Approval Signatures:

Department	Name	Signature	Date
QA	Andrea Miller	Andrea Miller	2/28/12
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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 validate specific revisions made to the 1.1.1.2 version of the ClearView software after performing the standard protocols. The test methods developed in this protocol will be added to the specific functional area (i.e., patient demographics, camera, capture, analysis, and application) protocols and future testing will be done using these protocols.

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 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.

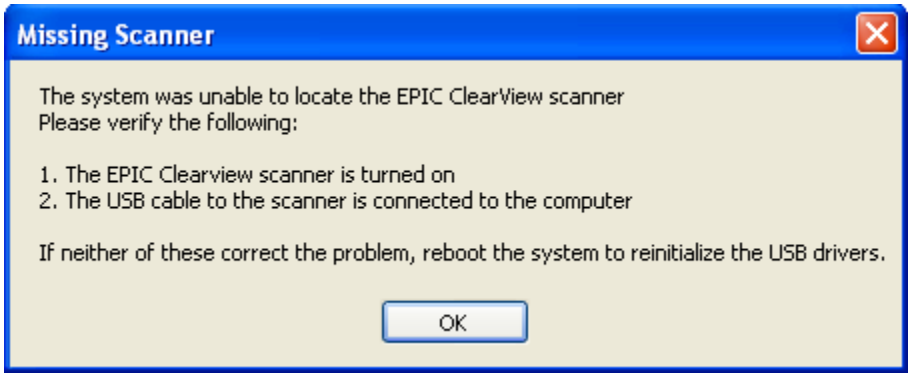
5.3 The written protocol is intended to capture the steps needed to properly challenge each software function/data point. However, given the evolving nature of software development, the instructions may not be 100% accurate. Therefore, any minor deviation from the written instructions will be corrected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

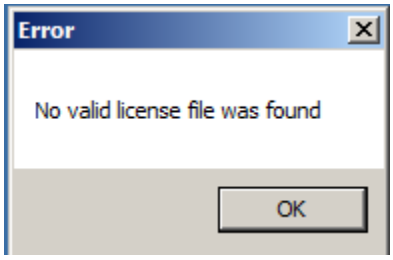
5.4 Record the results of each validation step by initialing and dating in the space provided. If the characteristic cannot be verified, record a reference number on the protocol and the Non-Conformances Worksheet (Attachment B) and describe the failure in a specific and complete manner by completing 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 Verify with QA and IT that the correct ClearView software revision, license, database, and scanner have been installed on the test workstation.

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

6.1.3 Place the calibration shroud over the lens cover.

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

6.1.5 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.

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

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

_____

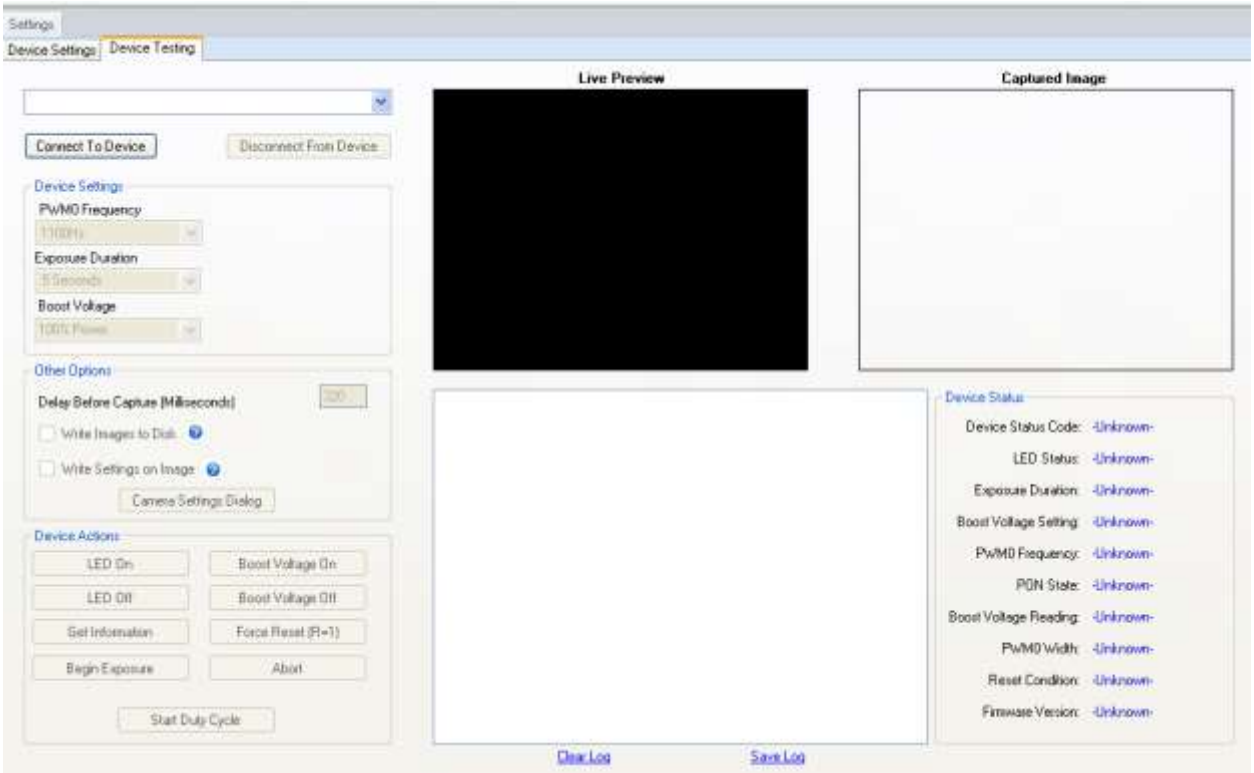
6.2 "Login As" function - Double click on the ClearView software icon located on the computer desktop. Click in the Username box and enter "Administrator". Click in the password box and enter the password provided by the Network Administrator. Click the Login button. Verify that the "Login As" window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

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

6.3 Application Functions

6.3.1 Settings Button – Device Testing tab

Click on the Settings button. Verify the Settings tab opens with the Device Settings subtab highlighted. Click on the Device Testing tab. Verify the Device Testing tab opens and appears as shown:



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

Click on the Connect to Device button. Verify the "A camera must be selected" dialog box opens. Click OK. Verify the dialog box closes.

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

In the dropdown menu, select the Phillips SPC 900NC PC Camera. Verify it is highlighted in the dropdown window. Click on the Connect to Device button. Verify the grayed out fields become active and the Log shows entries. Verify the Disconnect from Device button becomes active.

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

Click on the Disconnect from Device button. Verify the active fields become grayed out and the Connect to Device button becomes active. Click on the Connect to Device button. Verify the fields are active.

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

In the Device Settings section, select each option in each dropdown and verify it appears in the dropdown window, end by selecting the original values of 1100Hz, .5 Seconds, and 100% Power.

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

In the Device Actions section, click on the LED On button. Verify a live image of the calibration probe appears in the Live Preview box. Click on the LED Off button. Verify the image disappears.

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

Click on the Get Information button. Verify the entries in the Device Status section change from Unknown to an appropriate value. Record the last entry, Firmware Version, below:

_____

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

Click on the Begin Exposure button. Verify an energized image appears briefly in the Live Preview box, and an image appears and remains in the Captured Image box.

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

Click on the Boost Voltage On button. Click on the Begin Exposure button. Verify an image of similar brightness to the previous step appears in the Captured Image box.

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

Click on the Boost Voltage Off button. Click on the Begin Exposure button. Verify a dim image appears in the Captured Image box. Click on the Boost Voltage On button.

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

Click on the Force Reset button. Verify in the Log display a "Sending: R=1" entry displays followed by a "Received: " entry.

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

Click on the Abort button. Verify in the Log display a "Sending: a" entry displays followed by a "Received: " entry.

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

Click on the Start Duty Cycle button. Verify the energized images repeat in the Live Preview and Captured Image boxes at short intervals. Verify the Start Duty Cycle button now reads Stop Duty Cycle. Click the Stop Duty Cycle button. Verify the image taking stops, and the button now reads Start Duty Cycle.

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

In the Other Options section, change the value in the Delay Before Capture to 200. Click the Begin Exposure button. Verify the image in the Captured Image box is significantly dimmer than the original 320 setting. Change the value back to 320.

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

Next to the Write Images to Disk checkbox, hover over the question mark in the blue circle, and verify a pop-up message appears that reads "Checking this box will cause all captured images to be written to the same folder the app is being run in."

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

Next to the Write Settings on Image checkbox, hover over the question mark in the blue circle, and verify a pop-up message appears that reads “Checking this box will cause the captured images to have the voltage and frequency used transposed on them.”

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

Click to check the Write Images to Disk checkbox. Click the Begin Exposure button. Navigate to folder C:\Program Files\EPIC\Clearview1.1.1.g. Verify the file SampleImage0.gif appears in the folder with the correct date and time listed. Open the file, and verify it matches the image taken.

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

Click to check the Write Settings on Image checkbox. Click the Begin Exposure button. Verify the new image in the Captured Image box has the Voltage and Frequency written in the box. Navigate to folder C:\Program Files\EPIC\Clearview1.1.1.g. Verify the file SampleImage1.gif appears in the folder with the correct date and time listed. Open the file, and verify it matches the image taken.

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

Click to uncheck the Write Images to Disk checkbox. Click the Begin Exposure button. Verify the new image in the Captured Image box has the Voltage and Frequency written in the box. Navigate to folder C:\Program Files\EPIC\Clearview1.1.1.g. Verify a new file was not saved in the folder.

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

Under the Log window, click the Save Log link. Verify the “Save file as” dialog box opens. Navigate to folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation. Enter “samplelog” in the File name box. Click the Save button. Verify the Log saved as dialog box appears. Click OK.

Open the "samplelog" file in Notepad and verify it matches the data in the Log window.

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

Under the Log window, click the Clear Log link. Verify all entries in the Log window disappear. Click the Exit button to exit ClearView.

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

6.4 Techadministrator

Double click on the ClearView software icon located on the computer desktop. Click in the Username box and enter "techadministrator". Click in the password box and enter the password provided by the Network Administrator. Click the Login button. Verify the EPIC ClearView main screen is displayed and the User Options icons and the Settings icon are displayed.

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

Click on the Camera Calibration button. Verify the Calibration tab opens. Verify the Start Duty Cycle Testing and Reset Images buttons are present and functional. Right-click in the Calibration Image boxes and load a set of known passing calibration images and click on the Submit Calibration button. Verify the calibration passes and save the images to the CalibrationImages folder.

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

Click on the New Capture button. Verify the New Capture tab opens. Find subject Epic Validation and click on the New Capture button. Verify there is no Export Images button in the Capture window. Right-click in each Finger Image box and verify no Open dialog appears. Click the Close button to return to the ClearView main screen.

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

Click on the Search Capture button. Find a Treatment for subject Epic Validation and click on the View Capture button. Verify the View Capture tab opens. Verify there is no Resubmit Images for Analysis button. Click the Close button to return to the ClearView main screen.

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

Click on the Search Capture button. Find a Treatment for subject Epic Validation and click on the View Report button. Verify the Print Report tab opens displaying the ClearView Report. Verify the Worksheet tab, NS Analysis tab, and Biofield tab are present, but the Admin tab is not.

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

Click on the Biofield tab, verify the Biofield tab opens. Verify the Magnified View tab appears in the lower left corner of the display, but there is no Admin View tab option.

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

Click the "X" in the upper right corner of each tab displayed until the ClearView main screen appears. Click on the Settings button. Verify the Settings tab opens with the Device Settings subtab highlighted. Click on the Device Testing tab. Verify the Device Testing tab opens. Verify functionality by clicking several buttons and checking for responses. Click the "X" in the upper right corner of the Settings tab to return to the ClearView main screen. Click the Exit button to exit ClearView.

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

6.5 Audit Trail

1. Log in as "EPICUser". Under Manage Patient, enter a new patient with the name User A. Audit, birthdate of 7/7/77, and Gender is Male. Note the user ID, time (located in the lower left corner of the ClearView software screen) and date of the save below:

Original
User: _____ Date: _____ Time: _____

2. Log in as "administrator". Under Manage Patient, modify subject User A. Audit to Admin B. Audit, birthdate to 8/8/88, and Gender to Female. Note the user ID, time (located in the lower left corner of the ClearView software screen) and date of the save below:

Modified
User: _____ Date: _____ Time: _____

Obtain a printout from the Network Administrator showing the audit trail for subject Admin B. Audit and verify it shows the user who made the entries, the date and time of the saves, and the values changed. Verify the audit trail results match the data entry from #1 and #2 above. Sign and date the audit trail printout and attach the printout to the end of this protocol.

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

3. Login as "EPICUser". Perform an Auto Calibration and record the date and time (located in the lower left corner of the ClearView software screen) of the successful calibration below:

Calibration
User: _____ Date: _____ Time: _____

Perform a New Capture for subject Admin B. Audit. Record below the date and time the Submit for Analysis button was clicked and the date and time (located in the lower left corner of the ClearView software screen) the process completed successfully and the ClearView Report displayed, the Treatment ID listed in the RawData tab, and the Firmware version listed in the Worksheet tab.

User: _____

Submit Date: _____ Time: _____

Completion Date: _____ Time: _____

Treatment ID _____

Firmware version _____

4. Login as "administrator". Perform a Resubmit for subject Admin B. Audit and the Treatment ID listed above. Record below the date and time(located in the lower left corner of the ClearView software screen) the Resubmit for Analysis button was clicked and the date and time the process completed successfully and the ClearView Report displayed, the Treatment ID listed in the RawData tab, and the Firmware version listed in the Worksheet tab.

User: _____

Submit Date: _____ Time: _____

Completion Date: _____ Time: _____

Treatment ID _____

Firmware version _____

Obtain a printout from the Network Administrator showing the audit trail for subject Admin B. Audit and verify it shows the user who performed the functions (including calibration, patient image capture, raw data processed and report data processed), the date and time of the functions, and the Firmware version. Verify the audit trail results match the data entry from #3 and #4 above. Sign and date the audit trail printout and attach the printout to the end of this protocol. Record Pass or Fail in the appropriate column of the following table. If the verification fails, record the non-conformance number next to Fail in the table. Initial and date next to the recorded result.

Test	Calibration Images	Patient Images	Raw Data Processed	Report Data Processed
#3- New Capture				
#4- Resubmit				

6.6 License File

Right click on the ClearView icon on the desktop and click on Properties. A Properties window will open. Navigate to the folder identified in the "Start in:" field. Rename the file "ClearView.lic" to "ClearViewA.lic". Double click on the ClearView software icon located on the computer desktop. Verify the "No valid license file was found" error box appears. Click OK. Rename the file "ClearViewA.lic" back to "ClearView.lic". 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 the EPIC ClearView main screen is displayed.

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

6.7 Automatic Logout

Note the time. Do not perform any work in ClearView. After 15 minutes, verify a message appears at the bottom of the screen next to an exclamation mark in a blue circle that reads. "System will close in 5 minutes, due to inactivity."

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

Verify that after 5 minutes, ClearView automatically closes and the desktop appears.

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

6.8 Failed Login

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

"guess". Click the Login button. Verify the Login Failed message appears. Click OK. Repeat for a second and third attempt. Note the time after the third attempt.

Time: _____

Attempt to login for a fourth time using the correct password. Record the time attempted:

Time: _____

Verify the same error message appears.

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

Wait 30 minutes from the third failed login, attempt to login with the correct password. Record the time attempted:

Time: _____

Verify login is successful.

_____ **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