

User Centred Design and Development of Medical Products

Greek Life Science Business Day

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Dipl.-Ing. Physical Engineering

Author, *The Effect of New Standards on the Global Movement toward Usable Medical Devices*, 2007

Author, *The Impact of Usability on Patient Safety*, 2005

Co-Author, *Cross-National and Cross-Cultural Design of Medical Devices*, 2008

Co-Author, *Usability of Medical Devices*, International Encyclopedia of Ergonomics and Human Factors, 2006

Co-Author, *Design of Medical Devices for International Market*, IWIPS, 2005

Member, IEC Human Factors Committee



Use-Lab GmbH

Team:

- Usability Experts, Engineers, Nursing Staff, (UI)-Designer, Psychologists, Economists and external Specialists



Mission:

- Supporting medical device developers by tailoring products to the needs of the users

Focus:

- Exclusively Medical Products, incl. IVD- and Laboratory Devices

Geographical Reach:

- International

Technical Resources



Source: Use-Lab GmbH

Experience

- OR
- Intensive Care
- Radiology
- Laboratory
- Drug Application
- Home Care, Lay Care
- Dialysis
- Dental Care
- Ophthalmology
- Diabetes Care



Source: Use-Lab GmbH



Clients (sample)



Safety

Definition:

The condition of being safe;
freedom from danger, risk, or injury.

Which Cycle Path is safer?

a.



Source: <http://www.atzgersdorf.at/require/stadt/rad.jpg>

b.



Source: <http://www.hamsterecke.de/index.php?id=7>

Which OR is safer?

a.



b.



Source: Use-Lab GmbH

Hospitals present users diverse user interfaces

Consider the challenges facing people who use many different types of medical and laboratory instruments.

Each device speaks a somewhat different “user interaction language.”

It's not surprising that some users struggle to learn how to operate some devices.

Design shortcomings will induce some people operate devices incorrectly.

Design Diversity reflected in Sample Devices

Acronyms / abbreviations

Alarms

Automation

Color coding

Conceptual model

Connectors

Control arrangement

Control-display relationship

Display size

Functional grouping

Help system

Instructional syntax

Label placement

Language / terminology

Learning tools

Portability

Safeguards

Screen layout

Shape coding

Symbology / iconography

Text legibility

Visual appeal

The design of high-quality medical and scientific devices requires human factors engineering.

Good human factors engineering (HFE)
makes products safer.

HFE makes user interactions with products
more effective and efficient.

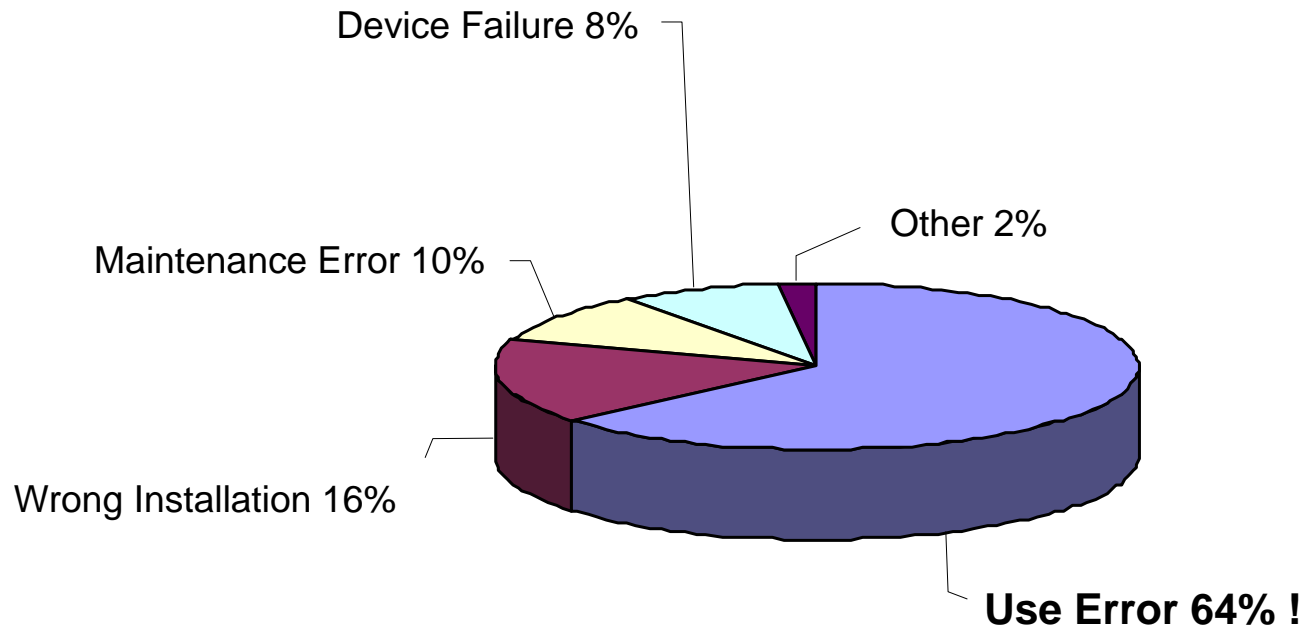
HFE creates satisfied and loyal customers
because products are “empowering.”

What happens when Human Factors is overlooked?



Source: D. Norman. *The Design of Everyday Things*.

Incidents while using Medical Electrical Equipment



Source: IOM, To Err is Human, 1999

Sources for Use Errors

Positioning a stopcock



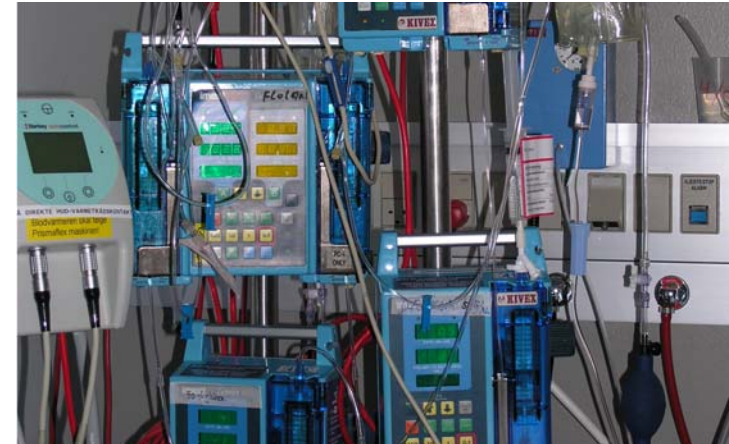
Reading a display



Identifying a drug vial



Connecting the wrong line



Source: Use-Lab GmbH

Sample Sources of Use Error

- Illogical operational sequences
- Lack of visual, audible, and/or tactile feedback
- Hidden and mysterious functions
- Ambiguous symbols and icons
- Unfamiliar terminology (including labels, prompts, headings)
- Complicated information layouts
- Lack of functional grouping
- Inconsistent formats
- Lack of safeguards
- Misapplication of prior operating experience
- Exceeding human capabilities (memory, information processing pace, visual acquisition, strength, reach, etc.)
- Excessive workload and stress



Consequences of poor Human Factors



Consequences of poor Human Factors



FDA U.S. Food and Drug Administration
CENTER FOR DEVICES AND RESEARCH QUALITY
[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [2008-11-06](#) | [2008](#)

[CDRH](#) > Medical Device Recalls

Medical Device Recalls

FDA posts consumer information about the most serious medical device recalls. These products are listed because there is a reasonable chance that they could cause serious health problems or death.

Use the list below to find information about Class I medical device recalls and some Class II recalls of interest to consumers. The text links following each listing give details about what you own or use one of these products.

For a list of all medical device recalls, see the [CDRH Device Recalls Database](#)

For other safety information on medical devices, see [CDRH Public Health Notifications](#)

[RSS](#) [Subscribe to email updates on Class I recalls](#)

Device Name
Integra LifeSciences Corporation (also known as Integra NeuroSciences) Endura™ No-Flap
Integra LifeSciences Corporation (also known as Integra NeuroSciences) Products Tissue Regenerators

Competition

Definition:

Competition is the rivalry over something on which a winner is selected from among two or more contestants.

Which Product do you prefer?

a.



b.



Source: Use-Lab GmbH

Hyper Functionality is causing Problems



Goal of the Usability Engineering Process

Before:



After:



Source: <http://www.marshu.com/images-website/funny/computer-switch-board-man-one-switch-woman-many-switches.jpg>

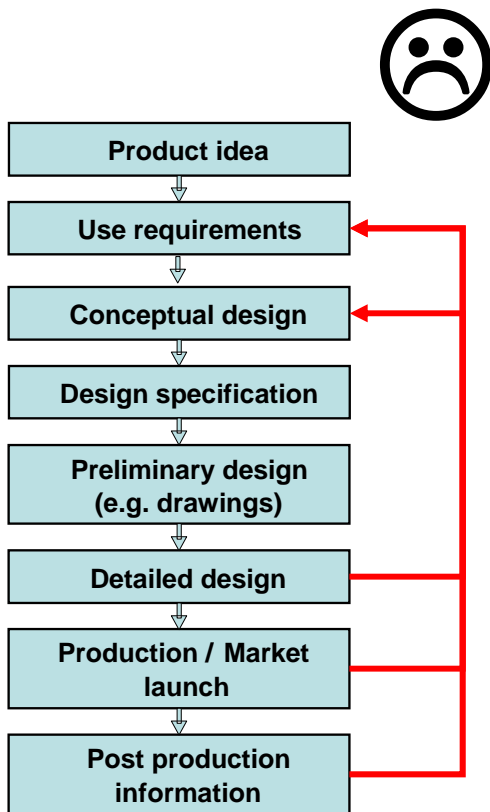
Example for Minimalism



Source: www.computerbase.de

Present

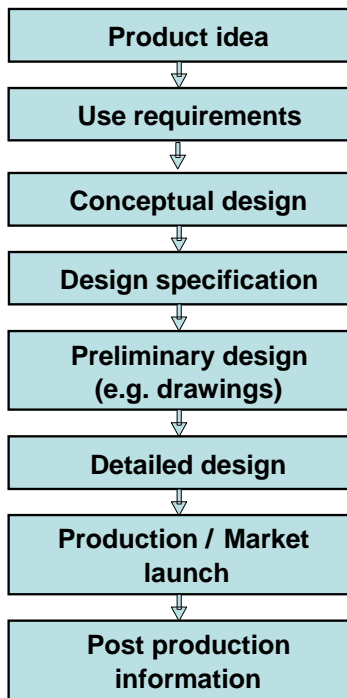
Development-, Risk- and Quality-Management Process



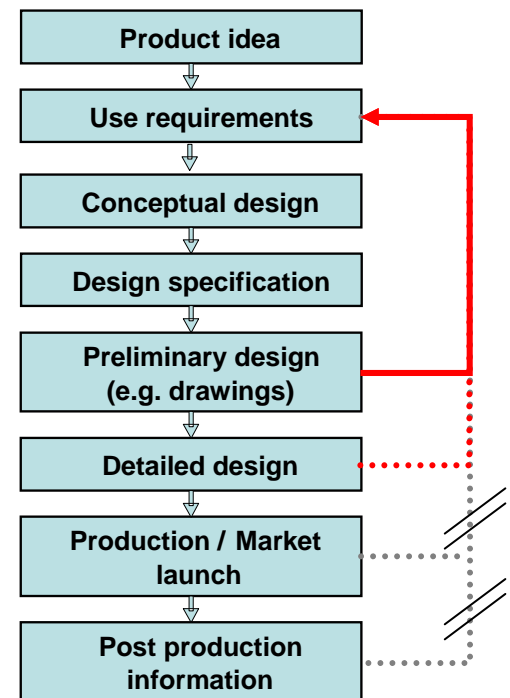
Source: Use-Lab GmbH

Future

Development-, Risk- and Quality-Management Process



+ Usability



Source: Use-Lab GmbH

To do List

- Analysis
- Specification
- Conceptual Design
- Verification
- Detailed Design
- Validation
- Final Risk Analysis
- Post Market Surveillance



Source: Use-Lab GmbH

Opportunities for Savings and Returns

- Reduced development times
- Simplified learning tools
- Increased sales
- Reduced customer support
- Product liability protection

- Patients receive better care!

 Reduced costs and higher customer satisfaction!

$ROI_{\text{Usability}} \geq 1:10!$

Sources:

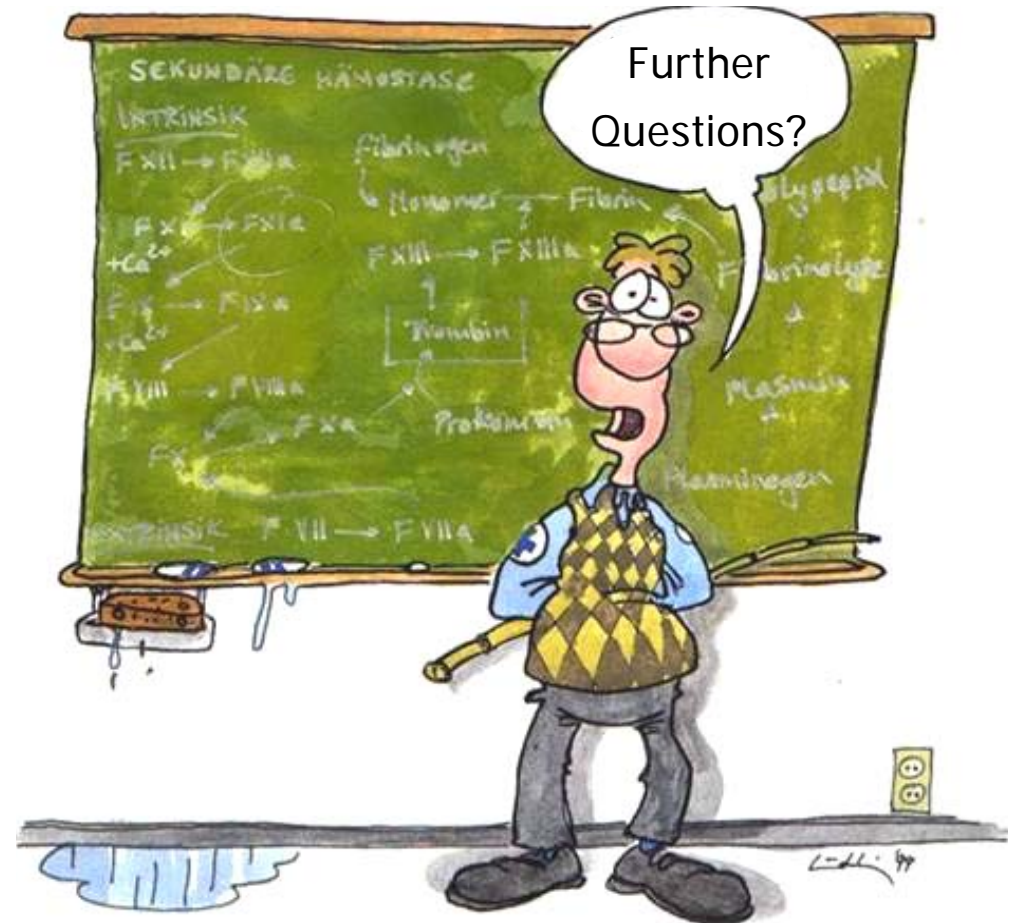
- Michael Wiklund, Concord MA
- Deborah Mayhew
- Fraunhoferinstitut
- IBM

Summary

- ✓ Starting HFE early can reduce time and costs in R&D
- ✓ HFE is making the products more competitive and safer
- ✓ HFE is increasing the sales opportunities

Discussion

**Thank you for
your attention!**



www.use-lab.com

Source: www.rippenspreizer.com