# Purpose

The purpose of this document is to define the structure of the *<ProjectName>* software and the identification of the software items that constitute it. In addition, it defines the interfaces between the software items and the components external to the software items (both software and hardware), and between the software items. The functional and performance requirements for any SOUP items are also defined to ensure its intended use, along with system hardware and software necessary to support the proper operation of the SOUP item.

# References

## *Doc. Ref. xxxxx: Document title - Requirements Traceability Matrix*

## *Doc Ref. xxxxx: Document Title – Medical Device Software Safety Classification*

## *Doc. Ref. xxxxx: Document Title – Software Requirements Specification and Traceability matrix*

## *Doc. Ref. xxxxx: Document Title - Design & Development Plan*

## *Doc. Ref. xxxxx: Document Title – Risk Management Plan*

## SSI-SOP-20, Software Development

## SSI-SOP-13, Risk Management

## SSI-SOP-10, Design and Development

# Definitions, Acronyms, and Abbreviations

*<Provide the definitions of all terms, acronyms, and abbreviations required>*

# General Description

## Intended Medical Indication

*<List the precise situations and reasons where and why you would use this software>*

## Intended Patient Population

*<List the patient population that the software may be used on>*

## Intended part of the body or type of tissue applied to / interacted with

*<List the Intended part of the body or type of tissue applied to / interacted with by the software>*

## Intended User Profile

*<Significant features of the users that are intended to use the software>*

## Intended conditions of use

*<Describe the use/use environment for the software>*

## Operating Principle

*<Explain the operating principle of the software>*

# Product Features and High-Level Functional Description

## Application Specification

## Primary Operating Functions (POF)

## Use Cases

### Use Scenario (Use Task Breakdown)

### Typical Use Task Breakdown

# System Functional Architecture

*<Identify the breakdown of the software structure in terms of software items and software units, in accordance with SSI-SOP-20.>*

## System Functional Block Diagram

*<Depict the software structure in terms of constituent software items, and the internal and external system functional interfaces. Each of the software items must be assigned a software safety classification in the reference software safety classification document.>*

## Functional Architecture Description

*<This section provides a description of each software component i.e. item. The component design requirements are traceable back to the software functional requirements. This section is repeated for each software item identified. Identify SOUP items.>*

## Functional Constraints and Dependencies

*<Describe any functional constraints or dependencies>*

## Internal System Interfaces (functional)

*<Define the interfaces between the software items>*

## External System Interfaces (functional)

*<Define the interfaces external to the software system.>*

## Functional Design Requirements

<Describe the functional requirements of the software items, the internal and external interfaces. Define functional and performance requirements for SOUP items.>

# System Physical Architecture

## System Physical Block Diagram

*<Define the physical architecture of the deployment of the software system>*

## Physical Architecture Description

*<Provide a block diagram for the physical architecture on which the software system will be deployed>*

## Physical Constraints and Dependencies

*<Identify physical constraints and dependencies, e.g. hardware, processor requirements etc.>*

## Internal System Interfaces (physical)

*<Identify the internal system interfaces depicted in the physical architecture diagram>*

## External System Interfaces (physical)

*<Identify the external system interfaces depicted in the physical architecture diagram>*

## Physical Requirements

*<Identify the physical/hardware requirements of the system on which the proper functioning of the software system depends>*

# Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Signature** | **Date** |
| **Software Engineer** |  |  |  |
| **Project Lead** |  |  |  |

# Document Change Control

|  |  |  |  |
| --- | --- | --- | --- |
| **Version umber** | **Date** | **Author(s)** | **Brief Description of Change** |
| <<###>> | <<###>> | <<###>> | <<###-###>> |