**SOFTWARE SYSTEM testing**

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

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

**Revision History**

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| **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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# Establish tests for software requirements

We will establish test including input, predicted result, pass/fail criteria etc. according to safety class classification of IEC 62304: 2006.

iDOLPHIN Viewer is Class B software, so development and testing conducted by Class B.

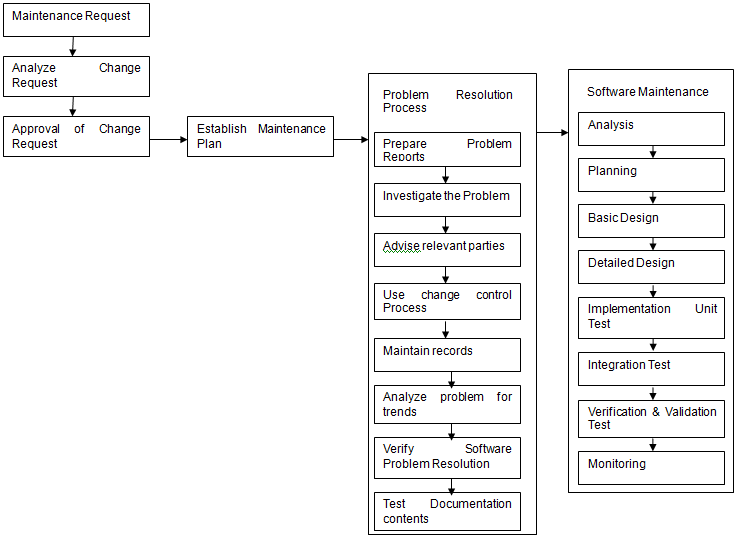
## Definition of Risk management

iDOLPHIN Viewer is the software to observe patient’s lesion through the camera.

The MANUFACTURER shall identify potential causes of the SOFTWARE ITEM contributing to a hazardous situation. [Class B, C] [Clause 7.1.2 of IEC 62304]

For detailed description, refer to ‘FMEA SW Validation’.

# Use software problem resolution PROCESS



This software resolve the problems of software like table above

본 소프트웨어는 위의 표와 같이 Software의 문제점을 해결 한다.

## Connect iDOLPHIN-View with PC (USP – 01)

Connect iDOLPHIN-View with PC or Laptop. And preparation to be supplied power and image is completed. But, if iDOLPHIN-View is not connected with PC, there is any other way to check connection status.

Viewer Box를 컴퓨터와 연결을 하게 된다. 연결됨으로써 전원 및 영상을 획득할 준비를 완료를 한다. 하지만, 문제가 발생시 연결이 되어있는지 안되어 있는지 확인 할 길이 없다.

## Connect iDOLPHIN-S with iDOLPHIN-View (USP – 02)

Connection status should be displayed when iDOLPHIN-View is connected with iDOLPHIN-S. Through this process, when a problem comes up, we will establish the cause of the problem.

View Box연결에도 확인 작업표시가 나와야 하지만, 카메라 연결 또한 문제가 있는지 확인을 해야 한다. 이 것을 통하여 장비에 문제가 있는지, 카메라에 문제가 있는지 확인이 필요하다고 판단이 된다.

## Save video (USP – 03)

As existing video format is .avi, user should be install separate program. For this point, we should change the video format.

## Display version (USP-03)

Existing program don’t display version. We thought it is needed to display software version.

# Retest after changes

## Connect iDOLPHIN-View with PC (USP – 01)



Connection status is displayed at the left upper end of the program. If iDOLPHIN-View isn’t connected with PC, the status display ‘No Device’. According to this display, user can check the connection status.

## Connect iDOLPHIN-S with iDOLPHIN-View (USP – 02)



Connection status is displayed at the left upper end of the program. If iDOLPHIN-View isn’t connected with iDOLPHIN-S, the status display ‘No Signal’. According to this display, user can check the connection status.

## Save video (USP – 03)



Video file format is .avi format. Thus, user can easily execute video.

## Display Version (USP-04)



Version is displayed at the left upper end of the program.

Software version will be managed consistently.

# Software System Test Verification

Test verification is refer to Software Integration and Integration testing [Q4-29-015(06)].

# Traceability

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| --- | --- | --- | --- |
| **Potential hazard** | **Design requirements** | **Design specification** | **Test/Objective** |
| HZ-01 | RH-01 / RS-03, 04 | SDS-M01, 02, 03, 05 | CR-M01, D05  MR-I01 |
| HZ-02 | RH-02 / RS-03, 04 | SDS-D02 | CR-M06  MR-I02 |
| HZ-03 | RH-03 / RS-01, 02 | SDS-D01 | CR-M02, 12, 13 |
| HZ-04 | RH-04 | SDS-D02 | CR-M07, 08 / D04 |
| HZ-05 | RH-05 | SDS-M04 / SDS-E01 | CR-E01, 02 |
| HZ-06 | RH-06 | SDS-E02 | CR-E03 |
| HZ-07 | RH-07 | SDS-E01 | CR-D03 |
| HZ-08 | RH-08 | SDS-S01 | CR-S01 |
| HZ-09 | RH-09 | SDS-S02 | CR-S02 |
| HZ-10 | RH-10 / RP-01, 03 | SDS-C01 | CR-M03, C01  MR-U01 |
| HZ-11 | RH-11 / RP-01, 03 | SDS-C02 | CR-M04, C02  MR-U02 |
| HZ-12 | RH-12 / RP-01, 03 | SDS-C03 | CR-C03 |
| HZ-13 | RH-13 / RP-01, 03 | SDS-C04 | CR-C04 |
| HZ-14 | RH-14 / RP-01, 03 | SDS-C05 | CR-C05, 06 |
| HZ-15 | RH-15 /RP-01,03 | SDS-C06 | CR-C07 |
| HZ-16 | RP-02 / RS-05 | SDS-M01 / SDS-D01 | CR-D01, 02 |
| HZ-17 | RI-01 / RI-02 | SDS-X01 | CR-X01 / MR-E01 |
| HZ-18 | RI-03 | SDS-X01 | CR-X01 / MR-E01 |
| HZ-19 | RI-04 | SDS-X01 | CR-X01 / MR-E01 |
| HZ-20 | RI-05 | SDS-X01 | CR-X01 / MR-E01 |
| HZ-21 | RS-06 | SDS-T02, 03 | CR-M05 / T02, 03  MR-I03 |
| HZ-22 | RS-07 /RP-04 | SDS-T01 | CR-T01 |
| HZ-23 | RS-08 | SDS-SW01, 08 | CR-SW01, 08  MR-U03 |
| HZ-24 | RS-09 | SDS-HW01  / SDS-SW02, 03, 04, 05, 06, 07 | CR-M09, 10, 11, / HW01 / SW02, 03, 04, 05, 06, 07  MR-I04, 05 / P01, 02, 03 |
| HZ-25 | RS-10 | SDS-SW09 | CR-SW09  MR-U02 |
| HZ-26 | RH-16 | SDS-C07 / SDS-SW10 | CR-C08 / SW10 |