

Progress Report April 2010

LNE/G-MED: Sharing a Passion for Progress

Usability Engineering Applied to Medical Devices: Re-enforced Requirement Introduced by Directive 2007/47/EC

*by Marc-Henri Winter, Technical Director
LNE/G-MED America*

We've all been there. Driving a rental car as day turns to night, then scrambling to find and operate the headlights in a darkened car as you zoom down the road.

What causes such a potentially dangerous situation? The car's design is not inherently unsafe; the headlights are working properly; and the user manual in the glove department is perfectly clear on headlight operation.

This example illustrates the importance of "Usability Engineering", which denotes the set of techniques developed to analyze and improve the user-machine interface. This approach, which takes into account real-world use situations, has gained increased prominence in how medical devices are evaluated according to European regulation.

This newsletter examines practical implications of this change and how the directive relates to harmonized standards for Usability Engineering (EN 62366 and EN 60601-1-6) and Risk Management (EN ISO 14971).

Latest MDD Revision Expands Concept of Safety

The 2007 revision of the European Medical Device Directive completed its Essential Requirements to enhance the awareness around the user-device interface. While the first Essential Requirement for a Medical Device is to be safe for everyone involved, Directive 2007/47/EC clarified the need to take into account the:

- Users' level of knowledge
- Risk of use-error (which is expected to be reduced to an acceptable level)

"Use Error" Explores Real World Hazards

The concept of "use error" sets a higher standard for manufactures, going beyond such measures as product safety and performance. Medical devices tend to be used differently during a bench test as compared to an actual clinical environment, where additional variables and stress can lead to unanticipated results.

While the FDA introduced this concept a decade ago, only recently has the European Union instructed manufacturers to consider how their products will be used in the field and evaluate the likelihood of use error, which can take a variety of forms:

- Attentional Failure: Intrusion, omission, inversion, lack of order, etc.
- Memory Failure: Omission of a planned action, lack of space, forgotten intention, etc.
- Rules-based Failure: Application of an inappropriate rule, non-application of an appropriate rule, etc.
- Knowledge-based Failure: Shortcut, improvisation in unusual circumstances, etc.

In the rental car example, the driver, unfamiliar with the car's headlight controls or assuming they are the same as other cars, commits a knowledge-based failure.

EXAMPLE: In a tragic case involving a company I audited, an incubator for premature children relied on holes on the top of the unit to vent hot air. A hospital staff member partially covered these holes to regulate temperature, resulting in the baby's death.

While the staff member's actions were inappropriate for this device (Rules-based Failure), a usability-engineering based approach is designed to anticipate and prevent such misuse.

Instructions are Part of User-Device Interface

Note that the Instructions for Use and other labeling are essential in the control of use error. Considered as part of the user-device interface, they should be equally user-friendly.

In both of the above examples, failure to read the instructions or warnings might be at the heart of the problem. Nonetheless, the manufacturer is ultimately responsible to provide instructions in a suitable fashion for the user and develop additional training tools to further reinforce the appropriate use of the device.

Relation of Usability and Risk Management

Complying with the harmonized standards is the recommend way to comply with the European Essential Requirements. Three main harmonized standards address the usability of medical devices:

- EN ISO 14971, on risk management, is helpful for identifying the potential use errors
- EN 62366 and EN 60601-1-6, respectively on the application of usability engineering to medical devices and electrical medical devices.

Note that usability engineering has a clear relationship with risk management. Exploring the ergonomics of a device can lead to discovery of ways to reduce risk to an acceptable level.

EN ISO 14971: Using Risk Management to Identify Use Errors

Widely used by medical device manufacturers, EN ISO 14971 should take into account the human factors that can be triggered by design flaws (see sidebar) and seeks to minimize such issues.

EXAMPLE: Imagine two devices with the same intended use. If one of the items operates with the push of a button, while the second requires a series of actions to achieve the same goal, the complexity of the second may be at the origin of more use error than the first one.

The ease of use, or usability, is an intrinsic characteristic of a medical device and the key to control the risk of use error. Note that the perception of the ease of use may vary from one individual from another, and therefore must take into account the education, experience, culture and other characteristics of the user.

EN 62366 and EN 60601-1-6: Implementing Usability-Engineering Practices

EN 62366 and EN 60601-1-6 provide directions and requirements for design processes to implement usability-engineering practices, covering such areas as identifying the principal service function and outlining a plan to validate specifications, user-interface design, training materials and related items from a usability perspective.

Tools commonly used to validate the usability of a medical device include:

- simulated use (through multiple scenarios) or real world environment
- observational studies
- functional analysis
- design audit
- comparison with other devices
- expert opinion
- interviews
- participative design

Medical device misuse has historically been blamed on the user for improper operation or other mistakes. Through the concept of usability engineering and application of the above tools, manufacturers can better analyze the user-device interface and account for real-world circumstances. This is an important component to risk management and one that European regulation now expects manufactures to use.



Editor's Note: Miss an issue of Progress Report? Get free access to the past year's issues of LNE/G-MED America's monthly newsletter at our NEW website: LNE-America.com. You can also check out our Ask the Expert, FAQs and other informative resources for quality and regulatory professionals.

Risk Management Conference: LNE/G-MED experts are preparing an intensive one-day training on Risk Management to be held in June. To be alerted as soon as details are available, please email a message to gmedna@lne-gmed.com with the words Training Alerts in the subject line.

Contact LNE/G-MED America: We'd love your feedback of this newsletter and to get your suggestions for future topics. Please contact us at gmedna@lne-gmed.com or at (301) 495-0477.

As a Notified Body and accredited registrar, LNE/G-MED gives North American companies access to European, Canadian, Asian and other regulated markets, while offering the convenience and efficiency of LNE/G-MED America's local team of technical experts, auditors and program managers. To receive a customized proposal for certification services, product/component testing or training opportunities – or to speak with one of our technical experts, contact us at the email or phone number above.