**Software Validation Plan**

**Model: iDOLPHIN (iDOLPHIN-S & iDOLPHIN-View)**

**Document No. : Q4-29-015(01) Rev. 02**

This document valid from the date of approval

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| **META BIOMED CO., LTD.** |

**Revision History**

|  |  |  |
| --- | --- | --- |
| **Revision No.** | **Revision history** | **Date** |
| 0 | Initial release, alpha-test | 2013.09.06 |
| 1 | Modified according to EN 62366, Class A | 2014.07.03 |
| 2 | According to Non-conformity, Modify Class B | 2016.02.19 |
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# Purpose

This document is the application specification document of Multi-Purpose Micro Endoscope for Software life cycle processing to IEC 62304: 2006.

This Software life cycle processing and mitigates risk caused by software problems associated with correct use and errors.

# Range

|  |  |  |
| --- | --- | --- |
| **Device** | **Description** | **Range** |
| Monitor | Image shot by device is diagnosed  through Monitor | Minimum  1280\*1024 resolution, 15 inch |
| Microprocessor |  | Minimum 3.3GHz Processor |
| Memory Device |  | Minimum 4GB RAM |
| Operating  System |  | Windows 7, 8 and 10 |
| Communications | Power supplying to device Data transferring to PC | USB 2.0, USB 3.0 |

# Definitions of Terms

|  |  |
| --- | --- |
| **Terms** | **Definition** |
| Auto Exposure | Automatically adjust exposure value according to distance between camera and object |
| Brightness | Adjust light and darkness |
| Control-Gain | Adjust brightness level (0~3) |
| Control-RGGB | Adjust Red, Green 1, Green 2, Blue value |
| Image Capture | Save the image as .jpeg format |
| Rotate | Rotate displayed image on the screen |
| Rotate-Reverse | Reverse displayed image on the screen |
| Video Recording | Save the video as .avi format |

# Project Overview

Micro Endoscope with Catheter for diagnosing the cause of pain within the patient’s lower spine and delivering saline solution, Anti-inflammatory drugs or anti-adhesion liquid to the inflamed nerve root or the point of pain during for Epidural endoscopy.

# Software Development Process

## Project reference

* + 1. Risk Management Plan
    2. Risk Management Report
    3. FMEA Software Validation
    4. TRF Document Software Validation

## Standard and Regulatory References

* + 1. Regulatory Standards & Guidances

1. FDA Quality System Regulation 21 CFR, Part 820
2. CDRH Guidance: General Principles of Software Validation
   * 1. Industry Standards & Guidances
3. ISO 13485: 2003, Quality management system
4. IEEE std 1012-1986, Standard for Software Verification and Validation
   * + 1. Plans
5. IEEE std 829-1983, Standard for Software Test Documentation
6. EN 60601-1-4[1996]: Programmable electrical medical systems

## Standard and Regulatory References

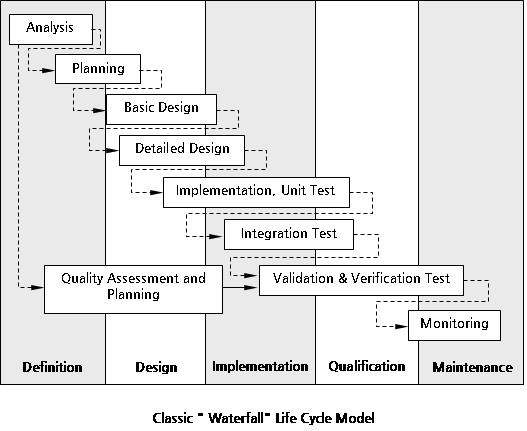
To aid the development process, task lists showing specific deliverables, by phase, are used as a form of guidance. A typical list is shown in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Phase**  **Group** | **Definition** | **Design** | **Implementation** | **Qualification** | **Maintenance** |
| System  Architecture | *Requirement*  *Specifications* | *Architecture Specification*  *System Design Specification*  *Design Reviews* |  | Test Support | Support |
| Software |  | *SW Requirements and Spec.*  *Software Design and Spec.*  *Design Reviews* | *Completed Software*  *Build Environment*  *Code Reviews & Inspections*  *Test Requirements Specification*  *Updated Software Design Specs* | Test Support | Support |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Design  Assurance | Preliminary Schedule  Independent V & V | Source Code Analysis  Problem Analysis  Hazard Analysis  Independent V & V | Additional test cases  Automated tests  Independent V & V | Execution of Tests  V & V Documentation  V & V Report  Internal Audit Report  Product & Test Certification | Support |
| Technical  Publications | Documentation  Support Plan | Documentation Design | Completed user and service  documentation | Documentation reviews | Support |

## Development Life Cycle Procedure

Software development process at ABC. Follows a classic waterfall methodology, as illustrated in the following char**t.**



**Analysis:** The activity consists of establishing requirements for as much as possible before the design phase. The requirements are documented in the software-specific requirements and design notes. When enough of the requirements are gathered and analyzed for this iteration of the prototype, the activities shift into the design phase.

**Planning:** This activity constructs the software development plan. This plan outlines the tasks, responsibilities, resources, and other items pertinent to the specific development project.

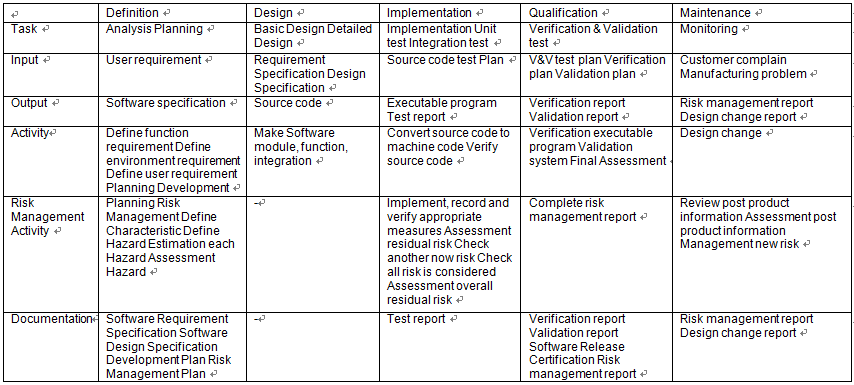
**Design:** This activity considers four functional attributes of the software: data structure, software architecture, functionality, and interface characterization. The design is documented in design documents.

**Implementation:** The implementation phase converts the design into a machine readable form. The software source code is created in accordance with META BIOMED CO., LTD. coding conventions. To verify that the code created is consistent with META BIOMED CO., LTD. standards, design reviews/inspections are held.

**Qualification:** The qualification phase verifies that the design and code implemented meet the requirements. Testing ensures that defined input will produce actual results that agree with required results.

**Maintenance:** Once the software enters a released state, the only software changes allowed are to fix identified defects in the code or to support approved enhancements.

* + 1. Description of Development Life Cycle



# Software Documents

Software Document will be created by Section 5 Software Development Process. Also comes the Project reference in the document, please see 5.1.

IEC 62034: 2006 will be to organize documents by topics presented.

|  |  |
| --- | --- |
| No | Contents |
|
| 1 | Level of Concern |
| 2 | Software description |
| 3 | RISK MANAGEMENT |
| 4 | Software Requirements Specification |
| 5 | Architecture Design Chart |
| 6 | Software Design Specification (SDS) |
| 7 | Traceability |
| 8 | Software development Environment Description |
| 9 | Verification and Validation Documentation |
| 10 | Revision Level History |
| 11 | Unsolved Bugs |
| 12 | Release Version Number |
| 13 | IEC 62304 Checklist : (TRF Report) |
| 14 | Appendix |

[Table1. Contents]

# Work Breakdown Structure

## Software

* + 1. Program Language

Editor: MS visual studio

Debugger: MS visual studio

C compiler: MS visual studio Compiler

Assembler: MS visual studio

Linker: MS visual studio

* + 1. Program size

Main UI & sequence: 80 MB

## Firmware

* + 1. Program Language

Editor: Xilinx

* + 1. Program Language

Main UI & sequence: .Net Framework

# Resource Management Plan

* + 1. Management Members

Jung Hyun Woo, Researcher of R&D Team

* + 1. Hazard Analysis Team: Members, Roles and Responsibilities

Jung Hyun Woo, Researcher of R&D Team

* + 1. V & V Testing Team: Members, Roles and Responsibilities

Oh Jae Hong, Senior researcher of R&D Team

* + 1. Documentation Review: Members, Roles and Responsibilities

Oh Jae Hong, Senior researcher of R&D Team

* + 1. Team Members/Qualifications

General Qualifications/Requirements as described in each individual’s

# Project Schedule

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **2012** | | | | | | | | **2013** | | | | |
|  | **06** | **07** | **08** | **09** | **10** | **11** | **12** | **01** | | **02** | **03** | **04** | **05** |
| **Analysis** |  |  |  |  |  |  |  |  | |  |  |  |  |
| **Planning** |  |  |  |  |  |  |  |  | |  |  |  |  |
| **Basic Design** |  |  |  |  |  |  |  |  | |  |  |  |  |
| **Detailed Design** |  |  |  |  |  |  |  |  | |  |  |  |  |
| **Implementation** |  |  |  |  |  |  |  |  | |  |  |  |  |
| **Integration** |  |  |  |  |  |  |  |  | |  |  |  |  |
| **V&V** |  |  |  |  |  |  |  |  | |  |  |  |  |

# Project Deliverables

To ensure the stability of the products through the CE certification. Therefore, this project will be completed.

# Risk Management Plan

Using the Risk Table below will be derived Risk.

Classification chart for the acceptance of risks

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Class A** | **Class B** | **Class C** | | |
| **Negligible(1)** | **Minor(2)** | **Serious(3)** | **Critical(4)** | **Catastrophic(5)** |
| **Frequent(5)** |  |  |  |  |  |
| **Probable(4)** |  |  |  |  |  |
| **Occasional(3)** |  |  |  |  |  |
| **Remote(2)** |  |  |  |  |  |
| **Improbable(1)** |  |  |  |  |  |

Risk Level: Severity x Probability

|  |  |
| --- | --- |
|  | Unacceptable risk |
|  | Acceptable risk |

Requirement in relation to the relationship derived through the Risk will create a Software Validation Report.  
  In related information, please see the Software Validation Report that is created later.

## Level of concern

**If the answer to any one question below is Yes, the Level of Concern for the Software**

**Device is likely to be Major.**

1. Does the Software Device qualify as Blood Establishment Computer Software? **No**

2. Is the Software Device intended to be used in combination with a drug or biologic? **No**

3. Is the Software Device an accessory to a medical device that has a Major Level of Concern? **No**

4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious

injury, either to a patient or to a user of the device? Examples of this include the following:

a. Does the Software Device control a life supporting or life sustaining function? **No**

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? **No**

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? **No**

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? **No**

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary? **No**

**If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.**

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern? **No**

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either

to a patient or to a user of the device? **Yes**

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

**Yes**

**If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is**

**Minor.**

The MANUFACTURER shall assign to each SOFT-WARE SYSTEM a software safety class (A, B,

or C) according to the possible effects on the patient, operator, or other people resulting from a

HAZARD to which the SOFTWARE SYSTEM can contribute.

The software safety classes shall initially be as-signed based on severity as follows:

|  |  |
| --- | --- |
| Class A | No injury or damage to health is possible |
| Class B | Non-SERIOUS INJURY is possible |
| Class C | Death or SERIOUS INJURY is possible |

Therefore, when you connect the class above-mentioned Major, Moderate and minor, it shows as

follows:

|  |  |
| --- | --- |
| Class A | Major |
| **Class B** | **Moderate** |
| Class C | Minor |

**Clssification char for the acceptance of risks**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Class A** | **Class B** | **Class C** | | |
| **Negligible(1)** | **Minor(2)** | **Serious(3)** | **Critical(4)** | **Catastrophic(5)** |
| **Frequent(5)** | 11 | 15 |  |  |  |
| **Probable(4)** |  |  |  |  |  |
| **Occasional(3)** |  |  |  |  |  |
| **Remote(2)** |  |  |  |  |  |
| **Improbable(1)** |  |  |  |  |  |

# Software Verification & Validation Plan

## Abbreviations and Symbols

ISO: International Organization for Standardization

SOP: Standard Operating Procedure,

QM: Abbreviation for Quality Manual Document

QR: Abbreviation for Quality Record

QWI: Abbreviation for Quality Work Instruction

SRS: Abbreviation for Software Requirements Specification

SVVP: Abbreviation for Software Verification and Validation Plan.

SVVR: Abbreviation for Software Verification and Validation Report.

## Definitions

In addition to an ordinary English-language meaning, each term listed in this section has a specific meaning applicable to the scope of this document.

Some of the terms are also defined in the ISO 13485 standard

* Acceptance Testing: Testing to determine if the software correctly implements hardware and software requirements in an operational environment.

Acceptance testing also challenges the adequacy of user documentation.

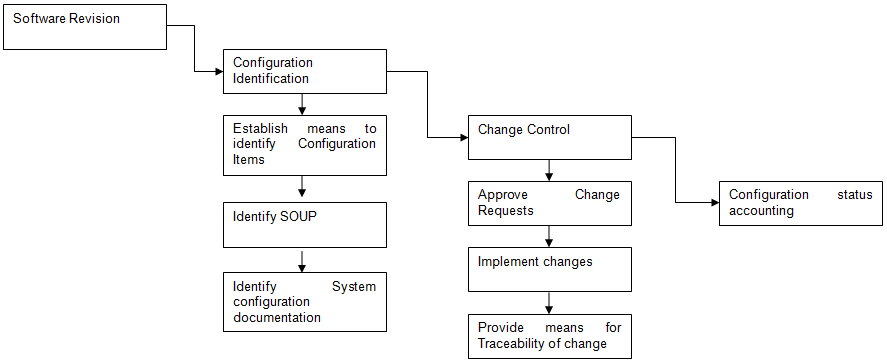
* Algorithm Analysis: Testing to determine that algorithms have been properly implemented according to the requirement and design specifications. Algorithm Analysis is performed using a variety of techniques including comparisons to measured data and hand computations.
* Performance of the product within its integrated system. Functional Testing methods focus on the functional requirements of the software as defined by the SRS, and include but are not limited to performance tests, interface tests, use case based tests, and design maturity tests.

Functional Testing approaches are used in Integration, System, Beta and Acceptance testing.

* Performance Tests: Functional tests intended to validate the System’s performance against prescribed industry standards and other performance requirements as specified in the SRS. Performance Tests are included in integration testing.
* System Testing: The process of testing an integrated hardware and software system in a production environment to verify that the system meets its specified requirements.
* Unit Testing: Testing conducted to verify the implementation of the design for a single element of software and/or hardware, or a collection of software and/or hardware elements. Employs the static and dynamic testing methodologies defined as “Structural Testing”.

# Software Configuration Management Plan

Software Configuration Management Life Cycle Procedure



# Software Quality Plan

**Software Quality Plan is the section set by the Development Life Cycle Procedure of 5.4.**