EPIC™ RESEARCH DIAGNOSTICS

Product Requirements
ClearView System

ORIGINATOR:

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

APPROVALS:

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

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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