The growing role of human factors and usability engineering for medical devices

What's required in the new regulatory landscape

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Background

Medical errors have been cited as the cause of nearly 100,000 deaths per year in the US healthcare system by the US Institute of Medicine in 1994 in its book, *To err is human: Building a safer health system*. According to the World Health Organization's website, similar trends exist for European healthcare systems, with estimates that 8 to 12 per cent of hospitalizations involve adverse events and that as many as 18 per cent of patients report having experienced a medical error-induced problem. Costs in the UK alone for hospital infection intervention is estimated at £1 million per year.

Adverse events over the past two decades have shown disturbing trends in post-market events that are attributable to design issues regarding the user interface (UI) of medical devices. Infusion pumps, automatic electronic defibrillators, ventilators, and combination products such as drug auto-injectors, have a history of use-related design problems resulting in overdoses, improper therapy delivery, incorrect diagnoses and dangerous delays in therapy. As part of the systematic process to reduce errors by regulatory bodies, medical device companies in the US and EU have been introduced to the disciplines of Human Factors and Usability Engineering (HF/UE). HF/UE has been applied in the automotive, aerospace, and telecommunications industries for more than 60 years, but has only recently been applied in the medical industry.

HF/UE focuses on the synergy of human operators, or users with systems, and their UIs by applying knowledge of human capabilities and limitations and performing tests and evaluations of user/system performance. Human factors also apply known principles and best practices in the design of displays, controls, and other UI aspects to optimize use and eliminate or limit use-related risks.

Is usability different from human factors? How do these terms relate?

The term 'usability engineering', often used as a synonym for 'human factors', is also focused on creating qualities of UIs that result in rapid learning, user satisfaction, and efficient interaction. The term 'usability' is a multi-dimensional quality that refers to the ability of a human to interact easily and relatively error-free with a system or product. Terms such as 'user-friendly' and 'intuitive' have emerged as descriptors of usability which translate to subjective attributes regarding whether a system or device works and acts in the way the user expects, therefore avoiding frustration and annoyance in carrying out an intention.

What is the impact of usability on healthcare?

Usability has a major impact on healthcare, particularly with regard to the overall effectiveness of medical devices. Simply put, if usability is lacking, the completion of user tasks may be slower and more error-prone. Therefore,

A child with an inhaler

delivery of therapy will suffer and patient safety may be compromised. Moreover, it is well known that easy-to-use products are more popular, resulting in market discrimination and a competitive advantage. Therefore, usability can be a positive attribute from a business and sales perspective as well as controlling risk .

How have medical device regulations incorporated HF/UE in regulatory activities?

Because of the rising instances of UI-induced adverse events, the US Food and Drug Administration (FDA) has begun to include HF/UE reviews as a routine part of their pre-market approval process at the Center for Devices and Radiological Health's (CDRH) Office of Device Evaluation. This process is described in a draft guidance issued in June 2011 entitled *Applying human factors and usability engineering to optimize medical device design*.

Likewise, the international regulatory community has incorporated IEC 62366, *Medical devices – Application of usability engineering to medical devices*, as a part of the approval process outside the US. Both the FDA HF/UE guidance and IEC 62366 outline a process including activities throughout device development culminating in validation testing with the final UI design in simulated use environments. In the following sections of this paper, we will summarize the major expectations of both the international and FDA expectations of manufacturers regarding HF/UE.

From the international regulatory perspective, what are the expected HF/UE outputs requested and reviewed by regulatory organizations?

IEC 62366:2007 (BS EN 62366:2008) is undergoing significant revision to provide improved organization and harmonization with the FDA's 2011 draft guidance on human factors. As a result, compliance with IEC 62366:2007 requires evidence of the conduct of a usability engineering process (UEP) which means that manufacturers would have to document their HF/UE work in accordance with the nine clauses comprising the process.

Why was IEC 62366:2007 revised?

IEC 62366:2007 was revised for several reasons. These were the main motivations for modification:

- In 2011, the FDA published its own updated HF/UE guidance to the industry. Several important aspects of risk analysis and summative testing were not in alignment between IEC 62366 and the FDA guidance. The new version of IEC 62366 will reflect a much more synergistic approach with the FDA guidance.
- Nomenclature differences also existed between US FDA and European terminology regarding usability and human factors which have since been resolved.
- There was a need for more clarity on implementation of the HF/UE process. An 'informative' counterpart document was created, dividing the standard into the streamlined normative part, 62366-1, and an informative part, 62366-2, which will also be listed as a TR (Technical Report).

What are the basic activities in the HF/UE process and what is their alignment with device risk assessment?

HF/UE activities can be categorized into three major phases:

1. preliminary analyses;
2. user interface design/evaluation;
3. simulated use testing (validation).

These phases of HF/UE activity align with both the EU and the FDA's pre-market human factors approval and compliance requirements described in IEC 62366 and the FDA HF/UE guidance. The relationship of these phases of HF/UE, in the context of risk assessment and risk management, are shown in Figure 1.

Preliminary analyses

Preliminary analyses are conducted to identify device user profiles, use environments, and use scenarios. These elements are vital to completing a detailed use risk analysis. These three elements are part of both the FDA and IEC 62366 documentation requirements.

(a) User profiles are descriptions of user group training, experience, knowledge and potential limitations, such as decreased visual acuity and manual dexterity. User groups are often differentiated on the basis of what use scenarios they perform, i.e. some users may do different tasks or interact differently than others with the device. This information is vital in determining the composition of user group testing in summative testing with the device, and in establishing design requirements to accommodate special needs of certain users.

(b) Use environments are brief descriptions of the ambient conditions of the places that the device will be used including parameters such as range of lighting, noise, temperature, and vibration. Other environmental factors should be noted, such as distractions or interruptions in the user-device interaction caused by interacting with other devices or personnel in the use environment.

(c) Use scenarios are brief descriptions of the sequences of user-device interaction that result in some intended healthcare outcome, e.g. initiating delivery of a given drug therapy, altering a previously initiated drug delivery order, troubleshooting or responding to alarms. Each use scenario will comprise multiple tasks or steps that can be further analysed from a use-risk perspective in the use error/use risk analysis.

(d) Task analysis is the analytical foundation for several other key activities that are conducted in preliminary analyses, including use error/use risk analysis, user interface design, and formative and summative usability testing. Task analysis provides a detailed description of the human requirements to perform the steps required to accomplish a use scenario.

(e) Use error/use risk analysis, also a key method in preliminary analyses, should be performed in conjunction with conventional risk analyses to determine specific potential risks of user-device interaction across the use scenarios. Use risk analysis is sometimes referred to as use failure mode effects analysis (U/FMEA) which identifies potential use errors for each task or step (from the task analysis) that could lead to potential patient or user harm. Such use errors should be identified from past history of device interaction, identifying potential confusion or incorrect assumptions about how the device works, and by observing user behaviour in formative usability as the UI design matures.

Table 1 provides an example of combining task analysis with use error/use risk analysis using a simple blood glucose meter to illustrate the format of a typical use risk analysis (two columns on the right) based on task analysis (two columns on the left).

Table 1 – Illustration of task analysis and use risk analysis

User task	Task requirements	Potential use errors	Consequences & risk severity
Power on meter	Know which button is power and push for two seconds	Failure to find button and hold for two seconds	Delay in knowing status of blood glucose (low risk)
Set correct time and date	Compare setting with today's time/date, use arrow keys to input settings	Failure to notice incorrect time/date or inputting wrong info	The history of blood glucose readings, used in setting insulin therapy, will be inaccurate, potentially leading to wrong therapy decisions (high risk)
Check test strip expiration	Compare today's date with expiry date on the strip vial	Failure to notice out-of-date strips	Potential of 10 per cent error in reading accuracy (medium risk)

The use error/use risk analysis is a complementary process to conducting conventional risk analyses as described in ISO 14971, *Medical devices – Application of risk management to medical devices*, the risk assessment standard for medical devices. The challenges of conducting use risk analyses within the scope and intent of ISO 14971 will be discussed later in this paper.

User interface design/evaluation

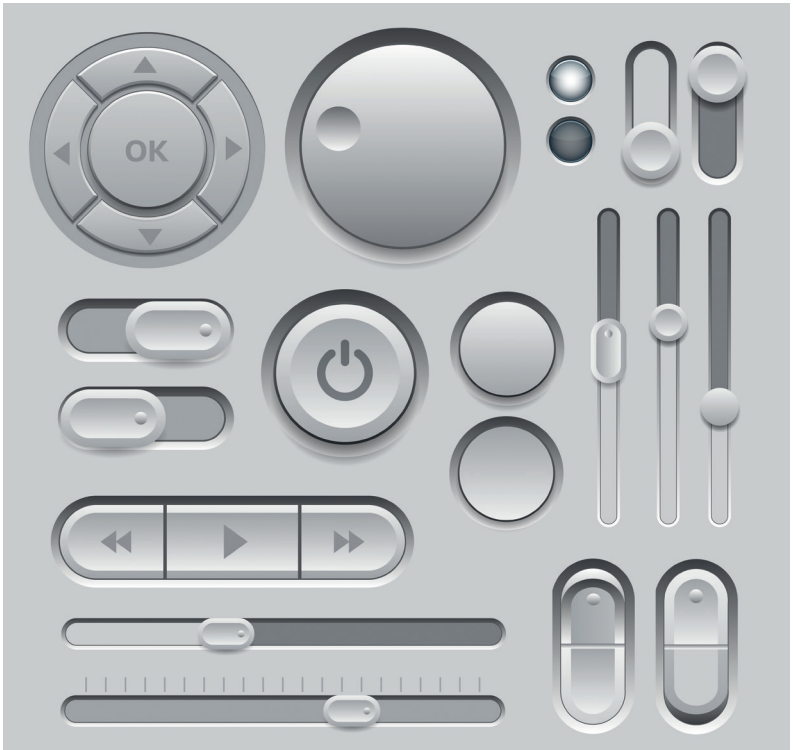
Both the FDA and IEC 62366 stress the importance of a UI design process that is driven by iterative formative evaluations. Formative evaluations are usability tests and assessments conducted early and throughout the design process. Formative evaluations address two design goals: (a) to make the device interface intuitive and easy to use, and (b) to control or mitigate potential use-related risks. These goals can pose design dilemmas because in some instances, ease of use and safety may be in conflict. For example, placing the power button for an IV drug delivery device next to the start/stop button controlling the infusion may appear convenient, however, the potential of an accidental shutdown of the device instead of halting the infusion may preclude this convenience, and dictate that the power button be mounted well away from the start/stop mechanism.

Formative evaluation method resources

AAMI HE75, *Human factors engineering – Design of medical devices*, Clause 9, Usability Testing, provides an excellent guide to the types of formative evaluations that are useful in early device UI development such as cognitive walkthroughs, heuristic evaluations, and walk-through-talk-through usability tests. Annex D of IEC 62366 also provides descriptions of these formative techniques.

Standards for interface design

Interface design standards and best practice references such as HE75 provide excellent guidance for the design of displays, controls, software graphical UIs, alarms, surgical tools, instructions for use (IFU), and other elements of the UIs. However, HE75 stresses the value of iterative user testing during the course of UI design. The role of formative techniques such as cognitive walkthroughs, heuristic evaluations, and walk-through-talk-through usability tests are vital for obtaining feedback for the design team regarding both ease of use and use error control and mitigation.



Different elements of user interface design.

Simulated use testing (validation)

Summative testing (also referred to as simulated use validation testing) of the UI with representative users performing a set of use scenarios is the central source of evidence of use safety for both IEC 62366 and the FDA human factors pre-market evaluations. To avoid obvious safety concerns to test participants, summative testing can be conducted under 'simulated use' conditions that are representative of real-world conditions.

How does summative testing differ from other usability testing?

There are several important differences in test methodology regarding summative simulated use tests compared to other usability evaluations such as formative tests listed here:

1. The summative test is *not* meant to be an exploratory effort seeking inputs on design features, but should serve as a 'final' demonstration of use safety for the device. Therefore, participants are not interrupted with questions or corrected in their performance.
2. Participants engage in use scenarios chosen to represent sequences of typical interaction with the device. These scenarios should cover all tasks that have been categorized as containing high risk in the use risk analysis.
3. Training and device familiarization should be provided and represent realistic conditions. This could be done by conducting a training session prior to testing with an appropriate intervening interval to represent potential memory and learning decay.
4. Device instructions for use should be available to the participant, but with no requirement to read the instructions prior to performing the use scenarios, unless the participant chooses to do so on their own.
5. User performance on each scenario task (or step) should be observed and categorized with respect to failure, success, and success with difficulties such as hesitation, self correcting of actions, and potential confusion. These instances, along with failures, should be noted for further post-test analysis.
6. The summative test should include a post-test dialogue with the study team in order to determine the cause of any failures and difficulties including both specific questions about particular unexpected or incorrect actions, or general questions about task difficulty during the test.
7. Results of the summative test should support an overall conclusion regarding use safety for the device. This conclusion should not be based on meeting pre-defined quantitative goals (i.e. 95 per cent success rate across tasks and participants), but on whether there is a remaining pattern of use-related problems that are directly attributable to the UI or accompanying documentation (labelling and instructions, etc.).

Insulin, pump, infusion set and reservoir

Alignment of HF/UE with medical device risk assessment and management

Figure 1 depicts the relationship with the major phases of HF/UE activities with medical device risk assessment and management. On the left are the phases of HF/UE activities, while the right side shows the stages of risk assessment and management and how these processes relate to each other.

The relationship between the HF/UE process and ISO 14971 risk assessment flow can be summarized as:

(a) ISO 14971 identifies an initial 'risk assessment' which is characterized by HF/UE preliminary analyses focused on understanding users, their use environment, tasks and risks when interacting with the device interface;

(b) ISO 14971 calls for 'implementing risk controls' which is congruent with the implementation of a device UI that will limit use risks and testing of that interface for its risk control effectiveness;

(c) ISO 14971 then requires an assessment of 'acceptance' of the implemented risk controls, which for HF/UE is accomplished by assessing simulated use testing results for a residual pattern of use errors on critical tasks, and deciding whether use risk has been controlled to an extent reasonably possible.

What are the biggest challenges for device manufacturers in meeting the expectations of HF/UE regulations and reviewers?

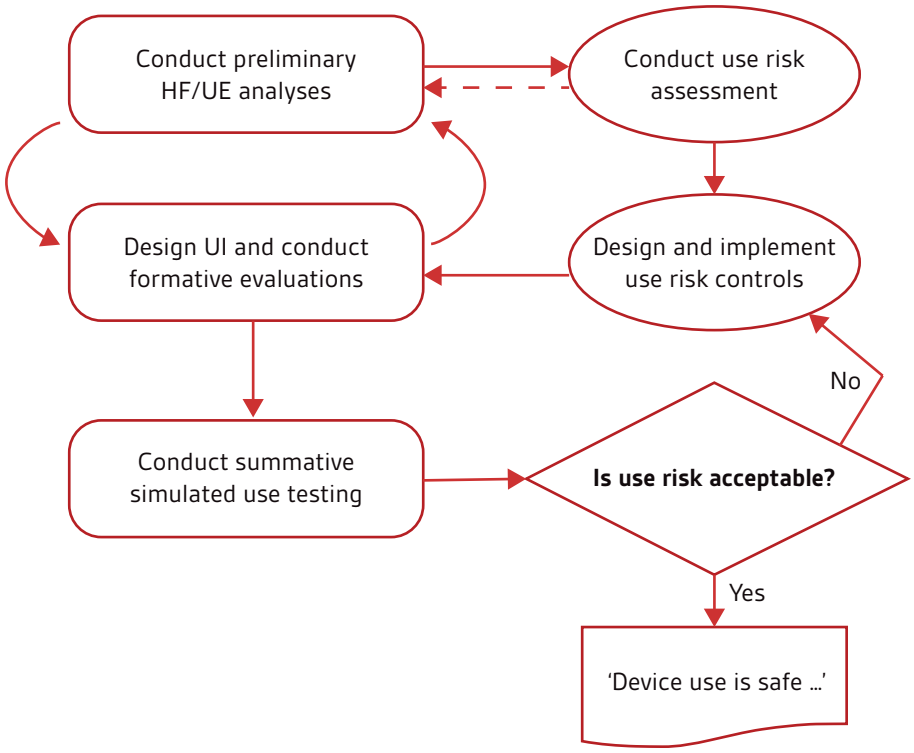
The following challenges remain in meeting the intent of the FDA HF/UR guidance and IEC 62366:

(a) conducting adequate formative evaluations prior to final design validations;

(b) conducting and documenting comprehensive use-risk assessment;

(c) the design and interpretation of summative test results in simulated use validation studies.

Figure 1 – Relationship of HF/UE process flow with ISO 14971 risk control process



Conducting adequate formative evaluations

Despite the modest resources required for formative evaluations and tests, manufacturers often short-circuit the process of UI design with little or no formative testing or evaluation. Misconceptions may inhibit the decision to conduct formative evaluations such as:

- *Belief that formatives are too costly and time consuming* – Formative studies can be relatively short and conducted with a small number of representative users. Conducted early in the design cycle, as few as 8-10 participants can reveal 90 per cent of existing design flaws in the UI that can be modified to eliminate errors and use problems. As the UI design matures, formative studies may be employed as trial run tests before conducting the final summative test, which saves significant time and cost by preventing the need to repeat the summative study due to residual problems in the interface or the study methodology itself.
- *Obtaining institutional review board approval causing delays in submissions* – Many companies may believe that formative tests require elaborate institutional review board (IRB) approval regarding participant safety. Most usability studies do not present the risk of participant harm (i.e. no therapy is actually delivered because the concentration is on user interaction with the UI). However, manufacturers may choose to protect themselves from liability by gaining IRB approval, but this can often take the form of 'expedited reviews', given the low complexity of the testing compared to clinical trials.
- *More testing means more documentation time required* – From a FDA and IEC 62366 compliance perspective, the conduct of formative studies does not require extensive documentation in pre-market submissions. FDA reviewers merely want to know that the manufacturer has conducted iterative tests on the product and has made a best effort to remove design flaws related to safety. This can be summarized, in submissions, as a table describing the study intents and results at a relatively high level. More detail can be provided in appendices if warranted, but this is seldom asked for by FDA reviewers.

Conducting and documenting comprehensive use–risk assessment

The publication of ISO 14971:2012 has brought welcome rigour to the device risk management assessment process. The standard describes a detailed process of risk estimation based on the combination of subjective estimation of individual types of risk severity and probabilities or likelihoods of occurrence of that risk. The product of these two subjective estimates produces risk priority numbers (RPNs) for a given risk. RPNs give manufacturers a method of determining the overall risk of the device and criteria for acceptance.

Estimating likelihood of occurrence is a fairly well-established process for chemical, mechanical, software, and electrical components because failure probabilities can be determined from laboratory 'hot bench' testing. When applied to user/device interaction, this process becomes inappropriate because of the variability and unpredictability of human behaviour compared to known electrical and chemical processes.

Thus, the FDA draft HF/UE guidance and IEC 62366 use ISO 14971's flow chart as a foundation for the use risk assessment and management process. Alignment with the ISO 14971 risk assessment process resides in the decision diamond labelled 'Is use risk acceptable?' (See Figure 1).

In place of hot bench tests, observational testing is employed to assess use risk, i.e. summative tests validating the final design of the device UI, not a subjective estimation of the likelihood that a user may fail. The 'acceptance' decision becomes the formulation of a solid argument based on user testing, which is the subject of the third HF/UE manufacturer challenge described in the next section.

The design and interpretation of summative test results in simulated use validation studies

Arguably the most challenging aspect of HF/UE implementation is the design, conduct and interpretation of summative simulated use test results becoming the major evidence of use safety for a device. These tests of

representative use with the production level designed UI are somewhat of a departure from conventional usability testing in that the most important aspect is in post-test investigation – determining a root cause of observed failures and problems.

These tests, described in both the FDA HF/UE draft guidance and IEC 62366, are intended to provide an opportunity for the manufacturer to 'see' into the future of the use of the device – a post-market experience. Thus, observations in these tests that are either unexpected or not desired are investigated in the same manner as an adverse event. We are seeking a root cause of errors occurring in critical tasks that could be mitigated prior to the device being approved and marketed.

Submissions to the FDA pre-market approval process have generally been required to include summative validation test results, especially for higher risk devices. Although the quality of these HF/UE tests has improved over time, typical manufacturer deficiencies in conducting and analyzing study results are:

- *Not using the preliminary use risk analysis to justify testing protocols* – The use scenarios that are tested should include critical tasks from a risk perspective. These critical tasks should be well documented, not left to the reviewer to 'guess' why certain tasks were tested. Tables such as Table 2 are a good example of a method of presenting your task analysis, use risk analysis, risk control measures and how those tasks were tested/scored in the summative test.

Table 2 – Example of task, use risk, risk control, and testing scheme

Function	Task	Possible use errors	Risk severity/ consequences	Risk control in UI design	How tested
Drug delivery order entry	Enter volume of drug to be infused on keypad	Incorrect numeric entries, incomplete entry	High: Patient Overdose (or underdose)	Software limits unsafe entries; prompts user to complete entry, entry requires final user confirmation	Simulated delivery order entered and scored for accuracy

- *Reporting just the success rates without making the overall use-safety case* – Many times manufacturers report only the testing numbers – 95 per cent of trials showed successful performance, and did not discuss the situations or causes of the 5 per cent of failure cases. Did that single use error instance in 20 reveal a pathway in which a user could interact with the device resulting in serious patient harm?
- *Declaring 'victory' from preference results* – The use of rating scales regarding ease of use and other subjective metrics is not adequate for making the overall use safety case to reviewers. Believing the device is easy to use does not equate to demonstration of correct use or a cogent argument to regulatory reviewers.
- *Failure to include the right user groups or enough user groups* – The FDA HF/UE guidance and IEC 62366 state that at least 15 participants should be included from each identified user group interacting with the device. But, how many user groups are required? There are two aspects to consider:

  (a) Who performs the use scenarios?
  Which user profiles, and so user groups, perform our use scenarios.

  (b) What are the user characteristics?
  Any differences in training, background, experience, disabilities or impairments in the user populations may dictate that we test those populations as different user groups. In some cases, especially home use devices and patient-used combination products, separate user groups for visually impaired or cognitively impaired may be required. Discussions with the FDA divisions responsible for these reviews may prove beneficial in determining the best strategy.

- *Failure to include a time interval between training and testing* – For the FDA simulated use test, it is generally recommended that there be a 'delay' between the exposure of the participant to some sort of representative

training and the actual test sequence. This is to 'simulate' the potential of forgetting key aspects of how the device works, because in the real world use is not likely to immediately follow training. In some combination product submissions, the FDA may require a trained and an untrained group.

- *Attributing test result failures to 'human error' without further justification or argument* – Summative test results should be analysed on a case by case basis related to observed failures and patterns of difficulties exhibited by participants. Merely attributing a failure to 'participant just forgot' during execution of a critical task is not a solid argument that the interface is safe to use, as the interface should support the user in all ways possible during task performance. Post-test interviews are crucial to making arguments as to whether these instances were actually transient lapses in user attention or memory or UI problems. Asking participants why they were confused, what led them to believe the device worked a certain way or why they made an error is absolutely essential to this argument process.
- *Failure to test the instructions for use when emphasizing the IFU as a primary means of use risk control* – When manufacturers assert repeatedly that the IFU will be the primary means of controlling certain use risk, the FDA will likely require some form of specific IFU testing to validate that assertion. This can sometimes take the form of a separate IFU test, since forcing the participant to use the IFU during simulated use task execution is not realistic.

Conclusions

Three main conclusions can be drawn regarding HF/UE:

1. HF/UE has become a vital part of the product development process ensuring medical device ease of use and safety of use. Worldwide, regulatory organizations have begun a systematic oversight and review process regarding manufacturer compliance with the usability engineering standard, IEC 62366. The FDA pre-market device review process now routinely includes human factors risk assessment and validation testing of the device UI with intended users.
2. HF/UE activities should be conducted throughout all phases of device design and development including preliminary task and risk analysis, UI design and evaluation, and final summative validation testing in simulated use.
3. The HF/UE process should be aligned with the overall device risk management process for the device. Final decisions regarding use risk acceptability should be based on the results of simulated use testing with representative users evaluating the presence of any remaining patterns of failures and difficulties on tasks with critical risk implications.

Resources and references

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BSI is grateful for the help of the following people in the development of the white paper series.

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Published white papers

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