



EPIC ClearView™ Software Failure Modes and Effects Analysis (FMEA) Form


Product/Project Name: EPIC ClearView™

Project Manager: Scott Pletzer



FMEA Team: Scott Pletzer, Nancy Rizzo, Andrew Mason

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ORIGINATOR:

Name	Job Title	Signature	Date
Scott Pletzer	Director of Quality & Program Management		18 JUL 12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		7/18/12
Andrew Mason	Chief Technology Officer		7/18/12



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REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	03Apr12	Initial Release	S. Pletzer
001	18Jul12	Updated detection rating and RPN for SR-6 due to improvements from EPIC ClearView 2.0.	S. Pletzer



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ID	Part Name and Part Number	Process/ Product Function	Potential Failure Modes	Potential Effects of Failure	Severity	Potential Causes of Failure	Occurrence	Current Controls	Detection	RPN	Comments
SR-1	EPIC ClearView™ Software	System instructions for use will provide all necessary instructions for a qualified professional to operate the software.	User doesn't read or misreads instructions	User is unable to properly operate system	3	Not following instructions listed in the IFU	1	IFU (CS-100) and on-site user training	1	3	
SR-2		User interface(s) should display information in an easily readable and easily understood manner by the user.	No information or incorrect information is displayed	Inappropriate results disseminated to user	5	Software bug	1	IFU (CS-100) and on-site user training	3	15	
						User input error	1		3	15	
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.	Ellipse is not drawn in the proper location	Incorrect calculation results	5	Not enough information for algorithm to properly determine orientation	1	IFU (CS-100), on-site user training, and software specifications	3	15	
			User changes the angle of orientation to an incorrect value								
SR-4		Capture, display and store a finger image and energized finger image for use in energized image orientation.	Finger image is not captured	Image angle is potentially less accurate	3	Software bug	1	IFU (CS-100), on-site user training, and algorithm specifications	3	9	
						Incorrect placement of finger image	2		5	30	
SR-5		Images analyzed to provide a response scale and report easily understood by the physician.	Report not easily understood by the physician	Physician gleans incorrect information	5	Not following instructions listed in the IFU	1	IFU (CS-100) and on-site user training	5	25	
SR-6	Image capture will be reasonably efficient and	System takes excessive time to	User inconvenience	3	Incorrect system specifications	2	Algorithm specifications	4	24		



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		timely, and allow the user to recapture the image prior to analysis.	calculate								
			User fails to recapture an incorrect image	Incorrect information is generated	5	Not following instructions listed in the IFU	1	IFU (CS-100), on-site user training, and software specifications	4	20	
SR-7		Software should prevent all but key designated settings from being accessed.	A key setting gets changed	Incorrect calculation results	5	User changes settings through unconventional means	1	User credentials, separate authentication mechanisms	4	20	
SR-8		Camera must be able to be controlled through the software for all settings pertaining to image quality.	Camera settings cannot be properly set	Incorrect calculation results	5	Installation procedure not followed	1	Installation procedures	1	5	
			Camera doesn't recognize settings			Defective camera	2	Acceptance testing	1	10	
SR-9		The database engine used will be Microsoft SQL Server current qualified version.	Wrong database engine or version installed	Inability to store data	5	Installation procedure not followed	1	Installation procedures	1	5	
SR-10		The ability to perform matrix math as well as standard integral calculations will be required in this application.	Calculations are not performed or performed incorrectly	No or incorrect calculation results	5	Incorrect version of mathematical engine installed	1	Installation procedures, design specification, acceptance testing	2	10	
SR-11		The business logic contained in the stored procedures must not be accessible to the users of	Intellectual property is exposed	Severe business impact	1	Stored procedures were not encrypted	1	Installation procedures	1	1	



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		the system.									
SR-12		A report of Response Scale values provided in the software viewable on the screen and printable in a hard copy report.	Report doesn't appear after calculations	Calculation error	5	Unexpected data	2	Software specifications and acceptance testing	2	20	
				Installation error	5	Improper installation or corruption of necessary components	2	Installation procedures and acceptance testing	2	20	
SR-13		The ability to create, update and search for patients.	Inability to create, update, and search for patients	Inability to perform a scan	5	Software bug	1	Software specifications and acceptance testing	1	5	
SR-14		Search for captures using established criteria and display capture search results.	Inability to view data	Inability to view a scan	5	Software bug	1	Software specifications and acceptance testing	1	5	
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.	Data cannot be exported	Inability to export data to a file	3	Software bug	1	Installation procedures and acceptance testing	2	6	
						Installation procedure not followed	1		2	6	
SR-16		Scan data can be rerun through the system algorithm by EPIC administrators.	Inability to rerun scanned data	New report cannot be produced with existing data	3	User doesn't have permission to run resubmitting	1	Acceptance testing, administrative privileges	3	9	



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SR-17		Software should interface with a remote service for data synchronization and management.	Inability to connect to server	Inability to synchronization data	5	Lack of Internet access	1	Acceptance testing, internal software checks	1	5	
						EPIC site not available	1		1	5	
SR-18		Software will have pre-defined user roles which define specific access rights for software functions within system.	User IDs or passwords are lost or incorrect	Inability to use software	5	User error	1	Installation procedures, EPIC support	1	5	



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Required Mitigation

Use this table to record actions taken upon determination of an unacceptable severity ranking, detection ranking, and/or RPN calculation. The ID referenced here should match the ID and the potential causes of failure identification from the table above.

		Recalculations						
ID	Actions Taken	Severity	Occurrence	Detection	RPN	Rationale	New Controls	Comments
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A