ORIGINATOR:

Name	Job Title	Signature	Date
Dan Miller	Manufacturing Engineer	Dan Miller	3/22/13

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO	N Rizzo	3/22/13
Lloyd Kurth	Technology Director	Lloyd N. Kurth	3/22/13
Andrea Miller	Quality Assurance Director	Andrea Miller	3/22/13
Don Pegg	Design Engineering Consultant (PADT)		

EPIC™ RESEARCH DIAGNOSTICS	**Risk Management Plan ClearView System**

ORIGINATOR:

Name	Job Title	Signature	Date
Dan Miller	Manufacturing Engineer	Dan Miller	3/22/13

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO	N Rizzo	3/22/13
Lloyd Kurth	Technology Director	Lloyd N. Kurth	3/22/13
Andrea Miller	Quality Assurance Director	Andrea Miller	3/22/13
Don Pegg	Design Engineering Consultant (PADT)	Don Pegg	3/22/13

1.0 Purpose

The purpose of this document is to document the risk management requirements and activities for the EPIC ClearView™ System.

2.0 Scope

2.1. Device - EPIC ClearView is plasma imaging device. A complete product description is maintained in the Design & Development Plan (DDP) ClearView System.

2.2. Life Cycle - Life cycle of this device is from 'development through obsolescence'. Risk Analysis will be performed in accordance with the EG-001 and EG-012 during the development process and transfer to manufacturing. Post-production monitoring will be performed and documented in the Risk Management File. Annual audits will be performed and documented on the Risk Management File.

2.3. Risk Management File Documents - The Risk Management File will include but is not limited to the following documents:

- DD-005 Risk Management Plan
- DD-006 EPIC ClearView Risk Analysis Report
- DD-009 EPIC ClearView System FMEA
- DD-010 EPIC ClearView Software FMEA
- Post Production monitoring documents or reference to those documents
- Annual reviews, including any changes to the Risk Management Documents

3.0 Definitions

The definitions of ISO 14971:2007 apply to the risk management requirements and activities of the EPIC ClearView system.

4.0 Responsibilities

Responsibilities for development and approval of all risk analysis activities will be conducted in accordance to the responsibilities outlined in the Design & Development Plan (DDP) ClearView System.

5.0 Criteria for Acceptability of Risk

5.1. Risks will be evaluated in accordance with EG-012 Risk Management procedure which provides methods for assessing Effects of Failure, Severity, Probability of Occurrence, Probability of Detection, and Risk Priority Number (RPN).

5.2. Acceptable Risk per RPN for EPIC ClearView is 216 as specified in EG-012.

5.3. Any RPNs above this value or any severity or detection ratings above six (6) require additional mitigation to reduce their rating as specified in EG-012.

6.0 Requirements for Review of Risk Management Activities

6.1. A Failure Mode and Effects Analysis will be initiated during product design and updated as necessary during the development.

- Device characteristics that could impact on safety (reference Annex C in ISO 14971) will be identified in the Risk Analysis Report or via other means.
- The EPIC ClearView FMEA contains product and use hazards.
- FMEAs will be completed using system, software, and process perspectives. Separate FMEA documents may be created to address individual concerns related to each. Data on the FMEA Table includes:
  - Process/Item Function Process/Function Description
  - Potential Failure Modes (Identification of Hazards)
  - Potential Effect(s) of Failure & Estimation of Risk
  - Potential Causes(s) Mechanism(s) of Failure & Estimation of Risk
  - Current Controls & Estimation of Detection
  - RPN value (Risk Evaluation)
  - Recommended Action(s) if RPN exceeds acceptable limits – including Responsibility & Target Completion Date; Action Taken; Severity, Occurrence & Detection values and revised RPN.

Note: If RPN still exceeds acceptable limits, further action will be required.

6.2. The Risk Analysis Report or other applicable documents will identify whether or not the RPN numbers meet the values in the Risk Management Plan and EPIC's Risk Management procedure.

7.0 Verification Activities

If applicable, verification and validation testing in EG-001 Design Control Procedure will be cross referenced in the Current Controls and/or the Actions Taken columns of the FMEA table.

8.0 Approvals

8.1. Approvals of this plan are outlined in the Design & Development Plan (DDP) ClearView System.

8.2. The Risk Analysis Report will be reviewed and approved to ensure completeness and conformance to EG-012 Risk Management procedure and this Risk Management Plan. Approvals are outlined in the Design & Development Plan (DDP) ClearView System.

9.0 Location of Risk Management Files

9.1. The Risk Management Files are a part of the product design history file. Design History File management is specified in the Design Control Procedure. Design History Files are kept for the life of the product.

9.2. Reviews and updates to the Risk Management Files after product release will be done on an annual basis through the internal audit procedure and project review meetings.

9.3. Reviews and updates will be documented and approved and included with the applicable Risk Management File.

10.0 Reference Documents

DD-006	Risk Analysis Report
DD-009	EPIC ClearView System FMEA
DD-010	EPIC ClearView Software FMEA
DD-011	EPIC ClearView Process FMEA
DDP-001	Design & Development Plan (DDP) ClearView System
EG-001	Design Control Procedure
EG-012	Risk Management
ISO 14971:2007	Medical devices – Application of risk management to medical devices

11.0 Attachments

None

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	03Apr12	Initial Release	S. Pletzer
001	22Mar13	Update document to comply with EPIC's Risk Management procedure (EG-012) and current design history documentation.	D. Miller