Human Factors Engineering Program Plan

Cathy Jennings

September 18, 2018

Lexie Kirsch

POLLEX CONSULTING

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September 18, 2018

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 US 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

Lexie Kirsch
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Pollex Consulting

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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 US 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 human factors research and analysis to comply with regulatory imperatives. By implementing this plan, Verb Surgical can assure the FDA and IEC that their surgical robot is suitable for market.

The following sections are included in the plan:

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

Each section includes activity descriptions, activity-related deliverables, and references to sections of the FDA HFE guidance and 62366-1 standard that ask manufacturers to perform the specified activities.

References:

- 62366-1:2015
- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*

Research Activities

❖ *Understand Users*

Verb shall visit at least three different hospitals to study surgeons as they use the surgical device. Verb shall conduct both observations and interviews with the surgeons and document their user research results in a report, which shall include photos and videos of the surgeons interacting with the device.

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.

By understanding the users of the device and how they use the device, Verb can better understand the strengths and areas for improvement of their surgical robot. For example, if surgeons are using a surgical robot with ease but have years of experience using a similar device, their success may be attributed to their experience as opposed to the usability of the device. To recreate such success with Verb's surgical robot and other surgeons, Verb may need to provide extensive training.

Deliverable: User research report with user profiles and descriptions of users (including photos and videos)
References:

- 62366-1: Subsection 3.24 USER, Subsection 3.25 USER GROUP, Subsection 3.29 USER PROFILE

- 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 operating rooms in which the surgical robots are being used 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 rooms.

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.

It is important to understand the use environment of the surgical device to ensure that unforeseen environmental characteristics do not negatively affect the usability of the device. For example, although the surgical robot may produce a warning sound that is audible during a standard procedure, the same warning sound may be inaudible when the device is located in a large room with multiple other devices which are also producing warning sounds.

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

- 62366-1: Subsection 3.20 USE ENVIRONMENT
- 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, within the past five years.

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.

For additional information, Verb can also interview users of predecessor devices.

By identifying problems with predicate and similar devices, Verb can indicate to the FDA and IEC the steps Verb has taken to avoid similar adverse events with their own surgical robot.

Deliverables: Report of known problems and UI requirements derived from known problems
References:

- 62366-1: Subsection 5.3 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS
- 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 Functions*

Verb shall perform a comprehensive analysis of all the functions of their surgical robot, which include functions performed within the system and by the user. Verb shall assess functions by performance relative to ensuring safety and frequency, and present each function in a function allocation table.

Deliverables: List of functions and function allocation table

References:
- 62366-1: Subsection 3.11 Primary operating functions; Subsection 5.2 Identify USER INTERFACE characteristics related to safety and potential use errors
- 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 Tasks*

Verb shall conduct a task analysis to identify use errors that may occur while using the surgical robot. To conduct a task analysis, Verb shall identify the necessary tasks involved in using the surgical robot during a procedure and then ask representative users, i.e., surgeons, to complete those tasks. It is important to provide only the tasks, and not the steps involved in each task, to gather unbiased data about what the user knows and is capable of doing on their own. To that end, Verb shall avoid assisting users on tasks by providing guidance or correcting the user's behavior if the user makes a mistake.

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?

The findings from the task analysis will help Verb identify use errors and risks of using the surgical robot, which is the first step to mitigating those errors and risks later.

Deliverables: List of critical tasks, task analysis diagrams (e.g., flow charts), and list of potential use errors
Reference:
- 62366-1: Subsection 5.2 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS
- 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 and Subsection 8.1.2 Tasks and Use Scenarios

❖ *Analyze Hazards and Associated Use Scenarios*

Verb shall perform a comprehensive analysis of the intended use scenarios for their surgical robot, particularly scenarios that could be hazardous (i.e., lead to use errors that may cause harm). The analysis shall include a review of all potential hazards and related use scenarios that could expose users to hazards, lead to a hazardous situation, cause actual harm, or compromise the patient's medical care, as the terms are defined in 62366-1. The analysis shall consider normal use, as opposed to "abnormal use," which the FDA defines in its HFE guidance as "an intentional act or intentional omission of an act that reflects violative or reckless use or sabotage beyond reasonable means of risk mitigation or control through design of the user interface."

Types of possible hazards include electrical, chemical, radiation, thermal, biological, physical, and ergonomic.

Deliverables: Hazard-related use scenario descriptions, and list of hazards and hazardous situations
References:

- 62366-1: Subsection 5.3 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS; Subsection 5.4 Identify and describe HAZARD-RELATED USE SCENARIOS
- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff.* Section 7 Elimination or Reduction of Use-Related Hazards

❖ *Analyze Use-Related Risks*

Using the results of the preceding analyses, Verb shall compile a list of potential use errors that may occur when surgeons operate the surgical robot.

Use-related risks may occur in 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.

Verb shall then assess the risk posed by every potential use error by performing a use-related failure modes and effects analysis (U-FMEA). Verb shall prepare a table in which the following information is included:

- The tasks that users must complete, derived from the task analysis
- A concise description of each user error that could occur during each task
- A concise description of the potential harm that might result from the use error
- An estimate of the likelihood of the use error occurring, according to the established rating scale
- An estimate of the severity of the harm that might result from the use error, according to the established rating scale

Verb shall seek to mitigate the risk of any use error with a severity rating greater than an established limit, which will be set by Verb's risk management team.

Deliverable: U-FMEA table
References:

- 62366-1: Subsection 4.1.2 RISK CONTROL as it relates to USER INTERFACE design; Subsection 5.2 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS; Subsection 5.3 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS
- 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

Specification Activities

❖ *Develop Use Specification*

Verb shall develop a use specification that includes a list of the following:
- Intended uses (i.e., procedures that the surgical robot can perform);
- Intended user population (see *Understand Users*);
- Intended conditions for use (see *Understand Use Environment*); and
- Intended part of body or type of tissue with which the surgical robot can be used.

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

❖ *Develop User Interface Requirements*

Verb shall develop user interface requirements for all aspects of the user interface that affect the user experience, with special emphasis on use safety, effectiveness, and usability.

The requirements will be based on the following inputs:
- Findings from the *Understand Users* activity (e.g., needs and preferences expressed by participants)
- Findings from the *Understand Use Environments* activity (e.g., environmental and situational factors that are likely to impact use)
- Task, function, and use-related hazards analyses and the resulting recommendations (e.g., design features implemented to mitigate against known problems)
- HFE design principles published in standards, guides, textbooks, and the like
- Customer satisfaction goals (of commercial interest, unrelated to use safety)

Deliverable: User interface requirements
References:
- 62366-1: Subsection 5.6 Establish USER INTERFACE SPECIFICATION
- 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

❖ *Develop User Interface Specification*

Verb shall develop a user interface specification based on the users (see *Understand Users*), use environments (see *Understand Use Environments*), functions (see *Analyze Functions*), use scenarios (see *Analyze Hazards and Associated Use Scenarios*), and UI requirements (see *Develop User Interface Requirements*).

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

Design Activities

❖ *Apply HFE Principles to User Interface Design*

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

The design shall address the use specifications, user interface requirements, and user interface specifications (see *Develop Use Specification*, *Develop User Interface Requirements*, 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 user interface

References:

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

❖ *Develop Design-Based Risk Mitigations*

Verb shall mitigate use-related risk by developing design solutions that either eliminate the chance of particular use errors, minimize the chance they will occur, or enable rapid detection and correction of the use errors before harm can occur.

Deliverable: Description of how Verb will mitigate risk through design
References:
- 62366-1: Subsection 5.9 Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE
- FDA, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. Section 7 Elimination or Reduction of Use-Related Hazards

❖ *Develop a Style Guide (optional)*

Verb may develop a user interface style guide that documents the user interface design principles of the surgical robot. The style guide will help ensure consistency within the user interface and any future modifications.

Deliverable: User interface style guide
References:
- None

❖ *Develop Accompanying Documentation (optional)*

Verb will ensure that user documentation (e.g., information for safe use) includes a description of the operating principles of the surgical robot, significant physical and performance characteristics, and a description of intended users and use environments.

Deliverable: Accompanying documents
Reference:
- 62366-1: Subsection 3.2 ACCOMPANYING DOCUMENTATION

❖ *Develop Training Resources*

Due to the high risk of using a surgical robot, Verb shall provide training resources for the expected users of the surgical robot.

Training materials shall inform users of correct device use and also indicate use-related problems to avoid. The effectiveness of these materials shall be assessed during formative and summative evaluations.

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

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

Evaluation Activities

❖ *Develop User Interface Evaluation Plan*

Verb shall frequently evaluate the user interface of their surgical robot, particularly during hazard-related use scenarios. Possible evaluation methods include the following, as listed in the FDA HFE guidance:

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

Formative usability tests shall involve Verb's intended users, who will perform a range of activities with the surgical robot, including those associated with critical tasks. The number of usability tests Verb shall conduct will vary on technical considerations and test results. Verb shall follow a test plan to guide each usability test and shall document the test results in a formal report or memo. The formality of the plans and reports will be determined by the evaluation team based on perceived need. The report shall document not only the findings of the test but also the associated design recommendations to ensure safety, effectiveness, usability, and appeal.

Deliverables: User interface evaluation plan, formative usability test plans and reports
References:

- 62366-1: Subsection 5.7 Establish USER INTERFACE EVALUATION plan; Subsection 5.8 Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION
- 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; Section 8 Human Factors Validation Testing

❖ *Conduct User Interface Design Verification*

Verb shall conduct a verification test to assess whether the user interface design meets the user interface requirements and specifications (see *Develop Use Specification*, *Develop User Interface Requirements*, and *Develop User Interface Specification*).

Deliverable: Verification table
References:

- None

❖ *Conduct Summative (Validation) Usability Test*

Verb shall conduct a validation test to demonstrate that the device is safe and effective for the intended users, uses, and use environments, thus validating the user interface design.

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.

As with the formative usability test, Verb shall develop a test plan to guide the summative usability test. The test plan will be submitted to the FDA for their review and comments and then revised accordingly. Then Verb will digitally record test sessions, document test results in a formal report, and perform a vigorous root cause analysis of all use errors with the potential for serious harm. Verb will update the use-related risk analysis to reflect these test results and determine what, if any, additional control measures are necessary. If no further risk control measures are necessary, Verb will proceed to document the entire HFE process in a final report. If further risk control measures are necessary, Verb will implement risk mitigations and conduct additional formative and summative usability tests as needed until risks have been reduced to an acceptable level.

Deliverables: Summative usability test plan for FDA review, revised summative usability test plan (if necessary), summative usability test report (with videos and photographs)
References:

- 62366-1: Subsection 5.5 Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION; Subsection 5.9 Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE
- 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

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:

1. Conclusion
2. Description of intended device users, uses, use environments, and training
3. Description of device user interface
4. Summary of known use problems
5. Analysis of hazards and risks associated with use of the device
6. Summary of preliminary analyses and evaluations
7. Description and categorization of critical tasks
8. Details of human factors validation testing

The FDA expects the HFE report to draw the conclusion that Verb's surgical robot has been found safe and effective for the intended users, uses, and use environments.

Deliverable: HFE report
References:

- 62366-1: Subsection 4.2 USABILITY ENGINEERING FILE
- 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