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This document is being written to establish the validation approach for the ClearView Software Solution version 1.1.1.2. FDA's General Principles of Software Validation; Final Guidance for Industry and FDA Staff (issued January 11, 2002) provides guidance regarding software validation after a change. This memo is intended to establish the extent and impact of the changes introduced in version 1.1.1.2 on the system as a whole and provides the justification for the validation plan.

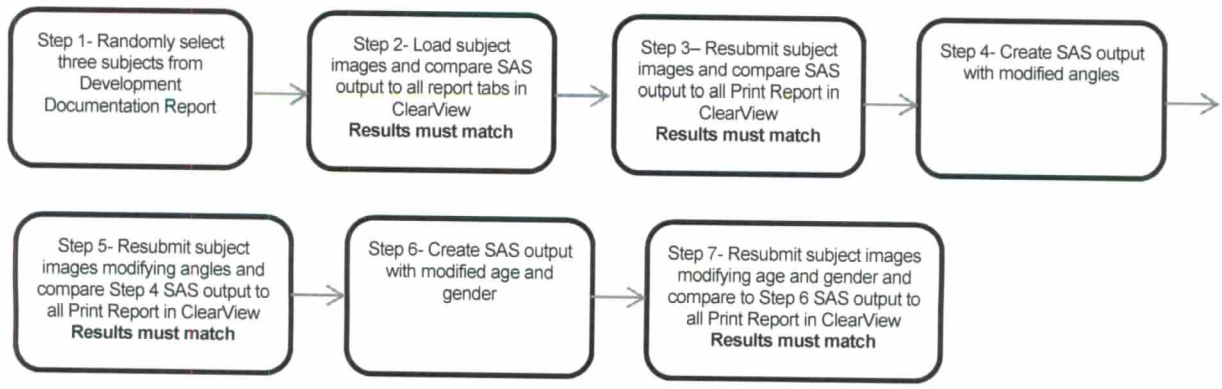
Version 1.1.1.2 introduced a large number of changes to the core functionality of the software. A total of 11 new raw data collection points were added to the application. A number of these are slightly different calculations of already existing coefficients, but there are two new and unique coefficients. Finally, a major change to the algorithm used to generate the data reported on the ClearView Report was made.

Additionally, a review of the ClearView Software was conducted to determine compliance to 21 CFR Part 11, Electronic Records; Electronic Signatures. Several areas of non-compliance were identified. The attached table summarizes the review and identifies these non-compliances. The software was then modified to implement an audit trail for all electronic records maintained by the ClearView database and bring the software into compliance with 21 CFR Part 11.

All the individual changes to the ClearView Software are compiled in the ClearView Revision History document (DD-002). This history details all the revisions from the beginning of revision control through 1.1.1.h. The ClearView Revision History document will be approved and maintained as a part of the

In order to establish a method for tracking changes to the software code during validation testing, a versioning system has been established. The last digit in the version number (for this round, the "2" in version 1.1.1.2) is replaced with an alpha character. This alpha character is then revised for any coding changes implemented during the verification and validation test cycle. As such, the version used to execute test protocols range from version 1.1.1.b through 1.1.1.h. This memo is intended to summarize the version changes and justify why the testing performed meets the verification and validation requirements.

The major change to this version of the software involved a modification to the algorithm. The algorithm verification test plan is summarized in the flowchart below:



A second major change to the software in this version is the implementation of a software licensing model; the previous versions of the software had no such mechanism. The license in conjunction with the user's role dictates what outputs users have access to in the application. In addition to the licensing model, the outputs of the software have also been modified (new report(s), new admin page displays, etc.) This being the case, it is recommended that the Application Functions protocol be updated and executed for this release to include verification that the licenses control user access as prescribed in the specifications.

Smaller, less significant changes are summarized in Table 1 below which provides the detailed information as to the validation activities performed to determine that ClearView Software version 1.1.1.2 works as intended and can be released for use in IDE investigations.

Table 1: Verification and Validation Summary

Test	Acceptance Criteria	Summary of Results
Validation testing of Patient Demographic data collection	Must meet the requirements outlined in the Patient Demographic Functions- Requirements. Currently, only First Name, Middle Initial, Last Name, Date of Birth and Gender may be data entered by the user. The Age of the patient is calculated and displayed on the Patient Demographics page. Additionally, the Patient Demographics data entered is collected into an audit trail that is not accessible by the user. EPIC IT personnel are able to access the audit trail which records the original value, modified value, User ID, date and time for each entry and subsequent modifications made to the patient demographic entries.	The changes to the patient demographic data collected and implementation of the audit trail functions were developed in ClearView version 1.1.1.f. • Protocol ENG-012 rev. 001 was developed and approved on 2/27/12 to test the patient demographics data entry functionality. This protocol was executed on 2/27/12 and 2/28/12 and summarized into the final report, ENG-012 rev. 001. All functions met the specified requirements. • Protocol ENG-027 rev. 000 was developed and approved on 2/28/12 to test the audit trail recordkeeping for the patient demographics information. This protocol was executed on 3/1/12 and 3/2/12 and summarized into the final report, ENG-027 rev. 000. During testing, a failure resulted in a modification to the ClearView Software. This modification was implemented in version 1.1.1.h of the ClearView software. Retest was performed which demonstrated that all functions met the specified requirements.
Validation testing of Camera functions including calibration testing	Must meet the requirements outlined in the Camera Functions- Requirements. Version 1.1.1.2 introduced one major change to the Camera Functions with the implementation of an audit trail for capture of calibration images. Additionally, the image export process for exporting calibration images was modified to include the finger reference in the file name.	The changes to the camera functions export process was developed in ClearView version 1.1.1.b. The implementation of the audit trail functions was developed in ClearView version 1.1.1.f. • Protocol ENG-010 rev. 003 was developed and approved on 1/9/12 to test the camera functions. This protocol was executed on 1/11/12 through 1/12/12 and summarized into the final report, ENG-010 rev. 003. One anomaly was identified (listed below) which remains

Table 1: Verification and Validation Summary

Test	Acceptance Criteria	Summary of Results
		outstanding. All other remaining functions met the specified requirements. • Protocol ENG-027 rev. 000 was developed and approved on 2/28/12 to test the audit trail recordkeeping for the calibration image capture. This protocol was executed on 3/1/12 and 3/2/12 and summarized into the final report, ENG-027 rev. 000. During testing, a failure resulted in a modification to the ClearView Software. This modification was implemented in version 1.1.1.h of the ClearView software. Retest was performed which demonstrated that all functions met the specified requirements.
Validation testing of Capture functions including image capture and orientation	Must meet the requirements outlined in the Capture Functions-Requirements. Version 1.1.1.2 implements modifications to the capture search results to list the original Treatment ID for any resubmitted data and the Scan Date for resubmitted data now displays the original date and time of patient image capture. Additionally, an audit trail was implemented for patient images captured to ensure that the user id, date and time of capture is recorded in the database. This audit trail is not visible to users, but is only visible to IT personnel.	The changes to the capture functions were made in various ClearView Software versions ranging from 1.1.1.b through 1.1.1.d. The implementation of the audit trail functions was developed in ClearView version 1.1.1.f. • Protocol ENG-011 rev. 003 was developed and approved on 3/1/12 to test the capture functions. This protocol was executed on 3/1/12 through 3/2/12 and summarized into the final report, ENG-011 rev. 002. One anomaly was identified (listed below) which remains outstanding. All other remaining functions met the specified requirements. • Protocol ENG-027 rev. 000 was developed and approved on 2/28/12 to test the audit trail recordkeeping for the

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Test	Acceptance Criteria	Summary of Results
		patient image capture. This protocol was executed on 3/1/12 and 3/2/12 and summarized into the final report, ENG-027 rev. 000. During testing, a failure resulted in a modification to the ClearView Software. This modification was implemented in version 1.1.1.h of the ClearView software. Retest was performed which demonstrated that all functions met the specified requirements.
Validation testing of Analysis data collection (This is broken into a protocol/report on the Report Tabs, Verification of the Values displayed on the ClearView Report, and the verification of the implementation of the audit trail	Must meet the requirements outlined in the Analysis Functions-Requirements regarding the displayed Report tabs. The changes are summarized in the final report.	• Protocol ENG-014 rev. 002 was developed and approved on 1/11/12 to test the Report tab functions. This protocol was executed on 1/13/12 using version 1.1.1.b of the software. The protocol was halted when a new change to the algorithm (and thus the output to the Report tabs was proposed by the development team. • Changes were made to the ClearView Software in versions 1.1.1.c and 1.1.1.d to address the requested algorithm change. The original protocol ENG-014 rev. 002 was again approved on 1/17/12 to test the Report tab functions. This protocol was executed on 1/17/12 through 1/20/12 using version 1.1.1.d. A non-conformance to the age displayed on the reports was identified which required a modification to the Clear View Software. • Protocol ENG-014 rev. 003 was developed and approved

Table 1: Verification and Validation Summary

Test	Acceptance Criteria	Summary of Results
		on 2/28/12 to test the Report tab functions. This protocol was executed on 2/29/12 using version 1.1.1.g of the software. All functions met the specified requirements.
	Must accurately report all expected values on all Report Tabs and in the ClearView Report.	Protocol ENG-022 rev. 000 was developed and approved on 1/23/12 to verify the values displayed on the ClearView Report. This protocol was executed on 1/27/12 through 3/3/12 using versions 1.1.1.e, 1.1.1.f, and 1.1.1.g of the software. Three non-conformances were identified during the original testing. These non-conformances were addressed in versions 1.1.1.f and 1.1.1.g and the test methods were retested. Upon retest, all functions met the specified requirements.
	Additionally, an audit trail was implemented for patient raw data and raw report data saved by the ClearView database. The audit trail ensures that the user id, date and time of analysis is recorded in the database. This audit trail is not visible to users, but is only visible to IT personnel.	Protocol ENG-027 rev. 000 was developed and approved on 2/28/12 to test the audit trail recordkeeping for the patient raw data and raw report storage. This protocol was executed on 3/1/12 and 3/2/12 and summarized into the final report, ENG-027 rev. 000. During testing, a failure resulted in a modification to the ClearView Software. This modification was implemented in version 1.1.1.h of the ClearView software. Retest was performed which demonstrated that all functions met the specified requirements.
Validation testing of Application functions including user authentication and device settings	Must meet the requirements outlined in the Application Functions- Requirements. Version 1.1.1.2 implements modifications to the camera settings controlled by EPIC Administrators, but not available to users. The settings were modified to include control of the gain parameter. Additionally, a new user role, TechnAdministrator, was developed to provide	• Protocol ENG-0009 rev. 002 was developed and approved on 1/9/12 to test the changes to the camera settings and the TechAdministrator role. This protocol was executed on 1/9/12 through 1/12/12 and summarized into the final report, ENG-009 rev. 001. During testing, two anomalies

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Test	Acceptance Criteria	Summary of Results
	access to EPIC Administrator functions for manufacturing and development personnel without exposing all EPIC Administrator functions. Finally, a device testing page to execute commands to the ClearView Device firmware was developed to aid manufacturing and development test efforts. The Application function requirements provide specific details regarding these specific changes.	were identified (listed below) which remain outstanding. All other remaining functions met the specified requirements. • Protocol ENG-027 rev. 000 was developed and approved on 2/28/12 to test the audit trail recordkeeping for the patient raw data and raw report storage. This protocol was executed on 3/1/12 and 3/2/12 and summarized into the final report, ENG-027 rev. 000. During testing, a failure resulted in a modification to the ClearView Software. This modification was implemented in version 1.1.1.h of the ClearView software. Retest was performed which demonstrated that all functions met the specified requirements.

Table 2: Unresolved Anomalies

Test Protocol	Anomaly	Impact on Performance	Plans for Correction
ENG-010 rev. 002	Spontaneous BSOD during calibration image capture using the ClearView software	Computer operating system spontaneously closes all applications and shuts down the computer system operating software. The computer system will also spontaneously restart the operating system, though the user will be required to restart the ClearView software.	Step 1- Retest this protocol to determine if the same anomaly occurs. Step 2- Verification/Validation testing of the device performance executes a protocol to collect data in the same manner as a clinical environment. This testing will be completed to determine if this anomaly occurs when using the device as expected in a clinical environment. Step 3- Anomaly investigation- Should anomalies continue to occur during steps 1 and 2, a formal developmental investigation will be completed to identify the cause of this anomaly.
ENG-011 rev. 002	Received "Unable to Perform Image Calculations" error and a subsequent Blue Screen of Death (BSOD).	The user attempts to resolve the calculation error by clicking "OK" and the computer operating system spontaneously launches a BSOD, the application and the system is shut down. The user loses functionality for the period of the shut down and the restart. User can begin to use the system after restart successfully.	
ENG-009 rev. 001	ClearView software not responding when attempting to modify the brightness and gain settings in Camera Settings tab.	ClearView Software will not continue to perform any functionality for the user. Screen appears "frozen" even though the cursor and mouse move. User is able to shut down the ClearView Software and restart the software to successfully modify the settings and continue testing.	
	Spontaneous BSOD during when attempting to modify the brightness and gain settings in the Camera Settings tab.	Computer operating system spontaneously closes all applications and shuts down the computer system operating software. The computer system will also spontaneously restart the operating system, though the user will be required to restart the ClearView Software. Upon restart of the ClearView Software, testing was continued and no further failure was experienced.	