



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

Date Performed: 02 April 2012

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



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

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	1	Component specification, IFU (CS-100), and on-site user training	3	15	
3	Calibration probe cable	Grounds calibration probe to device	Improper or no calibration image generated	Inability for device to pass calibration	5	Probe manufactured improperly	2	Cord does not securely fasten to probe	3	30	
4	Calibration probe shroud	Securely holds calibration probe in place to generate calibration image	Ambient light passes through shroud	Incorrect calibration image generated	5	Component specification, IFU (CS-100), and on-site user training	3	Component specification, IFU (CS-100), and on-site user training	3	45	
5	Capacitive barriers	Eliminate effects of moisture on the finger from affecting the image	Moisture effects image quality	Incorrect image generated	5	Probe not placed in proper position	5	Component specification, IFU (CS-100), and on-site user training	5	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	



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

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
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 Improper communication drivers loaded Faulty communication board on device	4	Acceptance testing, component specification, IFU (CS-100), and on-site user training	3	60	
8	Electrode cover	Covers glass electrode to block ambient light	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	
9	EPIC ClearView device	Scan images	Images improperly or not scanned	Inability to produce results	5	Communications problem Device unable to power up Malfunctioning device components	3	Acceptance testing, component specification, IFU (CS-100), and on-site user training	2	30	
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	

EPIC ClearView™ Design Failure Modes and Effects Analysis (FMEA) Form						
RESEARCH		EPIC DIAGNOSTICS				
ID	Part Name and Part Number	Process/ Product Function	Potential Failure Modes	Potential Effects of Failure	Severity	Potential Causes of Failure
13	Monitor	Visual interface to scanner	Does not properly display visual information	Prevents proper use of device	5	Improper system component specifications
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
15	Printer	Provides hard copy of scanning results	Improper or no scanning results produced	Cannot complete the procedure	3	Improper system component specifications
16	Uninterruptible power supply	Regulates input voltage to the device	Device sees improper voltage	Renders device inoperable	5	Improper system component specifications
17	USB external cable	Provides backup power to device	Does not provide backup power to device	Scanning process cannot be finished	5	Improper system component specifications
18	USB hardware key	Connects the computer to the scanner for communication	Does not properly link computer and scanner	Cannot complete the procedure	5	Improper system component specifications
		Add additional security to system to prevent unauthorized access	User cannot run software	Cannot use the device	5	Improper system component specifications



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

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