Is the medical device usability standard usable for manufacturers ?

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To prevent risks of use errors with medical devices (MD), the new European Directive 2007/47/EC regulates the CE marking procedure for MD, and requires a usability file which complies with the IEC 62366: (2007)* standard. “The manufacturer must analyze, specify, design, verify and validate usability, as related to safety of the device”.
We present a preliminary study that aimed at clarifying manufacturers’ difficulties with the application of this new standard.

Introduction

Now, a usability file is mandatory !

CE

- Application specification
- Frequently used functions
- Known or foreseeable hazards and hazardous situations
- Primary operating functions
- Usability Specification
- Usability validation plan
- Device design
- Usability verification
- Usability Validation

Information expected in the usability file

A challenge to apply !

Difficulties

- The standard suffers from « meta-usability problems »
- Difficulties for manufacturers to link the risk management process with the usability engineering process
- Without usability expertise the application is problematic

For Whom ?

- Manufacturers
- Certifications bodies
- Competent authorities

*International Electrotechnical Commission (2007). 62366:2007. *Medical Devices - Application of usability engineering to medical devices* – Collateral Standard: Usability Geneva, IEC.

The Case Study

Objective ? Identification of manufacturers difficulties to apply the standard

How ?
- Accompaniment of a manufacturer in the documentation of his usability file
- No adoption of a formal user centered approach

➢ Final evaluation of the device was conducted

What ? Innovative analgesia monitor which provides a new pain indicator (A.N.I.) to manage doses of analgesic drug

Methods

Collection of information expected for planning usability evaluation

- Application specification
- Frequently used functions
- Known or foreseeable hazards and hazardous situations
- Primary operating functions
- Usability Specification

Manufacturer’s interviews
With anaesthesiologist, an engineer and the manager of the company.

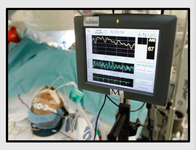
Analysis of the work system
In 2 anesthesia department of a French academic hospital to focus on the cognitive activities of anesthesiologists

Usability evaluation

- Usability validation plan
- Device design
- Usability verification
- Usability Validation

Heuristic analysis
Based on the INRIA ergonomics criteria (Scapin & Bastien, 1997).

Usability tests
With 13 Anesthesiologists.
Evaluation of the impact of the training on the monitor



Results

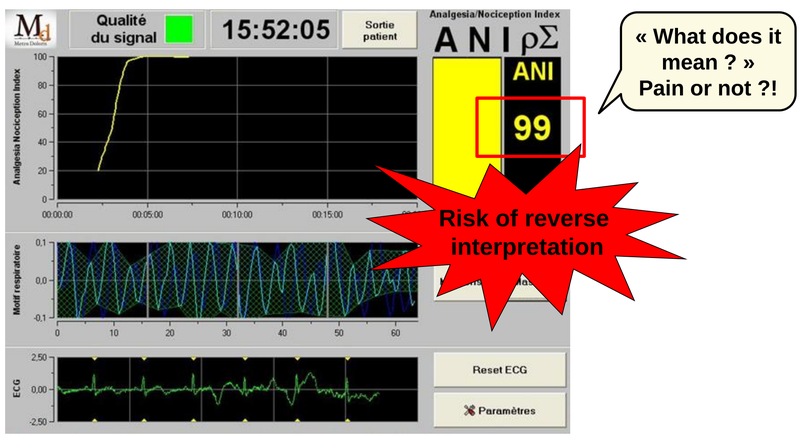
Manufacturers were conviced…

- They had provided all mandatory information to document their usability file
- They had identified all risks related to the monitor…

BUT

Manufacturers had difficulties to apply the standard

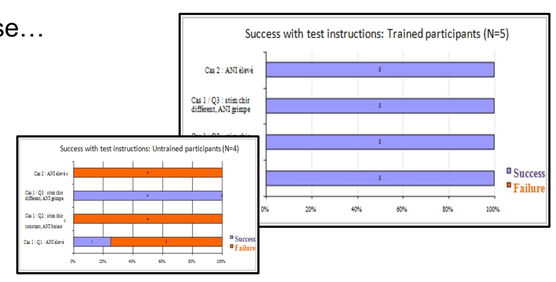
- Trouble in understanding some terms of the standard
- Not able to provide clear and accurate information for succeeding the usability evaluation
- **A major risk of use was obviously missing !!**



Training is not a realistic solution !

Manufacturers think that training can prevent this risk !!

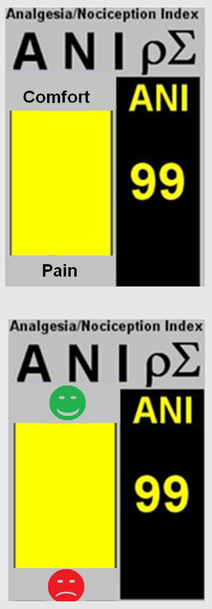
It’s not false…



BUT in most hospitals there is considerable turnover making systematic training difficult.

So

Usability experts proposition



Discussion/Conclusion

The implementation of the usability standard supports well the identification of the risks of use. It seems however that usability expertise is mandatory.
The results confirm that the operationalization of critical elements of the standard into understandable information able to structure and guide the design of medical devices, their usability evaluation and verification of compliance is a real issue.