Techniques for usability risk assessment during medical device design

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Abstract: Human errors during the use of medical devices, due to pitfalls in the design of the user interface, may lead to substantial risk to users and to patients. There are multiple techniques for the identification and for the assessment of user related risks, that may be chosen according to the step of the design (preliminary feasibility studies, minimum viable product assessment, verification and validation) and considering cognitive processes and information processing mechanisms of users, which may lead to errors. Some techniques are more adequate for a quick-and-dirty approach, during early stages of design: these include expert reviews, discussions among focus groups, standard reviews and heuristic analyses. Other techniques are adequate for a more detailed and systematic analysis of risk, in more advanced design stages, with a failure mode and effect analysis (FMEA) approach, including time-and-motion studies and task analyses. Lastly, user tests with the help of rapid prototypes, perhaps involving alternative embodiments to be studied, are very adequate for verification and validation of the interface. Usability analysis techniques should be part of the toolbox of a biomedical engineer and they should be carefully chosen. Each technique, regardless the step it is used, should allow the designers to define a precise level of risk in terms of probability, severity. Moreover, usability risk minimisation measures shall be measurable and able to be quantified, as well as the impact of risk mitigation strategies. For this reason, usability risk minimisation measures should be classified according to regulatory requirements as "safe by design"; "alarms and protections" and "information for safe use". Each class of risk minimisation measure should be then given a measurable risk reduction score, so that the risk assessment can be completed in a repeatable and regulatory compliant way.

1 INTRODUCTION

Biomedical engineers routinely include "users' needs" in the design requirements of medical devices. But what is a "user need"? Not only the patient clinical condition, but also the need of a device that is adequate to his skills, education and capabilities and can be used safely.

Usability is defined, by the standard IEC 62366, as "the characteristics or features of the user interface that facilitate use and thereby effectiveness, efficiency and user satisfaction in the intended environment of use" (International Electrotechnical Commission [IEC], 2015).

It is an essential concept in the design process of any medical device, for the benefit of healthcare professionals, patients and all stakeholders. We believe that usability should be part of the modern academic education of biomedical engineers, worldwide. Our group has tested this approach to the design of innovative open source devices as part of the UBORA project, including a drop foot frame, a face splint, a hand rehabilitation tool and more.

Design decisions should be driven not only by performance, cost or environmental impacts of the device, but also by its ergonomics and aesthetics, connected to usability, safety and user experience.

2 POSITION PROPOSAL

In this paper, we present a structured method for the identification and assessment of use-related risks of medical devices. These risks need to be considered during the whole design process, from specification and conceptualization, towards detailed design, prototyping, preparation of production and whole product life cycle.

We present different techniques as part of this method, to be chosen according to the kind of device under assessment, to the level of development of the device - in terms of ideation, testing and verification - and to the available resources for the analysis. We also present how to identify minimisation measures and how to evaluate their effectiveness.

The method is fully compliant to internationally recognised standards ISO 14971 (International Organization for Standardization, 2007) and IEC 62366. The application of this method would be appropriate during early design stages, during regulatory approvals and during health technology assessment, posing important benefits that overweight the current barriers (Shah, 2007). This method can be applied by designers, by legal manufacturers and by authorities involved in health technology assessment studies.

2.1 Why Is Usability Important for a BME?

In the upcoming Medical Device Regulation EU 2017/745, the usability of medical devices acquires extreme importance in the process of certification.

Usability tests are part of an engineering process that sees the collaboration of a team of experts in the specific medical sector (physicians, nurses, medical personnel), clinical and biomedical engineers and product designers, and include analysis of past adverse events, related to the use of the device, design thinking of devices in accordance with the repetitive and repeatable mental patterns of the human user, considerations on experience and technical knowledge of different types of user (laymen or professional) and the application of ergonomic principles on the design of the devices.

The classical techniques of human factors engineering allow to systematize the approach to medical device design with a view on usability, because they allow to describe the different types of users and to build around them a personalized interface. In fact, the entire process of usability assessment allows putting the patient and his/her needs at the center of the medical device design.

3 ERROR DEFINITION AND IDENTIFICATION

3.1 What is a User Error

User error is any error made by the user in interfacing with a device, i.e. any situation caused by the user that leads to device uses unintended by the manufacturer. It includes two distinct types of error: use error and abnormal use. Abnormal use is a "conscious, intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer" (IEC 62366, 2015).

Use error is "user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user" (IEC, 2015).

3.2 The Two Steps of the Usability Assessment

Assessments regarding usability start early during the design and are iteratively performed to increase knowledge about user needs and expectations, interface solutions that better match those needs, risks and their mitigation measures.

The standard defines two main steps of usability assessment: a formative (typically iterative) phase that is integrated in the development of further iterations and then a summative phase that is intended to validate and provide objective evidence regarding the latest (approved) iteration of the interface design.

3.2.1 Formative

Formative evaluation is a "user interface evaluation conducted with the intent to explore user interface design strengths, weaknesses, and unanticipated use errors" (IEC 62366, 2015).

It is generally iterative and should be performed until the manufacturer has reached a finalised version. Formative evaluation improves user interface, solving issues in preliminary analysis.

During formative iterations, it may be useful to identify early phase versus late phase studies.

Early phase studies are characterised by a higher uncertainty in the possible device variants, with many specifications not yet completely defined. At this stage, many prototypes are still available and they can be radically different one to another, so the employment of rapid and low-cost prototyping techniques (i.e. 3D printing, cardboard modelling) proves quite beneficial for first conceptual assessments.

Late phase studies are characterised by a better defined list of requirements and of specifications, which leads to a shorter list of device variants, with potentially small but very significant differences.

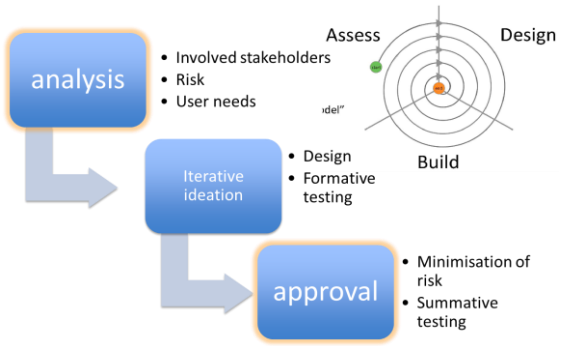

Figure 1: Usability engineering workflow.

3.2.2 Summative

The summative evaluation is conducted at the end of the development, on the finalized user interface, with the intent to obtain objective evidence that the user interface can be used safely. Summative verifies an acceptable risk-benefit profile under a usability point of view and also determines and confirms the expected effectiveness and clinical benefit.

3.3 Techniques for Usability Assessment in IEC 62366

System Description. It is an analysis of the main users and scenarios where the device will be used. Main functions and sub functions of the device should be well defined and understood.

Task Analysis. Task analysis broadens the system description, identifying all the relevant human interventions in the use of the device and where errors can occur. It has the objective to understand and represent in an organized manner the set of tasks that the human element carries out in the use of the device. Task analysis may include analysis of cognitive processes and performance shaping factors (individual, social and ergonomic) influencing on the device use. Some methods (Kirwan & Ainsworth, 1992) for this purpose are divided in "Task data collection" techniques and "Task description" techniques.

Task data collection techniques are techniques which are primarily used for collecting data on human-system interactions, and which then feed into other techniques. Some of these techniques are: Walkthrough, Talkthrough, Critical Incident Technique, Observation, Questionnaires, Structured interviews.

Task description techniques represent and structure the information collected into a systematic format, serving as a reference material. Some of these techniques are: Hierarchical Task Analysis, Tabular Task Analysis, Timeline Analysis, Decision-Action Diagram. Task description of various medical devices is present in literature, with a different level of detail, for example for volumetric infusion pumps (Chung, 2003)

Human Error Analysis. Including the identification of possible human errors based on previous Task analysis. Human errors modes can be analyzed at two layers: External Errors (Actions) or Internal Errors (Cognitive). Some techniques to allow human error identification are Human Hazard and Operability Study [HAZOP]. Incident analysis, or use of a Taxonomies and Checklists of possible generic human errors that might occur during the use of any device. Human error analysis includes assessment of probability and severity of each error.

Human Error Reduction and Mitigation. Based on previous stages a set of recommendations and requirements for device design are proposed to reduce and mitigate human errors. Combining the previous aspects, we can set priorities and propose strategies for human error reduction.

3.3.1 Which Technique in Each Phase?

The international standard IEC 62366 (IEC, 2016) presents a series of techniques, that we assessed in:

- early formative
- late formative
- summative

In early formative, a quick-and-dirty approach identifies the best interface. Then, in late feasibility, a more structured approach may help to refine the interface. Lastly, during summative, a frozen version of the interface is validated to confirm its risk-benefit profile. Criteria to choose the most appropriate technique(s) for each phase are:

- Need to involve experts in the technology.
- Need to involve real user(s).
- Time required to assess.
- Time required to report.
- Qualitative results (opinions) vs. quantitative results (usability scores).
- Depth of analysis.

We have identified some techniques that we consider particularly appropriate for each step. A detailed list is shown in Table 1.

The use of rapid prototyping and rapid tooling techniques, proves interesting for the straightforward creation of physical models, which can be used to support most of the aforementioned techniques for usability assessment. These physical prototypes or models can support decision making processes for selecting among different product ideas, on the basis

of ergonomics, aesthetics, basic performance, overall usability and safety, to reach the device concept in the first stages of the development process. They can also support in the creation of a first minimally viable product for interacting with healthcare professionals, patients, layperson. Prototypes according to different design iterations, consequence of the different decisions taken to mitigate risks and to improve usability, can, consequently, support the whole methodology and approach we propose here.

This evaluation has shown that a risk-based approach is easily adapted to a resource wise approach. During early formative, low resource review techniques such as expert reviews, standard analysis, cognitive walkthrough are easily performed on documentation and by design experts. They do not require the participation of a large number of real users nor the availability of a finalised prototype, while low-cost replication tools may provide effective samples to boost discussion.

Later stages of formative assessments may benefit of more structured techniques, such as a detailed task analysis that is linked to the FMEA technique. User tests with 5-10 users may be planned at later formative steps in order to allow refinement.

3.3.2 Which Technique for Which Device?

Medical devices belong to varied categories in terms of technology, intended use, intended users (layperson or professional), invasiveness in the human body or expected useful life, which affect design decisions in connection with usability and safety. For this reason, we have also assessed each technique presented by the norm IEC 62366 (IEC, 2016) in terms of adequateness to different kinds of devices. A detailed evaluation is shown in Table 2 .

In Table 2, the same technique is considered as adequate or inadequate for devices that may be apparently very similar from the usability point of view. However, this is explained by the technological differences in the device. As an example, the technique "standard review" proves "adequate" for very different devices such as heart valves and nasogastric tubes, but is considered "adequate with reserve" for Software as a Medical Device (SaMD). This is due to the poor standardisation that is still present in the SaMD sector, while traditional devices can be assessed by very consistent and complete international standards and guidelines. Also consider, the technique "participatory design" that is considered "not appropriate" for traditional electromedical devices for the layperson, such as pulse oximeters, but on the other hand is "adequate" for SaMD and apps for the layperson. This again is justified as participatory design may allow the designers to align the medical app to users' expectations, by allowing users to design an intuitive and user friendly app, with a user interface as similar as possible to a consumer app.

3.4 Linking Usability to Risk Identification

Each usability evaluation technique allows the designers to identify risks and potentially hazardous situations. We describe here some of the techniques identified above, in terms of capability of the assessment to be easily linked to a formal risk analysis as per ISO 14971 (ISO, 2007).

The preferred methods for early feasibility help the designers to identify risks in general terms and are potentially adequate to determine risk severity (worst case consequences of the risk scenario). For example, at very early stages of ideation of a electromedical device to be used in emergencies (e.g. a defibrillator) designers may already be aware of the importance of high visibility and audibility of the device, since it is expected to be used in loud, dark, confusing environments. During late feasibility, we propose a more structured method, by application of the Failure Modes and Effects Analysis FMEA technique. The Application FMEA technique yields the best results if the question "what happens if…" is posed at each application step or phase. So, we propose an integrated technique: firstly describe the use of the device in very fine detail by task analysis and then perform Application FMEA on each step.

We propose a very detailed task analysis and, where applicable, also a function analysis or use flowchart. Description of the intended use interface by a flowchart is particularly adequate for medical device software, both stand alone and integrated in an electromedical device. Use of this integrated method allows a very precise assessment of risk severity, thanks also to the possibility of obtaining a description of the chain of events that arise from an hazardous situation, for example thanks to brainstorming or focused expert reviews.

If the designers do not have enough past data or experience-based estimations to determine risk-related probability, a user test can be very useful to estimate probability of each hazard. If the user test are planned in this phase, the task list and use flowchart already available to designers from the

Application FMEA activity will be used to plan and record the user tests. For each use error or use uncertainty observed during user tests, designers can determine severity and estimate probability.

In late feasibility, user tests can also be integrated to other techniques to reach a new and refined iteration of the device interface. We encourage designers to plan, after user testing session, additional sessions with the users to gather information through interviews, SUS questionnaires (Brooke, 1996) and open-ended questions intended to encourage participatory design. These interactive sessions with end users are also very useful to gather information about expected probability of each encountered error or uncertainty. For example, late feasibility studies of a surgically invasive device for professional use, e.g. catheter for angioplasty, may include the definition of a task list based on standard reviews, guidelines, state of the art and interviews. For each task, designers may identify potential hazardous situations and their consequences. Then, user tests on a simulator or dummy may confirm or improve the estimated risk list; the same users may be involved after the test to discuss their errors, determine root causes and suggest improvements in the catheter shape, pliability or accessory list.

During user tests in the formative phase, assessments and integrations to reports for Perception-Cognition-Action technique PCA are also very common; users can also be invited to express their thoughts and impressions while they perform the tasks, as part of participatory design.

A detailed description of the use of different techniques is given in Table 3.

4 RISK MITIGATION TECHNIQUES

4.1 Risk Control Measures in Usability

Regulatory requirements (for example Medical Device Regulation EU 2017/745, Annex I) on risk minimisation are clearly indicating a preferred order in the identification and selection of risk minimisation measures.

Safe-by- design solutions are preferred and, if not available or not sufficient, other measures shall be added in terms of protections and alarms. Moreover, information for safe use shall be provided. Designers shall plan in eliminating the most severe risks by safe-by-design solutions from very early stages of design. To continue with the defibrillator example given for early feasibility, designers may decide to place all the interface commands on the same (front) side of the device and review standards for colours and icons at a preliminary stage of the ideation. Alarms and protections can be included during all iterations of the formative stage even adjunct to safe-by- design measures. For example while designing a software interface of an electromedical device, the designers may allow only an “admin” user (e.g. a qualified medical professional) to set performance parameters in a predefined interval, as based on state of the art clinical guidelines. Then designers may place adequate screens for password input as protection measures for the “admin” access. Moreover, for all interface screens designers may provide information for safe use with reference to the allowed interval for clinical parameters, tips to proceed to the next clinically relevant step of the therapy and so forth.

4.2 Summative as Part of Device Validation

The goal of device validation is to determine if the device is adequate for its intended purpose and to confirm its estimated risk benefit profile. No major modifications are expected at this phase. While not all parts of the interface may be subject to summative, designers should plan to validate all the critical ones. For example, summative assessment of the interface for the assistance and maintenance personnel of an electromedical device, when personnel is directly trained by the device legal manufacturer, may not be needed.

We propose to plan the summative evaluation by mirroring activities of the late formative step, on the final and frozen iteration of the interface. A complete task analysis should be available and checked for coherence to the user manual or instruction leaflet. Moreover, if applicable to the kind of device, also a complete use flowchart should be available.

Summative evaluation should be performed with real users and in a very well simulated or real use environment, depending on device kind and ethics considerations. During user tests, additional techniques may be integrated to determine the length of time needed for each task (by time-and-motion studies) and the workload of the user.

It should be noted that, while very adequate for summative activities, time of use and workload assessment are not easily evaluated during formative tests. The interface is still under modification and, more often than not, the tasks may be interrupted for

clarifications and comments from the users, a very common event if the participating users are aware that the device is under development and not under validation: most users are very keen to provide their feedback and opinions as part of participatory design activities. Interrupted and commented tasks disrupt the workload assessment and the time estimation.

The outcome of the summative step is the confirmation of all parts of the device interface, including the information for safe use. No additional risks should be encountered and all the foreseen risks should be confirmed in terms of severity and probability. Risk control measures should be formally reviewed for final implementation and effectiveness and the risk-benefit profile confirmed.

5 CONCLUSIONS

An integrated approach to usability and risk management, while complex in general terms, can be easily adapted to the design step, kind of device under assessment and available resources. Designers should be provided with a complete usability toolbox and be able to choose a adequate tools for each of their designs.

Integration of usability assessments in the wider risk management leads to safer and more intuitive medical devices, for the benefit of patient and professional users alike.

While our group has tested this method in multiple instances, we wish that it would be used widely. With more experience, this method can be refined, adapted to different cultural settings and various technical skills, and updated with device-specific tools. Moreover, this technique may be integrated with the risk mitigation measures required for the adequate management and protection of patient data.

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APPENDIX

Tables.

Table 1: Assessment of each evaluation technique according to predefined criteria.

Method as per table E.1 of IEC 62366-2:2016	Involve experts	Involve real user(s)	Time to assess	Time to report	Qualitative results (opinions)	Quantitative results (scores)	Depth of analysis	Proposed for step
Advisory panel reviews	Yes	No	Medium	Low	Yes	No	Low	Early formative
Brainstorm use scenarios	Yes	No	Low	Low	Yes	No	Low	Early formative
Cognitive walkthrough	Yes	No	Low	Low	Yes	No	Medium	Early formative
Expert reviews	Yes	No	Low	Low	Yes	No	Low	Early formative and summative
FMEA and FTA	Yes	Yes	High	High	No	Yes	High	Late formative
Focus groups	No	No	Low	Low	Yes	No	Low	Early formative
Function analysis	Yes	No	Medium	Low	Yes	Yes	High	Early formative
Heuristic analysis	Yes	No	Medium	Medium	Yes	Yes	High	Late formative
Observation	No	Yes	Medium	Medium	Yes	Yes	Medium	Early formative
One-on-one interviews	No	Yes	Medium	Medium	Yes	No	Medium	Early formative and late formative
Participatory design	Yes	Yes	Medium	Medium	Yes	No	Medium	Late formative
PCE analysis	Yes	Yes	High	High	Yes	Yes	High	Late formative
Simulation	Yes	Yes	High	High	Yes	Yes	High	Late formative and summative
Standards reviews	Yes	No	Low	Low	Yes	Yes	Medium	Early formative
Surveys	No	Yes	Low	Low	Yes	Yes	Low	Late formative and summative
Task analysis	Yes	Yes	High	High	Yes	Yes	High	Late formative and summative
Time-and-motion studies	No	Yes	Medium	Medium	Yes	Yes	Medium	Late formative and summative
Usability tests	Yes	Yes	High	High	Yes	Yes	High	Late formative and summative
Workload assessment	No	Yes	High	High	Yes	No	Medium	Late formative and summative

Table 2: Assessment of each evaluation technique related to device kind.

Method as per table E.1 of IEC 62366-2:2016		Advisory panel reviews	Brainstorm use scenarios	Cognitive walkthrough	Expert reviews	FMEA	Focus groups	Function analysis	Heuristic analysis	Observation	One-on-one interviews	Participatory design	PCA analysis	Simulation	Standards reviews	Surveys	Task analysis	Time-and-motion studies	Usability tests	Workload assessment
Implantable, electro-medical	e.g.: implantable defibrillator	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	May be	Yes	Yes	Yes	No	Yes	No	No	No
Implantable, not electro-Medical	e.g.: heart valve	Yes	Yes	Yes	Yes	Yes	Yes	May be	Yes	No	Yes	May be	May be	Yes	Yes	No	Yes	May be	May be	No
Electro-Medical for professional	e.g: ecg	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	May be
Electro-Medical for layperson	e.g: home thermometer	Yes	Yes	Yes	Yes	Yes	May be	Yes	Yes	Yes	No	May be	Yes	Yes	Yes	May be	Yes	May be	Yes	No
Samd for professional	e.g: surgical planning	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	May be	No	Yes	May be	Yes	May be
Samd for layperson	e.g: app for treatment adherence	Yes	Yes	Yes	Yes	Yes	May be	No	Yes	No	Yes	May be	Yes	Yes	May be	May be	Yes	May be	Yes	No
Not active device-professional	e.g: nasogastric tube	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	May be	Yes	May be
Not active device-layperson	e.g.: contact lenses	Yes	Yes	Yes	Yes	Yes	May be	No	Yes	No	No	May be	No	Yes	Yes	May be	Yes	May be	Yes	No

Table 3: Risk identification related to each evaluation technique. Methods as per Table E.1 of IEC 62366-2:2016.

Advisory panel reviews	By brainstorming and review of past experiences, panels may identify potentially hazardous situations, assess probability and severity, describe the risk minimization measures present in the state of the art
Brainstorm use scenarios	Designers involved in the brainstorming may identify user errors and misuse/abnormal use; designers may also identify risk control measures
Cognitive walkthrough	Designers involved in the brainstorming may identify usability pitfalls in the design and describe the hazardous situations that may arise; designers may also identify risk control measures
Expert reviews	Experts may point out usability strengths and pitfalls during their review. Usability pitfalls may then be linked to the hazardous situations; designers may also identify risk control measures. We recommend that experts answers to questions as per ISO 14971 ann. C
FMEA and FTA	FMEA technique is a very thorough method for the identification of risks. We recommend that this method is used in conjunction with a very detailed task analysis
Focus groups	During a focus group, designers may guide the discussion with users leading to the identification usability pitfalls in the design and describe the hazardous situations that may arise; designers may also identify risk control measures and ask participants to the focus group to comment the proposed measures
Function analysis	A functional flow diagram, commented with the identification of machine functions and user functions may be used in conjunction with a FMEA technique for a thorough identification of risks
Heuristic analysis	During heuristic analysis, usability experts may use heuristic principles to identify and give usability scores to usability pitfalls. They may describe the hazardous situations that may arise; designers may also identify risk control measures and ask experts participating to the heuristic review to comment the proposed measures and score their capability to lower the risk
Observation	During observation, designers may identify user uncertainties or errors; root cause should be discussed with the users to ensure that the hazardous situation is well understood by the designers; we believe that observation alone cannot provide sufficient information regarding risk and that it should be backed up with interviews or surveys as a de-brief activity
One-on-one interviews	Interviews are useful when used in conjunction with techniques involving users that perform actual tasks on the device, from observation to cognitive walkthrough to usability tests. Interviews are best used as de-briefing activities as they allow to identify not only the hazardous situations, but also their root causes
Participatory design	Partecipatory design very powerful tool when used in conjunction with techniques involving users that perform actual tasks on the device, from observation to cognitive walkthrough to usability tests. Focused on defining risk mitigation measures and their perceived effectiveness
PCA analysis	PCA analysis can be integrated in the task analysis and therefore in the FMEA analysis to provide a complete evaluation of risk; most applicable to complex tasks and/or interfaces
Simulation	We believe that simulation is one of the core techniques, as it can easily be adapted to all devices thanks to the use of mockups, dummies, animal models and other simulated settings. This allows the planning of all usability assessment activities in a cost-effective and ethical fashion
Standards reviews	We believe that standards review should be applied whenever an internationally recognized document is available, be it an ISO norm, a guideline from a scientific society, a local procedure. Non- fulfillment of standard requirements is a potential source of significant risk
Surveys	Surveys are useful tools in some situations, where the use of the medical device is difficult to observe; typically if it is used by the layperson as part of private life (contact lenses, in vitro testing for pregnancy, and so on). Surveys are not adequate to investigate root causes of hazardous situations
Task analysis	Task analysis is the most powerful tool for linking usability assessment to risk management. It is best used as an input to the FMEA technique but can also be used during preliminary steps of the device design to determine the user needs and consequent testable technical requirements. Non fulfillment of one of those requirements shall be treated as significant risk
Time-and-motion studies	We believe that time and motion studies are most adequate to assess risk of those devices in which the time of execution is a risk control measure, e.g. If a fast execution improves patient safety (for example, lowering chances of bacterial contamination or improving chances of patient recovery)
Usability tests	Usability tests are a very powerful tool to determine those risks that not identified by the designers, using techniques that do not directly involve users (such as brainstorming, standard reviews…). Usability tests allow to estimate the probability of an hazardous situation; they also allow designers to consolidate the task list
Workload assessment	Workload assessment reviews may allow designers to identify some kind of use errors related to overload or environmental distractions; we believe that this technique is most appropriate when professional users are involved, as they are more prone to burn out and also more aware of the impact of overload on their performance at work