EPIC™ RESEARCH DIAGNOSTICS

Design & Development Plan (DDP)
Clinical Builds

ORIGINATOR:

Name	Job Title	Signature	Date
Scott Pletzer	Quality & Program Management Director		02MAR12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		3/2/12.
Mike Stowell	Chief Financial Officer		3/2/12
Andrew Mason	Chief Technology Officer		3/2/12
Andrea Miller	Quality Assurance Manager		

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	02Mar12	Initial Release	Scott Pletzer

1.0 PURPOSE

1.1 The purpose is to define the Design & Development Plan (DDP) for assembling, testing, and releasing EPIC ClearView devices for use in clinical trials or internal use by EPIC Research & Diagnostics.

2.0 SCOPE

2.1 The DDP outlines the activities in order to assemble, test, and release four (4) EPIC ClearView systems consisting of the ClearView Device loaded with pre-release EPIC ClearView Firmware version 4.0.0 (part 06690 Rev. A), a computer system (1282-1511 rev. 001) loaded with the EPIC ClearView Software (designated ClearView version 1.1.1.2) and all relevant accessories.

2.2 Prior to this DDP, these devices have been partially assembled by MJS Designs and a previous contract manufacturer that went out of business (Ditron, Inc.). Full component traceability is not known, so the results of the design verification and validation testing will ensure the device performs as intended for the uses described.

2.3 The EPIC ClearView systems released under this DDP will not be sold or distributed, only used for clinical trials or internal purposes at EPIC Research & Diagnostics.

2.4 Up to four (4) additional EPIC ClearView systems may be assembled, tested, and released in the future. If this occurs, a separate summary report will be generated using this DDP if the requirements do not change.

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-009, Design History File (DHF)

3.3 QA-005, Documentation System Policy

4.0 PROJECT REQUIREMENTS

4.1 The necessary work instructions, inspection/test procedures, and forms will exist in at least draft form prior to continuing device builds under this DDP. Draft documentation will be included in the final summary report or controlled documents will be referenced.

4.2 Design verification testing of one (1) device will be performed by PADT under a pre-approved test protocol. All requirements of that test protocol will need to be met or accepted with appropriate justification and supporting rational prior to release of ClearView Systems for use in IDE investigations.

4.3 Design validation testing of the four (4) devices will be performed by EPIC Research & Diagnostics, Inc. under a pre-approved test protocol. All requirements of that test protocol will need to be met or accepted with appropriate justification and supporting rational prior to release of ClearView Systems for use in IDE investigations.

4.4 Prior to releasing the device for use in IDE investigations, EPIC Research & Diagnostics will generate a report summarizing the build activities and results, with a recommendation to use the devices as described.

5.0 RESPONSIBILITIES

5.1 Information Technology – release of ClearView software and firmware.

5.2 Quality & Operations – oversight of device, assembly, testing, and release.

5.3 EPIC - performing design validation testing (including protocol & report generation)

5.4 MJS Designs – assembly, testing, and release of devices.

5.5 PADT – generating necessary work instructions, inspection/test procedures, and forms and performing design verification testing (including protocol & report generation)

6.0 ORGANIZATION, INTERFACES, RESPONSIBILITES, AND APPROVAL AUTHORITY

6.1 EPIC Research & Diagnostics, Inc. will have overall responsibility for all clinical device build activities.

6.2 Work instructions, inspection/test procedures, and forms that are approved by EPIC Research & Diagnostics, Inc., PADT, Inc., and MJS Designs, Inc. will be controlled and released within MJS Designs' quality system.

6.3 Design verification test protocols and reports will be authored by PADT, Inc. and approved by EPIC Research & Diagnostics, Inc.

6.4 Design validation test protocols and reports will be authored and approved by EPIC Research & Diagnostics, Inc.

6.5 The final release of these devices will be the responsibility of EPIC Research & Diagnostics, Inc..

7.0 MAJOR TASKS (MILESTONES) & SCHEDULE

7.1 The tracking of tasks for completion of these builds is being tracked by EPIC Research & Diagnostics, Inc. The schedule at the time of this DDP approval is shown in Attached 1.

8.0 DESIGN VERIFICATION & VALIDATION APPROACH

8.1 Design verification and validation will be performed by testing device, software, and firmware 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. Design verification testing will be led by PADT and design validation testing will be led by EPIC Research & Diagnostics, Inc. Design verification and validation activities may be happening concurrently and the general outline of the steps are:

- Development & approval of design verification and validation test protocols
- Execution of design verification and validation test protocols
- Summary of design verification and validation testing into summary reports
- Approval of design verification and validation test reports
- Review of testing to determine that all design requirements have been adequately tested and the results demonstrate device performance meets the design requirements.

9.0 RISK ANALYSIS

9.1 No specific risk analysis activities are planned for this build. However, any relevant outputs may be incorporated in EPIC's drafted risk analysis. A risk analysis will be documented in the written summary prior to release.

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 Relevant documents and records from this build will be maintained in the DHF in accordance with EG-009, Design History File (DHF). Non-DHF documents and records will be maintained in accordance with QA-005, Documentation System Policy.

ATTACHMENT 1
(Project Schedule)

30	**Clinical Trial Production Units**	**32%**	**MJS,PADT**	**Wed 2/1/12**	**Fri 3/30/12**	
31	**Production Readiness Review (PRR)**	**52%**	**Scott**	**Wed 2/1/12**	**Tue 3/6/12**	
32	Device DDP	25%	Scott	Mon 2/27/12	Fri 3/2/12	
33	Production Planning	**100%**	**MJS**	**Fri 2/17/12**	**Thu 3/1/12**	
34	Procurement of materials	100%	Rob J.	Fri 2/17/12	Thu 3/1/12	
35	Fixtures build and document	100%	Rob J.	Fri 2/17/12	Thu 3/1/12	
36	DMR (Approved for Clinical Trial Devices)	**56%**	**Marcy**	**Wed 2/1/12**	**Mon 3/5/12**	
37	**Production Documents (WKI, FAT, Firms)**	**56%**	**Marcy**	**Wed 2/1/12**	**Mon 3/5/12**	
38	Power Entry	75%	Marcy	Wed 2/1/12	Thu 3/1/12	
39	Electrode Assembly	75%	Marcy	Wed 2/1/12	Thu 3/1/12	
40	Final Assembly and test	75%	Marcy	Wed 2/1/12	Thu 3/1/12	
41	Cable Assembly	0%	RJ	Wed 2/1/12	Thu 3/1/12	
42	Wki sign off	0%		Mon 3/5/12	Mon 3/5/12	
43	Device Released Firmware	**0%**	**EPIC**	**Fri 2/17/12**	**Thu 3/1/12**	
44	Code V&V Reviews	0%	Andy	Fri 2/17/12	Thu 3/1/12	
45	Design Review and Release	0%	Andrea	Fri 2/17/12	Thu 3/1/12	
46	System Released Software	0%	Andy	Mon 3/5/12	Mon 3/5/12	29
47	Readiness Review	0%	Scott	Tue 3/6/12	Tue 3/6/12	32,36,43,46
48	**Device Assembly and Acceptance Test (Lot 1, Qty 4)**	70%	**Rob J.**	**Tue 3/6/12**	**Thu 3/8/12**	**47**
49	**Production Release 1 (DMR-DHR Review)**	0%	**Scott**	**Fri 3/9/12**	**Fri 3/9/12**	**48**
50	**Device Verification Test (1 Unit)**	**0%**	**PADT**	**Fri 2/17/12**	**Mon 3/19/12**	
51	Device Requirements	0%	Scott	Fri 2/17/12	Wed 2/29/12	
52	Device Verification Test Plan (includes firmware testing)	0%	Don	Thu 3/1/12	Fri 3/9/12	51
53	Device Verification Test	0%	Don	Mon 3/12/12	Mon 3/19/12	52
54	**System V&V (Alpha)**	**0%**	**EPIC**	**Fri 2/17/12**	**Thu 3/29/12**	
55	V&V Test Plan	0%	Scott	Fri 2/17/12	Fri 3/9/12	
56	V&V 1-A, 1-B	0%	Jessica	Mon 3/12/12	Mon 3/19/12	49
57	V&V 1-C, 1-D (Device Verification Unit)	0%	Jessica	Tue 3/20/12	Tue 3/27/12	49
58	V&V Report	0%	Andrea	Tue 3/20/12	Thu 3/29/12	56
59	**Clinical Release Review**	**0%**	**Scott**	**Wed 2/22/12**	**Fri 3/30/12**	
60	Summary Document	0%	Scott	Wed 2/22/12	Thu 3/29/12	
61	Design Review	0%	Scott	Fri 3/30/12	Fri 3/30/12	60,56,53