**SOFTWARE SYSTEM testing**

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

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**Revision History**

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| 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.

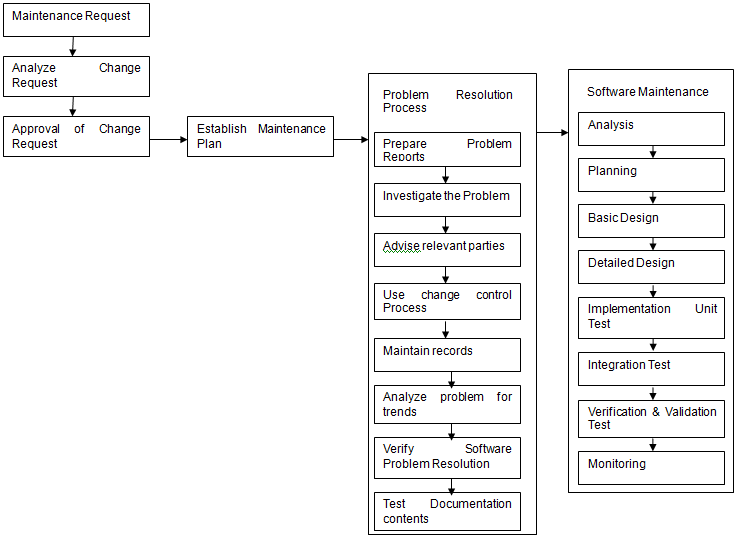
## Definition of Risk management

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)].