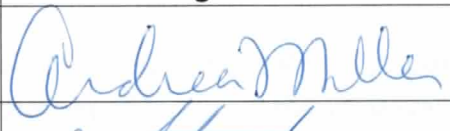
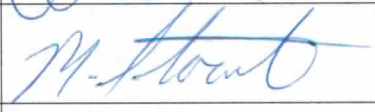
Approval Signatures:

Department	Name	Signature	Date
QA	Andrea Miller		3/1/12 ~~3/1/12~~ 3/1/12
OPS	Michael Stowell		3/1/12
Exec	Nancy Rizzo		5/1/12.
IS	Andrew Mason		3/1/12

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 CAPTURE 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.

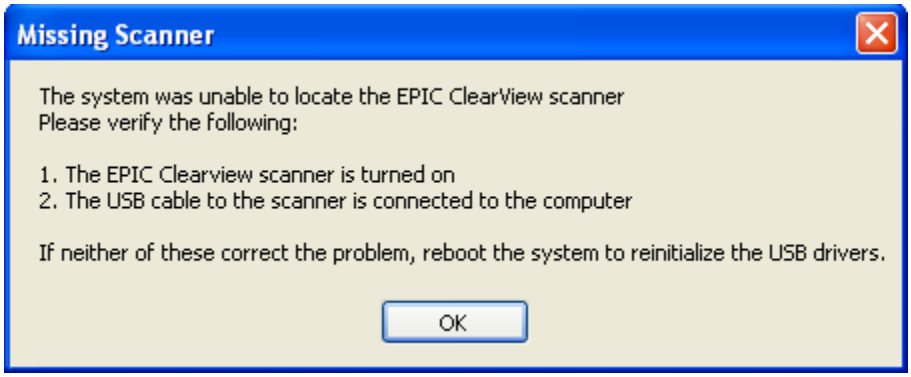
5.2.5 The validation designee should be aware during the execution of this validation protocol that the intention is to validate all functionality of the CAPTURE Icon. If at any time a portion of the software is identified as not being challenged notify the validation team immediately and document the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

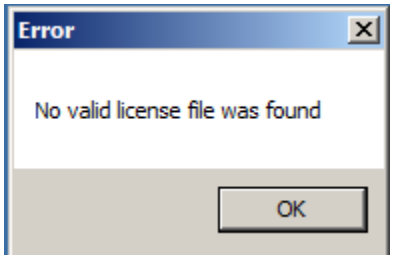
5.3 The written protocol is intended to capture the steps needed to properly challenge each software function/data point. However, given the evolving nature of software development, the instructions may not be 100% accurate. Therefore, any minor deviation from the written instructions will be corrected 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 wipes. Dry the calibration probe completely with a dry cloth or tissue.

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**- 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 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.** _____

NOTE: If the device has not been calibrated, Calibration must be completed prior to proceeding with the validation. Calibration Icon is validated in a different portion of this protocol.

NOTE: The ClearView software is divided into three levels: tabs, subtabs, and categories. These levels will be referenced throughout this document.

6.3 **New Capture** icon. The Capture button has two sections – **New** and **Search**.

From the EPIC ClearView main screen, click on the New Capture icon. Verify that the Search Patient window appears.

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

Search Patient Find function:
With all entry fields blank or null, click the Find button. Verify that a list of patients with various last names, first names, gender, and Patient ID is displayed:

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

Enter the patient's last name of NJMAA. Click the Find button. Verify that a patient by the last name of NJMAA is not displayed and record the result:

_____**Result**

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

Delete any previous entry. Enter the patient's last name as Validation and click Find. Verify that only patients with the last name of Validation are displayed and record the result:

_____**Result**
_____**Result**
_____**Result**

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

Delete any previous entry. Enter the patient's last name as O and click Find. Verify that only patients with last names beginning with O are displayed and record the result:

_____**Result**
_____**Result**
_____**Result**
_____**Result**
_____**Result**
_____**Result**
_____**Result**

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

Use the delete key to delete the "o" in the last name box.
Enter the patient's first name of NJMAA (last name box should be blank). Click the Find button. Verify that a patient by the first name of NJMAA is not displayed and record the result:

_____**Result**

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

Delete any previous entry. Enter the patient's first name as Epic and click Find. Verify that only patients with the first name of Epic are displayed and record the result:

_____**Result**

_____**Result**

_____**Result**

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

Delete any previous entry. Enter the patient's first name as E and click Find. Verify that only patients with a first name beginning with E are displayed and record the result:

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

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

Use the delete key to remove the "e" from the first name box. The Gender field is a drop down menu. With all other entry fields blank, select the Gender as Female by either clicking on the arrow to the right of the field to open the menu and select the correct gender or by clicking in the box which automatically displays the drop down box. Type "F" and click on the Find button. Verify that a list of female patients is displayed (no male patients listed):

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

With all other entry fields blank, select the Gender as Male by either clicking on the arrow to the right of the field to open the menu and select the correct gender or by

clicking in the box which automatically displays the drop down box. Type "M" and click Find. Verify that a list of Male patients is displayed (no female patients listed):

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

With all other entry fields blank, select the Gender as Either by either clicking on the arrow to the right of the field to open the menu and select the correct gender or by clicking in the box which automatically displays the drop down box. Type "E". Click Find. Verify that a list of Male and Female patients is displayed:

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

Click the "x" in the upper right corner of the Search Patient Screen. Verify that the screen is closed and you are returned to the main screen.

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

From the EPIC ClearView main screen, click on the New Capture icon. The Search Patient window appears.

With all other entry fields blank, enter a birth date of 05/13/1951 and click the Find button. Verify that a list of patients with a birth date of 05/13/1951 (slashes are required) is displayed (no patients listed with any other birth date) by opening all patients listed and verifying the birthdate entered.

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

With all other entry fields blank, enter a birth date of 11/18/1969 and click the Find button. Verify that a list of patients with a birth date 11/18/1969 (slashes are required) is displayed (no patients listed with any other birth date) by opening all patients listed and verifying the birthdate entered.

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

Click the "x" in the upper right corner of the Search Patient Screen. From the EPIC ClearView main screen, click on the New Capture icon. The Search Patient window

appears. With all other entry fields blank, enter a birth date as "A" only. Verify that all patients appear (invalid birth date results in a null entry and displays all patients).

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

Click the "X" in the upper right corner of the search patient screen.

6.4 New Capture - New Patient button.

Click the Capture New icon. The Search Patient window will open. Click the Find button. Verify that the New Patient button appears in the lower right corner of the Search Patient window. Click the New Patient button. Verify that the Search Patient window closes and a new screen appears with the Add Patient tab open.

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

General Info Section
Type the following into the appropriate locations:

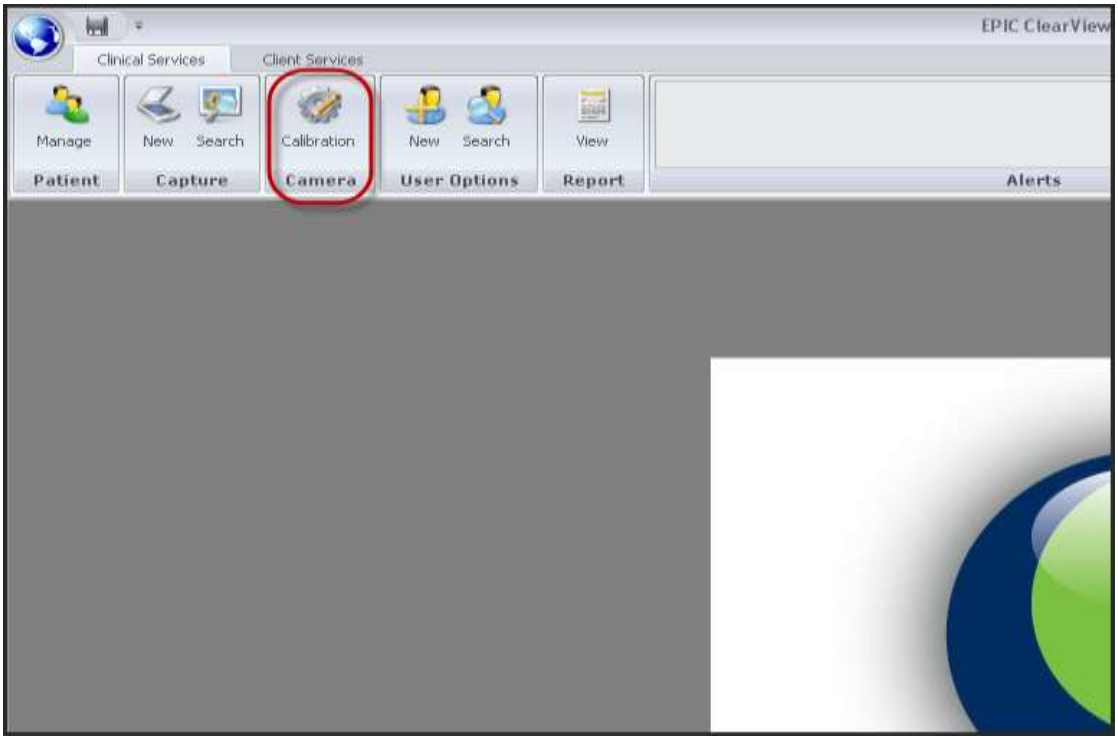
First Name	Clear
Mi (middle initial)	O
Last Name	ViewXXXc (where XXX represents the version number being validated and the c represents the Capture module)
Birth Date	11/25/1978
Gender	Male

Click the "X" in the upper right corner of the Patient Demographics tab. Click "Yes" to save the data. Verify that a message indicating the patient was saved is displayed. Click OK. Verify that the Patient Demographics tab closes and that the screen is returned to the Main Screen.

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

Calibration instructions- This section would only be performed if the device had not yet been calibrated during separate testing.

In the ClearView™ software, click on **Camera Calibration**.



The Scanner Calibration window will open. Click the Auto Calibration button in the lower right corner of the window.

The ClearView™ device will make a "beep" sound and will capture five warm-up images and ten calibration images, one after the other.

Do not touch the ClearView™ device, the USB cable, or the calibration probe during image capture at any time.

After all ten (10) images are automatically captured; the ClearView™ software will start analyzing the calibration images. If the calibration images pass, the next screen will return a message indicating the calibration process was successful. Click **OK** to close the message window and Close to leave the Calibration Tab.

If calibration fails, you will receive an error message that says "Unable to verify calibration. Please, repeat calibration process." Click **OK** to leave the Calibration Tab.

The ClearView™ software will only allow you to continue on to patient image capture if the calibration images have passed calibration testing. If calibration testing has not passed, try the following steps:

- Re-clean the glass surface and metal piece of the calibration probe.
    - Dry the glass surface and metal piece completely with the provided cleaning supplies, ensuring that no debris, lint, or oil remains.
    - Make sure to not touch the metal piece of the calibration probe.
- Ensure that the metal piece of the calibration probe fits snugly through the calibration cover and lays flat on the glass surface.
- Ensure that the testing surface is level.

After successful calibration:

New Capture – User Login

Click on the New Capture button. Verify that the Search Patient window opens. Click the Find button at the top of the displayed window. Search and identify patient Epic Validation. Click to highlight this patient and click the New Capture button in the lower right corner of the window. Verify that the New Capture tab opens and the "Gather a capture for" window is displayed.

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

Verify that the Submit for Analysis button in the lower right corner of the window is inactive. Verify that the Capture Image and Close buttons are active.

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

Verify that an image appears in the Finger Image box. Verify Right Thumb Finger appears in red and 1R label appears in the hands box. Verify that the System Messages box reads "Verify that there is not a capacitive barrier in the scanner."

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

Click on the Capture Image button in the lower right corner of the window. Verify that an image appears in Captured Image window and Right Thumb Finger window in the Images without Capacitive Barrier row.

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

Click into the Right Index Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Right Index Finger appears in red and 2R label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Right Index Finger window in the Images without Capacitive Barrier row.

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

Click into the Right Middle Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Right Middle Finger appears in red and 3R label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Right Middle Finger window in the Images without Capacitive Barrier row.

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

Click into the Right Ring Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Right Ring Finger appears in red and 4R label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Right Ring Finger window in the Images without Capacitive Barrier row.

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

Click into the Right Pinky Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Right Pinky Finger appears in red and 5R label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Right Pinky Finger window in the Images without Capacitive Barrier row.

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

Click into the Left Thumb Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Left Thumb Finger appears in red and 1L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Thumb Finger window in the Images without Capacitive Barrier row.

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

Click into the Left Index Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Left Index Finger appears in red and 2L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Index Finger window in the Images without Capacitive Barrier row.

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

Click into the Left Middle Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Left Middle Finger appears in red and 3L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Middle Finger window in the Images without Capacitive Barrier row.

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

Click into the Left Ring Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Left Ring Finger appears in red and 4L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Ring Finger window in the Images without Capacitive Barrier row.

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

Click into the Left Pinky Finger box of the Images without Capacitive Barrier row. Verify that an image appears in the Finger Image box. Verify that Left Pinky Finger appears in red and 5L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Pinky Finger window in the Images without Capacitive Barrier row.

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

Click into the Right Thumb Finger box of the Images with Capacitive Barrier row. Verify a previously captured energized image appears in the Right Thumb Finger box

in the Images with Capacitive Barrier Row. Verify that Right Thumb Finger appears in red and 1R label appears in the hands box. Click the Capture Image button. Verify that the image displayed in the Captured Image window changes and in the Right Thumb Finger window in the Images with Capacitive Barrier row.

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

Click into the Right Index Finger box of the Images with Capacitive Barrier row. Verify that a previously captured image appears in the Captured Image box. Verify that Right Index Finger appears in red and 2R label appears in the hands box. Click the Capture Image button. Verify that the image displayed in the Captured Image window changes and in the Right Index Finger window in the Images with Capacitive Barrier row.

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

Click into the Right Middle Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Right Middle Finger appears in red and 3R label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Right Middle Finger window in the Images with Capacitive Barrier row.

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

Click into the Right Ring Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Right Ring Finger appears in red and 4R label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Right Ring Finger window in the Images with Capacitive Barrier row.

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

Click into the Right Pinky Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Right Pinky Finger appears in red and 5R label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Right Pinky Finger window in the Images with Capacitive Barrier row.

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

Click into the Left Thumb Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Left Thumb Finger appears in red and 1L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Thumb Finger window in the Images with Capacitive Barrier row.

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

Click into the Left Index Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Left Index Finger appears in red and 2L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Index Finger window in the Images with Capacitive Barrier row.

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

Click into the Left Middle Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Left Middle Finger appears in red and 3L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Middle Finger window in the Images with Capacitive Barrier row.

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

Click into the Left Ring Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Left Ring Finger appears in red and 4L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Ring Finger window in the Images with Capacitive Barrier row.

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

Click into the Left Pinky Finger box of the Images with Capacitive Barrier row. Verify that an image appears in the Captured Image box. Verify that Left Pinky Finger

appears in red and 5L label appears in the hands box. Click the Capture Image button. Verify that the image appears in the Captured Image window and in the Left Pinky Finger window in the Images with Capacitive Barrier row.

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

Click on the Right Ring Finger box in the Images without Capacitive Barrier row. Click the Capture Image button. Verify that a new image appears in the Captured Image window and in the Right Ring Finger window in the Images without Capacitive Barrier row.

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

Click on the Right Thumb Finger box in the Images with Capacitive Barrier row. Click the Capture Image button. Verify that a new image appears in the Captured Image window and in the Right Thumb Finger window in the Images with Capacitive Barrier row.

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

Click on the Left Middle Finger box in the Images with Capacitive Barrier row. Click the Capture Image button. Verify that a new image appears in the Captured Image window and in the Left Middle Finger window in the Images with Capacitive Barrier row.

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

When all twenty images are displayed in the Images without Capacitive Barrier Row and the Images with Capacitive Barrier Row, verify that the Submit for Analysis button in the lower right corner of the window is active.

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

Click to uncheck the Show Axis/Angle box under the Finger Image box. Verify that the red crosshairs and yellow circle disappear. Click again to check and verify that the crosshairs and yellow circle reappear.

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

Click into the Right Thumb Finger box of the Images without Capacitive Barrier row. Under the Captured Image box, next to Angle, click the green clockwise arrow button ten times and verify that the crosshairs rotate 10 degrees clockwise in the Captured Image box and "10" appears in the Angle display box.

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

Click into the Right Index Finger box of the Images without Capacitive Barrier row. Under the Captured Image box, next to Angle, click the green counter-clockwise arrow button five times and verify that the crosshairs rotate 5 degrees counter-clockwise in the Captured Image box and "-5" appears in the Angle display box.

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

Click into the Right Middle Finger box of the Images without Capacitive Barrier row. Under the Captured Image box, next to X, click the green left arrow button five times and verify that the circle and crosshairs move 5 increments to the left along the x axis in the Captured Image box and decreases 5 points in the X display box.

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

Click into the Right Ring Finger box of the Images without Capacitive Barrier row. Under the Captured Image box, next to X, click the green right arrow button ten times and verify that the circle and crosshairs move 10 increments to the right along the x axis in the Captured Image box and increases 10 points in the X display box.

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

Click into the Right Pinky Finger box of the Images without Capacitive Barrier row. Under the Captured Image box, next to Y, click the green up arrow button ten times and verify that the circle and crosshairs move 10 increments up along the y axis in the Captured Image box and increases 10 points in the Y display box.

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

Click into the Left Thumb Finger box of the Images without Capacitive Barrier row. Under the Captured Image box, next to Y, click the green down arrow button five times and verify that the circle and crosshairs move 5 increments down along the y axis in the Captured Image box and decreases 5 points in the Y display box.

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

Click into the Right Thumb Finger box of the Images with Capacitive Barrier row. Under the Captured Image box, next to Angle, click the clockwise button ten times, next to X, click the left arrow ten times, and next to Y, click the green up arrow button ten times and verify that the circle and crosshairs moved 10 increments in the correct direction and in the display boxes.

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

Click into the Left Pinky Finger box of the Images with Capacitive Barrier row. Under the Captured Image box, next to Angle, click the counter-clockwise button five times, next to X, click the right arrow five times, and next to Y, click the green down arrow button five times and verify that the circle and crosshairs moved 5 increments in the correct direction and in the display boxes.

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

Click on any Finger image in the Images without Capacitive Barrier row. Verify that the System Messages box under the hands box reads “Note: Verify that there is not a capacitive barrier in the scanner”.

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

Click on any Finger image in the Images with Capacitive Barrier row. Verify that the System Messages box under the hands box reads “Note: Verify there is a capacitive barrier in the scanner”.

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

Click the Close button in the lower right corner of the window. Verify the Exit Process dialog box opens to confirm exit. Click the No button. Verify that the

"Gather a capture for" window stays open and that all captured images are displayed as previous displayed prior to clicking the Close button.

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

Click the Close button in the lower right corner of the window. Verify the Exit Process dialog box opens to confirm exit. Click the Yes button. Verify that the "Gather a capture for" window closes and the screen returns to the EPIC ClearView main screen.

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

Click on the New Capture button. Verify that the Search Patient window opens. Click the Find button at the top of the displayed window. Search and identify patient Epic Validation. Click to highlight this patient and click the New Capture button in the lower right corner of the window. Verify that the New Capture tab opens and the "Gather a capture for" window is displayed.

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

Verify that the Submit for Analysis button in the lower right corner of the window is inactive. Verify that the Capture Image and Close buttons are active.

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

Capture a full set of subject images by clicking into each finger image box of the Images without Capacitive Barrier row. Click the Capture Image button. Repeat the process until 10 Images without Capacitive Barrier and 10 Images with Capacitive Barrier have been captured. Verify that all twenty Images without Capacitive Barrier and Images with Capacitive Barrier image boxes contain energized images. Note: calibration images should not be used as they may cause a matlab error, therefore, human subject images should be used.

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

Click on each energized image box (both Images without Capacitive Barrier and Images with Capacitive Barrier). Verify that the displayed energized image and

displayed finger image change after clicking on a different image box. Repeat until all twenty images have been clicked.

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

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a new screen displays with the Print Report tab highlighted and the ClearView Report is displayed.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Sensory and Skeletal Systems; Hepatic, Endocrine, and Nervous System; Cardiovascular System; Respiratory System; Gastrointestinal System; and Renal and Reproductive Systems), and page 5 contains definitions.

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

Click on the Biofield Analysis tab. Verify that a new screen appears with the Item Tab displayed on the left containing boxes for Indexes, Organ Systems, and Settings, a Magnified View tab, and a visual representation of the body views.

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

Click on the NS Analysis tab. Verify that a new screen appears with two boxes containing body side views, graphs, and organ names.

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

Click on the Worksheet tab. Verify that a new screen appears with an Organ Systems box appears on the left side of the screen, containing a list of organ systems with checked boxes for each. Verify that below the Organ System box is the text “Use color coding for organ systems”, with an unchecked box.

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

Verify that on the right side of the new screen is a box labeled Organ, Physical System and Autonomic System, containing a list of organs and scores.

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

Click to check the box "Use color coding for organ systems". Verify that the Organ box is resorted by organ systems and grouped by color.

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

Click the "X" in the upper right corner of each tab. Verify each tab closes and the screen returns to the EPIC ClearView main screen.

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

NOTE: The validation of the Worksheet tab, NS Analysis tab, Bio-fields tab and the Print Report tab are performed as a separate validation(s).

6.5 New Capture - Administrator Login

Click on the Change Login icon at the top of the screen. Login as "Administrator" with the password provided by the Network Administrator. Click on the New Capture button. Verify that the Search Patient window opens.

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

Click the Find button at the top of the displayed window. Search and identify patient Epic Validation. Click to highlight this patient and click the New Capture button in the lower right corner of the window. Verify that the New Capture tab opens and the "Gather a capture for" window is displayed.

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

Verify that the Submit for Analysis button in the lower right corner of the window is inactive. Verify that the Capture Image and Close buttons are active. Verify that the Export Images button in the lower left corner of the window is active.

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

Capture a full set of subject images by clicking into each finger image box of the Images without Capacitive Barrier row. Click the Capture Image button. Repeat the process until 10 Images without Capacitive Barrier and 10 Images with Capacitive Barrier have been captured. Verify that all twenty Images without Capacitive Barrier and Images with Capacitive Barrier image boxes contain energized images. Note: calibration images should not be used as they may cause a matlab error, therefore, human subject images should be used.

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

Click on each energized image box (both Images without Capacitive Barrier and Images with Capacitive Barrier). Verify that the displayed energized image and displayed finger image change after clicking on a different image box. Repeat until all twenty images have been clicked.

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

Click on the Export Images button. Verify that the Browse for Folder window opens. Locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\ExportImages. Click OK. Verify the ClearView dialog box opens with the message "Images have been successfully saved." Click OK and verify that the dialog box 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\ExportImages. Verify that there are 40 images in the folder.

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

Maximize the ClearView screen from the taskbar. Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a new

screen displays with the Print Report tab highlighted and the ClearView Report is displayed.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Sensory and Skeletal Systems; Hepatic, Endocrine, and Nervous System; Cardiovascular System; Respiratory System; Gastrointestinal System; and Renal and Reproductive Systems), and page 5 contains definitions.

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

Click on the Biofield Analysis tab. Verify that a new screen appears with the Item Tab displayed on the left containing boxes for Indexes, Organ Systems, and Settings, a Magnified View tab (open) and an Admin View tab, and a visual representation of the body views.

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

Click on the Admin pages tab. Verify that the Raw Data sub tab is highlighted and a worksheet is displayed containing multiple columns and rows of data. Verify that the individual cells cannot be modified.

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

Click on the Raw Report Data sub tab. Verify that a worksheet is displayed with two tables containing multiple columns and rows of data. Verify that the individual cells cannot be modified.

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

Click on the Images without Capacitive Barrier sub tab. Verify that 10 scan images are displayed, labeled “Images without Capacitive Barrier”.

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

Click on the Toggle Sectors button in the lower left corner of the screen below the Images without Capacitive Barrier. Verify that the sector lines appear on each image. Click on the Toggle Sectors button again and verify that the sector lines disappear.

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

Click on the Images with Capacitive Barrier sub tab. Verify that 10 scan images are displayed, labeled "Images with Capacitive Barrier".

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

Click on the Toggle Sectors button in the lower left corner of the screen below the Images with Capacitive Barrier. Verify that the sector lines appear on each image. Click on the Toggle Sectors button again and verify that the sector lines disappear.

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

Click on the NS Analysis tab. Verify that a new screen appears with two boxes containing body side views, graphs, and organ names.

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

Click on the Worksheet tab. Verify that a new screen appears with an Organ Systems box appears on the left side of the screen, containing a list of organ systems with checked boxes for each. Verify that below the Organ System box is the text "Use color coding for organ systems", with an unchecked box.

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

Verify that on the right side of the new screen is a box labeled Organ, Physical System and Autonomic System, containing a list of organs and scores.

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

Click to check the box "Use color coding for organ systems". Verify that the Organ box is resorted by organ systems and grouped by color.

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

Click the "X" in the upper right corner of each tab. Verify each tab closes and the screen returns to the EPIC ClearView main screen.

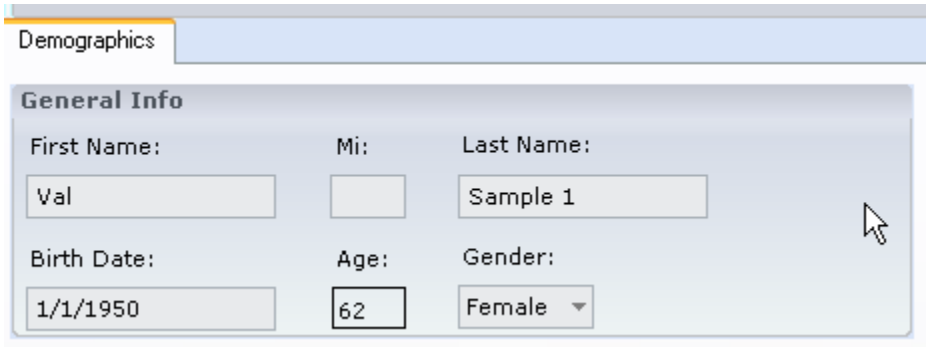
_____ Verified _____ Not Verified Non-Conformance Ref. No. _____

NOTE: The validation of the Worksheet tab, NS Analysis tab, Admin pages, Bio-fields tab and the Print Report tab are performed as a separate validation(s).

6.6 View Patient button.

Click on the Change Login icon at the top of the screen. Login as "EPICUser" with the password provided by the Network Administrator.

Click on the New Capture button. Verify that the Search Patient window opens. Enter "Val" in the First Name box. Click Find. Click to highlight patient name "Val Sample1" and click the View Patient button in the lower right corner of the window. Verify that the View Patient tab screen opens and appears as shown below and verify all fields with input data. Note: Age increasing from that shown is acceptable as the Age shown below is relative to when this protocol was created.



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

Click the "X" in the upper right corner of the View Patient tab. Verify that the tab closes and the screen returns to the EPIC ClearView main screen.

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

6.7 Search Capture

This button is used to search for previous treatments. Close all open Tabs. Verify that the system returned to the EPIC ClearView main screen.

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

From the EPIC ClearView main screen, click on the Search Capture icon. Verify that the Search Capture window appears.

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

Search Capture Find function:
With all entry fields blank or null, click the Find button. Verify that a list of patients with columns for Patient Name, Treatment Id, Version, Run Notes, Scan Type, Scan Date, and Archived, is displayed.

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

6.7.1 Select three (3) different Patient Names and record the name, Treatment Id, and Date Scanned below:

_____**Result 1**
_____**Result 2**
_____**Result 3**

6.7.2 For each Patient Name/Treatment Id pair recorded in section 6.7.1 of the original protocol, highlight and click on the View Report button. After processing, the ClearView Report screen will open. Click on the Change Login icon at the top of the screen. Login as “Administrator” with the password provided by the Network Administrator. Click on the Admin Pages tab to open the Raw Data tab. If the Admin pages are not displayed, close all report tabs. Locate the report for each Patient Name/Treatment Id pair in section 6.7.1 of the original protocol, highlight and click on the View Report button. After processing, the ClearView Report screen will open. Locate the name from the Admin Pages tab (name

follows Admin Pages for), locate the PatientTreatmentId column, and locate the DateAnalysed column and record the results below:

_____**Result 1**
_____**Result 2**
_____**Result 3**

Verify that the results match the entries from the step 6.7.1 (the time may be different by several minutes from the Date Scanned entry to the DateAnalysed column).

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

Click on the Change Login icon at the top of the screen. Login as "EPICUser" with the password provided by the Network Administrator. Click the Search Capture button. With all entry fields blank or null, click the Find button. Verify that a list of patients with columns for Patient Name, Treatment Id, Version, Run Notes, Scan Type, Date Scanned, and Archived, is displayed.

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

Enter the patient's last name of NJMAA. Click the Find button. Verify that a patient by the last name of NJMAA is not displayed and record the result:
_____**Result**

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

Delete any previous entry. Enter the patient's last name as Validation and click Find. Verify that only patients with the last name of Validation are displayed and record the result:
_____**Result**

_____**Result**

_____**Result**

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

Click into each column header box (i.e. Patient Name, Treatment Id, etc.) and verify that the list sorts by the column selected.

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

Delete any previous entry. Enter the patient's last name as E and click Find. Verify that only patients with last names beginning with E are displayed and record the result:

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

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

Use the delete key to delete the "e" in the last name box.
Enter the patient's first name of NJMAA (last name box should be blank). Click the Find button. Verify that a patient by the first name of NJMAA is not displayed and record the result:

_____**Result**

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

Delete any previous entry. Enter the patient's first name as Epic and click Find. Verify that only patients with the first name of Epic are displayed and record the result:

_____**Result**

_____**Result**

_____**Result**

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

Delete any previous entry. Enter the patient's first name as O and click Find. Verify that only patients with a first name beginning with O are displayed and record the result:

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

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

Delete any information in the first name and last name box. Click the Scan Type drop down menu arrow to reveal the options Search All Scans and ClearView. Click on the ClearView option. Verify that ClearView is now highlighted in the Scan Type window. Click Find. Verify that only items with Scan Type of ClearView are displayed and record the result:

_____**Result**

_____**Result**

_____**Result**

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

Click the Search All Scans option in the Scan Type drop down menu. Verify that Search All Scans is now highlighted. Click Find. Verify that the list of items includes all Scan Types and record the result:

_____**Result**

_____**Result**

_____**Result**

_____**Result**

_____**Result**

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

In the Scan From field, enter a date of 3/15/2011. In the Scan To field, enter a date of 3/16/2011. Click Find. Record the result:

_____**Result**

_____**Result**

_____**Result**

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

Close all open Tabs. Verify that the system returned to the EPIC ClearView main screen.

Click the Search Capture button. Verify that the Search Capture window opens. Click on the View Report button. Verify that the Search Capture window remains open and a report cannot be viewed.

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

Click on the View Calibration button. Verify that the Search Capture window remains open without further changes and the calibration screen does not appear.

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

Click on the View Capture button. Verify that the Search Capture window remains open without further changes.

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

6.8 View Report button.

Click the "X" in the upper right corner of the Search Capture window. Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient name Epic A. Validation. Click to highlight this patient and click the View Report button in the lower right corner of the displayed window.

Verify that after processing, a new screen appears with the Print Report tab data open and the ClearView Report is displayed. Verify that there are tabs for the Worksheet, NS Analysis, and Biofield Analysis.

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

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

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

6.9 View Calibration button.

Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient name Epic A. Validation with Scan Date 4/9/2010. Click to highlight this patient and click the View Calibration button in the lower right corner of the displayed window. Verify that the Calibration is opened and the View Calibration window is displayed. Verify that all ten calibration images are displayed.

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

Click into the Calibration Image #1 box in the thumbnail images row. Verify that the image appears in the Captured Images box.

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

Click into the Calibration Image #3 box in the thumbnail images row. Verify that the image appears in the Captured Images box.

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

Click into the Calibration Image #7 box in the thumbnail images row. Verify that the image appears in the Captured Images box.

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

Click the Close button in the lower right corner of the window. Verify that the View Calibration window is closed and the screen returns to the EPIC ClearView main screen.

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

Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient last name Sample1 with Treatment ID 2002. Click to highlight this patient and click the View Calibration button in the lower right corner of the displayed window. Verify that the Calibration tab is opened and the View Calibration window is displayed. Verify that all ten calibration images are displayed.

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

Click the Close button in the lower right corner of the window. Verify that the View Calibration window is closed and the screen returns to the EPIC ClearView main screen.

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

Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient last name Sample2 with Treatment ID 2008. Click to highlight this patient and click the View Calibration button in the lower right corner of the displayed window. Verify that the Calibration tab is opened and the View Calibration window is displayed. Verify that all ten calibration images are displayed.

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

Click the Close button in the lower right corner of the window. Verify that the View Calibration window is closed and the screen returns to the EPIC ClearView main screen.

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

6.10 View Capture button.

Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient name Epic O. Validation with Treatment ID 2099. Click to highlight this patient and click the View Capture button in the lower right corner of the displayed window. Verify that the View Capture tab is opened and the View Capture window is displayed. Verify that the Captured Image, the Finger Image, the ten Images without Capacitive Barrier and the ten Images with Capacitive Barrier are displayed.

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

Click to uncheck the Show Axis/Angle box under the Finger Image box. Verify that the red crosshairs and yellow circle in the Captured Image box disappear. Click again to check and verify that the crosshairs and yellow circle reappear in the Captured Image box.

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

Click into the Right Thumb Finger box in the Images without Capacitive Barrier row. Verify that the image appears in the Captured Images box. Under the Captured Image box, next to Angle, click the green clockwise arrow button ten times and verify that the crosshairs rotate 10 degrees clockwise in the Captured Image box. Repeat for all of the Images without Capacitive Barrier and Images with Capacitive Barrier.

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

Click into the Right Thumb Finger box in the Images without Capacitive Barrier row. Verify that the image appears in the Captured Images box. Under the Captured Image box, next to Angle, click the clockwise button ten times, next to X, click the left arrow ten times, and next to Y, click the green up arrow button ten times and verify that the circle and crosshairs moved 10 increments in the correct direction and in the display boxes. Repeat for all of the Images without Capacitive Barrier and Images with Capacitive Barrier.

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

Click into the Right Thumb Finger box in the Images without Capacitive Barrier row. Verify that the image appears in the Captured Images box. Under the Captured Image box, next to Angle, click the counter-clockwise button five times, next to X, click the right arrow five times, and next to Y, click the green down arrow button five times and verify that the circle and crosshairs moved 5 increments in the correct direction and in the display boxes. Repeat for all of the Images without Capacitive Barrier and Images with Capacitive Barrier.

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

Click the Close button in the lower right corner of the window. Verify that the View Capture window is closed and the screen returns to the EPIC ClearView main screen.

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

7.0 EPIC Administrator Challenges - View Capture Resubmit

7.1 Click on the Change Login Icon at the top of the screen. Enter "Administrator" as the Username and the password provided by the Network Administrator. This will login as an EPIC Administrator to challenge the steps that are exclusive to the EPIC Administrator.

Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient Camera Validation. Click to highlight this patient and Treatment ID 2147, and click the View Capture button in the lower right corner of the displayed window. Verify that the View Capture tab is opened and the View Capture window is displayed. Verify that the Captured Image, the Finger Image, the ten Images without Capacitive Barrier and the ten Images with Capacitive Barrier are displayed.

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

Click the Resubmit Images for Analysis button in the lower left corner of the View Capture screen. Verify that after processing, a new screen appears with the Print Report tab data open and the ClearView Report is displayed.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Sensory and Skeletal Systems; Hepatic, Endocrine, and Nervous System; Cardiovascular System; Respiratory System; Gastrointestinal System; and Renal and Reproductive Systems), and page 5 contains definitions.

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

Verify there are tabs for Worksheet, NS Analysis, Admin Pages, and Biofield Analysis and verify each tab contains the appropriate content per Section 6.5.

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

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

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

7.2 EPIC Administrator Challenges - New Capture Load Images Option

Click the New Capture Icon. Search the database for Epic Validation (select any one if there is more than one listed). Click the New Capture button. Click in the box above Right thumb Finger box in the Images without Capacitive Barrier row. 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 and open the following network folder: I:\Clinical_Trials\HVS_Development_Folder\Subjects\HVS-1061\wofilter_021940. Click to highlight the 1R_wofilter image and click Open. Verify that the image is displayed in the Capture Image box and the Right Thumb Finger box in the Images without Capacitive Barrier row.

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

Repeat this step for all twenty images (2R, 3R, etc.) for both Images without Capacitive Barrier and Images with Capacitive Barrier (Images with Capacitive Barrier are located in the folder I:\Clinical_Trials\HVS_Development_Folder\Subjects\HVS-1061\wfilter) images. Record the verification results below by placing initials in the appropriate box:

Sample	Verified?	Not Verified?	Non-Conformance Ref. No.
2R_wofilter			
3R_wofilter			

4R_wofilter			
5R_wofilter			
1L_wofilter			
2L_wofilter			
3L_wofilter			
4L_wofilter			
5L_wofilter			
1R_wfilter			
2R_wfilter			
3R_wfilter			
4R_wfilter			
5R_wfilter			
1L_wfilter			
2L_wfilter			
3L_wfilter			
4L_wfilter			
5L_wfilter			

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a new screen displays with the Print Report tab highlighted and the ClearView Report is displayed.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Sensory and Skeletal Systems; Hepatic, Endocrine, and Nervous System; Cardiovascular System; Respiratory System; Gastrointestinal System; and Renal and Reproductive Systems), and page 5 contains definitions.

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

Verify there are tabs for Worksheet, NS Analysis, Admin Pages, and Biofield Analysis and verify each tab contains the appropriate content per Section 6.5.

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

Click the “X” in the upper right corner of each tab and verify each tab closes and the screen returns to the EPIC ClearView main screen.

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

7.3 Angle Orientation

Click New Capture. Type "Subject" in the First Name box and "1" in the Last Name box and click Find. Click to highlight Subject 1 then click New Capture. Click on the box for Right Thumb. Ask a test subject to place their finger on the scanner per the ClearView Instructions for Use. Click the Capture Image button. Verify that an ellipse with crosshairs appears in the energized image in the Captured Image box.

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

Verify that an ellipse with crosshairs appears in the still image in the Finger Image box.

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

Record the values in the Angle, X and Y boxes under the Captured Image box below:

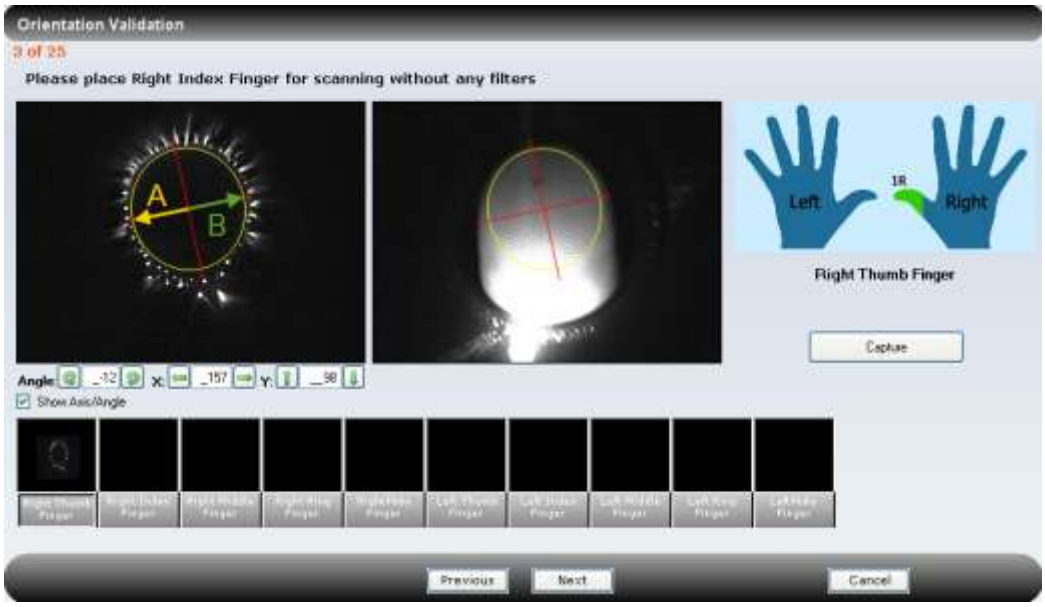
Angle: _____
X: _____
Y: _____

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

Using a ruler, measure the distance from the center of the crosshairs to either side of the horizontal axis of the crosshairs on the energized image. These are the horizontal radii A and B.

NOTE: The vertical radius is measured from the edge of the ellipse to the edge of the ellipse, not from the end of the line. The actual line is extended past the ellipse and the length of the line is not measured.

All screenshots are for reference only and may not represent the current software.

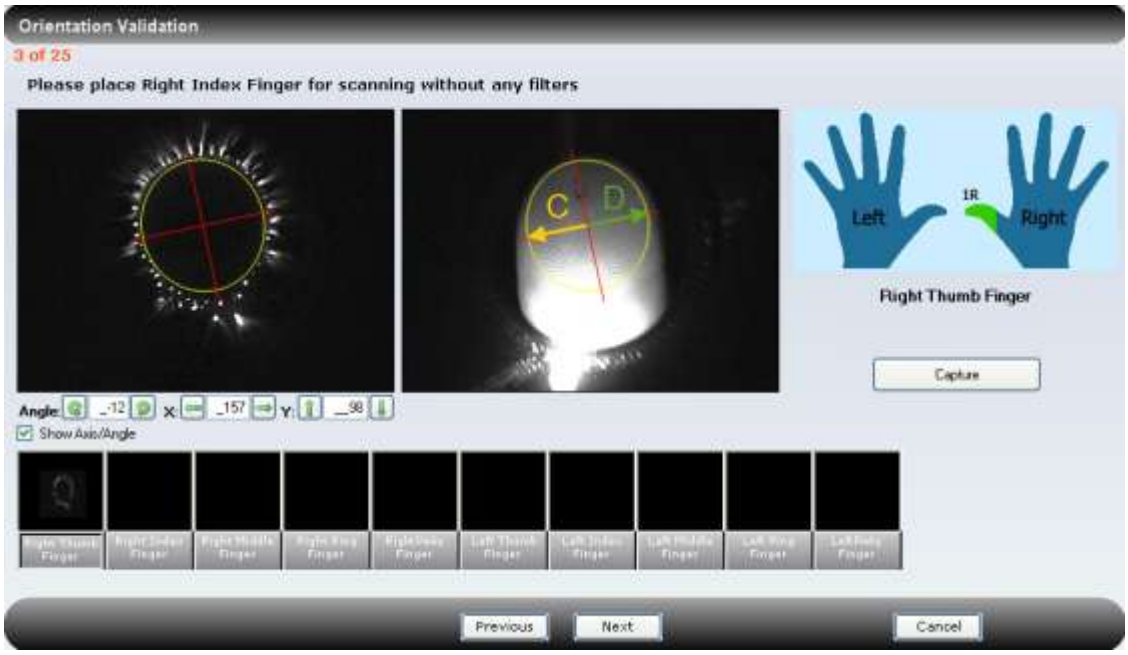


Horizontal radius A: _____ cm
Horizontal radius B: _____ cm

Verify that radius A is the same distance as radius B, within 0.1 centimeter:

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

Using a ruler, measure the distance from the center of the crosshairs to either side of the horizontal axis of the crosshairs on the live image. These are the horizontal radii C and D.

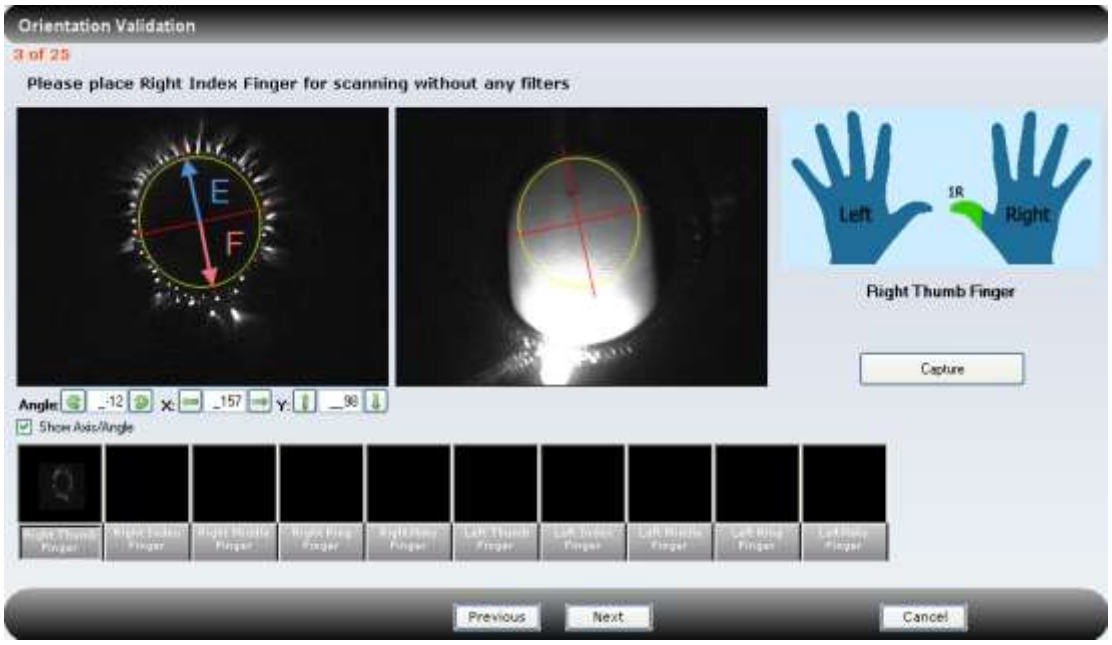


Horizontal radius C: _____ cm
Horizontal radius D: _____ cm

Verify that radius C is the same distance as radius D, within 0.1 centimeter:

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

Using a ruler, measure the distance from the center of the crosshairs to either side of the vertical axis of the crosshairs on the energized image. These are the vertical radii E and F.



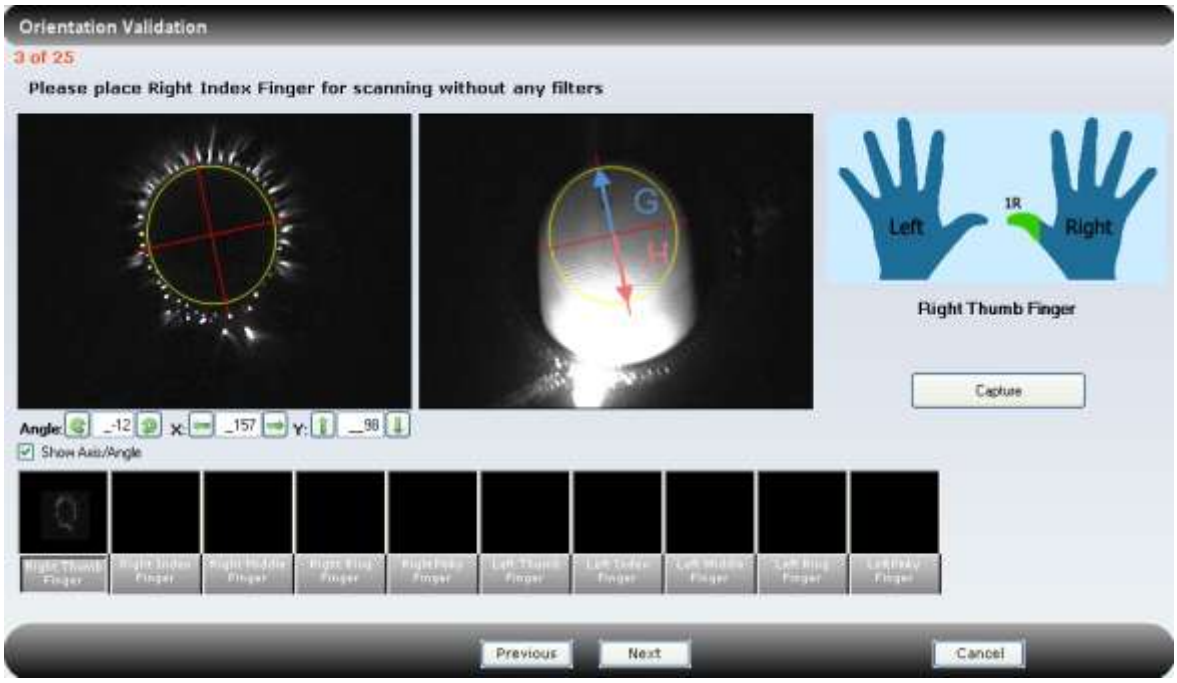
Vertical radius E: _____ cm
Vertical radius F: _____ cm

NOTE: The vertical radius is measured from the edge of the ellipse to the edge of the ellipse, not from the end of the line. The actual line is extended past the ellipse and the length of the line is not measured.

Verify that radius E is the same distance as radius F, within 0.1 centimeter:

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

Using a ruler, measure the distance from the center of the crosshairs to either side of the vertical axis of the crosshairs on the energized image. These are the vertical radii G and H.



Vertical radius G: _____ cm
Vertical radius H: _____ cm

Verify that radius G is the same distance as radius H, within 0.1 centimeter:

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

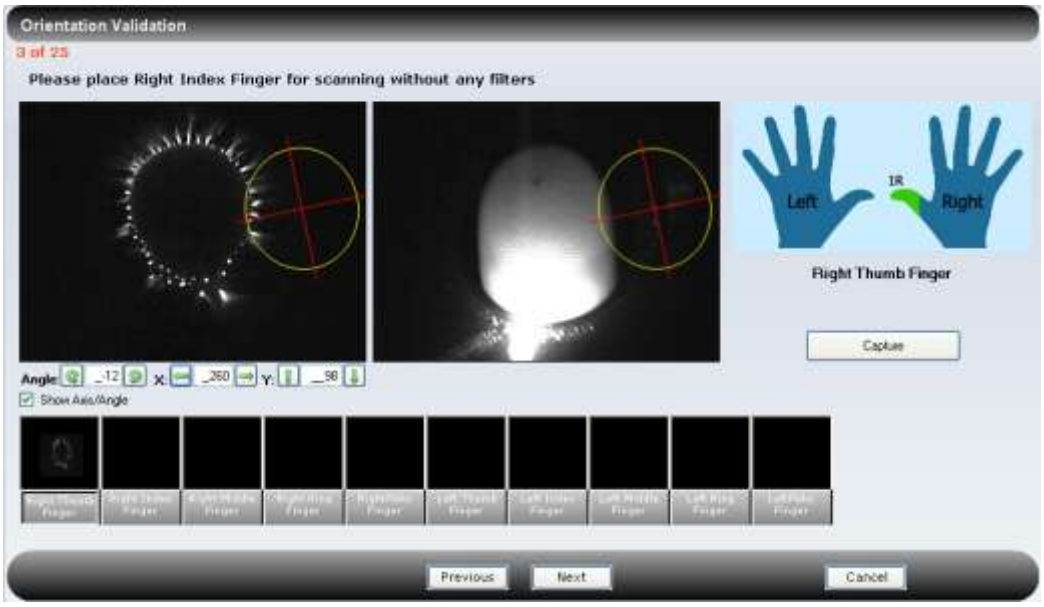
Verify that that radii A/B and C/D are equivalent.

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

Verify that the radii E/F and G/H are equivalent.

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

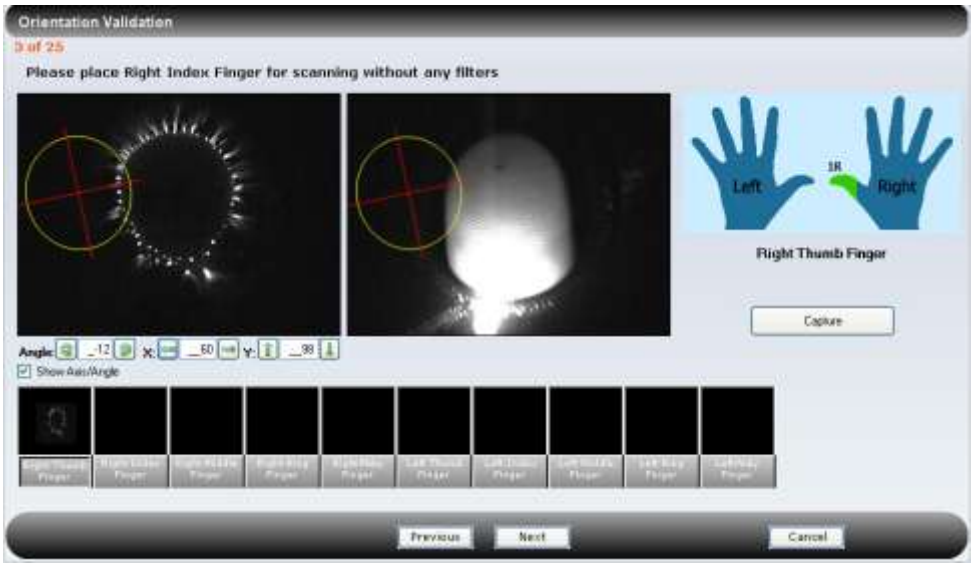
To test the functionality of the orientation box arrows, click the right arrow next to the X: orientation box until the value in the X: orientation box is 260.



Verify that the ellipses on both the energized image and the still image move far to the right.

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

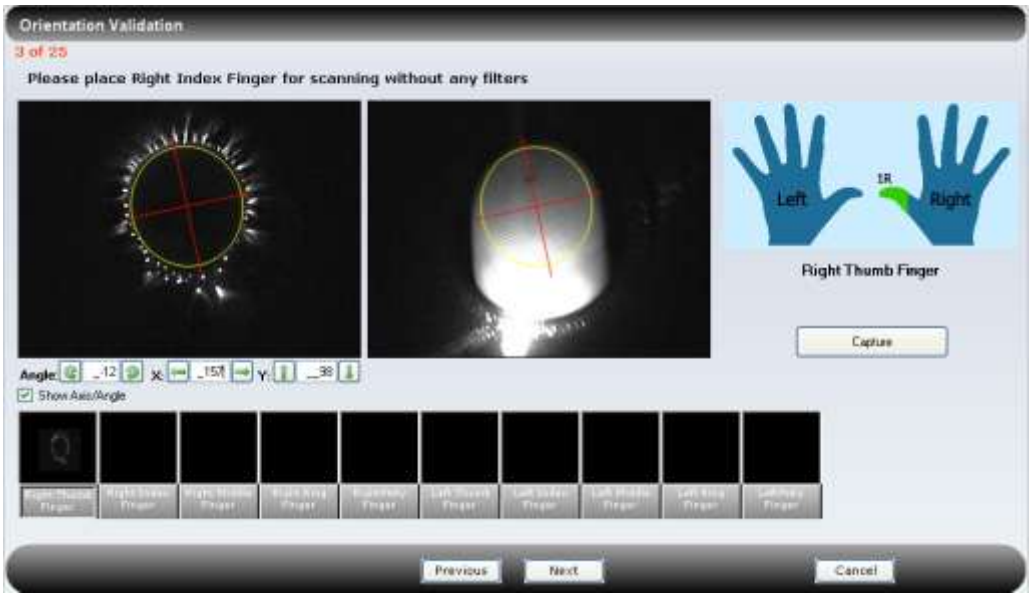
Click the left arrow next to the X: orientation box until the value in the X: orientation box is 60.



Verify that the ellipses on both the energized image and the still image move far to the left.

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

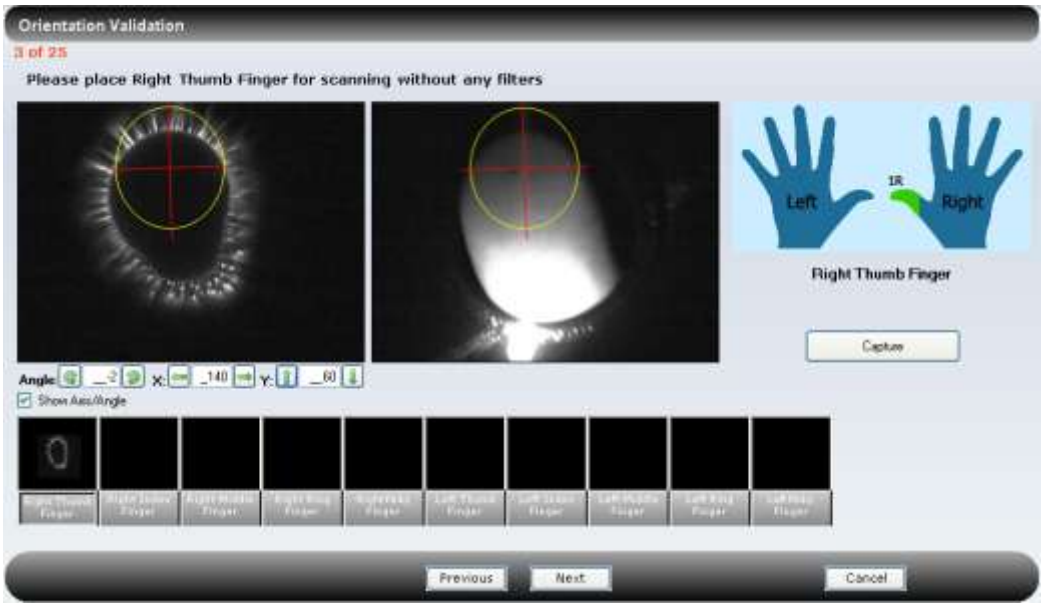
Enter the value for X recorded at the beginning of Section 7.19.



Verify that the ellipse moves back into the original centered position over the energized image and the lit image.

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

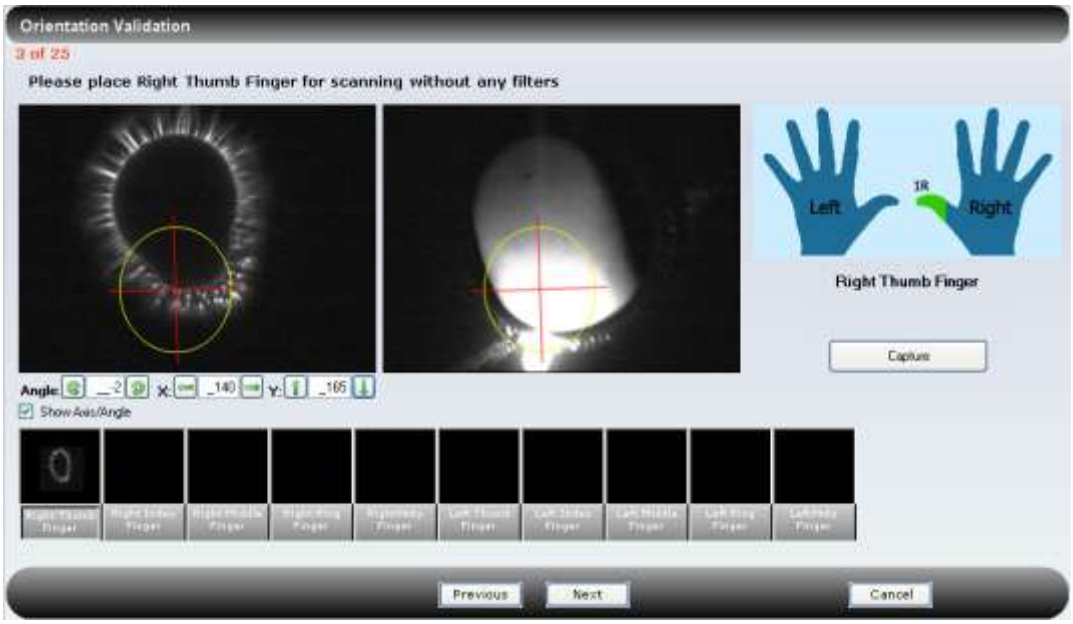
Click the up arrow next to the Y: orientation box until the value in the Y: orientation box is 60.



Verify that the ellipses on both the energized image and the still image move toward the top of the page.

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

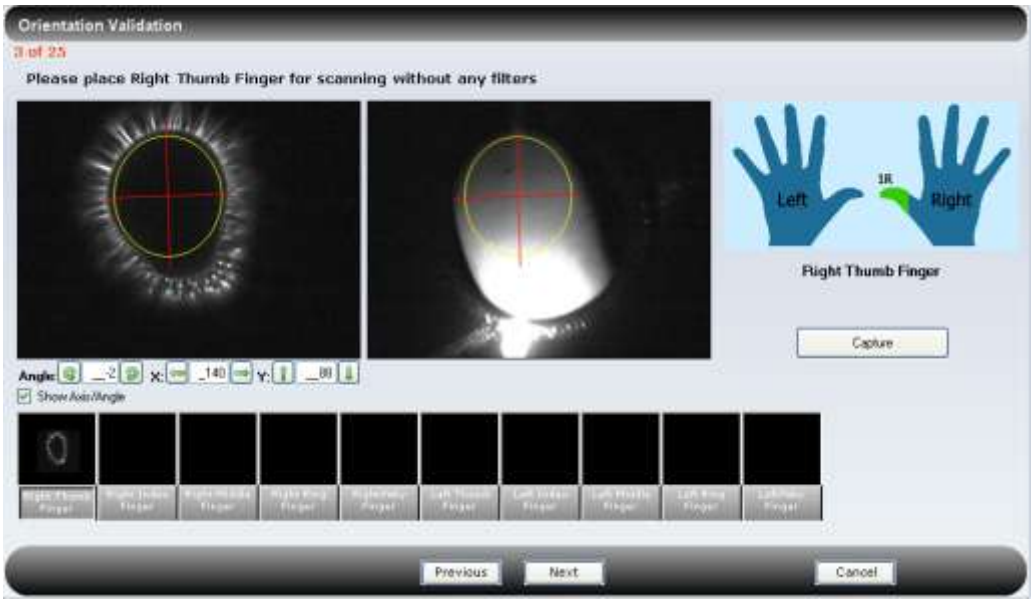
Click the down arrow next to the Y: orientation box until the value in the Y: orientation box is 165.



Verify that the ellipses on both the energized image and the still image move toward the bottom of the page.

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

Enter the value for Y recorded at the beginning of Section 7.19.



Verify that the ellipse moves back into the correctly centered position over the energized image and the lit image.

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

Record the automatically determined image angle, as listed in the angle orientation box.

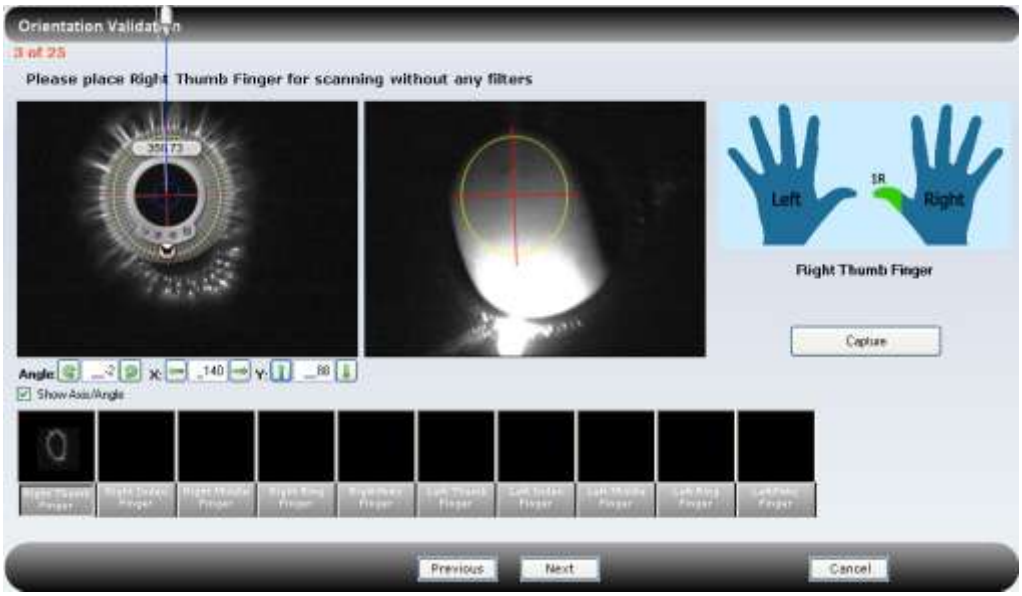
Automatic angle: _____

Screen Protractor:

Use the Iconico Screen Protractor Version 4.0. (To download this screen tractor, go to http://www.iconico.com/protractor/.) To determine the version number, double click on the Screen Protractor desktop icon. Record the version listed:

Iconico Screen Protractor Version: _____

Use the screen protractor (to measure the angle of the vertical ellipse axis of the energized image (left box). Do so by placing the bullseye of the protractor over the center point of the ellipse. Align the reference line (darker, longer line) of the protractor at 90 degrees (straight up and down) and line up the other line on top of the vertical ellipse axis. Record the measured angle (to the nearest degree):

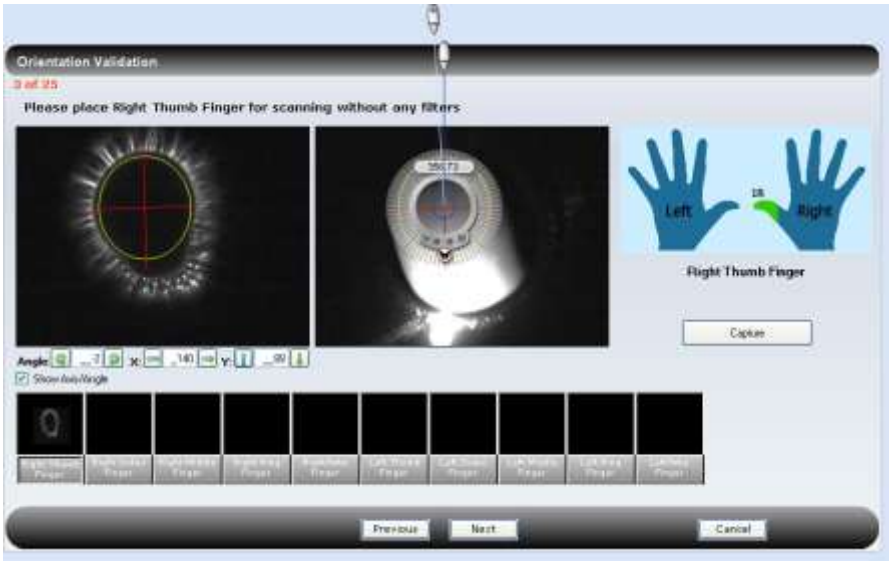


Measured energized image angle: _____

Verify that the automatically assigned angle is within 2 degrees of the measured angle for the energized image.

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

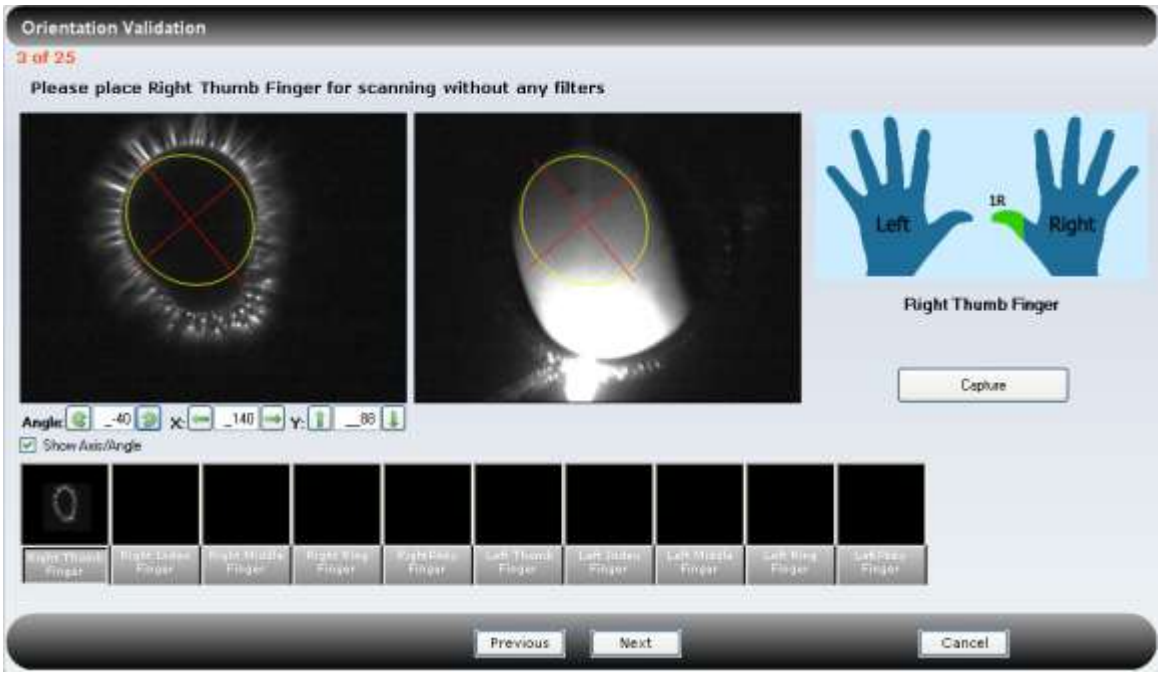
Using the same procedure listed above, measure the angle of the vertical axis on the finger image (right box).



Measured finger image angle: _____

Verify that the automatically assigned angle is within 2 degrees of the measured angle for the lit still image.

Click on the left rotation arrow next to the Angle: orientation box until the value in the box reads -40.



Verify that the ellipses on both the energized image and the still image rotate to the left.

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

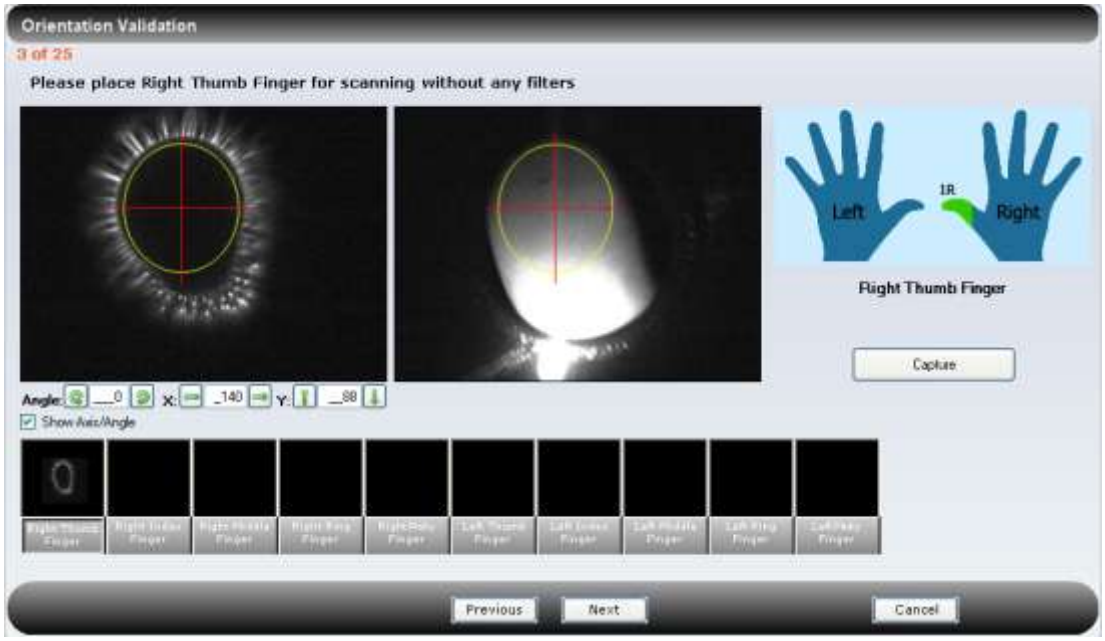
Use the screen protractor to measure this new angle.

Measured angle: _____

Verify that the angle measures within 2 degrees of -40.

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

Click in the angle rotation arrow until the angle is “0”.



Verify that the vertical axes on both the energized image and the still image appear vertical.

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

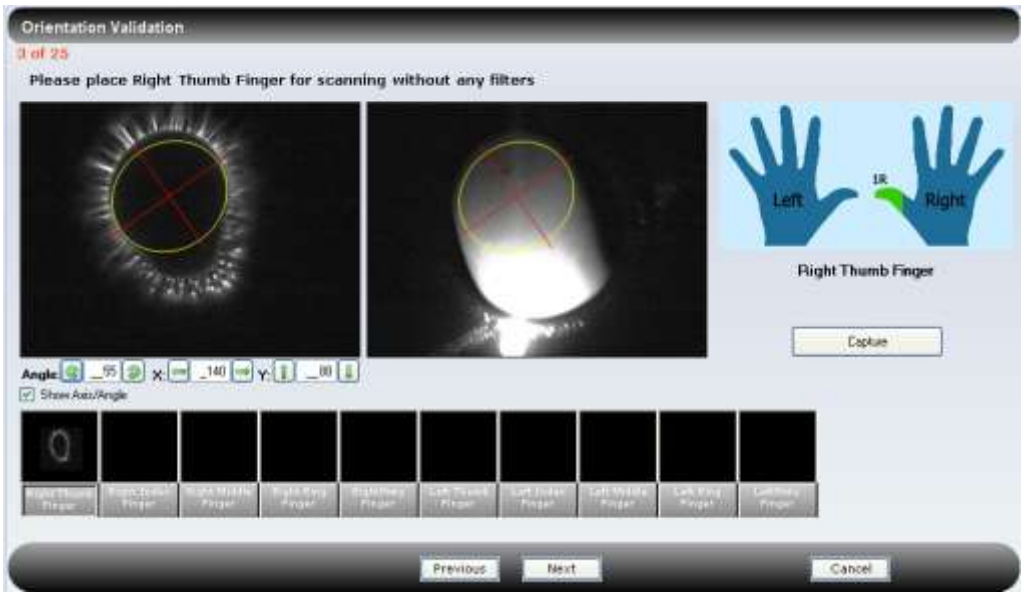
Use the screen protractor to measure this new angle.

Measured angle: _____

Verify that the angle measures within 2 degrees of zero.

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

Click on the right rotate button next to the angle orientation box until the box reads 55.



Verify that the ellipses on both the energized image and the still image rotate to the right.

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

Use the screen protractor to measure this new angle.

Measured angle: _____

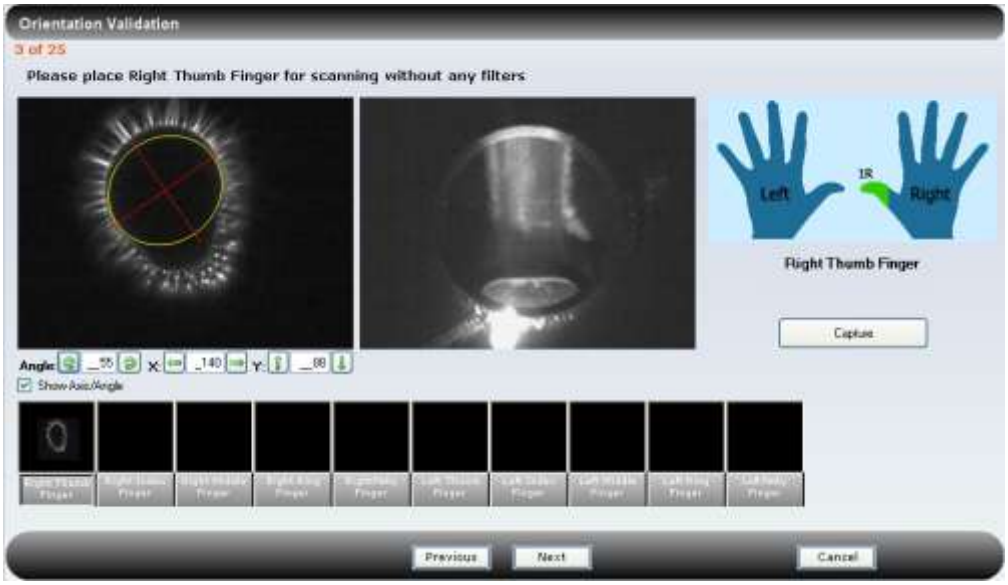
Verify that the angle measures within 2 degrees of 55.

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

Ensure that the subject's finger is not resting on the glass and the calibration probe or other objects are not on the glass. Verify that the lit image of the finger remains visible in the right box.

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

Click on the Right Index Finger box.



Verify that the lit image changes to a view of the inside of glass (without a finger in place) and the energized image remains the same, with the angle at 55 and the center point as what was determined correct via visual assessment (above).

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

Press the Capture Image button. Verify that the Captured Image box and the Finger Image box display the inside of the finger shroud and an ellipse with crosshairs, which may or may not be centered on the captured image.

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

Place a hand above the opening of the finger shroud to block the majority of the light. Press the Capture Image button. Verify that an error message "Unable to perform image calculations" appears. Click the OK button.

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

Click the "X" in the upper right corner of the New Capture tab to return to the ClearView main screen.

8.0 EPIC Administrator Challenges – Saving Calibration Data

8.1 Verification of the Calibration Data Storage to Temporary Files

The calibration data calculated during the calibration analysis is automatically stored by the software in a temporary location. This calibration information is temporarily stored whether or the calibration was acceptable or failed. If a human subject is scanned, the calibration data is stored in the ClearView database associated with all human subjects scanned after the successful calibration and before the next successful calibration. If a human subject is not scanned, this calibration data is not stored in the ClearView database and, therefore, is not accessible to the EPIC Administrator. This challenge verifies that the save function works and that the new calibration analysis results are replaced after each analysis.

Click on the Settings button in the Application toolbar. In the Settings box, adjust the Brightness to 50, 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 on the Camera 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 a message appears below the Scanner Calibration header notifying the user that the calibration process is progressing.

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

Upon completion of the calibration analysis, 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 dialog box. Click No when asked to save images. Record the image number (i.e., Calibration Image #1, etc.) below of any images displayed with colored pixels (which indicate calibration analysis failures).

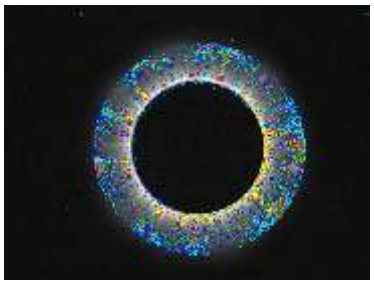


Figure 1 Example of colored pixels

Calibration Image Nos. 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 both low and high.

_____ **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 “Cal A”. Sign and date the labeling. 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.

Locate the temp folder at c:\temp\calib_work. Open the file and print the contents. Label the print out “StoredCal A”. Sign and date the labeling. Compare the results reported in the View Alerts printed out and labeled Cal A with the results stored in the temp filed printed and labeled StoredCal A. Verify that the results match for each and every calibration image.

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

Repeat the auto calibration process, printout of the View Alerts result and locating the temp folder two more times. Label each successive repeat Cal B/StoredCal B and Cal C/StoredCal C. Perform the same comparison on each of the successive repeats.
NOTE: It is important to open and print the stored calibration data file from the temp location prior to initializing the next autocalibration process as the data is overwritten upon completion of the next autocalibration process analysis.

Verify that the Cal B results and StoredCal B results match for each and every calibration image.

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

Verify that the Cal C results and StoredCal C results match for each and every calibration image.

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

9.0 License File Test

As of the 1.1.0.0 version of ClearView, a license key mechanism was implemented into the product, and the software will not operate without a valid license file present. The ClearView software now looks at start up for a file named “ClearView.lic” to be located in the same folder as the ClearView application itself. This file is a plain text file containing an encrypted string that represents the actual license structure. There are

three licenses; Full, CV (cardiovascular), and Basic. One of these three license files is copied into the ClearView folder and renamed as "ClearView.lic" to set the license.

9.1.1 CV License

The following procedure will copy the CV license file into the ClearView folder to verify the report functionality of the ClearView software with the CV license.

Click on the Exit Icon to exit ClearView. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation. Locate and select the file "ClearViewCV.lic" to copy (CTRL-C).

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, and copy the "ClearViewBasic.lic" file into this folder (CTRL-V). Locate and delete the "ClearView.lic" file in the same folder. Rename the "ClearViewBasic.lic" file to "ClearView.lic". This has now installed the basic license file for the ClearView software.

9.1.2 CV License – User Login – New Capture

Double click the EPIC ClearView icon on the desktop. Click in the Username box and enter "EPICUser". Click in the password box and enter the password provided by the Network Administrator. The EPIC ClearView main screen is displayed.

Click on the New Capture button. Verify that the Search Patient window opens. Click the Find button at the top of the displayed window. Search and identify patient Epic Validation. Click to highlight this patient and click the New Capture button in the lower right corner of the window. Verify that the New Capture tab opens and the "Gather a capture for" window is displayed.

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

Capture a full set of subject images by clicking into each finger image box of the Images without Capacitive Barrier row. Click the Capture Image button. Repeat

the process until 10 Images without Capacitive Barrier and 10 Images with Capacitive Barrier have been captured. Verify that all twenty Images without Capacitive Barrier and Images without Capacitive Barrier image boxes contain energized images. Note: calibration images should not be used as they may cause a matlab error, therefore, human subject images should be used.

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

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a report appears on the screen under Print Report tab for EPIC Validation.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Cardiovascular; Respiratory; Gastrointestinal System; Hepatic, Endocrine, and Nervous System; and Renal and Reproductive), and page 5 contains definitions.

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

Click on the Biofield Analysis tab. Verify that a new screen appears with the Item Tab displayed on the left containing boxes for Indexes, Organ Systems, and Settings, a Magnified View tab, and a visual representation of the body views.

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

Click on the NS Analysis tab. Verify that a new screen appears with two boxes containing body side views, graphs, and organ names.

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

Click on the Worksheet tab. Verify that a new screen appears with an Organ Systems box appears on the left side of the screen, containing a list of organ systems with checked boxes for each. Verify that below the Organ System box is the text “Use color coding for organ systems”, with an unchecked box.

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

Verify that on the right side of the new screen is a box labeled Organ, Physical System and Autonomic System, containing a list of organs and scores.

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

Click to check the box "Use color coding for organ systems". Verify that the Organ box is resorted by organ systems and grouped by color.

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

Click the "X" in the upper right corner of each tab. Verify each tab closes and the screen returns to the EPIC ClearView main screen.

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

9.1.3 CV License – Administrator Login – New Capture

Click 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. The EPIC ClearView main screen is displayed.

Click on the New Capture button. Verify that the Search Patient window opens. Click the Find button at the top of the displayed window. Search and identify patient Epic Validation. Click to highlight this patient and click the New Capture button in the lower right corner of the window. Verify that the New Capture tab opens and the "Gather a capture for" window is displayed.

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

Capture a full set of subject images by clicking into each finger image box of the Images without Capacitive Barrier row. Click the Capture Image button. Repeat the process until 10 Images without Capacitive Barrier and 10 Images with Capacitive Barrier have been captured. Verify that all twenty Images without Capacitive Barrier and Images without Capacitive Barrier image boxes contain

energized images. Note: calibration images should not be used as they may cause a matlab error, therefore, human subject images should be used.

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

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a report appears on the screen under Print Report tab for EPIC Validation.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Cardiovascular; Respiratory; Gastrointestinal System; Hepatic, Endocrine, and Nervous System; and Renal and Reproductive), and page 5 contains definitions.

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

Click on the Biofield Analysis tab. Verify that a new screen appears with the Item Tab displayed on the left containing boxes for Indexes, Organ Systems, and Settings, a Magnified View tab (open) and an Admin View tab, and a visual representation of the body views.

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

Click on the Admin pages tab. Verify that the Raw Data sub tab is highlighted and a worksheet is displayed containing multiple columns and rows of data. Verify that the individual cells cannot be modified.

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

Click on the Raw Report sub tab. Verify that a worksheet is displayed with two tables containing multiple columns and rows of data. Verify that the individual cells cannot be modified.

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

Click on the Images without Capacitive Barrier sub tab. Verify that 10 scan images are displayed, labeled “Images without Capacitive Barrier”.

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

Click on the Toggle Sectors button in the lower left corner of the screen below the Images without Capacitive Barrier. Verify that the sector lines appear on each image. Click on the Toggle Sectors button again and verify that the sector lines disappear.

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

Click on the Images with Capacitive Barrier sub tab. Verify that 10 scan images are displayed, labeled “Images with Capacitive Barrier”.

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

Click on the Toggle Sectors button in the lower left corner of the screen below the Images with Capacitive Barrier. Verify that the sector lines appear on each image. Click on the Toggle Sectors button again and verify that the sector lines disappear.

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

Click on the NS Analysis tab. Verify that a new screen appears with two boxes containing body side views, graphs, and organ names.

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

Click on the Worksheet tab. Verify that a new screen appears with an Organ Systems box appears on the left side of the screen, containing a list of organ systems with checked boxes for each. Verify that below the Organ System box is the text “Use color coding for organ systems”, with an unchecked box.

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

Verify that on the right side of the new screen is a box labeled Organ, Physical System and Autonomic System, containing a list of organs and scores.

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

Click to check the box "Use color coding for organ systems". Verify that the Organ box is resorted by organ systems and grouped by color.

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

Click the "X" in the upper right corner of each tab. Verify each tab closes and the screen returns to the EPIC ClearView main screen.

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

9.1.4 CV License – Administrator Login – View Capture Resubmit

Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient Camera Validation. Click to highlight this patient and Treatment ID 2147, and click the View Capture button in the lower right corner of the displayed window. Verify that the View Capture tab is opened and the View Capture window is displayed. Verify that the Captured Image, the Finger Image, the ten Images without Capacitive Barrier and the ten Images with Capacitive Barrier are displayed.

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

Click the Resubmit Images for Analysis button in the lower left corner of the View Capture screen. Verify that after processing, a new screen appears with the Print Report tab data open and the ClearView Report is displayed.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Cardiovascular; Respiratory; Gastrointestinal System; Hepatic,

Endocrine, and Nervous System; and Renal and Reproductive), and page 5 contains definitions.

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

Verify there are tabs for Worksheet, NS Analysis, Admin Pages, and Biofield Analysis and verify each tab contains the appropriate content per Section 6.5.

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

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

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

9.1.5 CV License – Administrator Login – New Capture Load Images Option

Click the New Capture Icon. Search the database for Epic Validation. Click the New Capture button. Click in the box above Right thumb Finger box in the Images without Capacitive Barrier row. 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 and open the following network folder: I:\Clinical_Trials\HVS_Development_Folder\Subjects\HVS-1061\wofilter_021940. Click to highlight the 1R_wofilter image and click Open. Verify that the image is displayed in the Capture Image box and the Right Thumb Finger box in the Images without Capacitive Barrier row.

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

Repeat this step for all twenty images (2R, 3R, etc.) for both Images without Capacitive Barrier and Images with Capacitive Barrier (Images with Capacitive Barrier are located in the folder I:\Clinical_Trials\HVS_Development_Folder\Subjects\HVS-1061\wfilter).

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a new screen displays with the Print Report tab highlighted and the ClearView Report is displayed.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Cardiovascular; Respiratory; Gastrointestinal System; Hepatic, Endocrine, and Nervous System; and Renal and Reproductive Systems), and page 5 contains definitions.

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

Verify there are tabs for Worksheet, NS Analysis, Admin Pages, and Biofield Analysis and verify each tab contains the appropriate content per Section 6.5.

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

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

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

9.1.6 Basic License

The following procedure will copy the basic license file into the ClearView folder to verify the report functionality of the ClearView software with the basic license.

Click on the Exit Icon to exit ClearView. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation. Locate and select the file "ClearViewBasic.lic" to copy (CTRL-C).

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, and copy the "ClearViewBasic.lic" file into this folder (CTRL-V). Locate and delete the "ClearView.lic" file in the same folder. Rename the "ClearViewBasic.lic" file to "ClearView.lic". This has now installed the basic license file for the ClearView software.

9.1.7 Basic License – User Login – New Capture

Double click the EPIC ClearView icon on the desktop. Click in the Username box and enter "EPICUser". Click in the password box and enter the password provided by the Network Administrator. The EPIC ClearView main screen is displayed. Click on the New Capture button. Verify that the Search Patient window opens. Click the Find button at the top of the displayed window. Search and identify patient Epic Validation. Click to highlight this patient and click the New Capture button in the lower right corner of the window. Verify that the New Capture tab opens and the "Gather a capture for" window is displayed.

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

Capture a full set of subject images by clicking into each finger image box of the Images without Capacitive Barrier row. Click the Capture Image button. Repeat the process until 10 Images without Capacitive Barrier and 10 Images with Capacitive Barrier have been captured. Verify that all twenty Images without Capacitive Barrier and Images without Capacitive Barrier image boxes contain energized images. Note: calibration images should not be used as they may cause a matlab error, therefore, human subject images should be used.

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

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a report appears on the screen under Print Report tab for EPIC Validation.

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

Verify that the only tab available is the Print Report tab. Verify that the report displays columns for Measurement Point with finger descriptions, Left and Right Physical and Left and Right Autonomic scores. The Measurement Point column

should consist of rows labeled Thumb #1 thru Thumb #8, Index #1 thru Index #12, Middle #1 thru Middle #9, Ring #1 thru Ring #9, and Pinky #1 thru Pinky #9. The scores data should consist of numbers from 0 thru 25, and some positions that are blank. Click the "X" at the far right of the Print Report subtab to return to the ClearView main screen. Click the Exit icon. Verify that the ClearView software closes and the desktop appears.

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

9.1.8 Basic License – Administrator Login – New Capture

Double click the EPIC ClearView icon on the desktop. Click in the Username box and enter "administrator". Click in the password box and enter the password provided by the Network Administrator. The EPIC ClearView main screen is displayed. Click on the New Capture button. Verify that the Search Patient window opens. Click the Find button at the top of the displayed window. Search and identify patient Epic Validation. Click to highlight this patient and click the New Capture button in the lower right corner of the window. Verify that the New Capture tab opens and the "Gather a capture for" window is displayed.

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

Capture a full set of subject images by clicking into each finger image box of the Images without Capacitive Barrier row. Click the Capture Image button. Repeat the process until 10 Images without Capacitive Barrier and 10 Images with Capacitive Barrier have been captured. Verify that all twenty Images without Capacitive Barrier and Images without Capacitive Barrier image boxes contain energized images. Note: calibration images should not be used as they may cause a matlab error, therefore, human subject images should be used.

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

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a report appears on the screen under Print Report tab for EPIC Validation.

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

Verify that the only tab available is the Print Report tab. Verify that the report displays columns for Measurement Point with finger descriptions, Left and Right Physical and Left and Right Autonomic scores. The Measurement Point column should consist of rows labeled Thumb #1 thru Thumb #8, Index #1 thru Index #12, Middle #1 thru Middle #9, Ring #1 thru Ring #9, and Pinky #1 thru Pinky #9. The scores data should consist of numbers from 0 thru 25, and some positions that are blank. Click the "X" at the far right of the Print Report subtab to return to the ClearView main screen.

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

9.1.9 Basic License – Administrator Login – View Capture Resubmit

Click the Search Capture button. Verify that the Search Capture window opens. Click on the Find button in the upper right corner of the displayed window. Search and identify patient Camera Validation. Click to highlight this patient and Treatment ID 2147, and click the View Capture button in the lower right corner of the displayed window. Verify that the View Capture tab is opened and the View Capture window is displayed. Verify that the Captured Image, the Finger Image, the ten Images without Capacitive Barrier and the ten Images with Capacitive Barrier are displayed.

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

Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a report appears on the screen under Print Report tab for EPIC Validation.

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

Verify that the only tab available is the Print Report tab. Verify that the report displays columns for Measurement Point with finger descriptions, Left and Right Physical and Left and Right Autonomic scores. The Measurement Point column should consist of rows labeled Thumb #1 thru Thumb #8, Index #1 thru Index #12, Middle #1 thru Middle #9, Ring #1 thru Ring #9, and Pinky #1 thru Pinky #9. The scores data should consist of numbers from 0 thru 25, and some positions

that are blank. Click the "X" at the far right of the Print Report subtab to return to the ClearView main screen.

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

9.1.10 Basic License – Administrator Login – New Capture Load Images Option

Click the New Capture Icon. Search the database for Epic Validation. Click the New Capture button. Click in the box above Right thumb Finger box in the Images without Capacitive Barrier row. 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 and open the following network folder: I:\Clinical_Trials\HVS_Development_Folder\Subjects\HVS-1061\wofilter_021940. Click to highlight the 1R_wofilter image and click Open. Verify that the image is displayed in the Capture Image box and the Right Thumb Finger box in the Images without Capacitive Barrier row.

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

Repeat this step for all twenty images (2R, 3R, etc.) for both Images without Capacitive Barrier and Images without Capacitive Barrier (Images with Capacitive Barrier are located in the folder I:\Clinical_Trials\HVS_Development_Folder\Subjects\HVS-1061\wfilter). Click on the Submit for Analysis button in the lower right corner of the window. After processing, verify that a report appears on the screen under Print Report tab for EPIC Validation.

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

Verify that the only tab available is the Print Report tab. Verify that the report displays columns for Measurement Point with finger descriptions, Left and Right Physical and Left and Right Autonomic scores. The Measurement Point column should consist of rows labeled Thumb #1 thru Thumb #8, Index #1 thru Index #12, Middle #1 thru Middle #9, Ring #1 thru Ring #9, and Pinky #1 thru Pinky #9.

The scores data should consist of numbers from 0 thru 25, and some positions that are blank. Click the "X" at the far right of the Print Report subtab to return to the ClearView main screen.

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

9.1.11 Restore Full License

The following procedure will copy the full license file into the ClearView folder to verify the full report functionality of the ClearView software has been restored.

Click the "X" in the upper right corner of the report tab to return to the ClearView main screen. Click on the Exit Icon to exit ClearView. Click on My Computer and locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation. Locate and select the file "ClearViewFull.lic" to copy (CTRL-C).

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, and copy the "ClearViewFull.lic" file into this folder (CTRL-V). Locate and delete the "ClearView.lic" file in the same folder. Rename the "ClearViewFull.lic" file to "ClearView.lic". This has now installed the full license file for the ClearView software.

Double click the EPIC ClearView icon on the desktop. Click in the Username box and enter "Administrator". Click in the password box and enter the password provided by the Network Administrator. The EPIC ClearView main screen is displayed.

Click the View Report icon. Click Display Report. Type "Epic" in the first name box of the Search Capture box. Click Find. Highlight the patient name Epic Validation. Click View Report button. Verify that a report appears on the screen under the Print Report tab for EPIC Validation.

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

Verify the report is five pages, page 1 contains explanations and Table 1, pages 2, 3 and 4 display Table 2 (containing organs and scores in the following order of Organ Systems: Sensory and Skeletal Systems; Hepatic, Endocrine, and Nervous System; Cardiovascular System; Respiratory System; Gastrointestinal System; and Renal and Reproductive Systems), and page 5 contains definitions.

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

Verify there are tabs for Worksheet, NS Analysis, Admin Pages, and Biofield Analysis and verify each tab contains the appropriate content per Section 6.5.

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

Click the "X" in the upper right corner of each tab and verify each tab closes and the screen returns to the EPIC ClearView main screen. Click the Exit button. Verify the ClearView software closes and the desktop appears.

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

10.0 Reference

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

11.0 Attachments

Attachment A, Deviations from Protocol
Attachment B, Non-conformances Worksheet
Attachment C, Resubmit Verification Samples

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