.6.1 | RS 1.5.10 | The controller shall support an internal Watchdog |
| 2.1.7 | RS 1.5.11 | Graphic Display shall be provided with following specification:  * Graphic LCD with backlight or OLED connected over 8/16-bit parallel interface or I2C or SPI interface * No perceivable delay during screen refresh, i.e., < 100 MS   Backlight brightness control/OLED brightness control required for power saving and sleep mode control. |
| 2.2.2 | RS 1.5.12 | * WIFI chip/module with embedded TCP IP stack, either on-chip or connected through simple UART/SPI interface. |
| 2.6.1 | RS 1.5.13 | Wi-Fi shall be able to reliably connect and transmit/receive data from a WIFI router placed at distance of up to 150 ft. |
| 2.2.1 | RS 1.5.15 | Wi-Fi shall support Over the Air updates of Firmware. |
| 2.7.1 | RS 1.5.16 | BT chip/module should be WPC certified |
| 2.2.2 | RS 1.5.17 | BT chip/module shall be with embedded stack (SPP (Serial Port Profile)), either on-chip or connected through simple UART/SPI interface |
| 2.6.1 | RS 1.5.18 | BT shall have a connectivity range of 30 ft |

## Communication Interfaces

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.2.2 | RS 1.6.1 | The Slave board interface shall use Custom Protocol defined in Master-SUBCPU Interface.docx |
| 2.2.2 | RS 1.6.2 | Refer Appendix for protocol for communication over Wi-Fi and Bluetooth. |

## Operating Environment

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.4.1 | RS 1.7.1 | Operating Humidity range: 30% to 75% RH (Relative Humidity), non-condensing |
| 2.4.1 | RS 1.7.2 | Operating temperature: 15o to 30o C |
| 2.4.2 | RS 1.7.3 | Storage temperature: -10o to 60o C |
| 2.4.2 | RS 1.7.4 | Storage Humidity range: 10% to 90% RH |

## Design and Implementation Constraints

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.6.1 | RS 1.8.1 | The firmware shall stabilize the weight within 20sec from press of Get weight button. |

## User Documentation

User Documentation is not in scope of this project.

## Assumptions and Dependencies

High level Assumptions, Dependencies are addressed in the SOW (Statement of Work).

Following are the assumptions that are considered while creating the solution based on the current understanding of the requirements.

**Risk and Mitigation:**

The ***Error! Reference source not found.***below provides a summary of the risks that have been identified and captured during the compilation of this response. This is not an extensive list but represents those risks identified, complete with an assessment of the probability and impact and the proposed risk mitigation strategy.

| **Risk ID** | **Risk and Impact** | **Impact**  (H, M, L) | **Risk Mitigation Strategy** |
| --- | --- | --- | --- |
| R1 | Bluetooth and Wi-Fi modules may cause EMC failures | Low | Team shall select wireless components which have compliance certifications. Team will collect WPC certificate or FCC and CE certificates from vendor. |
| R2 | Wi-Fi BT module integration failure | Low | The development boards will be ordered and tested before the start of design phase. |
| R3 | One Iteration/Re-spin of Display unit board | High | The development boards reference designs for BT/Wi-Fi modules will help reduce the risk.  Another iteration of hardware re-spin would cause a delay or 4 weeks. |
| R4 | Long lead time of the components | High | Look for alternate parts |
| R5 | 100ms refresh rate for LCD | Medium | Using 3-bits/pixel reduced color mode One-pixel data containing 3-bit color depth information |
| R6 | ESD (electrostatic discharge) | High | ESD protection diodes and ESD shielding to be provided on keypad overlay. |
| R7 | LCD may have high lead time. | High | More than one supplier considered during the prototyping phase. |

## Site Adaptation Requirements

There are no Site Adaption requirements for the Display Unit Firmware.

## Safety

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.7.1 | RS 1.9.1 | The firmware of the Main controller and Co-controller falls in Class  A as per Risk Analysis |

## Reliability

NA

## Security

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.2.2 | RS 1.10.1 | Bluetooth shall use pairing key mechanism to establish a connection. Bluetooth shall use custom encryption while transfer of data to increase data security. |
| 2.2.2 | RS 1.10.2 | Wi-Fi driver shall support WPA/WPA2 encryption mechanism. |
| 2.2.2 | RS 1.10.3 | Wi-Fi shall use SSID and passcode from the configuration file to establish connection. |

## System Performance

| **Ref** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.5.2 | RS 1.11.1 | The firmware shall boot to landing screen (screen after logo screen) in less than 20 seconds. |
| 2.6.1 | RS 1.11.2 | An abrupt power down shall not cause loss of any config and history data. |

## Internationalization

Only English is supported.

## Methods of Operation and Maintenance

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.2.1 | RS 1.12.1 | The system shall perform Over the Air upgrade when requested by the Tablet gateway application. |

## User Documentation

NA

## User Maintenance Requirements

NA

## Regulatory Requirements

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| 2.7.1 | RS 1.13.1 | IEC 60601-1 safety and effectiveness of medical electrical equipment |
| 2.7.1 | RS 1.13.2 | IEC 60601-1-2 compliance |

## Data definition and database requirements

NA

## Other Requirements

| **URS ID** | **RS ID** | **Description** |
| --- | --- | --- |
| NA | RS 1.14.1 | **Mechanical:**  **Form Factor:** Thissub-section lists the dimensions of the board   * Length – 90 mm (about 3.54 in) * Breadth – 80 mm (about 3.15 in) * Height – 17 mm (about 0.67 in) * PCB thickness – 1.6 mm (about 0.06 in)   In addition, this sub-section also provides the information on component height restrictions (if any).  **Front / Rear Panel**  This sub-section lists the I/O connectors that shall be there on the front or Rear panel.  **Connector, Keys & Switches**   * 10-pin box type JTAG header * RJ45 I2C and power connector * Display header * Keypad header * 5-key membrane keypad |
| NA | RS 1.14.2 | **Technology:**  This section lists the technology, tools and the logic levels that shall be used as listed below:   * Surface mount technology / Through hole: Both SMT and TH wherever applicable. * Electronic Design Automation (EDA) tools: Altium Designer 19 * Components logic level: Logic voltage = 3.3V * IC sockets (if any): None |

## Block Diagrams

**Overview of the product**

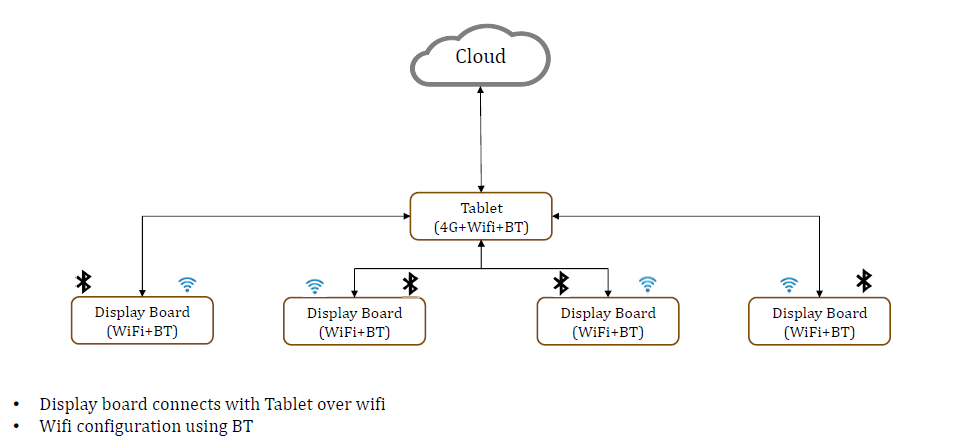


Figure 1: System Diagram

## Validation Specification

### Climatic Tests

* Dry Heat Test – NA
* Cold test – NA Climatic Tests
* Rapid Change of Temperature – NA
* Damp Heat, Cyclic Test – NA
* Low Temperature Functionality Test – NA
* High Temperature Functionality Test – NA

### Vibrations Tests

* Sine-Sweep – NA
* Random – NA 2.24.2 Vibrations Tests
* Shock – NA
* Combined Temperature Cycling / Sine-Sweep Vibration Stress Test – NA

### Voltage Performance Tests

* High Voltage – NA
* Low Voltage – NA

### Safety Performance Tests

Refer to D001020094 DFMECA Display Unit SmartMedic Phase II and INTEGRATION\_TEST\_CASE\_V1.3 for testing the safety performance.

## Engineering Methods

This sub-section lists the engineering methods that shall be performed during the phase of the project. The methods and the process that are to be performed during each method are as mentioned below

### Testability

The Design for Testability (DFT) document shall be implemented in the design process. PCB nets that are No Connects (NC) shall have test point included.

### Components Verification Matrix

A Component Verification Matrix (CVM) shall be generated that includes the availability status and second sources of equivalent components. This is to ensure obsolete, or end of life components will not be used especially for those not having form, fit and function replacement.

### Design Margin Analysis

A design margin analysis shall be provided. This will include voltage and current/power stress on all components. This will ensure that proper design margins and proper thermal design margins and proper thermal de-rating have been considered.

### Creepage/Clearance Analysis

An Electrical Creepage/Clearance compliance and isolation report shall be generated which examines any marginal items.

### EMC Modeling

As applicable, a circuit board level EMC model or simulation shall be prepared to identify EMC issues and test solutions prior to layout and any hardware delivery.

### DFM, DFA

This section will capture the requirements description on the design for manufacturability and design for assembly details.

# Document Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision**  **Level** | **Revision Date** | **Effective Date** | **Reason and Description of Revision** |
| 00 | 18 August 2021 | 18 August 2021 | Initial release - document was reviewed but not  approved and archived, thus archiving |
|  |  |  |  |
|  |  |  |  |

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| APPENDIX |

# Appendix A: References

The below attached documents will be used for screen flow details and communication over Wi-Fi and Bluetooth with the Tablet Gateway application.

|  |  |
| --- | --- |
| **Name** | **Description** |
| Annexure I: Screen Flow | SmartMedic Phase II Screen Flow Details |
| Annexure II: Wi-Fi Protocol | SmartMedic Phase II Wi-Fi Protocol Details |

# Appendix B: Checklist

Software Requirement Specification Checklist document as per SGTC template SGTC-QFM-DLC-001-03 Ver 07 reviewed and approved in this document.

| **Area of Concern** | **Item to be Verified** | **Is Implemented** | **Not Applicable** | **Comments** |
| --- | --- | --- | --- | --- |
| Organization and Completeness | Are all internal cross-references to other requirements, correct? | ✔ |  |  |
| Organization and Completeness | Are all requirements written at a consistent and appropriate level of detail? | ✔ |  |  |
| Organization and Completeness | Do the requirements provide an adequate basis for design? | ✔ |  |  |
| Organization and Completeness | Are all external hardware, software, and communication interfaces defined? | ✔ |  |  |
| Organization and Completeness | Does the SRS include the entire known customer or system needs including those relating to risk control? | ✔ |  |  |
| Organization and Completeness | Is any necessary information missing from a requirement? If so, is it mentioned in list of findings? | ✔ |  |  |
| Organization and Completeness | Are requirements written to cover software-driven alarms, warnings, and operator messages? | ✔ |  |  |
| Organization and Completeness | Are the requirements clear enough to be turned over to an independent group for construction and still be understood | ✔ |  |  |
| Organization and Completeness | Are all of the inputs to the system adequately specified? | ✔ |  |  |
| Organization and Completeness | Are all of the outputs from the system adequately specified? | ✔ |  |  |
| Organization and Completeness | Are all referenced documents listed? | ✔ |  |  |
| Organization and Completeness | Are you comfortable with all the requirements? | ✔ |  |  |
| Correctness | Are requirements free of conflict and not duplicate other requirements? | ✔ |  |  |
| Correctness | Is each requirement written in clear, concise, unambiguous language? | ✔ |  |  |
| Correctness | Is each requirement verifiable by testing, demonstration, review, or analysis? | ✔ |  |  |
| Correctness | Is each requirement in scope for the project? | ✔ |  |  |
| Correctness | Is each requirement free from content and grammatical errors? | ✔ |  |  |
| Correctness | Can all of the requirements be implemented within known constraints? | ✔ |  |  |
| Quality  Attributes | Are all performance objectives (like response time, processing time, data transfer rate, system throughput, etc.) properly specified? | ✔ |  |  |
| Quality  Attributes | Are all security and safety considerations properly specified? | ✔ |  |  |
| Quality  Attributes | Is critical information specified along with the requirements for error detection and recovery? |  | ✔ | NA Class A |
| Quality  Attributes | Are other pertinent quality attribute goals explicitly documented and quantified, with the acceptable tradeoffs specified? | ✔ |  |  |
| Traceability | Is each requirement uniquely numbered? | ✔ |  |  |
| Traceability | Is each software functional requirement traceable to a higher-level requirement (e.g., system requirement, use case)? | ✔ |  |  |
| Special Issues | Have internationalization issues been adequately addressed? |  | ✔ | Product to sold in India market |