EPIC™ RESEARCH DIAGNOSTICS	Document Name: **Design & Development Plan (DDP) EPIC ClearView 2.0**

APPROVALS:

Name	Job Title	Signature	Date
Scott Pletzer	Director of Quality & Program Management		18Jul12
Andrew Mason	Chief Technology Officer		7/18/12
Nancy Rizzo	Founder & CEO		7/18/12

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	18Jul12	Initial Release	S. Pletzer

1.0 PURPOSE

1.1 The purpose is to define the Design & Development Plan (DDP) for designing and coding the EPIC ClearView software version 2.0. This new release of ClearView is required because the existing iteration of the product has a significant amount of unused (also referred to as dead) code that needs to be removed in order to improve maintainability. In addition there are over 120 database tables that are no longer used that must be removed. During this process some of the existing currently functional code may be refactored to improve efficiency. A new report interface will be introduced to display the analysis results in an easy to understand manner. 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 2.0 to replace the current released version 1.1.1.3. 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 algorithm 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 Remove all unused or minimally used database tables and stored procedures in the ClearView system.

4.2 Remove the Microsoft entity database framework and replace with ORM tool database access.

4.3 Comment remaining code, including purpose of function or method as well as argument descriptions and return values where appropriate.

4.4 Optimize the Calibration process to achieve quicker process times.

4.5 Redesign the current analysis results display to align with the UI created by our design firm Buzzeo Designs.

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.

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 Algorithm Development - (July 2012)

7.2 Design and Development Plan created - (July 2012)

7.3 Executive Management reviews DDP and documents on approval form - (July 2012)

7.4 Design requirements finalized - (July 2012)

7.5 Design inputs and outputs documented and approved - (July 2012)

7.6 Design developed resulting in design outputs documentation - (July 2012)

7.7 Conduct unit testing - (July 2012)

7.8 Review and revise risk analysis documentation - (July 2012)

7.9 Design verification and validation - (August 2012)

7.10 Final design review and approval - (August 2012)

7.11 Design release for use - (August 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.