Approval Signatures:

Department	Name	Signature	Date
QA	Andrea Miller	*[signature]*	2/27/12
OPS	Michael Stowell	*[signature]*	2/27/12
Exec	Nancy Rizzo	*[signature]*	2/27/12
IS	Andrew Mason	*[signature]*	2/27/12

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 PATIENT 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

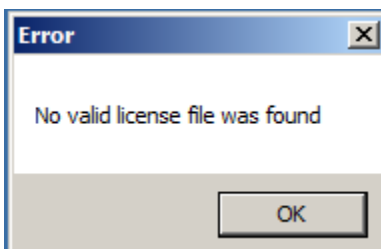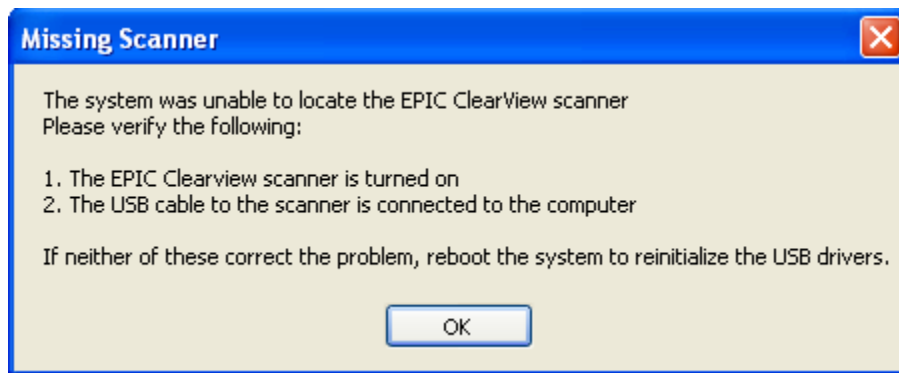| User	• Complies with the policy and procedure. • Ensures the most current version of this document is used when referenced.
Departmental Management	• Ensures departmental personnel are properly trained before using this policy or procedure. • Provides oversight to the validation process and ensures 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 PATIENT 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.

Missing Scanner

The system was unable to locate the EPIC ClearView scanner
Please verify the following:

1. The EPIC Clearview scanner is turned on
2. The USB cable to the scanner is connected to the computer

If neither of these correct the problem, reboot the system to reinitialize the USB drivers.

OK

Capture Message

Calibration required please contact your administrator.

OK

Error

Unable to perform image calculations

OK

Error

No valid license file was found

OK

6.0   Procedure

6.1   Device Set Up

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

6.1.2   Place the calibration shroud over the lens cover.

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

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

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

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

_____

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

Verify that the Username and Password box are empty.

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

Click in the Username box and enter "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 closed 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. Verify the User Options icons and the Settings button are not present on the icon tool bar at the top of the page.

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

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

6.2.1 **Manage Patient** icon.

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

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

6.2.2 **Search Patient** 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 birth dates 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.** _____

Clear the field of any previous entry. Enter the patient's last name as Olsen and click Find. Verify that a patient by the last name of Olsen is displayed and record the 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 patients with an "o" in their last name and record the result:

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

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

Highlight and 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 Elizabeth and click
Find. Verify that a patient by the first name of Elizabeth is 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 patients with an "e" in their first name 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 Manage Patient icon. The Search Patient window appears.

With all other entry fields blank, enter a birth date of 05/13/1951. 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):

_____ **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 Manage Patient 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 or the Search Patient Screen.
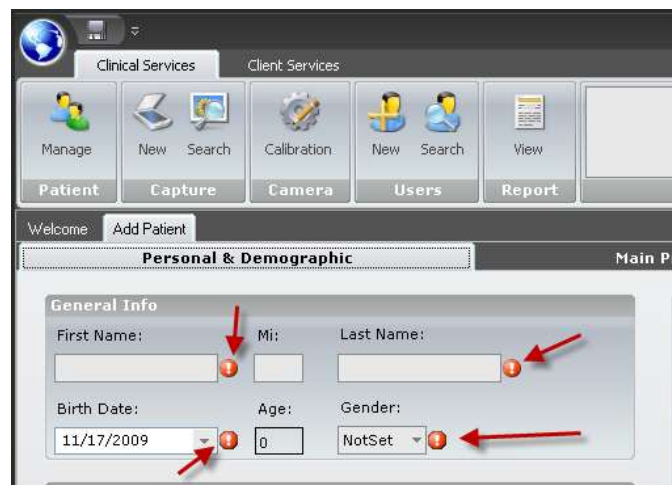
6.3   New Patient button

Click the Manage Patient icon. Click the Find button. Click the New Patient button. Verify the Search Patient Window closes and the Demographics tab opens with the General Info section displayed.

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

Without entering any information, click the Save button at the top left of the page.

Verify that the blank data set cannot be saved and error buttons are displayed next to the First Name, Last Name, Birth Date, and Gender.

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

6.3.1   General Info

Type the following into the appropriate locations:

First Name	Clear
Mi (middle initial)	O
Last Name	View

The Birth Date field can be entered in a few different ways. In this field, type today's date one year ago in the following format: mm/dd/yy (i.e. 11/25/08 for 11/25/2008). The slashes between month, day, and year are required. Verify

that the year defaults to the full four-digit year after clicking or tabbing out of the birth date field.

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

Modify the birth date to today's date one year ago in the following format: mmddyyyy (i.e. 11252008). Do not use slashes between month, day, and year. Click or tab out of the birth date field. Verify that the birth date field defaults to previous entry and a red exclamation error sign appears.

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

Type today's date one year ago as mm/dd/yyyy (i.e. 11/25/2008). Click the tab key on the keyboard to move out of the Birth Date data field. Verify that the Age was automatically populated with a "1" and the error sign disappears.

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

Click in the Age field. Verify that the software will not allow the age to be changed.

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

Use the arrow next to the Gender field and select Male. Click the tab key on the keyboard to move out of the Gender field. Verify that the data entered was retained and Male is now displayed for Gender.

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

Use the arrow next to the Gender field and select Not Set. Click the tab key on the keyboard to move out of the Gender field. Verify that the data entered was retained and Not Set is now displayed for Gender and a red exclamation sign appears.

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

Use the arrow next to the Gender field and select Female. Click the tab key on the keyboard to move out of the Gender field. Verify that the data entered was retained and Female is now displayed for Gender.

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

Click the "X" in the upper right hand corner of the Demographics tab. Verify the "Data has not yet been saved, are you sure you want to exit without saving?" message appears. Click No. Verify the screen returns to the Demographics tab.

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

Click the "X" in the upper right hand corner of the Demographics tab. Verify the "Data has not yet been saved, are you sure you want to exit without saving?" Click Yes. Verify that the screen returns to the EPIC ClearView main screen.

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

Click on Manage Patient icon. Type "View" in the last name box. Click Find. Verify that the patient name you entered above is not listed.

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

Click the New Patient button. Click into each data box and enter the following:

First Name   Clear
MI (middle initial)   O
Last Name   ViewXXXX (In place of the XXXX use the digits of the software version being validated)
Birthdate   11/25/2008
Gender   Female

Click on the Save button in the upper left corner of the screen. Verify the "Patient has been saved to the database" message appears. Click OK. Verify the message box closes. Click the "X" in the upper right corner of the Demographics tab. Verify the software returns to the EPIC ClearView main screen.

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

Verify that the record was saved. Locate the patient record using the Manage Patient button at the top of the main screen to access the search screen and open the record for Clear O. ViewXXXX. Verify that the patient record for Clear O. ViewXXXX is open for editing.

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

Close the patient record by clicking on the "X" in the upper right corner of the Demographics tab.

6.3.2   Customer Administrator mode

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

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

Double click the EPIC ClearView icon on the desktop. Enter the user name as "clearviewadmin". Click in the password box and enter the password provided by the Network Administrator. Verify the User Options icons are present on the icon tool bar at the top of the page.

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

Click the Manage Patient icon. Verify that the Search Patient box appears.

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

Type "v" in the last name box then Click Find. Verify that one or more patient lines appear. Highlight the last Epic Validation patient line. Click New Capture. Verify that the Capture Wizard screen appears.

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

Click Close. Verify that the Exit Process window opens. Click Yes. Verify that the New Capture screen is closed and the ClearView main screen appears.

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

Click the Manage Patient icon. Verify that the Search Patient box appears.

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

Click Find. Verify that one or more patient lines appear. Click New Patient button. Verify that the Demographics tab appears.

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

Click the "X" in the upper right corner of the Demographics tab. Verify the ClearView main screen appears.

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

6.3.3   EPIC Administrator mode

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

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

Double click the EPIC ClearView icon on the desktop. Enter the user name as "Administrator". Click in the password box and enter the password provided by the Network Administrator. Verify the User Options icons and the Settings button are present on the icon tool bar at the top of the page.

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

Click the Manage Patient icon. Verify that the Search Patient box appears.

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

Type "v" in the last name box then Click Find. Verify that one or more patient lines appear. Highlight the last Epic Validation patient line. Click New Capture. Verify that the Capture Wizard screen appears.

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

Click Close. Verify that the Exit Process window opens. Click Yes. Verify that the New Capture screen is closed and the ClearView main screen appears.

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

Click the Manage Patient icon. Verify that the Search Patient box appears.

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

Click Find. Verify that one or more patient lines appear. Click New Patient button. Verify that the Demographics tab appears.

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

Click the "X" in the upper right corner of the Demographics tab. Verify the ClearView main screen appears.

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

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

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

Attachment A

Deviations from Protocol

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

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

Attachment B

Non-conformances Worksheet

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

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