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1.0 Purpose

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

2.0 Executive Summary

The EPIC ClearView Software Camera function provides the end user with the ability to perform calibration verification. A summarized list of the version 1.1.1.2 modifications includes the following:

2.1 The image export process was modified include the finger reference in exported image file name for easier selection when later reloading calibration images.

2.2 Additionally, an audit trail was developed to record the user ID, date and time calibration images were collected (if calibration is successful).

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 Camera 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.

One outstanding anomaly remains to be resolved regarding the device and software communication difficulties experienced and recorded as Non-conformance #2 in the protocol. This anomaly can be mitigated by the user through restarting the application and/or the computer system. Therefore, the software can be considered validated for use in IDE investigations as long as users are instructed how to resolve device/software communication difficulties by following the mitigations outlined in this final report. The anomalies will continue to be investigated and resolution will be documented as a part of the ongoing investigation and prior to the release of the software for use in saleable ClearView Systems.

3.0 Protocol Execution and Results

All validation activities were conducted by EPIC staff on 1/11/12 through 1/12/12. The technician completed the protocol, recording the results directly on the protocol. The original protocol is located in Attachment A. A CD of electronic files generated during the validation testing is located in Attachment B. All ClearView printouts generated during the execution of the protocol are located in Attachment C.

3.1 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 Camera functions test protocol was version 1.1.1.b. 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.

3.2 Deviations- Minor red-lined protocol instructions will be included in future version of this protocol. No deviations were identified during the execution of this protocol.

3.3 Non-conformances- Two non-conformances were recorded.

The first non-conformance occurred when the Camera button was not present during execution of the protocol (see page 7 of the original protocol located in Attachment A). The user did not have the proper menu permissions. This 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.

The second non-conformance records the occurrence during test of a spontaneous "Blue Screen of Death (BSOD)". BSOD's occur when communication between the device and software is interrupted, confusing the operating system. This type of non-conformances observed can occur when the USB connection between the device and the software is interrupted. Device/software communication

anomalies can be mitigated by the user through restarting the application and/or the computer system. Ultimately, the technician did restart the application after experiencing the non-conformance which resolved the issue and the remaining portions of the protocol were executed without further non-conformances.

The cause of communications anomalies are under investigation. Although several potential contributors have been identified, an exact cause of the communication anomalies has not been identified. The anomalies 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
Spontaneous BSOD during device operation 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.

4.0 Conclusions

The Camera Functions of version 1.1.1.2 of ClearView Software Solution are considered validated for use in IDE investigations.

5.0 Attachments

Attachment A- Original Signed Protocol
Attachment B- CD of electronic files
Attachment C- ClearView Camera Validation Printouts