



## EPIC ClearView™ Design 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		03APR12

**APPROVALS:**

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		4/3/12
Andrew Mason	Chief Technology Officer		4/3/12

**REVISION HISTORY**

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	03Apr12	Initial Release	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
1	Alcohol swabs	Cleaning the glass electrode on the device	Fails to clean electrode properly	Improper image generated	5	Alcohol is not correct	3	Component specification, IFU (CS-100), and on-site user training	3	45	
2	Calibration probe	Generates calibration image	Device fails to pass calibration	Inability to use device	5	Probe made from wrong material Probe manufactured improperly	1 2	Component specification, IFU (CS-100), and on-site user training	3 3	15 30	
3	Calibration probe cable	Grounds calibration probe to device	Improper or no calibration image generated	Inability for device to pass calibration	5	Cord does not securely fasten to probe Cord does not securely fasten to device	3 3	Component specification, IFU (CS-100), and on-site user training	3 3	45 45	
4	Calibration probe shroud	Securely holds calibration probe in place to generate calibration image	Ambient light passes through shroud Probe not placed in proper position	Incorrect calibration image generated	5	Incorrect dimensions	3	Component specification, IFU (CS-100), and on-site user training	2	30	
5	Capacitive barriers	Eliminate effects of moisture on the finger from affecting the image	Moisture effects image quality	Incorrect image generated	5	Improper material Improper dimensions	3 3	Component specification, IFU (CS-100), and on-site user training	5 5	75 75	
6	Cleaning cloths	Cleaning the glass electrode on the device	Fails to clean electrode properly	Improper image generated	5	Improper material	3	Component specification, IFU (CS-100), and on-site user training	3	45	



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7	Computer tower with EPIC ClearView software	Generate report output based on images captured	Computer cannot communicate with device	No image can be generated	5	Faulty USB cable	4	Acceptance testing, component specification, IFU (CS-100), and on-site user training	3	60	
						Improper communication drivers loaded	2		1	10	
						Faulty communication board on device	1		2	10	
8	Electrode cover	Covers glass electrode to block ambient light	Allows ambient light to reach glass electrode	Improper image generation	5	Improper dimensions	3	Component specification, IFU (CS-100), and on-site user training	3	45	
						Improper material	3		3	45	
						Communications problem	3		2	30	
9	EPIC ClearView device	Scan images	Images improperly or not scanned	Inability to produce results	5	Device unable to power up	1	Acceptance testing, component specification, IFU (CS-100), and on-site user training	1	5	
						Malfunctioning device components	1		2	10	
						Improper dimensions	3		3	45	
10	Finger shroud	Block ambient light when finger is being scanned	Allows ambient light to reach glass electrode	Improper image generation	5	Improper material	3	Component specification, IFU (CS-100), and on-site user training	3	45	
11	Instructions for use	Communicate to users how to properly use the device	Information is inaccurate	Inability for system to scan a proper image	5	Inadequate content of IFU	2	Component specification and on-site user training	2	20	
12	Keyboard & mouse	Gains proper access to device	Mouse and/or keyboard with improper specification	Prevents use of device	5	Improper system component specifications	1	Component specification, IFU (CS-100), and on-site user training	1	5	



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13	Monitor	Visual interface to scanner	Does not properly display visual information	Prevents proper use of device	5	Improper system component specifications	1	Component specification, IFU (CS-100), and on-site user training	1	5	
14	Power cord	Supplies 120 volt A/C power to device	Improper connection to voltage source	No or improper power supplied to device	5	Improper system component specifications	1	Component specification, IFU (CS-100), and on-site user training	1	5	
15	Printer	Provides hard copy of scanning results	Improper or no scanning results produced	Cannot complete the procedure	3	Improper system component specifications	1	Component specification, IFU (CS-100), and on-site user training	1	3	
16	Uninterruptible power supply	Regulates input voltage to the device	Device sees improper voltage	Renders device inoperable	5	Improper system component specifications	3	Component specification, IFU (CS-100), and on-site user training	5	75	
		Provides backup power to device	Does not provide backup power to device	Scanning process cannot be finished	5		3		2	30	
17	USB external cable	Connects the computer to the scanner for communication	Does not properly link computer and scanner	Cannot complete the procedure	5	Improper system component specifications	3	Component specification, IFU (CS-100), and on-site user training	4	60	
18	USB hardware key	Add additional security to system to prevent unauthorized access	User cannot run software	Cannot use the device	5	Improper system component specifications	1	Component specification, IFU (CS-100), and on-site user training	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.

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