Applying Human Factors Engineering (HFE) to Produce Safe and Effective Medical Devices

Presented by:

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My background

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Research Director – Human Factors Engineering
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Based in Concord, Massachusetts / USA

Publications:

*Usability Testing of Medical Devices*

*Conducting Home-Based Usability Tests of Home Healthcare Devices (article)*

*Designing Usable Medical Devices for People with Diabetes (article)*

Member:

National Usability Professionals Organization (now UXPA)
New England Human Factors & Ergonomics Society
Agenda

Introduction to HFE
HFE in practice
Sample human factors
The regulatory imperative
Sample HFE techniques and end-products
Usability testing
The HFE report
Conclusion
Agenda

Introduction to HFE

HFE in practice
Sample human factors
The regulatory imperative
Sample HFE techniques and end-products
Usability testing
The HFE report
Conclusion
What is human factors engineering (HFE)?

- HFE blends engineering, design, and psychology.
- Early work focused on manufacturing efficiency.
- For several more decades, focused on hardware.
- HFE discipline expanded as software usability became an issue.
- Adverse events in healthcare stimulated the application of HFE in medical device development.
HFE as it applies to medical devices

HFE specialists seek to optimize the quality of interaction between people and medical products, making them:

- Safe
- Effective
- Efficient
- Satisfying
HFE as it applies to medical devices

- Therapeutic devices (insulin pump, dialysis machine)
- Diagnostic devices (X-ray machine, ultrasound scanner)
- Critical care devices (ventilator, defibrillator)
- Combination products (auto-injector, nebulizer)
- Lab instruments (blood analyzer, cancer cell screening system)
HFE activities

Research
• Observations
• Interviews
• Surveys

Analyses of…
• Anthropometrics
• Use-related risks
• Functions and tasks
• Hazards
HFE activities

Design and prototyping of...

- Software
- Hardware
- Documents

Evaluation / usability testing

- Critiques
- Usability tests

General

- HFE program development
- Adverse event analysis
- HFE education
Agenda

Introduction to HFE

**HFE in practice**

Sample human factors

The regulatory imperative

Sample HFE techniques and end-products

Usability testing

The HFE report

Conclusion
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
Can opener
Task: Drill a hole
Electric drill
Electric drill
Task: Deliver an injection
Syringe
Syringe
Task: Induce anesthesia
Anesthesia delivery system
Anesthesia delivery system
Task: Deliver insulin on a continuing basis

Diabetes

high blood sugar levels in the body. Insulin is the hormone that regulates glucose in the body, and a lack of insulin or resistance to insulin can lead to elevated blood sugar levels. This condition is known as diabetes.

Insulin pump
Insulin pump
HFE specialists improve medical 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.
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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

Normal view

Dim lighting conditions

Not wearing reading glasses

Color vision impaired (deuteranope: red/green)
Sample human factors

Hearing

• Detecting an alarm.

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

• Hearing the audible feedback produced by a button press.
Sample human factors

High Frequency Hearing Loss

Source: http://hydrogen.physik.uni-wuppertal.de/hyperphysics/hyperphysics/hbase/sound/imgso/u/audiom2.gif
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.
Sample human factors

Try to remember these numbers:

4, 36, 92, 31
Sample human factors

Now try to remember these numbers:

44, 65, 11, 96, 28, 2, 20, 87
Sample human factors

Anthropometrics

• Making catheters 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

Anthropometrics (continued)

Hand breadth:
5th percentile female: 7.3 cm
95th percentile male: 9.8 cm

Hand length:
5th percentile female: 16.5 cm
95th percentile male: 21.1 cm

Source:
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Imperative to apply HFE

- Today, FDA and other regulatory agencies expect medical devices to reflect good HFE.
- Applying HFE is a cornerstone of overall risk management.
Requirements, standards, and guidelines

- FDA’s Quality System Regulation 820 (21 CFR part 820) calls for HFE.
- Association for the Advancement of Medical Instrumentation (AAMI) and International Electrotechnical Commission (IEC) have published standards that call for HFE.
- FDA has released (and, will soon finalize) guidance related to the application of HFE.
Timeline

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 guidance
2012: Adoption of 3rd edition of IEC 60601 by Europe and Canada
2013: Adoption of 3rd edition of IEC 60601 by USA
2015: ISO/IEC 62366:2015-1 (with -2, a tutorial portion, to follow)
Key documents

FDA’s Draft Guidance (2011)

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, 2009).

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

IEC 62366-1 (2015)

INTERNATIONAL STANDARD
NORME INTERNATIONALE

Medical devices – Part 1: Application of usability engineering to medical devices
Dispositifs médicaux – Partie 1: Application de l’ingénierie de l’aptitude à l’utilisation aux dispositifs médicaux
Basic expectations

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

- Requirement regarding how to apply HFE to legacy devices is in flux.
- HFE efforts may be limited mostly to updating the risk analysis with a special focus on the potential for use error.
- A comprehensive HFE program might not be warranted when evaluating User interfaces of Unknown Provenance (UOUP), per a proposed Annex K to IEC 62366.
End-point (USA)

FDA expects manufacturers to submit an HFE Report describing:

• Users, uses, use environment, special factors influencing tasks
• Device’s user interface
• Accounting for known problems with related devices
• Method of use-related risk identification, analysis, and prioritization
• Formative evaluations
• Validation testing
• Conclusion
End-point (EU and other countries)

Other countries expect manufacturers to demonstrate conformance with IEC standards (particularly IEC 62366)

- Use specification
- User interface specification
- Validation plan
- Use-related risk analysis
- Validation test

(Partial list of expected end-products)
HFE 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)
Standards apply to diverse medical devices
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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 outpatient 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 nurses – 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., presbycusis).
- Some nurses – particularly those in their mid-50s and older – may have 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 disciplined to modify procedures in ways that place a patient at greater 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 scenario. 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 by using 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.
Sample user profile: registered nurses

### Hypothetical User Profile: Registered Nurses (RNs)

**Occupational description**

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#### Typical Characteristics

- Typically good at and prone to follow standard operating procedures.
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**Potential impacts**

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Sample use environment description: ED

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 strippers")
- 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 °C 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)
Sample use environment description: ED

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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
Task analysis

Deconstruct users’ interactions with a device into its myriad components: perceptions (P), cognitive processes (C), and actions (A). Yields: PCA analysis.
Sample flow diagram – decisions and events

User inserts new test strip
User inserts test strip into meter’s port.

Meter detects test strip
Meter detects test strip and prompts user to apply blood sample.

User applies sufficient blood sample

No

Yes

Meter displays glucose reading
Meter analyzes sample and displays glucose reading.

User selects “Re-test blood glucose”

Yes

No

User accepts result
User selects “Accept result” and the meter returns to the main menu.

User removes test strip
User removes and discards test strip.

Meter prompts user insert new strip
Meter notifies user that sample is too small and prompts user to insert a new test strip.
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 test strip end
- User applies too much blood to test strip
- User applies too little blood to test strip
- User does not select re-test when needed
- User does not remove used strip
- User misreads the blood glucose result
- User mistakes units of measure as mmol/L versus mg/dL
## Use-FMEA

<table>
<thead>
<tr>
<th>ID</th>
<th>User Error</th>
<th>Hazardous Scenario</th>
<th>Potential Harm</th>
<th>Mitigation</th>
<th>L</th>
<th>S</th>
<th>RPN</th>
<th>Accept?</th>
<th>Additional Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>User does not confirm changes to therapy settings.</td>
<td>Device continues</td>
<td>Patient receives incorrect therapy.</td>
<td>Screen prompts user to confirm the new settings.</td>
<td>5</td>
<td>8</td>
<td>38</td>
<td>No</td>
<td>Device does not reset back to original settings. Onscreen message cannot be dismissed until user accepts or cancels new settings. High-priority audible alarm sounds if user does not select accept or cancel within 30 seconds.</td>
</tr>
</tbody>
</table>

### Severity

<table>
<thead>
<tr>
<th>Death</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Injury</td>
<td>8</td>
</tr>
<tr>
<td>Serious Injury</td>
<td>6</td>
</tr>
<tr>
<td>Minor Injury</td>
<td>4</td>
</tr>
<tr>
<td>Delay</td>
<td>2</td>
</tr>
<tr>
<td>Inconvenience</td>
<td>1</td>
</tr>
</tbody>
</table>

### Likelihood

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Less than 1 ppm (1:1,000,000)</th>
<th>Less than 10 ppm (1:100,000)</th>
<th>Less than 50 ppm (1:20,000)</th>
<th>Less than 250 ppm (1:4000)</th>
<th>Less than 50 ppm (1:2000)</th>
<th>Less than 1000 ppm (1:1000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broadly acceptable risk - no need for specific risk control measures</td>
<td>ALARP risk - need risk reduction measures as low as reasonably practicable</td>
<td>Intolerable risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

1. **Identify use errors**
   - Enter incorrect flow
   - Enter incorrect patient information
   - Inadvertently stop treatment
   - Overlook alarm condition
   - Provide adult dialysis to pediatric patient

2. **Calculate RPN**
   - Likelihood: 5
   - Severity: 8
   - Detectability: 12

3. **Mitigate**
   - Add physical guard to button to protect against inadvertent selections.

4. **Usability Test**
   - Task 3: Move the dialysis machine from the storage area to the ICU.

5. **Assess**
   - No errors
   - Errors

6. **Validation**
   - Can errors be further mitigated?
   - Are they critical risks?

7. **Re-calculate RPN**
   - Likelihood: 2
   - Severity: 8
   - Detectability: 6
Life of a use error (continued)
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**Usability testing**
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Usability test basics

Representative users
  +

Representative tasks
  +

Representative environment
  +

Representative device
Usability test types

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

Summative / summation / sum
Focuses on a production-equivalent device. Serves to determine if use-related risk mitigations are effective.
Usability test sample sizes

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

• **Summative tests** typically involve 15 participants per distinct user group per FDA’s guidance.
Operating room simulator
Hospital meeting room
Usability test activities

• Orientation
• Pre-task interview
• Hands-on tasks
• Post-task interview
• Wrap-up
Ask users about interaction problems

• Do you recall making any mistakes? What do you think led to the mistakes?

• Do you recall any close calls, times where you came close to making a mistake, or did so and quickly recovered? What do you think caused the event?

• Was there anything difficult or confusing? What do you think caused the difficulties?
Ask users about interaction problems

• 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?
Sample use error report (abbreviated)

Did not attach needle securely

Related risk ID and potential harms:
4.3: User does not receive full dose / 16.1: Needlestick / 22.3: Needle contamination leading to infection

Occurrences
Five out of 30 test participants committed this use error one or more times when performing the tasks. This use occurred a total of eight times.

Description
Three participants pressed the needle onto the injector, but did not twist it counter-clockwise to lock it in place. Two participants initially twisted the needle to lock it in place, but then unlocked the needle when removing the needle cap by means of a twisting rather than pulling motion.

Participant reported root causes
Two participants did not realize the need to twist the needle to lock it in place, reportedly because they overlooked the arrow in the corresponding IFU graphic. Two participants speculated that they must have initially gripped the needle’s hub rather than the cap when removing the cap. One participant said she forgot she had to twist the needle into place, even though she had learned about the need to do so during training.

Root cause analysis
The arrow in the IFU graphic might be overlooked by some users due to its relatively small size and low contrast against the shaded gray background. There is no visual feedback to distinguished a needle that is locked 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.
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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
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
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HFE Report – Sections 4, 5, and 6

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| 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 |
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.
Device is adequately safe and effective for the intended users, its intended uses, and use environments.
Introduction to HFE
HFE in practice
Sample human factors
The regulatory imperative
Sample HFE techniques and end-products
Usability testing
The HFE report

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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