Approval Signatures:

Department	Name	Signature	Date
QA	Andrea Miller	Andrea Miller	1/9/12
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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 CAMERA 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.

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 CAMERA 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.

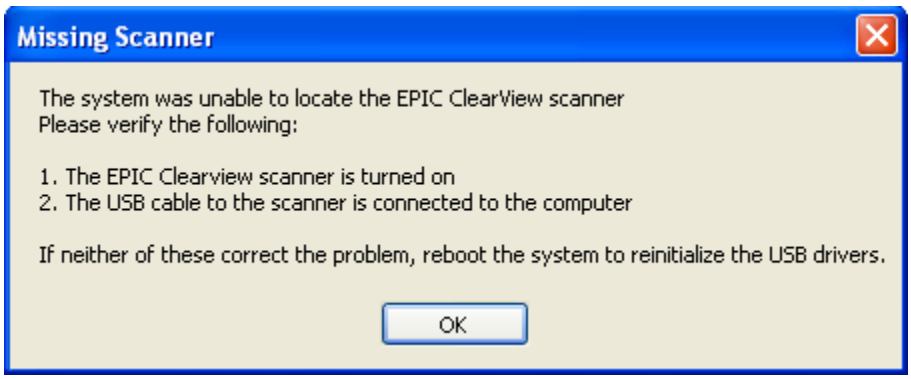
5.3 The written protocol is intended to capture the steps needed to properly challenge each software function/data point. However, given the evolving nature of software development, the instructions may not be 100% accurate. Therefore, any minor deviation from the written instructions will be corrected 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.

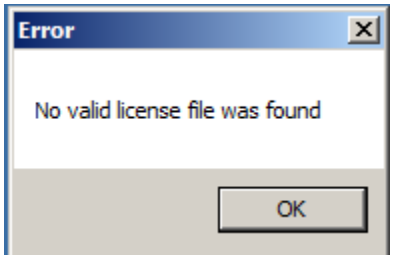
5.4 Record the results of each validation step by initialing and dating in the space provided. If the characteristic cannot be verified, record a reference number on the protocol and the Non-Conformances Worksheet (Attachment B) and describe the

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.

Double click on the ClearView software icon located on the computer desktop. Verify that the Username and Password box are empty.

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

Click in the Username box and enter "EPICUser". 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 "EPICUser". 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.** _____

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.** _____

6.3 **Camera Calibration** Icon

Double click the EPIC ClearView icon on the desktop. Enter the user name as "Administrator" and enter the password provided by the Network Administrator. 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.** _____

Click on the Settings button in the Application toolbar. Verify that the Scanner Settings tab opens.

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

In the Settings box, adjust the Brightness to 65, Gain to 50, and Exposure Delay to 200. Click on the Apply Settings button. Verify that the Scanner Setting tab closes and the screen returns to the ClearView main screen.

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

Click on the Settings button in the Application toolbar. Verify that the Brightness is set to 65, Gain 50, and Exposure Delay 200.

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

In the Settings box, adjust the Brightness to 82, Gain to 63 and Exposure Delay to 320. Click on 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 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. _____

Double click on the ClearView software icon located on the computer desktop. Click in the Username box and enter "EPICUser". 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. _____

Click on the Camera Calibration button. Verify that the Scanner Calibration window is displayed, with two large boxes labeled Captured Image and Image Preview, and a row of ten thumbnail boxes labeled Calibration Image #1 through #10. Verify that two buttons are in the lower right corner of the window labeled Close and Auto Calibration and that no other buttons are displayed.

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

6.3.1 Close Button

Click the close button. Verify that the Scanner Calibration window closes and the ClearView main screen appears.

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

Click on the Camera Calibration button. Verify that the Scanner Calibration window is displayed, with two large boxes labeled Captured Image and Image Preview, and a row of ten thumbnail boxes labeled Calibration Image #1 through #10. Verify that two buttons are in the lower right corner of the window labeled Close and Auto Calibration and that no other buttons are displayed.

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

6.3.2 Auto Calibration button

Click on the Auto Calibration button in the lower right corner of the Scanner Calibration window. Verify that 5 warm-up images are taken followed by 10 images that are displayed in the thumbnail boxes. Verify that the message appears below the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Verify that a message appears notifying the user that calibration was successful and the calibration success display window opens.

___ Verified _____ Not Verified (Proceed to section **6.3.2.1**)

Click the OK button in the Calibration Success window. Verify that the Calibration Success window closes and the screen returns to the ClearView main screen. (Proceed to section **6.3.2.2**)

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

6.3.2.1 Unable to verify calibration

If calibration was successful, skip this section and proceed to section 6.3.2.2. If calibration was not successful, verify that the Calibration Failure dialog box

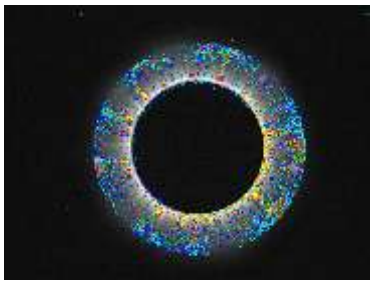


Figure 1 Example of colored pixels

opens with the message "Unable to verify calibration images. Please, repeat calibration process."

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

Click the OK button in the Calibration Failure dialog box. Record the image number (e.g. Calibration Image #1, #4, etc.) below of any images displayed with colored pixels (which indicate calibration analysis failures).

Calibration Image Numbers with colored pixels:

_____

Click the Close button at the bottom right of the Scanner Calibration window. Verify the Scanner Calibration window closes and the screen returns to the EPIC ClearView main screen.

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

Verify that the Alert box (located at the top of the screen) appears highlighted in red with the message "Calibration validation failed".

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

Move the cursor into the Alert box and verify that the red highlight turns off.

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

Click on the View Selected icon. Verify that a list appears with columns for Time, Type, Title, and Message, with entries under each and a list of image numbers that failed and the number of bad pixels.

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

Verify that the View Alerts tab appears in the upper left corner of the screen.

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

Verify that the calibration image numbers recorded above match the calibration image numbers listed on the View Alerts tab.

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

Print the screen and label it "UserCal #1". Click the "X" in the upper right corner of the View Alerts screen. Verify that the View Alerts tab closes and the screen returns to the ClearView main screen.

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

6.3.2.2 If calibration was successful, or after section 6.3.2.1 is completed, continue here.

Click on the Camera Calibration button. Verify that the Scanner Calibration window opens. Attempt to right click on each of the 10 thumbnail boxes and verify there is no response (such as an Open file dialog box opens).

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

Click the Close button in the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the system returns to the EPIC ClearView main screen.

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

6.3.3 EPIC Administrator mode

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.** _____

Double click the EPIC ClearView icon on the desktop. Enter the user name as "Administrator" and enter the password provided by the Network Administrator. 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. _____

Click on the Camera Calibration button. Verify that the Scanner Calibration window is displayed, with a tab labeled Calibration in the upper left corner, and two large boxes labeled Captured Image and Image Preview, and a row of ten thumbnail boxes labeled Calibration Image #1 through #10. Verify that three buttons are in the lower right corner of the window labeled Reset Images, Close and Auto Calibration. Verify that the Start Duty Cycle Testing button appears in the lower left corner of the window. Verify that the message line below the Scanner Calibration header reads "Ready to calibrate the scanner".

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

6.3.4 Close Button

Click the close button. Verify that the Scanner Calibration window closes and the ClearView main screen appears.

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

Click on the Camera Calibration button. Verify that the Scanner Calibration window is displayed, with two large boxes labeled Captured Image and Image Preview, and a row of ten thumbnail boxes labeled Calibration Image #1 through #10.

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

6.3.5 Auto Calibration button

Click on the Auto Calibration button in the lower right corner of the Scanner Calibration window. Verify that 5 warm-up images are taken followed by 10 images that are displayed in the thumbnail boxes. Verify that the message appears below

the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Verify that a message appears notifying the user that calibration was successful and the calibration success display window opens.

_____ Verified _____ Not Verified (Proceed to section **6.3.5.1**)

Click the OK button in the Calibration Success window. Verify that the Calibration Success window closes and that the Question dialog box opens with the message "Do you want to save the images to disk?"

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

Click Yes. Verify that the Browse for Folder window opens. Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder. Rename the New Folder to CalPass1. Highlight CalPass1 and click the OK button. Verify that the Browse for Folder window closes and the screen returns to the ClearView main screen.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalPass1. Verify that there are 10 calibration images in the folder in the following format:

1L_CalibrationImage#6.bmp
1R_CalibrationImage#1.bmp
2L_CalibrationImage#7.bmp
2R_CalibrationImage#2.bmp

3L_CalibrationImage#8.bmp
3R_CalibrationImage#3.bmp
4L_CalibrationImage#9.bmp
4R_CalibrationImage#4.bmp
5L_CalibrationImage#10.bmp
5R_CalibrationImage#5.bmp

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

6.3.5.1 If calibration was successful, skip this section and proceed to step 6.3.6. If calibration was not successful, verify that the Calibration Failure dialog box opens with the message "Unable to verify calibration images. Please, repeat calibration process."

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

Click the OK button in the Calibration Failure window. Verify that the Calibration Failure window closes and that the Question dialog box opens with the message "Do you want to save the images to disk?"

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

Click Yes. Verify that the Browse for Folder window opens.

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

Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder and name or rename the New Folder to CalFail1. Highlight CalFail1 and click the OK button. Verify that the Browse for Folder window closes and the screen returns to the Scanner Calibration screen.

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

Click the Close button on the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the screen is returned to the ClearView main screen.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalFail1. Verify that there are 10 calibration images in the folder in the following format:

1L_CalibrationImage#6.bmp
1R_CalibrationImage#1.bmp
2L_CalibrationImage#7.bmp
2R_CalibrationImage#2.bmp
3L_CalibrationImage#8.bmp
3R_CalibrationImage#3.bmp
4L_CalibrationImage#9.bmp
4R_CalibrationImage#4.bmp
5L_CalibrationImage#10.bmp
5R_CalibrationImage#5.bmp

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

6.3.6 Failure Detection

Click on the taskbar to maximize ClearView. Verify that the ClearView main screen appears.

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

Improperly seat the calibration probe at an angle to the glass electrode. If the probe is improperly seated, the energized image will contain light in the inner circle of the image that is typically black. Contact the validation coordinator for instructions for proper probe placement. Click on the Camera Calibration button. Verify that the

Scanner Calibration window opens. Click on the Auto Calibration button in the lower right corner of the Scanner Calibration window. Verify that 5 warm-up images are taken followed by 10 images that are displayed in the thumbnail boxes. Verify that the message appears below the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Verify that the Calibration Failure dialog box opens with the message "Unable to verify calibration images. Please, repeat calibration process."

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

Click the OK button in the Calibration Failure window. Verify that the Question dialog box opens with the message "Do you want to save the images to disk?"

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

Click Yes. Verify that the Browse for Folder window opens.

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

Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button and name or rename the New Folder to CalFail2. Highlight and click the OK button. Verify that the Browse for Folder window closes and the screen returns to the Scanner Calibration window.

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

Click the Close button on the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the screen is returned to the ClearView main screen.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalFail2. Verify that there are 10 calibration images in the folder.

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

Click on the taskbar to maximize ClearView. Verify that the ClearView main screen appears.

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

Move the cursor into the Alert box and verify that the red highlight turns off. Click on the View Selected icon. Verify that a list appears with columns for Time, Type, Title, and Message, with entries under each and a list of image numbers that failed and the number of bad pixels. Verify that the View Alerts tab appears in the upper left corner of the screen. Print screen and label it "Cal #2".

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

Click on the Setting button in the Application toolbar. In the Settings box, adjust the Brightness to 50, Gain to 50, and Exposure Delay to 200. Click on the Apply Settings button. Verify that the Settings tab closes and the View Alerts tab appears. Click the "X" in the upper right corner of the View Alerts tab to return to the ClearView main screen.

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

Click on the Camera Calibration button. Verify that the Scanner Calibration window opens. Click on the Auto Calibration button in the lower right corner of the Scanner Calibration window. Verify that 5 warm-up images are taken followed by 10 images that are displayed in the thumbnail boxes. During processing the message line below the Scanner Calibration header will display the progress. Verify that the message appears notifying the user that the calibration process is progressing.

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

Verify that the Calibration Failure dialog box opens with the message “Unable to verify calibration images. Please, repeat calibration process.”

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

Click the OK button in the Calibration Failure window. Verify that the Question dialog box opens with the message “Do you want to save the images to disk?”

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

Click Yes. Verify that the Browse for Folder window opens. Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder. Rename the New Folder to CalFail3. Highlight CalFail3 and click the OK button. Verify that the Browse for Folder window closes and the screen returns to the Scanner Calibration window.

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

Click the Close button on the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the screen is returned to the ClearView main screen.

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

Click the “-” in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalFail3. Verify that there are 10 calibration images in the folder.

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

Click on the taskbar to maximize ClearView. Verify that the ClearView main screen appears.

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

Move the cursor into the Alert box and verify that the red highlight turns off. Click on the View All icon. Verify that two alerts appear. Print screen and label it "Cal #3". Verify that the pixel counts have changes from Cal #2 to Cal #3.

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

Click the Camera Calibration button. Verify that the Scanner Calibration window opens and the Calibration tab appears in the upper left corner next to the View Alerts tab. Click on the View Alerts tab. Verify that the View Alerts screen opens with the list from the previous step. Click on the Calibration tab to return to the Scanner Calibration screen. Click "X" in the upper right corner of both windows.

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

Click on the Settings button in the Application toolbar. In the Settings box, adjust the Brightness to 115, Gain to 63, and Exposure Delay to 320. Click on the Apply Settings button. Verify that the ClearView main screen appears.

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

Click on the Camera Calibration button. Verify that the Scanner Calibration window opens. Click on the Auto Calibration button in the lower right corner of the Scanner Calibration window. Verify that 5 warm-up images are taken followed by 10 images that are displayed in the thumbnail boxes. Verify that the message appears below the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Verify that the Calibration Failure dialog box opens with the message "Unable to verify calibration images. Please, repeat calibration process."

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

Click the OK button in the Calibration Failure window. Verify that the Question dialog box opens with the message "Do you want to save the images to disk?"

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

Click Yes. Verify that the Browse for Folder window opens. Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder. Rename the New Folder to CalFail4. Highlight CalFail4 and click the OK button. Verify that the Browse for Folder window closes and the screen returns to the Scanner Calibration window.

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

Click the Close button on the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the screen is returned to the ClearView main screen.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalFail4. Verify that there are 10 calibration images in the folder.

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

Click on the taskbar to maximize ClearView. Verify that the ClearView main screen appears.

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

Move the cursor into the Alert box and verify that the red highlight turns off. Click on the View All icon. Verify that three alerts appear. Print screen and label it “Cal #4”. Verify that the pixel counts have changes from Cal #2 to Cal #3 to Cal #4.

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

Attach sheets Cal #2, Cal #3, Cal #4 to the final protocol. Click the “X” in the upper right corner of the View Alerts tab. Verify that the screen returns to the ClearView main screen. Click on the View All icon in the Alerts box. Verify that the View Alerts screen opens and the three alerts are displayed. Click on the Exit icon in the Application box. Verify that the EPIC ClearView is closed and the desktop now appears.

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

Double click the EPIC ClearView icon on the desktop. Enter the user name as “Administrator” and enter the password provided by the Network Administrator. 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. _____

Click the Camera Calibration button. Verify that the Scanner Calibration window opens. In the Alerts box, click on the down arrow and verify there are no alerts.

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

Click the Close button in the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the system returns to the EPIC ClearView main screen.

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

6.3.7 Load Calibration Images

Click the Camera Calibration button. Right click on the Calibration Image #1 box and verify that the Open dialog box opens. Locate the I:\Calibration_Testing\APR2011\NewCal_Images\Validation Images folder. Enter *.* in the File name box and click on the Open button. Click on filename SN09_21_1L.bmp and click the Open button. Verify that the Open dialog box closes and an image appears in the Calibration Images #1 box. Verify that the button in the lower right corner of the Scanner Calibration window changes from Auto Calibration to Submit Calibration.

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

Repeat the above step for each Calibration Image box and File name (#2 = SN09_22, #3 = SN09_23 … #10 = SN09_30) so that all Calibration Image boxes have images.

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

Click on the Submit Calibration button in the lower right corner of the Scanner Calibration window. During processing the message line below the Scanner Calibration header will display the progress. Verify that the Calibration Success dialog box opens with the message "The calibration was successful. Close this message to finalize the calibration data."

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

Click the OK button in the Calibration Success window. Verify that the Calibration Success window closes. Verify that the Question dialog box opens with the message "Do you want to save the images to disk?"

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

Click Yes. Verify that the Browse for Folder window opens. Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder. Rename the New Folder to CalPass5. Highlight CalPass5 and click the OK

button. Verify that the Scanner Calibration window closes and the screen is returned to the ClearView main screen.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalPass5. Verify that there are 10 calibration images in the folder.

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

Click on the taskbar to maximize ClearView. Verify that the ClearView main screen appears.

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

Click the Camera Calibration button. Right click on the Calibration Image #1 box and verify that the Open dialog box opens. Locate the I:\Calibration_Testing\APR2011\NewCal_Images\Validation Images folder. Enter *.* in the File name box and click on the Open button. Click on filename SN09_21_1L.bmp and click the Open button. Verify that the Open dialog box closes and an image appears in the Calibration Images #1 box. Verify that the button in the lower right corner of the Scanner Calibration window changes from Auto Calibration to Submit Calibration.

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

Repeat the above step for each Calibration Image box and File name (#2 = SN09_22, #3 = SN09_23 … #10 = SN09_30) so that all Calibration Image boxes have images.

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

Click the Reset Images button in the lower right corner of the Scanner Calibration window. Verify that the Captured Image box and the thumbnail boxes clear the images.

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

Click the Close button in the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the system returns to the EPIC ClearView main screen.

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

Click the Camera Calibration button to open the Scanner Calibration window. Click the Start Duty Cycle Testing Button in the lower left corner of the window. Verify that the scanner takes images in sequential order and fills the boxes in the row of Calibration Images with each image. Verify that the button in the lower left corner of the window now reads Stop Duty Cycle Testing and a message appears with each scan that reads “Duty cycle testing, capturing image #1”, and #2, #3, etc.

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

Click the Stop Duty Cycle Testing button. Verify that the scanner stops taking images.

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

Click the Reset Images button. Verify that the Calibration Image boxes #1 through #10 are blank.

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

Click the Start Duty Cycle Testing Button in the lower left corner of the window. Verify that the scanner takes images in sequential order and fills the boxes in the row of Calibration Images with each image. Verify that the button in the lower left corner of the window now reads Stop Duty Cycle Testing and a message appears with each scan that reads “Duty cycle testing, capturing image #1”, and #2, #3, etc.

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

Click the Stop Duty Cycle Testing button. Verify that the scanner stops taking images.

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

Click the Close button in the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the system returns to the EPIC ClearView main screen.

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

6.4 EPIC Administrator Challenges- Calibration Load Images Option

Click the Camera Calibration icon. Click in the box above Calibration Image #1 box. Right click and verify the Open window appears (a dialog box that allows you to locate the network file for loading of images).

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

Locate the I:\Calibration_Testing\APR2011\NewCal_Images\SN07\Validation folder. Enter *.* in the File name box and click on the Open button. Click to highlight the _1L image and click Open. Verify that the image is displayed in the Capture Image box and the Calibration #1 image box.

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

Repeat this step for all ten images (1R, 2L, etc.). Record the verification results below by placing initials in the appropriate box:

Sample	Verified?	Not Verified?	Non-Conformance Ref. No.
_1R			
_2L			
_2R			
_3L			
_3R			

_4L			
_4R			
_5L			
_5R			

Click the Close button in the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the system returns to the EPIC ClearView main screen.

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

Click the Camera Calibration icon. Click in the box above Calibration Image #1 box. Right click and verify the Open window appears (a dialog box that allows you to locate the network file for loading of images).

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

Locate the I:\Calibration_Testing\APR2011\NewCal_Images\SN07\Validation folder. Enter *.* in the File name box and click on the Open button. Click to highlight the _1L image and click Open. Verify that the image is displayed in the Capture Image box and the Calibration #1 image box.

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

Repeat this step for all ten images (1R, 2L, etc.). Record the verification results below by placing initials in the appropriate box:

Sample	Verified?	Not Verified?	Non-Conformance Ref. No.
_1R			
_2L			
_2R			
_3L			
_3R			
_4L			
_4R			
_5L			
_5R			

Click on the Submit Calibration button in the lower right corner of the Scanner Calibration window. Verify that the message appears below the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Verify that the Calibration Failure dialog box opens with the message "Unable to verify calibration images. Please, repeat calibration process."

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

Click the OK button in the Calibration Failure window. Verify that the Question dialog box opens with the message "Do you want to save the images to disk?"

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

Click Yes. Verify that the Browse for Folder window opens. Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder. Rename the New Folder to CalFail6. Highlight CalFail6 and click the OK button. Verify that the Browse for Folder window closes and the screen returns to the Scanner Calibration window.

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

Click the Close button on the lower right corner of the Scanner Calibration window. Verify that the Scanner Calibration window closes and the screen is returned to the ClearView main screen.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-

quality_system_records\1.1.1.2_Validation\CalibrationImages\CalFail6. Verify that there are 10 calibration images in the folder.

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

Click on the taskbar to maximize ClearView. Verify that the ClearView main screen appears.

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

Move the cursor into the Alert box and verify that the red highlight turns off. Click on the View All icon. Verify that the alert appears. Print screen and label it "Cal #6".

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

Compare the Cal #6 printout to the expected results documented in Attachment C. Verify that the results recorded on the Cal #6 printout match the expected results documented in Attachment C.

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

Attach sheet Cal #6 to the final protocol.

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

Click the Camera Calibration button. Verify that the Scanner Calibration window opens and the Calibration tab appears in the upper left corner next to the View Alerts tab. Click on the View Alerts tab. Verify that the View Alerts screen opens with the list from the previous step. Click on the Calibration tab to return to the Scanner Calibration screen. Click "X" in the upper right corner of both screens.

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

Click the Camera Calibration icon. Click in the box above Calibration Image #1 box. Right click and verify the Open window appears (a dialog box that allows you to locate the network file for loading of images).

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

Locate the I:\Calibration_Testing\APR2011\NewCal_Images\Validation Images folder. Enter *.* in the File name box and click on the Open button. Click on filename SN09_51_1L.bmp and click the Open button. Verify that the image is displayed in the Capture Image box and the Calibration #1 image box.

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

Repeat this step for all ten images (52_1R, 53_2L, etc.). Record the verification results below by placing initials in the appropriate box:

Sample	Verified?	Not Verified?	Non-Conformance Ref. No.
52_1R			
53_2L			
54_2R			
55_3L			
56_3R			
57_4L			
58_4R			
59_5L			
60_5R			

Click on the Submit Calibration button in the lower right corner of the Scanner Calibration window. Verify that the message appears below the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Verify that a message appears notifying the user that calibration was successful and the calibration success display window opens.

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

Click the OK button in the Calibration Success window. Verify that the Calibration Success window closes. Verify that the Question dialog box opens with the message "Do you want to save the images to disk?"

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

Click Yes. Verify that the Browse for Folder window opens. Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder. Rename the New Folder to CalPass7. Highlight CalPass7 and click the OK button. Verify that the Browse for Folder window closes.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalPass7. Verify that there are 10 calibration images in the folder.

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

Click on the taskbar to maximize ClearView. Verify that the ClearView main screen appears.

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

Click the Camera Calibration icon. Click in the box above Calibration Image #1 box. Right click and verify the Open window appears (a dialog box that allows you to locate the network file for loading of images).

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

Locate the I:\Calibration_Testing\APR2011\NewCal_Images\SN07\Validation180 folder. Enter *.* in the File name box and click on the Open button. Click to

highlight the _1L image and click Open. Verify that the image is displayed in the Capture Image box and the Calibration #1 image box.

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

Repeat this step for all ten images (1R, 2L, etc.). Record the verification results below by placing initials in the appropriate box:

Sample	Verified?	Not Verified?	Non-Conformance Ref. No.
_1R			
_2L			
_2R			
_3L			
_3R			
_4L			
_4R			
_5L			
_5R			

Click on the Submit Calibration button in the lower right corner of the Scanner Calibration window. Verify that the message appears below the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Verify that the Calibration Failure dialog box opens with the message “Unable to verify calibration images. Please, repeat calibration process.”

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

Click the OK button in the Calibration Failure window. Verify that the Question dialog box opens with the message “Do you want to save the images to disk?”

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

Click Yes. Verify that the Browse for Folder window opens. Locate and highlight folder O:\QualitySystems\Quality_System_Documents\Non-

quality_system_records\1.1.1.2_Validation\CalibrationImages. Click the Make New Folder button. Verify that a New Folder is created under the CalibrationImages folder. Rename the New Folder to CalFail8. Highlight CalFail8 and click the OK button. Verify that the Browse for Folder window closes and the screen returns to the Scanner Calibration window.

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

Click the "-" in the upper right corner of the ClearView main screen to minimize ClearView and to display the Desktop. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\CalibrationImages\CalFail8. Verify that there are 10 calibration images in the folder.

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

Click on the taskbar to maximize ClearView. Verify that the ScannerCalibration screen appears.

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

Move the cursor into the Alert box and verify that the red highlight turns off. Click on the View All icon. Verify that two alerts appear. Print screen and label it "Cal #8".

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

Compare the Cal #8 printout to the expected results documented in Attachment C. Verify that the results recorded on the Cal #8 printout match the expected results documented in Attachment C.

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

Attach sheet Cal #8 to the final protocol.

7.0 Reference

EG-011, Software Validation
QA-004, Deviations

8.0 Attachments

Attachment A, Deviations from Protocol
Attachment B, Non-conformances Worksheet
Attachment C, Expected Calibration Results (Bad Pixels)
Attachment D, Expected Calibration Results

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

Attachment C
Expected Calibration Results (Bad Pixels)
Cal #6

Sample	Number of Bad Pixels
_1L	474 low pixels and 8104 high pixels
_1R	365 low pixels and 8425 high pixels
_2L	519 low pixels and 7822 high pixels
_2R	332 low Pixels and 9087 high pixels
_3L	594 low pixels and 8184 high pixels
_3R	427 low pixels and 8490 high pixels
_4L	493 low pixels and 8215 high pixels
_4R	951 low pixels and 6943 high pixels
_5L	504 low pixels and 9133 high pixels
_5R	375 low pixels and 8673 high pixels

Attachment C
Expected Calibration Results (Bad Pixels)
Cal #8

Sample	Number of Bad Pixels
_1L	457 low pixels and 8046 high pixels
_1R	353 low pixels and 8677 high pixels
_2L	502 low pixels and 7902 high pixels
_2R	306 low pixels and 9094 high pixels
_3L	571 low pixels and 8143 high pixels
_3R	402 low pixels and 8539 high pixels
_4L	461 low pixels and 8260 high pixels
_4R	873 low pixels and 6862 high pixels
_5L	489 low pixels and 9289 high pixels
_5R	365 low pixels and 8772 high pixels

Attachment D
Expected Calibration Results

Test	Expected Result
UserCal #1	User login test that auto-calibration function works as expected. Pass is expected, but failure is acceptable.
CalPass1	Admin login test that auto-calibration function works as expected. Pass is expected, but failure is acceptable. If pass, images saved as CalPass1.
CalFail1	Admin login test that auto-calibration function works as expected. Pass is expected, but failure is acceptable. If failure, images saved as CalFail1.
CalFail2	Admin login test that improperly seated calibration probe results in calibration failure. Failure is expected, pass is a non-conformance to the requirements. Images saved as CalFail2.
CalFail3	Admin login test that low camera settings (Brightness = 50 and Exposure Delay = 50) result in calibration failure. Failure is expected, pass is a non-conformance to the requirements. Images saved as CalFail3.
CalFail4	Admin login test that high camera settings (Brightness = 100 and Exposure Delay = 320) result in calibration failure. Failure is expected, pass is a non-conformance to the requirements. Images saved as CalFail4.
CalPass5	Admin login test that known good calibration images loaded and resubmitted for calibration result in calibration success. Pass is expected, failure is a non-conformance to the requirements. Images saved as CalPass5.

Test	Expected Result
CalFail6	Admin login test that known bad calibration images loaded and resubmitted for calibration result in calibration failure. Failure is expected, pass is a non-conformance to the requirements. Images saved as CalFail6.
CalPass7	Admin login test that known good calibration images loaded and resubmitted for calibration result in calibration success. Pass is expected, failure is a non-conformance to the requirements. Images saved as CalPass7.
CalFail8	Admin login test that known bad calibration images loaded and resubmitted for calibration result in calibration failure. Failure is expected, pass is a non-conformance to the requirements. Images saved as CalFail8.