Human Factors Engineering Program Plan

Cathy Jennings

September 18, 2018

Lexie Kirsch

POLLEX CONSULTING

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Cathy Jennings
Director of Regulatory Affairs
Verb Surgical

Dear Cathy Jennings,

Thank you for choosing Pollex Consulting to develop a detailed human factors engineering program plan to guide the development of Verb Surgical's surgical robot.

In this report you will find a summary of the technical work required, the expected end-products, and citations of relevant requirements, expectations, and standards set forth by the FDA and IEC.

Please do not hesitate to reach out to me with any questions or comments. I look forward to working with you.

Sincerely,

Lexie Kirsch
Human Factors Engineering Consultant
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HFE PROGRAM PLAN

Overview

This project plan outlines the activities and end-products necessary to ensure that use of Verb Surgical's surgical robot is safe and effective, based on the expectations of the Food and Drug Administration (FDA) and International Electrotechnical Commission (IEC).

This project plan is tailored to Verb Surgical's surgical robot. Using a surgical robot is high risk and therefore merits intensive research and analysis.

The following sections are included in the plan:

- Research Activities
- Analysis Activities
- Specification Activities
- Design Activities
- Evaluation Activities
- Final Report Activity

Research Activities

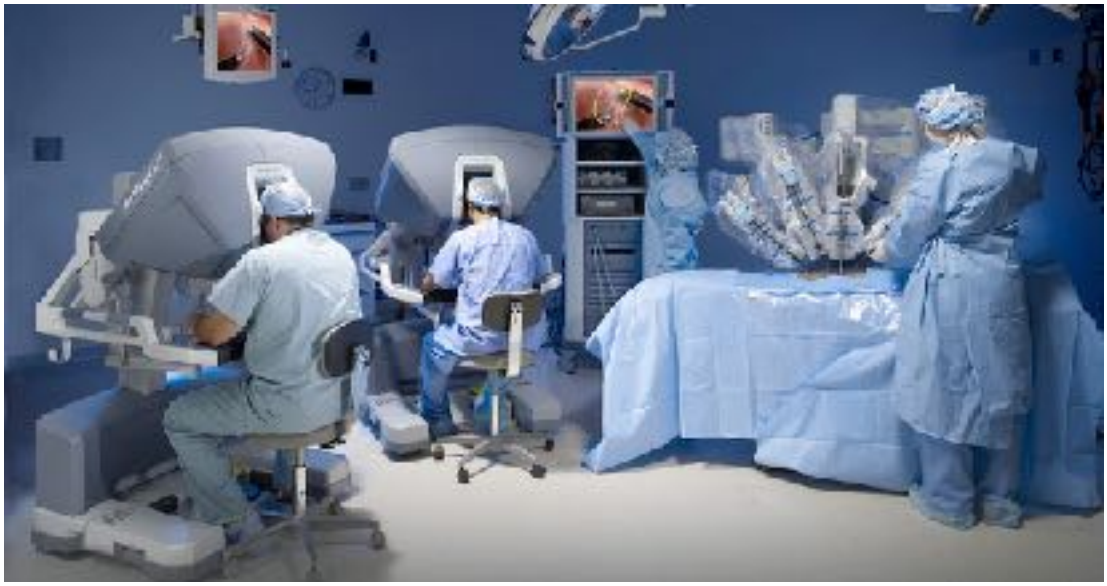
❖ *Understand Users*

Verb shall visit at least three different hospitals to study the expected users of the surgical device. Verb shall document the user research results in a report, which shall include photos and videos of the expected users.

Descriptions of the expected users may include characteristics such as the following, as listed in the FDA HFE guidance:

- Physical size, strength, and stamina,
- Physical dexterity, flexibility, and coordination,
- Sensory abilities (i.e., vision, hearing, tactile sensitivity),
- Cognitive abilities, including memory,
- Medical condition for which the device is being used,
- Comorbidities (i.e., multiple conditions or diseases),
- Literacy and language skills,
- General health status,
- Mental and emotional state,
- Level of education and health literacy relative to the medical condition involved,
- General knowledge of similar types of devices,
- Knowledge of and experience with the particular device,
- Ability to learn and adapt to a new device, and
- Willingness and motivation to learn to use a new device.

Deliverable: Description(s) of users (including photos and videos)
Sample image: Users performing robot-assisted surgery
(Source: https://westervillesurgical.com/robotic-surgery/)



Reference:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Subsection 5.1 Device Users

❖ *Understand Use Environments*

Verb shall study the expected use environments while conducting user research at the on-site visits described in *Understand Users*. Verb shall document the use environment research results in a report, which shall include photos and videos of the sampled use environments.

Descriptions of the use environments may reference the following elements, as listed in the FDA HFE guidance:

- The lighting level might be low or high, making it hard to see device displays or controls.
- The noise level might be high, making it hard to hear device operation feedback or audible alerts and alarms or to distinguish one alarm from another.
- The room could contain multiple models of the same device, component or accessory, making it difficult to identify and select the correct one.
- The room might be full of equipment or clutter or busy with other people and activities, making it difficult for people to maneuver in the space and providing distractions that could confuse or overwhelm the device user.
- The device might be used in a moving vehicle, subjecting the device and the user to jostling and vibration that could make it difficult for the user to read a display or perform fine motor movements.

Deliverable: Description(s) of the use environment (including photos and videos)
Reference:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Subsection 5.2 Device Use Environments

Analysis Activities

❖ *Analyze Known Use-Related Problems*

Verb shall investigate problems that have occurred with at least one predicate or similar device, such as the DaVinci Model SI.

Verb shall obtain this information from various sources, which may include the following, as listed in the FDA HFE guidance:

- FDA's Manufacturer and User Facility Device Experience (MAUDE) database;
- FDA's MedSun: Medical Product Safety Network;
- CDRH Medical Device Recalls;
- FDA Safety Communications;
- ECRI's Medical Device Safety Reports;
- The Institute of Safe Medical Practices (ISMP's) Medication Safety Alert Newsletters; and
- The Joint Commission's Sentinel Events.

Deliverable: Report of known problems
Reference:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff.* Subsection 6.2 Identification of Known Use-Related Problems

❖ *Analyze Tasks*

Verb shall conduct a task analysis to identify use errors that may occur while using the surgical robot.

Verb shall consider the following questions during the analysis, as listed in the FDA HFE guidance:

- What use errors might users make on each task?
- What circumstances might cause users to make use errors on each task?
- What harm might result from each use error?
- How might the occurrence of each use error be prevented or made less frequent?
- How might the severity of the potential harm associated with each use error be reduced?

Deliverable: Task analysis

Reference:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Subsection 6.3.1 Task Analysis

❖ *Analyze Use-Related Hazards*

Verb shall review at least six cases of use-related hazards involving similar surgical robots.

Use-related hazards may occur from any of the following situations, as listed in the FDA HFE guidance:

- Device use requires physical, perceptual, or cognitive abilities that exceed the abilities of the user;
- Device use is inconsistent with the user's expectations or intuition about device operation;
- The use environment affects operation of the device and this effect is not recognized or understood by the user;
- The particular use environment impairs the user's physical, perceptual, or cognitive capabilities when using the device;
- Devices are used in ways that the manufacturer could have anticipated but did not consider; or
- Devices are used in ways that were anticipated but inappropriate (e.g., inappropriate user habits) and for which risk elimination or reduction could have been applied but was not.

Deliverable: List of use-related hazards

References:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Subsection 4.1 HFE/UE as Part of Risk Management
- 62366-1:2015. Subsection 5.3 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

Specification Activities

❖ *Develop Use Specification*

Verb shall develop a use specification that includes a list of the intended uses (i.e., procedures that the surgical robot can perform), intended user population (see *Understand Users*), and intended conditions for use.

Deliverable: Use specification
Reference:
- 62366-1:2015. Subsection 5.1 Prepare USE SPECIFICATION

❖ *Develop User Interface Specification*

Verb shall develop a user interface specification based on the users (see *Understand Users*), use environments (see *Understand Use Environments*), and task analysis (see *Analyze Tasks*).

Deliverable: User interface specification
Reference:
- 62366-1:2015. Subsection 5.6 Establish USER INTERFACE SPECIFICATION

Design Activities

❖ *Apply HFE Principles to UI Design*

Verb shall use human factors engineering principles to ensure the user interface of the surgical robot supports safe and effective use.

The user interface shall be designed to mitigate the hazards and risks associated with the device users and use environments (see *Understand Users*, *Understand Use Environments*, *Analyze Known Use-Related Problems*, *Analyze Tasks*, and *Analyze Use-Related Hazards*).

The design shall address the use specifications and user interface specifications (see *Develop Use Specification* and *Develop User Interface Specification)*.

Design elements to consider include the following, as listed in the FDA HFE guidance:

- The size and shape of the device (particularly a concern for hand-held and wearable devices),
- Elements that provide information to the user, such as indicator lights, displays, auditory and visual alarms,
- Graphic user interfaces of device software systems,
- The logic of overall user-system interaction, including how, when, and in what form information (i.e., feedback) is provided to the user,
- Components that the operator connects, positions, configures or manipulates,
- Hardware components the user handles to control device operation such as switches, buttons, and knobs,
- Components or accessories that are applied or connected to the patient, and
- Packaging and labeling, including operating instructions, training materials, and other materials.

Deliverable: Description of how Verb will apply HFE design principles to UI
References:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Subsection 5.3 Device User Interface
- 62366-1:2015. Subsection 5.8 Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION

❖ *Develop Training Resources*

Verb shall provide training resources for the expected users of the surgical robot.

Training materials shall inform expected users of correct device use and also indicate use-related problems to avoid.

Deliverable: Training materials (e.g., user manual, reference guide, videos of users conducting robotic surgery)
Reference:

- 62366-1:2015. Subsection 5.8 Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION

Evaluation Activities

❖ *Develop UI Evaluation Plan*

Verb shall evaluate the user interface of the medical robot, particularly during hazard-related use scenarios, using at least one method. Possible evaluation methods include the following, as listed in the FDA HFE guidance:

- Expert reviews,
- Formative usability tests, and
- Simulated-use tests

Deliverable: Plan for UI evaluation
References:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Subsection 6.3 Analytical Approaches to Identifying Critical Tasks; subsection 6.4 Empirical Approaches to Identifying Critical Tasks
- 62366-1:2015. Subsection 5.5 Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION; subsection 5.7 Establish USER INTERFACE EVALUATION plan

❖ *Conduct UI Design Verification*

Verb shall conduct a validation test to verify that the UI design meets the UI specifications (see *Develop Use Specification* and *Develop User Interface Specification*).

Validation tests must adhere to the following rules, as listed in the FDA HFE guidance:

- The test participants represent the intended (actual) users of the device.
- All critical tasks are performed during the test.
- The device user interface represents the final design.
- The test conditions are sufficiently realistic to represent actual conditions of use.

Deliverable: Plan for UI verification
References:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Section 8 Human Factors Validation Testing
- 62366-1:2015. Subsection 5.9 Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE

Final Report Activity

Verb shall write a HFE report to summarize the HFE work involved in the user interface design of the surgical robot.

The HFE report shall include the following sections, as listed in the FDA HFE guidance:

- Conclusion
- Description of intended device users, uses, use environments, and training
- Description of device user interface
- Summary of known use problems
- Analysis of hazards and risks associated with use of the device
- Summary of preliminary analyses and evaluations
- Description and categorization of critical tasks
- Details of human factors validation testing

Deliverable: HFE report
Reference:

- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Table A-1. Outline of HFE/UE Report