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1.0 Purpose

This report summarizes the testing performed to validate various requirements in the ClearView software. Typical protocols are written to test functionality based on five basic functional areas of the software; Application, Patient Demographics, Camera, Capture, and Reports. This protocol was developed and executed to verify and validate functionalities within these five areas that were implemented after execution of some testing of the functional areas. Therefore, this testing involves all five areas and will be included within the functional group testing in future protocols.

2.0 Executive Summary

Version 1.1.1.2 implemented a major change to the algorithm and reporting structure. Testing was initiated on this version of the software in January 2012. After the testing was initiated, a review of the software for compliance to FDA's 21 CFR Part 11 compliance was conducted. During this review, several modifications to the software requirements were identified and modifications to the software were made. A protocol was developed to verify and validate the changes to the software to ensure the functionality works as expected. This report is being written to summarize the activities performed and the results of the verification and validation tests.

The device settings implemented are functions necessary to test the firmware installed in the ClearView device. Validation of the functionality of these functions requires extensive test equipment to measure device outputs such as PWM0, voltage, waveform, etc. This test equipment is outside the scope of the protocol executed. The validation of this functionality will be tested during the device verification testing and included in the test plan developed by EPIC's design engineering consultants at PADT, Inc. The device settings are not available to user logins and are only available to EPIC Administrators and TechAdministrators. As such, the functionality will not be utilized in IDE investigations.

The verification and validation activities demonstrate that the audit trail functionality implemented in the ClearView Software performs as expected. The ClearView audit trail is considered validated for use in IDE investigations.

3.0 Protocol Execution and Results

All validation activities were conducted by EPIC staff on 3/1/12. The technician completed the protocol, recording the results directly on the protocol. The original protocol is located in Attachment A. All testing was executed using device serial number SN0010 which had version _____ installed.

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 test protocol was version 1.1.1.g. 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 Protocol Printouts- The protocol required verification to an audit trail that is not visible to any ClearView users. This information is obtained from IT directly in the ClearView database tables accessed only by IT personnel. The audit trail information was printed and signed by the CTO upon creation. These printouts were utilized by the technician to perform the verification of the audit trail and are located in Attachment B. Each printout was signed by the technician to indicate the completion of the verification tests.

3.3 Deviations- There was no deviations other than minor red-lines to the protocol instructions which do not reflect changes to the test methodology. The red-lines will be implemented into the protocol for use in future validations.

3.4 Non-conformances- Only one non-conformance was experienced during the execution of the protocol. Section 6.4 on page 14- The audit trail printed by IT did not produce the information for calibration, patient image capture, raw data processed and the dates and times. IT added a time date created field into the Treatment table to ensure that the table will contain the time/date the record was created. This change was implemented in version 1.1.1.h of the ClearView Software and retest was performed of this section of the protocol. The retest demonstrated that the audit trail produces the required information.

Based on the testing completed (including the retest), the device settings and audit trail functions were found to perform as expected. The device settings portion of the protocol will be executed using the released version of the firmware to confirm that the functionality works as expected with the final version.

4.0 Conclusions

The audit trail functions of version 1.1.1.2 of ClearView Software are considered validated for use in IDE investigations. The device settings verified to produce the correct responses from the device. Actual validation of this functionality will be executed during device verification testing performed by PADT, Inc.

5.0 Attachments

Attachment A- Original Signed Protocol
Attachment B- Audit Trail Printouts