APPROVALS:

Name	Job Title	Signature	Date
Scott Pletzer	Director of Quality & Program Management	*(signature)*	25OCT12
Andrew Mason	Chief Technology Officer	*(signature)*	10/25/12
Nancy Rizzo	Founder & CEO	*(signature)*	10/25/12 .
Dan Miller	Manufacturing Engineer	*(signature)*	10/25/12

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	23Oct12	Initial Release	A. Mason

1.0 PURPOSE

1.1 The purpose is to define the Design & Development Plan (DDP) for designing and coding the EPIC ClearView software version 2.1. This new release of ClearView is required because the Calibration routine used in ClearView is being updated to use a newer more encompassing algorithm. This DDP will provide a comprehensive view of the project to assist the design team in successful completion of each phase and activity.

1.2 This will ensure that all necessary activities are addressed including the method in which they will be conducted and all responsible parties involved therein.

2.0 SCOPE

2.1 The objective of this DDP is to outline the activities to be performed in order to identify, develop, and implement EPIC ClearView software version 2.1 to replace the current released version 2.0. Included in this document are the roles and responsibilities of individuals that are required to perform these activities.

2.2 The scope of this project is to fully document the implementation of the developed calibration routine into the ClearView software. Additional user requirements and software improvements will be included in this project.

2.3 Aspects of the design process included within this DDP are planning, design, coding, verification, validation, and release. Included in the plan are all individuals, resources, and facilities involved.

3.0 REFERENCE DOCUMENTS

3.1 Regulatory Documentation:

- FDA 21 CFR 820, Quality System Regulations (QSRs)

- ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

3.2 EG-001, Design Control Procedure

3.3 EG-010, Software Development

4.0 PROJECT REQUIREMENTS

4.1 The latest calibration routine from Geost, Inc. must be implemented.

4.2 The adjustable parameters for the calibration routine must be adjustable by the administrator or techadministrator logins only.

5.0 RESPONSIBILITIES

5.1 Chief Technical Officer – oversight of software development and implementation

5.2 Quality and Project Management Director – oversight of software verification and validation, and management of quality system requirements.

5.3 Manufacturing Engineer – independent technical reviewer for the project.

6.0 ORGANIZATION, INTERFACES, RESPONSIBILITES, AND APPROVAL AUTHORITY

6.1 All pertinent steps and documents, such as design control documents, design review, verification, and validation, must be approved in accordance with the requirements of EG-001, Design Control Procedure and EG-010, Software Development.

7.0 MAJOR TASKS (MILESTONES) & SCHEDULE

7.1 Project planning, requirements and specifications (October 2012)

7.2 Software Development (October 2012)

7.3 QA and Release (November 2012)

The above will be closely tracked as part of EPIC's regularly scheduled staff and process review meetings.

8.0 DESIGN VERIFICATION & VALIDATION APPROACH

8.1 Design verification and validation will be performed by testing all software functionality to the requirements. The final results of the verification and validation testing will be formalized through design verification and validation protocols to be written prior to performance of the testing and summarized into final reports which outline the results of all verification and validation testing. The general outlines of the steps taken are as follows:

8.1.1. Development of Verification and & Validation (V&V) test protocols

8.1.2. Execution of the V&V test protocols

8.1.3. Analysis and summary of V&V test results into final reports.

8.1.4. Review and approval of all documentation

9.0 RISK ANALYSIS

9.1 The existing risk analysis documentation associated with EPIC ClearView software will be reviewed and revised (if required) as part of this project.

10.0 PROJECT CONSTRAINTS

10.1 There are not any constraints at this time. Any additional constraints will be noted in a further revision of this plan.

11.0 DESIGN HISTORY FILE (DHF)

11.1 The outputs of this effort will be generated and added to the Design History File (DHF) in accordance with the requirements of EG-001, Design Control Procedure and EG-010, Software Development.