Medical Device HF&E Heuristic Analysis

ESTIMATING LEVEL OF EFFORT FOR HFE HEURISTIC ANALYSIS

The US FDA requires that Class 2 & 3 medical devices comply with the Design Control regulation (21 CFR 820.30). Human factors and ergonomics (HF&E) engineering and resultant device usability is an element of design controls. HF&E engineering is fundamentally about developing, deploying, and maintaining products, processes, and services for human use. The discipline can be roughly divided into sets of 4 major areas (see diagram on last page). HF&E engineering considerations participate in a manner similar to hardware, software, and economic considerations in the development of requirements, in compliance with appropriate regulations and standards, and in the engineering of system reliability, safety, and security. HF&E considerations are important at all stages of the system lifecycle (development, deployment, maintenance, and disposal). HF&E engineering is not merely about usability or user experience, although these are important factors. "Cradle to grave" HF&E engineering addresses not only physical, behavioral, social, and cultural factors of the intended user(s) (e.g., clinicians, BMETs, managers, etc.) in the intended use environment(s), but also addresses the HF&E issues during development (e.g., integration of hardware, software, and human factors design and testing) and during deployment (e.g., selection, installation, maintenance, and disposal).

A heuristic analysis (HA) is an expert-based analytical evaluation of the HF&E engineering issues relevant to a specific medical device. The strength of the HA depends upon the expertise of the analyst(s), the breadth and extent of coverage, and the use of structured, systematic analytical tools. The HA may result in the following recommendations: HF&E engineering design changes, execution of a usability validation study, and/or a user experience study. Often, with very simple devices, the HA report may be sufficient to justify not doing validation studies at the subsystem (e.g., usability) level; system validation (actual or simulated intended use by intended users in the intended use environment) is always required (21 CFR 820.30(g)).

We typically prefer to include the heuristic analysis as part of a formal formative evaluation (FE). FEs may be subject-free, may use SMEs, or may use small (<5) numbers of prospective user subjects to analyze critical functions, tasks, and labeling comprehension. FEs consist of:

a. Detailed definition of the intended user population(s)
   i. User demographics
   ii. User needs analysis
   iii. User limitations analysis (physical, cognitive, etc.)
b. Detailed device analysis
   i. Function & task analysis
   ii. Physical ergonomics analysis
c. Heuristics
   i. Summarized history of problems of same or similar predicate devices
   ii. Heuristic evaluation (with minimum 2 CPEs and a variable number of SMEs)
   iii. Selected cognitive walk-thrus
d. Risk Analysis (you can find our standard dFMEA template for a complete device risk analysis on our website: www.samaras-assoc.com/risk management.htm; it shows many of the standard elements for the following two hazard categories – sections E & F)
   i. Use of device hazards
   ii. User interface hazards (that includes labeling)
e. Labeling Analysis
   i. Typographic analysis (font selection, font size, visual organization)
   ii. Graphics analysis
   iii. Readability analysis
   iv. Logic of instructions versus expected device operation modes (expected use, unexpected use, misuse, and abuse) analysis

Each FE iteration results in a FE report that will reside in the device Design History File (21 CFR 820.30j). To complete a Formative Evaluation, the following items are required (they may be in DRAFT form):

a. dimensioned, annotated engineering drawing(s) of the device case, controls, and access panels;
    i. the device risk analysis (dFMEA and, if available, FTA or RCA) including all identified risks and proposed mitigations (mitigations do not have to be implemented yet);
    ii. if a device risk analysis is not available, we will generate the human factors portion of the risk analysis, as it is required for the effort
b. the Directions for Use (e.g., user manual and/or package insert(s));
c. the advertising platform describing the various claims and intended use(s);
d. a working production prototype unit with all labels (they can be in draft form);
e. one complete set of all accessories;
f. one preproduction, or mockup, version of the packaging.

Initial Formative Evaluations, conducted early in the device development lifecycle, do not require all the aforementioned elements. However, the final Formative Evaluation will require all these elements and the report of that final FE will also be an appendix to the Summative Evaluation human study protocol.

Summative evaluations (SEs) are based upon the final FE and consist of:

a. A SE human study protocol for review and approval by the IRB for the study site
b. Execution of the SE study with a typically minimum of 15-20 subjects per user group
c. Analysis the acquired study data (e.g., demographics, baseline physical assessments such as visual & auditory acuity, fine motor control, reading comprehension, etc., scoring of the subject questionnaire, subject video, subject measurement data and subject interviews, as appropriate)
d. Completion of a SE report

One or more SE studies may be required; typically, more than one SE study is required for drug-device combinations, as they tend to correspond to the phase (safety, efficacy, non-inferiority) of the medical or surgical trials being conducted.

In order to estimate the level of effort to conduct the analysis, the aforementioned documents are required. Missing or poorly constructed documents require correction or completion and increase the estimated level of effort. The level of effort required for analysis and generation of the report depends upon the complexity and extent of the device, accessories, and labeling.

One result of a heuristic analysis is that the device design (hardware, software, and/or labeling) may have to be changed. The following are a few useful references for medical device human factors engineering development; you should familiarize yourself and your development team with these documents PRIOR TO BEGINNING your engineering development efforts:

a. Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff, April 3, 2016
b. ANSI/AAMI/IEC 62366-1:2015, Medical Devices - Part 1: Application of usability engineering to medical devices
c. ANSI/AAMI HE75:2009 (R) 2013, Human factors engineering - Design of medical devices.

Two good reference texts are:

a. Salvendy G (Ed). Handbook of human factors and ergonomics, 4th Edition. NY: Wiley. 2012.
b. Woodson WE, Tillman B, & Tillman P. Human Factors Design Handbook. NY:McGraw-Hill. 1992

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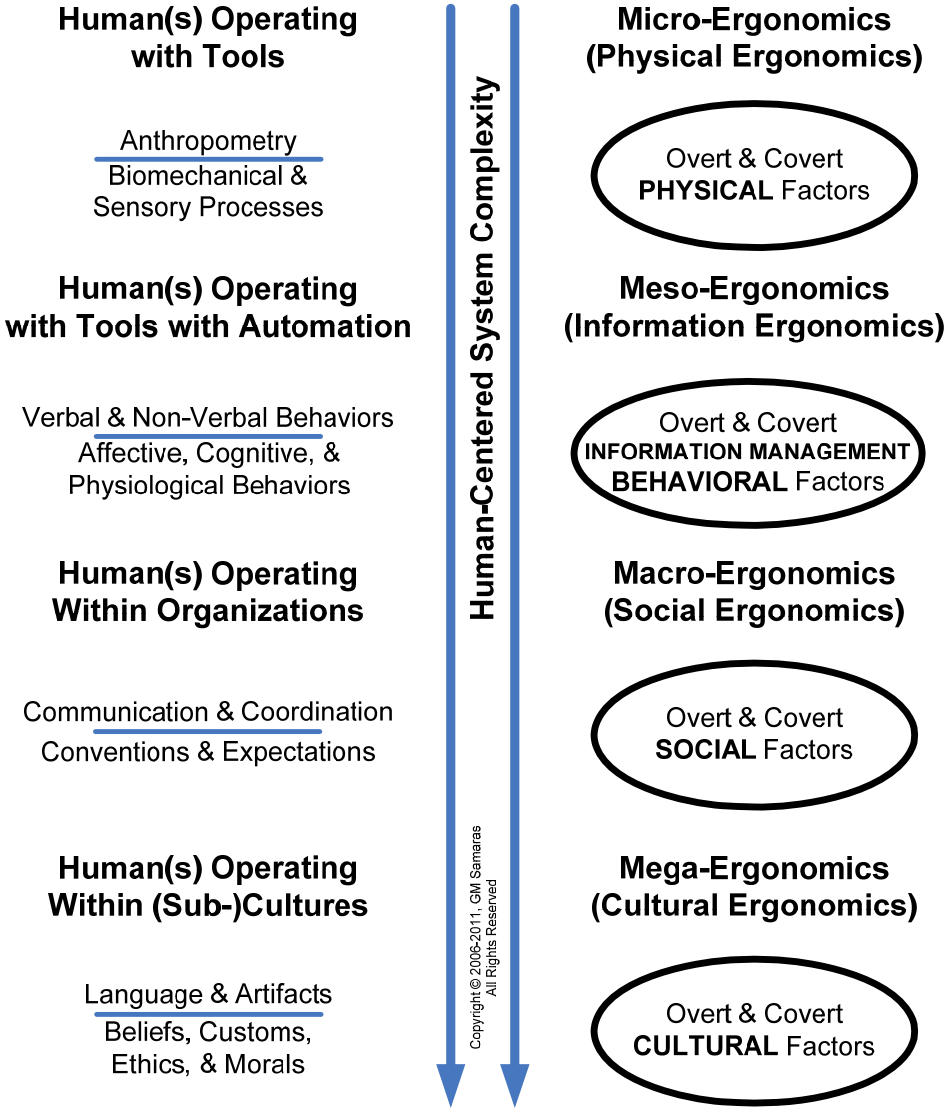

THE BREADTH OF HF&E CONSIDERATIONS

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