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1.0 Purpose

This report summarizes the testing performed to validate the Report function in the ClearView software.

2.0 Executive Summary

The EPIC ClearView software Report functions provides the end user with a method for searching patient results and viewing the reports generated for a scan. A summarized list of the version 1.1.1.2 modifications includes the following:

2.1 Modify algorithm to match development algorithm to include new coefficients, Naïve Bayes calculation, and Logistic Regression numbers which ultimately result in a new EPIC scoring system.
2.2 Modify the Report layout to include paragraphs explaining the new algorithm outputs.
2.3 Modify color coding system for Out of Range values reported.
2.4 Modify method for exporting data (only for EPIC Administrator users) data to ensure all data is exported (including the raw data, raw report data, calibration images, calibration data, energized images, and lit finger images).
2.5 Audit trail established to ensure that the database stores the user ID, date and time of all raw data, raw report data, calibration images, energized images and lit finger image captures.
2.6 Biofields analysis tab now utilizes radio buttons rather than the leading tab to select the Organ Systems displayed.
2.7 The magnification algorithm has been modified to use a more smooth scaling routine.
2.8 The report view was modified from the Microsoft report viewer to use a Crystal Reports reporting system.
2.9 The device firmware version is stored in the database and displayed in the Worksheet tab.

The validation activities demonstrate that the EPIC ClearView software Report functions perform as expected as non-conformances were not identified during the execution of the protocol. The verification of the final values displayed in the Report tabs and printed on the ClearView Report is conducted in a separate protocol and reported in a separate report. The EPIC ClearView Report functions are considered validated for use.

3.0 Protocol Execution and Results

Three separate protocols were approved and executed (first protocol was only partially executed due to a proposed change in the algorithm). The following table summarizes the protocols executed, along with the reasons for retest, and the protocol location within this final report. In each case, the technician completed the protocol, recording the results directly on the protocol.

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 Report functions test protocol began with using version 1.1.1.b and ultimately was re-executed using version 1.1.1.g. All versions between 1.1.1.b and 1.1.1.g 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.

Table 1

Protocol Execution Results

No.	Software Version	Test Dates	Results of protocol	Original Protocol Attached in:
1	1.1.1.b	1/13/12	Deviation- A change was proposed to the algorithm which invalidated the original test results obtained during the execution of this protocol and halted protocol execution on page 20 of the protocol. The protocol was re-executed using version 1.1.1.d of the ClearView Software. Non-conformances- 1. Page 10 testing using 0.9.9.2 data did not display values in the Raw Report Data subtab. This is because the 0.9.9.2 data did not save Raw Report data. Future protocols will be written to verify pre 1.1.1.2 data is displayed correctly and 1.1.1.2 data and newer is displayed correctly. 2. Page 18, section 6.3.6.4- Physical and autonomic values do not display for the throat, heart, and cardiovascular circulation. IT reviewed the sample and determined that the samples from the test database were not updated with the new organ descriptions which also affect the display of	Attachment A All original printouts generated during protocol execution are located behind the protocol in Attachment A.

No.	Software Version	Test Dates	Results of protocol	Original Protocol Attached in:
			values on the Biofield page. IT updated the test database and the functionality of this section will be tested by future protocols. 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.	
2	1.1.1.d	1/17/12 through 1/19/12	Only minor deviations to the instructions indicated as red-lined changes made during the execution of the testing were noted. These minor deviations did not significantly impact/modify the testing being done and will be incorporated in future versions of the test protocol. One non-conformance was experienced during the execution of the protocol. After logging in as EPIC User, the View Reports showed an age one year older than the Print Reports for samples A, C, D, and E. Only Sample B had the correct age on both reports. IT found this bug and corrected the bug in version 1.1.1.f making the age routine consolidated and enhanced to ensure that the age displayed on all versions of the report match.	Attachment B All original printouts generated during protocol execution are located behind the protocol in Attachment B.
3	1.1.1.g	2/29/12	Based on the results of the protocols executed in #1 and #2 above, the entire Report Functions verification and validation test protocol was re-executed on the most recent version of the ClearView software. See below for summary of final results of this protocol.	Protocol is located in Attachment C.

3.2 Protocol Documentation- The protocol required that ClearView Reports be printed. The hard copy printouts are located in Attachment D of this report.

3.3 Deviations- Three deviations were generated during the final protocol development. These deviations are summarized in the table below.

Table 2
Deviation

No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken

No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken
1	Section 6.3.6.1, page 17- Protocol requires 5 samples each for 2 logins to be completed.	Due to the numerous repetitive testing (Protocol #1 executed on 1.1.1.b and Protocol #2 executed on 1.1.1.d) has been successfully performed for this version of the ClearView software, the repetitions of this verification were reduced from 5 samples for each login to one sample for each login. Non-conformances were not identified during the first two executions, therefore, this confirmatory verification (i.e., one sample for each login) is considered sufficient testing. No non-conformances were identified.
2	Section 6.4.7.1, page 35- Protocol requires 5 samples each for 2 logins to be completed.	The rationale for reducing the test sample number is the same as that for deviation #1 above. This section is simply the second user id login testing. Because a sample was already in progress prior to initiation of this deviation, two samples were actually evaluated. No non-conformances were identified.
3	Section 6.3.3, Page 10- Protocol did not include a test for historic data displays.	A separate test protocol (located in Attachment E) was developed to provide test methods for historic data which is displayed differently. This is a one-time test needed for the conversion of the data collection pre-1.1.1.2 and will not be necessary in future protocols. No non-conformances were identified during this verification testing.

3.4 Non-conformances- No deviations from the protocol were recorded.

Table 1

Non-Conformances

No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken
1	Section 6.3.6, page 16- In the Biofield Analysis tab under cardiovascular system in autonomic and physical, the upper left quadrant for the Heart is labeled incorrectly.	The Heart label is not labeled incorrectly. The label displayed accurately represents the values displayed, meaning the values match those displayed on the ClearView Report as verified by CEO/CSO Nancy Rizzo. This issue is not a non-conformance.

3.5 Protocol Electronic Files- The protocol required that data be saved for certain verification tests. The data from the first execution of the protocol (referred to in Table

1 as No. 1) was saved on a cd and is named “Protocol #1 Files”. The data from the second execution of the protocol (referred to in Table 2 as No. 2) was saved on a cd and is named “Protocol #2 Files”. The data from the third execution of the protocol (referred to in Table 2 as No. 3) was saved on the same cd and is named “Protocol #3 Files”. The CD is located in Attachment F.

4.0 Conclusions

The Report 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 Executed Using Version 1.1.1.b
Attachment B- Original Signed Protocol Executed Using Version 1.1.1.d
Attachment C- Original Signed Protocol Executed Using Version 1.1.1.g
Attachment D- Validation Test Printouts (Version 1.1.1.g only)
Attachment E- Deviation #3 Retest Protocol
Attachment F- CD of Downloaded Files (Version 1.1.1.b, 1.1.1.d and 1.1.1.g)