

EHR Usability Test Report of UDIXpress, version 1.5.0.0

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

UDIXpress, version 1.5.0.0

Date of Usability Test: 08/15/2018
 Date of Report: February 4, 2019

Contents

EXECUTIVE SUMMARY	2
Objectives	2
Participant Task Results	3
Major findings	3
Areas for improvement	3
INTRODUCTION	4
METHOD	4
PARTICIPANTS	4
STUDY DESIGN	5
TASKS	5
PROCEDURES	5
TEST LOCATION	6
TEST ENVIRONMENT	6
TEST FORMS AND TOOLS	6
PARTICIPANT INSTRUCTIONS	6
USABILITY METRICS	7
DATA SCORING	7
RESULTS	8
DATA ANALYSIS AND REPORTING	8
APPENDICES	10
Appendix 1: Participant Demographics	11
Appendix 2: Example Moderator’s Guide	11
Appendix 3: Example Informed Consent	13
Appendix 4: Example Orientation and Preliminary Question	14
Orientation (5 minutes)	14
Preliminary Questions (3 minutes)	14
Appendix 5: Example Tasks	15
Task 1: First Impressions (90 Seconds)	15
Task 2: Select the EHR Implant Documentation Screen (5 Seconds)	16
Task 3: Scan the Unique Device Identifier (UDI) barcode on the implant (85 Seconds)	17
Appendix 6: Example Final Question	36
Appendix 7: SYSTEM USABILITY SCALE QUESTIONNAIRE	37

EXECUTIVE SUMMARY

A Usability Test (UT) of UDIXpress, version 1.5.0.0 was conducted in Pittsburgh, PA by TeamEHR. The purpose of UT was to test and validate the usability of UDIXpress and provide evidence of usability in the EHR Under Test (EHRUT). During UT, twelve healthcare providers (RNs and Auditors), matching the exact target demographic criteria served as participants and used the EHRUT in exact representative tasks used when documenting during a procedure.

UT collected performance data on the tasks conducted when documenting an implant in a patients EHRs. The objective of the event was to validate that UDIXpress meets the requirements outlined in 170 315(a)(14), Implantable Device List. The objective of the event was to parse all UDI and GUDID data in the patients EHR keeping the user in their known workflow. Additional objectives met; training and showing how the scan prevents the use of Expired and Recalled implants.

Objectives

- i. Scan the UDI required for the case (GS1, HIBC, ICCBBA)
 - o During the case scan all formats (1D, 1D-Stacked, 2D)
- ii. Validate the implants identifiers from a UDI parsed into the discrete fields in the patients EHR
- iii. Validate the scan obtained and associated a description of the implantable device with each implants UDI
- iv. Validate the scan parsed the GMDN-PT Name in the documentation against the UDI
- v. Make a modification to the UDI data fields and attributes associated with the UDI (GUDID)
- vi. Change the status of the implant in the EHR:
 - o If previously implanted (prior to case) verify implant on histories tab, change the status of the distinct UDI to explant the exact implant.
 - o If implanted during case, verify implant on implant log segment, change the status of implant to explant on the distinct UDI trialed or removed during the case.

Participants had prior experience with the EHR and no prior experience with UDIXpress. Training took place in the live environment, in surgical operating rooms and procedure rooms with a review of the instructions and demonstration given to each participant. The administrator introduced UT and instructed participants to complete a series of tasks (identified above) using the EHRUT. During the procedure, the administrator timed the process and collected performance data results electronically.

Participant user sessions were recorded and analyzed following the procedure. The following data was collected for each participant:

- Task Performed
- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- 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. A compliant HIPAA system was used throughout testing. Following the conclusion of UT, participants were asked to complete a post-test questionnaire. 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.

Participant Task Results

ID	Task Description	Task Success - Mean (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time Deviation - Mean Optimal (seconds)	Task Errors Mean(%)	Task Rating	Participant Identifiers
i	Record the Unique Device Identifier (UDI) associated with a patient's Implantable Devices	100.0	2	2	15	15	100	100	01,02,03,04,05,06,07,08,09,10,11
ii	Parse identifiers from a UDI (UDI-DI and UDI-PI)	100.0	1	1	15	15	100	100	01,02,03,04,05,06,07,08,09,10,11
iii (a)	Obtain and associate a description of the implantable device with each UDI and GMDN-PT Name (from GUDID)	100.0	2	2	10	10	100	100	01,02,03,04,05,06,07,08,09,10,11
iv	Display to a user an implantable device list consisting of: (A) The active UDI recorded for a patient; and (B) For each active UDI, the description of the implantable device specified by subparagraph (iii)(a) above	100.0	2	2	5	5	100	100	01,02,03,04,05,06,07,08,09,10,11
v	For each patients UDI, enable a user to access: The UDI, description of the implantable device, the identifiers associated with the UDI, the attributes associated with the UDI	100.0	2	2	10	10	100	100	01,02,03,04,05,06,07,08,09,10,11
vi	Enable a user to change the status of Unique Device Identifier recorded for a patient. Allow for the implant to show explant with date and time of procedure (retains original implant date)	100.0	2	2	15	15	100	100	01,02,03,04,05,06,07,08,09,10,11

In order to compensate for being in a production environment, results were rounded in 5 second increments. It is determined for future testing that results should round to the 1 second. The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be **100**. In addition to the performance data, the following qualitative observations were made:

Major findings

- No findings with application
- Difficulties around understanding all barcode types UDI barcode and GUDID
 - Not all implants are required to contain UDI
 - Confusing example: HCT/P if considered a medical device is required to have UDI
 - Rationality: HCT/P has more requirements/paper or added 3rd party since
 - barcodes don't parse information, why?
- Training needed on Unique Device Identification barcodes (and how to report bad barcodes)
- Policies and training required on what's considered an implant in documentation
- Policies and training of importance of complete and accurate documentation

Areas for improvement

- Help features (report a label problem, version 1.5.0.0)
- For Future testing it is recommended not to round the results in 5-minute increments

INTRODUCTION

The EHRUT tested is UDIXpress, version 1.5.0.0. UDIXpress designed to perform a GUDID lookup, scan and parsing of a medical device or HCT/Ps barcode. UDIXpress reads all accredited agencies UDI labels (GS1, HIBC, ICCBBA) and the three formats (1D, 1D-Stacked and 2D barcodes) and validate the GUDID at the Point of Care (POC) or at inventory. The EHRUT consists of scanning implantable devices and parsing manufacturers UDI-DI, UDI-PI and GUDID data into the patients EHR. When scanning occurs, Expired, Recalled or items with adverse events (MAUDE) are prevented from being implanted. UDIXpress is designed to be used in storerooms or procedural areas for hospitals or healthcare practices that use medical devices or implants (medical device and HCT/P). The UT represents realistic exercises and conditions and is performed in a live environment. The purpose of the UT is to 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 parsing of UDI-DI, UDI-PI and GUDID data into the patients EHR in less than 25 seconds, are captured and shown during the UT.

METHOD

PARTICIPANTS

A total of twelve (12) participants were tested on the EHRUT(s). Participants in the test were operating room and procedural area RNs and auditors. Participants had no direct connection to the development of or organization producing the EHRUT(s). Participants were not from the testing or supplier organization. Participants were given the same orientation and level of training as the actual end users would have received. The following is a table of participants by characteristics. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities. Twelve participants (matching the demographics in the section on Participants) were recruited and participated in UT. Participants were scheduled for surgical cases; each debriefed by the administrator. A spreadsheet was used to keep track of the participants schedule and included each participant's demographic characteristics.

Participant	Age	Education	Position	Experience			Tech needs
				Professional	Computer	EHR	
Female	40-49	Bachelor's degree	RN/Circulator	48	48	36	No
Female	40-49	Bachelor's degree	RN/Circulator	48	48	36	No
Female	50-59	Bachelor's degree	RN/Circulator	48	48	36	Yes
Female	30-39	Bachelor's degree	RN/GI Nurse	48	48	36	No
Female	40-49	Bachelor's degree	RN/GI Nurse	48	48	36	No
Female	50-59	Bachelor's degree	RN/Circulator	48	48	36	No
Female	40-49	Bachelor's degree	RN/GI Nurse	48	48	36	No
Male	50-59	Bachelor's degree	RN/Circulator	48	48	36	No
Male	40-49	Bachelor's degree	RN/Circulator	48	48	36	No
Male	30-39	Bachelor's degree	RN/Circulator	48	48	36	No
Female	40-49	Bachelor's degree	Auditor	48	48	36	No
Male	40-49	Bachelor's degree	Auditor	48	48	36	No

STUDY DESIGN

Overall, the objective of UT 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 UT 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 UT, participants interacted with one EHR with UDIXpress in the system tray. Each participant used the system in the same area 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
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's comments
- Participant's satisfaction ratings of the system

TASKS

Tasks were constructed that would be realistic and mimic the exact activities a user might do with this EHR, including:

- Record Unique Device Identifiers associated with a patient's Implantable Devices (GS1, HIBC)
- Parse identifiers from a Unique Device Identifier (UDI)
- Obtain and associate a description of the implantable device with each Unique Device Identifier (UDI)
- Display to a user an implantable device consisting of: The active Unique Device Identifiers and GMDN-PT Name
- Enable a user to access: The Unique Device Identifier; The description of the implantable device, the identifiers and attributes associated with the Unique Device Identifier (GUDID)
- Allow the user to change the status of Unique Device Identifier recorded for a patient.

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. 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. 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. Scoring is discussed below in Section 3.9. Following the session, the administrator gave the participant the post-test questionnaire (e.g., the System Usability Scale, see Appendix 5), compensated them for their time, and thanked the 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.

TEST LOCATION

The test was performed in an operating room. Only the participant and administrator were at the circulator's station during testing. The environment was comfortable for users, noise levels kept to a minimum with the ambient temperature within a normal range for an operating room.

TEST ENVIRONMENT

The EHRUT is used in a healthcare operating or procedure area. In this instance, the testing was conducted in the operating rooms. For testing, the computer used were Dell workstation running Windows 7 Enterprise. The participants used a Zebra 4308-HC when interacting with the EHRUT. The EHRUT used a 22" monitor with the resolution set to 1920x1080, the required resolution for the EHR. The application was set up by the healthcare organization according to the vendor's documentation describing the system set-up and preparation. The UDI interface requires a working Internet connection and a firewall which allows bidirectional traffic to <https://accessgudid.nlm.nih.gov/api/v1/devices/lookup.xml?di=xxxx>. The application composes a complete URL using the government web address and escaped UDI and reads the returned XML in real-time. Technically, the system performance (i.e., response time) was representative to what actual users would experience in any operating room. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

TEST FORMS AND TOOLS

During UT the following documents were used

- Label and Scanning Instructions laminated and attached to workstation.
- CEHRT UAT Participant workbook

Examples of these documents can be found in Appendices 3-6 respectively. The CEHRT UAT Participant workbook was devised to capture required UT data. The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running.

PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to the participant (Moderator's guide can be reviewed in the Appendix). Participants were then given six tasks to complete. Tasks are listed under the Task section.

Thank you for participating in Unit Testing (UT). Your input is very important. During that time, you will use an instance of an electronic health record (EHR) with UDIXpress running in the system tray. 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 was involved in its creation, so please be honest with your opinions. All of the information provided will be used to improve the application and is kept confidential. The healthcare organization uses a tool in the background that record screens and transmit those recordings across a local area network for remote observations and 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 "Scan." At that point, please perform the task. The system will return the cursor to page 1 indicating you have successfully completed the task. I would like to request that you not talk aloud or verbalize while you are doing the tasks. I will ask you your impressions about the task once you are done.

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:

- Effectiveness of EHRUT by measuring participant success rates and errors
- Efficiency of EHRUT by measuring the average task time and path deviations
- Satisfaction with EHRUT 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. 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. Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator’s Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 1.25] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was [x] seconds then allotted task time performance was [x * 1.25] seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.
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 “Failures.” No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. ¹¹ This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.
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. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said “Begin” until the participant said, “End/Done.” If he or she failed to say “End/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 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants’ confidence in and likeability of the EHRUT overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, “I think I would like to use this system frequently,” “I thought the system was easy to use,” and “I would imagine that most people would learn to use this system very quickly.” See full System Usability Score questionnaire in Appendix

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. If participants failed to follow session and task instructions the data would have been excluded from the analyses. Testing was performed in a live environment testing irregularities or issues that would have affected data collection were mitigated. The survey yields a single number that represents a composite measure of the overall perceived usability of the system.

The usability testing results for the EHRUT are detailed below (see Table xxx The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

(i) Record Unique Device Identifiers associated with a patient's Implantable Devices.			Actual Time (target time - rounded)			Success Rate		Optimal Time (target time - rounded)			Deviation and Errors		Rating - Scale	Rating - Standard Deviation	
Pass/Fail	Task Identifier	Task Description	Path - Number of Steps	Time - Deviation - Mean Observed	Usability Scale	Success - Mean (%)	Success - Standard Deviation (%)	Path - Optimal Number of Steps	Time - Mean (seconds)	Time - Deviation - Mean Optimal	Time - Standard Deviation (seconds)	Errors - Mean (%)	Errors - Standard Deviation (%)	Rating - Scale Type	Rating - Standard Deviation
			steps taken for the Task	Observed time taken for the Task (Rounded to 5 second increments)	1. Very Easy 2. Easy 3. Neither Easy nor Difficult 4. Difficult 5. Very Difficult	Mean task success rate (in percentages)	Standard deviation of the task success rate (in percentages)	Steps required for the Task	Average time needed to complete Task	Optimal time needed to complete Task	Standard deviation for task time.	Mean task error rate (in percentages)	Standard deviation of the task error rate (in percentages)	Mean usability rating of the corresponding task, based on	Standard deviation of the mean usability rating of the corresponding task, based on the specified
(i) Record Unique Device Identifiers associated with a patient's Implantable Devices.															
Pass	UDI-1	Unique Device Identifiers (UDI-DI, UDI-PI): Select patient's record & enter data for unique device identifiers (UDI) for an implantable medical device in all formats (1D, 1D-Stacked (lateral) and 2D (square) established by the 3 UDI Issuing Agencies. Verify UDI-DI and UDI-PI populate in UDI field of the patient's record. UDI must match label barcode information. Entry of discrete fields can be completed manually if not using a scanning device. Example, human readable format located next to a UDI barcode: GS1 (01) or HIBC *X	2	15	2	100%	0%	2	15	15	0	0.0%	0.0%	Likert	0.0%
(ii) Parse Identifiers from a Unique Device Identifier (UDI):															
Pass	UDI-2	Scan/Parse Unique Device Identifiers (UDI-DI, UDI-PI): Scan manufacturer supplied barcode for medical device and HCT/P to test data parsing into the patient's implant document in the clinical record of the EHR. Validate data parses into the clinical record from original manufacturer label. Parse unique device identifiers (UDI) in all formats (1D, 1D-stacked, 2D) established by the 3 UDI Issuing Agencies (GS1, HIBC, ICCBA) for the patient's implantable device list of the patients EHR. (A) Device Identifier; (B) Production Identifiers: (1) lot or batch the device was manufactured in; (2) serial number of a specific device; (3) expiration date of a specific device; (4) date a specific device was manufactured; & (5) For an HCT/P (human cell, tissue, or cellular & tissue-based product) regulated as a device, the distinct identification code required by: 21 CFR § 1271.290(c).	1	15	1	100%	0%	1	15	15	0	0.0%	0.0%	Likert	0.0%
(iii) Obtain and associate a description of the implantable device with each Unique Device Identifier (UDI):															
Pass	UDI-3	(A) Validate Scan Association Description of Implantable Device: Validate scan from GUDID obtained a GNDN description in all formats established by the 3 UDI Issuing Agencies & associate it with the patient's implantable device: (A) A description of the implantable device referenced by at least one of the following: (1) "GMDN_PT_Name" attribute associated with the Device Identifier in the Global Unique Device Identification Database (GUDID) in the surgical record.	2	5	1	100%	0%	2	5	5	0	0.0%	0.0%	Likert	0.0%
Pass	UDI-4	(B) Validate Scan Association Description of Implantable Device: Validate scan from GUDID obtained description attributes in all formats established by the 3 UDI Issuing Agencies & associate it with the patient's implantable device: (B) The following Global Unique Device Identification Database (GUDID) attributes: (1) "Brand Name"; (2) "Version or Model"; (3) "Company Name"; (Manufacturer) (4) "What MRI safety information does the labeling contain?"; (5) "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)."	1	10	1	100%	0%	1	10	10	0	0.0%	0.0%	Likert	0.0%
(iv) Display to a user an implantable device list consisting of: (A) The active Unique Device Identifiers recorded for a patient; and (B) For each active Unique Device Identifier, the description of the implantable device specified by subparagraph (iii)(A) of this paragraph.															
Pass	UDI-5	Display Unique Device Identifiers on the Implant Log on patients implant document: Select patient's record & verify scan details display for unique device identifiers (UDI) for a patient's implantable device as follows: (A) The active UDI recorded for a patient. (B) For each active UDI, the description of the implantable device specified by Obtain & Associate step above	1	10	1	100%	0%	1	10	10	0	0.0%	0.0%	Likert	0.0%
(iv) Display to a user an implantable device list consisting of: The active UDI recorded for a patient; For each active UDI, the description of the implantable device specified by subparagraph (iii)(A) of this paragraph; and A method to access all UDIs recorded for a patient.															
Pass	UDI-6	Display Implantable Device List on the Histories - Implant tab: Verify the implantable device lists consist of: (A) The active UDI recorded for a patient. (B) For each active UDI, the description of the implantable device (C) A method to access all UDI recorded for a patient	1	5	1	100%	0%	1	5	5	0	0.0%	0.0%	Likert	0.0%
(v) For each Unique Device Identifier for a patient, enable a user to access: The Unique Device Identifier; The description of the implantable device; The identifiers associated with the Unique Device Identifier; The attributes associated with the Unique Device Identifier															
Pass	UDI-7	Access UDI: Select patient's record & access UDI for a patient's implantable device: (A) UDI; (B) description of the implantable device (Obtain & Associate step UDI-7A) (C) identifiers associated with the UDI (Parse UDI step UDI-2) (D) attributes associated with the UDI (Obtain & Associate step UDI-7B)	1	10	1	100%	0%	1	10	10	0	0.0%	0.0%	Likert	0.0%
(vi) Enable a user to change the status of UDI recorded for a patient.															
Pass	UDI-8	Change Status of Unique Device Identifier Histories - Implant tab: Select patient's record Histories, Implant tab. Select UDI, explant. Status of UDI changes on history.	3	15	1	100%	0%	3	15	15	0	0.0%	0.0%	Likert	0.0%

Discussions followed the procedures. The inconsistency of the barcodes from manufacturers seem to be the barrier. 1D-Stacked barcodes were the most troublesome in testing.

EFFECTIVENESS	UDIXpress is effective at improving the workflow of implant documentation. In light of the barcode issues identified the application was shown to decrease documentation time to <20 seconds per implant. The application proved it could prevent Expired items from being documented. The application proved it could prevent Recalled items from being documented.
EFFICIENCY	UDIXpress adds efficiency by parsing all UDI-DI, UDI-PI and GUDID data elements at POC within the RNs (circulators) workflow in the patients EHR, where manual documentation occurred (familiar). Workflow was significantly decreased from 360 seconds to <20 seconds per implant. Documentation accuracy improved with complete implant details; no errors from hand keying of data. Reports contain all fields completed.
SATISFACTION	Users satisfied with labels tested. Concerned about process when the barcode isn't UDI compliant.
MAJOR FINDINGS	Participants found UDIXpress very easy to use. Participants concerned about training and how to interpret labels. Participants concerned about what is considered an implant.
AREAS FOR IMPROVEMENT	Participants requested additional help features. Participants requested training for barcodes. Participants requested uniformity in barcodes and where they display on packaging.

APPENDICES

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

1. Example Participant Demographics
2. Example Moderator's Guide
3. Example Informed Consent
4. Example Orientation and Preliminary Question
5. Example Tasks
6. Example Final Question
7. Example System Usability Scale Questionnaire

Appendix 1: Participant Demographics

The report contains a breakdown of the key participant demographics. A representative list shown below is followed by the overview of the participants in UT.

Gender/Age

Male	[X]
Female	[X]
Age	[X]
Total (participants)	[X]

Education/Position

Education	[X]
RN/BSN	[X]
Admin Staff	[X]
Total (participants)	[X]

Years of Experience

Years of experience	[X]
Computer	[X]
EHR	[X]

The full participant breakdown (de-identified) follows:

Participant	Age	Education	Position	Experience Exceeds			Tech needs
				Professional	Computer	EHR	
Female	40-49	Bachelor's degree	RN/Circulator	48	48	36	No
Female	40-49	Bachelor's degree	RN/Circulator	48	48	36	No
Female	50-59	Bachelor's degree	RN/Circulator	48	48	36	Yes
Female	30-39	Bachelor's degree	RN/GI Nurse	48	48	36	No
Female	40-49	Bachelor's degree	RN/GI Nurse	48	48	36	No
Female	50-59	Bachelor's degree	RN/Circulator	48	48	36	No
Female	40-49	Bachelor's degree	RN/GI Nurse	48	48	36	No
Male	50-59	Bachelor's degree	RN/Circulator	48	48	36	No
Male	40-49	Bachelor's degree	RN/Circulator	48	48	36	No
Male	30-39	Bachelor's degree	RN/Circulator	48	48	36	No
Female	40-49	Bachelor's degree	Auditor	48	48	36	No
Male	40-49	Bachelor's degree	Auditor	48	48	36	No

Appendix 2: Example Moderator's Guide

EHRUT Usability Test

Moderator's Guide

Administrator _____

Data Logger _____

Date _____ Time _____

Participant # _____

Location _____

Prior to testing

- Confirm OR schedule with participant and OR board runner
- Ensure Scanning and label reading instructions laminated and on workstation
- Ensure workstation equipment and scanning device is running properly
- Ensure EHRUT production environment is running properly
- Ensure primary EHR and patient chart opens
 - Implant segment is able to focus as opened application

Prior to each participant:

- Reset application

Prior to each task:

- Verify application returns to implant segment

After each participant:

- End session, log off patient chart, close primary EHR

After all testing

- Back up data files

Appendix 3: Example Informed Consent

Team^{EHR} would like to thank you for participating in the UT. The purpose of this test is to evaluate the scanning capabilities of UDIXpress directly into the patients record of the EHR. If you decide to participate, you will be asked to scan actual implants and give your feedback. The scan takes approximately 20 seconds per implant. Testing will not take longer then your case nor will it interfere with patient care. Scanning all barcodes and allowing for questions after each task will take less than 20 minutes.

Agreement

I understand and agree that as a participant in the UT, I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the UT conducted.

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 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 request to stop UT 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 4: Example Orientation and Preliminary Question

Orientation (5 minutes)

Thank you for participating in the UT. Scanning performed during the case should take less than 20 seconds per implant. During your case, within your current EHR, you will be asked to scan your implants.

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; unless you call time. 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.

I did design this system and it is imperative for you to be honest with your opinions.

The product you will be using today is UDIXpress, it reads and parses all of the UDI-DI, UDI=PI and GUDID data about the implant into the patients EHR. You are using UDIXpress 1.5.0.0. We have been live with this application in several facilities.

As it is routine in this environment, we record all EHR data entries in a screen capturing tool. The system is HIPAA compliant. All of the information that you provide is kept confidential and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

Preliminary Questions (3 minutes)

What is your job title / appointment?

How long have you been working in this role? What are some of your main responsibilities?

Tell me about your experience with electronic health records?

- Please don't click on anything just yet. What do you notice? What are you able to do here? Please be specific.

Notes / Comments:

Appendix 5: Example Tasks

Task 1: First Impressions (90 Seconds)

On your workstation, you will see the EHR Implant documentation used in your daily workflow. In the system tray (lower right corner), this is the applications icon that will be working in the background to perform the scan. 

Have you seen or heard of it? Yes No

If Yes, tell me what you know about it:

I'm going to do a quick scan so you can see UDIXpress' functionality within your current EHR. The goal of the application is to meet § 170.315(a)(14) Implantable Device List requirements while keeping the circulator within their current EHR and workflow. Not adding to time but reducing time in documentation to 20 seconds. Currently it can take six to nine minutes to document an implant correctly .

The scan of the UDI parses all of the UDI-DI, UDI-PI information from the manufacturer's barcode. It then validates the GUDID and returns the information registered by the manufacturer. If the barcode scans and has not been registered with the FDAs GUDID it is not an authorized medical device. If the system instructs that the GUDID was not validated, a notification is fired to follow up on that medical device to ensure that it has been registered.

- *Show test participant the EHRUT.*

Appendix 5: Example Tasks (continued)

Task 2: Select the EHR Implant Documentation Screen (5 Seconds)

Take the participant to the starting point for the task

Review documentation window and prepare for scan:

- Is your workstation setup correctly?
- Does your record display two rows of toolbars?
- Does the segment show three (3) pages?
- Is your cursor in the first field?
- Is CAPS lock off?

Please review *the implant so you can identify the components of the UDI on the packaging*. Find this information. Following the scan, you can validate and view that all the data from the UDI-DI, UDI-PI and GUDID parse into the patients EHR.

Success:

- Easily completed
- Completed with difficulty or help :: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path: *Workstation setup correctly, ready to scan*

- Correct
- Minor Deviations / Cycles :: Describe below
- Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

- Overall, this task was: _____

Participant shown written scale: "Very Easy" (1) to "Very Difficult" (5)

1. Very Easy
2. Easy
3. Neither Easy nor Difficult
4. Difficult
5. Very Difficult

Administrator Comments:

Appendix 5: Example Tasks (continued)

Task 3: Scan the Unique Device Identifier (UDI) barcode on the implant (85 Seconds)

Take the participant to the starting point for each task in this section .

Review implant label and prepare for scan:

- Is your workstation and scanner setup correctly?
- Reset the scanner (right click on icon in system tray, Reset Scanner, Beethoven V – Victory sounds)

Tasks.

- vii. Scan the UDI required for the case (GS1, HIBC, ICCBBA)
- viii. Validate the implants identifiers from a UDI parsed into the discrete fields in the patients EHR
- ix. Validate the scan obtained and associated a description of the implantable device with each implants UDI
- x. Validate the scan parsed the GMDN-PT Name in the documentation against the UDI
- xi. Make a modification to the UDI data fields and attributes associated with the UDI (GUDID)
- xii. Change the status of the implant in the EHR:
 - o If previously implanted (prior to case) verify implant on histories tab, change the status of the distinct UDI to explant the exact implant.
 - o If implanted during case, verify implant on implant log segment, change the status of implant to explant on the distinct UDI trialed or removed during the case.

Please note that 85 seconds is allowed for this task in total. Please review CEHRT UAT participant workbook for document used during testing.

Success:

- Easily completed
- Completed with difficulty or help :: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path: *Workstation and scanning device setup correctly, ready to scan*

- Correct
- Minor Deviations / Cycles :: Describe below
- Major Deviations :: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

- Overall, this task was: _____

Participant shown written scale: "Very Easy" (1) to "Very Difficult" (5)

- 1. Very Easy
- 2. Easy
- 3. Neither Easy nor Difficult
- 4. Difficult
- 5. Very Difficult

Administrator Comments:

Appendix 6: Example Final Question

Final Questions (5 Minutes)

- ✓ What was your overall impression of this system?

- ✓ What aspects of the system did you like most?

- ✓ What aspects of the system did you like least?

- ✓ Were there any features that you were surprised to see?

- ✓ What features did you expect to encounter but did not see?
 - That is, is there anything that is missing in this application?

- ✓ Compare this system to other systems you have used.

- ✓ Would you recommend this system to your colleagues?

Appendix 7: SYSTEM USABILITY SCALE QUESTIONNAIRE

		Strongly Disagree			Strongly Agree	
		1	2	3	4	5
1	I think that I would like to use this system when scanning implants					
2	I found the system unnecessarily complex					
3	I thought the system was easy to use					
4	I think that I would need the support of a technical person to be able to use this system					
5	I found the various functions in this system were well integrated					
6	I thought there was too much inconsistency in this system					
7	I would imagine that most people would learn to use this system very quickly					
8	I found the system very cumbersome to use					
9	I felt very confident using the system					
10	I needed to learn a lot of things before I could get going with this system					
11	I think that there is a lot to understand about barcodes outside of the scanning system and training on barcodes and reason behind the symbology is essential					