Overview of International Medical Device Human Factors Standards

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Outline

- History of Medical Device Human Factors Standards
- Summary of major current international HF Standard
# History of Medical Device HF Standards Development

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
<th>Main Purpose</th>
</tr>
</thead>
</table>
| IEC 62366: 2007   | *Medical Devices – Application of Usability Engineering To Medical Devices* | • HFE process extended to all medical devices with emphasis on Risk Management and lifecycle  
      • Harmonized by European Union as EN 62366:2008 |
| AAMI HE75: 2009   | *Human Factors Engineering - Design of Medical Devices*               | Interface design practices; special medical application issues; test & evaluation methods |
## Other Medical Device Standards

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<tr>
<td>IEC 60601-1:2005</td>
<td><strong>General safety &amp; essential performance standard for medical electrical equipment</strong></td>
<td>Introduction to broad standard with numerous subparts for a wide variety of electrical medical devices. (multiple subparts for type acceptance)</td>
</tr>
<tr>
<td>IEC 60601-1-8:2006</td>
<td><strong>Collateral to IEC 60601-1:2005 on general requirements, tests and guidance for alarm systems</strong></td>
<td>Recommends visual and auditory alarm design parameters, e.g. color, frequency and cadence.</td>
</tr>
<tr>
<td>IEC TR 60878:2003</td>
<td><strong>Graphical symbols for electrical equipment in medical practice</strong></td>
<td>Collects existing symbols applicable to medical devices and presents them in 15 medical device categories</td>
</tr>
<tr>
<td>ISO 15223-1:2007</td>
<td><strong>Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied</strong></td>
<td>Part 1– Lists MDD + IVD Symbols Part 2 – Symbol development, selection and validation</td>
</tr>
<tr>
<td>ISO 15223-2:2010</td>
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# Other Medical Device Standards

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<tr>
<td>ISO 14971:2007</td>
<td>Medical devices -- Application of <strong>risk management</strong> to medical devices</td>
<td>The definitive standard on principles of risk management, e.g. FTA, FMEA to medical devices</td>
</tr>
<tr>
<td>IEC 60601-1-11:2011</td>
<td>- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the <strong>home healthcare environment</strong></td>
<td>Describes particular requirements for home healthcare medical devices</td>
</tr>
<tr>
<td>ISO 80369 – 1:2010</td>
<td><strong>Small-bore connectors</strong> for liquids and gases in healthcare applications - Part 1: General Requirements Parts 2 to 7 for particular devices</td>
<td>Describes standard connectors that are usable and impossible to misconnect across medical device categories</td>
</tr>
<tr>
<td>IECEE – TRF’s</td>
<td><strong>TRF – Test Report Forms</strong></td>
<td>Used by Notified Bodies in EU and elsewhere to gauge compliance with IEC/ISO standards</td>
</tr>
</tbody>
</table>
**IEC 62366: Medical Devices – Application of Usability Engineering to Medical Devices**

- Usability Engineering process document like HE74 & IEC 60601-1-6
- IEC 60601-1-6:2010 essentially is a reference/pointer to IEC 62366:2007
  - i.e. links IEC 62366:2007 into the IEC 60601-series for medical electrical equipment
- Similar content to previous version (2007) of IEC 60601-1-6 with some changes
  - “Medical Electrical equipment” changed to **all** medical devices
  - “Operator” changed to “user”
  - Includes Risk Management language (ISO 14971:2007)
  - Has many more Informative Annexes
- Contains HE-74 as Annex D
- Although uses term “usability”, also stresses risk assessment and control
- IEC (EN) 62366:2008 harmonized under the European MDD directive as of November 27, 2008
1: Scope
2: Normative references
3: Terms and definitions
4: Principles
   - 4.1 General Requirements
     • 4.1.1 Usability Engineering Process
     • 4.1.2 Residual Risk
     • 4.1.3 Information for Safety
   - 4.2 Usability Engineering File
   - 4.3 Scaling the Process

The Manufacturer shall establish, document and maintain a **Usability Eng Process** to provide safety for the Patient, User and others... The process shall address User interactions with the Medical Device...

If the **Usability Eng Process** detailed in this standard has been complied with and the acceptance criteria documented in the **Usability Validation Plan** have been met, .. for the purposes of ISO 14971, the residual risks associated with usability of the device shall be .. acceptable, unless there is objective evidence to the contrary.

If **Information for Safety** is a risk control, it shall be subjected to the **Usability Eng Process**.

**Usab. Eng Process** may be scaled .. based on nature of device...extent of modifications determined by risk analysis...
5: Usability Engineering Process

- 5.1: Application Specification
- 5.2: Frequently Used Functions
- 5.3 Identification. Hazardous Situations
  - 5.3.1 Identify characteristics related to safety
  - 5.3.2 Identify known or foreseeable hazards
- 5.4: Primary Operating Functions
- 5.5: Usability Specification
- 5.6 Usability Validation Plan
- 5.7 User Interface Implementation
- 5.8 Usability Verification
- 5.9 Usability Validation

6: Accompanying Document

7: Training/Training Materials
Relationship of FDA HF Guidance to IEC 62366

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- 5.1: Application Specification
- 5.2: Frequently Used Functions
- 5.3: Identifying Hazardous Situations
  - 5.3.1: Identify characteristics related to safety
  - 5.3.2: Identify known or foreseeable hazards
- 5.4: Primary Operating Functions
- 5.5: Usability Specification
- 5.6: Usability Validation Plan
- 5.7: User Interface Implementation
- 5.8: Usability Verification
- 5.9: Usability Validation

6: Accompanying Document

7: Training/Training Materials
Main Features

- Shows relationship of all HFE processes to design cycle (Design Controls, etc.)
- Provides detail on recommended analysis and testing methods with examples

HE-74 has been incorporated into IEC 62366 as an annex. It is no longer a stand-alone standard.

Revisions to the HE-74 HFE process will be incorporated in future revisions to IEC 62366
Future Revisions to IEC 62366:2007

- Feedback is that IEC 62366 could be more usable

- Fast Track Revision
  - Add annex that will address process for:
    - Legacy Devices,
    - Changes to Legacy Devices
    - Additions of accessories not subject to IEC 62366 (Usability of Unknown Provenance)

- Standard will be rewritten and split
  - IEC 62366-1 (Shorter Normative Standard)
  - IEC TR 62366-2 (Informative Tutorial Tech Report on Usability Engineering for Medical Devices)
  - Will be Harmonized with new FDA HF Guidance (draft June, 2011)
  - Target is for 2014 Publication
Use Error Chart from IEC 62366:2007

- **Use Error**
  - Intentional Failure
    - Omission
    - Reversal
    - Misordering
    - Misreading
  - Memory Failure
    - Orbiting planned item
    - Place-looking
    - Forgetting intentions
  - Rule-based error
    - Misapplication of good rule
    - Application of bad rule
  - Knowledge-based error
    - Misapplication of good rule
  - Nescience error
    - Routine violation
    - Well-meant "omnipotence"
    - Shortcut
    - Improvisation in unusual circumstances
  - Following good practice
  - Accompanying documents
  - Professional knowledge
  - Maintenance, training, calibration

- **Abnormal Use**
  - Inadequately trained or unqualified use
  - Exceptional violation
  - Action that is contraindicated
  - Reckless use
  - Sabotage
Figure E.1 - Pictorial representation of the relationship of hazard, sequence of events, hazardous situation and harm

NOTE
$P_1$ is the probability of a hazardous situation occurring.
$P_2$ is the probability of a hazardous situation leading to harm.
Example of a Fault Tree (FTA)

- Incorrect Rx programmed
  - AND
    - Reviewed/Confirmed incorrect Rx
    - Press Start Key
    - Misprogrammed Rx
      - OR
        - Initial Program
          - OR
            - Change to Rx
              - OR
                - Additional Loading Dose
                - Delivery Mode
                - PCA Dose
                - Lockout
                - Rate
                - Dose Limit

Initial Loading Dose
Delivery Mode
PCA Dose
Lockout
Rate
Dose Limit
Concentration
Units
Example of a Fault Tree

Gate 1: Free T4 drift resulting in falsely elevated T4 result
Q: 1.00004e-006

Gate 5: Undetected drift—due to microparticle deposition
Q: 3.75615e-011

Gate 3: Microparticle deposition in bottle
Q: 1.87808e-005

Gate 7: Insufficient agitation
Q: 0.000751982

Gate 8: Manual swirl procedure failed to remove microparticle deposition
Q: 0.0312

Event 7: Swirl—insufficient magnitude
Q: 0.0001

Event 8: Swirl done infrequently, intermittent deposition
Q: 0.0001

Gate 9: Automatic swirl procedure failed to remove microparticles
Q: 0.024102

Event 11: Electrical or mechanical failure—agitation failure
Q: 1e-006

Event 12: Daily maintenance repeatedly interrupted before swirl completion
Q: 1e-006

Gate 10: Automatic swirl (within daily maintenance) not performed
Q: 0.0011

Event 13: Automatic swirl software not installed.
Q: 0.001

Gate 12: Users failed to perform manual swirl
Q: 0.031

Event 15: Operator failed to perform daily maintenance
Q: 0.0001

Gate 6: Controls failed to detect drift
Q: 2e-006

Gate 4: Other causes for drift—see FMEA
Q: 1e-006

Gate 14: Users did not receive notification.
Q: 0.001

Gate 15: Users failed to read instructions or forgot to manually swirl
Q: 0.001
### Example of Use Error FMEA

<table>
<thead>
<tr>
<th>Task #</th>
<th>TASK</th>
<th>Hazard</th>
<th>Faults</th>
<th>Prob</th>
<th>Crit</th>
<th>RI</th>
<th>Method of Control</th>
<th>Effectiveness of Control</th>
<th>Risk Acceptability</th>
<th>Reference</th>
<th>Category</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Set-up</td>
<td>Delay in therapy</td>
<td>User fails to seat vial fully into bottom bracket</td>
<td>Occ</td>
<td>Mod</td>
<td>Med</td>
<td>Message displayed/alarms will not function if not properly seated</td>
<td>Reduces to Low</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Damage to vial or device</td>
<td>User fails to squeeze cradle release while pushing down on top bracket to seat vial.</td>
<td>Rare</td>
<td>Mod</td>
<td>Low</td>
<td>Message displayed/alarms will not function if not properly seated</td>
<td>Will not change</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient overdose</td>
<td>Use non-Abbott tubing, causing free flow</td>
<td>Rare</td>
<td>Maj</td>
<td>Med</td>
<td>Labeling on pump, manual and set requires Abbott sets</td>
<td>Reduces to Low</td>
<td>Acceptable</td>
<td></td>
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<tr>
<td>2</td>
<td>Data Retention</td>
<td></td>
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<tr>
<td></td>
<td>Purging the System</td>
<td>Infusion of drug remaining in line</td>
<td>User fails to disconnect patient and does not purge line before infusing another drug</td>
<td>Occ</td>
<td>Mod</td>
<td>Low</td>
<td>Message on pump reminds user to disconnect set and must press and hold purge key to purge.</td>
<td>Will not change</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delay in therapy</td>
<td>PCA line is connected to patient - established as secondary instead of primary line.</td>
<td>Rare</td>
<td>Mod</td>
<td>Low</td>
<td>Labeling on pump, manual and set requires Abbott sets</td>
<td>Will not change</td>
<td>Acceptable</td>
<td></td>
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Summary

- Human Factors Standards have been expanded, revised, replaced
  - Process Standards: (IEC 62366: 2007, HE-74)
  - 62366 is now the usability engineering standard as 60601-1-6:2010 (3rd ed.) is a “pointer” to it
  - HE-74 has been phased out, incorporated into IEC 62366 as annex
  - Design Principles: HE-75 replaces HE-48
  - There are individual standards for Alarms, Symbols, Home Devices and Risk Management that relate to HF
  - More Standards being written (HF Complaints, Contextual Inquiry, Healthcare IT)
  - IEC 62366 will be split and updated by 2014