URN etd-0407109-183712-993
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Statistics This thesis had been viewed 76 times. Download 0 times.
Department
Year 2007
Semester 1
Degree Master
Type of Document Master's Thesis
Language zh-TW.Big5 Chinese
Title The Verification and Validation of Software Contained in the Medical Devices: The Example of Cephalometric Analysis System
Date of Defense 0000-00-00
Page Count 87
Keyword
Software Verification and Validation
V- model
FTA

Abstract
The failures of medical device might cause hazard to patients or operators. So, the software contained in a medical device should be verified and validated to insure the safety and the quality. Software engineering practices, risk analysis and management, and configuration management should be integrated in the study of software verification and validation (SV&V). Those approaches are acceptable by the FDA for the SV&V. In this work, the V-model was introduced in the software development process for the quality management of software development. The fault tree analysis (FTA) techniques were applied in the procedure of risk analysis and management for the SV&V. All of the procedures should be integrated in the so called “configuration management”. The procedures of SV&V for the developing “Cephalometric Analysis system” (CEPH) and its related works, such as software developed model, requirements specification, design specification, software test, SV&V and risk managements are also presented in the study. Finally, the documents developed in this study are hoped that to be agreeable with FDA’s conditions for the content of premarket submissions of software contained in a medical device.
Advisory Committee Pei-Jarn Chen - advisor

Files No Any Full Text File.
Date of Submission 2008-08-14