Medical Device Usability

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Topics

- What is usability?
- Why usability is so important
- The regulatory requirements
- EN 62366 Usability engineering process
- Notified Body Expectations

Lifts in apartment and BSI office in China

What is usability?

Definition of Usability

- Characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY , ease of USER learning and USER satisfaction

Source: Clause 3.17 of BS EN 62366:2008+A1:2015

Why usability is so important

True Stories

Denise Melanson

- Four days of chemo drug in four hours; no antidote and died 22 days later

Nurse’s suicide highlights twin tragedies of medical errors

- Kimberly Hiatt committed suicide after overdose killed baby.

Why Usability is so important for Medical Devices?

- 98,000 recorded deaths annually in US caused by medical errors!
- A significant proportion of these involve devices
- Over a third of device incidents in US involve usability issues

Source: the pivotal 2000 report “To Err is Human,” by the Institute of Medicine

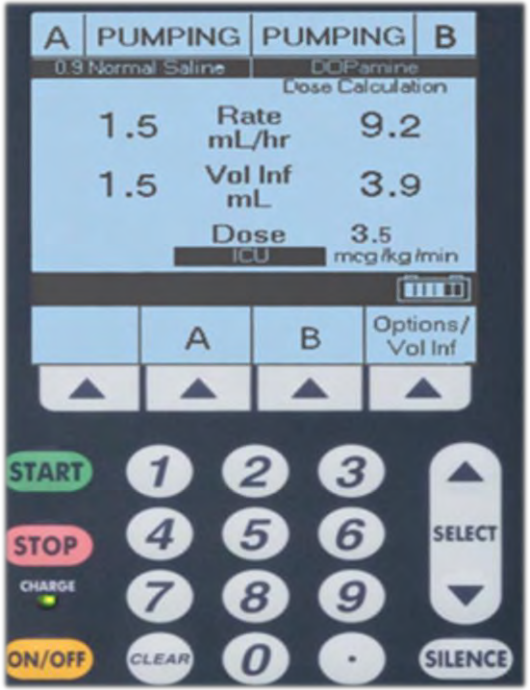
Injuries associated with Infusion Pumps

- Between 2005 - 2009, FDA received approx. 56,000 reports of adverse events with infusion pumps
  - including numerous injuries and deaths.

- FDA Guidance on Infusion Pumps

  http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/

Different screens



Hand-held pulse oximeter – Redesigned Display

Why Usability is important?

- Reduce use error
- Improve performance in using devices
- Reduce training effort needed
- Usable products reduces the stress of the user

Usability Involves a Shift of Mind-set

- **Previously:** "we design a device – its up to the user to use it according to our instructions"

- **Now:** "we design a device, accompanied by instructions and training courses, which is easy to use correctly and guards against intentional misuse."

Regulatory Requirements

EU & MDD - Ergonomic Design of Devices

As design for patient safety initiatives play an increasing role in public health policy, **it is necessary to expressly set out the need to consider ergonomic design in the essential requirements.**

In addition the **level of training and knowledge of the user**, such as in the case of a lay user, should be further emphasised within the essential requirements.

The manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body.

Directive 2007/47/EC Recital 18

MDD Annex I Essential Requirement

- ER 1.....any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

— reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

— consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).'

MDD Annex I Essential Requirement

- ER 9.2 the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate **ergonomic features**...
- ER 10.2 The measurement, monitoring and display scale must be designed in line with **ergonomic principles**, taking account of the intended purpose of the device.
- ER 13.1 Each device must be accompanied by the information needed to use it **safely and properly**, taking account of the training and knowledge of the potential users, and to identify the manufacturer."
- Other ERs that may be affected to some degree by ergonomics include 2, 3, 6, 12.8, 12.9

Standards

- EN 60601-1:2005 3rd Ed +A1:2013 – Medical electrical equipment – Safety & Essential Performance
  - Cl 12.2 Manufacturer shall address risk of poor usability, including marking and documents, through a Usability Engineering process in accordance with EN 60601-1-6.

Standards

- EN 60601-1-6:2010
  Collateral Standard: Usability (IEC 60601-1-6:2010) – reference EN 62366
- EN 62366:2008 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
- EN 60601-1-8: 2007 - Alarm systems
- ISO 15223-1:2007 – Symbols
- .....

EN 62366

Application of usability engineering to medical devices

EN 62366:2008

- Process based standard
- Objective: design in usability, design out errors
- Only 8 pages of requirements and 77 pages of guidance
- Process spans design and development life cycle

EN 62366:2008

- A User centred design process = Usability Engineering Process
- Also applies to accompanying documents and user training
- Performs Risk Management – ISO 14971
- Results of Usability Engineering Process shall be recorded in the Usability Engineering File
- Usability Engineering Process has 9 stages

Usability Engineering Process

1. Specify application of device –Intended use & User
2. Identify frequently used functions - Task
3. Identify hazards and hazardous situation related to usability – ISO 14971 – foreseeable misuse
4. Identify device primary operating functions
5. Develop usability specification
6. Prepare usability validation plan
7. Design and implement user interface
8. Usability verification - verify user interface
9. Validate usability of medical device

NB Expectations of manufacturers

Technical Audit Considerations

- Does ER1 address use error and intended users?
- Does manufacturer have a UE Process and a UEF? (Ideally the harmonised standard or rationale to meet ERs)
- Where labelling and documentation are referenced in the Risk Management process, has the usability of such documentation been established?
- Has the effectiveness of training requirements and material been established?
- Has suitability of Usability studies been justified?

Technical Audit Considerations

- Sample from:
  - Application Specification
  - Determined frequently used functions
  - Identified hazards and determined primary operating functions
  - Usability specification
  - Verified against usability specification
  - Usability Validation Plan and Validation against plan
  - .....
  - NB would go into greater depth for design dossiers review

Legacy Products

- Use Annex K of BS EN 62366:2008 + A1 2015 as benchmark/guide
- Establish an application specification
- Identify and record Primary Operating Functions
- Review PMS
- Risk Assessment

Regulatory expectation increasing

- Central Management Committee Statement on “Improvement of Readability of Instructions for Use (IFU)”
- http://www.cmc-md.eu/mediapool/97/978504/data/Agenda_-5-CMC-Statement_on_Readability_of_IFU.pdf

- FDA’s expectations have also increased.

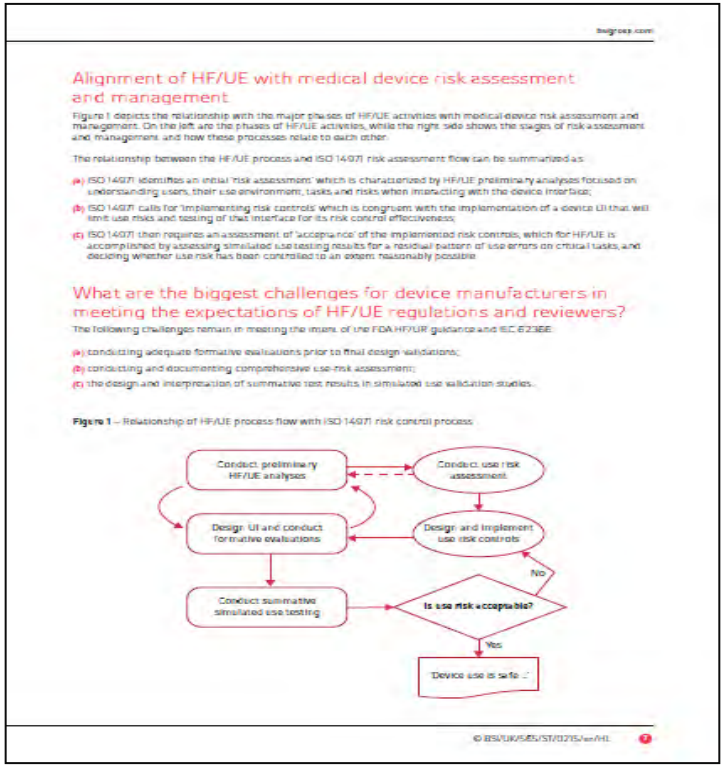
MHRA Human Factors Project Group

- Purpose
  - Raise profile of Clinical HF/Usability in UK and Europe
- Output – Human Factors Guidance Document
  - Draft by April 2016
  - Publish July 2016?
- MHRA expect their NBs (and EU) to give sufficient importance to this topic during assessments.

Conclusion

- Usability is very important and has become a vital part of a medical device
- Usability activities should be conducted throughout all phases of the development process,
- Usability should be part of the overall risk management process
- The regulators are increasing and enhancing the requirements for usability.

Take home – BSI Whitepaper



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/UE 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

http://medicaldevices.bsigroup.com/en-GB/resources/Whitepapers-and-articles/

Questions?

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Appendix

New Standards

- BS EN 62366:2008 + A1 2015
  - 5.10 User interface of unknown provenance
  - Annex K – Evaluation of a user interface of unknown provenance

- IEC 62366-1:2015 Part 1: Application of usability engineering to medical devices
- IEC TR 62366-2:2016? Part 2: Guidance on the application of usability engineering to medical devices
  - To be more “usable”, easier to understand than original 62366
  - Contains the “what” requirements in Part 1, the “how” is in 62366-2
  - Closer ties to risk management, EN ISO 14971
  - Closer to FDA guidance

New Standards

- New ISO 13485 Draft (DC2)
  - 7.3.3 Design inputs include usability
    - NOTE For information related to usability see ISO/IEC 62366

US & FDA

- ANSI/AAMI **HE48** (1988-2009) "Human factors engineering guidelines and preferred practices for the design of medical devices"
- ANSI/AAMI **HE74** (2001-2010) "Human factors design process for medical devices"
- ANSI/AAMI **HE75** (2009-) "Human factors engineering - Design of medical devices" (a Tutorial to HE-74)

US & FDA

- FDA Human Factors Draft Guidance Document: Agency Expectations for Human Factors Data in Premarket Submissions
- Applying Human Factors and Usability Engineering to Optimize Medical Device Design
- The FDA Perspective on Human Factors in Medical Device Software Development