EPIC ClearView™ System/Clinical 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: 16 March 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

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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		Cleaning of the device	Incorrect Image	Film or haze on the picture	5	Improper cleaning or no cleaning materials/methods	4	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	1	20	None
2			Unusable	Image is distorted	5	Saturated the electrode with liquid	1	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	1	5	None
3	EPIC ClearView System	Calibration of the device	Improper seating of the calibration probe	Fail calibration through the software system	5	Not following instructions listed in the IFU	2	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	1	10	None
4		Scanning of the Patient	Improper Image	Wrong Information will be calculated	5	Placement of Finger on the Scanner	5	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	5	125	None
5			Improper Image	Wrong Information will be calculated	5	Wrong Finger placed on the scanner	5	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing	5	125	None

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
6			Ambient Light	Incorrect Image or wrong information will be calculated	5	Finger Shroud is not placed correctly on the scanner	5	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	4	100	None
7			Invalid Image	Incorrect Image or wrong information will be calculated	5	Compasitive Barrier is not placed in 2nd set of images	1	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	4	20	None
8				Incorrect Image or wrong information will be calculated	5	Compasitive Barrier is wrinkled	3	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	4	60	None
9			Tingling of the Fingertip	The scan has to be repeated.	5	Not enough pressure placed onto the scanner	1	IFU (CS-100), EPIC ClearView™ System Verification & Validation Testing (ENG-017) and on-site user training	5	25	None

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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