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Capture Function ClearView Software Solution v. 1.1.1.2 Verification and Validation Report
Document Number: ENG-011
Revision: 002

Confidential & Proprietary

Page 1 of 7

1.0   Purpose

This report summarizes the testing performed to validate the Capture functions in the ClearView software.

2.0   Executive Summary

The EPIC ClearView software Capture functions provides the end user with a method for adding new patients to the database, searching patient database, and perform a new capture/measurement of a patient using the ClearView hardware device. A summarized list of the version 1.1.1.2 modifications includes the following:

2.1   The capture search results now list the original Treatment ID for any resubmitted data and the Scan Date displayed is always the original date the patient images were collected.

2.2   The patient image capture table was updated to collect the user ID along with the date and time that a new patient image capture is submitted for analysis.

A validation protocol was developed to test the application functions after the changes were implemented for item 2.1. This protocol was performed to determine if all Capture functions perform as expected. The audit trail developed for item 2.2 was implemented after the completion of the protocol. Therefore, the verification and validation of the audit trail functional requirements was executed under a separate protocol and summarized in a separate report.

The validation activities demonstrate that the EPIC ClearView software Capture functions perform as expected.   The EPIC ClearView Capture functions are considered validated for use in IDE clinical investigations.

3.0   Protocol Execution and Results

All validation activities were conducted by EPIC staff between 1/17/12 and 3/2/12. The original validation protocol was approved on 1/11/12 and the retest protocol was signed on 3/1/12.

The results were recorded directly on the protocol. This original protocol is located in Attachment A. The following summarizes the original validation protocol test results.

Capture Function ClearView Software Solution v. 1.1.1.2 Verification and Validation Report   Confidential & Proprietary
Document Number: ENG-011
Revision: 002   Page 2 of 7

3.1   Protocol Outputs- The protocol required that ClearView Reports be printed for samples 1-6. The hard copy printouts are located in Attachment C of this report.

3.2   Revision History- 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 the Capture functions test protocol was version 1.1.1.d. The additional versions were created to respond to non-conformances raised during the verification and validation test cycle. A summary of these test versions will be collated and presented at the final design review and approval of version 1.1.1.2. This summary will demonstrate the justification for testing of the final version of 1.1.1.2 released for use.

3.3   Deviations- One deviation occurred during the execution of this protocol. Verification steps 6.2 through section 6.7 were executed during the original testing on the incorrect test database. As such, the expected outcomes do not match those expected. This error is a test system set up error made during the software installation and is not related to software code performance. IT will review the Software Release Standard Operating Procedure to ensure that the proper system checks are executed to prevent this type of installation error in future ClearView Software installations. Pages 5 through 35 were re-executed on the correct database to ensure that the functionality meets the requirements. The protocol sections were reprinted and the technician recorded the results on the printout which is located in Attachment B of this final report. All expected outputs were met during retest.

3.4   Non-conformance- Table 1 below summarizes the non-conformances that occurred during testing and the resolution/action taken for each.

Table 1
Original Test Protocol Non-Conformances

No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken
1	Section 6.7.2 on page 31- After clicking on the patient in the Search Capture box (ID 2145), the technician received an error message (see attachment to original Non-conformances Worksheet located in	This failure is a system configuration issue on the test machine. Likely a c++ runtime dll is an incorrect version. This machine should not be used for further testing until the issue has been resolved. To emphasize, this is not a software issue with ClearView,

Table 1
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No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken
	Attachment A). This error was also experienced on pages 39, 56, and 68.	but an environmental configuration issue.
2	Page 55- ClearView error message appeared (from section 5.5) when trying to capture images of shroud (no finger/probe on glass).	Same issue as #1 above, to detail further, this will only occur one time per instance of ClearView. Per instance is defined as each time ClearView is started.
3	Page 55- After blocking out light using the technician's hand (as stated in the protocol), the software allowed the technician to capture a dark image without an error message appearing as required.	Same issue as #1 above.

Since the test environment was not properly set up during the execution of the protocol, the protocol was re-executed.

4.0   Retest

Retest validation activities were conducted by EPIC staff between 3/1/12 and 3/2/12. The technician completed the protocol, recording the results directly on the protocol. The retest protocol is located in Attachment D.

4.1   Protocol Outputs- The protocol required that ClearView Reports be printed for samples 1-6. The hard copy printouts are located in Attachment E of this report.

4.2   Revision History- The version used to execute the retest Capture functions test protocol was version 1.1.1.g and 1.1.1.h. The additional versions were created to respond to non-conformances raised during the verification and validation test cycle. A summary of these test versions will be collated and presented at the final design review and approval of version 1.1.1.2. This summary will demonstrate the justification for testing of the final version of 1.1.1.2 released for use.

4.3   Deviations- No deviations were required during the execution of the retest protocol.

4.4   Non-conformance- Table 2 below summarizes the non-conformances that occurred during testing and the resolution/action taken for each.

Table 2

Retest Protocol Non-Conformances

No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken
1	Section 6.4, page 12- Received "Unable to Perform Image Calculations" error and a subsequent Blue Screen of Death (BSOD).	Restarted computer and ClearView. Changed Camera brightness from 127 to 100. Continued in protocol execution.
2	Section 6.4, page 15- Received "Unable to Perform Image Calculations" error and a subsequent Blue Screen of Death (BSOD).	Restarted computer and ClearView. Changed Camera brightness from 127 to 100. Continued in protocol execution.
3	Section 6.7.2, page 28- Patient Name Camera Validation, ID 2188, Search Capture listed Scan Date of 9/15/2011 3:52 pm and the Admin Tab listed Scan Date 1/20/2012 10:52am.	Version 1.1.1.g no longer keeps a time stamp of the resubmit, but displays the original date and time of scanning. The protocol will be red-lined to create the correct test for the current functionality. The red-lines were retested and recorded on the protocol. The retest worked as expected.
4	Section 8.1, page 55- Calibration process stopped at "Verifying image 10 of 10".	Calib_work file was opened by the technician performing the verification and validation protocol. The file being open prevented the ClearView Software from writing a new file, which stopped the calibration process. Technician was instructed to close the file and repeat the verification step. Upon closing of the file, the protocol requirements were met.
5	Section 9.1.2, page 57- Analysis process stopped before report display. ClearView Main Screen was displayed only.	IT stopped protocol execution to issue revision 1.1.1.h. The protocol was stopped to allow install of the new version which should address this failure. The testing was repeated starting at section 8.1 on page 55. The results of this retest were recorded on the protocol next to the original results. Upon retesting using 1.1.1.h, all protocol requirements were met.

Two non-conformances were recorded for which a cause could be identified (i.e., #1 and #2). Both recorded non-conformances demonstrated difficulty in maintaining the communication between the device and software. These errors can occur when the USB connection between the device and the software is interrupted. The error was resolved in each instance by the technician. The resolution required the technician to shut down the software and the computer system, restarting both the application and

the computer system. Upon initializing the ClearView software, each error was resolved and the software was found to perform as expected.

These communication failures are being categorized as anomalies since the technician was able to demonstrate that the software works as expected once the communication interruption is resolved (i.e., mitigation occurred). Device/software communication anomalies can be mitigated by the user through restarting the application and/or the computer system. The cause of this anomaly is under investigation. Although several potential contributors have been identified, an exact cause of the communication anomalies has not been identified. The anomaly will continue to be investigated and resolution will be documented. The validation team recommends releasing the software for use in clinical investigation only where users are instructed how to detect and resolve these types of communication errors. The cause of this anomaly and/or resolution of the anomaly will be completed prior to release of the software in saleable ClearView Systems.   Additionally, this test protocol should be re-executed when new versions of the device are available to determine if this communication anomaly continues to exist when interacting with the current design of the device.

Table 1: Unresolved Anomalies

Anomaly	Impact on Performance	Plans for Correction
Received "Unable to Perform Image Calculations" error and a subsequent Blue Screen of Death (BSOD).	The user attempts to resolve the 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.	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.

Other than the two unresolved anomalies listed above, the Capture Functions were found to perform as expected for all requirements.

1.0   Conclusions

The Capture functions of version 1.1.1.2 of ClearView Software are considered validated for use in IDE investigations.

2.0 Attachments

Attachment A- Original Signed Protocol

Attachment B- Original Protocol Deviation #1 Retest Documentation

Attachment C- ClearView Report Validation Printouts

Attachment D- Retest Protocol

Attachment E- Retest ClearView Report Validation Printouts