Approval Signatures:

Department	Name	Signature	Date
QA	Andrea Miller	*Andrea Miller*	1/9/12
OPS	Michael Stowell	*M. Stowell*	9 Jan 12
Exec	Nancy Rizzo	*N. Rizzo*	1/9/12
IS	Andrew Mason	*A. Mason*	1/9/12

1.0 Purpose

This document is intended to provide a protocol for use in validating the ClearView ™ software. This protocol is intended to provide a method for conducting the testing as well as to be used as a formal record of the validation activities.

2.0 Scope

This protocol is intended to be used to fully validate the APPLICATION Icon portion of the ClearView software for use. The protocol can be executed in total or in part. Any deviation from performing all sections of this validation must be resolved with appropriate written justifications prior to final approval of the validation report.

3.0 Definitions

N/A

4.0 Responsibilities

| User	• Complies with the policy and procedure. • Ensures the most current version of this document is used when referenced.
Departmental Management	• Ensures departmental personnel are properly trained before using this policy or procedure. • Provides oversight to the validation process and ensures that all quality system requirements are met.
Quality Assurance	• Monitors the implementation and effectiveness of this document. • Audits to ensure compliance with the referenced procedures

5.0 Policy

5.1 This protocol is intended to be updated for any changes made to the software such that the instructions provide a comprehensive test to demonstrate whether the software meets the intended use. Validation of the technical analyses and mathematical computations are completed under a separate protocol.

5.2 Follow the instructions provided within this protocol as written. Any deviations from the written protocol will be recorded on Attachment A, Deviations from Protocol.

ClearView Software Validation Protocol Version 1.1.1.2 – APPLICATION Functions   Confidential & Proprietary
Document Number: ENG-009   Page 2 of 21
Revision: 002

5.2.1   An individual will be assigned responsibility from the Validation Team to oversee the execution of the protocol. This validation designee will review each deviation as documented prior to moving forward in the validation process.

5.2.2   The validation designee will be required to determine whether the deviation requires formal documentation through EPIC's Deviation procedure or if the deviation is minor enough to warrant documentation only.

5.2.3   Upon completion of the protocol, the Validation Team has the responsibility to review all deviations recorded to determine whether or not they significantly impact the protocol/validation process. Any deviation deemed significant will be handled through EPIC's Deviations procedure.

5.2.4   The individual performing the validation protocol will complete each column of Attachment A for all deviations from the written protocol prior to moving forward. The validation designee will review each deviation prior to moving forward in the validation process. This review is indicated by documenting a signature and date in the Review column of the Deviations from Protocol worksheet located in Attachment A.

5.2.5   The validation designee should be aware during the execution of this validation protocol that the intention is to validate all functionality of the APPLICATION Icon. If at any time a portion of the software is identified as not being challenged notify the validation team immediately and document the omission on the non-conformances worksheet.

5.3   The written protocol is intended to capture the steps needed to properly challenge each software function/data point. However, given the evolving nature of software development, the instructions may not be 100% accurate. Therefore, any minor deviation from the written instructions will be corrected in writing during the execution of the validation protocol. These corrections will be reviewed by QA as a part of the validation analysis. The review will determine appropriate corrective and preventive action for any deviations notes.

5.4   Record the results of each validation step by initialing and dating in the space provided. If the characteristic cannot be verified, record a reference number on the protocol and the Non-Conformances Worksheet (Attachment B) and describe the failure in a specific and complete manner by completing all columns on the Non-Conformance Worksheet. Some validation steps ask the validation designee to

record the results side-by-side. In these cases, record initials and date on each side of the slash mark after validating each step as instructed.

5.5   ClearView Error Messages
The three acceptable error messages generated by the ClearView software are shown below. If any other error message is displayed during the execution of this protocol, describe and record the error on the Non-Conformances Worksheet.
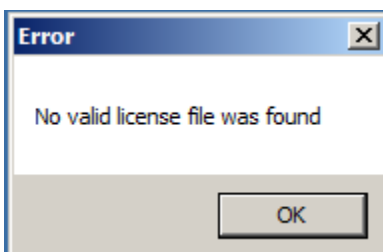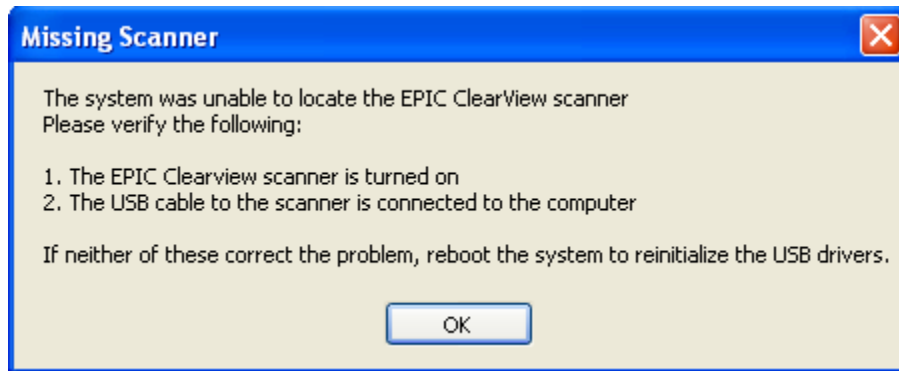
6.0   Procedure

  6.1   Device Set Up

   6.1.1   Clean the glass lens with isopropyl alcohol and the provided cloth. Dry the glass lens completely with a separate dry cloth.

   6.1.2   Place the calibration shroud over the lens cover.

   6.1.3   Clean the metal cylinder of the calibration probe with isopropyl alcohol and the provided cloth. Dry the calibration probe completely with a dry cloth.

   6.1.4   Place the calibration probe, metal cylinder first, through the opening of the calibration shroud until the bottom of the probe sits flat on the glass lens.

   6.1.5   Double click on the ClearView software icon located on the computer desktop. This will open the ClearView software and present the "Login As" window.

   6.1.6   The version of the ClearView software is displayed across the top header of the software. Record the software version being validated:

   _____

  6.2   **"Login As" function**- This window provides the user a method to enter their user name and password in order to access the ClearView software application.

   Verify that the Username and Password box are empty.

   _____ **Verified**   _____ **Not Verified   Non-Conformance Ref. No. _____**

   Click in the Username box and enter "Administrator". Click in the password box and enter the password provided by the Network Administrator. Click the Cancel button. Verify that the "Login As" window and the ClearView software window close and returned to the computer desktop.

   _____ **Verified**   _____ **Not Verified   Non-Conformance Ref. No. _____**

Double click on the ClearView software icon located on the computer desktop. Click in the Username box and enter "Administrator". Click in the password box and enter the password provided by the Network Administrator. Click the Login button. Verify that the "Login As" window is closed and EPIC ClearView main screen for the ClearView software is displayed.

_____ **Verified** _____ **Not Verified   Non-Conformance Ref. No.** _____

6.3   Application Functions

This section has four (4) buttons – Settings, Change Login, Update Login Info, and Exit.

6.3.1   **Change Login Button**- This button is used to open the "Login As" window in order to change users.

Click on the ClearView software Change Login button. Verify that the "Login As" window is displayed.

_____**Verified** _____ **Not Verified   Non-Conformance Ref. No.** _____

Click in the Username box and enter epicval and click in the password box and enter the 1234abc! as the password. Click the Login button. Verify that the Login Failed window with the message "Please enter valid Username and Password" appears.

_____**Verified** _____ **Not Verified   Non-Conformance Ref. No.** _____

Click OK. Verify that the Login As screen appears requesting user name and password.

Login as epicvalidation for the username and enter the password provided by the Network Administrator. Verify the main ClearView software screen appears.

_____**Verified** _____ **Not Verified** **Non-Conformance Ref. No.** _____

6.3.2 **Update Login Info Button**- This button is used to open the Application User window in the AddUserForm tab in order to modify the user's profile and login information.

Click the Update Login Info button. Verify that the AddUserForm tab opens with the epicvalidation user information displayed on the screen.

_____**Verified** _____ **Not Verified** **Non-Conformance Ref. No.** _____

Modify the user information as follows:

User Name epicvalidation (no change)
Click on Change Password:
Password epic5678!
Confirm Password epic5678!
First Name Epic
Middle Initial E
Last Name Administrator
 E-mail a@b.com

Save the data entered by clicking the Disc Icon Save button in the upper left corner of the screen. Verify that the Save Successful box appears. Click the OK button. Click the "X" in the upper right corner of the AddUserForm tab. Verify that the ClearView main screen is displayed.

_____**Verified** _____ **Not Verified** **Non-Conformance Ref. No.** _____

Click the Update Login Info button. Verify that the AddUserForm tab opens and the information modified in the previous step was saved completely. Click the "X" in the upper right corner of the AddUserForm tab. Verify that the Unsaved Information dialog box opens. Click the Cancel button. Verify that the dialog box closes. Click the "X" in the upper right corner of the AddUserForm tab.

Verify that the Unsaved Information dialog box opens. Click the No button.
Verify that the dialog box closes, the AddUserForm tab closes, and the ClearView
main screen is displayed.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Change Login button. Click in the Username box and enter
"aclearview". Click in the password box and enter the password provided by the
Network Administrator. Click the Login button. Verify that the Login Failed box
opens. Click the OK button and verify that the Login As box appears. Click the
Cancel button. Verify that the ClearView main screen appears.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Change Login button. Click in the Username box and enter
"Administrator". Click in the password box and enter the password provided by
the Network Administrator. Click the Login button. Click Search User and enter
"aclearview" in the User Name search box and click Find. Highlight the User
Name "aclearview", click the View User button. Select the Login Enabled option
located at the bottom of the Login Info section by clicking on the check mark
beside the words. Click the Save button in the upper left corner of the screen.
Click OK. Close the window by clicking the "X" in the upper right corner of the
AddUserForm tab.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Change Login button. Click in the Username box and enter
"aclearview". Click in the password box and enter the password provided by the
Network Administrator. Click the Login button.   Verify that the ClearView main
screen appears.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Change Login button. Click in the Username box and enter
"epicvalidation". Click in the password box and enter the password as modified
above. Click the Login button. Verify that the ClearView main screen appears.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

6.3.3 **Exit Button**- This button is used to exit and close the ClearView software system.

Click the Exit button. Verify that the ClearView software application closes and the screen returns to the computer desktop.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

6.3.4 **Settings Button**-   This button is used to change the camera settings in the ClearView software.

Login as Administrator with the password provided by the Network Administrator. Verify that the ClearView main screen opens. Click on the Application Settings button. Verify that the Settings tab opens.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Note: Many of the steps in this section will be performed on one scanner and repeated on another. The actual serial number of the scanner will be recorded on the printouts, and the filenames will be differentiated by the suffix A or B.
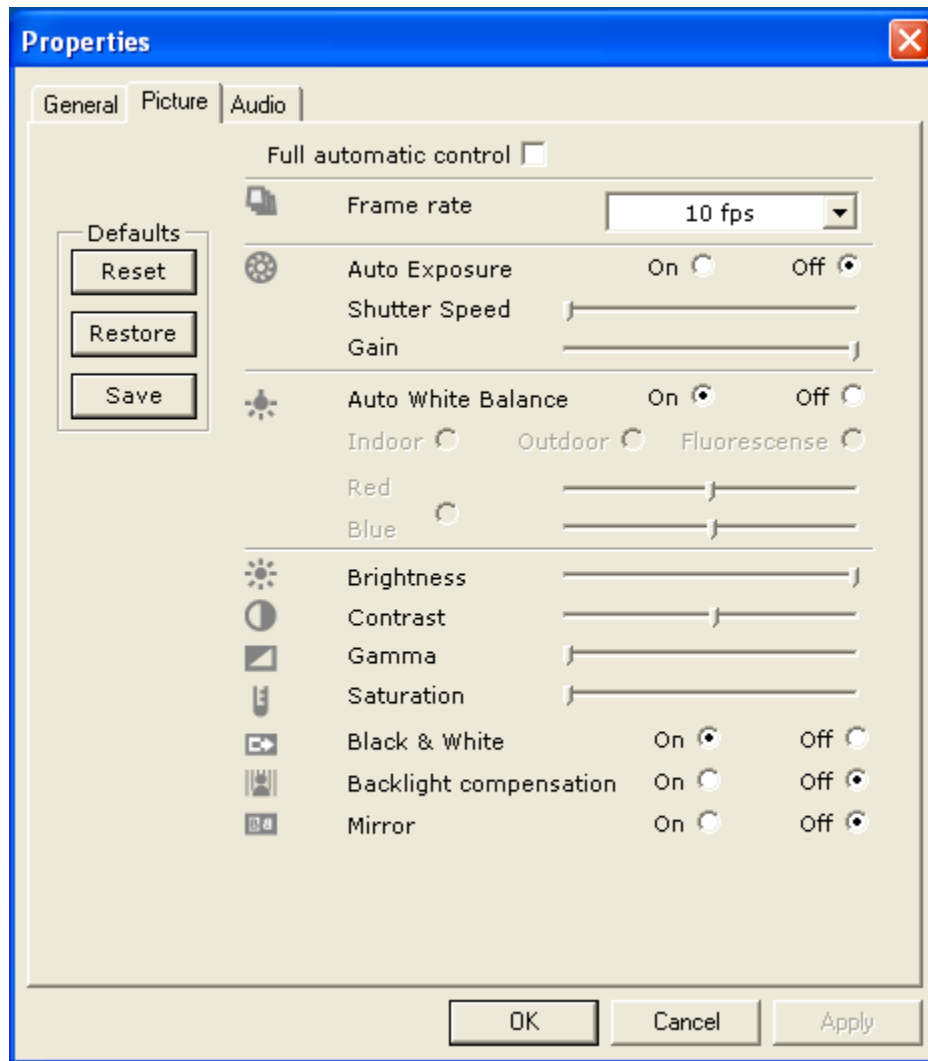
In the Device Settings section, next to Brightness, click on the arrow and select a Brightness setting of 127. Next to Gain, click the arrow and select a Gain of 63. Next to Exposure Delay, click the arrow and select an Exposure Delay of 320. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the ClearView main screen.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. The Properties window should open as shown below:

Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB127G63A. Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Camera Calibration button. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B127G63A.

Click on the Settings tab. Click on the arrow next to Brightness and select 64. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the Calibration tab.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB64G63A. Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Calibration tab. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B64G63A.

Verify that the image in file B127G63 is significantly brighter than the image in file B64G63.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Settings tab. Click on the arrow next to Brightness and select 127. Click on the arrow next to Gain and select 50. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the Calibration tab.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB127G50A. Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Calibration tab. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B127G50A.

Verify that the image in file B127G63 is significantly brighter than the image in file B127G50.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Settings tab. Click on the arrow next to Brightness and select 64. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the Calibration tab.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB64G50A. Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Calibration tab. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B64G50A.

Verify that the image in file B64G50 is significantly dimmer than the images in files B64G63 and B127G50.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Connect a different scanner for the remainder of this section.

In the Device Settings section, next to Brightness, click on the arrow and select a Brightness setting of 127. Next to Gain, click the arrow and select a Gain of 63. Next to Exposure Delay, click the arrow and select an Exposure Delay of 320.

Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the ClearView main screen.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB127G63B. Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Camera Calibration button. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B127G63B.

Click on the Settings tab. Click on the arrow next to Brightness and select 64. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the Calibration tab.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB64G63B. Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Calibration tab. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B64G63B.

Verify that the image in file B127G63 is significantly brighter than the image in file B64G63.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Settings tab. Click on the arrow next to Brightness and select 127. Click on the arrow next to Gain and select 50. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the Calibration tab.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file:

O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB127G50B. Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click on the Calibration tab. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B127G50B.

Verify that the image in file B127G63 is significantly brighter than the image in file B127G50.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click on the Settings tab. Click on the arrow next to Brightness and select 64. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the Calibration tab.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

Click the "X" in the upper right corner of the screen to minimize ClearView. Click on the Camera Properties icon. Using a clipping tool or SnagIt, capture the image of the Properties window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\PropB64G50B.

Print this file and label with the filename and serial number of the scanner and attach to the end of this protocol. Click on the ClearView tab in the taskbar to restore ClearView.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click on the Calibration tab. Click the Start Duty Cycle Testing button. Allow the scanner to take two or three images and click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner Calibration window and save as the following file: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\BrightnessImages\B64G50B.

Verify that the image in file B64G50 is significantly dimmer than the images in files B64G63 and B127G50.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click on the Settings tab. Click on the arrow next to Brightness and select 127. Click on the arrow next to Gain and select 63. Click on the arrow next to Exposure Delay and select 150. Click the Apply Settings button. Verify that the Settings tab closes and the screen returns to the Calibration tab.

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click on the Application Settings button. Verify the settings above were saved and record the Settings results below.

Brightness _____   Gain _____   Exposure Delay _____

_____Verified   _____ Not Verified   Non-Conformance Ref. No. _____

Click the "X' in the upper right corner of the Settings tab. Verify that the Settings tab closes and the Calibration tab opens. Click the Start Duty Cycle Testing button. Allow the scanner to take several images until there are images showing the probe and/or images displaying both the probe and the energized ring, and not the energized ring only, and then click the Start Duty Cycle Testing button again to stop. Using a clipping tool or SnagIt, capture the image of the Scanner

Calibration window and save as the following file:
O:\QualitySystems\Quality_System_Documents\Non-
quality_system_records\1.1.1.2_Validation\BrightnessImages\Delay150.

Click the "X" in the upper right corner of the Calibration tab and verify the screen returns to the ClearView main screen.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click Application Change Login icon. Verify that the Login As box appears.

_____ **Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click Cancel.   Verify that the ClearView main screen appears.

_____ **Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click Application Update Login icon. Verify that the AddUserForm tab opens.

_____ **Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Click the "X" in the upper right corner of the AddUserForm tab. Click No to saving changes.   Verify that the ClearView main screen appears.

_____ **Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Scanner and Camera Status
At the bottom of the screen, verify that the Scanner Status is Available and the Camera Status is Available. Unplug the USB cable from the scanner. After a few seconds of delay, verify that the Scanner Status and Camera Status change to Unavailable.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

Reconnect the USB cable to the scanner. After a few seconds of delay, verify that the Scanner Status and Camera Status change to Available.

_____**Verified**   _____ **Not Verified   Non-Conformance Ref. No.** _____

6.3.5 **Customer User and Admin modes**

Click the Exit icon in the upper right hand corner of the screen. Verify that the EPIC ClearView is closed and the desktop now appears.

_____ **Verified** _____ **Not Verified** **Non-Conformance Ref. No.** _____

Customer User
Double click the EPIC ClearView icon on the desktop. Enter the user name as "clearviewuser" and the password provided by the Network Administrator.
Verify that the ClearView main screen appears and the User Options icon and the Settings icon are not displayed on the Application tool bar at the top of the page.

_____ **Verified** _____ **Not Verified** **Non-Conformance Ref. No.** _____

Customer Admin
Click Application Change Login icon. Verify that the Login As box appears. Enter the user name as "epicvalidation" and the password as modified in section 6.3.2. Verify that the ClearView main screen appears and the User Options icon appears in the Application tool bar.

_____ **Verified** _____ **Not Verified** **Non-Conformance Ref. No.** _____

Click Application Update Login Info. Verify that the Login Info box appears. Click the "X" in the upper right corner of the AddUserForm tab. Click No to saving changes. Verify that the ClearView main screen appears.

_____ **Verified** _____ **Not Verified** **Non-Conformance Ref. No.** _____

7.0 Reference
EG-011, Software Validation
QA-004, Deviations
CS-003, Customer Feedback

8.0 Attachments
Attachment A, Deviations from Protocol
Attachment B, Non-conformances Worksheet

Attachment A
Deviations from Protocol

NOTE: This form is used for minor deviations from the protocol as written. Fill out all sections of this form prior to moving forward in the validation process.

No.	Date	Name	Description of Deviation (include reference to the protocol section)	Resolution/Action Taken	Reviewed

Attachment B - Non-conformances Worksheet

NOTE: This form is used for all protocol steps which did not perform as expected. Fill out all sections of this form prior to moving forward in the validation process.

No.	Date	Name	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken