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ClearView Software Validation Protocol Version 1.1.1.2 – Report Verification and Validation
Document Number: ENG-011 022 ALL PAGES DM 2/28/12
Revision: 002 000

ALL PAGES DM 2/28/02

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1.0 Purpose

This document is intended to provide a protocol for use in validating the ClearView ™ software. This protocol is intended to provide a method for conducting the testing as well as to be used as a formal record of the validation activities.

2.0 Scope

This protocol is intended to be used to fully verify and validate the ClearView Report 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

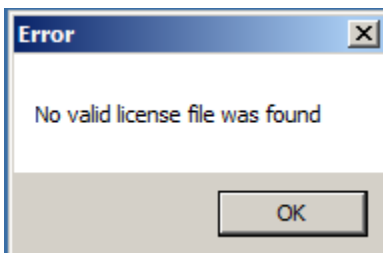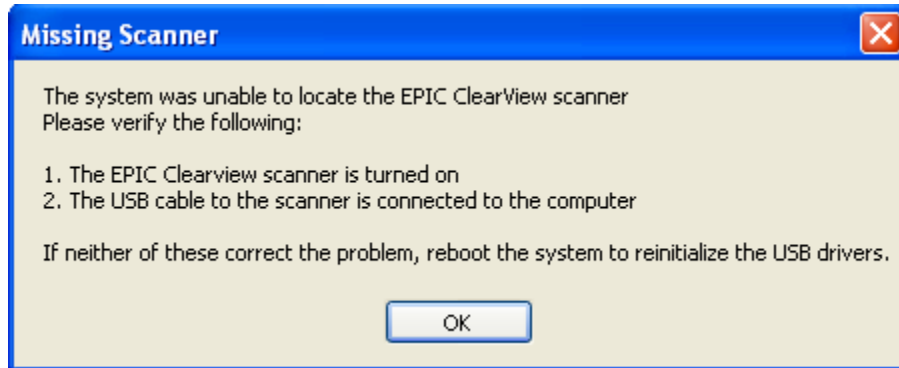| User	• Complies with the policy and procedure. • Ensures the most current version of this document is used when referenced.
Departmental Management	• Ensures departmental personnel are properly trained before using this policy or procedure. • Provides oversight to the validation process and ensures 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 ClearView Report. 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 four acceptable error messages generated by the ClearView software are shown below. If any other error message is displayed during the execution of this protocol, describe and record the error on the Non-Conformances Worksheet.

6.0   Device Set Up and Select Verification Samples

   6.1   Device Set Up

   6.1.1   Verify with QA and IT that the correct ClearView software revision, license, database, and scanner have been installed on the test workstation.

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

   6.1.3   Place the calibration shroud over the lens cover.

   6.1.4   Clean the metal cylinder of the calibration probe with isopropyl alcohol wipes. Dry the calibration probe completely with a dry cloth or tissue.

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

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

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

   _____

   6.1.8   Click in the Username box and enter "Administrator". Click in the password box and enter the password provided by the Network Administrator. Click the Login button.

   6.2   Select and Record Development Samples

   During this verification, three sample Patient Names will be selected at random from a group of development subjects. These will be referred to as Development1, Development2, and Development3. These will be processed in the ClearView software and will be used to verify that the functions of the ClearView software work as expected, including Submit for Analysis, Resubmit, and Resubmit with center points and angle modifications. Table 1 provides space to record Treatment IDs assigned by the software during these functions which may be used in later steps. Table 2 provides an overview of the verification steps in this protocol.

   Select Development Samples
   From a list of Patient Names provided from Development, select at random three samples to use for this verification. Record each Patient Name below.

   Development1   _____

Development2 _____

Development3 _____

Notify QA personnel of the assigned samples and request the patient names (with same age and gender) be created in ClearView per Table 1.

Table 1 - Patient Names and Treatment IDs

Subject	Patient*	Treatment	Patient*	Treatment	Patient*	Treatment
NewSubmit	Subject1		Subject2		Subject3	
Resubmit	Subject1		Subject2		Subject3	
Modify	Subject1		Subject2		Subject3	
AgeGender	Subject1		Subject2		Subject3	

*ClearView Patient Names: First Name = Verification, Last Name = Subject1, Subject2, or Subject3

Table 2 – Verification Overview

Section	Subject	Load from	Resubmit Subject	Verify to	Verify different than
7.1	NewSubmit1	Development1	N/A	Development1	
7.2	NewSubmit2	Development2	N/A	Development2	
7.3	NewSubmit3	Development3	N/A	Development3	
8.1	Resubmit1	N/A	NewSubmit1	NewSubmit1	
8.2	Resubmit2	N/A	NewSubmit2	NewSubmit2	
8.3	Resubmit3	N/A	NewSubmit3	NewSubmit3	
9.1	Modify1	N/A	NewSubmit1		NewSubmit1
9.2	Modify2	N/A	NewSubmit2		NewSubmit2
9.3	Modify3	N/A	NewSubmit3		NewSubmit3
10.1	AgeGender1	N/A	NewSubmit1		NewSubmit1
10.2	AgeGender2	N/A	NewSubmit2		NewSubmit2
10.3	AgeGender3	N/A	NewSubmit3		NewSubmit3
11.1	NewSubmit1	Full Report		CV Report	
11.2	NewSubmit1	Full Report		Basic Report	

6.3 Development Report Data and Raw Data

Obtain from Development the Report Data, Calibration Data and Raw Data for the three patients selected. Print out and label each with patient name.

For each Development patient, locate the ClearView generated folder in I:\Clinical_Trials\Raw Data Export … and copy to O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\ReportVerification\Development (1, 2, or 3).

7.0   New Submit for Analysis Verification

Notes:

Detailed instructions for the steps listed in bold print requiring further explanation are found in Section 12.0.

Unless otherwise specified, the path for loading files begins with: O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\ReportVerification\…

File extensions (e.g. .bmp) may or may not display depending on the configuration of the local computer file system.

During the Submit and Resubmit functions, ClearView generates a folder name based on the time of processing in a *Name_Date_Time* format, which will be indicated in this protocol as "*filename*" where applicable.

7.1   NewSubmit Subject1

LOAD CALIBRATION IMAGES for Development1
…\Development1*Development1filename*\CalibrationImages

SUBMIT FOR CALIBRATION

LOAD ENERGIZED IMAGES for Development1
…\Development1*Development1filename*\EnergizedImages

ADJUST ANGLES
…\Development1*Development1filename*\RawData\RawData.csv

SUBMIT FOR ANALYSIS

RECORD TREATMENT ID of NewSubmit Subject1 here _____ and in **Table 1**

VERIFY WORKSHEET TAB vs. Development1 Report Data

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

VERIFY NS ANALYSIS TAB vs. Development1 RawData

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. Development1 Report Data

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

EXPORT DATA for NewSubmit Subject1
…\Development1\NewSubmit

PRINT CalibrationData for NewSubmit Subject1 and label "NewSubmit1"
…\Development1\NewSubmit*filename*\CalibrationData\CalibrationData.csv

PRINT RawData for NewSubmit Subject1 and label "NewSubmit1"
…\Development1\NewSubmit*filename*\RawData\RawData.csv

VERIFY CalibrationData NewSubmit1 vs. Development1 CalibrationData

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

VERIFY RawData NewSubmit1 vs. Development1 RawData

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

7.2 NewSubmit Subject2

LOAD CALIBRATION IMAGES for Development2
…\Development2*Development2filename*\CalibrationImages

SUBMIT FOR CALIBRATION

LOAD ENERGIZED IMAGES for Development2
…\Development2*Development2filename*\EnergizedImages

ADJUST ANGLES
…\Development2*Development2filename*\RawData\RawData.csv

SUBMIT FOR ANALYSIS

RECORD TREATMENT ID of NewSubmit Subject2 here _____ and in **Table 1**

VERIFY WORKSHEET TAB vs. Development2 Report Data

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

VERIFY NS ANALYSIS TAB vs. Development2 RawData

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. Development2 Report Data

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

EXPORT DATA for NewSubmit Subject2
…\Development2\NewSubmit

PRINT CalibrationData for NewSubmit Subject2 and label "NewSubmit2"
…\Development2\NewSubmitA*filename*\CalibrationData\CalibrationData.csv

PRINT RawData for NewSubmit Subject2 and label "NewSubmit2"
…\Development2\NewSubmit*filename*\RawData\RawData.csv

VERIFY CalibrationData NewSubmit2 vs. Development2 CalibrationData

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

VERIFY RawData NewSubmit2 vs. Development2 RawData

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

7.3   NewSubmit Subject3

LOAD CALIBRATION IMAGES for Development3
…\Development3*Development3filename*\CalibrationImages

SUBMIT FOR CALIBRATION

LOAD ENERGIZED IMAGES for Development3
…\Development3*Development3filename*\EnergizedImages

ADJUST ANGLES
…\Development3*Development3filename*\RawData\RawData.csv

SUBMIT FOR ANALYSIS

RECORD TREATMENT ID of NewSubmit Subject3 here   _____   and in **Table 1**

VERIFY WORKSHEET TAB vs. Development3 Report Data

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

VERIFY NS ANALYSIS TAB vs. Development3 RawData

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. Development3 Report Data

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

EXPORT DATA for NewSubmit Subject3
…\Development3\NewSubmit

PRINT CalibrationData for NewSubmit Subject3 and label "NewSubmit3"
…\Development3\NewSubmit*filename*\CalibrationData\CalibrationData.csv

PRINT RawData for NewSubmit Subject3 and label "NewSubmit3"
…\Development3\NewSubmit*filename*\RawData\RawData.csv

VERIFY CalibrationData NewSubmit3 vs. Development3 CalibrationData

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

VERIFY RawData NewSubmit3 vs. Development3 RawData

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

8.0   Resubmit for Analysis Verification

8.1   Resubmit Subject1

RESUBMIT IMAGES FOR ANALYSIS of NewSubmit Subject1

RECORD TREATMENT ID of Resubmit Subject1 here   _____   and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit1 ClearView Report.

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

8.2   Resubmit Subject2

RESUBMIT IMAGES FOR ANALYSIS of NewSubmit Subject2

RECORD TREATMENT ID of Resubmit Subject2 here   _____   and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit2 ClearView Report.

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

8.3   **Resubmit Subject3**

RESUBMIT IMAGES FOR ANALYSIS of NewSubmit Subject3

RECORD TREATMENT ID of Resubmit Subject3 here   _____   and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit3 ClearView Report.

_____ **Verified**   _____ **Not Verified**   **Non-Conform Ref #** _____

9.0   **Modify Angles and Resubmit for Analysis Verification**

> **Note:** Modified angles should result in data points differing from the original.

9.1   **Modify and Resubmit Subject1 (Modify1)**

MODIFY ANGLES of NewSubmit Subject1

Click the **RESUBMIT IMAGES FOR ANALYSIS** button.

RECORD TREATMENT ID of Modify Subject1 here   _____   and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit1 ClearView Report (differences)

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_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

9.2   **Modify and Resubmit Subject2 (Modify2)**

MODIFY ANGLES of NewSubmit Subject2

Click the **RESUBMIT IMAGES FOR ANALYSIS** button.

RECORD TREATMENT ID of Modify Subject2 here _____ and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit2 ClearView Report (differences)

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

9.3   **Modify and Resubmit Subject3 (Modify3)**

MODIFY ANGLES of NewSubmit Subject3

Click the **RESUBMIT IMAGES FOR ANALYSIS** button.

RECORD TREATMENT ID of Modify Subject3 here _____ and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit3A ClearView Report (differences)

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

10.0 **Modify Age and Gender and Resubmit for Analysis Verification**

Note: Modified Age and Gender should result in data points differing from the original.

10.1 **Modify Age and Gender and Resubmit Subject1 (AgeGender1)**

MODIFY AGE AND GENDER of patient Verification Subject1.

RESUBMIT IMAGES FOR ANALYSIS

RECORD TREATMENT ID of AgeGender Subject1 here _____ and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit1 ClearView Report (differences)

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

10.2 **Modify Age and Gender and Resubmit Subject2 (AgeGender2)**

MODIFY AGE AND GENDER of patient Verification Subject2.

RESUBMIT IMAGES FOR ANALYSIS

RECORD TREATMENT ID of AgeGender Subject2 here _____ and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit2 ClearView Report (differences)

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

10.3 **Modify Age and Gender and Resubmit Subject3 (AgeGender3)**

MODIFY AGE AND GENDER of patient Verification Subject3.

RESUBMIT IMAGES FOR ANALYSIS

RECORD TREATMENT ID of AgeGender Subject3 here _____ and in **Table 1**

PRINT ClearView REPORT

VERIFY ClearView REPORT vs. NewSubmit3 ClearView Report (differences)

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

11.0 Verify CV and Basic License Reports

Up to this point in the protocol, the ClearView software has been using the Full License. This section will verify the CV License and Basic License Reports will report the same scores as the Full License.

11.1 Verify CV License Report – NewSubmit Subject1

Change ClearView license from Full License to CV License (see QA or IT personnel for assistance).

PRINT ClearView REPORT CV License Report for NewSubmit Subject1. Verify all scores for all organs listed match the Full License Report. One exception: the Throat/Cervical and Supraclavicular Lymphatics score (found only in the Full Report in the Respiratory System section) is a duplicate score to the Cervical Vascular System score in the Cardiovascular System section of both Reports.

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

11.2 Verify Basic License Report – NewSubmit Subject1

Change ClearView license from CV License to Basic License (see QA or IT personnel for assistance).

PRINT ClearView REPORT Basic License Report for NewSubmit Subject1. Verify all scores for all organs listed on the Full License Report match the listed Basic License Report Measurement Point below:

Basic License	Full License
Measurement Point	Description
Thumb #1	Cerebral Cortex
Thumb #2	Cervical Vascular

Thumb #3	Ear/Nose/Sinus (L)
Thumb #4	Ear/Nose/Sinus (R)
Thumb #5	Eye (L)
Thumb #6	Eye (R)
Thumb #7	Jaw/Teeth (L)
Thumb #8	Jaw/Teeth (R)
Index #1	Appendix
Index #2	Ascending Colon
Index #3	Blind Gut
Index #4	Cervical Spine
Index #5	Coccyx/Pelvis
Index #6	Descending Colon
Index #7	Lumbar Spine
Index #8	Rectum
Index #9	Sacrum
Index #10	Sigmoid Colon
Index #11	Thoracic Spine
Index #12	Transverse Colon
Middle #1	Abdominal Region
Middle #2	Cardiovascular Circulation
Middle #3	Cerebral Vessels
Middle #4	Gallbladder
Middle #5	Immune System
Middle #6	Kidney (L)
Middle #7	Kidney (R)
Middle #8	Liver
Middle #9	Thorax Respiratory
Ring #1	Adrenal
Ring #2	Genitourinary System
Ring #3	Hypothalamus
Ring #4	Nervous System
Ring #5	Pancreas
Ring #6	Pineal
Ring #7	Pituitary
Ring #8	Spleen

Ring #9	Thyroid
Pinky #1	Coronary Vessels
Pinky #2	Duodenum
Pinky #3	Heart (Left Side)
Pinky #4	Heart (Muscle)
Pinky #5	Heart (Right Side)
Pinky #6	Ileum
Pinky #7	Jejunum
Pinky #8	Respiratory/Mammary
Pinky #9	Urokidney

_____ **Verified** _____ **Not Verified** **Non-Conform Ref #** _____

12.0   Instructions

PRINT ClearView REPORT

Click the Search Capture button. Enter the name of the subject in the First Name and/or Last Name box of the Search Capture window as applicable. Click the Find button. Locate the Treatment ID and click to highlight. Click the View Report button. Click the printer icon in the upper left corner of the report toolbar to print the report. Click the "X" in the upper right corner of the tabs screen until the ClearView main screen appears.

EXPORT DATA

Click the Search Capture button. Enter the name of the subject in the First Name and/or Last Name box of the Search Capture window as applicable. Click the Find button. Locate the Treatment ID and click to highlight. Click the Export Data button. Locate the folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\ReportVerification\...(per step) and click OK to save.

LOAD CALIBRATION IMAGES

Click the Camera Calibration button. Right-click in the Calibration Image #1 box. In the Open file window, locate the folder O:\QualitySystems\Quality_System_Documents\Non-quality_system_records\1.1.1.2_Validation\ReportVerification\DevelopmentX\

DevelopmentXfilename\CalibrationImages and click Open. The file
1R_Calibration_Image_#1.bmp is the only file listed. Highlight this file and it appears
in the File name box. Click Open. The Open file window closes and the calibration
image appears in the Calibration Image #1 box.

Repeat the above step for Calibration Image #2 thru Calibration #10:
Calibration Image #2 (2R_Calibration_Image_#2.bmp)
Calibration Image #3 (3R_Calibration_Image_#3.bmp)
Calibration Image #4 (4R_Calibration_Image_#4.bmp)
Calibration Image #5 (5R_Calibration_Image_#5.bmp)
Calibration Image #6 (1L_Calibration_Image_#6.bmp)
Calibration Image #7 (2L_Calibration_Image_#7.bmp)
Calibration Image #8 (3L_Calibration_Image_#8.bmp)
Calibration Image #9 (4L_Calibration_Image_#9.bmp)
Calibration Image #10 (5L_Calibration_Image_#10.bmp)

SUBMIT FOR CALIBRATION

Click the Submit Calibration button. The line below the Scanner Calibration header
indicates the calibration is progressing. After processing, the Calibration Success
window opens. Click OK. Click No to the "save the images" window. The Calibration
tab closes and the ClearView main screen appears.

LOAD ENERGIZED IMAGES

Click the Search Capture button. Enter the name of the subject in the First Name
box and the Last Name box of the Search Capture window. Click the Find button.
Click to highlight the subject name and click the New Capture button. The "Gather a
capture for" window opens. Right-click in the Right Thumb Finger box of the Images
without Capacitive Barrier row. In the Open file window, locate the folder
O:\QualitySystems\Quality_System_Documents\Non-
quality_system_records\1.1.1.2_Validation\ReportVerification\DevelopmentX\per
step\EnergizedImages and click Open. Two files appear; 1R_filter.bmp and
1R_wofilter.bmp. Note: *filter* translates to *with Capacitive Barrier*, and *wofilter*
translates to *without Capacitive Barrier*. Click to highlight 1R_wofilter.bmp and it
appears in the File name box. Click Open. The Open window closes and the
1R_wofilter.bmp energized image appears in the Right Thumb Finger box.

Repeat the above step for the remaining 19 image boxes:

Images without Capacitive Barrier row:

Right Index Finger box – 2R_wofilter.bmp

Right Middle Finger box – 3R_wofilter.bmp

Right Ring Finger box – 4R_wofilter.bmp

Right Pinky Finger box – 5R_wofilter.bmp

Left Thumb Finger box – 1L_wofilter.bmp

Left Index Finger box – 2L_wofilter.bmp

Left Middle Finger box – 3L_wofilter.bmp

Left Ring Finger box – 4L_wofilter.bmp

Left Pinky Finger box – 5L_wofilter.bmp

Images with Capacitive Barrier row:

Right Thumb Finger box – 1R_filter.bmp

Right Index Finger box – 2R_filter.bmp

Right Middle Finger box – 3R_filter.bmp

Right Ring Finger box – 4R_filter.bmp

Right Pinky Finger box – 5R_filter.bmp

Left Thumb Finger box – 1L_filter.bmp

Left Index Finger box – 2L_filter.bmp

Left Middle Finger box – 3L_filter.bmp

Left Ring Finger box – 4L_filter.bmp

Left Pinky Finger box – 5L_filter.bmp

ADJUST ANGLES

Locate and open the RawData file indicated. For each of the 20 images, highlight the box and verify it appears in the Captured Image box. Adjust the angle by clicking the CW or CCW arrow to match the value in the RawData spreadsheet column V (AngleofRotation). Verify the X and Y values match the spreadsheet columns R (CenterX) and S (CenterY) respectively and adjust to match if needed.

SUBMIT FOR ANALYSIS

Click the Submit for Analysis button. After processing, a new screen displays with the Print Report tab highlighted and the ClearView Report is displayed.

RECORD TREATMENT ID

Click on the Admin Pages tab. Record (per step) the PatientTreatmentID number listed in the second column of the RawData subtab of the Admin Pages tab.

VERIFY WORKSHEET TAB

Click on the Worksheet tab. Compare the values listed in the Organ section of the Worksheet tab against the indicated Report Data or ClearView Report printout. Verify each data point matches, unless indicated that differences are an expected result. Circle every data point that does not match. Sign and date the report.

VERIFY NS ANALYSIS TAB

Click on the NS Analysis tab. Compare the values charted graphically against values listed in the NS Plot Value column of the indicated RawData printout. Verify each data point matches, unless indicated that differences are an expected result. Circle every data point that does not match. Sign and date the report.

VERIFY ClearView REPORT

Compare the values listed between the two indicated ClearView Report printouts. Verify each data point matches, unless indicated that differences are an expected result. Circle every data point that does not match. Sign and date the report.

VERIFY CalibrationData

Compare the values listed between the two indicated CalibrationData printouts. Verify each data point matches, unless indicated that differences are an expected result. Circle every data point that does not match. Sign and date the printout.

VERIFY RawData

Compare the values listed between the two indicated RawData printouts. Verify each data point matches, unless indicated that differences are an expected result. Circle every data point that does not match. Sign and date the printout.

RESUBMIT IMAGES FOR ANALYSIS

Click the Search Capture button. Enter the name of the subject in the First Name box and the Last Name box of the Search Capture window. Click the Find button. Click to highlight the row containing the Treatment ID for the appropriate step recorded in Table 1 of Section 6.2. Click the View Capture button. Click the Resubmit Images for Analysis button. After processing, a new screen displays with the Print Report tab highlighted and the ClearView Report is displayed.

MODIFY ANGLES

Click the Search Capture button. Enter the name of the subject in the First Name box and the Last Name box of the Search Capture window. Click the Find button. Click to highlight the row containing the Treatment ID for the appropriate step recorded in Table 1 of Section 6.2. Click the View Capture button. Per the instructions in the appropriate step, click in the Finger box and modify the angles per the tables below, and verify the CenterX and CenterY values and modify if needed. Click the Resubmit Images for Analysis button. After processing, a new screen displays with the Print Report tab highlighted and the ClearView Report is displayed.

NewSubmit Subject 1 – Images without Capacitive Barrier

Finger	CenterX	CenterY	Angle
1R	163	110	11
2R	158	88	5
3R	171	92	-10
4R	160	82	0
5R	200	114	-10
1L	158	128	0
2L	150	88	0
3L	144	90	10
4L	127	116	-9
5L	135	118	0

NewSubmit Subject 1 – Images with Capacitive Barrier

Finger	CenterX	CenterY	Angle
1R	173	112	11
2R	156	82	31
3R	153	92	0
4R	162	86	0
5R	145	95	7
1L	150	110	-3
2L	154	92	-1
3L	156	87	8
4L	153	90	0
5L	166	98	-4

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Finger	CenterX	CenterY	Angle
1R	159	114	7
2R	165	103	-20
3R	170	102	-3
4R	183	102	25
5R	164	93	17
1L	165	116	-4
2L	172	91	-4
3L	170	98	9
4L	153	101	25
5L	149	94	-18

NewSubmit Subject 2 – Images with Capacitive Barrier

Finger	CenterX	CenterY	Angle
1R	160	123	-2
2R	164	99	0
3R	170	105	-8
4R	183	98	20
5R	164	87	16
1L	173	126	1
2L	174	92	-2
3L	175	101	-1
4L	173	102	-16
5L	139	108	16

NewSubmit Subject 3 – Images without Capacitive Barrier

Finger	CenterX	CenterY	Angle
1R	166	109	-25
2R	144	85	-8
3R	156	100	-6
4R	168	100	10
5R	183	121	50
1L	156	98	-1
2L	171	100	10
3L	161	109	-2
4L	153	111	-6
5L	156	113	-13

NewSubmit Subject 3 – Images with Capacitive Barrier

Finger	CenterX	CenterY	Angle
1R	163	99	5
2R	157	92	2
3R	155	97	35
4R	173	106	3
5R	176	96	10
1L	156	90	-3
2L	178	92	7
3L	156	112	-6
4L	165	109	-8
5L	176	98	-38

MODIFY AGE AND GENDER

Click the Manage Patient button. Enter the name of the subject in the First Name box and the Last Name box of the Search Capture window. Click the Find button. Click to highlight the row containing the patient name for the appropriate step. Click the View Patient button. Modify the date in the Birth Date field per the table below. Change the gender from the Gender dropdown per the table below. Click on the Disc Icon Save button in the upper left corner of the screen. Click OK to the Save Successful dialog box. Click the "X" in the upper right corner of the Manage Patient tab containing the patient name. Click the Yes button for Save Changes. Click OK. The screen returns to the ClearView main screen.

Subject	Age	Male
NewSubmit Subject1	32	No
NewSubmit Subject2	83	Yes
NewSubmit Subject3	25	No

13.0   Reference

EG-011, Software Validation

QA-004, Deviations

CS-003, Customer Feedback

14.0   Attachments

Attachment A, Deviations from Protocol

Attachment B, Non-conformances Worksheet

Attachment C, Resubmit Verification Samples

Attachment A

Deviations from Protocol

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

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

Attachment B

Non-conformances Worksheet

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

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