Design & Development Plan (DDP)
EPIC ClearView 1.1.1.4

APPROVALS:

Name	Job Title	Signature	Date
Scott Pletzer	Director of Quality & Program Management		30JUL12
Andrew Mason	Chief Technology Officer		7/30/12

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	30Jul12	Initial Release	A. Mason

1.0 PURPOSE

1.1 To define the Design & Development Plan (DDP) for the EPIC ClearView 1.1.1.4 application at EPIC. 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 develop and manufacture the ClearView 1.1.1.4 application. 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 make modifications to the ClearView software to improve the design and performance in the following areas:

- Calibration
- Camera Setting Persistence
- Scanner Connectivity

2.3 Aspects of the design process included within this DDP are planning, design, verification, validation, design transfer, and premarket submission (i.e., 510k) to the FDA. 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

4.0 PROJECT REQUIREMENTS

4.1 Update the calibration limit values (The high and low value ranges for the acceptable intensity values) for each of the 76,800 pixels in the captured image.

4.2 The ClearView software must correctly and consistently set the necessary camera settings each time the camera is accessed.

4.3 The ClearView software should make an attempt to automatically reconnect to the scanner when communication errors occur.

5.0 RESPONSIBILITIES

5.1 IT – Software Development

5.2 Quality – Software Verification

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, Engineering Studies, etc. must have at least the signature of the following individuals: Andrew Mason and Scott Pletzer.

7.0 MAJOR TASKS (MILESTONES) & SCHEDULE

7.1 Completion of the software development process

7.2 Completion of validation

7.3 Release into the field

8.0 DESIGN VERIFICATION & VALIDATION APPROACH

8.1 Design verification will be performed through the standard testing process using test scripts and will be formalized through design verification protocols to be written prior to performance of the testing.

9.0 RISK ANALYSIS

9.1 The core risk in this change is the adjustment of the calibration limits. This will be addressed and supported by an engineering study that will be done to prove out the validity of the change. The camera settings change and connectivity change are mainly to improve the user experience and are of minimal risk. No additional changes will be made to the current risk analysis documentation.

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 DHF will be assembled and can be documented either electronically or in paper format.