Siemens Healthineers
Business Area Ultrasound

Title: Compass VA10A Usability Validation Report

Part Number: 11290281-EPT-008-01

Revision Data

Rev	ECO #	Change Description	Printed Name
01	677403	Initial Release	Tony Sottile

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1.0 Executive Summary/Conclusion

A Human Factors usability validation study for the Compass VA10A system was conducted between March 7th and April 4th 2018. The validation study scenarios were designed to incorporate workflows associated with the functionality of the Compass system that are associated with hazardous situations. Two protocols were used to accomplish the objectives of the usability validation plan. Both the radiologist protocol and the sonographer protocol included tasks associated with general imaging, biopsy and fusion features.

To accomplish this study, 35 participants (18 interventional radiologists and 17 sonographers) who are representative of the intended end users, performed a variety of tasks were studied. Participants interacted with production equivalent hardware and software during individual sessions to attempt to complete tasks in the context of realistic use scenarios. The moderator and a note-taker collected both objective measures of task performance as well as the participant's subjective views of the tasks during debriefing interviews.

Some use errors, close calls and use difficulties were associated with potential for harm. For the tasks performed by radiologists, 2 of the 18 participants were able to perform all tasks with no close calls or use errors (with no failures). Of the 35 critical tasks included in the radiologist protocol, 18 were performed with no use errors or close calls. For the tasks performed by sonographers, 3 of the 17 participants were able to perform all tasks with no close calls or use errors (with no failures). Of the 23 critical tasks included in the sonographer protocol, 10 were performed with no use errors or close calls. All use errors and close calls are described and analyzed for root cause in Section 9.2.

In summary, this study tested the effectiveness of the usability mitigations developed for the user interface identified in the Compass Product Analysis and Report of Hazards and Risks. 30 tasks out 58 had use errors or close calls. The effectiveness of the mitigations associated with 30 of the 58 critical tasks cannot be confirmed due to the use errors and close calls that occurred.

Root cause analysis was performed to understand the cause of the error and effectiveness of existing mitigation. The residual risks will be evaluated by the risk team identified in the Risk Management Plan. The findings of the residual risk analysis will be summarized in the Compass Product Analysis and Report of Hazards and Risks according to the Product Risk Management Procedure.

This report is evidence of fulfillment of the validation criteria for Requirement ID 527711 System Usability (Compass VA10A Design Validation Plan).

2.0 Purpose

The purpose of this report is to document the results of the Compass VA10A Human Factors Validation Testing. This test was conducted to validate that the user interface enables effective use and protects against potentially harmful use errors.

3.0 Scope

The effectiveness of the usability mitigations developed for the user interface elements, which should reduce use errors/hazards, were tested.

Validation testing incorporated workflows associated with the functionality of the Compass system that have hazardous situations identified in the Compass Product Analysis and Report of Hazards and Risks. These workflows were identified based on the task analysis (Compass VA10A Task Analysis,). General imaging, Biopsy and Fusion features were evaluated with corresponding user groups. The goal of validation was to provide evidence of the effectiveness of the risk control measures and of the fulfillment of the Compass VA10A Requirements Specification, Requirement # 527711 for System Usability.

3.1 Product Description

The Compass VA10A system is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive ultrasound echo data and display it in B-Mode, M-Mode, Pulsed Wave (PW) Doppler Mode, Continuous Wave (CW) Doppler Mode, Color Doppler Mode, Color M-Mode, Doppler Tissue Mode, Amplitude Doppler Mode, a combination of modes and Harmonic Imaging on a display.

The system includes the following elements:

- Cart
- Main display for the ultrasound image
- Control panel with articulating touch screen

System accessories include:

- Physical Qwerty keyboard (optional)
- Transducer holders & 1 gel warmer (both standard)
- Footswitch (optional)
- Transducers (optional)
- Transducer Biopsy guides and brackets (optional)
- Back shelf for storage or optional component enclosure (Fusion box, CD/DVD, and black & white printer depending upon box purchased)

The system supports the following transducers: 10L4, 14L5, 18L6, 4V1, 5V1, 8V3, CW2, DAX, 5C1, 9C3, 9EC4.

4.0 Responsibility

The Principal Investigator and contact person for this study was Tony Sottile.
The test was conducted by the following individuals:

- Test Site #1 (Issaquah, WA):
    - Tony Sottile (Human Factors Engineer/Study Moderator)

- Isabelle Banville (Human Factors Senior Manager/Study Moderator/Actor)
- Valerie Ho (Human Factors Intern/Note-taker)
- Margo Woller-Carter (Human Factors Engineer contractor/Note-taker/Actor)
- Jason Wise (Human Factors Engineer/Actor)
- Micha Coleman (Systems Engineer/Actor)
- Sridevi Wagle (Software Engineer/Actor)
- Narayanan Periyaswamy (Software Test Engineer/Actor)
- Mamata Kotehal (Module Manager/Actor)

- Test Site #2 (Los Angeles, CA):
  - Barry Beith (Human Factors Engineer consultant/Study Moderator)
  - Christine Zomorodian (Medical Device consultant/Note-taker)
  - Craig Williams (Product Marketing Specialist/Actor)
  - Yashvika Khurana (Clinical Applications Specialist/Actor)
  - Danny Estrada (Zone Clinical Sales Team Lead/Actor)

The moderators and note-takers were experienced in the relevant Human Factors methods as well as the systems, devices, and components under test.

The test was partitioned into 3 teams:

- Team 1 ran test sessions in Issaquah, included Tony Sottile and Valerie Ho, and primarily ran Radiologist test sessions with acting support from: Micha Coleman, Jason Wise, Sridevi Wagle, Narayanan Periyaswamy, and Mamata Kotehal.
- Team 2 ran test sessions in Issaquah, included Isabelle Banville and Margo Woller-Carter, and primarily ran Sonographer test sessions with acting support from: Micha Coleman, and Jason Wise.
- Team 3 ran test sessions in Los Angeles, included Barry Beith and M Christine Zomorodian, and ran both Sonographer and Radiologist test sessions with acting support from: Craig Williams, Yashvika Khurana, and Danny Estrada.

4.1 Human Factors Engineering Review

All use errors and close calls on critical tasks that were observed during the study were reviewed by the Human Factors Engineering Lead with an internal peer review with the following personnel:

- Tony Sottile (Human Factors Engineer, Lead)
- Margo Woller-Carter (Human Factors Engineer)
- Valerie Ho (Human Factors Engineer Intern)

5.0 Definitions

Table 1: Acronyms and Terms

Acronym/Term	Definition
AAMI	Association for the Advancement of Medical Instrumentation
Critical Task	A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care.
CW	Continuous Wave Doppler

Acronym/Term	Definition
Simulated Use Testing	This kind of testing involves systematic collection of data from test participants using a device, device component or system in realistic use scenarios but under simulated conditions of use (e.g., with the device not powered or used on a manikin rather than an actual patient).
U.S.	United States of America
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

6.0 References

Table 2: References

Document Name	Document or Part Number
Compass Product Analysis and Report of Hazards and Risks	11147457-EGA-011-06
Compass Risk Management Plan	11147457-EGA-010-06
Compass Use Specification	11474581-EPH-008-03
Compass User and Reference Manuals	11288517
Compass VA10A Design Validation Plan	11147457- EPH-032-01
Compass VA10A Radiologist Usability Validation Protocol	11147457-EFT-062-03
Compass VA10A Sonographer Usability Validation Protocol	11147457-EFT-061-04
Compass VA10A Task Analysis	11289931-EPH-001-01
Compass VA10A Usability Engineering Summary Report	11290395-EPT-001-01
Compass VA10A Usability Validation Plan	11289348-EFT-001-02
Product Risk Management Procedure	PN 7859486-QMS-001
Usability Engineering Process	10851935
TFS Defect Management Work Instruction	11150115

7.0 Test Method

7.1 Staffing and Environment

This usability validation study was conducted at two locations in the U.S. The primary location for usability validation was in a simulated clinical ultrasound environment at the Siemens Healthcare facility in Issaquah, WA. The secondary location for this validation was conducted at a rented marketing research company of Schlesinger Group in Los Angeles (10880 Wilshire Blvd. Suite 1100, Los Angeles, CA 90024), also set up as a simulated clinical ultrasound environment. Schlesinger Group provided two rooms for the study. Similarly, test and training rooms were also set up in Issaquah. Siemens staff and contracted resources were responsible for the test sessions run in both Los Angeles and Issaquah. The clinical use environments simulated during validation testing were limited to the Ultrasound Scanning Room / Procedure Room as described in Compass VA10A Use Specification. This allowed the test to cover the high risk workflows associated with the system.

7.2 Test Items and Equipment

Test rooms were set up to simulate key aspects of a clinical ultrasound scanning environment. Radiologists and sonographers typically conduct exams in such environments as described in the Compass VA10A Use Specification. The rooms at both locations contained all test items listed in Table 3 and the supplemental materials listed in Sections 12.2 and 12.3 which were needed for testing. The test rooms did not include other non-ultrasound equipment such as life-support systems or other medical devices. Room lighting was set to a high (bright) level similar to facilities where puncture procedures (such as biopsy) are performed in order to help generate a realistic environment for the simulated use scenarios. The lighting levels were similar across test sites and between radiologist and sonographer sessions but were not specifically controlled to at a specific level. Ambient noise levels were low and similar across test sites and test sessions but were not specifically controlled in this study.

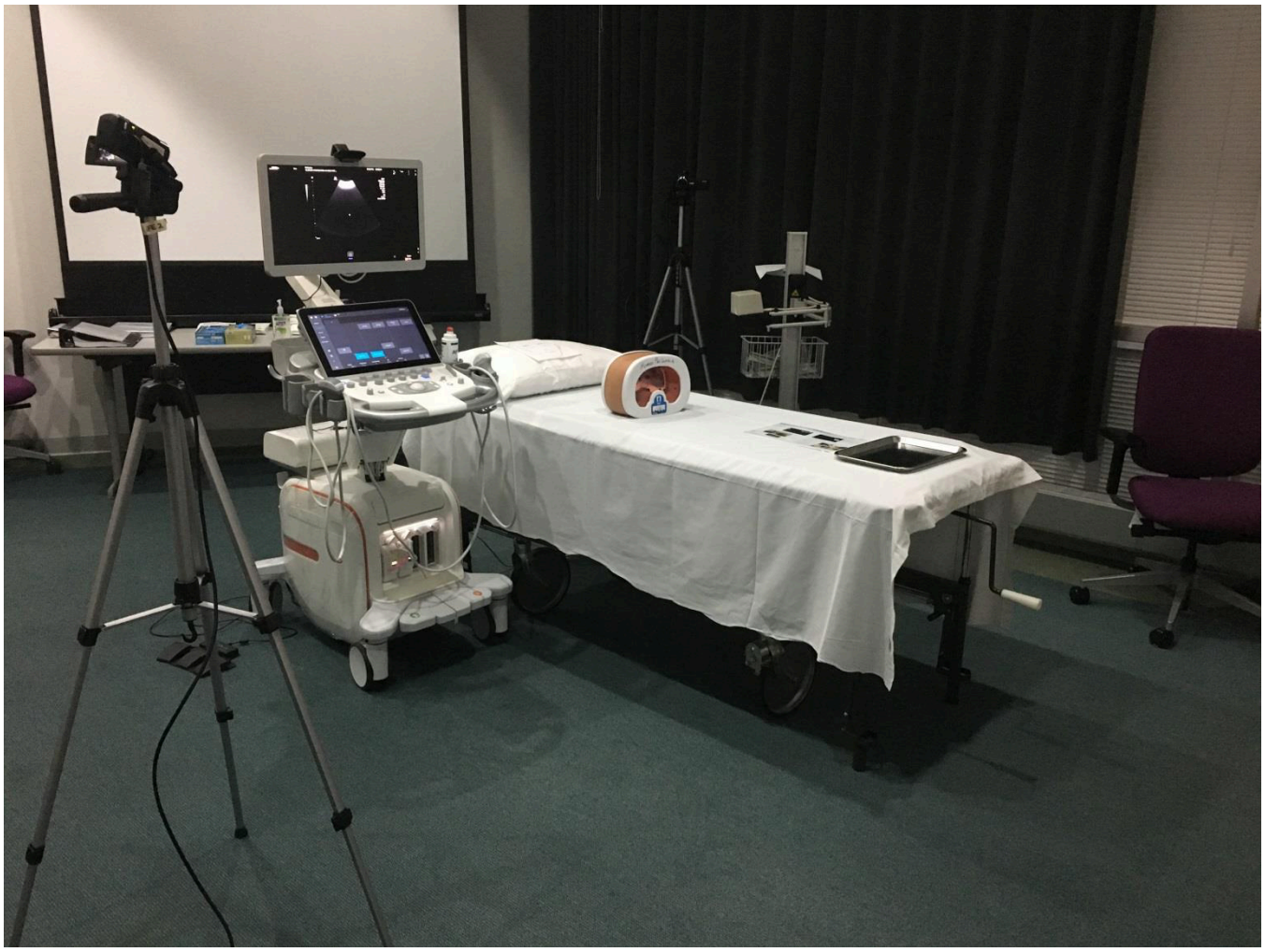


Figure 1. Room setup for radiologist scenario testing in Issaquah.

Production equivalent systems were used at both test sites (see Section 11.0). The serial numbers for all items used were documented using the protocol's Annex C (see Section 11.0). The software labeled build 1000.0.073 was installed on all systems used for all test sessions (see Section 11.0). Refer to the Compass VA10A Usability Engineering Summary Report for a description of software changes that occurred between build 1000.0.073 and the final software build for the product. All items that were made available for the use scenario are listed in Table 3.

Supplemental materials that supported the workflow of participants in each validation session were also used in the training and testing sessions in order to simulate the various use scenarios. To simulate scanning conditions, a multi-modality phantom was used as an alternative to a live patient. A phantom was needed for this study so participants could perform simulated use tasks that involved inserting biopsy and Fusion eTrax needles into a "simulated patient".

Table 3: Validation Items

Name	Part Number
Compass VA10A System	11287535
Software Version (Labeled Build)	Labeled Build 1000.0.073
DAX Transducer	10787116
9C3 Transducer	10787112
18L6 Transducer (Only for sonographers)	10787112
5C1 Transducer (Only for sonographers)	11291794
DAX Biopsy Bracket	11287652
9C3 Biopsy Bracket	10136145
18L6 Biopsy Bracket	10044200
5C1 Biopsy Bracket	11287651
VerzaLink Needle Guide Kits	610-1500-5
Ultra-Pro II Needle Guide Kits	610-608
General Purpose Sensor	10441627
eTRAX Needle Tracking Sensor Kit	10441628
eTRAX Needles	610-1057
Mid-Range Transmitter	10441625
Fusion Electronics Unit	11287532 (upgraded kit)
Compass User and Reference Manuals	11288517
Verza Guidance System Reference Guide: Tracking Bracket for use with Siemens DAX and 5C1 transducers	043-811A
Ultra-Pro II™ Needle Guidance System for use with Siemens transducers, Reference Guide (for support of 9C3 and 18L6 transducers)	610-608
General Purpose Sensor Reference Guide	043-729G
eTRAX Needle System Reference Guide	043-721M
Fusion Imaging with eTRAX Quick Reference Guide	11147457-EFT-061-04 Annex F-4 11147457-EFT-062-03 Annex F-4

7.3 Participants

7.3.1 Summary

For this validation testing, sonographers and radiologists were recruited as a representative sample of all clinical user groups. For this study, a total sample size of 35 for all user populations was used across the two testing facilities. Specifically, 13 interventional radiologists and 12 sonographers were tested at Siemens facilities in Issaquah. Additionally, 5 interventional

radiologists and 5 sonographers were tested at the rented facilities of Schlesinger Group in Los Angeles (10880 Wilshire Blvd. Suite 1100, Los Angeles, CA 90024).

7.3.2 Participant Demographics

A total of 18 Interventional Radiologist and 17 Sonographers participated in this usability validation. The following tables summarize the demographic distribution of participants that were recruiter across the two facilities. Complete demographic information for each participant can be found in Appendix B-1 and B-2.

Table 4: Radiologist Participant Demographics (*n* = 18)

Questionnaire Item	Participant Average	
Average Age Range	26-35 yrs	1 participant
	36-45 yrs	9 participants
	46-55 yrs	3 participants
	56-65 yrs	5 participants
Average Years Of Supporting/Performing Ultrasound Guided Procedures	16.7 years (Range: 4 to 42 years)	
Primary Systems (some participants indicated that they have more than 1 primary system)	GE	7
	Philips	12
	Siemens	7
	Toshiba	2
	Sonosite	3
	Veno	1
Scanning Hand	Right	9
	Left	3
	Both	6
Vision	Normal	7
	Corrected	11
Color Blindness	No	18
	Yes	0

Table 5: Sonographer User Group Demographics (*n* = 17)

Questionnaire Item	Participant Average	
Average Age Range	18-25 yrs 26-35 yrs 36-45 yrs 46-55 yrs	2 participants 6 participants 6 participants 3 participants
Average Years Of Supporting/Performing Ultrasound Guided Procedures (4 out of 17 participants did not respond to this question)	13 years (Range: 1 to 25 years)	
Primary System (some participants indicated that they have more than 1 primary system)	GE Philips Siemens Toshiba Mindray	7 13 2 3 1
Scanning Hand	Right Left Both	15 0 2
Vision	Normal Corrected	11 6
Color Blindness	No Yes	17 0

7.4 Training

All participants received training that is representative of the training that would be expected for users in their clinical environment.

The personnel that delivered training for this usability validation were internal Siemens technical staff familiar with the Compass system. Trainers included two clinical specialists (Shauna Seiber and Peter Prince), a test engineer (Jason Roberts), and the lead software engineer (Neerja Baru) that is responsible for the development of the Fusion feature. Training sessions started by having participants fill out a Non-Disclosure Agreement and a Demographics Questionnaire. In each training session, trainers followed training scripts and checklists and gave participants knowledge checks after each training topic. The tables below outline the training sessions that corresponded to each user group.

Table 6: Radiologist Training Session Overview

Radiologists were trained individually
1. Welcome participant and training environment orientation.
2. Complete Non-Disclosure Agreement
3. System Overview training and hands-on practice
4. Biopsy training and hands-on practice

5. Fusion application training and hands-on practice
6. 1 to 5 practice exams with the trainer present and available to provide guidance

Table 7: Sonographer Training Session Overview

Sonographers were trained individually or in pairs
1. Welcome participant and training environment orientation.
2. Complete Non-Disclosure Agreement
3. System Overview training and hands-on practice
4. Biopsy training and hands-on practice
5. Fusion equipment training and hands-on practice
6. 1 to 5 practice exams with the trainer present and available to provide guidance

All participants received 4 to 9 hours of training on a day different from their scheduled test sessions, as detailed in Table 8. After each training day, participants were then asked to come back for the test session within the next 7 days to allow for learning decay. The minimum decay time for participates was 16 hours (the next day).

Table 9: Participant Training Durations

Radiologists			Sonographers	
Participant ID	Training Duration		Participant ID	Training Duration
RAD01	5hrs 10mins		VS01	5hrs
RAD02	6hrs 30mins		VS02	8hrs
RAD03	4hrs		VS03	8hrs 10mins
RAD04	5hrs 45mins		VS04	8hrs 15mins
RAD05	5hrs		VS05	8hrs 15mins
RAD06	6hrs 15mins		VS06	7hrs 30mins
RAD07	5hrs 35mins		VS07	8hrs
RAD08	5hrs 30mins		VS08	8hrs
RAD09	7hrs 51mins		VS09	6hrs 45mins
RAD10	6hrs		VS10	6hrs 45mins
RAD11	6hrs 30mins		VS11	8hrs
RAD12	7hrs 30mins		VS12	6hrs 10mins
RAD13	9hrs		VS01-LA	7hrs 20mins
IR01-LA	9hrs 15mins		VS03-LA	7hrs 55mins
IR02-LA	6hrs		VS04-LA	7hrs 55mins
IR03-LA	6hrs 45mins		VS05-LA	7hrs
IR04-LA	6hrs 20mins		VS06-LA	7hrs 10mins
IR05-LA	7hrs 10mins		-	-

7.5 Test Sessions

The duration of test sessions lasted up to 3 hours for radiologists and 2.5 hours for sonographers. Test participants completed three simulated use scenarios. Participants also experienced Debrief Interviews, and provided answers to Post-Test Questionnaires. An overview of test sessions for both user groups are outlined in Table 10 and Table 11. The documents used during participant sessions can be found in the Compass VA10A Radiologist Usability Validation Protocol and the Compass VA10A Sonographer Usability Validation Protocol.

7.5.1 Test Personnel

Validation test personnel consisted of the moderator, note-taker, and actor. Specifically, the moderator was positioned near the participant and test system to prompt tasks and use scenarios for the participant. Moderators followed the test protocols to ensure consistency across all test sessions. The note-taker was also positioned near the participant and test system to observe interactions and note performances and comments. Similar to moderators, note-takers also followed the scenario protocol to ensure inter-rater consistency. Moderators and note-takers have training in human factors, systems, and/or biomedical engineering, or related clinical field.

During test sessions, the sonographer user group had an actor playing the role of a radiologist and the radiologist participants had an actor playing the role of a sonographer. The actors followed the test protocol.

7.5.2 Simulated Use Scenarios

Each validation session consisted of three main use scenarios to assess use safety and usability of the system.

- General imaging and biopsy with first randomized transducer
- General imaging and biopsy with second randomized transducer
- Fusion with eTrax

The study moderator and note-taker stayed in the room with the participant throughout the entire test session. The moderator occasionally interrupted the participant to provide instructions.

The tables below outline the high-level tasks in the radiologist and sonographer protocols.

Table 10: Radiologists Test Session Overview

Radiologists' Protocol (3.5 hour test session) Actor: Sonographer
1. Welcome and test environment orientation.
2. General Imaging and Biopsy tasks – Part 1 Biopsy procedures
3. General Imaging and Biopsy tasks – Part 2 Biopsy procedures
4. Biopsy Debrief Interview and Post-Test Questionnaire
5. Fusion with eTrax eTrax needle sensor preparation; Fusion image planning and image alignment; Interventional procedures
6. Fusion Debrief Interview and Post-Test Questionnaire
7. Thanking participants for their interest and involvement in the study

Table 11: Sonographers Test Session Overview

Sonographers' Protocol (2.5 hour test session) Actor: Radiologist
1. Welcome and test environment orientation.
2. General Imaging and Biopsy tasks – Part 1 Biopsy accessories assembly; General scanning tasks
3. General Imaging and Biopsy tasks – Part 2 Biopsy accessories assembly; General scanning tasks
4. Fusion with eTrax Patient data management; Fusion hardware connections;

Patient's image preparation; eTrax needle sensor preparation
5. Debrief Interview and Post-Test Questionnaire
6. Thanking participants for their interest and involvement in the study

7.6 Data Collection and Analysis

Throughout the simulated use scenarios, the note-taker tracked and recorded the participants' performance on tasks. Interactions with the system or components, and any verbal comments made by the participants were recorded on the note-taker datasheet. Video cameras were also set up in the test rooms to record each validation session. Performance on each task and its sub-task were categorized according to the following criteria and definitions:

Table 12: Task Performance Categorization

Rating	Description
Correct Use	Normal use without use error.
Use Difficulty	When a user appears to be confused and struggled to perform a task. Use difficulty might also appear as multiple attempts to perform the same task, comments about the task's difficulty, requests for assistance with the task, or facial expressions and vocalizations that suggested frustration or confusion. Ultimately, the user completes the tasks independently without assistance.
Close Calls	Instances in which a user has difficulty or made a use error that could have resulted in harm, but took an action to "recover" and prevented the harm from occurring.
Use Error	User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by device failure and (3) did or could result in harm.

Failures are defined as either a Use Error or Close Call. Passes are defined as either a Correct Use or a Use Difficulty.

The methods used to assess participant performance were:

- Observations made by the note-taker and study moderator.
- Self-reporting by test participants during debrief interview.

The tasks included in each scenario, including the critical tasks and their associated harms, are documented in the Compass VA10A Task Analysis. The task analysis associates the Task ID with the Risk Hazard Analysis Hazard ID for tasks that are critical tasks.

Use errors, close calls, and use difficulties during critical tasks were analyzed to determine root causes. Root cause analysis was performed to understand the cause of the error and effectiveness of existing mitigation. The residual risks will be evaluated by the risk team identified in the risk management plan (11147457-EGA-010-06). The findings of the residual risk analysis will be summarized in the Compass Product Analysis and Report of Hazards and Risks.

8.0 Study Deviations

8.1 Transducer Randomization

Randomization tables were created to balance the order in which participants used transducers across the two biopsy tasks. Each transducer has a unique bracket model. Two styles of needle guide brackets were tested:

- Verza Link that attaches to the DAX and 5C1 transducer
- Ultra-Pro II that attaches to the 9C3 and 18L6 transducer

Participants were required to perform two simulated biopsy scenarios to use each of the two bracket styles. The transducer/bracket combination in test sessions was randomized to ensure that participants exercised each needle guide bracket style.

The randomization deviations for the studies already conducted were reviewed after approximately 20 participants had already been tested. The executed run list was compared against the randomization table. In each case, Sonographer and Radiologists, the randomization was put into place to balance the order of presentation of the Verza Link and Ultra-Pro II biopsy brackets. Two possible presentation orders had to be balanced to ensure the risk of order effect was reasonably minimized in the study. The order is either Verza Link followed by Ultra-Pro II, or Ultra-Pro II followed by Verza Link. A count of participants in each condition was established based upon the record for each executed run. Then the count was compared against the remaining scheduled runs, which were adjusted to allow for an equal count of each condition for each user group. No randomization changes were required for the radiologist user group. Adjustments were made to the Sonographer group to perform additional runs in the Verza first condition.

Table 13: Radiologist Distribution across Transducers/Brackets

DAX/Verza First	9C3/Ultra-Pro II First
10	8

Note: According to the randomization table IR01-LA should have used the 9C3 transducer first, but instead used the DAX transducer first.

Table 14: Sonographer Distribution across Transducers/Brackets

	Verza		Ultra-Pro II	
	DAX	5C1	9C3	18L6
First Transducer	2	6	7	2
Second Transducer	6	3	3	5

Note: According to the randomization table VS06 should have used the 5C1 transducer followed by the 9C3 transducer, however the 18L6 transducer was used instead of the 9C3 transducer. table VS01-LA should have used the 9C3 transducer followed by the 5C1 transducer, however the DAX transducer was used instead of the 5C1 transducer. VS03-LA should have used the 9C3 transducer followed by the DAX transducer, however the 5C1 transducer was used instead of the DAX transducer. VS04-LA should have used the 9C3 transducer followed by the DAX transducer, however they used the DAX transducer followed by the 18L6 transducer. VS05-LA should have used the 5C1 transducer followed by the 9C3 transducer, however they used the 9C3 transducer followed by the DAX transducer. VS06-LA should have used the DAX transducer followed by the 9C3 transducer, however the DAX transducer was used instead of the 5C1 transducer.

8.2 eTrax Needles

This validation test was run with 3 test teams across 2 sites which created the need for many eTrax needles. The team used many eTrax needles, some of which were production equivalent whereas others were not. Visual inspection of the needles showed them to be equivalent physically

and from a user interaction standpoint. The only visible difference was in the color and texture of the white handle of the eTrax, and the presence/absence of a marking on the white handle indicating the gauge of the needle.

Figure 2. a) Stamped eTrax and b) unstamped eTrax.

8.3 Radiologist Training in Los Angeles

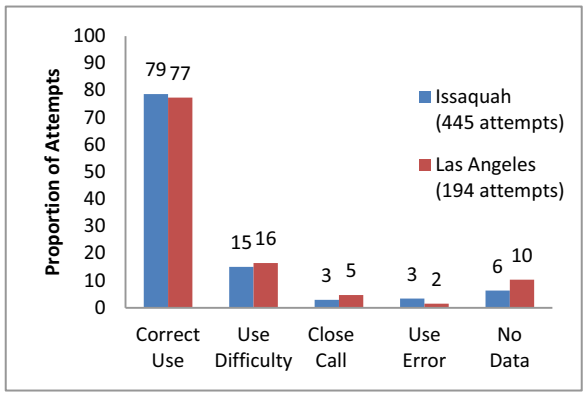
A system availability issue came up at the Los Angeles location that created the need for a radiologist and a sonographer to be trained together. Otherwise, all radiologists were trained individually. Radiologist are more likely to be trained separately from sonographers it is not uncommon for a radiologist to receive training at the same time as other clinical staff.

8.4 Los Angeles Data Collection

Test sessions in Los Angeles were run with less structure and rigor than test sessions in Issaquah. Videos of test sessions taken in LA were reviewed and, if needed, rescored by the Issaquah team to ensure consistency across sites in the data. This also ensured inter-rater consistency between all participants.

The performance results from both sites was compared. The resulting frequency of correct use, use difficulties, close calls and use errors of the Los Angeles participants was comparable to the Issaquah., The 2 data sets were combined (see Figure 2 for radiologist and Figure 3 for sonographers).

a)



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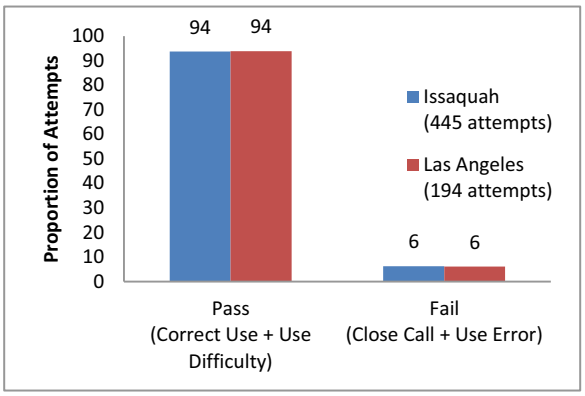
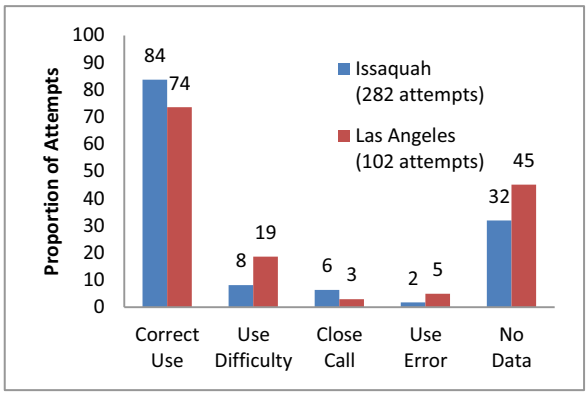


Figure 2. Radiologist a) task performance rates by site and b) pass/fail rates by site.

a)



b)

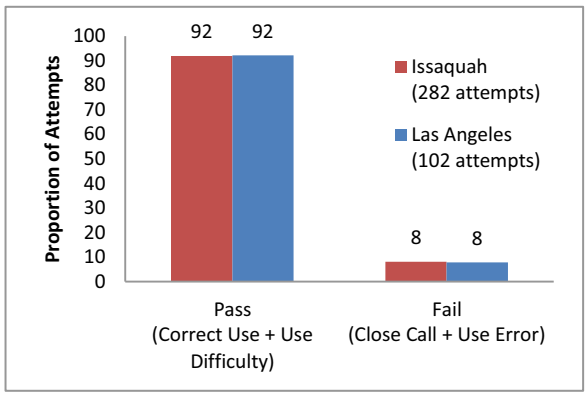


Figure 3. Sonographer a) task performance rates by site and b) pass/fail rates by site

9.0 Results

9.1 Performance Summary

Eighteen (18) radiologists and seventeen (17) sonographers completed a series of simulated use scenarios for general imaging, biopsy and fusion.

Radiologist task performance :

- 2 of 18 participants were able to perform all tasks with no close calls or use errors (with no failures).
- 5 of 18 participants were able to perform all tasks with no use errors.
- Of the 35 critical tasks tested, 11 tasks had a use error rate above 5%.
- 18 of 35 tasks were performed with no use errors or close calls.
- Detailed Radiologist task performance is further summarized in

Sonographer task performance :

- 3 of 17 participants were able to perform all tasks with no close calls or use errors (with no failures).
- 10 of 18 participants were able to perform all tasks with no use errors.
- Of the 23 critical tasks tested, 4 tasks had a use error rate above 5%.
- 10 of 23 tasks were performed with no use errors or close calls.
- Detailed Sonographer task performance is further summarized in Table 15 and Table 16.

The number of attempts, correct use, use difficulty, close calls, use errors for tasks that are associated with potential for serious harm (i.e., a critical task) are counted and summarized in the following tables (Table 15 and Table 16). The protocol scenario steps are identified as Step ID's and each is identified as a critical task. For tasks within the two biopsy scenarios that were performed using the randomized order of bracket styles, Verza and Ultra-Pro II, participant performances are grouped according to the type of bracket used under the Step ID column. Table 15 below indicates performance data for both radiologist and sonographer user groups within the general imaging and biopsy use scenarios, while Table 16 summarizes performance data for tasks completed within the Fusion scenario for both user groups . The column labelled "No data" indicates occurrences when data was not available for reasons such as:

- moderator missed the preparation or prompting step
- hardware unavailable
- limited applicability of the scenario (test artifact)
- performance could not be confirmed by video review (for Los Angeles participants)

- For all critical tasks that have a performance rating of "Fail" (tasks that had close calls or use errors) in the tables below, an analysis of each use problem's root cause based on participant is addressed in Section 9.2.

The number of attempts, correct use, use difficulty, close calls, use errors for tasks that are associated with potential for serious harm (i.e., a critical task) are counted and summarized in the following tables. The protocol scenario steps are identified as Step ID's and each is identified as a critical task. For tasks within the two biopsy scenarios that were performed using the randomized order of bracket styles, Verza and Ultra-Pro II, participant performances are grouped according to the type of bracket used under the Step ID column. Table 15 below indicates performance data for both radiologist and sonographer user groups within the general imaging and biopsy use scenarios, while Table 16 summarizes performance data for tasks completed within the Fusion scenario for both user groups . The column labelled "No data" indicates occurrences when data was not available for reasons such as:

- moderator missed the preparation or prompting step
- hardware unavailable
- limited applicability of the scenario (test artifact)
- performance could not be confirmed by video review (for Los Angeles participants)

For all the critical tasks that have a performance rating of "Fail" (tasks that had close calls or use errors) in the below tables, an analysis of each use problem's root causes based on participant is addressed in Section 9.2.

Table 15: Radiologists and Sonographers General Imaging and Biopsy Critical Task Performance

Task ID - Description	Hazard ID	User Group	Step ID	No. of Attempts	Correct Use	Use Difficulty	Close Calls	Use Error	No data	Failure Rate (%)	Error Rate (%)	Pass / Fail
TA074 - Freeze image	4.5.0, 4.6.0	Radiologist	R9C3-17	13	12	0	1	0	5	8	0	Pass
		Sonographer	GI01-007	15	15	0	0	0	2	0	0	Pass
TA084 - Perform measurements	6.8, 6.11	Radiologist	R9C3-05	18	13	5	0	0	0	0	0	Pass
			RDAX-05	17	17	0	0	0	1	0	0	Pass
		Sonographer	GI01-011	17	15	1	1	0	0	6	0	Pass
TA114 - Delete Images	7.9.1	Sonographer	GI01-015	15	12	3	0	0	2	0	0	Pass
TA133 & TA136 - Clean and Disinfect the system and transducers	N/A	Sonographer	GI01-021	15	15	0	0	0	2	0	0	Pass
TA156 - Attach Bracket to Transducer	4.1.0, 4.1.2	Radiologist	R9C3-10 & RDAX-10 Verza	18	13	4	1	0	0	6	0	Pass
			RDAX-10 & R9C3-10 Ultra-Pro II	18	15	3	0	0	0	0	0	Pass
TA157 - Attach Needle Guide to Bracket	4.1.0, 4.1.2	Radiologist	R9C3-14 & RDAX-14 Verza	18	9	8	1	0	0	6	0	Pass
			RDAX-14 & 9C3-14 Ultra-Pro II	18	9	8	1	0	0	6	0	Pass
TA156 & TA157 - Prepare transducer and attach Needle Guide	4.3.5, 4.4.5	Sonographer	B01-002 & B02-002 Verza	17	12	4	1	0	0	6	0	Pass
			B02-002 & B01-002 Ultra-Pro II	17	5	9	2	0	0	12	0	Pass
TA159, TA174, TA176, TA187 - Set Needle Guide Angle and match it onscreen	4.3.5, 4.3.6, 4.4.5, 4.4.6	Radiologist	R9C3-20 & RDAX-18 Verza	18	17	0	0	1	0	6	6	Fail
			RDAX-18 & R9C3-20 Ultra-Pro II	18	15	1	1	1	0	11	6	Fail
TA161 - Place Needle gauge insert	4.3.5, 4.4.5, 4.3.6	Radiologist	R9C3-28 & RDAX-24 Verza	18	13	4	1	0	0	6	0	Pass
			RDAX-24 R9C3-28 Ultra-Pro II	18	17	0	1	0	0	6	0	Pass
TA171 - Activate Biopsy Mode	4.3.5, 4.4.5, 4.3.6	Radiologist	R9C3-18	18	16	2	0	0	0	0	0	Pass
			RDAX-16	18	18	0	0	0	0	0	0	Pass
		Sonographer	B01-007	17	16	1	0	0	0	0	0	Pass
			B02-007	16	15	1	0	0	1	0	0	Pass
TA174 - Select correct angle	4.3.6, 4.4.6	Sonographer	B01-009	17	17	0	0	0	0	0	0	Pass
			B01-011	17	17	0	0	0	0	0	0	Pass
			B02-009	17	15	0	2	0	0	12	0	Pass
			B02-011	17	17	0	0	0	0	0	0	Pass

Task ID - Description	Hazard ID	User Group	Step ID	No. of Attempts	Correct Use	Use Difficulty	Close Calls	Use Error	No data	Failure Rate (%)	Error Rate (%)	Pass / Fail
TA178 - Confirm angle selection	4.3.5, 4.4.5	Radiologist	R9C3-21	18	18	0	0	0	0	0	0	Pass
			RDAX-19	18	17	1	0	0	0	0	0	Pass
TA181, TA 184 - Calculate appropriate length of needle required to perform biopsy	4.11.1, 4.11.4, 4.12.1, 4.12.4	Radiologist	R9C3-23	18	16	0	0	2	0	11	11	Fail
			R9C3-25 (Optional)	11	10	1	0	0	7	0	0	Pass
TA184 - Use Minimum Needle Length feature	4.11.1, 4.12.1	Sonographer	B01-014	17	16	0	0	2	0	12	12	Fail
			B02-014	17	16	0	0	1	0	6	6	Fail
TA190 - Insert needle to reach biopsy target	4.11.1, 4.11.3, 4.12.3	Radiologist	R9C3-30	18	17	1	0	0	0	0	0	Pass
			RDAX-25	18	10	4	3	1	0	22	6	Fail

Table 16: Radiologists and Sonographers Fusion Critical Task Performance

Task ID and Description	Hazard ID	User Group	Step ID	No. of Attempts	Correct Use	Use Difficulty	Close Calls	Use Error	No data	Failure Rate (%)	Error Rate (%)	Pass / Fail
TA212 - Attach transmitter cube to the tracking system	7.14.1	Sonographer	eT-002	16	13	2	1	0	1	6	0	Pass
TA214 - Attach the transducer sensor to the tracking system	4.3.3, 4.4.3	Sonographer	eT-003	16	10	2	4	0	1	25	0	Pass
			eT-007	15	14	0	1	0	2	7	0	Pass
TA217 - Connect the needle sensor to port 4 on the Fusion tracking system	4.3.3, 4.4.3	Sonographer	eT-016	17	9	4	4	0	0	24	0	Pass
TA219 - Attach Fusion/Biopsy bracket to transducer	4.1.0, 4.2.0	Sonographer	eT-008	17	14	3	0	0	0	0	0	Pass
TA222 - Attach transducer sensor to the Fusion/Biopsy bracket	4.3.3, 4.4.3	Sonographer	eT-009	17	15	1	1	0	0	6	0	Pass
TA227 - Ensure sensor tracks transducer and needle correctly	4.3.3, 4.3.4, 4.5.6, 4.6.6, 4.9.0	Radiologist	RF-054	16	13	1	1	1	2	13	6	Fail
		Sonographer	eT-013	16	14	1	0	1	1	6	6	Fail
TA231 - Tracking quality	4.3.4, 4.4.4, 4.10.0, 4.10.4	Radiologist	RF-022	15	14	1	0	0	3	0	0	Pass
TA240 - Load images for Fusion	4.9.4, 4.10.4	Radiologist	RF-008	18	15	3	0	0	0	0	0	Pass
		Sonographer	eT-011	18	16	2	0	0	0	0	0	Pass
TA301 - Reset Alignment	4.9.4, 4.10.4	Radiologist	RF-039	15	9	5	0	1	3	7	7	Fail
TA303 - Activate Scan mode to use functions	4.3.4, 4.4.4, 4.9.4, 4.10.4	Radiologist	RF-041	18	10	8	0	0	0	0	0	Pass
TA307 - Pan image	4.7.0, 4.8.0	Radiologist	RF-043	11	5	3	2	1	7	27	9	Fail
TA326 - Insert needle sensor into needle	8.4.4	Radiologist	FeT-003	18	15	3	0	0	0	0	0	Pass

Task ID and Description	Hazard ID	User Group	Step ID	No. of Attempts	Correct Use	Use Difficulty	Close Calls	Use Error	No data	Failure Rate (%)	Error Rate (%)	Pass / Fail
TA327 - Lock needle sensor onto needle handle	8.4.4	Radiologist	FeT-004	17	15	2	0	0	1	0	0	Pass
TA326 & TA327 - Insert and lock needle sensor into needle	8.4.4	Sonographer	eT-019	14	9	1	2	2	3	29	14	Fail
TA328 - Track real-time needle position where needle sensor is in relation to the ultrasound/reference image	4.3.4, 4.4.4	Radiologist	FeT-006	18	14	4	0	0	0	0	0	Pass
			FeT-007	18	18	0	0	0	0	0	0	Pass
TA333 - Activate Needle Tip Graphics	4.5.0, 4.5.6	Radiologist	FeT-012	17	14	1	0	2	1	12	12	Fail
TA332 - Insert and direct needle to reach biopsy target	4.3.4, 4.4.4, 4.11.0	Radiologist	FeT-009	18	11	7	0	0	0	0	0	Pass
TA338 - Unscrew and removing the stylet hub (with needle sensor attached)	4.1.2	Radiologist	FeT-010	17	8	1	5	3	1	47	18	Fail
TA340 - Insert biopsy needle inside the cannula	4.12.3	Radiologist	FeT-011	17	10	4	2	1	1	18	6	Fail
TA362 & TA363 - Fuse reference image to ultrasound	4.9.4, 4.10.4, 4.10.0	Radiologist	RF-024	18	11	6	0	1	0	6	6	Fail
TA364 - Use Point method during Alignment	4.3.4, 4.4.4, 4.9.4, 4.9.0, 4.10.4	Radiologist	RF-030	16	11	3	0	2	2	13	13	Fail

9.2 Use Error and Close Call Analysis

All use errors and close calls on critical tasks were reviewed by the Human Factors Engineering team to determine root cause and potential solutions. The results of the root cause analysis are provided below.

The issues identified during the root cause analysis will be documented as defects according to the TFS Defect Management Work Instruction. The risk team identified in the risk management plan (11147457-EGA-010-06) will conduct the residual risk analysis (RRA). The findings of the RRA will be summarized in the Compass Product Analysis and Report of Hazards and Risks.

Table 17: Root Causes

Task ID	Hazard ID	Test Objective	Correct Use/ Use Difficulty/ Close Call/ Use Error	Step ID	Participant	Issue	Root Cause	Defect #
TA074	4.5.0, 4.6.0	Participant notices that the system entered freeze (moderator tapped footswitch).	Close Call	R9C3-17	RAD01	Participant didn't notice the system was frozen via the footswitch but selected exam type on transducer menu which unfroze the image.	• Participant was in the middle of a non-scanning task (looking for button to enable Biopsy) and was therefore not looking at the image. • The system does not provide enough guidance for new/inexperienced users	Defect 826151
TA084	6.8, 6.11	Participant can place the measurement caliper and confirm the measurement.	Close Call	GI01-011	VS09	Participant turned off caliper feature instead of setting the active caliper. Participant restarted measurements and figured it out the second time.	• Negative transfer from competitor products • The system does not provide enough guidance for new/inexperienced users	Defect 826149
TA156	4.1.0, 4.1.2	Participant assembles the biopsy kit and confirms bracket is applied correctly	Close Call	RDAX-010 with Verza	RAD01	Participant didn't open the latch at first but recovered and figured it out.	• Needing to open the latch not obvious enough • Negative transfer from push-on brackets • The IFU does not provide enough guidance for new/inexperienced users	Defect 826145; Defect 826146
TA157	4.1.0, 4.1.2	Participant attaches the needle angle guide to the bracket.	Close Call	RDAX-14 With Ultra-Pro II	RAD09	Participant checked needle angle guide to make sure it was secured on the bracket but it was not secured. The guide fell off in step RDAX-24.	• The instructions for how to attach, assemble and lock in an angle are printed on the non-sterile outer package, which would most likely not be available to the user during use of the guide.	Defect 826145; Defect 826146
			Close Call	R9C3-14 with Verza	RAD07	Participant attached the needle angle guide to the bracket and started to place the sheath over it but then took the bracket out before applying sheath.	• The instructions for how to attach, assemble and lock in an angle are printed on the non-sterile outer package, which would most likely not be available to the user during use of the guide.	Defect 826145; Defect 826146
TA156, TA157	4.3.5, 4.4.5	Participant assembles the biopsy kit and confirms the Transducer Bracket is applied correctly.	Close Call	B01-002 with Ultra-Pro II	VS07	Participant was not sure because it was labeled 8C3 (instead of 9C3). Participant grabbed 5C1 bracket and tried it but could see it was wrong bracket. Participant checked sensor boxes and eventually, correctly selected the 8C3 bracket.	• The bracket is labeled 8C3 but the transducer is labeled 9C3	Defect 826133; Defect 826134
			Close Call	B01-002 with Verza	VS04-LA	Participant needed prompting from the actor who asked if angle guide should go under or over the sheath.	• Needle guide labeling does not adequately inform users that the guide is only good for one use • The needle guide instructions are on the non-sterile package, which may not be available at the time of application	Defect 826133; Defect 826134
			Close Call	B02-002 with	VS06-LA	Participant forgets to lock the bracket and put the sterile sheath on then takes it off and attaches.	• The bracket requires more force than the user expected to lock in place	Defect 826133; Defect 826134

Task ID	Hazard ID	Test Objective	Correct Use/ Use Difficulty/ Close Call/ Use Error	Step ID	Participant	Issue	Root Cause	Defect #
				Ultra-Pro II				
TA159, TA174, TA176, TA187	4.3.5, 4.3.6, 4.4.5, 4.4.6	Participant synchronize the onscreen display and angle guide angles	Use Error	RDAX-18 with Ultra-Pro II	RAD09	Participant did not check physical guide.	• The message box to check physical is synced to system does not draw users' attention or give indication of the severity of not having the two synced	Defect 826133; Defect 826134; Defect 826135
			Use Error	RDAX-18 with Verza	RAD13	Participant did not lock angle guide	• Verza needle guide is not locked to an angle from the sterile package, which could cause the user to assume they do not need to lock the angle selector. • The instructions for how to attach, assemble and lock in an angle are printed on the non-sterile outer package, which would most likely not be available to the user during use of the guide.	Defect 826133; Defect 826134
			Close Call	RDAX-18 with Ultra-Pro II	IR04-LA	Participant was about to start scanning before the Actor asked if the participant can verify it, the participant then realized he was on angle “A” on the physical guide, participant then successfully changed angle.	• The message box to check physical is synced to system does not draw users' attention or give indication of the severity of not having the two synced	Defect 826133; Defect 826134
TA161	4.3.5, 4.4.5, 4.3.6	Participant selects the needle gauge insert and correctly inserts it into the needle guide.	Close Call	R9C3-28 with Verza	IR01-LA	Participant inserted 16G needle gauge insert into angle guide (completed before R9C3-18). Needle insert was not locked into guide properly, participant realized and corrected himself when he was about to insert needle into guide to perform biopsy.	• The system and the informational insert for the needle guide do not provide enough guidance for new/inexperienced users	Defect 826133; Defect 826134
			Close Call	RDAX-24 with Ultra-Pro II	IR04-LA	Participant completed this step in RDAX-14. Tried to put insert into guide from the other end, quickly corrected himself. When participant tried to put needle through insert, he realized he used a 17G needle gauge insert as he couldn't get the needle to go into needle guide, realized he was wrong and took out 17G insert. At this point, the participant is distracted, participant then took 18G needle gauge insert, which was also too small, participant had a 16G biopsy needle. P eventually recovered.	• The gauge insert labeling is the same color as the background and is in a position that can be covered while using	Defect 826133; Defect 826134
TA174	4.3.6, 4.4.6	Participant can select the correct angle on the touch screen.	Close Call	B02-009 with Verza	VS01	Participant selected angle 4, and hit OFF instead of OK to confirm the angle selection, but corrected it before needle insertion.	• The buttons are easily confused as they both start with "O" and are the same color.	Defect 826134; Defect 826136; Defect 826135
			Close Call	B02-009 with Verza	VS11	Participant selected the correct angle and hit OFF instead of OK to confirm the angle selection, but then went back and chose 3 and hit OK.	• The buttons are easily confused as they both start with "O" and are the same color.	Defect 826134; Defect 826136
TA181, TA184	4.11.1, 4.11.4, 4.12.1, 4.12.4	Participant can identify the needle length needed	Use Error	R9C3-23 With Verza	RAD04	Participant measured the distance from skin line to the lesion but didn’t account for the dead zone due to the biopsy bracket.	• The system does not inform the user of the dead zone distance of 5cm • The feature is not prominent enough on the display	Defect 826137
			Use Error	R9C3-23 with Ultra-Pro II	RAD08	Participant acknowledged he didn't account for bracket and needle guide when he originally asked for 10cm needle as his measurement indicated that it is 6cm from skin line.	• The system does not inform the user of the dead zone distance of 5cm • The feature is not prominent enough on the display	Defect 826137
TA184	4.11.4,	Participant can	Use Error	B01-014	VS03	Participant had Minimum Needle Length tool ON but	• The system does not inform the user of the dead zone	Defect 826152

Task ID	Hazard ID	Test Objective	Correct Use/ Use Difficulty/ Close Call/ Use Error	Step ID	Participant	Issue	Root Cause	Defect #
	4.12.4	scroll to the suspected lesion and announce the minimum needle length.				counted tick marks instead of using tool.	distance of 5cm • The feature is not prominent enough on the display • The participant misunderstood the feature included the distance between the skin line and the bracket	
			Use Error	B01-014	VS03-LA	Actor asked for wrong thing when asked for MNL 6.6 using calipers	• The system does not inform the user of the dead zone distance of 5cm • The feature is not prominent enough on the display • The participant misunderstood the feature included the distance between the skin line and the bracket	Defect 826152
			Use Error	B02-014	VS03	Participant turned OFF Minimum Needle Length tool and used calipers to measure the distance.	• The system does not inform the user of the dead zone distance of 5cm • The feature is not prominent enough on the display • The participant misunderstood the feature included the distance between the skin line and the bracket	Defect 826152
TA190	4.11.1, 4.11.3, 4.12.3	Participant uses the needle guide to perform the biopsy	Use Error	RDAX-025 with Ultra-Pro II	RAD04	Transducer was moved by the participant off the skin surface during needle insertion, which caused him to lose the image. Rad 04 then proceeded to perform a second needle insertion.	• Needle gauge insert of the needle guide does not have enough affordances for aging eyes, which can cause the user to move the transducer while attempting to insert the needle.	Defect 826147; Defect 826152; Defect 826153
			Close Call	RDAX-025 with Ultra-Pro II	IR01-LA	Participant forgot to pull needle out before taking biopsy. Participant corrected himself and successfully takes biopsy.	• The biopsy needle only has a change in length to indicate if it is engaged, which will change between different length needles	Defect 826147; Defect 826152; Defect 826153
			Close Call	RDAX-025 with Ultra-Pro II	IR04-LA	From step RDAX-24, participant almost directed biopsy needle into phantom with the wrong needle gauge insert. Participant eventually recovered, but when the needle reach target and when participant was about to perform biopsy, he realized he forgot to engage needle before firing.	• The biopsy needle only has a change in length to indicate if it is engaged, which will change between different length needles.	Defect 826147; Defect 826152; Defect 826153
			Close Call	RDAX-025 with Ultra-Pro II	IR05-LA	Needle was not engaged when participant directed it into the phantom, realized it, took out needle and re-poked. Saved 3 images during biopsy.	• The biopsy needle only has a change in length to indicate if it is engaged, which will change between different length needles.	Defect 826147; Defect 826152; Defect 826153
TA212	7.14.1	Participant attaches transmitter cube to the tracking system.	Close Call	eT-002	VS05	Participant went to attach transmitter cube to port 3 then corrected the issue.	• The Fusion box labeling is inadequate for new/inexperienced users	Defect 826138; Defect 826139; Defect 826140
TA214	4.3.3, 4.4.3	Participant attaches the transducer sensor to the tracking system.	Close Call	eT-003	VS03	Participant put sensor in port 4 but took it off right away. Participant then used Quick Reference Guide and tried the sensor in port 4 again and finally got it inserted. Participant eventually moved sensor to port 3.	• The Fusion box labeling is inadequate for new/inexperienced users • The amount of force needed to attach the cables to the Fusion box is more than expected by the user • There is no indication how to lineup the connectors when attaching the cables to the Fusion box	Defect 826142
			Close Call	eT-003	VS06	Participant attached transducer sensor to port 4 then moved to port 3 then to port 2 after referring to the Quick Reference Guide. Eventually connected fusion	• The Fusion box labeling is inadequate for new/inexperienced users • The system does not give enough guidance for	Defect 826142

Task ID	Hazard ID	Test Objective	Correct Use/ Use Difficulty/ Close Call/ Use Error	Step ID	Participant	Issue	Root Cause	Defect #
						sensor to port 4 to match 5C1 port.	new/inexperienced users	
			Close Call	eT-003	VS07	Participant had trouble connecting sensor. Referred to the Quick Reference Guide and then successfully performed the task.	• The amount of force needed to attach the cables to the Fusion box is more than expected by the user • There is no indication how to lineup the connectors when attaching the cables to the Fusion box	Defect 826142
			Close Call	eT-003	VS05-LA	Connected to port 4, moved to 3, then went to port 4, 2, and 3.	• The Fusion box labeling is inadequate for new/inexperienced users	Defect 826142
		Participant moves the transducer from port 4 to a different port for Fusion.	Close Call	eT-007	VS09	Participant saw the error message then initially moved transducer sensor to a different port before realizing that the she had confused eTrax sensor cord and the General Purpose Sensor cord. Participant then matched up the transducer and sensor ports correctly. and attached the eTrax sensor to port 4	• The Fusion box labeling is inadequate for new/inexperienced users • The system does not give enough guidance for new/inexperienced users • The eTrax and General Purpose Sensor cords look the same at the connector end making them easy to confuse	Defect 826142
TA217	4.3.3, 4.4.3	Participant attaches the needle tracking sensor.	Close Call	eT-016	VS03	Participant tried to attach sensor to port 4 but it didn't work. Participant used Quick Reference Guide and attached transducer sensor to port 4. Participant asked if they could move transducer because eTrax needs to be in port 4. Participant eventually got needle tracking sensor inserted into port 4.	• The Fusion box labeling is inadequate for new/inexperienced users • The amount of force needed to attach the cables to the Fusion box is more than expected by the user • There is no indication how to lineup the connectors when attaching the cables to the Fusion box	Defect 826142
			Close Call	eT-016	VS06	Participant vocalized: "Can't remember where this one goes. I think port 1". The participant then put it in 1, then changed it to port 4, went to refer to the QRG and moved it to 1. System showed an error message, and then participant moved it to 4. Participant moved needle sensor from port 4 to port 1, then moved transducer sensor to port 2 and then moved transducer to port 2.	• The Fusion box labeling is inadequate for new/inexperienced users • The system does not give enough guidance for new/inexperienced users	Defect 826142
			Close Call	eT-016	VS08	goes for IFU "this is where I forget where they go" after IFU put in port 2; after fusion started + using QRG moves to Port 4 Needle sensor in port 2. moved to port 4 why?	• The Fusion box labeling is inadequate for new/inexperienced users • The system does not give enough guidance for new/inexperienced users	Defect 826142
			Close Call	eT-016	VS09	Participant tried to put the eTrax needle onto the transducer bracket, then finds the eTrax needle instructions. Participant put the needle sensor and eTrax needle together without the sterile sheath. Participant then tried to attach it to the transducer again.	• The system does not give enough guidance for new/inexperienced users	Defect 826142
TA222	4.3.3, 4.4.3	Participant attaches transducer sensor to the bracket.	Close Call	eT-009	VS09	Participant tried to put the eTrax needle onto the transducer bracket, then corrected. However, participant had the sensor attached on backwards, it then fell off the bracket while the actor was scanning. Participant replaced it correctly on the bracket.	• The system and QRG do not give enough guidance for new/inexperienced users	Defect 826142
TA227	4.3.3,	Participant	Close Call	RF-054	RAD02	Participant did not see it but system failed to load	• The system does not accommodate the large workload	Defect 826155

Task ID	Hazard ID	Test Objective	Correct Use/ Use Difficulty/ Close Call/ Use Error	Step ID	Participant	Issue	Root Cause	Defect #
	4.3.4, 4.5.6, 4.6.6, 4.9.0	confirms tracking quality is acceptable				reference images and had to restart. Participant also did not see or commented on the tracking quality. Participant directly went to load volume.	needed to complete a Fusion exam • The system only gives a visual indication of the tracking quality	
			Use Error	RF-054	RAD06	Participant skipped this step and went to load images which resulted in the system going to Plan Mode where the quality indicators are not shown. The participant did not move the MRT cube within range before initializing the alignment.	• The system does not accommodate the large workload needed to complete a Fusion exam • The system only gives a visual indication of the tracking quality •	Defect 826155
		Participant sees and interprets the tracking indicator and corrects the quality of the tracking.	Use Error	eT-013	VS03-LA	The cube was correctly moved away, but the participant recognize that the loaded CT data set did not match with the phantom she was using during the session	• The system only gives a visual indication of the tracking quality • Participant was focused on understanding the differences in the dataset and not the tracking quality of the indicator • Test Artifact – the CT data that the participant successfully loaded did not match the phantom	Defect 826155
TA301	4.9.4, 4.10.4	Participant is able to reset Fusion alignment and start over	Use Error	RF-039	RAD01	Participant had to ask actor for help after the CT image was lost.	• The software does not provide enough indication to let the user know the alignment was complete (only cubes indicate the alignment has been completed), which can led to the user thinking there is a system issue rather than an alignment issue.	Defect 826154
TA307	4.7.0, 4.8.0	Participant can Pan the images	Close Call	RF-043	RAD04	Moderator asked the participant if he was satisfied with image, Participant said "yes".	• Test Artifact - This is an artificial task that is not needed when the whole needle path is visible to the participant	Defect 826161
			Close Call	RF-043	RAD08	Moderator prompts participant that different companies calls the pan feature differently. Moderator then says “it’s called pan the image”. Participant successfully activated pan & turned it off after.	• Test Artifact - This is an artificial task that is not needed when the whole needle path is visible to the participant	Defect 826161
			Use Error	RF-043	RAD07	Participant needed multiple hints but after figuring out the button name and pressed it, did not move the images with the trackball.	• This is an artificial task that is not needed when the whole needle path is visible to the participant • The participant did not understand the Moderator’s instruction to use the feature (Test Artifact)	Defect 826161
TA326, TA327	8.4.4	Participant assists with connecting the eTrax sensor to the eTrax needle.	Close Call	eT-019	VS07	Participant almost connected eTrax sensor to the eTrax needle with the cover on but Actor stopped the participant.	• The cover is hard to see and not easy to tell it needs to be removed prior to use.	Defect 826144
			Close Call	eT-019	VS11	Participant almost puts in tube, the Actor tells the participant that it is just the sensor.	• The cover is hard to see and not easy to tell it needs to be removed prior to use.	Defect 826144
			Use Error	eT-019	VS01-LA	not sterile A not sure what to do because needle already on eTrax; P puts on sheath + helps thread on needle	• Test Artifact – storage procedure led the participant to think that the eTrax sensor was sterile and ready for use.	Defect 826144
			Use Error	eT-019	VS06-LA	Participant attached the sensor to the eTrax needle before putting on the sheath.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users	Defect 826144
TA333	4.5.0, 4.5.6	Participant activates and uses needle tip graphics	Use Error	FeT-012	RAD06	Participant didn’t turn the feature on even after being asked to do so more than once by the Moderator. He thought the feature was already on when he was using the red – blue indicators.	• The participant misunderstood the needle tip graphics feature to be included in the needle tracking feature • The system do not provide enough guidance for new/inexperienced users	Defect 826148

Task ID	Hazard ID	Test Objective	Correct Use/ Use Difficulty/ Close Call/ Use Error	Step ID	Participant	Issue	Root Cause	Defect #
			Use Error	FeT-012	RAD12	Participant turned on the feature but did not use it. Participant did not understand what the green circle from the feature indicates.	• The system do not provide enough guidance for new/inexperienced users	Defect 826148
TA338	4.1.2	Participant unscrew the stylet hub to remove the trocar	Close Call	FeT-010	RAD03	Participant took out the eTrax sensor from trocar and asked for 18G. Participant left eTrax needle inside phantom, asked for a needle, then said he “completely forgot, should have taken out the whole stylet”; realized it and successfully removed stylet/trocar.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users • The design of The eTrax needle does not make The separation action intuitive to the user	Defect 826146
			Close Call	FeT-010	RAD07	Participant almost took out then eTrax sensor from the eTrax needle. The actor then prompt the participant that it is a trocar and a cannula. Participant successfully completed step after prompt.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users • The design of the eTrax needle does not make the separation action intuitive to the user	Defect 826146
			Close Call	FeT-010	RAD12	Participant tried to take needle sensor out, took it out and then tried to put the biopsy needle into the eTrax needle. Participant realized the mistake and put the sensor back into the eTrax needle and successfully removed the trocar of eTrax.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users • The design of the eTrax needle does not make the separation action intuitive to the user	Defect 826146
			Close Call	FeT-010	RAD13	Participant took out the eTrax needle sensor, the actor then prompt “I would unscrew”. Participant tried to push needle into eTrax needle, but actor prompted and successfully completed.	• The design of the eTrax needle does not make the separation action intuitive to the user	Defect 826146
			Close Call	FeT-010	IR04-LA	Participant unlocks sensor, intended to put out sensor from needle. Note-taker said "oh, OH". Then the actor prompted "how would you do it if it is coaxial". Participant then realizes that it has to be turned for it to be removed.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users • The design of the eTrax needle does not make the separation action intuitive to the user	Defect 826146
			Use Error	FeT-010	IR03-LA	Participant took out the sensor from the eTrax needle.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users	Defect 826146
			Use Error	FeT-010	RAD02	Participant didn’t realize he was using a trocar system. Rad 02 said this was not covered in training	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users • The design of the eTrax needle does not make the separation action intuitive to the user	Defect 826146
			Use Error	FeT-010	RAD05	Participant tried to put the needle into trocar.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users • The trocar and the stylet hub are difficult to handle with one hand	Defect 826146
TA340	4.12.3	Participant can insert the biopsy needle into the cannula to take the biopsy	Close Call	FeT-011	RAD04	Participant said “FNA - fine needle aspiration – in which case I would have a syringe pretend”. Participant then successfully took out the eTrax needle.	• The system and the informational insert for the eTrax needle do not provide enough guidance for new/inexperienced users • The design of the eTrax needle does not make the separation action intuitive to the user	Defect 826147
			Use Error	FeT-011	RAD05	Participant tried to insert needle (16G) into cannula (also 16G)	• Labeling on the eTrax needle to indicate its gauge is white text on white background and is in a position that can be covered while using • Due to limited needle supply during the study, only 16 and 18	Defect 826147

Task ID	Hazard ID	Test Objective	Correct Use/ Use Difficulty/ Close Call/ Use Error	Step ID	Participant	Issue	Root Cause	Defect #
							gauge needles were made available to the participant, which may have led him to believe a 16 gauge needle would fit into a 16 gauge needle cannula.	
			Close Call	FeT-011	IR04-LA	Needle gauge was too big, participant couldn't direct needle to enter cannula. Note-taker and actor asked participant to pretend he had the right needle to perform biopsy.	• Labeling on the eTrax needle to indicate its gauge is white text on white background and is in a position that can be covered while using	Defect 826147
TA362, TA363	4.9.4, 4.10.0, 4.10.4	Participant can fuse reference images with ultrasound	Use Error	RF-024	RAD02	Participant tried to use auto alignment but forgot to attach the transducer sensor. Participant needed help from the sonographer actor to continue.	• The tracking quality is green with the transducer sensor not attached to the transducer, as the sensor is in the emitter field • The system does not provide enough guidance for new/inexperienced users	Defect 826154
TA364	4.3.4, 4.4.4, 4.9.0, 4.9.4, 4.10.4	Participant can align the images using the point method.	Use Error	RF-030	RAD04	Participant struggled to use point alignment and tried it multiple times by setting the points using the white cross hairs instead of the green arrow.	• The system does not provide enough guidance for new/inexperienced users • White cross hairs are more prominent than the green arrow within Point Method • The green arrow does not match active state of the trackball on the system display	Defect 826143; Defect 826154; Defect 826155
			Use Error	RF-030	IR04-LA	Moderator prompted participant to use reference points. Participant did not use point method after initializing, only manual alignment was on during this time.	• The system does not provide enough guidance for new/inexperienced users • Participant was satisfied with the alignment and did not feel that further refinement with reference points was required. • According to a trainer (Peter Prince): Alignment should be started by setting 1 set of reference points, then using the auto method, and lastly, using manual alignment to the refine alignment. • The addition of reference point sets beyond one, increases error in an additive function	Defect 826143; Defect 826154; Defect 826155

10.0 Subjective Evaluation Data

Participant subjective feedback was collected by recording comments made during simulated use (task execution) and the debrief interview. Participants also provided answer to post-test questionnaires.

The methods used to assess the participant subjective feedback were:

- Comments made by the participant during task execution.
- Comments made by the participant during the debriefs.
- Responses to multiple choice, open-ended and rating questions in the post-test questionnaires.

Refer to Section 11.0 for further detail.

10.1 Participant Identified Harms

During the debrief interview of each test session, all participants were asked to provide subjective feedback on the potential harm that could have resulted from the critical tasks observed to have any close calls or use errors, and on tasks in which they were aware that they struggled or had difficulty on.

Within the General Imaging and Biopsy debrief interview:

- 2 participants mentioned that contamination might result if the bracket was placed outside of the sterile sheath cover of the transducer. 1 participant mentioned that it was confusing and the other participant mentioned that it worked better attaching the bracket outside of the transducer cover.
- 2 participants responded that extra puncture might result due to measurement errors for the needle length needed during biopsy using the transducer bracket. Both participants realized that they forgot to add in extra length to account for the dead zone and mentioned that they were not used to using transducer brackets.

Within the Fusion debrief interview:

- 1 sonographer noticed that the system was frozen during the session, she indicated that perhaps if the controls were not touched for a while, the system may freeze. Unbeknown to her, the system was frozen on purpose by the Study Moderator using a footswitch per the study design. For this participant, she responded that there may be potential for delaying a procedure if that is the case.
- 1 sonographer responded that she had difficulty selecting the correct ports to plug in equipment during the Fusion section of the test. During debrief, she mentioned that time may be lost and patient may need to have additional sedation only if the equipment was not setup ahead of time.

Table 19 and Table 20 list the potential harms that were identified by participants.

Table 20: Radiologists identified harms

Potential Harm	Participant Count
General Imaging and Biopsy tasks (some participants responded to more than 1 critical tasks, or indicated that there may be more than 1 potential harm)	
Contamination	2
Extra Puncture	2
Longer Sedation	1
Wrong/Miss Lesion	1

N/A	13
Fusion tasks (some participants responded to more than 1 critical tasks, or indicated that there may be more than 1 potential harm)	
Contamination	2
Extra Puncture	1
Longer Sedation	1
Delay Procedure	3
Inadequate Sample	1
Lower Quality Exam	1
Wrong/Miss Lesion	5
N/A	8

Table 21: Sonographers identified harms

Potential Harm	Participant Count
Overall: General Imaging and Biopsy, and Fusion tasks (some participants responded to more than 1 critical tasks, or indicated that there may be more than 1 potential harm)	
Longer Sedation	1
Delay Procedure	1
Breaking Nail	2
N/A	17

10.2 Post-Test Questionnaires

10.2.1 Radiologists' Responses

Risk Control ID 4.6.6: All 18 radiologists were able to successfully interpret the on-screen message of "Needle Unplugged" to mean that the needle sensor being unplugged or disconnected from the system. 17 out of 18 participants also understood that the needle tracking sensor had poor quality when the red text "Poor tracking quality is detected" appears in the top right corner of the main display. If the poor tracking quality message is displayed, radiologists were asked what they would do; all participants correctly responded that they would either move the needle sensor or the transmitter unit closer to the patient. In addition to moving the needle sensor and/or the transmitter unit, 3 participants also said that they would check the connections to see if they were plugged in correctly.

Risk Control ID 5.20.1: Radiologist failed to understand the image orientation marker that appears on the display. Only 12 out of 18 radiologist correctly understood the meaning of the icon.

10.2.2 Sonographers' Responses

Risk Control 5.20.1: 16 out of 17 sonographers correctly understood the meaning of the image orientation marker.

Risk Control 4.9.4 and 4.10.4: Furthermore, sonographer participants were also asked what they would do if the following messages appeared on the system while loading CT images into the Fusion application:

- “Fusion could not load the chosen series. Select a series that contains fewer slices and try again.”
- “Fusion could not load the chosen series. Select a series that contains more than 3 slices and try again”.

Specifically, 15 out of 17 participants indicated that they would either reselect a different data set, or double check to see if they have selected the correct data set for the corresponding patient, and then reload the fusion application. One participant responded that she would follow directions on screen (if applicable), and another participant did not provide any written responses.

Risk Control ID 6.6.2 (Evaluated but not a required element of the usability validation criteria): Participants were asked how often do they check the date and time on the system. 6 out of 17 participants answered “not often”, while 10 out of 17 participants responded that they would check it either once a day or before scanning each patient. Participants were then asked the reason behind their need to check the date and time on the system. 15 out of 17 participants responded that they check it to ensure the date, time, and duration of their exams, as well as images, are captured accurately for future record keeping purposes. Participants also answered that it is important to report accurate date and times in order to schedule exams and procedures. Only one participant said that she doesn’t rely on the time to be correct as she glanced it once on the system she was using and noticed that is was incorrect. The other outstanding participant responded that she only checks the date and time on the system twice a year in order to reset the system to adjust for daylight savings time.

11.0 Annexes

11290281-EPT-008-01 Annex A Radiologist datasheets

11290281-EPT-008-01 Annex B Sonographer datasheets

11290281-EPT-008-01 Annex C Compass_1.0 VA10 Production Units SandE.pdf

11290281-EPT-008-01 Annex D SSR 1000.0.073 Approval Form.doc.pdf

11290281-EPT-008-01 Annex E Subjective Evaluation Data.docx

12.0 Appendices

12.1 Appendix A Disqualified participant

Participant VS02-LA was disqualified due to being an unqualified user. During the training session the trainer learned that the participant did not have a valid sonographer license/certificate, and had not had clinical scanning responsibilities for several years. The participant was asked to leave the training prior to completion and was not asked to return for the testing session. Table A-1 includes the participant screener responses and Table A-2 includes the demographic information collected from the disqualified participant.

Table A-1: Disqualified participant's screener information

Question	Response
What best describes you?	Sonographer
Are you licensed and able to provide evidence of licensure?	*Yes
Years in Practice	7
Have you worked/consulted/contracted for an ultrasound-related manufacturer/marketing firm in the last 12 months?	*No
Have you performed an ultrasound guided "puncture" procedure such as Biopsy in the past 6 months?	*Yes
Do you have experience using image fusion modalities (blending of ultrasound images with CT or MRI imaging)?	Yes
Do you have experience using image fusion in ultrasound?	*Yes
Are you willing to read and fill-out some materials prior to arriving at your test session?	Yes
Are you willing to sign a Non-Disclosure agreement (NDA) to participate in this test?	Yes
Do you have a pacemakers and implantable cardioverter-defibrillators (ICDs)?	No

*Suspicious answers that lead to disqualification.

Table A-2: Disqualified participant's demographic information

Question	Response
Age Range	36-45
Gender	Male
Relevant Education	Sonographer school
Relevant Certifications	[left blank]
Currently working for or consulting for any ultrasound manufacturer?	No
What area(s) of ultrasound would you consider yourself experienced?	Abdomen, Cardiac, Small Parts (Thyroid), Vascular
Total years of relevant clinical experience	5+ years
Clinical specialty	Cardiac, Vascular, Abdomen
What type of clinical procedures do you support or conduct that are ultrasound guided?	Ablation, Injections
If you do ultrasound guided biopsy, what type are they?	Abdominal, Liver
Total years of supporting/performing ultrasound guided procedures	1
What types of facility do you work in?	Private Practice
What are the primary ultrasound systems do you use?	GE 7
What other ultrasound systems have you used in the past?	Siemens, Philips, GE, Toshiba
Rate your experience level with each of the imaging modalities	
2D	Intermediate
Color	Intermediate
Doppler	Intermediate
Image Fusion	Novice
Do you scan predominantly with your left or right hand?	Right
Vision	Far-sighted (hyperopic)
Do you wear Glasses/Contact Lenses?	Yes
Color Blindness	No

12.2 Appendix B-1: Radiologist Participants' Demographics

	RAD01	RAD02	RAD03	RAD04	RAD05	RAD06	RAD07	RAD08	RAD09	RAD10	RAD11	RAD12	RAD13	IR01-LA	IR02-LA	IR03-LA	IR04-LA	IR05-LA
Age Range	36-45 years	36-45	36-45	56-65	26-35	36-45	36-45	36-45	46-55	46-55	36-45	56-65	56-65	56-65	36-45	56-65	36-45	46-55
Gender	Male	Female	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male
Relevant Education	MD	BS, MD, MS	MD	MD	M.D., Radiology Residency, Int. Rad. Fellowship	Medical School, Residency, Fellowship	B.S. Biochemistry, M.D.	MD	MD	MD, Diagnostic Radiology, IR fellowship	Doctor of medicine	MD	12 yrs graduate training after medical school	IR Fellowship	MD FSIR	M.D.	MD, Radiology Residency, IR Fellowship	BSBE, MD, MDA
Relevant Certifications	IR Board Cert	Vascular & Interventional Radiology; American Board of Radiology	Radiology/Interventional	IR board certification	ABR Diagnostic Radiology, CAQ Interventional Radiology	Board Certification Diagnostic Radiology	ABR DR/IR	American Board of Radiology	Board Certified Radiologist, Fellowship Interv. Radiology	ABR	MD		Boarded in Diagnostic Radiology, Interventional Radiology, Nuclear Radiology	ABR, IR/DR	IR/DR CAQ	IR/DR ABR Certification	ABR Certified, IRCAQ	ABULM, CAQIR
Currently working or consulting for any ultrasound manufacturer?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
What area(s) of ultrasound would you consider yourself experienced	Abdomen, Vascular	Abdomen, Vascular	Abdomen, Vascular	Abdomen, Small Parts (Thyroid), Vascular	Abdomen, Shared Services, Small Parts (Thyroid), Vascular	Abdomen, Shared Services, Small Parts (Thyroid), Vascular	Abdomen, Brest, Vascular	Abdomen, Small Parts (thyroid), Vascular	Abdomen, OB/GYN, Small Parts (Thyroid), Vascular)	Abdomen, OB/GYN, Small Parts (Thyroid), Vascular	Abdomen, Vascular, Other (Interventional radiology)	Abdomen, Small Part (Thyroid)	Abdomen, Small Parts (Thyroid), Vascular	Abdomen Small Parts (Thyroid) Vascular Other: IR	Abdomen, Vascular	Abdomen, Vascular	Abdomen OB/GYN Small Parts (Thyroid) Vascular	Abdomen Breast OB/GYN Small Parts (Thyroid) Vascular
Total years of relevant clinical experience	5 (attending) & 6 (Training post MD)	12	9	22	8 (4 post residency)	4	9	8	20	20	9	30+	25	43	10	26	10	20
Clinical specialty	IR	Interventional Radiology	IR	Interventional Radiology	Interventional radiology (adult & pediatric)	Interventional Radiology	IR	Interventional Radiology	Radiology, Interventional	Interventional Radiology	Interventional Radiology	interventional radiology	Interventional Radiology	Diagnostic & Interventional Radiology	Interventional Radiology	International Radiology	IR	Interventional Radiology
What type of clinical procedures do you support or conduct that are ultrasound guided?	Ablation, Aspiration, Biopsy, Injections, Line Placement	Ablation, Aspiration, Injections, Line Placement	Ablation, Aspiration, Biopsy, Injections, Line Placement	Aspiration, Biopsy, Line Placement, US guided renal & hepatic (biliary) procedures	Ablation, Aspiration, Biopsy, Injections, Line Placement, Other (lumbar puncture, sclerotherapy)	Ablation, Aspiration, Biopsy, Injections, Line Placement, Other (Vascular access, dermatology injection)	Ablation, Aspiration, Biopsy, Injections, Line Placement	Ablation, Aspiration, Biopsy, Injections, Lin Placement	Aspiration, Biopsy, Injections, Line Placement	Aspiration, Biopsy, Injections, Line Placement	Ablation, Aspiration, Biopsy, Injections, Line Placement	Ablation, Aspiration, Biopsy, Injections, Line Placement	Ablation, Aspiration, Biopsy, Injections, Line Placement, Other (Absceuus)	Ablation Aspiration Biopsy Injections Line Placement	Aspiration, Biopsy, Line Placement	Ablation, Aspiration, Biopsy, Injections, Line Placement	Ablation Aspiration Biopsy Line Placement	Ablation Aspiration Biopsy Line Placement Other: Vascular Intervention

	RAD01	RAD02	RAD03	RAD04	RAD05	RAD06	RAD07	RAD08	RAD09	RAD10	RAD11	RAD12	RAD13	IR01-LA	IR02-LA	IR03-LA	IR04-LA	IR05-LA
If you do ultrasound guided biopsy, what type are they?	Abdominal, Liver, Thyroid	Participant doesn't do ultrasound guided biopsy	Abdominal, Liver	Liver	Abdominal, Liver, Thyroid, Other (kidney, general soft tissue (masses))	Abdominal, Liver, Thyroid, Other (kidney)	Abdominal, Liver	Abdominal, Liver, Thyroid, Other (lymph node)	Abdominal, Liver, Thyroid	Abdominal, Liver, Thyroid, Other (Renal)	Abdominal, Liver, Thyroid, Other (soft tissue)	Abdominal, Liver, Thyroid, Other (chest)	Abdominal, Liver, Thyroid	Abdominal GYN Liver Thyroid Other: MSK, Soft Tissue, Lymph node	N/A	N/A	N/A	N/A
Total years of supporting/performing ultrasound guided procedures	10	12	9	22		4	9	5	20	20	7	30+	25	42	N/A	N/A	N/A	N/A
How many procedures using needle guides do you perform each year, on average?	1-5 years	0	20+	0	0	1-5	5-10	20+	20+	>500	0	10-20 per week	20+ (300)	-	N/A	N/A	N/A	N/A
What types of facility do you work in?	Educational institution, In-patient hospital	Educational Institution, In-patient hospital, Out-patient clinic	Educational Institution, In-patient hospital	Educational Institution	Educational Institution	In-patient hospital, Private Practice	Educational Institution	In-patient hospital	In-patient hospital	In-patient, Out-patient, Private Practice	Educational Institution	Educational Institution, In-patient hospital, Out-patient clinic	In-patient hospital	Out-patient Clinic Private Practice	N/A	N/A	N/A	N/A
What are the primary ultrasound systems do you use?	Philips (IU22, other models)	Philips (CX 50, IU-22)	Philips (IU22/affinity 70/Epiq), Sonosite (tuploo-M?)	Siemens, Philips, GE	Siemens, Philips (most commonly (iU22), sometimes Epiq), Other (VENO, Sonosite)	Siemens, Philips, GE	Philips (IU-22, EPIQ 7)	Siemens, Philips (can't remember models)	Siemens, Philips, GE, Toshiba	Siemens, Philips, GE, Toshiba, Other (Sonosite)	Philips (S200)	Siemens (? Old model), Philips (? New), GE (? New model)	GE	GE	N/A	N/A	N/A	N/A
What other ultrasound systems have you used in the past?	Siemens, Philips, GE	Sonosite	Philips (IU22/affinity 70/Epiq), Sorosite (tuploo-M?)	Siemens, Philips, GE	Siemens, Philips, Other (VENO, Sonosite)	Siemens, Philips, GE		GE, Toshiba, Other (Sonosite	Siemens, Philips, GE, Toshiba	Siemens, Philips, GE, Toshiba, Other (Sonosite)	GE (S9)	Siemens (? Old model), Philips (? New), GE (? New model)	Siemens, Philips, GE	Siemens GE Other: Acuson	Siemens, Toshiba	Siemens, Philips, GE, Toshiba	N/A	Siemens Philips GE Other: Acuson Sequoia
Rate your experience level with each of the imaging modalities																		
2D	Expert	Intermediate	Expert	Intermediate	Expert	Intermediate	Expert	Expert		Intermediate	Expert	Intermediate	Expert	Expert	Intermediate	Intermediate	Expert	Expert
Color	Expert	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Expert	Expert	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Expert	Intermediate	Expert	Intermediate	Expert
Doppler	Expert	Intermediate	Intermediate	Intermediate	Novice	Intermediate	Intermediate	Expert	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Expert	Intermediate	Intermediate	Intermediate	Expert
Image Fusion	Intermediate	Novice	Novice	None	Novice	Novice	Novice	Novice	None	None	Novice	Novice	Novice	Novice	Intermediate	Novice	Intermediate	Novice
Do you scan predominantly with your left or right hand?	Right	Left	right for dx; both for procedures	Right	Both	Both	Both	Left	Right	Left	Both	Right	Right	Right	Right	Right	Both	Right

	RAD01	RAD02	RAD03	RAD04	RAD05	RAD06	RAD07	RAD08	RAD09	RAD10	RAD11	RAD12	RAD13	IR01-LA	IR02-LA	IR03-LA	IR04-LA	IR05-LA
Vision	Normal	Near-sighted (myopic)	Near-sighted (myopic)	Normal	Normal	Near-sighted (myopic)	Near-sighted (myopic)	Near-sighted (myopic)	Far-sighted (hyperopic)	Near-sighted (myopic)	Near-sighted (myopic)	Normal	Normal	Near-sighted (myopic)	Normal	Near-sighted (myopic)	Near-sighted (myopic)	Normal
Do you wear Glasses/Contact Lenses?	No	Yes	Yes	Yes (sometimes)	No	Yes	Yes	Yes	Yes	Yes; computer glasses	Yes	No	Yes	Yes	No	Yes	Yes	No
Color Blindness	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

12.3 Appendix B-2: Participant Demographics (Sonographer)

	VS01	VS02	VS03	VS04	VS05	VS06	VS07	VS08	VS09	VS10	VS11	VS12	VS01-LA	VS02-LA	VS03-LA	VS04-LA	VS05-LA	VS06-LA
Age Range	26-35	26-35	26-35	46-55	36-45	36-45	18-25	46-55	36-45	36-45	36-45	18-25	26-35	36-45	26-35	46-55	26-35	36-45
Gender	Female	Female	Female	Male	Male	Female	Female	Female	Female	Male	Female	Male	Female		Female	Male	Female	Female
Relevant Education	B.S. in Diagnostic Ultrasound; 12 years scanning	Certificate DMS Program	2 yr AS	B.S. Diagnostic Ultrasound	BSc. Biology	DCRAY Program Graduate; Sonography Program Graduate	Associates in Diagnostic Ultrasound	Associates degree in Diagnostic Medical Ultrasound	Degree in Sonography	Associates	Diagnostic Medical Sonography	Bachelors of Science in Diagnostic Ultrasound	A.S. Sonography	Sonographer school	AS Diagnostic medical Sonography	AA	BS Radiologic Screnaes	
Relevant Certifications	RDMS (ABD, OB/GYN, P.S.); RVT	RDMS, PUT	RDMS Abd, OB/GYN	Anaub - OB, ABD, small parts, cardiac	RVT	ARDUS (ABD, OB, FE) RVT (VT)	RDMS, RVT	RDMS	NT, OB/GYN	ARDMS	RDMS, RVT	RDMS (Abdomen & OB/GYN), RVT)	Diagnostic medical Sonographer		ARDMS (OB, General, Breast)	ARDMS	ARDMS ARRT (RT) CRT	ARDMS
Currently working or consulting for any ultrasound manufacturer?	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
What area(s) of ultrasound would you consider yourself experienced	Abdomen, OB/GYN, Small Parts (Thyroid), Vascular	Abdomen, OB/GYN, Small Parts (Thyroid)	Abdomen, OB/GYN, Small Parts (Thyroid)	Abdomen, OB/GYN, Small Parts (Thyroid), Other (Liver + Kidney transplant procedures	Vascular	Abdomen, Breast, OB/GYN, Small Parts (Thyroid), Vascular, Other (Fetal echo)	Abdomen, OB/GYN	Abdomen, OB/GYN, Small Parts (Thyroid), Other (Ultrasound guided procedures)	Abdomen, OB/GYN, Small Parts (Thyroid), Other (transplants, biopsies)	Abdomen, OB/GYN, Small Parts (Thyroid)	Abdomen, Breast, OB/GYN, Small Parts (Thyroid), Vascular	Abdomen, OB/GYN, Small Parts (Thyroid), Vascular	Abdomen, Breast, OB/GYN, Small Parts (Thyroid), Vascular, Other (MSK)	Abdomen, Cardiac, Small Parts (Thyroid), Vascular	Abdomen, Breast, OB/GYN	Abdomen, Breast, OB/GYN, Small Parts (Thyroid) Vascular	Abdomen, Breast, OB/GYN, Small Parts (Thyroid), Vascular	Abdomen, OB/GYN, Small Parts (Thyroid) Vascular
Total years of relevant clinical experience	12	10	6 years	24	16	20	4	10	4	5	10.5 years	2.5 years	8 years	5+ years	4 years	25 years	7 years	15
Clinical specialty		General	General	Fetal echo, high risk, biopsy's, transplants (liver + kid) contrast nan & system	Vascular ultrasound	OB - Maternal Fetal Medicine - Fetal Echo	High risk OB/Abdomen	Abd/OB GYN	Abd, GYN/OB	General Sonography	General, Vascular	Abdomen, High risk OB, guided procedures	RUT	Cardiac, Vascular, Abdomen				General/ Vascular
What type of clinical procedures do you support or conduct that are ultrasound guided?	Previously (Ablation, Biopsy), Currently (Aspiration, Injections, Line Placement,	Aspiration, Biopsy, Injections	Aspiration, Biopsy - Thyroid FNA's	Ablation, Aspiration, Injections, Amineo, CVS, Fetal transfusions	Ablation, Injections, Line Placement	Aspiration (Amniocentesis), Biopsy, Other (Amniocentesis, Chorinic Villus sampling)	Other (Amniocentesis)	Aspiration, Biopsy	Ablation, Aspiration, Biopsy	Aspiration, Biopsy, Injections	Aspiration, Biopsy	Ablation, Aspiration, Biopsy, Injections, Other (ablation planning)	Ablation, Aspiration, Biopsy, Injections	Ablation, Injections	Aspiration, Biopsy, Other (needle LOC, FNA)	Aspiration Biopsy, Injections, Line Placement	Aspiration, Biopsy	Aspiration, Biopsy

	VS01	VS02	VS03	VS04	VS05	VS06	VS07	VS08	VS09	VS10	VS11	VS12	VS01-LA	VS02-LA	VS03-LA	VS04-LA	VS05-LA	VS06-LA
	Venous closer procedures)																	
If you do ultrasound guided biopsy, what type are they?	Past(Abdominal, Liver, Thyroid), Current (GYN)	Thyroid, Other (Lymph node)	Thyroid	Abdominal, GYN, Liver, Thyroid	N/A; vascular access occasionally	Abdominal (Liver, Kidney), Other (Amniocentesis, Chorionic Villus Sampling)	i	Abdominal, Liver, Thyroid	Abdominal, GYN, Liver, Thyroid, Other (Renal tx)	Abdominal, Liver, Thyroid	Abdominal, Breast, Liver, Thyroid	Abdominal, Liver, Thyroid, Other (CVS)	Abdominal, Breast, GYN, Liver, Thyroid, Other (MSK)	Abdominal, Liver	Abdominal, Breast, Liver, Thyroid	Abdominal, Breast, Liver, Thyroid	Breast, Liver, Thyroid	Breast, Thyroid
Total years of supporting/performing ultrasound guided procedures		10	6	22	2	20	3	7	4	5	6	2	7	1	4	25	6	13
What types of facility do you work in?	Out-patient clinic, Private Practice	In-patient hospital	Radiology Department	Educational Institution, In-patient hospital, Out-patient clinic	In-patient hospital, Out-patient clinic	Out-patient clinic	In-patient hospital, Out-patient clinic	Educational Institution, In-patient hospital	In-patient hospital	Out-patient clinic	In-patient hospital	Educational Institution, In-patient hospital, Out-patient clinic	Educational Institution, In-patient hospital, Out-patient clinic	Private Practice	In-patient hospital, Out-patient clinic	In-patient hospital, Out-patient Clinic	Out-patient clinic	Out-patient clinic
What are the primary ultrasound systems do you use?	Philips (iU22), GE (old laptop, E6, E8)	Philips (IU22, EPIQ)	Philips (IU22, EPIQ)	Philips (IV22 + EPiQ)	Toshiba (Aplio 300)	Philips (IU22), GE (Voluson E8, E10)	Philips (IU22), GE (E10, E8)	Philips (IU22, Epiq)	Philips	Philips (IU22, Epiq 9)	Siemens, Philips (currently use - Epic 500), GE, Toshiba (currently use - Aplio 500), Other	Philips (IU22, Epiq?? Epic)	Philips: Iu22	GE 7	GE	Philips, Other: Mindray	GE: Logic S8	Siemens, GE, Toshiba
What other ultrasound systems have you used in the past?	Siemens (Ellegra, Antares), Philips (Epiq), GE (E9)	GE(logiq e9)		Siemens (Slegna), GE (700)	Philips (Sonos 4500/5500)	Siemens (Antares), Philips (+ATL, 3000 + 5000, IU22), GE (Volusuns - E6, E8, E10), Toshiba (?), Other (Samsung - Demo - x2; ? Model #'s)		Siemens (Antares)	Siemens, Philips, GE	Siemens (Sequoia, Antares), GE (Logiq), Toshiba	Siemens, Philips, GE, Toshiba, Other (Biosaotite)	Siemens, GE	Siemens: Sequoia	Siemens, Philips, GE, Toshiba	Siemens, Philips, GE, Other (HDM1)	Siemens, Philips, GE, Other (Mindray)	Siemens, Philips, GE	Siemens, GE, Toshiba. Other (Zonare)
Rate your experience level with each of the imaging modalities																		
2D	Expert	Expert	Expert	Expert	Intermediate	Expert	Intermediate	Expert	Expert	Expert	Expert	Expert	Expert	Intermediate	Expert	Expert	Expert	Expert
Color	Expert	Expert	Expert	Expert	Expert	Expert	Intermedia	Expert	Expert	Expert	Expert	Expert	Expert	Interme	Expert	Expert	Expert	Expert

	VS01	VS02	VS03	VS04	VS05	VS06	VS07	VS08	VS09	VS10	VS11	VS12	VS01-LA	VS02-LA	VS03-LA	VS04-LA	VS05-LA	VS06-LA
							te							diate				
Doppler	Expert	Expert	Expert	Expert	Expert	Expert	Intermedia te	Expert	Expert	Expert	Expert	Expert	Expert	Interme diate	Expert	Expert	Expert (also Novice)	Expert
Image Fusion	Interme diate +	Novice	Novice	Intermediate		Novice		Novice	Interme diate	Novice	Novice	Intermediate	Novice	Novice		Interme diate	Novice	Novice
Do you scan predominantly with your left or right hand?	Right	Right	Right	Both (right main some with Left Hand)	Right	Right	Right	Right	Right	Right	Right, Both + can do	Right	Right	Both	Right	Right	Right	Right
Vision	Near-sighted (myopic)	Normal	Normal	Normal	Near-sighted (myopic)	Near-sighted (myopic)	Normal	Normal	Normal	Normal	Near-sighted (myopic)	Near-sighted (myopic)	Far-sighted (hyperopic)	Far-sighted (hyperopic)	Normal	Normal	Norma l	Normal
Do you wear Glasses/Contac t Lenses?	Yes	No	No	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No
Color Blindness	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

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APPROVAL	**2018-05-02T19:54:40-02:00**	**Burke, Laurel**