Usability - Continuation and Update from 2016 Webinar

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Input provided by David Adams

Topics

- What is usability?
- Why usability is so important for medical devices?
- Standards
- Regulatory MDD/IVD, MDR
- Notified Body Expectations of Manufacturers
- MHRA HF Guidance
  - MHRA Guidance 15 September 2017
- Case Studies will not be shown, see 2015 Webinar

What is usability?

Definition of Usability

- The ability for a human to interact easily and relatively error-free with a system, product or procedure
- Synonym: Human Factors, Ergonomics
- Characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT

- Source: Clause 3.16 of BS EN 62366-1:2015
- See also: Human Factors, Ergonomics

Why usability is so important

Why Usability is so important for Medical Devices?

To understand the device, use the device safely to obtain the intended performance without errors, adverse events

- 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

Infusion Pump initiative at FDA

Confused when working with following examples of Different screens from Infusion Devices?

[Infusion Pump initiative at FDA]

True Stories - Safety

Denise Melanson dies from fatal overdose

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

Twin tragedies of medical errors

- Dispensed 1.4 grams of calcium instead of 140 milligrams
- Kimberly Hiatt committed suicide after overdose killed baby

True Stories - safety

Angelcare Monitors Inc.'s recall of 600,000 baby monitors

- Two infants suffocated
- Wound electrical cord* around their neck

* 11 feet connects sensor pad to monitor

True Stories – safety

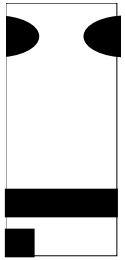
Scopes Linked to Superbug Outbreaks

- Olympus recalled 4400 duodenoscopes
- Implicated in superbug outbreaks in hospitals
- Affecting >250 patients in US & Europe *
- Modified design to make them easier to clean.

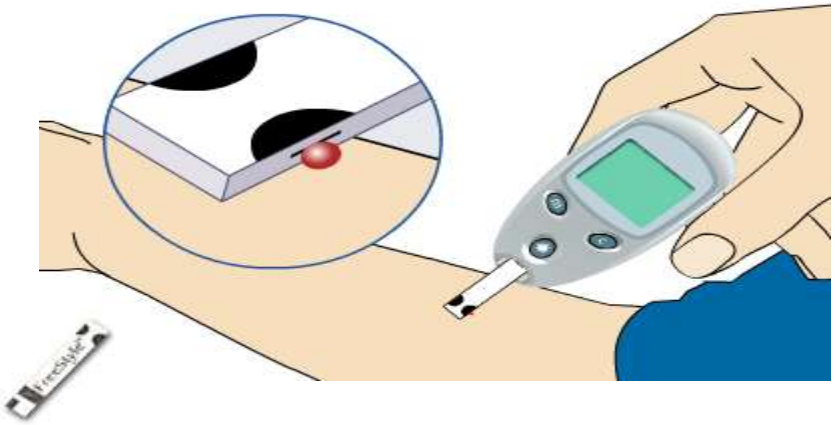
* U.S. Senate report

What is Usability – IVD Examples

Blood glucose test strip



Where to apply the blood?



Why Usability is important?

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

Standards


BS EN 62366-1:2015
BSI Standards Publication
Medical devices
Part 1: Application of usability engineering to medical devices
bsi.
...making excellence a habit.

What standards do for usability of Medical Devices?

Where we've been…usability in the manual

reactive…

"Did not read the manual"

May lead to errors

Where are we going…usability in the design

proactive….

Works as expected, minimal use of manual

Should have minimal errors

Usability Standards

- EN 62366:2008 –Harmonised Standard For Usability **OLD**

- BS EN 60601-1-6:2010+A1:2015 Medical devices, collateral standard, usability

- BS EN 62366-1:2010+A1:2015* Medical devices, Part 1: Application of usability engineering to medical devices This is the Usability Process!

- IEC/TR 62366-2:2016* Medical devices, Part 2: Guidance on the application of usability engineering to medical devices This is how to do the Process!

*Not yet harmonized, usability is not in the priorities for harmonization CEN/CENLEC statement from Medtech Insight

Major activities in EN/IEC 62366-1:2015

- Usability Engineering activities shall be planned
- To reduce risk do: safe design, protective measures, and/or information on safety
- Establish a usability engineering process
- Documents Usability activities to a usability file
- Use specification
- ID user interface characteristics
- ID hazards & situations (foreseeable, the unforeseeable is gone)
- ID hazard use scenarios for summative *evaluation*
- User interface spec
- Prepare user interface evaluation plan (summative & formative)
- Perform the design & summative evaluations

CONTENTS

IEC/TR 62366-2:2016

This is the "how" document or "tutorial"

- How safety relates to usability
- Reasons to invest in usability
- How to implement a usability program
- Overall usability process
- Prepare the use specification
- Identify characteristics related to safety and potential use errors
- Identify hazard-related use scenarios
- Select hazard-related use scenarios for summative evaluation
- Establish user interface specification
- Establish user interface evaluation plan
- Design/implement user interface
- Perform formative evaluations
- Perform summative evaluations

Note: the above is paraphrased by the author

What to do for Legacy Products (prior to standard) already on the market?

- Follow the approach described in EN 62366-1:2015 Annex C
  - User Interface of Unknown Provenance' (UOUP)
- Essentially, use-related risk analysis
  - Use available post-market data
  - Establish if adequate controls are in place

*Note: Review past/current device/IVD Post Market surveillance required per MEDDEV, MDD, MDR. Apply Risk based decisions to determine if current device/IVD is safe or changes are required.

What about the “Non-Clinician”

- EN 60601-1-11:2010
- Medical electrical equipment used in the home healthcare environment
    - Usability of the marking and IFU for Lay users
        - Valuated based on an operator profile that includes a **<u>maximum</u> of eight years of education [12 year old?]**.
    - Device designed to be simple to use
    - Not require reference to complex documentation

Clause 7.1

EN 1041: 2008 (and EN 1041:2008+A1:2013)
Information supplied by the manufacturer of medical devices

- Information with medical devices shall take into account:
  - IFU/Labels
  - the intended users
  - the conditions of use

Clause 5.1.1

EN ISO 13485: 2016 Quality management systems

Usability requirements included in EN ISO 13485: 2016.

- 7.3.3a design and development inputs
  - Include usability requirements according to the intended use

- 7.3.9 control of design and development changes
  - Consider significance of a change to usability

EN ISO 14971: 2012 Application of risk management

Usability requirements included in EN ISO 14971: 2012

- Risk Management integrates into the usability engineering process (EN 62366-1)
- Include usability tests data when estimating risks

- Can the user interface design contribute to use error?
- Is device used in environment where distractions can cause use error?
- Will device be used by persons with special needs, etc.?

Annex C

Regulatory Requirements

Usability Essential Requirements in MDD/IVDR….Today

MDD Annex I Essential Requirement

ER 1 acceptable risks when weighed against the benefits to the patient

Shall include:

— reducing, as far as possible, the risk of use error due to the **ergonomic** features of the device and the environment…….

— 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 physical features, including **ergonomic features**…
- **ER 10.2** The measurement, monitoring and display scale must be designed in line with **ergonomic principles**
- **ER 13.1** Device accompanied by the information needed to use it
  - **safely and properly**,
  - taking account of the training and knowledge of the potential users
- Other ERs that may be affected include 2, 3, 6, 12.8, 12.9

IVD ERs

Same principles of MDD also apply to IVD

- **ER 3.6**.The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with **ergonomic principles**, taking account of the intended purpose of the device.
- **ER 7.1**.

  - ensure that the device is easy to **use** by the **intended lay user**,

  - **reduce as far as practicable the risk of user error** in the handling of the device and in the interpretation of the results.

Self-test IVD Specific requirements

- **ER 7.2**. manufacturer must have data showing the **handling suitability** of the device in view of its intended purpose for **self-testing**.

Usability in MDR…Tomorrow


Official Journal L 117
of the European Union
Legislation
EN

MDR – Usability in Definitions – articles - Excerpts

Definitions

14 **‘instructions for use’**

- means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

59 **'device deficiency'** (new)

- includes use errors or inadequacy in information supplied by the manufacturer

64 '**incident**' (new)

- includes use-error due to ergonomic features, as well as any **inadequacy in the information supplied by the manufacturer**

MDR Annex I Chapter 1 Usability in General Requirements - Excerpts

Annex I Chapter 1 General Requirements

5: In eliminating or reducing risks related to **use error**, the manufacturer shall: (a) reduce as far as possible the risks related to the **ergonomi**c features of the device and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of **intended users** (design for lay, professional, disabled or other users). Similar of **MDD ER 1**

14.2: Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate **ergonomic** features. Similar of **MDD ER 9.2**

14.6: Any measurement, monitoring or display scale shall be designed and manufactured in line with **ergonomic** principles, taking account of the intended purpose, **users** and the environmental conditions in which the devices are intended to be **used**. Similar of **MDD 10.1**

21.3: The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be **understandable to the user** and, **as appropriate, the patient**. Similar of **MDD 12.9**

Annex I Chapter 1 General Requirements...Highlights

23.1: Each device shall be accompanied by the **information** needed to identify the device and its manufacturer, and by any safety and performance information relevant to the **user, or any other person, as appropriate**… Similar of **MDD 13.1**

17.3 …Software used on **mobile/tablet** … Take account of **size** and **contrast ratio** of the screen…varying environment as regards level of light or noise

20.5 …Removable and moving parts… Fitting/refitting risk made **impossible** by the design and construction…Direction of movement information

22 …Medical Devices for **lay person**… Take account of **their skills**…Information/instructions provided shall be easy for them to understand/apply

22.2 …Devices for use by **lay person**… Device can be used safely and accurately by intended user…Reduce risk from unintended cuts and pricks e.g. needle stick injury…Reduce handling errors and interpretation of results

MDR Usability in Post Market Surveillance - Excerpts

Annex III Post Market Surveillance

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used: …..(f) for the identification of options to improve the usability, performance and safety of the device;

ARTICLE 83 Post-market surveillance system of the manufacturer

- PMS system data shall in particular be used for:
  - Identification of options to improve the usability, performance and safety of the device

MDR…Usability in Clinical Excerpts

Clinical

Article 61 **Clinical evaluation**

1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the **intended use**…. The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its **intended purpose**.

3. A clinical evaluation shall follow a defined and methodologically sound procedure based on the following: (a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied: — it is demonstrated that the device subject to clinical evaluation for the **intended purpose**

Article 62 **General requirements regarding clinical investigations conducted to demonstrate conformity of devices**

- Clinical investigations shall be designed, authorized, conducted, recorded and reported in accordance…. following purposes:
- (a) to establish and verify that, under normal conditions of use..
- c) to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device,…

Clinical

Article 32 **Summary of safety and clinical performance**

2. The summary of safety and clinical performance shall include at least the following aspects:

(g) suggested **profile** and **training** for **users**

Annex XV **Chapter I General Requirements**

2.4. Clinical investigations shall be performed in accordance with the clinical investigation plan by a sufficient number of **intended users** and in a **clinical environment** that is representative of the intended normal conditions of **use of the device** in the target patient population.

ANNEX II **Technical Documentation**

6.1. Pre-clinical and clinical data

- Includes **Simulated use testing**
- Software V and V typically includes summary results of all V and V and testing performed both in-house and in a **simulated or actual user environment** prior to final release.

NB Expectations of Manufacturers

Today: Evidence of safety & performance without error, *Future*: Sufficient evidence of compliance to MDR

Technical Audit Considerations

- Does the response to Essential Requirements address use error and intended users?
- Does manufacturer have a Usability Engineering Process and a Usability Engineering File? (Ideally the harmonised or latest 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?
- What was learned (design improvements) from have Formative Evaluations?

Technical Audit Considerations (Cont.)

Sample from EN 62366-1

- Is there a Usability Engineering process?
- Is there a Use Specification including indications for use, intended user profile, use environment, device operating principle (how it works)?
- Have User Interface characteristics related to safety and potential use errors been identified?
- Have known or foreseeable Hazards and Hazardous Situation been identified?
- Have Hazard-Related Use Scenarios been described and selected for Summative Evaluation?

Technical Audit Considerations (Cont.)

- Is there a User Interface Evaluation Plan including:
  - **Formative** Evaluation (iterative design and development testing)?
  - **Summative** Evaluation (IFU and training, user testing – final testing to confirm user interface can be used safely)?
- Are appropriate user groups used for testing (numbers and types of user)?
- Is there a User interface design process including formative testing related to the User Interface Specification?
- Were the results from Formative testing applied to the device design?
- Has Final Summative Evaluation of the usability of the user interface taken place which confirms compliance with the User Interface Specification, including evaluation of residual risks?

Technical Audit Considerations (Cont.)

- Has User Interface of Unknown Provenance (UOUP) been considered (See Annex C of EN 62366-1) – previously developed product for which usability engineering process records do not exist (Legacy product)?
- Is there consideration of Post Production information in the Usability Engineering Process?

Nonconformity examples

- Entire tech file does not consider Usability
- Execution of Usability validation plan, including V & V criteria, not established:
  - Report states that data collected by user feedback forms
  - Only one completed form provided
  - The conclusions not documented
  - Design improvements are not captured/implement from Formative
- The Usability V and V report indicate the requirements met and did not identify participants/evaluators.
- No consideration seen of the usability of the software user interface

Nonconformity examples

- But not enough detail in results to verify:
  - What was done
  - The feedback of each evaluator
  - If all relevant requirements were verified and validated.
- Finding: Usability risks are not in the risk analysis for the device, therefore not considered in design requirements or usability.
- Vigilance demonstrates consistent mechanical/usability issues
- Vigilance Reports make reference to warnings in IFU
- IFU is ineffective at informing users of residual risk
- Inadequate design controls/risk reduction in light of known foreseeable misuse.

MHRA Human Factors Project Group

- Raise profile of Clinical HF/Usability in UK and Europe
- Published September 2017
- NBs assessments to demonstrate consideration of usability
- Addresses:
  - Usability Risks
  - Essential Requirements in support of Usability
  - Standards
  - All devices including drug-delivery devices and combination devices
  - Life cycle of devices (PMS)
  - Usability process (62366)
  - See 62366 for usability sample sizes.
- Advisory not prescriptive

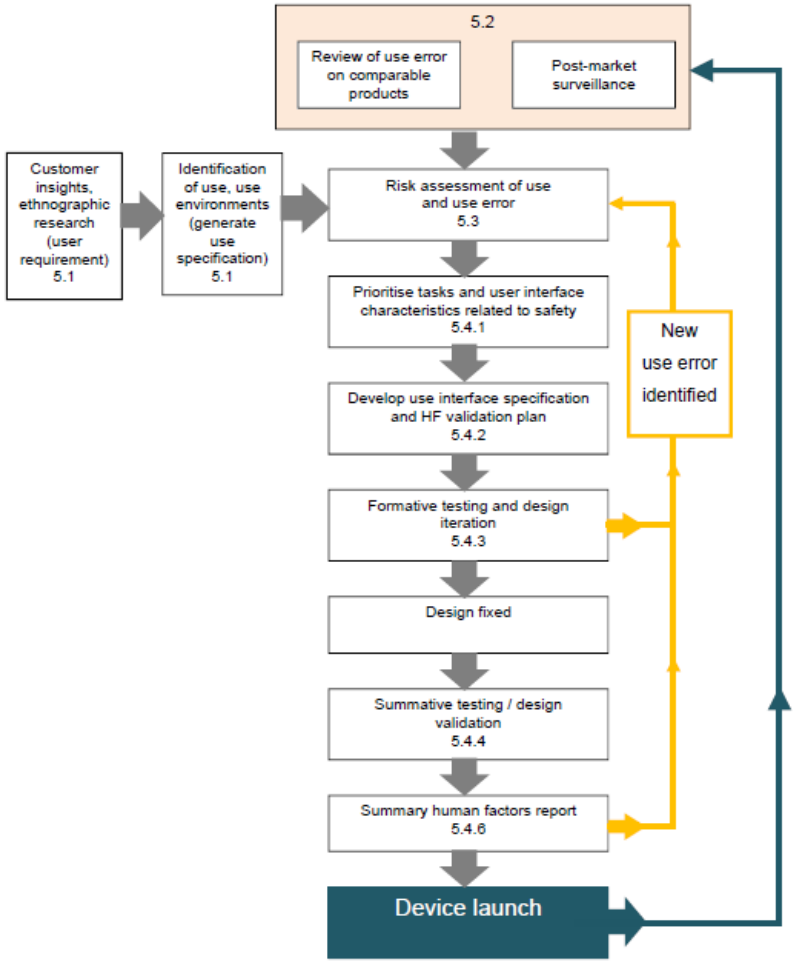
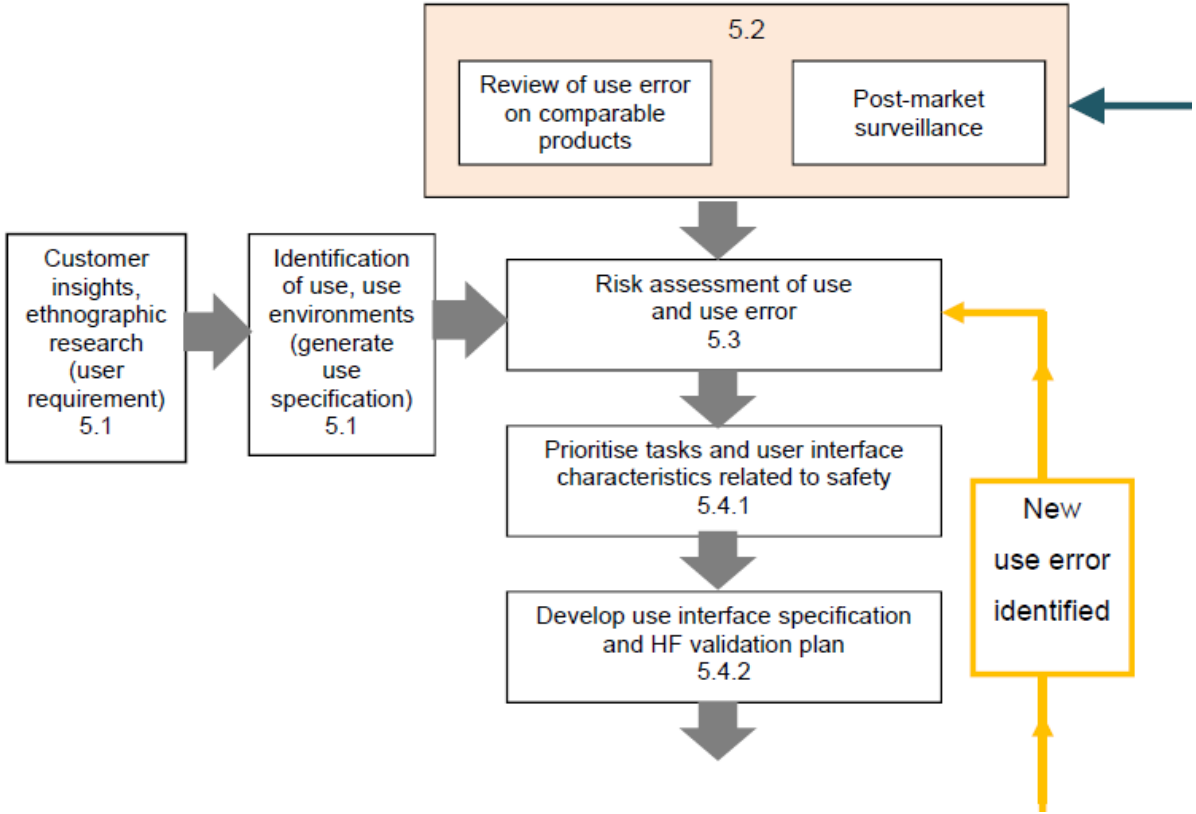
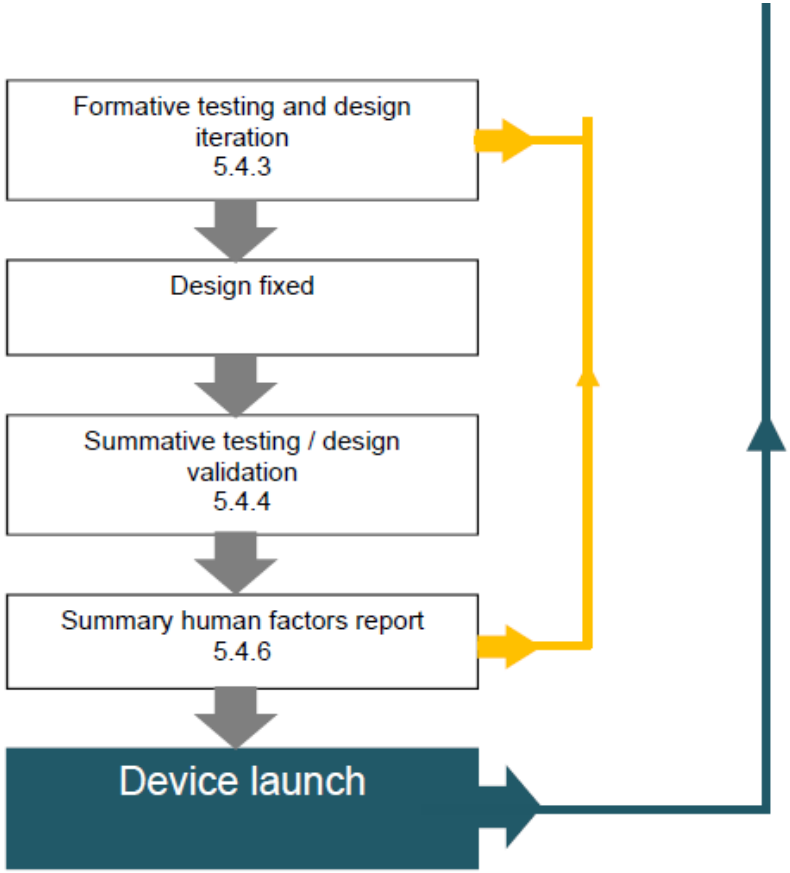


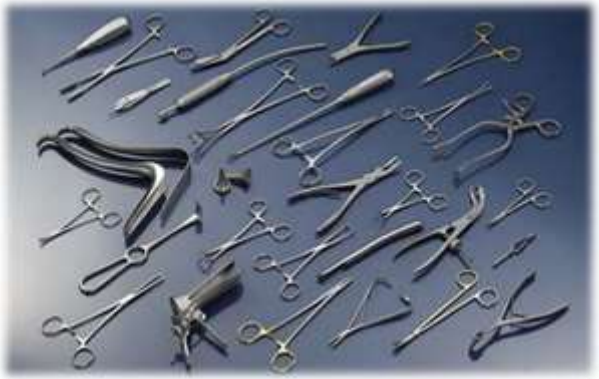
Figure 2
Example of usability engineering process

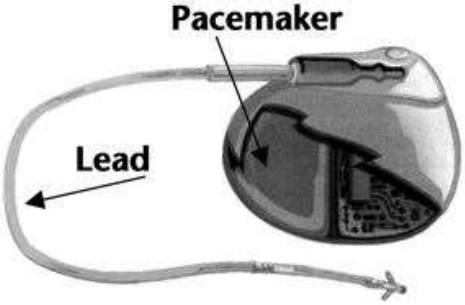
Similar to 62366


5.2
Review of use error on comparable products
Post-market surveillance
Customer insights, ethnographic research (user requirement) 5.1
Identification of use, use environments (generate use specification) 5.1
Risk assessment of use and use error 5.3
Prioritise tasks and user interface characteristics related to safety 5.4.1
Develop use interface specification and HF validation plan 5.4.2
New use error identified


Formative testing and design iteration
5.4.3
Design fixed
Summative testing / design validation
5.4.4
Summary human factors report
5.4.6
Device launch

What types of devices does usability apply?





Summary

- Usability is very important and has become a vital part of a medical device
- Usability is increasingly being added into regulatory requirements
- Standards available to support the Usability Engineering Process
- 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
- NB needs to include usability requirements in sampling during assessments

Further reading

- 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)
- ISO 9241-210 User-Centered Design
- BSI Post-market surveillance, BSI/UK/440/ST/0614/en/HL
- http://www.bsigroup.com/LocalFiles/en-GB/Medical-devices/whitepapers/WP-Post-market-surveillance.pdf
- Handbook of Human Factors Medical Device Design, Matthew Weinger et.al. ISBN 978-0-8058-5627-9
- FDA Guidance, http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm259748.htm
- The psychology of everyday things, Donald A. Norman ISBN 0-465-06709-3
- Set Phasers on stun, Steven Casey, ISBN 0-936178-8-5
- Usability testing of medical devices, Michael Wicklund et. al. ISBN 978-1-4398-1183-2
- The growing role of human factors and usability engineering for medical device, http://medicaldevices.bsigroup.com/en-GB/resources/Whitepapers-and-articles

Questions?

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