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

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
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

  - 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 60601-1-8: 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

- 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)”

- 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

The growing role of human factors and usability engineering for medical devices
What's required in the new regulatory landscape
Bob Nertin, Human Centred Strategies

Questions?
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 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