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

ORIGINATOR:

Name	Job Title	Signature	Date
Dan Miller	Manufacturing Engineer	Dan Miller	5/10/13

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder, President and CTO	N Rizzo	5/10/13
Lloyd Kurth	Technology Director	Lloyd N. Kurth	5/10/13
Jan Ayres	Operations Director	Jan Ayres	5/10/13
Andrea Miller	Quality Assurance Director	Andrea Miller	5/10/13
Don Pegg	Design Engineering Consultant (PADT)	See Attached	

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Andrea Miller	Quality Assurance Director		5/10/13
Don Pegg	Design Engineering Consultant (PADT)		5/10/13

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 and DD-033, EPIC ClearView Software Design Control Statement which documents the design control history for the ClearView device and software development. DD-026 and DD-033 summarize the design controls utilized during early development through current development of the ClearView device and software. 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.

3.0 REFERENCE DOCUMENTS

DD-005, Risk Management Plan for EPIC ClearView System

DD-012, EPIC ClearView Product Requirements – System

DD-026, EPIC ClearView Device Design Control Statement

DD-033, EPIC ClearView Software Design Control Statement

DDP-003, Clinical Build Project Plan

EG-001, Design Control Procedure

EG-012, Risk Management

EG-021, Software Change Control Procedure

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, and system 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 device camera and the 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 Operations Director. Process Review Meetings will be conducted monthly to review and update the project activities.

5.3 Development of the ClearView software has a unique development process within EPIC's Design Control Procedure. The tasks associated with this development and the official design review board members may be different than those for system or hardware.

5.4 Software changes will be managed in compliance to EG-021, Software Change Control Procedure.

5.5 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. The verification and validation testing will be reviewed to demonstrate that the product requirements have been met.

5.6 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.

5.7 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).

5.8 The necessary work instructions, inspection/test procedures, and forms will be approved and released in MJS Designs, Inc. 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. Controlled documents will be referenced.

5.9 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 Phoenix Analysis and Design Technologies (PADT) and MJS Designs, Inc. (MJS).

5.10 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.

5.11 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.

5.12 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.

5.13 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.

5.14 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 Operations – maintaining Project Task List and monitoring progress of project and business goals.

6.4 IT, Manufacturing Engineering, QA, and Clinical Programs – performing design verification and validation testing (including protocol and 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 and 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 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 specific tasks.

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

Name	Title/Role	Company	Review Approval Required
Nancy Rizzo	Founder, President, CTO, 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 documentation approvals
Jan Ayres	Operations Director	EPIC	• Design Review Board Member • Project Task List management

Name	Title/Role	Company	Review Approval Required
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 (Not required for software specific design reviews) • 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. The general outline of the steps is:

9.3.0. Development and 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 by EPIC Clinical Programs.

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	22Mar13	Update document to comply with EPIC's Design Control Procedure (EG-001) and current design history documentation.	D. Miller
001	5/10/13	Update document to clarify software design specific activities including update to the software design review board members. Remove reference to DDP-010 which will not be implemented and add references to DD-033.	D. Miller

EPIC™ RESEARCH DIAGNOSTICS

Product Requirements
ClearView System

ORIGINATOR:

Name	Job Title	Signature	Date
Dan Miller	Manufacturing Engineer		5/10/13

APPROVALS:

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Nancy Rizzo	Founder, President and CTO		5/10/13
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Andrea Miller	Quality Assurance Director		5/10/13
Don Pegg	Design Engineering Consultant (PADT)		

1.0 Purpose

The purpose of this document is to define the design input requirements for the EPIC ClearView System.

2.0 Scope

This document defines requirements for the ClearView System which consists of the ClearView device, ClearView software installed on a computer, and system accessories.

3.0 Product Description

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 device camera and the 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. Currently 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.

4.0 Origin of Product

The ClearView System was developed from research and clinical activities.

5.0 Intended Use

EPIC ClearView™ is a plasma imaging device for the evaluation of the human body's primary organ systems (Cardiovascular; Respiratory; Gastrointestinal; Hepatic, Endocrine and Nervous System; Renal and Reproductive) to provide data points that may assist a physician when choosing further standard of care testing.

6.0 Definitions

The use of the words **shall**, **should**, **may**, and **will** are used in this document with these specific meanings. The word **shall** denotes a mandatory requirement. The word **should** denotes a recommendation. Before disregarding a **should** statement, the full implementation impact must be considered. The word **may** denotes an optional or recommended implementation. The word **will** denotes a declaration of how another part of the system, outside the scope of this document, must operate. For example, "The ClearView System will be compliant with all regulatory requirements."

Informative statements are used to provide additional information or background, but do not denote requirements.

7.0 Traceability

Requirements are numbered in a manner to support tracing of the design detail to this higher level requirements document. ClearView System product requirements begin with a uniquely numbered label "PR-XX.XX".

8.0 Patient/User Requirements

PR-1.1	The device shall be comfortable for the patient.
PR-1.2	The device should have a clean appearance appropriate for a medical device.
PR-1.3	The device materials shall be non-toxic wherever skin comes in contact with the device.
PR-1.4	Patient shall access the glass electrode through a guided, light-preventing, single-finger sleeve.
PR-1.5	System shall be used by trained personnel.
PR-1.6	Instructions for use shall guide user through system operation.

PR-1.7 System operation and output should be efficient and clear.

9.0 Software Operation Requirements

PR-2.1 Software shall control device functions.
PR-2.2 Software shall prompt for, collect and save setup verification images.
PR-2.3 Software shall perform analysis on setup verification images.
PR-2.4 Software shall prompt for, collect and save patient information.
PR-2.5 Software shall prompt for, collect and save patient finger images.
PR-2.6 Software shall perform analysis on patient finger images.
PR-2.7 Software shall generate and display report of measurements.
PR-2.8 Software shall generate printable report of measurements.
PR-2.9 Software shall have search, view and edit functions for patient information.
PR-2.10 Software shall have search and view functions for images, scans and reports.
PR-2.11 Software shall have separate privileged and non-privileged user functions.
PR-2.12 Software shall allow users with privileged access to modify image alignment and resubmit patient scan for analysis.
PR-2.13 Software shall allow users with privileged access to export patient scan information.
PR-2.14 Software shall prohibit users from access to code.
PR-2.15 Software shall communicate with the device firmware to limit device operation to appropriate levels of power, frequency and duration.
PR-2.16 Software may use licensing to allow report customization.
PR-2.17 Software may include functionality to aid in investigation and correction of system issues.

10.0 Hardware Requirements

Camera

PR-3.1 The camera shall be USB powered.
PR-3.2 The camera shall be controllable by software.

PR-3.3	The camera shall have adjustable controls for imaging with brightness and gain (or equivalent) at a minimum.
PR-3.4	The camera shall have adjustable frame rate control, and be capable of 10 frames per second operation continuously.
PR-3.5	The camera shall be capable of capturing the low light photon emission images.
	Electrode
PR-3.6	The electrode shall consist of two outer layers of glass and an inner layer of conductive indium tin oxide (ITO) coating.
PR-3.7	The electrode shall allow the transfer of light (UV, IR, and visible) through the layers of glass.
PR-3.8	The electrode ITO coating shall conduct energy evenly across the inner layer.
PR-3.9	The electrode shall withstand voltages up to 20,000 volts at high frequencies.
PR-3.10	The electrode patient interface surface shall be cleanable.
	Electrical
PR-3.12	The supply voltage should allow for use in intended markets (countries).
PR-3.13	The device operation shall be controlled by software via USB.
PR-3.14	The circuit shall be capable of sufficient power for the formation of plasma, ionization and photon emission.
PR-3.15	The circuit shall be capable of providing power to the electrode with adjustable voltage, frequency and pulse duration.
	Physical
PR-3.16	The device shall have an on/off power switch.
PR-3.17	The device shall have no operative controls other than the on/off power switch.
PR-3.18	The device shall have a power indicator light.
PR-3.19	The device shall have connectors for AC power, USB, and calibration probe cable.
PR-3.20	The device shall have provisions for mounting to mobile platform.
PR-3.21	The device materials which come into contact with patient/user shall be cleanable.
PR-3.22	The device should be lightweight enough for portability by average installer.

11.0 Computer Requirements

	Computer
PR-4.1	The computer system shall have sufficient performance capability to execute software.
PR-4.2	The computer system shall have sufficient capability to display software graphics.

PR-4.3 The computer system shall have sufficient USB connections to accommodate all necessary USB devices.

PR-4.4 The computer shall have a wired and a wireless network connection(s).

Security

PR-4.5 Software operation shall require a security method to prevent use by unauthorized users.

UPS

PR-4.6 ClearView system shall have an Uninterruptible Power Source (UPS).

Compatibility

PR-4.7 ClearView system should be compatible for use with multiple computer system configurations.

12.0 General Requirements

Product Life

PR-5.1 System shall be a multiple-use system.

Environment

PR-5.2 System is intended to be used in a temperature controlled clinical environment.

Functional

PR-5.3 The ClearView system shall be repeatable and reliable against IFU stated conditions.

Capacitive Barrier

PR-5.4 The capacitive barrier shall prevent moisture on finger from directly contacting electrode but not inhibit image capture.

Cleaning

PR-5.5 The cleaning materials shall clean the glass surface and calibration probe.

PR-5.6 The cleaning materials shall not damage glass surface or calibration probe.

PR-5.7 The cleaning materials should be disposable.

PR-5.8 The cleaning materials should be non-toxic.

PR-5.9 The cleaning materials should not leave a residue which may inhibit image capture.

Installation

PR-5.10 ClearView system may be installed on fixed surfaces or mobile workstations.

Packaging

PR-5.11 ClearView system packaging shall prevent damage to the system during shipment and storage.

Maintenance and Service

PR-5.12 System should be serviced by authorized personnel only.

PR-5.13 The device shall be tamper-proof without the use of tools.

Manufacturing

PR-5.14 The device design should allow assembly with common tools and processes.

Cost of Goods

PR-5.15 System cost of goods target should be $5000.00 US.

13.0 Regulatory Requirements

Regulatory

PR-6.1 System shall comply with the regulations for saleable devices in the intended markets, including but not limited to the United States and Europe.

Labeling

PR-6.2 System shall be labeled to comply with the regulations for saleable devices in the intended markets.

PR-6.3 The device should have an EPIC branded logo on the top surface.

REVISION HISTORY

Revision	Revision Date	Reason for Revision/Change Request	Revised By
000	22Mar13	Initial Release	D. Miller
001	5/10/13	PR-2.2, PR-2.3 - "calibration" replaced by "setup verification", PR-2.10 – added "images", deleted "patient", PR-2.11, PR-2.12, PR-2.12 – "administrator" replaced by "privileged", PR-2.15 rewritten to replace existing PR-2.15 and PR-2.16, PR-2.17 added	D. Miller