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TronsHealth

§170.315(g)(3) Safety-enhanced design

PREPARED FOR

ONC-ACB
ONC Certification

PREPARED DATE
Aug 23, 2024

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1. Executive Summary

The §170.315(g)(3) Safety-Enhanced Design criterion is an ONC Health IT Certification Program component. It emphasizes the importance of incorporating user-centered design processes into certified health IT products to enhance system safety. This criterion requires health IT developers to integrate usability principles into the design and development of their systems, especially for features critical to patient safety.

1.1. Product Detail

- Name: TronsHealth
- Version: 1.0

1.2. User center design process

The TronsHealth product development process is based on an iterative methodology. Instead of traditional requirements-based development, we leverage a user centered design process, rapidly iterating to an ideal state which is then used to anchor requirements and development discussions. TronsHealth utilizes a user-centered design process based on the principles of UCD Standards:

1.2.1. ISO 9241-11

Description: International Standard ISO 9241-11 was prepared by Technical Committee ISO/TC 159, Ergonomics, Subcommittee SC 4, Ergonomics of human system interaction. ISO 9241-11 explains the benefits of measuring usability in terms of user performance and satisfaction. These are measured by the extent to which the intended goals of use are achieved, the resources that have to be expended to achieve the intended goals, and the extent to which the user finds the use of the product acceptable. ISO 9241-11 emphasizes that visual display terminal usability is dependent on the context of use and that the level of usability achieved will depend on the specific circumstances in which a product is used. The context of use consists of the users, tasks, equipment (hardware, software and materials), and the physical and social environments which may all influence the usability of a product in a work system. Measures of user performance and satisfaction assess the overall work system, and, when a product is the focus of concern, these measures provide information about the usability of that product in the particular context of use provided by the rest of the work system. The effects of changes in other components of the work system, such as the amount of user training, or the improvement of the lighting, can also be measured by user performance and satisfaction.
Citation: Ergonomic requirements for office work with visual display terminals (VDTs) — Part 11: Guidance on usability
Source: https://cdn.standards.iteh.ai/samples/16883/44acafdfd9a24edd9c66ed2f0e2a50e2/ISO-9241-11-1998.pdf
Utilizing many of the cited methods for gathering feedback from our user community and evaluating the usability of our product. The following approach is used for this study.

- Research – We have utilized quantitative research methods to understand our users, their behaviors, and the needs of their practices.
- Model – Using the results from research in Health IT we designed a model for TronsHealth.
- Frame – With the model, we made a flexible frame for the structure of TronsHealth.
- Refine – TronsHealth's design team works closely with our developers and program managers as they scope and prepare for development. As part of this process, we provide the development team with detailed visual designs including all states for each component.

- Test – occurs throughout the design and development process and after a piece of functionality is released. The testing process also involves actively seeking feedback and guidance from users and subject matter experts to help improve.
- Feedback – We are always listening and responding to our users.

This study collected performance data on 5 tasks typically conducted on an EHR:

- Recording and Verifying Patient Demographics
- Decision Support Interventions
- Record and Review Implantable Device
- Inactivate Implantable Device
- Computerized Provider Order Entry- Medications

The following types of data according to the SED ONC guidelines for conformance of the ONC ID §170.315(g)(3) Safety-enhanced design was collected for each participant.

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations
- Participant's satisfaction ratings of the system

1.3. Description of Intended Users

Following are the users that are intended to use TronsHealth's features or functions as described in the above tasks:

- Ambulatory Physicians
- Nurse Practitioners
- IT Specialists
- Pharmacists
- Clinician
- Administrative Staff
- Surgeon

2. Method

The Safety-Enhanced Design (SED) testing will involve lab-based usability testing focused on critical safety-related functionalities within the TronsHealth EHR system. Participants will perform tasks that simulate real-world scenarios to evaluate the system's interface's effectiveness, efficiency, and user satisfaction, particularly in areas that impact patient safety. The test will follow a user-centered design (UCD) process, incorporating feedback from healthcare professionals to identify and mitigate potential safety risks.

3. Test Location

Clinical sessions were held remotely on 18 Aug 2024. During this remote session, the moderator was in the office, the data logger recorded data from the exact location, and each participant participated from their respective locations.

Configuration and registration sessions held from April 19 to May 12, 2024, and from July 29 to August 23, 2024, were conducted remotely. In these sessions, the moderator and data logger were in the moderator's office, while each participant joined from their location.

4. Test Environment

The TronsHealth EHR system is primarily designed for ambulatory settings. Usability testing was conducted using a remote testing procedure. System data was not collected from participants during the remote testing sessions. Participants interacted with the TronsHealth EHR system using a keyboard and mouse.

The remote sessions were conducted via Zoom. Participants were instructed to join an audio conference and log in to a Zoom meeting. Control of the moderator's computer was passed to the participants, and the sessions were moderated using the same materials and methods as those used in face-to-face sessions. All sessions were audio and video recorded for analysis. For clinical sessions, the study was conducted on a Dell Latitude 5520; the screen resolution was set to 1920 x 1080. The moderator's computer, with a screen size of 15.6", ran on Windows 10 Professional. Participants used their computers with varying screen sizes. Participants used machines with various screen sizes and resolutions to interact with the application.

The study was conducted on an Apple MacBook Pro (2020); the screen resolution was 2560 x 1600. The moderator's computer, with a screen size of 13.3", ran on macOS Big Sur. For remote sessions, participants used their machines with various screen sizes. All participants interacted with the TronsHealth EHR system using a keyboard and a mouse when interacting with the application during these sessions.

5. Participants

A total of 10 participants were tested on TronsHealth EHR. Participants in the test were nurses (N=2), ambulatory clinical personnel (N=5), and configuration specialists (N=3). Participants were recruited by the TronsHealth EHR team and were not compensated for their time. In addition, participants had no direct connection to the development team or organization. Participants were not from the testing or supplier organization. Participants were given the opportunity to have a similar orientation and level of training to the actual end users would have received. For the test purposes, end-user characteristics were identified and translated into a recruiting screener used to solicit potential participants; an example of a screener is provided in Heding 10: Recruiting Form. Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screener. The following is a table of participants by characteristics, including demographics, professional experience, computing experience and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities. See Table 1

Table 1: Participants

ID	Gender	Age (years)	Education	Role	Professional Experience (months)	Computer Experience (months)	Product Experience (months)	Assistive Technology Needs
TR1	Male	40-49	High school Graduate	Physician	240	180	5	None
TR2	Male	30-39	Master's Degree	Clinician	96	120	4	None
TR3	Male	40-49	PharmD	Pharmacist	180	150	6	None
TR4	Female	20-29	BS in Health IT	IT Specialist	40	150	4	None
TR5	Male	70-79	MD	Surgeon	300	240	6	None
TR6	Female	50-59	MSN	Nurse Practitioner	200	180	4	None
TR7	Male	40-49	MD	Radiologist	70	192	3	None
TR8	Female	20-29	DO	Family Physician	30	216	4	None
TR9	Male	30-39	Master's Degree	Registered Nurse	84	96	5	None
TR10	Male	20-29	Associate degree	IT Specialist	24	70	3	None

These participants represent a diverse group of healthcare professionals and IT specialists with varying levels of experience with both technology and the TronsHealth EHR system. Each participant contributed to the usability testing to ensure the system's safety and effectiveness, particularly for safety-critical tasks.

6. Study Design

Overall, the objective of this study was to evaluate the features required for Safety-Enhanced Design M2 certification. For each feature we sought to identify areas where the application performed well, as well as areas where it fell short of customer needs and our company's user experience goals. The data from this test will serve as a baseline for future evaluations.

6.1. Usability Metrics

The system was evaluated for effectiveness, efficiency, and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Task ratings: Ease and efficiency
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)

- Participant's satisfaction ratings of the system

6.3. Data Scoring

The following table details how tasks were scored, errors evaluated, and the time data analyzed. See Table 2.

Table 2: Participants

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. The standard deviation for each percent success is a required calculation by the ONC. It is not appropriate to calculate a mean or standard deviation for a percentage in the way we are reporting task success. Therefore, the standard deviation for each task success percentage was calculated by representing each "Pass" value as 1 and each "Fail" value as 0, then applying the formula for standard deviation with the values. Note, a zero standard deviation represents a 100% pass or fail rate. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded. If the defined threshold time for inactivity (30 seconds) passed, the moderator would stop the participant
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, received assistance from the moderator associated with completing the task directly related to the certification criteria or reached the end of the allotted time before successful completion, the task was counted as a "Failure." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. The standard deviation for each percent failure is a required calculation by the ONC. It is not appropriate to calculate a mean or standard deviation for a percentage in the way we are reporting task success. Therefore, the standard deviation for each task success percentage was calculated by representing each "Fail" value as 1 and each "Pass" value as 0, then applying the formula for standard deviation with the values. Note, a zero standard deviation represents a 100% pass or fail rate. On a qualitative level, an enumeration of errors and error types was collected
Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps

	to provide a ratio of path deviation. Optimal paths (i.e., procedural steps) were recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said, "Begin" until the participant said, "Done." If he or she failed to say, "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation) were also calculated.
Satisfaction: Task Rating	Participant's subjective impression of the ease-of-use of the application was measured by administering both a post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. To measure participants' confidence in and likeability of the TronsHealth EHR overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." See full System Usability Score questionnaire in **Heading 9:** System Usability Scale Questionnaire.

7. Procedures

7.1. Record - § 170.315(a)(5) - Recording and Verifying Patient Demographics

7.1.1 Scenario 1: Recording and Verifying Patient Demographics for John Doe

To verify that the TronsHealth EHR system accurately captures and displays demographic information for a patient named John Doe, ensuring compliance with § 170.315(a)(5).

Patient Details:

- **Name:** John Doe
- **Date of Birth:** 1990-08-15
- **Sex:** Male
- **Race:** Asian
- **Ethnicity:** Not Hispanic or Latino
- **Preferred Language:** English
- **Gender Identity:** Identifies as Male

Steps:

1. **User Login:**

- **Step 1.1:** Log in to the TronsHealth EHR system using authenticated credentials.
- **Expected Outcome:** The user successfully accesses the dashboard.

2. **Navigate to Patient Record:**
   - **Step 2.1:** Select the patients' icons from the sidebar menu, search for the patient "John Doe," and open his profile.
   - **Expected Outcome:** The system retrieves and displays John Doe's existing demographic record.
3. **Enter Demographic Information:**
   - **Step 3.1:** Navigate to the "Demographics" by selecting the Patient.
   - **Step 3.2:** Enter or verify the following demographic information:
     - Race: Black or African American
     - Ethnicity: Hispanic or Latino
     - Preferred Language: Spanish
     - Sexual Orientation: Cisgender
     - Gender Identity: Unknown
   - **Step 3.3:** Save the demographic information.
   - **Expected Outcome:** The system successfully saves the demographic information and displays a confirmation message (e.g. " Patient Updated Successfully!").
4. **Verify Demographic Information:**
   - **Step 4.1:** Review John Doe's demographic information to ensure all details have been correctly entered and saved.
   - **Expected Outcome:** The demographic section accurately reflects the information entered for John Doe, with all fields correctly populated.

Expected Result:

- The TronsHealth EHR system should accurately capture, save, and display the demographic information for John Doe, confirming that the system meets the requirements of § 170.315(a)(5).

Actual Result:

- The TronsHealth EHR system successfully captured, saved, and displayed the demographic information for John Doe, with all details correctly reflected in his medical record, confirming that the system is functioning as intended.

User	Task Success	Path Deviation (Observations)	Path Deviation (Optimal)	Task Time (seconds)	Task Time (Observed)	Task Time (Optimal)	Errors	Task Rating (5=very easy) 1-5	Task Efficiency (5=very efficient) 1-5
01	Y	7	7	100	110	100	0	5	5
02	Y	7	7	100	100	100	0	5	4
03	Y	8	7	100	120	100	0	4.5	4
04	Y	7	7	100	80	100	0	4.7	5
05	Y	7	7	100	90	100	0	5	4.8
06	Y	9	7	100	130	100	1	3.5	4.2
07	Y	7	7	100	100	100	0	5	5
08	Y	7	7	100	95	100	0	4	4
09	Y	8	7	100	105	100	0	4.5	4.8
10	Y	7	7	100	120	100	0	5	5
	Mean1.00	Mean 7.40	Mean 7.00	Mean 100	Mean 105	Mean 100	Mean 0.1	Mean 4.62	Mean 45.33
	SD 0.00	SD 0.70	SD 0.00	SD 0.00	SD 14.49	SD 0.00	SD 0.316	SD 0.515	SD 0.469

7.2. Record - §170.315(a)(1) Computerized Provider Order Entry- Medications

7.2.1. Scenario 2: Ordering Medication for Patient Mary Johnson

To verify that the TronsHealth EHR system accurately processes and records a medication order using the CPOE functionality for a patient named Mary Johnson, ensuring compliance with § 170.315(a)(1).

Patient Details:

- **Name:** Mary Johnson
- **Date of Birth:** 1980-11-05
- **Sex:** Female

Steps:

1. **User Login:**
    - **Step 1.1:** Log in to the TronsHealth EHR system using authenticated credentials.
    - **Expected Outcome:** The user successfully accesses the dashboard.
2. **Navigate to Patient Record:**

- **Step 2.1:** Click on the patient icon from the sidebar menu, navigate to the patient's screen, search for "Mary Johnson" from patient's screen, and open her medical record.
- **Step 2.2: Open** Mary Johnson's profile and go to Clinical>Medications.
- **Expected Outcome:** The system retrieves and displays Mary Johnson's medical record.

3. **Enter Medication Order:**
   - **Step 3.1:** Navigate to the "Medication" section within Mary Johnson's medical record.
   - **Step 3.2:** Enter a new medication order for "Metformin 500mg, to be taken orally twice daily for diabetes management."
   - **Step 3.3:** Review the medication for accuracy and confirm the entry.
   - **Expected Outcome:** The system successfully saves the medication, displays a confirmation message (e.g., Medication Added Successfully), and adds the order to Mary Johnson's active medication list.
4. **Verify Medication Order:**
   - **Step 4.1:** Review Mary Johnson's active medication list to verify that the Metformin has been correctly added.
   - **Expected Outcome:** The active medication list displays "Metformin 500mg, twice daily" as an active medication.

Expected Result:

- The TronsHealth EHR system should correctly process, save, and display Mary Johnson's medication, confirming that the CPOE functionality works as intended.

Actual Result:

- The TronsHealth EHR system successfully processed, saved, and displayed the medication for Mary Johnson, confirming that the CPOE functionality is working as intended.

User	Task Success	Path Deviation (Observations)	Path Deviation (Optimal)	Task Time (seconds)	Task Time (Observed)	Task Time (Optimal)	Errors	Task Rating (5=very easy) 1-5	Task Efficiency (5=very efficient) 1-5
01	Y	8	8	120	100	120	0	4.9	4.6
02	Y	9	8	120	125	120	0	4.2	3.9
03	Y	7	8	120	95	120	0	5	5
04	Y	8	8	120	100	120	0	4	4.2
05	Y	10	8	120	130	120	2	3.5	4

06	Y	9	8	120	105	120	1	4.1	3.8
07	Y	8	8	120	115	120	0	4.7	4.9
08	Y	7	8	120	120	120	0	4.6	4.8
09	N								
10	Y	7	8	120	120	120	0	4	5
	Mean0.9	Mean 7.3	Mean 7.2	Mean 108	Mean 101	Mean 108	Mean 0.3	Mean 3.9	Mean 4.02
	SD 0.3	SD 0.99	SD 0.00	SD 0.00	SD 11.81	SD 0.00	SD 0.66	SD 0.46	SD 0.46

7.3. Record - § 170.315 (b)(11) Decision Support Intervention

7.3.1. Scenario 3: Decision Support Intervention for Patient Emily Davis

To verify that the TronsHealth EHR system provides appropriate decision support Intervention alerts when entering a new diagnosis and medication order for a patient named Emily Davis, ensuring compliance with § 170.315(b)(11).

Patient Details:

- **Name:** Emily Davis
- **Date of Birth:** 1988-07-10
- **Sex:** Female
- **Diagnosis:** Benign Intracranial Hypertension

Steps:

1. **User Login:**
    - **Step 1.1:** Log in to the TronsHealth EHR system using authenticated credentials.
    - **Expected Outcome:** The user successfully accesses the dashboard.
2. **Navigate to Patient Record:**
    - **Step 2.1:** Click the patient icon from the sidebar menu and navigate to the patient's screcord.Search for the patient "Emily Davis" from the patient's screen and open her medical record.
    - **Expected Outcome:** The system retrieves and displays Emily Davis's medical record, including her history of hypertension.
3. **Enter New Diagnosis and Medication Order:**
    - **Step 3.1:** Navigate to the "Diagnoses" section and enter a new diagnosis of "Type 2 Diabetes."

- **Step 3.2:** Navigate to the " Prescription" section within Emily Davis's medical record and enter a new order for "Metformin 500mg, to be taken orally twice daily."
- **Expected Outcome:** The system provides a clinical decision support alert related to the newly diagnosed Type 2 Diabetes.

4. **Review CDS Alert:**
   - **Step 4.1:** Review the clinical decision support alert provided by the system.
   - **Expected Outcome:** The system displays a CDS alert recommending renal function tests and highlighting potential interactions or contraindications between hypertension and the newly prescribed Metformin.

Expected Result:

- The TronsHealth EHR system should provide a clinical decision support alert recommending renal function tests before starting Metformin due to the patient's history of hypertension and new Type 2 Diabetes diagnosis. The alert should also include general guidance on managing diabetes and hypertension together.

Actual Result:

- The TronsHealth EHR system successfully generated a clinical decision support alert, recommending renal function tests before initiating Metformin and offering additional guidance on managing Type 2 Diabetes and hypertension. The alert was appropriately displayed to the user, confirming that the CDS functionality works as intended.

User	Task Success	Path Deviation (Observations)	Path Deviation (Optimal)	Task Time (seconds)	Task Time (Observed)	Task Time (Optimal)	Errors	Task Rating (5=very easy) 1-5	Task Efficiency (5=very efficient) 1-5
01	Y	8	7	90	95	90	0	4.5	4.3
02	Y	9	7	90	100	90	1	4.3	4.8
03	Y	7	7	90	90	90	0	5	4.8
04	Y	8	7	90	85	90	0	4.9	5
05	Y	6	7	90	80	90	0	5	5
06	Y	7	7	90	95	90	1	4.8	4.2
07	Y	8	7	90	97	90	0	4.6	5
08	Y	9	7	90	105	90	0	3.8	4.2
09	N								
10	N								
	Mean0.8	Mean 6.2	Mean 5.6	Mean 72	Mean 74.7	Mean 72	Mean 0.2	Mean 3.69	Mean 3.73

	SD 0.16	SD 0.96	SD 0.00	SD 0.00	SD 7.56	SD 0.00	SD 0.43	SD 0.38	SD 1.89

7.4. Record - § 170.315 (a)(14) Record and Review Implantable device

7.4.1. Scenario 4: Recording and Verifying an Implantable Device for Patient Robert Johnson

To verify that the TronsHealth EHR system accurately captures and displays an implantable device for a patient named Robert Johnson, ensuring compliance with § 170.315(a)(14).

Patient Details:

- **Name:** Robert Johnson
- **Date of Birth:** 1955-09-30
- **Sex:** Male

Steps:

1. **User Login:**
    - **Step 1.1:** Log in to the TronsHealth EHR system using authenticated credentials.
    - **Expected Outcome:** The user successfully accesses the dashboard.
2. **Navigate to Patient Record:**
    - **Step 2.1:** Click the patient icon from the sidebar menu and navigate to the patient's screen. Search for the patient "Robert Johnson" and open his implantable devices record from side menu under Clinical > Implantable Devices.
    - **Expected Outcome:** The system retrieves and displays Robert Johnson's Implantable Devices Record.
3. **Add Implantable Device:**
    - **Step 3.1:** Click the "Parse UDI" section within Robert Johnson's Devices record.
    - **Step 3.2:** Enter the details of a new implantable device:
        - **Unique Device Identifier (UDI):** (01)00012345678912(10)1234A (17)251231
        - **Date of Implantation:** 2024-07-15
    - **Expected Outcome:** The system successfully parses the implantable device details and displays all information parsed according to the ID i.e. Serial Number, Batch or Lot number, Device ID, Manufacturing Date, expiry date etc.
4. **Verify Implantable Device Entry:**

- **Expected Outcome:** The implantable device list displays the correct UDI, implantation date, and other details like serial and batch numbers.

Expected Result:

- The TronsHealth EHR system should accurately capture and display the details of the device, including the UDI and date of implantation, confirming that the implantable device list functionality works as intended.

Actual Result:

- The TronsHealth EHR system successfully recorded and displayed the device implanted, including the UDI and implantation date, in Robert Johnson's medical record. This confirms that the implantable device list functionality is working as expected.

User	Task Success	Path Deviation (Observations)	Path Deviation (Optimal)	Task Time (seconds)	Task Time (Observed)	Task Time (Optimal)	Errors	Task Rating (5=very easy) 1-5	Task Efficiency (5=very efficient) 1-5
01	Y	6	6	120	90	95	0	4.9	4.8
02	Y	7	6	95	100	95	0	4.5	4.2
03	Y	6	6	95	90	95	0	5	5
04	Y	5	6	95	97	95	0	4.9	4.5
05	Y	6	6	95	95	95	0	4.7	4.8
06	Y	5	6	95	90	95	1	5	4.9
07	Y	8	6	95	105	95	0	3.9	4.1
08	Y	7	6	95	100	95	0	4.2	4.5
09	Y	5	6	95	92	95	0	5	4.9
10	Y	6	6	95	95	95	0	4.8	4.5
	Mean 1.00	Mean 6.1	Mean 6.00	Mean 95	Mean 95.4	Mean 95	Mean 0.1	Mean 4.69	Mean 4.65
	SD 0.00	SD 0.94	SD 0.00	SD 0.00	SD 4.86	SD 0.00	SD 0.3	SD 0.35	SD 0.38

7.4.2. Scenario 5: Inactivating an Implantable Device for Patient Robert Johnson

To verify that the TronsHealth EHR system accurately processes and displays the inactivation of an implantable device for a patient named Robert Johnson, ensuring compliance with § 170.315(a)(14).

Patient Details:

- **Name:** Robert Johnson
- **Date of Birth:** 1962-11-15

- **Sex:** Male
- **Current Implantable Device ID:** 10885862001863

Steps:

1. **User Login:**
    - **Step 1.1:** Log in to the TronsHealth EHR system using authenticated credentials.
    - **Expected Outcome:** The user successfully accesses the dashboard.
2. **Navigate to Patient Record:**
    - **Step 2.1:** Click the patient icon from the sidebar menu and navigate to the patient's screen. Search for the patient "Robert Johnson" and open his implantable devices record from side menu under Clinical > Implantable Devices.
    - **Expected Outcome:** The system retrieves and displays Robert Johnson's medical record, including the details of the currently active implantable device.
3. **Inactivate Implantable Device:**
    - **Step 3.1:** Navigate to the "Implantable Device List" section within Robert Johnson's medical record.
    - **Step 3.2:** Select the active device (ID = 10885862001863) and click on edit, uncheck Active checkbox option to "Inactivate Device."
    - **Step 3.3:** Save the inactivation details.
    - **Expected Outcome:** The system should update the implantable device list, marking the Coronary Stent as "Inactive" with the inactivation date and reason documented.
4. **Verify Inactivation:**
    - **Step 4.1:** Review the implantable device list in Robert Johnson's medical record to ensure the device is now marked as inactive.
    - **Expected Outcome:** The implantable device list should correctly display the device as inactive, with the inactivation reason and date documented.

Expected Result:

- The TronsHealth EHR system should accurately process and display the inactivation of the Coronary Stent, marking it as inactive with the correct reason and date in Robert Johnson's implantable device list.

Actual Result:

- **Actual Result:** The TronsHealth EHR system successfully processed and displayed the Coronary Stent's inactivation, accurately marking it as inactive with the correct reason and date in Robert

Johnson's implantable device list. This confirms that the system's implantable device management functionality works as intended.

User	Task Success	Path Deviation (Observations)	Path Deviation (Optimal)	Task Time (seconds)	Task Time (Observed)	Task Time (Optimal)	Errors	Task Rating (5=very easy) 1-5	Task Efficiency (5=very efficient) 1-5
01	Y	3	4	60	55	60	0	5	5
02	Y	4	4	60	60	60	0	4.5	4.4
03	Y	5	4	60	70	60	0	4.9	4.6
04	Y	4	4	60	65	60	0	4.3	4.3
05	Y	3	4	60	50	60	0	4.5	5
06	Y	3	4	60	50	60	0	4.5	4.4
07	Y	5	4	60	65	60	0	4.8	3.9
08	Y	6	4	60	70	60	0	4.1	3.8
09	Y	5	4	60	69	60	0	3.9	4.1
10	Y	4	4	60	60	60	0	5	5
	Mean1.00	Mean 4.1	Mean 4.00	Mean 60	Mean 61.4	Mean 60	Mean 0.00	Mean 4.55	Mean 4.45
	SD 0.00	SD 1.13	SD 0.00	SD 0.00	SD 7.32	SD 0.00	SD 0.00	SD 0.35	SD 0.42

8. Results

The results calculated after the study are given below including each participant's feedback for rating and standard deviation of each scenario with time taken to perform the task.

8.1. Analysis and Reporting

One participant had a close call when s/he couldn't initially find the way to select and add medications. The data was not included in the analyses. The participant was able to complete the task. An artifact of testing occurred when one participant fully ordered a new medication, but potentially used a clinical judgement for the specified duration of the medication. That data was not included in the analyses. Multiple participants misunderstood the directions and defaulted to common clinical practices when performing the ordering new medication and changing the medication tasks. The participants completed the tasks and after verifying they had used their clinical judgements; the tasks were scored as task successes.

Task	Number	Task SuccessMean (SD)	Path Deviation	Task Time	Errors	Task Rating 1-5

			Deviations (Observed/Optimal)	Mean (seconds)	Deviations (Observed/Optimal)	Mean (SD)	Mean (SD)
Recording and Verifying Patient Demographics	10	100% (0.00)	1.05	100 (0.00)	1.05	0.1 (0.31)	4.62 (0.51)
Decision Support Intervention	10	80% (0.16)	1.10	72 (0.00)	1.03	0.2 (0.43)	3.69 (0.38)
Computerized Provider Order Entry-Medications	10	90% (0.3)	1.01	108	1.01	0.3 (0.66)	3.9 (0.46)
Record and Review Implantable Device	10	100% (0.00)	1.01	95 (0.00)	1.00	0.1 (0.3)	4.69 (0.35)
Inactivate Implantable Device	10	100% (0.00)	1.025	60 (0.00)	1.02	0.00 (0.00)	4.55 (0.35)

8.2. Effectiveness

Task performance for all the subtasks was at or above the 85% success criterion. Errors associated with medication order entry are discussed below.

8.3. Efficiency

Some participants specified they would like, when they choose a medication and dose (e.g., Lisinopril 10 mg tablet). For example, “tablet” would prepopulate in Take 1 tablet daily, and the user would only need to choose the “1” and the “daily”.

8.4. Satisfaction

Satisfaction levels were rated at the system level and at a scenario level. Refer to the chapter System Satisfaction for the system level Satisfaction ratings. Participants rated the scenario, which included these tasks, on a 1 (very difficult) to 5 (very easy) scale. The mean for the providers’ tasks was 4.2 with a standard deviation of 0.13. The mean for the nurses’ task was 4.5 with a standard deviation of 0.87.

8.5. Major Findings

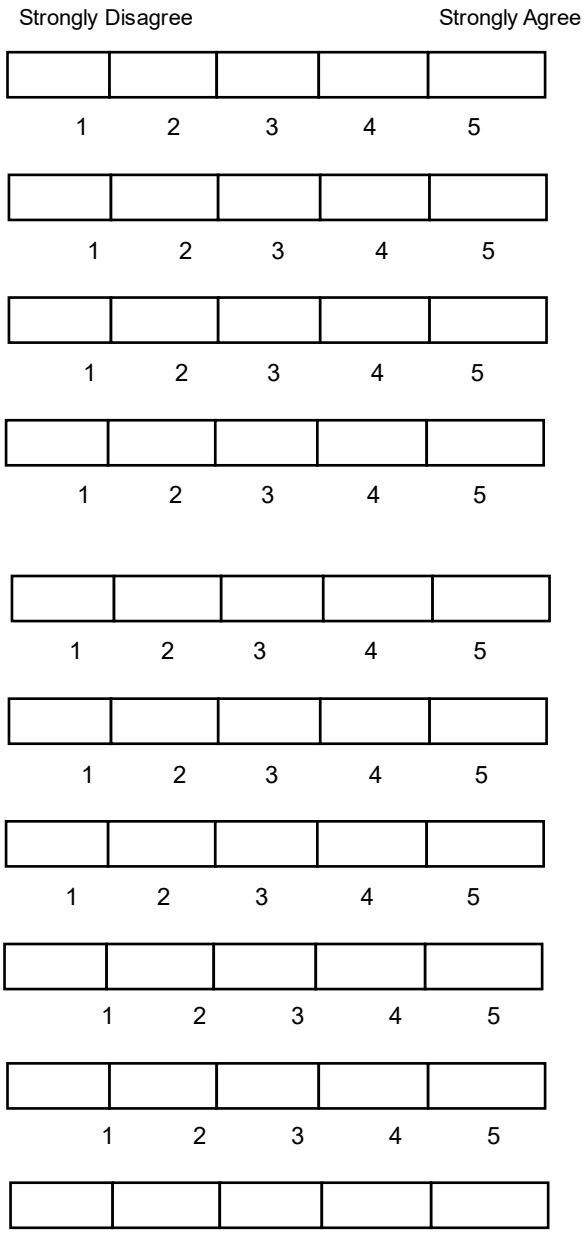
Participants were satisfied after participating in test scenarios with TronsHealth. It was an interactive session and found substantial experience feedback from them. This feedback would aid for future consistencies and implementations for seamless and better user experiences.

8.6. Areas for Improvement

Considering the feedback and areas identified during testing experiences, TronsHealth requires a better UI experience as per the user suggestions for smooth usage and better experience.

9. System Usability Score

We have used a system usability scale introduced and elaborated by Lewis and Sauro in 2009, known as “low-cost usability scale that can be used for global assessments of systems usability” or the System Usability Scale or SUS.
Source: https://www.researchgate.net/publication/228593520_SUS_A_quick_and_dirty_usability_scale



I could get going with this system.	1	2	3	4	5

10. Recruiting Form

Name: _____
Organization: _____
Phone Number (xxx-xxx-xxxx): _____
Email: _____
What is your Current Position?

- ○ Nurse
- ○ Care Coordinator
- ○ Physician
- ○ Physician Assistant
- ○ Administrative Staff Member
- ○ Radiologist
- ○ IT Specialist
- ○ Other:_____

Which of the following describes your highest level of education?

- ○ High school graduate, diploma or the equivalent (for example: GED)
- ○ Some college credit, no degree
- ○ Trade/technical/vocational training
- ○ Associate degree
- ○ Bachelor's degree
- ○ Master's degree
- ○ Doctorate degree (e.g., MD, DNP, DMD, PhD)

What sort of activities do you perform on a computer? (Check all that apply)

- □ Email
- □ Access EHR
- □ Research
- □ Word Processing
- □ Reading News 29
- □ Social Networking
- □ Shopping/Banking
- □ Other: _____

About how many hours per week do you work on a computer? (Hours)

- 0-5
- 5-10
- 11-25
- 26-35
- 36+

What other EHRs have you used?
:_____