ONC HIT Certification Program
Test Results Summary for 2014 Edition EHR Certification

Part 1: Product and Developer Information

1.1 Certified Product Information

Product Name:	MaximEyes Electronic Health Records
Product Version:	2.0.3.0
Domain:	Ambulatory
Test Type:	Complete EHR

1.2 Developer/Vendor Information

Developer/Vendor Name:	First Insight Corporation
Address:	22867 NW Bennett Street, Suite 200 Hillsboro OR 97124
Website:	www.first-insight.com
Email:	maximeyes@first-insight.com
Phone:	1-800-920-1940
Developer/Vendor Contact:	Shandra Cossey

Part 2: ONC-Authorized Certification Body Information

2.1 ONC-Authorized Certification Body Information

ONC-ACB Name:	Drummond Group
Address:	13359 North Hwy 183, Ste B-406-238, Austin, TX 78750
Website:	www.drummondgroup.com
Email:	ehr@drummondgroup.com
Phone:	817-294-7339
ONC-ACB Contact:	Bill Smith

This test results summary is approved for public release by the following ONC-Authorized Certification Body Representative:

Bill Smith	Certification Body Manager
ONC-ACB Authorized Representative	**Function/Title**
8/20/2015	
Signature and Date	

2.2 Gap Certification

The following identifies criterion or criteria certified via gap certification

§170.314			
☐ (a)(1)	☐ (a)(19)	☐ (d)(6)	☐ (h)(1)
☐ (a)(6)	☐ (a)(20)	☐ (d)(8)	☐ (h)(2)
☐ (a)(7)	☐ (b)(5)*	☐ (d)(9)	☐ (h)(3)
☐ (a)(17)	☐ (d)(1)	☐ (f)(1)	
☐ (a)(18)	☐ (d)(5)	☐ (f)(7)**	

*Gap certification allowed for Inpatient setting only
**Gap certification allowed for Ambulatory setting only

☒ No gap certification

2.3 Inherited Certification

The following identifies criterion or criteria certified via inherited certification

§170.314			
[x] (a)(1)	[ ] (a)(16) *Inpt. only*	[ ] (c)(2)	[x] (f)(2)
[x] (a)(2)	[ ] (a)(17) *Inpt. only*	[ ] (c)(3)	[x] (f)(3)
[x] (a)(3)	[ ] (a)(18)	[x] (d)(1)	[ ] (f)(4) *Inpt. only*
[x] (a)(4)	[ ] (a)(19)	[x] (d)(2)	[ ] (f)(5) *Amb. only*
[x] (a)(5)	[ ] (a)(20)	[x] (d)(3)	
[x] (a)(6)	[x] (b)(1)	[x] (d)(4)	[ ] (f)(6) *Amb. only*
[x] (a)(7)	[x] (b)(2)	[x] (d)(5)	
[x] (a)(8)	[x] (b)(3)	[x] (d)(6)	[ ] (f)(7)
[x] (a)(9)	[x] (b)(4)	[x] (d)(7)	[ ] (g)(1)
[x] (a)(10)	[x] (b)(5)	[x] (d)(8)	[x] (g)(2)
[x] (a)(11)	[ ] (b)(6) *Inpt. only*	[ ] (d)(9) *Optional*	[x] (g)(3)
[x] (a)(12)	[x] (b)(7)	[x] (e)(1)	[ ] (g)(4)
[x] (a)(13)	[ ] (b)(8)	[x] (e)(2) *Amb. only*	[ ] (h)(1)
[x] (a)(14)	[ ] (b)(9)	[x] (e)(3) *Amb. only*	[ ] (h)(2)
[x] (a)(15)	[ ] (c)(1)	[x] (f)(1)	[ ] (h)(3)

[ ] No inherited certification

Part 3: NVLAP-Accredited Testing Laboratory Information

Report Number: GI-08152015-228

Test Date(s): 8/15/2015

3.1 NVLAP-Accredited Testing Laboratory Information

ATL Name:	Drummond Group EHR Test Lab
Accreditation Number:	NVLAP Lab Code 200979-0
Address:	13359 North Hwy 183, Ste B-406-238, Austin, TX 78750
Website:	www.drummondgroup.com
Email:	ehr@drummondgroup.com
Phone:	817-709-1627
ATL Contact:	Kyle Meadors

For more information on scope of accreditation, please reference NVLAP site.

Part 3 of this test results summary is approved for public release by the following Accredited Testing Laboratory Representative:

Gary Isaac	Test Proctor
ATL Authorized Representative	**Function/Title**
GARY ISAAC 8/20/2015	Sarasota, FL
Signature and Date	**Location Where Test Conducted**

3.2 Test Information

3.2.1 Additional Software Relied Upon for Certification

Additional Software	Applicable Criteria	Functionality provided by Additional Software
DrFirst Rcopia	a.2, a.10, b.3	e-Prescribing
Updox Direct 2014	b.1, b.2, e.1	Direct HISP
EyeClinic.net	e.1, e.3	Patient Portal

☐ No additional software required

3.2.2 Test Tools

Test Tool	Version
[x] Cypress	2.4
[x] ePrescribing Validation Tool	1.0.4
[ ] HL7 CDA Cancer Registry Reporting Validation Tool	1.0.3
[ ] HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool	1.8
[x] HL7 v2 Immunization Information System (IIS) Reporting Validation Tool	1.8
[x] HL7 v2 Laboratory Results Interface (LRI) Validation Tool	1.7
[x] HL7 v2 Syndromic Surveillance Reporting Validation Tool	1.7
[x] Transport Testing Tool	179
[x] Direct Certificate Discovery Tool	3.0.2
[ ] Edge Testing Tool	0.0.5

[ ] No test tools required

3.2.3 Test Data

[ ] Alteration (customization) to the test data was necessary and is described in Appendix [*insert appendix letter*]

[x] No alteration (customization) to the test data was necessary

3.2.4 Standards

3.2.4.1 Multiple Standards Permitted

The following identifies the standard(s) that has been successfully tested where more than one standard is permitted

Criterion #	Standard Successfully Tested	
(a)(8)(ii)(A)(2)	[ ] §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain	[x] §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide
(a)(13)	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	[ ] §170.207(j) HL7 Version 3 Standard: Clinical Genomics; Pedigree

Criterion #	Standard Successfully Tested	
(a)(15)(i)	☐ §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain	☒ §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide
(a)(16)(ii)	☐ §170.210(g) Network Time Protocol Version 3 (RFC 1305)	☐ §170. 210(g) Network Time Protocol Version 4 (RFC 5905)
(b)(2)(i)(A)	☐ §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	☒ §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
(b)(7)(i)	☐ §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	☒ §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
(b)(8)(i)	☐ §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	☐ §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
(e)(1)(i)	Annex A of the FIPS Publication 140-2 [*list encryption and hashing algorithms*] AES SHA-1	
(e)(1)(ii)(A)(2)	☐ §170.210(g) Network Time Protocol Version 3 (RFC 1305)	☒ §170. 210(g) Network Time Protocol Version 4 (RFC 5905)
(e)(3)(ii)	Annex A of the FIPS Publication 140-2 [*list encryption and hashing algorithms*] AES SHA-1	
Common MU Data Set (15)	☒ §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	☐ §170.207(b)(2) The code set specified at 45 CFR 162.1002(a)(5) (HCPCS and CPT-4)

Criterion #	Standard Successfully Tested

☐ None of the criteria and corresponding standards listed above are applicable

3.2.4.2 Newer Versions of Standards

The following identifies the newer version of a minimum standard(s) that has been successfully tested

Newer Version	Applicable Criteria

☒ No newer version of a minimum standard was tested

3.2.5 Optional Functionality

Criterion #	Optional Functionality Successfully Tested
☐ (a)(4)(iii)	Plot and display growth charts
☐ (b)(1)(i)(B)	Receive summary care record using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
☐ (b)(1)(i)(C)	Receive summary care record using the standards specified at §170.202(b) and (c) (SOAP Protocols)
☐ (b)(2)(ii)(B)	Transmit health information to a Third Party using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
☐ (b)(2)(ii)(C)	Transmit health information to a Third Party using the standards specified at §170.202(b) and (c) (SOAP Protocols)
☐ (e)(1)	View, download and transmit data to a third party utilizing the Edge Protocol IG version 1.1
☐ (f)(3)	Ambulatory setting only – Create syndrome-based public health surveillance information for transmission using the standard specified at §170.205(d)(3) (urgent care visit scenario)
☐ (f)(7)	Ambulatory setting only – transmission to public health agencies – syndromic surveillance - Create Data Elements
☐ Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(3) (45 CFR162.1002(a)(4): Code on Dental Procedures and Nomenclature)
☐ Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(4) (45 CFR162.1002(c)(3): ICD-10-PCS)

☒ No optional functionality tested

3.2.6 2014 Edition Certification Criteria* Successfully Tested

Criteria #	Version		Criteria #	Version	
	TP**	TD***		TP	TD
☐ (a)(1)	1.3	1.5	☒ (c)(3)	1.11	1.11
☐ (a)(2)	1.2		☐ (d)(1)	1.2	
☐ (a)(3)	1.2	1.4	☐ (d)(2)	1.6	
☐ (a)(4)	1.4	1.3	☐ (d)(3)	1.3	
☐ (a)(5)	1.4	1.3	☐ (d)(4)	1.3	
☐ (a)(6)	1.3	1.4	☐ (d)(5)	1.2	
☐ (a)(7)	1.3	1.3	☐ (d)(6)	1.2	
☐ (a)(8)	1.3		☐ (d)(7)	1.2	
☐ (a)(9)	1.3	1.3	☐ (d)(8)	1.2	
☐ (a)(10)	1.2	1.4	☐ (d)(9) *Optional*	1.2	
☐ (a)(11)	1.3		☐ (e)(1)	1.11	1.5
☐ (a)(12)	1.3		☐ (e)(2) *Amb. only*	1.2	1.6
☐ (a)(13)	1.2		☐ (e)(3) *Amb. only*	1.3	
☐ (a)(14)	1.2		☐ (f)(1)	1.2	1.2
☐ (a)(15)	1.5		☐ (f)(2)	1.3	1.3
☐ (a)(16) *Inpt. only*	1.3	1.2	☐ (f)(3)	1.3	1.3
☐ (a)(17) *Inpt. only*	1.2		☐ (f)(4) *Inpt. only*	1.3	1.3
☐ (a)(18)	1.1	1.5	☐ (f)(5) *Amb. only*	1.2	1.2
☐ (a)(19)	1.1	1.5			
☐ (a)(20)	1.1	1.5	☐ (f)(6) *Amb. only*	1.4	1.4
☐ (b)(1)	1.7	1.4			
☐ (b)(2)	1.4	1.6	☐ (f)(7) *Amb. only*	1.1	
☐ (b)(3)	1.4	1.4	☐ (g)(1)	2.0	2.0
☐ (b)(4)	1.3	1.4	☐ (g)(2)	2.0	2.0
☐ (b)(5)	1.4	1.2	☐ (g)(3)	1.4	
☐ (b)(6) *Inpt. only*	1.3	1.3	☒ (g)(4)	1.2	
☐ (b)(7)	1.4	1.7	☐ (h)(1)	1.1	
☐ (b)(8)	1.2	1.2	☐ (h)(2)	1.1	
☐ (b)(9)	1.1	1.1	☐ (h)(3)	1.1	
☒ (c)(1)	1.11	1.11			
☒ (c)(2)	1.11	1.11			

Criteria #	Version		Criteria #	Version	
	TP**	TD***		TP	TD

☐ No criteria tested

*For a list of the 2014 Edition Certification Criteria, please reference http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

**Indicates the version number for the Test Procedure (TP)

***Indicates the version number for the Test Data (TD)

3.2.7 2014 Clinical Quality Measures*

Type of Clinical Quality Measures Successfully Tested:

- [x] Ambulatory
- [ ] Inpatient
- [ ] No CQMs tested

*For a list of the 2014 Clinical Quality Measures, please the CMS eCQM Library (Navigation: June 2014 and April 2014 Updates)

Ambulatory CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
[ ] 2		[ ] 90		[ ] 136		[ ] 155	
[ ] 22		[ ] 117		[ ] 137		[x] 156	v2
[x] 50	v2	[ ] 122		[x] 138	v2	[ ] 157	
[ ] 52		[ ] 123		[ ] 139		[ ] 158	
[ ] 56		[ ] 124		[ ] 140		[ ] 159	
[ ] 61		[ ] 125		[ ] 141		[ ] 160	
[ ] 62		[ ] 126		[x] 142	v2	[ ] 161	
[ ] 64		[ ] 127		[x] 143	v2	[ ] 163	
[ ] 65		[ ] 128		[ ] 144		[ ] 164	
[ ] 66		[ ] 129		[ ] 145		[x] 165	v2
[x] 68	v3	[ ] 130		[ ] 146		[ ] 166	
[x] 69	v2	[x] 131	v2	[ ] 147		[x] 167	v2
[ ] 74		[ ] 132		[ ] 148		[ ] 169	
[ ] 75		[ ] 133		[ ] 149		[ ] 177	
[ ] 77		[ ] 134		[ ] 153		[ ] 179	
[ ] 82		[ ] 135		[ ] 154		[ ] 182	

Inpatient CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
[ ] 9		[ ] 71		[ ] 107		[ ] 172	
[ ] 26		[ ] 72		[ ] 108		[ ] 178	
[ ] 30		[ ] 73		[ ] 109		[ ] 185	
[ ] 31		[ ] 91		[ ] 110		[ ] 188	
[ ] 32		[ ] 100		[ ] 111		[ ] 190	
[ ] 53		[ ] 102		[ ] 113			
[ ] 55		[ ] 104		[ ] 114			
[ ] 60		[ ] 105		[ ] 171			

3.2.8 Automated Numerator Recording and Measure Calculation

3.2.8.1 Automated Numerator Recording

Automated Numerator Recording Successfully Tested			
☐ (a)(1)	☐ (a)(11)	☐ (a)(18)	☐ (b)(6)
☐ (a)(3)	☐ (a)(12)	☐ (a)(19)	☐ (b)(8)
☐ (a)(4)	☐ (a)(13)	☐ (a)(20)	☐ (b)(9)
☐ (a)(5)	☐ (a)(14)	☐ (b)(2)	☐ (e)(1)
☐ (a)(6)	☐ (a)(15)	☐ (b)(3)	☐ (e)(2)
☐ (a)(7)	☐ (a)(16)	☐ (b)(4)	☐ (e)(3)
☐ (a)(9)	☐ (a)(17)	☐ (b)(5)	

☒ Automated Numerator Recording was not tested

3.2.8.2 Automated Measure Calculation

Automated Measure Calculation Successfully Tested			
☒ (a)(1)	☒ (a)(11)	☐ (a)(18)	☐ (b)(6)
☒ (a)(3)	☒ (a)(12)	☐ (a)(19)	☐ (b)(8)
☒ (a)(4)	☒ (a)(13)	☐ (a)(20)	☐ (b)(9)
☒ (a)(5)	☒ (a)(14)	☒ (b)(2)	☒ (e)(1)
☒ (a)(6)	☒ (a)(15)	☒ (b)(3)	☒ (e)(2)
☒ (a)(7)	☐ (a)(16)	☒ (b)(4)	☒ (e)(3)
☒ (a)(9)	☐ (a)(17)	☒ (b)(5)	

☐ Automated Measure Calculation was not tested

3.2.9 Attestation

Attestation Forms (as applicable)	Appendix
☒ Safety-Enhanced Design*	A
☒ Quality Management System**	B
☒ Privacy and Security	C

*Required if any of the following were tested: (a)(1), (a)(2), (a)(6), (a)(7), (a)(8), (a)(16), (a)(18), (a)(19), (a)(20), (b)(3), (b)(4), (b)(9).

**Required for every EHR product

3.3 Appendices

Attached below.

Test Results Summary Change History

Test Report ID	Description of Change	Date

2014 Edition Test Report Summary

USER CENTER DESIGN REPORT –
TEST REPORT UPDATE

This test report was updated in December 2015 to satisfy User Center Design Report specifications by ONC.

The new Test Report ID is amended as follows:
“Part 3: NVLAP-Accredited Testing Laboratory Information: Report Number” plus the suffix “_Dec2015”.

First Insight

MAKE YOUR PRACTICE PERFECT™
www.first-insight.com

A 22867 NW BENNETT STREET
SUITE 200
HILLSBORO, OREGON 97124
P 800.920.1940
P 503.707.8600
F 503.707.8188

170.314(g)(3) Safety Enhanced Design Certification Attestation

MaximEyes Electronic Health Records, versions 2.0.0.0 & higher

First Insight Corporation Senior Representative:
Shandra Cossey
Product Specialist
1-800-920-1940 x6926
shandrac@first-insight.com

For Public Release:

MaximEyes Electronic Health Records, version 2.0.0.0 (& higher) was created using a UCD process following NISTR 7741 & 7742 guidance as well as a homegrown process to determine safety enhanced design for criteria covering 170.314(a)(1), (a)(2), (a)(6), (a)(7), (a)(8), (a)(16), 170.314(b)(3) and (b)(4). Covered criteria in this UCD were 170.314(a)(1), 170.314(a)(6), & 170.314(a)(7).

The “homegrown” associated tasks in summary include “Find a Patient”, “Create an Encounter”, “Order a Lab Test”, “Enter Lab Test Result”, “Order Radiology Test”, “Enter Radiology Test Results”, “Save and Close Encounter”, “Find a Patient”, “Create an Encounter”, “Review and Add Medication History”, “Save and Close Encounter”, “Find a Patient”, “Create an Encounter”, “Review and Add Medication Allergy”, “Save and Close Encounter”.

Process summary outline:
1. Objectives - Main goals defined. Without assistance: Can users complete key tasks? Do users understand the content? Do users feel the EHR meets their clinical needs?
2. Application – Each participant will be rated by a data logger on Success, Task Time, Optimal Path, Difficulty Rating, Comments. Each participant will also complete orientation questions, final questions and system usability scale questionnaire.
3. Evaluate - Identify areas for improvement based on effectiveness, efficiency, & difficulty.
4. Strategy – Implementation plan for improvements

Additional supporting documentation including all details of the process provided are ‘PartDemographics’, ‘Results’, & ‘UCDProcessDetails’.

11/23/2015

X 

Shandra Cossey
Product Specialist, MaximEyes
Signed by: Shandra Cossey

EHR Usability Test Report of MaximEyes EHR 2.0.0.0

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

MaximEyes EHR 2.0.0.0

Date of Usability Test: 6/1/2013 & 6/2/2013
Date of Report: 6/3/2013
Report Prepared By: Shandra Cossey, Product Specialist
First Insight Corporation

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Table of Contents

EXECUTIVE SUMMARY

A usability test of MaximEyes SQL Electronic Health Records was conducted on 6/1/2013 & 6/2/2013 in Portland Oregon. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT).

During the usability test, 14 healthcare providers consisting of 11 doctors and 3 office staff matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 9 tasks typically conducted on an EHR:

- Find a Patient
- Create an Encounter
- Review and Add a Medication Allergy
- Review and Add Medication History
- Order a Lab Test
- Enter Lab Test Results
- Order a Radiology Test
- Enter Radiology Test Results
- Save Patient Encounter

During the 40 minute one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 3); they were instructed that they could withdraw at any time. Participants had prior experience with the EHR. Help material was provided to the participants during the test. The questions were printed out and laid next to the workstation for reference as the medication details were difficult to remember after reading them aloud and starting the task time. A copy of the help material is provided.

The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

Participant screen 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 without assistance
- Path deviations
- Participant's verbalizations
- 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 compensated with $100 Max Bucks credits 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. Following is a summary of the performance and rating data collected on the EHRUT.

ATTACHED RESULTS TABLE "TASKRESULTSSUMMARY" "TASKRESULTSDETAILS"

The results scored the subjective satisfaction with the system based on performance with these

tasks to be: 81.

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

1. Major findings
    a. The specialists (OD's) that use the EHRUT will not use Lab & Radiology tests often
    b. All subjects were unfamiliar with Lab & Radiology testing including LOINC codes
    c. The system of data entry was intuitive
    d. Finding pages of an encounter is easily accessible

2. Areas for improvement
    a. " Ok" button to add result is easily confused with the "Add & Continue" that closes the data entry screen
    b. List of Lab and radiology test needs to be editable
    c. System of data entry for medications needs to be allowed without sig value

INTRODUCTION

The EHRUT tested for this study was MaximEyes EHR ver 2.0.0.0., designed to present medical information to healthcare providers in private practice Optometry & Ophthalmology. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate 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 rating difficulty and optimal path were captured during the usability testing.

METHOD

PARTICIPANTS

A total of 14 participants were tested on the EHRUT. Participants in the test were Optometrists, Ophthalmologists, Office Managers,& Office Staff. Participants were recruited by Shandra Cossey (FIC Product Specialist) and were compensated $100 Max Bucks Credits for their time. In addition, participants had no direct connection to the development of or organization producing the EHRUT(s). Participants were actual end users of various previous products. They were given "help material" during the test so they did not have to memorize verbal instruction. The "help material" contained no additional information from the verbal instruction. Help material is attached as "help material".

For the test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants

Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screener. 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	Connection to Development	Age Range	Race Ethnicity	Education	Position & Title	Years @ position	Environment	Assistive Technologies	Hrs/wk on Computer	Years using an EHR	Familiar with EHR's
1001	M	N	40-59	Caucasian	postgrad	optometry	21	private practice	N	26+	1	1
1002	F	N	40-59	Caucasian	college	manager	16	private practice	N	26+	1	1
1003	F	N	30-45	Caucasian	college	practice ma	>1	private practice	N	26+	>1	1
1004												
1005	F	N	40-59	Caucasian	postgrad	OD	17	private practice	N	26+	11	1
1006	F	N	40-59	Caucasian	postgrad	Optometris	30+	private practice	N	26+	17	1
1007	M	N	23-39	Asian	postgrad	Optometris	2	private practice	N	26+	4	4
1008	F	N	23-39	Caucasian/As	college	biller	>1	private practice	N	26+	4	2
1009	M	N	40-59	Caucasian	postgrad	optometry	35	private practice	N	26+	7	1
1010	F	N	23-39	Caucasian	postgrad	OD	6	private practice	N	26+	5	2
1011	M	N	40-59	Caucasian	postgrad	Optometris	28	private practice	N	26+	8	1
1012	M	N	60-74	Caucasian	postgrad	optometry	34	private practice	N	26+	6	1
1013	M	N	40-59	Caucasian	postgrad	Optometris	33	private practice	N	26+	1.5	1
1014	M	N	60-074	Caucasian	postgrad		30	private practice	N	26+	1	2+
1015	M	N	23-39	Caucasian	postgrad	Optometry	5	private practice	N	26+	8	1

ATTACHED "PARTDEMOGRAPHICS" TABLE ALSO AVAILABLE

14 participants (matching the demographics in the section on Participants) were recruited and 14 participated in the usability test. No participants failed to show for the study.

Participants were scheduled for 40 min max sessions. A spreadsheet was used to keep track of the participant schedule, and included each participant's demographic characteristics.

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 1 EHR. 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 the allotted time without assistance

- Tasks completed in allotted time
- Deviations
- Participant's written comments
- Participant's written, open ended satisfaction observations

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. Find a patient
2. Create an encounter with optometry or ophthalmology workflow
3. Review and add medication allergy
4. Review and add medication history
5. Order a lab test
6. Enter lab test results
7. Order radiology test
8. Enter radiology test result
9. Save patient encounter

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.

PROCEDURES

Upon arrival, 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. A representative from the test team witnessed the participant's signature. To ensure that the test ran smoothly, three staff members participated in this test, the usability administrator, administrator assistant, and the data logger. The usability testing staff conducting the test was EHRUT staff members. Each data logger was given training ahead of the test with specific instructions. The same guidance was given to each data logger.

The administrator moderated the session including administering instructions and tasks an monitored task times. The data logger, obtained post-task rating data, 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.
- Without using a think aloud technique.

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, compensated them for their time, and thanked each individual for their participation. Participants signed a receipt and acknowledgement form (See Appendix 6) indicating that they had received the compensation.

Participants' demographic information, task success rate, time on task, errors, deviations, written responses, and post-test questionnaire were recorded into a spreadsheet.

TEST LOCATION

The test facility included a quiet testing room with 7 tables, 7 computers for the participants. 7 participants were tested at one time. The only people in the room were the administrator, administrator assistant, a data logger for each participant, and 7 participants. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range.

TEST ENVIRONMENT

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted in training room with similar setup of computer as would be at their office workspace. For testing, the computer used a Dell running windows 7.

The participants used mouse, keyboard, touch screen monitor when interacting with the EHRUT.

The [EHRUT] used 21 inch monitors, windows 7 basic color scheme, 1920 x 1080 resolution. The application was set up by the First Insight technical staff according to the vendor's documentation describing the system set-up and preparation. The application itself was on a cloud server using a training / test database on a LAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants did not 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. Non-Disclosure
3. Administrator packet
4. Moderator's Guide
5. Final Questionnaire
6. Incentive Receipt

The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. An audio recording was made of administrator; participants were not verbally communication during the test, only written.

PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to the each participant:

> *Thank you for participating in this study. Our session today will last 40 minutes maximum. During that time you will take a look at MaximEyes EHR electronic health record system.*
>
> *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 we cannot answer or 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.*

We cannot improve MaximEyes SQL without accurate understanding of how you use it, so please be honest with your opinions.

The product you will be using today is the release version of MaximEyes EHR 2.0.0.0. Some of the data may not make sense as it is test data.

We are recording the computer screen of your session today. All of the information that you provide will be kept confidential. You may be contacted in the future to discuss your feedback.

Following the procedural instructions, participants were shown the EHR and as their first task, were given time 6 minutes to complete the preliminary questions.. 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. I would like to request that you not talk aloud or verbalize while you are doing the tasks. 9

Participants were then given 9 tasks to complete. Tasks are listed in the administrators guide.

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 MaximEyes EHR by measuring participant success rates and errors
2. Efficiency of MaximEyes EHR by measuring the average task time and path deviations
3. Task Difficulty/Satisfaction with MaximEyes EHR by measuring ease of use ratings

DATA SCORING

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

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as "Easily Completed" (Success) if the participant was able to achieve the correct outcome, within the time allotted on a per task basis. No assistance was given for any task. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.
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 an "Not Completed". No task times were taken for non-completed tasks. The total number of failures was calculated for each task and then divided by the total number of times that task was attempted. Errors and error types were collected by data loggers' comments.

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. Correct Path, Minor Deviations, Major Deviations were recorded. The number of correct paths and deviations were scored 1-3, 3 being optimal path taken to get an average.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant had completed the task. Average time per task was calculated for each task. Optimal task time for each task was calculated by time to complete task/optimal task time.
Difficulty: Task Rating	Data logger observed difficulty of each task. Participant was rated based on the amount of difficulty to perform each task. 1=Very Difficult 5= Very Easy. Participant's impression of the ease of use and confidence of the application was measured by administering a post-session questionnaire. Common convention is that average ratings for systems judged easy to use should be 3.3 or above.

ATTACHED "RESULTS" "TASK SCORING SYSTEM" WORKSHEET ALSO AVAILABLE

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 excluded from the data.

The usability testing results for the EHRUT are detailed in the attached workbook "Results" on worksheets "ResultsSummary" & "ResultsDetails". The results should be seen in light of the objectives and goals outlined in Study Design.

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: 81. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

Total Usability Test Results Score	81
§170.314(a)(6) Medication List Results	83
§170.314(a)(7) Medication Allergy List Results	90
§170.314(a)(1) Computerized Provider Order Entry Results	76

DISCUSSION OF THE FINDINGS

EFFECTIVENESS

- The effective total score is 88. Num (# of successful completions) / Denom (# of attempts)
- Success ratings for effectiveness were satisfactory. We allowed 4 test participants that would not be regular end user (doctors) to get results. These 4 participants attended training in the past on the MaximEyes EHR in general and had no actual use experience. They were the lowest of our scores and had the most negative feedback regarding the final questions and usability scores.
- Failures were not counted in success average.
- 170.314(a)(1) – Success = 78; Task Failures 14/56 25% The CPOE related tasks are not as relevant to our users than the other tasks. They will rarely order lab and radiology tests or enter results. This is also an area that is newly developed; users had no prior experience entering in radiology tests. In light of those issues I believe that 78 average is fair.
- 170.314(a)(6) – Success = 86; Task failures 2/14: Entering a medication list in EHRUT has more required fields and takes more focus than a med allergy list. ie. Sig is required.
- 170.314(a)(7) - Success = 93; Task failures 1/14: These higher averages show the data entry becomes more intuitive after visiting similar elements. The participants that were able more slowly complete the medication list and then were familiar with the med allergy list as it is very similar to enter.

EFFICIENCY

- The efficiency total average is 76. Num (3 Optimal Path, 2 Minor Deviations, 1 Major deviations) Denom (3). Task times are label here for the amount of time not used out of the allotted time.
- 170.314(a)(1) Deviations = 77; Task Time = 78: Deviations from optimal path and more time used here I assume because this area of the EHR is not widely used within our specialty providers.
- 170.314(a)(6) Deviations = 83; Task Time = 76: The increase in task time used here indicates that the data entry for medications may need to be easier pre populated or less entry that has to be filled in. For example the Sig is required to close the element.
- 170.314(a)(7) Deviations = 90; Task Time = 86: There are not as many required fields for the allergy element and it shows faster and more efficient data entry.

DIFFICULTY (RATED BY DATA LOGGER)

- The difficulty average score is 80. Num (1 Very Difficult 5 Very Easy) Denom (5)
- 170.314(a)(1) – Difficulty 71. CPOE tasks of entering lab and radiology tests and results were scored the most difficult tasks of the study. These tasks required the participant to be intuitive while performing tasks as this is new criteria in the EHR and they have not seen this actual element designed this way.
- 170.314(a)(6) – Difficulty 84: More data entry and smaller fields make this task slightly more difficult than a7. Definitely easier to perform than a1.
- 170.314(a)(7) – Difficulty 90: This task required less data to close the element. Participants found it easier to enter required data.

SATISFACTION

- SUS = 75. As I have read, 78 is average. The low score created from ratings on the usability scorecard filled out by participants creates an area of improvement in the ease of use. The questions were positioned where the ratings should have gone back and forth on the scale to maintain a good average for the EHR. I do believe that created confusion and at the end of the test participants were anxious to leave. Participants that rated everything else high had some low SUS ratings which does not make sense.
- Final Questions – Although participants had not been previously exposed to the radiology tests, not one of them commented on being surprised to see it. Several Comments were made on the pre-population of fields and how that makes it easier to enter data quickly.

MAJOR FINDINGS

- Efficiency score proved lowest with several deviations of the optimal path even if the user was able to complete the task in the time allotted. Training, documentation, and verbal communication from the FIC training team needs to stay consistent. The wording being used in the test may not be what the user was familiar with depending on the type of training received.
- Data pre-population was rated well and commented on.
- Creation of favorite LOINC codes will make it easier to select.

AREAS FOR IMPROVEMENT

- Create faster data entry in all areas, medication list, medication allergy list and entering lab/radiology tests.
- Have predefined short cuts in base for entering new information or pulling previous information into the current encounter.
- The process of closing the data entry screen for entering a lab/result needs to be clear. There are too many buttons that could mean the same thing near the results entering. Based on data logger comments many participants tried closing the lab/radiology screen with the add button for results.
- During initial training processes we need to maintain the same descriptive word usage so that each user is able to read and understand verbal instruction and supporting documents.

Quality Management System

A “home grown” QMS system inspired by the agile development methodology is utilized. During the development process our QMS system ensures that the quality assurance team receives iterative builds to catch any initial development issues in the cycle. Early in the development cycle customer feedback is provided on new features.
The implementation of the software is done by a dedicated deployment team once the application is configured on the customer’s system then the training team takes over to ensure that the customers have no issues in using the system live at the practice.
Once the customers are up and running using the system they have access to quality customer support team which ensures that all the customers get prompt response and resolution of their issues. Any issues requiring a code change are sent to development team to be fixed in the next upgrade.

Privacy and Security

170.314(d)(2):

The user interface for the application does not allow the end user to disable the audit log. The end user cannot use the application, if for any reason the :

- Windows service responsible for communicating with the audit log database goes down or stops. Or
- The audit log database itself goes offline.

170.314(d)(7):

AES encryption is used.