Medflow EHR
Version 9.0

Usability Testing
170.315(a)(5) Demographics
170.315(a)(14) Implantable devices

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Usability Test Report of Medflow EHR Version 9.0 for 170.315(a)(5) Demographics and 170.315(a)(14) Implantable devices

Report based on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports

Vendor Name: Medflow Holdings, LLC
Product Name: Medflow EHR
Version: 9.0
Usability Test Date: 08/31/2017-09/01/2017
Report prepared: 09/01/2017
Test Location: Online
Test Environment: Medflow EHR Version 9.0
Test Administrator: Meredith Hill, COA
Data Logger: Kathleen Gerin
Description of Intended Users: Clinical users
Total Number of Participants: 10
Description of Participants: See section METHOD: PARTICIPANTS and Appendix 1 for details.
Date of Report: 09/01/2017
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EXECUTIVE SUMMARY

A usability test of Medflow EHR Version 9.0 170.315(a)(5) Demographics and 170.315(a)(14) Implantable devices was conducted on 08/31/2017 to 09/01/2017 in multiple locations; Eye Care Center of Central PA, Vision First, Wooster Eye Center, The Eye Center of Fayetteville, Levine and Lumines, Williamson Eye Institute, Huron Ophthalmology, by Meredith Hill, official representative of Medflow, Inc. The purpose of this test was to test and validate the usability of the Medflow elements above user interface, and provide evidence of usability in the EHR under test (EHRUT).

During the usability test, 10 (ten) credentialed healthcare professionals and other users matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on numerous typically related to the eye care workflow.

The following was some of the functionality which was tested and validated during the individual presentations and test:

I.   §170.315(a)(5) Demographics

A. Enable a user to access a patient's demographic data according to applicable specified standards that includes:
1) Race and Ethnicity
2) Preferred Language
3) Sex
4) Sexual Orientation
5) Gender Identity
6) Date of Birth

B. Enable a user to record a patient's demographic data according to applicable specified standards that includes:
1) Race and Ethnicity
2) Preferred Language
3) Sex
4) Sexual Orientation
5) Gender Identity
6) Date of Birth

C. Enable a user to change a patient's demographic data according to applicable specified standards that includes:
1) Race and Ethnicity
2) Preferred Language
3) Sex
4) Sexual Orientation
5) Gender Identity
6) Date of Birth

II.   §170.315(a)(14) Implantable devices

A. Allow a user to access unique device identifier (UDI) attributes obtained from AccessGUDID. Enable users to change the status of the UDI.

B. Allow a user to parse unique device identifier (UDI) attributes obtained from AccessGUDID. Enable users to change the status of the UDI.

C. Allow a user to record unique device identifier (UDI) attributes obtained from AccessGUDID. Enable users to change the status of the UDI.

D. Enable users to change the status of the unique device identifier (UDI).

During the 60-minute one-on-one usability test, each participant was greeted by the administrator. Participants have had prior experience with the legacy Medflow EHR Version 8.2. The administrators / proctors introduced the test, went through some training of the system as would be typical for an end user and instructed participants to complete a series of tasks (given one at a time) using the EHRT. During the testing, the administrator timed the test and, along with the data logger(s), recorded user performance data on paper and electronically.

Participant screens and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time w/o assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations and comments
- Participant's satisfaction ratings of the system

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were thanked for their time. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHRUT.

The results from the System Usability Scale (included in APPENDIX 4) scored the subjective satisfaction of the system/application by the participants to Strongly Agree (4-5 score) that it was user friendly, not complex or cumbersome to use, and the functionality to be well integrated.

In addition to the performance data, the following qualitative observations were made:

Major findings: All participants experienced ease of workflow and overall usability was seamless. There were no application/system errors and the result was a positive experience for all participants, the tasks tested successfully. Method of delivery for training material affects user perception on usability as well as performance times.

Areas for improvement: System design, functionality, and usability were accepted by all participants as being an improvement in the areas of question. Suggestions were made that the drop downs auto close, the font be bigger, and that the new implantable device screen be customizable.

INTRODUCTION

The EHRUT tested for this study was Medflow EHR Version 9.0. The system is designed to present medical information to healthcare providers in ambulatory settings exclusive to the ophthalmology and optometry specialties. Medflow EHR Version 9.0 consists of electronic health records exclusive to ophthalmology and optometry. The usability testing attempted to represent realistic exercises and conditions. The purpose of this study was to test and validate 170.315(a)(5) Demographics and 170.315(a)(14) Implantable devices. Also, the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, such as; Accessing, Recording and Changing these fields.

METHOD

PARTICIPANTS

A total of ten participants were tested on the EHRUT(s), ten of which represented typical users of the system. Participants in the test were certified and credentialed of a physician team associated with 3 small, 4 medium and 3 large multi-specialty eye care practices. Participants were recruited by Meredith Hill, the authorized representative of Medflow, Inc. and were not compensated for their time. Participants were given the opportunity to have the same orientation and level of training as the actual end users would have received. For the test purposes, end-user characteristics were identified and used to solicit potential participants; an example of a screener is provided in Appendix [1].

Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment requirements. The following is a table of participants by characteristics, including demographics, professional experience, computing experience and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities.

ID	Gender	Age	Education	Occupation / Role	Professional Experience	Computer Experience	EHR Experience	Assistive Technology
1	F	34	HS diploma, some college, COT	COT, compliance/implementation, clinic manager	Medflow super user, technician, audits and coding, 12 years ophthalmology/6 years Medflow	very comfortable	limited office mate 12+ years ago, Medflow 6 years	
2	F	41	BA, COA	Ophthalmic technician	Technician 11 years	proficient	Medflow x 5 years	
3	F	46	high school, college (no degree), Detroit Institute of Ophthalmology	Lead tech	Medflow super user – technician x 23 years	word/Medflow 10 years	Medflow 7+ years	No electronic assistance for devices
4	F	43	Some college	Administrator	technician for 25 years – Medflow 9 years	25 years computer literate and comfortable, word, excel, etc.	Medflow 9 years, Integrity 3 months	No electronic assistance for devices
5	F	38	High school, COA	Lead Tech	Ophthalmology x 20 years	Comfortable with computer skills	Medflow x 9 years, epic x 2 years	No electronic assistance for devices
6	F	43	Some college	COA, Clinical IT Coordinator, Compliance Auditor	Technician x 10 years, Medflow super user x 7 years	Over 20 years of computer experience. I consider myself to be proficient in all Microsoft office products	Medflow 7 years. Some experience in Sapphire eMAR, Nextech, EPIC, EyeMD, EMAMD	No electronic assistance for devices
7	F	50	high school, COA, OSC	Clinical Coordinator x 6 years, head technician previously	In ophthalmology 32 years – Medflow super-user x 2012	confident in computer skills x many years, proficient in Word	Medflow x 2012	No electronic assistance for devices
8	F	49	4-year university degree (Bachelor of Applied Science in Optometry-Australia), also COA and OSC	clinical supervisor and assistant office manager	Medflow superuser since 2010 and technician since 1993 years	comfortable, act as onsite IT (by default), we have regular IT on call office products	Medflow 7 years	No electronic assistance for devices
9	F	46	2 yr associates degree	Technician, patient care	Medflow super user, technician x24 years	comfortable with word, power point, excel		No electronic assistance for devices
10	F	51	COA	Ophthalmic tech	28 years ophthalmic tech	COMPUTER LITERATE AND PROFICIENT IN WORD	Medflow x 2012	No electronic assistance for devices

A total of ten participants (matching the demographics in the section on Participants) were recruited and a total of ten participated in the usability test. None of the participants failed to show for the study. Participants were scheduled for sixty (60) minute sessions with 30 minutes in between each session for debrief by the administrator(s) and data logger(s), and to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule, and included each participant's demographic characteristics as provided by the testing administrator.

STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made. During the usability test, participants interacted with two EHR systems both of which are systems developed by Medflow. Each participant used the system in the same location, and was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within allotted time w/o assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Demographics
    Enable a user to record, change, and access a patient's demographic data according to applicable specified standards that includes:
    - Race and Ethnicity
    - Preferred Language
    - Sex
    - Sexual Orientation
    - Gender Identity
    - Date of Birth

2. Implantable Devices
   - Allow a user to record, parse, and access unique device identifier (UDI) attributes obtained from AccessGUDID. Enable users to change the status of the UDI.

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users. Tasks should always be constructed in light of the study objectives.

PROCEDURES

Upon the start of the tests participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID. Each participant reviewed and signed an informed consent and release form (See Appendix 2). The usability testing staff conducting the test are experienced usability practitioners with a combined 23 years of clinical EHR experience and over 32 years associated specifically to the field of eye care. The administrator moderated the session including administering instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. A second person served as the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Participants were instructed to perform the tasks (see specific instructions below):
As quickly as possible, making as few errors and deviations as possible.
Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use. A Think – aloud technique was not permitted.

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task.

Following the session, the administrator gave the participant the post-test questionnaire (e.g., the System Usability Scale, see Appendix 4), thanked each individual for their participation. Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet. Participants were thanked for their time.

TEST LOCATION

The test facilities were the individual's office locations at their respective business environments. The participants were asked to have the session be conducted without interruption from other staff members. The sessions were conducting using a one-on-one GoToMeeting session and the users' devices were their own personal computer typically used in the practice as their current workstation and working environment for their daily work with the current Medflow EHR Version 8.2 system.

To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range.   All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

The EHRUT would typically be used in a healthcare office or facility. In this instance, the testing was conducted in the participant's private offices of the eye care practices. For testing, the computer used was running Windows 10 operating system. The participants used a keyboard and mouse when interacting with the EHRUT. The Medflow Release 9.0 used resolution 1366x768 with orientation Landscape. The application was set up by the eye care practice based upon and according to the vendor's documentation describing the system set-up and preparation. The application itself was running on a hosted server environment using a test database on a LAN connection to an Internet switch connection enabling the access of the Medflow EHR Version 9.0. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

TEST FORMS AND TOOLS

During the usability test, various documents and instruments were used, including:

1. Informed Consent
2. Moderator's Guide
3. Post-test Questionnaire

Examples of these documents can be found in Appendices 2-4 respectively. The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. The test sessions were electronically recorded and observed real-time during each of the test session.

PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to each participant:

> *Thank you for participating in this study. Your input is very important. Our session today will last about 60 minutes. During that time, you will use an instance of an electronic health record. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.*

> *Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. I did not have any involvement in its creation, so please be honest with your opinions. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time. Should you feel it necessary you are able to withdraw at any time during the testing.*

Following the procedural instructions, participants were shown the EHR and as their first task, were given time (30 minutes) to explore the system and make comments. Once this task was complete, the administrator gave the following instructions:

> *For each task, I will read the description to you and say "Begin." At that point, please perform the task and say "Done" once you believe you have successfully completed the task. I would like to request that you* not *talk aloud or verbalize while you are doing the task. I will ask you your impression about the task once completed.*

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness of recording Demographics in Medflow EHR Version 9.0 by measuring participant success rates and errors
2. Efficiency of recording Demographics in Medflow EHR Version 9.0 by measuring the average task time and path deviations

3. Satisfaction with recording Demographics in Medflow EHR Version 9.0 by measuring ease of use ratings

4. Effectiveness of recording Implantable Devices in Medflow EHR Version 9.0 by measuring participant success rates and errors

5. Efficiency of recording Implantable Devices in Medflow EHR Version 9.0 by measuring the average task time and path deviations

6. Satisfaction with recording Implantable Devices in Medflow EHR Version 9.0 by measuring ease of use ratings

DATA SCORING

The following table details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. Task times were recorded for successes.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a "Failures." No task times were taken for errors.
Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (easy) to 5 (very difficult). These data are averaged across participants. To measure participants' confidence in and likeability, the testing team administered the System Usability Scale (SUS) post-test questionnaire. See full System Usability Score questionnaire in APPENDIX 4.

Table details of how observed data were scored.

RESULTS

DATA ANALYSIS AND REPORTING
The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. There were no participants who failed to complete the test, all results from all participants are included in the data collection and results.

The usability testing results for the EHRUT are detailed below. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. [Furthermore, the data should be presented in forms such as the table below so that the tasks can be easily identified and their performance results examined and compared.]

Measure	#	Task Success	Path Deviation	Task Time Mean	Task Time	Errors	Task Ratings 1 (easy) to 5 (difficult) Mean
§ 170.315(a)(5) Demographics	1	Easily Completed	No Deviations Optimal Path	115.6 sec	No Deviations	No Errors	1.3
§ 170.315(a)(14) – Implantable Device List	2	Easily Completed	No Deviations Optimal Path	97.1 sec	No Deviations	No Errors	1.4

DISCUSSION OF THE FINDINGS

The discussions should commence with an open commentary of the user's experience and overall impression.

EFFECTIVENESS
Based on the consistent participant feedback from all, the usability test was a success and the overall effectiveness of the process was positive.

EFFICIENCY
Based on the observations of the task time and the fact that there was only one minor deviation from the workflow or click-stream navigation, the efficiency was reported by all participants as being successful.

SATISFACTION
Based on the task ratings and documented results, the participants were very satisfied with the outcome of the system/application usability.

MAJOR FINDINGS

All participants experienced ease of workflow and overall usability was seamless. There were no performance issues; except for two users had some internet connectivity issues which slowed down the process. Some questions were asked in regards repeating questions. There were no application/system errors. End result was a positive experience for all participants, the tasks tested successfully, and consistent positive feedback.

AREAS FOR IMPROVEMENT

System design, functionality, and usability were accepted by all participants as being an improvement in the software system/application.

APPENDICES

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

> 1: Participant demographics
> 2: Informed Consent Form
> 3: Example Moderator's Guide
> 4: System Usability Scale Questionnaire

Appendix 1: PARTICIPANT DEMOGRAPHICS

Following is a high-level overview of the participants in this study. As an appendix to the report, the full participant breakdown (de-identified) should be included.

ID	Gender	Age	Education	Occupation / Role	Professional Experience	Computer Experience	EHR Experience	Assistive Technology
1	F	34	HS diploma, some college, COT	COT, compliance/implementation, clinic manager	Medflow super user, technician, audits and coding, 12 years ophthalmology/6 years Medflow	very comfortable	limited office mate 12+ years ago, Medflow 6 years	
2	F	41	BA, COA	Ophthalmic technician	Technician 11 years	proficient	Medflow x 5 years	
3	F	46	high school, college (no degree), Detroit Institute of Ophthalmology	Lead tech	Medflow super user – technician x 23 years	word/Medflow 10 years	Medflow 7+ years	No electronic assistance for devices
4	F	43	Some college	Administrator	technician for 25 years – Medflow 9 years	25 years computer literate and comfortable, word, excel, etc.	Medflow 9 years, Integrity 3 months	No electronic assistance for devices
5	F	38	High school, COA	Lead tech	Ophthalmology x 20 yrs	Comfortable with computer skills	Medflow X 9 yrs, Epic x 2 yrs	No electronic assistance for devices
6	F	43	Some college	COA, Clinical IT Coordinator, Compliance Auditor	Technician x 10 years, Medflow super user x 7 years	Over 20 years of computer experience. I consider myself to be proficient in all Microsoft office products	Medflow 7 years. Some experience in Sapphire eMAR, Nextech, EPIC, EyeMD, EMAMD	No electronic assistance for devices
7	F	50	high school, COA, OSC	Clinical Coordinator x 6 years, head technician previously	In ophthalmology 32 years – Medflow super-user x 2012	confident in computer skills x many years, proficient in Word	Medflow x 2012	No electronic assistance for devices
8	F	49	4-year university degree (Bachelor of Applied Science in Optometry-Australia), also COA and OSC	clinical supervisor and assistant office manager	Medflow superuser since 2010 and technician since 1993 years	comfortable, act as onsite IT (by default), we have regular IT on call office products	Medflow 7 years	No electronic assistance for devices
9	F	46	2 yr associates degree	Technician, patient care	Medflow super user, technician x24 years	comfortable with word, power point, excel	comfortable with word, power point, excel	No electronic assistance for devices
10	F	51	COA	Ophthalmic tech	28 years ophthalmic tech	COMPUTER LITERATE AND PROFICIENT IN WORD	Medflow x 2012	No electronic assistance for devices

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Appendix 2: INFORMED CONSENT FORM

Informed Consent

Medflow, Inc. would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about *60* minutes.

Agreement
I understand and agree that as a voluntary participant in the present study conducted by *Medflow, Inc.* I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and recorded by the *Medflow, Inc.*

I understand and consent to the use and release of the recording by *Medflow, Inc.* I understand that the information and recording is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the recording and understand the recording may be copied and used by *Test Company* without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared outside of *Medflow, Inc*. I understand and agree that data confidentiality is assured, because only de- identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

☐   YES, I have read the above statement and agree to be a participant.
☐   NO, I choose not to participate in this study.

Signature: _____   Date: _____

Appendix 3: EXAMPLE MODERATOR'S GUIDE

EHRUT Usability Test Moderator's Guide

Administrator _____

Data Logger _____

Date _____

Time _____

Participant # ___

Location _____

I will ask you to complete a few tasks using this system and answer some questions. We are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. You will be asked to complete these tasks on your own trying to do them as quickly as possible with the fewest possible errors or deviations. Do not do anything more than asked. If you get lost or have difficulty I cannot answer help you with anything to do with the system itself. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

The product you will be using today is *Medflow EHR Version 9.0*. Some of the data may not make sense as it is placeholder data.

We are recording the audio and screenshots of our session today. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

Task I: 170.315(a)(5) Demographics

1.   Access demographics
    a. Select Specialized Exam Screen

2.   Record demographics
    a. In Payor code enter Medicare
    b. In functional status enter Normal
    c. Enter the following data in the corresponding fields:
        •   Sexual orientation choose Lesbian, gay or homosexual
        •   Gender identity choose Identifies as Male
        •   Birth Sex choose Male
        •   Ethnicity category choose Hispanic or Latino
        •   Ethnicity choose Colombian
        •   Race choose African
        •   Preferred Language choose Chinese
        •   choose Save and exit

3.   Change demographics
    a. Select CTRL D
    b. Change the following data in the corresponding fields
        •   Sexual orientation change to Patient Declined to answer
        •   Gender identity change to Patient Declined to answer
        •   Birth Sex change to Patient Declined to answer
        •   Ethnicity change to Patient Declined to answer
        •   Race change to Patient Declined to answer
        •   Preferred Language change to Patient Declined to answer
    c. choose Save and exit

Task II: 170.315(a)(14) Implantable devices
1. Access UID
    a. Double click in PMH field
    b. Select quick entry
    c. Double click in ocular procedure column
    d. Select patient implantable device button

2. Parse UID
    a. Enter the following data in the UDI field:
            (01)10884521062856(11)141231(17)150707(10)A213B1(21)1234
    b. select Get Data

3. Record UID
    a. In Implanted by field select CORNEA
    b. In Implanted Staff select EMR
    c. Location of Implant choose OD
    d. Select SAVE

e. Select OK

4. Change Status of UID
   a. Select CLEAR
   b. Enter the following data in the UDI field:
      =/W4146EB0010T0475=,000025=A99971312345600=>014032=}013032&,10
      00000000000XYZ123
   c. Select Get Data
   d. In Implanted by field select CORNEA
   e. In Implanted Staff select EMR
   f. Location of Implant enter OS
   g. Select SAVE
   h. Select OK
   i. Select CLEAR
   j. At the bottom of the screen, locate our first entry that was for OD
   k. Select first entry
   l. Top fields should change and pull in that first entry
   m. Uncheck "Active"
   n. Select SAVE

Appendix 4: SYSTEM USABILITY SCALE QUESTIONNAIRE

Task Description: 170.315(a)(5) Demographics					
Task Description: Enable a user to access, record and change a patient's demographic data according to applicable specified standards.					
Optimal Path: Enter the Meaningful Use work up screen, record the required data, save data, reenter Meaningful Use work up screen, change data, save and exit.					
	ID #1	ID #2	ID #3	ID # 4	ID #5
	Result	Result	Result	Reslut	Result
Correct	Yes	Yes	Yes	Yes	Yes
Minor Deviations /Cycles (comments)	No	No	No	No	No
Major Deviations (comments)	No	No	No	No	No
Total Time, Complete Task	89 sec	149sec	72sec	126sec	88sec
Success: Easily Completed	Yes	Yes	Yes	Yes	Yes
Success: Completed with Difficulty or Help (comment)	No	No	No	No	No
Success: Not Completed	No	No	No	No	No
Overall Rating: Scale 1 (easy) to 5 (difficult)	3	2	1	1	1
	ID #6	ID #7	ID #8	ID #9	ID #10
	Result	Result	Result	Result	Result
Correct	Yes	Yes	Yes	Yes	Yes
Minor Deviations /Cycles (comments)	No	No	No	No	No
Major Deviations (comments)	No	No	No	No	No
Total Time, Complete Task	74sec	185sec	125sec	124sec	125sec
Success: Easily Completed	Yes	Yes	Yes	Yes	Yes
Success: Completed with Difficulty or Help (comment)	No	No	No	No	No
Success: Not Completed	No	No	No	No	No
Overall Rating: Scale 1 (easy) to 5 (difficult)	1	1	1	1	1
Comments:					
Participant 1: lag time in the system					
Participant 2: No comment					
Participant 3: No comment					
Participant 4: difficulty seeing small screen, font is too small					
Participant 5: No comment					
Participant 6: No comment					
Participant 7: lag time and had to restart system					
Participant 8: easy, just a few extra buttons, increased level of frustration with more questions to ask patients					
Participant 9: fields do not auto close					
Participant 10: dropdowns do not close after selection is made					

Administrator / Data Logger Observed Errors, Verbalizations, and Comments: All participants were attentive and there were no technical or functional issues. User testing was completed successfully.

Task Description: 170.315(a)(14) Implantable Devices

	ID #1	ID #2	ID #3	ID #4	ID #5
	Result	Result	Result	Result	Result
Correct	Yes	Yes	Yes	Yes	Yes
Minor Deviations /Cycles (comments)	No	No	No	No	Yes
Major Deviations (comments)	No	No	No	No	No
Total Time, Complete Task	78sec	108sec	97sec	126sec	65sec
Success: Easily Completed	Yes	Yes	Yes	Yes	Yes
Success: Completed with Difficulty or Help (comment)	No	No	No	No	No
Success: Not Completed	No	No	No	No	No
Overall Rating: Scale 1 (easy) to 5 (difficult)	2	2	1	1	1
	ID #6	ID#7	ID #8	ID #9	ID#10
	Result	Result	Result	Result	Result
Correct	Yes	Yes	Yes	Yes	Yes
Minor Deviations /Cycles (comments)	No	No	No	No	No
Major Deviations (comments)	No	No	No	No	No
Major Deviations (comments)	No	No	No	No	No
Total Time, Complete Task	65sec	65sec	109sec	128sec	113sec
Success: Easily Completed	Yes	Yes	Yes	Yes	Yes
Success: Completed with Difficulty or Help (comment)	No	No	No	No	No
Success: Not Completed	No	No	No	No	No
Overall Rating: Scale 1 (easy) to 5 (difficult)	1	1	1	1	1

Comments:
Participant 1: lag time in the system
Participant 2: requested drop downs to auto close
Participant 3: No comment
Participant 4: No comment
Participant 5: No comment
Participant 6: UDI number is very cumbersome and it would be very helpful to be able to scan this data
Participant 7: No comment
Participant 8: easy to use, hopefully it will be customizable (implanted by and implanted staff)
Participant 9: No comment
Participant 10: new screen and was not difficult to use
Administrator / Data Logger Observed Errors, Verbalizations, and Comments: All participants were attentive and there were no technical or functional issues. User testing was completed successfully.

Signature: _____ Date: 9/7/2017