EPIC™
RESEARCH
DIAGNOSTICS

ClearView Software Validation Protocol
Version 1.1.1.2
REPORT Functions

Approval Signatures:

Department	Name	Signature	Date
QA	Andrea Miller	*(signature)*	2/28/12
OPS	Michael Stowell	*(signature)*	2/28/12
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1.0   Purpose

This document is intended to provide a protocol for use in validating the Report Icon within 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 REPORT 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. The verification that the reported data (e.g., reported response scale values, Biofields tab display, NS values in the NS tab, etc.) is accurate will be performed in a separate protocol(s).

3.0   Definitions

N/A

4.0   Responsibilities

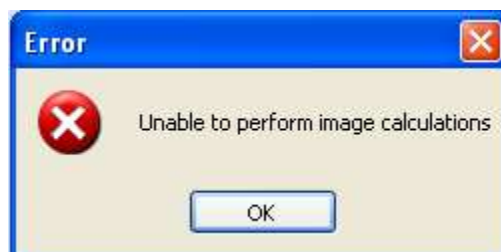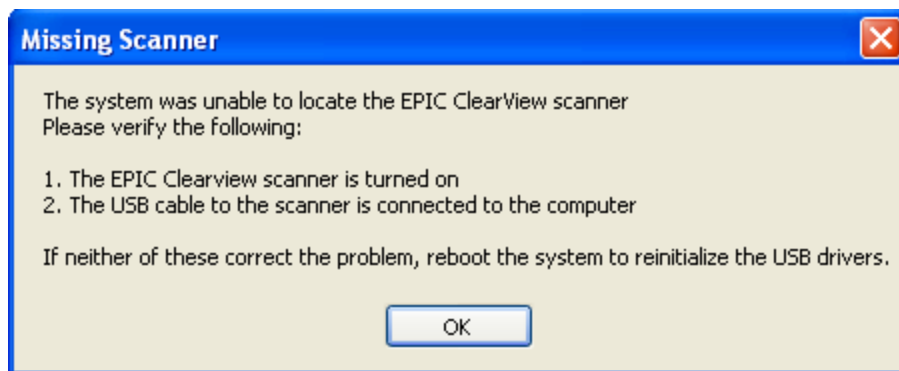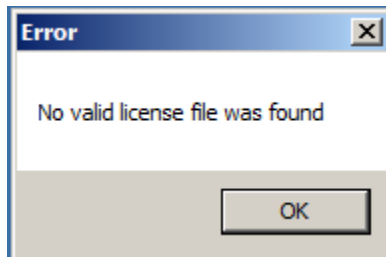| User	• Complies with the policy and procedure. • Ensures the most current version of this document is used when referenced.
Departmental Management	• Ensures departmental personnel are properly trained before using this policy or procedure. • Provides oversight to the validation process and ensures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

ClearView Software Validation Protocol Version 1.1.1.2 – REPORT Functions   Confidential & Proprietary
Document Number: ENG-014   Page 4 of 61
Revision: 003

6.0 Procedure

6.1 Device Set Up

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

6.1.2 Place the calibration shroud over the lens cover.

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

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

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

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

_____

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

Double click 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.

ClearView Software Validation Protocol Version 1.1.1.2 – REPORT Functions   Confidential & Proprietary
Document Number: ENG-014   Page 5 of 61
Revision: 003

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

6.3 **"Report" icon**.

6.3.1 **View Report Button**. Click the View Report button. Verify that the Report Menu is displayed and that "Analysis Report" is highlighted.

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

Click the Display Report button at the bottom right of the Report Menu box. Verify that the Search Capture window is displayed.

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

The Search Capture functionality for "New Capture" and "View Capture" will be validated in a separate protocol. No further challenge for these buttons is required.

View Calibration button

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

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

View Capture button

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

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

View Report button

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

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

Export Data

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

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

6.3.2   Exporting Data

Type "V" in the last name box of the Search Capture box. Click Find. Highlight Epic O. Validation with Treatment ID 2185. Click the Export Data button. Verify that the Browse for Folder window opens.

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

Locate folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation. Click OK. Verify that the Information dialog box opens with the message "The export process is complete." Click OK.

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

Click the "X" in the upper right hand corner of the Search Capture screen. 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. Verify that under 1.1.1.2_Validation the folder Validation_6_3_2011_9_12_56_PM was created.

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

Verify that the following folders were created under Validation_6_3_2011_9_12_56_PM:

AdminData
CalibrationData
CalibrationImages
EnergizedImages
FingerImages
RawData
ReportData

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

Click to open folders AdminData, CalibrationData, RawData, and ReportData and verify that .csv files were created under each folder with the same name as folder.

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

Open the CalibrationImages folder and verify that it contains ten (10) .bmp files (one for each finger) in the following format:

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

5R_CalibrationImage#5.bmp

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

Open the EnergizedImages folder and verify that it contains twenty (20) .bmp files (one for each finger _filter, and one for each finger _wofilter).

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

Open the FingerImages folder and verify that it contains twenty (20) .bmp files (one for each finger _filter, and one for each finger _wofilter).

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

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

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

6.3.3   Admin Pages tab

Type "V" in the last name box of the Search Capture box. Click Find. Highlight Epic O. Validation with Treatment ID 2185. Click View Report button. Verify that a report appears on the screen, that the Print Report tab for patient EPIC Validation is highlighted and the Print Report subtab is open.

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

Verify that the following tabs are listed in the gray bar just below the icons:
Worksheet for Epic Validation
NS Analysis for Epic Validation
Admin pages for Epic Validation
BioField Analysis for Epic Validation
Print Report for Epic Validation

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

Verify that when the Admin Pages tab is highlighted, five subtabs as listed below are visible:

Raw Data (open)

Raw Report Data

Images without Capacitive Barrier

Images with Capacitive Barrier

Calibration Data

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

Verify that the open Raw Data subtab contains multiple columns and rows of data and the cells are not editable.

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

Click on the Raw Report Data subtab. Verify that two tables with multiple columns and rows of data appear and the cells are not editable.

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

Click on the Images without Capacitive Barrier subtab. Verify that one set of images appears – 10 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. Verify that multiple intersecting lines and numbers appear on each image. Click on the Toggle Sectors button. Verify that the lines and numbers disappear.

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

Click on the Images with Capacitive Barrier Scan Images subtab. Verify that one set of images appears – 10 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. Verify that multiple intersecting lines and numbers appear on each image. Click on the Toggle Sectors button. Verify that the lines and numbers disappear.

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

Click on the Calibration Data subtab. Verify that one set of images appears – 10 Calibration Images.

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

6.3.4   Worksheet for Epic Validation tab (where Epic Validation is the patient name)

Click the Worksheet tab on the gray bar below the icons. Verify that the table displayed on the right side of the tab has column headings of Organ, Physical Systems (both Left Hand and Right Hand) and an Autonomic Systems (both Left Hand and Right Hand) and that data (numbers) are present in the Physical System and Autonomic System table.

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

Verify that a listing of the Organ Systems is displayed on the left side of the tab. Verify that the Organ Systems listed have a check mark inside the box and that the systems listed are as follows:

Gastrointestinal System
Hepatic, Endocrine, and Nervous System
Sensory and Skeletal Systems
Cardiovascular System
Respiratory System
Renal and Reproductive Systems

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

Verify the Scan Details box appears below the Organ Systems box, and contains entries for Patient Name, Scan Date (including time), Software and Firmware. Click on the Search Capture button. Click the Find button in the Search Capture window. Locate and highlight Treatment ID 2185. Verify the Name, Scan Date, and Software highlighted match the entries in the Scan Details box. In the Search Capture window, locate and highlight the original scan (this is the ID listed in the Run Notes column next to Reprocessing of Treatment ID). Verify the Scan Date (including time) of the original scan matches the Scan Date (including time) of Treatment ID 2185. Verify the Firmware is listed as Revision E.

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

Click the "Use color coding for organ systems" box just below the Organ Systems block. Verify that the names of the organ systems and organs are now color coded by system (i.e. Cardiovascular System is now gold in the Organ Systems box and Circulation, Coronary Vessels, Heart, etc., are also gold).

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

Click on each of the boxes in the Organ systems block to remove the check mark. Verify that there are no organs listed in the Physical and Autonomic System tables.

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

Click to check the Gastrointestinal System box. Verify Gastrointestinal is purple and the following organ names are purple in color and listed in the Physical and Autonomic System table:

Abdominal Region
Appendix
Ascending Colon
Blind Gut
Descending Colon
Duodenum
Ileum

Jejunum

Rectum

Sigmoid Colon

Transverse Colon

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

Deselect the Gastrointestinal box in the Organ Systems block. Click to check the Hepatic, Endocrine and Nervous System box. Verify Hepatic is green and the following organ names are green in color and listed in the Physical and Autonomic System table:

Cerebral Cortex

Cerebral Vessels

Gallbladder

Hypothalamus

Immune System

Liver

Nervous System

Pancreas

Pineal

Pituitary

Spleen

Thyroid

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

Deselect the Hepatic in the Organ Systems block. Click to check the Sensory and Skeletal Systems box. Verify Sensory and Skeletal is red and the following organ names are red in color and listed in the Physical and Autonomic System table:

Cervical Spine

Coccyx/Pelvis

Ear/Nose/Sinus (L)

Ear/Nose/Sinus (R)

Eye (L)

Eye (R)

Jaw/Teeth (L)

Jaw/Teeth (R)

Lumbar Spine

Sacrum

Thoracic Spine

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

Deselect the Sensory and Skeletal Systems box in the Organ Systems block. Click to check the Cardiovascular Systems box. Verify Cardiovascular is gold and the following organ names are gold in color and listed in the Physical and Autonomic System table:

Cardiovascular Circulation

Cervical Vascular System

Coronary Vessels

Heart

Heart – (Left Side)

Heart – (Right Side)

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

Deselect the Cardiovascular box in the Organ Systems block. Click on the Respiratory System box. Verify the Respiratory color is blue and the following organ names are blue in color and listed in the Physical and Autonomic System table:

Respiratory/Mammary

Thorax Respiratory

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

Deselect the Respiratory box in the Organ Systems block. Click on the Renal and Reproductive Systems box. Verify the Renal color is light blue and that the

following organs are light blue in color and listed in the Physical and Autonomic System table:

Adrenal
Genitourinary System
Kidney – Left
Kidney – Right
Urokidney

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

Click to check the Gastrointestinal, Hepatic, Sensory, Cardiovascular, Respiratory and Renal boxes. Verify that all boxes in the Organ System block are checked.

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

Verify that all organs are listed in the Physical and Autonomic System table and that all are properly color coded.

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

Click to uncheck the "Use color coding for organ systems" box below the Organ Systems block. Verify that all color coding has been removed.

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

6.3.5   **NS Analysis for Epic Validation tab (where Epic Validation is the patient name)**

Click on the NS Analysis tab for "Epic Validation" in the gray bar below the icons. Verify that two boxes with a skeleton graphic is displayed surrounded with graph lines around each one.

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

Further verification of the displayed NS values will be conducted in a separate protocol.

6.3.6 Biofield Analysis for Epic Validation tab (where Epic Validation is the patient name)

Click on the Biofield Analysis for "Epic Validation" tab in the gray bar below the icons. Verify that three body images appear and that the Item Data subtab is open, with boxes labeled "Indexes", "Organ Systems" and "Settings", and an image box below with the subtabs Magnified View (open) and Admin View.

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

Under Settings, click the button next to "Autonomic" to choose the "Unfiltered" system (Images without Capacitive Barrier). Under Organ Systems, click on each of the radio buttons to display different organ systems. Verify that the CT scans and portions of scan images change for each organ system. Document the verification in the table below by placing your initials in the appropriate column.

Organ	Verified Unfiltered	Non-Conforming?	Ref. No.
Skeletal System			
Cardiovascular System			
Small Intestine			
Large Intestine			
Renal & Reproductive			
Head & Upper Back			
Lower Back			
Immune System			
Respiratory System			
Nervous System			

Repeat for the "Physical" or "Filtered" system (Images with Capacitive Barrier)

Organ	Verified Filtered	Non-Conforming?	Ref. No.
Skeletal System			
Cardiovascular System			
Small Intestine			
Large Intestine			
Renal & Reproductive System			
Head & Upper Back			
Lower Back			
Immune System			
Respiratory System			
Nervous System			

6.3.6.1   Five samples will be randomly selected from development test subjects. The ClearView Reports for these randomly selected individuals will be printed and used in the verification. This data will be referred to as the Reference Data for subsequent steps.

NOTE: A sample size of 5 was selected as this verification is to ensure that the software is pulling data from the database accurately in a repeatable method. The data is not actually being calculated for display, but instead is being sourced from the database. The verification of the accuracy of the calculation will be documented in a separate validation protocol.

6.3.6.2   The reference data results will be compared to the Biofield Analysis report tab in the ClearView software. The data points compared for each sample are as follows:

6.3.6.3   Organ Systems- Compare each organ system listed on the Reference Data ClearView Report to ensure that the proper organs are listed in the Organ Systems section of the Biofield Analysis tab. This verification is done once as the systems are the same for all subjects.

6.3.6.4   Item Data- For each sample, verify the following:

6.3.6.4.1   Verify that the Physical and Autonomic reported values of Right Index and Left Index are displayed accurately for each organ within all organ systems.

NOTE: Several organs within the Skeletal Organ System are titled differently in the Biofield Analysis display. These structures include the shoulder, hip, knee and ankle. In order to verify these structures, the finger/sector displayed in the Admin View will be used to ensure that the proper organ system is being compared.

6.3.6.5 Verify that the Color Enhanced button when selected displays a color version of the image in the box on the left of the screen.   See example below.
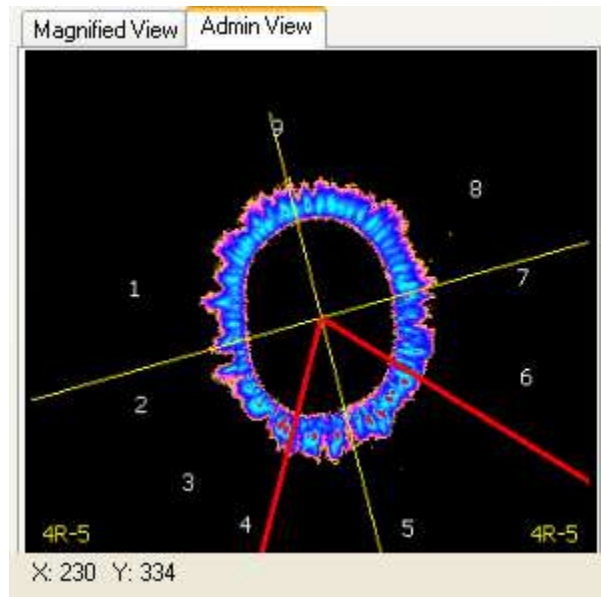
Figure 1

6.3.6.6 Verify that the B&W button when selected displays a black and white version of the image in the box on the left of the screen. See example below.
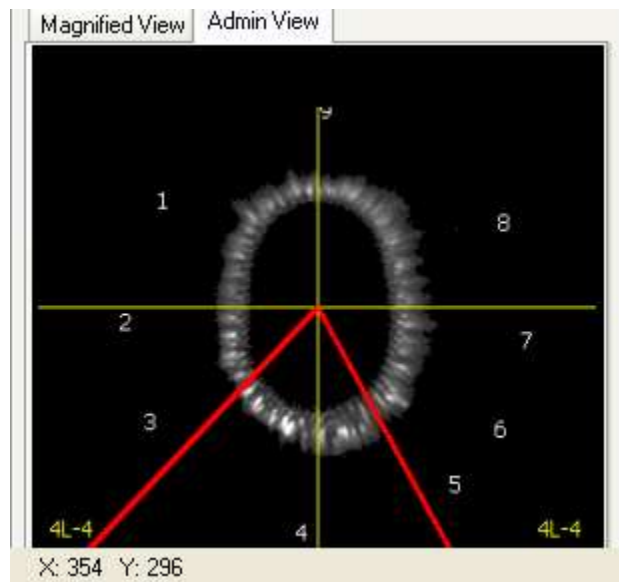
Figure 2

6.3.6.7 Verify that the finger/sectors match the organ for all organ systems. Note: finger/sector displayed in the bottom left and right corners of the Admin View in Figure 2 above.

Sector	Organ	Sector	Organ
1L-7	Eye (L)	1L-4	Cervical Vascular System - Left
1R-1	EYE (R)	1R-4	Cervical Vascular System - Right
1L-6	Ear, Nose, Sinus (L)	5L-6	Coronary Vessels
1R-2	Ear, Nose, Sinus (R)	5R-6	Coronary Vessels
1L-5	Jaw, Teeth (L)	5R-5	Heart (muscle)
1R-3	Jaw, Teeth (R)	5L-1	Heart (Left Side)
2L-8	Cervical Spine	5L-5	Heart (Right Side)
2R-1	Cervical Spine	3L-1	Cardiovascular Circulation (whole body) - Left
2L-7	Thoracic Spine	3R-6	Cardiovascular Circulation (whole body) - Right
2R-2	Thoracic Spine	5R-1	Duodenum
2L-6	Lumbar	5L-4	Jejunum
2R-3	Lumbar	5R-2	Ileum
2L-5	Sacrum	2R-6	Blind Gut
2R-4	Sacrum	3L-4	Abdominal Region
2L-4	Coccyx / Pelvis	4R-2	Thyroid
2R-5	Coccyx / Pelvis	4L-7	Thyroid
4L-2	Nervous System	4L-6	Pancreas
4R-7	Nervous System	4R-3	Pancreas
4L-1	Hypothalamus	3L-3	Liver
4R-8	Hypothalamus	3R-4	Liver
4L-8	Pituitary	3R-3	Gallbladder
4R-1	Pituitary	2R-7	Appendix
4L-9	Pineal	2R-8	Ascending Colon

Sector	Organ	Sector	Organ
4R-9	Pineal	2L-9	Transverse Colon
1L-8	Cerebral Cortex	2R-9	Transverse Colon
1R-8	Cerebral Cortex	2L-1	Descending Colon
3L-7	Cerebral Vessels	2L-2	Sigmoid Colon
3R-7	Cerebral Vessels	2L-3	Rectum
3L-5	Immune System	4L-5	Adrenal
3R-2	Immune System	4R-4	Adrenal
4L-3	Spleen	3L-2	Kidney - Left
4R-6	Spleen	3R-5	Kidney - Right
5L-3	Respiratory/Mammary	5L-2	Urokidney - Left
5R-3	Respiratory/Mammary	5R-4	Urokidney - Right
3L-6	Thorax Respiratory	4L-4	Genitourinary System - Left
3R-1	Thorax Respiratory	4R-5	Genitourinary System - Right

6.3.6.8 Visually verify that the finger image displayed in Admin View matches the finger image displayed in the Admin Pages tab for each finger.

6.3.7   Verification that the image captured is displayed in the Admin View- Ensuring that the images called out in the report tab represent the images captured in the Capture function.

6.3.7.1 Initialize the capture function.   This may require calibration of the device prior to use. See Instructions for Use for instructions to conduct calibration and/or image capture.

6.3.7.2 Generate finger images using the ClearView software solution. After capture of energized and finger images without a filter and again with a filter, save the images to file.

6.3.7.3 Generate the report analysis and pull up the Report tabs. See Instructions for Use for instructions on how to generate and view report tabs.

6.3.7.4 Compare the saved images to the images displayed in the Admin View box of the Biofield Analysis tab.

6.3.7.5 The functionality of image capture and storage is verified in another software protocol. Only one patient sample is being taken for this verification in order confirm the Admin View box only.

6.3.8   An executive staff member with clinical experience will verify that the image placement on the actual biofield image and the correct finger/sector is applied appropriately. The executive staff member will document this verification by signature and date of the Verification Record.

6.3.9   All verification steps will be recorded on the form located in Attachment C-Verification Record. Any discrepancies noted on the Verification Record. Appropriate investigation will be conducted and all discrepancies will be addressed in the final report with appropriate corrective and preventive action documented.

6.3.10 Print Report for Epic Validation tab (where Epic Validation is the patient name)

Click on the Print Report tab for "Epic Validation" tab in the gray bar below the icons. Verify the "ClearView Report" appears and has the patient name, visit date, age and gender displayed at the top. Verify the five pages contain the descriptions and tables for data as shown below. Verify the Organ Systems groups contain the elements shown in the sample report. Verify the Physical and Autonomic (Normal and Out of Range) columns contain score data that consists of numbers from 0 thru 5 (pages 1 and 5) and 0 thru 25 (pages 2, 3, and 4), and some positions that are blank.

Note: Report shown is for reference only, score values will change, but odds ratio values are fixed.

ClearView Report
Prepared for: Epic Validation

Demographics and Summary

Visit Date: 12/28/2011   Age: 49   Gender: Female

The EPIC ClearView™ is a Galvanic Skin Response (GSR) measurement tool for the evaluation of the human body's primary organ systems (Cardiovascular; Respiratory; Gastrointestinal; Hepatic, Endocrine, and Nervous System; Renal and Reproductive) to help direct the physician when choosing further standard of care testing.

The tables below provide both the overall ClearView Response Scale results (Table 1), and the detailed GSR point measurements (Table 2, attached). The ClearView Response Scale ranges from 0-5, with higher values representing increased association which may indicate a need for further testing of a particular primary organ system.

Table 1

Primary Organ Systems	Physical Score	Autonomic Score
Cardiovascular System	1.1	1.9
Respiratory System	0.7	1.3
Gastrointestinal System	1.3	1.3
Hepatic, Endocrine, and Nervous System	0.1	0.6
Renal and Reproductive Systems	0.2	0.2

Quantification of the increased association is defined by odds ratios, which are presented in (Table 3), in the definitions section at the end of this report.

The supporting detailed GSR point measurements range from 0-25, and should be interpreted in the context of other signs, symptoms, and test results.

Table 2 — Supporting Organ Systems Detail with Standard GSR Point Measurements

Sensory and Skeletal Systems	Physical Normal (L/R)		Out of Range				Autonomic Normal (L/R)	
Eye (L) **	5	13					5	7
Eye (R) **			5	16			8	7
Ear/Nose/Sinus (L) **			15	7	16	9		
Ear/Nose/Sinus (R) **			15	18			12	7
Jaw/Teeth (L) **	6	6			17	16		
Jaw/Teeth (R) **			4	15			4	13
Cervical Spine **	7	5					6	6
Thoracic Spine **			7	17			7	7
Lumbar Spine **	7	6					12	6
Sacrum **	14	13					13	12
Coccyx/Pelvis **			6	17	16	16		

Hepatic, Endocrine, and Nervous System	Physical Normal (L/R)		Out of Range				Autonomic Normal (L/R)	
Nervous System **	6	7			15	13		
Hypothalamus **			8	15			5	6
Pituitary **	7	6			16	14		
Pineal **	8	7			6	19		
Thyroid **			6	16	15	15		
Cerebral Cortex **	8	5			20	6		

** GSR Point Measurement

Hepatic, Endocrine, and Nervous System	Physical Normal (L/R)		Out of Range				Autonomic Normal (L/R)	
Cerebral Vessels **			16	5	25		5	
Immune System **			6	20	8	15		
Spleen **			7	15			6	5
Pancreas **	7	14					7	4
Liver **	6	7					7	13
Gallbladder **				15				5

Cardiovascular System	Physical Normal (L/R)		Out of Range				Autonomic Normal (L/R)	
Cervical Vascular System **	7	8			15	9		
Coronary Vessels **			19	6	16	7		
Heart (muscles) **		7						5
Heart (left side) **	7						6	
Heart (right side) **			21				11	
Cardiovascular Circulation (whole body) **	5	5					4	4

Respiratory System	Physical Normal (L/R)		Out of Range				Autonomic Normal (L/R)	
Throat/Cervical and Supraclavicular Lymphatics	7	8			15	9		
Respiratory/Mammary **			18	9				
Thorax Respiratory **			16	12			5	5

Gastrointestinal System	Physical Normal (L/R)		Out of Range				Autonomic Normal (L/R)	

** GSR Point Measurement

Gastrointestinal System

Gastrointestinal System	Physical Normal (L/R)		Out of Range		Autonomic Normal (L/R)	
Duodenum **			16			12
Jejunum **		21		21		
Ileum **		14				11
Blind Gut **		7				6
Abdominal Region **	6				5	
Appendix **		6				7
Ascending Colon **		9		16		
Transverse Colon **		21	8	20	6	
Descending Colon **	6		16			
Sigmoid Colon **	6				4	
Rectum **	6		19			

Renal and Reproductive Systems

Renal and Reproductive Systems	Physical Normal (L/R)		Out of Range		Autonomic Normal (L/R)	
Kidney (L) **			16		9	
Kidney (R) **			15			6
Adrenal **	5	13			13	14
Genitourinary System **			15	8	7	4
Urokidney **		8	15	6	15	

** GSR Point Measurement

Run by: Administrator (Id: 2248)

EPIC RESEARCH DIAGNOSTICS

ClearView Report

Prepared for: Epic Validation

Definitions

Autonomic Nervous System GSR point measurements represent a measure of how the perception of stress by the individual is affecting the different body systems.

Physical System GSR point measurements represent the functional GSR measures for the body.

The Odds Ratio is a measure that describes the strength of association between the ClearView Response Scale and the presence of a disease state in the body's primary organ systems. With an odds ratio greater than 1.0, an increase on the ClearView Response Scale is indicative of greater odds of a disease state within an organ system. See table 3 below.

Table 3

Primary Organ Systems	Physical Odds Ratio	Score	Autonomic Odds Ratio	Score
Cardiovascular System	3.9	1.1	2.8	1.9
Respiratory System	7.8	0.7	2.7	1.3
Gastrointestinal System	45.5	1.3	8.6	1.3
Hepatic, Endocrine, and Nervous System	13.9	0.1	5.8	0.6
Renal and Reproductive Systems	39.1	0.2	3.2	0.2

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

Click on the Print Report button which is located at the far left of the SAP Crystal Reports tab. Ensure that a local system printer is selected and click the "Print"

button. Label the printout "AdminReport#1" and place your initials and date on the first page. Verify that the printout matches the values displayed on the screen.

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

Click on the Refresh button. Verify that the screen reprints the report in the display area.

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

Click the right arrow button in order to advance the displayed report to the next page. Verify that the page is advanced and the next page of the report is displayed and continue advancing to the last page.

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

Click the left arrow button in order to return the displayed report to the previous page. Verify that the page returns to the previous page and continue until the first page of the report appears.

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

In the "Go to Page" entry field, type in "2" and enter. Verify that page 2 of the report is displayed. Repeat for pages 3, 4 and 5. In the "Go to Page" entry field, type in "1" and enter. Verify that page 1 of the report is displayed.

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

Click on the Find Text button. Verify that the Find Text dialog box opens. Type in "colon" and enter. Verify that the report advances to page 4 and a red rectangle surrounds Ascending Colon, and the Find Text dialog box remains open.

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

ClearView Software Validation Protocol Version 1.1.1.2 – REPORT Functions   Confidential & Proprietary
Document Number: ENG-014   Page 26 of 61
Revision: 003

Click the Find Next button. Verify that a red rectangle surrounds Transverse Colon. Click the Find Next button. Verify that a red rectangle surrounds Descending Colon. Click the Find Next button. Verify that a red rectangle surrounds Sigmoid Colon.

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

Click the Find Next button. Verify that a dialog box opens with the message "Finished searching the document". Click the OK button. Verify that the dialog box closes. In the Find Text dialog box, click the Cancel button. Verify that the dialog box closes. Click the Refresh button. Verify that the report returns to page 1 and the red rectangle disappears.

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

Click on the Zoom button. Select and click from the list the option to display Whole Page. Verify that the whole page of the report is displayed.

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

Click on the Zoom button. Select and click from the list the option to display 150%. Verify that only a portion of the first page of the report is displayed.

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

Report Scores

Click on the Search Capture button. Find Verification Subject1 Treatment ID 2191. Resubmit for Analysis. Record the Treatment ID below:

Subject1   _____

Print out the ClearView Report. Print out the ClearView Report for Treatment ID 2191. Compare the two reports and verify all data points match. Circle each data point that does not match. Sign and date the reports.

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

Verify the report scores are listed correctly on each of the two different reports per the following criteria:

-Any pair with both scores with a value of 14 or lower appears in the Normal (L/R) columns.

-Any pair with one or more scores of 15 or higher appears in the Out of Range columns.

-Scores displayed in the Out of Range columns with values from 15 through 18 are highlighted in yellow.

-Scores displayed in the Out of Range columns with values from 19 through 21 are highlighted in orange.

-Scores displayed in the Out of Range columns with values from 22 through 25 are highlighted in red.

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

Click on the Search Capture button. Find Verification Subject1 Treatment ID 2193. Resubmit for Analysis. Record the Treatment ID below:

Subject2   _____

Print out the ClearView Report. Print out the ClearView Report for Treatment ID 2193. Compare the two reports and verify all data points match. Circle each data point that does not match. Sign and date the reports.

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

Verify the report scores are listed correctly on each of the two different reports per the following criteria:

-Any pair with both scores with a value of 14 or lower appears in the Normal (L/R) columns.

-Any pair with one or more scores of 15 or higher appears in the Out of Range columns.

-Scores displayed in the Out of Range columns with values from 15 through 18 are highlighted in yellow.

-Scores displayed in the Out of Range columns with values from 19 through 21 are highlighted in orange.

-Scores displayed in the Out of Range columns with values from 22 through 25 are highlighted in red.

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

Click on the Search Capture button. Find Verification Subject1 Treatment ID 2197. Resubmit for Analysis. Record the Treatment ID below:

Subject3   _____

Print out the ClearView Report. Print out the ClearView Report for Treatment ID 2197. Compare the two reports and verify all data points match. Circle each data point that does not match. Sign and date the reports.

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

Verify the report scores are listed correctly on each of the two different reports per the following criteria:

-Any pair with both scores with a value of 14 or lower appears in the Normal (L/R) columns.

-Any pair with one or more scores of 15 or higher appears in the Out of Range columns.

-Scores displayed in the Out of Range columns with values from 15 through 18 are highlighted in yellow.

-Scores displayed in the Out of Range columns with values from 19 through 21 are highlighted in orange.

-Scores displayed in the Out of Range columns with values from 22 through 25 are highlighted in red.

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

Click the Exit button to exit ClearView. Attach the printed reports to the end of this protocol. Further validation of this tab will be conducted in a separate protocol.

6.4   User Login Verification

6.4.1   The EPIC User login does not have the same access to Admin pages. This
section confirms the access restrictions for these users.

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

6.4.3   Click on the View Report button. Verify that the Report Menu is displayed and
that "Analysis Report" is highlighted.

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

Click the Display Report button at the bottom right of the Report Menu box.
Verify that the Search Capture window is displayed.

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

The Search Capture functionality for "New Capture" and "View Capture" has
been previously validated. No further challenge for these buttons is required.

View Calibration button

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

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

View Capture button

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

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

View Report button

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

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

Export Data

Verify that the Export Data button is not displayed and/or available to the user.

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

6.4.4   Search for Epic O. Validation with Treatment ID 2185. Click View Report button. Verify that a report appears on the screen, that the Print Report tab for patient EPIC Validation is highlighted and the Analysis Report subtab is open.

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

Verify that the following tabs are listed in the gray bar just below the icons
Worksheet for Epic Validation
NS Analysis for Epic Validation
BioField Analysis for Epic Validation
Print Report for Epic Validation

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

6.4.5   Worksheet for Epic Validation tab (where Epic Validation is the patient name)

Click the Worksheet tab on the gray bar below the icons.
Verify that the table displayed on the right side of the tab has column headings of Organ, Physical Systems (both Left Hand and Right Hand) and an Autonomic Systems (both Left Hand and Right Hand) and that data (numbers) are present in the Physical System and Autonomic System table.

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

Verify that a listing of the Organ Systems is displayed on the left side of the tab. Verify that the Organ Systems listed have a check mark inside the box and that the systems listed are as follows:

Gastrointestinal System

Hepatic, Endocrine, and Nervous System

Sensory and Skeletal Systems

Cardiovascular System

Respiratory System

Renal and Reproductive Systems

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

Verify the Scan Details box appears below the Organ Systems box, and contains entries for Patient Name, Scan Date (including time), Software and Firmware. Click on the Search Capture button. Click the Find button in the Search Capture window. Locate and highlight Treatment ID 2185. Verify the Name, Scan Date, and Software highlighted match the entries in the Scan Details box. In the Search Capture window, locate and highlight the original scan (this is the ID listed in the Run Notes column next to Reprocessing of Treatment ID). Verify the Scan Date (including time) of the original scan matches the Scan Date (including time) of Treatment ID 2185. Verify the Firmware is listed as Revision E.

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

Click the "Use color coding for organ systems" box just below the Organ Systems block. Verify that the names of the organ systems and organs are now color coded by system (i.e. Cardiovascular System is now gold in the Organ Systems box and Circulation, Coronary Vessels, Heart, etc., are also gold).

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

Click on each of the boxes in the Organ systems block to remove the check mark. Verify that there are no organs listed in the Physical and Autonomic System tables.

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

6.4.6   NS Analysis for Epic Validation tab (where Epic Validation is the patient name)

Click on the NS Analysis tab for "Epic Validation" in the gray bar below the icons. Verify that two boxes with a skeleton graphic is displayed surrounded with graph lines around each one.

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

Further verification of the displayed NS values will be conducted in a separate protocol.

6.4.7   Biofield Analysis for Epic Validation tab (where Epic Validation is the patient name)

Click on the Biofield Analysis for "Epic Validation" tab in the gray bar below the icons. Verify that three body images appear and the Item Data subtab is open, with boxes labeled "Indexes", "Organ Systems" and "Settings", and a Magnified View image box below.

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

Under Settings, click the button next to "Autonomic" to choose the "Unfiltered" system (Images without Capacitive Barrier). Click on each of the radio buttons to display different organ systems. Verify that the CT scans and portions of scan images change for each organ system. Document the verification in the table below by placing your initials in the appropriate column.

Organ	Verified Unfiltered	Non-Conforming?	Ref. No.
Skeletal System			
Cardiovascular System			

Organ	Verified Unfiltered	Non-Conforming?	Ref. No.
Small Intestine			
Large Intestine			
Renal & Reproductive System			
Head & Upper Back			
Lower Back			
Immune System			
Respiratory System			
Nervous System			

Repeat for the "Physical" or "Filtered" system (Images with Capacitive Barrier)

Organ	Verified Filtered	Non-Conforming?	Ref. No.
Skeletal System			
Cardiovascular System			
Small Intestine			
Large Intestine			
Renal & Reproductive System			
Head & Upper Back			
Lower Back			
Immune System			

Organ	Verified Filtered	Non-Conforming?	Ref. No.
Respiratory System			
Nervous System			

6.4.7.1 The same five samples selected in section 6.3.6.1 above will be used to verify the Biofield display. The previously printed ClearView Reports for these randomly selected individuals will be used in the verification. This data will be referred to as the Reference Data for subsequent steps.

NOTE: A sample size of 5 was selected as this verification is to ensure that the software is pulling data from the database accurately in a repeatable method. The data is not actually being calculated for display, but instead is being sourced from the database. The verification of the accuracy of the calculation will be documented in a separate validation protocol.

6.4.7.2 The reference data results will be compared to the Biofield Analysis report tab in the ClearView software. The data points compared for each samples are as follows:

6.4.7.2.1 Organ Systems- Compare each organ system listed on the Reference Data ClearView Report to ensure that the proper organs are listed in the Organ Systems section of the Biofield Analysis tab. This verification is done once as the systems are the same for all subjects.

6.4.7.2.2 Item Data- For each sample, verify the following:

- Verify that the Physical and Autonomic reported values of Right Index and Left Index are displayed accurately for each organ within all organ systems.

NOTE: Several organs within the Skeletal Organ System are titled differently in the Biofield Analysis display. These structures include

the shoulder, hip, knee and ankle. These were verified in the Admin view and cannot be compared here as the login does not provide the finger reference.

6.4.7.3 Verify that the Color Enhanced button when selected displays a color version of the biofield images displayed on the CT scans and in the Magnified View box on the left.

6.4.7.4 Verify that the B&W button when selected displays a black and white version of the biofield images displayed on the CT scans and in the Magnified View box on the left.

6.4.8 All verification steps will be recorded on the form located in Attachment C-Verification Record. Any discrepancies noted on the Verification Record. Appropriate investigation will be conducted and all discrepancies will be addressed in the final report with appropriate corrective and preventive action documented.

6.4.9 Verification that the Admin View is not available- The EPICUser login should not have access to the Admin View tab. Verify that the Admin tab cannot be opened and does not display an energized finger image.

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

6.4.10 Print Report for Epic Validation tab (where Epic Validation is the patient name)

Click on the Print Report tab for "Epic Validation" tab in the gray bar below the icons. Verify the "ClearView Report" appears and has the patient name, visit date, age and gender displayed at the top. Verify the five pages contain the descriptions and tables for data as shown in Section 6.3.10. Verify the Organ Systems groups contain the elements shown in the sample report. Verify the Physical and Autonomic (Normal and Out of Range) columns contain score data that consists of numbers from 0 thru 25, and some positions that are blank.

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

Click on the Print Report button. Ensure that a local system printer is selected and click the "Print" button. Label the printout "UserReport#2" and place your initials and date on the first page. Verify that the printout matches the values displayed on the screen.

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

Further validation of this tab will be conducted in a separate protocol. Click the "X" in the upper right corner until the ClearView main screen is displayed.

6.5   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.

6.5.1   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 "ClearViewCV.lic" file into this folder (CTRL-V). Locate and delete the "ClearView.lic" file in the same folder. Rename the "ClearViewCV.lic"

file to "ClearView.lic". This has now installed the CV license file for the ClearView software.

6.5.2 CV License – Administrator Login – View Report

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. Type "V" in the last name box of the Search Capture box. Click Find. Highlight Epic O. Validation with Treatment ID 2185. Click View Report button. 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 following tabs are listed in the gray bar just below the icons:
Worksheet for Epic Validation
NS Analysis for Epic Validation
Admin pages for Epic Validation
BioField Analysis for Epic Validation
Print Report for Epic Validation

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

CV License – Admin Login - Worksheet Tab
Click the Worksheet tab on the gray bar below the icons. Verify that the table displayed on the right side of the tab has column headings of Organ, Physical Systems (both Left Hand and Right Hand) and an Autonomic Systems (both Left Hand and Right Hand) and that data (numbers) are present in the Physical System and Autonomic System table.

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

Verify that a listing of the Organ Systems is displayed on the left side of the tab. Verify that the Organ Systems listed have a check mark inside the box and that the systems listed are as follows:

Cardiovascular
Respiratory
Gastrointestinal System
Renal and Reproductive Systems
Hepatic, Endocrine, and Nervous System

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

Click the "Use color coding for organ systems" box just below the Organ Systems block. Verify that the names of the organ systems and organs are now color coded by system (i.e. Cardiovascular System is now purple in the Organ Systems box and Circulation, Coronary Vessels, Heart, etc., are also purple).

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

Click on each of the boxes in the Organ systems block to remove the check mark. Verify that there are no organs listed in the Physical and Autonomic System tables.

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

Click to check the Cardiovascular box. Verify Cardiovascular is purple and the following organ names are purple in color and listed in the Physical and Autonomic System table:

Cardiovascular Circulation
Cervical Vascular System
Coronary Vessels
Heart
Heart – (Left Side)
Heart – (Right Side)
Thoracic Spine

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

Deselect the Cardiovascular box in the Organ Systems block. Click on the Respiratory box. Verify the Respiratory color is green and the following organ names are green in color and listed in the Physical and Autonomic System table:

Cervical Spine
Ear/Nose/Sinus (L)
Ear/Nose/Sinus (R)
Eye (L)
Eye (R)
Jaw/Teeth (L)
Jaw/Teeth (R)
Respiratory/Mammary
Thorax Respiratory

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

Deselect the Cardiovascular box in the Organ Systems block. Click to check the Gastrointestinal System box. Verify Gastrointestinal is red and the following organ names are red in color and listed in the Physical and Autonomic System table:

Abdominal Region
Appendix
Ascending Colon
Blind Gut
Descending Colon
Duodenum
Ileum
Jejunum
Lumbar Spine
Rectum
Sigmoid Colon
Transverse Colon

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

Deselect the Gastrointestinal box in the Organ Systems block. Click on the Renal and Reproductive box. Verify the Renal color is gold and that the following organs are gold in color and listed in the Physical and Autonomic System table:

Adrenal
Coccyx/Pelvis
Genitourinary System
Kidney – Left
Kidney – Right
Sacrum
Urokidney

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

Deselect the Renal and Reproductive box in the Organ Systems block. Click to check the Hepatic, Endocrine and Nervous System box. Verify Hepatic is blue and the following organ names are blue in color and listed in the Physical and Autonomic System table:

Cerebral Cortex
Cerebral Vessels
Gallbladder
Hypothalamus
Immune System
Liver
Nervous System
Pancreas
Pineal
Pituitary
Spleen
Thyroid

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

Click to check the Gastrointestinal, Hepatic, Sensory, Cardiovascular, Respiratory and Renal boxes. Verify that all boxes in the Organ System block are checked.

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

Verify that all organs are listed in the Physical and Autonomic System table and that all are properly color coded.

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

Click to uncheck the "Use color coding for organ systems" box below the Organ Systems block. Verify that all color coding has been removed.

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

CV License – Administrator Login – Print Report Tab
Click on the Print Report tab for "Epic Validation" tab in the gray bar below the icons. Verify the "ClearView Report" appears and has the patient name, visit date, age and gender displayed at the top. Verify the five pages contain the descriptions and tables for data as shown below. Verify the Organ Systems groups contain the elements shown in the sample report. Verify the Physical and Autonomic (Normal and Out of Range) columns contain score data that consists of numbers from 0 thru 5 (pages 1 and 5) and 0 thru 25 (pages 2, 3, and 4), and some positions that are blank.

Note: Report shown is for reference only, score values will change, but odds ratio values are fixed.

EPIC RESEARCH DIAGNOSTICS

ClearView Report
Prepared for: Epic Validation

Demographics and Summary

Visit Date: 12/28/2011   Age: 49   Gender: Female

The EPIC ClearView™ is a Galvanic Skin Response (GSR) measurement tool for the evaluation of the human cardiovascular system to help direct the physician when choosing to do further standard of care testing.

The tables below provide both the overall ClearView Response Scale results (Table 1), and the detailed GSR point measurements (Table 2, attached). The ClearView Response Scale ranges from 0-5, with higher values representing increased association which may indicate a need for further testing of a particular primary organ system.

Table 1

Primary Organ Systems	Physical Score	Autonomic Score
Cardiovascular System	1.1	1.9
Respiratory System	0.7	1.3
Gastrointestinal System	1.3	1.3
Hepatic, Endocrine, and Nervous System	0.1	0.6
Renal and Reproductive Systems	0.2	0.2

Quantification of the increased association is defined by odds ratios, which are presented in (Table 3), in the definitions section at the end of this report.

The supporting detailed GSR point measurements range from 0-25, and should be interpreted in the context of other signs, symptoms, and test results.

Table 2 — **Supporting Organ Systems Detail with Standard GSR Point Measurements**

Cardiovascular

	Physical Normal (L/R)		Out of Range		Autonomic Normal (L/R)	
Cervical Vascular System **	7	8		15	9	
Coronary Vessels **			19	6	16	7
Heart (muscles) **		7				5
Heart (left side) **	7				6	
Heart (right side) **			21		11	
Cardiovascular Circulation (whole body) **	5	5			4	4
Thoracic Spine **			7	17	7	7

Respiratory

	Physical Normal (L/R)		Out of Range		Autonomic Normal (L/R)	
Respiratory/Mammary **			18	9	20	22
Thorax Respiratory **			16	12	5	5
Ear/Nose/Sinus (L) **			15	7	16	9
Ear/Nose/Sinus (R) **			15	18	12	7
Jaw/Teeth (L) **	6	6			17	16
Jaw/Teeth (R) **			4	15	4	13
Eye (L) **	5	13			5	7
Eye (R) **			5	16	8	7
Cervical Spine **	7	5			6	6

** GSR Point Measurement

Run by: Administrator (Id: 2249)
Printed on: 1/17/2012 at 9:37 am

Page 2 of 6

Gastrointestinal System	Physical Normal L	Physical Normal R	Physical Out of Range L	Physical Out of Range R	Autonomic Out of Range L	Autonomic Out of Range R	Autonomic Normal L	Autonomic Normal R
Duodenum **				16				12
Jejunum **			21		21			
Ileum **		14						11
Blind Gut **		7						6
Abdominal Region **	6						5	
Appendix **		6						7
Ascending Colon **		9			16			
Transverse Colon **			21	8	20	6		
Descending Colon **	6				16			
Sigmoid Colon **	6						4	
Rectum **	6				19			
Lumbar Spine **	7	6					12	6

Hepatic, Endocrine, and Nervous System	Physical Normal L	Physical Normal R	Physical Out of Range L	Physical Out of Range R	Autonomic Out of Range L	Autonomic Out of Range R	Autonomic Normal L	Autonomic Normal R
Liver **	6	7					7	13
Gallbladder **				15				5
Pancreas **	7	14					7	4
Thyroid **			6	16	15	15		
Spleen **			7	15			6	5
Immune System **			6	20	8	15		

** QSR Point Measurement

Run by: Administrator (Id: 2248)

ClearView Report
Prepared for: Epic Validation

Hepatic, Endocrine, and Nervous System	Physical Normal L	Physical Normal R	Physical Out of Range L	Physical Out of Range R	Autonomic Out of Range L	Autonomic Out of Range R	Autonomic Normal L	Autonomic Normal R
Nervous System **	6	7			15	13		
Hypothalamus **				8	15		5	6
Pituitary **	7	6			16	14		
Pineal **	8	7			6	19		
Cerebral Cortex **	8	5			20	6		
Cerebral Vessels **			16	5	25	5		

Renal and Reproductive	Physical Normal L	Physical Normal R	Physical Out of Range L	Physical Out of Range R	Autonomic Out of Range L	Autonomic Out of Range R	Autonomic Normal L	Autonomic Normal R
Adrenal **	5	13					13	14
Kidney (L) **			16				9	
Kidney (R) **			15					6
Urokidney **			8	15	6	15		
Genitourinary System **			15	8			7	4
Sacrum **	14	13					13	12
Coccyx/Pelvis **			6	17	16	16		

ClearView Report
Prepared for: Epic Validation

Definitions

Autonomic Nervous System GSR point measurements represent a measure of how the perception of stress by the individual is affecting the different body systems.

Physical System GSR point measurements represent the functional GSR measures for the body.

The Odds Ratio is a measure that describes the strength of association between the ClearView Response Scale and the presence of a disease state in the body's primary organ systems. With an odds ratio greater than 1.0, an increase on the ClearView Response Scale is indicative of greater odds of a disease state within an organ system. See table 3 below:

Table 3

Primary Organ Systems	Physical		Autonomic	
	Odds Ratio	Score	Odds Ratio	Score
Cardiovascular System	3.9	1.1	2.8	1.9
Respiratory System	7.8	0.7	2.7	1.3
Gastrointestinal System	45.5	1.3	8.6	1.3
Hepatic, Endocrine, and Nervous System	13.9	0.1	6.8	0.6
Renal and Reproductive Systems	99.1	0.2	3.2	0.2

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

Click on the Print Report button which is located at the far left of the SAP Crystal Reports tab. Ensure that a local system printer is selected and click the "Print" button. Label the printout "CVReport#3" and place your initials and date on the first page. Verify that the printout matches the values displayed on the screen.

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

Report Scores

Click on the Search Capture button. Find Verification Subject1 Treatment ID 2191. Resubmit for Analysis. Record the Treatment ID below:

Subject1 _____

Print out the ClearView Report. Print out the ClearView Report for Treatment ID 2191. Compare the two reports and verify all data points match. Circle each data point that does not match. Sign and date the reports.

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

Verify the report scores are listed correctly on each of the two different reports per the following criteria:

-Any pair with both scores with a value of 14 or lower appears in the Normal (L/R) columns.

-Any pair with one or more scores of 15 or higher appears in the Out of Range columns.

-Scores displayed in the Out of Range columns with values from 15 through 18 are highlighted in yellow.

-Scores displayed in the Out of Range columns with values from 19 through 21 are highlighted in orange.

-Scores displayed in the Out of Range columns with values from 22 through 25 are highlighted in red.

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

Click on the Search Capture button. Find Verification Subject1 Treatment ID 2193. Resubmit for Analysis. Record the Treatment ID below:

Subject2   _____

Print out the ClearView Report. Print out the ClearView Report for Treatment ID 2193. Compare the two reports and verify all data points match. Circle each data point that does not match. Sign and date the reports.

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

Verify the report scores are listed correctly on each of the two different reports per the following criteria:

-Any pair with both scores with a value of 14 or lower appears in the Normal (L/R) columns.

-Any pair with one or more scores of 15 or higher appears in the Out of Range columns.

-Scores displayed in the Out of Range columns with values from 15 through 18 are highlighted in yellow.

-Scores displayed in the Out of Range columns with values from 19 through 21 are highlighted in orange.

ClearView Software Validation Protocol Version 1.1.1.2 – REPORT Functions   Confidential & Proprietary
Document Number: ENG-014   Page 46 of 61
Revision: 003

-Scores displayed in the Out of Range columns with values from 22 through 25 are highlighted in red.

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

Click on the Search Capture button. Find Verification Subject1 Treatment ID 2197. Resubmit for Analysis. Record the Treatment ID below:

Subject3   _____

Print out the ClearView Report. Print out the ClearView Report for Treatment ID 2197. Compare the two reports and verify all data points match. Circle each data point that does not match. Sign and date the reports.

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

Verify the report scores are listed correctly on each of the two different reports per the following criteria:
-Any pair with both scores with a value of 14 or lower appears in the Normal (L/R) columns.
-Any pair with one or more scores of 15 or higher appears in the Out of Range columns.
-Scores displayed in the Out of Range columns with values from 15 through 18 are highlighted in yellow.
-Scores displayed in the Out of Range columns with values from 19 through 21 are highlighted in orange.
-Scores displayed in the Out of Range columns with values from 22 through 25 are highlighted in red.

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

Click the Exit button to exit ClearView. Attach the printed reports to the end of this protocol.

6.5.3   CV License – User Login – View Report

ClearView Software Validation Protocol Version 1.1.1.2 – REPORT Functions   Confidential & Proprietary
Document Number: ENG-014   Page 47 of 61
Revision: 003

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 the View Report icon. Type "V" in the last name box of the Search Capture box. Click Find. Highlight Epic O. Validation with Treatment ID 2185. Click View Report button. 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 following tabs are listed in the gray bar just below the icons:
Worksheet for Epic Validation
NS Analysis for Epic Validation
BioField Analysis for Epic Validation
Print Report for Epic Validation

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

CV License – User Login - Worksheet Tab
Click the Worksheet tab on the gray bar below the icons. Verify that the table displayed on the right side of the tab has column headings of Organ, Physical Systems (both Left Hand and Right Hand) and an Autonomic Systems (both Left Hand and Right Hand) and that data (numbers) are present in the Physical System and Autonomic System table.

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

Verify that a listing of the Organ Systems is displayed on the left side of the tab. Verify that the Organ Systems listed have a check mark inside the box and that the systems listed are as follows:

Cardiovascular
Respiratory
Gastrointestinal System

Renal and Reproductive Systems
Hepatic, Endocrine, and Nervous System

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

Click the "Use color coding for organ systems" box just below the Organ Systems block. Verify that the names of the organ systems and organs are now color coded by system (i.e. Cardiovascular System is now purple in the Organ Systems box and Circulation, Coronary Vessels, Heart, etc., are also purple).

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

Click on each of the boxes in the Organ systems block to remove the check mark. Verify that there are no organs listed in the Physical and Autonomic System tables.

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

Click to check the Cardiovascular box. Verify Cardiovascular is purple and the following organ names are purple in color and listed in the Physical and Autonomic System table:

Cardiovascular Circulation
Cervical Vascular System
Coronary Vessels
Heart
Heart – (Left Side)
Heart – (Right Side)
Thoracic Spine

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

Deselect the Cardiovascular box in the Organ Systems block. Click on the Respiratory box. Verify the Respiratory color is green and the following organ names are green in color and listed in the Physical and Autonomic System table:

Cervical Spine
Ear/Nose/Sinus (L)
Ear/Nose/Sinus (R)
Eye (L)
Eye (R)
Jaw/Teeth (L)
Jaw/Teeth (R)
Respiratory/Mammary
Thorax Respiratory

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

Deselect the Cardiovascular box in the Organ Systems block. Click to check the Gastrointestinal System box. Verify Gastrointestinal is red and the following organ names are red in color and listed in the Physical and Autonomic System table:

Abdominal Region
Appendix
Ascending Colon
Blind Gut
Descending Colon
Duodenum
Ileum
Jejunum
Lumbar Spine
Rectum
Sigmoid Colon
Transverse Colon

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

Deselect the Gastrointestinal box in the Organ Systems block. Click on the Renal and Reproductive box. Verify the Renal color is gold and that the following organs are gold in color and listed in the Physical and Autonomic System table:

Adrenal
Coccyx/Pelvis
Genitourinary System
Kidney – Left
Kidney – Right
Sacrum
Urokidney

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

Deselect the Renal and Reproductive box in the Organ Systems block. Click to check the Hepatic, Endocrine and Nervous System box. Verify Hepatic is blue and the following organ names are blue in color and listed in the Physical and Autonomic System table:

Cerebral Cortex
Cerebral Vessels
Gallbladder
Hypothalamus
Immune System
Liver
Nervous System
Pancreas
Pineal
Pituitary
Spleen
Thyroid

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

Click to check the Gastrointestinal, Hepatic, Sensory, Cardiovascular, Respiratory and Renal boxes. Verify that all boxes in the Organ System block are checked.

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

Verify that all organs are listed in the Physical and Autonomic System table and that all are properly color coded.

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

Click to uncheck the "Use color coding for organ systems" box below the Organ Systems block. Verify that all color coding has been removed.

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

CV License – User Login – Print Report Tab

Click on the Print Report tab for "Epic Validation" tab in the gray bar below the icons. Verify the "ClearView Report" appears and has the patient name, visit date, age and gender displayed at the top. Verify the five pages contain the descriptions and tables for data as shown in Section 6.7.3. Verify the Organ Systems groups contain the elements shown in the sample report. Verify the Physical and Autonomic (Normal and Out of Range) columns contain score data that consists of numbers from 0 thru 25, and some positions that are blank.

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

Click on the Print Report button which is located at the far left of the SAP Crystal Reports tab. Ensure that a local system printer is selected and click the "Print" button. Label the printout "CVReport#4" and place your initials and date on the first page. Verify that the printout matches the values displayed on the screen.

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

Click the "X" in the upper right corner until the ClearView main screen is displayed.

6.5.4   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.

Basic License - Administrator Login - Print Report Tab
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. Type "V" in the last name box of the Search Capture box. Click Find. Highlight Epic O. Validation with Treatment ID 2185. Click View Report button. 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 as shown below with 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.

ClearView Report
Prepared for: Verification Subject1
Processed: 1/24/2012 11:06:12 AM

Results Overview

Measurement Point	Physical Left	Physical Right	Autonomic Left	Autonomic Right
Thumb #1	7	5	13	8
Thumb #2	21	22	23	25
Thumb #3	15	6	6	5
Thumb #4	6	16	15	7
Thumb #5	15	6	6	7
Thumb #6	19	8	16	6
Thumb #7	7	6	21	4
Thumb #8	8	16	17	5
Index #1		20		6
Index #2		8		9
Index #3		24		11
Index #4	9	15	4	4
Index #5	21	19	6	8
Index #6	10		5	
Index #7	8	8	5	4
Index #8	25		7	
Index #9	12	9	13	6
Index #10	23		7	
Index #11	16	15	6	5
Index #12	16	14	5	16
Middle #1	14		16	
Middle #2	8	7	14	6
Middle #3	15	8	7	4
Middle #4		13		8
Middle #5	17	7	7	6
Middle #6	8		22	
Middle #7		9		15
Middle #8	8	9	23	5
Middle #9	10	8	14	16
Ring #1	16	13	13	12
Ring #2	8	7	14	19
Ring #3	8	7	6	15
Ring #4	15	7	7	7
Ring #5	9	16	5	6

Run by: Administrator
Printed on: 2/28/2012 at 11:28am

ClearView Report
Prepared for: Verification Subject1
Processed:1/24/2012 11:06:12AM

Ring #6	10	8	5	5
Ring #7	16	14	6	6
Ring #8	16	7	13	13
Ring #9	8	9	6	6
Pinky #1	13	14	19	19
Pinky #2		14		14
Pinky #3	9		6	
Pinky #4		14		6
Pinky #5	7		8	
Pinky #6		11		9
Pinky #7	12		8	
Pinky #8	25	18	19	25
Pinky #9	14	8	5	7

Report shown is for reference only, score values will be different.

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

Click on the Print Report button. Ensure that a local system printer is selected and click the "Print" button. Label the printout "BasicReport#5" and place your initials and date on the first page. Verify that the printout matches the values displayed on the screen.

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

Basic License – User Login - Print Report Tab
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. 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.

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

Click the View Report icon. Type "V" in the last name box of the Search Capture box. Click Find. Highlight Epic O. Validation with Treatment ID 2185. Click View Report button. 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 as shown in previous section with 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. Report shown is for reference only, score values will be different.

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

Click on the Print Report button. Ensure that a local system printer is selected and click the "Print" button. Label the printout "BasicReport#6" and place your initials and date on the first page. Verify that the printout matches the values displayed on the screen, and the values from BasicReport#5.

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

6.5.5 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. Type "Epic" in the first name box of the Search Capture box. Click Find. Highlight Epic O. Validation with Treatment ID 2185. 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.** _____

Click on the Print Report button. Ensure that a local system printer is selected and click the "Print" button. Label the printout "FullReport#7" and place your initials and date on the first page. Verify that the printout matches the values displayed on the screen.

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

Verify that the following tabs are listed in the gray bar just below the icons:
Worksheet for Epic Validation
NS Analysis for Epic Validation
Admin pages for Epic Validation
BioField Analysis for Epic Validation
Print Report for Epic Validation

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

Verify that when the Admin Pages tab is highlighted, five subtabs as listed below are visible:

Raw Data (open)

Raw Report Data

Images without Capacitive Barrier

Images with Capacitive Barrier

Calibration Data

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

7.0   Reference

EG-011, Software Validation

QA-004, Deviations

8.0   Attachments

Attachment A, Deviations from Protocol

Attachment B, Non-conformances Worksheet

Attachment C, Verification Record

Attachment A
Deviations from Protocol

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

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

Attachment B

Non-conformances Worksheet

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

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

Attachment C

Biofield Verification Record

Organ Systems								
System	Verified?		System	Verified?		System	Verified?	
	Admin	User		Admin	User		Admin	User
Skeletal System			Cardiovascular System			Small Intestine		
Large Intestine			Renal & Reproductive System			Head & Upper Back		
Lower Back			Immune System			Respiratory System		
Nervous System								

Item Data										
	Physical		Autonomic		Color		B&W		Sector/ Organ Verify	Admin View Verify
Sample	Right Index	Left Index	Right Index	Left Index	Auto	Phys	Auto	Phys		
A - Admin										
B - Admin										
C - Admin										
D - Admin										
E - Admin										
A - User										
B - User										
C - User										
D - User										
E - User										
Verification of the Correct Biofield to the Image Displayed										
Signature:				Title:				Date:		