





EPICTM
RESEARCH
DIAGNOSTICS

Application Functions Requirements

ORIGINATOR:

Name	Job Title	Signature	Date
Andrew Mason	Chief Technology Officer		7/18/12

APPROVALS:

Name	Job Title	Signature	Date
Nancy Rizzo	Founder and CEO		7/18/12
Scott Pletzer	Director of Quality & Program Management		180212

1.0 Purpose

The purpose of this document is to describe the high level application specific requirements for the ClearView system.

2.0 Scope

The scope of this document consists of the Application Functions as a whole, no other systems requirements are defined in this document. The initial release of this document addresses only the requirements for the core system; this will be augmented as new requirements are introduced.

3.0 Definitions

Bitmap	A graphic format used by the system. All images captured by the system are stored in this format. The images are all 320 pixels by 240 pixels in size.
Calibration Image	An image captured using a probe rather than a human finger. This is used as a baseline in performing a calculation.
Coefficients	Numerical calculations that describe specific attributes of the image.
Energized Image	The image capturing the energy that is evoked from the finger when the voltage is applied to the plate.
Finger Image	The raw image of the finger captured before the voltage is applied to the plate.
License Key	File containing a value or string that represents the capabilities of the software. This string is always encrypted.
Pixel	A graphical component that has the ability to turn on and off and display color and intensity.

4.0 System Requirements

- 4.1 The system must close after a specific amount of time of inactivity per HIPPA regulations. The initial amount of time should be 15 minutes. Inactivity is defined as no keyboard input or mouse clicks within the time frame.
- 4.2 The system must contain a main menu in order for the user to easily navigate through the application.

- 4.3 The system must be Microsoft Windows based and be written using the .net framework.
- 4.4 The system must persist data in a Microsoft SQL Server Database, version 2005 or greater.
- 4.5 The system should synchronize with an external controlling server. This server will be used to provide authentication for scans, archival functionality for images and other tasks.
- 4.6 The system should allow patients to be added and managed. The requirements for this functionality are defined in the Patient Services- Requirements document.
- 4.7 The system should allow a calibration process to be performed on the scanning devices. The requirements for this functionality are defined in the Camera Functions- Requirements document.
- 4.8 The system should allow for the capture of new images for a patient, as well as the analysis and results reporting for the images. The requirements for this functionality are defined in the Capture Functions- Requirements document.
- 4.9 The system should allow historical scans (i.e., patient energized images) and the analysis results (i.e., report displays) to be searched and reviewed by a user. The requirements for this functionality are defined in the Capture Functions- Requirements document.

NOTE: Scan functions include the Manage Patients functions, Capture functions, Camera functions, and the Report functions excluding the Admin Page and all associated functions.

- 4.10 The system should display the version number in the upper section of the main page.
- 4.11 The system should allow for notifications to the user to be displayed in a noticeable area regardless of the function that is currently being performed.

- 4.12 The system should allow the device settings to be modified and persisted. These settings will be used by the application when controlling the device. This section is accessible to the "administrator" or "techadministrator" login only. These settings include:
- Camera to use
 - Firmware Type
 - Brightness
 - Gain
 - Exposure Delay
- 4.13 A throttling mechanism should be put in place on the login screen to prevent a user from attempting to log in more than 3 times in a row with a invalid password. 'In a row' can be defined as within a 3 minute period. If three or more attempts are made with a single user id, the id should be logged and banned from logging in (even with the right password) for a period of 30 minutes. No error message should be shown to the user other than the standard invalid login message. The user id and date and time attempted should be logged in and login audit table and an error message should be presented to the user. If the user is banned there is no reason to log additional failures for that user.
- 4.14 The system must only be accessible to a user that has a valid User Id and password combination.
- 4.15 The system should allow the currently logged in user to be changed without requiring a shutdown of the application.
- 4.16 Functions within the system must be delegated by role. There will be four roles in the system:
- **EPIC User**- has access to scan functions only.
 - **EPIC Administrator**- has access to scan functions as well as user administrative functions like the Users functions.

Application Functions Requirements

- **System Administrator**- has access to all areas of the ClearView software including Administrative functionality in the Capture, Camera and Report functions.
- **TechAdministrator**- has access to camera setting functionality and will be shared with manufacturing parties and others that require access to camera settings. The TechAdministrator should not be able to see or change the core 'Administrator' user.

4.17 The system should allow for the creation and management of system users. The following information should be captured for a user:

Field Name	Validation	Required
Username	(4 -50 Characters, Unique)	Yes
Password	(8-50 Characters, must have a minimum of 1 upper case letter, 1 lowercase letter, one number and one symbol	Yes
First Name	None	Yes
Last Name	None	Yes
Middle Initial	None	No
Email Address	Valid format	No
Phone Number	Valid format	No
User Role	Must be one of roles specified in this requirements document	Yes

4.18 The administrator and techadministrator logins should have the ability to capture an image from the settings page in order to perform testing of the device.

4.19 The administrator and techadministrator logins shall have the ability to see the feedback from the firmware 'Get' command after an image capture has been performed on this page. This display would include the following values:

- Device Status Code
- LED Status
- Exposure Duration
- ~~Boost Voltage Setting~~
- PWM0 Frequency
- PON State
- Boost Voltage Reading
- PWM0 Width
- Reset Condition Code
- Firmware Version

- 4.20 The administrator and techadministrator logins shall have the ability to save the captured image (with or without the voltage and frequency displayed on the image).
- 4.21 The administrator and techadministrator logins shall have the ability to see a log of the commands that were sent to the device.
- 4.22 The command log shall be able to be saved and cleared at any time.
- 4.23 The ClearView system should require that a license file be present before the software can be used.
- 4.24 The license file should be strongly encrypted as to not be able to be modified by the average user.
- 4.25 The ClearView system should support three types of licenses, Basic, Full and Cardiovascular (CV).
- 4.26 A ClearView system utilizing a Basic license will display ~~only two one~~ output tab upon completion of processing. One will contain that will contain the ClearView Basic printable rReport and the other will contain the working report (graphics, etc.).

- 4.27 A ClearView system utilizing a Full or CV license will display ~~all of two~~ output tabs upon completion of processing. ClearView Users, ClearView Administrators, and TechAdministrators will have the Print Report and working report tables. ~~Worksheet, Biofields, and NS Analysis tabs displayed.~~ EPIC Administrators will have ~~all four of these tabs in addition to the Admin tab.~~ the above mentioned tabs and a tab of admin pages as well as a tab of Biofields.
- 4.28 The ClearView report displayed in the ClearView system utilizing a 'Full' license will be significantly different in format and content than the report under the 'Basic' license. The report formats will be developed based on Regulatory department feedback and documented in the final Application Functions Specifications.
- 4.29 The ClearView report displayed in the ClearView system utilizing a 'CV' license will be significantly different in format and content than the report under the 'Basic' license.
- 4.30 The license type being used (Full, Basic or CV) should be displayed to the user in an easy to recognize location.
- 4.31 The ClearView system must interact with EPIC Central (the SaaS) application on a regular basis. If communication does not occur for a configurable amount of time or more, a scan cannot be performed.
- 4.32 The system must check prior to every scan if it is allowed to perform a scan. If it is not the scan must be prevented.
- 4.33 The system must allow for a configurable number of 'Grace' scans to be performed with the number of paid scans reaches 0.
- 4.34 The ClearView system must upload data to EPIC Central when a scan is completed, the data will consist of: (Patient demographic info, report data, raw data, and images).



Application Functions Requirements

- 4.35 Users with the EPIC Administrator role must be able to see the number of scans the device has available to use.
- 4.36 Users with the EPIC Administrator role must be able to access the EPIC Central UI from with ClearView to make purchases and manage their account.
- 4.37 ClearView must warn users when the number of scans available for a given device falls below a configured threshold.
- 4.38 Users with EPIC Administrsator roles must be able to configure the scan count value that will trigger the “Low scan count” warning.

5.0 Reference Documents

SR-001, Patient Demographics Functions- Requirements
SR-002, Capture Functions- Requirements
SR-003, Analysis Functions- Requirements
SR-004, Camera Functions- Requirements
SS-205, Application Functions- Specifications



Application Functions Requirements

Document Revision History

Version Number:	Description of Change:	Date:	Updated by:
000	Introduction	5/24/11	A. Mason
001	Update to include camera settings requirement.	5/24/11	A. Mason
002	Update to include requirements for the license key and different license functionality. Reorder requirements to group user management (i.e., user roles, creation and management of users, and changing login without shutdown of the application) together. Clarify that the name of the camera settings button will be labeled "Settings". Added requirements 4.26-4.31 defining a new camera testing section that will be visible only to administrators and techadministrators. Changes to the listed order of the requirements.	3/5/12	A. Mason
003	Added requirements pertaining to the integration into EPIC Central.	7/18/12	A. Mason