Do It By Design - An Introduction to Human Factors in Medical Devices - Appendix, Glossary and References

APPENDIX

Points to Consider

In considering the need for, and conduct of, human factors analysis and testing, there are a number of issues and questions to ask.

1. Does the device require user interaction with respect to operation, maintenance, cleaning, or parts installation? If so, do the technology and device functions permit alternative user interface designs?
2. Given the combination of user interface, user population, and operating conditions, are errors likely?
3. Could the consequences of error be serious for the patient or user?
4. In doing actual testing:
   - Is someone integral to the design team focusing on the user-related issues?
   - Are users involved?
   - Are hardware and software designers, technical writers, and others coordinating their efforts with respect to human factors?
   - Has a test plan been developed?
   - Have user requirements been developed, and are they being updated?
5. Has the design team checked the literature and company files for useful human factors information?
6. What studies, analyses, and test steps are being performed? Are staff examining all relevant issues related to the installation of accessories and operation of the device?
7. Has the project team done testing in simulated and/or actual environments?
8. Have user requirements been met?
9. User interface changes can be inadvertently introduced into production models during manufacturing. Have they been accounted for?

GLOSSARY

The definitions in this section are pertinent to this document. In some cases they are general and may not coincide with a specific usage or application.

Administration set (intravenous): A device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, flow regulator, drip chamber, filter, stopcock, fluid delivery tubing, connectors, capped side tube to serve as an injection site, and hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

Anthropometry: The field that involves the measurement of the dimensions and other physical characteristics of people and the application of this information to the design of things they use.

Blood glucose monitor: A device that quantitatively measures glucose concentrations in the blood.

Calibration: To check, adjust, or standardize systematically the graduations of a quantitative measuring instrument.

Cardiac monitor (including cardiotachometer and rate alarm): A device used to measure the heart rate from an analog signal produced by an electrocardiograph, vector cardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.
**Catheter:** A tubular medical device for insertion into canals, vessels, passageways, or body cavities, usually to permit injection or withdrawal of fluids or to keep a passage open.

**Coding:** Identifying objects or events with the use of recognizable symbols, typically visual or auditory, utilizing readily apparent variables such as color, shape, size, direction, pitch, or duration.

**Cognition:** Processing information about the environment and oneself in conscious intellectual activity, as in thinking, reasoning, remembering, and imagining.

**Default:** Parameters that are automatically selected by a machine in case deliberate actions by the user do not occur.

**DC-Defibrillator:** A device that delivers an electrical shock for defibrillating (restoring to normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device delivers the electrical shock through paddles placed directly across the heart or on the surface of the body.

**Enteral Feeding Tube:** A tube for passing of food or medicines into the stomach.

**Function:** The action or accomplishment intended of a system where the system consists of a device and a user. Alternatively, individual primary functions, such as installation, maintenance, operation, and monitoring, are needed to accomplish the intended use of the user-device system.

**Guide wire:** A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

**Human Factors:** In the broadest sense, a discipline devoted to the effects of user interface design, job aiding, and personnel training in the operation, maintenance, and installation of equipment.

**Heart valve leaflets:** Any of the leaf-like flaps of the bicuspid or tricuspid valves of the heart.

**Infusion pump:** A device used to pump fluids into a patient in a controlled manner. The device may use a piston pump, roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.

**Infusion pump cassette:** That part of the set of intravenous tubing that fits into an infusion pump. Each cassette is "dedicated" or designed to fit a specific pump.

**Iterative Prototyping:** Successive small-scale tests on variations of a limited function prototype. Such tests permit continual design refinements based upon human performance.

**Interlock:** To prevent initiation of new operations until current operations are completed (computer science). To connect in such a way that no part can operate independently.

**MedWatch Form 3500A:** A form that must be completed by user facilities and manufacturers to report device-related adverse events to FDA under the medical device reporting (MDR) system (21 CFR, Parts 803 and 804).

**Mockup:** Usually a full-sized scale model of a structure, used for demonstration, study, or testing.

**Negative transfer:** Transfer of training that results in increased likelihood of human error, due to changes in the user interface or situations that are not obvious to the user.

**Oxygen concentrator:** A device that produces a high concentration of oxygen (85% to 95%) at clinically useful flow rates (up to 5 L/min) by physical separation of oxygen from ambient air. Oxygen concentrators are commonly used in home healthcare and occasionally in general anesthesia.

**Screen print:** A static image, represented on paper, which is used to show how a computer program will appear on a monitor.

**Storyboard:** One page in a series of paper representations of the sequence of actions possible in a system. Story boards representing a computer program could show keys, prompts, and changes in status.

**Task:** The steps or work activities required of the user in order to perform functions.

**Task analysis:** Identification and analysis of the key user tasks and steps for a device. The analysis may be conducted as a paper-and-pencil exercise for a device concept, or by running through the procedures on a prototype or actual device.

**Transfer-of-training:** The automatic application of skills, habits, or expectations to a new situation that appears similar to the one in which the skills and expectations were originally developed.
Usability Test: A test of either an actual device or an advanced prototype with a fully functional user interface. Data obtained includes user performance (time, errors, and accuracy) and subjective responses of test participants.

User performance data: Information describing human behaviors and responses during task performance. Examples of the criteria measured are frequency of accomplishing a task, time required for task accomplishment, and changes in performance with practice.

Ventilator: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas.

REFERENCES FOR FURTHER READING

Standards


National Committee for Clinical Laboratory Standards. (1996) Laboratory instruments and data management systems: Design of software user interfaces and end user software systems validation, operation, and monitoring. NCCLS GP-19-P. Villanora, PA.: NCCLS.


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