



EPIC ClearView Product Requirements Trace Matrix - Software

ORIGINATOR:

Name	Job Title	Signature	Date
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APPROVALS:

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REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	03Apr12	Initial Release	S. Pletzer



EPIC ClearView Product Requirements Trace Matrix - Software

Software (SR)					
Ref. #	Requirement	Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)
SR-1	System instructions for use will provide all necessary instructions for a qualified professional to operate the software.	Software instructions for use	IFU	Documentation System Policy, QA-005	EPIC ClearView IFU, CS-100
SR-2	User interface(s) should display information in an easily readable and easily understood manner by the user.	Interface and graphic requirements standards as defined by industry practices	EPIC ClearView Software Description, SD-001 EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Software Specifications: SS-001, SS-202, SS-203, SS-204, SS-205 Device Design Verification and Validation Software Validations: <ul style="list-style-type: none">• Application Functions ClearView Software Solution Validation Report, ENG-009• Camera Functions ClearView Software Solution Validation Report, ENG-010• Capture Functions ClearView Software Solution Validation Report, ENG-011• Patient Demographics Functions ClearView Software Solution Validation Report, ENG-012• Users Functions ClearView Software Validation Report,	EPIC ClearView System Performance Reports: <ul style="list-style-type: none">• GBMC Clinical Trial, ENG-018• DV-001 Clinical Trial, ENG-019• DV-002 Clinical Trial, ENG-020• EPIC-003 Clinical Trial, ENG-021	EPIC ClearView System Performance Reports: <ul style="list-style-type: none">• GBMC Clinical Trial, ENG-018• DV-001 Clinical Trial, ENG-019• DV-002 Clinical Trial, ENG-020• EPIC-003 Clinical Trial, ENG-021



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Software (SR)		Design Inputs (Specification)		Verification Methodology		Design Outputs (Verification)		Validation Results		Status
Ref. #	Requirement	Source of Requirement								
SR-3	System software places a centered ellipse on the energized image in the correct orientation with option for a user to modify the orientation.	Established by electrophotography techniques	EPIC ClearView Software Description, Code, and Specifications Documents	Device Design Verification and Validation Code Branching Procedure, IT-003	EPIC ClearView Software Description, SD-001 Code Branching Procedure, IT-003	EPIC ClearView Software Description, SD-001 EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Capture Functions Specifications, SS-202 Capture Functions Validation Report, ENG-011	EPIC ClearView Software Description, SD-001 EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Capture Functions Specifications, SS-202 Capture Functions Validation Report, ENG-011	EPIC ClearView IFU, CS-100	EPIC ClearView IFU, CS-100	
SR-4	Capture, display and store a finger image and energized finger image for use in energized image orientation.	Established by electrophotography techniques	EPIC ClearView Software Description, Code, and Specifications Documents	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	EPIC ClearView Software Description, SD-001 EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Capture Functions Specifications, SS-202 Capture Functions Validation Report, ENG-011	EPIC ClearView Software Description, SD-001 EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Capture Functions Specifications, SS-202 Capture Functions Validation Report, ENG-011	EPIC ClearView Software Description, SD-001 EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Capture Functions Specifications, SS-202 Capture Functions Validation Report, ENG-011	EPIC ClearView IFU, CS-100	EPIC ClearView IFU, CS-100	



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Ref. #	Requirement	Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)
					Validation Results
SR-5	Images analyzed to provide a response scale and report easily understood by the physician.	Established software requirements by company founder	EPIC ClearView Software Description and Code Documents	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Response Scale Calculation Verification Report, ENG-026 Analysis Functions Specifications, SS-203 Algorithm Development
SR-6	Image capture will be reasonably efficient and timely, and allow the user to recapture the image prior to analysis.	Internal requirements by company founder Potential customer feedback	IFU EPIC ClearView Software Description and Code Documents	Documentation System Policy, QA-005 Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	EPIC ClearView IFU, CS-100 EPIC ClearView Software Description, SD-001 EPIC ClearView Software Code, (Perforce Controlled – “ClearView”) Capture Functions Validation Report, ENG-011
SR-7	Software should prevent all but key designated settings from being accessed.	Internal requirements by company founder	IFU and System Description Documents	Documentation System Policy, QA-005	EPIC ClearView IFU, CS-100 EPIC ClearView System Description, SD-003



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Software (SR)					
Ref. #	Requirement	Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)
		EPIC ClearView Software Description and Code Documents	Device Design Verification and Validation	Code Branching Standard Operating Procedure, IT-003	Application Functions ClearView Software Solution Validation Report, ENG-009 Camera Functions ClearView Software Solution Validation Report, ENG-010 Capture Functions ClearView Software Solution Validation Report, ENG-011 Users Functions ClearView Software Validation Report, ENG-013
SR-8	Camera must be able to be controlled through the software for all settings pertaining to image quality.	Internal requirements by company founder	Device Design Verification and Validation	Code Branching Standard Operating Procedure, IT-003	EPIC ClearView Software Solution Calibration Testing Report, ENG-006 EPIC ClearView Software Solution Calibration Testing Modification Report, ENG-007 Software Specifications Camera Functions, SS-204 Application Functions, SS-205 Application Functions ClearView Software Solution Validation Report, ENG-009 Camera Functions ClearView Software Solution Validation Report, ENG-010



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Software (SR)		Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)	Validation Results	Status
Ref. #	Requirement						
SR-9	The database engine used will be Microsoft SQL Server current qualified version.	Internal requirements by company founder	Software Specifications Documents	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Software Specifications: SS-001, SS-202, SS-203, SS-204, SS-205		
SR-10	The ability to perform matrix math as well as standard integral calculations will be required in this application.	Internal design requirements by company founder, algorithms internally developed to go from the image to the score.	EPIC ClearView Analysis Requirements Document	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Analysis Functions Specifications, SS-203 Report Functions ClearView Software Solution Validation Report, ENG-014	GBMC Development Data – Algorithm Development Report, ENG-025	GBMC Development Data – Algorithm Development Report Not Completed
SR-11	The business logic contained in the stored procedures must not be accessible to the users of the system.	Internal design requirement by company founder.	EPIC ClearView Software Code, (Perforce Controlled- ("ClearView"))	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Software Specifications: SS-001, SS-202, SS-203, SS-204, SS-205		
SR-12	A report of Response Scale values provided in the software viewable on the screen and printable in a hard copy report.	Internal design requirement by company founder.	Response Scale Report	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Report Functions ClearView Software Solution Validation Report, ENG-014		
SR-13	The ability to create, update and search for patients.	Internal design requirement by company founder.	Patient Demographics Functions Requirements, SR-001	Device Design Verification and Validation Code Branching Standard Operating	Patient Demographics Functions Validation Report, ENG-012		



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Ref. #	Requirement	Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)
					Validation Results
SR-14	Search for captures using established criteria and display capture search results.	Internal design requirement by company founder.	Capture Functions Requirements, SR-202	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Capture Functions Validation Report, ENG-011
SR-15	Export subject data including calibration images, finger images, energized images, raw data and report data using established folder directory structure by EPIC administrators.	Internal design requirement by company founder.	Camera Functions Requirements, SR-204 Capture Functions Requirements, SR-202 Analysis Functions Requirements, SR-203	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Camera Functions Validation Report, ENG-010 Capture Functions Validation Report, ENG-011 Report Functions Validation Report, ENG-014
SR-16	Scan data can be rerun through the system algorithm by EPIC administrators.	Internal design requirement by company founder.	Capture Functions Requirements, SR-202 Analysis Functions Requirements, SR-203	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Capture Functions Validation Report, ENG-011 Report Functions Validation Report, ENG-014
SR-17	Software should interface with a remote service for data synchronization and management.	Business operations	EPIC Central Requirements, SR-002	Device Design Verification and Validation Code Branching Standard Operating Procedure, IT-003	Synchronization Testing Report EPIC Central Description, SD-002 EPIC Central Specifications, SS-002
SR-18	Software will have pre-defined user roles which define	Security/marketing	IFU	Documentation System Policy, QA-005	EPIC ClearView IFU, CS-100



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Software (SR)					
Ref. #	Requirement	Source of Requirement	Design Inputs (Specification)	Verification Methodology	Design Outputs (Verification Results)
	specific access rights for software functions within system.	Users Software Requirements Specifications	Code Branching Standard Operating Procedure, IT-003	Device Design Verification and Validation	Application Functions Specifications, SS-205 Users Functions ClearView Software Validation Report, ENG-013