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Patient Demographics Functions ClearView Software v. 1.1.1.2 Verification and Validation Report
Document Number: ENG-012
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## 1.0    Purpose

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

## 2.0    Executive Summary

The EPIC ClearView software Patient Demographics functions provides the end user with a database for entering patient information, including name, birth date and gender.  Version 1.1.1.2 included modifications to limit the Patient Demographics scope of information to the above mentioned data, thus removing from the database contact information, medical history, diet, and lifestyle data that could have been collected using previous versions.  This data collection may be added back in future versions.  Version 1.1.1.2 also included the development of an audit trail for data entered into the patient demographics.  The verification and validation of the audit trail was executed under a separate protocol and summarized in a separate report.

The current validation work was performed to determine if the Patient Demographics functions perform as expected for both users and EPIC administrators.  The validation activities demonstrate that the EPIC ClearView software Patient Demographics functions perform as expected.  The EPIC ClearView Patient Demographics functions are considered validated for use.

## 3.0    Protocol Execution and Results

All validation activities were conducted by EPIC staff on 2/28/12.  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.f.  This means that versions 1.1.1.a through 1.1.1.e were used in previous test protocols.  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 and Non-Conformances- No deviations from the protocol were recorded. One non-conformance was documented during the execution of the protocol.  Table 1 summarizes the non-conformance and the resolution/action taken.

**Table 1**
**Non-Conformances**

| No. | Description of Non-conformance (include reference to the protocol section) | Resolution/Action Taken |
|---|---|---|
| 1 | Pg. 11, Section 6.3.1 – The last sentence of the protocol requires the technician to verify that the birth date field defaults to the previous entry when the user clicks or tabs out of the field, but it remains the same.  The red error message was displayed to the user to notify the user of the data entry error. | The data is not reformatted when entered incorrectly as specified in the protocol.  However, the incorrect information is also not saved and the appropriate error message is displayed to the user.  This anomaly is not considered a non-conformance to the requirements since the software requirements to restrict the incorrectly formatted data from being saved and display an error message to the user are met.   The protocol will be modified to expect that the error message is displayed and to confirm that the incorrect data is not saved. |

## 4.0    Conclusions

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

## 5.0    Attachments

Attachment A- Original Signed Protocol