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1.0 Purpose

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

2.0 Executive Summary

The EPIC ClearView software Application function provides the end user with the ability to control user logins and access device settings. A summarized list of the version 1.1.1.2 modifications includes the following:

2.1 The 'Camera Settings' icon has been changed to just 'Settings'.
2.2 The 'Settings saved' message that appears after you save settings on the Camera Setting dialog has been removed. A message will only appear if there is an issue saving the settings.
2.3 The 'Gain' control as been re-exposed on the new version of ClearView. The user can select from a range of values between 0 and 63 inclusive.
2.4 Added a 'TechAdministrator' login that has slightly different permissions than the base 'Administrator' login.
2.5 Added device testing page in the Settings section of the application.
2.6 Added login tracking to prevent a user from attempting to log in unsuccessfully more than three times in a row.

A validation protocol was developed to test the application functions after the changes were implemented for items 2.1 through 2.4 above. This protocol was performed to determine if all Application functions perform as expected. Changes specified in items 2.5 and 2.6 were implemented after the completion of the protocol. Therefore, the verification and validation of these 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 #1 and 2 in the protocol. These anomalies 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 1/9/12 through 1/12/12. The technician completed the protocol, recording the results directly on the protocol. The original protocol is located in Attachment A.

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 patient demographics 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. These changes did not affect the tests performed but would provide clearer instructions for future testing. However, a significant deviation to the test protocol occurred in section 6.3.4 of the protocol. During the original execution of this section, screen prints were made of the camera settings dialog box in order to document the setting changes made using the ClearView software. When reviewing the screen prints, the camera settings displayed in the screen prints did not match the expected outcome and the documented results of the validation tests (as demonstrated by an initials and date in the "Verified" placeholder for each step). These screen prints are located in Attachment B and are labeled with Deviation #1- Incorrect Screen Prints. Upon investigation, the ClearView software was found to work as expected (i.e., the camera settings dialogue box changed as expected upon modification of the Camera Settings in the ClearView software). The suspected cause of this error is technician error when capturing screen prints. The technician may not have collected a new image of the screen after each adjustment of the setting(s) using the ClearView software. The technician was retrained as to the method for accurately collecting screen prints. Section 6.3.4 of the protocol, starting on page 9 and continuing until page 17 (all steps where the screen prints did not match the expected outcome) was re-executed. The screen prints for this round are located in Attachment C and are labeled with Deviation #1- Re-Executed. All re-executed screen prints match the expected outcome. Therefore, the "Verified" section for each step was again initialed and dated by the technician. The protocol will be updated to provide instruction

to the technician to ensure that the printouts match the display prior to moving on to the next test.

3.3 Non-conformances- Two non-conformances were recorded. Both recorded non-conformances demonstrated difficulty in maintaining the communication between the device and software. These errors 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/or the computer system, restarting either the application and/or 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 occurs). 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
ClearView software not responding	ClearView Software will not continue to perform any functionality for the user. Screen appears "frozen" even though the cursor and mouse move.	Same plan for both anomalies: 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.
Spontaneous BSOD during device operation using the ClearView	Computer operating system spontaneously closes all applications and shuts down the computer system operating software. The computer system	

software	will also spontaneously restart the operating system, though the user will be required to restart the ClearView software.	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 Applications Functions of version 1.1.1.2 of ClearView software are considered validated for use in IDE investigations with the recommendation that users are instructed how to detect and resolve communication errors between the device and the software. Additional testing of this software validation protocol should be executed once a new version of the device is available for testing in order to determine whether the communication issues continue to occur during use.

5.0 Attachments

Attachment A- Original Signed Protocol
Attachment B- Deviation #1: Incorrect Screen Prints
Attachment C- Deviation #1: Re-Executed Screen Prints