Anatomy of an Effective Human Factors Engineering Program

Workshop presented to:

IEEE – Long Island Section

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My presentation

Human factors engineering (HFE)

The regulatory imperative to practice HFE

HFE process basics

User interface validation by usability testing

Applying HFE to “legacy” devices

Human factors engineering (HFE)

About human factors engineering (HFE)

HFE specialists help ensure the quality of interaction between people and devices / machines / systems.

- Safe
- Effective
- Efficient
- Satisfying

Human factors engineering (HFE)

Sure, it’s part common sense.

Human factors engineering (HFE)

Sure, it’s part common sense.

Human factors engineering (HFE)

We see evidence of human factors engineering all around us.

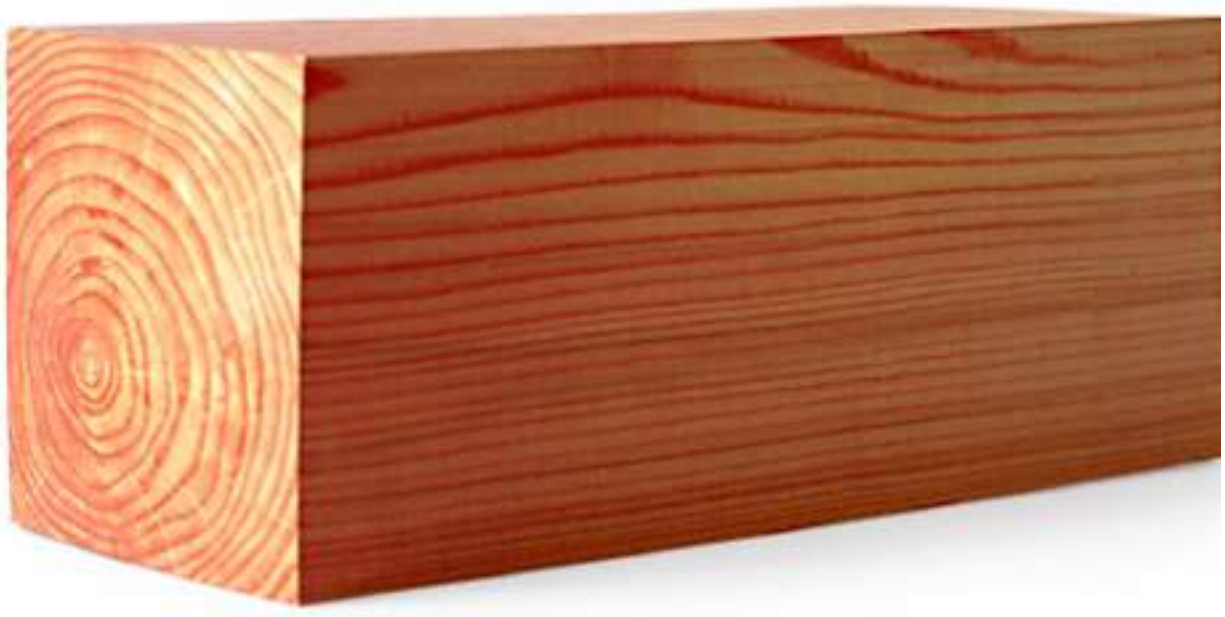
Task: Open a tin can

Can opener

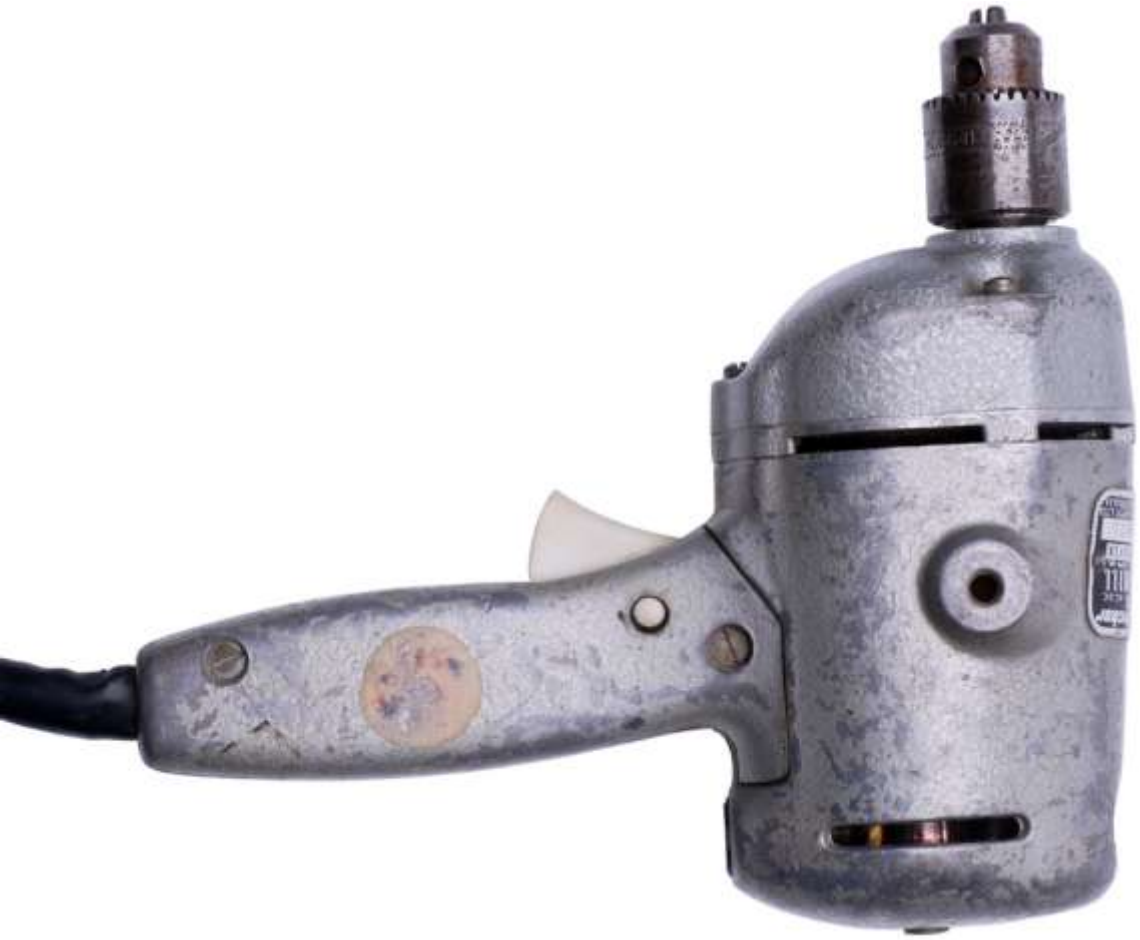
Open and obvious hazards

Can opener

Task: Drill a hole



Electric drill



Electric drill

Task: Perform a rescue

Source: http://www.fraunhofer.de/content/dam/zv/en/press-media/2011/big-image/md02_fo3g-notfallerkennung.jpg

Defibrillator

Defibrillator

HFE specialists improve devices by…

- Studying how people interact with devices to generate requirements and validate solutions.
- Matching devices to people's bodies, for example size, strength, and range of motion.
- Matching devices to people's minds, for example reaction time, memory capacity, and processing pace.
- Presenting displays and controls in a task-oriented manner.

Let’s consider specific human factors

Sample human factors

Vision

Inserting a guidewire in a catheter

Determining fluid level in collection bag.

Reading the vital signs on patient monitor.

Reading an injector’s dose setting.

Sample human factors

Normal

Cataract

Retinopathy

Glare on screen

Deuteranope
(color vision impairment)

Macular Degeneration

Sample human factors

Touch

Sensing that a control panel button has fully actuated (i.e., registered).

Turning a Luer-type connector until it feels tight.

Sensing that a patch is moistened.

Sensing that a syringe plunger cannot be pressed any further.

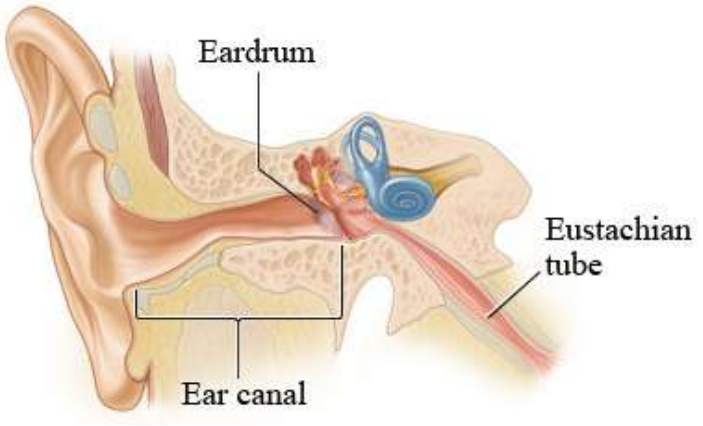
Sample human factors

Hearing

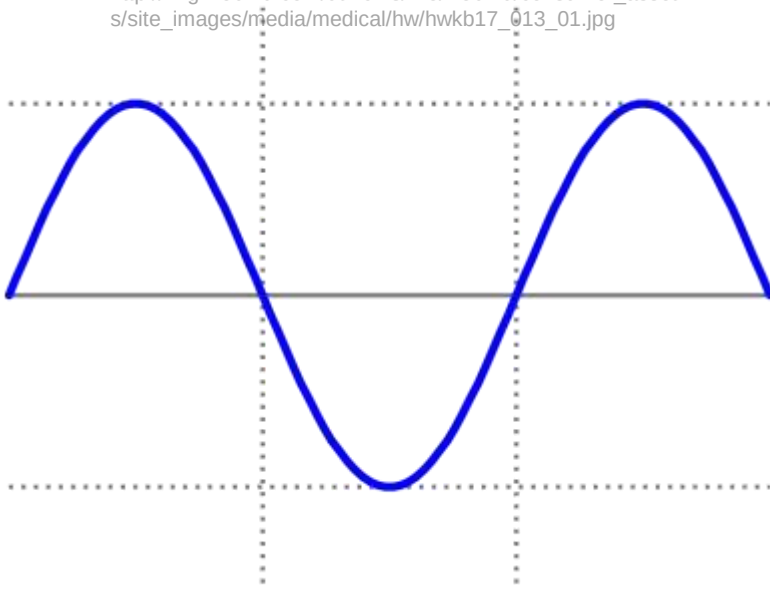
Detecting an occlusion alarm.

Detecting a change signal tone indicating a patient's oxygen saturation level is dropping.

Hearing the audible feedback produced by a button press.



Source: http://img.webmd.com/dtmcms/live/webmd/consumer_assets/site_images/media/medical/hw/hwkb17_013_01.jpg



Sample human factors

Anthropometrics

Hand breadth:

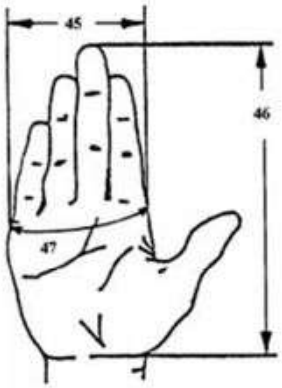
5th %-tile female: 7.3 cm

95th %-tile male: 9.8 cm

Hand length:

5th %-tile female: 16.5 cm

95th %-tile male: 21.1 cm



45 Hand breadth. The breadth of the hand, measured across the ends of the metacarpal bones (metacarpal-phalangeal joints).

	Sample		Percentiles 1st	5th	50th	95th	99th
A	Men	cm	8.1	8.4	9.0	9.8	10.0
		(in)	(3.2)	(3.3)	(3.5)	(3.9)	(3.9)
B	Women	cm	7.1	7.3	7.9	8.6	8.9
		(in)	(2.8)	(2.9)	(3.1)	(3.4)	(3.5)

46 Hand length. The distance from the base of the hand at the wrist crease to the tip of the middle finger.

	Sample		Percentiles 1st	5th	50th	95th	99th
A	Men	cm	17.3	17.9	19.3	21.1	21.9
		(in)	(6.8)	(7.1)	(7.6)	(8.3)	(8.6)
B	Women	cm	15.9	16.5	18.0	19.7	20.5
		(in)	(6.3)	(6.5)	(7.1)	(7.8)	(8.1)

47 Hand circumference. The circumference of the hand, measured around the knuckles (metacarpal-phalangeal joints).

	Sample		Percentiles 1st	5th	50th	95th	99th
A	Men	cm	19.2	19.9	21.3	23.0	23.7
		(in)	(7.6)	(7.8)	(8.4)	(9.1)	(9.3)
B	Women	cm	16.7	17.3	18.6	20.0	20.7
		(in)	(6.6)	(6.8)	(7.3)	(7.9)	(8.2)

Source: *http://upload.wikimedia.org/wikipedia/en/thumb/f/fc/HandAnthropometry.JPG/563px-HandAnthropometry.JPG*

Sample human factors

Anthropometrics

Making components easy to grasp and manipulate

Fitting an oral endotracheal tube to a patient’s face

Reaching the controls on an X-ray machine

Tearing open a disposable device’s package

Holding a pen injector comfortably using one hand

Grasping and manipulating the hand control for a surgical robot

Sample human factors

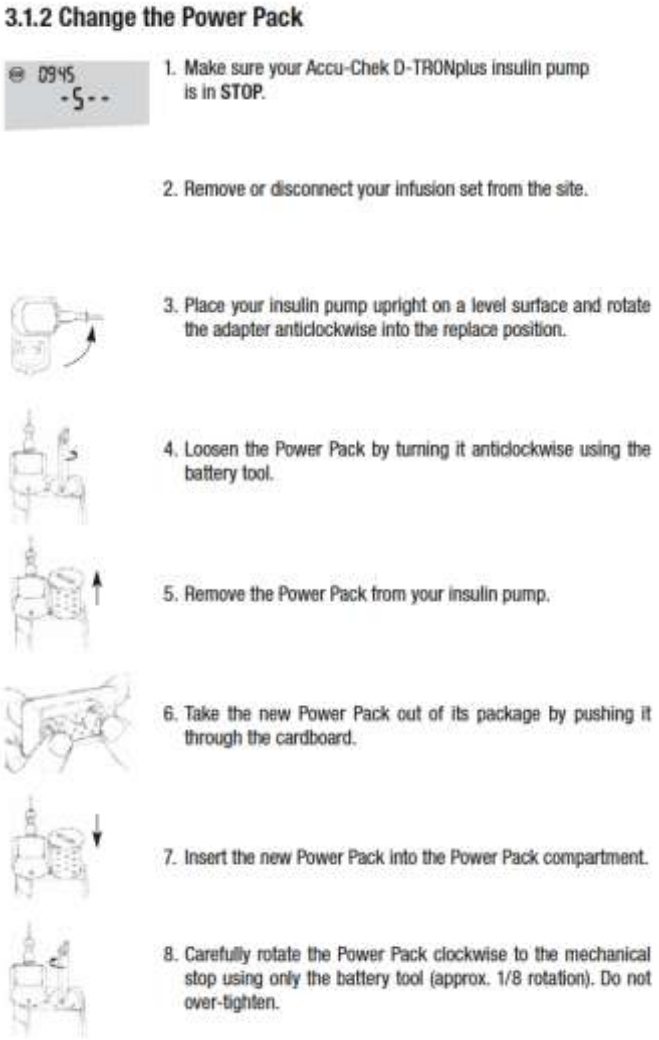
Memory

Remembering the proper steps on how to open a package and present the contents to those working in the sterile field

Remembering to document parameter values on patient record.

Setting alarm limits at the appropriate level.

Finding the menu option that leads to a list of dose delivery dates, times, and amounts.



3.1.2 Change the Power Pack

1. Make sure your Accu-Chek D-TRONplus insulin pump is in **STOP**.
2. Remove or disconnect your infusion set from the site.
3. Place your insulin pump upright on a level surface and rotate the adapter anticlockwise into the replace position.
4. Loosen the Power Pack by turning it anticlockwise using the battery tool.
5. Remove the Power Pack from your insulin pump.
6. Take the new Power Pack out of its package by pushing it through the cardboard.
7. Insert the new Power Pack into the Power Pack compartment.
8. Carefully rotate the Power Pack clockwise to the mechanical stop using only the battery tool (approx. 1/8 rotation). Do not over-tighten.

Now, let’s talk about usability.

Usability:

Usability is a product attribute.

It is the integrated result of many design features that act collectively to serve to smooth the interaction between user and product.

There is no perception of task hindrance.

A usable product serves its intended purpose well.

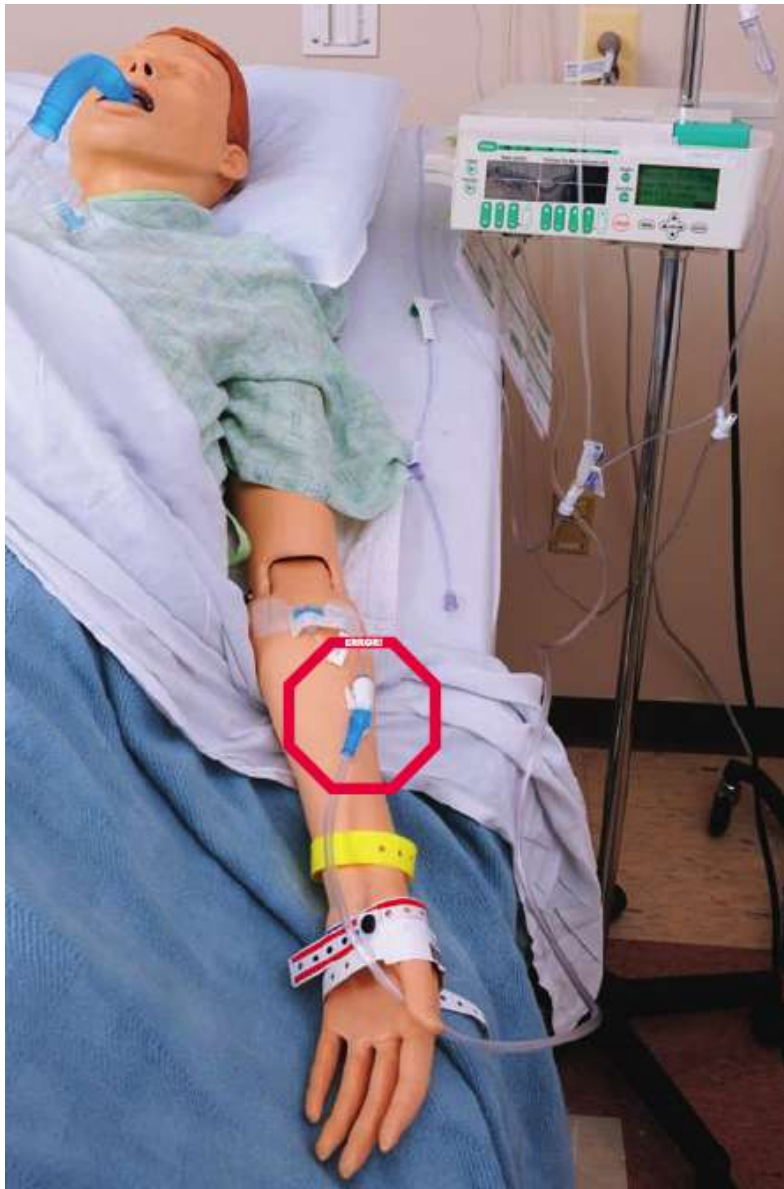
Users feel satisfied when they use the product.

Usability can be quantified.

Let’s get back to the general topic of HFE…

In the absence of good HFE → use errors

- Torn catheter
- Tube and cable misconnection
- Undetected alarm
- Incorrect data entry
- Components assembled wrong



User errors → harm

- Basal rate profile offset by 12 hours upsets dosing regimen
- Failure to change infusion set on time leads to infection
- Delivery of excess bolus causes diabetic coma

Source: http://i1.squidoocdn.com/resize/squidoo_images/-1/lens1526030_1327006460diabetic_coma.jpg

Adverse outcome – overdose

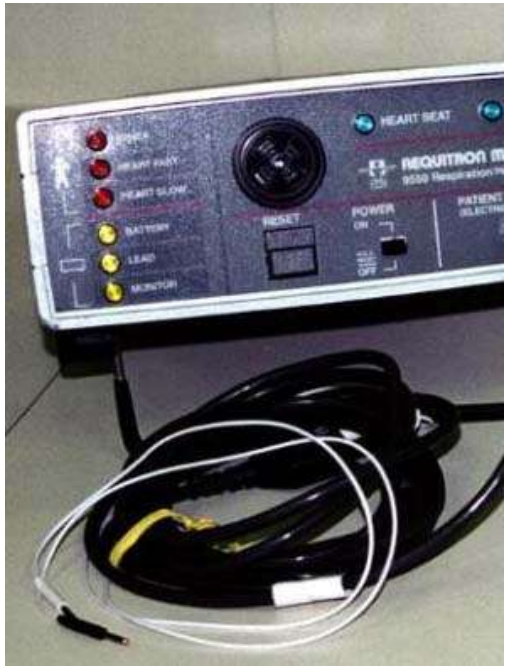
"Death by decimal."

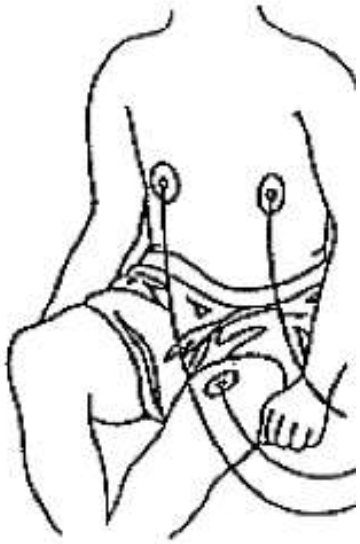
On Sunday, May 28, 2000, the Tallahassee Democrat (FL) reported that a 19-year-old mother died hours after a routine cesarean section when a nurse accidentally mis-programmed an Abbott Lifecare PCA Plus II Infusion pump.

The nurse apparently set the pump's concentration setting lower than the concentration of the narcotic loaded into the pump. For every 1 mL of narcotic solution that the pump delivered, the patient received an amount of drug that was severalfold greater than prescribed.

Source: Institute for Safe Medication Practices, June 2000.

Adverse outcome – electrocution





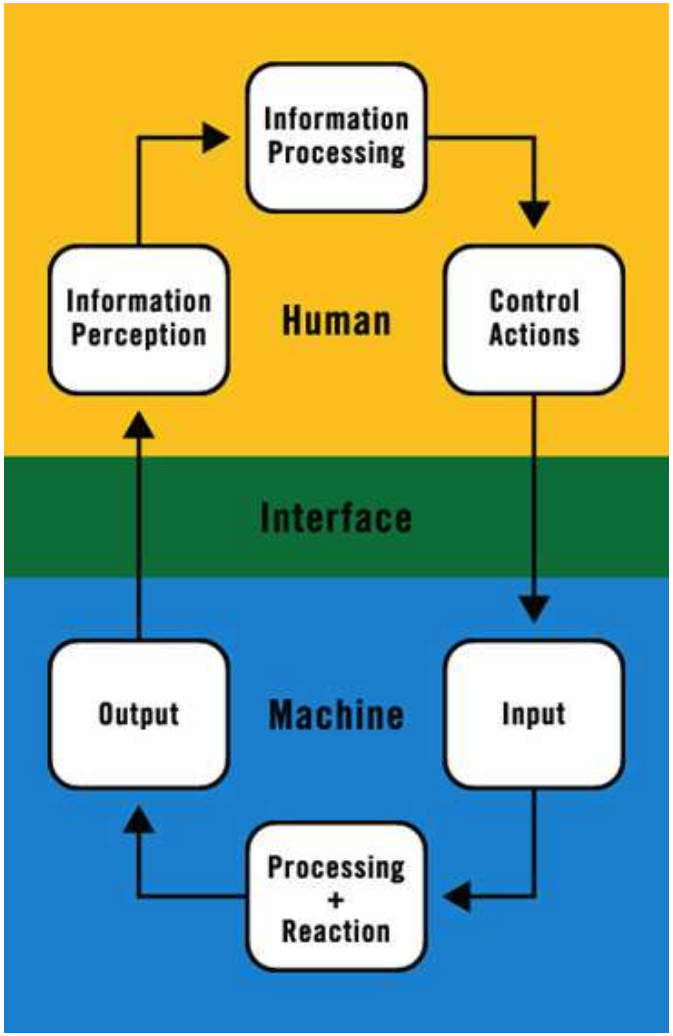
Five cases of electrical injury to young children caused by misuse of components of home cardiorespiratory monitors are reported. The injuries, which included one electrocution, occurred when partially or completely disconnected electrode wires were inserted, by an older monitored child or preschool-aged sibling, into a live power cord or an uncovered wall outlet.

Source: Pediatrics, Nov. 1986.

Business impacts

- Higher development costs
- Increased time to market
- Recalls, embargos, bans
- Damaged reputation
- Lost sales

[User] interface is key to the user experience



Goal is to create a safe, effective, usable, and satisfying device.

Meeting this goal rides on producing a high-quality user interface

Image source: FDA

The HFE imperative

Imperative to apply HFE

Now, the FDA and other regulatory agencies expect that medical devices will reflect good HFE.

Applying HFE is a cornerstone of overall risk management.

Timeline

1993: ANSI/AAMI HE48:1993 (design guidelines)

1995: Joint AAMI and FDA conference on HF

1996: Quality System Regulation (QSR); indirect requirements for HFE added

1997: End of “grace period” to incorporate HFE in medical device design process

1999: IOM report on medical error

2001: ANSI/AAMI HE74:2001 (HFE process standard)

2006: IEC 60601-1-6 collateral standard (AAMI HE74 is informative annex)

2007: ISO/IEC 62366:2007 (AAMI HE74 included as informative annex)

2008: EU adopts ISO/IEC 62366:2007 as basis for CE mark

2008: FDA’s HFE team moves into Office of Device Evaluation

2009: ANSI/AAMI HE75:2009 (HFE methods and design guidelines)

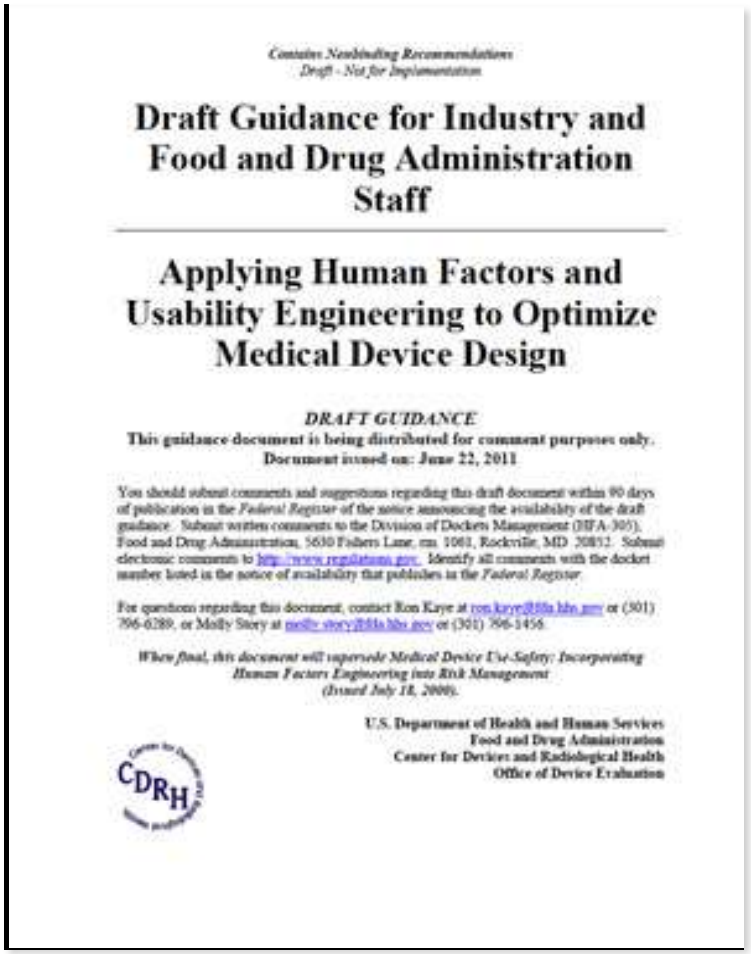
2011: FDA publishes draft HFE guidelines

2012: Adoption of 3rd edition of IEC 60601 by Europe and Canada

2013: Adoption of 3rd edition of IEC 60601 by USA

Key documents

FDA's Draft Guidance



Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Applying Human Factors and Usability Engineering to Optimize Medical Device Design

DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.
Document issued on: June 22, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Ron Kaye at ron.kaye@fda.hhs.gov or (301) 796-6289, or Molly Story at molly.story@fda.hhs.gov or (301) 796-1456.

When final, this document will supersede Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

IEC 62366

IEC ISO

IEC 62366

Edition 1.0 2007-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices – Application of usability engineering to medical devices

Dispositifs médicaux – Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

XD

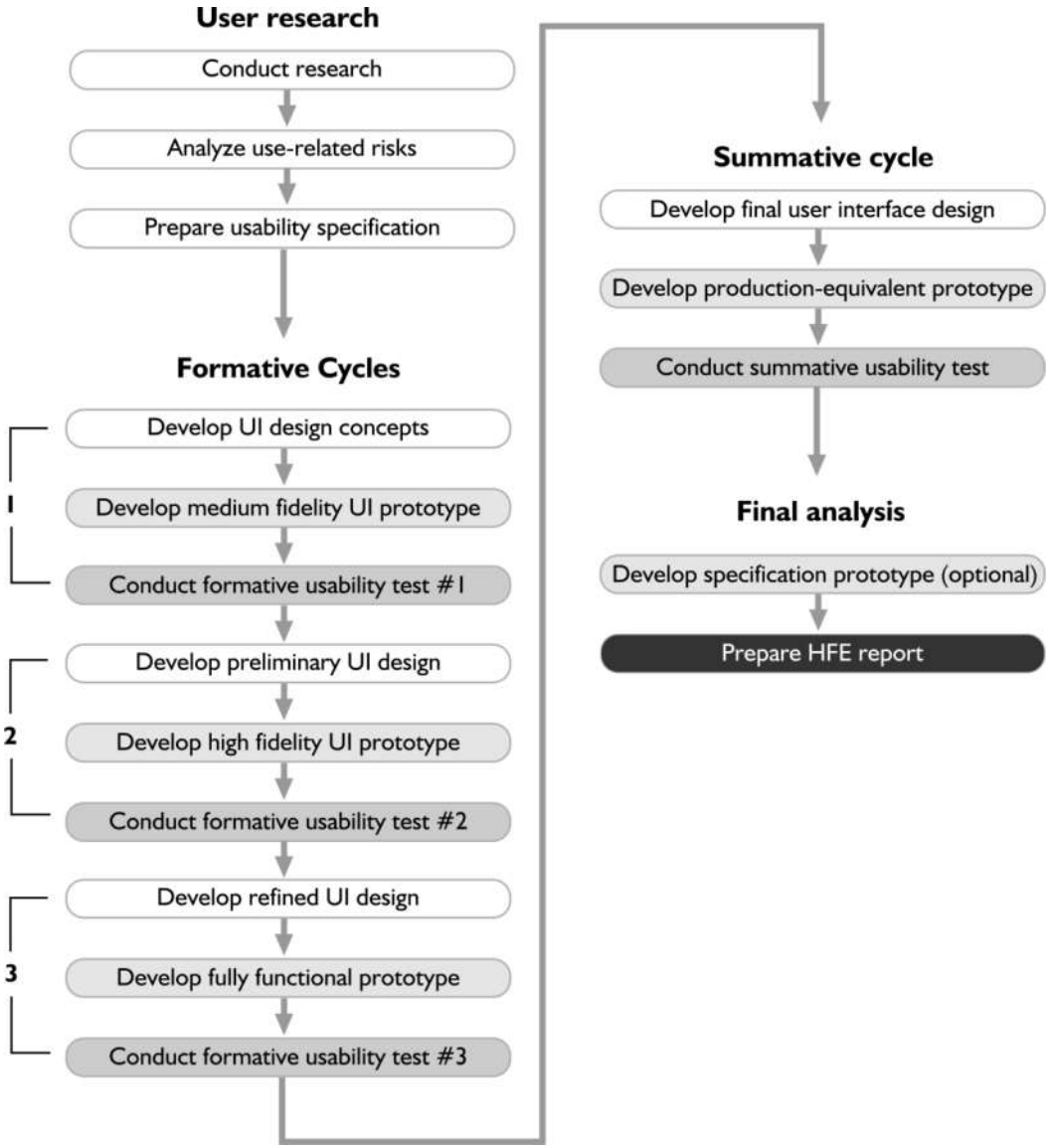
Basic expectations

- Implement an HFE program
- Define intended users, use environments, potential hazards, potential use errors, and use-related risk
- Mitigate use-related risk
- Validate user interface designs, proving risk control measures work
- Document HFE activities and outcomes

HFE Process Characteristics (one example)

- Iterative
- Increasing level of prototype fidelity
- Multiple formative usability tests
- Addresses use-related risks early and repeatedly
- Culminates in claim that residual, use-related risk associated with device is acceptable

Note: Illustrated process is a simplified depiction.



A need to integrate HFE and risk analysis

- User interactions with a medical device may be safe or pose risks.
- Developers must consider a wide range of possibly harmful use errors and their potential consequences.
- Developers must implement risk control measures and prove that they work.

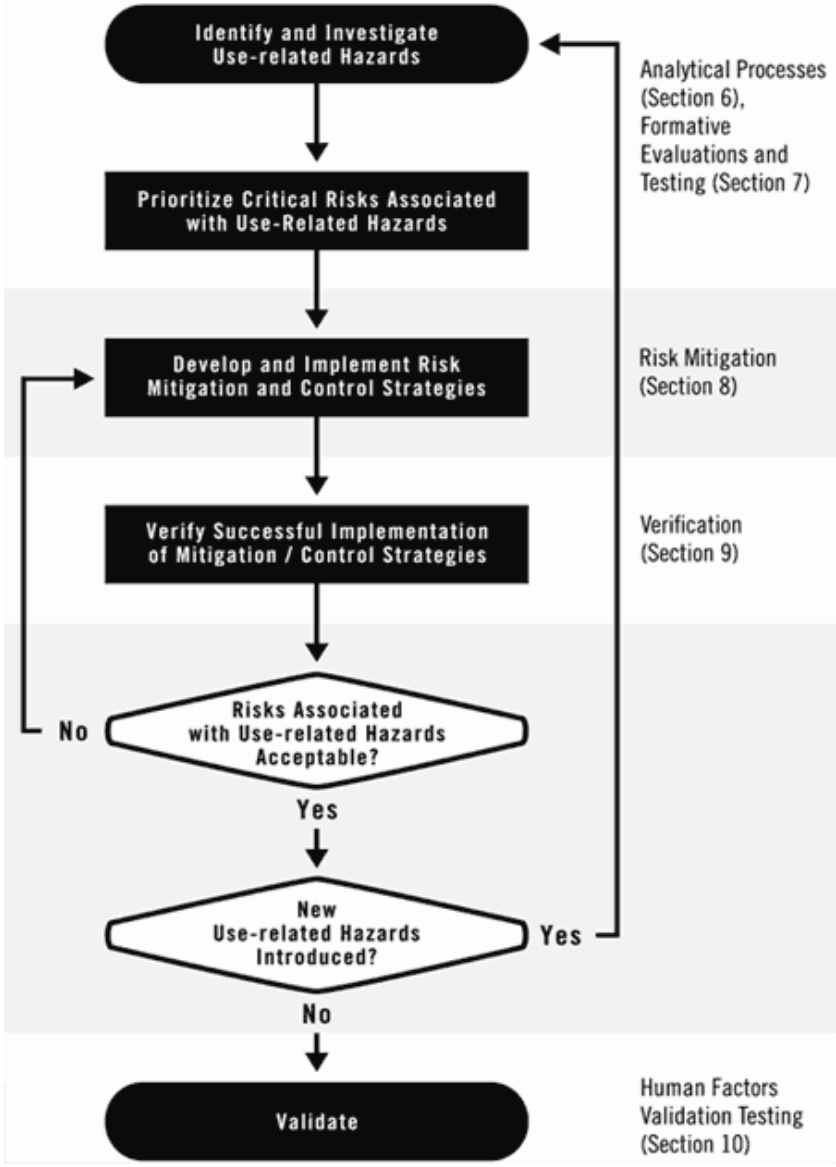


Image source: FDA

Applicability

FDA expects manufacturers to follow good HFE practices when:

- Developing a device for clinical trial (IDE)
- Enhancing an existing device (510(k))
- Developing a next generation device (510(k))
- Developing an altogether new device (PMA)
- Analyzing an adverse event (post-market surveillance)

IMPORTANT

Enhancing an existing device calls for a thorough HFE evaluation of the device's entire user interface, not just the revised portion.

60601-1: HFE-related collateral standards

60601-1-1 Medical Electrical Systems

60601-1-2:2007 Electromagnetic Compatibility (EMC)

60601-1-3:2008 Radiation Protection for Diagnostic X-ray Systems

60601-1-4 Programmable Electrical Medical Systems (PEMS)

60601-1-6:2007 Usability

60601-1-8:2007 Medical Alarms

60601-1-9:2008 Environmentally Conscious Design

60601-1-10:2008 Physiologic Closed Loop Controllers

60601-1-11:2010 Home Healthcare Equipment

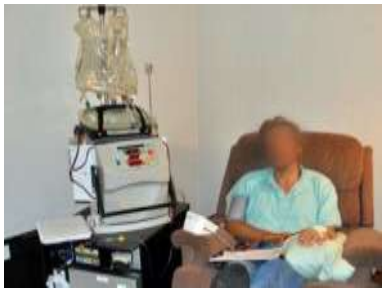
HFE-related collateral standards

Usability
(medical electrical equipment)

Usability
(medical devices)

Alarms

Home
(medical electrical equipment)



End-products suggested in IEC 62366

Analyze user needs and specify design

- Medical indication
- Patient indication
- User profiles
- Use environment(s)
- Operating principles
- Task analysis
- Functional analysis
- Characteristics related to safety
- Primary operating functions
- Usability requirements
- Usability goals
- Usability specification

Analyze risks

- Hazard analysis
- Use error analysis
- Known or foreseen hazards and hazardous situations

Design the user interface

- UI models and prototypes
- Usability test reports
- User interface design

Verify and validate the user interface

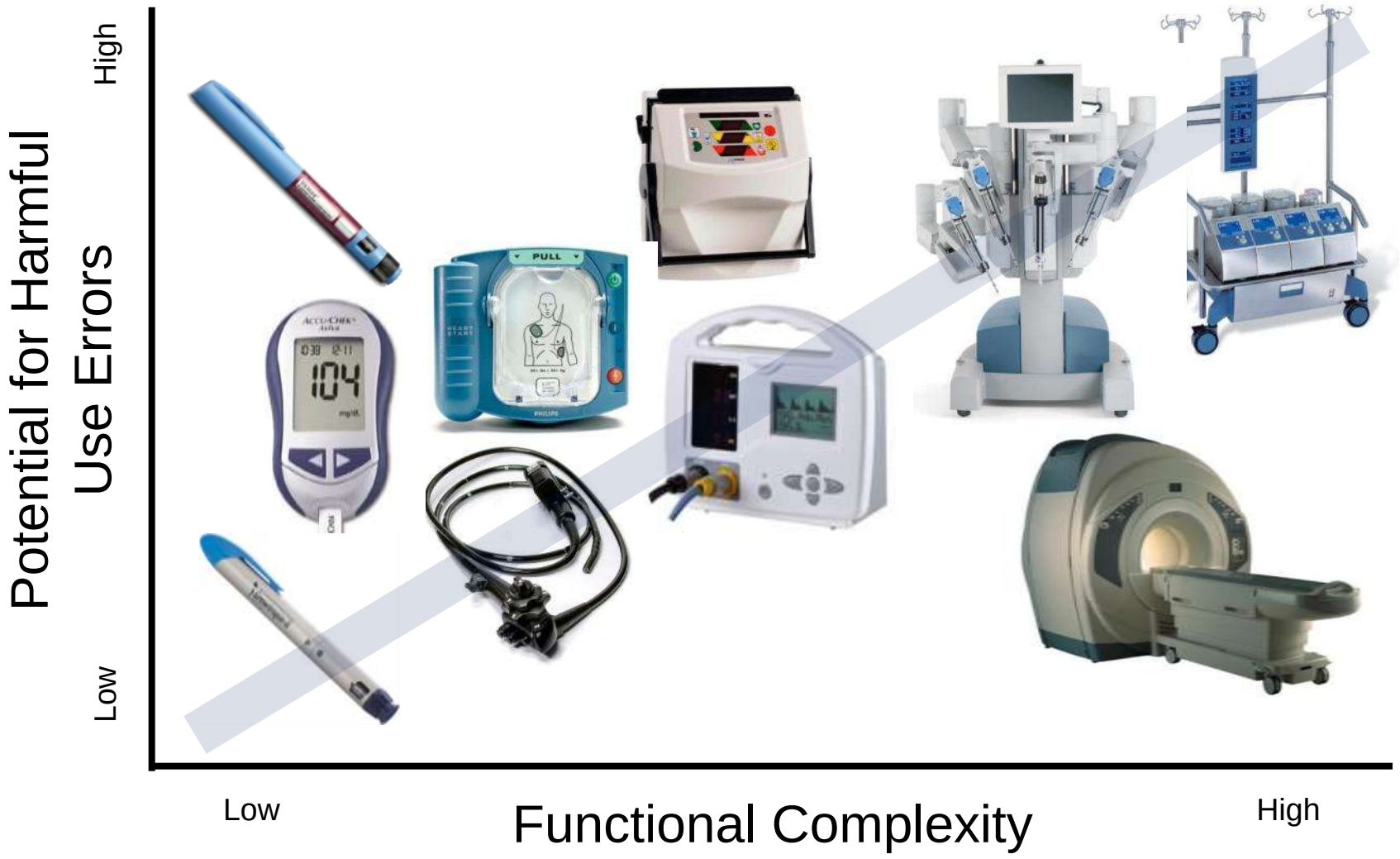
- Usability validation plan
- Usability validation report

HFE (usability engineering) process

The MANUFACTURER shall establish, document and maintain a USABILITY ENGINEERING PROCESS to provide SAFETY for the PATIENT, USER and others related to USABILITY. The PROCESS shall address USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT, including, but not limited to:

– transport;
– storage;
– installation;
– operation;
– maintenance and repair; and
– disposal.

Scaling based on complexity and risk



Scalable HFE activities and decision factors

User research

- Number of users, use environments, and use scenarios warranting investigation
- Number of locations in which to conduct research
- Number of research types

Usability specification and verification

- Number of user requirements

Risk analysis

- Number of users, use environments, and use scenarios to consider

User interface design

- Extent of user interactions
- Number of risks requiring mitigation
- Number of design iterations

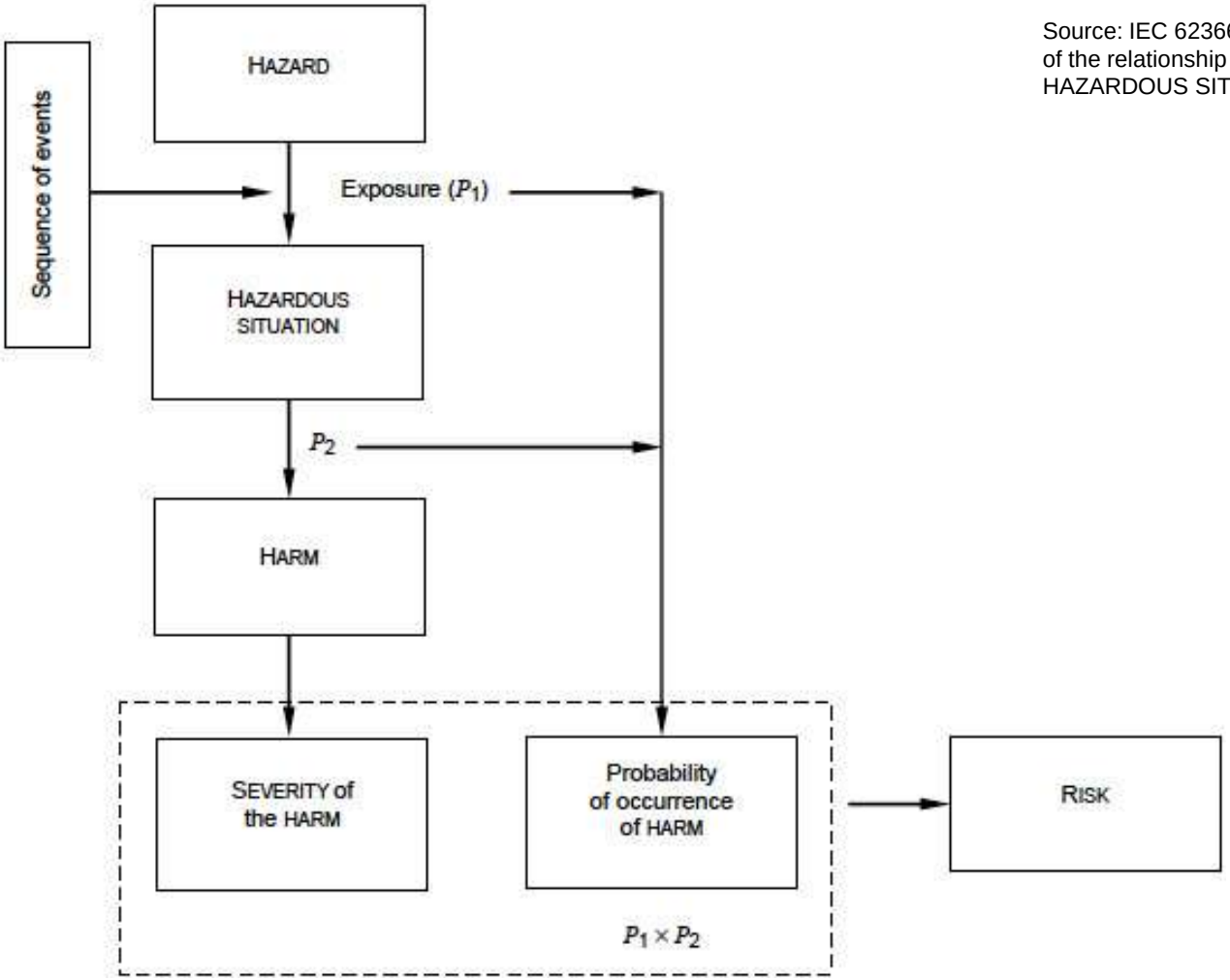
Usability testing

- Number of formative usability tests
- Size of test participant sample (i.e., number of distinct user groups)
- Number of locations in which to conduct research
- Number of tasks performed with hardware, software, and/or learning tools
- Extent of report

Application specification

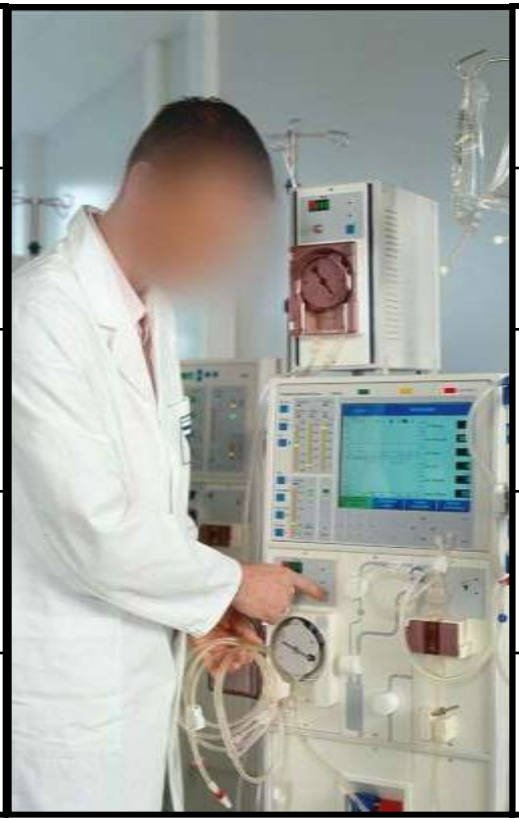
- Medical indication – describes the condition(s) or disease(s) that the device will screen, monitor, diagnose, treat, or prevent
- Patient population – describes the types of people on whom the device will be used
- Intended part of the body or type of tissue applied to or interacted with
- User profile(s) – describes the people who will operate the device (possibly including the patient)
- Conditions of use – describes the real world conditions that will influence how users interact with the device
- Operating principle – describes the physical means used to accomplish the device's intended use and the mechanisms by which it works

Use-related risk analysis

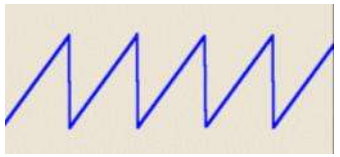


Source: IEC 62366, Figure F.1 – Pictorial representation of the relationship of HAZARD , sequence of events, HAZARDOUS SITUATION and HARM

Functional strengths of devices and users

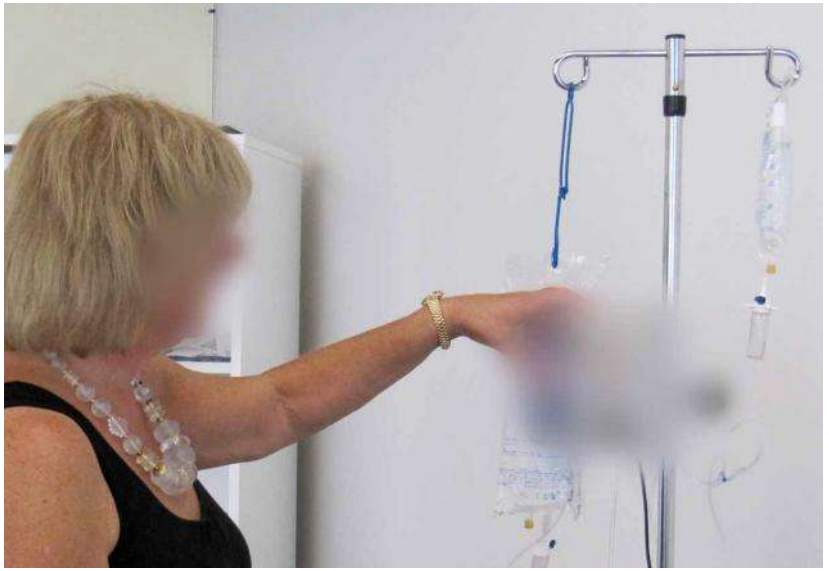
Humans (users)		Machines (devices)
Sensing things that machines cannot		Vigilant monitoring
Dealing with the unpredictable		Performing repetitive tasks correctly
Pattern recognition		Applying logic
Problem solving		Detecting trends

Matching requirements to UI features

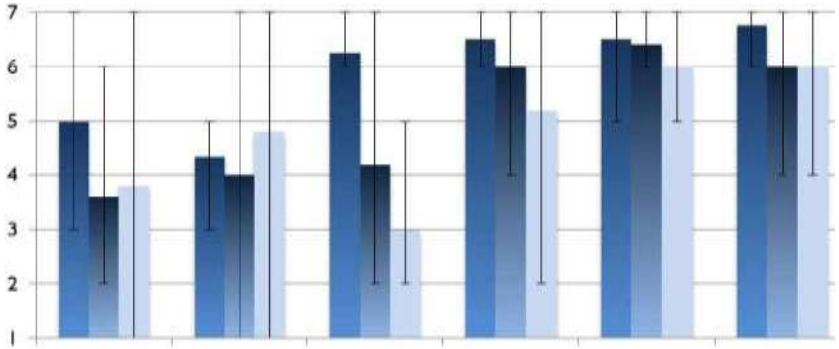
Requirement	User interface feature	
The device shall have an immediately accessible emergency stop button.	Red switch on front panel	
Audible alarms shall be audible in noisy environments	80 dBA, 2000 Hz, saw tooth waveform	
The device shall continuously indicate the battery power level	Battery icon displayed on all screens	
Hardware key centers shall be spaced at least 0.75 inches apart	Hardware key centers spaced ≤ 0.75 inches	

Validation usability tests

Infusion set



IV Infusion Pump



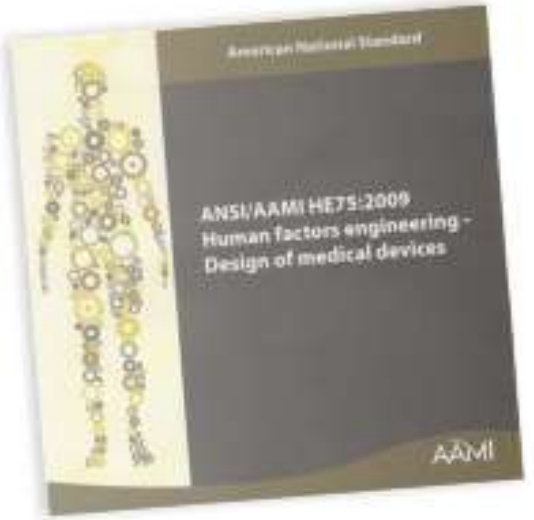
Total opportunities by task type	172	103	127
Number of participants who committed a use error	2	0	1
Number of use errors	3	0	1

Qualitative and quantitative test data

HFE applies to user documentation

AAMI standards

ANSI/AAMI HE 75:2009, *Human factors engineering – design of medical devices*. Provides detailed guidance on how to perform specific human factors analyses and provides a wealth of design principles



ANSI/AAMI HE 74:2001, *Human factors design process for medical devices*. Describes a range of approaches to applying human factors during the design of a medical device; links the approaches to the FDA's design controls. (Withdrawn, but persists as the core of IEC's standard – Appendix D – Guidance on the USABILITY ENGINEERING PROCESS)

AAMI HE75's content

- Managing the risk of use error
- Basic human skills and abilities
- Anthropometry and biomechanics
- Environmental considerations
- Usability testing
- General principles
- Signs, symbols, and markings
- User documentation
- Packaging design
- Design for post-market issues
- Cross-cultural / cross national design
- Alarm design
- Accessibility considerations
- Connectors and connections
- Controls
- Visual displays
- Use of automation
- Software user interfaces
- Hand tool design
- Workstations
- Design of mobile medical devices
- Home health care

HE75 on Displays

Example: Handheld Pulse Oximeter

19.3.5.2 - Luminance contrast: *Luminance contrast is one of the most important factors in display legibility. It is defined as the difference in luminance between the foreground and background of displayed elements.*

19.4.1.2 – Optimal character height: *The minimum character height should be 16 minutes of visual angle (ANSI/HFES 100). The preferred height of characters should be 20 to 22 minutes of visual angle when displayed characters are viewed frequently or rapid comprehension is essential (ISO 9241-3).*

19.4.2 – Font style: *Displays should be designed to avoid misinterpretation when a seven-segment display is inverted. Seven segment displays (typically light-emitting diodes [LEDs] or LCDs) are commonly used to display numeric information (and some alphabetic characters) in medical devices.*

HE75 on Displays

Example: Handheld Pulse Oximeter

HE75 on Displays

Example: Infusion Pump

15.4.7.2 – Attention-getting visual alarm signals. *Attention-getting visual alarm signals are usually point sources such as warning lights; however, other implementations are possible.*

15.4.7.3 - Information-providing visual-alarm signals: *Information-providing visual alarm signals provide specific, detailed information to users regarding an alarm condition… They should be legible at a distance of 1 meter… Alarm information should be differentiated from other information if the same display is used for both. This differentiation may be accomplished by color, reverse video, change in luminance, inclusion in a box, or symbols.*

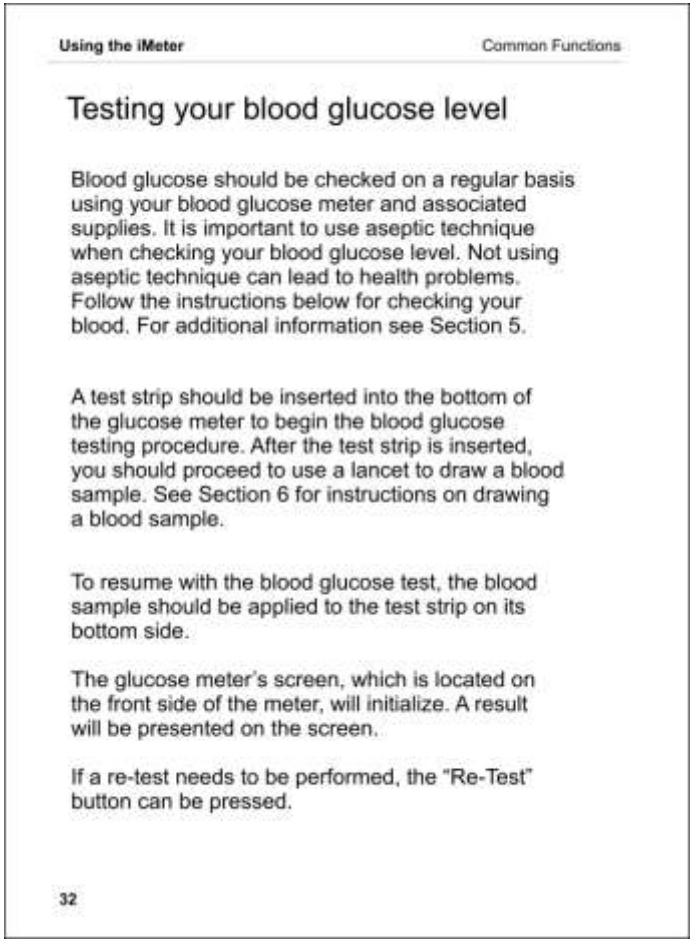
15.4.8.3.4 - Loudness: *To ensure that an auditory alarm signal is loud enough, the ideal approach is to use an algorithm that considers the intensity and frequency of ambient sounds.*

HE75 on Displays

Example: Infusion Pump

HE75 on User Documentation

Example: Glucose Meter



Using the iMeter Common Functions

Testing your blood glucose level

Blood glucose should be checked on a regular basis using your blood glucose meter and associated supplies. It is important to use aseptic technique when checking your blood glucose level. Not using aseptic technique can lead to health problems. Follow the instructions below for checking your blood. For additional information see Section 5.

A test strip should be inserted into the bottom of the glucose meter to begin the blood glucose testing procedure. After the test strip is inserted, you should proceed to use a lancet to draw a blood sample. See Section 6 for instructions on drawing a blood sample.

To resume with the blood glucose test, the blood sample should be applied to the test strip on its bottom side.

The glucose meter's screen, which is located on the front side of the meter, will initialize. A result will be presented on the screen.

If a re-test needs to be performed, the "Re-Test" button can be pressed.

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11.2.3.5 Facilitate translating the instruction into action: *Users should not be required to interpret or translate instructions into actions by having to recall experiences from their past or employ "guesswork" about what the instruction means. Therefore, simple stimulus–response approaches to writing instructions are preferred: "When you see/hear/feel X, do Y [action]."*

11.2.3.8 - Simplify language for ease of understanding: *Write in short, declarative, active voice sentences and avoid providing background information…Use precise terms. Instructions are intended to guide user behavior. Direct, behavioral descriptors are more effective in guiding user performance.*

11.2.3.11 - Use visuals and graphics to facilitate performance: *Visual illustrations and graphics should never be used instead of text. The text should be fully understandable before visual illustrations and graphics are even considered. Visuals should be simple line drawings.*

HE75 on User Documentation

Example: Glucose Meter

Testing your blood glucose level

Blood glucose should be checked on a regular basis using your blood glucose meter and associated supplies. It is important to use aseptic technique when checking your blood glucose level. Not using aseptic technique can lead to health problems. Follow the instructions below for checking your blood. For additional information see Section 5.

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Using the iMeter Common Functions

Testing your blood glucose level

IMPORTANT
Be sure to follow disinfect your hands before testing your blood glucose.

1. 
Insert test strip into the glucose meter's strip port.

2. 
Apply blood sample to bottom of test strip.

3. 

The glucose meter's screen will turn on and present the blood glucose result.

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User requirements

FDA's Quality System Regulation states:

•Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the users and patient.

•Design validation shall ensure that devices conform to defined user needs and intended uses, and shall include testing of production units under actual or simulated use conditions…

Source of user needs

- Users
- Predecessor product documentation
- Analysis of known problems with predecessor and comparable devices
- HFE design guidelines (e.g., AAMI HE75)
- Designer creativity

Example 1 – Adapt UI design guidelines

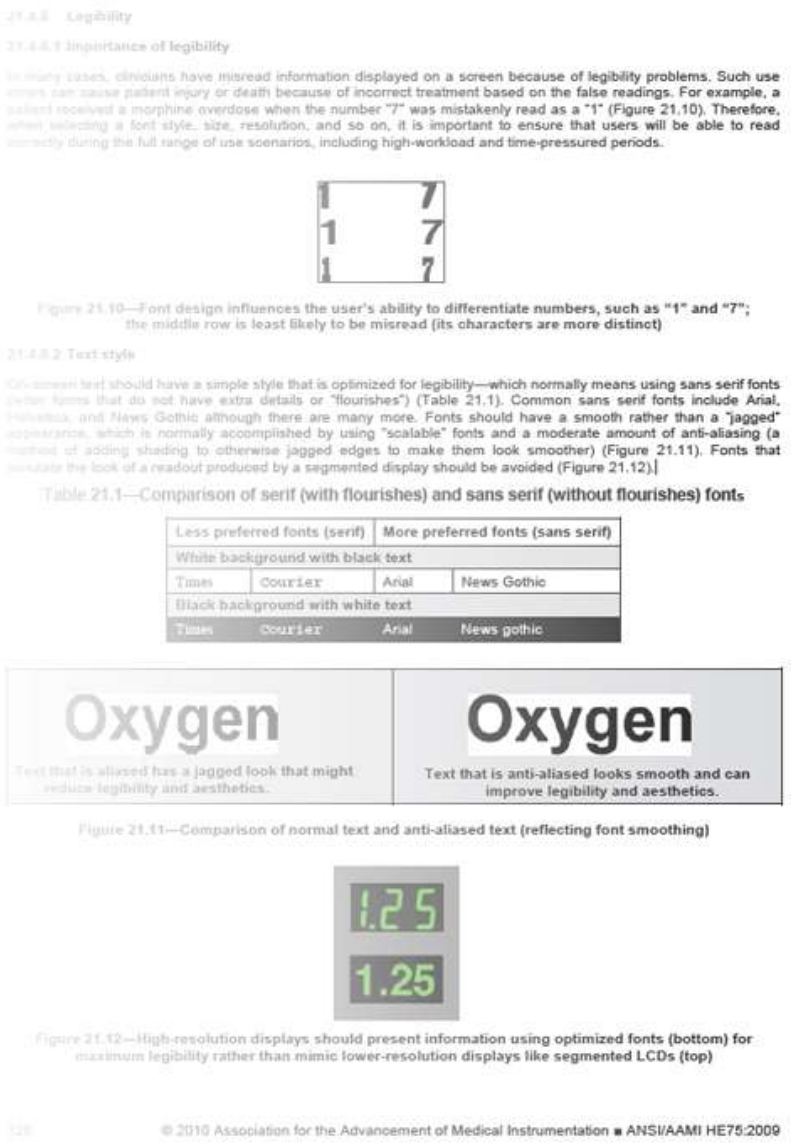
AAMI HE75, Section 21.4.6.2 Text style

On-screen text should have a simple style that is optimized for legibility—which normally means using sans serif fonts (letter forms that do not have extra details or “flourishes”) (Table 21.1).

Common sans serif fonts include Arial, Helvetica, and News Gothic although there are many more.

Fonts should have a smooth rather than a “jagged” appearance, which is normally accomplished by using “scalable” fonts and a moderate amount of anti-aliasing (a method of adding shading to otherwise jagged edges to make them look smoother) (Figure 21.11).

Fonts that simulate the look of a readout produced by a segmented display should be avoided (Figure 21.12).


21.4.6.1 Importance of legibility

In many cases, clinicians have misread information displayed on a screen because of legibility problems. Such use errors can cause patient injury or death because of incorrect treatment based on the false readings. For example, a patient received a morphine overdose when the number "7" was mistakenly read as a "1" (Figure 21.10). Therefore, when selecting a font style, size, resolution, and so on, it is important to ensure that users will be able to read correctly during the full range of use scenarios, including high-workload and time-pressured periods.

1 7
1 7
1 7

Figure 21.10—Font design influences the user's ability to differentiate numbers, such as "1" and "7"; the middle row is least likely to be misread (its characters are more distinct)

21.4.6.2 Text style

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Table 21.1—Comparison of serif (with flourishes) and sans serif (without flourishes) fonts

Less preferred fonts (serif)		More preferred fonts (sans serif)	
White background with black text			
Times	Courier	Arial	News Gothic
Black background with white text			
Times	Courier	Arial	News gothic

Oxygen

Text that is aliased has a jagged look that might reduce legibility and aesthetics.

Oxygen

Text that is anti-aliased looks smooth and can improve legibility and aesthetics.

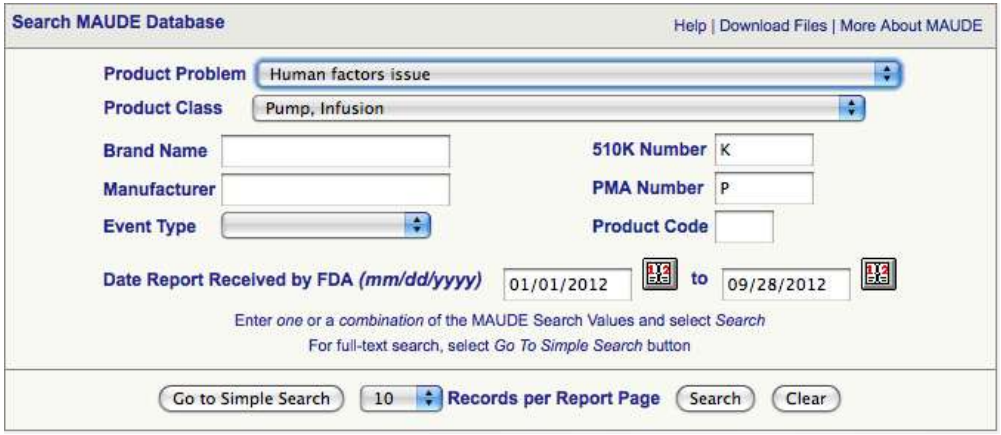
Figure 21.11—Comparison of normal text and anti-aliased text (reflecting font smoothing)

1.25

1.25

Figure 21.12—High-resolution displays should present information using optimized fonts (bottom) for maximum legibility rather than mimic lower-resolution displays like segmented LCDs (top)

Example 2 – Research known problems



Reason for Recall: This is an expansion of a previous recall, initiated by B. Braun in January, 2012, due to the potential for breakage of the anti free flow clip catch located inside the infusion pump door. Breakage may occur when the IV set anti free flow clip catch is inserted improperly into the pump and the pump door is forced closed. Misloading of the anti free flow clip catch may create the potential for free flow of medication. Free flow, especially of narrow therapeutic range drugs, can cause life-threatening effects and injuries.

The infusion pump interprets a single keystroke as multiple keystrokes (a problem called a "key bounce"). For example, the user programs an infusion rate of 10 mL/hour, but the device registers an infusion rate of 100 mL/hour.

A patient returns from ambulating and forgets to plug in the infusion pump. The infusion pump alarms with a low battery message, but the speaker volume is set too low, and the alarm goes unnoticed. The infusion pump powers off after the battery is depleted.

Example 3 – Collect user input

Observe people while they work

Conduct one-on-one interviews

Conduct group interviews

Conduct advisory panel discussions

Review complaints and suggestions

Conduct benchmark usability tests

Sample user profile: registered nurses

Hypothetical User Profile: Registered Nurses (RNs)

Occupational description

Registered nurses (RN) comprise the largest group of healthcare workers. Most RNs work directly with patients and their families. They are the primary point of contact between the patient and the world of health care, both at the bedside and in out-patient settings. RNs perform frequent patient evaluations, including monitoring and tracking vital signs, performing procedures such as IV placement, phlebotomy, and administering medications. Because the RN is much more regular contact with patients than are physicians, the RN is usually first to notice problems or raise concerns about patient progress.

RNs also develop the day-to-day nursing care plans both in hospital, and for care after discharge by families and visiting nurses.

While there is a national component to RN training (culminating in the NCLEX licensing exam), state laws determine the formal responsibilities of the RN. Nonetheless, because of the relatively broad nursing job description for RNs, the particular work environment determines what the daily routine is. (Source: http://www.studentdoc.com/nursing-job-description.html, retrieved on 9-16-10)

RNs may manage the work of other nurses, including RNs, licensed practical nurses, and practical nurses (nurse aids). They may also train nurses on the details of nursing practice and how to use equipment, serving the role of preceptor.

Demographic characteristics

- Gender: In the USA, over 93% of RNs are female and 7% are male
- Age range: 22-65+, averaging 47 (i.e., post-graduate to retirement age)
- Education: 2- or 4-year college degree as a minimum. Some nurses might have advanced degrees (e.g., MS in nursing) and multiple certifications (e.g., advanced life support, certification as a critical care nurse)

Skills assessment

- Typically skilled at using devices that have an embedded computer and a software user interface. Are able to develop accurate mental models of moderately complex software user interfaces and are likely to develop a moderate to high level of skill navigate with it.
- Typically good at and prone to follow standard operating procedures
- Often develop "work-arounds" to deal with repeating problems and inefficiencies.
- Often exhibit a "can-do" attitude regarding the performance of unfamiliar tasks, noting that someone has to get it done.
- Often exercise creativity to deal with one-of-a-kind difficulties.
- Spend a considerable amount of time documenting their work.
- Have sufficient math skills to determine appropriate infusion parameters, including.
- In the USA, nurses are expected to speak English fluently.
- A decreasing but still substantial proportion of nurse – perhaps those in their 50s and older – are less comfortable operating computer-based medical devices that their younger colleagues, principally because they are late-adopters of computer-based technology and didn't "grow up on them."
- Newer and younger nurses might be incrementally more over-reliant on an infusion pump's automated capabilities, never having had to use older pumps in a less automated manner.

Potential impairments

- Some nurses – particularly those in their mid-40s and older – may have a reduced ability to focus on near objects (far sightedness due to one form of presbyopia) and, therefore, require reading glasses that they might not have them available at the point of patient care.
- Some nurses – particularly males in their early 50s and older – may have a progressive degree of high frequency hearing loss (i.e., presbycussis).
- Some nurses – particularly those in their mid-50s and older – may have of dexterity and strength limiting conditions, such as arthritis.
- Some nurses – particularly males in their 50s and older – may have minor short-term memory problems that are typically a function of advancing age and not considered clinical significant or an occupational disqualification.

Performance shaping factors

- A majority of nurses have a high workload that leads them to work as efficiently as possible and sometimes develop "workarounds" to overcome obstacles to their productiveness.
- Nurses have to multi-task, which places relative high demands on their short-term memories.
- Nurses are taught to carefully check their work, such as the details of an inputted infusion pump program, to ensure correctness. Often, they might have a equal or senior colleague check their work (i.e., perform a double-check).
- As they gain occupational experience, some nurses may perform less rigorous checks on their work, reflecting a degree of complacency bred from confidence in their abilities and tendency to perform tasks by rote.
- Nurses are prone to pay attention to on-product warnings when they are unfamiliar with a medical device. Such warnings become "invisible" after a short period of habituation.
- Nurses will reliably perform tasks as necessary to ensure patient safety (i.e., they are disinclined to modify procedures in ways that place a patient at greater than usual risk).
- As effective time managers, nurses tend to learn as much about how to use a medical device as needed to "make it work" in the expected use scenarios. As such, they become masters at the frequent tasks and might remain relative novices or only moderately able and confident at performing infrequent tasks, some of which might be life-critical.

Learning style

- Most nurses prefer to learn to use a new medical devices by being shown how it works by a knowledgeable colleague or manufacturer's representative.
- In-service training typically lasts 20-40 minutes and might involve a limited degree of hands-on use of the given device.
- A limited percentage of nurses (perhaps 20-30%) will take the time to thoroughly read a medical device's user manual. They are more likely to refer to a user manual when they are dealing with a problem that they cannot resolve by direct, immediate actions.
- Nurses value quick reference and troubleshooting guides to deal with common and complex problems.

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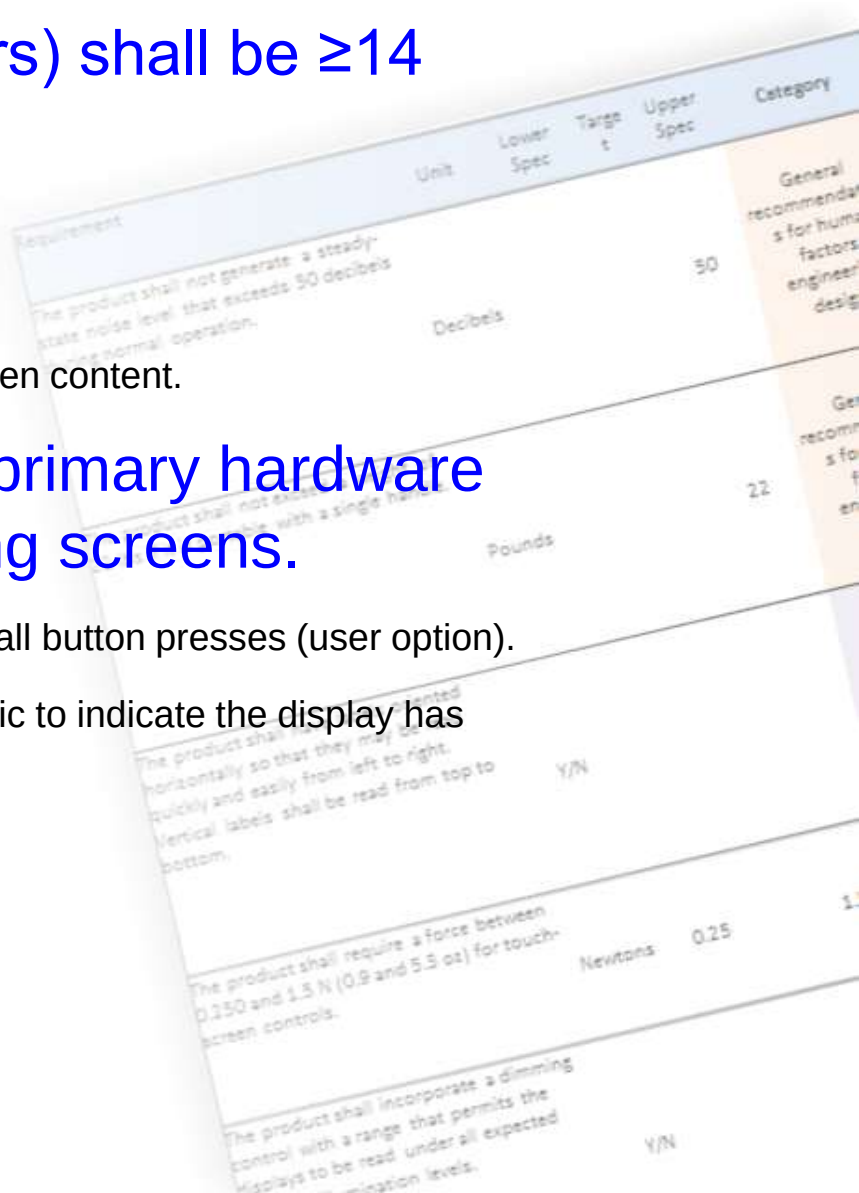
User needs – glucose meter

- “I’d like to be able to read the screen without a magnifying glass.”
- “The bG result should stand out from everything else. Make it big!”
- “You should be able to confirm the time and date so that you know the readings are being logged properly.”
- “The information labels don’t have to be as big.”
- “It shouldn’t have too few or too many controls. Too many controls would be intimidating.”
- “I want it to make a noise when I press a button so that I know it got my input.”
- “I want to know that the device is alive – awake – at all the times.”
- “Don’t let the screen time out too quickly.”

Derived user requirements – glucose meter

- Text (capital letters and numbers) shall be ≥14 point (5 mm).
- Blood glucose readout shall be ≥ 60 point (21 mm).
- Main screen shall include the time and date.
- Labels shall be visually subordinate to primary onscreen content.
- There shall be no more than 4 primary hardware controls used to navigate among screens.
- Device shall provide audible feedback in response to all button presses (user option).
- At least one visual element shall be constantly dynamic to indicate the display has not failed.
- Power-down screen after ≥ 2 minutes of inactivity.



Design concepts – glucose meter

Use environment description (sample)

Hypothetical User Environment: Emergency Department

General description

Emergency departments (EDs) are widely varying patient care environments. The typical ED in the USA has a central station for staff that is adjacent to or surrounded by multiple patient care bays.

Personnel

The following types of people may be present in the ED.

- Physicians
- Nurses (RNs)
- Nurse technicians
- Volunteers (a.k.a. "candy stripers")
- Emergency response personnel (EMTs, paramedics)
- Patients and their family members

Lighting

- Most area are well lit by overhead, fluorescent lights
- Some areas are spotlighted by intense exam lights
- Patient care areas might be brightly or dimly lighted (to be more soothing to the patient and/or enable sleep)
- Shadows might be cast by drawn curtains around the patient

Other equipment

- Wall gasses and suction ports and tubes
- Patient monitors on swinging arms
- Non-invasive blood pressure monitor and cuff
- Emergency medications on shelving
- Sink
- Patient examination table
- Gurneys
- Rolling chairs and tables

Elements

- Temperature in the 18-24 ºC degree range
- Moderate humidity

Distractions

- Equipment noise (e.g., beeps, air flow, document printing, doors opening and closing)
- Overhead pages and telephones ringing
- Personnel talking
- Personnel moving within the workspace
- Emergencies that demand attention (e.g., patient collapsed on floor, psychiatric patient acting out, Code Blue)

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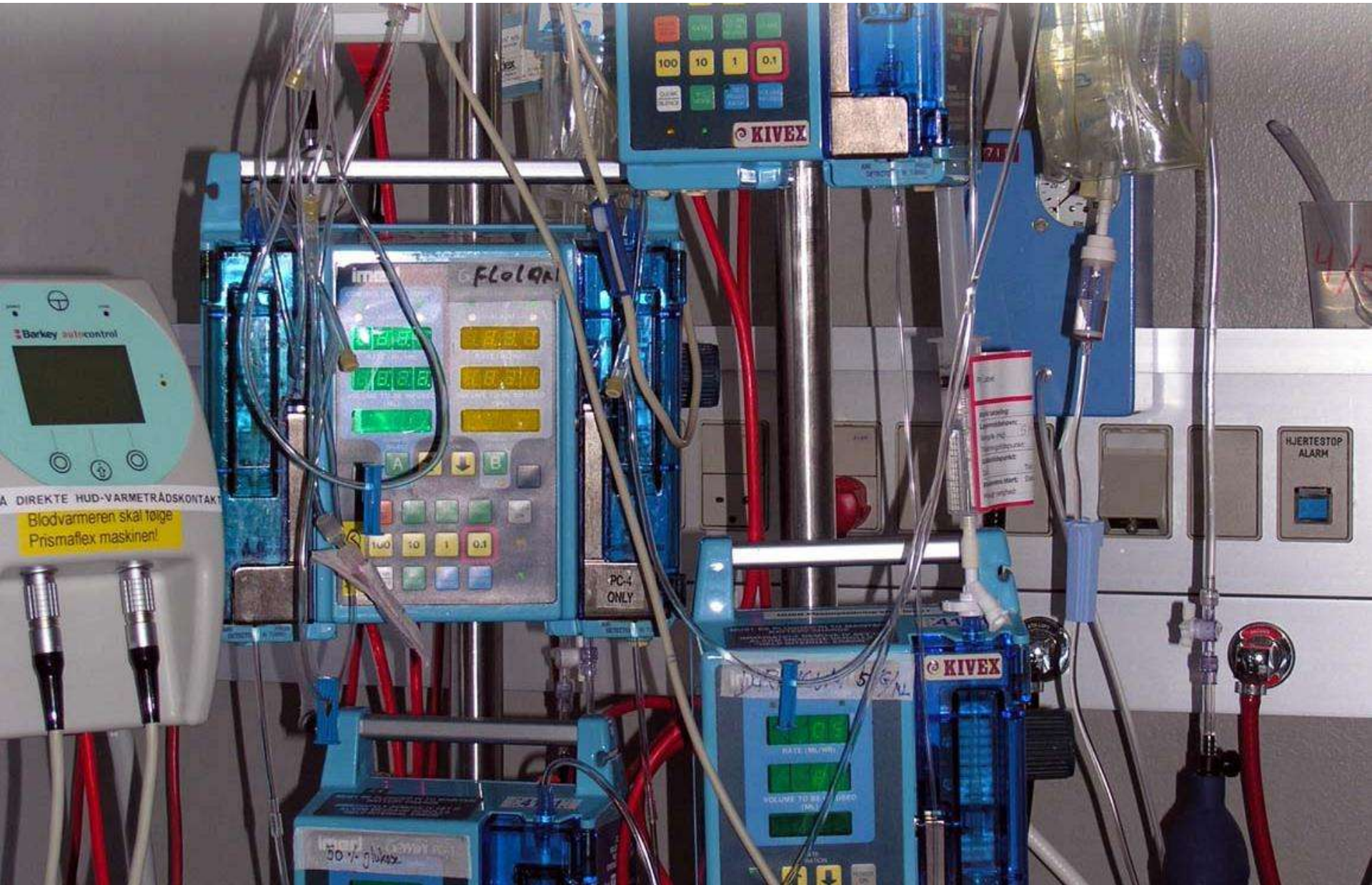
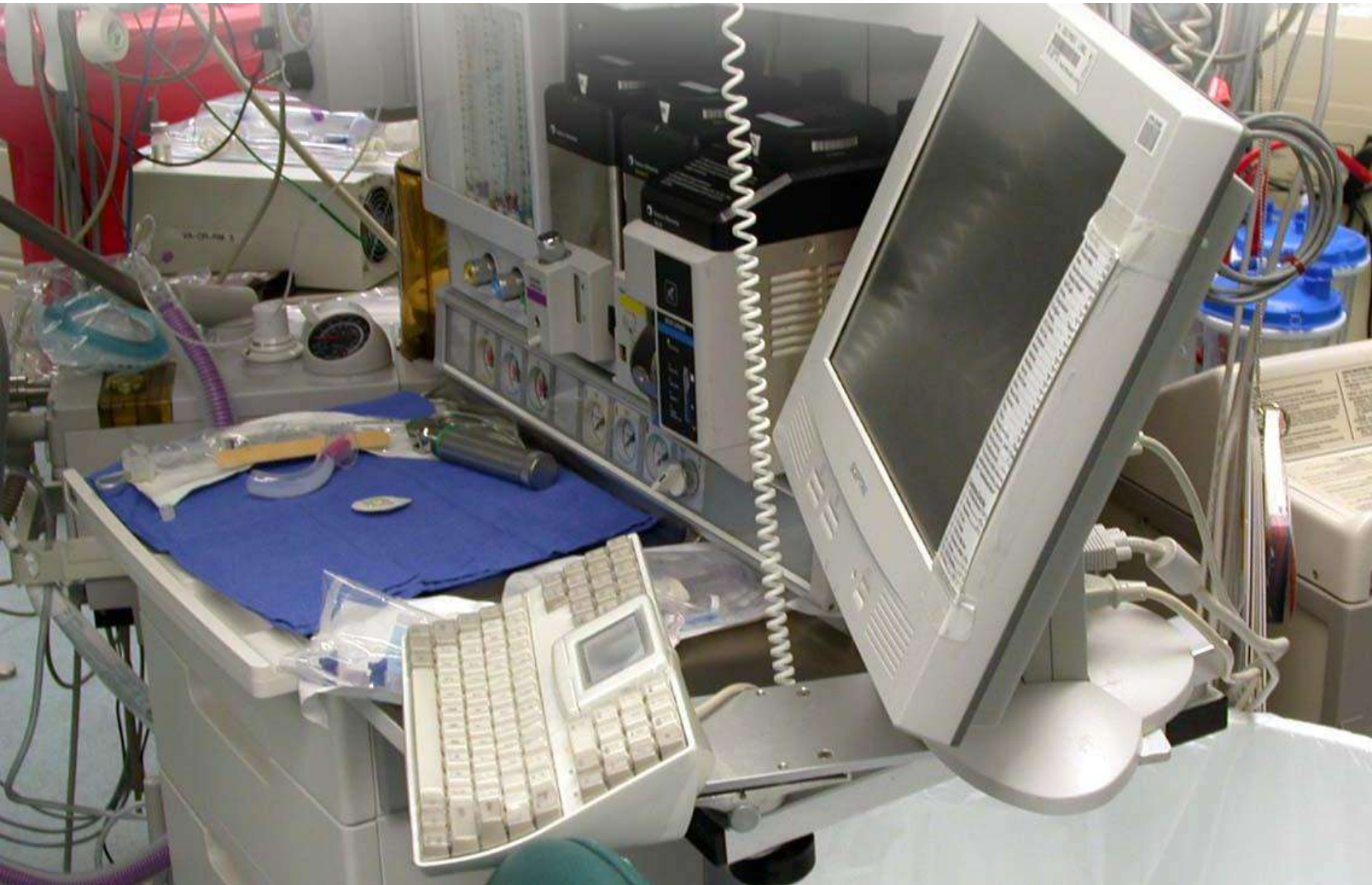
Pediatric intensive care unit



Operating room



Ambulance

Dialysis clinic

Doctor’s office

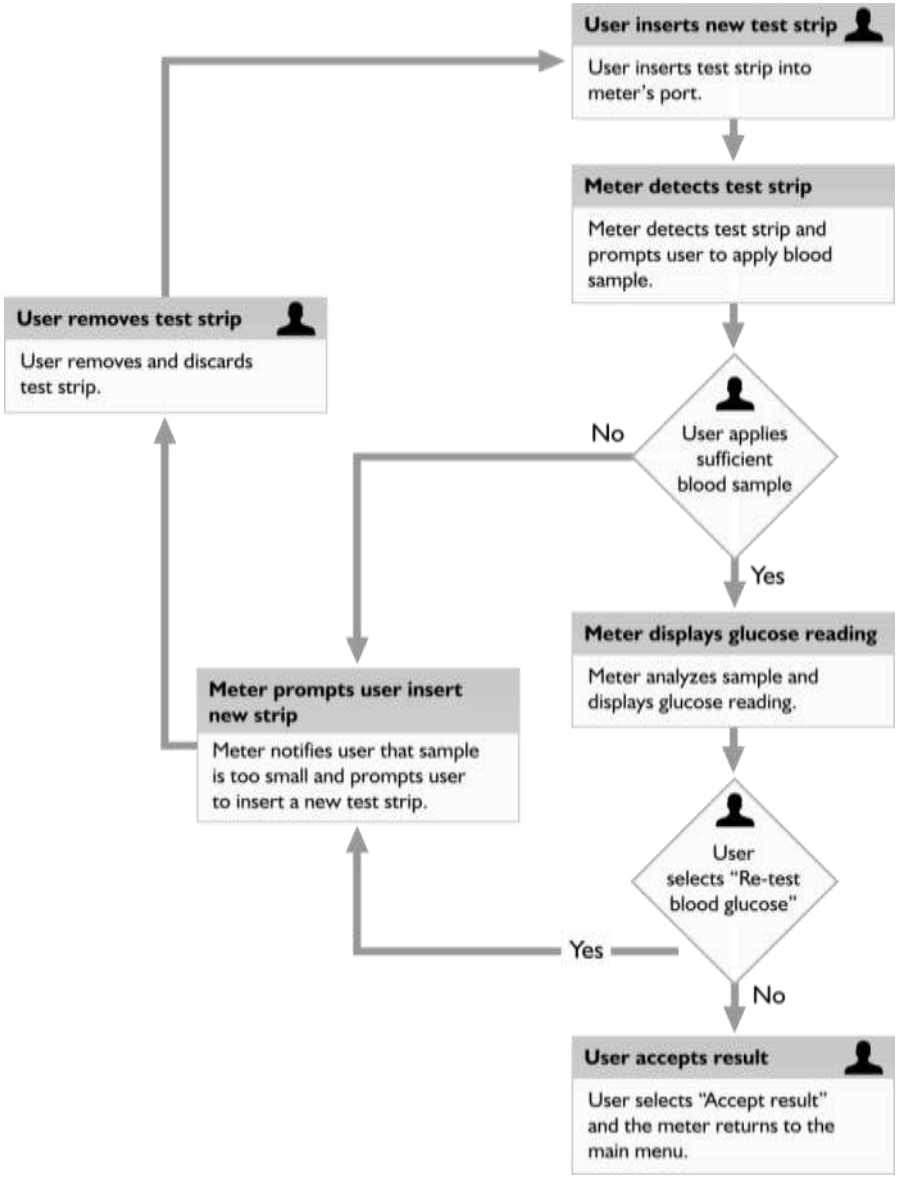
Home - living room

Home - bathroom

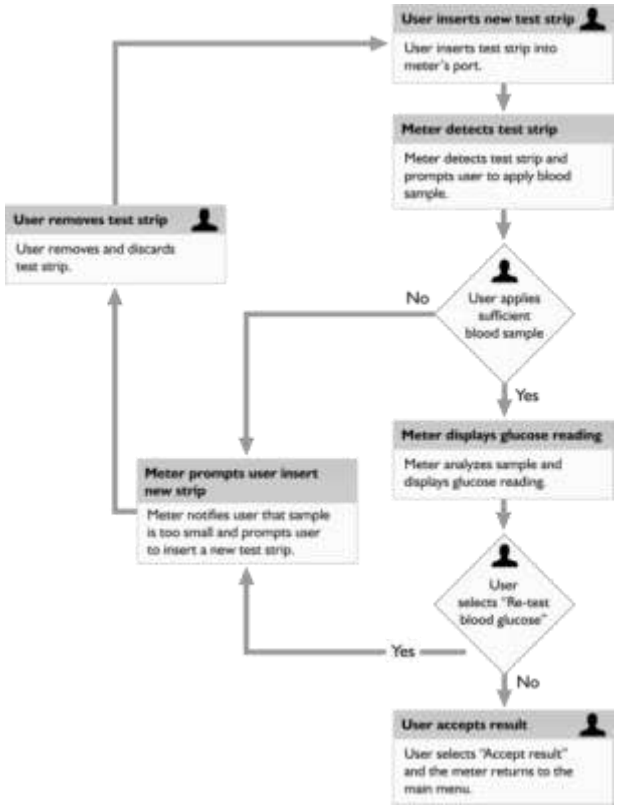
Office

Automobile

Sample flow diagram showing decisions and events



Use errors derived from task analysis

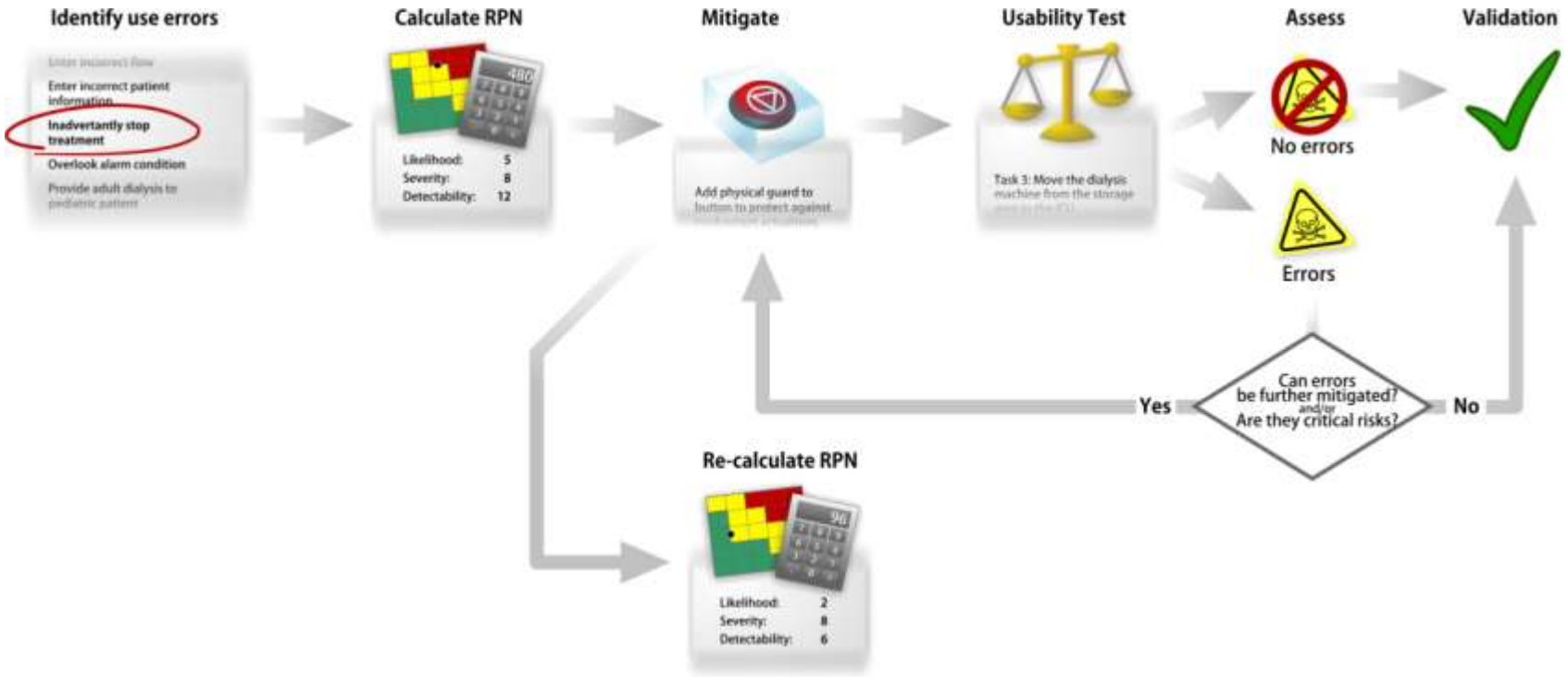


- User inserts wrong test strip
- User inserts test strip in wrong orientation
- User inserts test strip in wrong port
- User damages test strip during handling
- User applies blood to wrong part of test strip
- User applies too much blood to test strip
- User applies too little blood to test strip
- User does not select re-test when prompted
- User does not remove used strip from meter
- User misreads the blood glucose readout
- User mistakes units of measure as mmol/L versus mg/dL

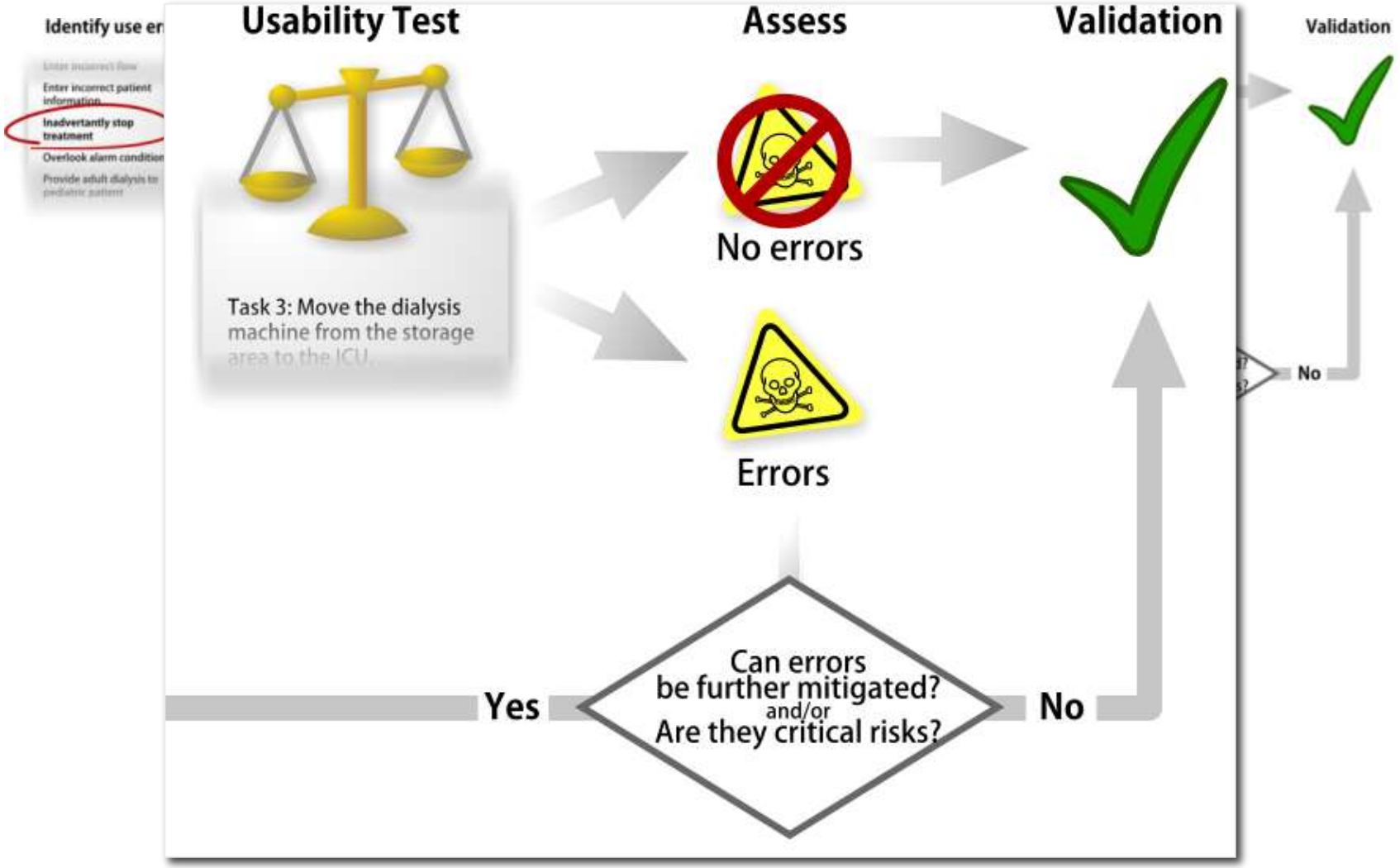
Sample risk mitigations

Advisory message
Audible feedback
Clear instructions
Color coding
Confirmation message
Emergency power cutoff
Familiar symbol
Lack of parting lines
Large label
Interlock
Needle guard
Non-glare display
Orientation cue
Quick reference card
Resistance force
Setting limits
Shape coding
Size coding
Switch cover
Tactile feedback
Textured grip
Training
Warning label
Warning light
Wider pushbutton spacing
Cable/tube strain relief

Life of a use error



Life of a use error (continued)



Usability testing scenes






Usability testing

Basics

Representative users

+

Representative tasks

+

Representative environment

+

Production-equivalent device

Formative usability testing

Formative / formation / form

Focuses on a design-in-progress, identifying interactive strengths and opportunities for further improvement.

Summative (validation) usability testing

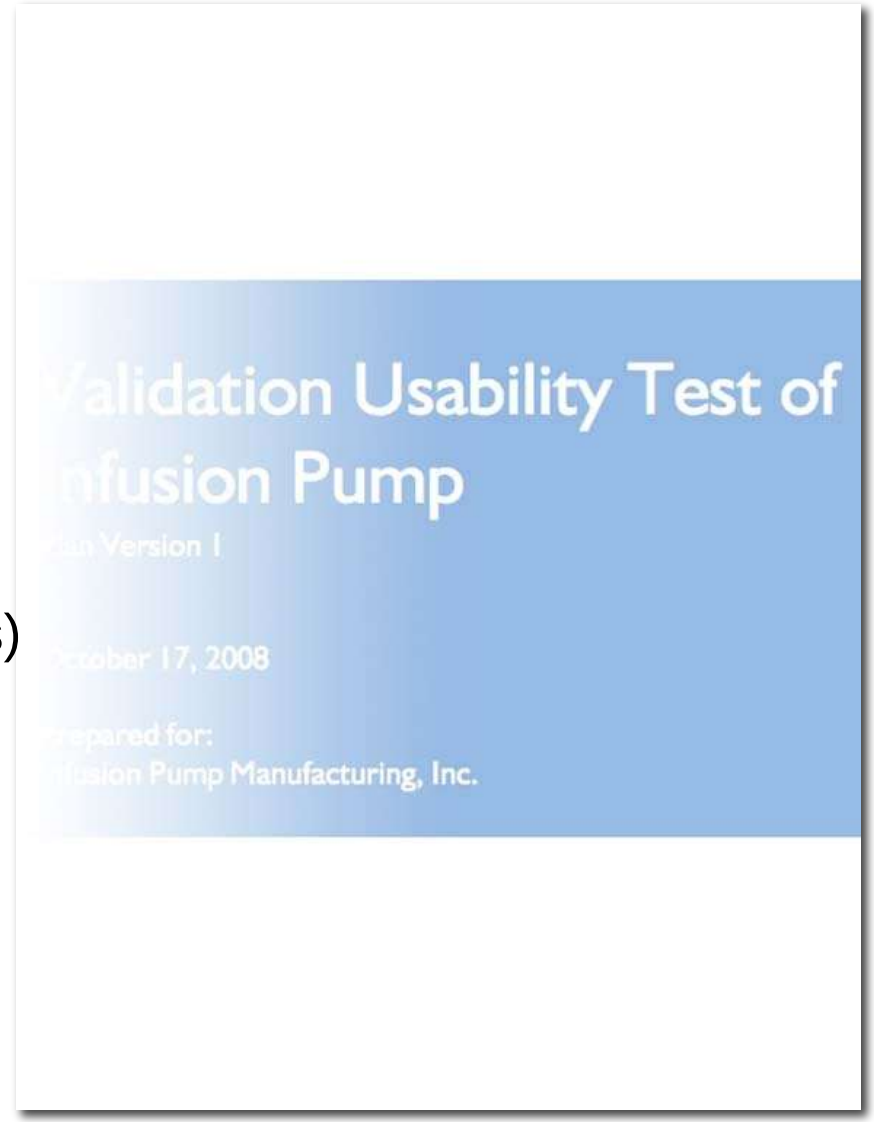
Summative / summation / sum

Focuses on a production-equivalent device (i.e., refined prototype).

Serves primarily to determine if use-related risk mitigations are effective.

Write a test plan

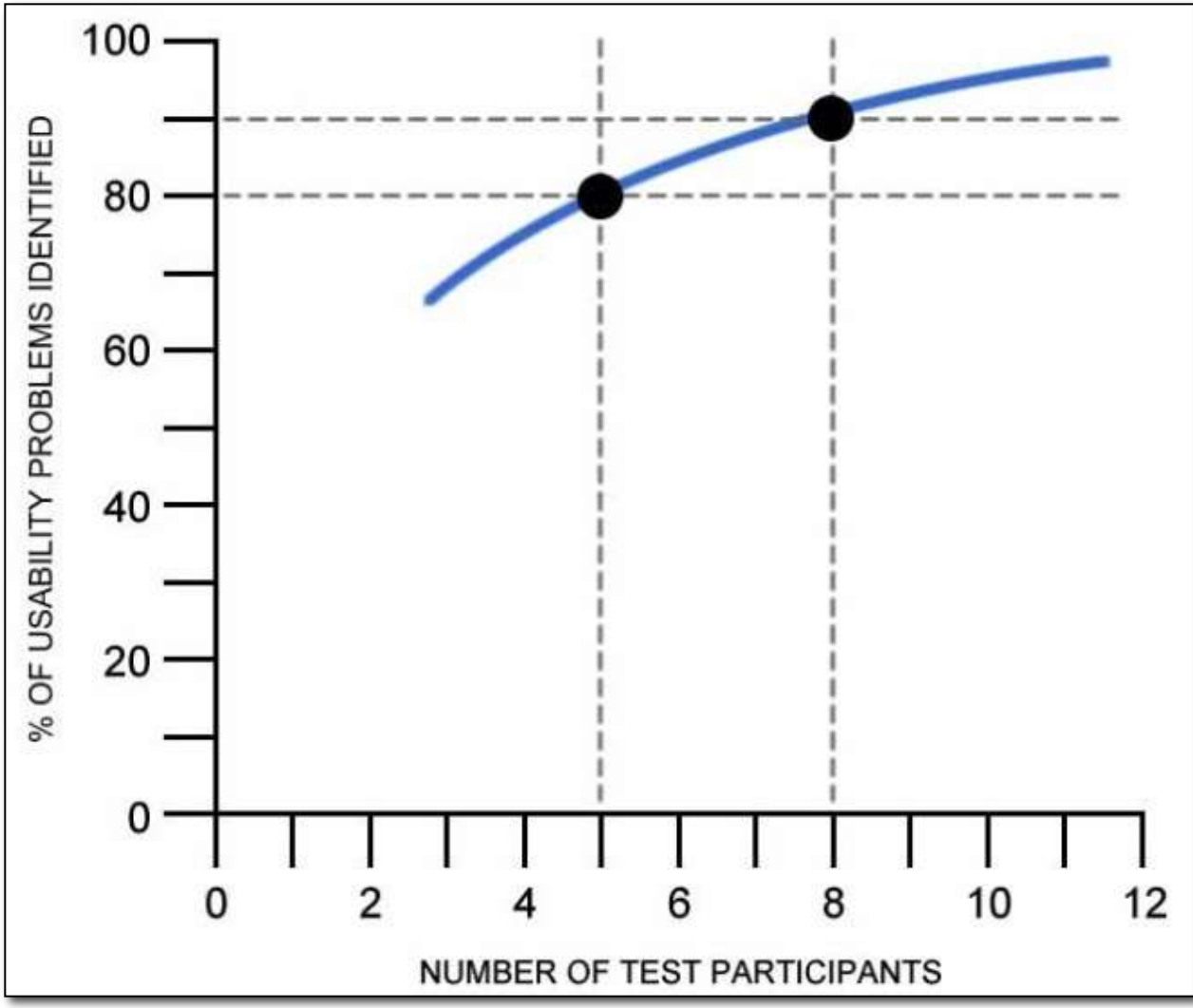
- Determine test objectives
- Write a plan addressing:
  - Purpose
  - Participants and recruiting
  - Human subjects protection
  - Test personnel
  - Test items and environment
  - Task selection
  - Activities (i.e., interviews, tasks)
  - Distractions
  - Data collection
  - Data analysis
  - Reporting
  - Schedule



Select a sample size

A rule of thumb among usability specialists is that a 5-participant usability test will yield 80% of the important findings; an 8-participant test 90%.

But, the medical industry upholds a higher standard of care, at least for summative usability testing.



Select a sample size (continued)

- Formative tests typically involve ≤12 participants, yielding excellent insights while preserving resources for additional tests.

- Summative tests typically involve either 15 participants per distinct user group, or 25 participants if the user population is relatively homogeneous (i.e., there is 1 distinct user group).

Defining tasks to validate mitigations

Use errors (listed in FMEA)

- Insulin cartridge expired
- Enters wrong basal rate
- Enters wrong basal time
- Enters wrong carbohydrate amt.
- Does not detect audible alarm
- Does not detect vibratory alarm
- Infusion set not fully connected
- Infusion catheter pulled-out
- Misreads delivery rate

Mitigations (risk control measures)

- Prominently located, larger expiry rate
- Graphical and numerical confirmation
- Larger AM and PM indications
- Confirmation screen
- Louder alarm; protection against muffling
- Multi-channel annunciation
- Distinct tactile feedback
- Stronger adhesive
- Larger display

Operating room simulator

Hospital meeting room

Usability testing laboratory (at UL-Wiklund)

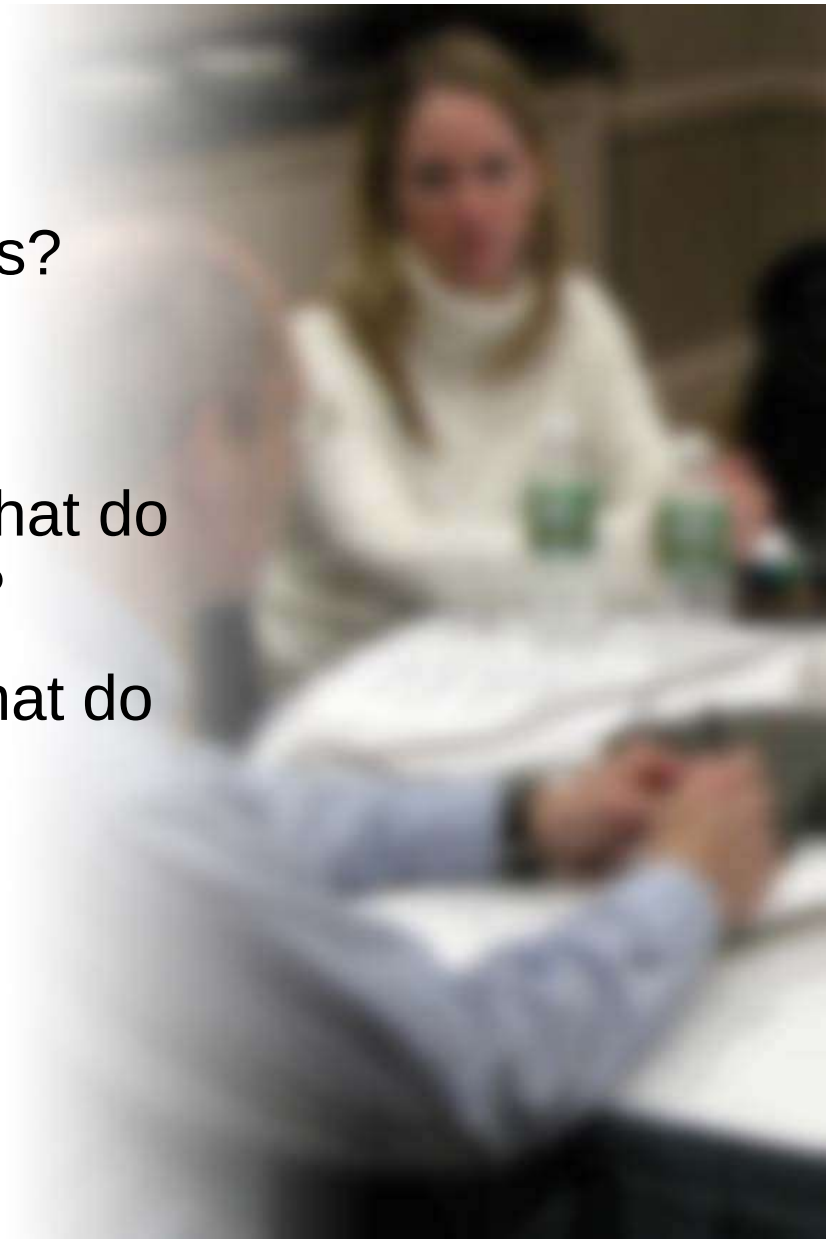
Test activities

- Orientation – Introduce the participant to the test environment and staff. Ask the participant to sign an informed consent / confidentiality form.
- Pre-task interview – Administer a background interview to collect demographic and occupational information.
- Hands-on tasks – Ask the participant to perform hands-on tasks with the device and/or learning aids. After each task, ask questions about any interaction difficulties and collect ratings.
- Post-task interview – Administer an interview after all tasks to collect summary participant feedback.
- Wrap-up – Thank, compensate, and dismiss the participant.

Ask users about interaction problems

Interview questions:

- Do you recall making an mistakes? What do you think caused the mistakes?
- Do you recall any close calls? What do you think caused the close calls?
- Do you recall any difficulties? What do you think caused the difficulties?



Ask users about interaction problems (continued)

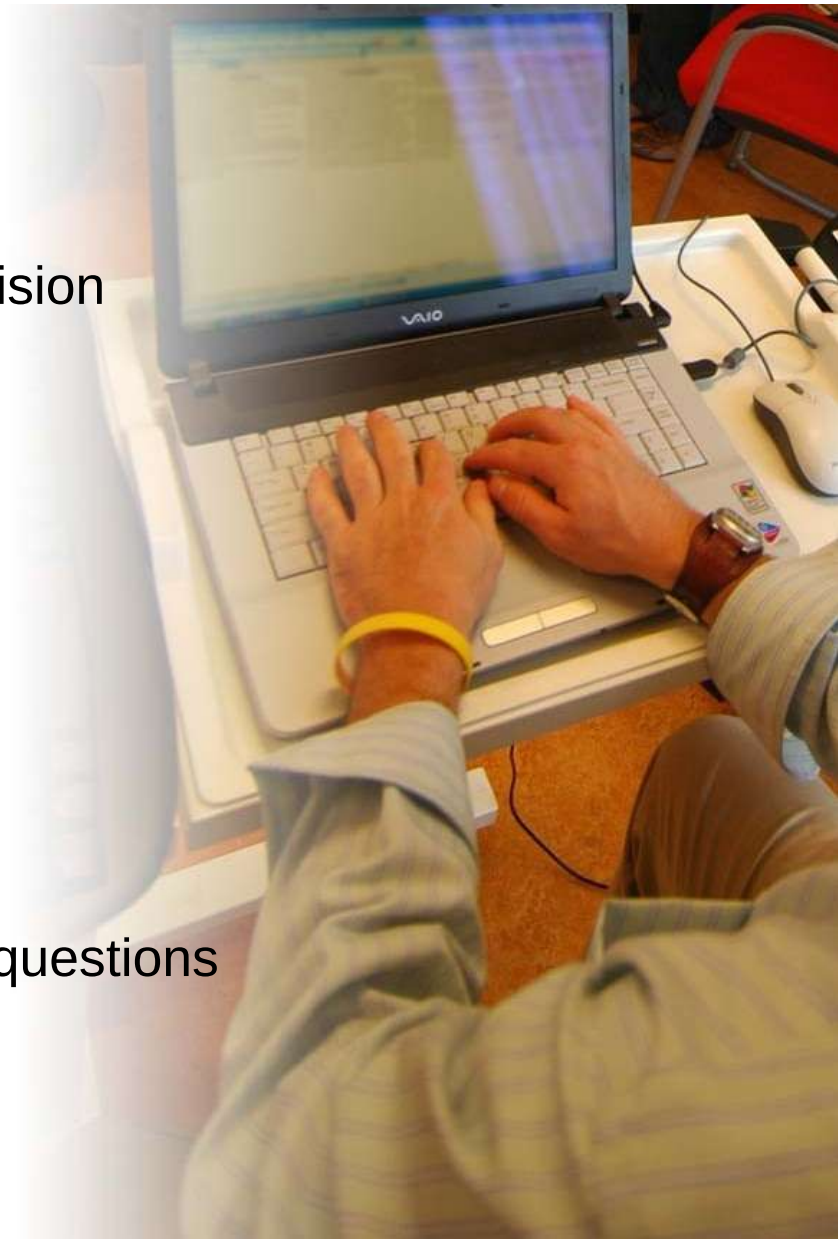
Interview questions:

- Do you consider the device safe to use as is? If not, how would you change it?
- Do you consider the device easy to use as is? If not, how would you change it?

Document task performance

Performance measures:

- Task completion status
- Task correctness / accuracy / precision
- Use errors
- Close calls
- Operational difficulties
- Task times
- Subjective ratings and rankings
- Need for assistance
- Responses to interview or survey questions
- Anecdotal comments



Sample use error report

Did not attach needle securely

Risk identifier(s)

4.3, 16.1, 22.3

Task priority

4 of 16

Occurrences

5 test participants committed this use error one or more times during 5 repeated injection trials. The use error occurred 8 times out of the 150 opportunities to err, yielding a use error rate of 5.3%.

Description

3 participants pressed the needle on to the injector but did not twist it to lock it in place. 2 participants initially twisted the needle to lock it in place, but then unlocked it when they removed the needle cap by means of a twisting rather than pulling motion.

Participant reported root causes

3 participants said they forgot to twist the needle to lock it in place. 2 participants speculated that they must have initially gripped the needle's hub rather than the cap when removing the cap.

Root cause analysis

There is no visual feedback to distinguished a needle that is looked in place from one that is not. The needle cap gripping surface is adjacent to the needle gripping surface, making it vulnerable to unintended twisting during cap removal.

Interaction patterns

Patterns of close calls and operational difficulties

Describe any patterns of interaction problems that suggest a greater chance of use error.

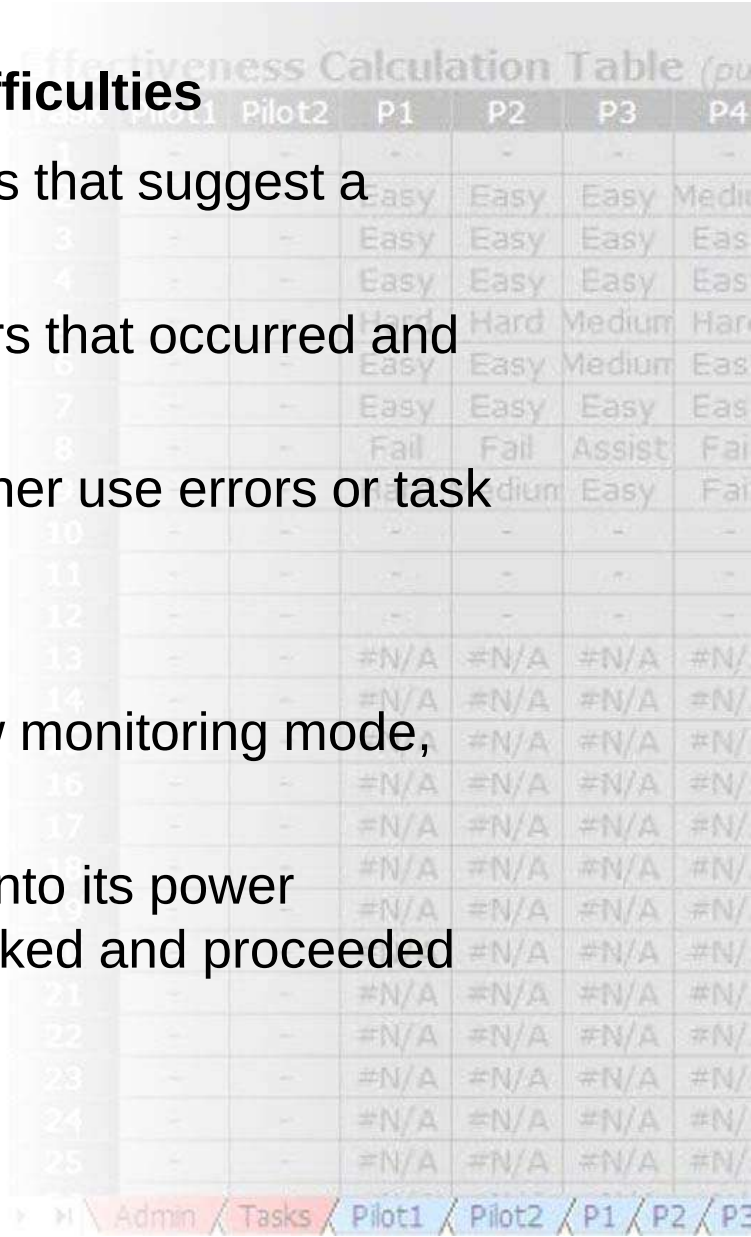
Such patterns might simply point to use errors that occurred and are reported separately.

Or, patterns might suggest vulnerability to other use errors or task performance issues of concern.

Examples:

8 participants initially did not confirm the new monitoring mode, but then corrected the oversight.

3 test participants did not lock the drive line into its power receptacle, but then noticed that it was unlocked and proceeded to lock it.



Sample use error (hypothetical)

Participant P3 (patient) did not detect that the insulin had expired.

Analyze test participant comments

- The trainer said nothing about checking the expiration date.

  Inadequate training.

  Fix: Revise training to include instruction to check expiration date,
- I didn’t see the harm in using expired insulin.

  Warning in IFU does not state consequences.

  Fix: Include statement of consequence of using expired insulin in warning.
- I thought the expiration date (3-6-13) was June 3, 2013 instead of March 6, 2013.

  Negative transfer of European date format.

  Fix: Spell-out the month.

Apply HFE knowledge and design principles

- Misread the dose setting.

  8 pt. text does not subtend adequate visual arc to ensure legibility

  Fix: Use 12 pt. or larger text
- Chose wrong carton.

  Expectancy (user searched for and found green carton)

  Fix: Vary carton color to differentiate drug strength
- Forgot to prime the injector.

  Over-dependence on memory

  Fix: Introduce pocket quick reference card

Temptations to blame the user

- Forgetful
- Inattentive
- Careless
- Fatigued
- Non-compliant
- Disinterested
- Not serious
- Ignorant
- Rushed
- Disregarded directions
- Risk-taking
- Anxious
- Camera shy
- Negative attitude

FDA's guidance calls for an HFE/UE report

Appendix A

HFE/UE Report

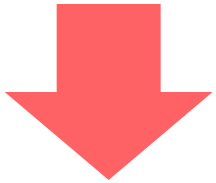
A HFE/UE report included in premarket approval application (PMA) or as requested by FDA under certain circumstances (see Section 11, Documentation, above) should provide information pertaining to device use safety in summary form. The level of detail of documentation submitted should be consistent with the nature of the use-related hazards for the device. The report should highlight the major human factors considerations, issues, resolutions, and conclusions. When key portions of this information are contained in various parts of a submission, a comprehensive cross-reference should be provided to the specific and separate components of a HFE/UE evaluation.

Excerpted from: Applying Human Factors and Usability Engineering to Optimize Medical Device Design

Good HFE Process

Good HFE Report

Poor HFE Process



Poor HFE Report

HFE report outline

- FDA specifically describes the content that belongs in a HFE Report.

- Manufacturers not required to comply with HFE Report outline, but the report should include the requested contents.

Table A-1. Outline of HFE/UE Report

Sec.	Contents
1	Intended device users, uses, use environments, and training • Intended user population(s) and critical differences in capabilities between multiple user populations • Intended uses and operational contexts of use • Use environments and key considerations • Training intended for users and provided to test participants
2	Device user interface • Graphical depiction (drawing or photograph) of device user interface • Verbal description of device user interface
3	Summary of known use problems • Known problems with previous models • Known problems with similar devices • Design modifications implemented in response to user difficulties
4	User task selection, characterization and prioritization • Risk analysis methods • Use-related hazardous situation and risk summary • Critical tasks identified and included in HFE/UE validation tests
5	Summary of formative evaluations • Evaluation methods • Key results and design modifications implemented • Key findings that informed the HFE/UE validation testing protocol
6	Validation testing • Rationale for test type selected (i.e., simulated use or clinical evaluation) • Number and type of test participants and rationale for how they represent the intended user populations • Test goals, critical tasks and use scenarios studied • Technique for capturing unanticipated use errors • Definition of performance failures • Test results: Number of device uses, success and failure occurrences • Subjective assessment by test participants of any critical task failures and difficulties • Description and analysis of all task failures, implications for additional risk mitigation
7	Conclusion The <Name Model> has been found to be reasonably safe and effective for the intended users, uses and use environments. • The methods and results described in the preceding sections support this conclusion. • Any residual risk that remains after the validation testing would not be further reduced by modifications of design of the user interface (including any accessories and the IFU), is not needed, and is outweighed by the benefits that may be derived from the device's use.

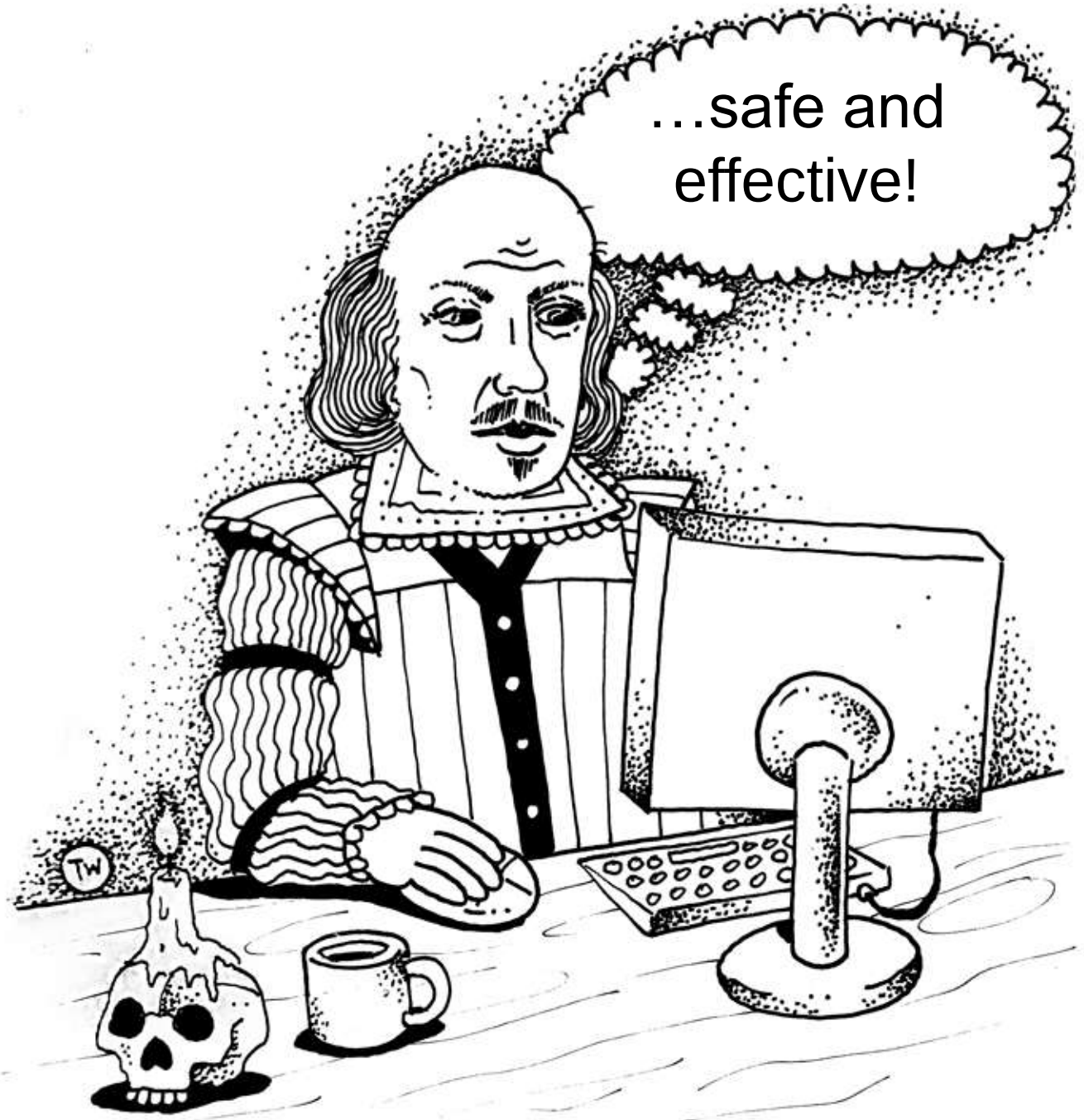
Analogy

An HFE Report is like a court case.

•Opening statement about the manufacturer's HFE efforts

•Presentation of HFE evidence and testimony (i.e., results of summative usability test)

•Closing argument that device is safe and effective


…safe and effective!
TW

Closing argument

Per FDA's guidance, start this section with the claim that the device has been found:

"…adequately safe and effective for the intended users, its intended uses, and use environments."

Logically, a manufacturer would not submit a HFE Report that claimed otherwise.

Key word: "adequately"

Recognizes that user-device interactions may be imperfect. Manufacturer's task is to present a compelling argument and supporting evidence of adequacy.

Rationale for keeping the device “as is”

Tell the FDA why further risk mitigation measures are not warranted.

Possible rationales:

- Impossible. There are no possible ways to further reduce use-related risks.
- Impractical. Further risk reduction is impractical. (Meaning of “impractical” subject to interpretation.)
- Worth the risk. Benefits of device outweigh the use-related risks.

OX Auto-Retractable Safety Scalpel, image source: http://www.prlog.org/10992395-ox-auto-retractable-safety-scalpel.png

Legacy devices

Retrospective on existing devices

Manufacturer did not formally apply HFE during the development process.

User studies consisted primarily of showing customers prototypes and soliciting their feedback.

Manufacturer established product specifications, but not many user requirements per se.

There were no formal usability tests – formative or summative.

Potential relief

Amendment 1 (a.k.a. Annex K) addresses the application of IEC 62366 to “user interfaces of unknown provenance” after a device has been commercialized.

prov·e·nance. n. 1. Place of origin; derivation. 2. a. The history of the ownership of an object, especially when documented or authenticated.

Satisfying Annex K

- Write application specification
- Identify frequently used functions
- Identify primary operating functions
- Review post-market data to identify use-safety issues
- Identify hazards and hazardous situations related to usability
- Determine if use-related risks warrant additional risk control measures

Conclusion

Experience suggests…

- HFE is cost-effective
- Existing staff can perform a substantial amount of HFE work, but specialists are needed at times
- HFE, if implemented in a timely manner, is not a paperwork exercise. It leads to better devices.
- HFE offers commercial advantages.
- Today, HFE is a mandate rather than an option.

Questions?

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