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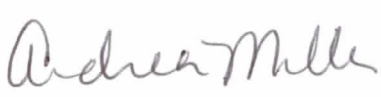
Andrea Miller	Quality Assurance Manager		3/5/12

1.0 Purpose

This document provides a description of the software used in the EPIC ClearView System. The EPIC ClearView™ System consists of a hardware device which is connected to a computer system through a USB port. The ClearView software is installed on the computer and is used to control the ClearView device, camera functions, and analyze the image through a complex algorithm to provide a printable report.

2.0 Scope

This document describes at a high level the various software components that make up the ClearView software. The specific requirements and specifications for the ClearView software are captured in the specific requirements and specifications located in the DHF and/or controlled through EPIC's quality system.

3.0 Definitions

Computer System	The computer system is installed with the ClearView software and works with the ClearView device to capture, store, and analyze images to measure galvanic skin response.
ClearView Software	The ClearView software is the end user application that manages the capture and processing of images information and is responsible for storing and managing patient demographics.
ClearView Report	A report produced by the ClearView software that summarizes the physical and autonomic responses, and is utilized by a licensed physician.

4.0 Operational Environment

The ClearView product consists of a hardware device that measures galvanic skin response and captures those responses with a digital video camera. A dedicated computer workstation supplied as part of the system houses the ClearView software and provides the user interface for the device. The application analyzes the scan data to provide a printable report of galvanic skin response (GSR) measurements. The ClearView system is intended for use in a clinical environment by qualified professionals only.

5.0 Functional Description

The primary application running on the device workstation is the ClearView software. The ClearView software is used to provide the following functionality:

- Control the device for calibration and patient scanning.
- Manage patient demographic and test configuration data.
- Manage security to control access to data.
- Perform analysis on the captured images.
- Store raw data analysis and final results in a database.
- Present results to end user in a printable report.
- Securely save the results for future use and reference.

This functionality can be divided into device functions controlled by software and user features provided by software.

5.1 Device Control Functions

The ClearView software is used to control the EPIC device. The device is connected to the workstation running the ClearView software through a USB port. The device consists of a digital video camera, USB hub, power supply, and controller all managed by a dedicated laptop. The software communicates with the device via the USB to configure camera properties, and set up the device interactions necessary to manage the device. In addition to setting up the various control parameters, the interface supports initializing and resetting the device. The software controls the digital camera using a Microsoft DirectShow implementation that provides real-time capture and rendition of video data. Detailed information about the device interface can be found in the following documents:

- EPIC ClearView Device Description
- FTDI DX22 Programmer Guide

5.2 User Feature Functions

In addition to controlling the device, the software provides the following major functions:

5.2.1 Application Functions- Authentication and Security

This feature controls access to various system functions. Users must be authenticated to the system through a combination of a user ID and a strong password. The software provides both Administrative and User functions through a single application. In addition to security, the system uses encryption to store specific sensitive patient data in a manner that restricts unauthorized use.

5.2.2 Patient Demographic Management

This system function permits an authenticated user to add, modify and where appropriate, delete any patient demographic information.

5.2.3 Camera (i.e., Calibration) Wizard

Provide an easy intuitive work flow for users to operate the device. The camera functions execute the automatic capture of energized images created through the use of a test probe referred to as the calibration probe. Upon completion of the image capture, the software launches an analysis function which evaluates the calibration images against established criteria to confirm acceptable device setup. The software controls prevent the user from capturing human subject images and analyzing those images until the calibration images meet the prescribed acceptance criteria.

5.2.4 Capture Wizard

Provide an easy intuitive work flow for users to operate the device to capture and analyze human subject images. The capture functions wizard allows the user to energize the device when the subject fingertip is placed on the glass electrode. The software also captures a lit finger image for use in the orientation of the energized image. Users may capture energized images of the fingers in any order and to recapture new energized images until the submit button is selected. The software displays for the user an automatically calculated orientation of the captured image based on the lit finger image and the final energized image. The wizard allows the user the ability to modify the orientation and will automatically change the

displayed orientation. Upon selection of the submit button, the Analysis Engine is initiated to process the energized images collected from the human subject.

5.2.5 Analysis Engine

Sophisticated analysis engine that analyzes energized images and calculates all of the coefficients that contribute to establishing the final GSR measurements. The analysis engine stores the required raw data and final analysis results in the proper location within the database.

5.2.6 Reporting Function

All raw data and final GSR measurements are generated at the time of scan and stored by the analysis engine. Immediately upon completion of the analysis, results are organized and displayed to the user in various manners for use by the licensed professional. These reports are also available to view as historical results using a search function to locate the subject data.

The software licenses control which of the report tabs are displayed to the user. The specific contents of these tabs are outlined in the specific requirements and specifications documents. Tabs may include the following:

- Print Report- Displays the ClearView Report using a Crystal Reports reporting system that allows the user the ability to print the ClearView Report. Different versions of the reports are established based on the specific intended use/indications for use and are specified in the appropriate requirements and specifications documents.
- Worksheet- Displays the ClearView Report allowing the user to select major organ system groups (i.e., Gastrointestinal System, Hepatic, Endocrine, and Nervous System, Sensory and Skeletal Systems, Cardiovascular System, Respiratory System, Renal and Reproductive System) to display the final GSR measurements. All

six or any combination of the six systems can be selected one at a time or together in any combination by the user. This tab also has the ability to sort the individual GSR measurements by the organ system name.

- Biofields- Displays the energized image sectors in relation to a visual representation of the body known as the biofield. This tab will also display the individual GSR measurement when the user passes the mouse over the biofield image.
- NS Analysis- Displays a graphical representation of the transformed NS coefficient for use by the licensed professional.
- Admin- Displays raw data (coefficients, orientation data, energized and finger images, calibration images, and calibration data) for use by EPIC Administrators only.

6.0 Development Environment

This section describes the development environment used to develop and support the EPIC ClearView software.

6.1 Programming Languages and Tools

The ClearView software has been developed using Microsoft .NET Framework Version 4 in a Microsoft Visual Studio 2010 Development Environment. The majority of the application has been written in managed code, C# being the language of choice. The application also uses some C++ assemblies in areas where speed of processing is critical. The system uses Microsoft SQL Server 2005 as a database engine. SQL Server provides a robust database engine that ensures a high level of referential integrity among all of the related data. The application also uses several third party products including Infragistics, Microsoft Enterprise Manager and The MathWorks™ MATLAB®. Infragistics provides powerful Windows Forms controls and Enterprise Manager provides sophisticated logging for all system events. The computational engine has been built using MATLAB. This engine makes use of the MATLAB base product and also uses the Image and Signal Processing toolboxes. The MATLAB NE product and complier provides .NET compatible assemblies that make up the analysis services for the application.

6.2 Environment

The development environment consists of various development systems dedicated to specific functions. These systems are dedicated to user interface development, reporting development, computational development, and testing.

6.3 Configuration Management and Version Control

Configuration management and version control is handled through Perforce, a SCCS (Source Code Control System), which is specified in EPIC's Software Development procedure, EG-010. Software development lifecycle is specified in EPIC's Software Development Lifecycle procedure, EG-018.

6.4 Documentation

All software documentation is contained in several sources including:

6.4.1 Software Requirements Documents

The entire product life cycle is contained in the software requirements specification (SRS) documents and summarized into an Input/Output Matrix table. The software requirements specifications (denoted as SR-XXX in the Design History File) contain all of the software requirements for the ClearView software. The requirements specifications are very detailed and have been split into separate documents based on the different user functional requirements (Patient Demographics Functions, Camera Functions, Capture Functions and Analysis Functions).

6.4.2 Detailed Software Design Specifications

Detailed software design specifications were developed to document the implemented functions of the software in response to the requirements documents. The detailed specifications (denoted as SS-XXX in the Design History File) provide specific detail regarding the functionality available to users of the ClearView software. The specifications serve as a basic for

testing design and include screen shots of the implemented functionality as available to users.

6.4.3 In Code Documentation

An open source product called Sandcastle was used to support source code documentation. Sandcastle is a documentation compiler for managed class library that generates Microsoft-style Help topics, both conceptual and API reference. It creates API reference topics by combining the XML documentation comments embedded in our source code with the syntax and structure of the types which it acquires from reflecting against the associated .NET Framework assembly. All assemblies are documented at the Public visible scope.

7.0 Workstation Hardware and Software

The ClearView software runs on a dedicated business class workstation. The initial release product will run on a Dell Optiplex workstation with the following minimum specifications:

- Operating System: Microsoft Windows XP Professional Service Pack 4
- Processor: Intel Core™ Duo T7250 2Ghz
- Memory: 2GB RAM

8.0 References

EPIC ClearView System Description, SD-003
EPIC ClearView Device Description, SD-002
FTDI DX22 Programmer Guide, DD-004
Software Development, EG-010
Software Development Lifecycle, EG-018

Document Revision History

Version Number:	Description of Change:	Date:	Updated By:
000	New Document	3/5/12	A. Mason