EPIC™ RESEARCH DIAGNOSTICS

Design & Development Plan (DDP)
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, Chief Executive Officer	N Rizzo	3/22/13
Lloyd Kurth	Technology Director	Lloyd N. Kurth	3/22/13
Jan Ayres	Project Implementation Manager	Jan Ayres	3/22/13
Andrea Miller	Quality Assurance Director	Andrea Miller	3/22/13
Don Pegg	Design Engineering Consultant (PADT)	See attached AM	3/24/13

EPIC RESEARCH DIAGNOSTICS	Design & Development Plan (DDP) ClearView System

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1.0 PURPOSE

1.1 The purpose is to define the Design & Development Plan (DDP) for assembling, testing, and releasing EPIC ClearView systems for commercial or investigational device exemption (IDE) use by EPIC Research & Diagnostics, Inc. (EPIC).

1.2 This DDP is supported by the content of DD-026, EPIC ClearView Device Design Control Statement which documents the design control history for the ClearView Device development. DD-026 summarizes the design controls utilized during early development through the present of the ClearView Device, and this DDP summarizes design controls going forward through ClearView System commercialization.

1.3 This DDP is also supported by DDP-003, Clinical Build Project Plan which documents the design controls required for clinical builds to date and sets precedence for requirements of this DDP.

2.0 SCOPE

2.1 The DDP outlines the design control activities required to systematically assess the design of the EPIC ClearView System. As such, the DDP provides guidance regarding all activities necessary to assemble, test, and release the EPIC ClearView System consisting of the device loaded with firmware (p/n 06690), a computer system (p/n 1282-1511) loaded with the ClearView software and all relevant accessories (reference p/n EPC-100).

2.2 The release of EPIC ClearView systems will be addressed under this DDP.

2.3 Design and development of the ClearView software is controlled by DDP-010.

3.0 REFERENCE DOCUMENTS

3.1 DD-005, Risk Management Plan for EPIC ClearView System

3.2 DD-012, EPIC ClearView Product Requirements – System

3.3 DD-026, EPIC ClearView Device Design Control Statement

3.4 DDP-003, Clinical Build Project Plan

3.5 DDP-010, Design and Development Plan, ClearView Software

3.6 EG-001, Design Control Procedure

3.7 EG-012, Risk Management

3.8 Regulatory Documentation:

- FDA 21 CFR 820, Quality System Regulations (QSRs)
- ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- FDA's Design Control Guidance For Medical Device Manufacturers, March 11, 1997

4.0 PRODUCT DESCRIPTION

4.1 The EPIC ClearView System consists of the ClearView device and ClearView software installed on a computer, plus the device and computer accessories. The ClearView signal is generated when a finger is placed on the glass electrode and a high frequency voltage impulse is applied to the underside of the glass dielectric. The high voltage impulse generates a localized electromagnetic field around the finger thus exciting and amplifying the biophotonic field within the skin. This combination leads to an excitation of the local air molecules, forming room temperature plasma. The energy of the plasma is released via the ionization of the local air molecules, thus emitting photons within the UV and visible light spectrum. The light is captured via the embedded camera and relayed to the computer system. The resultant image is analyzed via a plurality of algorithms to assess it for normality. The ClearView software creates a prioritized scoring method for the body systems/structures at risk for disease. ClearView produces a two-part report. The first part provides the associated risk for disease presence in the main organ systems/structures on a scale of 0-5, comparing the patient to others of the same gender and age. The second part gives specific data regarding 49 separate organs/structures within the body and their relative functionality on a scale of 0-25.

5.0 PROJECT REQUIREMENTS

5.1 The ClearView System is expected to be classified as an FDA Class II medical device, and as such will be required to comply with all elements of the EPIC Design Control process (reference EG-001, Design Control Procedure). All required design control documentation will be included in the design history file (DHF) maintained by EPIC.

5.2 Design and development planning is initially documented via this DDP. Specific planning is maintained in a separate Project Task List by the Project Implementation Manager. Process Review Meetings will be conducted monthly to review and update the project activities.

5.3 Development of the ClearView software is a unique process and development from definition of software requirements through portions of software verification testing will be controlled by DDP-010, Design and Development Plan, ClearView Software. Final software verification, validation and Phase Release Reviews are controlled by this DDP.

5.4 ClearView System product requirements are documented in DD-032, ClearView System Requirements. The requirements will be used to determine the verification and validation activities, and will be revised as required throughout the commercialization process, and the verification and validation testing will be reviewed to demonstrate that the product requirements have been met.

5.5 Design verification and validation testing will be performed under pre-approved test protocols to support established product requirements. All requirements of those protocols will need to be met or accepted with appropriate justification and supporting rationale prior to release of ClearView Systems for commercial or clinical use.

5.6 A Design Verification and Validation (V&V) Plan will be developed to ensure that all required activities are performed. This plan will be developed and approved during the design phase prior to beginning the next round of V&V activities. The V&V plan will include product safety testing and a first factory inspection (FFI).

5.7 The necessary work instructions, inspection/test procedures, and forms will be approved and released in MJS Designs' quality system prior to continuing device builds under this DDP. Draft documentation will be allowed for any non-critical work instructions with proper written documentation and approval and/or controlled documents will be referenced.

5.8 A complete Device Master Record (DMR) will be created to document the approved procedures used in the assembly of the systems. A summary of assembly deviations will be generated and included in the review and approval of the DMR. Portions of the DMR may be controlled by PADT and MJS.

5.9 Upon completion of the ClearView System Device Master Record (DMR), the final ClearView System DMR will be compared to the Clinical Trial DMR generated as a part of DDP-003. The comparison will be made to ensure that the devices assembled are significantly equivalent to the predicate Clinical Trial DMR requirements. Any deviations/discrepancies will be identified and resolved prior to the completion of any commercial distribution of devices built under this DDP.

5.10 A review of all component and material specifications will be conducted to ensure that all design outputs are properly documented among EPIC, PADT, and MJS. This review is intended to supplement the design controls for the DMR due to the nature of working with three different quality systems.

5.11 Release requirements for devices will be established by MJS and EPIC in accordance with their respective quality management system requirements. Release requirements for the system will be established by EPIC in accordance with EPIC's quality management system requirements.

5.12 Design transfer activities will be done, either on the entire device or subassemblies, as needed to meet the commercial product build schedule, and documented via design reviews.

5.13 Risk analysis activities (including component level and process analysis) will be performed in accordance with Risk Management Plan for EPIC ClearView System, DD-005.

6.0 RESPONSIBILITIES

6.1 Information Technology (IT) – development and release of ClearView software and firmware.

6.2 Quality Assurance (QA) – approval and oversight of design control activities for ClearView system, assembly, testing, and release.

6.3 Project Implementation – maintaining Project Task List and monitoring progress of project and business goals.

6.4 IT, Manufacturing Engineering, QA, and Clinical - performing design verification and validation testing (including protocol & report generation).

6.5 Manufacturing Engineering– development of the ClearView System device master record (DMR) and coordinating the development of contract manufacturing DMR records.

6.6 MJS Designs, Inc. (MJS) – assembly documentation control, generating necessary work instructions, inspection/test procedures, and forms used in the assembly, testing, and release of devices to EPIC. MJS will be responsible to conduct production process validation prior to Product Release Review.

6.7 PADT, Inc. (PADT) – design, documentation control, and providing assistance in the development of work instructions, inspection/test procedures, forms, and performing firmware functional validation and device performance verification testing (including protocol & report generation). Participates in design control activities as assigned.

7.0 ORGANIZATION, INTERFACES, ROLES, AND APPROVAL AUTHORITY

7.1 EPIC will have overall design authority for all ClearView system design control and build activities.

7.2 Work instructions, inspection/test procedures, and forms for the assembly of the ClearView device that are approved by EPIC, PADT, and MJS will be controlled and released within the MJS quality system. Work instructions, inspection/test procedures and forms for the assembly and kitting of all other ClearView System components (e.g., computer system, UPS, cleaning supplies, etc.) will be controlled and released within EPIC's quality system.

7.3 Design verification/validation test protocols and reports will be authored by EPIC and approved within EPIC's quality system.

7.4 The final release of ClearView Systems for use in clinical investigations will be the responsibility of EPIC .

7.5 EPIC's Program Manager will be responsible for oversight of design and development and to ensure compliance to EPIC's quality system and to all applicable standards and regulations.

7.6 EPIC's Hardware Project Leader will be responsible for day-to-day management and oversight of this DDP and communicating relevant project information to team members.

7.7 EPIC's Software Project Leader will be responsible for oversight of the ClearView software development per DDP-010.

7.8 Approval Authority will be executed according to the following matrix:

Name	Title/Role	Company	Review Approval Required
Nancy Rizzo	Founder and CEO, CSO ClearView System Program Manager	EPIC	• Design Review Board Leader • Software development documentation approvals
Lloyd Kurth	Technology Director Software Project Leader	EPIC	• Design Review Board Member • Software Phase Design Review • Software development

Name	Title/Role	Company	Review Approval Required
			documentation approvals
Jan Ayres	Project Implementation Manager	EPIC	• Design Review Board Member • Project Task List management
Andrea Miller	Quality Assurance Director	EPIC	• Design Review Board Member • Phase Design Review • Design documentation approvals • Manufacturing related documentation approvals • Verification and Validation Protocols and Reports • Software development documentation approvals
Dan Miller	Manufacturing Engineer Hardware Project Leader	EPIC	• Design Review Board Member • Hardware Phase Design Review • Hardware design documentation approvals • Manufacturing related documentation approvals • Verification and Validation Protocols and Reports • Product Safety Testing management including FFI
Don Pegg	Design Engineering Consultant	PADT	• Design Review Board Member • Hardware Phase Design Review • Hardware design documentation approvals • Manufacturing related documentation approvals • Verification and Validation Protocols and Reports
Brian Cullinan	Software Developer	EPIC	• Software Phase Design Review
Robert Jones	Quality Manager	MJS	• MJS Manufacturing related documentation approvals • MJS DMR documentation approval

8.0 MAJOR TASKS (MILESTONES) & SCHEDULE

8.1 Product Requirements

8.2 Initial Risk Analysis

8.3 Engineer ClearView System

8.4 Design Specifications

8.5 Build clinical devices

8.6 Design verification testing

8.7 Develop packaging

8.8 Develop labeling

8.9 Design validation testing and clinical trials

8.10 IEC 60601-1 certification

8.11 Process validation

8.12 Finalize Risk Analysis

8.13 Finalize Traceability Analysis

8.14 Final design review and approval

8.15 Design transfer

8.16 Design release for use

8.17 Build commercial devices

8.18 FDA approval

8.19 CE Mark

The Project Task List will detail the above milestones with dates and will be closely tracked and documented as part of EPIC's regularly scheduled staff and process review meetings. Changes to the schedule and milestones can occur within those forums without the need to revise this DDP, unless significant project requirement changes occur. Additionally, other DDPs may be generated if required to support this DDP.

9.0 DESIGN VERIFICATION & VALIDATION APPROACH

9.1 Design verification and validation will be performed by testing ClearView System functionality to the established requirements and specifications.

9.2 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.

9.3 Design verification and validation activities can occur concurrently, and the general outline of the steps are:

9.3.0. Development & approval of design verification and validation test protocols.

9.3.1. Execution of design verification and validation test protocols.

9.3.2. Summary of design verification and validation testing into summary reports.

9.3.3. Approval of design verification and validation test reports.

9.3.4. Review of testing to determine that all design requirements have been adequately tested and the results demonstrate device performance meets the design requirements.

9.3.5. Execution of Traceability Analysis.

9.3.6. Clinical activities (e.g., trials) that support design validation will be managed via EPIC's Clinical group.

10.0 RISK ANALYSIS

10.1 A Risk Management Plan for EPIC ClearView System, DD-005, was initially approved on 4/3/12. All current and future risk management activities will be managed through this plan and in accordance with EG-012, Risk Management, and EG-001, Design Control Procedure.

11.0 PROJECT CONSTRAINTS

11.1 Known project constraints at this time are identified and maintained in the Project Task List. Any additional constraints will be managed through EPIC staff and process review meetings and/or documented via revisions of this plan.

12.0 DESIGN HISTORY FILE (DHF)

12.1 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.

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	08Aug12	Initial Release	S. Pletzer
001	22Mar13	Update document to comply with EPIC's Design Control Procedure (EG-001) and current design history documentation.	D. Miller